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A closer look at depression and sleep quality relation: A cross-sectional study of taxi drivers in Tabriz metropolis

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Abstract

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Background and Aim: Taxi drivers play a significant role in urban mobility and safety as professional drivers. They typically have poor incomes, long work hours, lack of sleep, and high levels of stress, which increase the risk of physical and mental illnesses. The goal of this study was to explore the relationship between sleep disorders and depression among Tabriz metropolis taxi drivers.

Methods: Using the street intercept technique, a cross-sectional study was conducted with the participation of 402 taxi drivers in Tabriz during January and March 2020. Data collection tools included the Pittsburgh Sleep Quality Index (PSQI) and Patient Health Questionnaire as well as demographic information. Twenty taxi stops were used as sampling sites, and the method used was random sampling based on the number of drivers at each stop. Statistical analysis was performed using Stata 13. **Results:** The majority of drivers worked an average of 6 days each week, with a mean tenure of 13.3 years. The sleep quality mean score for drivers was 5 (SD = 2.3). Approximately, 21% of them had sleep disorder (PSQI >6). Moderate depression was recognized in 13% of drivers and moderately severe depression has been found in 5% of them. Drivers were more likely to experience sleep disorders if they had mild (odds ratio [OR] = 3.9), moderate (OR = 16.4), or fairly severe depression symptoms (OR = 35.3). A seven times higher risk of depression was identified among drivers with sleep disorders.

Conclusion: It might be contended that a mutual relationship has been found between sleep disorders and depression, and disregarding this will deteriorate sleep turbulences. Considering the pivotal role of taxi drivers in urban mobility, accommodating initiatives that give a break time for drivers and improve their mental health is recommended.

KEYWORDS

depression, health, prevention, professional driver, sleep quality

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1 | INTRODUCTION

Occupational health and safety is vital not only for workers individually but also for the community.^{1,2} Declining work-related injuries were emphasized by World Health Organization (WHO) policies.³ Majority of countries have employed proper policies in this regard; however, professional drivers, as a vulnerable group, are still ignored.⁴ Professional taxi drivers are at risk of physical and mental health concerns due to long working hours, highly sedentary occupations, and daily hassles.^{5,6}

Safe driving in an urban environment requires taxi drivers to be mentally alert and react consciously while maintaining good relations with passengers.⁶ This function is disturbed by fatigue and sleepiness. Sleep disorders are a prevalent problem among professional drivers which impair not only their driving function but also life quality.^{5,7} Previous studies revealed that the prevalence of sleep disorders in professional drivers was high and many of them complain of poor sleep.^{8–10} Tabrizi et al. reported a sleep disorder prevalence of 53.4% among Iranian drivers.¹¹ Drowsy driving was reported as one of the risky driving behaviors increasing the likelihood of the crash.^{4,12,13} Crash due to sleepiness proportion was reported from 1% in the United States, 10% in France, and 33% in Australia.^{12,14} Ebrahimi et al. similarly have reported a significant association between drivers sleep quality and accident in Iran.¹⁵

On the other hand, people who suffer from sleep problems are more prone to mental disorders such as anxiety disorders and depression.^{16,17} Research showed that sleep problems can cause many physical and mental disorders, including loss of appetite, physical and mental fatigue, lack of concentration, neurological, behavioral, and physiological changes, slowing down the analysis of information, increasing Human error and accident, decrease in consciousness, depression and anxiety.^{9,15,18,19} Crizzle et al. indicated that drivers who drove for long periods of time and reported poor sleep were five times more likely to be depressed. They suggest that poor sleep quality may play a significant role in the development, exacerbation, and recurrence of depressive symptoms in drivers.²⁰ Results of a study in San Francisco in 2019 also revealed that 38% of taxi drivers had depression symptoms.⁶ A study by Rathi et al. in New Delhi showed that 60.5% of taxi drivers suffer from depression.²¹

Despite the high importance of urban taxi drivers' role in transportation safety in cities, this highly populated workforce is ignored, especially regarding health issues. Taxi driving in Tabriz City is one of the hardest and most stressful occupations, with more than 11,000 active drivers. The low income of the drivers made them work more hours in a day and days in a week. Regarding their health status, there are not any routine health checkups or special health services for drivers. High sedentary and stressful working conditions of taxi drivers put them as a group at risk of various health problems in Tabriz. Considering the vital role of mental health in safe driving, exploring the association between depression and sleep quality among professional urban taxi drivers in Iran was followed in this study.

