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Original Paper

Time to Treatment and In-Hospital Major Adverse Cardiac Events Among Patients With ST-Segment Elevation Myocardial Infarction Who Underwent Primary Percutaneous Coronary Intervention (PCI) According to the 24/7 Primary PCI Service Registry in Iran: Cross-Sectional Study

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Abstract

Background: Performing primary percutaneous coronary intervention (PCI) as a preferred reperfusion strategy for patients with ST-segment elevation myocardial infarction (STEMI) may be associated with major adverse cardiocerebrovascular events (MACCEs). Thus, timely primary PCI has been emphasized in order to improve outcomes. Despite guideline recommendations on trying to reduce the door-to-balloon time to <90 minutes in order to reduce mortality, less attention has been paid to other components of time to treatment, such as the symptom-to-balloon time, as an indicator of the total ischemic time, which includes the symptom-to-door time and door-to-balloon time, in terms of clinical outcomes of patients with STEMI undergoing primary PCI.

Objective: We aimed to determine the association between each component of time to treatment (ie, symptom-to-door time, door-to-balloon time, and symptom-to-balloon time) and in-hospital MACCEs among patients with STEMI who underwent primary PCI.

Methods: In this observational study, according to a prospective primary PCI 24/7 service registry, adult patients with STEMI who underwent primary PCI in one of six catheterization laboratories of Tehran Heart Center from November 2015 to August 2019, were studied. The primary outcome was in-hospital MACCEs, which was a composite index consisting of cardiac death, revascularization (ie, target vessel revascularization/target lesion revascularization), myocardial infarction, and stroke. It was compared at different levels of time to treatment (ie, symptom-to-door and door-to-balloon time <90 and ≥90 minutes, and symptom-to-balloon time <180 and ≥180 minutes). Data were analyzed using SPSS software version 24 (IBM Corp), with descriptive statistics, such as frequency, percentage, mean, and standard deviation, and statistical tests, such as chi-square test, *t* test, and univariate and multivariate logistic regression analyses, and with a significance level of <.05 and 95% CIs for odds ratios (ORs).

Results: Data from 2823 out of 3204 patients were analyzed (mean age of 59.6 years, SD 11.6 years; 79.5% male [n=2243]; completion rate: 88.1%). Low proportions of symptom-to-door time ≤ 90 minutes and symptom-to-balloon time ≤ 180 minutes were observed among the study patients (579/2823, 20.5% and 691/2823, 24.5%, respectively). Overall, 2.4% (69/2823) of the patients experienced in-hospital MACCEs, and cardiac death (45/2823, 1.6%) was the most common cardiac outcome. In the univariate analysis, the symptom-to-balloon time predicted in-hospital MACCEs (OR 2.2, 95% CI 1.1-4.4; $P=.03$), while the symptom-to-door time (OR 1.4, 95% CI 0.7-2.6; $P=.34$) and door-to-balloon time (OR 1.1, 95% CI 0.6-1.8, $P=.77$) were not associated with in-hospital MACCEs. In the multivariate analysis, only symptom-to-balloon time ≥ 180 minutes was associated with in-hospital MACCEs and was a predictor of in-hospital MACCEs (OR 2.3, 95% CI 1.1-5.2; $P=.04$).

Conclusions: A longer symptom-to-balloon time was the only component associated with higher in-hospital MACCEs in the present study. Efforts should be made to shorten the symptom-to-balloon time in order to improve in-hospital MACCEs.

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KEYWORDS

ST-segment elevation myocardial infarction; time to treatment; percutaneous coronary intervention; registries; Iran

Introduction

Acute myocardial infarction with and without ST-segment elevation is a prevalent cardiac emergency, which is responsible for potential morbidity and mortality worldwide [1]. For patients with ST-segment elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI) has been considered as the preferred reperfusion therapy, which can be provided by an experienced team [2]. Additionally, for patients with contraindication of thrombolytic therapy, this reperfusion strategy can be a reliable substitute [3]. Moreover, in high-volume hospitals, primary PCI can be performed faster and can lead to lower mortality [4]. However, performing primary PCI for patients with STEMI may be associated with major adverse cardiocerebrovascular events (MACCEs) [5]. On the other hand, introducing a STEMI network, such as a 24/7 primary PCI regional service, may lead to improved accessibility for invasive diagnosis and treatment and may reduce mortality [6].

Although a recent guideline emphasized a timely reperfusion strategy in patients with STEMI [7], a longer time to treatment has been found [8]. According to Kim et al, the time to treatment has different components, including the symptom-to-door time (ie, time from symptom onset to hospital arrival), door-to-balloon time (ie, time from hospital arrival to balloon inflation), and symptom-to-balloon time (ie, time from symptom onset to balloon inflation) [9]. A longer time to treatment may affect clinical outcomes following primary PCI [10]. Thus, any delay related to time to treatment should be noticed [2] and should be recorded and reviewed regularly in every system providing care to patients with STEMI [11].

Although several studies reported no improvement in clinical outcomes and survival of patients who underwent primary PCI, despite improvement in the door-to-balloon time over the years [9,12-15], other studies focused on the door-to-balloon time because of an association between a lower door-to-balloon time and better outcomes in terms of both in-hospital outcomes and long-term survival [16-21]. On the other hand, other components of time to treatment, such as the symptom-to-balloon time and symptom-to-door time, have not been considered. The

symptom-to-balloon time, as an estimate of total ischemic time, is strongly correlated with infarct size and mortality compared with its subintervals, such as the door-to-balloon time and symptom-to-door time, as a substantial duration of myocardial ischemia prior to hospital arrival accounts for a large number of deaths during the prehospital period [22]. Therefore, it is required to pay attention to all components of time to treatment when evaluating MACCEs among patients with STEMI who have undergone primary PCI.

According to a research project in Iran (Iranian Project for Assessment of Coronary Events 2 [IPACE2]), despite relatively timely in-hospital reperfusion performed for patients with STEMI, long-time patient delay was found [23]. However, its impact on MACCEs among patients with STEMI undergoing primary PCI in a health care setting of a developing country, such as Iran, has not been evaluated. On the other hand, previous studies indicated controversy among different components of treatment times and short-term and long-term MACCEs [13,19,24,25]. Therefore, owing to the predictive role of treatment times in clinical outcomes, the association between time to treatment and 1-month mortality was studied by Kim et al in 2017 for the first time [9]. However, this association with in-hospital MACCEs has not been evaluated. In addition, previous studies have been performed in developed countries, which may limit applicability in Iran having a different quality of care.

There is a lack of information on the association between time to treatment and in-hospital MACCEs among patients with STEMI undergoing primary PCI in Iran, and such information can help health care systems to identify sources of time delays, achieve better planning, and apply preventive strategies for improving clinical outcomes following primary PCI in order to plan and manage STEMI more properly. Thus, we designed and conducted this study to determine the association between all components of time to treatment (ie, symptom-to-door time, door-to-balloon time, and symptom-to-balloon time) and in-hospital MACCEs among patients with STEMI who underwent primary PCI, according to the 24/7 primary PCI service registry of Tehran Heart Center (THC) in Iran.

Methods

Study Design and Setting

We conducted an observational study according to the 24/7 primary PCI service registry of THC in Iran. Details of the study design and setting have been published previously [26]. The study protocol was approved by the institutional review board and research ethics committee of Tehran University of Medical Sciences. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were used to report study results [27].

Participants

All patients who were treated with primary PCI at one of the six catheterization laboratories of THC between November 2015 and August 2019, and whose data were registered prospectively in the 24/7 primary PCI service registry were included as study participants.

Inclusion criteria for this study were age older than 18 years, confirmed diagnosis of STEMI, and primary PCI through a standard technique without bolus administration of fibrinolytic agents in the catheterization laboratory of THC. Those with incomplete data regarding one of the time to treatment variables (eg, symptom-to-door time, door-to-balloon time, and symptom-to-balloon time) and the study outcome (ie, in-hospital MACCEs) were excluded from the analysis [26].

Data Sources

We used the registered data in the 24/7 primary PCI service registry as the main source of data. Details of the registry have been previously published [26]. Collected data from the time of admission to the emergency department (ED) to transfer to the catheterization laboratory through the STEMI management registry form were entered in the 24/7 primary PCI service registry by research staff weekly [26]. A flow chart of patient admission to the ED and transfer to the catheterization laboratory of THC has been published previously [28].

Variables

We explained study variables in the study protocol completely [26]. Demographic and clinical variables were recorded. Demographic variables were age, sex, BMI, and current smoking. Clinical variables were medical history of myocardial infarction (MI), PCI, and coronary artery bypass grafting (CABG); comorbidities of diabetes, hypertension, and hyperlipidemia; family history of cardiovascular diseases (CVDs); previous cardiopulmonary resuscitation (CPR); emergency medical service (EMS) user; infarcted territories including anterior, posterior, inferior, or lateral; infarct-related arteries (IRAs) including the graft, left main, left anterior descending, left circumflex, and right coronary arteries; multivessel disease; procedural support including pacemaker, mechanical ventilation, intra-aortic balloon pump, inotropes, cardioversion, and defibrillator; and pre- and postprimary PCI thrombolysis in myocardial infarction (TIMI) flow.

The main independent variables were time to treatment, including the symptom-to-door time (ie, time from self-reported onset of symptoms to hospital arrival), door-to-balloon time (ie,

time from hospital arrival to reperfusion), and symptom-to-balloon time (time from self-reported onset of symptoms to reperfusion). All components of time to treatment were recorded as continuous quantitative variables (in hours and minutes), and then, they were reported separately (in minutes) as categorical variables (ie, symptom-to-door time and door-to-balloon time <90 and ≥90 minutes; symptom-to-balloon time <180 and ≥180 minutes), according to the study by Kim et al [9]. The study outcome was in-hospital MACCEs, which were measured before hospital discharge. In-hospital MACCEs represented a composite index including different elements of MI, stroke, cardiac death, target vessel revascularization, and target lesion revascularization that have been defined previously [26]. It should be noted that first medical contact and STEMI diagnosis have been considered according to the definition provided in the 2017 European Society of Cardiology guidelines [11]. Therefore, first medical contact time was the time between hospital arrival and initial assessment by a physician, paramedic, or nurse, or other trained EMS personnel who could obtain and interpret an electrocardiogram (ECG). Additionally, STEMI diagnosis time was the time between first medical contact to STEMI ECG verification and diagnosis, which was reported categorically (ie, ≤10 minutes and >10 minutes) [11].

Statistical Methods

We compared the baseline characteristics of patients who underwent primary PCI across in-hospital MACCEs. Continuous variables are reported as mean (SD) or median (IQR) and were compared using independent sample *t* tests or Mann-Whitney *U* tests. In order to compare categorical variables, chi-square tests were used, and the data are reported as proportions and percentages.

Univariate binary logistic regression analysis was performed to determine the relationship between time to treatment and in-hospital MACCEs and between other variables and in-hospital MACCEs. In order to modify the effect of other dependent variables on the studied relationship, variables with a significance level of ≤.2 in the univariate binary logistic regression were taken for multivariate analysis and entered in a multiple logistic regression model. After removing insignificant variables through backward elimination regression analysis, the studied relationship was reported.

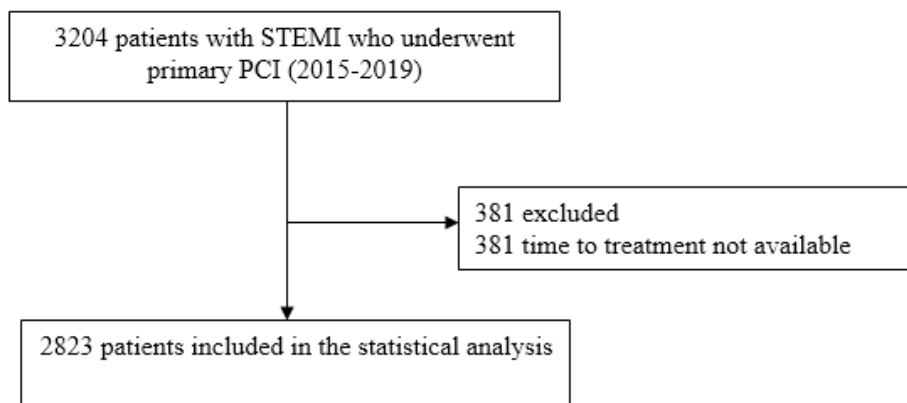
Each relationship between the variables was expressed as an odds ratio (OR) with a 95% CI. All statistical tests were set as two-tailed tests. A *P* value <.05 was considered statistically significant. The statistical package IBM SPSS for Windows, version 24.0 (IBM Corp) was used for the statistical analyses.

Results

Participants

From November 2015 to August 2019, 3204 consecutive patients with STEMI underwent primary PCI in THC, and their data were recorded in the 24/7 primary PCI service registry. Patients were excluded if time to treatment data were not available. Thus, 2823 out of 3204 patients were included in this study (completion rate: 88.1%) (Figure 1).

Figure 1. Study population diagram. PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction.



Descriptive Data

Baseline characteristics of the study patients are shown in [Table 1](#). According to [Table 1](#), the mean age of the study population was 59.6 years, with overall obese BMI. There were high

proportions of male sex and hyperlipidemia and low proportions of current smoking, EMS use, family history of CVDs, previous CPR, and medical history of MI, PCI, and CABG among the study population ([Table 1](#)).

Table 1. Baseline characteristics of the study patients and comparison according to in-hospital major adverse cardiocerebrovascular events.

Characteristic	Overall value	In-hospital MACCEs ^a , value		P value
		Yes	No	
Demographic characteristics				
Age (years) (n=2823), mean (SD)	59.6 (11.6)	65.8 (12.6)	59.5 (11.6)	<.001 ^b
Age ≥75 years, n/N (%)	316/2823 (11.2)	18 (26.1)	298 (10.8)	
Sex				
Male, n/N (%)	2243/2823 (79.5)	47/69 (68.1)	2196/2754 (79.7)	.02 ^b
Female, n/N (%)	580/2823 (20.5)	22/69 (31.9)	558/2754 (20.3)	
BMI (kg/m ²) (n=2760), mean (SD)	27.8 (4.4)	27.9 (4.3)	27.8 (4.4)	.80
Current smoker, n/N (%)	1045/2803 (37.3)	14/68 (20.6)	1031/2735 (37.7)	.004 ^b
Clinical characteristics				
EMS ^c user, n/N (%)	456/2463 (18.5)	9/54 (16.7)	447/2409 (18.6)	.72
Family history of CVDs ^d , n/N (%)	445/2749 (16.2)	10/68 (14.7)	435/2681 (16.2)	.74
Previous CPR ^e , n/N (%)	62/2755 (2.3)	4/68 (5.9)	58/2687 (2.2)	.04 ^b
Medical history				
MI ^f , n/N (%)	350/2755 (12.7)	7/68 (10.3)	343/2687 (12.8)	.55
PCI ^g , n/N (%)	424/2755 (15.4)	5/68 (7.4)	419/2687 (15.6)	.06
CABG ^h , n/N (%)	132/2755 (4.8)	2/68 (2.9)	130/2687 (4.8)	.47
Comorbidities				
Diabetes mellitus, n/N (%)	1135/2803 (40.5)	33/68 (48.5)	1102/2735 (40.3)	.17
Hypertension, n/N (%)	1307/2803 (46.6)	35/68 (51.5)	1272/2735 (46.5)	.42
Hyperlipidemia, n/N (%)	1493/2803 (53.3)	28/68 (41.2)	14.65/2735 (53.6)	.04 ^b
FMC ⁱ (min) (n=2823), median (IQR)	1 (0-6)	2 (0-7)	1 (0-6)	.33
STEMI ^j diagnosis time ≤10 min, n/N (%)	1923/2823 (68.4)	45/69 (65.2)	1885/2754 (68.4)	.57
Symptom-to-door time <90 min, n/N (%)	579/2823 (20.5)	11/69 (15.9)	568/2754 (20.6)	.34
Door-to-balloon time <90 min, n/N (%)	2089/2823 (74.0)	50/69 (72.5)	2039/2754 (74.0)	.77
Symptom-to-balloon time <180 min, n/N (%)	691/2823 (24.5)	9/69 (13.0)	682/2754 (24.8)	.03 ^b
Infarct-related artery				
Graft, n/N (%)	91/2823 (3.2)	2/69 (2.9)	89/2754 (3.2)	.88
Left main, n/N (%)	21/2823 (0.7)	3/69 (4.3)	18/2754 (0.7)	<.001 ^b
Left anterior descending, n/N (%)	1377/2823 (48.8)	45/69 (65.2)	1332/2754 (48.4)	.006 ^b
Left circumflex, n/N (%)	668/2823 (23.7)	13/69 (18.8)	655/2754 (23.8)	.34
Right coronary, n/N (%)	965/2823 (34.2)	22/69 (31.9)	943/2754 (34.2)	.68
Preprimary PCI TIMI ^k flow <3, n/N (%)	2249/2499 (90.0)	60/65 (92.3)	2189/2434 (89.9)	.53
Postprimary PCI TIMI flow <3, n/N (%)	206/2493 (8.3)	15/65 (23.1)	191/2428 (7.9)	<.001 ^b
Infarcted territory				
Anterior, n/N (%)	1286/2823 (45.6)	43/69 (62.3)	1243/2754 (45.1)	.005 ^b
Inferior, n/N (%)	1240/2823 (43.9)	24/69 (34.8)	1216/2754 (44.2)	.12
Lateral, n/N (%)	425/2823 (15.1)	12/69 (17.4)	413/2754 (15.0)	.58

Characteristic	Overall value	In-hospital MACCEs ^a , value		P value
		Yes	No	
Posterior, n/N (%)	302/2823 (10.7)	4/69 (5.8)	298/2754 (10.8)	.18
Multivessel disease, n/N (%)	1836/2773 (66.2)	48/69 (69.6)	1788/2704 (66.1)	.55
Procedural supports, n/N (%)	29/2820 (1.0)	9/69 (13.0)	20/2751 (0.7)	<.001 ^b

^aMACCEs: major adverse cardiocerebrovascular events.

^bP value for independent sample *t* tests and chi-square tests.

^cEMS: emergency medical service.

^dCVDs: cardiovascular diseases.

^eCPR: cardiopulmonary resuscitation.

^fMI: myocardial infarction.

^gPCI: percutaneous coronary intervention.

^hCABG: coronary artery bypass graft surgery.

ⁱFMC: first medical contact.

^jSTEMI: ST-segment elevation myocardial infarction.

^kTIMI: thrombolysis in myocardial infarction.

The study patients were initially assessed by the medical team with a median time of 1 minute (first medical contact time of 1 minute). For the majority of patients, STEMI was diagnosed in less than 10 minutes after obtaining the first ECG. The median door-to-balloon time was 55 (IQR 40-92) minutes, and door-to-balloon time ≤90 minutes was noted in most of the patients. The median symptom-to-door time and symptom-to-balloon time were 258 (IQR 108-574) and 355 (180-720) minutes, respectively. Additionally, low proportions of symptom-to-door time ≤90 minutes and symptom-to-balloon time ≤180 minutes were observed among the study patients. The left anterior descending artery was the most common infarct-related artery, and the anterior infarcted territory was seen in the majority of patients. Most of the patients had preprimary PCI TIMI flow <3, and a low proportion of patients had postprimary PCI TIMI flow <3. Multivessel disease was observed in the majority of patients, and only 1.03% (29/2820) of patients received procedural support (Table 1).

Outcome Data

During the study period, in-hospital MACCEs occurred in 69 patients (N=2823, 2.4%), and cardiac death (45/2823, 1.6%), target vessel revascularization/target lesion revascularization (16/2823, 0.57%), MI (5/2823, 0.18%), and stroke (3/2823, 0.11%) were the most common events.

Baseline characteristics according to in-hospital MACCEs are presented in Table 1. In the in-hospital MACCE group, there

were more women and patients with age ≥75 years, previous CPR, left main and left anterior descending arteries as IRAs, anterior infarcted territory, initial TIMI flow <3, and procedural support. In contrast, less patients with current smoking, hyperlipidemia, and final TIMI flow <3 were seen in the in-hospital MACCE group (Table 1).

From the different components of time to treatment, only symptom-to-balloon time ≥180 minutes was significantly higher in the in-hospital MACCE group (*P*=.03). Other characteristics were similar between the two groups (Table 1).

Main Results

In the univariate analysis, the symptom-to-balloon time predicted in-hospital MACCEs (OR 2.2, 95% CI 1.1-4.4; *P*=.03), while the symptom-to-door time (OR 1.4, 95% CI 0.7-2.6; *P*=.34) and door-to-balloon time (OR 1.1, 95% CI 0.6-1.8; *P*=.77) were not associated with in-hospital MACCEs.

