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Contents

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Telemonitoring in Cystic Fibrosis: A 4-year Assessment and Simulation for the Next 6 Years

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Abstract

Background: Innovative technologies and informatics offer a wide range of services to health districts, doctors, nurses, and patients, and is changing the traditional concept of health care. In the last few years, the availability of portable devices, their easiness to transport and use, and the capability to collect and transmit various clinical data have resulted in the fast development of telemedicine. However, despite its potential impact in improving patient conditions, and its cost effectiveness reported in literature, telemedicine is not in daily practice.

Objective: The aim of this study is to provide evidence of the positive impact of telemonitoring proving the sustainability of an application by sending spirometry outcomes from patients' homes to the hospital doctors via the Internet, and from doctors to patients by an additional phone call solution.

Methods: We examined collected data related to clinical improvement of patients with cystic fibrosis (CF). The patients were followed-up at home using telemonitoring for a period of 10 years, with the aims to prove the sustainability of the methodology (transmissions of spirometry from the patients' home to the doctors and feedback from the doctors to the patients by phone call from the hospital). We stored and analyzed all spirometry transmissions received, and tested the possible presence to decrease the costs between the standard clinical trial (only ambulatory visits) and standard clinical trial with telemonitoring for the follow-up of patients with CF (telemedicine). This was done through an economic analysis of the costs for patients followed at home by telemonitoring. We assessed four years of observation and a simulation of total long-term costs between 2010 and 2020.

Results: We discovered a potential saving of €40,397.00 per patient for 10 years, actualized at €36,802.97 for the follow-up of all patients enrolled.

Conclusions: The results from the study suggest that telemedicine can improve the health of patients with CF. It is a relatively cheap and potentially sustainable solution, compared to standard clinical trials. However, to establish and prove the long-term effectiveness and cost-effectiveness, more controlled psychological and behavioral studies are needed.

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KEYWORDS

cystic fibrosis; telemonitoring; cost effectiveness; follow-up; eHealth

Introduction

Innovative technologies and informatics offer a wide range of services to health districts, doctors, nurses, and patients, and is changing the traditional concept of health care. In the last few years, the availability of portable devices, its easiness to transport and use, and the capability to collect and transmit various clinical data have resulted in a fast development of telemedicine [1].

The use of portable devices for monitoring patients can find its application both within and out of hospitals [2]. With respect to the former, telemonitoring has the advantage of increasing efficiency in managing more patients, increasing patients' safety, increasing quality of works, and reducing those opportunity costs (costs related to the fact that professionals spend a lot of time performing activities that do not need professional skills and competencies). That the standard of care is not able to reduce this effect still remains to be demonstrated without a real reorganization of competences and activities of health care professionals. Meanwhile, the use of devices able to remotely monitor and assist patients at home (in cases of temporary disease like rehabilitation after an accident and chronic diseases) has been of increasing importance for many decades. In recent years, telemonitoring and games have been introduced in this second field of application as valid alternatives to the standard of care, not only for monitoring patients' progress but also motivating them and increasing adherence to treatment and telerehabilitation [3]. In both fields of application, literature and research are progressing together and research on electronic medical records (EMR) [4] has a natural ally in telemedicine.

However, despite its potential impact in improving patient conditions and its cost effectiveness reported in the literature, telemedicine is not in daily practice. The same is the case regarding the economic dimension and societal impact of telemedicine [5]. The lack of clear evidence is relevant for the low registering of telemedicine and telemonitoring diffusion (in hospital and home assistance cases) by the following five mechanisms. The first is reduced acceptability of information and communication technology (ICT) by the elderly. However, this barrier shows a decreasing trend; people in general and the elderly are more and more confident using ICT. The common idea that people over the age of 65 tend to be less interested in adopting new technologies for everyday problems is a myth. The second is the resistance by physicians and other health care professionals within and outside of hospitals who consider telemedicine and telemonitoring as a substitutive solution of their activities instead of tools for improving the quality and quantity of services delivered. The third is the fact that telemedicine modifies medical information exchanges between health care producers probably by increasing coordination problems. The fourth is the fact that telemedicine and telemonitoring can be considered good solutions for increasing the quality of life for young people (eg, reducing productivity losses), but it can be a poor solution for the elderly that live alone and need more human relations [6]. The fifth mechanism is increasing privacy problems and the related resistance of transferring more information on patient conditions over a long period of time [6,7]. However, these problems seem theoretically bigger than they actually are.

Our work has the objective to add evidence of the positive impact of telemonitoring and to provide an economic perspective of its usefulness in the second field of application: the follow-up of patients with chronic diseases at home with the direct consequence of lowering periodical and emergency hospital visits.

This study is focuses on the follow-up of patients with cystic fibrosis (CF) using telemedicine. CF is characterized by progressive lung destruction caused by the obstruction of the airway due to dehydrated thickened secretions. Obstructed airways results in endobronchial infection and an exaggerated inflammatory response leading to the development of bronchiectasis and progressive obstructive airways diseases [8]. For these patients, spirometry shows a reduction in forced expiratory volume in the first second (FEV1), and in forced current volume (FVC) (around 2% of the expected yearly value) [9].

Prevention and control of lung infections is one of the main objectives of therapy for patients with CF with the aim of reducing the progressive decline of pulmonary function [10]. Distance monitoring of lung parameters has been used in the follow-up of patients with CF in the Cystic Fibrosis Centre of Pediatric Hospital Bambino Gesù in Rome since 2001. A statistically significant reduction in hospital admissions and an over-time tendency towards a better stability of respiratory function was observed. [11].

In the present study we examined economic data related to the activities of telemonitoring for patients with CF followed at home for a period of 10 years, with the aim to better understand the evolution of clinical trends and costs over time. Here, we attempted to quantify the costs of telemonitoring (application of telemedicine) in the follow-up of the patients.

Methods

The study was conducted in the Cystic Fibrosis Centre of Paediatric Hospital Bambino Gesù in Rome, Italy. The Cystic Fibrosis Centre of Pediatric Hospital Bambino Gesù is recognized as the national support center for CF; the center follows 280 patients from all over Italy each year. Since 2001, 57 patients were enrolled using telemedicine as follow-up, and 41 of them are still under telemedicine assistance (telemonitoring). The telemedicine CF team consists of three doctors, two respiratory physiotherapists, a nutritionist, two psychologists, two doctors in microbiology, and a biomedical engineer.

We analyzed data collected from 2010 to 2014, and then we simulated the saving of costs for the next 6 years. We enrolled 39 patients, but for the economical evaluation, we included only a subgroup of 25 patients. These 25 patients are those we were able to track for real costs, that is limited to the national health system (direct health), for the follow-up of patients with CF with telemonitoring assistance. Patients included in the telemonitoring program are still followed-up and treated using the standard protocols for follow-up. These protocols are the same for the patients not included in the telemedicine program (control group) [12].

We used MIR-Spirotel instrumentation, which collects and remotely transmits data from a spirometer and overnight pulse oximetry. The method was described and discussed in a previous study [8]. The doctor prescribed each patient a spirometer after the diagnosis, which was delivered by the local dealer of regional health system (cost not provided for control group). Patients and parents were trained by physicians on the use of the device and how to send data to the Pediatric Hospital Bambino Gesù. Patients sent information twice a week. Data interpretation was performed using WinspiroPRO (Figure 1). The software was provided for free by the hospital's spirometer dealer, and can display the spirometry curves and the main parameters FEV1, FVC, peak expiratory flow (PEF), and forced expiratory flow (FEF, 25-75%).

Further, the anamnestic data and graphs obtained were discussed in a meeting between CF doctors for an overall evaluation of clinical significance to decide on the possible therapeutic action. Patients showing a significant decrease of peripheral capillary oxygen saturation (SpO2) and/or FEV1 were invited to ambulatory visits.

Additional maintenance costs of instrumentations are not included on rental costs because the rental dealers absolved it. The annual median value of FEV1 was calculated using "before the month median value" for each patient and after we meshed the data. We also kept track of other indicators related to the interaction between doctors and patients with possible economic interest. For the economical evaluation, it was only possible to collect and keep track of all cost entries incurred for 64% (25/39) of the enrolled patients with CF. The type of data collected is shown in Textbox 1.

Textbox 1. Collected data.

Data

- Hospitalization costs
  - Day hospital
  - Ambulatory visit
  - Intravenous therapy at home (minimum 21 days)
  - Oral therapy at home (minimum 21 days)
- Instrumentation costs
  - Monthly fee for instrumentation Spirotel
  - Rental of instrument for 25 pieces
- Doctors working days

We also considered all the cost entries for the Italian National Health System in the follow-up of patients with CF without telemonitoring assistance (control group), using historical data (hospital's annual reports). For the analysis, we included 25 patients (17 female, 8 male), compliant and less compliant with the protocols, but adherent to the study. For the saving projection, we performed an analysis of the costs. The starting costs during the first year of telemonitoring assistance compared with the cost incurred to the follow-up of patients with CF with traditional trials (control group) are presented in Table 2.

For the economic evaluation, we analyzed 4-year costs using the following equations:

Total costs = net cost + rental of instruments (1)

Total savings = savings of vacant beds + saving of working days recovery (2)

Net cost = total costs – total savings (3)

Actual saving = theoretical cost – actual cost (4)

Here, "savings of vacant beds" refers to saving costs obtained for lower days of hospitalization compared with hospitalization day for the control group, and "saving of working days recovery" is defined as saving costs obtained for lower hours of works for visits of patients with CF under telemedicine protocol, compared to hours of works for visits of patients with CF in the control group. For "theoretical cost" we made a simulation of costs incurred for the follow-up of patients in the control group. Having different cost items, it was only possible to make a simulation thanks to the expertise of the doctors, in addition to envision diagnosis-related group (DRG) costs (Table 1). We assumed that these reimbursements will not change during the period of simulation.

Based on these results, we made three different simulations of the long run cost: 2010-2020 for two groups, and then calculated their differences. Analysis started including the top four most compliant patients previously enrolled in the telemedicine protocol (Table 2). Therefore, the lowest compliant patients have been enrolled. Finally, simulation involved all the 25 patients previously enrolled in the telemedicine protocol (Table 3).

Table 1. Starting costs for follow-up of 25 patients with and without telemonitoring during the first year.

Group		Cost, €
Control group (without telemonitoring) costs (hospitilization and home treatment), n=25		156,085.00
Study group (telemonitoring)		116,139.81
Cost of services provided by the National Health Service		
	Equipment rental (25 pieces)	126,000.00
	Total debit	242,139.81
	Additional revenue for the use of beds	123,019.00
	Recovery of working days	9284.00
	Total credit	132,303.00
	Current costs (debit-credit	109,836,81
Budget		
	Saving with telemedicine	46,248.19
	Savings cost on first year per patient of follow-up with telemonitoring assistance	1986.42

Table 2. Saving projection including only the four must compliant patients enrolled, until 2020, at 2015 prices (base year).

Year	Saving, €	Average consumer price index (CPI) inflation[a], %	CPI correct saving, €
2010	5351.00	n/a	5748.70
2011	8090.00	2.78	8456.19
2012	16,038.50	3.04	16,269.88
2013	21,382.25	1.22	21,429.28
2014	26,726.00	0.24	26,720.65
2015	32,069.75	-0.02	32,069.75
2016	37,413.50	-0.02	37,420.98
2017	42,757.25	-0.02	42,774.36
2018	48,101.00	-0.02	48,129.87
2019	54,444.75	-0.02	54,488.33
2020	58,788.50	-0.02	58,847.32

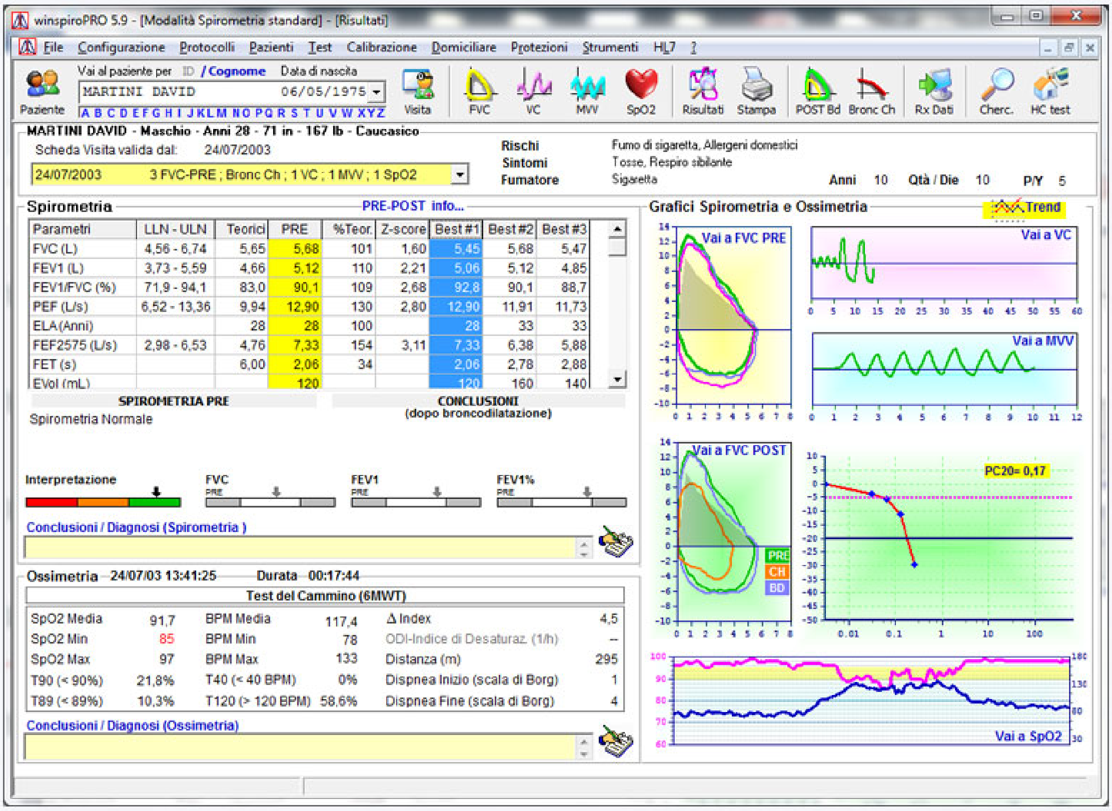
[a] Source is the Worldwide Inflation Data website [13].

Table 3. Savings projection for all 25 patients enrolled, until 2020, at 2015 prices (base year).

Year	Saving, €	Saving projection at 2015 prices, €
2010	1849.00	1986.42
2011	2030.00	2121.89
2012	6293.00	6383.79
2013	10,556.00	10,579.22
2014	14,819.00	14,816.04
2015	19,089.00	19,089.00
2016	23,345.00	23,349.67
2017	27,608.00	27,619.05
2018	31,871.00	31,890.13
2019	36,134.00	36,162.92
2020	40,397.00	40,437.42

Using 2015 as base year, saving actualization was based on the previous rates for saving before 2015 and the inflation rate of 2015 for each of the simulated savings from 2015-2020. The 10-year total saving was obtained at the current prices. Italian average inflation rates based on the consumer price index (CPI) for the years 2010-2015 were obtained from the Worldwide Inflation Data website [13].

Figure 1. Screenshot of the software interface.



MARTINI DAVID 06/05/1975

MARTINI DAVID - Maschio - Anni 28 - 71 in - 167 lb - Caucasico

Scheda Visita valida dal: 24/07/2003

24/07/2003 3 FVC-PRE ; Bronc Ch ; 1 VC ; 1 MVV ; 1 SpO2

Rischi Fumo di sigaretta, Allergeni domestici

Sintomi Tosse, Respiro sibilante

Fumatore Sigaretta **Anni** 10 **Qtà / Die** 10 **P/Y** 5

Spirometria PRE-POST info...

Parametri	LLN - ULN	Teorici	PRE	%Teor.	Z-score	Best #1	Best #2	Best #3
FVC (L)	4,56 - 6,74	5,65	5,68	101	1,60	5,45	5,68	5,47
FEV1 (L)	3,73 - 5,59	4,66	5,12	110	2,21	5,06	5,12	4,85
FEV1/FVC (%)	71,9 - 94,1	83,0	90,1	109	2,68	92,8	90,1	88,7
PEF (L/s)	6,52 - 13,36	9,94	12,90	130	2,80	12,90	11,91	11,73
ELA (Anni)		28	28	100		28	33	33
FEF2575 (L/s)	2,98 - 6,53	4,76	7,33	154	3,11	7,33	6,38	5,88
FET (s)		6,00	2,06	34		2,06	2,78	2,88
EVol (mL)			120			120	160	140

SPIROMETRIA PRE

Spirometria Normale

CONCLUSIONI
(dopo broncodilatazione)

Conclusioni / Diagnosi (Spirometria)

Ossimetria 24/07/03 13:41:25 Durata 00:17:44

Test del Cammino (6MWT)

SpO2 Media	91,7	BPM Media	117,4	Δ Index	4,5
SpO2 Min	85	BPM Min	78	ODI-Indice di Desaturaz. (1/h)	--
SpO2 Max	97	BPM Max	133	Distanza (m)	295
T90 (< 90%)	21,8%	T40 (< 40 BPM)	0%	Dispnea Inizio (scala di Borg)	1
T89 (< 89%)	10,3%	T120 (> 120 BPM)	58,6%	Dispnea Fine (scala di Borg)	4

Conclusioni / Diagnosi (Ossimetria)

The analysis was performed making three different simulations, with the economic equation, according to the number and type of patients included in the study, for each year under observation. Based on these results, we made a simulation of the long-term cost until 2020 for two groups, and then calculated the difference (Figure 2).

Figure 2. Economic equations used in the calculations. Equation (a) is the actualization of saving st (t<2015), and equation (b) is the actualization of saving st (t>2015).

$$S_{t,2015} = S_t \prod_{j=t+1}^{2015} (1 + i_j) \qquad (a)$$

$$S_{t,2015} = \frac{S_t}{(1 + i_{2015})^{t-2015}} \qquad (b)$$

Results

In 10 years of telemonitoring assistance, Dr Bella's team followed a total of 39 patients. During the years of observation, we received 6647 spirometry transmissions. Some patients were excluded from the study for the absence of transmission, transmission problems of the oldest technology, or for death.

With respect to the economic perspective, by tracking the costs of the follow-up of 25 patients with CF (compliant and less compliant with the protocol) with telemonitoring for 4 years, we show a difference between the cost incurred to the follow-up in compliance and non-compliance patients, as mentioned for diabetic tetrahydrocannabinol (THC) [10,11,14-17].

We found an increased cost saving, year by year, for prompt hospitalization with lower acute illness levels, before the incurrence of symptoms. After the second year of observation we already discovered decreased costs compared with cost incurred for the follow-up of patients with CF compared with traditional trials. In the economic analysis, including all patients enrolled, we observed a stabilization of the saving cost equal to €4263.00 per patient after the second year (Table 3).

The health service component done by the hospital to the patients with CF under telemonitoring, and savings cost compared with cost incurred for the follow-up of CF with traditional trials at 2015 prices are shown in Table 4.

Table 4. Health service component done by the hospital and savings cost compared with cost incurred for the follow-up of years 3 and 4 of the observation period at 2015 prices.

Health service component done by the hospital	2010	2011	2012
Day hospital, n	3	15	30
Ambulatory visits, n	0	0	4
Hospitalizations, n	12	15	12
No services, n	5	2	2
Total saving costs compared to traditional trials, €	1986.42/patient	2121.89/patient	6383.79/patient

Based on the years of accurate observation, we did a simulation of long-term saving from 2010-2020, adjusted by the inflation rate at 2015 price. This shows a saving of €40,437.42 per patient for the follow-up of all patients enrolled (Table 3). We made the same simulation including only the four most compliant patients, hoping to have a higher adherence with the treatment in the future [11]. From this simulation, as shown in Table 2 , we found a saving of €58,788.50 per patient for 10 years, €58,847.32 per patient at 2015 prices (the base year characterized by deflation instead of inflation). However, since price changes are not constant among years, it is necessary to update costs and saving once inflation rates will be available.

Discussion

Principal Findings

Here, we analyzed the quality and quantity of information transmitted and costs and/or savings of health resources related to telemonitoring in CF within a period of 4 years, and made a projection of costs for the next 6 years. The assessed potential saving of adopting a telemonitoring solution is relevant for a disease characterized by high costs for long-term treatments and follow-up. The adopted approach could be one of the first contributions in the field and also be used as a basis for analogous studies in different fields and diseases.

We found a decrease of costs incurred to the follow-up of compliant and non-compliant patients, as found in a previous study for telemonitoring of patients with diabetes [10]. We also found a significant difference between the three simulations and a greater decrease in cost with the more compliant patients and a reduction of savings in the patients with lower compliance to the telemedicine protocol. We show a similar trend with an exponential reduction of cost after the second year of follow-up with the telemonitoring protocols. The study shows an increase of cost saving incurred to the follow-up of compliant versus non-compliant patients, consistent with the literature of telemonitoring of patients with diabetes [15]. Data are encouraging with regard to the possibility of adopting telemonitoring and telemedicine solutions, offering a potentially more effective and cost-effective alternative to the current homecare assistance.

The approach is conservative since it does not take into account additional cost saving related to the improvement of therapy adherence induced by the use of technology. The progressive increasing adherence to treatment means a better overall use of the method.

With respect to the frequency of transmissions, we recommend to our patients a variable interval depending on the clinical condition: a minimum of twice per week, on average. We expect the optimal adherence to treatment to be 100% for two transmissions per week over a period of 5 working days [15]. Clinical practice shows a constant and progressive increase of treatment's adherence to achieve, in practice, a doubling of the values during the period under review.

Correlations between better therapy compliance for patients enrolled in telemonitoring, the increasing number of physiological parameters registered, and the lower costs for both national and international health systems suggest a technology-embedded solution for improving the quality of life of chronically ill patients.

These preliminary results have some implications for both the academy (from the medical and health economics perspectives), and the management of changes in activities of the health professionals involved.

This work provides an economic perspective of the assessment of telemonitoring, beyond the effectiveness and performance of the technology. With respect to the telemedicine literature, cost-effectiveness analyses are usually absent or the quality of analysis is very low [11]. Although a cost-effectiveness analysis should be the best approach in proving the utility of adopting telemonitoring, our work starts the process toward a cost-effectiveness analysis to focus on the national health care system perspective. However, this is the first step toward a simulation of the potential saving and the budget impact positive change induced by adopting technology in the follow-up of patients with CF.

Benefits of Investing in Telemonitoring

The potential impact of the study results on current medical practices and management of the disease can be summarized in stressing the importance of telemonitoring inducing health care professionals and operators to invest in it. Investing in telemonitoring has the potentiality to produce benefits for patients, the national health care system, as well as the industrial sectors. Five benefits of investing in telemonitoring are described here. The first is improvements in the efficiency in managing different patients with respect to the current practice. The second are improvements in the quality of work of professionals (ie, reduction of stress and reduction of time spent in low value activities that can be performed by using telemonitoring). As a consequence, a reduction of opportunity costs for low-value routines and activities that are still performed by human beings is expected. The third are increases in the quantity and/or quality of available information from or to the patients and health care professionals, at lower costs and in reduced time. If integrated into a communication network, stakeholders and operators like patients, caregivers, health policy decision makers, governments, and public institutions can benefit by the network externalities produced by use of telemonitoring. In effect, the utility of adopting an additional telemonitoring device depends to the number of previous systems adopted. The virtuous cycle induced by adopting telemonitoring passes from an increasing adoption of telemonitoring devices to more available information (here data management and processing under the normative constraints related to patients' privacy are mandatory) including (1) a deeper knowledge of cases that produce a better knowledge of the disease; (2) the increase of quality of individual care and assistance offered to singular patients; (3) the increasing demand of telemonitoring devices; (4) more competition in the market for heath device; (5) the improvement of technology performance and/or reduction of devices' prices; and (6) the increasing utility of adopting new devices. The fourth benefit is turning negative into positive expectations among the health technology producers. Positive expectations induce more investment and new technological solutions sustained by the supply side of the market, reducing the risk of medium and long-run service and monitoring discontinuities. There is no health care sustainability without health technology sustainability, and vice versa. Finally, the fifth benefit is producing relatively cheaper and efficient technological solutions that should be considered the first.

Limitations

One limitation is that we only considered direct health cost (ie, direct non-health and indirect saving costs for patients and their family) and indirect costs such as saving travel cost, saving working days, and saving school days have not been taken into account. A second limitation is that the simulation does not consider confidence intervals (ie, variance of costs and/or savings among patients) because costs are based on hospital tariffs rather than a micro-costing approach that may assess different costs for singular treatments and observations; costs of technology and a micro-costing approach should also be included considering different reimbursement scenarios. A micro-costing approach seems the best approach since up to now, telemonitoring or telemedicine solutions are not included in the Essential Levels of Assistance (LEA) provided by the Italian National Healthcare System (NHS), and there is not a DRG-based reimbursement. Adoption of telemonitoring still depends on individual cases and on voluntarily resources made available by the local health authorities. Because of its high potentiality in terms of medium and long-run saving from the societal perspective (the potential saving for the NHS perspective has been confirmed in the current study), we made a simulation of costs with actualization without taking under consideration the evolution of the disease as incurrence of not predictable comorbidity. In this, it is possible that during 10 years of monitoring some patients die from the disease or incurred co-morbidities. The increasing number of patients enrolled could increase the possibility that some patients' expected lifespan will increase with a relative higher number of hospitalization for tests and related antibiotic treatments. This is especially true for the non-compliance patients with increases of per patient direct and indirect costs due to an increasing of working days lost for both patients and their caregivers.

For assessing the cost-effectiveness of telemonitoring in chronic disease, the best way for modeling the evolution of disease and the managerial perspective could share a discrete event model approach [18], rather than the usually adopted Markov models [19]. If the scope is to take into account the organizational implications of the disease management involving interacting agent, agent-based model simulations [20] should be implemented.

Future Work

To track the impact of new technology with higher performance and be able to send the transmission directly from the device with mobile (SIM), and with the dissemination of broadband on the adherence of telemonitoring, future studies have to be implemented. We think that the constant evolution of technologies can help doctors to incentivize the patients on a better adherence to telemonitoring and self-management of their respective disease. At the same time, new studies are needed to track all costs incurred for the NHS for the follow-up of patients with or without telemonitoring assistance.

In addition, it could be of some interest to adopt a micro-costing approach for assessing the direct health costs and direct non-health costs. We expect a transportation cost-saving in using telemedicine and a reduction of time by formal and informal caregivers during their leisure time spent for assisting patients induced by the use of the technological solution to track the indirect cost (ie, productivity loss) incurred by the patients and their parents during the two different kinds of follow-up.

A comparison among different technology performances in terms of acceptability, effects, and costs could be investigated. This will allow the definition of requirements for new technology diffusion and adoption that is not related to technology only. Introducing new technology always has impact on organizations and decision-making. [21]. Organization, including activity, role, decision making, and interaction changes of current professional operators and patients and their relatives induced by telemedicine solutions should be investigated in more details. It is not only a necessary and very ambitious objective for an updated version of the current study, but a general need for proving the cost-effectiveness of telemedicine, and increasing its actual adoption for years to come.

Conclusion

The current analysis reports a feasibility case study on adopting telemonitoring for CF follow-up. Patients included in this study report are still followed and treated with the usual protocols of follow-up, similar to those who do not practice [17].

The first results of this work have been encouraging. In a previous study we found a statistically significant reduction in hospital admissions and a tendency over-time towards a better stability of the respiratory function [22].

The equipment, a mobile phone with Skype connection, was used to keep in touch with the patients. The percentage of the successful calls appears to have improved over-time, but the mobile phone, in our opinion, continues to be valuable but not always completely reliable.

This study focuses on a preliminary simulation of the economic impact of telemedicine in terms of expected saving. From an economic perspective, health resource saving for the NHS is confirmed, supporting an economically viable method and/or trial. The increase in the calculated savings compared to our previous study indicates, in our opinion, a better efficiency of follow-up.

The advantage, in terms of quality of life for the patients, remains due to an at-home tool that allows patients to more easily stay in contact with the CF center. Expected positive contributions of the technology in supporting patients located in rural areas, to interact and transfer information to the hospital without a connection problem, could be possible with a SIM connection. We expect a better compliance of patients with a related better management of the CF disease, and reduction of costs incurred by the NHS for the onset of co-morbidity.

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Conflicts of Interest

None declared.

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Abbreviations

CF: cystic fibrosis
CPI: consumer price index
DRG: diagnosis-related group
FEVI: forced expiratory volume in the first second
FVC: forced current volume
ICT: information and communication technology
NHS: National Healthcare System
SIM: subscriber identity module

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Original Paper

An Observational Study to Evaluate the Usability and Intent to Adopt an Artificial Intelligence–Powered Medication Reconciliation Tool

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Abstract

Background: Medication reconciliation (the process of creating an accurate list of all medications a patient is taking) is a widely practiced procedure to reduce medication errors. It is mandated by the Joint Commission and reimbursed by Medicare. Yet, in practice, medication reconciliation is often not effective owing to knowledge gaps in the team. A promising approach to improve medication reconciliation is to incorporate artificial intelligence (AI) decision support tools into the process to engage patients and bridge the knowledge gap.

Objective: The aim of this study was to improve the accuracy and efficiency of medication reconciliation by engaging the patient, the nurse, and the physician as a team via an iPad tool. With assistance from the AI agent, the patient will review his or her own medication list from the electronic medical record (EMR) and annotate changes, before reviewing together with the physician and making decisions on the shared iPad screen.

Methods: In this study, we developed iPad-based software tools, with AI decision support, to engage patients to “self-service” medication reconciliation and then share the annotated reconciled list with the physician. To evaluate the software tool’s user interface and workflow, a small number of patients (10) in a primary care clinic were recruited, and they were observed through the whole process during a pilot study. The patients are surveyed for the tool’s usability afterward.

Results: All patients were able to complete the medication reconciliation process correctly. Every patient found at least one error or other issues with their EMR medication lists. All of them reported that the tool was easy to use, and 8 of 10 patients reported that they will use the tool in the future. However, few patients interacted with the learning modules in the tool. The physician and nurses reported the tool to be easy-to-use, easy to integrate into existing workflow, and potentially time-saving.

Conclusions: We have developed a promising tool for a new approach to medication reconciliation. It has the potential to create more accurate medication lists faster, while better informing the patients about their medications and reducing burden on clinicians.

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KEYWORDS

medication reconciliation; adverse drug event; medication errors; medication adherence; patient medication knowledge; decision making, shared

Introduction

Medication error is one of the most common patient safety issues in the health care system [1-3]. Medication error is a major contributor to preventable adverse drug events (ADEs), which cause more than 3.5 million physician office visits, an estimated 1 million emergency department visits, and approximately 125,000 hospital admissions each year [4]. The national cost of ADEs is estimated to be $3.5 billion dollars every year [5]. Medication reconciliation is an intervention designed to reduce medication errors and ADEs. It is a process of creating the most accurate list possible of all medications that a patient is taking—including drug name, dosage, frequency, and route—and comparing that list against the existing medication list in the patient record [6].

Due to its early promise and large potential impact, medication reconciliation is mandated and reimbursed throughout the health care system. The Joint Commission specified medication reconciliation across the care continuum as a National Patient Safety Goal [7]. The Institute for Healthcare Improvement has medication reconciliation as part of its 5 Million Lives Campaign [8]. Medicare reimburses for medication reconciliation (Current Procedural Terminology code 111F) and has it as part of the requirement for Electronic Medical Record (EMR) Meaningful Use certification [9].

However, despite the high hopes, 2 large meta reviews revealed that medication reconciliation only had limited success in reducing ADEs in hospital settings [10,11]. Further investigations indicated that multidisciplinary team-based medication reconciliation approaches tend to work best. For example, a study showed a reduction of medication discrepancy from 89% to 49% by involving everyone, including patient, front desk staff, nurse, and physician, in the medication reconciliation process [12]. Specifically, 2 factors have emerged as important to medication reconciliation success. It includes the following:

1. Patient’s knowledge about his own medication use is of crucial importance for successful reconciliation [13]. In multiple studies, patients have demonstrated that they can identify discrepancies in their own medication lists with assistance from electronic tools [14,15].
1. The clinician team’s clinical knowledge gap is a major barrier for successful medication reconciliation [16]. For instance, nurses are inadequately trained on pharmacy subjects [17]. Pharmacist-led or nurse-pharmacist medication reconciliation demonstrated greater improvement in clinical outcomes [10,18,19]. It is also shown that providing specialized medication reconciliation training to medical residents could reduce medication discrepancy [20].

A promising approach to address both factors is to engage patients and supplement clinical knowledge using artificial intelligence (AI)-based electronic systems. The AI system can guide the patient to review his own medication lists and then to flag potential issues for the physician to review. For instance, the AI can understand hundreds of nonstandard abbreviations in handwritten prescriptions and can discern medications with multiple names that could confuse even expert clinicians [21]. It is shown that computerized systems have the capability to process medication terminologies [22].

The technology solution could also facilitate patient education by automatically showing the medication indications, side effects, prices, and other relevant information to patients. Such information is crucial for patients to make informed decisions on their medications. It could also flag potential discrepancies and prompt the patient to ask the clinicians in the care team to explain.

Electronic decision support tools have already shown promise in improving medication reconciliation [23-25]. A portable AI-powered decision support tool can not only help the patient identify and manage medications but also enable better team work because everyone can review the information on the screen together. Incorporating patients in the medical decision-making process has resulted in increased patient’s commitment and understanding of treatment plans, improved adherence, and increased patient satisfaction [26,27]. A recent survey indicated that patients themselves are very interested in using tablet devices in clinics to exchange information with the clinicians [28]. In primary care setting, having the patient do the work also has added benefits of saving clinician time and minimizing workflow interruptions.

In this paper, we will discuss how we built an AI-powered iPad tool to improve medication reconciliation and then evaluate the solution in real-world primary care settings.

Methods

Intervention

The software we developed for medication reconciliation is a Web-based app optimized for touch screen tablets, such as the Apple iPad. It takes a team approach to organize its workflow: The patient provides information on his up-to-date medication use and flags medications that he wants to discuss. The clinicians review the list together with the patient to determine what the most accurate list is. During the shared-screen review process, the clinicians can answer patient's questions about each medication and provide an opportunity to adjust certain medications to address patient concerns such as cost and side effects.

The app allows the front desk administrator to load a list of currently scheduled patients on the screen. The front desk administrator can tap on a patient name and then hand the tablet device to the patient at the time of check-in together with other medical or financial forms the patient needs to fill out.

The Use of AI Assistance

The intervention tool uses AI in 3 ways. First, it contains a machine learning (ML) module to recognize and parse prescription instructions written in natural language. The module is trained on over 2000 real-world prescription records from EMRs and achieved an error rate of less than 2%. Because all parsed medication records are again reviewed by both the patient and physician, the AI is truly an assistant and will not endanger patient safety. The details of the ML and natural language processing algorithms are beyond the scope of this paper.

Second, the tool aggregates multiple medication databases from National Institutes of Health, Food and Drug Administration (FDA), and commercial vendors to figure out equivalent or conflicting prescriptions in its medication reconciliation algorithm. The ability to organize data into knowledge representations and apply the knowledge to deduce meaning from real-world data is a hallmark of AI algorithms.

Finally, the tool can converse with the patient to go through the medication review process. The conversation is semistructured and rule-based.

Patient Workflow

The patient receives the tablet and confirms that his or her name is indeed on the screen. Following the screen instructions, the patient now starts the medication reconciliation process for the clinic visit.

