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The Influence of Vaginal Radiofrequency on Quality of Life and Sexual Activity Post-Surgery

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ABSTRACT

Background & Objective: The objective of this research was to investigate the influence of post-surgical vaginal radiofrequency on life quality and sexual function, using a control group for comparison.

Materials & Methods: This clinical trial enrolled women with recurrent POP who underwent surgery at Imam Khomeini Hospital in Tehran, Iran, between November 2022 and July 2023. Patients were divided into an intervention group, which received vaginal radiofrequency treatment post-surgery, and a control group, which received radiofrequency treatment in silent mode. Both groups completed the Pelvic Floor Distress Inventory-20 (PFDI-20) and Female Sexual Function Index (FSFI) before surgery and five months post-surgery. Data analysis was performed using SPSS software, with a p-value of less than 0.05 indicating statistical significance.

Results: The research encompassed a total of 60 participants, evenly split between the control group (age 56.16 ± 9.94 years) and the intervention group (50.70 ± 10.57 years). Statistical analysis showed no significant differences between the two groups in terms of demographic data, cough test results, and POP-Q test results, indicating similarity ($P > 0.05$). However, the intervention group, which received post-surgery radiofrequency treatment, showed a significantly greater reduction in PFDI-20 scores and a higher increase in FSFI scores than the control group ($P<0.001$).

Conclusion: The results suggest that the application of radiofrequency treatment post-surgery led to more pronounced enhancements in PFDI-20 and FSFI scores compared to the group that was not subjected to this treatment. Consequently, it can be inferred that radiofrequency is a secure and efficacious approach for the repair of the pelvic floor.

Keywords: Sexual and Gender Disorders, Pelvic Floor Disorders, Pelvic Organ Prolapse, Radiofrequency

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1. Introduction

When the support structures - muscles, ligaments, and tissues - fail to hold pelvic organs like the bladder, uterus, rectum, or vagina in their proper position, these organs may descend and bulge into the vaginal canal. This condition is known as pelvic organ prolapse (POP) **(1)**. This may be caused by various factors that weaken or damage the pelvic floor. These factors include childbirth, undergoing hysterectomy, experiencing menopause, chronic coughing, constipation, being overweight, or aging **(2)**.

The symptoms of POP vary among women. While some individuals may not notice any changes, others may experience discomfort or a sense of heaviness in the pelvis. Difficulties in sexual activity, urination, or bowel movements may also occur **(3)**. Some women may notice blood or discharge from the vagina or feel as though something is protruding. The type and severity of symptoms depend on POP and the extent of its descent **(4)**.

Although POP does not pose a direct threat to life, it can significantly impact an individual's quality of life, potentially leading to discomfort or distress. Currently, several treatment options are available for this condition **(5)**. The optimal decision is influenced by several considerations, encompassing the patient's age, general health condition, personal inclinations, and the particular type and severity of the prolapse. These options might include lifestyle adjustments, pelvic floor strengthening exercises, utilization of vaginal pessaries for pelvic organ support, or surgical interventions aimed at repairing or removing the prolapsed organ **(6)**.

Given that many of the underlying factors of POP cannot be prevented or controlled, the primary focus is on selecting the most effective treatment method. Despite the availability of nonsurgical approaches, a significant number of women prefer a definitive solution **(7)**. Surgical treatment with an 85% success rate is often the preferred choice. At present, this form of treatment constitutes 20% of female surgeries in developed countries. Nonetheless, the influence of POP surgery on women's sexual function and life quality continues to be a topic of discussion in the academic community **(8)**. Some studies have reported improvements in sexual performance and satisfaction following prolapse surgery (9), whereas others have found no change or even a decline in sexual performance post-surgery **(10, 11)**.

Radiofrequency is a noninvasive treatment method that leverages radio waves to address various conditions. It has been proven beneficial in eliminating obesity, eye wrinkles, and facial spots. This technique stimulates the skin without the need for surgery by using radio waves to heat deeper layers, including collagen, elastic fibers, and muscles **(12)**. This process results in muscle contraction and skin tightening. Interestingly, stimulation of fibroblasts accelerated collagen production. In this treatment methodology, the waves strengthen the vessels within the vaginal mucosa, promote the production of new collagen, contribute to the synthesis of the extracellular matrix in the vaginal connective tissue, and enhance the thickness of the vaginal epithelium through the development of new papillae, thereby reinstating equilibrium in the body. These morphological changes can lead to the repair of the vaginal muscles **(13)**.