2 | MATERIALS AND METHODS

2.1 | Design and setting

This cross-sectional study was conducted in 2020 in Tabriz through the street intercept method. As the province capital, Tabriz is one of the metropolitans in Iran, with approximately 2 million people in the Northwest.

2.2 | Sampling and data collection

Sampling was done using a two-stage sampling method. First, the city was divided into five main areas, and then four taxi lines were selected randomly from each area (cluster) (Figure 1). In each line, 20 taxi drivers were recruited through random sampling based on the drivers' number in line main stop. The sample size was estimated to be 371 based on the study population size (11,000) and using the Cochrane Formula. After adjusting for nonresponse (+10%), the final sample size was 408. Data collection was done by a trained interviewee lasting for 15 min, maximum. In case of driver interest and ability, questionnaires were filled by themselves. Each cluster was approached for data collection from 5 to 9 afternoon to cover both day and night hours. Working as a full-time taxi driver in the last 6 months was the inclusion criteria. Online taxi service drivers were excluded. Participants were gifted a notebook and a pen.

2.3 | Questionnaires

Along with a researcher-made checklist to gather the participants' demographic information (age, body mass index, education level, having some disease such as cardiovascular disease, history of myocardial infarction, respiratory diseases [such as asthma], working history as a taxi driver, working hours per day, working hours per night, working days per week, smoking and hookah consumption), Pittsburgh Sleep Quality Index (PSQI), and Patient Health Question-naire (PHQ-9) were also used in this study.

PSQI is a self-reported instrument that measures sleep habits for the last month and is a suitable tool to measure sleep quality on workdays.²² This questionnaire had 14 questions scored based on a 4-point Likert scale (scores of 0, 1, 2, 3 indicate normal condition, mild, moderate, and severe problems, respectively). It has seven subscales that measure subjective quality, latency, duration, sleep efficiency, disturbance, medication use, and daytime dysfunction. The sum of the scores of the seven subscales forms the total score, which is from 0 to 21. An overall score of 6 or higher indicates sleep disorder. The validity and reliability of the Persian version were proved by Kakoei et al. The reliability of the questionnaire was estimated to be $\alpha = 0.83$.²³

The PHQ-9 was used as screening tool for assessment and monitoring of the severity of depressive symptoms. It includes nine items, and each item was scored on a scale of 0-3 (0 = not at all;



FIGURE 1 Selected taxi stops in Tabriz City.

1 = several days; 2 = more than a week; and 3 = nearly every day). The score range of the PHQ tool was from 0 to 27 (scores of 0-4 are classified as healthy, 5-9 as mild depression, 10-14 as moderate depression, 15-19 as moderately severe depression, and 20-27 as severe depression). This tool was validated by Farrahi et al. Cronbach's alpha coefficient and intraclass correlation coefficient of tool were 0.856 and of 0.869, respectively.²⁴ The protocol of this study was approved by the ethical committee of Tabriz University of Medical Sciences (Ethical code: IR.TBZMED.REC.1397.1090). Informed consent was obtained from all subjects involved in the study.

2.4 | Data analysis

Descriptive statistics was used to report quantitative data as mean and standard deviation (SD), and for qualitative variables, frequency (percent) was reported. Age, body mass index (BMI; was calculated based on the driver's weight and height), marital status, cardiovascular disease, respiratory diseases (such as asthma), time being as a taxi driver, time at work during day, time at work per week, and smoking were submitted as independent variables, and the PSQI score category and having depression symptoms were the dependent variable. We generated the having depression symptoms variable as a new variable by recording the depression severity symptoms variable into two categories: "healthy" as none and 1 "having depression symptoms included mild and upper symptoms."

We used logistic regression to assess the relationship between PSQI and some variables. Also, bivariate and multivariate logistic regression were performed to check the relationship between some variables and depression symptoms. In the bivariate model, we entered all independent variables and tested the association of these variables with the PSQI score category. In the multivariate model, the variables with *p* value < 0.1^{25} in the bivariate were included in the model. In addition, for assessing the relationship between some variables and having depression symptoms, we also used the bivariate and multivariate models. The backward elimination by using the Wald test was used to reduce the model. In this study, *p* < 0.05 was the significance level. Statistical analysis was performed using Stata 13 (Stata Corp, College Station, TX, USA).

