

Examining the effect of polyurethane dressing containing silver particles on the rate of diabetic foot ulcer infection in hospitalized patients: A randomized control study

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Abstract

Background and Aims: One of the new types of dressings is the polyurethane dressing containing silver particles. This study was designed to evaluate the effect of polyurethane dressing containing silver particles on the rate of diabetic foot ulcer infection in hospitalized patients in a military hospital.

Methods: This was a randomized clinical trial study on 48 patients with diabetic foot ulcers who were referred to the wound clinic of Shahid Dr. Chamran Hospital in 2022. The qualified samples were divided into two groups of silver polyurethane dressing and simple sterile dressing based on a randomization block method. The wounds of both groups of patients were initially cleaned with normal saline and in the first round of dressing, and a sample of tissue secretions was collected by the researcher using a sterile swab from the wounds of the patients on two occasions, superficially and deeply. The patients' wounds in the intervention group were dressed with polyurethane foam dressing containing silver particles, while the simple sterile routine dressing was used in the control group. The rate of infection and wound secretions were examined and recorded on the first, seventh, fourteenth, and twenty-first days from the start of dressing in both groups. To collect data, the IDSA tool was used.

Results: The rates of wound infection before the intervention showed no significant differences in the two groups ($p = 0.242$). However, these rates changed on the 7th, 14th, and 21st days after the intervention. Moreover, the infection rate was significantly lower in the polyurethane dressing group containing silver particles ($p < 0.001$ and $F = 30.31$).

Conclusions: Using polyurethane dressing was proven to be more effective in this study on the rate of diabetic ulcer infection in patients compared to the simple sterile dressing. Thus, nurses can use this dressing for faster treatment of diabetic foot ulcers infection.

KEYWORDS

diabetic foot ulcer, polyurethane dressing, wound healing, wound infection

1 | INTRODUCTION

Diabetes mellitus is a metabolic disorder with multiple causes, characterized by chronic hyperglycemia associated with impaired metabolism of carbohydrates, proteins, and fats following impairments in insulin secretion, insulin functioning, or both.¹ The disease's worldwide prevalence is around 9.8%.² There were approximately 450 million patients (aged 18–99) with diabetes in 2017, and as predicted, the statistics are expected to reach 552 million people in 2030³ and 693 million people in 2045.⁴ The prevalence of diabetes in Iran is estimated at about 12.2%–13.3%, which will increase to 14% by 2045.⁵

Besides causing the death of about 4 million people every year,³ diabetes is associated with many complications such as heart failure,⁶ nephropathy, retinopathy, cataracts, and diabetic foot ulcers.⁷ Diabetic foot is referred to as a set of syndromes in which neuropathy, ischemia, and infection cause tissue abnormalities or secondary ulcers to microtrauma.⁸ About 15% of diabetic patients develop such a complication, and currently, about 70 million diabetic patients have foot ulcers.^{9,10} These types of wounds are seen as serious and dangerous complications of diabetes since they worsen the patient's clinical condition and diminish their quality of life.⁸ By causing many socioeconomic effects, this complication enhances the possibility of amputation in diabetic patients.¹¹ If the diabetic foot wound becomes infected, the conditions will become more difficult for the patient and the healing process will be very slow.¹²

The intensity of the diabetic foot infection can be superficial or the infection might have involved the bone deeply. Different types of these infections include cellulitis, myositis, abscess, necrotizing fascia, septic arthritis, tendonitis, and osteomyelitis.¹³ About 40%–80% of ulcers caused by diabetes become infected and cause long hospitalization of patients and increase treatment costs, and even lead to amputations.¹⁴ Thus, early diagnosis and management of diabetic foot ulcers can reduce such complications.⁸ Out of different types of pathogenic organisms, *Staphylococcus aureus* seems to be the most common cause of infection. This finding may be effective in choosing the type of antibiotic and recommended dressing.¹⁵ In this regard, foam and alginate have been proposed for excreting wounds due to their high absorption properties. However, silver compounds have been suggested for infected wounds.¹⁶ Foam is generally referred to as a substance in which there is gas dispersion in liquids and solids. Calcium alginate is a water-soluble and gelatinous compound, which is extracted from seaweed or made by adding calcium chloride to sodium alginate.¹⁷