The patient's current medication list is loaded by the app from the clinic's connected EMR. The AI parses each natural language prescription record to break it into medication name, formulation, dose, and frequency information. The app will then present the medications to the patient one screen at a time (Figure 1). The screen shows the medication name, dose, instructions, and an image of the pill or package, if available. The patient has the options to do the following:

- Confirm that the patient is taking this medication as instructed.
- Remove the medication from the list because the patient is not taking it, or no longer taking it, or has not filled it.
- Mark the medication as uncertain if the patient is unsure whether he or she is taking it.
- Edit the strength and dose of the medication if those are incorrect.

After the patient reviews all his or her current medications in the EMR, the app asks the patient if there are more to add. If the user chooses to add more medications, the app will show an auto-complete text field for the patient to add medications by just spelling out a few letters in the name. Once the patient chooses a medication name, the app lists all brand names and generic variations of this medication, with pill pictures if available. The user can select a medication from the list and then specify the number of pills taken every time and number of times the pills are taken per day. This process is depicted in Figure 2. The patient repeats this process until he or she has no more medications to add.

Once the patient is done, the app shows a "reconciled" list on the screen (Figure 3). When building this list, the AI goes through each medication, determines its generic active ingredients, and then compares them with other medications on the list. All duplicates will be automatically flagged by the AI. The AI-built reconciled list highlights medications that have been deleted, altered, or added. It also flags medications that the patient has marked as "unsure." The patient can review the list for accuracy, and he or she can still add, delete, or make changes to any medication on the list. Notice that the screen shown in Figure 3 follows the patient into the clinical interview or encounter. The physician will work on this screen with the patient later.

After the patient is done reviewing his or her medication list, he or she might be still waiting to see the physician. The reconciled list provides a content page of educational material for each medication for the patient to learn more about his or her own medications, if the patient is interested. The educational page contains the following details:

- Link to FDA-structured label of the medication.
- Link to Medline Plus consumer content for selected medications.
- Link to GoodRx for selected medication so that the patient can look up cheapest prices for the medication in nearby local market.

Next, the patient brings the reconciled list on the tablet into the examination room. When the physician comes in, he or she will review the list with the patient together on the shared tablet screen (Figure 3). They will discuss why certain medications are stopped (eg, side effect, cost, and so forth) and make shared decisions on whether to change or discontinue certain medications. Once they are finished, the physician can close this screen and send the updated list back to the EMR.

After medication reconciliation, the clinical encounter happens as usual. The physician will examine the patient and potentially adjust medications based on new patient complaints. After the clinical encounter is over, the patient is likely to have an updated prescription. The patient will then follow on-screen instructions on the tablet to load the updated list from the EMR. The screen now shows the difference between the patient's previous reconciled list and the new prescription list. It shows which medications are removed or added. The patient should now review this list and confirm whether it is indeed correct to his or her understanding. If the patient spots any issue at this time, he or she should request to clarify with the physician or a nurse before leaving the office.

The patient also has the option to access his or her medication lists from home. The patient will receive a secure message containing his or her login credentials in the clinic's patient portal.

Figure 1. Review of a medication from the patient's list.

Do you take this medicine?

ABILIFY 10 MG TABLET; TAKE 1 TABLET DAILY

Observational Study

To evaluate the usability of the solution, an observational study was conducted in a South Austin Family Practice clinic. We followed and observed 10 patients with complex medications over a span of 2 days. We examined whether they were able to complete the core medication reconciliation tasks on the tablet device and structured the observation using a software usability heuristic checklist.

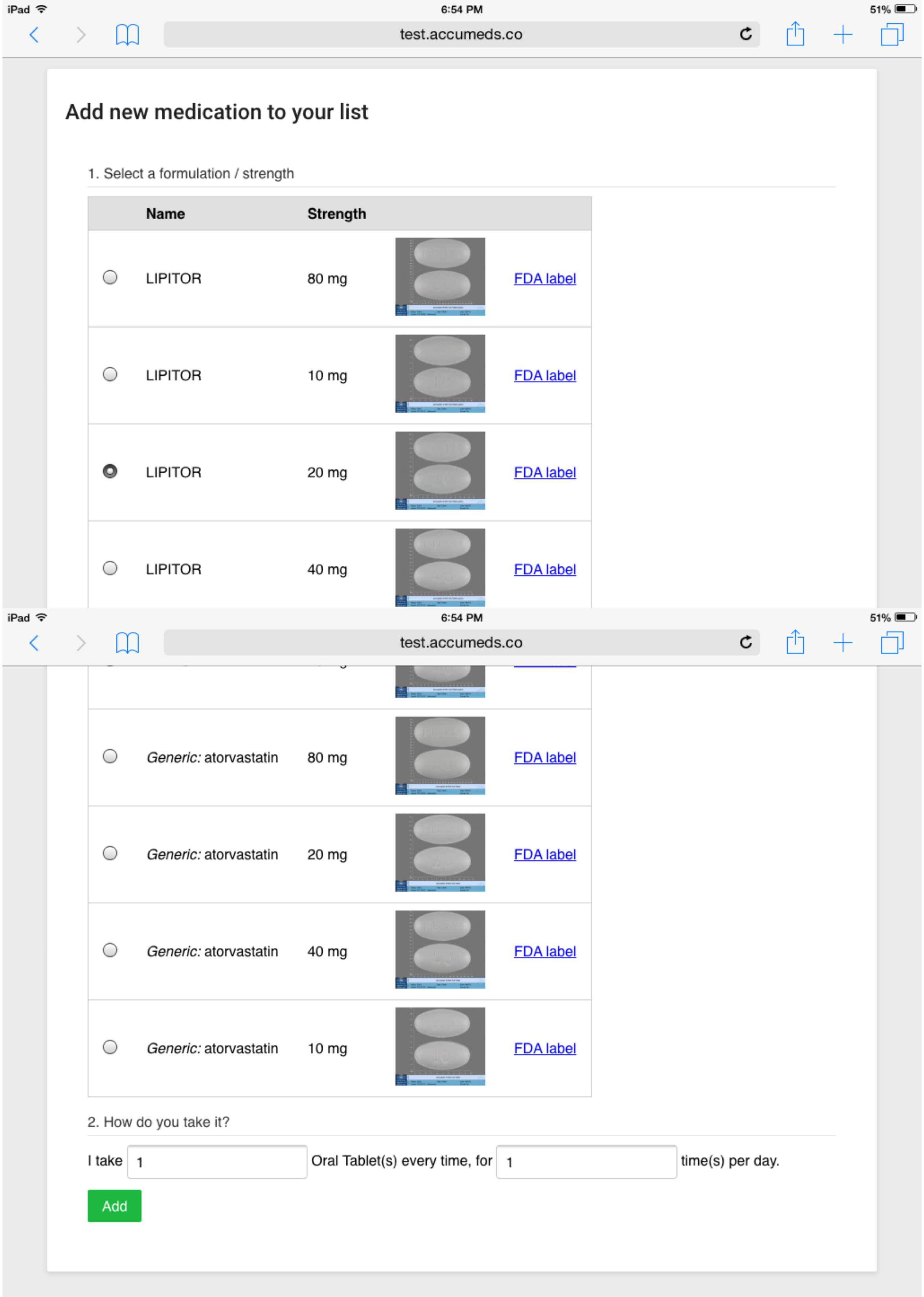
The patients are selected by the office administrator the day before the study based on the current appointment schedule. The patient selection criteria are as follows:

- Each patient must have at least 5 active prescribed medications.
- The patient is previously scheduled to see Dr. Poonawala in the clinic on the 2 study dates.
- Medicare patients are prioritized for recruitment.

The selected patient is recruited at the time to check-in at the front desk. If the patient indicates that he or she is willing to participate, reads or writes English, and knows how to use a tablet device, the study coordinator will go over the informed consent with her. After the patient reviews and agrees to the consent, a tablet device will be provided to the patient with his or her personal and medical history information already loaded to start the study.

The study coordinator stays with the patient and passively observes how the patient is using the device. The study coordinator observes the patient’s interaction with the app and then notes any problems or difficulties the patient encounters. The patient issues are categorized according to 10 heuristics [29] commonly used to evaluate computer user interfaces.

Figure 2. The process to add a medication to the list.



Add new medication to your list

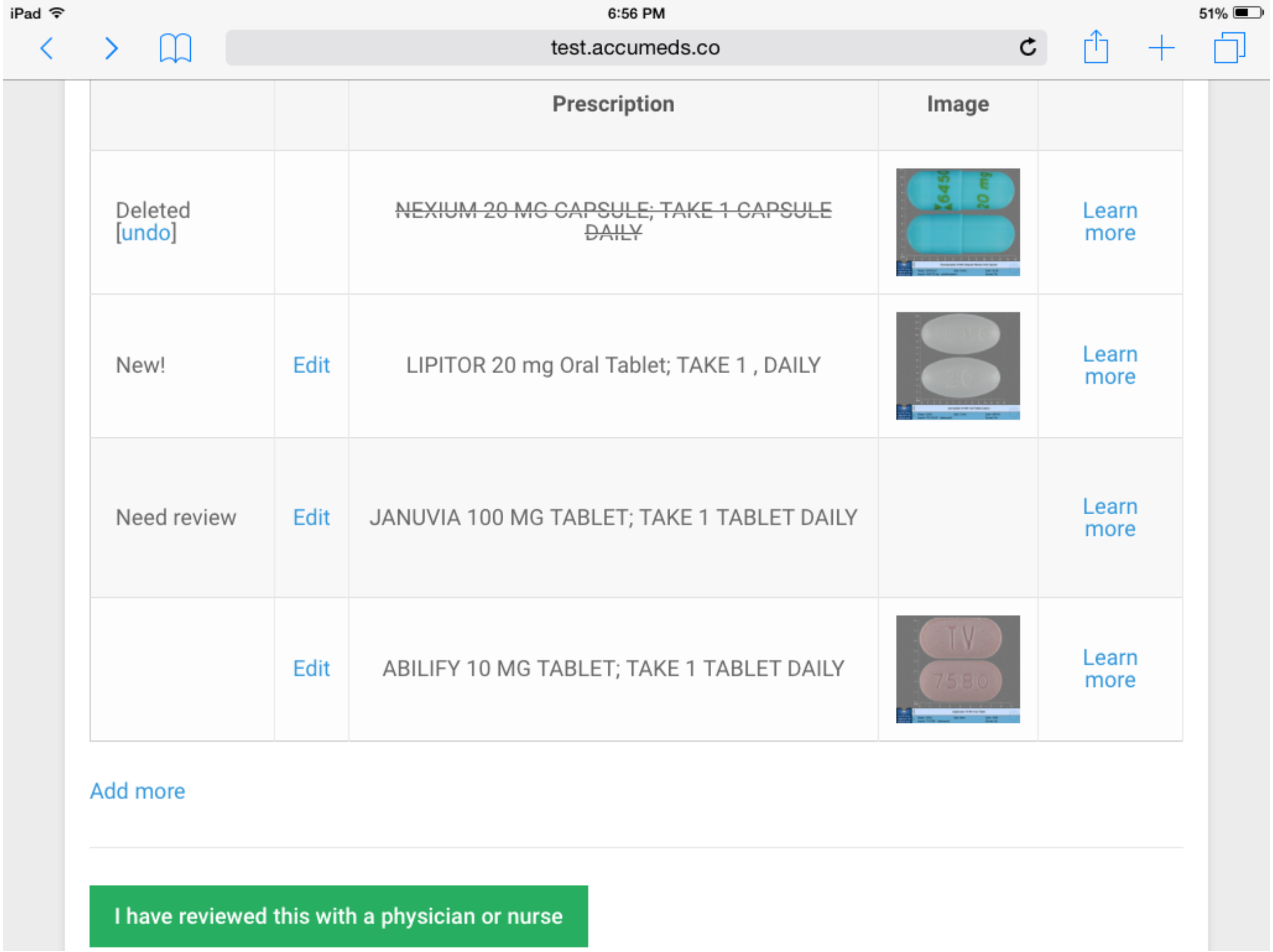
1. Select a formulation / strength

	Name	Strength		
○	LIPITOR	80 mg		FDA label
○	LIPITOR	10 mg		FDA label
●	LIPITOR	20 mg		FDA label
○	LIPITOR	40 mg		FDA label
○	*Generic:* atorvastatin	80 mg		FDA label
○	*Generic:* atorvastatin	20 mg		FDA label
○	*Generic:* atorvastatin	40 mg		FDA label
○	*Generic:* atorvastatin	10 mg		FDA label

2. How do you take it?

I take 1 Oral Tablet(s) every time, for 1 time(s) per day.

Figure 3. The reconciled medication list. This is the shared screen that the patient and clinician can work together to make and approve medication changes.



		Prescription	Image	
Deleted [undo]		~~NEXIUM 20 MG CAPSULE; TAKE 1 CAPSULE DAILY~~		Learn more
New!	Edit	LIPITOR 20 mg Oral Tablet; TAKE 1 , DAILY		Learn more
Need review	Edit	JANUVIA 100 MG TABLET; TAKE 1 TABLET DAILY		Learn more
	Edit	ABILIFY 10 MG TABLET; TAKE 1 TABLET DAILY		Learn more

Patient Survey

In addition to the observational study conducted by a heuristic evaluator, the patient was directly asked at the end of the session how he or she perceives the usability of the product. We used the standard and widely used Computer System Usability Questionnaire [30] for this purpose. The patients answer those questions from SurveyMonkey Web site on the same tablet device they just used.

To evaluate the patients' readiness to adopt and use the solution in future clinic visits, we surveyed them using a customized unified theory of acceptance and use of technology (UTAUT) instrument [31]. The UTAUT is designed to evaluate factors that could facilitate or impede future adoption of the technology. Our small sample of users does not have the statistical power to evaluate the entire model, but the survey answers gave us important suggestions on how to improve the product and deployment process to foster future adoption.

Clinicians Interview

At the end of the clinical days, the researchers conducted one-to-one interviews with the physician and nurse who participated in the study. The one-to-one interview is unstructured [32], and it is designed to prompt free-form suggestions from the clinicians on how the tool impacted their clinical workflow. Specifically, we asked questions about whether the tool saved time for the clinicians and whether the clinicians feel the tool helped improve patient care or reduce potential medication errors.

The clinician responses were recorded in interview notes and are summarized in the Results section.

Results

The medication reconciliation tool is successfully deployed in the clinic and used by both patients and clinicians in the 2 days. In this section, we report results from the observation study, patient survey, and clinician interviews.

Observational Study

Medication Reconciliation

We collected valid data from 10 patients in the study. The patients have the following characteristics:

- Between 50 and 87 years old.
- Seven are women, and 3 are men.
- Have between 5 and 16 active medications each before the appointment.

The 10 patients have a combined 92 active medications before the appointment. After review, they changed 26 medication records, representing 28% of the total records. All the patients changed at least 1 medication record. This indicates widespread problem in medication discrepancy and highlights the patient's essential role in providing accurate medication information.

After the initial medication review and consultation with the physician, only 1 patient identified problem with the new prescription list at discharge. This indicates that the reconciliation has successfully brought the patient and clinicians on the same page with regard to medications.

Learning About Medications

Although the software tool provides extensive materials for the patient to learn more about their medications, including indications, side effects, and prices, no patient has taken advantage of these features. It appears that the clinic environment is not well suited for reading long articles and research reports. Several patients remarked that short video clips will be much more appealing while they wait.

In addition, patients have also indicated that they are more likely to read about their medications after they go home. This indicates the need to follow-up with the patient with email or other content after they go home to complete the patient education cycle.

Heuristic Evaluation of the User Interface

Key usability problems identified in the heuristic evaluation are categorized by the heuristics (Table 1).

Table 1. Heuristics of the software usability.

Heuristics	Examples
Aesthetic and minimalist design	• The blank space for missing pill images is a waste of space and could be confusing to some users. • The text boxes for dose or frequency in "add medication" are inconsistent with the rest of the UI.
Consistency and standards	• The "confirm" action button colors and locations are inconsistent—it could be blue or green and could be located to the left or right.
Documentation and help	• There is minimum in-app documentation or help available.
Error prevention	• If the user taps on a wrong button while reviewing medications, there is no easy way to correct it. The user has to wait until the review screen, and the steps to correction are difficult.
Flexibility and efficiency of use	• Adding medication to the list is inefficient. The user needs to figure out terms he or she is not familiar with, such as dose and frequency.
Help user recognize, diagnose, and recover from errors	• When the user accidentally hits the home button, the iPad exits to the home screen without an obvious way to go back into the app. • The user could force exit the app and lose the session. • Some of the "invalid input" alert boxes are poorly worded.
Match between system and the real world	• The delay in Web page loads mismatches the user experience in reviewing real-world paper-based forms.
Recognition rather than recall	• Abbreviations are sometimes used in the text description.
User control and freedom	• It is difficult to go back a few screens to correct a prior error.
Visibility of system status	• There are often delays when the next Web page loads. During that time, the system appears unresponsive. Need to give strong visual clues for the "wait" status.

Patient Survey

Usability

Almost all patients saw themselves as "not good at technology" and were initially uneasy about using the iPad. However, all the patients were able to use the core features of the tool with minimal help.

On the scale from 1 to 7 (7 being the most easy-to-use), the patients rated the tool a 6.5—very easy to use. The user satisfaction score for the tool is 6.0 of 7. Patients strongly agreed that the tool is a good idea (score 6.5 of 7).

Intent for Future Adoption

The patients showed strong interests in using the tool for future medical visits. When the patients were asked whether they will use the tool again in this clinic, 9 of 10 patients answered *Yes*. Of 10 patients, 8 answered that they will use it in a different clinic. However, only 5 of 10 patients would use the app to manage medications at home. We dictate that this reflects the user's perception of limited utility for medication management at home without professional help nearby.

The tool is thought to be easy-to-use and have high perceived usefulness. However, at least 1 patient questioned the value of the tool to patients. She remarked that the tool seems to save time for clinicians but does not save time for the patient because the patient now needs to do more work. We dictate that this objection can be mitigated by emphasizing the tool's benefit to patients in terms of reducing potential medication errors and harms.

Seven of 10 patients indicated that having someone to help in the clinic is a critical factor for them to adopt the tool. It is also true that the patient can more easily act on the results from the tool inside a clinic because the prescribing physician is on hand to review the results and potentially make changes to the prescription.

Clinician Interview Results

The general consensus is that the tool saved the nurse time by reducing their questions about patient medications. However, making changes to medication on the tool is harder than doing it on paper. But, that is probably a reflection of the nurses being unfamiliar with the tool with only 10 patients using it.

During the pilot, the tool does not save time for the physician although increased familiarity with the tool could result in time-saving in the future. The physician reported more confidence in the accuracy of the patients' medication list reported by the tool.

Conclusions

The tablet-based medication reconciliation tool in medical clinic is well accepted by patients and clinicians. The AI component facilitated the patients themselves to recognize their own medications and report discrepancies for the clinicians to review. It has potentials to improve medication accuracy and reduce medication errors in the clinic.

Conflicts of Interest

Michael Yuan is the CEO of Ringful Health, which creates the software tool and could benefit from its commercial use.

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Abbreviations

AI: artificial intelligence
ADEs: adverse drug events
EMR: electronic medical record
ML: machine learning
UTAUT: unified theory of acceptance and use of technology

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Original Paper

Media Use by Children, and Parents' Views on Children's Media Usage

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Abstract

Background: New (mobile phones, smartphones, tablets, and social media) and traditional media (television) have come to dominate the lives of many children and adolescents. Despite all of this media time and new technology, many parents seem to have few rules regarding the use of media by their children and adolescents.

Objectives: The aim of this study was to evaluate media access/use of children and to evaluate beliefs and attitudes of parents concerning the use of old and new media in Turkey.

Methods: This is a cross-sectional electronic survey of a national convenience sample in Turkey via SurveyMonkey, including 41 questions regarding topics relevant to television, computers, mobile phones, iPad/tablet use, and social media accounts.

Results: The responses of the 333 participants (238 women, 95 men; 27-63 years) were evaluated. The average daily watching alone time was 0 to 2 hours among 53.4% (46/86), and daily coviewing time with parents of children was 0 to 2 hours among 62.7% (54/86) of children below 2 years of age. Regarding parents' monitoring their children's computer use (n=178), 35.4% (63/178) of the parents prefer coviewing, 13.5% of the parents use a family filter (24/178), and 33.1% (59/178) of the parents prefer to check Web history. Approximately 71.2% (237/333) of the participants had an iPad/tablet in the house, 84.3% (200/333) of the parents give their children permission to use the iPad/tablet. Of the parents, 22.5% (45/200) noted that their children used the iPad/tablet at the table during lunch/dinner and 57.9% (26/45) of these children were aged 5 years and below. Of parents, 27.3% (91/333) agreed that the optimal age for owning a mobile phone was 12 years, and 18.0% (60/333) of the parents noted that their children (one-third was below 2 years) used the mobile phone at the table during meals. A total of 33.3% (111/333) children/adolescents have a Facebook profile, and 54.0% (60/111) were below 13 years of age. Approximately 89.2% (297/333) of the parents emphasized that the Internet is essential for their child's education.

Discussion: According to our study results, knowledge regarding the use of old and new media is limited among the parents in Turkey. Our study showed that screen time and mobile device use (including during meals) are common in children below 2 years of age, whereas no screen time was recommended for children below 2 years of age. We concluded that there is need for evidence-based guidelines regarding the use of the Internet and social media for parents and parents should ensure that there is a plan in place for the use of children's media.

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KEYWORDS

Internet; social media; children; parents; screen time

Introduction

In recent decades, there has been an overload in the diversity of media available. New (mobile phones, smartphones, tablets, and social media) and traditional media (television) have come to dominate the lives of many children and adolescents and the spaces where they spend their leisure time [1,2]. The presence of a computer and/or television in the child's bedroom and access to the Internet, has also increased; the majority of children and adolescents own mobile phones [1,3,4]. There is an increasing trend among younger children and infants to use mobile devices [5]. The study by Kabali et al [6] showed that children ranging in age from 6 months to 4 years spend 45 minutes a day watching television, 27 minutes watching television shows or videos using a mobile device, 22 minutes using apps on a mobile device, and 15 minutes playing games on a video console. Recently reported "Digital in 2016" of "We Are Social" showed that 58% of whole population in Turkey are active Internet users, 53% are active social media users, 90% have mobile connections, and 45% are active mobile social users [7]. Among the whole population, 86% have a mobile phone (all types), 56% have a smartphone, 48% have a desktop or laptop computer, and 11% have a tablet device. In Turkey, the average daily television viewing time is 2 hours 18 minutes, the average daily use of the Internet via computer or tablet is 4 hours 14 minutes, and the average daily use of social media via any device is 2 hours 32 minutes. Regarding Facebook user profiles, 19% of all users are aged between 13 and 19 years [7].

It is important that parents become aware of the nature of the Internet and social media sites, given that not all of them are healthy environments for children and adolescents. Despite all of this media time and new technology, many parents seem to have few rules regarding the use of media by their children and adolescents [1]. In a recent study, two-thirds of the children and teenagers reported that their parents have "no rules" regarding time spent using social media [3]. There is limited information about the parent's attitudes in Turkey. The aim of this study was to evaluate media access/use of children, and to evaluate certain beliefs and attitudes of parents about children's media use including optimal age for use, presence of media in the bedroom, age for having media in the bedroom, time of use, age for opening accounts on social networks, and parental control.

Methods

Survey

This study was a cross-sectional electronic survey of a national convenience sample in Turkey. A self-completion questionnaire was developed for parents who use social media to determine their attitudes, beliefs, and opinions concerning the use of mobile phones, television, Internet, and social media of their children. We created a Web-based questionnaire via SurveyMonkey, including 41 questions relevant to topics concerning television, mobile phones, Internet, iPad/tablet use, Facebook, and other social media accounts. A cover letter and questionnaire were electronically mailed via SurveyMonkey to a convenience sample of participants. The questionnaire was mailed with a cover letter explaining the details of the study, identifying the purpose and confidentiality of the study, and reminding potential participants that their participation was voluntary. Anonymity was insured by not requiring names on the questionnaire. No financial incentives were provided for participating in the study

We evaluated the presence of television, computers, mobile phones, and iPad/tablets at home or in the child's bedroom as well as daily media use of children and adolescents. Our aims also included parents' views about their children's media use, and the ways that parents opt to monitor use of media.

Questionnaire

The questionnaire included questions regarding the following topics: (1) demographic variables (age, gender, educational status, number of children, and age of children), (2) "television" (optimal time for viewing television in the child's room, presence of television in the participant's child's room, age at which the parents allowed the television into the child's room, average daily watching alone time of children, average daily watching time of children with parents, and preferred and nonpreferred program format for your children), (3) "computer" (optimal time for using the computer in the child's room, presence of computer in the participant's child's room, age at which the parents allowed the computer into the child's room, presence of Internet connection by the participants in the child's room, control method of Internet safety/presence of family filter, and use of parent's computer by the children), (4) "iPad/tablet" (presence of iPad/tablet in the home, parental consent of iPad/tablet use in the home, average daily use of iPad/tablet by the children, and use of iPad/tablet during the child's meal time), (5) "mobile phone" (optimal time for mobile phone use for children, presence of a mobile phone for the participant's child, presence of supervision of the child's mobile phone use, and use of mobile phone during the child's meal time, (6) "Facebook" (optimal age for opening a Facebook account for children under parental supervision, optimal age for opening a Facebook account for children with their control, presence of a Facebook account for the participant's child, supervision of the child's Facebook account by the parents, and attitude concerning the use of child photos by parents in Facebook), and (7) "miscellaneous questions about the use of Internet" (need for use of the Internet for the child's development and favorite websites and apps for the child's health and education).

Data Analysis

A statistical analysis was performed using SurveyMonkey and SPSS 16. The descriptive analysis was calculated within SurveyMonkey and statistical program and described as numbers and percentages.

Results

Questionnaire

A self-completion questionnaire was sent via email including a SurveyMonkey questionnaire link to a random selection of 500 people in 2014. In total, 381 participants completed the questionnaire; however, 48 participants were excluded from the study because they had no children.

The responses of the 333 participants (238 women and 95 men) aged between 27 and 63 years (mean age, 38.7 ± 6.1 years) were evaluated. Regarding the educational status of the participants, 44.4% (148/333) were university graduates, and 49.5% (165/333) had PhDs or had achieved a similar level of higher education. A total of 49.8% (166/333) of the participants had one child, 45.0% (150/333) had two children, 4.5% (15/333) had three children, one participant had four children, and one had five children, totally 520 children. The age of the participants' children varied between 1 month and 18 years; 5.4% (28/520) of the children were below 1 year of age, 11.1 % (58/520) of the children were aged between 1 and 2 years, 16.9% (88/520) of the children were aged between 2 and 5 years, 43.2% (225/520) of the children were aged between 6 and 11 years, and 23.2% (121/520) of the children were aged between 12 and 17 years. Approximately 89.2% (297/333) of the parents emphasized that the Internet is essential for their child's education.

Television

According to the participants' responses, 49.8% (166/333) indicated that there was no need for the presence of television in the child's room until the child was 18-years old; and 12.2% (41/333) of the participants had no idea regarding the optimal time that television should be available in the child's room (Table 1). A total of 7.8% (26/333) of participants had a television in their child's room. Among the all-age group, regardless of the child's age, the average daily watching alone time of children was 0 to 1 hour according to 42.3% (141/333) of the participants, 1 to 2 hours according to 33.6% (112/333) of the participants, 2 to 4 hours according to 6.3% (21/333) of the participants, >4 hours according to 8.4% (28/333) of the participants, and 9.3% (31/333) of the participants said that they prefer no watching alone. Among the parents who have children below 2 years of age (n=86), the average daily watching alone time of children was 0 to 1 hour according to 33.7% (29/86) of the participants, 1 to 2 hours according to 19.7% (17/86) of the participants, 2 to 4 hours according to 15.1% (13/86) of the participants, >4 hours according to 4.6% (4/86) of the participants, and 26.7% (23/86) of the participants said that they prefer no watching alone. Among the parents who have children aged between 2 and 17 years of age (n=267), the average daily watching alone time of children was 0 to 1 hour according to 42.6% (114/267) of the participants, 1 to 2 hours according to 35.2% (94/267) of the participants, 2 to 4 hours according to 5.2% (14/267), >4 hours according to 9.8% (26/267) of the participants, and 7.2% (19/267) of the participants said that they prefer no watching alone.

The average daily watching time of children with parents (coviewing) was 0 to 1 hour according to 28.2% (94/333) of the participants, 1 to 2 hours according to 36.0% (120/333) of the participants, 2 to 4 hours according to 18.6% (62/333) of the participants, >4 hours according to 12.0% (40/333) of the participants, and 4.8% (16/333) of the participants said that they prefer no watching alone. Among the children below 2 years of age, the average daily coviewing time was 0 to 1 hour according to 38.3% (33/86) of the participants, 1 to 2 hours according to 24.4% (21/86) of the participants, 2 to 4 hours according to 8.1% (7/86) of the participants, >4 hours according to 10.4% (9/86) of the participants, and 18.6% (16/86) of the participants said that they prefer no watching alone. Among the children aged between 2 and 17 years, the average daily coviewing time was 0 to 1 hour according to 26.5% (71/267) of the participants, 1 to 2 hours according to 37.8% (101/267) of the participants, 2 to 4 hours according to 20.2% (54/267) of the participants, >4 hours according to 11.9% (32/267) of the participants, and 3.3% (9/267) of the participants said that they prefer no watching alone.

Table 1. Belief and Attitudes of Parents About Television Use During Childhood

Television		n	%	95% confidence interval
Optimal time to presence of television in child's room				
	No television in child's room until 18	166	49.8%	44.3-55.1
	<2 years	0	-	-
	2-5 years	8	2.4%	0.8-4.0
	6-11 years	37	11.3%	7.9-14.7
	12-17 years	81	24.3%	19.7-28.9
	Not known	41	12.2%	8.7-15.7
Presence of television in the child's bedroom				
	Total	26	7.8%	4.9, 10.7
	0-2 years	1	3.8%	0, 11.5
	2-5 years	2	7.6%	0, 17.8
	6-11 years	11	42.3%	23.3, 61.3
	12-17 years	12	46.1%	26.9, 65.2

Computer

According to the participants' responses, the optimal time for the presence of a computer in the child's room varies between 1 and 18 years. Table 2 summarized the results of parental beliefs and children use of computer. The optimal time has been defined as 6 to 10 years by 38.9% (123/333) of parents and 11 to 14 years by 24.0% (80/333) parents, 17.4% (58/333) of the participants had no idea, and 6.9% (23/333) of the participants thought that there was no need for a computer to be available in the room of a child below 18 years of age. Approximately 28.0% (82/333) of the participants have a computer in the child's room, and the age at which the parents brought the computer into the child's room varies from 1 to 17 years (median age, 9 years). Approximately 95.1% (78/82) of the children who have a computer in their room also have an Internet connection via a wireless modem in the house. Regarding the parents' monitoring of their child's computer use, 35.4% (63/178) of the parents prefer coviewing, 13.5% (24/178) of the parents use a family filter, 33.1% (59/178) of the parents prefer to check Web history, and 17.9% (32/178) of the participants do not monitor their child's computer use (Table 2).

Table 2. Belief and Attitudes of Parents About Computer Use During Childhood

Computer		n	%	95% confidence interval
Optimal time to presence of computer in child's room				
	No computer in child's room until 18	23	6.9%	4.2, 9.6
	1-5 years	16	6.3%	3.7, 8.9
	6-10 years	123	36.9%	31.7, 42.1
	11-14 years	80	24.0%	19.4, 28.6
	15-17 years	33	9.9%	6.7, 13.1
	Not known	58	17.4%	13.3, 21.4
Presence of computer in the child's bedroom		82	27.8%	23, 32.6
	1-2 years	2	2.4%	0, 5.7
	2-5 years	2	2.4%	0, 5.7
	6-11 years	34	41.5%	30.8, 52.1
	12-17 years	44	53.7%	42.9, 64.5
Presence of monitoring method for child's computer use		178		
	Coviewing	63	35.4%	28.3, 42.4
	Family filter	24	13.5%	8.4, 18.5
	No monitoring	32	17.9%	12.2, 23.5
	Check website history	59	33.1%	26.1, 40.0

iPad/Tablet

Approximately 71.2% (237/333) of the participants have an iPad/tablet in the house, and 84.3% (200/237) give their children permission to use the iPad/tablet. The age distribution of the children were summarized in Table 3. Among the all-age group, the average daily iPad/tablet use of children was 0 to 1 hour according to 63.9% (213/333) of the participants and 1 to 2 hours according to 16.8% (56/333) of the participants. Among the children below 2 years of age, the average daily iPad/tablet use of children was 0 to 1 hour according to 59.3% (9/15) of the participants. Among the children aged between 2 and 17 years of age, the average daily iPad/tablet use of children was 0 to 1 hour according to 64.7% (120/185) of the participants, 1 to 2 hours according to 18.9% (35/185) of the participants, 2 to 4 hours according to 5.4% (10/185) of the participants, and more than 4 hours according to 10.8% (20/185) of the participants.

Approximately 22.5% (45/200) of the parents noted that their children used the iPad/tablet at the table during lunch/dinner. Of these children, 26.6% (12/45) were aged between 0 and 2 years, 31.1% (14/45) of the children were aged between 2 and 5 years (Table 3).

Table 3. Belief and Attitudes of Parents About iPad/Tablets Use During Childhood

iPad/Tablet		n	%	95% confidence interval
Presence of iPad/tablet at home		237	71.2%	66.3, 76.0
Child's use of iPad/tablet at home		200	84.3%	79.7, 88.9
	0-1 years	2	1.0%	0, 2.4
	1-2 years	13	6.5%	3.0, 9.9
	2-5 years	31	15.5%	10.5, 20.5
	6-11 years	111	55.5%	48.6, 62.3
	12-17 years	43	21.5%	15.8, 27.2
Use of iPad/tablet during lunch/dinner		45	22.5%	16.7, 28.2
	0-1 years	1	2.4%	0, 6.8
	1-2 years	11	24.4%	11.9, 37
	2-5 years	14	31.1%	17.8, 44.6
	6-11 years	12	26.7%	13.7, 39.6
	12-17 years	7	15.6%	5.0, 26.2

Mobile Phone

According to the participants' responses, 3.3% (11/333) indicated that there was no need for the presence of a mobile phone for children until the age of 18 years. Approximately 19.5% (65/333) of the participants responded as 6 to 11 years, 59.8% (199/333) of the participants responded as 12 to 17 years (Table 4). According to the participants' responses, 27.3% (91/333) indicated that the optimal time for owning a mobile phone was 12 years of age. Parents commonly bought their children a mobile phone when they were more than 7-years old, and 17.4% (58/333) of the participants thought that the optimal time for owning a mobile phone was when their children started to attend college. A total of 91 children had mobile phones during the study period, and among them, 64.8% (59/91) are between the ages of 12 and 17 years. Approximately 18.0% (60/333) of the parents noted that their children used a mobile phone at meal times or crying and 6.7% (4/60) were less than 1-year old, 23.3% (14/60) of these children ranged in age between 1 and 2 years, 26.7% (16/60) were aged between 2 and 5 years, 36.7% (22/60) were aged between 6 and 11 years, and 6.8% (4/6) were more than 11-years old (Table 4).

