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Original Article

The role of medication adherence in the association between health literacy and diabetes self-care among reproductive-aged women with diabetes mellitus: A Structural Equation Model

Mahtab Nameni[1], Shabnam Omidvar[2*], Mohammadreza Kordbagheri[3]

1. Student of Pharmacy, School of Pharmacy, Ayatollah Amoli Branch, Islamic Azad University, Amol, Iran
2. Social Determinants of Health Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, I.R. Iran
3.Department of Statistics, Faculty of Mathematical Sciences, Shahid Beheshti University, Tehran, Iran

Abstract

***Background*:** The increasing global burden of diabetes, especially in developing nations, highlights the imperative to know more about medication adherence and self-care practices among reproductive-age women with diabetes. The objective of this research was to assess the interrelations between health literacy, medication adherence, and diabetes self-care among reproductive-age women with diabetes

***Methods*:** In this cross-sectional study, 214 diabetic women (30.29 ± 6.52 years old) visited a diabetes clinic in Tehran, Iran (December 2022–March 2023). Convenience sampling was conducted, and the participants responded to questionnaires on demographics, diabetes self-care (DSCA), health literacy (HELIA), and medication adherence (MMAS-8). Structural equation modeling (SPSS26/AMOS24) examined variable relationships (significance: $p < 0.05$).

***Results*:** Adherence to medication was low (83.7%), with no demographic correlations of note. Health literacy was positively related to adherence ($r = 0.389$, $p < 0.001$) and self-care ($r = 0.315$, $p < 0.001$). Adherence to medication mediated the relationship between health literacy and self-care ($\beta = 0.447$, $p < 0.001$). Health literacy was directly related to better adherence ($\beta = 0.401$, $p < 0.001$) and self-care ($\beta = 0.331$, $p < 0.001$).

***Conclusion*:** Poor adherence to medication continues to exist among women of reproductive age with diabetes. Health literacy improves adherence and self-care, with adherence acting as a mediator. Interventions aimed at health literacy could potentially enhance diabetes care in this group.

Keywords: Medication adherence, Diabetes Mellitus, reproductive health, health literacy, self-care

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*** Corresponding Author:**

Shabnam Omidvar
E-mail:
shomidvar@yahoo.com
Tel: 011-32199592-6

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Introduction

Diabetes mellitus (DM) is a significant global public health issue, with 463 million individuals (9.3% prevalence) affected in 2019 and estimates increasing to 700 million (10.9%) by 2045 .(1) This increasing trend is of particular concern in developing nations such as Iran, where more than 10% of adults are diabetic(2-7). The burden of disease arises mainly from vascular complications, underlying morbidity, mortality, and excessive healthcare expenditure—70% of which are due to chronic diseases such as DM (3-6).

Effective diabetes management relies heavily on self-care behaviors, including medication adherence, diet, exercise, and blood glucose monitoring (4-6). Such practices enhance glycemic control (e.g., lower HbA1c), decrease complications, and reduce hospitalization costs(6, 8). Self-care, however, is shaped by sociocultural characteristics, health knowledge, and health literacy (HL)—the capacity to access, comprehend, and use health information (9-13). Low HL is associated with inadequate disease control, greater use of emergency care, and poorer health outcomes(12, 14, 15). Decision-making, one of the fundamental HL aspects, is a strong predictor of health behaviors(12, 16-18).

For women of reproductive age, diabetes has further risks: poor glycemic control negatively impacts fertility, pregnancy outcomes, and neonatal health, increasing mortality and morbidity risks(6, 19, 20). Yet, despite this, medication non-adherence is still common, with rates for oral hypoglycemics between 36–93% and insulin adherence at ~63%(5, 21-24). In Iran, studies reports are widespread non-adherence (16, 25), fueled by factors such as health beliefs, self-efficacy, and medication regimen complexity (26-30). Non-adherence costs more than $100 billion per year in avoidable costs(22) and increases complications (6).

Although previous studies have investigated social determinants of women's diabetes care(31-34), there are gaps in knowledge regarding how HL and medication adherence collectively influence self-care. The present study fills this gap by investigating HL's association with self-care, as mediated by adherence, in reproductive-aged diabetic women in Iran—a group that experiences distinctive hardship due to healthcare system limitations and gendered health inequities(10, 35-38).