In the multivariate analysis, after adjustment by age ≥75 years; female gender; current smoking; diabetes mellitus and hyperlipidemia; history of CPR; medical history of PCI; left main and left anterior descending arteries as IRAs; final TIMI flow <3; procedural support; and anterior, inferior, and posterior territories of MI (Multimedia Appendix 1), only symptom-to-balloon time ≥180 minutes was associated with in-hospital MACCEs and was a predictor of in-hospital MACCEs (OR 2.3, 95% CI 1.1-5.2; *P*=.04) (Table 2).

Table 2. Univariate and multivariate analyses of time to treatment and in-hospital major adverse cardiocerebrovascular events.

Characteristic	Unadjusted OR ^a (95% CI)	P value	Adjusted ^b OR (95% CI)	P value
Symptom-to-door time ≥ 90 min	1.4 (0.7-2.6)	.34	N/A ^c	N/A
Door-to-balloon time ≥ 90 min	1.1 (0.6-1.8)	.77	N/A	N/A
Symptom-to-balloon time ≥ 180 min	2.2 (1.1-4.4)	.03 ^d	2.3 (1.1-5.2)	.04 ^e

^aOR: odds ratio.

^bAdjusted by age ≥ 75 years; female gender; current smoking; diabetes mellitus and hyperlipidemia; history of cardiopulmonary resuscitation; medical history of percutaneous coronary intervention; left main and left anterior descending arteries as infarct-related arteries; final thrombolysis in myocardial infarction flow < 3 ; procedural support; and anterior, inferior, and posterior territory of myocardial infarction.

^cN/A: not applicable.

^dIncluded in the multiple logistic regression model ($P < .2$).

^e P value $< .05$.

Discussion

To our knowledge, this is the first study to evaluate the association of treatment times and in-hospital MACCEs among patients with STEMI who underwent primary PCI, according to a 24/7 primary PCI service registry in Iran.

Our study findings indicated that the majority of patients had symptom-to-balloon time ≥ 180 minutes, and it was the only component of time to treatment that was an independent predictor of in-hospital MACCEs among study patients. However, in the study by Song et al in China, there was no association between longer symptom-to-balloon time and in-hospital mortality or MACCEs [25], which may be due to the different classification of the symptom-to-balloon time. In addition, regarding the relationship between treatment time and short-term outcomes, the study by Kim et al showed that a total ischemic time < 180 minutes could be a predictor of 1-month mortality and could lead to a relevant reduction in the 1-month mortality incidence compared with symptom-to-balloon time ≥ 180 minutes [9]. Moreover, symptom-to-balloon time ≤ 240 minutes was reported as a strong predictor of 1-year major adverse cardiovascular events (MACEs) [24]. What is clear in previous studies is the different classifications of the symptom-to-balloon time, which makes it difficult to compare the results of studies and provide a single conclusion about the association between the symptom-to-balloon time and clinical outcomes. Although the door-to-balloon time is well known as a clinical indicator of care quality [29], the symptom-to-balloon time is an estimate of total ischemic time, which is strongly correlated with infarct size and mortality [22], and a longer symptom-to-balloon time results in impaired myocardial perfusion [25] and worse ejection fraction when the left anterior descending artery is the culprit vessel [30]. Thus, the symptom-to-balloon time can be the correct focus of attention for optimal STEMI care instead of its subintervals, such as the door-to-balloon time [22]. In addition, owing to the higher frequency of patients with a longer symptom-to-balloon time in our study setting, efforts and planning should be focused on improving prehospital STEMI diagnosis and direct transfer to the catheterization laboratory, which shortens the treatment time compared with diagnosis in the ED, and it could be associated with less mortality [31].

The symptom-to-balloon time is a combination of two subintervals, including the symptom-to-door time and door-to-balloon time. In our study, the majority of patients had a shorter door-to-balloon time, and the door-to-balloon time was not an independent predictor of in-hospital MACCEs, which was consistent with the finding in the study by Kim et al [9]. In contrast to our study, it has been shown that shortening the door-to-balloon time, even if less than 60 to 90 minutes, is associated with survival benefits [20,32] and lower mortality over time [21]. Moreover, according to a systematic review and meta-analysis in 2019, a longer door-to-balloon time (≥ 90 minutes) is associated with a higher risk of mortality [33]. A door-to-balloon time of < 90 minutes depends on hospital systems and can be achieved easily with effective hospital strategies [34] and by emphasizing on guideline adherence in order to minimize reperfusion delay and improve survival among patients with STEMI undergoing primary PCI [20].

Another subinterval of the symptom-to-balloon time is the symptom-to-door time. In this study, a longer symptom-to-door time was seen, and it was not associated with in-hospital MACCEs. According to a previous study in THC, a higher symptom-to-door time was associated with female gender, transfer via vehicles other than an ambulance, atypical chest pain, low level of education, late night and morning onset of pain, history of hypertension, and opium abuse, whereas a history of CABG was associated with lower prehospital delay [35]. In addition, it was negatively associated with postinfarction left ventricular ejection fraction in patients with STEMI [36]. Although a door-to-balloon time target of < 90 minutes can be achieved easily by effective hospital strategies [34], the time taken for the patient to recognize ischemic symptoms is the main contributor to a longer total ischemic time [34]. Thus, public education about cardiovascular symptoms and a prompt emergency call is necessary in order to reduce the symptom-to-door time in patients with STEMI [37].

In conclusion, among the different components of time to treatment, the symptom-to-balloon time was the only component that was associated with in-hospital MACCEs in the study patients, and a longer symptom-to-balloon time was associated with higher in-hospital MACCEs. It seems that attention should be shifted from the door-to-balloon time, as a care quality indicator among primary PCI service providers, to the

symptom-to-balloon time, as the total ischemic duration, in order to improve clinical outcomes in patients with STEMI undergoing primary PCI. In order to shorten the symptom-to-balloon time and improve clinical outcomes, prehospital emergency systems should be improved and the symptom-to-door time, as the main contributor to a longer symptom-to-balloon time, should be improved by special educational programs to raise public awareness on STEMI symptoms and prompt seeking of medical care.

There were several limitations in this study. First, it was a single-center observational study. Thus, no causal association between time to treatment and MACCEs could be proven conclusively. Second, the study population included patients with STEMI treated with primary PCI, and the study findings cannot be applied to patients with STEMI receiving thrombolytic therapy. Third, Killip class is a variable that may have affected the study results. However, because it was not recorded in the registry, we did not consider it in the analysis.

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Authors' Contributions

All authors fulfilled the authorship criteria based on the recommendations of the International Committee of Medical Journal Editors. YN is the principal investigator of this study. YN, BG, KA, and MN initiated the study design. KA, HA, AA, HP, MS, MA, AH, EN, and SHM helped with implementation and data collection. SHM, MN, and KA prepared the data for statistical analysis. MN performed the statistical analysis. All authors contributed to refinement of the final manuscript and are accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Univariate and multivariate analyses of time to treatment and in-hospital major adverse cardiocerebrovascular events. [[DOCX File , 19 KB - ijmr_v9i4e20352_app1.docx](#)]

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Abbreviations

CABG: coronary artery bypass grafting
CPR: cardiopulmonary resuscitation
CVDs: cardiovascular diseases
ECG: electrocardiogram
ED: emergency department
EMS: emergency medical service
IRA: infarct-related artery
MACCEs: major adverse cardiocerebrovascular events
MI: myocardial infarction
OR: odds ratio
PCI: percutaneous coronary intervention
STEMI: ST-segment elevation myocardial infarction
THC: Tehran Heart Center
TIMI: thrombolysis in myocardial infarction

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Original Paper

Dental Treatments During the COVID-19 Pandemic in Three Hospitals in Jordan: Retrospective Study

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Abstract

Background: Cases of COVID-19 first emerged in December 2019. Since then, the virus has spread rapidly worldwide, with daily increases in the numbers of infections and deaths. COVID-19 spreads via airborne transmission, which renders dental treatment a potential source of virus transmission. Dental treatments require the use of handpieces, ultrasonic devices, or air-water syringes, which generate considerable amounts of aerosols. Jordan, being one of the affected countries, instituted preventive lockdown measures on March 17, 2020. Emergency dental treatments were only allowed in dental clinics of the Royal Medical Services of Jordan Armed Forces and Ministry of Health, and were prohibited in other sectors such as private clinics and universities.

Objective: The aim of this study is to investigate the dental treatments performed in three military hospitals during the 44-day lockdown period in Jordan. The investigation explores the impact of COVID-19 on the number of patients and types of performed dental treatments.

Methods: Data such as number of patients, patients' age and gender, and performed dental treatments were collected retrospectively from the hospital records and were analyzed.

Results: Our results showed a 90% (17,591 to 1689) decrease in patient visits during the lockdown period compared to regular days. The total number of treatments (n=1689) during the lockdown period varied between endodontic cases (n=877, 51.9%), extraction and other surgical cases (n=374, 22.1%), restorative cases (n=142, 8.4%), orthodontic treatments (n=4, 0.2%), and other procedures (n=292, 17.3%). The differences in gender and age group among all clinics were statistically significant ($P<.001$ and $P=.02$, respectively).

Conclusions: The COVID-19 pandemic had a significant effect on the number of patients seeking dental treatments. It also affected the types of treatments performed. Endodontic treatment accounted for almost 50% of patient load during the lockdown compared to approximately 20% during regular days.

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KEYWORDS

COVID-19; dental treatments; Jordan; lockdown; pandemic

Introduction

The World Health Organization declared the outbreak of COVID-19 a Public Health Emergency of International Concern on January 30, 2020. On March 11, 2020, the outbreak was

declared a pandemic [1]. COVID-19 is caused by a novel coronavirus, which is suspected to have originated from an animal host, followed by human-to-human transmission. The symptoms of COVID-19 are mainly respiratory, including fever, body ache, dry cough, fatigue, chills, headache, sore throat, loss

of appetite, and loss of smell [2]. In severe cases, the symptoms worsen to cause respiratory failure. It can also affect other organs, leading to multi-organ failure caused by acute myocardial injury, renal failure, liver injury, or sepsis [3].

Dentists are among the highest occupational risk categories for the transmission and contraction of COVID-19. Routine dental treatments that produce significant amounts of aerosols, composed of saliva, blood, and tissue fluids, are considered to be at high risk for the spread of the virus, as it can spread via airborne transmission. Such treatments include the use of a turbine handpiece, air-water syringes, and ultrasonic scalers. During dental treatment, aerosols from a person who is infected or an asymptomatic carrier can transmit the virus directly to the dentist or dental assistant. Contact with contaminated instruments, surfaces, or airborne particles from such individuals is considered as the possible route of transmission [4]. Accordingly, the American Dental Association (ADA), National Health Service of the United Kingdom, and National Health Commission of China, along with other dental associations worldwide, urged dentists to postpone elective dental procedures and provide only emergency dental treatments [5-7]. The ADA has defined dental emergencies as “potentially life-threatening conditions that require immediate treatment to stop ongoing tissue bleeding and/or alleviate severe pain and/or infection including trauma, cellulitis, and uncontrolled bleeding” [8].

Jordan responded to the pandemic by implementing early lockdown from March 17, 2020 [9], followed by the declaration of a state of emergency on March 20, 2020, and then by implementation of a curfew. During the lockdown period, schools and universities were closed, public gatherings were banned, and borders and airports were shut down. Many activities and practices including public transport, hotels, and restaurants were also restricted. Among medical practices, dental clinics were closed, and emergency dental treatments were restricted to a few clinics in military hospitals and the Ministry of Health. Substantial protective measures were implemented in functional dental clinics to prevent cross-infection and the spread of the virus.

There is a need for establishing clear guidelines and regulations for the management of dental emergency procedures during possible future epidemic or pandemic situations. Accordingly, the aim of this study is to assess the dental treatments performed

in three military hospitals during the lockdown period in Jordan. This research explores the impact of COVID-19 on the number of patients and treatments performed.

Methods

This retrospective study was approved by the ethical committee of Royal Medical Services of Jordan Armed Forces. Data pertaining to patients requiring dental treatments during the lockdown due to the COVID-19 pandemic were obtained from the records of three major military hospitals in Jordan.

Data were collected from the lockdown and prelockdown periods. The lockdown period extended from March 17, 2020, to April 29, 2020 (44 days), during which the Government of Jordan had announced a total lockdown due to the COVID-19 pandemic; this period was referred to as T1. The prelockdown period extended from January 16, 2020, to February 29, 2020 (44 days), before Jordan recorded its first COVID-19 positive case on March 2, and this period was referred as T2. Data from T1 included the number of patients, their age and gender, and the performed dental treatments. Data from T2 included the number of patients and the performed dental treatments. The number of patients and performed treatments were compared between T1 and T2.

Data from T1 were entered and coded using the SPSS software version 17.0 (SPSS Inc). Values were reported as frequencies, means, and SDs. Cross-tabulation was used to test the correlations between variables. *P* values <.05 were considered statistically significant.

Results

During T1, 1689 patients, with an average age of 35.04 (SD 10.96, range 14-87) years, were treated in the three selected major military hospitals. A total of 39 (2.3%) patients were older than 60 years, 650 (38.5%) were aged between 14 and 30 years, and 1000 (59.2%) were aged between 30 and 60 years.

Statistical analysis of the distribution of the 1689 patients visiting the dental clinics in T1 showed that 877 (51.9%) patients were treated in endodontic clinics and only 4 (0.2%) were treated in orthodontic clinics, as depicted in Table 1.

Table 1. Distribution of patients visiting the dental clinics during T1 (the lockdown period extending from March 17 to April 29, 2020; 44 days).

Clinics	Patients (n=1689), n (%)	Valid percentage (%)
Oral surgery	374 (22.1)	22.1
Endodontics	877 (51.9)	51.9
Restorative dentistry	142 (8.4)	8.4
Orthodontics	4 (0.2)	0.2
Others	292 (17.3)	17.3

Further analysis of the distribution of patients visiting dental clinics with respect to gender and age showed that, of all 1689 patients, almost two-thirds were male (n=1105, 65.4%) and

one-third were female (n=584, 34.6%). The differences in gender and age groups among all clinics were statistically significant ($P<.001$ and $P=.02$, respectively), as shown in Table 2.

Table 2. Distribution of patients in terms of gender and age in different clinics during T1 (the lockdown period extending from March 17 to April 29, 2020; 44 days).^a

Clinics	Male age groups (years), n				Female age groups (years), n			
	14-29	30-60	>60	Total	14-29	30-60	>60	Total
Oral surgery	86	113	5	204	62	106	2	170
Endodontics	252	371	14	637	82	151	7	240
Restorative dentistry	33	74	6	113	8	20	1	29
Orthodontics	1	0	0	1	3	0	0	3
Others	72	76	2	150	51	89	2	142
Total	444	634	27	1105	206	366	12	584

^aThe differences in gender ($P<.001$) and age groups ($P=.02$) were statistically significant.

The total number of patients had decreased by 90.4% (17,591 to 1689) when the number of patients visiting dental clinics was compared between T1 and T2. The highest reduction in the number of patients was recorded in orthodontic clinics, and the lowest reduction was observed in endodontic clinics (Table 3).

Table 3. Number of patients visiting dental clinics in T2 and T1.

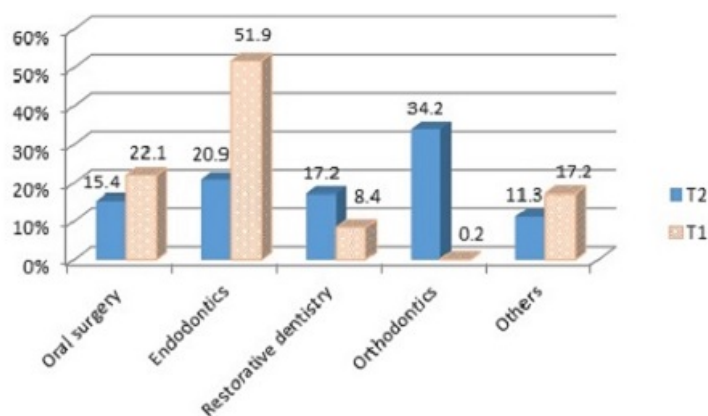
Clinics	T2 ^a , n	T1 ^b , n	Change (%)
Oral surgery	2715	374	-86.2
Endodontics	3683	877	-76.2
Restorative dentistry	3018	142	-95.3
Orthodontics	6146	4	-99.9
Others	2029	292	-85.6
Total	17,591	1689	-90.4

^aT2: prelockdown period extending from January 16, 2020, to February 29, 2020 (44 days).

^bT1: lockdown period extending from March 17, 2020, to April 29, 2020 (44 days).

Although the total number of patients visiting dental clinics decreased in T1, there was a noticeable increase in the proportion of patients visiting endodontic and oral surgery clinics. Out of 1689 patients, 877 (51.9%) required endodontic treatment in T1, while out of 17,591 patients, only 3683 (20.9%) required treatment in T2. Out of 1689 patients, 374 (22.1%) were treated in oral surgery clinics in T1, while out of 17,591 patients, only 2715 (15.4%) were treated in T2 (Figure 1).

Figure 1. Distribution of treated patients in the dental clinics at T1 and T2. T1: lockdown period extending from March 17, 2020, to April 29, 2020 (44 days); T2: prelockdown period extending from January 16, 2020, to February 29, 2020 (44 days).



Discussion

Principal Findings

To the best of our knowledge, this is the first study to analyze the effect of the pandemic on dental treatments during the lockdown period in Jordan. In accordance with the results of other similar studies [10,11], the results of this study also confirmed that the COVID-19 pandemic had detrimental effects on the number of patients seeking dental treatments. Our results show that the COVID-19 pandemic even affected the distribution of patients in different dental specialties. During the lockdown period of 44 days, the number of patients who were treated in the three selected military hospitals was less than during the prelockdown period, in spite of the same duration of the periods (44 days). However, an overall decrease of approximately 90.4% (17,591 to 1689) in the number of patients visiting the dental clinics was observed, although the workload in the military hospitals was expected to increase to compensate for the obligatory closure imposed by the Government of Jordan on private dental practices and clinics across universities. Dental treatments were restricted to limited number of clinics in the Royal Medical Services and Ministry of Health during the lockdown period.

Several reasons could be attributed to the decrease in the number of dental patients and treatments. The primary reason could be the knowledge pertaining to the nature of COVID-19 spreading easily through aerosols, splashes, and droplets, inevitable with almost all types of dental treatments [12-14]. This knowledge has caused fear among patients regarding the possible transmission of the virus through dental treatments. Another reason that could have affected the number of dental patients in Jordan directly was the measures enforced by the Government of Jordan during lockdown; these measures included the ban on the use of private cars and public transport, and emergency transport of citizens being limited to Civil Defence Services [9].

There was also a decrease in the number of treatments performed in different specialty clinics, with the highest decrease being observed in the number of patients visiting orthodontic clinics. In total, only 0.2% (4/1689) of orthodontic patients visited the orthodontic clinics during T1 compared to 34% (6146/17,591) in T2. This represents a decrease of 99.9%, which can be explained by the fact that orthodontic emergencies are well tolerated. The number of performed restorations (amalgam, composite, glass-ionomer, and temporary fillings) also showed a 95.3% (3018 to 142) decrease during the COVID-19 lockdown.

This study showed that more male patients sought dental treatments than female. Of the 1689 patients, 1105 (65.4%) male patients sought dental treatments, in comparison to only 584 (34.6%) female patients. This result is in concordance with that of a similar study [15], which attributed the gender difference to the fact that women are more apprehensive toward dental treatment than men considering the possibility of respiratory infections. However, another study did not show any obvious difference between the number of male and female patients [10].

This total reduction in the number of patients treated in dentistry is alarming, as it increases the risk of dental health deterioration. The reluctance to seek treatment resulting from fear of the virus should not be underestimated. Understanding the current situation can help in the accurate prediction of future dental needs. In addition, requirements for dental services might increase dramatically post COVID-19.

The results of this study show that COVID-19 affected the distribution of patients in different dental specialties. A high percentage of treatments (877/1689, 51.9%) were performed for pulp-related pathosis such as acute pulpitis, acute apical periodontitis, and acute apical abscess. Endodontic emergencies account for the majority of dental emergencies in normal conditions [16], and in this study as well, endodontic emergencies contributed to the largest number of performed dental treatments.