Table 4. Belief and Attitudes of Parents About Mobile Phone Use During Childhood

Mobile phone		N	%	95% confidence interval
Optimal time to presence of mobile phone (children)				
	No mobile phone until 18	11	3.3%	1.4, 5.2
	<2 years	-	-	-
	2-5 years	-	-	-
	6-11 years	65	19.5%	15.2, 23.8
	12-17 years	199	59.8%	54.5, 65.1
	Not known	58	17.4%	13.3, 21.4
Percentage of children who have a mobile phone		91	27.3%	22.5-32.1
	1-2 years	2	2.2%	0, 5.2
	2-5 years	1	1.1%	0, 3.2
	6-11 years	29	31.9%	22.3, 41.4
	12-17 years	59	64.8%	54.9, 74.6
Use of mobile phone during lunch/dinner or crying		60	18.0%	13.8, 22.1
	0-1 years	4	6.7%;	0.37, 13.0
	1-2 years	14	23.3%,	12.6, 34.0
	2-5 years	16	26.7%;	15.5, 37.9
	6-11 years	22	36.7%;	24.5, 48.9
	12-17 years	4	6.7%;	0.37, 13.0

Facebook

According to the participants’ responses, the median optimal age for opening a Facebook account for children under parental supervision was 8 years; the optimal age for a Facebook account for children with their control was 13 years. Regarding the participants’ response, the optimal age for a Facebook account for their children under parental supervision was below 5 years (6/333, 1.8%), 5 to 12 years (114/333, 34.2%), 13 to 17 years (117/333, 34.8), and above 18 years (22/333, 6.6 %).

Table 5 summarized the optimal age for opening a Facebook account for their children with their control. Of 85 participants 25.5% (22/85) had no idea regarding the optimal age for opening a Facebook account for their children under their control. A total of 111 children/adolescents have Facebook profiles; 53.2% (60/111) of them are below 13 years of age. When we evaluated the monitoring method for childhood Facebook, 16.2% (18/111) of the parents prefer “coviewing,” 45.0% (50/111) of the parents prefer their children’s Facebook account share the same password, and 32.4% (36/111) of the parents have no monitoring method.

Table 5. Belief and Attitudes of Parents About Facebook Use During Childhood

Facebook		N	%	95% confidence interval
Optimal time for presence of Facebook account for children under the parent’s supervision				
	0-5 years	6	1.8%	0.37, 3.2
	5-12 years	114	34.2%	29.1, 39.3
	13-17 years	117	34.8%	29.6, 39.9
	18 years/above	22	6.6%	3.9, 9.2
	Not known	75	22.5%	18.0-26.9
Optimal time for presence of Facebook account for children with their control				
	0-5 years	1	0.3%	0, 2.0
	5-12 years	29	8.7%	5.7, 11.7
	13-17 years	124	37.2%	32.0, 42.4
	18 years/above	94	28.3%	23.4, 33.11
	Not known	85	25.5%	20.8, 30.1
Presence of child’s Facebook account		111	33.3%	28.2, 38.3
	0-1 years	3	2.7%	0, 5.7
	1-2 years	3	1.8%	0, 4.2
	2-5 years	8	7.2%	2.4, 12.0
	6-11 years	46	41.4%	32.2, 50.5
	12-17 years	52	46.8%	37.5, 56.1
Monitoring method for child’s Facebook account		111		
	Coviewing	18	16.2%	9.3, 23.1
	Facebook friend with child	7	6.3%	1.8, 10.8
	No monitoring	36	32.4%	23.7, 41.1
	Check child’s account	50	45.0%	35.8, 54.2

Discussion

Strengths of This Study

To the best of our knowledge, this study is the first to evaluate knowledge regarding the use of media relative to parents and their children in Turkey. This study showed that there is widespread access and use of media by children of all ages and the majority of the participating parents have limited information regarding this subject.

Television

According to the participants’ responses, 50.0% (166/333) of them thought that the television should be kept out of the child’s bedroom if the child is below 18 years of age. Approximately 8.0% (26/333) of the participants’ children have a television in their bedroom, and 50.0% (13/26) of them are below 10 years of age. The average daily watching alone time was less than 2 hours among 75.9% (253/333) of the participants; however, 55.0% of the children under the age of 2 years watch television <2 hours. The American Academy of Pediatrics (AAP) recommends limiting the amount of total entertainment screen time to <1 to 2 hours per day (above 2 years and no screen below 2 years of age), keeping the television out of the child’s bedroom, and to coview television with children and adolescents [1]. Parents should watch television with their children to teach them how to interpret the media messages or the content of commercials. Parental supervision during watching enables the children to distinguish between reality and fantasy [7]. Several studies have documented that higher levels of screen time are associated with less sleep, more attention problems, and lower academic performance [8-10]. Tomopoulos et al [11] showed that young children under age two frequently watch background media that has age-inappropriate content or has not been turned on for them to watch. Brockmann et al [12] showed that the presence of a television in the child's bedroom was associated with significantly reduced sleep quality, "sleep terrors," "nightmares," and "sleep talking" among children aged between 1 to 4 years. Two-year-old children in the United States watch an average of 2 hours of television each day, with nearly half watching more than that amount. Australian 2- to 4-year-old children participate in 83 minute per day of electronic media use, and only 26% of those children meet the Australian recommendation [5,13]. In our study, approximately 65% of the participants meet the AAP recommendations for watching television, which is higher than in other countries and this result might be related our study population, which includes parents with high-education levels.

Computer

In our study, the parents have a lack of knowledge regarding the optimal time for computer presence in the child's bedroom, and only 6.9% (23/333) of the participants thought that there was no need for a computer to be present in their child's room. Approximately 28% (82/333) of these study participants have a computer in the child's room, and the age at which the parents brought the computer into the child's room was a median of 9 years; the majority of the children have WiFi access in their bedroom. Approximately 82.0% (146/178) of the parents employ safety monitoring for supervision including coviewing, using a family filter or checking their child's website history. In the United States, nearly one-third of TV programming is viewed on alternative platforms in computers, iPads, or mobile phones, nearly all have Internet access, and one-third have access to a variety of social media in their own bedroom [1]. Children and adolescents spend up to 1.5 hours per day with their computer; half of this time is spent social networking, playing games, or viewing videos. The AAP has recommended keeping Internet-connected electronic devices out of the child's bedroom and monitoring what type of media their children are using [1].

iPad/Tablets

In our study, 84.3% (200/237) of the parents who have iPads/tablets give their children permission to use the iPads/tablets; 81.0% of the children used the devices less than 2 hours per day, whereas 59.3% of the children aged below 2 years used iPad/tablets approximately 1 hour. Nearly 22.5% (45/237) of the parents noted that their children used iPads/tablets at the table during meal time; 26.6% (12/45) of these children were aged below 2 years. Recent recommendations discourage screen media exposure for children <2 years of age and also enforcing a meal time "curfew" for media devices [1]. Contrary to the recommendations regarding television, the parents have no knowledge about the use of new media devices, such as tablets. The AAP recommendations for media use have been maintained before the first generation iPad and the overload of apps aimed at young children [6,14]. In the United States, more than 30% of young children play with a mobile device, as mentioned in our study [6,15]. In the United States, a recent survey among children aged 6 months to 4 years showed that 96.6% of the children had used a mobile device; the devices were mainly iPads and the majority of the parents let their children play with the mobile devices while they did chores (70%), to keep the child calm in public places (65%), while running errands (58%), or to put their child to sleep (28%) [6]. Parents gave or took away mobile devices to reward or punish their child's behavior, using it as a "digital pacifier" to placate or distract children or as a means to manage their children's behavior [6]. For this reason, new recommendations are required for use of iPads/tablets and apps for children.

Mobile Phone

There was no consensus among parents regarding the optimum time for mobile phone use; they commonly bought mobile phones for their children older than 7 years of age. In our study, 18.0% (60/333) of the parents noted that their children used mobile phones at the table during meal times or crying and that 30.0% (15/60) of the children were below 2 years of age. AAP recommended that to build a model for active parenting, it was essential to establish a family home use plan for all types of media, including cell phones, and establish reasonable but firm rules relative to cell phones and texting [1]. The younger children also like to use multiple media platforms, such as television and tablets, at the same time [6]. Approximately 50% of the parents of children aged 6 months to 4 years downloaded apps (educational, entertainment, and content delivery) on their mobile devices mainly for their children. Excessive media use is not only a problem in Western countries; the results of the national school violence study in South Africa showed that 80% of secondary school learners have a mobile phone. Approximately 70% of these children were reported to use social network sites and talk with strangers at least once a week [15].

Social Media

According to the participants' responses, the majority of participants have no idea about the optimal age for opening a Facebook account. Barbovschi et al [16] showed that 42% of children aged 9 to 12 years have profiles on Facebook, many with the explicit permission of their parent, despite the explicit policy between 2012 and 2014 from the Net Children Go Mobile (NCGM) project allowing only children aged 13 years and older to have a profile on Facebook. Among the children ranging in age between 9 and 12 years, Facebook use was connected to daily use of the Internet from home, looking for new friends online [16]. In our study, 53.0% (60/111) of the children who have Facebook accounts were below 13 years of age, which was similar to the NCGM project. In our study, parents brought the computer into the child's room at a median age of 9 years, and the majority of the children have WiFi access in their bedroom. Although Facebook has an explicit policy that allows only children older than 13 years of age to have a profile, parents should supervise Internet activity, including the social media accounts of their children. According to the Eurokids Online study results Turkey is categorized as a “low use, some risk” country [17]. Eurokids Online report emphasized that because many Turkish children are heavily dependent on out-of-home Internet access, the parents may find it difficult to regulate their children’s Internet use. Approximately 15% of the children in Turkey have visited at least one harmful website (websites related to committing suicide, being anorexic, or hate groups, etc), whereas the incidence in Europe is 18% [17].

Media Use and Health Effect

The current international recommendations are that children aged 2 to 5 years should engage in 1 hour or less of electronic media use (television/digital versatile disc/video, computer use, and electronic games) per day [1,5]. In our study, we observed that screen time and mobile device use are common in children below 2 years of age. Higher levels of early childhood electronic media use are associated with children being at risk for poor outcomes in several indicators of well-being. Hinkley and colleagues [5] emphasized that participation in high levels of electronic media use during early childhood (more than 2 hours per day) has been linked with increased weight status, behavioral problems, poor language and cognitive development, and poor social competence. Increased weight and obesity might be associated with television viewing and sedentary behaviors during childhood, and both of these conditions coexist with multiple other unhealthy behaviors, including poor dietary behaviors [5,18]. Falbe et al [19] showed that each hour-per-day screen time increase was associated with increased intake of total foods of low nutritional quality, increased intakes of sugar-sweetened beverages, fast food, sweets, and salty snacks, and decreased intakes of fruits and vegetables. It is important to encourage families to monitor their children’s media use and spend more time doing physical activities with their children to improve cardiovascular health in their adulthood [7]. There are contradictory results regarding the effect of electronic media use, and there is a two-sided coin that may affect both physical and psychological health [2]. Boniel-Nissim et al [20] evaluated the international trends in electronic media communication among the 11- to 15-year olds in 30 countries from 2002 to 2010. They mentioned that although Internet usage is often blamed for its negative effects on teenagers’ social interactions in the physical world, an electronic device was found to predict ease of communication with friends as a powerful tool for helping people to connect.

Limitations

We studied parents with social media access, we realized that this population may not represent the entire population, and we determined that our findings may not be generalizable. Some results about the use of mobile device are not credible and are probably biased by the Web-based questionnaire administration. A higher percentage use of technology might be more likely to complete the Web-based survey and are the most likely to have mobile devices at home. Our study does not evaluate the impact that mobile media devices have on children; we have provided a recent situation concerning the usage of media devices among children. This study also demonstrated the need for a guide that includes recommendations for both health care providers and families on the use of mobile media by young children.

Conclusion

According to our study results, there is limited knowledge regarding the use of old and new media among parents in Turkey. Mobile phones, tablet computers, and social media are widely used by children, especially in the age group where electronic media use should be discouraged. However, there is a lack of sufficient research and guidelines on protecting children’s safety in the use of media devices in developing countries, as well as in Turkey. Therefore, physicians, especially pediatricians, should make parents and teachers media-literate, meaning that pediatricians should comprehend the risks of media exposure because they are uniquely positioned to provide scientifically based recommendations to families [7,21]. Encouraging parents to monitor children’s media carefully can have a wide range of health benefits for children. Specifically, there are four types of parental monitoring: (1) coviewing with the child, (2) restricting amount of media use time, (3) restricting the types of content, and (4) actively discussing the meanings and effects of media content with children (active mediation). Several studies have found that coviewing paired with active mediation, restricting amount of media exposure, and restricting content are all powerful protective factors for children.

Active mediation can include offering opinions of media content, educating children regarding the purposes of various media (eg, advertising), or providing guidance and explanations [21]. Gentile et al [22] evaluated the prospective effects of parental monitoring of children’s media on the physical, social, and academic outcomes. They showed that parental monitoring of children’s media influences children’s sleep, school performance, and prosocial and aggressive behaviors, and that these effects are mediated through total screen time and exposure to media violence. Parental monitoring of media has protective effects on a wide variety of academic, social, and physical child outcomes. According to the results obtained from our study, we concluded that there is a need for evidence-based guidelines on the use of the Internet and social media for parents. Parents should ensure that there is a plan for the use of children’s media.

Conflicts of Interest

None declared.

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Abbreviations

AAP: American Academy of Pediatrics
NCGM: Net Children Go Mobile

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Original Paper

Relationship Between Difficulties in Daily Activities and Falling: Loco-Check as a Self-Assessment of Fall Risk

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Abstract

Background: People aged 65 years or older accounted for 25.1% of the Japanese population in 2013, and this characterizes the country as a “super-aging society.” With increased aging, fall-related injuries are becoming important in Japan, because such injuries underlie the necessity for nursing care services. If people could evaluate their risk of falling using a simple self-check test, they would be able to take preventive measures such as exercise, muscle training, walking with a cane, or renovation of their surroundings to remove impediments. Loco-check is a checklist measure of early locomotive syndrome (circumstances in which elderly people need nursing care service or are at high risk of requiring the service within a short time), prepared by the Japanese Orthopaedic Association (JOA) in 2007, but it is unclear if there is any association between this measure and falls.

Objective: To investigate the association between falls during the previous year and the 7 “loco-check” daily activity items and the total number of items endorsed, and sleep duration.

Methods: We conducted an Internet panel survey. Subjects were 624 persons aged between 30 and 90 years. The general health condition of the participants, including their experience of falling, daily activities, and sleep duration, was investigated. A multivariate analysis was carried out using logistic regression to investigate the relationship between falls in the previous year and difficulties with specific daily activities and total number of difficulties (loco-check) endorsed, and sleep duration, adjusting for sex and age.

Results: One-fourth of participants (157 persons) experienced at least one fall during the previous year. Fall rate of females (94/312: 30.1%) was significantly higher than that of males (63/312: 20.2%). Fall rate of persons aged more than 65 years (80/242: 33.1%) was significantly higher than that of younger persons (77/382: 20.2%). Logistic regression analysis revealed that daily activities such as “impossibility of getting across the road at a crossing before the traffic light changes” are significantly related to falling. Logistic regression analysis also demonstrated a relationship between the number of items endorsed on loco-check and incidence of falling, wherein persons who endorsed 4 or more items appear to be at higher risk for falls. However, logistic regression found no significant relationship between sleep duration and falling.

Conclusions: Our study demonstrated a relationship between the number of loco-check items endorsed and the incidence of falling in the previous year. Endorsement of 4 or more items appeared to signal a high risk for falls. The short self-administered checklist can be a valuable tool for assessing the risk of falling and for initiating preventive measures.

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KEYWORDS

accidental falls; disability evaluation; self-assessment; activity of daily living

Introduction

People aged 65 years or older accounted for 25.1% of the Japanese population in 2013 [1], and this characterizes the country as a “super-aging society.” As the Japanese society ages, fall-related injuries are becoming a greater concern. Falls cause severe injuries such as femoral neck fractures and compression fractures of vertebrae, leading to disability in daily life [2-4]. Aging is also related to increased risk of musculoskeletal problems such as lumbar stenosis and osteoarthritis in knee and hip joints [5,6]. These musculoskeletal problems, including fall-related injuries, underlie the necessity for nursing care services in approximately 21% of cases receiving such services among elderly people in Japan [5,7].

“Locomotive syndrome,” which was proposed by the Japanese Orthopaedic Association in 2007, refers to circumstances in which elderly people need nursing care service or are at high risk of requiring the service within a short time [7,8]. Locomotive syndrome is, in part, due to diseases of the locomotive organs such as osteoarthritis, spinal canal stenosis, osteoporosis, and rheumatoid arthritis, and is associated with symptoms that include pain, limitations in the range of joint movement, reduced balance capability, and slow pace of walking, as well as frequent falling. A self-check tool called “loco-check” can assess whether a person is at risk of locomotive syndrome. Loco-check comprises 7 items regarding daily activities and is an acceptable measure for detecting early-stage locomotive syndrome [8]. Because the public health burden of fractures by accidental falls is increasing, studies of fall prevention and risk assessment have been a major focus of public health and nursing care [9]. To prevent falls and subsequent disability in daily life, measures such as exercise, muscle training, walking with a cane, or renovating one’s surroundings to remove impediments are important [10-12]. Risk assessment tools are required for screening those at risk of falls. In this study, we focused on the association between the number of loco-check items endorsed and falling.

Methods

Survey Method and Subjects

This study was conducted with the approval of the Ethics Committee of Nara Medical University (authorization code: 335). The general health condition of the participants, including their experience of falling and their loco-check data, was investigated with an Internet-based questionnaire in April of 2011. We conducted the survey using an Internet panel survey company. All respondents were registered as panel members with the company.

The panel survey in this study included registrants aged between 30 and 90 years. Participants were stratified into 3 age groups that spanned 20-year categories (30-49, 50-69, and 70-90 years). Each group included 208 participants (104 males and 104 females), for a total sample of 624. The survey was closed when the number of participants in each group achieved the target sample size. Registrants completed and transmitted their responses via the website.

Questionnaire for Degree of Recognition

Demographic characteristics of participants, such as age, sex, educational background, occupation, and residential area were already recorded during their registration as a member of the firm’s Internet panel. The first question specific to our study asked whether participants were familiar with locomotive syndrome, metabolic syndrome, and cognitive impairment, to determine the recognition rates for these conditions. The survey also inquired about the medical conditions of participants, their falling experiences, and loco-check items, as described in the following sections.

Self-Assessment Using Loco-Check

The loco-check checklist for locomotive syndrome was prepared by the Japanese Orthopaedic Association (JOA) in 2007 [8]. According to the JOA proposal, a participant who endorses at least one of the 7 statements on the checklist may have locomotive syndrome. The 7 categories are as follows: (1) you cannot put on a pair of socks while standing on one leg; (2) you stumble or slip in your home; (3) you need to use a handrail when going upstairs; (4) you cannot get across the road at a crossing before the traffic light changes; (5) you have difficulty walking continuously for 15 minutes; (6) you find it difficult to walk home carrying a shopping bag weighing about 2 kg (eg, two 1-L milk cartons); and (7) you find it difficult to do housework requiring physical strength (eg, use of a vacuum cleaner, moving futons into and out of a closet).

Survey of Falling Experience, Sleep Duration, and Medical History

We asked about falling experiences and sleep duration over the previous year. Sleep duration was a multiple-choice item with 4 response options (6 hours or less, 7 hours, 8 hours, and 9 hours or more). Personal medical history items asked whether the participant had osteoarthritis of the knee or hip joints, spondylosis deformans, spinal canal stenosis, osteoporosis, low back pain, slipped disk, rheumatoid arthritis, cerebral infarction, stroke, brain tumor, or myocardial infarction.

Statistical Analysis

The recognition rate for locomotive syndrome was calculated and compared with those for metabolic syndrome and cognitive impairment. Number of falls was compared between persons with and without disease of locomotive organs using a chi-square test.

A logistic regression analysis was conducted. The presence or absence of falls in the past year was the dependent variable. The independent variables included sex, age category, and presence or absence of endorsement of the 7 loco-check items. We also carried out a separate logistic regression analysis identical to the first with the exception that the total number of loco-check items endorsed was recoded into 3 categories (0, 1-3, and ≥4). The relationship between sleep duration and falling experience was analyzed by logistic regression analysis adjusted for sex and age.

The statistical analyses were conducted with SPSS version 21.0 (IBM, Chicago, IL, USA). The level of significance was set at *P*<.05.

Results

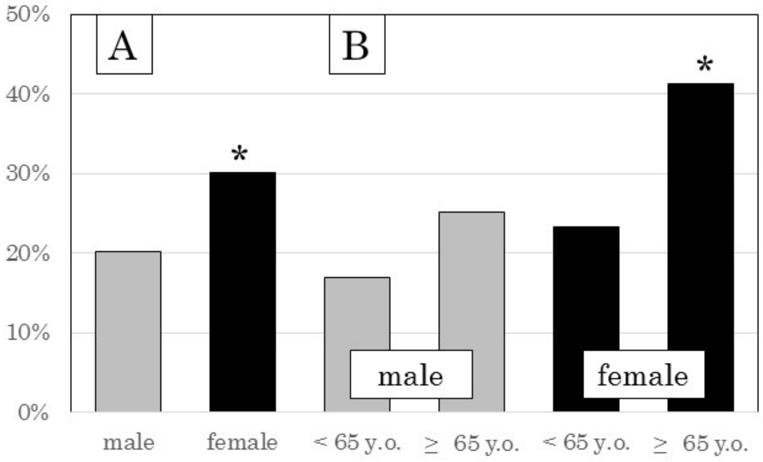
Baseline Characteristics and Recognition Rates

The mean and standard deviation (SD) for age of participants was 58.5 (SD 16.2) years and 58.5 (SD 16.5) years in male and female participants, respectively. Height and weight of the male group were significantly higher than those of the female group (mean 168.5, SD 6.4 cm vs mean 155.5, SD 5.9 cm; mean 66.8, SD 12.9 kg vs mean 52.0, SD 7.6 kg; *P*<.001). Prevalence of personal medical history was as follows: osteoarthritis of knee (22/624: 3.5%) or hip (10/624: 1.6%), spondylosis deformans (10/624: 1.6%), spinal canal stenosis (21/624: 3.4%), osteoporosis (29/624: 4.6%), low back pain (75/624: 12.0%), slipped disk (38/624: 6.1%), rheumatoid arthritis (13/624: 2.1%), cerebral infarction (19/624: 3.0%), stroke (4/624: 0.6%), brain tumor (2/624: 0.3%), and myocardial infarction (13/624: 2.1%). Recognition rates for locomotive syndrome, metabolic syndrome, and cognitive impairment were 6.3% (39/624), 84.9% (530/624), and 87.3% (545/624), respectively.

Falling Experience in the Previous Year

A total of 157 participants (157/624: 25.2%) had experienced at least one fall in the previous year. The percentage of females (94/312: 30.1%) who had fallen was significantly higher than that of males (63/312: 20.2%, *P*=.004, Figure 1, part A). The percentage of those 65 years and older who had fallen (80/242: 33.1%) was significantly higher than that of younger persons (77/382: 20.2%, *P*<.001); however, this result appeared to be attributable mostly to differences among older and younger females (49/119: 41.2% vs 45/193: 23.3%, *P*=.001 for females; 31/123: 25.2% vs 32/189: 16.9%, *P*=.08 for males; Figure 1, part B).

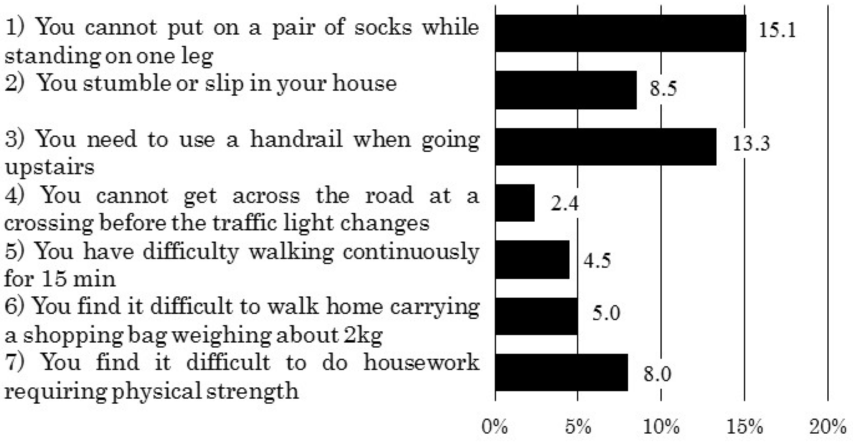
Figure 1. A. Percentage of males and females who experienced falls. B. Percentage of participants who had fallen, by age and sex. *Statistical significance (*P*< .05).



Percentage of Endorsements for Each Item of the Checklist

Percentages of endorsement by item are shown in Figure 2. The percentage of participants who endorsed at least one item of the checklist was 23.2% (145/624).

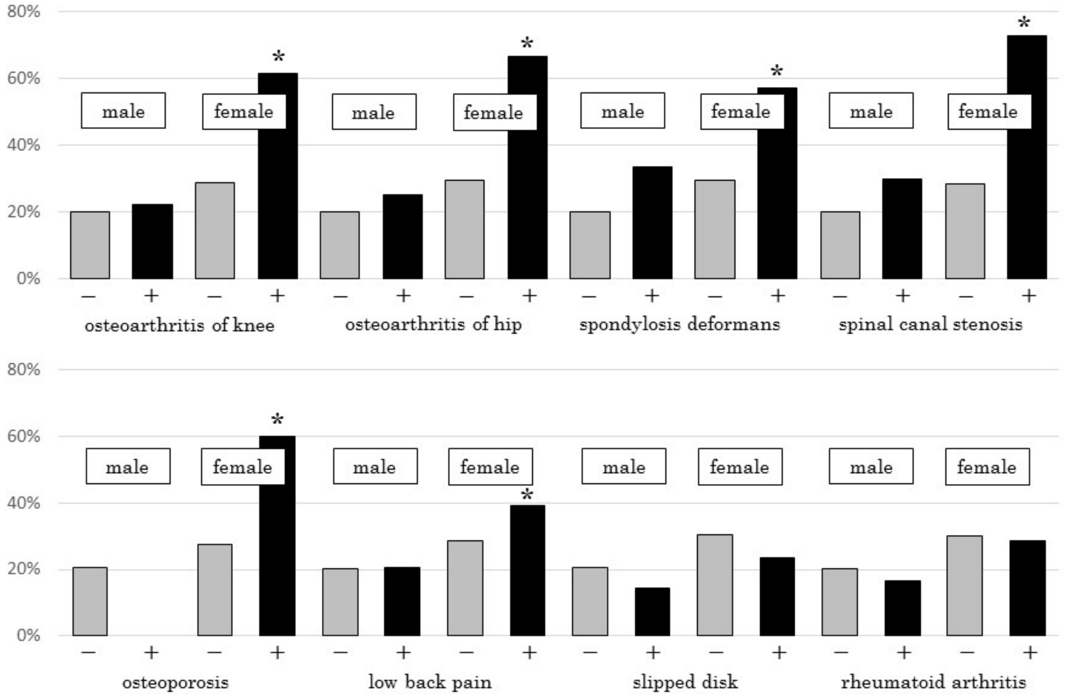
Figure 2. Percentage of participants who endorsed each item of the self-assessment checklist.



Falling Experience According to Disease of Locomotive Organs

The incidence of falling among persons who had disease of locomotive organs is shown in Figure 3. There was no significant difference among males with and without disease of locomotive organs. In contrast, females who had osteoarthritis of the knee or hip, spondylosis deformans, spinal canal stenosis, osteoporosis, or low back pain had a significantly higher incidence of falling in the previous year compared with females who did not have these diseases of locomotive organs.

Figure 3. Incidence of falling among participants with diseases of locomotive organs. *Statistical significance (*P*<.05).



Self-Assessment Checklist and Falling Experience

Logistic regression analysis revealed a significant relationship between all but one of the 7 loco-check items and falling. As shown in Table 1, particularly high odds ratios were found for items 2, “You stumble or slip in your home,” and 4, “You cannot get across the road at a crossing before the traffic light changes.” No significant relationship was found for item 6, “You find it difficult to walk home carrying a shopping bag weighing about 2 kg (eg, two 1-L milk cartons).”

Number of Items Endorsed, Sleep Duration, and Falling

Logistic regression analysis revealed a significant relationship between 2 of the 3 categorical measures of loco-check items endorsed (0, 1 to 3, or ≥4 items) and falling. As shown in Table 2, endorsing 1-3 items or ≥4 items predicted falling, but endorsing 0 items did not. Logistic regression analysis for sleep duration demonstrated that there was no significant relation between this variable and falling (Table 3).

Table 1. Logistic regression analysis for the 7 loco-check items.

Checklist items	OR[a]	95% CI	*P* value[b]
1. You cannot put on a pair of socks while standing on one leg	3.25	1.98-5.33	<.001
2. You stumble or slip in your house	8.81	4.53-17.18	<.001
3. You need to use a handrail when going upstairs	2.95	1.74-4.99	<.001
4. You cannot get across the road at a crossing before the traffic light changes	8.13	2.17-30.47	<.001
5. You have difficulty walking continuously for 15 minutes	2.42	1.07-5.50	.03
6. You find it difficult to walk home carrying a shopping bag weighing about 2 kg	2.02	0.93-4.37	.08
7. You find it difficult to do housework requiring physical strength	3.53	1.86-6.71	<.001

[a] OR: odds ratio.

[b] Statistical significance (*P*<.05).

Table 2. Logistic regression analysis for accumulation of 7 loco-check items.

Independent variables		Odds ratio	95% CI	*P* value[a]
Sex		1.60	1.08-2.36	.19
Age		1.01	0.99-1.02	.32
Accumulation of items				
	0	Reference		
	1-3	3.21	2.04-5.12	<.001
	≥4	10.36	4.00-26.85	<.001

[a] Statistical significance (*P*<.05).

Table 3. Logistic regression analysis for sleep duration.

Independent variables		Odds ratio	95% CI	*P* value[a]
Sex		1.78	1.22-2.59	<.001
Age		1.03	1.01-1.04	<.001
Sleep duration, hours				
	≤6	Reference		
	7	1.10	0.71-1.71	.68
	8	1.22	0.75-2.00	.43
	≥9	0.57	0.18-1.81	.34

[a] Statistical significance (*P*<.05).

Discussion

Overall

Our study demonstrated a reliable relationship between the number of loco-check items endorsed and incidence of falling, indicating that persons who endorsed 4 or more items appear to be at high risk for falls. Those who have difficulty in certain daily activities such as being able to get across the road before the traffic light changes may be at particularly high risk. A previous study reported that older people recognize falls as a serious threat and that information dissemination, along with fall risk self-assessment, may be a low-cost way to improve identification of fall risk and stimulate fall-prevention activities [13]. Although evaluating fall risk using self-check items is becoming common [13,14], it is still problematic because the checklists tend to be lengthy. In contrast, loco-check is easy to use because it has only 7 items, all of which describe familiar daily activities. To our knowledge, ours are the first data to show that loco-check is useful as a self-assessment tool for evaluating fall risk.

Critical Health Problem by Falling

Falling is an event that often results in critical health problems such as femoral neck fracture or compression fractures of vertebrae; therefore, falls remain a major public health problem among people aged 65 years or older. Some elderly people require nursing care services as a result of these problems. There are two categories of risk factors in falls: intrinsic and extrinsic. The former includes an individual’s physical and cognitive abilities such as muscle strength, balance capacity, reactive power, dual tasking, and sleep disturbances; and the latter includes home hazards, improper use of assistive devices, and inappropriate footwear [9]. Behavior-related risk factors are hurrying, risk-taking, and physical inactivity [15]. Studies of fall prevention and risk assessment have been a major focus of public health and nursing care [9]. Previous studies have reported that falls at home are more frequent than in nursing care homes [16] and inpatient settings [17]. To prevent falls, it would be ideal for persons at home to evaluate their potential risk by means of a simple self-checklist. Self-assessment of risk factors can help identify individuals who might benefit from interventions aimed at fall prevention. Our results demonstrated that one’s risk of falling can be self-evaluated by a short checklist that consists solely of items about daily activities. Individuals who endorse 4 items or more on the checklist are particularly advised to meet with a physician or physical trainer to treat their musculoskeletal disorders as well as reducing their extrinsic risk factors. One can reduce extrinsic risk factors by removal of environmental hazards, renovation of the home, proper selection of assistive devices, and maintenance of muscular strength and balance through muscle training with activities such as walking, squatting, and balancing.

Relationship between Sleep Duration and Falling

Insomnia and disturbed sleep are increasingly common for older people [18]. Sleep disturbances cause slowed responses and subsequently result in greater risk of accidents and injuries such as falls and fractures. Falls are a major syndrome in the elderly, in which sleep disturbance may play an important role [18-21]. Although a few studies have reported the relationship between falls and sleep disturbances, we did not find any link between sleep duration and falling. This may be because the relationship between sleep disturbances and risk of falls is mediated by mechanisms such as balance ability, cognitive function, and medication. We used an Internet panel survey in this study; therefore, our participants may have been healthier, with fewer cognitive problems and less depression than is observed in the elderly population in general. Elderly persons sometimes exhibit different circadian rhythms compared with younger individuals, for example, earlier bedtimes and wake-up times. Participants in our study were generally sleeping more than 6 hours per night, and there was not a single participant whose sleep duration was less than 5 hours, indicating that our sample generally slept well.

Fall Prevention

Fall prevention is a major public health theme because falls occur frequently and can cause subsequently devastating problems for elderly individuals, affecting their morbidity, mortality, and locomotive ability. Falls occur in 30%-60% of older persons each year, and 10%-20% of these result in injury, hospitalization, and/or death [22]. The cause of falls is generally multifactorial, including certain medications, environmental hazards in daily life, and physiological changes due to aging. The most important risk factors are muscle weakness and problems with gait and balance [22]. Environmental barriers are responsible for 30%-50% of falls. At home, thresholds, stairs, carpets, and slippery surfaces represent barriers [23]. Our study indicated that one can assess the risk factors such as muscle weakness and gait and balance problems using the self-administered loco-check for locomotive syndrome. Even elderly persons can easily detect their risk of fall using this tool. Loco-check is simple and easy to understand because its 7 daily activities represent gait and balance abilities. Adding the number of items endorsed is also easy, resulting in a quick assessment of one's fall risk. Families of high-risk adults could be alerted to remove dangerous barriers at home such as slippery surfaces and carpets, and public health staff could apply interventions such as balance exercises for the high-risk person.

Previous studies have reported an association between locomotive syndrome and health-related quality of life (HRQoL). Iizuka et al [24] reported that endorsing a larger number of items in loco-check was associated with reduced HRQoL as assessed by the EuroQoL-5 dimensions (EQ-5D) and EuroQoL visual analogue scale (EQ VAS). EQ-5D consists of 5 items regarding HRQoL: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. EQ VAS is a self-reported questionnaire regarding one's health status. However, neither instrument focuses on the incidence of falls. Seichi et al [25] reported a positive relationship between locomotive syndrome and incidence of falls in the previous year. They used the 25-question Geriatric Locomotive Function Scale (GLFS-25) to identify locomotive syndrome. Others have also reported an association between locomotive syndrome and reduced HRQoL [26]. Our suggested method for assessing fall risk is simply determining the number of items endorsed on the 7-item loco-check self-assessment. Such an assessment would be easy to perform, both for the individual and for public health staff.