Considering the necessity for an efficacious intervention with limited adverse effects to ameliorate pelvic prolapse and augment patients' post-treatment life quality, the objective of this research was to explore the influence of vaginal radiofrequency on life quality and sexual function subsequent to surgery.

2. Materials and Methods

Study population

In this clinical trial study, women with recurrent POP who underwent surgery at Imam Khomeini Hospital in Tehran, Iran, between November 2022 and July 2023 were enrolled as participants. The study included women who had been examined by a specialist doctor, had their POP confirmed, and completed vaginal radiofrequency treatment sessions post-surgery. However, patients who had used other non-surgical treatment methods for pelvic prolapse, those who did not regularly attend treatment sessions, those with active or recurrent genital infections (such as genital herpes or candidiasis), recurrent urinary tract infections, those who had undergone pelvic radiation therapy or brachytherapy, and those who had undergone pelvic reconstructive surgery were excluded from the study.

In this study, we employed the block randomization method using the SAS statistical analysis software. The trial consisted of two groups with six blocks each, with three participants in the intervention group and three in the control group. Upon participant registration, an envelope was opened in order of eligible participant entry, revealing the assigned group for that participant. The control group comprised patients who underwent surgery only and received vaginal radiofrequency treatment without energy in the silent mode. The intervention group, on the other hand, included patients who received vaginal radiofrequency treatment post-surgery (Figure 1).

This study was conducted in a double-blind manner. Opaque envelopes were used to ensure that neither the participants nor the person responsible for data collection was aware of the group assignments or the type of treatment method.

Study protocol

Initially, the patient's demographic information, including age, number of deliveries, type of delivery (natural or cesarean section), and the purpose of the patient's visit, was recorded. Prior to surgery, the extent of the patient's POP was assessed using the Pelvic Organ Prolapse Quantification System (POP-Q). The study was single-blinded; the individual responsible for data collection was unaware of the timing of the patient's visit (pre- or post-surgery).

The surgical intervention involved correcting all areas that required surgery. The surgical procedure was decided upon by the gynecologist, taking into account the findings from the physical examination and the patient's expressed concerns. All procedures were performed under general or spinal anesthesia. Postoperative prophylactic antibiotics (metronidazole/cephalosporin) were prescribed for patients. To prevent thromboembolism, low-molecular-weight heparin was administered subcutaneously post-operation.

After undergoing prolapse surgery, the intervention group received vaginal radiofrequency treatment using a device equipped with an energy-deficit electronic circuit provided by Nova Vision Company, Italy. This device includes a vaginal pen with 64-micron needles, each having a diameter of 200 microns and a length of 1 mm. The first session was held 6 weeks after the operation, and it was followed by three additional sessions, each approximately one month apart. Each treatment session lasted 15 to 20 minutes. During treatment, patients were placed in a lithotomy position, and 0.2% chlorhexidine antiseptic and 0.9% sterile saline solution were used for cleaning. Upon conclusion of the initial session and again three months following treatment, each participant was tasked with filling out both a quality of life and a sexual satisfaction questionnaire.

This study employed the Iranian adaptation of the Pelvic Floor Distress Inventory-20 (PFDI-20) to measure the quality of life of patients with floor disorders as a result of related symptoms. A verified survey instrument was employed to evaluate the quality of life and pelvic discomfort, focusing on symptoms related to intestinal, bladder, or pelvic issues. Each subscale consists of six to eight questions regarding the patient's symptoms, rated from 0 (no complaints) to 4 (extremely distressing symptoms). The scores on each scale were summed, multiplied by 25, and divided by the number of questions. Each scale ranges from zero to 100, and the total PFDI-20 score ranged from zero to 300. A higher score (near 300) signifies a lower quality of life. The questionnaire's reliability and validity within the context of Iran have been confirmed by Hakimi, Hajebrahimi **(14)**.