A higher percentage of patients visited oral surgery clinics during the lockdown (374/1689, 22.1%) compared to the prelockdown period (2715/17,591, 15.4%). The performance of other procedures (examination, diagnosis, consultation, and referrals) increased in the COVID-19 lockdown (292/1689, 17.2%) compared to the prelockdown period (2092/17,591, 11.3%). This increase could be attributed to the fact that dentists chose to perform procedures with minimal aerosol generation to relieve the pain of patients, since health authorities worldwide had classified general dentists and dental hygienists as high-risk professions [17]. This has led to the development of fear among dentists and dental assistants regarding the possible transmission of the virus during the performance of dental procedures.

This study shows the effect of the COVID-19 pandemic on dental treatments performed during the lockdown period in Jordan; data from the prelockdown period served as a control. Additional studies are needed to analyze the effects of the COVID-19 pandemic on dental treatments performed in the postlockdown period. Jordan has not attained the peak of infection yet; therefore, the impact on dentistry should be analyzed while the COVID-19 cases are rising.

Conclusion

The COVID-19 pandemic has had a substantial influence not only on the number of patients seeking dental treatments but also on the type of treatment performed. The overall decrease in the number of treated patients was 90.4% (17,591 to 1689). This decrease affected all dental specialties, especially orthodontics. However, endodontic treatments dominated the number of performed treatments during the COVID-19 lockdown, as 51.9% (877/1689) of performed treatments were related to endodontics.

Recommendations

As the pandemic is still not under control, only focusing on the direct causes and control measures of COVID-19 alone could be shortsighted. The possible deterioration in the dental health of the population should be considered. Requirements for dental services might increase dramatically post COVID-19, especially in the field of orthodontics.

In case of a possible second lockdown, augmenting the endodontic specialty with adequate staff and more clinics to help in catering to the increased demands seems essential. Sufficient planning to organize and direct the available dental

resources during and after the COVID-19 pandemic is the needed. There is also a need for regulations and preventive approaches in dental treatments to control the spread of COVID-19 in both governmental and private sectors.

Conflicts of Interest

None declared.

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Abbreviations

ADA: American Dental Association

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Original Paper

Carotid Endarterectomy Versus Carotid Artery Stenting: Survey of the Quality, Readability, and Treatment Preference of Carotid Artery Disease Websites

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Abstract

Background: The internet is becoming increasingly more important in the new era of patient self-education. Carotid endarterectomy (CEA) and carotid artery stenting (CAS) are recognized interventions to treat patients with carotid artery stenosis. Using the Google search platform, patients encounter many websites with conflicting information, which are sometimes difficult to understand. This lack of accessibility creates uncertainty or bias toward interventions for carotid artery disease. The quality, readability, and treatment preference of carotid artery disease (CAD) websites have not yet been evaluated.

Objective: This study aimed to explore the quality, readability, and treatment preference of CAD websites.

Methods: We searched Google Canada for 10 CAD-related keywords. Returned links were assessed for publication date, medical specialty and industry affiliation, presence of randomized controlled trial data, differentiation by symptomatic status, and favored treatment. Website quality and readability were rated by the DISCERN instrument and Gunning Fog Index.

Results: We identified 54 unique sites: 18 (33.3%) by medical societies or individual physicians, 11 (20.4%) by government organizations, 9 (16.7%) by laypersons, and 1 (1.9%) that was industry-sponsored. Of these sites, 26 (48.1%) distinguished symptomatic from asymptomatic CAD. A majority of sites overall (57.4%) and vascular-affiliated (72.7%) favored CEA. In contrast, radiology- and cardiology-affiliated sites demonstrated the highest proportion of sites favoring CAS, though they were equally likely to favor CEA. A large proportion (21/54, 38.9%) of sites received poor quality ratings (total DISCERN score <48), and the majority (41/54, 75.9%) required a reading level greater than a high school senior.

Conclusions: CAD websites are often produced by government organizations, medical societies, or physicians, especially vascular surgeons. Sites ranged in quality, readability, and differentiation by symptomatic status. Google searches of CAD-related terms are more likely to yield sites favoring CEA. Future research should determine the extent of website influence on CAD patients' treatment decisions.

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KEYWORDS

patient information; carotid artery disease; carotid endarterectomy; carotid stenting; carotid stenosis; carotid surgery; Google; quality; readability; treatment; preference; online health information

Introduction

The internet is a popular source of information for Canadians seeking medical advice. According to Statistics Canada, Internet

User Surveys revealed that 91.3% of Canadians used the internet [1], and 69.9% of home internet users searched for health information online [2]. With this trend toward health information acquisition online, carotid artery disease (CAD) poses a particular challenge for medical websites because there is no

consensus on its optimal management [3,4]. Mixed interpretation of data, rapid evolution in technology and expertise, and pharmacotherapy improvements have led to inconsistent treatment guidelines and practice patterns across specialties and organizations [5]. Consequently, CAD patients searching for ways to treat their condition online may struggle to find a clear answer.

The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) aimed to settle the carotid endarterectomy (CEA) versus carotid artery stenting (CAS) debate by eliminating confounding factors present in earlier CAD clinical trials. Strict CAS operator training requirements were implemented, standardized embolic protection devices were employed, and cardiac enzymes, electrocardiogram changes, and clinical presentations were routinely monitored. With its publication in 2010, CREST revealed no significant difference between CAS and CEA up to four years for the composite primary outcome: periprocedural stroke, myocardial infarction (MI), or death and subsequent ipsilateral stroke. The CEA group did demonstrate higher rates of MI and the CAS group higher rates of stroke. [6]. Ten-year CREST results published in March of 2016 yielded similar results that were sustained when the endpoints were stratified by symptomatic status, age, sex, or degree of stenosis [7]. Translation of CREST trial results into clinical practice was explored in a recent study by Otite et al [8]. Interestingly, the utilization of CAS increased post-CREST (2011-2014) compared with pre-CREST (2007-2010) for patients >70 years of age in the United States. Similarly, Hussain et al investigated the effects of clinical trial publications, including the CREST trial, on rates of carotid revascularization procedures in Ontario, Canada, between 2002-2014 [9]. In this period, CEA utilization decreased by 36%, while CAS increased by 72%. The CREST trial and the publication of other conflicting trials between 2006-2010 were associated with a decline in CEA rates [9]. The contradiction in clinical practice and trial results may be attributed to an interplay of multiple factors including, but not restricted to, differential interpretation of trial results, advances in CAS technology, availability and accessibility of physician providers and physician specialty.

CEA has traditionally been the treatment of choice for patients with severe and/or symptomatic carotid stenosis. Nevertheless, with continued advances in best medical therapy (BMT) and the recent equivalent long-term CREST results, BMT and CAS challenge CEA as primary treatment modalities [10]. Variation in patient anatomy, age, comorbidities, surgical risks, use of embolization protection devices, and operator experience further complicate treatment decisions for individual patients. Since many patients today look to the internet for medical advice, we sought to identify the most easily accessible websites to patients, evaluate their quality, readability, and balance of information, and determine whether there was a preference for one treatment option.

Methods

Site Selection

To generate a list of easily accessible CAD websites, we searched ten keywords commonly associated with CAD, such

as “carotid stenosis,” “carotid stenting,” and “carotid endarterectomy” in Google Canada (Multimedia Appendix 1). Google searches yield approximately 10 unique links per page; the top ten websites returned by each search were recorded for a total of 100 websites. Of this sample, websites were excluded from content evaluation if they were repeats from a previous search. Repeat links were recorded to track how frequently a particular website appeared in similar searches. Of all the websites consulted, none was found to be a broken link, lack information regarding carotid disease, require a paid subscription, or be inaccessible.

Demographic Information

Demographic information collected from each site included (1) type of organization that created the website (specifically: physician/hospital/medical department, government organization, industry, layperson, other), (2) specialty affiliation of the website or its authors, (3) year of publication, (4) inclusion of randomized control data, and (5) differentiation between symptomatic and asymptomatic carotid disease for treatment preference.

Assessment Tools

Gunning Fog Index

Each site was evaluated for readability using the Gunning Fog Index (GFI). The GFI estimates the years of formal education required to understand a passage based on the passage's average sentence length and the number of complex words. For ease of use and avoidance of human error, an online calculator was used to calculate the GFI for each website [11]. If a website was divided into various webpages, we evaluated the summary overview webpage or the webpage that encompassed the bulk of the information contained in that site. Texts with near-universal understanding generally require a GFI score <8, indicative of an eighth-grade reading level; a score >12, equivalent to a high school senior reading level, is considered too difficult for the general populous [12].

DISCERN Instrument

Two researchers independently evaluated each site (SS, MY) for reliability and quality using the DISCERN instrument [13]. The DISCERN instrument consists of three sections totaling 16 questions, each with a rating scale from 1 (low, with serious or extensive shortcomings) to 5 (high, with minimal shortcomings). Section one evaluates each publication's reliability based on various factors, including relevance, sources, and balance. Section two explores the quality of information concerning treatment options available. Section three consists of an overall rating of the publication based on sections one and two. Websites that received total DISCERN scores <48 were considered poor quality, as 48 represents an average score of <3 across each subsection.

We deviated from the company's instructions for section two (quality of information) in our use of the DISCERN instrument. Rather than evaluate each site according to how it addressed a single treatment choice, we evaluated each website according to how it addressed all three major treatment modalities for carotid stenosis: BMT, CEA, and CAS. Thus, if a website only

addressed two out of the three main treatment options, that website automatically lost a minimum of one point for each question concerning the description, benefits, risks, and impact of the treatments. This method provided more consistency when comparing a site's ability to honestly and thoroughly inform patients about all treatment options available for carotid disease.

Site Preference

An overall impression of preferred treatment was recorded for each website. Websites were considered to prefer CEA if they (1) stated that CEA was the standard of care; (2) started the discussion with CEA; (3) devoted far lengthier text to CEA without necessarily declaring that it was better; (4) and/or presented CAS as an alternative treatment intended for special circumstances only. These sites often described CEA as "older and effective," "very safe," "traditional," and "durable." Websites were considered to favor CEA and CAS equally if they devoted equal amounts of text to each treatment option and/or did not imply that one treatment was preferable to the other. Websites were considered to prefer CAS if they emphasized CAS as a newer, promising, less invasive option with a shorter hospital stay or devoted far lengthier text to CAS without necessarily declaring that it was better. Treatment preference was recorded as not applicable in websites that focused on transient ischemic attacks (TIAs) and strokes of various etiologies since these did not deal exclusively with carotid disease. For websites that recommended different therapies based on symptomatic status, preference was determined based on the recommendation for the symptomatic patient of average surgical risk.

Statistical Analysis

Statistical analysis was performed in Microsoft Excel. Interrater reliability for the DISCERN ratings was assessed using the

Spearman correlation coefficient. Total DISCERN scores were averaged between the two evaluators. Differences between average total DISCERN and GFI scores for sites that preferred CEA, sites that preferred CAS, and sites that presented CEA and CAS equally were calculated using analysis of variance testing. Chi-square test of independence or Fisher's exact test as appropriate, was performed using an online calculator to determine whether there was a relationship between higher DISCERN scores and the presence of randomized controlled trial (RCT) data among the websites assessed. Spearman correlation coefficient was also employed to determine whether there was a correlation between DISCERN and GFI scores.

Results

Site Demographics

A total of 54 unique CAD websites were identified using the search terms. Among these, 18 (33.3%) were produced by medical societies or individual physicians, 11 (20.4%) were produced by government organizations, 9 (16.7%) were produced by laypersons, and 1 (1.9%) was industry-sponsored (Table 1). Of the websites affiliated with or authored by a particular specialty/specialist, the three most common affiliations were vascular surgery (11 sites), neurology (7 sites), and internal medicine (6 sites) (Table 1). Of note, sites with multiple authors from different specialties were tallied multiple times in this category for each additional specialty represented among the authorship. We found that 44 (81.5%) websites were published after CREST, and 18 (33.3%) mentioned RCT data. Symptomatic was distinguished from asymptomatic disease on 26 sites (48.1%), 14 sites (25.9%) did not distinguish disease types, and 14 sites (25.9%) were excluded from this category because they were symptomatic stroke sites addressing various stroke etiologies (Table 1).

Table 1. Website demographics.

Characteristic	Websites
Organization type, n (%)	
Medical—society	8 (14.8)
Medical—Doctor of Medicine (MD)/Doctor of Osteopathic Medicine (DO)	10 (18.5)
Government	11 (20.4)
Medical—hospital/clinic	8 (14.8)
Medical—journal	4 (7.4)
Medical—university affiliation	2 (3.7)
Layperson	9 (16.7)
Industry	1 (1.9)
Other	1 (1.9)
Medical specialty, n	
Vascular	11
Neurology ^a	7
Neurosurgery	4
Cardiology ^a	4
Internal medicine	6
Family medicine	2
Emergency medicine	2
Radiology ^a	2
Other ^b	3
Not specified ^c	23
Time of Publication, n (%)	
Pre-CREST ^d	7 (13)
Post-CREST	44 (81.5)
Not reported	3 (5.6)
RCT^e data presented, n (%)	
Yes	18 (33.3)
No	36 (66.7)
Distinguish symptomatic vs asymptomatic, n (%)	
Yes	26 (48.1)
No	14 (25.9)
Not applicable	14 (25.9)

^aNeurology includes interventional radiology; cardiology includes interventional cardiology; and radiology includes interventional neuroradiology.

^bOther includes radiation oncology, physical and rehabilitation medicine, and rheumatology.

^cNot specified includes MD unspecified, non-MD, and unspecified author.

^dCREST: Carotid Revascularization Endarterectomy Versus Stenting Trial.

^eRCT: randomized controlled trial.

DISCERN and GFI Data

DISCERN scores from researchers SS and MY demonstrated strong interrater reliability (Spearman $\rho=0.98$). When averaged between the two researchers, DISCERN scores for all sites

ranged from 28.5 to 76 out of a possible 80 points. A total of 21/54 websites (38.9%) received a poor-quality rating (total DISCERN score <48). There was no significant difference between average total DISCERN scores for sites that preferred CEA, sites that preferred CAS, and sites that presented CEA

and CAS equally ($P=.85$). Sites with the ten highest DISCERN scores were more likely to contain RCT data than the remaining sites ($P=.012$). Specialty affiliation among sites with the top 10 DISCERN scores included neurology/neurosurgery (3 sites), vascular surgery (2 sites), and cardiology (2 sites). The remaining three sites did not state affiliation with any specialty, and two were Wikipedia pages.

GFI readability scores ranged from 7.7 to 29.1, and 13 websites received a GFI score of <12 , corresponding with a reading level at or below that of a high school senior. There were no statistically significant differences between average GFI scores for sites that preferred CEA, sites that preferred CAS, and sites that presented CEA and CAS equally ($P=.99$). GFI and DISCERN scores demonstrated a weakly positive correlation (Spearman $\rho=0.34$), indicating that websites containing a higher quality of information do not necessarily require a higher reading level.

Treatment Preference

Overall, most websites (31/54, 57%) demonstrated a preference for CEA, 8/54 (15%) presented CEA and CAS as equal

treatment modalities, and 8/54 (15%) demonstrated a preference for CAS. Treatment preference was considered not applicable (N/A) in 7/54 (13%) of sites due to focus on stroke and TIA of various etiology rather than carotid disease alone. While recommended by most sites in conjunction with either CEA or CAS, best medical therapy was not cited as the best treatment modality *alone* in cases of average surgical risk with sufficiently severe carotid stenosis to warrant intervention. Among the ten sites with the highest DISCERN scores, CEA was preferred in six, CEA and CAS were presented equally in two, and CAS was preferred in two.

Vascular surgery was the most common specialty affiliation, with 72.7% of vascular-affiliated sites favoring CEA, 9.1% presenting CEA and CAS equally, and 18.2% favoring CAS. Likewise, sites affiliated with neurology, neurosurgery, internal medicine, and family medicine more often demonstrated a preference for CEA (ranging from 50%-100% of websites affiliated with that specialty) than for CAS or no preference (Table 2). Websites affiliated with interventional radiology or cardiology demonstrated the highest proportion of sites favoring CAS, though they were equally likely to favor CEA (Table 2).

Table 2. Website treatment preferences by medical specialty of the websites' authors.

Author's medical specialty affiliation (N=41)	Treatment preference, n (%)			
	Carotid endarterectomy	No preference	Carotid artery stenting	Not applicable
Vascular surgery (n=11)	8 (72.7)	1 (9.1)	2 (18.2)	0 (0.0)
Neurology (n=7)	6 (85.7)	0 (0.0)	1 (14.3)	0 (0.0)
Cardiology (n=4)	1 (25.0)	1 (25.0)	1 (25.0)	1 (25.0)
Neurosurgery (n=4)	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Internal medicine (n=6)	3 (50.0)	0 (0.0)	2 (33.3)	1 (16.7)
Interventional radiology (n=2)	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)
Family medicine (n=2)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Emergency (n=2)	0 (0.0)	1 (50.0)	0 (0.0)	1 (50.0)
Other (n=3 ^a)	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)

^aOther includes radiation oncology, physical and rehabilitation medicine, and rheumatology.

Among the 10 keywords searched, 7 yielded a majority of sites that favored CEA. Only one keyword—"carotid stenting"—yielded a majority of sites that favored CAS (Table 3). Of all 8 sites that demonstrated a preference for CAS, 7 appeared in the "carotid stenting" search, 1 appeared in the "carotid artery stenosis" search, and 1 appeared in the "mini stroke" search. The remaining 7 keywords yielded no sites that favored CAS. Two keywords—"TIA" and "mini

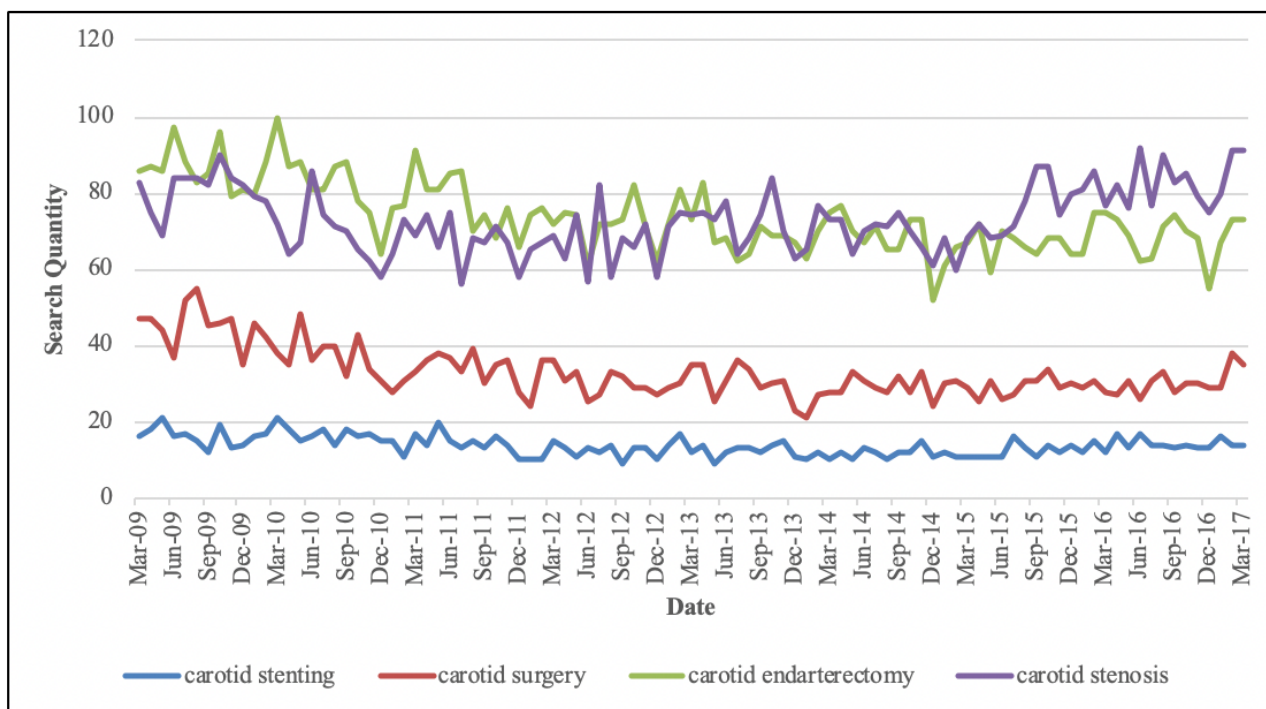
stroke"—accounted for all the sites where treatment preference was deemed not applicable. Every keyword searched generated at least one site that presented CEA and CAS as equal treatment modalities (Table 3). Analysis of Google search trends dating back to 2009 revealed that "carotid stenting" was searched less frequently than "carotid endarterectomy" and "carotid surgery" (Figure 1).