Recognition Rate of Locomotive Syndrome

Participants' recognition rate of locomotive syndrome was quite low compared with metabolic syndrome and cognitive impairment at the time our survey was conducted in April 2011. The recognition rate has increased dramatically in recent years, for example, it was reported at 36.1% in 2014 [27] and at 44% in 2015 [28]. However, these rates still fall far short of those for metabolic syndrome and cognitive impairment. The Ministry of Health, Labour and Welfare of Japan has set a target recognition rate of 80% by 2022. Major musculoskeletal disorders that may cause locomotive syndrome include osteoarthritis, spondylosis, and osteoporosis. Osteoporosis represents a major public health problem through its association with fragility fractures. The public health burden of osteoporotic fractures is increasing, due in part to an increase in life expectancy. The results of our study indicate that approximately 1 in 4 of our participants (between the ages of 30 and 90 years) could be at risk of locomotive disability, which means that their circumstances could cause them to require nursing care services currently or to be at high risk of requiring such services within a short time.

Questionnaire Survey and Its Advantages

When we recruited the participants in this study, we created 3 age categories that spanned 20-year categories because the distribution of participant numbers needed to be equivalent among ages. As the actual ages of the participants were recorded, we were able to divide the subjects into 2 groups (<65 years and ≥65 years, as shown in Figure 1) and analyze the relationship between falling experience and daily activities by logistic regression analysis using the actual ages of the participants (as shown in Tables 2 and 3). In general, the risk of falling increases with advancing age [29], and many studies have investigated the fall risk in elderly people only [13,14,26,30]. In contrast, we investigated the fall risk across people of all ages in our study and also analyzed the fall risk of the elderly generation compared with that of the younger generation. It is easy to recognize whether a person is at risk of falling by comparing the fall risk of the elderly generation with that of the younger generation.

Limitations

This study has a few limitations. First, all measures were based on self-reporting by Internet survey. This may result in some misclassification. Second, we used an Internet panel survey company to collect data from registrants aged between 30 and 90 years. Elderly persons who use computers and the Internet may be more active and healthier than those who do not; therefore, we may have underestimated the incidence of falling. However, Internet panel surveys are becoming common for epidemiology research in the social sciences [31-33]. Third, our study did not find a relationship between sleep duration and falling. However, it is also important to pay attention to sleep quality among older adults, considering the documented impact of sleep disturbances on health [34]. Therefore, in future studies we need to analyze the relationship between falls and sleep quality. Fourth, our study was a survey conducted using an Internet-based questionnaire, therefore we could not justify whether simple self-assessment using loco-check is useful for screening and preventing falls. Concerning these points, further investigation such as prospective cohort study will be needed.

Conclusions

We conducted an Internet panel survey to investigate the relationship between falls in the previous year and difficulties with specific daily activities, total number of difficulties (loco-check) endorsed, and sleep duration. A multivariate analysis was carried out using logistic regression to investigate the relationship, with adjustments for sex and age. Our study demonstrated a relationship between the number of loco-check items endorsed and the incidence of falling in the previous year. Endorsement of 4 or more items appeared to signal a high risk for falls. To prevent falls, it would be ideal for people at home to evaluate their potential risk by means of a simple self-checklist. The short self-administered checklist of loco-check can be a valuable tool for assessing the risk of falling and for initiating preventive measures.

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Conflicts of Interest

None declared.

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Abbreviations

EQ-5D: EuroQoL-5 dimensions
EQ VAS: EuroQoL visual analogue scale
HRQoL: health-related quality of life
JOA: Japanese Orthopaedic Association
SD: standard deviation

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Original Paper

YouTube Videos to Create a “Virtual Hospital Experience” for Hip and Knee Replacement Patients to Decrease Preoperative Anxiety: A Randomized Trial

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Abstract

Background: With declining reimbursement to health care systems, face-to-face time between patients and providers to optimize preoperative education and counseling may be challenging.

Objective: Because high patient anxiety prior to surgery has been linked to more severe and persistent pain after joint replacement surgery, the Orthopedic Surgery Department at Mayo Clinic in Florida created a playlist of 16 YouTube videos aimed at creating a virtual hospital experience for primary total hip and knee joint replacement patients. A randomized trial was then performed to evaluate the potential impact of viewing this playlist on preoperative anxiety.

Methods: Each patient completed a Generalized Anxiety Disorder (GAD) score assessment at the time of the routine preoperative clinic visit and then randomized based on his/her gender, type of surgery, and initial GAD score to either the control group of standard education (education at face-to-face clinical visits as well as printed educational materials) or the treatment group (standard education plus access to the YouTube playlist). On the morning of the patient’s surgery, the same survey was repeated. Of the 65 patients who consented to participate in the study, 53 completed the study (82%) with 28 of 29 (97% completed) in the control group and 25 of 36 (69% completed) in the treatment group.

Results: Overall, the results showed a trend toward less anxiety in patients who viewed the YouTube videos; this was exhibited by a reduction in the median GAD score by 1 point. This trend is more clearly present in patients with high preoperative anxiety (predominantly women), as seen in the reduction of the median GAD score by 6 points in the treatment group.

Conclusions: Although our experience is limited, our results indicate that a series of tailored videos may decrease patient anxiety preoperatively. We recommend further exploration of both this concept and the use of social media tools in preoperative patient education.

Trial Registration: Clinicaltrials.gov NCT02546180; http://clinicaltrials.gov/ct2/show/NCT02546180 (Archived by WebCite at http://www.webcitation.org/6f6y0Dw7d).

(Interact J Med Res 2016;5(2):e10) doi:10.2196/ijmr.4295

KEYWORDS

hip arthroplasty; hip replacement; knee arthroplasty; knee replacement; preoperative anxiety; virtual hospital experience; YouTube videos

Introduction

Total knee and total hip replacement surgeries are two of the most commonly performed surgeries in patients over the age of 65. The demand and volumes for these surgeries continue to increase in accordance with the aging of the population, increasing incidence of arthritis, and patient expectations of quality of life [1]. With declining reimbursement to health care systems, face-to-face interaction between patients and providers to optimize preoperative education and counseling may be challenging. As high patient anxiety prior to surgery has been linked to more severe and persistent pain up to 1 year after joint replacement surgery, efforts to decrease patient's concerns prior to arthroplasty may improve outcomes [2]. Recognizing the importance of preoperative education as a potential tool to decrease preoperative patient anxiety, limitations with expanding face-to-face clinical encounters, and constrained financial resources, the Orthopedic Surgery Department at Mayo Clinic Florida created a playlist of 16 YouTube videos aimed at creating a virtual hospital experience for primary total knee arthroplasty and total hip arthroplasty surgery patients. By creating a series of videos showing and explaining the anticipated hospital experience, patients would be able to virtually meet the nurses, surgeons, anesthesiologists, and others on their care team as well as view the physical locations in which their care would be delivered (eg, preoperative holding, operating room, recovery room, and hospital room; Figure 1). This method may establish a higher level of education and emotional comfort prior to surgery than with standard formats, such as pamphlets. A pilot study with patients scheduled to undergo primary hip and knee replacement surgery was then performed to evaluate usability of the video series and its potential impact on preoperative anxiety.

Figure 1. We provided the patients in the video-watching group with a handout that included the title, a brief description, and a picture, representing each video. This video sheet is our current version of the handout. The information is identical, but the images associated with each video have been altered to more accurately represent what the patient will see when accessing each video. By permission of Mayo Foundation for Medical Education and Research. All Rights Reserved.

MAYO CLINIC

YOUR VIRTUAL HOSPITAL EXPERIENCE
Total Hip or Knee Replacement Surgery
#VideoPaper

In these 16 videos, Mayo Clinic health-care team members show patients scheduled for total hip or total knee replacement surgery at Mayo Clinic in Florida what to expect. From pre-operative planning, through surgery and discharge from the hospital, these videos explain how the Mayo Clinic team cares for you every step of the way. As you prepare for surgery, please take time to watch these short, informative videos designed to answer many questions you may have. There's no need to watch them all at once, but please view them before your surgery.

1. Planning Ahead for Going Home: Before the Surgery

The best time to plan for discharge from the hospital is before you have surgery. That's why, during a pre-operative appointment, you meet with a case manager, who explains the many factors considered in discharge planning. **Link:** bit.ly/hipkneemc01

2. Pre-registration Appointment

Before you are admitted to the hospital, you are scheduled for a pre-registration appointment to review demographic and insurance information, sign consent forms and go over the hospital check-in procedure. **Link:** bit.ly/hipkneemc02

3. Meeting Your Emotional or Spiritual Needs

A chaplain explains how to access chaplaincy services to help you cope with anxiety or concerns you may have regarding your surgery or hospitalization. **Link:** bit.ly/hipkneemc03

4. Checking in at the Surgery Waiting Room

Learn about the surgery check-in process and how your family and friends will receive communication and updates about you during and after surgery. **Link:** bit.ly/hipkneemc04

5. Pre-op Holding Area

From the surgery waiting room, you are escorted to the pre-op holding area, where you are prepared for surgery. Learn about sage wipes and the barber. **Link:** bit.ly/hipkneemc05

6. The Operating Room

Take a virtual tour of the operating room to meet surgery team members and understand their roles caring for you during surgery. **Link**: bit.ly/hipkneemc06

7. Safety and Teamwork in the OR

Mary O'Connor, M.D.,an orthopedic surgeon, talks about the many steps your surgical team takes with every procedure to assure the safest operating environment possible. **Link:** bit.ly/hipkneemc07

8. The Recovery Room

When the procedure is finished, you are taken to the recovery room, where you are monitored closely and learn the importance of deep breathing, coughing and moving to reduce the risk of postoperative complications. **Link:** bit.ly/hipkneemc08

9. Your Hospital Room

Learn what to expect during your hospital stay, including shift reports, purposeful rounding, the white board, safety measures and chair alarms. **Link:** bit.ly/hipkneemc09

Total Hip or Knee Replacement Surgery

10. Keeping You Comfortable: Anesthesia and Pain Management

A medical team member reviews anesthesia during surgery and pain management after surgery. **Link:** bit.ly/hipkneemc10

11. Pain Management at the Bedside

Keeping you as comfortable as possible while you recover is very important. That's why pain management is a team effort that involves you as well. **Link:** bit.ly/hipkneemc11

12. Falls Not Allowed! Patient Safety after Surgery

Learn about the many measures we use to keep you safe and protect you from falls after surgery. **Link**: bit.ly/hipkneemc12

13. Take a Deep Breath! Respiratory Therapy after Surgery

A respiratory therapist explains why it's important to breathe deeply and how respiratory therapists can help you. **Link**: bit.ly/hipkneemc13

14. Getting You Moving: Physical Therapy after Surgery

A physical therapist explains your therapy schedule, your rehab goals and what to expect from physical therapy sessions. **Link:** bit.ly/hipkneemc14

15. Occupational Therapy after Surgery

For patients who have total hip replacement surgery, an occupational therapist describes the purpose and goals of occupational therapy and the therapy schedule. **Link:** bit.ly/hipkneemc15

16. Your Discharge Home

Mayo Clinic orthopedic surgeons review how you will manage pain at home, reduce the risk of blood clots, when you will be allowed to drive and walk without a walking aid and what symptoms your doctor wants to know about. **Link:** bit.ly/hipkneemc16

How to use this #VideoPaper:

1. If necessary, install a QR code reader on your smartphone. QR readers can be downloaded at the iTunes App Store or at Google Play for Android.
2. Open the QR code reader on your phone or tablet.
3. Hold your device over the black and white QR code so that it's clearly visible within your screen.
4. If necessary, press the button to start the reader.
5. Or simply type the web address link listed under each video into your browser.

Mayo Clinic has thousands of videos available to you on YouTube, including more from our Orthopedic Surgery team. Scan the code or go to bit.ly/hipkneeallvideos to be taken to our "Virtual Hospital Experience: Total Hip or Knee Replacement Surgery" playlist within the Mayo Clinic YouTube Channel.

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Methods

Patients undergoing primary total hip or knee replacement at Mayo Clinic Florida between February and May, 2014, were asked to participate in this research study at the time of their preoperative appointment, typically 7-14 days prior to surgery. After consenting to participate, the patient completed a preoperative Generalized Anxiety Disorder (GAD) score assessment during the same appointment. The GAD score rates the patient's self-reported level of anxiety on a scale of 0-21 (0=lowest score; 21=highest score). Patients were categorized into one of the following groups based on GAD score: minimal (GAD: 0-4), mild (GAD: 5-9), moderate (GAD: 10-14), or severe anxiety (GAD: 15-21). Patients were then randomized based on their gender, type of surgery, and initial GAD score to either the control group, which received standard education that included receiving information at routine face-to-face clinical visits and printed educational materials, or the treatment group, which included standard education plus access to the YouTube playlist. Randomization was established by the study coordinator using a preset chart with alternating treatment and control groups in each of the 16 categories (eg, a group including male, total hip replacement, minimal GAD score). On the morning of the patient's scheduled surgery, the same surveys were repeated.

A Mayo Clinic Florida production team created the 16 videos used in this study (Figure 1). The run-time for the entire presentation was 1 hour. The videos were uploaded onto a private Mayo Clinic YouTube channel, and access to the videos required a link from the study coordinator. Patients were asked to watch all 16 videos before arriving on the morning of their scheduled surgery. In addition to watching the videos, patients were asked to rate each of the 16 videos on a scale of 1-5 points, with 1 being the lowest and 5 representing the highest level of agreement with the statement, “After watching this video I feel better prepared for surgery.” Of the 130 patients who were approached during the 3-month enrollment period, 65 agreed to participate (50% of the patients approached provided consent for participation). Those who declined enrollment cited not wanting additional information or not having enough time before their surgery date to watch videos as their reason for not participating. Of the 65 who provided consent to participate, 12 were excluded (11 for not watching at least 12 of the 16 videos and 1 for cancelled surgery). As the study progressed, new participants were randomized to appropriate treatment arms to maintain balance of the study if a participant dropped out. Of the 53 patients who participated in the study, 28 participants were in the control group and 25 in the treatment (video-watching) group (Table 1). In the treatment group, 22 patients watched all 16 videos. If patients did not watch all of the videos, it was recorded by the patients on a sheet and discussed on the morning of their surgery. Those who did not watch all of the videos cited lack of time or technical difficulties, which were quickly addressed, allowing most patients to view the videos. If patients watched less than 12 of the 16 videos, their survey answers were excluded from the dataset and the patient was withdrawn from the study. The CONSORT checklist for this study is presented in Multimedia Appendix 1. This study has been registered with clinicaltrials.gov (Registration number NCT02546180).

The distribution of patients into control and treatment groups was randomized based on gender, type of surgery (total hip arthroplasty or total knee arthroplasty), and initial GAD score (Table 1). Mean, SD, and range for the control and treatment groups are presented for age; frequency and percentage are presented for all other variables. All *P* values were calculated using Statistical Analysis Software (SAS). The *P* value for gender is based on Fisher exact test and *P* values for all other variables are based on the Kruskal-Wallis rank sum test.

Table 1. Patient distribution.

Characteristics		Control (n=28)	Treatment (n=25)	*P* value
Age				.22
	Mean (SD)	63.1 (10.7)	67.4 (10.3)	
	Range	36-78	41-86	
Gender, n (%)				>.99
	Males	12 (42.9)	10 (40.0)	
	Females	16 (57.1)	15 (60.0)	
Type of surgery, n (%)				.79
	Total knee arthroplasty	16 (57.1)	14 (56.0)	
	Total hip arthroplasty	12 (42.9)	11 (44.0)	
Generalized Anxiety Disorder, n (%)				.86
	Minimal (0-4)	16 (57.1)	15 (60.0)	
	Mild (5-9)	7 (25.0)	3 (12.0)	
	Moderate (10-14)	3 (10.7)	6 (24.0)	
	Severe (15+)	2 (7.1)	1 (4.0)	

Results

Viewing this series of YouTube videos focused on creating a “virtual hospital experience” for hip and knee replacement patients may decrease preoperative anxiety. In our small series, the overall results showed a 1-point decrease in GAD score in the treatment group (Table 2). However, when the moderate and severe anxiety groups were analyzed, the declines in the median GAD score were more notable: 3 points in the control group and 6 points in the treatment group. Statistical Analysis Software (SAS) was used to run a Wilcoxon Rank sum test to determine statistical significance. None of these results reached statistical significance, as we had a low number of participants in this pilot study, particularly for the moderate to severe GAD categories. Furthermore, it is important to note that some individuals had an increase in GAD scores in both the control and treatment groups, although overall the trend showed lower GAD scores in moderate to high anxiety patients in the treatment group. Of the 12 patients with moderate to severe GAD ratings prior to surgery, 11 were women.

Table 2. Differences in Generalized Anxiety Disorder score.

Change in Generalized Anxiety Disorder (GAD) score	All study participants		Moderate and severe GAD scores[a]	
	Control (N=28)	Treatment (N=25)	Control (N=5)	Treatment (N=7)
Median (range)	0.0 (−7, 4)	−1.0 (−12, 7)	−3.0 (−7, 1)	−6.0 (−12, 7)

[a] 11 of 12 of these patients were female.

In Table 2, the median and range of changes in GAD score from the initial to final surveys are presented for each treatment group for all study participants and for those who had moderate or severe initial GAD scores (score of 10-21). A reduction in the GAD score indicates a lower level of anxiety. The *P* values are based on Wilcoxon Rank sum tests (SAS). For all study participants, *P*=.53; for the moderate and severe GAD score group, *P*=.51.

The ratings for each video were favorable, and most participants indicated that they felt better prepared for surgery after watching the videos. Patient ratings of the individual videos ranged from 3.9 to 4.6 (1=lowest agreement; 5=highest agreement). Furthermore, the second GAD score was obtained on the day of surgery for all patients in the preoperative holding or family waiting area, providing a standard time point for assessment.

Discussion

Medical information is easily accessed on the Internet and patients of all ages search the Internet [3]. Active Internet users include 72% of adults aged between 50 and 64 years and 41% of seniors (aged ≥ 65 years), and this audience often uses the Internet to search for health-related information [4,5]. Unfortunately, the quality of the information available on the Internet is not always exceptional. Excellence in quality and/or content of videos does not determine how many viewers a health-related video will attract; it has even been proposed that lower-quality videos receive more views [6]. By self-producing video content, medical institutions and providers can tailor accurate and appropriate educational content to their patients.

Patient recovery can be difficult to measure in a quantitative manner [7]. However, increased preoperative anxiety levels can predict worse pain outcomes in the 1st year following total knee replacement [2]. Improved preoperative education may decrease patient anxiety related to an upcoming surgical procedure. The potential benefits of reducing preoperative anxiety in patients include better postoperative recovery, higher levels of patient satisfaction with their surgical experience, and reduced levels of self-reported pain up to 1 year after surgery [2,8,9]. By providing total hip and knee replacement patients with a series of YouTube videos in an attempt to better prepare them for their surgery, they may feel better prepared for their surgical and hospital experience, decreasing anxiety and potentially improving outcomes.

Previous studies have attempted to determine the most effective means of reducing patient anxiety to improve patient recovery through the use of informational tools but have received mixed results [10-13]. Most agree that an effective means of reducing preoperative anxiety is to provide information to the patient about their upcoming hospital experience [14-16]. Various methods of delivering the information have been explored. In general, tailored information provided in a unique or interactive format yields the best results [17-19]. Educational materials for patients may be in the format of a booklet, handout or video [19]; video format permits patients to virtually meet staff members who may be involved with their postoperative care [20]. Of note, there are some patients who wish to avoid additional information and prefer to leave the details in the hands of the hospital staff [21]. These patients are referred to as “information deniers,” and by offering videos on a voluntary basis, these patients can avoid information if they do not wish to receive it [9-22]. For patients who desire more information, often referred to as “information seekers,” additional videos could be an effective means for providing this information and could result in reduced anxiety levels if the videos are of a quality that answers questions without overwhelming the patient [11,20].

Patient decision making regarding recommended surgical treatment is influenced by many factors and impacts the utilization of surgical procedures. Disparities in the utilization of surgical procedures between gender, racial, and ethnic groups have been well documented [23-25]. The patient’s willingness to proceed with surgery may be influenced by how completely their questions are answered regarding the procedure [26]. Women have been shown to ask more questions related to their upcoming surgery, have higher anxiety levels regarding their surgery, and thus may benefit more from additional information as related to reducing preoperative anxiety [11,22]. In prior research conducted by the senior author (MIO), women were shown to ask a significantly greater number of questions than men in an online preoperative patient education program for hip and knee replacement [22]. In particular, women asked questions related to their condition, the surgical procedure, and risks and benefits [22]. In this study, we also found that women had higher preoperative anxiety than men; 11 of the 12 patients with moderate to severe GAD scores in our study were women. Adequately addressing patient questions and concerns prior to surgery may require more resources for women than men.

A strength of this study is that the control and treatment groups were well balanced relative to gender, type of surgery, and preoperative GAD score (Table 2). Limitations of this study were the low numbers of patients enrolled due to time constraints of the study schedule (the resources were only available for a 3-month period). In addition, while patients were asked to record the date and number of views for each video, we did not have a method to validate the viewing of the videos by the patients. Finally, we did not study in detail whether the videos were also viewed by the patient’s family or caregivers, which could have provided additional information on the value of YouTube videos as a tool for patient and family education.

Creating innovative and effective engagement with patients to augment face-to-face encounters is essential in the new health era. With increasing financial pressure to see more patients, surgeons and their support staff may not have adequate time for addressing all concerns with each patient.

Our early experience supplementing traditional preoperative education with a series of online YouTube videos that highlight the surgical and hospital experience was well received by our patients. In our small number of patients with moderate to severe anxiety prior to surgery, we found a trend toward less anxiety after viewing the videos. Further exploration of this approach, including specific tailoring of video content to gender, race, and ethnicity may prove to be highly beneficial to both patients and health care providers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [27].

[PDF File (Adobe PDF File), 157KB - jmir_v5i1e10_app1.pdf]

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Abbreviations

GAD: Generalized Anxiety Disorder

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Original Paper

Assessing Quality of Life and Medical Care in Chronic Angina: An Internet Survey

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Abstract

Background: Angina is a clinical syndrome whose recognition relies heavily on self-report, so its identification can be challenging. Most data come from cohorts identified by physicians and nurses at the point of care; however, current widespread access to the Internet makes identification of community cohorts feasible and offers a complementary picture of angina.

Objective: To describe a population self-identified as experiencing chronic angina by use of an Internet survey.

Methods: Using email and an Internet portal, we invited individuals with a diagnosis of angina and recent symptoms to complete an Internet survey on treatment and quality of life (QOL). In total, 1147 surveys were received. The main analysis was further limited to those reporting a definite coronary heart disease (CHD) history (N=646, 56% of overall).

Results: Overall, about 15% reported daily angina and 40% weekly angina. Those with more frequent angina were younger, more often depressed, and reported a shorter time since diagnosis. They also had substantially worse treatment satisfaction, physical function, and overall QOL. Fewer than 40% were on ≥ 2 anti-anginals, even with daily angina. The subjects without a history of definite CHD had unexpectedly low use of antianginal and evidence-based medicines, suggesting either a lack of specificity in the use of self-reported angina to identify patients with CHD or lack of access to care.

Conclusions: Use of inexpensive electronic tools can identify community-based angina cohorts for clinical research. Limitation to subjects with a definite history of CHD lends diagnostic face validity to the approach; however, other symptomatic individuals are also identified.

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KEYWORDS

Angina; Surveys and Questionnaires; Internet; Quality of Life

Introduction

Angina is a clinical syndrome whose recognition relies heavily on self-report. The subjective nature of angina challenges its efficient recognition and proper identification. The prevalence of angina has been estimated to be ~3.2% among US adults >20 years of age and 8-10% among those aged over 60 years old [1]. In addition, among trials and registry populations of patients with coronary artery disease, 20-30% continue to report angina symptoms despite contemporary medical care [2-8]. Since angina is associated with risk for morbidity, poor quality of life (QOL), and increased health care costs, evidence suggesting poor control of symptoms is concerning [9-11]. The diagnosis still rests upon patient report, with no fully satisfactory method of objective confirmation yet accepted. Despite these difficulties, chest discomfort symptoms remain a huge source of patient distress, and incomplete control may be an important signal of inadequate quality of care. The use of electronic tools on the Internet, including email and patient surveys, provides potentially useful new methods to survey large cohorts and identify unmet needs deserving of more intensive study.

We postulated that we could identify a cohort of individuals with a diagnosis of angina and recent symptoms via Internet and email links that could provide some insights into the levels and effectiveness of care from the patient's perspective. We were specifically interested in the group with greater symptom burden, to understand the impact of their angina on treatment and QOL.

Methods

Participants

Participants were identified through email and the Internet. Direct-to-patient emails with survey links were sent to two advocacy LISTSERVs maintained by professional organizations: Mended Hearts Inc., a cardiovascular patient membership organization, and the American College of Cardiology (ACC) Vendor "Opt-in" cardiovascular patient LISTSERV. In addition, a Web-based survey was available through an Internet link following search engine inquiries for "angina" or "angina treatment" and on the webpage of the Society for Cardiovascular Angiography and Interventions. [12] Unique US IP addresses were required. In both the email and the Internet link, a brief description of the survey was provided, and respondents opted in by clicking on the survey URL.

The target respondents were individuals aged ≥50 years who had a diagnosis of angina at any time in the past and also experienced angina in the prior 6 months. The survey was distributed during an 8-week period from November 2012 to January 2013. Respondents were invited to complete the survey if they met the eligibility by indicating yes to each criterion in the screening survey (age ≥50 years, provider diagnosis of angina, and occurrence of angina in the past 6 months). A description of angina was provided: "Angina is a pain, discomfort, or pressure localized in the chest that is caused by an insufficient supply of blood (ischemia) to the heart muscle. It is also sometimes characterized by a feeling of choking, suffocation, or crushing heaviness. This condition is called angina pectoris." Respondents were excluded if they were employed or had an immediate family member employed by a marketing/research organization, or if they had participated in a research study on angina in the last 6 months. As an incentive, survey participants were offered entry into a drawing to win one of five $100 gift cards.

Survey

The survey was composed of 34 questions and took approximately 15 minutes to complete. The survey included demographic and clinical factors, contact with health care providers, medication use, and health-related QOL (HRQOL): overall health, angina burden, physical functioning, and social and emotional well-being. Angina and disease-specific HRQOL items were assessed using the Seattle Angina Questionnaire (SAQ). The SAQ is a 19-item self-administered questionnaire that measures 5 clinically important dimensions of coronary disease: physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception [13]. Domain scores range from 0 to 100, with lower scores indicating more angina and worse QOL. The specific measure of angina frequency used to stratify patients for analysis was based on the following question: "Over the past 4 weeks, on average, how many times have you had to take nitroglycerin for chest pain, chest tightness, or angina?" Patients were grouped according to the following responses: daily, ≥4 times daily, and 1-3 times daily; weekly, >3 times weekly but not daily, and 1-2 times per week; none/monthly, < once a week or no angina in last 4 weeks.

Global health status was assessed using the Global Health Question from the RAND Medical Outcomes Study (MOS) questionnaire, the EuroQol-5D questionnaire (EQ-5D), and the Work/Regular Physical Activity questionnaire. The 5-item MOS questionnaire is a self-assessment of a patient's overall general health, with responses ranging from excellent to poor [14]. The EQ-5D is a 5-item tool that assesses a patient's perception of his or her mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [15]. EQ-5D responses can be converted to a standard scale using an algorithm developed for the US population [16], which range from 0 to 1, with 0 representing the worst imaginable health state and 1 representing perfect health [15]. The Work/Regular Physical Activity questionnaire is a 1-item questionnaire that assesses how active a subject is at work (including volunteer work and housework) [17]. The possible ordinal responses to the question are 1 = Mainly sedentary, 2 = Predominantly walking on one level, 3 = No heavy lifting, 4 = Mainly walking, including climbing stairs, walking uphill, or lifting heavy objects, 5 = Heavy physical labor, and 6 = Do not work. The response "Do not work" is not applicable to the physical activity at work endpoint, and therefore, individuals with this response were excluded from analysis of this domain of health.

Analysis

Respondents confirmed that they had received a provider diagnosis of angina. However, the main analysis was further limited to respondents who also reported a confirmatory CHD history—who reported taking antiplatelet agents and had a prior percutaneous coronary intervention (PCI), prior coronary artery bypass grafting (CABG), or coronary heart disease diagnosis. Demographics, clinical history, comorbidities, general clinical care, and HRQOL were compared according to SAQ angina frequency groups. Supplementary analyses for the non-CHD confirmed cohort are shown in Multimedia Appendix 1, Multimedia Appendix 2, and Multimedia Appendix 3. The purpose of the analysis was descriptive and no specific hypotheses were prespecified. Analyses were performed using SAS Version 9.4.

All pages of the survey required complete answers prior to advancing; therefore, there were no missing items. As participants voluntarily submitted responses to this anonymous survey, the Duke institutional review board waived the need for consent. The study concept originated with the sponsor, Gilead Sciences. The sponsor contracted with members of the Outcomes Group at Duke Clinical Research Institute (DCRI) to design the survey, perform the analyses, and report the results. The DCRI retained full independence in matters of analysis, interpretation, and publication. The sponsor was given an opportunity to review and comment on the publication prior to submission, but final responsibility for content remained with DCRI authors. One sponsor representative who worked with DCRI on the study design was included as a coauthor.

Results

A total of 13,482 individuals were approached to complete the survey (10,866 through email, 2616 through an Internet link), of which 44.6% (6015/13,482) did not respond (Figure 1). Screening questions excluded 76.3% (5698/7467) (respondents who initiated the screening phase. In the email survey invitation group (half of emails received no response), 35.6% did not meet screening criteria, and 84.9% of those who did meet criteria completed the survey. In the Internet link group who had clicked on the survey invitation, 70% (1834/2616) did not meet screening criteria, and 39.5% (309/782) of those who did meet criteria completed the survey. Of the 1769 respondents who passed screening criteria, an additional 622 did not complete the survey. This left 1147 complete survey respondents; 73% (838/1147) from email invitations and 27% (309/1147) from Internet invitations—a response rate that exceeded the anticipated target of 1000 patients in 8 weeks. The survey was completed by 64.8% (1147/1769) of those respondents who started it, and 9% (1147/13,482) of all those approached.

Of the 1147 respondents with completed surveys, 73% were from obtained from email and 27% from Internet contact (Table 1). Email respondents were more often male, with higher educational attainment, and longer time since first angina diagnosis compared to Internet respondents. Over half of Internet respondents reported a diagnosis of angina within the last year in contrast to 15.5% of email respondents. Also, more Internet respondents said their angina diagnosis date was unknown. Uncertainty about cardiovascular disease among Internet respondents was also suggested by fewer visits to a cardiologist, lower rates of having a cardiologist, and less prior revascularization. Therefore, the primary analysis was limited to those reporting use of a daily antiplatelet and a prior PCI, CABG, or CHD history (CHD group). The CHD group comprised over half of survey respondents (N=646, 56%). The CHD group more often came from email (n=544) than from Internet (n=102) invitations.

Demographics and treatment of the CHD group stratified by self-reported angina frequency are shown in Table 2. Patients with more angina (daily) were younger and less likely to have a college education. Out-of-pocket medication costs and insurance coverage were similar across groups. Patients with more angina had notably more depression compared to those with less frequent or no angina.

Patients with more angina (daily) had a shorter time since initial angina diagnosis (Table 3). Most reported care by a cardiologist, and the majority discussed angina at their last visit. Differences in medication use revealed more long-acting nitrates and more anti-anginals for respondents with daily angina.

Subjects with self-reported angina but without definite CHD (non-CHD group) had lower use of anti-anginal and prevention medicines, even with daily angina, and more anxiety and depression (Multimedia Appendix 1). Over half were female, 9.6% were uninsured, and they were more likely to not have a cardiologist. In addition, symptom burden as reflected in the SAQ responses was nearly the same, and treatment satisfaction was lower in this group.

All disease-specific health status measures confirmed that QOL was substantially impaired in those reporting more angina (Table 4). As compared to those with no angina or monthly angina, those with daily angina had more angina-related physical limitations, worse disease-specific QOL, and lower angina-related treatment satisfaction. In addition, those reporting more angina had more problems in all 5 EQ-5D domains—particularly anxiety/depression, pain, and limitations in usual activities. Work/Regular Physical Activity questionnaire scores correlated with angina frequency, as respondents with more angina were less likely to report engaging in moderate to strenuous exercise.

Table 1. Demographics and characteristics by mode of invitation.

Variable		Email n=838	Internet n=309	*P* Value
Age, mean years ± SD		64.8 ± 8.3	64.1 ± 9.3	.095
Male, n (%)		511 (61.0)	155 (50.2)	.001
White race, n (%)		793 (94.6)	278 (90.0)	.005
Education (≥HS), n (%)		831 (99.2)	287 (92.9)	<.001
Married, n (%)		600 (71.6)	211 (68.3)	.27
Insurance, n (%)	Medicare/Medicaid	496 (59.2)	150 (48.5)	.001
	Private/employer	537 (64.1)	176 (57.0)	.028
	No insurance	28 (3.3)	33 (10.7)	<.001
Angina diagnosis, mean years ± SD		9.7 ± 8.9	3.7 ± 6.4	<.001
	<1 year (%)	130 (15.5)	175 (56.6)	
	1-5 years (%)	236 (28.2)	78 (25.2)	
	6-10 years (%)	185 (22.1)	22 (7.1)	
	>10 years (%)	287 (34.3)	34 (11.0)	
	Unknown (%)	27 (3.2)	27 (8.7)	
Cardiologist last 6 months	Yes	608 (72.6)	142 (46.0)	<.001
	No	183 (21.8)	103 (33.3)	
	Don’t have one	47 (5.6)	64 (20.7)	
Antiplatelet daily[a]		710 (84.7)	203 (65.7)	<.001
CHD[b]		438 (52.3)	87 (28.2)	<.001
Prior revascularization		518 (61.8)	98 (31.7)	<.001
	Prior PCI[c]	437 (52.2)	85 (27.5)	<.001
	Prior CABG[d]	288 (34.4)	30 (9.7)	<.001
Primary CHD group		544 (64.9)	102 (33.1)	<.001

[a] Antiplatelet is either aspirin or other antiplatelet agent

[b] CHD: coronary heart disease

[c] PCI: percutaneous coronary intervention

[d] CABG: coronary artery bypass grafting

Table 2. Demographics and conditions: overall and by angina frequency.

Variable		Overall N=646	Daily n=90	Weekly n=238	None/Monthly n=318	*P* Value
Age, mean years (SD)		65.9 (8.3)	63.3 (8.0)	66.0 (8.1)	66.5 (8.4)	.005
Male, %		68.7	68.9	64.7	71.7	.21
White race, %		94.4	93.3	94.5	94.7	.89
Education ≥HS, %		98.5	95.6	99.2	98.7	.052
Married, %		74.8	77.8	72.7	75.5	.59
Insurance status	Medicare/Medicaid, %	61.6	52.2	67.7	59.8	.024
	Private/employer, %	64.6	75.6	58.4	66.0	.011
	No insurance, %	2.0	3.3	1.7	1.9	.62
Out-of-pocket prescription costs, %	1 (almost negligible)	27.6	20.0	26.5	30.5	.36
	2	26.0	26.7	25.6	26.1	
	3	27.1	28.9	25.6	27.7	
	4	14.7	18.9	16.0	12.6	
	5 (can’t fill all meds)	4.6	5.6	6.3	3.4	
Conditions, %	CHD[a]	76.0	81.1	77.3	73.6	.28
	Hypertension	63.0	64.4	60.5	64.5	.60
	Prior revascularization	88.2	87.8	85.7	90.3	.26
	Prior PCI[b]	74.9	74.4	70.6	78.3	.12
	Prior CABG[c]	47.1	46.7	47.1	47.2	.99
	Atrial fibrillation	15.9	22.2	17.2	13.2	.095
	Depression	22.6	33.3	25.6	17.3	.002
	Diabetes	34.2	37.8	34.0	33.3	.73
	Sleep apnea	29.6	28.9	31.1	28.6	.81
	Cancer	7.4	8.9	7.1	7.2	.85
	Osteoarthritis	24.3	16.7	29.8	22.3	.024
	Erectile dysfunction	50.7	56.5	50.0	49.6	.62
	PVD[d]	13.0	20.0	12.2	11.6	.10

[a] CHD: coronary heart disease

[b] PCI: percutaneous coronary intervention

[c] CABG: coronary artery bypass grafting

[d] PVD: peripheral vascular disease

Table 3. General care: overall and according to reported angina frequency.