Methods

The cross-sectional study was conducted among diabetic women of reproductive age referring to a diabetic center from 12.12.2022 to 10.03.2023, in Tehran, Iran. After the approval of the protocol by the research board of Azad University (Ayatollah Amol Branch), sampling was carried out from a single outpatient diabetes center using a convenience sampling method in Tehran, Iran. The participants were women of

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reproductive age, who had a recorded file in the center and met the inclusion criteria.

Participants and settings:

Participants for the study were recruited from a diabetic clinic. Participants were diabetic women of reproductive age who met the study inclusion criteria such as age 18 to 45 years old, diagnosed with diabetes for at least 1 year, taking diabetes treatment, ability to read and write, not being addicted to alcohol and drugs, not suffering from debilitating motor diseases or mental disorders (according to their medical records), and completing the informed consent form to participate in the study. Sampling was done by convenience method. The subjects who attended the diabetic center during the sampling and had inclusion criteria entered the study. Subjects who were pregnant or failed to answer 10% or more of the questions were excluded from the study(39).

Sample size estimation was done by G*Power software. According to the prevalence of diabetes among Iranian women equal to 11.2 % (40) the power of the test was 90%, error type 1 was 5%, and the sample size was calculated to be 214 people. Considering the drop of 20%, the sample size was equal to 254 people. Given the complexity of SEM and established methodological guidelines (Kline, 2016), a minimum sample size of 200 participants was ensured. This threshold guarantees adequate power for evaluating model fit and latent variable relationships—a criterion met in the current study.

Data collection tools and techniques

The participants completed four questionnaires, including a demographic and clinical characteristics questionnaire, Diabetes Self-Care Activities, health literacy, and medication adherence.

Demographic and Clinical Characteristics

1. Demographic and Clinical Characteristics such as age, education, occupation, marital status, spouse's education, spouse's age, and occupation, family income sufficiency, Insurance, pregnancy history, Number of children type of diabetes, type of treatment, duration of disease, other comorbidities, HbA1C (extracted from the patient's record), and BMI(Weight(Kg)/Length(m)^2).

2. Morisky Medication Adherence Scale (MMAS-8): This questionnaire contains 8 questions that measure medication adherence. This questionnaire has seven double-choice questions (yes= zero and no=one point) and one question with a five-point option (never=zero, rarely = 1, sometimes = 2, most of the time = 3, always = 4). A score of 6 or higher was classified as optimal adherence to treatment. The validity of this questionnaire was evaluated in a Laghousi et al. study and Cronbach's alpha was reported. 83 (41).

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3. Diabetes Self-Care Activities Questionnaire (SDSCA): The questionnaire has 40 questions that show the self-care status of patients in the last month. The questionnaire was scored based on a 5-point Likert scale (ranges from 1= never to 5= always). Higher scores indicate better self-care status. This questionnaire examines the domains of self-care. The psychometric properties of the Persian version have been assessed by Ebadi, and its validity and reliability have been measured(42).The validity of this questionnaire was evaluated and Cronbach's alpha was reported 0.91.

4. Health Literacy of Iranian Adults (HELIA): The questionnaire has 33 questions in 5 dimensions including reading, accessibility, comprehension, evaluation, decision-making, and behavior. The measure assesses the health literacy of the Iranian population aged 18 to 65. Montazeri designed and assessed the reliability and validity of the instrument. Responses were recorded using a five-point Likert scale. Thus, in the questions related to reading skills, 5 =completely easy, 4= easy, 3= neither easy nor difficult, 2= difficult, and 1=completely difficult. Regarding the other 4 dimensions of health literacy, a score of 5 is assigned to the always, 4= most of the time, 3 = sometimes, 2 = rarely, and a score of 1 = not at all or never

The raw scores of the 5 domains of health literacy are calculated and then converted into a standard score between 0 and 100 so that scores from 0 to 50 are considered insufficient health literacy, scores from 50.1 to 66 as Inadequate health literacy, 66.1 to 84 is considered as adequate health literacy and 84.1 to 100 as excellent health literacy(43).The validity of this questionnaire was evaluated in a study and Cronbach's alpha was reported 0.77.

