



Comparison of the Effect of Radiofrequency and Laser Treatment on Mixed Urinary Incontinence and Vulvovaginal Atrophy in Iranian Menopausal Women: A Randomized Controlled Trial

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Abstract

Objectives: Radiofrequency (RF) and laser are minimally invasive methods that are used to treat mixed urinary incontinence (MUI) and vulvovaginal atrophy (VVA). The purpose of this study was to compare the effect of RF and laser on UI and VVA in Iranian menopausal women.

Materials and Methods: Two hundred and forty women participated in this randomized clinical trial, including those who referred to Valiasr hospital, Tehran, Iran and underwent MUI and VVA treatments in 2018. Participants were randomly divided into the RF (n=80), laser (n=80), and placebo (n=80) groups. Before and after the intervention, UI was assessed using the International Consultation on Incontinence. Finally, pelvic organ prolapse/urinary incontinence sexual questionnaire, vaginal health index (VHI), and visual analog score were used to determine sexual satisfaction.

Results: VVA symptoms decreased in RF and laser groups after the intervention although changes in the RF group were more compared to the laser group (15.813 vs. 10.075, $P < 0.001$). Contrarily, VHI improved in RF and laser groups after the intervention although changes in the RF group were more remarkable in comparison with the laser group (10.425 vs. 2.231, $P < 0.001$). Based on the results, MUI symptoms decreased after the intervention in RF and laser groups although changes in the laser group were not significant ($P < 0.149$). Eventually, emotional behaviors in the RF group improved after the intervention ($P = 0.04$) although changes in the laser group were not significant.

Conclusions: In general, a greater reduction was observed in the RF group regarding MUI and VVA symptoms compared to the laser group. In addition, using the RF method for the treatment of the genitourinary syndrome of menopause (GSM) symptoms had significantly greater effects on the improvement of the quality of life and sexual satisfaction of menopausal women compared to laser therapy. Thus, RF seems to be an effective and acceptable non-surgical method for the treatment of UI and VVA.

Keywords: Pulsed radiofrequency treatment, Laser therapy, Mixed urinary incontinence, Vulvovaginal atrophy, Genitourinary syndrome of menopause

Introduction

The genitourinary syndrome of menopause (GSM) is a common condition among half of the perimenopausal and postmenopausal women. From 2014, the term GSM replaced terms such as vulvovaginal atrophy (VVA) and atrophic vaginitis (1).

GSM is significantly associated with some vaginal and urinary symptoms such as urinary incontinence (UI), urinary frequency, vaginal dryness, dyspareunia, and burning sensation that appear because of the VVA (2). These symptoms significantly affect the quality of life of large populations of women (3). Meanwhile, the estimations of the crude prevalence rate of UI range from 16.1 to 68.8% in cross-sectional studies (4). In addition, the prevalence of VVA is consistently reported at around 84% among menopausal women (1). Due to the embarrassment

and a belief that their symptoms are a natural part of aging, only about 25% of affected women may be reluctant to seek help from a healthcare professional (5). Probably, the knowledge of treatment options and the effectiveness of these methods can persuade women to seek treatment for their symptoms (6). There are several non-surgical ways for treating VVA and UI. If estrogen therapy does not contain any contraindications for the patient, oral or topical estrogen is used to treat VVA (7). Further, a pelvic floor training program guided by a physiotherapist is recommended as first-line therapy for women with UI symptoms (8).

Today, minimally invasive methods are proposed to improve both VVA and UI symptoms. Laser treatment through a depth-controlled photo-thermal action, using pulsed CO₂ or Er:YAG laser, leads to the induction of

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Key Messages

- ▶ VHI in RF and laser groups improved after the intervention although changes in the RF group were more compared to the laser group.
- ▶ In addition, emotional behaviors in the RF group improved after the intervention.
- ▶ RF seems to be an effective and acceptable non-surgical method for the treatment of UI and VVA.

collagen denaturation, the shrinkage of mucosa and the underlying supportive tissue without destruction, enriching, and tightening and more elasticity of tissues (9-11). Radiofrequency (RF) is another safe, non-surgical method with minimal risk of adverse effects which emits high-frequency wavelengths to the tissue impedance, resulting in a local temperature increase, inducing the synthesis of collagen by fibroblasts and denaturation collagen without significant necrosis or injury to nearby vascular or nerve tissues (3,12,13). These two methods are used for collagen contraction, neocollagenesis, vascularization, and improvement of the elasticity, tension, and rejuvenation of the vulvo-vagina (14).