3 | RESULTS

In total, 402 taxi drivers participated and completed the questionnaire (response rate = 98.5%). The mean of drivers age was 51.1 (SD = 6.6). More than half of taxi drivers had less than a diploma in schooling, and only 0.7% of them were single. The majority of drivers worked an average of 6 days each week, with a mean tenure of 13.3 years. Nearly 12.4% of drivers had cardiovascular disease and 10.2% of them had a myocardial infarction history (Table 1).

Table 2 shows that about 36% of the drivers were smokers. Moreover, hookah consumption prevalence was 20%. The sleep quality mean score for drivers was 5 (SD = 2.3). About 21% of drivers had poor sleep quality (PSQI >6). Fifty-seven percent of drivers had between 6 and 7 h of daily sleep duration, and more than two thirds of them reported sleep efficiency. Sleep disturbances (1–2 times a week) were reported by 19% of taxi drivers, and 33% of them used sleep medication once a week. Almost 43% of drivers had daytime dysfunction, 1–2 times a week. Moderate ILEY_Health Science Reports

TABLE 1 Demographic characteristics of the taxi drivers in
Tabriz.

Characteristic	Mean ± SD or frequency (%)
Age	51.1 ± 6.6
Body mass index (kg/m ²)	25.4 ± 3.3
Marital status	
Married	398 (99.3%)
Single	3 (0.7%)
Education level	
Illiterate	13 (3.2%)
Under diploma	262 (65.7%)
Diploma	98 (24.6%)
Academic	26 (6.5%)
Cardiovascular disease	
Yes	50 (12.4%)
No	352 (87.6%)
History of myocardial infarction	
Yes	41 (10.2%)
No	361 (89.8%)
Respiratory diseases (such as asthma)	
Yes	121 (30.1%)
No	281 (69.9%)
Working experience (years)	13.3 ± 6.3
Time at work in a day (h)	10.4 ± 1.9
Working time at night (h)	1.1 ± 1.5
Time at work per week (days)	5.9 ± 0.8

TABLE 2PSQI general score, components, and behaviors of taxidrivers in Tabriz.

Characteristic	Frequency (%)
Smokers	
Yes	143 (35.6)
No	259 (64.4)
Hookah consumption	
Yes	82 (20.4)
No	320 (79.6)
Depression severity symptoms	
None (0-4)	186 (46.3)
Mild (5-9)	144 (35.8)
Moderate (10-14)	53 (13.2)
Moderately severe (15-19)	19 (4.7)
Severe (20-27)	-

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Characteristic	Frequency (%)
PSQI score category	
≤6 (good sleep)	308 (78.8)
>6 (sleep disorder)	83 (21.2)
Components of PSQI	
Sleep quality	
Very good	138 (34.3)
Relatively good	237 (58.9)
Relatively bad	26 (6.47)
Very bad	1 (0.25)
Sleep latency (h)	
None	163 (40.6)
1-2	212 (52.7)
3-4	25 (6.2)
5-6	2 (0.5)
Sleep duration (h)	
More than 7	70 (17.4)
6-7	189 (47)
5-6	124 (30.9)
Less than 5	19 (4.7)
Sleep efficiency	
More than 85%	390 (99.7)
84%-75%	1 (0.3)
74%-65%	-
Less than 65%	-
Sleep disturbances	
None	35 (8.7)
Less than 1 time in a week	287 (71.3)
1–2 times a week	75 (18.7)
3 or more times a week	5 (1.3)
Sleep medication	
None	234 (58.2)
Less than 1 time in a week	134 (33.3)
1–2 times a week	23 (5.8)
3 or more times a week	11 (2.7)
Daytime dysfunction	
None	196 (48.8)
1-2 times a week	173 (43)
3-4 times a week	24 (6)
5-6 times a week	2 (2)

Abbreviation: PSQI, Pittsburg Sleep Quality Index.

depression was recognized in 13% of drivers and moderately severe depression has been found in 5% of them (Table 2).