One of the new types of dressings used in recent years is the polyurethane dressing containing silver particles according to the various conditions of wounds and ulcers.¹⁸ This dressing is a three-layer adhesive-free foam. A layer of polyurethane, the outermost layer, is impermeable to water and bacteria; the middle layer absorbs wound secretions, and the inner layer that is in contact with the wound bed has reticulated silver particles and does not stick to the wound bed, and causes the wound secretions to be transferred to

Key points

- About 15% of diabetic patients develop such a complication, and currently, about 70 million diabetic patients have foot ulcers. These types of wounds are seen as serious and dangerous complications of diabetes since they worsen the patient's clinical condition and diminish their quality of life.
- This study was designed to evaluate the effect of polyurethane dressing containing silver particles on the rate of diabetic foot ulcer infection in hospitalized patients in a military hospital.
- Using polyurethane dressing containing silver particles was proven to be more effective in this study on the rate of diabetic ulcer infection in patients compared to the simple sterile dressing.

foam, and finally, prevents the skin around the wound from getting wet.^{19,20}

Namviriyachote et al.²¹ reported that the antimicrobial and restorative properties of polyurethane dressing containing silver particles are useful in reducing infectious skin wounds. Wang et al.²² concluded in their study that the silver-releasing foam is more effective than traditional silver sulfadiazine cream for the initial period of wound care. However, they recommended other alternative dressings would be used to maintain the speed of wound healing and prevent the negative effects of silver ions following 3 weeks of treatment with silver ions. Whilst Cutting et al.²³ believe that silver-containing dressings are not effective in reducing infection despite their beneficial effects.

The results of these studies indicate that it is still too early to definitely answer the following questions: Which dressing is more appropriate for healing diabetic ulcers caused by infection? And Out of various types of dressings, is silver-containing dressing effective in treating the infection of these wounds?

The problem of diabetic foot ulcer management requires the intervention of the care team, and it should be considered from a multidisciplinary perspective. Therefore, it requires teamwork and the participation of nursing and medical professionals.⁸ Especially the nurses of diabetic patients who are responsible for dressing their wounds need to be quite familiar with the best and most effective type of new dressings and how to use them.¹² By reviewing the relevant studies conducted so far, the research team realized that there is still no consensus on the effect of Eurofarm dressing containing polyurethane foam with silver particles on diabetic foot ulcer infection. This study was designed to evaluate the effect of polyurethane dressing containing silver particles on the rate of ulcer infection in patients with diabetic ulcers and compare the rate of wound infection on days 0, 7, 14, 21, and 28 in both intervention and control groups.

2 | METHODS

2.1 | Participants

The research population encompassed all patients with diabetic ulcers who had been referred to Dr. Chamran Shahid Hospital between early April and late August 2022. The sample size was determined as 22 subjects for each group using the G-Power software (Ver. 3.0.10) based on the study by Afshar et al.¹⁴ and considering the first type error of 0.05 and the test power of 80%. Ultimately, the sample size was calculated as 24 subjects for each group by taking into account the possibility of a 10% dropping. The inclusion criteria were set as the rate of foot ulcer infection with grade 2 and higher based on the IDSA (Infectious Diseases Society of America) criteria and the patients aged 40–65 years with diabetic foot ulcers. The exclusion criteria were also the refusal to continue cooperation, known sensitivity to the studied dressing, and the need for surgery for wound debridement during the study.

The sampling was done using the convenience sampling method according to the study inclusion criteria. Hence, 48 patients were assigned to two groups by a randomization block approach: The intervention group (polyurethane dressing containing silver particles: 24 subjects) and the control group (simple sterile dressing: 24 subjects). After receiving the necessary permits to do the research in this medical center, the research objectives were explained to the samples included in the study and an informed consent form was received from them in writing. After talking with the patients, the researcher completed the demographic profile questionnaire and required medical information, and then evaluated their diabetic ulcers based on the IDSA criterion—the ulcer infection assessment checklist (Diagram 1).