A few studies with small study populations and short-term follow-ups have been carried out to assess the safety and efficacy of laser treatment and RF devices, as well as the clinical response of patients with GSM symptoms such as UI and VVA (11).

Considering the safety of noninvasive methods such as laser therapy and RF for the treatment of GSM symptoms in affected women, this study was conducted to compare the effect of RF and laser treatment on MUI and VVA in Iranian menopausal women referring to the pelvic floor clinic of Valiasr hospital, Tehran, Iran.

Materials and Methods

Study Design and Population

This randomized clinical trial included all Iranian menopausal women with UI symptoms referring to Valiasr hospital, Tehran, Iran in 2018. The inclusion criteria were history of UI symptoms, sexual intercourse, sexual problems due to VVA, at least one year after the termination of menstruation, the presence of VVA symptoms, and sexual dysfunction. On the other hand, the exclusion criteria included patients with urinary infection, hematuria, pelvic organ prolapse, Pelvic Organ Prolapse Quantification (POP-Q) >2, pregnancy, childbirth in less than a year, abnormal vaginal bleeding, damaged vaginal tissue, history of damage to spinal nerves, radical hysterectomy with neuropathy, epilepsy, autoimmune diseases, and >50 g of urine leakage per hour. In general, 246 eligible patients were recruited in this study using the available sampling method. The sample size was estimated as 71 patients per group considering the power of 80% and a 95% confidence interval. Finally, 82 people were included given a 10% drop in each group. Participants were randomly allocated to three laser, RF, and control groups. The flow diagram of the trial according to CONSORT is visualized in Figure 1.

Procedure

After obtaining the approval of the Ethics Committee of Tehran University of Medical Sciences, general information about the study and its goals was provided to eligible women. After providing written informed consent to participate in the study, first, all participants were assessed for VVA through performing clinical examinations and checking the vaginal PH level. UI was evaluated using the International Consultation on

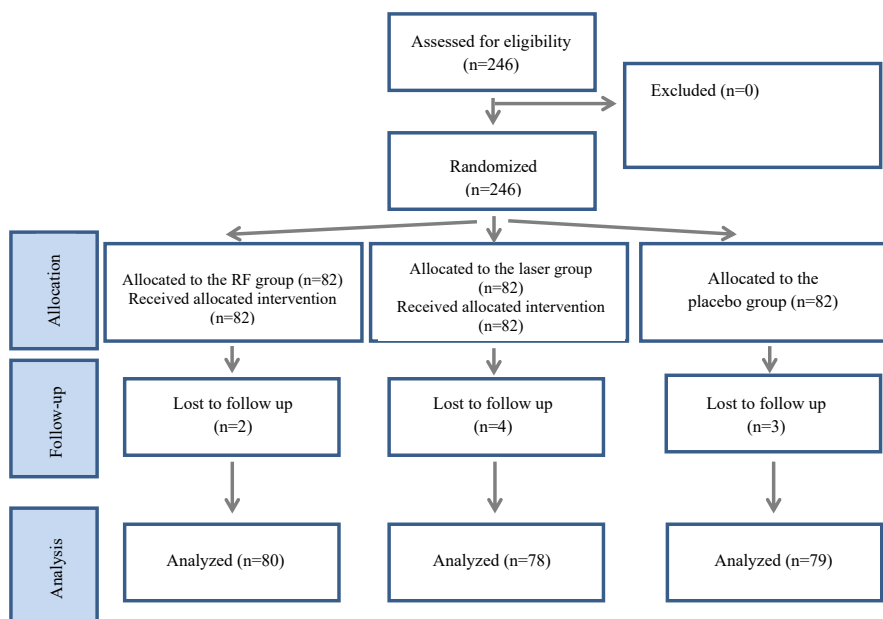


Figure 1. Flow Diagram of the Study. Note. RF: Radiofrequency.