Almost 24% of drivers with more than 10 h of work in a day reported bad quality of sleep (sleep disorder), but this relation was not statistically significant (p > 0.05). Moreover, 20% of drivers who work more than 5 days a week had sleep disorders, but this relation was not statistically significant (p > 0.05) (Figure 2).

In bivariate analysis, there were significant associations between age group, cardiovascular disease, time of being a taxi driver (work experience), depression symptoms, and sleep disorder (p < 0.05) (Table 3).

No association between marital status, respiratory diseases (such as asthma), smoking, BMI, daily working time, working days in a week, and sleep quality was found.

In the multivariate model, after controlling for other variables, there were significant relationships between age group, having cardiovascular disease, work experience (year), depression severity symptoms, and sleep quality. Drivers in age-group of 41–50 experience a significantly 49% lower sleep disorder (95% confidence interval [CI] = 0.27–0.96, *p* value nearest hundred) compared with individuals with more than 50 years old. Drivers with Cardiovascular disease had a 2.8 (95% CI = 1.3–6.2, *p* < 0.007) fold increase in the rate of sleep disorder. The odds of poor sleep quality in drivers with depression symptoms were approximately seven times higher than in other drivers (odds ratio [OR] = 6.91; 95% CI = 3.5–13.4, *p* < 0.001).

In bivariate analysis, there was a significant association between having cardiovascular disease, daily working time, PSQI score, and depression symptoms (p < 0.05). In the multivariate model, after controlling other variables, a significant relationship between daily working time, sleep quality, and depression symptoms was seen. Drivers who work more than 10 h a day have more odds of depression symptoms than others (OR = 2.7; 95% CI = 1.7–4.2, p < 001). The odds of having depression symptoms in drivers with poor sleep quality were approximately seven times higher than in other drivers (OR = 6.7; 95% CI = 3.5-12.7, p < 0.001) (Table 4).

4 | DISCUSSION

This study investigated the sleep quality and depression symptoms among taxi drivers in Tabriz, a capital city in Northwest Iran. Results revealed that more than 21% of participants suffer from sleep disorders, and almost 18% had moderate or moderately severe symptoms of depression. Drivers' age, working experience, and cardiovascular disease were significantly associated with sleep disorders. Moreover, drivers with moderately severe depression symptoms were at 35-fold more risk of sleep disorders versus those without symptoms. Drivers with poor sleep quality were at higher risk of getting depressed.

Sleepiness and drowsy driving are among the main risk factors of road traffic accidents, especially in professional drivers.⁸ Results illustrated that only 17.4% of drivers had slept more than 7 h a day. Moreover, 34.3% of drivers had reported a very good sleep quality, while 33% of them reported consuming sleep related medicines. Previous studies in the United States and Singapore also reported that more than 50% and 72% of taxi drivers had slept less than 7 h in a day, respectively,^{26,27} which was in line with our findings. Amini et al. study results indicated that drivers with insufficient sleep duration were at more risk of road traffic crashes.²⁸ In a study of taxi drivers in Singapore, results showed that 47% of them had poor sleep quality.²⁶ Robbins et al. reported that 52% of yellow taxi drivers in New York City had an unhealthy amount of sleep.²⁹ In another study among taxi drivers (2021), it was revealed that 47% of drivers had sleep quality lower than the US public population.²⁷ In a metaanalysis, Tabrizi et al. declared that sleep quality disorders prevalence among Iranian drivers was to be 53.4%.¹¹ Considering other



FIGURE 2 PSQI score category based on working hours in a day (lower than 10 h vs. upper than 10 h) and working days in a week (less than 5 days vs. more than 5 days) between taxi drivers. PSQI, Pittsburg Sleep Quality Index.

TABLE 3	Bivariate and multivariate logistic regression results for
prediction of	f sleep disorder.

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TABLE 4Bivariate and multivariate logistic regression results forprediction of having depression symptoms in taxi drivers.