The questionnaires were completed by the participants, and in average, completing took 10 minutes and it was self-reporting by the subjects.

Ethics approval and consent to participate: The study design was approved by the Ethics Committee of Azad University, Ayatollah Amoli Branch, Amol, Iran (IR.IAU.AMOL.REC.1401.106). Written informed consent was taken from all the participants. All methods were carried out following relevant guidelines and regulations.

Statistical analysis

In this research, SPSS26 and AMOS24 software were used for analysis and the significance level of the tests was considered less than 0.05.

We also used ANOVA, t-test, regression (correlation coefficient) for statistical analysis.

1. **Missing data:**

A number of items had missing data. The missing values were handled using Multiple Imputation by Chained Equations (MICE), which generates several plausible replacements for each missing value based on patterns in the observed data

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2. Multivariate outlier data:

To check the absence of multivariate outlier data, the Mahalanobis d2 index was examined and significance levels less than 0.05 were indicating the outlier data. No outliers' data were identified.

3. Univariate normality:

To check the normality of a single variable, the state of distribution of observation variables in the model (i.e., the main variables of the research) was investigated using skewness and kurtosis indices. According to Klein (2016), the absolute value of the skewness is less than 3 and the kurtosis is less than 10, indicating the absence of data problems in terms of univariate normality (44). Based on skewness and kurtosis indices, the absolute value of skewness was not greater than 3 for none of the variables. Also, the absolute value of elongation was not greater than 10 for none of the variables. Therefore, it can be said that there is no problem in performing this analysis in terms of the normality of univariate.

4. Multivariate normality:

Mardia standardized kurtosis coefficient and critical ratio have been used to check the normality of several variables. According to Blunch (2012), values less than 5 for the critical ratio are considered for multivariate normality (45). If the critical ratio based on Mardia's standardized kurtosis coefficient is less than 5, it means that the assumption of multivariate normality has been met. In this research, the Mardia standardized kurtosis coefficient was 4.654 and the critical ratio was 2.289. Therefore, the assumption of multivariate normality is maintained.

The proposed model was tested, after establishing important presuppositions of structural equations model. To fit the proposed model based on the covariance method, Amos software version 24 was used and the parameters were estimated by the maximum likelihood (ML) method.

Results

In the present study, the information of 214 reproductive-aged women with diabetes who were referred to the diabetes center for their medical visits was analyzed. The average age of the participants was 30.29 ± 6.52 years (ranging from 18 to 45 years). Most of them were educated (Bachelor degree and higher) (59.8%),72.9% married, 51.9% non-employed,70% were overweight/obese, 71.5% had diabetes type 1, 79% had health insurance.

Table 1 exhibits the mean score of medication adherence among reproductive-aged women. The results showed that 83.2% of the women were non-adherent. The results exhibited no statistically significant relationship between demographic, clinical variables, and medication adherence, in women with diabetes (Table 2).

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Table 1: The medication adherence among reproductive-aged women with diabetes referred to the diabetes center

Variable	Mean±Sd	Range	Classification	
			Non-adherence n (%)	Adherence n (%)
Medication adherence	1.8±1.11	0-8	178(83.2)	36(16.8)

Non-adherence<6, Adherence≥6

Table 2: Socio-demographic and clinical characteristics of the participants (n=214)

Demographic variables		n (%)	Medication adherence	F/T - P value
			Mean±SD	
Education	**Literate**	25(11.7)	1.76±1.26	**F=0.08, P=0.92**
	intermediate school/Diploma	61(28.5)	1.85±0.94	
	Bachelor degree and higher	128(59.8)	1.79±1.15	
Occupation	**Employed**	82(38.3)	1.81±1.16	**F=0.02, P=0.97**
	Freelancer job	21(9.8)	1.76±0.99	
	Non-employed	111(51.9)	1.81±1.07	
Marital status	**Single**	19(8.9)	1.63±1.38	**F=1.14, P=0.32**
	Married	156(72.9)	1.87±1.12	
	Widow/Divorced	39(18.2)	1.61±0.87	