Incontinence (ICIQ-SF). In this study, only patients with MUI were studied and patients with other incontinence types were excluded from investigation. In addition, pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12), vaginal health index (VHI), and visual analog score (VAS) were used to determine sexual satisfaction. After a definitive diagnosis of UI and VVA and the randomized allocation of patients to each group, RF and laser treatments were performed in their own groups while patients in the control group only received the placebo treatment.

Laser treatment consisted of a series of three treatments using the fractional CO₂ laser system 4 weeks apart taking about 1-2 minute(s) per session as an in-office procedure using the Monalisa Touch device aimed at treating VVA, MUI, and sexual problems. Treatment parameters included the power of 40 w, dwell time of 100 ms, and 1000 mm spacing using a normal scan mode with the Smartstack setting of 1 and 3 for the first and the third treatment, respectively.

In the RF therapy group, all patients had 3 sessions of treatment with a frequency of 4-6 weeks. The Physio Vag Device, which is based on RF technology, was used in this study. The device works with both monopolar and bipolar modes, 4 working frequencies (i.e., 420, 500, 720, and 1000 Hz), and both continuous and pulsed modes of operation. In this study, a frequency of 500 Hz was used for both intravaginal and extravaginal treatments. In general, the depth of the penetration of waves into the tissue is less at higher frequencies. Each treatment session was held in the group for 20 minutes (10 minutes for each of the intravaginal and extravaginal treatments) with a working temperature range of 38-44°C. In the monopolar mode, RF waves are transmitted between the probe and the metal plate normally placed under the buttocks of the patient, creating a magnetic field between the probe and the plate. In this case, the waves have the highest penetration compared to the bipolar mode. In the bipolar mode, RF waves are transmitted between two electrodes designed on the bipolar probe. Hence, the amount of wave penetration will be less than that of the monopolar mode.

After the intervention, participants were examined in terms of UI and sexual satisfaction. Any possible pain and adverse outcome during the treatment were recorded as well.

Instruments

The Prolapse/Urinary Incontinence Sexual Questionnaire

The PISQ-12 is a validated and reliable, self-administered questionnaire for evaluating sexual function in women with UI and/or pelvic organ prolapsed. It is composed of 12 items in behavioral-emotive (4 items), physical (5 items), and partner-related (3 items) domains. The first domain comprises questions about sexual desire, orgasm, excitement, and satisfaction. The physical domain contains questions about pain and UI during intercourse, avoidance

of sexual function due to prolapse, and fear of urine or stool incontinence. The partner-related domain includes questions about erection disorder, early ejaculation, and orgasm. Responses are graded on a 5-point Likert-type scale from 'never' to 'always'. The score of each domain is calculated by adding the score of each question (15).

International Consultation on Incontinence

ICIQ-SF is a validated instrument that provides a brief measure to assess the impact of IU symptoms on the quality of life and the outcome of the UI treatment. It is composed of four items including the frequency of urinary incontinence, the amount of leakage, the overall impact of UI, and the self-diagnostic item. The score for the frequency of urine leakage ranges from 0 (never) to 5 (always). The amount of leakage scores is between 0 (none) and 6 (a large amount) in the form of paired numbers. The overall impact of the UI score ranges from zero to ten. The self-diagnostic portion of the questionnaire is not given a score. The total score for the ICIQ-SF is calculated as the sum of the obtained scores from the four items. Therefore, the overall range of the total score values is 0-21, and higher scores indicate greater incontinence (16,17).

Vaginal Health Index

The VHI has five items in the vaginal examination for assessment of vaginal health. These five items include vaginal elasticity, fluid volume, vaginal pH level, epithelial integrity, and moisture after treatment and at follow-ups after the final treatment. Responses are graded on a 5-point Likert-type scale, and in total, the minimum and maximum scores for a VHI are 5 and 25, respectively (18).

Visual Analog Score

The severity of VVA symptoms such as irritation, itching, dryness, dispersion, and dysuria was evaluated by VAS before and after the intervention. The subject placed a mark representing the level of pain or discomfort (from asymptomatic to severe) on a four-point scale (19).

Statistical Analysis

The collected data were entered in SPSS, version 20. First, the *t* test and Mann-Whitney U test were used to compare normally distributed and not normally distributed data, respectively. $P < 0.05$ was considered statistically significant.