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	Crude		Adjusted	
Characteristic	p Value	OR (95% CI)	p Value	OR (95% CI)
Age group (years)				
≤40	<0.06	0.24 (0.1-1.1)	>0.02	0.12 (0.02-0.7)
41-50	>0.009	0.49 (0.29-0.83)	>0.03	0.51 (0.27-0.96)
51-60	-	Reference	-	Reference
>60	<0.59	0.73 (0.23-2.3)	<0.63	0.72 (0.19-2.7)
Marital status				
Single	<0.64	1.8 (0.16-20.7)	-	-
Married	-	Referent	-	-
Cardiovascular disea	ise			
Yes	>0.001	4.6 (2.4-8.6)	<0.007	2.8 (1.3-6.2)
No	-	Reference	-	Reference
Respiratory diseases	s (such as a	asthma)		
Yes	<0.8	0.94 (0.55-1.6)	-	-
No	-	Referent	-	-
Smoking				
Yes	<0.7	1.1 (0.66-1.8)	-	-
No	-	Reference	-	-
Body mass index	<0.32	0.96 (0.87-1.1)	-	-
Time of being a taxi driver (years)	>0.08	0.96 (0.92-1.1)	<0.003	0.92 (0.88–0.97)
Time at work in a day				
≤10 h	-	Reference	-	-
>10 h	<0.29	1.3 (0.79-2.1)	-	-
Time at work per weekdays				
≤5 day	-	Reference	-	-
>5 days	<0.35	0.75 (0.41-1.4)	-	-
Having depression symptoms				
Yes	<0.001	1.85 (1.21-2.48)	<0.001	6.91 (3.5-13.4)
No	-	Referent	-	Referent

Abbreviations: CI, confidence interval; OR, odds ratio.

	Crude	0.0	Adjusted	
Characteristic	p Value	OR (95% CI)	p Value	OR (95% CI)
Age group (years)				
≤40	>0.4	0.7 (0.3-1.7)	-	-
41-50	>0.7	0.9 (0.6-1.4)	-	-
51-60	-	Reference	-	-
>60	>0.2	2.2 (0.7-6.4)	-	-
Marital status				
Single	>0.6	1.7 (0.2-19.3)	-	-
Married	-	Reference	-	-
Cardiovascular diseas	se			
Yes	<0.03	1.9 (1.1-3.7)	>0.9	0.9 (0.3-1.7)
No	-	Reference	-	Reference
Respiratory diseases	(such as a	sthma)		
Yes	>0.2	1.3 (0.9-2.1)	-	-
No	-	Referent	-	-
Smoking				
Yes	>0.1	1.4 (0.9–2.2)	>0.1	1.5 (0.9–2.3)
No	-	Reference	-	Reference
Body mass index	>0.3	0.96 (0.9-1.02)	-	-
Time of being a taxi driver (years)	>0.3	1.01 (0.9-1.1)	-	-
Time at work during day				
≤10 h	-	Reference	-	Reference
>10 h	<0.001	2.6 (1.7-3.9)	<0.001	2.7 (1.7-4.2)
Time at work per weekdays				
≤5 day	-	Reference	-	-
>5 days	>0.7	1.1 (0.7-1.8)	-	-
PSQI score category				
≤6 (good sleep)	-	Reference	-	Reference
> 6 (sleep disorder)	<0.001	6.3 (3.4-12)	<0.001	6.7 (3.5-12.7)

Abbreviations: CI, confidence interval; OR, odds ratio; PSQI, Pittsburg Sleep Quality Index.

professional drivers, poor sleep quality was reported in 27.2%, 17.3%, and 54% among truck drivers in Belgium, Italy, and Iran, respectively.^{9,30,31} The majority of mentioned studies had reported a higher prevalence of poor sleep quality in comparison with our study. Discrepancies in results may be due to the sample's homoheterogeneity, the culture of nighttime life in the cities encouraging more working hours of taxi drivers, and working and community cultural characteristics. High prevalence of sleep disorders among taxi drivers may result in unsafe driving behaviors and injury as it was estimated that drivers with sleep disorders were 26% more likely to drive inattentively.³² Prediction of rest stops and proper regulations supporting taxi drivers' adequate sleep should be considered by responsible authorities.