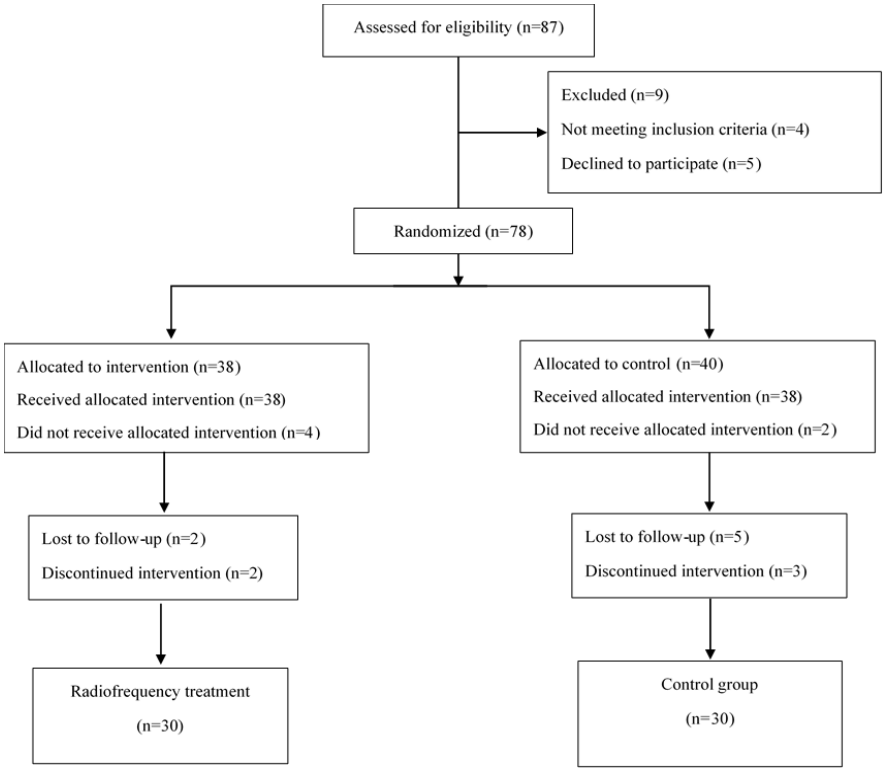


Figure 1. Flowchart diagram of the selection process of patients

Sexual function was evaluated using the Female Sexual Function Index (FSFI) questionnaire. This instrument consists of 19 items that measure various aspects of a woman's sexual activity, including sexual desire, arousal, lubrication, pain, orgasm, and overall sexual satisfaction. Scores for the questions were as follows: sexual desire (1-5), sexual arousal, vaginal lubrication, orgasm, painful intercourse (0-5), and sexual satisfaction (1-5 or 0). A person's score within each domain was calculated by adding the scores within that domain and multiplying the sum by the corresponding domain factor. The domain factors are assigned as follows: 0.6 for desire, 0.3 for both lubrication and arousal, and 0.4 for orgasm, satisfaction, and pain. The overall score was determined by summing the scores across all domains. The total score can range from 2 to 36, with higher scores denoting superior sexual performance. The zero score signifies no sexual activity. The questionnaire was validated by Heydari and Faghihzadeh **(15)**.

Each patient completed these questionnaires both before the operation and five months after the operation.

Statistical analysis

Descriptive statistics were presented as means, standard deviations, and/or percentages. The normality of the data was verified using Shapiro-Wilk tests prior to analysis. Continuous quantitative variables with normal distributions were analyzed using the Student's t-test and the Wilcoxon test. All statistical analyses were conducted using SPSS software (version 22, Chicago, IL, USA), and a p-value of less than 0.05 was deemed to indicate statistical significance.

Ethical considerations

The study protocol underwent review and received approval from the Ethics Committee of Tehran University of Medical Sciences as part of its endorsement of the research project (No: IR.TUMS.IKHC.REC.1401.127). Furthermore, the study was officially registered with the Iranian Registry for Clinical Trials (code: IRCT20220906055897N1).

3. Results

The study involved 60 patients who were eligible for vaginal surgery due to Pelvic Organ Prolapse (POP). The intervention group consisted of 30 patients, with ages ranging from 32 to 75 years. The average age in this group was 50.70 years, with a standard deviation of ±10.57 years. The control group also comprised 30 patients, with a mean age of 56.16 years (±9.94 standard deviation) and an age range of 29 to 73 years.

The highest frequency of fertility and pregnancy in the intervention and control groups was three, respectively, with the frequency of 11 (36.7%) and 13 (43.3%). Statistical analysis of demographic information for both groups showed no significant differences in any of the cases (P>0.05). This indicated that the two groups were similar.