Results

In the present study, 9 out of 246 patients were excluded because of unwillingness to continue the study. Therefore, the data of 80 patients in the RF group, 78 patients in the laser group, and 79 patients in the placebo group underwent an assessment. The mean (standard deviation, SD) age of participants was 57.7 ± 7.3 , 56.3 ± 7.2 , and 54.8 ± 11.5 years in the RF, laser, and placebo groups, respectively. The mean (SD) of gravity was $3.7 (\pm 1.9)$,

3.9 (±2), and 3.9 (±2) and 3.3 (±1.6). Furthermore, the mean (SD) of the number of children was 3.2 (±1.6), 3.8 (±1.6), and 3.4 (±1.6) in the RF, laser, and placebo groups, respectively ($P = 0.069$). There was no difference between the three groups in terms of the mean (SD) of the type of delivery ($P > 0.05$). Before data analysis, the analysis of variance (ANOVA) assumptions such as normalization, homogeneity of variances, and homogeneity of slope regression were investigated and all three assumptions received confirmation. First, the Kolmogorov-Smirnov test was used and the results were obtained as $z = 1.28$ ($P = 0.07$) in VVA symptoms, $z = 1.53$ ($P = 0.06$) in VHI, $z = 1.1$ ($P = 0.8$) in MUI, $z = 1.29$ ($P = 0.07$) in the emotional behavior of sexual satisfaction questionnaire from PISQ-

12., $z = 0.48$ ($P = 0.62$) in physical behavior, and $z = 2.04$ ($P = 0.16$) in the partner-related domain (Table 1).

In terms of VVA symptoms, the results of ANOVA (Table 2) showed that there was a significant difference in the mean scores between the groups after the intervention ($F=43.669$, $P<0.001$). The results of Tukey test (Table 3) demonstrated that VVA symptoms in RF and laser groups decreased after the intervention although changes in the RF group were more compared to the laser group (15.813 vs. 10.075, $P<0.001$).

Regarding VHI, the results of ANOVA (Table 4) represented a significant difference in the mean scores of VHI between the groups after the intervention ($F=173.23$, $P<0.001$). Based on the results of Tukey test

Table 1. Comparison of Study Variables Before and After the Intervention

		Before the Intervention		After the Intervention		P Value
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
VAS	RF group	26.5±12.6	13.5±9.9	13.5±9.9	17.6±12.2	<0.001
	Laser group	23.3±12.6	17.6±12.2	17.6±12.2	23.3±15.3	<0.001
	Placebo group	24.5±15.8	23.3±15.3	23.3±15.3		0.006
VHI	RF group	10.1±2.1	20.9±1.5	20.9±1.5	12.7±4.8	<0.001
	Laser group	10.9±3.4	12.7±4.8	12.7±4.8	10.5±4.0	0.002
	Placebo group	10.6±4.6	10.5±4.0	10.5±4.0		0.636
MUI	RF group	7.6±5.1	4.1±3.6	4.1±3.6	4.9±3.1	<0.001
	Laser group	6.5±3.3	4.9±3.1	4.9±3.1	6.1±3.9	<0.001
	Placebo group	6.7±4.0	6.1±3.9	6.1±3.9		0.067
Emotional behavior	RF group	6.7±3.3	10.0±2.6	10.0±2.6	7.9±3.2	<0.001
	Laser group	6.3±3.2	7.9±3.2	7.9±3.2	8.8±3.8	<0.001
	Placebo group	8.8±3.8	8.8±3.8	8.8±3.8		0.1
Physical behavior	RF group	11.4±4.0	16.3±2.9	16.3±2.9	10.5±4.2	<0.001
	Laser group	11.1±4.1	10.5±4.2	10.5±4.2	14.5±2.7	0.029
	Placebo group	14±2.5	14.5±2.7	14.5±2.7		0.197
Partner related	RF group	6.7±2.2	8.1±2.7	8.1±2.7	6.9±2.1	0.002
	Laser group	6.8±2.2	6.9±2.1	6.9±2.1	7.3±2.9	0.566
	Placebo group	7.0±2.1	7.3±2.9	7.3±2.9		0.159

Note. SD: Standard deviation; VAS: Visual analog score; VHI: Vaginal health index; MUI: Mixed urinary incontinence; RF: Radiofrequency.