Variable		Overall N=646	Daily n=90	Weekly n=238	None/monthly n=318	*P* value
Angina diagnosis, mean years ± SD		9.6 (8.8)	7.5 (7.4)	9.9 (9.2)	10.0 (8.7)	.026
Cardiology visit, % yes		80.8	73.3	84.0	80.5	.088
	If yes, discussed angina	81.8	87.9	89.0	74.6	<.001
Medication type, %	Aspirin	94.1	87.8	96.6	94.0	.010
	Any antiplatelet	100.0	100.0	100.0	100.0	n/a
	Statin	88.2	83.3	88.7	89.3	.29
	Any anti-anginal[a]	84.5	83.3	87.0	83.0	.42
	≥2 anti-anginals	35.5	44.4	38.7	30.5	.022
	Beta-blocker	74.5	72.2	73.5	75.8	.73
	Ca channel blocker	24.5	27.8	29.0	20.1	.041
	Long-acting nitrates	24.0	35.6	26.5	18.9	.003
	Ranolazine	11.5	15.6	13.5	8.8	.099

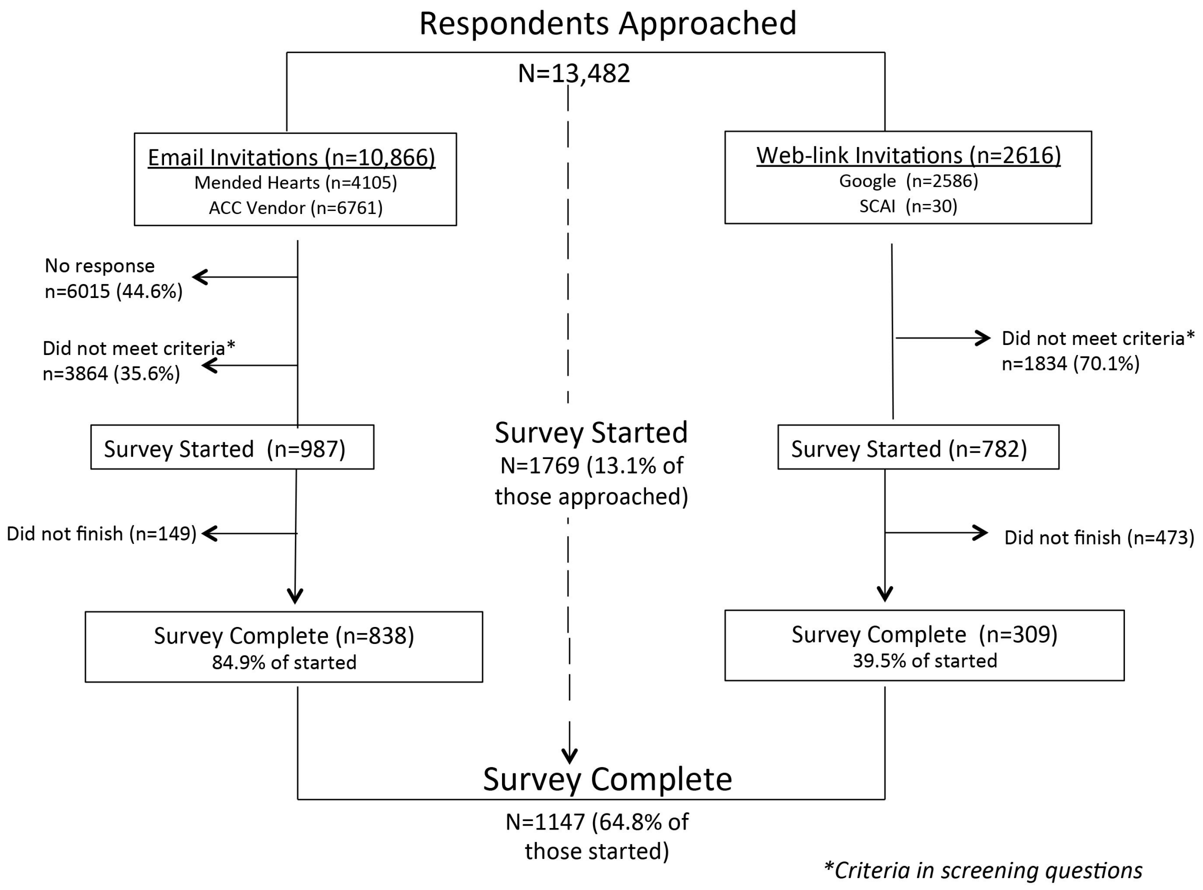
[a] Any anti-anginal includes beta blockers, calcium channel blockers, long-acting nitrates, and ranolazine.

Table 4. Health-related quality of life: overall and by reported angina frequency.

Measure		Overall N=646	Daily n=90	Weekly n=238	None/Monthly n=318	*P* value
Seattle Angina Questionnaire (SAQ), mean (SD)	Angina frequency	75.4 (21.6)	41.0 (17.6)	66.9 (13.4)	91.5 (8.7)	<.0001
	Angina stability	52.4 (23.5)	33.6 (23.2)	49.6 (22.8)	59.7 (20.6)	<.0001
	Physical limitations[a]	64.7 (22.7)	52.7 (21.0)	59.5 (22.2)	72.1 (21.1)	<.0001
	Treatment satisfaction	77.5 (20.4)	60.6 (23.6)	73.0 (19.3)	85.7 (15.8)	<.0001
	Quality of life	59.0 (23.1)	33.5 (18.3)	54.0 (20.7)	69.9 (18.5)	<.0001
Global health		46.0 (23.1)	35.6 (22.8)	43.9 (22.7)	50.6 (22.2)	<.0001
EQ-5D, % no problem	Mobility	59.3	43.3	55.5	66.7	.0006
	Self-Care	91.2	81.1	89.5	95.3	<.0001
	Usual Activities	61.6	37.8	55.0	73.3	<.0001
	Pain Discomfort	29.3	6.7	12.6	48.1	<.0001
	Anxiety/Depression	53.3	27.8	49.2	63.5	<.0001
Work/Physical Activity, %	Mainly sedentary	14.1	16.7	11.8	15.1	.39
	Moderate/strenuous	33.1	28.9	26.5	39.3	0.017

[a] 21 respondents had missing SAQ Physical Limitations scores due to more than 4 missing values out of 9.

Figure 1. Flow diagram of respondents by invitation and completion.



Discussion

Principal Findings

This anonymous angina Internet survey provides insights into the range of symptomatic individuals in the community and raises questions about their identification and treatment. We found that approximately 15% of respondents reported daily angina, and approximately 40% reported weekly angina. In both the CHD group and non-CHD group, more frequent angina was associated with worse QOL. The cardiac origin of the symptoms cannot be proven with the methods we used; however, similarities in comorbidity, treatments, and symptoms in both the CHD and non-CHD group suggest that the burden of angina is similar in both. The majority of respondents had seen a cardiologist in the prior 6 months, yet medication and revascularization seemed lower than expected given their symptomatic status. While this methodology was successful in rapid accrual of data directly from patients, responses must be viewed in context. The Internet may be able to build a bridge for symptomatic individuals to enter the clinical setting for more timely recognition and treatment of angina.

Angina in population surveys, trials, and registries also takes place through patient report without objective confirmation, which elevates the comparability of our findings [18,19]. Most of the reported angina is likely from coronary artery disease as a majority had a prior revascularization. Angina typically persists in approximately 20% of post-MI or prior revascularization patients and exists in the same proportion among a population with stable ischemic heart disease [20]. However, up to 40% of angina patients, even those with a history of CHD, who undergo angiography have nonobstructive coronary artery disease [21]. Angina in the absence of epicardial disease may come from microvascular dysfunction, spasm, and diffuse plaques [22,23]. The possible existence of angina without ischemia or epicardial disease is important, as some providers may discount symptoms in the absence of obstructive coronary disease. For respondents in this survey with a history of angina, daily angina occurred in ~15%, and weekly angina in another 40%. Some of the subjects may have nonanginal chest pain, or somatic manifestations of depression; however, the data suggest the cause is believed to be angina from the patient perspective. Therefore, to succeed in alleviating “angina” as a source of patient suffering and impaired QOL, a broader perspective on its identifying criteria seems warranted. Requiring the presence of significant angiographic disease or abnormal stress testing may be overemphasized. Angina should be an important criterion for study inclusion in its own right.

Respondents with more angina were younger, more often female, less likely to have had prior PCI or CABG, on fewer antianginal medications, and more depressed (34.1 vs. 19.6%). Only 27% of those with daily angina reported freedom from anxiety or depression on the EQ-5D survey. Comparing to similar populations from trials and registries is challenged by the inclusion of patients with other qualifying criteria such as angiographic disease or ischemia, in addition to some degree of angina. The TERISA population enrolled patients with chronic angina in addition to diabetes [24]. The use of long-acting nitrates in the TERISA population was similar to the respondents with daily or weekly angina in this survey, with most other preventive medication use being similar. The CLARIFY registry population enrolled patients with stable ischemic heart disease, of whom 20% had angina with or without documented ischemia. In the CLARIFY population, those with angina were younger, female, and had less frequent history of revascularization than those without angina [20]. We observed that antianginal medication use increased among those with more reported angina, yet only 44% with daily symptoms were on two or more of these medications [6]. Control of blood pressure, cholesterol, and weight may also be low in this group. Of those reporting daily or weekly angina, 10-15% did not discuss it with their cardiologist, making effective treatment unlikely. Angina is associated with a significant increase in CV-related death or MI across every Canadian Cardiovascular Society Angina class [20]. This association is probably due primarily to the effect of atherosclerotic coronary artery disease; however, linkages with other prognostically important disorders such as depression might also contribute. This Internet population was identified purely through patient-reported symptoms, adding a unique comparator to symptomatic populations assembled using other inclusion criteria, and underscoring that those with chronic angina are often female and younger.

It is possible that the qualifying angina in this survey population occurred between visits to providers. The identification of a population with angina (via the Internet) raises the question of access in the event of symptom return between clinic visits. Strategies such as the brief SAQ instrument for patients with coronary disease or angina as part of routine visits, or between visits, could identify those likely to benefit from treatment intensification or revascularization [25]. Despite screening, variation in the level of angina control across health care clinics is also known to exist [26]. Although the vast majority reported having health insurance, 15% of the daily angina group also reported having no cardiologist. This suggests a lost opportunity in access to health care. Regional clinic accessibility, travel limitations, or social barriers to receiving clinic-based care may be contributors in this population.

Limitations

To participate in an Internet survey, respondents must have computer access, which may limit generalizability [27]. As responses were voluntary, individuals with a greater burden of angina may have been more motivated to participate, leading to an overestimation of the effect of angina on QOL. Demographic or clinical data on nonrespondents could not be assessed. In addition, data on clinical diagnoses and medications were based on self-report. However, profiles and angina severity are consistent with those of contemporary populations with angina in more traditional clinical studies [28]. The possibility remains that a diagnosis of angina, as required by the screener, was misunderstood. We selected the CHD cohort for the main analysis, limited to those with documented coronary disease, to address this concern. Lastly, there was no mechanism to verify unique responses; however, each IP address could only be associated with one completed survey. This study describes responses at a single point in time, so follow-up information on treatment or outcomes was not available.

Conclusion

This survey provides a snapshot of those with angina in an online community—at a single time point, across providers and treatment stages—and finds 15% of this group experiences daily angina. This study suggests the promise of Internet surveys for assessing patient-reported symptoms, and raises the possibility that screening tools such as this could be deployed inexpensively between health care provider encounters for better angina control and potentially improved QOL.

Acknowledgments

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Conflicts of Interest

Dr Alexander has received research support from Sanofi Aventis (significant), Gilead Sciences (modest), and NIH (modest). Dr Alexander serves on the DSMB for CytRx. Dr Mark has received research support from Eli Lilly & Company (significant), Gilead (significant), AstraZeneca (significant), AGA Medical (significant), Bristol Myers Squibb (significant), has served as a consultant for Milestone Pharmaceuticals (modest), Medtronic, Inc. (modest), CardioDx (modest), and St. Jude Medical (modest). Dr Anstrom has received research support from AstraZeneca (significant), Bristol-Meyers Squibb (significant), Eli Lilly & Company (significant), Boehringer Ingelheim (significant), Pulmonary Fibrosis Foundation (significant), and Medtronic (significant); has served as a consultant for Abbott Vascular (modest), AstraZeneca (modest), Bristol-Meyers Squibb (modest), Gilead (modest), Pfizer (modest), and GlaxoSmithKline (modest); and has served on data monitoring committees for NIH (modest), Forest (modest), Pfizer (modest), and GlaxoSmithKline (modest). Dr Anstrom has an equity interest in Biscardia. Olena Stadnyuk is an employee of Gilead Sciences. The other authors report no conflicts.

Multimedia Appendix 1

Non-CHD respondents demographics, overall and by angina frequency.

[PDF File (Adobe PDF File), 66KB - ijmr_v5i2e12_app1.pdf]

Multimedia Appendix 2

Non-CHD respondents general care, overall and by angina frequency.

[PDF File (Adobe PDF File), 52KB - ijmr_v5i2e12_app2.pdf]

Multimedia Appendix 3

Non-CHD respondents health-related quality of life assessments, overall and by angina frequency.

[PDF File (Adobe PDF File), 58KB - ijmr_v5i2e12_app3.pdf]

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Abbreviations

ACC: American College of Cardiology
CABG: prior coronary artery bypass grafting
CHD: coronary heart disease
DCRI: Duke Clinical Research Institute
EQ-5D: EuroQol-5D
HRQOL: health-related QOL
MOS: Medical Outcomes Study
PCI: percutaneous coronary intervention
PVD: peripheral vascular disease
QOL: quality of life
SAQ: Seattle Angina Questionnaire

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Original Paper

Evaluating the Quality of Website Information of Private-Practice Clinics Offering Cell Therapies in Japan

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Abstract

Background: Although the safety and effectiveness of stem cell therapies are yet to be proven, recent studies show that such therapies are being advertised with some questionable marketing techniques to effect positive portrayal of the therapies on the webpages of private-practice clinics to sell their therapies worldwide. In such context, those clinics communicate directly with consumers (patients and their family members) via the clinics' websites. Meanwhile, the Health Science Council at the Ministry of Health, Labour, and Welfare (MHLW) in Japan has pointed out noncompliance of some local clinics with the provisions concerning medical advertising in the Medical Care Act in the past. However, locally little is known about the current status of those clinics including the quality of their webpage information disseminated.

Objective: To evaluate the quality of website information of private-practice clinics offering cell therapies in Japan.

Methods: Twenty-four websites with 77 treatments from the Google search were identified for evaluation. The following three exploratory analyses were performed: first in order to ascertain web-based portrayal of private-practice clinics offering cell therapies, a descriptive analysis was conducted using a coding frame; second we evaluated the quality of the target website information from the viewpoint of the level of consideration taken for patients and their family members, using 10 quality criteria ("the Minimum Standard") from the e-Health Code of Ethics 2.0; third we counted and coded expressions that matched set categories for "name-dropping" and "personalized medicine" in the information posted on these websites.

Results: Analysis on the treatments (N=77) revealed 126 indications (multiple response): the top three indications were "cancer," "skin-rejuvenation/antiaging/anti–skin aging," and "breast augmentation/buttock augmentation." As for the portrayal of treatment risks and benefits, 78% (60/77) of treatments were mentioned with "benefits," whereas 77% (59/77) of treatments were mentioned with "risks." As for the source(s) cited for the discussions of treatment risks and benefits, no treatment quoted an expert's opinion for the risks, whereas 7% (6/77) treatments quoted external sources for the benefits. As for the results with e-Health Code of Ethics 2.0, not a single clinic fulfilled all the 10 criteria; 63% (15/24) of the clinics was found exercising "name-dropping," and 21% (5/24) of the clinics mentioned expressions related to "personalized medicine" on their websites.

Conclusions: Our website content analyses confirmed the following: (1) the clinics mentioned the risks or benefits of the treatments with hardly any scientific citations, (2) the way the website information was disseminated was inappropriate for patients and their families, and (3) many websites seemed to be using marketing techniques in order to draw patients' interests or attentions. It is important that more similar studies are undertaken globally to enable an orchestrated regulatory approach toward private-practice clinics.

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KEYWORDS

stem cell; health information; regulations; regenerative medicine; misrepresentation; medical tourism; direct-to-consumer; online marketing; web survey; descriptive analysis

Introduction

The use of regenerative medicine, including stem cell therapy, has been experimentally attempted to treat diseases that cannot be cured by conventional treatment methods [1]. Currently, little is known about the safety, efficacy, or effectiveness of regenerative medicine. Thus, as a rule, experts do not recommend the use of this technology for the treatment of patients outside the framework of research [2]. Meanwhile, in reality patients from many countries are accessing website information related to unapproved regenerative therapies, crossing borders if necessary to visit private-practice clinics that offer such therapies for hefty fees [3]. In such context, the Internet plays an important role, and in fact, those private-practice clinics communicate directly with consumers (patients and their family members) via the Internet [4,5].

However, recent studies have raised some questions about problematic ways that website information is being advertised with some marketing techniques [6,7]. For example, one previous study indicated that there were websites that used several marketing methods related to information concerning stem cell treatments in order to affect a positive portrayal of the treatments [6]. The market trend to use the language of research papers, including those concerning stem cell research, has also been indicated in cases when the stem cell business industry advertises their own antiaging stem cell products via the Internet [7]. In addition, there is a common advertising technique known as “name-dropping,” which is defined by a web-based dictionary [8] as follows: “The act of talking about famous people that you have met, often pretending that you know them better than you really do, in order to appear more important and special.” In response to such advertising, the International Society for Stem Cell Research expressed concerns in its handbook that patients and their family members should not be rushed to make a decision on receiving treatment based on the web-based information disseminated by these clinics [9].

In Japan, an incident in which a Korean patient who received stem cell therapy died of pulmonary embolism was reported in 2010 [10]. At that time, there were no laws in Japan concerning regenerative medical treatments that were not covered by public health insurance. However, after the enforcement of the 2014 Act on the Safety of Regenerative Medicine (ASRM), such clinics became bound by the same regulations as clinical research [11]. A medical institution that attempts to offer regenerative medical treatments not covered by health insurance (ie, private practice) must first submit a plan to a Certified Special Committee or a Certified Committee, and after receiving an approval from said committee, submit the approved plan to the Ministry of Health, Labour and Welfare (MHLW) [11].

Now, new laws and regulations are in place, but the current situation of private-practice clinics offering cell therapies in Japan remains unclear. This remains so in spite of the fact that some private-practice clinics offering cell therapies in Japan have been indicated to have a variety of problems [11]. For example, before the enforcement of the ASRM, the Health Science Council of the MHLW was informed that some private-practice clinics in Japan offering cell therapies were in violation of the regulations concerning advertising that are stipulated in the Medical Care Act [12]. However, the actual status of these violations have not been elucidated either.

An assessment of the current problems and concerns of regenerative medicine as referred to earlier reveals the following points: (1) although the use of various marketing techniques such as name-dropping on English language websites has been investigated, the current status of Japanese language websites remains unclear, and (2) it has been indicated that some Japanese private-practice clinics offering cell therapies treatments use medical advertisements that are in violation of the regulations concerning advertisements stipulated in the Medical Care Act [12], but the current status of the problem is unclear.

In order to ascertain the current situation surrounding private-practice clinics offering cell therapies in Japan, we evaluated the quality of the clinics’ website information from consumers’ points of view.

Methods

Analysis Overview

In the present study, after systematically downloading the websites of these clinics, we performed the following three exploratory analyses. Analysis 1: in order to ascertain the portrayal of private-practice clinics offering cell therapies, we performed a descriptive analysis. Analysis 2: we evaluated the information of these websites concerning regenerative medicine from the viewpoint of the level of consideration taken for patients and their family members, and if that information was appropriately disseminated. Analysis 3: we counted and coded expressions that can be construed as name-dropping in the information posted on these websites. The present study is a part of the grant-aided project to investigate the status of regenerative medical treatments in Japan (see Acknowledgements), thus part of the data is shared with a previous study [13].

The definitions for regenerative medicine in the present study are based on the definitions found in the ASRM [11]. For more detailed definitions of the terms, please see the Multimedia Appendix 1 (Scope of Application of the ASRM).

Data Collection

The results of a multi-stage extraction of the websites are as follows:

1. Google search: our study is based on a sample of websites identified from May 24, 2014 to May 27 using Google search engine and the browser Mozilla Firefox with the following keywords: (“cell therapy” OR “regenerative medicine” OR “stem cells”) AND {(“private practice” OR “private expenses”)

OR (“hospital” OR “clinic” OR “medical office” OR “doctor’s office”)}. The language of the actual search terms used was Japanese. We used the following search expressions: (“saibo chiryo” OR “saisei iryo” OR “kansaibo”) AND {(“jiyu shinryo” OR “jihi”) OR (“byoin” OR “kurinikku” OR “shinryosho” OR “iin”)}. The results of the search showed approximately 1,590,000 hits, of which 836 could be displayed.

2. Storage of data: of the 836 hits, 762 hits (clinics that do not provide regenerative medicine stipulated by ASRM, public research institutions/public health institutions and university hospitals, program information, such as television, news, and blogs, hospital information sites, and duplicate sites) were excluded. The remaining 74 websites were electronically saved using Firefox add-on software ScrapBook 1.5.9.

3. Selection of the targets for analysis: based on the following two reasons, the present study was limited to analysis of 24 websites; it has been indicated that the top 20 websites displayed on the browser reflect the actual websites that search engine users view [14,15]. Moreover, the principal aim of the present study was to perform an exploratory investigation.

Analysis 1: Descriptive Analysis

In order to ascertain the overview of the 24 clinics that were extracted above, we performed a descriptive analysis of the information concerning the clinics themselves and treatment methods listed on the websites of the clinics. We analyzed (1) clinic location/foreign language page and (2) advertised departmental name. With regard to information concerning treatment methods, of the 24 clinics that offer therapies, we collected 77 regenerative medical treatments that fell within the scope of the ASRM and analyzed the following items: (3) target disease, (4) method of transplantation (“local,” “general,” “unknown/not listed”), (5) the presence or absence of explanation of benefits and effects (Yes/No), (6) cited evidence of benefits or efficacy (if any) from scientific journals, (7) the presence or absence of description of risks and safety (Yes/No), (8) cited evidence of risks or safety (if any) from scientific journals, and (9) costs (ie, cost of each therapy or treatment if mentioned).

Moreover, with regard the items concerning the benefits and risks of treatment (items 5-8, above), we created a coding frame while referring to a previous study [15]. Websites in which a reference to the benefits and efficacy of treatments (eg, “the effects are not the same in all patients,” “your skin will appear 10 years younger,” and “the risks are different for each person”) could be confirmed were evaluated as “Yes” with regard to explanation of benefits and efficacy. Descriptions that clearly listed information concerning safety and expected side effects of said treatments (eg, “It is safe because samples are cultured in a clean cell processing center” and “A fever may occur after infusion of immune cells”) were evaluated as “Yes” with regard to explanation of risk and safety. On the other hand, descriptions that listed only basic medical explanations such as the characteristics of the cells used in treatment and their mechanisms of action were evaluated as “No.” In items 6 and 8, we confirmed the presence of research citations, which served as the basis for claims of benefits and risks made on the websites. Data confirming process for items 1 to 6 was already implemented by two authors (TH and MF) in the previous study [13], and as for 7 to 9 the coding validity was confirmed by two authors (HK and TH).

Analysis 2: Assessment with e-Health Code of Ethics 2.0

The “e-Health Code of Ethics 2.0” was used in order to evaluate the quality of website information to ascertain whether said information was appropriately provided for patients and their family members who need information concerning regenerative medicine [16]. The Code was created by the nonprofit organization Japan Internet Medical Association (JIMA), and its origin can be traced back to the “Medical Information Usage Guidebook” developed in December 1999 [17].

The following 10 quality criteria called the “Minimum Standards” from the e-Health Code of Ethics 2.0 were used in our study. See Multimedia Appendix 2 (The 10 Quality Criteria of Minimum Standard from e-Health Code of Ethics 2.0) for more details. We compared the information presented on the 24 websites that were targets of the present study with the 10 Minimum Standards using the following three scales: “1- Complied,” “2- Not complied,” “3- Not Applicable (NA).” The outline of the 10 Standards is as follows:

1. Disclosure of information about the website operator

2. Disclosure of information about sponsorship

3. Provision of contact center for further inquiries

4. Clarifying intended recipients of content

5. Disclosure of the information concerning writing, production, and/or editorial supervision of conduct

6. Adherence to relevant laws and regulations

6-1. Prohibited advertising of names of the medical institutions (eg, “Regenerative Medicine Clinic”)

6-2. Prohibited advertising of names of hospital departments (eg, “Department of Regenerative Medicine”)

6-3. Prohibited claim of specialization (eg, “Certified Specialist in Regenerative Medicine”)

6-4. Prohibited use of the term (eg, “regenerative medicine”) in the explanations of treatments

6-5. Prohibited use of photos (eg, claiming the effectiveness of a surgery by showing the pre- and post-operational photographs of patients)

7. Notification to the users of profit-oriented activities on the websites

8. Displaying a pop-up message box that reminds the user that they were being transferred to external websites when clicking the links to external websites

9. Displaying handling of personal information

10. Displaying a privacy protection policy

One author (HK) evaluated 24 websites based on the 10 Standards, and another author (TH) verified the coherence of the evaluation. To keep the reliability of evaluation, two authors jointly went back to each website and referred to the relevant section of e-Health Code of Ethics 2.0.

Analysis 3: Focusing on “Name-dropping”

We counted clinics that used the following types of items that fell under the category of expressions of name-dropping on the homepage of their respective websites: academic conference presentation, articles published in academic journals, media coverage, anecdotes by celebrities, medical doctors or specialists, and governmental or regulatory authorities/academic institutions.

Moreover, techniques similar to name-dropping include the use of language used in research papers in order to show the plausibility of the treatment method [7]. Personalized health care has been proposed in an integrated conceptual model where not only genomic medicine but also advanced technologies such as regenerative medicine are included as components [18]. In the present study, we focused on language similar to “personalized medicine,” and counted the number of clinics using the following expressions: “Order-Made Medicine,” “Tailor-Made Medicine,” and “Personalized Medicine.”

Two authors (HK and TH) independently evaluated 24 websites. When there was a disagreement in evaluation results, the two authors jointly went back to each website in question and discussed the issues until all disagreements were resolved.

Results

Descriptive Analysis

The results of the descriptive analysis of information concerning the 24 target clinics and information concerning 77 treatments are mentioned below. As for the locations of clinics and presence of foreign language websites, the majority of clinics were concentrated in the capital of Tokyo and 21% (5/24) of the clinics had a foreign language website. For more details of the clinics’ demographic information, see Multimedia Appendix 3. Concerning advertised departmental names, a wide variety of 33 departmental names were observed in 19 clinics, but five clinics did not specifically advertise any departmental names. The type of clinic with the highest number was cosmetic dermatology followed by cosmetic surgery, internal medicine, and dentistry (Textbox 1). Please note that the numbers in parenthesis in the Textbox are the subtotal of each departmental name(s) used by 24 clinics.

Textbox 1. Departmental Names Used by 24 Clinics (multiple response).

Aesthetic Dermatology (7) Plastic Surgery (5) Internal Medicine (3) Dentistry (3) Immunotherapy (2) Aesthetic Medicine (2) Plastic Surgery (2) Regenerative Medicine (2) Aesthetic Dentistry (2) Cancer Immunotherapy (1) Regenerative Medicine of Skin (1) Neurosurgery (1) Neurology (1) Radiology (1) Orthopaedics (1) Cardiology (1) Urology (1) Surgery (1) Gastrointestinal Medicine (1) Proctology (1) Dermatology (1) Medical Oncology and Immunology (1) Medical Oncology (1) Mammary Gland Medicine (1) Gynaecology (1) Respiratory Medicine (1) Obstetrics (1) Paediatrics (1) Dental Surgery (1) Orthodontic Dentistry (1) Preventive Dentistry (1) Haematology (1) Paediatric Dentistry (1) Unknown (5)

Information Concerning Treatment Methods

With regard to target diseases, the authors observed 126 target diseases and symptoms (nondisease). This is shown in Table 1.

With regard to “transplantation methods,“ local injection was the most commonly performed method (30 treatments). Twenty-five treatments (approximately one-third of all treatments) fell under the category of ”unknown/no description” (Table 2).

Table 3 shows that 78% (60/77) of the treatments listed the expected benefits and efficacy, and Table 4 indicates that 77% (59/77) of the treatments listed information concerning safety and expected side effects. Six citations from scientific papers concerning the benefits and efficacy of the treatments were confirmed, but no citations concerning the safety and side effects of treatments were noted. Moreover, all of the cited studies supported the benefits and efficacy of the treatment method in question, and no literature that cast doubt on the treatment efficacy was cited. With regard to costs, the prices were clearly listed for 82% (63/77) of the medical treatments, and 18% (14/77) of the treatments had no information concerning prices.

Table 1. Stated indications of treatments (multiple response) (N=77).

Diseases [a]		n
	Cancer	42
	Diabetes/type I diabetes	6
	Myocardial infarction	4
	Cerebral infarction	4
	Hepatitis	3
	Renal failure	3
	Rheumatoid arthritis	3
	Alveolar bone atrophy/missing jaw bone/missing teeth	3
	Alopecia	3
	Cirrhosis	2
	Refractory ulcer	2
	Periodontosis	2
	Collagenosis	2
	Osteoarthrosis	2
	Vascular dementia	2
	Parkinson’s disease	2
	Immunological diseases	2
	Burger disease	2
	Liver diseases	2
	Lower limbs ischemia/critical limb ischaemia/peripheral artery diseases	2
	Atopic dermatitis	1
Nondiseases [a]		
	Skin beauty/antiaging	19
	Breast augmentation/buttock augmentation	7
	Nutritional fortification/immunostimulation	2
	The glans/penis enlargement	1
	Nontypable	3
Total [b]		126

[a] Indications have been classified into “Diseases,” which are based on the International Statistical Classification of Disease and Rerated Health Problems, version 10 (ICD-10) [19], and into “Nondiseases,” which is based on the patients’ own symptoms and conditions, and accordingly labelled.

[b] The frequencies do not sum to n=77 because several treatments fitted into more than one category per concept.

Table 2. Route of administration of treatments (N=77).

Route of administration		n	%
	Local	30	39
	Systemic	18	23
	Local and Systemic	4	5
	Unknown/Not specified	25	33
Total		77	100

Table 3. Mentioned benefits for treatments (N=77).

Account of benefits		n	%
Applicable		60	78
	Scientists or researchers	5	7
	Medical specialists	0	0
	Others	1	1
	No citations from the third party	54	70
Not applicable		17	22

Table 4. Mentioned risks for treatments (N=77).

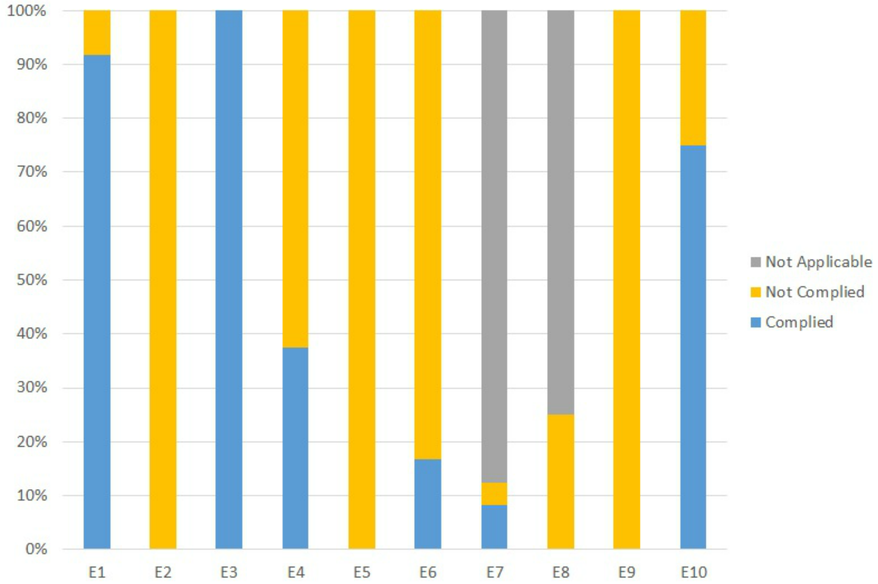
Account of risks		n	%
Applicable		59	77
	Scientists or researchers	0	0
	Medical specialists	0	0
	Others	0	0
	No citations from the third party	59	77
Not applicable		18	23

Assessment with e-Health Code of Ethics 2.0

Of the websites of the 24 clinics that were a target of study, no website was compliant with all of the 10 Minimum Standards of the e-Health Code of Ethics (Figure 1). The items with the highest compliance rates were E3 (provision of contact center for further enquiries) (100%, 24/24), followed by E1 (disclosure of information about the website operator) (92%, 22/24), and E10 (displaying a privacy protection policy or privacy policy) (75%, 18/24). The three items with the lowest compliance rates (0%, 0/24) were as follows: E2 (disclosure of information about sponsorship), E5 (disclosure of the information concerning writing, production, and/or editorial supervision of conduct), and E9 (displaying handling of personal information).

We conducted an evaluation of violations of related laws and regulations stipulated in E6 (adherence to relevant laws and regulations) using a five-point negative list. A negative list approach requires listing those items that are prohibited as exceptions while those not listed in the list are in principle deemed permitted. The most common item of the negative list was E6-4 “prohibited use of the term (ie, regenerative medicine) in the explanations of treatments“ on the websites (71%, 17/24). The second most common item was E6-5 ”prohibited use of photos” (ie, claiming the effectiveness of a surgery by showing the pre- and post-operational photographs) (54%, 13/24). With regard to item E6-2 “prohibited advertising of names of hospital departments,” 37% of the clinics (9/24) advertised the name “regenerative medicine department” (Textbox 1). The least common item was E6-3 “prohibited claim of specialization” (ie, certified specialist of regenerative medicine), and no sites using this expression in relation to specialty was confirmed. Following this, one clinic 1% of the clinics (1/24) fell under item E6-1 “prohibited advertising of names of the medical institutions” by using the term “Regenerative Medicine Center” or “Regenerative Medicine Clinic.”

Figure 1. Reviewed Websites (n=24) and their Compliance with e-health Code of Ethics 2.0. E1 Disclosure of information about the website operator; E2 Disclosure of information about sponsorship; E3 Provision of contact center for further enquiries; E4 Clarifying intended recipients of content; E5 Disclosure of the information concerning writing, production, and/or editorial supervision of conduct; E6 Adherence to relevant laws and regulations; E7 Notification to the users of profit-oriented activities on the websites; E8 Displaying a pop-up message box that reminds the user of being transferred to external websites when clicking the links to external websites; E9 Displaying the handling of personal information; E10 Displaying a privacy protection policy.