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Spouse's education	**Literate**	10(6.4)	1.7±1.15	**F=0.52, P=0.59**
	intermediate school/Diploma	42(26.9)	1.76±1.1	
	BS degree and higher	104(66.7)	1.94±1.13	
Spouse's occupation	**Employee**	51(32.7)	2.09±1.20	**t=1.71**
	Freelancer job	105(67.3)	1.77±1.07	**P =0.08**
Number of children	**Zero**	47(24.1)	1.72±0.97	**F=1.54, P=0.20**
	1	50(25.6)	1.88±0.89	
	2	64(32.8)	1.68±1.06	
	≥3	34(17.4)	2.14±1.43	
BMI(kg/m2)	**Normal**	64(29.9)	1.78±1.11	**F=1.09, P=0.33**
	Overweight	105(49.1)	1.73±0.99	
	Obese	45(21)	2.02±1.33	
Insurance	**Yes**	169(79)	1.85±1.17	**t=1.12, P=0.26**
	No	45(21)	1.64±0.82	
Other comorbidities	**Yes**	28(13.1)	2.00±1.58	**t=0.98, P=0.32**
	No	186(86.9)	1.77±1.02	
Type of diabetes	**1**	153(71.5)	1.86±1.18	**t= 0.61, P=0.54**
	2	61(28.5)	1.85±0.94	

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Type of treatment	**Oral**	75(35)	1.73±1.13	**t=-0.39, P=0.73**
	Insulin	139(65)	1.82±1.10	
Duration of diagnosed(years)	**1-3**	197(92.1)	1.78±1.02	**t=-0.97, P=0.33**
	≥4	17(7.9)	2.05±1.88	
HbA1C	**<7**	120(56.1)	1.74±0.94	**t=-0.99, P=0.32**
	≥7	94(43.9)	1.89±1.29	
Age(year)		**r=-0.04, P= 0.57**		
Spouse age(year)		**r=-0.06, P=0.51**		

Table 3: Standard coefficients of paths of the final pattern (modified)

Paths	β	*SE*	*CR*	*P value*
Health literacy → Self-care	0.331	0.105	4.076	<0.001
Health literacy → medication adherence	0.401	0.097	4.861	<0.001
Medication adherence → Self-care	0.447	0.162	6.230	<0.001

Standardized path coefficients (β), Critical Region (C.R.).

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The results showed that health literacy was positively associated with medication adherence (β=0.401, P<0.001), as well as was positively associated with self-care (β=0.331, P <0.001). Medication adherence was also significantly linked to self-care (β=0.447, P<0.001). It means that decreased medication adherence was observed among women with lower levels of health literacy and self-care. Table 3 also shows the standard coefficients of the paths.

The structural equation modeling method was used to test the proposed model of the mediation model of medication adherence in the relationship between health literacy and diabetes self-care of women with diabetes. The structural equation model includes a set of structural equations that depict causal relationships between factors. The proposed model of the current study has 3 variables, one variable as an exogenous (independent) variable, one variable as an endogenous (dependent) variable, and one variable as a mediating variable.

Table 4 presents the fit indices of the proposed model, which includes chi-square (χ^2) as an absolute goodness-of-fit measure. The higher the chi-square value, the weaker the model fit. Since the chi-square formula is sensitive to sample size and may yield falsely significant results in large samples, the relative chi-square (CMIN/DF) [42] was used, where values ≤ 3 indicate a desirable model fit. For a more comprehensive evaluation, additional indices were calculated, including the Comparative Fit Index (CFI ≥ 0.90 acceptable, ≥ 0.95 excellent), the Goodness-of-Fit Index (GFI ≥ 0.90), the Root Mean Square Error of Approximation (RMSEA ≤ 0.08 acceptable, ≤ 0.05 excellent), the Incremental Fit Index (IFI ≥ 0.90), and parsimony indices (PNFI and PCFI > 0.50). The results presented in Table 4 demonstrate that all examined indices fall within acceptable ranges, confirming the favorable fit of the proposed model. To assess the assumptions of the research, before using the structural equations method, the presuppositions of this method were checked.