2.2 | Data collection tools

The data collection tool included a questionnaire to gather the patient's demographic information and the rate of diabetic ulcer infection according to the guidelines of the IDSA criteria of the Infectious Diseases Society of America. The patients' demographic information questionnaire measured the age, gender, marital status, education level, occupation, body mass index, vital signs, blood sugar levels, antidiabetic drugs, antibiotic use, duration of diabetes, history of previous ulcers, duration of diabetic ulcer, wound culture, and WBC, ESR, CRP tests, which was completed by the researcher by referring to the patient's medical records and interviewing them. The rate of diabetic ulcer infection was evaluated based on the guidelines of the IDSA criteria of the Infectious Diseases Society of America. According to this guideline, the severity of the infection is divided into four grades. Grade I ulcers are noninfected wounds. Grade II ulcers are considered mild infections, in which, two or more signs of inflammation (pus or erythema, pain and tenderness, warmth and stiffness) are present along with one of the following findings: cellulitis, erythema with lower spread, and an infection

limited to the skin and subcutaneous tissue without systemic symptoms. In Grade III ulcers, cellulite with a size of more than two centimeters is seen around the wound associated with lymphangitis, subcutaneous tissue infection, abscess, gangrene, and the involvement of tendons, joints, or bone infection. In the Grade IV ulcers, systemic symptoms such as fever and chills, tachycardia, hypotension, confusion, metabolic acidosis, azotemia, severe hyperglycemia, and leukocytosis are added to the table of Grade III. This tool had an inter-rater validity agreement of 0.95 and an inter-rater reliability of 0.96.²⁴

2.3 | Sampling

In the first round of dressing, the wounds of patients in both test and control groups were initially cleansed with normal saline and sterile gas by the first-line researcher. Also, paraclinical tests, including sampling were done on both test and control groups by Chamran Hospital laboratory to check possible infection before initiating the first round of dressing. Moreover, tissue culture samples, superficially and from the depth of the wounds of the patients were taken by the researcher using a sterile swab on two occasions. Until the results of wound culture and antibiogram are prepared, which usually took 72 h, an experimental antibiotic regimen was prescribed by the attending physician for both test and control dressing groups based on the clinical manifestations of the infection, hematological indices, and liver and kidney function. Usually, the fourth-generation moxifloxacin or a combination of third-generation cephalosporin or metronidazole was prescribed since all diabetic ulcers with infection should be treated with antibacterial drugs. Once the results of the bacterial culture and antibiogram were prepared, broad-spectrum antibiotics were prescribed by the attending physician. Therefore, antibiotic medication was started for both groups and there was no difference in this regard between the two groups. In the intervention group, the polyurethane dressing containing silver particles was changed, on average, every 3–7 days depending on the degree and amount of wound secretions. The dressing in the control group was done with simple sterile gauze and Oper tape and changed daily. The ulcer infection was examined on days 1, 7, 14, and 21 from the start of the polyurethane dressing containing silver particles and the data was recorded (Diagram 1).

2.4 | Statistical analysis

The SPSS (Ver. 21) statistical software was utilized in this study for data analysis. The significance level in all statistical tests was considered lower than 0.05. Descriptive statistics (including mean, standard deviation and frequency) and inferential statistics (Chi-square tests, Fisher's exact test, one-way analysis of variance, repeated measures and independent *t* test) were used to analyze the data.