Table 3. Website treatment preference by keyword search.

Keyword search	Treatment preference (number of websites)			
	Carotid endarterectomy, n	Treatments presented as equivalent, n	Carotid artery stenting, n	No preference, n
Carotid endarterectomy	9	1	0	0
Carotid stenosis	8	2	0	0
Carotid artery stenosis	8	1	1	0
Carotid stenting	2	1	7	0
Carotid surgery	9	1	0	0
Carotid blockage	6	4	0	0
Carotid disease	7	3	0	0
TIA ^a	5	1	0	4
Mini stroke	2	1	1	6
Carotid treatment	4	6	0	0

^aTIA: transient ischemic attack.

Figure 1. Google search trends by keyword since 2009.



Discussion

Principal Findings

High rates of reported information-seeking and use of web-based health technology places an onus on health care providers and educators to capitalize on these resources for disease education and management. Healthcare websites must be accessible, have high usability and reliability, and accommodate the average reading level of American adults, which is reportedly between the seventh- and eighth-grade [14,15]. To our knowledge, this is the first study to explore the quality, readability, and treatment preference of CAD websites. We found that CAD websites were often produced by medical societies or physicians (18/54, 33.3%) and government organizations (11/54, 20.4%). Websites

ranged in quality and readability, and higher quality CAD websites did not necessarily require higher user reading levels. Treatment preference varied as a function of physician specialty, with vascular surgery-affiliated websites favoring CEA and interventional radiology and cardiology-affiliated websites favoring CAS.

Consistent with current literature and guidelines, the majority of CAD websites demonstrated a preference for CEA. Abbott et al conducted a systematic review of guideline recommendations for the management of asymptomatic and symptomatic CAD published between 2008 and 2015. Of 28 guidelines with asymptomatic and 33 guidelines with symptomatic CAD procedural recommendations, 24 (86%) and 31 (94%) endorsed CEA for patients with average surgical risk.

For symptomatic patients deemed higher surgical risk (due to comorbidities, unfavorable carotid anatomy, etc), CAS was endorsed by 27 guidelines (82%) [5]. Recently, Brott et al conducted a pooled analysis of individual patient-level data acquired from the four largest RCTs completed to date, assessing the relative efficacy of CAS versus CEA for treatment of symptomatic carotid stenosis. They showed that long-term outcomes continue to favor CEA. However, improvements in the periprocedural safety of CAS could provide similar outcomes of the two procedures in the future [16]. The majority of CAD websites reflect the treatment preference of medical practitioners for patients at average surgical risk.

The majority of RCTs investigating CEA versus CAS found significant differences in perioperative outcomes, largely in symptomatic patients [17]. In our study, 48.1% (26/54) of CAD websites distinguished between symptomatic and asymptomatic CAD. Complication risks associated with CAE and CAS are higher in symptomatic than in asymptomatic patients [4,18]. Researchers have speculated that symptomatic carotid disease is associated with greater overall cardiovascular risk. Studies have also shown that annual stroke risk is lower for asymptomatic patients than symptomatic patients [18]. The benefit of CEA is greater among symptomatic compared [19-23] and remains the gold standard for this patient population [24,25]. Currently, clinical equipoise remains regarding the optimal management of asymptomatic CAD, as evidenced by the recent review article by Abbot et al and the response by Cambria et al, with the former advocating for optimal medical intervention as routine practice and the latter defending the use of mechanical intervention for asymptomatic patients [3,4]. Differentiation by symptomatic status is crucial in determining disease management, procedural risk, and subsequent treatment preference.

Treatment preference for CAD websites varied as a function of physician specialty. Variation in patient treatment preferences is largely physician-driven, as the patients often depend on their physicians to prescribe appropriate treatment [26]. Provider enthusiasm for treatment recommendations may be driven by several factors, including availability, accessibility and operator experience, sociodemographic factors, and provider specialty.

Wallaert et al examined the relationship between physician specialty and annual rates of CAS and CEA using Medicare claims from 2002 to 2010 [26]. Cardiologists performed the majority of CAS procedures, and regions with the highest proportion of cardiologists performed the most CAS procedures. Cardiologists and interventionalists have led efforts to extend CAS funding, while surgeons and neurologists have cautioned against expanding CAS approval outside of clinical registries and trials [26]. These findings are consistent with our findings that vascular surgery-affiliated websites favor CEA, and interventional radiology and cardiology-affiliated websites are more likely to favor CAS by comparison. Interestingly, a study by Keogh et al found that the number of available online CAS-related peer-reviewed sources is double the number of hospital- or health service-generated resources; the opposite is true for CEA [27]. Hospital and health service resources lend themselves to patient populations, which is reflected in the observation of higher readability of CEA than CAS resources

[27]. The source of information—physician specialty, peer-reviewed sources, hospitals, or health services—influence website treatment preference in addition to readability based on the resource's intended audience.

It is recommended that patient health materials be written at or below the fourth to sixth-grade reading level by the American Medical Association (AMA), National Institutes of Health, and the Centers for Disease Control and Prevention [28]. If written below the sixth-grade level, material is considered easy to read; if written between the seventh and ninth grade levels, it is of average difficulty; and if written above the ninth grade level, it is difficult to read [14]. A minority of CAD websites included in our study (13/54, 24%) received a GFI score of less than twelve, corresponding with a reading level at or below that of a high school senior. A recent study also found that 99.5% of online cardiovascular disease-related health education materials recommended by the AMA were written above the fifth to sixth-grade level [29]. Our study found that the CAD websites' readability was higher than recommended, which could have far-reaching implications for patients' health literacy [29]. However, it is important to note that readability is only one element of literacy. The GFI may not reflect the reading level as it relies on the number of syllables in a word and the number of words in a sentence. Overall readability may be influenced by images, layout, design, and content organization [30]. As the internet is a growing resource for health information, it is critical to ensure web-based health resources are written at a level accessible to the general patient population.

Additional limitations of this study must be taken into account. The literacy level of carotid stenosis patients may differ from that of the average American, and web-based resources written at a higher readability level may or may not be appropriate for this subgroup. While the DISCERN tool has demonstrated validity and reliability for evaluating the quality of online health information for treatment choices across conditions, there is subjectivity involved for certain rating criteria, which introduces interstudy variability when comparing studies and interrater variability within studies. However, our study demonstrated strong interrater reliability (Spearman $\rho=0.98$). Also, this study looked at static web-based delivery of health education. There is speculation that an interactive health education delivery approach, compared with a static one, may allow health material to be tailored to readers of a wide breadth of educational backgrounds. The literature has shown that adults with chronic illnesses have associated online health information use with behavior changes and decision-making [31]. Future research should assess how interactive web-based technologies, such as blogs and social networking sites, compared to websites, affect patient-provider communication.

This study did not assess the usability and social reach of CAD websites. Future studies should evaluate how websites are engaging audiences. Many methods can be used to do so, including but not limited to (1) the LIDA online app to assess the usability of healthcare websites [27]; (2) global estimated website traffic over 30 days and over 3 months; and (3) counts of social bookmarking/networking links [31]. It is well known that patient preference for participation in health care varies greatly. Future research would also benefit from evaluating

CAD patients' decision-making preferences and preferences for online information regarding treatment options. The Health Information Wants Questionnaire collects data on the information and associated decision-making autonomy patients want in seven areas of health care [32].

Conclusion

CAD websites were most often affiliated with, or authored by, vascular surgeons, and CAD-related Google search terms were more likely to yield sites favoring CEA. Sites ranged in quality, readability, and differentiation by symptomatic status. Further research is needed to determine if website treatment preferences consistently and appropriately influence final treatment decisions by patients with carotid artery disease.

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SS and MY completed data collection, data analyses, and drafting of the manuscript. AB was involved in drafting and editing the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of keywords used for Google Search.

[DOCX File , 12 KB - [ijmr_v9i4e23519_app1.docx](#)]

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Abbreviations

AMA: American Medical Association

BMT: best medical therapy

CAD: coronary artery disease

CAS: carotid artery stenting

CEA: carotid endarterectomy

CREST: Carotid Revascularization Endarterectomy versus Stenting Trial

GFI: Gunning Fox Index

MI: myocardial infarction

RCT: randomized controlled trial

TIA: transient ischemic attack

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Original Paper

Using Friendship Ties to Understand the Prevalence of, and Factors Associated With, Intimate Partner Violence Among Adolescents and Young Adults in Kenya: Cross-Sectional, Respondent-Driven Survey Study

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Abstract

Background: Optimization of innovative approaches is required for estimating the intimate partner violence (IPV) burden among adolescents and young adults (AYA). Further investigation is required to identify risk and protective factors associated with IPV among AYA. There remain significant gaps in understanding these factors among this vulnerable population.

Objective: The goal of our study was to determine the prevalence of IPV among an urban population of AYA and to identify factors associated with IPV among AYA.

Methods: A cross-sectional study design utilizing respondent-driven sampling was adopted. The study was conducted among 887 AYA, aged 15 to 24 years, residing in Nairobi, Kenya. Data were collected through a phone-based survey using the REACH (Reaching, Engaging Adolescents and Young Adults for Care Continuum in Health)-AYA app. Questions on behavioral and psychosocial factors were adopted from different standardized questionnaires. Descriptive, bivariate, and multivariable statistics were used to describe the characteristics of the study sample.

Results: Of the 887 participants, a higher proportion were male (540/887, 60.9%) compared to female (347/887, 39.1%). The prevalence of IPV was 22.3% (124/556). IPV was associated with being unsure if it was okay for a boy to hit his girlfriend, living in a home with physical violence or abuse, and being bullied ($P=.005$). The likelihood of experiencing IPV was higher among respondents whose friends and family members used alcohol (odds ratio [OR] 1.80, 95% CI 1.09-2.98) and among those who had repeated a class at school in the past two years (OR 1.90, 95% CI 1.11-3.23). Respondents who visited a health facility or doctor for reproductive health services were 2 times more likely to experience IPV (OR 2.23, 95% CI 1.40-3.70). Respondents who had used illicit drugs were 2 times more likely to experience IPV (OR 4.31, 95% CI 2.64-7.04). The probability of experiencing IPV decreased by 63% (OR 0.37, 95% CI 0.16-0.85) among respondents who refused to have sex with someone who was not prepared to use a condom.

Conclusions: IPV remains a significant public health priority because of its impact to society. Our results are in congruence with other similar studies. Efforts toward incorporating appropriate IPV core measures into the comprehensive care package for every AYA seeking health services should be explored. Programs need to address constellations of risk and protective factors linked to IPV in an effort to prevent its occurrence.

KEYWORDS

intimate partner violence; adolescents; young adults; bullying; physical abuse; abuse; Africa; prevalence; risk

Introduction

While efforts have been made in Kenya to address gaps in intimate partner violence (IPV) programming [1], little has been done to understand the epidemic from the perspective of adolescents and young adults (AYA) [2]. The World Health Organization (WHO) reports a 19% to 66% lifetime prevalence of IPV among AYA who are between the ages of 10 and 24 years [3]. IPV is characterized as behavior by a partner that causes emotional, sexual, or physical abuse, as well as other controlling behaviors, and generally occurs from adolescence to adulthood [4,5]. Consequently, IPV survivors are at risk of suffering from poor social and health outcomes related to reproductive health, substance use, sexual health, and mental health [6].

Risk factors for AYA operate at multiple levels that include individual, dyadic (ie, interactions with peers, partners, or parents), community (ie, school environment), and societal levels [7]. At the individual level, young age, low level of education, childhood sexual abuse, drug and alcohol use, and mental health are some of the risk factors for IPV. Economic hardships, relationship conflicts, and patriarchy have been associated with IPV risk at the dyadic level. Furthermore, lack of legal sanctions against IPV and women's civil rights, violence, poverty, and gender inequality norms are associated with community- and societal-level factors [8]. Thus, the identification of such multifaceted determinants of risky behaviors is critical in informing contextually relevant interventions in Kenya [9,10]. Risk factors can be mitigated by employing protective factors, such as social support, quality friendships, access to resources, funding for services to support community-based initiatives and interventions, and community cohesiveness [7].

In Kenya, there are significant gaps in IPV-prevention knowledge among AYA. Prevention strategies should be developed with nuance, especially because there is a lack of adequate well-coordinated efforts incorporating interventions that address biological, behavioral, psychosocial, and structural factors among AYA in Kenya [11]. Adolescents are avid users of mobile devices, and frequent virtual communication among adolescents has been shown to strengthen the quality of existing relationships [12]. Network analysis and content analysis of adolescent online communication shows that most of their online communication involves positive interactions between friends, and that mobile devices are used as tools for better understanding and supporting their positive development [13]. Access to mobile phones among young people is steadily increasing, with no difference in penetration between formal and informal settings [14]. The rapid increase in mobile penetration in Kenya provides platforms for social interactions and engagements [15], with AYA more likely to own smartphones. This is exacerbated by declining costs and increasing reliance on mobile phones, even in the most

resource-poor settings [14]. Communicating information via mobile phones is highly appealing to young people and can positively influence their health outcomes by improving knowledge, reducing sexual risk behavior, and increasing the use of health services [16]. Additionally, mobile phones offer more privacy compared to face-to-face meetings with researchers or health care providers [15], an aspect embraced by AYA. Furthermore, mobile phone solutions may help users overcome barriers to accessibility by soliciting and providing accurate, timely, and engaging information and appropriate care related to highly sensitive topics [16]. Therefore, using a piloted, interactive, digital survey tool, this study adopted a comprehensive psychological, social, and developmental perspective focusing on variables related to AYA's IPV experiences in Kenya. Our digital survey tool assessed behavioral and psychosocial aspects among AYA between the ages of 15 and 24 years; the prevalence of IPV among AYA in Nairobi was determined and factors associated with IPV risk among AYA were identified.

Methods

About the App

The REACH (Reaching, Engaging Adolescents and Young Adults for Care Continuum in Health)-AYA interactive mobile app survey combines existing screening tools, adapted for use jointly with AYA in Kenya through a co-design process. The tools, which were reported in our other published studies, include the WHO, multicountry, gender-based violence study screening tool; the HEEADSSS (Home, Education/employment, Eating, Activities and peer relations, Drugs and alcohol, Sexuality, Suicide/depression, and Safety) assessment instrument [17]; the CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble) screening tool [18]; and the RAST (Risk Assessment Screening Tool) that was adapted by the Kenya Ministry of Health. The app required location access in order to ensure participants resided within Nairobi. Participants did not have to complete the questions all at one time and had the ability to change responses as needed. The survey was structured into 10 modules: (1) social network and support, (2) education, (3) home and family, (4) media and internet use, (5) alcohol and drugs, (6) sexuality, (7) use and perception of health services, (8) mental health, (9) gender and social norms, and (10) religion and spirituality. The app was downloaded from Google Play or the Apple Store and could be used offline only to communicate with the REACH web application once the survey was completed. Data were then synchronized with the hosting server over the mobile network.

Study Implementation

Prior to study implementation, a team of AYA researchers, health care professionals experienced with AYA, and Nairobi AYA reviewed the data collection instrument and mobile app design. A pilot was conducted to access the mobile app and

iterations were performed. We tested the app on 13 potential users selected from our institutional community youth programs from a neighboring county—Kiambu County, due to its proximity and similarity to Nairobi—in order to gain a sense of usability and determine where it may need improvements. Testing assessed three constructs: (1) functionality, (2) time, and (3) adaptability. As part of the iterative process, it was further vetted among 33 AYA, aged 15 to 24 years, who provided user feedback to specific questions. Once the technical and business requirements were met, the app was ready for launch and beta testing among a broader group of young people; further information on the pilot test is included in a manuscript that is currently under review.

The study targeted 1061 AYA between the ages of 15 and 24 years. Sample size was calculated for a simple random sample without replacement and adjusted for the clustered nature of the survey and for the finite population correction, yielding a total sample size of 564. Respondent-driven sampling was used for this study population. The theoretical advantage of using respondent-driven sampling among a seldom-heard population is that the dual-incentive system of financial reward in combination with peer pressure could reduce nonresponse bias, since those who would not participate for financial reasons alone may do so as a favor to a friend [19].

Our REACH-AYA Facebook page [20] was used to initiate recruitment; the recruitment process was monitored by our website [21] to ensure that all age groups were represented. Study participants each received 300 Kenyan shillings (US \$3) electronically once they completed the survey and an additional 100 Kenyan shillings (US \$1) of airtime (ie, phone credit that could be used for calling or browsing) for each friend that was referred and completed the survey, up to a maximum of five friends. All payments and transactions were automated via phone (ie, mobile phone transfer) to minimize human interaction and to promote confidentiality.

Data were captured using Microsoft Excel 2018 with an interface to the app-based survey. As part of the app's download process, all consenting and enrolled participants were uniquely identified by a participant ID on the central database in Microsoft Excel. Participants within a social network were additionally linked by a network ID.

Data Analysis

The analysis of data from the formative study included the following components: (1) prevalence of IPV and descriptive analysis of participants' sociodemographics and (2) descriptive, bivariate, and multivariate analysis of factors contributing to protective and risk factors associated with experiencing IPV.

Outcome Variable

Intimate violence was classified as a composite variable of physical, sexual, and emotional violence. To determine the presence of physical violence, women were asked whether a current or former partner had ever slapped her or thrown something at her that could hurt her; pushed or shoved her; hit her with a fist or something else that could hurt her; kicked her, dragged her, or beaten her up; choked or burned her on purpose; or threatened her with, or actually used, a gun, knife, or other

weapon against her. Sexual violence was defined by the following three behaviors: being physically forced to have sexual intercourse against her will, having sexual intercourse because she was afraid of what her partner might do, or being forced to do something sexual she found degrading or humiliating. Emotional violence included the following: being insulted or made to feel bad about oneself, being humiliated or belittled in front of others, being intimidated or scared on purpose (eg, by a partner yelling and smashing things), or being threatened with harm, directly or indirectly, in the form of a threat to hurt someone the respondent cared about.

Other Variables

In addition to gender and age, other data collected included sociodemographic data (ie, school status, living arrangements, and economic status), religion and spirituality data, gender norms (ie, beliefs and perceptions of the roles of boys and girls), health activities (ie, sexuality, exercise, and diet), risk behaviors (ie, drugs, alcohol, and sex), psychosocial status (ie, suicidal feelings and depression), and social networks. Coding and statistical analysis were done using Stata 14 (StataCorp). Descriptive statistics were used to summarize participants' characteristics. Associations between the studied variables and outcome measures were analyzed using bivariate analysis, with all variables that had *P* values of .05 or lower being subjected to multivariable logistic regression. The magnitude of association was measured using adjusted odds ratios (ORs) and 95% CIs. *P* values lower than .05 were considered statistically significant.

Ethical Approval

Approval for this study was obtained from both the Ethics and Scientific Review Committee of Amref Health Africa in Kenya and the Institutional Review Board of the University of West Florida. All ethical procedures were conducted and maintained throughout the study period.

Results

IPV Prevalence

The prevalence of IPV in our population was 22.3% (124/556). A significantly higher proportion of male participants (64/124, 51.6%) had experienced IPV compared to female participants (60/124, 48.4%) ($P=.01$). Age was not included in the analysis tables, as it was not associated with IPV (see [Multimedia Appendix 1](#)).

IPV, Social Network, and Behavioral Risk Factors

Bivariate Comparison of Participant Characteristics and Gender

A significantly higher proportion of females (218/320, 68.1%) versus males (308/526, 58.6%) had used the internet to search for health information. There was a significant difference between males (143/318, 45.0%) and females (231/505, 45.7%) who claimed that their friends sometimes let them down. Compared to their female counterparts (212/504, 42.1%), a significantly higher proportion of males (159/313, 50.8%) reported to have never been bullied in school.

Bivariate Comparison of Participant Characteristics and IPV Prevalence

Variables that were significantly associated with IPV included respondents doing the following: using the internet to search for information about health issues, reporting that sometimes their friends asked them to do things that they were not very sure about, being criticized by friends, being made angry by friends, often being let down by friends, socializing with a diverse crowd, being bullied at school, having been suspended from school, having had friends or family who used tobacco, and having used illegal drugs to get high ($P < .05$).