The fitness of the proposed model was evaluated based on the introduced fit indices. The results of the fit indices show that the proposed model does not have an acceptable fit, although the CMIN/DF indices are smaller than 5 and PCFI

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and PNFI greater than 0.5 in the proposed model are acceptable(46). To improve the model, the final pattern of the research was made by plotting the correlation between the covariance errors. The results showed that after the modifications, the final model of the research has a good fit. The fit indices of these patterns are shown in Table 4.

The self-care variable presents 0.36 % (R^2 = 0.36) of the changes associated with health literacy and adherence to medication in this model.

Figure 1 shows the hypothesized model of the research and Figure 2 shows the final path of the study.

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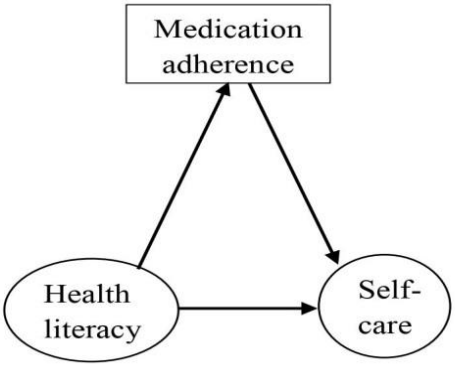

Fig 1. Hypothesized model of the variables

Table 4. Fit indices of the proposed and modified model

	GFI	IFI	PCFI	CFI	PNEI	RMSEA($CL_{90\%}$)	CMNI/DF	P-value	df	x^2
Primary model	0.899	0.896	0.507	0.894	0.528	0.087(0.07-0.09)	2.613	<0.001	33	86.255
Modified model	0.923	0.910	0.511	0.907	0.596	0.077(0.06-0.08)	2.282	<0.001	31	70.753

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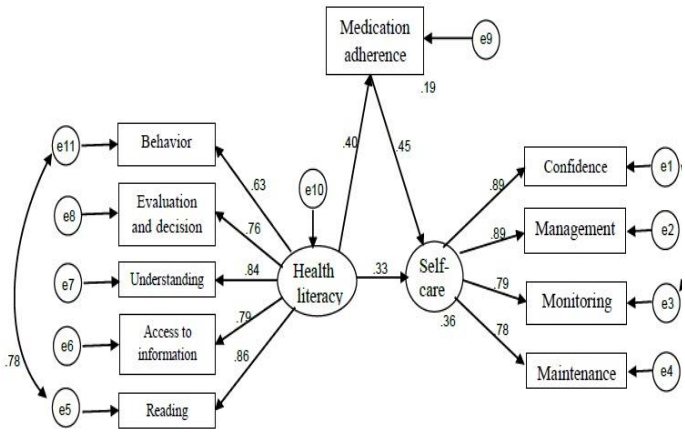

Fig 2. Standard coefficients of the modified model

Therefore, according to the estimated indicators, the results show that the mediation model of medication adherence is suitable in the relationship between health literacy and diabetes self-care of reproductive-aged women with diabetes.

The results of the direct relationships of the variables in the final (modified) model showed that all path coefficients were statistically significant.

Discussion

The present study showed that the level of medication adherence among reproductive-aged women with diabetes is poor and there is a direct relationship between health literacy and diabetes self-care. Moreover, medication adherence plays a mediating role in the relationship between health literacy and diabetes self-care.

Non-adherence to medications not only leads to disease-related complications but is also associated with increased hospitalization rates and higher healthcare costs(47). It has been estimated that 10% of hospital admissions in the elderly can be attributed to medication non-adherence (48), which can lead to poor management of disease. In addition, a longitudinal cohort study estimated that a 10% increase in medication adherence could reduce annual healthcare costs in diabetic patients by 8.6 to 28.9%(49). In the current study, we found 83.7% of diabetic women had poor medication adherence, which is similar to another recent study in Iran (26) and significantly higher than the results of other similar studies in the world (50-52). Since most of the medication adherence studies have been conducted among elder people or those with multiple problems, it seems that younger subjects in the current study as well as the lack of attention to the disease and its side effects because of being younger age are important factors in poor medication adherence. Interestingly, In the present study, no significant relationship was found between medication adherence and demographic characteristics and it was similar to other studies from Iran and other countries(53, 54). However, medication adherence is a variable that is influenced by various factors, as other studies have pointed out (55-57).