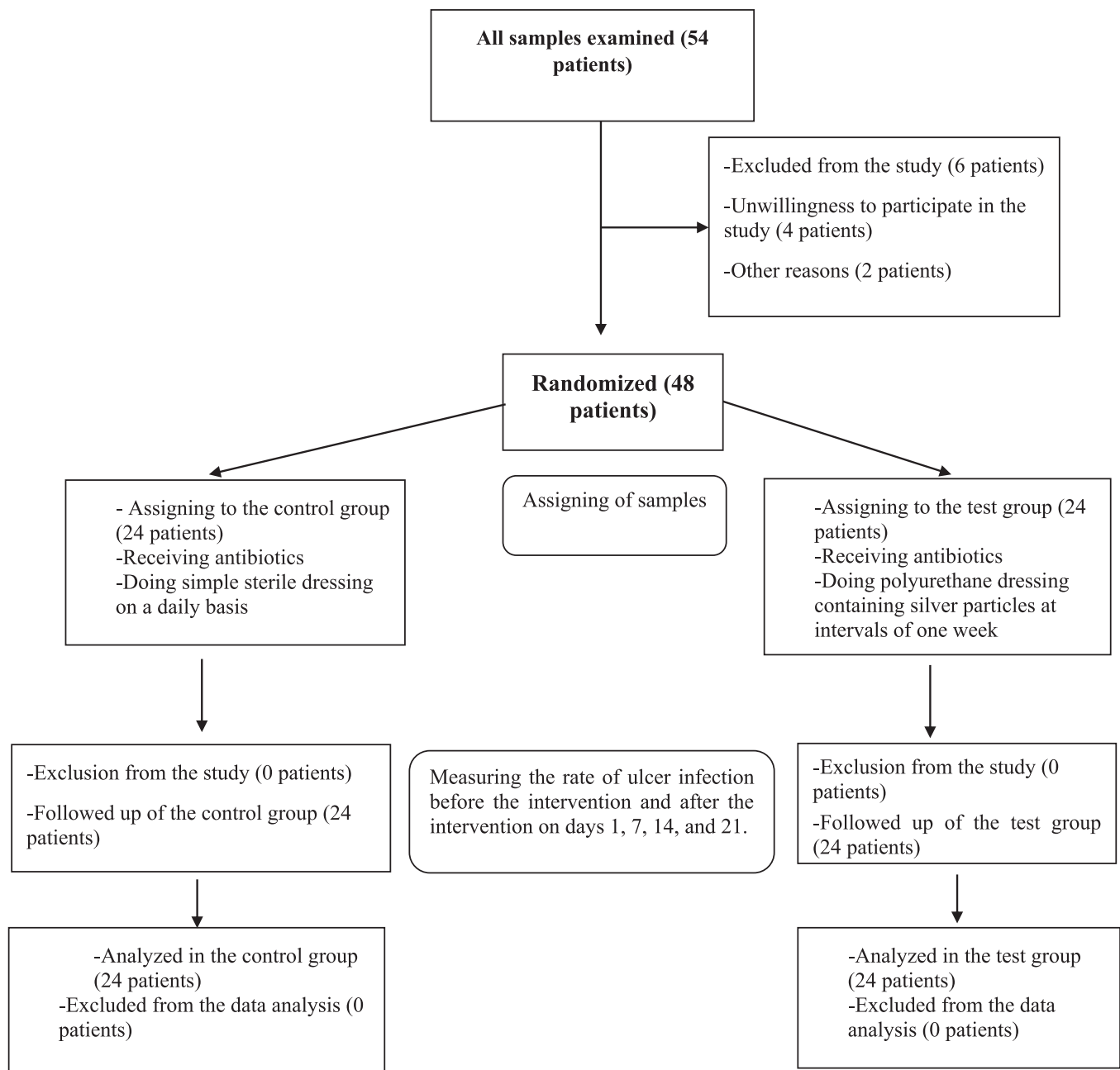


DIAGRAM 1 The process of performing the study.

3 | RESULTS

A total of 48 patients participated in this research, all of whom stayed until the end of the study. The factors of gender, marital status, previous ulcer, and duration of diabetic ulcer were compared between the two groups using the Chi-square test. Also, the factors of age, height, weight, body temperature, FBS, WBC, ESR, and CRP were compared between the two groups using Fisher's exact test. The results of both tests indicated that the two groups had no statistically significant differences ($p > 0.05$) (Table 1). Before

conducting the tests, the normal distribution of the data was confirmed using the Kolmogorov–Smirnov test.

Table 2 reveals a significant difference between the changes in the intervention and control groups. According to results, one can clearly realize that the process of infection reduction in the intervention group was significantly better than the control group. In fact, the increasing trend in infection has been significant in the control group, while the trend of infection reduction has been significant in the intervention group (Table 2).

TABLE 1 The demographic characteristics of the research subjects in the intervention and control groups.