Regression Analysis

Upon unadjusted analysis, male respondents were significantly less likely to experience IPV as compared to females (OR 0.62, 95% CI 0.41-0.92). Respondents who were rarely criticized by their friends were 74% less likely to experience IPV as compared to those who were criticized most of the time (OR 0.26, 95% CI 0.14-0.49). Similarly, the probability of experiencing IPV was reduced by 79% (OR 0.21, 95% CI 0.08-0.56) among respondents who claimed that their friends never let them down as compared to those who were let down most of the time. Respondents who were rarely made angry by friends were significantly less likely to experience IPV as compared to those who were made angry most of the time (OR 0.23, 95% CI 0.13-0.43). Those who socialized with people of the opposite sex were twice as likely to experience IPV relative to those who socialized with a diverse crowd (OR 2.12, 95% CI 1.32-3.40). Similarly, those who were bullied just once were twice as likely to experience IPV relative to those who had never been bullied (OR 2.01, 95% CI 1.17-3.44). The likelihood of experiencing IPV increased by 90% among respondents who had repeated a class in school in the past two years (OR 1.90, 95% CI 1.11-3.23). Respondents living in households that had physical violence or abuse were 3 times more likely to experience IPV relative to those living in homes with no physical violence or abuse (OR 3.70, 95% CI 2.27-6.04).

Respondents whose friends or family used tobacco were twice as likely to experience IPV as compared to those whose friends or family did not (OR 2.55, 95% CI 1.65-3.95). Similarly, the likelihood of experiencing IPV significantly increased by 80% among respondents who had friends or family members who used alcohol (OR 1.80, 95% CI 1.09-2.98). Respectively, during the previous 12 months, respondents who drank a few sips of alcohol and smoked marijuana or hashish were more likely to experience IPV (OR 1.64, 95% CI 1.08-2.49; and OR 1.84, 95% CI 1.17-2.87). The likelihood of experiencing IPV significantly increased by over 2 folds among respondents who had visited a health facility or doctor to receive reproductive health services (OR 2.23, 95% CI 1.40-3.70). The probability of experiencing IPV significantly decreased by 63% among respondents who refused to have sex with someone who was not prepared to use a condom (OR 0.37, 95% CI 0.16-0.85).

Upon adjusted analysis, the likelihood of experiencing IPV significantly increased by over 9 folds among respondents who had been suspended from school as compared to those who considered dropping out (OR 9.73, 95% CI 1.26-75.26). Respondents who resided in homes with physical violence or

abuse were 8 times more likely to experience IPV as compared to those that did not (OR 8.90, 95% CI 1.43-55.42).

Availability of Data

Data used in the analyses for this study are available upon request from the corresponding author.

Discussion

Principal Findings

This study assessed behavioral and psychosocial aspects among AYA between the ages of 15 and 24 years as well as the prevalence of IPV among AYA in Nairobi. Consistent with other studies, these findings demonstrate that females were more likely to experience IPV than males [22,23]. In addition, the IPV prevalence of 22.3% among the AYA, 15 to 24 years of age, who participated in the survey is consistent with other global findings among 15-49-year-old women, where IPV prevalence ranged from 15% to 71% in sub-Saharan Africa [24,25]. In relation to social well-being, these findings demonstrate that friendship ties were linked to IPV, thus calling for improved utilization of such ties in understanding IPV among AYA. The interaction between peer influence and adolescent behavior [26,27] was based on homophily theories [28], which state that similarities between AYA and their friends are due to socialization effects. Based on the findings, socialization across genders has different effects on the likelihood of experiencing IPV. Respondents who socialized with people of the opposite sex were twice as likely to experience IPV in contrast to those who socialized with a mixed crowd.

Positive peer influences are linked to protective behaviors among AYA, while negative peer influences are linked to risky behaviors [29]. For example, in the findings, respondents who were satisfied with their social networks and had positive peer interactions (ie, were rarely let down, less criticized, and less angry) were less likely to experience IPV.

IPV is characterized by violence, which is a learned behavior, such that those AYA brought up in violent homes are more likely to perpetuate or suffer from IPV [30-33]. Concurrent with other studies, this study established that respondents who resided in homes with physical violence or abuse were 8 times more likely to experience IPV as compared to those who did not. Children brought up in violent homes are likely to use violence in interpersonal relationships to dominate others, based on the influence of the modeled behavior [34-36]. Additionally, children who see their parents use a weapon are more likely to commit an offense involving a weapon as an adult [37]. Adolescents' peer relationships are influential and can adversely impact their behaviors [38]. Supportive peer relationships serve as a buffer against violence [39]. The findings from this study established that those who experienced bullying, repeated a class in school, and were suspended from school were more likely to experience IPV compared to their peers who had not gone through such experiences. Programs that seek to utilize schools to prevent IPV among AYA [40] should, therefore, accord special attention to students who have been suspended and/or have undergone bullying.

Our findings demonstrate that participants who used or had social networks that used tobacco, alcohol, or marijuana were more likely to experience IPV compared to those not indulging in such maladaptive behaviors. Deviant peers are linked to a diverse range of delinquent behaviors, including drug use [27,41-43]. Drug and alcohol use are associated with the perpetration of dating- and gender-based violence [44] and physical assault [45]. While a causal relationship between IPV and substance use and abuse cannot be inferred, a positive correlation has been documented [25,46].

Based on the findings, respondents who refused to have sex with someone who was not prepared to use a condom had a significantly reduced likelihood of experiencing IPV. Such findings are encouraging because previous studies have demonstrated that IPV and condom use have an inverse relationship. For example, men who perpetrated violence against their female partners were less likely to engage in consistent condom use [47].

Regarding health information, our findings demonstrate that the majority of the participants were savvy with technology and knew how to find information on the internet related to health issues regarding their bodies, sex, or general issues. The internet supports health-related services among AYA [48], and such health information-seeking behavior may reduce the chances of IPV among AYA; hence, targeted utilization of the internet could be an alternative method for supporting women experiencing IPV [49,50]. Nevertheless, the internet has a lot of inaccurate information, so AYA should be made aware of legitimate websites and how to screen out inaccurate information.

The likelihood of experiencing IPV significantly increased by over 2 folds among respondents who had visited a health facility or doctor to receive reproductive health services. Given that health systems provide a suitable entry point for the advancement of well-being for adolescents [51], these findings

affirm the need to explore the integration of appropriate IPV-preventive strategies within youth-friendly clinics.

Novelty of the Results From This Study

In the adolescent space, friendship ties play a significant role since they are the most salient networks through which behavioral and normative influences are shared. This study, therefore, clearly highlights the significance of adolescent friendship ties as avenues to understand the context of IPV among AYA. These networks can be leveraged to address occurrences of IPV and to examine the risk of IPV among adolescents.

Limitations

This study utilized a cross-sectional sample that may limit the likelihood of generalizing findings to the general population of AYA. In addition, the app was only accessible to people who could download it on their mobile phones or other technological apparatus. Thus, information from AYA who are not technologically savvy or from those who experienced technological difficulties was not collected. In future, such youth can serve as the control sample. In addition, the study sample was only from one part of Kenya (ie, Nairobi), which limits comparison with other AYA in other cities. Nevertheless, this study served as a pilot that can be enhanced and rolled out to other cities in Kenya and Africa.

Conclusions

Maladaptive friendship ties, violence at home, health information-seeking behaviors, and alcohol and drug use have significant roles in the experience of IPV and can be utilized to identify the risk and protective factors associated with IPV among AYA. IPV-prevention strategies in this vulnerable population should be contextualized to meet targeted needs. Efforts toward integrating IPV prevention in youth-friendly clinics is critical. In addition, adequate funding and policies that support such efforts are necessary.

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Authors' Contributions

PM conceived the study, performed analysis and interpretation of data, drafted the manuscript, and critically reviewed the manuscript. EN, FH, YO, SM, and CC contributed to data editing, performing analysis and interpretation of data, developing the draft manuscript, and the critical review of the manuscript. All authors participated in the critical appraisal and revision of the manuscript and read and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Participant characteristics and risk factors associated with intimate partner violence (IPV).

[DOCX File , 65 KB - [ijmr_v9i4e19023_app1.docx](#)]

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Abbreviations

AYA: adolescents and young adults

CODESRIA: Council for the Development of Social Science Research in Africa

CRAFFT: Car, Relax, Alone, Forget, Friends, Trouble

HEEADSSS: Home, Education/employment, Eating, Activities and peer relations, Drugs and alcohol, Sexuality, Suicide/depression, and Safety

HISTP: HIV Intervention Science Training Program

IPV: intimate partner violence

OR: odds ratio

RAST: Risk Assessment Screening Tool

REACH: Reaching, Engaging Adolescents and Young Adults for Care Continuum in Health

WHO: World Health Organization

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Original Paper

Leveraging Walking Performance to Understand Work Fatigue Among Young Adults: Mixed-Methods Study

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Abstract

Background: Work fatigue negatively impacts personal health in the long term. Prior research has indicated the possibility of leveraging both walking parameters and perceptual measures to assess a person's fatigue status. However, an effective and ubiquitous approach to assessing work fatigue in young adults remains unexplored.

Objective: The goals of this paper were to (1) explore how walking rhythms and multiple streams of data, including reaction time, self-reports, and an activity diary, reflect work-induced fatigue in the lab setting; (2) identify the relationship between objective performance and subjective perception in indicating fatigue status and fatigability; and (3) propose a mobile-based assessment for work-induced fatigue that uses multiple measurements.

Methods: We conducted a 2-day in-lab study to measure participants' fatigue status using multiple measurements, including the stair climb test (SCT), the 6-minute walk test (6MWT), and the reaction time test. Both the SCT and the 6MWT were conducted at different points in time and under 2 conditions (measurement time, including prior to and after work, and pace, including normal and fast). Participants reported their fatigue perception through questionnaires completed before conducting walking tests and in an activity diary recorded over a week. Walking performance data were collected by a smartphone with a built-in 3-axis accelerometer. To examine the effect of fatigability on walking performance, we first clustered participants into 2 groups based on their reported mental fatigue level in the entry surveys and then compared their walking performance using a generalized linear model (GLM). The reaction time was examined using a 2-way repeated-measures GLM. We conducted semistructured interviews to understand participants' fatigue perception after each day's walking tests.

Results: All participants (N=26; mean age 24.68 years) were divided into 2 groups—the fatigue-sensitive group (11/26, 42%) and the fatigue-nonsensitive group (15/26, 58%)—based on their mental subscores from 3 entry surveys: Fatigue Scale-14, Three-Dimensional Work Fatigue Inventory, and Fatigue Self-Assessment Scale (FSAS). The fatigue-sensitive group reported a significantly higher FSAS score in the before-work setting ($t_{50}=-3.361$; $P=.001$). The fatigue-sensitive group covered fewer steps than the fatigue-nonsensitive group ($\beta_1=-0.099$; SE 0.019; $t_1=-5.323$; $P<.001$) and had a higher step-to-step time variability in the 6MWT ($\beta_1=9.61 \times 10^{-4}$; $t_1=2.329$; $P=.02$). No strong correlation between subjective and objective measurements was observed in the study.

Conclusions: Walking parameters, including step counts and step-to-step time variability, and some selected scales (eg, FSAS) were found to reflect participants' work-induced fatigue. Overall, our work suggests the opportunity of employing mobile-based walking measurements to indicate work fatigue among young adults.

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KEYWORDS

work fatigue; fatigability; walking performance; 6MWT; mobile health

Introduction

Cognitive fatigue induced by intense or prolonged work has become a severe health issue among young adults and may result in depression and other mental conditions if not relieved in time [1]. In a study conducted by Johnston et al [2], researchers found that it was the cognitive demand rather than the physical work that led to persistent fatigue perception among nurses. The sustained mental work compressed in a short amount of time may have a severe negative impact on an individual's well-being [2]. Fatigue is a complex reported syndrome that is associated with one's physical and mental functionalities [3,4]. According to Enoka and Duchateau [3], fatigue has two interdependent attributes: perceived fatigability and performance fatigability. Both attributes are used to characterize the trait and state properties of fatigue [3]. The trait level of fatigue describes a person's fatigue experienced in the preceding several days, whereas the state level of fatigue represents the changes of one's fatigue status in response to a fatiguing task [3]. Drawing on the taxonomy of fatigability in the literature [3,4], we categorize work-induced fatigue among young adults in the working environment as a state level of fatigue, which could be measured from both perceived (subjective) and performance (objective) aspects.

To investigate both perceived and performance fatigability in current practice, researchers leverage subjective and objective measurements [3-5]. We categorize the subjective measurements of fatigue, which are usually questionnaires, into 3 genres: (1) general fatigue scales [6], (2) specific fatigue indexes (physical, mental, work, or emotional) [7-9], and (3) auxiliary diagnoses to evaluate health status, such as sleep quality and diet. In particular, the Fatigue Scale-14 (FS-14) [6], the Three-Dimensional Work Fatigue Inventory (3D-WFI) [7], and the Fatigue Self-Assessment Scale (FSAS) [8,9] have subscales evaluating physical and mental aspects. They are all valid and applicable to healthy and subhealthy populations of 18 years and older. The FSAS is specifically designed in accordance with the cultural characteristics and language habits of Chinese populations [8,9]. It has been clinically evaluated and has adequate internal consistency, with an overall Cronbach α of .953 [8,9]. The 18-item 3D-WFI identifies work exhaustion from physical, mental, and emotional dimensions [7]. Notwithstanding the effectiveness of using scales to understand perceived fatigue, such data collection methods require users to manually record experience data. Especially in field studies, recording fatigue perception upon system prompts in different situations would put a high demand on participants and cause interruptions to their ongoing work [10]. The demand placed on users points to a need to consider measuring people's fatigue status through nonintrusive methods, such as passive sensing.

Prior research has demonstrated that physical outcome variables, for example, heart rate variability [11], reaction time (or flicker perception time) [12], and walking performance, can reflect the level of cognitive fatigue. These measurements are thought to be more reliable (less biased due to their objective nature) and less obtrusive to participants' everyday life as opposed to self-reported data. Specifically, some variables, such as reaction time and walking performance, could be easily captured by

daily mobile and wearable devices like smartphones and smartwatches. For example, Iwaki and Harada [12] designed a mobile app to measure reaction time and exploited it to infer cognitive fatigue. In addition, walking performance measurements like the 6-minute walk test (6MWT) have been widely used in prior work to indicate individuals' physical and mental health status [13-16]. Researchers have extracted multiple walking parameters (eg, step count, speed, covered distance in the given time) to reflect one's cognitive fatigue. For example, in a single- and dual-task 6-minute walking study with 16 young adults and 16 older participants, researchers found that only older adults' walking performance was susceptible to mental fatigue, manifesting as an increase in their gait variability in the dual-task condition (ie, walking speed, stride length, stance time, double support time, and swing time) [17].

With the development of mobile and wearable computing technologies, the investigation of fatigue can be expanded into everyday contexts [18-23]. Prior work on fatigue measurements mainly tested these variables in the lab setting, which was limited in ecological validity. In recent years, researchers have employed walking performance measurements like the 6MWT in field studies to measure fatigability [24,25] and physical capability [15,26]. However, little research has been done to investigate how physical performance, as well as the subjective perception of fatigue, can reflect users' state fatigue triggered by cognitive work in a natural setting. The association between individuals' physical performance, subjective perception of fatigue, and real-life work status remains unstudied yet highly valuable. By identifying the impact of intense or prolonged work on people's performance and their perception related to fatigability, researchers can predict people's work performance and productivity and further make health interventions. In addition, there is also little work examining work-induced fatigue among young healthy adults, who usually do not get sufficient clinical care but face a high risk of being mentally exhausted and worn out [27]. Therefore, in order to investigate perceived and performance fatigability among young adults, we conducted a 2-day in-lab study to examine how physical performance and subjective perception could indicate young adults' work-induced fatigue status. In particular, we aimed to answer 3 research questions: (1) How do different subjective and objective measurements indicate fatigability among young adults? (2) Is there a relationship between subjective and objective measurements of fatigability among young adults? and (3) How should we design mobile health systems that are effective and user-friendly for young adults?

To answer the 3 research questions in this paper, we designed a smartphone-based integrated measurement framework that used the 6MWT as an essential assessment to investigate Chinese college students' and young researchers' work fatigue. We employed reaction time and walking tests (ie, the stair climb test [SCT] and the 6MWT) as the 2 main objective measures, as well as 3 subjective scales (ie, FS-14, FSAS, and 3D-WFI). We used these measures to compare the performance and perception data between a fatigue-nonsensitive group and a fatigue-sensitive group, which were grouped by participants' reported fatigue level preceding their participation in the study.

Overall, the contributions of this work are threefold. First, we demonstrate the feasibility of using selected walking parameters (ie, step count and step-to-step time variability) to indicate work fatigue among young healthy adults. Second, we investigate the relationship between perceived fatigue and performance measurements of fatigue and their capabilities of reflecting work-induced fatigue. Third, combining perceived and performance measurements of work-induced fatigue, we propose a mobile design framework, along with 3 design implications.

Methods

Overview

The goal of our study was to investigate performance fatigability and perceived fatigability among young adults who conduct intense cognitive work daily. Moreover, we aimed to understand the relationship between subjective and objective measurements surrounding the state property of fatigability. To achieve these goals, we conducted a 2-day in-lab study to examine participants' physical performance in different conditions, varying the test's time of occurrence and walking pace. By implementing walking tests at different times, we studied how participants' fatigue changed as their work proceeded.

Participant Recruitment

We randomly selected 26 participants (14 women and 12 men; mean age 24.68 years, SD 4.34) out of 49 volunteers from Tsinghua University who met the screening requirements. To meet the eligibility criteria of this experiment, participants had to (1) have no walking disabilities, (2) work at least 6 hours per day, and (3) have not been involved in workout activities during work. All participants reported high research pressure and work stress. The average work duration per day was 9.10 (SD 1.59) hours during the last 3 months, and the average self-reported work-induced fatigue score (within the last 3 months) was 7.80 (SD 1.35) out of 10. We ensured that the selected participants met our research criteria based on their activity diaries and responses to the questionnaires. In the study, participants were free to schedule their personal work and time to relax. The actual measurement time was dependent on participants' work schedules and therefore varied from person to person.

Selecting Fatigue Measurements

In this study, we applied both subjective and objective fatigue measurements. In terms of subjective measurements, we referred to the literature and selected the FS-14 [6], FSAS [8,9], and 3D-WFI [7]. These measurements cover the examination of general fatigue level and work-related fatigue level in the mental subscales. The selection of objective measurements was based on the criteria that (1) the investigated data could be captured in the working environment, (2) the measurements were not obtrusive to participants' regular work, and (3) the measurements could reflect a person's real-time or nearly real-time fatigue state. Based on the criteria, we selected walking performance and reaction time for investigation. First, walking

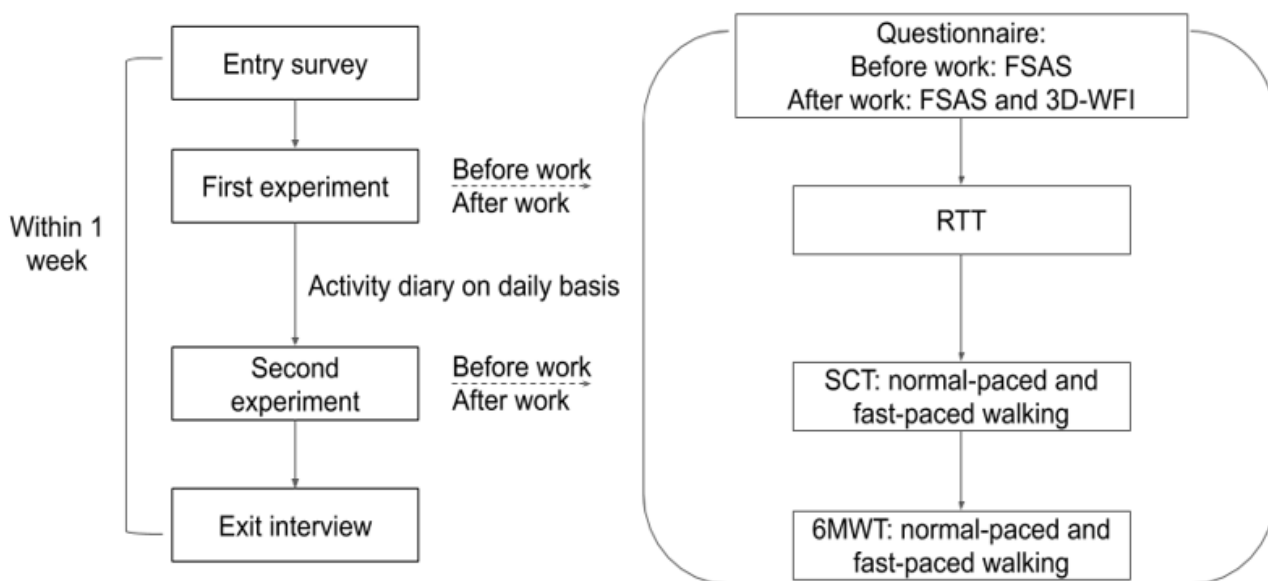
performance has been demonstrated to be a valid physical measurement that indicates older adults' cognitive fatigue [17], but it has not been validated in young adults. Moreover, the measurement of walking performance could be conducted by smartphones without additional sensors. Among various walking performance tests, we selected the 6MWT because the short duration was thought to be less intrusive on a person's daily work and more acceptable. Second, reaction time has been widely used in prior work to measure cognitive fatigue in situ [18]. It can be executed within a minute and implemented on personal devices such as laptops and smartphones [18]. In our study, we were interested in examining how these variables reflect fatigability and how they correlate with one another.