Table 2. Results of ANOVA for VVA Symptoms

		Sum of Squares	df	Mean Square	F	P Value
Before the intervention	Between groups	411.233	2	205.617	1.080	0.341
	Within groups	45109.763	234	12.374		
	Sum	45520.996	236			
After the intervention	Between groups	10252.258	2	5126.129	43.669	<0.001
	Within groups	27820.538	234	117.386		
	Sum	38072.796	236			

Note. ANOVA: Analysis of variance; VVA: Vulvovaginal atrophy.

Table 3. Results of Tukey's Test for VVA Symptoms

		Mean Difference	Standard Error	P Value
RF group	Laser group	-5.738	1.713	0.003
	Placebo group	-15.813	1.713	<0.001
Laser group	Placebo group	-10.075	1.73	<0.001

Note. RF: Radiofrequency; VVA: Vulvovaginal atrophy.

Table 4. Results of ANOVA for VHI

		Sum of Squares	df	Mean Square	F	P-value
Before the intervention	Between groups	31.158	2	15.579	1.259	0.286
	Within groups	2932.575	234	12.374		
	Sum	2963.733	236			
After the intervention	Between groups	4813.427	2	2406.714	173.230	<0.001
	Within groups	3264.896	234	13.893		
	Sum	8078.324	236			

Note. ANOVA: Analysis of variance; VHI: Vaginal health index.

Table 5. Results of Tukey's Test for VHI

		Mean Difference	Standard Error	P Value
RF group	Laser group	8.194	0.593	<0.001
	Placebo group	10.425	0.589	<0.001
Laser group	Placebo group	2.231	0.589	<0.001

Note. SD: Standard deviation; VHI: Vaginal health index; RF: Radiofrequency.

(Table 5), VHI improved in RF and laser groups after the intervention although changes in the RF group were more considerable in comparison with the laser group (10.425 vs. 2.231, $P < 0.001$).

As regards MUI symptoms, ANOVA results (Table 6) revealed a significant difference in the mean scores between the groups after the intervention ($F = 5.942$, $P = 0.003$). The results of Tukey test (Table 7) showed that MUI symptoms in RF and laser group decreased after the intervention although changes in the laser group were not significant ($P < 0.149$).

Further, the results of ANOVA (Table 8) revealed that there was a significant difference in the mean scores of emotional behaviors between the groups after the intervention ($F = 3.057$, $P = 0.04$). According to the results of Tukey's test, emotional behaviors improved in the RF group after the intervention ($P = 0.04$) although changes in the laser group were not significant. In addition, a significant difference was found between the groups regarding the mean scores of physical behavior after the

intervention ($F = 56.49$, $P < 0.001$). Based on the results of Tukey's test (Table 9), physical behavior improved in RF and laser groups after the intervention. On the other hand, there were no significant differences between the groups with respect to the partner-related domain after the intervention ($F = 2.706$, $P = 0.07$).

Discussion

To the best of our knowledge, no previous study has so far compared the effectiveness of RF and laser methods for the treatment of females suffering from MUI and VVA symptoms. All previous studies have reported that the RF or laser treatment was effective in improving MUI and VVA symptoms in the intervention group compared to the control group.

The results of this study are comparable and validated with previous data. Most studies, similar to this study, demonstrated a significant reduction in incontinence symptoms while significant improvements in the quality of life and sexual function in women who used the RF

Table 6. Results of ANOVA for MUI

		Sum of Squares	df	Mean Square	F	P-value
Before the intervention	Between groups	53.930	2	26.965	1.508	0.224
	Within groups	3969.199	222	17.879		
	Sum	4023.129	224			
After the intervention	Between groups	155.992	2	77.996	5.942	0.003
	Within groups	2743.570	209	13.127		
	Sum	2899.561	211			

Note. ANOVA: Analysis of variance; MUI: Mixed urinary incontinence.

Table 7. Results of Tukey's Test for MUI

		Mean Difference	Standard Error	P Value
RF group	Laser group	-0.871	0.633	0.355
	Placebo group	-2.025	0.591	0.002
Laser group	Placebo group	-1.154	0.616	0.149

Note. SD: Standard deviation; MUI: Mixed urinary incontinence; RF: Radiofrequency.