Group		Intervention group	Control group	Statistic	Sig
Age (years) ^a	Standard deviation ± mean	58.92 ± 6.6	58.95 ± 5.6	$t = 0.18$	0.852
Height (cm) ^a	Standard deviation ± mean	1.78 ± 0.34	1.69 ± 0.16	$t = 1$	0.327
Weight (kg) ^a	Standard deviation ± mean	79.67 ± 15.11	80.12 ± 18.67	$t = 0.9$	0.927
Body temperature (centigrade) ^a	Standard deviation ± mean	37.02 ± 0.29	37.01 ± 0.28	$t = 0.98$	0.336
FBS ^a	Standard deviation ± mean	191 ± 69	213 ± 67	$t = 1.10$	0.273
WBC ^a	Standard deviation ± mean	10095 ± 3210	10525 ± 3716	$t = 0.42$	0.671
ESR ^a	Standard deviation ± mean	89.04 ± 59.48	71.58 ± 34.12	$t = 1.24$	0.219
CRP ^a	Standard deviation ± mean	70.04 ± 51.99	87.11 ± 62.05	$t = 1.03$	0.307
Variable		Number (percentage)	Number (percentage)		
Gender ^b	Female	7 (29.2)	13 (54.2)		0.142
	Male	17 (70.8)	11 (45.8)		
Education ^c	Below diploma	7 (29.2)	7 (29.2)	$\chi^2 = 0.51$	0.819
	Diploma	12 (50)	10 (41.7)		
	Bachelor	5 (20.8)	7 (29.2)		
Marital status ^b	Single	2 (8.3)	3 (12.5)		$p = 1$
	Married	22 (91.7)	21 (87.5)		
History of medication ^c	Injective	7 (29.2)	8 (33.3)	$\chi^2 = 0.84$	0.764
	Oral	10 (41.7)	7 (29.2)		
	Both	7 (29.2)	9 (37.5)		
Previous ulcer ^b	Has	17 (70.8)	11 (45.8)		0.142
	Does not have	7 (29.2)	13 (54.2)		
Diabetic ulcer duration ^b	1–7 days	5 (20.8)	3 (12.5)	$\chi^2 = 3$	0.418
	7–14 days	9 (37.5)	5 (20.8)		
	14–28 days	4 (16.7)	6 (25)		
	More than a month	6 (25)	10 (41.7)		

^aIndependent t test.^bFisher's exact test.^cChi-square test.

4 | DISCUSSION

This study was performed to evaluate the effect of polyurethane dressing containing silver particles on the rate of diabetic foot ulcer infection in patients admitted to a military hospital in Tehran, Iran. A significant difference was found between the infection rate of the intervention group (the polyurethane dressing group containing silver particles) and the control group (the simple sterile dressing) on days 1, 7, 14, and 21 based on the results. Hence, the level of infection in the intervention group was significantly better on days 1, 7, 14, and 21 and the wound had not been infected. However, this was not the case in the control group. This finding implies that the use of polyurethane dressing containing silver particles can be useful in reducing and preventing diabetic foot ulcers.

Some of the studies conducted in this field have obtained similar and consistent results. According to Bolton et al.,²⁵ silver ions can bind to negatively charged bacteria, increase the permeability of the bacterial outer membrane, and induce bacterial apoptosis. The results of a study by Zhang et al.²⁶ in China, entitled "Examining the effect of silver nanoparticles with thermoplastic polyurethane on post-operative rehabilitation of diabetic patients with lower limb open fracture" demonstrated that the use of this combination can both reduce the inflammation and unwanted reactions and lead to the wound healing by inhibiting the bacterial infection of the wound. Lázaro Martínez et al.¹⁹ suggested in their study that the silver ion dressings can continuously and effectively release silver ions, destroy the bacteria around the diabetic foot ulcer, improve the wound healing environment, and can also hydrate and soften necrotic tissues

TABLE 2 The comparison of mean ulcer infection rate in sessions on days 0, 7, 14, 21, and 28 of both intervention and control groups.