The results exhibited a significant positive relationship between health literacy and diabetic self-care as well as medication adherence among diabetic women. Other studies also have shown that a significant relationship has been found

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between diabetes knowledge and self-care, these results are in line with our study because knowledge related to diabetes can be influenced by the level of health literacy(58, 59). Several studies suggested that health literacy is effective in enlightening health outcomes including self-care performances (60) (61).

The capacity to obtain, process, and understand basic health information and services has an important role in appropriate health decision-making. Moreover, according to other studies, the role of limited health literacy is known in poor adherence to medication in patients with chronic diseases(62, 63). Our finding is in line with a report from a study from Iran which found associations between health literacy and medication adherence among elder women (64).

Health literacy is a factor that has been considered due to its influence on self-care management, knowledge about the disease, health outcomes, self-efficacy, and medication adherence (65, 66). However, some studies did not report a significant relationship between health literacy and medication adherence (66, 67). This difference can be justified due to the different tools used in the assessment of health literacy or cultural differences and the type of diseases investigated.

The evidence showed that people with chronic diseases spend only 0.01% of their care time with professional healthcare providers, and the rest of the care activities related to disease prevention, monitoring, and disease management are done by individuals with chronic disease as self-care activities(68, 69). The most important aspects of diabetes treatment include medication regimens and diabetes self-care behaviors. Therefore, identifying and understanding the relationship between health literacy and diabetes self-care behaviors is the key to better-implementing intervention strategies to improve health outcomes, especially in socially challenged environments. Although we found the mediating role of medication adherence in the relationship between health literacy and self-care, this relationship may not always be established and self-care behaviors may be more influenced by disease knowledge, patient and service provider relationships, and other factors. This is however a concern that requires attention since most of the participants in the study was well-educated but education and other demographic factors were not related to the adherence to medication.

Strengths Limitations and of the study

An important strength of the current study was considering the relationship between three variables of health literacy, self-care and medication adherence as a structural model among reproductive-aged women. The study clarified the relationship between health literacy, medication adherence and diabetic self-care and provided significant information for health providers of diabetic women. The study has several potential limitations. First, our sample was taken from a single outpatient clinic in Tehran, and patients' characteristics may differ

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from other regions, hence limiting the representativeness of the study and it may not be generalizable to other regions. Second, the cross-sectional nature of the research avoids the assessment of causality relationships among variables. The last one, some factors such as attitude towards long-term medicine use, recall bias, and also modifiers which might influence medication adherence were unable to be controlled.

We suggest conducting interventional studies in a population with different socio-economic situations in the future. Further research is needed to determine the generalizability of the results to other area of Iran.

Conclusion

Medication adherence was very poor in reproductive-aged women with diabetes. A significant relationship was found between health literacy, medication adherence, and diabetes self-care; moreover, medication adherence might mediate health literacy and diabetes self-care of reproductive-aged women with diabetes. Therefore, by promoting health literacy and encouraging medication adherence, it is possible to improve diabetes self-care behavior, which is an important factor in controlling the complications caused by the disease. Considering the effect of diabetes on women's fertility, paying attention to medication adherence among this group of women has special importance. Designing interventional studies aiming to promote medication adherence levels to improve self-care behaviors among women is promising.

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Conflicts of interest: There are no conflicts of interest.

Availability of data and material: The datasets used and/or analyzed during the current study are not publicly available due to restrictions imposed by the Research Ethical Committee of Islamic Azad University, Amol Branch, Iran. However, the data can be made available upon reasonable request from the corresponding author.

Author's contribution

SO contributed to the concept and design of the study; supervised the project, drafted the manuscript, and prepared the final version. MK analyzed and interpreted the data, reviewed and edited the draft of the manuscript. MN collected the data, entered the data, reviewed and edited the draft. All the authors read and approved the final version of the manuscript to be published.

Consent for publication: Not applicable.

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