Experiment Design and Procedure

The goal of our study was to explore the effect of work-induced fatigue on multiple variables, including walking performance, reaction time, and subjective perception. We first grouped our participants into 2 groups (fatigue-nonsensitive group and fatigue-sensitive group) based on their perceived work fatigue level in the preceding 6 months. We then conducted a 2-day in-lab walking test to measure participants' walking performance before and after their work time. The walking tests were conducted under 2 settings (stair climbing and flat-ground walking) and at 2 different paces (normal and fast pace), resulting in 4 walking conditions. Each participant was required to perform the walking tests under each condition before and after work. Thus, the number of computing instances for a single participant was 16 (2 days \times 2 times \times 2 paces \times 2 settings). In addition to the walking test, we applied a reaction time test (RTT) to assess participants' fatigue performance. For perceptual measures, participants were required to fill out a set of scales at the beginning of each day's tests, including FS-14, FSAS, and 3D-WFI (only applied to the after-work test). The questionnaires were used to study participants' perceived work fatigue and its change throughout the day. In addition, we invited participants to record their daily activities during the week of the study. This was to help us investigate participants' work-related schedules, which might affect their fatigue perception and performance.

The experiment procedure is shown in [Figure 1](#), with specific items noted. On each visit, upon participants' arrivals, they were asked to first fill out a questionnaire and then conduct the RTT. Next, we invited participants to conduct the SCT and 6MWT at normal and fast paces. Participants were not allowed to pause between the SCT and 6MWT. There were 16 steps (15 cm in height for each stair), and the participant was required to walk up and down 2 levels of the building, resulting in 64 steps in total. The flat-ground walking test had no constraints and participants walked to the end and back of a 75-m corridor. The start point and end point were clearly marked on the ground. After the walking tests, we held a brief semistructured interview with our participants, asking questions such as "How are you feeling right now after taking the walk?" and "Did you have any difficulties in the fast-paced walking?"

Figure 1. Experiment procedures. 3D-WFI: Three-Dimensional Work Fatigue Inventory; 6MWT: 6-minute walk test; FSAS: Fatigue Self-Assessment Scale; RTT: reaction time test; SCT: stair climb test.



Device

A set of digital questionnaires were offered to participants, and they were required to take an online computer-based RTT prior to each walking test. The RTT that we used in the study was developed by Human Benchmark (see Figure 2) [28], and we adapted the colored block into a full screen to avoid other website components disrupting participants. Participants were asked to click as fast as possible when they perceived that the red block (ready mode) turned green (react mode). To measure

walking performance, we used a benchmark sensor system (ErgoLab; Beijing King Far Corp) and an Android smartphone (Huawei 5C with 3-axis accelerometer sensors built in) (see Figure 3). The ErgoLab accelerometer sensor (frequency of 64 Hz) was placed on the participants’ right wrist, the same side as the hand holding the smartphone. Data from the sensor were used as ground truth data for smartphone sensor data processing and analysis. In their right hands, participants carried an Android smartphone with a mobile app installed to collect and preprocess the walking data.

Figure 2. Reaction time test user interface [28]: (1) preparation of the test and instructions, (2) “wait for green” text alerting users that test has begun, (3) appearance of green and the text hint “Click!” and (4) result shown to users, with average result attached.

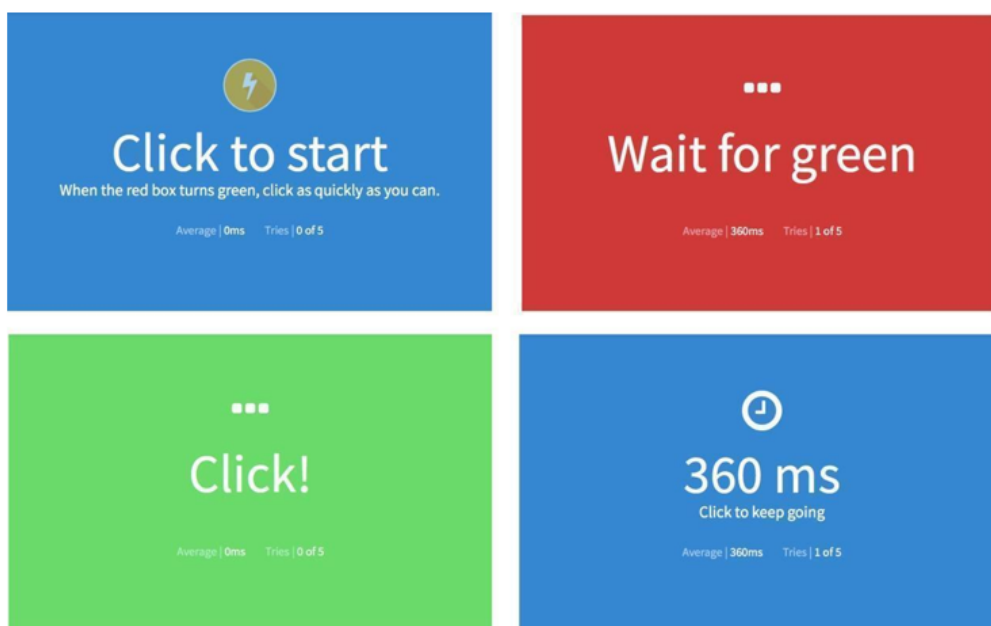
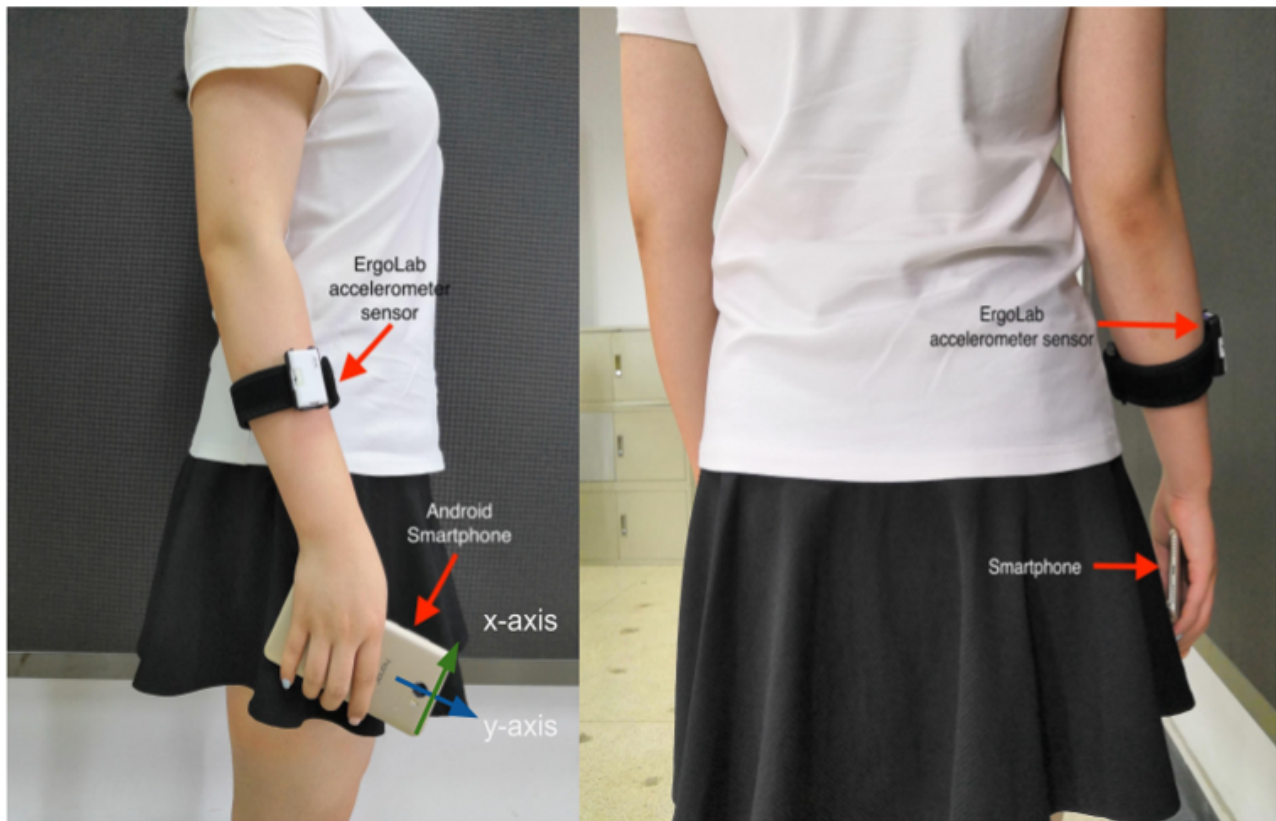


Figure 3. Participants wore the ErgoLab sensor and carried the Huawei smartphone during the walking tests.

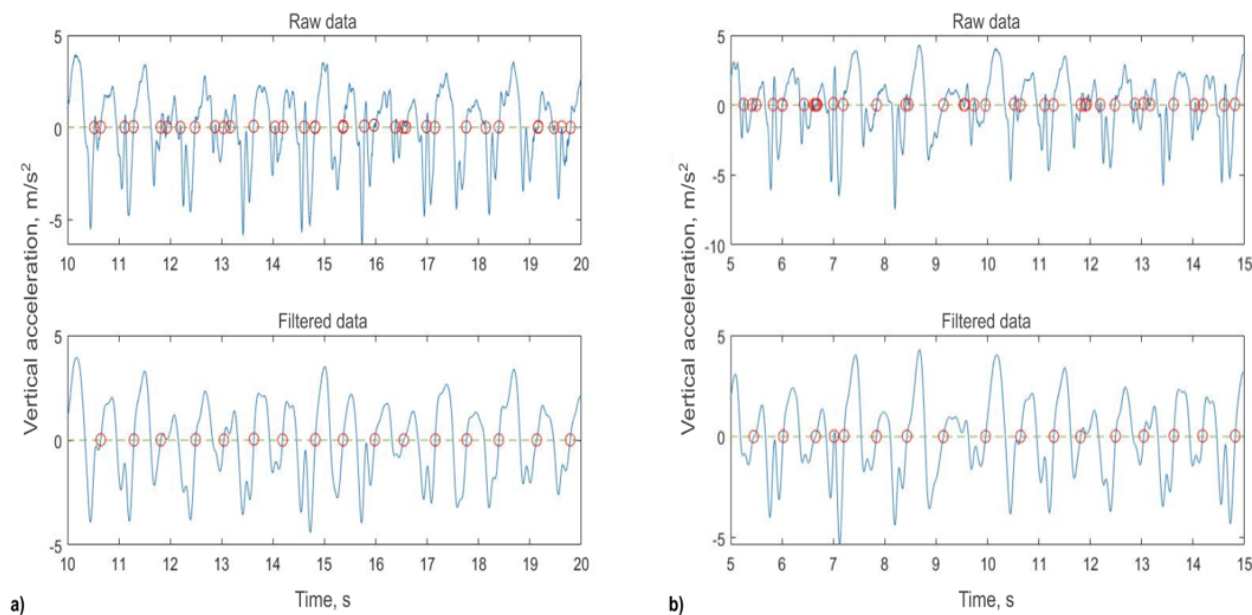


Walking Signal Processing

The sampling frequency of the smartphone built-in sensor was around 30 to 50 Hz. The unequal sampling frequency was caused by the delay of the software reading in the accelerometer data. For signal processing, we referred to the algorithm proposed by Capela et al [29], which offered a solution to analyze the calibration-free 6MWT data [29]. The signal processing was conducted through MATLAB (MathWorks Inc). We first resampled the data to 30 Hz to address the unequal sampling frequency issue. We then applied a fourth-order zero-lag Butterworth low-pass filter using 4 Hz as the cutoff frequency [29]. We applied a moving window of 4 seconds to analyze the vertical acceleration data and identified positive zero-crossings for step detection (see Figure 4). In Figure 4, all positive

zero-crossings were labelled and used to determine the step duration. Based on the study by Capela et al [29], we set the thresholds of step duration time as between 0.4 seconds and 0.7 seconds. We also set the rule that the time change between 2 consecutive steps should not exceed 20%. Otherwise, we would drop the positive zero-crossing data and take the average of the prestep and poststep time duration as the current step time. As we instructed our participants to hold the smartphone in their hand, we processed and analyzed both the x-axis and y-axis signals (the z-axis signal was uncorrelated with the walking direction). The results from both the x-axis and y-axis signals were compared with ground truth data. We found that the results from the x-axis signal had higher accuracy in this study. Therefore, we adopted data from the x-axis for analysis.

Figure 4. We adopted the x-axis for signal processing and presented two 5-second computing examples.



Statistical Analysis

The mental subscores of the 3 entry surveys were first rescaled to 0 or 1 and used to divide all the participants into 2 groups. The clustering performance was evaluated using a silhouette coefficient and a 2-tailed Welch t test due to unequal variance and unequal sample sizes. The silhouette score was used to measure how well data points were matched to the clustered group. We applied a repeated-measures generalized linear model to compare the step counts between the fatigue-sensitive group and fatigue-nonsensitive group. We chose quasi-Poisson regression to model the step count data, as it is generally used for modeling count data and performs better when there is overdispersion in the model [30]. It is also advantageous in comparing the performance of 2 groups with unequal sizes. We applied dummy coding for the grouping variable (fatigue-nonsensitive group: 0; fatigue-sensitive group: 1), time (before work: 0; after work: 1), and pace (normal: 0; fast: 1). We used a linear mixed-effects model to analyze step-to-step time variability. Linear mixed-effects models do not require the data to be independent (different walking trials of a person might be intercorrelated) and can account for both fixed and random effects. In the models for both step count and step-to-step time variability, we had 3 categorical variables, which were time, pace, and group membership, and participants were treated as random effects. A 2-way repeated-measures generalized linear model with group membership and time as independent variables was applied to analyze the reaction time because of the unequal

sample size in the 2 clustered groups. For correlation analysis, we applied Pearson correlation analysis. It was used to investigate the relationships between walking performance and the fatigue perception information that was acquired by questionnaires. We used the correlation coefficient r to determine the strength of the correlation between two variables (strong correlation was >0.8). Statistical significance was defined as $P < .05$ for all tests. In addition to the quantitative results, we also present activity diary data and key findings from the interviews.

Results

Generating Group Memberships and Analyzing Subjective Scales

In Table 1, we present the subjective scale data collected during the entry survey and the 2-day in-lab sessions. The FS-14 is a yes-or-no questionnaire, so in our analysis, it was first adapted into the 1 or -1 rating form. We grouped all participants into 2 groups (group 1: $n=11$; group 2: $n=15$; silhouette coefficient=0.429). Results showed that participants in group 1 reported significantly higher fatigue related to cognitive work on all 3 scales (see Table 2). We classified group 1 as the fatigue-sensitive group, that is, participants who were more likely to perceive exhaustion and tiredness due to cognitive work. In contrast, participants in the fatigue-nonsensitive group were relatively less likely to perceive fatigue under similar workloads.

Table 1. Subjective scale performance of all participants.

Scales	FS-14 ^a	3D-WFI ^b (total)	3D-WFI (mental)	FSAS ^c (total)	FSAS (mental)
Score, range	-14 to 14	0 to 72	0 to 24	0 to 56	0 to 32
Type	Mental	Total score	Mental	Total score	Mental
Overall, mean (SD) ^d	3.00 (1.06)	49.42 (11.88)	18.15 (4.16)	36.46 (12.26)	9.77 (3.49)
Day 1					
Before work, mean (SD)	N/A ^e	N/A	N/A	30.95 (9.59)	21.13 (5.82)
After work, mean (SD)	N/A	57.60 (13.57)	19.88 (4.87)	39.36 (9.21)	23.24 (5.03)
Day 2					
Before work, mean (SD)	N/A	N/A	N/A	31.88 (8.82)	21.04 (5.32)
After work, mean (SD)	N/A	49.96 (11.22)	17.81 (3.94)	37.50 (9.62)	22.77 (5.82)

^aFS-14: Fatigue Scale-14.^b3D-WFI: Three-Dimensional Work-Fatigue Inventory.^cFSAS: Fatigue Self-Assessment Scale.^dThe overall mean was the average score of the measurements that participants took before performing all the tests.^eN/A: not applicable.**Table 2.** The *t* tests are performed on mental subscores collected from the FS-14, FSAS, and 3D-WFI in entry surveys to examine the clustering performance.

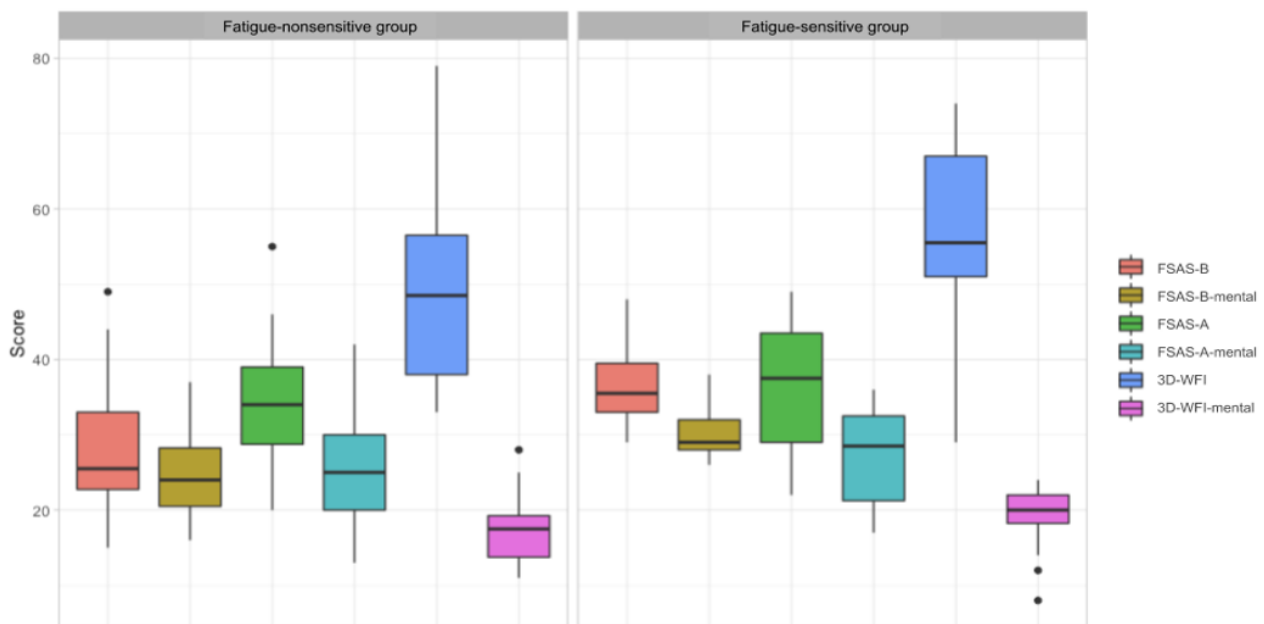
Scale	FS-14 ^a (mental)	FSAS ^b (mental)	3D-WFI ^c (mental)
Fatigue-sensitive group, mean (SD)	-5.40 (0.47)	7.47 (0.91)	21.27 (0.47)
Fatigue-nonsensitive group, mean (SD)	-1.00 (0.62)	-3.55 (0.77)	15.87 (0.49)
<i>P</i> value	<.001	<.001	<.001
<i>t</i> test (<i>df</i>)	-5.18 (22.27)	-6.01 (18.80)	-4.22 (21.40)

^aFS-14: Fatigue Scale-14.^bFSAS: Fatigue Self-Assessment Scale.^c3D-WFI: Three-Dimensional Work-Fatigue Inventory.

The perception data in [Figure 5](#) presents participants' responses to the 3D-WFI and the FSAS (before and after work) in the 2-day lab study. The *t* tests performed on each scale showed that the fatigue-sensitive group reported significantly higher scores on both the before-work FSAS ($t_{50}=-3.361$; $P=.001$; 95%

CI -14.27 to -3.50) and the before-work FSAS mental ($t_{50}=-3.30$; $P=.002$; 95% CI -8.91 to -2.11) compared with the fatigue-nonsensitive group. No significant difference was found in terms of the change in responses to the FSAS.