Poor sleep quality in taxi drivers was significantly associated with their age. Drivers with more than 50 years old were more at risk of sleep disorder. It was reported in previous literature that drivers with older age had lower sleep efficiency which result in their driving performance.³³ Meanwhile. Scarpelli et al., in a systematic review. concluded that older drivers were less vulnerable than young to sleep-related driving events.³⁴ These findings were in line with our study results. It may be due to older drivers' self-regulation as they avoid driving in high-risk times and settings. Taxi driving is a sedentary, long-time work that limits employing healthy behaviors and lifestyles. Results illustrated that 1-year increase in working experience as a taxi driver led to an 8% reduction in sleep disorders. The findings were inconsistent with the results of Ferreira et al. study in Brazil, which indicated that urban public transport drivers' working experience had a positive relation with their poor sleep quality.³⁵ This may be due to the difference in the working situation of taxi and public transport drivers.

Daily hassles increase the likelihood of drivers expose with various stressors which may rise the risk of mental and physical illnesses.⁵ Results showed that 10.2% of drivers had MI history and 12.4% of participants had cardiovascular disease, which was significantly related to their sleep quality. It was reported by Hachesdu et al. that approximately 90% of taxi drivers in Yazd had at least one risk factor of cardiovascular disease.³⁶ Similar results were also reported in other studies that chronic disease such as cardiovascular disease and depression are more prevalent in professional drivers compared with general population.^{20,37} A recent study by Chalmers et al. revealed an association between heart performance and negative and depressive mood in drivers.³⁸ Significant associations between cardiovascular disease and depression symptoms were also seen in this study through bivariate analysis, which emphasizes the importance of healthy lifestyle promotion interventions among taxi drivers. Moreover, communitybased initiatives addressing risk factors such as smoking, physical inactivity etc. besides providing a green and encouraging urban environment, could be a strategy to decrease cardiovascular disease.³⁹ Depression was reported as one of the most prevalent mental disorders among taxi drivers because of long time working hours, low economic status, and other special working situations.^{6,21} Interestingly, a mutually significant relationship appeared between sleep disorders and depression. It was revealed that drivers with moderately severe

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depression symptoms were 35 times more at risk of sleep disorders. On the other hand, drivers with sleep disorders were at approximately seven times more risk of being depressed. It was evident in previous literature that drivers with sleep disorders are at higher risk of depression.²⁰ Taxi drivers as an inner-city public transport agent not only interact with various passengers with different backgrounds and moods in a day but also confront with traffic jams, air pollution and other environmental situations which lead to higher distraction during driving and risk of accident.⁴⁰ They should be mentally alert and stable to effectively manage the circumstances. Identifying physiological, psychophysiological, and environmental factors that exacerbate poor sleep quality and depression among taxi drivers would help develop effective strategies and policies to decline. The establishment of daily rest-hour regulation using a taximeter and encouraging drivers to selfregulate would be helpful in reducing sleep disorders and depression. Policies on health check-ups basically on the taxi licensing process and biannually could also help drivers' health monitoring and promotion.⁴¹ Taxi drivers' sleep disorders and depression might have negative impacts on their physical and mental health, and increased accident risk, which results in public safety impairment, public health burden, economic loss, and social costs. This underscores the importance of taxi drivers working regulations considering occupational health and supportive rules to ensure higher traffic safety on inner city roads, especially in countries with high numbers of road traffic casualties, including pedestrians, cyclists, and motor riders.

4.1 | Conclusions

Taxi drivers were at higher risk of poor sleep quality and depression, especially older. Their work time and circumstances affect their physical and mental health, which increases the risk of unsafe behavior and crashes. Some interventions such as the establishment of short rest stops with furniture in various points in the city, employing regulations that support drivers' adequate sleep and mental recovery such as providing group exercise programs, and so on, and policies addressing their financial well-being and social support by related authorities could be beneficial. Moreover, periodic health screening would help timely identification of the disorders and employing proper solutions.

4.2 | Limitations

Night shift (11pm-6am) taxi drivers were not included in this study which was a limitation. Moreover, drivers may over/underestimate their responses which was addressed by the interviewer through creating a friendly climate.

AUTHOR CONTRIBUTIONS

Leili Abedi: Writing—original draft; methodology; writing—review and editing; formal analysis; visualization; data curation. Mohammad Bagher Naghizad: Investigation; writing—original draft; methodology; VILEY_Health Science Reports

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study was approved by the ethical committee of Tabriz University of Medical Sciences (Ethical code: IR.TBZMED.REC. 1397.1090). Informed consent was obtained from all subjects involved in the study.

TRANSPARENCY STATEMENT

The lead author Mohammad Saadati affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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