Focusing on Name-Dropping

Expressions related to name-dropping were observed on 63% (15/24) of websites (Table 5), and of these, expressions related to media coverage were the most common (n=10). For example, the names of television or radio programs that covered the clinic were listed on the homepage of websites. Moreover, with regard to governmental or regulatory authorities/academic institutions or associations, five websites using the names of universities that have conducted clinical research in collaboration with the clinic were confirmed, but use of the names of Japanese or international regulatory authorities or organizations associated with patent sales was not confirmed.

The use of the term “personalized medicine” or similar language was confirmed in 21% (5/24) of sites. Of these, the expression “Personalized Medicine” was observed in one site and “Order-Made Medicine” in four.

Table 5. Name-dropping and citations on clinics’ websites (N=24).

Codes	No. of clinics
Applicable (name-dropping) [a]	15
Academic conference presentations	2
Articles published in academic journals	2
Media coverage[b]	10
Anecdotes by the celebrities[c]	4
Medical doctors or specialists[d]	4
Regulatory authorities/academic institutions or associations[e]	5
Others	0
Not applicable	9

[a] In total, 15 clinics were found to be name-dropping. However, frequencies do not sum to n=15 as several clinics referred to more than one category per citation.

[b] Examples include TV programs or beauty magazines.

[c] Examples include the head of a well-known beauty clinic in Japan, a female celebrity, and a famous scientist.

[d] In this category, an individual with either MD or PhD title as a specialist was counted.

[e] Examples include regulatory authorities or academic associations as well as universities that are associated with the clinic in question for the purpose of joint research projects.

Discussion

Principal Findings

The present study is the first study to analyze the quality of information presented on the websites of Japanese private-practice clinics offering cell therapies from the viewpoint of patients and their family members. The results of the present study revealed that in total, 24 clinics specializing a wide variety of specialties offered 77 treatment methods for a variety diseases and conditions. No clinics complied with the 10 Minimum Standards of the e-Health Code of Ethics 2.0, which was developed as a guideline for medical institutions to create websites with high transparency. Moreover, approximately two-thirds of clinics used name-dropping on the home page of the website. Here, we discuss several noteworthy results of the present study.

Status of Adherence to the e-Health Ethical Code

The JIMA, the developer of the e-Health Code of Ethics 2.0, defines e-Health as “the continued provision and use of highly valuable medical information in the fields of medicine and insurance, with the assistance of new information and communication technologies such as the Internet” [20]. This suggests that the information listed on the websites of the target clinics offering cell therapies was not of high value from the viewpoint of patients and family members. It is desirable that clinics that offer such therapies are committed to careful dissemination of information to patients and their family members.

Upon viewing each item of the e-Health Code of Ethics 2.0, it should be noted that almost no clinics adhered to the items of “E2 Disclosure of information about sponsorship,” “E5 Disclosure of the information concerning writing, production, and/or editorial supervision of conduct,” or “E9 Displaying the handling of personal information.” If information concerning sponsorship and the author of the contents of the medical information is not displayed, it is difficult for patients and their family members to judge the information on websites concerning conflict of interests and attribution, and the following points can be suspected: (1) the possibility that the contents and data are favorably biased toward the managing operators and sponsors, (2) the possibility that fair information is not objectively provided without being influenced by the sponsor, and (3) the possibility that the information provided on the website is not based on the appropriate judgment of a medical specialist. Considering the fact that the 24 websites that were a target of the present study contained no information concerning the handling of personal information, doubts remain whether website operators have appropriately maintained confidentiality or not.

When creating the criteria to assess E6 (adherence to relevant laws and regulations), the law concerning medical advertisements (the Medical Care Act) was referred to, but several supplementary explanations are necessary to interpret these results. The Medical Care Act that governs medical advertising issued by medical institutions such as flyers, newspaper advertisements, and advertisements in print media, does not cover websites. Although the Japanese MHLW has issued guidelines concerning the advertisements of websites, these have no legal force [21]. Accordingly, the following conclusion is reached: if the extent of the current law were extended to regulate websites, more than 80% of the private-practice clinics offering cell therapies on the present study would be subject to prosecution.

Name-Dropping and Scienceploitation

Expressions that fell under name-dropping were used by two-thirds of the 24 clinics that were targets of the present study. Many websites that posted information designed to capture the interest of patients and their family members on the respective homepages were confirmed (Table 5). However, almost no websites that cited a scientific basis for treatment could be confirmed (Tables 3,4). The same trend has been reportedly observed in the websites of beauty/health websites, nonstem cell–based cosmetic companies, web-based news sources, stem cell–based cosmetic companies, web-based magazines, beauty/health blogs, and stem cell supplement companies [7]. Based on the results of such previous studies, it can be inferred that the targeted transmitters of the websites information also believe that name-dropping actions such as displaying news reports, photographs, and comments from celebrities, have equivalent or greater effects in eliciting the interest of patients and their family members, in comparison with displaying the scientific basis for treatment.

Petersen et al [6] focused on marketing techniques referred to as “representational devices,” that is, the websites of said clinics that emphasize having a human network of experts and cooperative relationships. Moreover, direct-to-consumer advertising that relies on claims that appear to be scientific to wrongfully attract patients and their family members through media such as websites is called “misrepresentation” [22]. The industry trend for excessively inappropriate misrepresentation based on the relentless pursuit of profit is referred to as “scienceploitation” [23], a phenomenon that has been widely observed in fields related to regenerative medicine [7].

However, not all name-dropping and “representational devices” are necessarily ethically inappropriate. For example, in the present study, we counted some listing of names of universities as name-dropping, but most cases were clinical research conducted jointly with the clinics. It is difficult to say that such information itself unfairly exploits patients and their family members. Thus, the expressions that fell under the category of name-dropping in the present study contained a mixture of some problematic expressions that could be construed as scienceploitation and others that were not. If we assume that the phenomenon known as scienceploitation can be empirically elucidated, then further research by having actual users such as patients and their family members browse the website and asking their impressions and opinions would be necessary.

The Need for Global Criteria

In the present study, we adopted the 10 Minimum Standards of the e-Health Code of Ethics 2.0, but these are primarily the quality criteria for evaluating overall forms of websites, and not necessarily best fit to evaluate the contents of the websites.

However, the contents of the information provided on websites is important information for patients to make a decision whether to actually receive treatment. For this reason, in the present study, we created items related to risks and benefits as well as name-dropping and subsequently conducted analyses of the items so that we could evaluate this point. The results of the present study revealed that there is a problem in the quality of information: many websites do not cite any scientific basis for their claims and tend to use name-dropping in order to attract the attention of patients. Using the Minimum Standards of the e-Health Code of Ethics 2.0 alone would not have revealed such findings.

Interestingly, the full version of the e-Health Code of Ethics 2.0 contains the following phrase: “in cases when the evaluation of the provided information cannot be determined, consideration toward users should be made by adding an explanation or providing reference information so that users can judge for themselves” [16]. This type of item that evaluates the contents of information is particular to the e-Health Code of Ethics 2.0, and has not been confirmed in other similar Japanese or international guidelines [24-27]. Such criteria are deemed essential when evaluating the websites of private-practice clinics providing unestablished cell therapies with information of questionable quality. If the said criteria is widely used in Japan and abroad, then global issues such as the exploitation of patients and their family members who are sacrificed to the detriment of the medical practitioners [22], could be addressed effectively.

However, in the past medical information providers have developed such guidelines as self-regulation by medical information providers [28]. We consider that it is difficult to expect compliance from those problematic clinics with the guidelines based on the spirit of self-regulation. In fact, although critical social views of stem cell therapies have grown more common, private clinics that offer unestablished stem cell therapies continue to disseminate easily accessible information on their websites. For this reason, a fundamental problem-solving approach that does not rely on self-regulation is also needed [14]. As an example of such an approach, one study suggested a promotion of the development of international certification standards for private-practice clinics offering stem cell therapies, as well as the joint creation of national policies in tandem with the policymakers of countries in which such clinics offer problematic noncovered treatments [14]. In order to create realistic standards, it is necessary to first investigate the actual situation of such clinics in various countries and their respective websites, and comprehensively analyze the obtained data.

Conclusion

The present study examined websites, and does not investigate the actual conditions of regenerative medicine performed as treatment not covered by insurance. Moreover, not all Japanese clinics that provide such treatments were a target of study. However, in the present study, an exploratory analysis of the contents of website information confirmed the following points: (1) these sites have poor citation of scientific evidence, and (2) there were many websites that used marketing techniques such as name-dropping in order to solicit the attention of patients. Based on these findings, it has become clear that the website information provided by clinics that were a target of study paid insufficient considerations to patients and their family members and that there is a problem with the quality of the website information concerning cell therapies. It is important that more fact-finding studies be undertaken on a global scale so that a body of supervisory authorities can effectively implement an orchestrated regulatory approach toward private-practice clinics offering cell therapies across nations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Scope of Application of the ASRM.

[PDF File (Adobe PDF File), 63KB - ijmr_v5i2e15_app1.pdf]

Multimedia Appendix 2

The 10 Quality Criteria of Minimum Standard from e-Health Code of Ethics 2.0.

[PDF File (Adobe PDF File), 12KB - ijmr_v5i2e15_app2.pdf]

Multimedia Appendix 3

Demographic Information of 24 Private-Practice Clinics.

[PDF File (Adobe PDF File), 177KB - ijmr_v5i2e15_app3.pdf]

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Abbreviations

ASRM: Act on Safety for Regenerative Medicine
JIMA: Japan Internet Medical Association
MHLW: Ministry of Health, Labour, and Welfare

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Original Paper

Quality of Web-based Information for the 10 Most Common Fractures

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Abstract

Background: In today's technologically advanced world, 75% of patients have used Google to search for health information. As a result, health care professionals fear that patients may be misinformed. Currently, there is a paucity of data on the quality and readability of Web-based health information on fractures.

Objectives: In this study, we assessed the quality and readability of Web-based health information related to the 10 most common fractures.

Methods: Using the Google search engine, we assessed websites from the first results page for the 10 most common fractures using lay search terms. Website quality was measured using the DISCERN instrument, which scores websites as very poor (15-22.5), poor (22.5-37.5), fair (37.5-52.5), good (52.5-67.5), or excellent (67.5-75). The presence of Health on the Net code (HONcode) certification was assessed for all websites. Website readability was measured using the Flesch Reading Ease Score (0-100), where 60-69 is ideal for the general public, and the Flesch-Kincaid Grade Level (FKGL; −3.4 to ∞), where the mean FKGL of the US adult population is 8.

Results: Overall, website quality was “fair” for all fractures, with a mean (standard deviation) DISCERN score of 50.3 (5.8). The DISCERN score correlated positively with a higher website position on the search results page (r^2=0.1, P=.002) and with HONcode certification (P=.007). The mean (standard deviation) Flesch Reading Ease Score and FKGL for all fractures were 62.2 (9.1) and 6.7 (1.6), respectively.

Conclusion: The quality of Web-based health information on fracture care is fair, and its readability is appropriate for the general public. To obtain higher quality information, patients should select HONcode-certified websites. Furthermore, patients should select websites that are positioned higher on the results page because the Google ranking algorithms appear to rank the websites by quality.

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KEYWORDS

fractures; quality; readability; patient; online; information; HONcode; DISCERN; Google

Introduction

In today's technologically advanced world, patients are increasingly using the Internet as their first source of health information [1,2]. Given the increased accessibility of the Internet, 75% of patients have used Google in the past to search for health information [3-6]. Although this is a large step toward shared decision making, health care professionals have expressed fear of patients becoming misinformed, potentially leading to adverse health outcomes. Furthermore, physicians are burdened, as they must clarify inaccuracies in the patients' understanding of their illness or details surrounding treatment options [7]. Their concern is supported by several individual studies that have demonstrated that the quality and readability of health information websites is low and variable, as well as a systematic review by Eysenbach et al, evaluating studies assessing the quality of Web-based health information, which showed that quality was a problem [8-10]. Furthermore, these studies discovered that websites that are granted Health on the Net code (HONcode) certification for being high quality are just as variable as noncertified websites [11]. However, little is known about the usefulness of the information on the Internet for patients concerning fracture care. To address the usefulness of the information on the Internet for patients regarding fracture care, we determined the quality and readability of Web-based health information on the 10 most common fractures [12]. Therefore, the aims of this study are 2-fold: (1) to evaluate the quality of Web-based health information on fracture care and (2) to investigate the readability of this information.

Methods

Search Engine

The Google search engine was chosen for this study because 92% of patients who use the Internet as a resource for health information reported using Google [5]. The Google Chrome web browser was used. Web browsing data were deleted before each search was performed. Default search engine settings were used, producing 10 website results per search. The location settings on the search engine were set to Hamilton, Ontario, and the search was performed on March 23, 2015.

Search Terms

We investigated the 10 most common fractures as they make up 83.8% (4990/5953) of all fractures [12]. We used lay search terms because it is known that patients are unsure of the meaning of orthopedic terms [13]. The search terms corresponding to each fracture type were: ‘‘broken wrist” (ie, distal radius fracture), “broken hand” (ie, metacarpal fracture), “broken hip” (ie, proximal femur fracture), “broken finger” (ie, finger phalanx fracture), “broken ankle” (ie, ankle fracture), “broken foot” (ie, metatarsal fracture), “broken shoulder” (ie, proximal humerus fracture), “broken elbow” (ie, proximal forearm fracture), “broken toe” (ie, toe phalanx fracture), and “broken collarbone” (ie, clavicle fracture).

Inclusion and Exclusion Criteria

We used the first page of results for each search term because 92% of Google traffic is limited to the first page [14]. Websites were eligible for inclusion if they were (1) in English, (2) free to access, and (3) provided information on the fracture associated with the search term. Websites were excluded if they were primarily non–text-based (eg, YouTube), Web-based shopping sites, news articles, password protected, Google AdWords sponsored links, and forums.

Quality Assessment

The quality of each website was scored using the DISCERN instrument (Multimedia Appendix 1). The DISCERN instrument is a validated questionnaire that assesses the reliability of websites and the quality of information on treatment choices [15]. This 16-question instrument is easy to use and can even be used by patients [15]. Each of the questions can receive a score from 1 to 5, corresponding to low and high quality, respectively. Questions 1-8 evaluate the reliability of the publication, questions 9-15 address the quality of information on treatment choices, and question 16 is an overall quality rating. Two independent raters who were medical and premedical students reached consensus on their DISCERN scores for each website (M.M. and L.G.). These 2 raters were supervised by an MD (Y.K.).

Different categorization ranges have arbitrarily been used in previous literature to interpret the total DISCERN score. We used categorical ranges, which have cut-off points set to the midpoint between each possible total DISCERN score to yield a more accurate interpretation of numeric total DISCERN scores. For example, if each question for one website scored a 1, the total DISCERN score would be 15, and if each question for a second website scored a 2, the total DISCERN score would be 30. The mean of the total DISCERN score of these 2 websites would be 22.5, which is what we set as the transition point between “very poor” and “poor.” Therefore, websites can score a total DISCERN score that is very poor (15-22.5), poor (22.5-37.5), fair (37.5-52.5), good (52.5-67.5), or excellent (67.5–75).

The presence of a HONcode certification seal was also assessed independently by the same 2 reviewers as the DISCERN rating (M.M. and L.G.). The Health on the Net Foundation provides HONcode certification to websites that demonstrate the intent to publish high-quality Web-based health information.

Readability Assessment

The readability of each website was assessed using the Flesch Reading Ease Score (FRES) and the Flesch-Kincaid Grade Level (FKGL) [16]. See FRES formula in Figure 1. The FRES holds a value between 0-100 where passages scoring between 90 and 100 are easy to understand, passages scoring between 60 and 69 are ideal for the general public, and passages scoring under 30 are difficult to comprehend. See FKGL formula in Figure 2. The FKGL indicates the minimum US grade level required for a reader to comprehend a passage. The recommended FKGL for an adult patient in the United States is 6, whereas the mean FKGL of the US adult population is 8 [17,18]. To generate these scores, the website URLs were input into www.read-able.com, which automatically calculated these scores.

Figure 1. Fres formula.

$$206.835 - \left(1.015 \times \left[\frac{Total\ Words}{Total\ Sentences}\right]\right) - \left(84.6 \times \left[\frac{Total\ Syllables}{Total\ Words}\right]\right)$$

Figure 2. Fkgl formula.

$$\left(0.39 \times \left[\frac{Total\ Words}{Total\ Sentences}\right]\right) + \left(11.8 \times \left[\frac{Total\ Syllables}{Total\ Words}\right]\right) - 15.59$$

Website Frequency and Affiliation

The frequency of websites among the top 3 search results for each search term was tabulated. Website affiliation was also tabulated into 5 categories including, Private Medical Company, Hospital or Clinic Network, Professional Medical Society, Governmental Organization, and Open Source Websites. Private Medical Companies included websites such as WebMD, which had no primary association with governmental or medical societies. Hospital or Clinic Networks included websites such as Mayo Clinic, which are run by large hospital networks and also smaller private clinics. Professional Medical Societies included the American Association of Orthopaedic Surgeons' website, which were run by their respective societies. Governmental Organizations included websites such as Medline Plus, which are run by government organizations such as the US National Library of Medicine. Finally, open source websites included sites such as Wikipedia, which are freely editable by its users.

Statistics

SPSS 20.0 statistics software (SPSS Inc, Chicago, IL, USA) was used to conduct all statistical analyses. Inter-rater agreement was assessed using weighted Kappa for ordinal data. Agreement was categorized a priori as follows: κ of .61 or greater was considered substantial agreement; κ of .21-.60, moderate agreement; and κ of .20 or less, slight agreement. Linear regressions were conducted to determine the association between DISCERN score and website position on the search results page, to determine an association between readability scores (FRES and FKGL) and website position on the search results page and to determine the association between readability scores and total DISCERN scores. These tests yielded $r^2$and P values. A logistic regression was conducted to determine the association between website position on the search results page and HONcode presence, which yielded an odds ratio and P value. One-way analysis of variances were conducted to determine variance between the mean DISCERN score of websites produced for different search terms (ie, different fracture types), to assess variance between readability scores for websites that resulted for different search terms, and to assess variance between the DISCERN score, FRES, and FKGL for the different website affiliation categories. Independent t tests were conducted to determine whether a difference existed between the DISCERN scores of questions 1-8 and questions 9-15, to determine if there was a statistical difference between the DISCERN scores of websites with and without HONcode certification, and to determine if there was a statistical difference between the FRES and FKGL of websites with and without HONcode certification. The sensitivities and specificities of HONcode accreditation to predict poor, fair, and good quality websites, based on the DISCERN score, were calculated. A chi-square test was conducted to determine the correlation between HONcode presence and the fracture types associated with the search terms and the Fisher's exact test P value was used, as the expected count was less than 5 in more than 1 cell. A $P \leq .5$ was considered to be significant.

Results

Website Search Results

Each of the search terms for the 10 fracture types returned 10 results on the first page, totaling 100.0 websites that were assessed. Thirteen websites were excluded because they did not include information on the fracture type associated with the search term (5), they were news articles (4), they were duplicates (3), and one website was a forum. The remaining 87 websites were included for quality assessment, readability calculation, and assessment of HONcode presence. The Kappa among reviewers for website inclusion was 1.00 and the Kappa for DISCERN ratings was .94.

DISCERN Scores and HONcode Accreditation

Overall, the mean (standard deviation, SD) total DISCERN score for the 10 fractures was 50.3 (5.8), which is "fair" quality. "Broken hip" scored highest with a mean (SD) score of 55.1 (4.9), which is considered "good" quality. "Broken shoulder" and "broken finger" scored the lowest with mean (SD) scores of 46.5 (5.9) and 46.8 (4.9), respectively. However, the differences in the mean DISCERN scores of websites for each search term were statistically nonsignificant. The mean total DISCERN scores for each fracture type are shown in Figure 3. On average, DISCERN questions 4 and 12 received a mean score below 2, questions 2, 3, and 14 received a mean score above 4, and the remaining questions received a mean score between 2 and 4, inclusive. There was no statistical difference between questions 1-8 assessing website reliability, which had a mean (SD) DISCERN score of 3.6 (1.4) and questions 9-15 assessing quality of treatment information, which had a mean (SD) DISCERN score of 3.1 (1.5). The mean DISCERN scores for each question are shown in Multimedia Appendix. 1

There was a positive correlation between the DISCERN score and a higher website position on the search results page (r^2=0.1, P=.002). As shown in Figure 4, websites positioned higher on the search results page had a higher total DISCERN score than websites positioned lower on the search results page.

With regard to HONcode accreditation, 49% (43/87; range 30%-75%) of websites displayed the HONcode certification seal. Furthermore, the DISCERN score demonstrated a positive correlation with HONcode accreditation, where the total DISCERN scores of HONcode accredited websites, which had a mean (SD) total DISCERN score of 52.0 (4.9), were statistically higher (*P*=.007) than the total DISCERN scores of websites that were not HONcode certified, which had a mean (SD) total DISCERN score of 48.8 (6.2) (Table 1). Specifically, the sensitivity and specificity (95% CI) of the HONcode accreditation was 0 (0-0.80) and 0.49 (0.38-0.60), respectively, for poor quality websites, 0.40 (0.27-0.56) and 0.40 (0.25-0.57), respectively, for fair quality websites, and 0.63 (0.46-0.78) and 0.61 (0.46-0.74), respectively, for good quality websites. The sensitivity and specificity of the HONcode accreditation for very poor and excellent quality websites was not calculated, as there were no websites within our data that ranked in those quality categories. With regard to website ranking, there was a positive correlation between a higher website position on the first Google results page and the presence of HONcode accreditation on the websites (odds ratio=0.723, *P*<.001) (Table 2). However, there was no significant correlation between the presence of HONcode accreditation on websites and the search term used (Tables 3 and 4).

Table 1. Statistical output of independent 2-sample *t*-test comparing HONcode accreditation and DISCERN score.

		Levene's test for equality of variances		*t*-test for equality of means						
		F	Sig.	*t*	df	Sig. (2 tailed)	Mean difference	Std. error difference	95% CI of the difference	
									Lower	Upper
DISCERN score	Equal variances assumed	2.714	.103	2.853	85	.005	3.40962	1.19493	1.03378	5.78546
	Equal variances not assumed			2.861	81.231	.005	3.40962	1.19163	1.03876	5.78048

Table 2. Statistical output of logistic regression comparing HONcode accreditation and website position on the search results page.

Source	DF	Adjusted deviation	Adjusted mean	Chi-square	*P* value
Regression	1	15.83	15.834	15.83	<.001
Website position	1	15.83	15.834	15.83	<.001
Error	85	104.76	1.232		
Total	86	120.60			
	Odds ratio	95% CI			
Website position	0.7231	0.6075-0.8606			

Table 3. Statistical output of R×C contingency table comparing HONcode accreditation and search term used for each fracture type.

		Search Term										Total
		Broken wrist	Broken hand	Broken hip	Broken finger	Broken ankle	Broken foot	Broken shoulder	Broken elbow	Broken toe	Broken collarbone	
HONcode accreditation	No	5	4	6	4	4	2	4	4	4	7	44
	Yes	4	4	4	6	4	6	2	5	5	3	43
Total		9	8	10	10	8	8	6	9	9	10	87

Table 4. Statistical output of chi-square test comparing HONcode accreditation and search term used for each fracture type.

	Value	df	Asymp. sig. (2 sided)	Exact sig. (2 sided)	Exact sig. (1 sided)	Point probability
Pearson chi-square	5.389[a]	9	.799	.819		
Likelihood ratio	5.546	9	.784	.817		
Fisher's exact test	5.491			.820		
Linear-by-linear association	.056[b]	1	.813	.829	.421	.028
N of valid cases	87					

[a] Seventeen cells (85.0%) have expected count less than 5. The minimum expected count is 2.97.

[b] The standardized statistic is −.236.

Figure 3. Correlation of total DISCERN score to website position on Google search results page (r^2=0.104, *P*=.002).

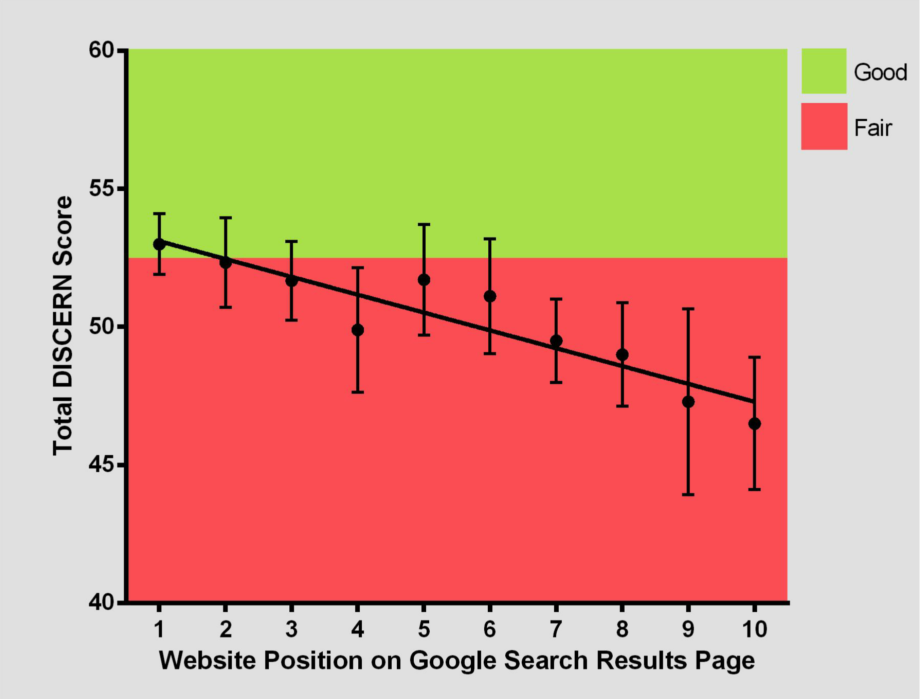
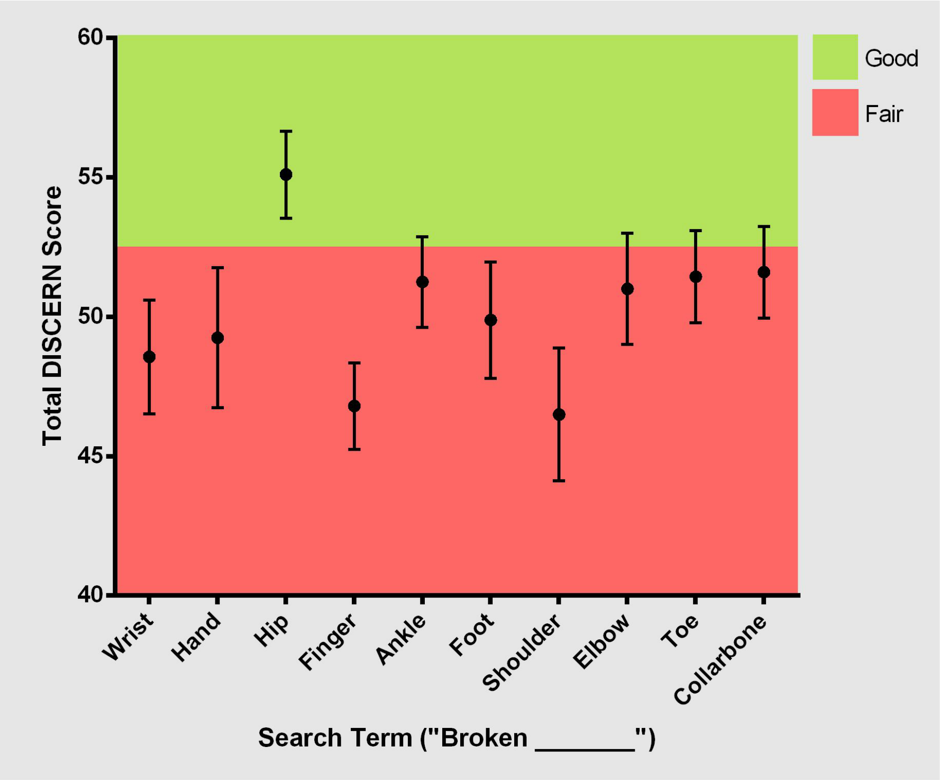


Figure 4. Distribution of total DISCERN score by search term.



Readability Scores

The mean (SD) FRES for all websites was 62.2 (9.1), which is ideal for the general public. The fracture types that had a mean (SD) below the range of scores ideal for the general public included “broken hip,” 59.3 (6.2); “broken shoulder,” 51.9 (8.6); “broken elbow,” 55.6 (13.8); and “broken collarbone,” 59.7 (11.5). The mean (SD) FKGL for all websites was 6.7 (1.6), which is greater than 6, the recommended reading level for the general public, but lower than 8, which is the mean FKGL of an average US adult. The only fracture type above the mean FKGL of a US adult was broken shoulder, with a mean (SD) of 8.1 (1.0). There was no statistically significant correlation between the FRES or FKGL and (1) the position of websites on the search results page, (2) the DISCERN score, and (3) the presence of HONcode certification (Tables 5 and 6). Furthermore, there was no statistically significant difference between the FRES or FKGL of the websites that resulted from the different search terms.

Website Frequency and Affiliation

The frequency of the websites from the first 3 search results for all search terms in order of popularity was 6 of 30 (20%) for OrthoInfo, 6 of 30 (20%) for eMedicineHealth, 4 of 30 (13.3%) for WebMD, 3 of 30 (10%) for MedicineNet, 3 of 30 (10%) for Mayo Clinic, 1 of 30 (3.3%) for Drugs, 1 of 30 (3.3%) for Healthline, 1 of 30 (3.3%) for Wikipedia, 1 of 30 (3.3%) for Boots WebMD, 1 of 30 (3.3%) for Cleveland Clinic, 1 of 30 (3.3%) for Physio Works, 1 of 30 (3.3%) for Foot Health Facts, and 1 of 30 (3.3%) for National Health Service (Table 7) [19-30].

Table 5. Statistical output of independent 2-sample *t*-test comparing HONcode accreditation and Flesch Reading Ease Score (FRES)

		Levene's test for equality of variances		*t*-test for equality of means						
		F	Sig.	*t*	df	Sig. (2 tailed)	Mean difference	Std. error difference	95% CI of the difference	
									Lower	Upper
FRES	Equal variances assumed	.253	.617	−1.271	85	.207	−2.46131	1.93718	−6.31293	1.39031
	Equal variances not assumed			−1.271	84.999	.207	−2.46131	1.93656	−6.31171	1.38909

Table 6. Statistical output of independent 2-sample *t*-test comparing HONcode accreditation and Flesch-Kincaid Grade Level (FKGL)

		Levene's test for equality of variances		*t*-test for equality of means						
		F	Sig.	*t*	df	Sig. (2 tailed)	Mean difference	Std. error difference	95% CI of the difference	
									Lower	Upper
FKGL	Equal variances assumed	.589	.445	1.373	85	.173	.47156	.34339	−.21118	1.15431
	Equal variances not assumed			1.370	81.526	.174	.47156	.34412	−.21306	1.15619

Table 7. Frequency of websites from first 3 search results for all search terms.

Website title	Frequency (n=30)	Percentage	DISCERN, mean ± SD (range)	FRES, mean ± SD (range)	FKGL, mean ± SD (range)
OrthoInfo	6	20	52.2±5.0 (47.0-57.0)	57.9±7.0 (44.7-63.8)	7.2±0.8 (6.7-8.8)
eMedicineHealth	6	20	53.3±1.5 (52.0-55.0)	59.6±4.4 (55.8-64.5)	8.1±0.8 (7.2-8.6)
WebMD	4	13.3	50.3±2.5 (47-53)	65.9±2.5 (64.1-69.6)	5.7±0.5 (5-6.3)
MedicineNet	3	10	53.3±1.5 (52-55)	59.6±4.4 (55.8-64.5)	8.1±0.8 (7.2-8.6)
Mayo Clinic	3	10	56.0±1 (55.0-57.0)	56.9±6.3 (49.7-61.5)	6.9±0.4 (6.6-7.3)
Drugs	1	3.3	55.0	75.7	4.7
Healthline	1	3.3	56.0	65.9	5.7
Wikipedia	1	3.3	60.0	47.7	8.5
Boots WebMD	1	3.3	45.0	69.0	5.5
Cleveland Clinic	1	3.3	45.0	47.5	7.7
Physio Works	1	3.3	45.0	57.7	6.8
Foot Health Facts	1	3.3	45.0	58.1	9.1
National Health Service	1	3.3	52.0	75.6	4.5

Table 8. Distribution of website affiliation for all search results.

Website affiliation	Frequency (n=87)	Percentage	DISCERN, mean ± SD (range)	FRES, mean ± SD (range)	FKGL, mean ± SD (range)
Private Medical Company	39	44.8	50.0±4.9 (39.0-57.0)	60.1±13.1 (-2.7-78.4)	7.2±2.4 (4.5-17.0)
Hospital or Clinic Network	16	18.4	50.2±8.4 (37.0-60.0)	58.0±9.7 (31.4-65.4)	7.1±1.2 (5.5-9.9)
Professional Medical Society	16	18.4	49.6±5.0 (42.0-57.0)	60.6±6.3 (44.7-68.5)	6.4±1.0 (3.8-7.5)
Governmental Organization	9	10.3	52.6±4.6 (44.0-62.0)	66.8±7.7 (46.7-75.6)	5.8±1.1 (4.5-8.5)
Open Source Websites	7	8.0	48.0±9.1 (37.0-60.0)	66.5±13.3 (47.7-79.1)	5.7±1.9 (4.2-8.5)

With regard to website affiliation, 39 of 87 (44.8%) websites were from a Private Medical Company, 16 of 87 (18.4%) were from a Hospital or Clinic Network, 16 of 87 (18.4%) were from a Professional Medical Society, 9 of 87 (10.3%) were from a Governmental Organization, and 7 of 87 (8.0%) were from Open Source Websites (Table 8). Furthermore, there were no significant differences in the DISCERN scores, FRES, and FKGL values between the different website affiliation categories.

Discussion

The aim of this study was to elucidate the quality of Web-based health information on the 10 most common fractures as increasingly more patients access the Internet for medical information [31]. Specifically, when patients turn to the Internet, 92% (207.0/225.0) of them research specific medical conditions as opposed to searching for general information on healthy lifestyles. Furthermore, although there is existing literature investigating other orthopedic conditions such as femoroacetabular impingement and rotator cuff tears, there is no comprehensive study on fracture care information. As there is variability in quality within Web-based orthopedic literature and throughout nonorthopedic topics, there is a need for studies investigating specific medical conditions [32-34]. Moreover, many physicians are unaware whether or not to encourage patient use of the Internet for medical information because they do not want patients to be misinformed [35]. With a better understanding of the literature that exists for patients on fracture care, surgeons can give better “internet prescriptions,” or recommendations for improved Internet use [35]. The overall goal is for the patient to be best informed on the topic of fractures as this may lead to better self-care and improved health decisions [36].

Key Findings and Recommendations

In this study, we found that the quality of Web-based information on the 10 most common fractures was in general “fair.”