The severity of the wound Group	Intervention	Control	The independent t-test result (two- tailed)	95% Confidence interval		Effect size (Cohen's d)
	Mean \pm SD	Mean \pm SD		Lower	Upper	
Befor intervention	2.29 \pm 0.46	2.24 \pm 0.50	$t = 1.18$; $p = 0.242$	-0.44	0.11	0.10
After intervention 1	2.12 \pm 0.44	2.66 \pm 0.56	$t = 3.68$; $p = 0.001$	-0.83	-0.24	0.50
After intervention 2	1.75 \pm 0.60	2.75 \pm 0.60	$t = 5.69$; $p < 0.001$	-1.35	-0.64	0.60
After intervention 3	1.66 \pm 0.70	2.79 \pm 0.65	$t = 5.72$; $p < 0.001$	-1.52	-0.72	0.68
After intervention 4	1.62 \pm 0.76	2.91 \pm 0.77	$t = 5.91$; $p < 0.001$	-1.74	-0.84	0.77
The repeated measures ANOVA test	$F = 2.89$	$F = 7.58$				
	$p = 0.096$	$p = 0.002$				
	$F = 31.30$; $p < 0.001$					

Abbreviation: ANOVA, analysis of variance.

and clean the wound, and thereby, contribute to the wound infection reduction. Seyyed Mir et al.²⁷ performed a study, entitled "Evaluating the effect of nano-silver dressings on wound healing in adult male rats." Their results indicated that the use of nanosilver dressings can be effective in controlling the infection of superficial wounds. They also suggested that nano-silver dressings seem to be effective to an acceptable level in the healing of deep infections caused by thermal, chemical, and electrical burns. The results of the study by Cao et al.²⁸ in China, entitled "The nursing care of diabetic foot ulcer based on antibacterial nano-silver dressings," revealed that these dressings are better and more effective in preventing diabetic foot ulcer infection. According to the results of some studies, silver dressings significantly reduce odor, improve pain-related symptoms, decrease wound secretion, and have a longer dressing time compared to alternative wound treatments in chronic infected and non-healed wounds.^{29,30}

However, inconsistent with the current study, Cutting et al.²³ believe that dressings containing silver are not effective in reducing infection despite their useful effects. The study of Cutting et al.²³ goes back to 16 years ago when there were still few studies on the antiseptic effects of silver-containing dressings. Moreover, the present study was conducted as a clinical trial, while the study by Cutting et al. was a review of the results of other studies.

By reviewing the studies made in the area of the effect of polyurethane dressing containing silver particles on the rate of diabetic foot ulcer infection and after confirming the sources, one may say that the research hypothesis was confirmed, and thus, polyurethane dressing containing silver particles is effective in reducing the rate of diabetic foot ulcer infection.

4.1 | Limitations

Some of the limitations of the research can be mentioned as the effect of intervening factors such as the non-hospitalization of patients and the lack of stress control, which were beyond the researcher's control.

5 | CONCLUSION

This research hypotheses demonstrated that the use of polyurethane dressing containing silver particles is effective on the rate of diabetic foot ulcer infection. This implies that using polyurethane dressings containing silver particles besides the use of simple dressings can be beneficial as a simple, cheap, applicable, and effective method.

AUTHOR CONTRIBUTIONS

Saeideh Hosseinpour: software; validation; writing—original draft. **Fatemeh Kalroozi:** supervision; writing—original draft; writing—review & editing. **Maryam Nezamzadeh:** conceptualization; validation. **Seyed AmirHosein Pishgoosie:** data curation; formal analysis.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

All authors have read and approved the final version of the manuscript. Fatemeh kalroozi (CORRESPONDING AUTHOR) had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

ETHICS STATEMENT

A letter of introduction was obtained from the Vice President of Research and Technology of AJA University of Medical Sciences and

a permit from the Ethics Committee of AJA University of Medical Sciences with the code (IR.AJAUMS.REC.1400.334) to observe ethical considerations. The confidentiality of all the documents related to the participants and compliance with the information sources used were maintained and observed according to the COPE publication regulations. Also, the researcher reminded the patients that participation in the study is completely voluntary and will not affect their treatment and care process of them and the participants' information will remain confidential, while informed consent was obtained from all the patients.

TRANSPARENCY STATEMENT

The lead author Fatemeh Kalroozi 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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