Figure 5. Participants reported their fatigue perception using the 3D-WFI and FSAS in the 2-day in-lab study. A: after work; B: before work; FSAS: Fatigue Self-Assessment Scale; 3D-WFI: Three-Dimensional Work Fatigue Inventory.



Reaction Time

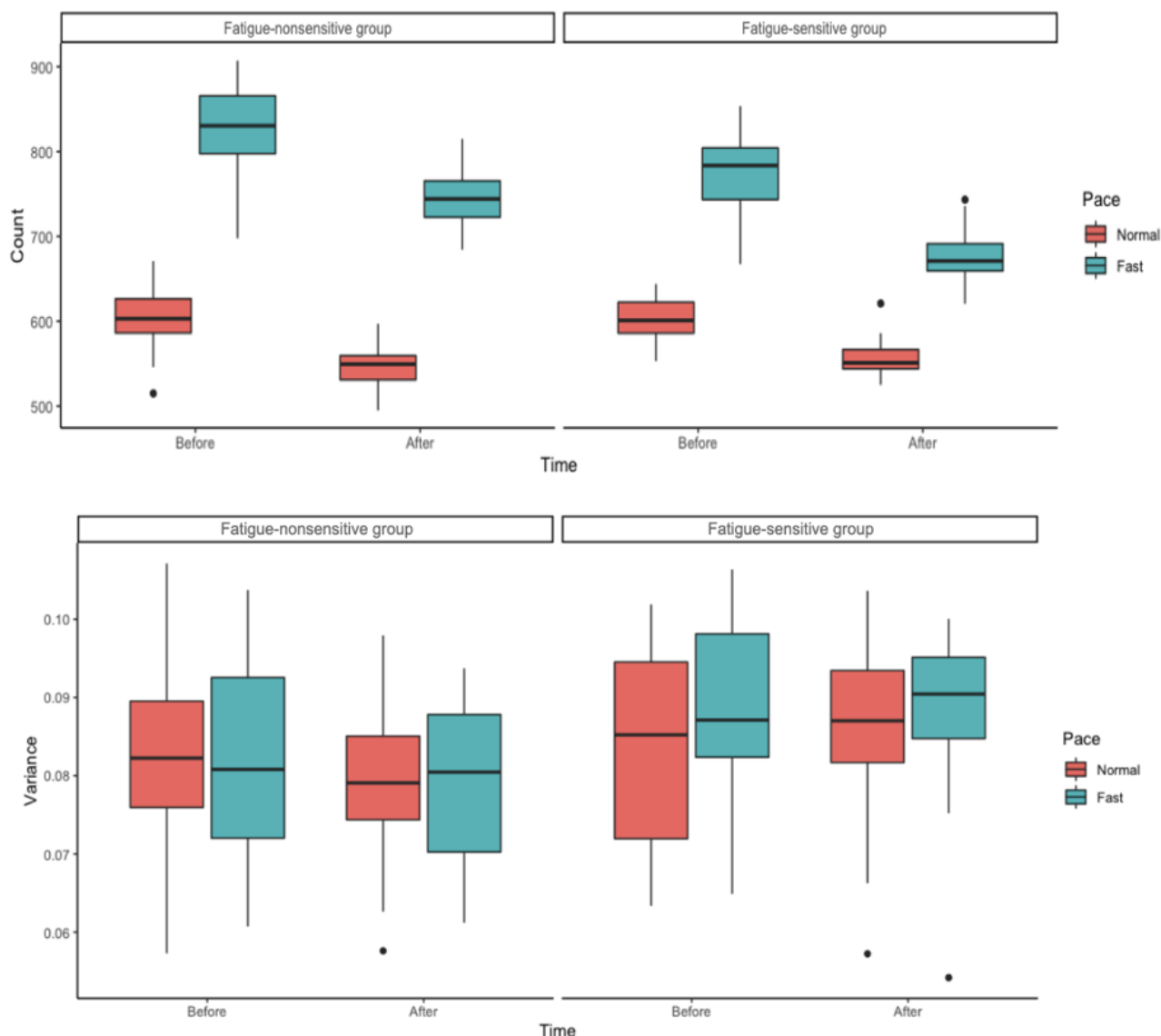
Participants conducted 5 trials for each RTT, resulting in 520 trials in total (mean 313.47, SD 72.17 milliseconds). We did not exclude the maximum or minimum data unless participants claimed that they had difficulty using the system. There was no significant difference between the average reaction times (in milliseconds) in the fatigue-sensitive group (before work: mean 295.63, SD 37.99; after work: mean 310.83, SD 29.87) and the

fatigue-nonsensitive group (before work: mean 306.33, SD 47.78; after work: mean 308.39, SD 53.33). However, from before work to after work, the average reaction time variance of all participants was significantly increased by 9.15 milliseconds ($t_{25}=-2.31$; $P=.03$).

Walking Performance

In Figure 6, we present the step count data and step-to-step time variability of the 6MWT for the 2 groups.

Figure 6. Above: Participants' step counts in the 6-minute walk test under different conditions. Below: Participants' step-to-step time variability in the 6-minute walk test under different conditions.



Results from the 2 models showed that group membership ($\beta_1=-0.099$; SE 0.019; $t_1=-5.323$; $P<.001$), time ($\beta_2=-0.102$, SE=0.016; $t_1=-6.370$; $P<.001$), and pace ($\beta_3=0.309$, SE=0.018; $t_1=17.289$; $P<.001$) all had a significant effect on step counts in the 6MWT. There was also an interaction effect between group membership and pace ($\beta_5=0.119$, SE=0.028; $t_1=4.240$; $P<.001$) on step counts in the 6MWT. This means that the change in step counts from normal to fast pace was significantly higher in the fatigue-nonsensitive group compared with the fatigue-sensitive group regardless of the measurement time. In terms of the step-to-step time variability, only group membership had a significant effect on step-to-step time variability ($\beta_1=9.61 \times 10^{-4}$; $t_1=2.329$; $P=.02$). This means that, overall, compared with the fatigue-sensitive group, the fatigue-nonsensitive group could maintain more stable step rhythms within the 6 minutes. No significant difference was observed in the SCT under different conditions.

Relationship Between Subjective and Objective Measurements

Overall, there was not a strong correlation between subjective and objective measurement variables. There was a moderate correlation between average cadence (natural and fast-paced walk after work) and the 3D-WFI mental subscore ($r=0.46$; $P<.001$). However, step-to-step time variability during after-work walk tests did not show a significant correlation with the 3D-WFI mental subscore. The change in FSAS scores during the day had a moderate correlation with step-to-step time variability in the after-work trials ($r=0.40$; $P=.004$).

User Interview

We did a brief semistructured interview after each walking test with participants. Under most conditions, most participants (20/26) reported that they felt refreshed after taking a walk, especially after the fast-paced walk in the before-work experiment, yet they had not expected such a positive outcome. On the contrary, nearly all participants (22/26) reported that they felt exhausted during the after-work trials. Particularly,

they perceived more difficulties in keeping the initial pace during the after-work fast-paced trials compared with the before-work trials. Interestingly, participants seemed to have anticipated their walking performance before taking the walking tests. For example, nearly half of the participants (12/26) told us that they had anticipated their unsatisfactory walking performance in the after-work fast-paced trials.

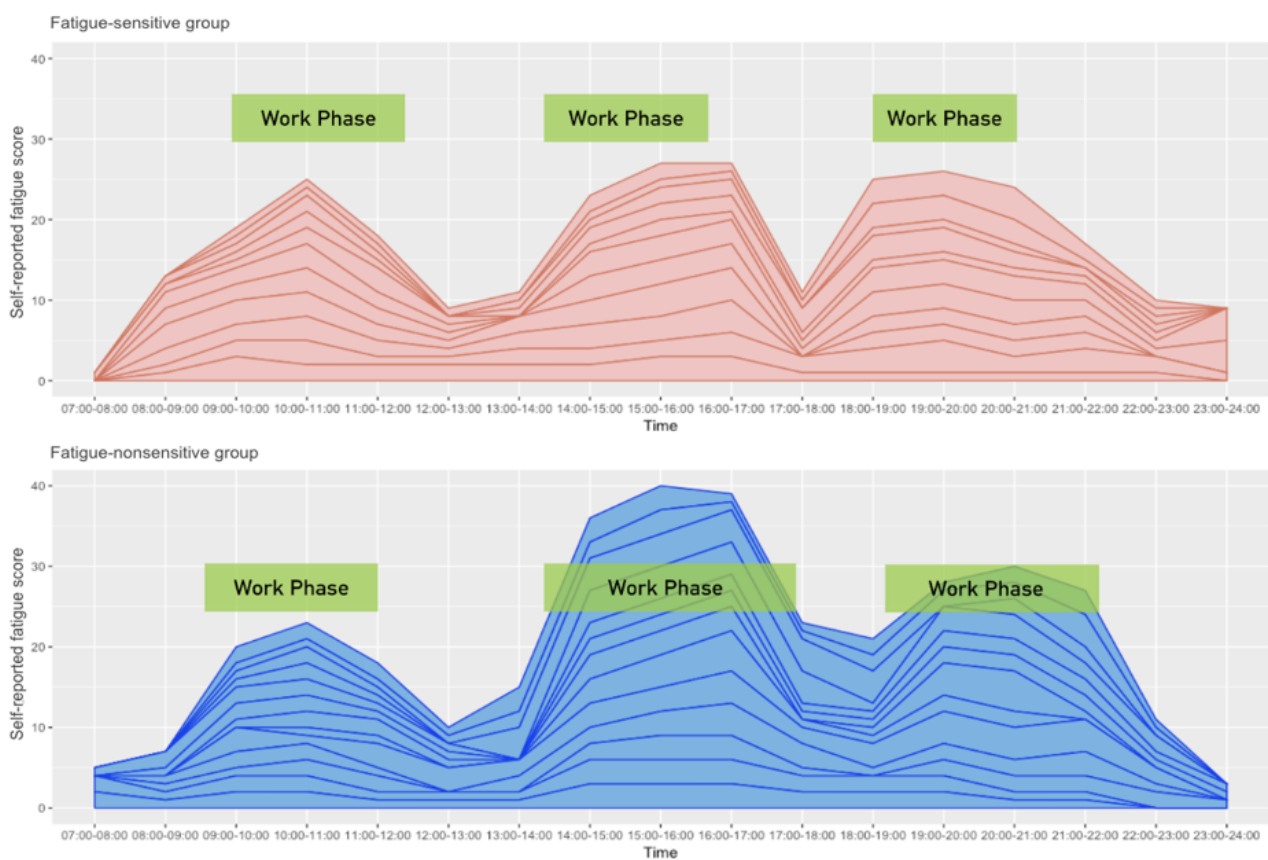
In addition, we found that during the walking experiment, over half of the participants (15/26) expressed their fatigue perception, starting from around the fourth minute. For example, participant 5 told us, “I feel that I cannot walk faster now.” Moreover, when participants associated their fatigue perception with daily activities, they could tell the reasons they were tired or exhausted. For instance, participant 7 reported, “I am feeling very exhausted right now, probably because I did not take a nap

at noon.” Similarly, 3 participants reported that they had done much repetitive work during the afternoon, resulting in their perceived mental fatigue.

Activity Diary

Participants were assigned an Excel (Microsoft Corp) template and asked to record their ongoing activities, rate in-the-moment fatigue perception, and annotate the activity if necessary. This task was performed to examine participants' self-reported work fatigue status and its association with daily activities. We used a 6-point rating scale for participants to rate their work fatigue perception (none, little, some, medium, severe, or very exhausted). In Figure 7, we visualized the 2 groups' average work fatigue scores over the week. We used green boxes to label the overlapped work phases for all participants.

Figure 7. We visualized the self-rated perceived fatigue collected from the activity diary and the average work time duration for the 2 groups.

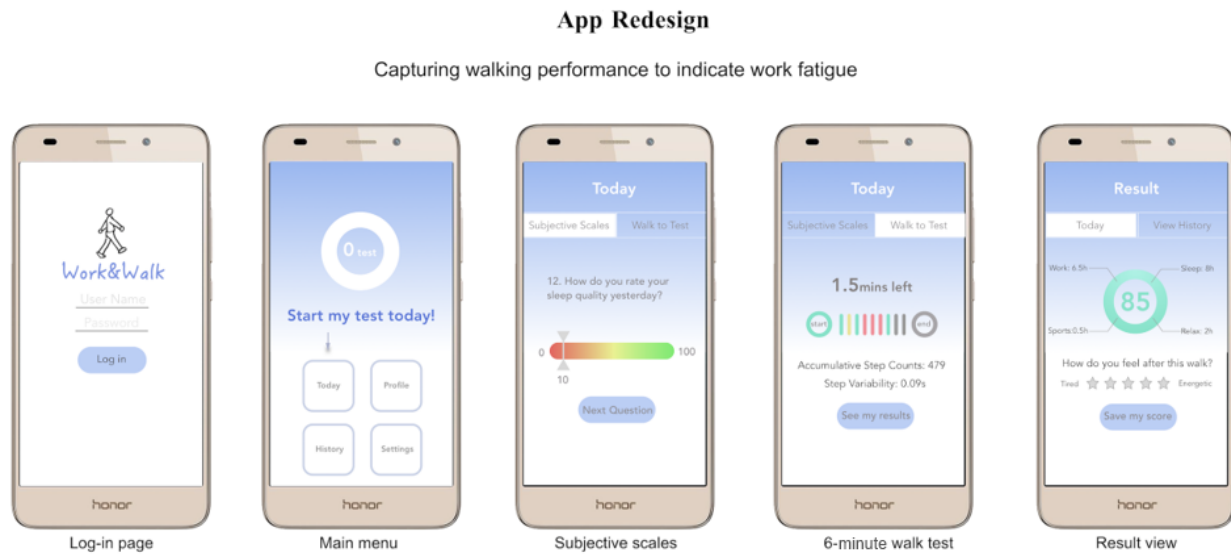


Overall, the trends of the 2 groups were similar, with 3 notable peaks of work fatigue at around 10:00 AM to 11:00 AM, 3:00 PM to 4:00 PM, and 8:00 PM to 9:00 PM. Interestingly, we found that the fatigue-nonsensitive group reported higher self-rated fatigue perception in the afternoon and evening, but were able to keep working 1.5 times longer on average compared with the fatigue-sensitive group. This might be because the fatigue-sensitive group tended to perceive work fatigue easier and thus might have reduced their work time due to the fatigue perception. In this regard, the fatigue-sensitive group reported lower fatigue perception compared with the fatigue-nonsensitive group.

System Improvement

In light of our study results, we determined the measurements that were indicative of users' fatigue perception. In our proposed system, there are three main features: walking tests (not limited to the 6MWT), subjective questionnaires (eg, the FSAS), and activity diary logging, where participants are expected to record daily activities and their fatigue level. To reduce the length of the questionnaires, researchers could only include the mental subquestionnaires in the system. We redesigned and sketched the mobile app (see Figure 8), which contains the added selective questionnaires and activity diary not included in its original version.

Figure 8. We redesigned and proposed a mobile app framework based on the results from our study.



Discussion

Principal Findings

In this paper, we reported findings from an in-lab study with young adults that explored effective measurement methods for revealing work-induced fatigue perception and performance. We leveraged multiple objective and subjective measurements, with a focus on walking performance, to investigate the best method with which to indicate young adults' fatigue status. Moreover, we preliminarily studied how performance fatigability and perceived fatigability correlated with each other by comparing subjective scales and walking performance.

Findings from this study showed that in general, participants took significantly fewer step counts after work compared with before work. Overall, the fatigue-nonsensitive group took significantly more steps compared with the fatigue-sensitive group. Interestingly, regardless of the measurement time, we found that the change in step counts from normal pace to fast pace was significantly higher in the fatigue-nonsensitive group compared with the fatigue-sensitive group. This suggested that the fatigue-nonsensitive group showed better physical capabilities when asked to modify their walking pace. In terms of the step-to-step time variability, our findings showed that the fatigue-nonsensitive group could better maintain their walking rhythms compared with the fatigue-sensitive group. In our study, the step time variability reflected how much a participant's step frequency was impacted by the energy exertion during the 6MWT. We think that this was pertinent to a person's fatigability, which means that under the same physical activity exposure, participants who were more sensitive to fatigue were more likely to decrease their walking frequency in response to the increased fatigue perception. This contrasts with a previous study measuring young participants' and older participants' walking performance under single-task and dual-task conditions [17], as our study shows that young participants increased their gait variability over a day of work. One possible explanation is that in our study, all participants perceived cognitive workloads in a relatively naturalistic setting, and after a day of work, their

fatigue level was significantly increased, especially for participants in the fatigue-sensitive group.

In reaction time, we only observed a significant change caused by the time of measurement, which means that both the fatigue-sensitive group and the fatigue-nonsensitive group had an increase in cognitive fatigue after work but did not significantly differ from each other. This might be caused by the experiment design, in which all of our participants might have become more alert when researchers asked them to conduct the RTT. Hence, we could not conclude that RTT was not an effective measurement method for identifying young adults' fatigability. In general, correlation analysis between subjective and objective measurements did not yield strong correlations. However, we observed a moderate correlation relationship between the step counts and the 3D-WFI mental subscore ($r=0.46$; $P<.001$). The activity diary and user interview data after each walking test contributed to our understanding of work-induced perceived fatigue in young populations. Drawing on these findings, we sketched a mobile framework to study work-induced fatigue perception daily. In the "Design Implications" section, we propose 3 design implications for future work.

Design Implications

Using Walking Performance Data to Identify People With a Higher Work-Induced Fatigue Level

The relationship between performance fatigability and perceived fatigability has gained growing research attention [3,4,31,32]. Among various physical outcome variables (eg, heart rate data, electroencephalography), walking is a ubiquitous human activity in everyday life and can be captured through smartphone or smartwatch built-in sensors. Prior work has demonstrated the feasibility of measuring walking performance to indicate fatigability in an older population [31]. For example, researchers found that covered distance was indicative of perceived fatigability [31]. In another study, the progression of fatigability had an effect on walking performance (eg, covered distance) during the 6MWT [32]. Building on prior work, we investigated

walking performance and assessed its relationship with perceived fatigability in a different context—through work-induced fatigue among young adults. We believe that studying this population is highly valuable because the younger population undergoes high pressure in the working environment but has received less attention regarding their work-induced fatigue. In this regard, our study contributes to the investigation of fatigue among young adults. First, on the group level (fatigue-nonsensitive group and fatigue-sensitive group), we found that compared with the fatigue-nonsensitive group, the fatigue-sensitive group covered fewer steps in all the testing conditions and performed more poorly in maintaining their walking rhythms, which manifested as having larger step-to-step time variability. Our findings suggest that step count and step-to-step time variability could be used to indicate young adults' fatigue status. This further implies the opportunity of leveraging walking measurements to signal perceived fatigability for this research population.

Leveraging Prompted Assessments to Track Work-Induced Fatigue Daily

In our study, we designed 2-paced 6MWTs to be required at 2 time points related to a person's work schedule. The 6MWT is a physical performance measurement that has been extensively used in previous research quantifying individuals' physical and cognitive exertion [31-33]. It is generally believed to be safer, easier to administer, and more reflective of the activities than other walk tests [33]. In the literature, there has been a growing trend in applying mobile technologies (eg, smartphones) to implement the 6MWT in natural settings. For instance, Brooks et al [33] developed a self-administered 6MWT mobile app and tested its usability among patients with congestive heart failure about three times a week over 2 weeks. Building on prior work, we asked participants to do a 6MWT in different conditions to capture performance changes that were subject to the measurement conditions. Findings from our study show that participants' fatigue status had an effect on their walking performance. This points to an opportunity to introduce brief in-lab assessments (eg, the 6MWT) conducted at different conditions into participants' daily lives. Researchers could use mobile apps to implement a research protocol similar to an in-lab study, for example, by measuring cognitive fatigue before and after being exposed to a period of cognitive work. However, in contrast to the lab setting, where researchers usually adopt a uniform cognitive task for all participants, the real-world setting has more complexity, as working status varies from person to person. In this regard, our work suggests that researchers could engage participants in recording their daily activities and rating their perceived fatigue level. In addition to this, researchers could also consider leveraging context and context awareness to identify when the user is about to work or has completed a day of work. In detecting a key event related to work, the mobile system could prompt the user to conduct a brief walking test, such as the 2MWT [32] or 6MWT, depending on the user's availability and ongoing activities. By prompting a user to do brief walking tests at different time points in a day, researchers would be able to analyze the user's walking performance and its association with their behavioral context, which helps better identify triggers for the user's fatigue status. Furthermore,

similar to our experiment design, in future work, researchers may instruct users to conduct walking tests at different paces. Findings from this study show that the difference in step counts between fast-paced and normal-paced walking tests could be a variable that signals fatigue status. We think that designing such multicondition prompted walking assessments would help capture the nuanced change in one's fatigue status.