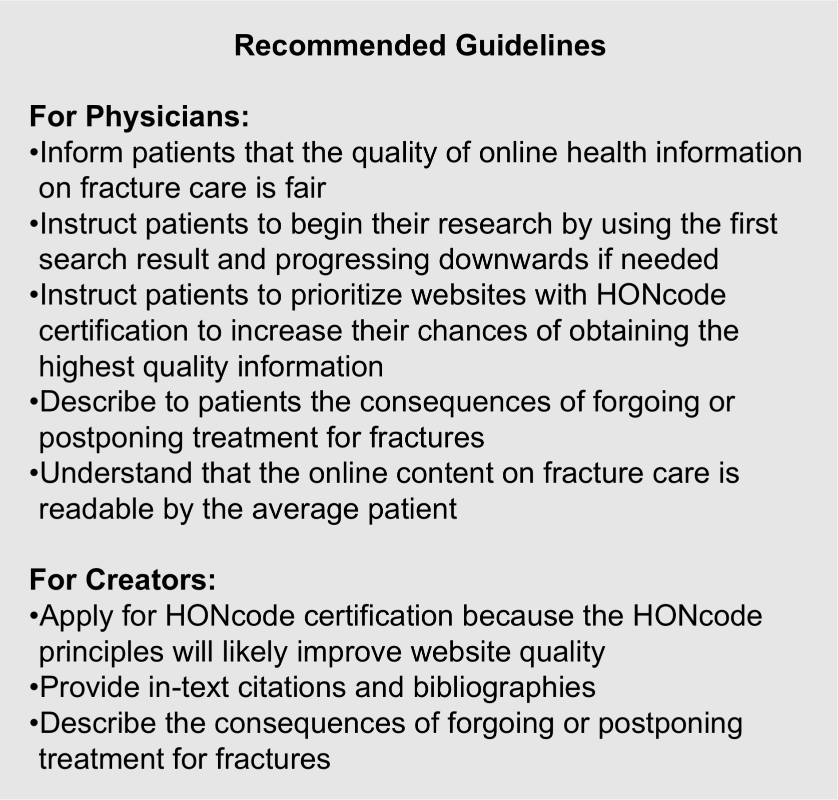
Furthermore, there was a significant decrease in the quality of websites as the search engine user progressed to each subsequent website result on the search results page. Therefore, physicians should instruct their patients to begin their research by using the first website on the search results page and progress downward if needed.

Furthermore, the presence of a HONcode certification had a significant positive correlation with the quality of websites. As a result, physicians may inform their patients that they are more likely to find higher quality information on websites displaying a HONcode certification seal. In addition, creators of health information websites should apply for HONcode certification because following HONcode principles will likely improve the quality of their websites.

On average, the readability of all websites fell within the recommended range for the general public using the FRES formula. The FKGL was above the recommended range for the general public, however, it still fell below the cutoff for the FKGL of the average US adult, which suggests that most patients still easily understand the material.

One question on the DISCERN instrument that was consistently answered poorly was question 4 (Is it clear what sources of information were used to compile the publication [other than the author or producer]?). As a result, health information website creators should increase the presence of in-text citations and bibliographies. Another question that was consistently answered poorly was question 12 (Does it describe what would happen if no treatment is used?). Therefore, during medical encounters, physicians should describe to their patients the consequences of forgoing or postponing treatment. Health information website creators should also provide this information on the Web. These recommendations are summarized in Figure 5, which presents a practical guideline based solely on the results of this study, aimed to assist physicians and creators of Web-based health information.

Figure 5. Recommended guidelines for physicians and creators of Web-based health information websites.



Recommended Guidelines

For Physicians:

- Inform patients that the quality of online health information on fracture care is fair
- Instruct patients to begin their research by using the first search result and progressing downwards if needed
- Instruct patients to prioritize websites with HONcode certification to increase their chances of obtaining the highest quality information
- Describe to patients the consequences of forgoing or postponing treatment for fractures
- Understand that the online content on fracture care is readable by the average patient

For Creators:

- Apply for HONcode certification because the HONcode principles will likely improve website quality
- Provide in-text citations and bibliographies
- Describe the consequences of forgoing or postponing treatment for fractures

Strengths and Limitations

This was the first study investigating the quality of Web-based health information on fracture care. Furthermore, it simulated real-world search engine usage by using the results on the first page. Many other studies have used the first 3 pages of results, which may not be representative of the search strategies used by the average search engine user and may also lower the mean quality of the results if the websites on the second and third page are of lower quality. Another reason this study is applicable is that it used the Google search engine rather than incorporating other search engines less commonly used by patients. Google is overwhelmingly the most popular search engine among patients and including other search engines in the study may have produced results that are not generalizable to a patient population [10].

There are some limitations inherent in this study. In an effort to increase the external validity of the findings by limiting the search results to the first page, one limitation was that the sample size was reduced. Second, the results were gathered at one time point and at one geographical location. In reality, search results vary over time and also vary with geographical location. Third, website names, URLs, and designs may have biased the quality assessment. A fourth limitation was that websites were excluded if they were non-English, and therefore, the results may not be applicable to a non–English-speaking population. Finally, websites that are primarily nonreadable formats (eg, video) were excluded. This may have decreased the generalizability of our results as patients may use video-sharing websites given that video-sharing websites such as YouTube are among the most visited websites worldwide.

Implications for Future Research

It has been suggested that patients may limit themselves to using lay search terms because they are unfamiliar with orthopedic terminology [13]. However, data from the iProspect Search Engine User Behavior Study show that search engine use is dynamic and that 41% (971.0/2369) of users change their search terms if they do not find what they are looking for on their first search [37]. Therefore, patients may modify their search strategy by replacing lay search terms with newfound medical terminology. For example, a search using the term, “broken wrist” may lead them to a search using the term, “distal radius fracture.” Therefore, it would be appropriate to investigate how the quality of Web-based health information on fracture care changes with search term usage.

Furthermore, as more Web-based evidence-based materials become available for patients through UpToDate, BMJ Best Practice, Mercks Manuals, and so forth, physicians are urged to direct their patients to these resources. However, the quality and readability of these materials has not been evaluated for fracture care and reviewing these materials will help physicians make better recommendations for patients who wish to obtain information via the Internet.

Conclusion

The quality of Web-based health information on fracture care is fair. The readability of this information is appropriate for the general public. We recommend that physicians inform their patients of the quality of Web-based health information. Furthermore, physicians should instruct their patients to select websites that have a HONcode certification seal to increase their chances of obtaining the highest quality information. Finally, physicians should instruct their patients to select websites that are positioned higher on the Google search results page because the Google ranking algorithms order the search results in a hierarchy by popularity and consequently appear to rank the websites by quality.

Conflicts of Interest

None declared.

Multimedia Appendix 1

DISCERN instrument with mean score per question.

[PNG File, 446KB - ijmr_v5i2e19_app1.png]

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Abbreviations

HONcode: Health on the Net code
FRES: Flesch Reading Ease Score
FKGL: Flesch-Kincaid Grade Level

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Original Paper

eHealth Literacy: In the Quest of the Contributing Factors

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Abstract

Background: Understanding the factors that influence eHealth in a country is particularly important for health policy decision makers and the health care market, as it provides critical information to develop targeted and tailored interventions for relevant patient–consumer segments, and further suggests appropriate strategies for training the health illiterate part of the population.

Objective: The objective of the study is to assess the eHealth literacy level of Greek citizens, using the eHealth Literacy Scale (eHEALS), and further explore the factors that shape it and are associated with it.

Methods: This empirical study relies on a unique sample of 1064 citizens in Greece in the year 2013. The participants were requested to answer various questions about their ability to solve health-related issues using the Internet, and to provide information about their demographic characteristics and life-style habits. Ordered logit models were used to describe a certain citizen's likelihood of being eHealth literate.

Results: The demographic factors show that the probability of an individual being eHealth literate decreases by 23% (*P*=.001) when the individual ages and increases by 53% (*P*<.001) when he or she acquires higher level of education. Among the life-style variables, physical exercise appears to be strongly and positively associated with the level of eHealth literacy (*P*=.001). Additionally, other types of technology literacies, such as computer literacy and information literacy, further enhance the eHealth performance of citizens and have the greatest impact among all factors.

Conclusions: The factors influencing eHealth literacy are complex and interdependent. However, the Internet is a disruptive factor in the relationship between health provider and health consumer. Further research is needed to examine how several factors associate with eHealth literacy, since, the latter is not only related to health care outcomes but also can be a tool for disseminating social inequalities.

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KEYWORDS

eHealth literacy; health information; Internet; demographic factors; life-style habits

Introduction

Health literacy has been identified as a public health goal for the twenty-first century and a significant challenge in health education. Trending toward a more consumer-centric health care system as part of an overall effort to improve the quality of health care and to reduce health care costs, it is important that services and training be provided so that the health care consumer could take a more active role in health care-related decisions [1]. Despite the concerns regarding the quality of online health information [2], the advent of the Internet has dramatically changed the landscape of health information, as recent estimates document that more than 80% of the Internet users search for health-related information online [3,4]. According to a recent Pew Internet Research [5] study on health, Internet, and mobile phones, “80% of Internet users, or 59% of

U.S. adults, look online for health information” and “17% of cell phone owners, or 15% of adults, have used their phone to look up health or medical information”. Another study [6] estimates that 75 million people will use their mobile phones in 2014 to access health information.

With the tremendous growth of available information, users face challenges in searching, locating, evaluating, and effective use of the health-related information available on the Internet, as data safety remains one of the most commonly identified barrier with respect to the effective use of information available on the Web [1,7]. Despite these perils, studies have showed that health consumers increasingly use the Internet not only for information but also for communicating with peers and health professionals, and purchasing health products and services [8,9].

Recently, a subfield within medical informatics has emerged that develops information and communication technology tools, and applications for use in health care, particularly that of eHealth, that is, the ability of the individuals in searching, analyzing, and processing information from the Internet in order to address or solve health-related issues [10].

Among the first studies in the field is the seminal study of Norman and Skinner [11], which examines, in a systematic way, attributes that contribute to eHealth literacy. The authors state that eHealth literacy could be defined by a set of factors such as a person’s ability to present the health issue, educational background, health status at the time of the eHealth encounter, motivation for seeking the information, and the technologies used, and aims to empower individuals and enable them to fully participate in health decisions informed by eHealth resources. Numerous subsequent studies have investigated the relationship between eHealth literacy and various, mainly demographic, factors.

Our research study contributes to the aforementioned vein of literature and brings evidence on the factors that influence the eHealth literacy in Greece, where, lately, government policies were focused on enabling the access to the Internet for a large part of population.

We focused on Greece as 8 out of 10 Internet users there searched the Internet seeking health information [12]. This is a surprisingly high rate, given the low penetration of Internet in Greece [13]. A recent study [12] identified and explained the reasons for the slower than anticipated growth of Internet use in Greece. A series of factors hindering e-services adoption were identified, such as: (1) limited commercial trust and user concerns for transactions security, (2) factors connected with social background, (3) low quality of available Greek electronic services, (4) intellectual property rights and privacy issues, and (5) complex or time consuming processes. Furthermore, according to the OECD health data [14], Greece has demographics that could constitute a serious issue for the future, such as low birth rate and population distribution. At the same time, Greeks are on severe economic crisis and an elevated prevalence of certain diseases is already reported [15].

Therefore, we first constructed an index for the measurement of eHealth literacy, enriching and adapting the Norman and Skinner [16] eHealth Literacy Scale and using unique survey data from a sample of 1064 individuals for the year 2013. The marking of the eHealth literacy index is based on the answers of the interviewees on eight questions about a user’s ability in searching, analyzing, and processing information from the Internet in order to address or solve health-related issues. Next, we estimated the effect of various demographic, life-style factors and levels of technology literacy on the users’ eHealth performance.

The novelty of our study lies in, first, investigating an important question for health policy implications for Greece—there is no prior study in this subject matter. Second, we include a variety of life style factors that no other existing relating study has included so far—the related literature offers piece-meal approach (eg, some studies examine only the relation between eHealth and smoking, while others focus on eHealth age effects). Third, with our econometric approach (logit model) we were able to assess the effect of the covariates on different classes (1: low; 2: fair; 3: medium; 4: high) of eHealth literacy of citizens.

Our results demonstrate the important impact of the age and education level as well as that of physical exercise on eHealth literacy. Other types of technology literacy, such as computer literacy and information literacy, further enhance the eHealth performance of citizens and have the greatest impact among all factors.

Methods

This section discusses the survey data, the modified eHealth literacy index, and presents the selection of the estimation method.

Data

This empirical analysis relies on Web- and interview-based data obtained from a sample of 1064 citizens in Greece for the year 2013, using the Convenience Sampling Technique, that is, a nonprobability sampling technique where the subjects are selected due to their convenient accessibility and proximity to the researcher, that is, they are easiest to recruit for the study. The participants were requested to answer various questions about their ability to solve health-related issues using information from the Internet. The dependent variable, the eHealth literacy index, is defined as the ability of a certain individual to seek, find, understand, and appraise health information from electronic resources and apply that knowledge to address or solve a health problem, according to Norman and Skinner [16]. Table 1 presents the components’ marking-evaluation, based on which the eHealth literacy index is constructed. Each component was measured on a 5-grade scale so that the total summary of the eHealth literacy index ranges from 8 to 40 grades.

Table 1. Description and share of the components of the eHealth literacy index.

Variable	Percentage
I know what health resources are available on the Internet	11.6%
I know where to find helpful health resources on the Internet	12.2%
I know how to find helpful health resources on the Internet	13.3%
I know how to use the Internet to answer my health questions	13.4%
I know how to use the health information I find on the Internet to help me	13.3%
I have the skills I need to evaluate the health resources I find on the Internet	12.7%
I can differentiate high-quality health resources from low-quality health resources on the Internet	12.5%
I feel confident in using information from the Internet to make health decisions	11.0%

Further, the users were asked to provide information about their demographic characteristics and life-style habits (Table 3). Various demographic factors were included in the questionnaire, such as gender, age, marital status, education, and income, grouped according to Hellenic Statistical Authority classification. More specifically, demographic variables were grouped as follows: Gender: 0 for male and 1 for female; Age: 1 for ages 15–24 years, 2 for 25–39 years, 3 for 40–54 years, 4 for 55–64 years, 5 for 65–79 years, and 6 for >80 years; Marital Status: 1 for single, 2 for married, 3 for divorced, 4 for separated, and 5 for widow; Education: 1 for primary school, 2 for high school (first 3 years), 3 for technical education, 4 for high school (last 3 years), 5 for post-high school (excluding university), 6 for university, 7 for Masters, and 8 for PhD; Income: 1 for <€750, 2 for €751–1100, 3 for €1101–1450, 4 for €1451–1800, 5 for €1801–2200, 6 for €2201–2800, 7 for €2801–3500, 8 for >€3501.

Additionally, they were requested to answer whether they smoke or not, whether they workout more than once per week, and whether they consume alcohol on a regular basis.

Finally, the participants were invited to evaluate their skills related to computer and information literacy. The former, measures the skills of the participant regarding the use of computers, that is, use of search engines, sending e-mails, uploading messages on forums, use of the Internet for chatting, or construction of Web pages, while the latter measures the degree of frequency of relying on Internet search as a primary source of health-related issues and the importance of accessing the internet in order to find health-related sources.

Model

The likelihood of a certain user (citizen–patient) being eHealth literate (able to search, analyze, and process information from the Internet in order to address or solve health-related issues), can be described by an ordered logit model defined as follows:

$$\Pr(Y=c|Xi)=F(X_i\beta),$$

where the endogenous variable Y is the degree of eHealth literacy and takes values from 1 to 4 (c) in accordance with the aforementioned abilities (1 for low, 2 for fair, 3 for enough, 4 for high); F is the standard logistic cumulative distribution function and X_i is a set of covariates defined as:

$$X_i\ \beta=\beta_0+\ \beta_1 Gender_i+\ \beta_2 Age_i+\ \beta_3\ Marital\ Status_i+\ \beta_4 Education_i+\beta_5 Income_i+\ \beta_6 Smoking_i+\ \beta_7 Exercise_i+\ \beta_8 Alcohol_i+\ \beta_9 CI_i+\ \beta_{10} IL_i$$

where the first five variables consist the demographic factors (set D): Gender is a dummy variable that takes the values 0 and 1 if the participant is male and female respectively; Age is the age of the participants clustered as follows: class 1 (15–24), class 2 (25–39), class 3 (40–54), class 4 (55–64), class 5 (65–79), class 6 (>80 years old); Marital Status represents whether a participant is single (1), married (2), divorced (3), separated (4) or widow (5); Education is the level of education of each participant ranging from primary school (1) to PhD (8); Income is the income level of the participants clustered in eight groups (refer preceding discussion about classes' classification).

The next three variables form the life-style set (set L) and are: Smoking is a dummy variable and represents whether the participants are smokers or not; Exercise is a dummy variable that takes the value 0 if the participant is not exercising more than once per week, otherwise is 1; Alcohol is a dummy variable and takes the value 0 if the participant is not drinking on a regular basis, otherwise is 1.

Finally, we also included technology related literacy covariates, namely CL, which captures the computer literacy of each participant and ranges from (0) for no knowledge to (2) for high knowledge, and IL is the information literacy of the participant and takes the values (1), (2), and (3) for low, fair, and high knowledge (refer preceding discussion about classes' classification).

The selection of the variables in X_i set can be justified by relevant studies. More specifically, the demographic variables of age and education are documented in the studies of Baker et al. [17], Petch et al. [18], Watkins and Xie [19]; while Schwartz et al. [20], Andreasen et al. [21], Rudd et al. [22], and Veenhorf et al. [23], along with the variables of age and education, take into account the variable of income. Further, the variable of gender is explored in the study of Norman and Skinner [16]. The life-style factors, such as smoking, are mentioned in the study of Bodie and Dutta [24]. Finally, technology literacy is included in a handful of studies [11,24,25].

The model only applies to data that meet the proportional odds assumption. Suppose that the proportions of members of the statistical population who would answer Y=1, Y=2, Y=3, Y=4, and Y=5 are, respectively, p1, p2, p3, p4, and p5; then the logarithms of the odds (not the logarithms of the probabilities) of answering in certain ways are as shown in Table 2.

Table 2. The proportional odds assumption

Probabilities	Logarithms of odds
Y=1,	log [p1/(p2+p3+p4+p5)], 0
Y=1 or Y=2,	log [(p1+p2)/(p3+p4+p5)], 1
Y=1, Y=2 or Y=3,	log [(p1+p2+p3)/(p4+p5)], 2
Y=1, Y=2, Y=3 or Y=4,	log [(p1+p2+p3+p4)/p5], 3

The proportional odds assumption is that the number added to each of these logarithms to get the next is the same in every case. In other words, these logarithms form an arithmetic sequence.

Results

Before presenting our estimates of the model, we first show some descriptive statistics in Table 3.

As shown in Table 3, our sample participants have fair level of eHealth literacy. Further, half of the participants are men, while the majority of the interviewers are between the age of 25 and 39 years, and belong to middle income class. Furthermore, participants appear to lead healthy life-style, as they do not smoke or consume alcohol daily and workout more than once a week.

The correlation between the dependent variable of eHealth literacy and all the other factors (independent variables) are presented in Table 4.

As Table 4 shows, the two types of technology literacy, computer and information literacy, are highly related with eHealth literacy (0.46 and 0.45, respectively). These two variables are also positively related with each other. Further, age, education, and exercise are also strongly related with eHealth literacy (-0.29, 0.41, and 0.20, respectively).

The odds ratios for all specifications are presented in Table 5. One can read the odds ratios as follows: if the odd ratio, a, is bigger than 1 (a>1), then the probability of a user being health literate, (ie, Y_{it}=4; maximum level of eHealth literacy), increases by (a-1)*100%, whereas the probability decreases by (1-a)*100%, if the odds ratio is smaller than 1 (a<1).

Columns (1) and (2) present estimates of the model, where only the demographic (D) and literacy factors (C) are included. Next, columns (3) and (4) show estimates of the model, where only the indicators of the participants' life-style (L) and literacy are included. Finally, columns (5) and (6) present estimates, where the full set of covariates (X) are included.

As Table 5 shows, among the demographic factors (D) presented in columns (1) and (2), only Age and Education have a statistical significant effect on the probability of being eHealth literate. More specifically, when it comes to the Age effect, there is a negative relationship between eHealth literacy and aging. We find that as the participants grow older, the likelihood of being eHealth literate at the maximum level decreases by 38%, as column (1) indicates. By including other literacy factors (C), namely Computer Literacy and Information Literacy (column 2) the Age effect decreases to 25%. The opposite finding emerges with respect to the Education effect, which is positively related to the eHealth literacy. Particularly, the higher the level of education of the participant, higher is the likelihood of the eHealth maximum level of literacy of the participant, ranging from 70% increase (excluding literacy factors, column 1) to 53% (when literacy factors are included, column 4). The literacy factors are found to greatly affect the eHealth literacy performance of the participants. For example, when we control both literacy factors in column (4), results show that the higher the Computer Literacy and the Information Literacy, the probability of a participant's maximum level of eHealth literacy increases by 116 and 210%, respectively. The inclusion of these factors slightly decreases the role of the demographic variables, with the former still to pertain their significance.

Next, columns (3) and (4) include only the health life-style (L) factors along with the literacy factors (C). Results demonstrate that all health habit factors carry the expected sign related to their impact on eHealth literacy; however, only physical Exercise is found to be statistically important. If a user does workout more than once a week, his or her eHealth literacy increases by 108% (column 3). In addition, if the participant has high computer and information literacies, then the effect of physical exercise reduces to 64%, as column (4) indicates.

Finally, columns (5) and (6) show estimates of various combinations of all sets of variables. Particularly, last column presents the full-fledged specification with all demographic, life-style, and literacy variables included. As aforementioned, the same variables appear to be statistically significant, maintaining the expected sign according to the theory. For instance, among the demographic factors, the probability of a participant's eHealth literacy decreases by 23% when the participant ages, while the probability increases by 53% when the participant acquires higher level of education. There is also a positive Marital effect, significant at 10%, on participant's eHealth literacy; however it's difficult at this stage of analysis to draw concrete conclusions about the marital effect on eHealth literacy. The reason is that during the movement from one class to the next, one would not be necessarily the case in reality (eg, a divorced person who belongs to class 3 does not necessarily become separated, meaning being member of class 4). Therefore, we cannot compare whether there is an improvement (or deterioration), of any sort, by changing classes, as it is the case with the rest of the variables, which follow an order. Therefore, the marital effect on eHealth literacy requires a marginal effect analysis, which is displayed in Table 6 in this section). With respect to the life-style variables, again physical exercise appears to have a positive and statistical significant effect on a participant’s eHealth literacy, which is about 54%. Literacy factors, relating to computers and information, also document their strong association with eHealth literacy and range from 157% (Computer Literacy) to 207% (Information Literacy).

In total, estimates do not alter either in signor in statistical importance across all specifications of Table 5, and remain robust. Overall, our findings strongly support that the age and education are important contributors to eHealth literacy of an individual. The (negative) effect of age ranges from 23% (column 6) to 37% (column 1), while the (positive) effect of education varies from 70% (column 1) to 53% (column 6). Marital status, only in some cases has a statistically borderline significant role (at 10% level of significance), while the two other remaining demographic variables, that is, income and gender, play no role at all. Physical exercise is the only factor among the life-style set of habit indicators that has a positive and significant effect ranging from 108% (column 3) to 54% (column 6). Smoking and alcohol consumption have no impact on eHealth. In addition, high level of computer and information literacy is positively associated with high probability of eHealth status: 302%–157%, for computer literacy, and 312%–207%, for information literacy. Finally, as diagnostics the later part of Table 4 demonstrates that all specifications have a satisfactory fitness. For the last column, in particular, the fitted values and the actual values are related by 60%.

Next, we performed a marginal effect analysis (Table 6), which captured the effect on maximum eHealth literacy level when an individual changed within variable classes (eg, from low to high income, from primary to high school, etc) at the data means. The analysis was performed for the last column of Table 5, which is the full-fledged specification and is only for the statistical significant variables.

Holding all variables at their mean value, the probability of an individual being eHealth literate at the maximum level is 7% among those aged 15–24 years, 5% among those aged 25–39 years, 4% among those aged 40–54 years, 4% among those aged 55–64 years, 3% among those aged 65–79 years, and 0.3% among those aged above 80 years. For example, as an individual grows old and moves to class 8 (above 80 years old), her probability of being eHealth literate at the maximum level decreases by 2.5% (=[0.028–0.003]*100%). The marginal effect analysis of the effect of various age classes on eHealth literacy confirms the findings from Table 5 that the age effect on eHealth literacy increases as participants become older.

The marginal effect analysis of the marital status on eHealth literacy can be read as follows: the probability of an individual being eHealth literate at the maximum level is about 5% among the singles, 5% among the married, 0.8% among the divorcees, 9% among the separated, and 36% among the widows.

The education effect on eHealth literacy is also consistent with findings from Table 4 as the marginal effects indicate. Overall, higher the level of education of the participant, the larger is the effect on eHealth literacy. For example, when a master holder user (group 7) obtains his PhD and moves to group 8, there is a 7% (=[0.174–0.103]*100%) higher probability in being eHealth literate.

Relating to the impact of physical exercise on eHealth literacy, the marginal effect indicates that someone who is physically active more than once per week (group 1) has a 20% more chance to be eHealth literate.

Finally, when it comes to the technology literacy effects on eHealth literacy, we find that the higher the Computer literacy, higher is the eHealth performance. Particularly, there is not much difference when an individual moves from one computer literacy class to the next higher one. In contrast, there is a two-fold and a four-fold effect when a participant increases his abilities on Information literacy moving from class (1) to (2) and (2) to (3), respectively.

Overall, the marginal effect analysis is in accordance with the odds ratio analysis and further strengthens the robustness of our results.

Table 3. Descriptive statistics of all variables.

Variable	Observations	Percentage	Cumulative percentage
eHealth literacy			
Low	189	17.76%	17.76%
Fair	328	30.83%	48.59%
Enough	445	41.82%	90.41%
High	102	9.59%	100.00%
Gender			
Male	477	44.83%	44.83%
Female	587	55.17%	100.00%
Age			
15–24 years	186	17.48%	17.48%
25–39 years	503	47.27%	64.76%
40–54 years	232	21.80%	86.56%
55–64 years	56	5.26%	91.82%
65–79 years	72	6.77%	98.59%
> 80 years	15	1.41%	100.00%
Marital Status			
Single	549	51.60%	51.60%
Married	448	42.11%	93.70%
Divorced	34	3.20%	96.90%
Separated	31	2.91%	99.81%
Widow	2	0.19%	100.00%
Education			
Primary	35	3.29%	3.29%
High school–first 3 years	30	2.82%	6.11%
Technical education	33	3.10%	9.21%
High school—last 3 years	272	25.56%	34.77%
Post-high school—excluding university	51	4.79%	39.57%
University	516	48.50%	88.06%
Masters	106	9.96%	90.03%
PhD	21	1.97%	100.00%
Income			
≤€750	143	13.44%	13.44%
€751–1100	242	22.74%	36.18%
€1101–1450	100	9.40%	45.58%
€1451–1800	164	15.41%	61.00%
€1801–2200	155	14.57%	75.56%
€2201–2800	114	10.71%	86.28%
€2801–3500	94	8.83%	95.11%
>€3500	52	4.89%	100.00%
Smoke			
Nonsmokers	641	60.24%	60.24%
Smokers	423	39.76%	100.00%

Variable	Observations	Percentage	Cumulative percentage
Exercise			
Once per week	564	53.01%	53.01%
More than once per week	500	46.99%	100.00%
Alcohol			
Not on a regular basis	829	77.91%	77.91%
On a regular basis	235	22.09%	100.00%
Computer literacy (CL)			
Low	122	11.47%	11.47%
Fair	381	35.81%	47.27%
High	561	52.73%	100.00%
Information literacy (IL)			
Low	160	15.04%	15.04%
Fair	547	51.41%	66.45%
High	357	33.55%	100.00%

Table 4. Correlation between eHealth literacy and all independent variables.

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
1) eHealth	1.00										
(2) Gender	0.01	1.00									
(3) Age	-0.29	-0.02	1.00								
(4) Marital Status	-0.17	0.08	0.57	1.00							
(5) Education	0.41	0.01	-0.22	-0.16	1.00						
(6) Income	0.07	-0.07	0.05	0.11	0.18	1.00					
(7) Smoking	-0.02	-0.07	-0.06	0.01	-0.09	0.04	1.00				
(8) Exercise	0.20	-0.11	-0.22	-0.22	0.11	-0.09	-0.06	1.00			
(9) Alcohol	-0.03	-0.18	-0.01	-0.05	-0.01	-0.02	0.19	0.01	1.00		
(10) Computer literacy	0.46	-0.05	-0.45	-0.31	0.35	0.13	-0.01	0.17	0.04	1.00	
(11) Information literacy	0.45	0.04	-0.17	-0.08	0.27	0.13	-0.06	0.12	-0.09	0.31	1.00

Table 5. Logit estimates (odds ratios) of different specifications (maximum level of eHealth literacy is the dependent variable).

	Demographic (D)		Life-style (L)		Full set (X)	
	(1)	(2)	(3)	(4)	(5)	(6)
Gender	1.022	1.021			1.059	1.069
	(.854)	(.863)			(.635)	(.591)
Age	0.617	0.752			0.635	0.771
	(<.001)	(<.001)			(<.001)	(<.001)
Marital Status	1.081	1.169			1.121	1.201
	(.455)	(.145)			(.279)	(.092)
Education	1.698	1.526			1.686	1.530
	(<.001)	(<.001)			(<.001)	(<.001)
Income	1.020	0.950			1.033	0.958
	(.476)	(.029)			(.273)	(.164)
Smoking			0.956	1.070	1.024	1.157
			(.701)	(.585)	(.846)	(.253)
Exercise			2.083	1.638	1.704	1.540
			(<.001)	(<.001)	(<.001)	(<.001)
Alcohol			0.877	0.926	0.868	0.929
			(.339)	(.602)	(.332)	(.626)
CL		2.584		3.246		2.568
		(<.001)		(<.001)		(<.001)
IL		3.102		3.273		3.072
		(<.001)		(<.001)		(<.001)
Observations	1064	1064	1064	1064	1064	1064
LR	260.45	506.93	42.88	424.24	280.79	519.79
Pseudo-R2	0.097	0.189	0.016	0.158	0.105	0.194

Note: Numbers in parenthesis are *P* values.

Table 6. Marginal Effects Analysis (maximum level of eHealth literacy is the dependent variable).

Variables	Marginal effect	Standard error
Age		
1 (15–24)	0.069	0.012
2 (25–39)	0.052	0.007
3 (40–54)	0.044	0.008
4 (55–64)	0.038	0.011
5 (65–79)	0.028	0.008
6 (>80)	0.003	0.004
Marital Status		
1 (single)	0.046	0.006
2 (married)	0.053	0.007
3 (divorced)	0.008	0.005
4 (separated)	0.095	0.032
5 (widow)	0.364	0.326
Education		
1 (primary)	0.016	0.007
2 (high school—first 3 years)	0.009	0.004
3 (technical education)	0.021	0.008
4 (high school—last 3 years)	0.029	0.005
5 (post-high school—excluding university)	0.025	0.007
6 (university)	0.066	0.008
7 (Masters)	0.103	0.019
8 (PhD)	0.174	0.062
Exercise		
0 (once per week)	0.040	0.006
1 (more than once per week)	0.061	0.008
Computer Literacy		
0 (low)	0.005	0.001
1 (fair)	0.048	0.008
2 (high)	0.078	0.009
Information Literacy		
1 (low)	0.016	0.003
2 (fair)	0.035	0.005
3 (high)	0.120	0.014

Discussion

Understanding what shapes eHealth in a specific country is particularly important for health policy decision makers and the health care market, as it provides critical information to develop targeted and tailored interventions for relevant patient–consumer segments, and further suggests appropriate strategies for training the health illiterate part of the population. Furthermore, the implementation of eHealth and health information technologies is seen by many as an effective way to address recent concerns about the quality and safety of a health care system, with the rising costs of health care being another major concern that eHealth may help address [26].

For example, the study of Adreassen et al. [21] documents that the use of Internet for health purposes is positively related with youth, higher education, white-collar or no paid job, visits to the general practitioner during the past year, long-term illness or disabilities, and a subjective assessment of one’s own good health. Our findings support the association documented between eHealth literacy, age, and educational level and are in line with many studies that document a similar association [18,20,27]. The study by Rudd et al. [22], along with more recent studies [28,29], further documents the importance of education and age for a person's eHealth performance. Therefore, the suggestions of another study [30], that is, professional schools should incorporate health literacy into their curricula and areas of competence, seems very reasonable.

The Greek educational system can justify this relationship as Greek students are heavily exposed in new technologies throughout their education, and further enhance the positive age effect demonstrated. In addition, the findings of Watkins and Xie [19] emphasize the need for researchers to develop and assess theory-based interventions applying high-quality research design in eHealth literacy interventions targeting the older population. Baker et al. [17] concluded that higher education is associated with higher use of the Internet for health purposes. A more recent study of Amante et al. [31] has examined various reasons and odds of using the Internet to obtain health information. Cross-country evidence also emphasizes the significance of general literacy level on using information technologies [32,33]. For instance, as literacy skill levels rise, the perceived usefulness of computers, diversity, and intensity of Internet use, and use of computers for task-oriented purposes also rise, even when factors such as age, income, and education levels are taken into account [23].

In contrast, the study of Norman and Skinner [11] has revealed that baseline levels of eHealth literacy are higher among males; age did not predict eHealth literacy scores at any point in time, while overall no significant relationship was found between eHealth literacy and the use of information technology. We do not particularly align studies that find strong association between income and gender with eHealth literacy [29,34,35], as our results do not reveal a strong relation between sex and eHealth literacy, such as the findings of similar studies. In particular, the negative relationship we find can be justified as elderly, who live in the urban regions, may not have access to the Internet.

The link between life-style factors and eHealth literacy is mentioned in the study of Bodie and Dutta [24], but the positive association of these two is not supported. Also, the Neufingerl et al. [36] findings support the low eHealth literacy of smokers; a statement that has not be documented in our research. In contrast, our findings are in line with the Hsu et al. [37] findings, where higher levels of critical eHealth literacy have promoted students' health status and their practice of multiple positive health behaviors, including eating, exercise, and sleep behaviors. Likewise, the Kontos et al. [33] study finds link between physical activity and eHealth literacy.

Further, our results are in accordance with the studies supporting a positive and strong association between technology literacy and eHealth literacy [24,31,38]. As van Deursen and van Dijk [39] have documented, operational and formal Internet skills are not sufficient when using the Internet for health purposes. Particularly in Greece, limited Internet skills are identified as significant contributing factors to low eHealth literacy [40]. Patients with inadequate health literacy often have poorer health outcomes and increased utilization and costs [41]. The findings of a recent study [42] provide strong evidence that consumer eHealth interventions are of a growing importance in the individual management of health and health behaviors. The latter, is confirmed by the findings of Xie [43] according to which, regardless of the specific learning method used, the eHealth literacy intervention has significantly improved knowledge, skills, and eHealth literacy efficacy from pre- to post-intervention, has been positively perceived by the participants, and led to positive changes in their own health care.

So far, there is thin evidence of theory-based interventions and the eHealth interventions evaluating health outcomes, as the outcome of interest [19]. The incorporation of health literacy assessment into health care information systems and the evaluation of system interventions are recommended by the Institute of Medicine [44] in order to facilitate large-scale studies of the health literacy effects and to improve care by addressing health literacy, respectively. However, a range of access, resources, and skills barriers prevent health care consumers from fully engaging in and benefiting from the spectrum of eHealth interventions such as participating in health discussion forums [42]. Nevertheless, it is feasible to incorporate health literacy screening into clinical assessment, with the next steps being the evaluation of the relation between eHealth literacy and processes and outcomes of care across inpatient and outpatient populations [41].