Table 8. Results of ANOVA for Sexual Satisfaction

			Sum of Squares	df	Mean Square	F	P Value
Emotional behavior	Before the intervention	Between groups	220.710	2	110.355	9.405	<0.286
		Within groups	1912.621	163	11.734		
		Sum	2133.331	165			
	After the intervention	Between groups	68.523	2	34.261	3.057	0.04
		Within groups	1703.348	152	11.206		
		Sum	1771.871	154			
Physical behavior	Before the intervention	Between groups	910.243	2	455.122	36.412	0.123
		Within groups	2037.371	163	12.499		
		Sum	2947.614	165			
	After the intervention	Between groups	1229.601	2	614.801	56.049	<0.001
		Within groups	1667.275	152	10.969		
		Sum	2896.877	154			
Partner related domain	Before the intervention	Between groups	2.689	2	1.345	0.279	0.757
		Within groups	793.882	165	4.811		
		Sum	796.571	167			
	After the intervention	Between groups	36.524	2	18.262	2.706	0.07
		Within groups	1039.183	154	6.748		
		Sum	1075.707	156			

Note. ANOVA: Analysis of variance.

Table 9. Results of Tukey's Test for Sexual Satisfaction

			Mean Difference	SD	P Value
Emotional behavior	RF group	Laser group	1.767	0.718	0.39
		Placebo group	0.944	0.697	0.039
	Laser group	Placebo group	-0.823	0.616	0.377
Physical behavior	RF group	Laser group	5.760	710	<0.001
		Placebo group	-0.194	690	0.04
	Laser group	Placebo group	-5.955	609	<0.001

Note. SD: Standard deviation; RF: Radiofrequency.

method for the treatment of GSM symptoms such as UI and VVA (13,20-25). On the other hand, most other studies reported the laser method as a safe and effective treatment for improvements in sexual satisfaction indices and the quality of life and sexual function in women with UI and VVA symptoms (6,26-30).

The results of this clinical trial indicated that improvements in VVA and MUI symptoms were achievable by either the RF or laser treatment method. However, improvement rates were significantly higher with the RF treatment as compared with laser therapy. In addition, women with MUI in the behavioral-emotive domain had better sexual functions after the RF treatment compared to laser therapy, meaning that RF and laser treatment were effective for improving VVA and MUI symptoms while better results for VVA and MUI improvements were obtained in the RF group. Therefore, RF technology seems to be a more effective option in treating female MUI symptoms in menopausal women.

The review of the literature recommends that RF is a minimally invasive procedure for the treatment of female UI and improvements in the quality of life and sexual function. In other words, RF application seems to be a

promising, reasonable alternative for the treatment of symptoms related to GSM (13,31).

However, the sense of the improvement of symptoms and satisfaction may vary from woman to woman. In this study, two different treatment options were compared in different women with various levels of pain or discomfort, making the assessment difficult. On the other hand, the effectiveness of treatment protocols greatly depends on the applied device, and the variety of devices makes it difficult to compare the effectiveness of RF and laser devices (32).

The present study, as the first one to report on RF and laser for the treatment of VVA and MUI, gives a solid basis for future research. It is notable that the limitation of the present study was probably related to the short follow-up. However, in some studies, improvements were registered immediately at the end of treatment. Nevertheless, it has been reported that long-term treatment improves MUI and VVA symptoms.

Conclusions

In general, the results of this study showed a greater reduction in MUI and VVA symptoms in the RF group compared to the laser group. In addition, using the

RF method for the treatment of GSM symptoms had significantly greater effects on the improvement of the quality of life and sexual satisfaction of menopausal women compared to laser therapy. Therefore, RF can be recommended as a safe and acceptable non-surgical method for the treatment of MUI and VVA symptoms.

Authors' Contribution

TE and ZG conceived and planned the implementation. Further, LG and FD carried out the implementation. Moreover, TE and LG contributed to sample preparation. JR performed the calculations of the research. Finally, all authors provided critical feedback and helped shape the research, analysis, and manuscript.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki. In this study, we considered written consent of the pregnant women, the confidentiality of personal data, and free measurements as the principles of medical ethics. The Ethics Committee of Tehran University of Medical Sciences approved this study under the ethics code IR.TUMS.IKHC.REC.1398.035. Additionally, the study was registered at Iranian Registry of Clinical Trials (identifier: IRCT20190708044143N1; <https://www.irct.ir/trial/40663>).

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