Integrating Multiple Measurements to Gain a Holistic View of Work-Induced Fatigue

According to prior work, fatigability is a phenotype characterized by the relationship between an individual's perceived fatigue and the activity level with which the fatigue is associated [4,34]. Fatigability is largely unexplored among younger populations, which means that there are no clinically validated metrics to derive the fatigability score for young adults using mobile sensing methods. This work acts as an initial step to explore the parameters that may have the potential to reveal young adults' fatigability. Findings from this study show that measurements, including the 3D-WFI, FSAS mental score (its change during the day), and walking performance, can help differentiate the fatigue-sensitive group from the fatigue-nonsensitive group. Interestingly, in our study, there were also seemingly contradictory results. For example, the fatigue-nonsensitive group reported a higher perceived fatigue score in the activity diary compared with the fatigue-sensitive group. We think that this finding enriches the notion of fatigability among young adults. Although the fatigue-nonsensitive group reported higher fatigue perception compared with the fatigue-sensitive group, they could work longer and seemed to be more capable of bearing fatigue perception. The activity diary also enabled us to understand daily activities that might trigger or have an impact on one's fatigue status. Taken together, our work points to the need for understanding fatigue status in a natural setting from multiple perspectives, such as objective performance measurements (eg, 6MWT and RTT) and self-reports, as well as activity data in context. Combining multiple sources of data available from smartphones, researchers may build a holistic view of work-induced fatigue and fatigability. In this respect, our study has contributed to several variables (eg, step count and step-to-step time variability) that are valuable for future investigation.

Limitations

Our work has several limitations. First, due to the in-lab experiment setting, our study could not fully represent ecological validity. However, to probe one's fatigue level, we adjusted each participant's testing time according to their work schedule. Second, the enrolled participants were all college students or research workers, which might not be able to represent the general young adult population. Third, we only used the 3-axis accelerometer signals for analysis due to device capability, and we instructed participants to hold the phone in their hand while walking. A location-independent mobile system is needed in the future to enable the field investigation. Lastly, we applied a dichotomous classification of fatigue perception for all participants. For a more precise health-tracking purpose, a fine-level classification of fatigue levels for users would be

highly valuable. Overall, this study acts as an initial step in investigating relationships between walking rhythms and work-related fatigue. Going forward, we plan to conduct a longitudinal field study to explore the effect of fatigability on multiple outcome variables.

Conclusion

In this paper, we conducted an in-lab experiment to investigate how fatigue elicited by daily work could be captured through

multiple measurements. Findings showed that there was a significant difference in walking performance (ie, step count and step-to-step time variability) and FSAS scores between the fatigue-sensitive group and the fatigue-nonsensitive group. The fatigue-sensitive group was more vulnerable to fatigue perception and less productive in daily work. Overall, our study paves the way for future work studying work-induced fatigue among young adults and designing mobile systems to capture nuanced changes in fatigue status.

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Conflicts of Interest

None declared.

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Abbreviations

- 3D-WFI:** Three-Dimensional Work Fatigue Inventory
- 6MWT:** 6-minute walk test
- FS-14:** Fatigue Scale-14
- FSAS:** Fatigue Self-Assessment Scale
- RTT:** reaction time test
- SCT:** stair climb test

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Original Paper

Prevalence of and Factors Associated With Eustachian Tube Dysfunction Among the Public in Jeddah, Saudi Arabia: Cross-Sectional Survey-Based Study

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Abstract

Background: Obstruction of the Eustachian tube is a common condition that is unpleasant and might lead to various middle ear disorders.

Objective: This study aimed to estimate the prevalence of Eustachian tube dysfunction (ETD) among the public in Jeddah, Saudi Arabia.

Methods: This cross-sectional survey-based study was conducted in Jeddah during August 2018 by distributing an electronic survey form to participants from different districts of the city. All male and female residents of Jeddah aged 10 years and above had the chance to participate in this study.

Results: A total of 2372 participants (female, 1535/2372, 64.71%; male, 837/2372, 35.28%; mean age 31.31 years, SD 11.85 years) agreed to contribute to our study. Upon analysis of their answers to the questionnaire, the overall prevalence of ETD in our sample was found to be 42.49% (1008/2372). The prevalence was higher among participants who reported a previous diagnosis of ETD and hearing loss (1897/2372, 80.00% and 1902/2372, 80.21%, respectively). Additionally, participants with a family history of hearing loss had a significantly higher prevalence (1136/2372, 47.92%) of ETD than those with no family history of hearing loss. Our analysis also showed that females were at a greater risk of developing ETD than males ($P=.01$).

Conclusions: As per our prevalence data, ETD is a common disease in Jeddah, pointing to the need for more attention, awareness, and research.

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KEYWORDS

Eustachian tube; Eustachian tube dysfunction; chronic otitis media; hearing loss; electronic survey; cholesteatoma; 7-item Eustachian Tube Dysfunction Questionnaire

Introduction

The Eustachian tube is a thin tube that links the middle ear with the nasopharynx. It is responsible for ventilation and pressure equalization in the middle ear [1]. Therefore, any dysfunction of the Eustachian canal may lead to impaired sound conduction.

Eustachian tube obstruction is a common condition that is unpleasant and might lead to various middle ear disorders such as chronic otitis media (OM) and cholesteatoma [2]. Eustachian tube dysfunction (ETD) can be due to intrinsic causes such as anatomical anomalies in the cleft palate, or acquired and extrinsic factors such as an allergic response at the site of the

Eustachian tube opening, a viral upper respiratory tract infection, or a combination of intrinsic and extrinsic factors [3].

The prevalence of ETD among the adult general population is approximately 1% [4], and around 40% of children develop at least transient ETD [5]. Several studies have determined that ETD exists in up to 70% of patients undergoing tympanoplasty for middle ear disorders such as cholesteatoma and chronic OM [6,7]. A recent study conducted in the United States assessed the burden of ETD and determined that the condition is related to more than 2 million clinic visits per year among patients aged 20 years and above [8]. Some possible consequences of ETD include communication problems, decreased productivity, and poor quality of life. One of the main consequences of ETD is OM with effusion (OME), which is a common cause of hearing loss and is related to speech delay among children [9].

Patients with ETD complain of ear fullness, pain, muffled hearing, “popping” sounds, or tinnitus [6]. Hence, to diagnose ETD, a patient must exhibit the abovementioned symptoms of pressure disequilibrium in the involved ear. Nonetheless, it has always been challenging to identify appropriate diagnostic methods and tests as well as establish criteria for identifying individuals with ETD [6]. Several tools have been reported for evaluating Eustachian tube function. However, the use of Eustachian tube function tests is limited by the requirement of expensive tools and trained staff, which are commonly available in specialized health centers only [10]. Thus, a simple instrument such as a questionnaire that can reliably identify individuals with ETD would be a helpful tool for in-office practice, since it is the most appropriate way to self-evaluate a patient’s complaints and symptoms. The 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is considered to be a disease-specific instrument for evaluation of the symptoms associated with obstructive ETD and its treatment outcomes [11].

Knowledge of the prevalence of a disease within a population is of value in establishing possible current and future community service requirements. To the best of our knowledge, no study in Saudi Arabia has assessed the prevalence of ETD in the community to date. This study aims to evaluate the prevalence of ETD in Jeddah, Saudi Arabia, by using the ETDQ-7 instrument.

Methods

Questionnaire

This study was approved by the institutional review board of King Abdulaziz University Hospital, Saudi Arabia. This cross-sectional survey-based study was conducted by distributing an electronic questionnaire among the general population of Jeddah during August 2018. The electronic questionnaire only accepted a one-time response per participant so that there would be no instances of multiple responses from the same person. Jeddah, an urban metropolis and one of the biggest cities in Saudi Arabia, is located in the western region of the country and has a population of approximately 3.5 million.

Participants

This study aimed to estimate the prevalence of ETD in all areas of Jeddah. An electronic survey form was distributed by trained medical students to the participants. Randomly distributed city districts were selected for the study in order to obtain a realistic representative sample of the population of Jeddah, taking into account the more densely populated northern and southern regions of the city. All male and female residents of Jeddah aged 10 years and above had the chance to participate in this study. The purpose of the study was disclosed to the participants, and written consent was obtained before they could fill out the questionnaire.

Measurements

The ETDQ-7, designed by McCoul et al [11] 5 years prior to this study, was established as a new scoring system for the evaluation of the symptoms associated with obstructive ETD [11]. Each of the 7 items have scores ranging from a minimum of 1 to a maximum of 7 points, resulting in a total score of between 7 and 49 points. A total score ≥ 14.5 or a mean score ≥ 2.5 is considered abnormal, with higher scores indicating a greater level of symptom severity.

The ETDQ-7 is a valid measure [11] and has been translated into German [12], Dutch [13], and Japanese [14]. The original English ETDQ-7 was translated into Arabic by 2 independent native Arabic doctors with excellent knowledge of the English language. The Arabic version was then translated again into English by 2 independent native English doctors with excellent knowledge of Arabic; the authors compared the back-translated version from Arabic to English with the original English version, and all differences were reconciled. This process was followed to make all aspects abundantly clear to readers.

To avoid recall bias, the participants were instructed to answer the questions of the ETDQ-7 based on the symptoms they had experienced in the past month [11]. The ETDQ-7 is a self-administered survey; yet, when needed, children received help from their parents to clarify and answer the questionnaire.

Statistical Analysis

The data were organized in an Excel sheet and transferred to Statistical Package for Social Sciences (SPSS) software (version 24; IBM Corp.) for further analysis. Categorical variables were described using a frequency table, whereas continuous variables were described using the mean and SD. The data were then processed for determining statistical significance using the Chi-square test. For all statistical tests, P values $< .05$ were considered significant.

Results

A total of 2372 participants agreed to contribute to our study, resulting in a response rate of 78.00% (2372/3041). The study population comprised 64.71% (1534/2372) female and 35.28% (837/2372) male participants, with a mean age of 31.31 (SD 11.85) years. The largest age group comprised 45.06% (1070/2372) of our total sample and included participants aged 19-29 years. Data on the past medical history of our sample showed that only 3.37% (80/2372) and 5.52% (130/2372) of

the participants had been diagnosed with ETD and hearing loss, respectively. Among the total sample, 37.48% (889/2372) reported a positive family history of hearing loss. Other demographic characteristics of the population are presented in [Table 1](#).

The results of our analysis of the participants' responses to the ETDQ-7 demonstrated that the overall prevalence of ETD in our sample was 42.49% (1008/2372). The fourth question—regarding “the presence of ear symptoms when having a cold or sinusitis”—recorded the highest mean score of the entire questionnaire. The mean scores of all the questions in the ETDQ-7 are shown in [Table 1](#).

Table 1. Demographic characteristics of the sample and mean results of the ETDQ-7 (N=2372).

Variables	Values
Age, mean (SD)	31.31 (11.85)
Age groups (years), n (%)	
≤18	181 (7.63)
19-29	1069 (45.06)
30-39	486 (20.48)
≥40	636 (26.81)
Sex, n (%)	
Male	837 (35.28)
Female	1535 (64.71)
Nationality, n (%)	
Saudi	2137 (90.09)
Non-Saudi	235 (9.90)
Diagnosed with ETD^a, n (%)	
Yes	80 (3.37)
No	2292 (96.62)
Diagnosed with hearing loss, n (%)	
Yes	131 (5.52)
No	2241 (94.47)
Family history of hearing loss, n (%)	
Yes	889 (37.47)
No	1483 (62.52)
Smoking, n (%)	
Yes	332 (13.99)
No	2040 (86.00)
Overall prevalence of ETD according to the ETDQ-7 ^b , n (%)	1008 (42.49)
Questions, mean (SD)	
1- Pressure in the ears?	1.961 (1.44)
2- Pain in the ears?	2.046 (1.47)
3- A feeling that your ears are clogged or ‘under water’?	2.280 (1.68)
4- Ear symptoms when you have a cold or sinusitis?	2.417 (1.81)
5- Crackling or popping sounds in the ears?	1.972 (1.59)
6- Ringing in the ears?	2.066 (1.62)
7- A feeling that your hearing is muffled?	2.172 (1.72)

^aETD: Eustachian tube dysfunction.

^bETDQ-7: 7-question Eustachian tube dysfunction questionnaire.

Upon comparison of the prevalence of ETD on the basis of the demographic and clinical features of our sample, the condition was found to be most prevalent among participants aged 18 years or younger (45.3%), and its prevalence was similar in the groups aged 19-29 and 30-39 years (41.8% and 41.2%, respectively). In this study sample, ETD was more prevalent among females compared to males and among Saudi participants compared to non-Saudi participants. The prevalence of ETD was significantly higher among participants who had reported a previous diagnosis of ETD and hearing loss (1897/2372, 80%

and 1902/2372, 80.2%, respectively; $P < .001$) than among participants with no history of such diagnoses. Additionally, participants with a family history of hearing loss had a significantly higher prevalence of ETD (1136/2372, 47.9%; $P < .001$) than those with a negative family history. Details of the prevalence of ETD in the sample are presented in [Table 2](#).

Multivariate regression revealed that a diagnosis of hearing loss, family history of hearing loss, diagnosis of ETD, gender, and smoking were associated with the prevalence of ETD. These data are presented in [Table 3](#).

Table 2. Prevalence of ETD according to the ETDQ-7 (N=2372).

Variables	ETD ^a	P value ^b
Age groups (years), n (%)		.65
≤18	82 (45.30)	
19-29	447 (41.81)	
30-39	200 (41.23)	
≥40	279 (43.92)	
Sex, n(%)		.01
Male	326 (38.91)	
Female	682 (44.39)	
Nationality, n (%)		.61
Saudi	904 (42.30)	
Non-Saudi	104 (44.34)	
Diagnosed with ETD, n (%)		<.001
Yes	64 (80.00)	
No	944 (41.23)	
Diagnosed with hearing loss, n (%)		<.001
Yes	105 (80.21)	
No	903 (40.33)	
Family history of hearing loss, n (%)		<.001
Yes	426 (47.92)	
No	582 (39.22)	
Smoking, n (%)		.17
Yes	153 (46.09)	
No	855 (41.91)	

^aETD: Eustachian tube dysfunction.

^bP values were derived via the Chi-square test.

Table 3. Prevalence of ETD according to the ETDQ-7, based on multivariate analyses (N=2372).

Variables	R	Confidence interval	P value
Diagnosed with hearing loss	0.349	0.263 to 0.436	<.001
Diagnosed with ETD ^a	0.308	0.199 to 0.417	<.001
Family history of hearing loss	0.063	0.023 to 0.103	.002
Gender	-0.073	-0.117 to -0.030	.001
Smoking	0.064	-0.004 to 0.124	.04

^aETD: Eustachian tube dysfunction.

Discussion

The aim of this study was to estimate the prevalence of ETD among the public in Saudi Arabia—which, to our knowledge, has not been measured before—using the ETDQ-7 instrument. ETD negatively affects the outcomes of middle ear surgery and is highly associated with OME and cholesteatoma [15]. Multiple studies have shown that patients with other diseases such as temporomandibular joint dysfunctions also have tinnitus, vertigo, hypersensitivity to sounds, and hearing loss, but no recent studies have focused on using a specific tool to assess the general population [16-18]. Knowledge of the prevalence and risk factors of ETD will help improve the treatment options for patients and provide a better understanding of the condition with regard to a particular population. The overall prevalence of ETD in our sample was 42.49% (1008/2372), with the presence of “ear symptoms when having a cold or sinusitis” reported most frequently. Although this prevalence rate can be considered high, it is difficult to make a definitive judgement in this regard since there are no recent studies on the prevalence of ETD among general populations. Moreover, the ETDQ-7 has a score range of 7-49, and since any score above 14.5 was considered abnormal, the narrow range of scores might have led to a high number of diagnosed cases of ETD. Note that the estimated prevalence of ETD in the UK population is 0.9%, which was described by that study’s authors as a “common” condition [4].

In this study, a family history of hearing loss was significantly correlated with the presence of ETD ($P<.001$). Thus, family history played a major role in ETD prevalence in our study. Similarly, family history of OM has previously been suggested as a genetic factor for the development of OM [19-21]. We believe that the same factors might have contributed to the high prevalence of ETD in our study. Moreover, since families live together and share the same lifestyle habits, they are equally vulnerable to the same environmental risk factors of hearing loss.

Among participants below the age of 18 years, 45% (1067/2372) were diagnosed with ETD, making them the age group with the highest prevalence of ETD in this study. This finding is similar to that of a German study, which found that least 40% of all German children are affected by ETD [5]. The other age groups in our study exhibited similar prevalence rates of ETD. This might be partly attributed to the fact that the city of Jeddah is very crowded. It is the second largest city in Saudi Arabia, with an estimated population of around 4.03 million [22]. The city has significant industrial capabilities and is highly developed. The high population density and industrial environment of the city might serve as a major risk factor for ETD.

An unexpected finding was that females were at a greater risk of developing ETD than males ($P=.01$). A previous large-scale study reported that women above the age of 20 years are at a greater risk of developing ETD/OME/tympanic membrane retraction than men in the same age group [8]. The social lifestyles of men and women are different in Saudi Arabia, which might lead to the differences in the risk factors between the two sexes. Currently, we are unable to explain the reason

behind this finding in our study, and thus, further research on the differences in lifestyle-based risk factors between the two sexes is needed.

Multiple recent diagnostic evaluations have helped improve the understanding of the human anatomy; examples include the dynamic functions of the eustachian tube orifice via simple nasal endoscopy and other research-related diagnostic tests such as sonotubometry, tubomanometry, the pressure chamber test, and inflation deflation test [23-30]. Bearing this in mind, ETD is diagnosed when symptoms of pressure disequilibrium exist in either ear, particularly with symptoms of aural fullness, popping, or discomfort/pain [31]. To our knowledge, no previous study has used the ETDQ-7 to measure the prevalence of ETD; however, since this study is the first to do so, our findings, which show a high prevalence of ETD (up to 40%) in the community, might indicate an overdiagnosis. Although the questionnaire was validated, it has not been previously used in a study following a methodology similar to ours; moreover, the authors who validated the questionnaire mentioned that their work was limited by the small sample size [11]. Additionally, one of the questions in the ETDQ-7 asked if the individual experiences ear symptoms when they have a cold or sinusitis, to which many of the participants gave a score of 7. This question might have misled the participants and thus affected the prevalence rates in our study, suggesting that this question might need to be more specific. Thus, if the ETDQ-7 is to be used as a tool to assess the prevalence of ETD in a clinical setting, the abovementioned question might affect its overall sensitivity considerably; indeed, this observation was also made by similar studies [32,33].

A major limitation of this research related to our inability to include people of all socioeconomic sections of society in Jeddah or ensure that our study covered all residential regions of the city. Future studies should consider different environmental risk factors when collecting data and attempt to identify an association between hearing loss and ETD. They should also evaluate the prevalence of ETD in all regions and neighborhoods of the city and consider the extent of noise exposure in each region. Another suggestion for future investigations would be to analyze the prevalence of ETD among vulnerable population groups such as those exposed to occupational and environmental risk factors. Our study design can be applied to larger studies on a national or an international scale, which will help compare the prevalence of ETD among different cultures and identify more specific risk factors for the condition. Given the high prevalence of ETD in our study, more research and awareness on ETD in the community are needed.

In conclusion, this study aimed to determine the prevalence of ETD among the public in Saudi Arabia by using the ETDQ-7. Our results showed that ETD is a common disease in Jeddah. The prevalence of ETD was significantly higher among participants who had reported a previous diagnosis of ETD and hearing loss. Therefore, this condition needs more attention, awareness, and research (particularly the use of advanced statistical analysis). In addition, since smoking has a significant impact on ETD and tends to cluster in families, the potential role of smoking in family history of ETD should be examined.

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Authors' Contributions

All authors contributed equally during the preparation of this paper. The final proofreading of the manuscript was completed by KA.

Conflicts of Interest

None declared.

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Abbreviations

ETD: Eustachian tube dysfunction

ETDQ-7: 7-item Eustachian Tube Dysfunction Questionnaire

OM: Otitis media

OME: Otitis media with effusion

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