A handful of studies have demonstrated so far that there is a positive potential with respect to eHealth literacy interventions, though there might be several confounding factors that have contributed to this finding. Although it has been demonstrated that educational level and age play an important role in shaping eHealth literacy level, further research is required in order to evaluate the use of the corresponding questionnaire and the possible ceiling effect. Findings might change in a significant manner if the research addresses only patients (both inpatients and outpatients). Individual motivation, attitudes, and emotional factors are not taken into account, along with the severe Greek economic crisis and its documented association with many health outcomes.

Overall, new measures of eHealth literacy must be developed and evaluated, and eHealth literacy interventions must be incorporated into daily life; therefore, nonfederal funds for eHealth literacy research are further needed particularly in countries under financial crisis, like Greece.

Conclusion

The advent and development of Internet and its use via various devices, was certainly a disruptive factor in the health provider–consumer (patient) relationship. Further, the Internet has a great potential for disseminating health information to the general public and at the same time is a tool that can be utilized to reach low-income, less educated, minority, and older populations.

Our research aims to study whether certain factors such as demographic, life-style, and types of technology literacy, shape the ability of the individuals in searching, analyzing, and processing information from the Internet in order to address or solve health-related issues.

Using unique survey data of 1064 citizens in Greece for the year 2013, we constructed an eHealth literacy index, based on eight questions, as it has been proposed in the literature, relating a participant's ability to use the Internet for health issues. Further, we estimated the effect of various factors on an individual's eHealth activity.

Our results reveal the important role of the age and education effect as well as that of physical exercise on eHealth literacy. Other types of technology literacy, such as computer skills and information obtained from the Internet, further enhance the eHealth performance of an individual having the greatest impact among all others factors.

Our study confirmed that factors influencing eHealth literacy are complex and interdependent. Therefore, more research should be conducted to further explore how these factors may influence one another, taking into consideration specific characteristics of users in various countries.

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Conflicts of Interest

None declared.

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Viewpoint

Information Needs in the Precision Medicine Era: How Genetics Home Reference Can Help

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Abstract

Precision medicine focuses on understanding individual variability in disease prevention, care, and treatment. The Precision Medicine Initiative, launched by President Obama in early 2015, aims to bring this approach to all areas of health care. However, few consumer-friendly resources exist for the public to learn about precision medicine and the conditions that could be affected by this approach to care. Genetics Home Reference, a website from the US National Library of Medicine, seeks to support precision medicine education by providing the public with summaries of genetic conditions and their associated genes, as well as information about issues related to precision medicine such as disease risk and pharmacogenomics. With the advance of precision medicine, consumer-focused resources like Genetics Home Reference can be foundational in providing context for public understanding of the increasing amount of data that will become available.

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KEYWORDS

individualized medicine; patient education as topic; databases, genetic; health resources

Introduction

In January 2015, President Obama announced the Precision Medicine Initiative [1], a research effort aimed at changing how diseases are diagnosed and treated in the United States. Its goal is to bring precision medicine—an approach to disease management that considers individual variability in genes, environment, and lifestyle—into the field of cancer and then ultimately into all areas of health and health care [2,3]. Integral to the initiative's effectiveness is the recruitment of a longitudinal cohort of 1 million volunteers, who will be overseen by the National Institutes of Health (NIH). This cohort will provide genetic data, biological samples, and other health information to researchers [4]. Detailed analyses of this database of health information, including genome-sequencing data and lifestyle and environmental factors, will help determine the genetic contribution to disease development, identify disease risk factors, and generate effective treatments that incorporate the way genes affect a person's response to drugs (a field of study called pharmacogenomics). This knowledge will enable clinicians to use genetic and other molecular information as part of routine medical care.

Reliable resources are necessary to support the public as they seek to educate themselves. Individuals searching online for information about the Precision Medicine Initiative may encounter unfamiliar concepts relating to health and genetics. Genetics Home Reference [5], an online resource from the US National Library of Medicine, provides consumer-focused information on various topics related to precision medicine, including how genetic variants relate to disease, pharmacogenomics, and genetic testing. In the era of precision medicine, online resources aimed at the general public, like Genetics Home Reference, are needed as more people become interested in the genetic aspects of health care.

Information Needs in the Precision Medicine Era

The need for new tools for researchers and clinicians to store, manage, and analyze large amounts of data has been discussed as a key factor in the implementation and success of precision medicine [2,6,7]. While storage and management of these data will be challenging, current tools may be helpful for data analysis. For example, to parse the meaning of newly identified genetic changes, researchers and clinicians can use tools such as Polymorphism Phenotyping (PolyPhen) [8] to determine whether a genetic change is likely involved in the development of disease. For pharmacogenomics associations, researchers and clinicians can use Pharmacogenomics Knowledgebase (PharmGKB) [9], a database that organizes information about genetic variants playing a role in drug response. Resources such as these will expand as more data are collected through precision medicine, making the databases more robust and increasingly useful for analysis.

While the utility of clinical resources for precision medicine has so far been paramount, the need for patient resources is equally important. Resources that are accessible for health care consumers can be used as a starting point for understanding precision medicine and its applications to health care. The influx of data generated by precision medicine means individuals will have access to more details about their health than ever before when making precision medicine-based health care decisions [10]. For people to make informed decisions in the era of precision medicine, it is imperative that they have an understanding of basic genetic principles; however, studies suggest that a substantial proportion of the general public lacks this understanding [11-13]. To support patient engagement in precision medicine and promote informed decision making, both clinicians and patients will require trusted online resources that provide easy-to-read information about genetic principles, genetic disorders, gene functions and their roles in disease, and pharmacogenomics. The use of Internet-based health tools increases patient engagement, which leads to better health outcomes [14].

The Internet is a major tool people use to research their health concerns; up to 80% of adults on the Internet report searching for health-related topics annually [15,16]. As precision medicine is adopted in clinical settings, it is inevitable that the public will turn to the Internet for information, as they have for other health inquiries. The Genetic and Rare Disease Information Center, an NIH resource that provides information targeted to consumers, reports that their users are primarily looking for diagnosis, prognosis, and treatment information for particular diseases [17]. A customer satisfaction survey on Genetics Home Reference also suggests that this website's users are looking for information related to precision medicine. Our staff is collecting results from an ongoing survey of randomly selected website users, who are provided with the opportunity to suggest improvements via open-ended questions. The survey's unpublished, preliminary results indicate a strong interest in the relationship between genetic mutations and disease course, the role of genetics in treatment options, and the interaction of lifestyle and genetic factors in disease. Survey respondents want information that is applicable to their particular health situation, with one user lamenting that "There is very limited information on my specific mutation." Another user stated their interest as simply wanting to know "about mutations in real life." (unpublished data, 2015). While conclusions cannot be drawn from this qualitative data, these responses do suggest that Genetics Home Reference users have an interest in precision medicine and the application of genetic information.

Clinicians can also benefit from patient resources; clinicians can add to their own knowledge and share these resources with patients. Continuing education of health care professionals is vital to the long-term success of the Precision Medicine Initiative [18]. Despite the spread of genetic testing into various areas of medicine, many clinicians lack familiarity with genetics and the important role it plays in health care. Recent reports from the Secretary's Advisory Committee on Genetics, Health, and Society [19] and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children [20] raise concerns about the amount of medical genetics education health care workers receive. Health care professionals need an understanding of genetic concepts to interpret precision medicine data and explain them to patients. As a supplement to professional training, point-of-care education allows the clinician to become knowledgeable in specific topics as they present in practice [21]. In addition, clinicians can use consumer resources to help explain genetic conditions and concepts to their patients.

Genetics Home Reference and Precision Medicine

Genetics Home Reference provides information targeted to patients and families with genetic disorders and to individuals interested in genetics who do not have a science background. Genetics Home Reference receives an average of 1.5 million visitors and 3.6 million page views each month. This website offers summaries of more than 1000 genetic conditions and more than 1300 genes. To construct these summaries, pertinent information is gleaned from scientific literature and written into summaries using language that can be understood by the lay public. Genetics Home Reference has information on dozens of topics aimed at educating the public about issues related to precision medicine, including genetic risk factors for disease and pharmacogenomics. For example, this resource provides information about the function of the *BRCA1* and *BRCA2* genes and explains how a mutation in either of these genes increases the risk of developing breast cancer and other types of cancer [22]. The presence of a mutation in either of these genes can help determine appropriate cancer screening and treatment approaches. Genetics Home Reference also offers information about genetic factors that alter a person's response to a common blood-thinning drug called warfarin. These genetic variants predispose people who might need warfarin to develop either blood clots (warfarin resistance) [23] or abnormal bleeding (warfarin sensitivity) [24]. If a patient had one of these genetic variants, a doctor might target the initial warfarin dose for optimum effectiveness and reduce the risk of an adverse drug reaction.

Genetics Home Reference also covers other types of cancer, immune deficiencies and dysfunctions, enzyme deficiencies, and other drug sensitivities (see Table 1). A benefit to clinicians is the inclusion of numerous rare conditions that might never be covered during formal education, in addition to a variety of common disorders.

Table 1. A sample of conditions on Genetics Home Reference to which precision medicine could be applied.

Condition	Genetics Home Reference link
Cancers	
Breast cancer	https://ghr.nlm.nih.gov/condition/breast-cancer
Lynch syndrome	https://ghr.nlm.nih.gov/condition/lynch-syndrome
Prostate cancer	https://ghr.nlm.nih.gov/condition/prostate-cancer
Familial adenomatous polyposis	https://ghr.nlm.nih.gov/condition/familial-adenomatous-polyposis
Acute promyelocytic leukemia	https://ghr.nlm.nih.gov/condition/acute-promyelocytic-leukemia
Neuroblastoma	https://ghr.nlm.nih.gov/condition/neuroblastoma
Core binding factor acute myeloid leukemia	https://ghr.nlm.nih.gov/condition/core-binding-factor-acute-myeloid-leukemia
Immune system disorders	
Celiac disease	https://ghr.nlm.nih.gov/condition/celiac-disease
Type 1 diabetes	https://ghr.nlm.nih.gov/condition/type-1-diabetes
Autoimmune Addison disease	https://ghr.nlm.nih.gov/condition/autoimmune-addison-disease
Rheumatoid arthritis	https://ghr.nlm.nih.gov/condition/autoimmune-addison-disease
Graves disease	https://ghr.nlm.nih.gov/condition/graves-disease
Autoimmune lymphoproliferative syndrome	https://ghr.nlm.nih.gov/condition/amyotrophic-lateral-sclerosis
Systemic lupus erythematosus	https://ghr.nlm.nih.gov/condition/systemic-lupus-erythematosus
Enzyme deficiencies	
Lactose intolerance	https://ghr.nlm.nih.gov/condition/lactose-intolerance
Glucose-6-phosphate dehydrogenase deficiency	https://ghr.nlm.nih.gov/condition/glucose-6-phosphate-dehydrogenase-deficiency
Hereditary antithrombin deficiency	https://ghr.nlm.nih.gov/condition/hereditary-antithrombin-deficiency
Familial hypercholesterolemia	https://ghr.nlm.nih.gov/condition/hypercholesterolemia
Protein C deficiency	https://ghr.nlm.nih.gov/condition/protein-c-deficiency
Autosomal recessive congenital methemoglobinemia	https://ghr.nlm.nih.gov/condition/autosomal-recessive-congenital-methemoglobinemia
Gaucher disease	https://ghr.nlm.nih.gov/condition/gaucher-disease
Adverse drug reactions	
Warfarin sensitivity	https://ghr.nlm.nih.gov/condition/warfarin-sensitivity
Warfarin resistance	https://ghr.nlm.nih.gov/condition/warfarin-resistance
Malignant hyperthermia	https://ghr.nlm.nih.gov/condition/malignant-hyperthermia
Pseudocholinesterase deficiency	https://ghr.nlm.nih.gov/condition/pseudocholinesterase-deficiency
Dihydropyrimidinase deficiency	https://ghr.nlm.nih.gov/condition/dihydropyrimidinase-deficiency
Thiopurine S-methyltransferase deficiency	https://ghr.nlm.nih.gov/condition/thiopurine-s-methyltransferase-deficiency
Dihydropyrimidine dehydrogenase deficiency	https://ghr.nlm.nih.gov/condition/dihydropyrimidine-dehydrogenase-deficiency
Stevens-Johnson syndrome/toxic epidermal necrolysis	https://ghr.nlm.nih.gov/condition/stevens-johnson-syndrome-toxic-epidermal-necrolysis

Genetics Home Reference also provides a primer called *Help Me Understand Genetics* for individuals who need foundational information. This primer has multiple chapters, covering topics from basic biology to the application of genetics in medicine. The precision medicine section of the primer explains this new approach to health care as well as the goals, benefits, and limitations of the Precision Medicine Initiative (see Table 2). Also of interest are health care–based issues, such as chapters on mutations and health, pharmacogenomics, and genetic testing. *Help Me Understand Genetics* provides information on the many facets of genetic testing that individuals will need to become familiar with as genetic testing becomes more routine for disease diagnosis and defining treatment options, such as indications for testing, interpretation of test results, and the difference between research and clinical testing.

Table 2. Background information about precision medicine from Genetics Home Reference.

Topic	Genetics Home Reference link
What is precision medicine?	https://ghr.nlm.nih.gov/handbook/precisionmedicine/definition
What is the difference between precision medicine and personalized medicine? What about pharmacogenomics?	https://ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalized
What is the Precision Medicine Initiative?	https://ghr.nlm.nih.gov/handbook/precisionmedicine/initiative
What are some potential benefits of precision medicine and the Precision Medicine Initiative?	https://ghr.nlm.nih.gov/handbook/precisionmedicine/potentialbenefits
What are some of the challenges facing precision medicine and the Precision Medicine Initiative?	https://ghr.nlm.nih.gov/handbook/precisionmedicine/challenges
What is pharmacogenomics?	https://ghr.nlm.nih.gov/handbook/genomicresearch/pharmacogenomics

Conclusion

Consumers are required to take an increasingly active role in their health care decisions, and they turn to the Internet to gather information regarding health issues. In the era of precision medicine, individuals will search for information to understand their genetic profiles and other health concerns. Various aspects of precision medicine are covered in online resources, including ClinVar [25], Genetic Testing Registry (GTR) [26], GeneReviews [27], Online Mendelian Inheritance in Man (OMIM) [28], and Orphanet [29]. However, these resources are designed primarily for researchers and clinicians, using technical information and language that can be overwhelming for most lay individuals.

Few consumer-focused resources about precision medicine exist, and the need for such resources will only increase. Resources are needed to put into context the growing amount of genetic and other health data that are becoming available [5]. Genetics Home Reference provides consumer-friendly information on topics relevant to precision medicine, including genetic conditions, gene function, and the effects of genetic variation on health, genetic testing, and pharmacogenomics. This information is useful to a variety of people, patients and clinicians alike, as the public increasingly turns to the Internet as a health resource. During this era of precision medicine, Genetics Home Reference seeks to facilitate health consumers in becoming well informed.

Research into consumers' specific information needs related to precision medicine could help guide the evolution of existing educational resources and the development of new resources [30]. These studies should first assess existing resources to identify areas that are not covered. For example, we are unaware of any comprehensive consumer databases that connect specific genetic variants to the development of disease or that outline treatment options based on particular genetic profiles. Such resources would help patients gather targeted information that is specific to their health situation and would be valuable additions in the age of precision medicine.

Genetics Home Reference is committed to supporting patient engagement through the ongoing addition of new information that is relevant to precision medicine. To determine which topics are relevant for inclusion on the website, Genetics Home Reference staff frequently collaborates with outside groups that include other NIH institutes, advocacy and support groups, and unsolicited user feedback. These collaborations ensure that the content on Genetics Home Reference appeals to a wide range of audiences. Genetics Home Reference will also continue to provide links to other reputable online resources that offer information beyond our scope. Developers of consumer-focused health resources, including Genetics Home Reference, have the opportunity to be proactive in providing education about precision medicine to the public concurrently with the implementation of this new approach to care.

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Conflicts of Interest

None declared.

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Abbreviations

GTR: Genetic Testing Registry
NIH: National Institutes of Health
OMIM: Online Mendelian Inheritance in Man
PharmGKB: Pharmacogenomics Knowledgebase
PolyPhen: Polymorphism Phenotyping

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Original Paper

Relationship of Buckling and Knee Injury to Pain Exacerbation in Knee Osteoarthritis: A Web-Based Case-Crossover Study

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Abstract

Background: Knee osteoarthritis (OA) is one of the most frequent causes of limited mobility and diminished quality of life. Pain is the main symptom that drives individuals with knee OA to seek medical care and a recognized antecedent to disability and eventually joint replacement. Evidence shows that patients with symptomatic OA experience fluctuations in pain severity. Mechanical insults to the knee such as injury and buckling may contribute to pain exacerbation.

Objective: Our objective was to examine whether knee injury and buckling (giving way) are triggers for exacerbation of pain in persons with symptomatic knee OA.

Methods: We conducted a case-crossover study, a novel methodology in which participants with symptomatic radiographic knee OA who have had knee pain exacerbations were used as their own control (self-matched design), with all data collected via the Internet. Participants were asked to log-on to the study website and complete an online questionnaire at baseline and then at regular 10-day intervals for 3 months (control periods)—a total of 10 questionnaires. They were also instructed to go to the website and complete pain exacerbation questionnaires when they experienced an isolated incident of knee pain exacerbation (case periods). A pain exacerbation “case” period was defined as an increase of ≥2 compared to baseline. At each contact the pain exacerbation was designated a case period, and at all other regular 10-day contacts (control periods) participants were asked about knee injuries during the previous 7 days and knee buckling during the previous 2 days. The relationship of knee injury and buckling to the risk of pain exacerbation was examined using conditional logistic regression models.

Results: The analysis included 157 participants (66% women, mean age: 62 years, mean BMI: 29.5 kg/m^2). Sustaining a knee injury was associated with experiencing a pain exacerbation (odds ratio [OR] 10.2, 95% CI 5.4, 19.3) compared with no injury. Knee buckling was associated with experiencing a pain exacerbation (OR 4.0, 95% CI 2.6, 6.2) compared with no buckling and the association increased with a greater number of buckling events (for ≥ 6 buckling events, OR 20.1, 95% CI 3.7, 110).

Conclusions: Knee injury and buckling are associated with knee pain exacerbation. Reducing the likelihood of these mechanical events through avoidance of particular activities and/or appropriate rehabilitation programs may decrease the risk of pain exacerbation.

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KEYWORDS

knee osteoarthritis; injury; buckling pain exacerbation; case-crossover study; web-based

Introduction

Osteoarthritis (OA) is a leading cause of musculoskeletal pain and disability where the knee is commonly affected [1]. Pain is dominant, becoming persistent and more limiting with disease progression, leading to disability, reduced quality of life, and often joint replacement [2]. Pain results from a complex interaction between structural joint changes [3], physical impairments [4], and psychosocial factors [4]. Evidence has shown that patients with symptomatic OA experience fluctuations of relatively short durations in pain severity [2,5,6]. These intense and intermittent pain fluctuations are called pain exacerbations or pain flares [7]. Pain flares are often exacerbated during activities and are relieved with rest, although later in the disease course, pain can also occur at night and during rest [2,7]. If we are to impact the experience of pain, particularly intermittent pain having a greater impact on quality of life [5], then identification of factors predisposing to fluctuations in pain severity is crucial.

Mechanical insults to the knee such as injury and buckling may contribute to pain exacerbation. The latter is defined as giving way during weight bearing activities [8]. The buckling event can be caused by pain, knee instability, or insufficient muscle strength, and furthermore, may lead to injurious falls [8].A cross-sectional study suggested that almost 12% of participants with knee OA had at least one event of knee buckling during the last 3 months and that buckling was associated with functional loss and limitation of daily activities [8]. The study of Nguyen et al [9] reported that within 3 months study period among those who suffered knee buckling, the overwhelming majority had two or more episodes of knee buckling during that time. For these participants, 74% reported 2-5 buckling episodes, 17% reported 6-10 episodes, and 9% reported 11 or more episodes [9]. Knee buckling and especially sensations of knee instability without buckling were found to be associated with fear of falling, poor balance confidence, activity limitations, and poor physical function [9]. To date however, the role of knee injury and buckling in predisposing to exacerbations of pain in persons with knee OA remains unclear. Thus we aimed to investigate this relationship using an Web-based case-crossover study.

Methods

Study Design

We conducted a Web-based case-crossover study to investigate the relationship between knee buckling and/or knee injury and OA knee pain exacerbation as described in our recent protocol paper [10]. This design is ideally suited to assess the effects of transient and intermittent exposures (triggers) on recurrent acute events (such as pain flares). The case-crossover study uses each participant as his or her own control and compares the frequency of exposure to a suspected precipitating factor (eg, knee buckling and/or knee injury) from an acute episode onset (case period, ie, a knee OA pain exacerbation in this study) to that during control periods. Self-matching of each participant minimizes the bias in control selection and removes the confounding effects of factors that are constant over time [11,12]. The case-crossover study design has been successfully utilized to evaluate associations between transient exposures and the onset of acute events [13-15]. A case-crossover study design can also be used to evaluate risk factors for recurrent acute events such as multiple pain exacerbations during the study follow-up period [13]. A participant can contribute both case and control periods multiple times during the study follow up.

Study Population

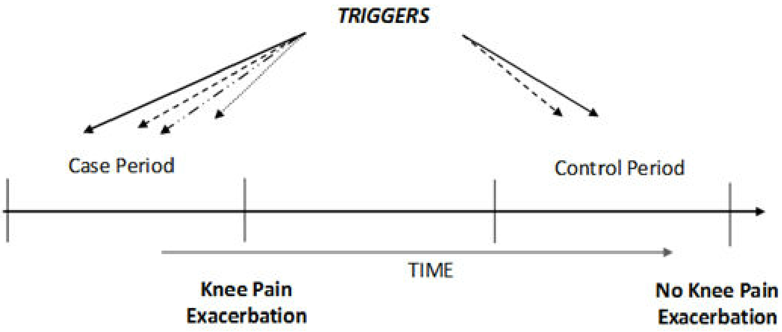
Participants were recruited from existing databases at the Royal North Shore Hospital of Sydney and the University of Melbourne that included people diagnosed with symptomatic radiographic knee OA who had agreed to be contacted for future studies. Another source of recruitment was volunteers responding to advertisements placed in the general community and in health care settings.

A set of prescreening questions was used to identify eligible participants. All participants had to undergo knee X-rays. The inclusion criteria for participation were: 1) age above 40 years; 2) pain on most days (≥15 days) of the previous month; 3) fluctuations in pain level; 4) at least one knee that met the American College of Rheumatology criteria of OA (knee pain, stiffness, or aching) [16]; 5) tibiofemoral Kellgren and Lawrence Grade (KLG)≥ 2 [17] or patellofemoral [18] OA documented on a radiograph; 6) no plan to have a total knee replacement in the symptomatic knee in the next 6 months; 7) no history of OA secondary to inflammatory joint disease, osteonecrosis, Paget’s disease, etc; 8) have an active email account and access to the Web; and 9) have good understanding of spoken and written English. This study was approved by the Human Ethics Committee of the University of Sydney and the University of Melbourne and all participants provided informed consent. Participants were screened and enrolled via the website. The study participants were followed for 3 months and were asked to complete the online questionnaires at the commencement of the study (baseline) and then at regular 10-day intervals.

Ascertainment of Knee Pain Exacerbation

At the commencement of the study, we asked participants to rate the severity of their current knee pain using a 0-10 numeric rating scale (NRS) with zero being “no pain” and 10 being "extreme pain." Each questionnaire was preceded by a clear description of how to complete it. Participants were instructed to log-on to the study website and complete the questionnaires when they experienced an increase in their pain level (a disabling increase in their knee symptoms that lasted for longer than 8 hours without settling) (Figure 1). The online study website then automatically calculated and determined whether the current knee pain was defined as a "pain exacerbation" by comparing it with their baseline pain level measured as the mildest level of their background pain on the NRS scale (defined as an increase of ≥ 2 on a 0-10 numerical rating scale from baseline [19]. Participants were prompted to complete the online questionnaires by means of automated reminder emails. If participants did not meet this threshold and were not due to complete their regular 10 day questionnaire, no further information was collected. If two pain exacerbations occurred within 7 days, then the subsequent pain exacerbation was excluded from the analysis. The content of the questionnaires for the case and regular 10-day contact visits was the same, with both ascertaining the frequency of knee buckling and knee injuries.

Figure 1. Case-crossover study design and timing of exposure measurements in relation to knee osteoarthritis pain exacerbation.



Ascertainment of Knee Injury and Buckling

Knee buckling episodes were assessed by recall in the first 2 days and have been found to be common in patients with knee OA. As knee injuries are likely to be less frequent than buckling and as we also wanted to capture minor injuries (which may have a longer interval from injury to pain exacerbation), our interval of assessment of the occurrence of knee injury was extended to the first 7 days.

The participants were asked whether they experienced knee buckling, defined as giving way [8], during the previous 2 days; how often the knee buckled during that period of time; whether they fell during that event; and what they were doing when the knee buckled? These self-reported instruments have been widely used and validated from previous studies for buckling [8,9], injury/ trauma [20], and falls [21].

The questions about knee buckling and injury for both control period and case period questionnaires were the same:

1) Did you have an injury to your index knee during the last 7 days that limited your activities? How did this injury occur?

2) Did you meet with an incident in the past 2 days where your knee buckled or gave way? How many times in the past 2 days did you experience such an episode? As a result of knee buckling or giving way, did you accidentally fall and hit the floor or ground? In general what were you doing when your knee buckled?

Statistical Analysis

Descriptive statistics were computed for all participants as well as for those with at least one case period and one control period. Comparisons of the baseline characteristics between participants with both case (exacerbation) and control periods and those without discordant outcomes were assessed using a chi-square test for categorical variables and analysis of variance for continuous variables when normality and homogeneity of variance assumptions were satisfied.

As each participant could contribute multiple case and control periods, an m:n matched study design was used to assess the relation of knee buckling and knee injury to risk of knee pain exacerbation using conditional logistic regression (SAS PHREG, v. 9.4). Only participants with both case and control periods were used in the regression analysis as participants with only case or only control periods will not contribute information for such an analysis (ie, no information for comparing differences in presence of the study triggers between exacerbation and control periods within an individual). To ensure a no overlap between any analyzed periods, only questionnaires with at least a 7-day interval between any two assessments were used.

Results

Among 297 subjects recruited into the study, 157 had data on both case and control periods (Table 1). Out of 795 Web contacts where the participants said that they were experiencing an increase in pain, only 571 (71.8%) were identified by the system as having a pain exacerbation (case period) based on the required criteria (an increase of ≥ 2 on a 0-10 numerical rating scale). Out of 571 case periods reported, 513 (89.8%) were reported at one of their regular control period visits.

Table 1. Demographic characteristics of study participants.

	Study participants with both case and control periods[a] (n=157)	Participants with only case or control periods but not both (n=140)	*P* value
Female, n (%)	103 (65.6)	79 (56.4)	.12[b]
Age (year), mean (SD)	61.8 (8.4)	62.4 (7.7)	.55[c]
BMI[d](kg/m^2), mean (SD)	29.5 (5.6)	29.1 (5.1)	.48[c]
KOOS[e]Symptoms mean(SD)	44.2 (14.1)	44.8 (11.7)	.72[c]
KOOS Pain, mean (SD)	55.1 (15.9)	56.1 (17.4)	.59[c]
KOOS ADL[f], mean (SD)	62.0 (19.7)	63.3 (19.0)	.57[c]
KOOS Sport/Recreation mean(SD)	22.3 (23.8)	22.4 (22.7)	.96[c]
KOOS QOL[g], mean (SD)	39.6 (17.7)	41.7 (18.8)	.33[c]

[a] The study participants included in the case-crossover analysis; participants with only case or control periods are in the right column and did not contribute information for the conditional logistic regression analyses.

[b] chi-square test

[c] ANOVA test

[d] BMI: body mass index

[e] KOOS: knee injury and osteoarthritis outcome score

[f] ADL: function in daily living

[g] QOL: quality of life

During the 3-month follow-up period, 400 knee pain exacerbations occurred. Among the participants, no statistically significant differences were seen in the baseline characteristics between those who had both case and control periods and those who did not; although there was a greater proportion of women among those who had both periods, which may be clinically relevant (Table 1).

There were 102 out of 1244 (8.2%) reports of injury to the index knee during the previous 7 days and 249 (19.9%) reports of knee buckling or giving way in the previous 2 days. The most frequent causes of injury were sport injuries (20.0%), tripping (13.0%), slipping (11.0%), and falling (11.0%). Of the 297 participants, 131 (44.1%) participants complained of one or more buckling episodes during the 3 months of follow up. The most common activity reported when buckling occurred was walking on level ground (52.9%), followed by twisting or turning (18.8%), and going upstairs or downstairs (17.8%). 71 participants (54.2%, 71/131) reported that buckling occurred two to five times, 47 participants (35.9%, 47/131) reported that the buckling occurred only once, and 17 (13.0%, 17/131) participants reported a fall during buckling.

About 81.6% (83 out of 102) of participants who reported a knee injury and 85.5% (213 out of 249)who reported knee buckling indicated that their pain exacerbation started within the last 2 days.

As shown in Table 2, the odds ratio of experiencing a pain exacerbation with an injury in the previous 7 days was 10.2 (95% CI 5.4, 19.3). For an event of knee buckling in the previous 2 days the odds ratio of experiencing a pain exacerbation was 4.0 (95% CI 2.6, 6.2). Furthermore, there was a dose–response relationship between the number of knee buckling episodes and the risk of knee pain exacerbation. The odds ratios of knee pain exacerbation were 3.5 (95% CI 2.0, 6.0), 4.1 (95% CI 2.4, 7.0), and 20.1 (95% CI 3.7, 110), respectively, if participants experienced knee buckling once, 2-5 times, and more than 5 times during the previous 2 days (Table 3).

Table 2. Association of knee injury and risk of knee pain exacerbation.

Knee injury	Case periods (N)	Control periods (N)	Odds ratio (95% CI)
No	329	820	1.0 (referent)
Yes	71	31	10.2 (5.4, 19.3)

Table 3. Association of knee buckling and risk of knee pain exacerbation.

		Case periods (N)	Control periods (N)	Odds ratio (95% CI)
Knee buckling	No	259	743	1.0 (referent)
	Yes	141	108	4.0 (2.59, 6.18)
Number of episodes	1	64	54	3.5 (2.0, 6.0)
	2-5	66	50	4.1 (2.4, 7.0)
	≥ 6	11	4	20.1 (3.7, 110)

Discussion

This study demonstrates a strong association between knee buckling and injury with pain exacerbation in people with knee OA. Of these mechanical insults, knee injury provides the most potent risk of exacerbation; albeit injury occurred less frequently in our cohort than buckling.

The most common type of knee injury was sustained as a consequence of sports injuries and tripping. Of the participants who complained of buckling, the most common frequency was from two to five times, whereas more than six buckling episodes were associated with the highest odds ratio suggesting some dose response effect. Knee buckling may be associated with an increased risk of falling and furthermore with a risk of fractures [8], however in our study only a small percentage (13%, 17 out of 131) of participants fell during an event of buckling. When buckling occurred, walking on level ground was by far the most common activity preceding an episode of buckling.

An injury to the synovial joint may lead to an exacerbation of pain by leading to an inflammatory response and release of chemical mediators into the joint [7]. Furthermore, primary afferent nerves may be sensitized and otherwise harmless movements may become more painful [7].

Principal Findings

Our findings are consistent with the hypothesis that knee injuries and buckling are important trigger factors for knee pain exacerbation. By implication, it is possible that preventing knee buckling and knee injuries can reduce pain exacerbation. Instability of the knee, a main cause of knee buckling is associated with quadriceps weakness and is thought to be highly treatable [22]. Quadriceps strengthening and balance training are elements of successful rehabilitative efforts to treat knee instability [22,23]. It can be speculated that this type of training might prevent knee buckling, and therefore, reduce the reoccurrence of pain exacerbation episodes.

As many injuries result from slipping or tripping, modifying falls risk or the predisposition to such, could assist in the prevention of knee injury. Cognizant of the fact that our study sample is younger than those typically at greater risk of falls, one potentially important piece of advice for elderly patients is to wear proper footwear indoors, as many falls occur due to lack of fixation in the shoe or due to an excessively soft sole [24,25]. A person is likely to slip or trip due to improper shoes sizes (either too small or too large)—a common risk factor for falls [25].

Neuromuscular exercise training is beneficial in prevention of knee injury and is known to be a promising avenue in reducing knee injury risk [26]. It aims to improve control and alignment of the knee during functional activities [27]. Neuromuscular exercise and strengthening exercise were compared with each other and it was found that both similarly improved pain and function [28].

Limitations

Possible limitations of our study include incomplete data in questionnaires, in addition to some potential for recall bias and participant fatigue. Every participant was followed regularly for 3 months and the possibility that they may have logged-on during a pain exacerbation is assumed to be null. There is potential for recall bias given that a participant is first asked questions about a recent knee pain exacerbation, which is followed by questions asking them to recall knee-related events that occurred during the same recall interval. The potential effects of time-varying potential predictors including medication, shoe wear, and weather have not been controlled in these analyses. Similarly, after accounting for potential overlap, the independent effects of buckling and injury have not been assessed.

For defining knee injury, we included injuries occurring in daily life without further delineation, for example, falling over, slipping, tripping, twisting the ankle, or landing from a jump. This may lead to misclassification that could reduce the effects found. Furthermore, if a person experiencing a pain exacerbation wonders why this may have occurred, an open-ended definition of the exposure invites an opportunity for recall bias.

Of the participants, 82% (83 out of 102) who reported that they had a knee injury during the last 7 days indicated that their pain exacerbation started within the last 2 days, whereas, 86% (213 out of 249) of those participants who reported knee buckling indicated that their pain exacerbation started within the last 2 days. All pain exacerbations either overlap the buckling recall period or precede it. We have assumed that the knee injury and/or buckling may play a triggering role for pain exacerbation but causation cannot be proven in this study and reverse causality remains a possibility. It is entirely plausible for pain exacerbations to be a “trigger” for increased knee instability and falls, both of which could themselves be a source of a knee injury.

Psychosocial aspects contribute to the genesis of pain, as people with lower self-efficacy or higher catastrophizing have a higher perception of pain [29]. Patients often develop anxiety about pain exacerbations, which can lead to avoidance of activities, depression, or sleep-onset insomnia [5,30]. As each participant acts as his or her own control, constant personal factors are controlled via the case-crossover study design and cannot bias our results. Catastrophizing and self-efficacy are considered traits that should not change unless intervened upon and also not likely change over a 3-month period. On the other hand, mood fluctuations, for instance, could certainly influence these results and will be examined in future analyses. We have also collected data on other time-varying potential predictors including medication, shoe wear, and weather, which will also be examined in future analyses.

Conclusions

This investigation demonstrated the potential importance of knee injury and buckling as triggers for knee pain exacerbation in participants with symptomatic knee OA. These findings make a noteworthy contribution to the etiology of knee pain in OA and potentially counseling of persons with knee OA to avoid activities that lead to knee injuries or buckling.

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Authors' Contributions

DJH conceived and designed the study, supervised its conduct, revised the manuscript and takes responsibility for the integrity of the work as a whole, from inception to finish. YZ, LM, and KB were also involved in the design and conduct of the study. All authors contributed to acquisition of the data and its interpretation. All authors critically revised the manuscript and gave final approval of the article for submission.

Conflicts of Interest

None declared.

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Abbreviations

KLG: Kellgren and Lawrence Grade
NRS: Numerical rating scale
OA: Osteoarthritis

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