Table 1. Demographic information of patients, divided into intervention and control groups

Variable		Intervention group Frequency (%)	Control group Frequency (%)	P-value
Gravida	1	4 (13.3)	5 (16.6)	0.523
	2	4 (13.3)	4 (13.3)	
	3	11 (36.7)	13 (43.3)	
	4	5 (16.7)	4 (13.3)	
	5	5 (16.7)	4 (13.3)	
	6	1 (3.3)	0 (0.0)	
Parity	1	5 (16.7)	3 (10.0)	0.999
	2	7 (23.3)	8 (26.6)	
	3	11 (36.7)	8 (26.6)	
	4	5 (16.7)	6 (20)	
	5	2 (6.7)	5 (16.7)	
Death	None	28 (93.3)	30 (100)	0.607
	1	2 (6.7)	0 (0.0)	
Abortion	None	25 (83.3)	24 (80)	0.356
	1	3 (10)	4 (13.3)	
	2	2 (6.7)	2 (6.7)	
Delivery method	Vaginal	28 (93.3)	29 (96.66)	0.133
	Vaginal delivery + cesarean	2 (6.7)	1 (3.3)	
Menstrual history	Menopause	15 (50)	15 (50)	0.629
	Regular	15 (50)	15 (50)	
Main compliant	Discharge of the mass from the vagina	13 (43.3)	11 (36.66)	0.999
	Urinary incontinence + Uterine prolapse	4 (13.3)	6 (20)	
	Discharge of the mass + Urinary incontinence	4 (13.3)	7 (23.3)	
	Urinary incontinence	7 (23.3)	4 (13.3)	
	Uterine prolapse	1 (3.3)	2 (6.6)	
	Frequent urination	1 (3.3)	0 (0.0)	

The POP-Q test results for the intervention and control groups are presented in Table 2. According to the results, the majority of patients in both groups were at the second stage of prolapse before the operation, with 13 (43.33%) in the control group and 12 (40%) in the intervention group. Statistical analysis revealed no significant difference between the two groups in terms of the preoperative POP-Q results (P > 0.05), indicating that both groups were at the same POP-Q stage. Five months postoperatively, the POP-Q test results showed

that most patients were at stage one (66.66% of the control group and 73.3% of the intervention group). A comparison of the POP-Q test results before and after surgery within each group indicated a significant improvement in prolapse (P<0.05). However, there was no significant difference between the two groups (P>0.05).

Table 2. Preoperative and postoperative POP-Q findings, divided into intervention and control groups

Stage	Intervention group (N = 30) Frequency (%)		Control group (N = 30) Frequency (%)		P-value
	Preoperative	Postoperative	Preoperative	Postoperative	
0	0 (0)	0 (0)	0 (0)	0 (0)	
1	8 (26.7%)	22 (73.3%)	5 (16.66)	20 (66.66)	
2	12 (40%)	5 (16.7%)	13 (43.33)	8	0.606
3	6 (20%)	3 (10.0%)	9 (30)	2	
4	4 (13.3%)	0 (0)	3 (10)	0 (0)	
P-value	0.001		0.001		-

Prior to surgery, the cough test results were normal in 24 patients (80%) and abnormal in 6 patients (20%) in the control group. In the intervention group, the results were normal in 22 patients (73.3%) and abnormal in 8 patients (26.7%). Postoperatively, all 30 patients (100%) in both groups had normal cough test results. Statistical analysis revealed no significant difference between the two groups before treatment, indicating homogeneity (P > 0.05). However, the post-treatment results within each group were significant (P<0.05), suggesting patient improvement. Despite this, there was no significant difference between the two groups in the cough test results after the operation (P>0.05).

Table 3. Scores of PFDI-20 and FSFI preoperative and postoperative, divided into intervention and control groups

Variable	Intervention group (N = 30) (Mean ± SD)		Control group (N = 30) (Mean ± SD)		P-value
	Preoperative	Postoperative	Preoperative	Postoperative	
Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6)	28.33 ± 18.12	10.54 ± 11.56	36.51 ± 13.70	20.54 ± 98.22	0.01
Colorectal-Anal Distress Inventory 8 (CRAD-8)	28.43 ± 18.17	10.41 ± 7.88	38.65 ± 12.69	22.83 ± 16.50	0.012
Urinary Distress Inventory 6 (UDI-6)	45.86 ± 18.18	15.93 ± 15.39	56.71 ± 24.09	47.50 ± 16.49	0.022
Total Scores of PFDI-20	100.86 ± 41.82	36.91± 29.86	121.87 ± 34.48	57.87± 26.48	0.001
FSFI test	9.92 ± 10.13	17.81± 9.98	8.74 ± 5.03	11.60± 5.08	0.001
P-value	0.001		0.001		

The PFDI-20 scores and FSFI scores for the intervention and control groups are reported in Table 3. The scores for the Pelvic Prolapse Distress Questionnaire 6 (POPDI-6), Colorectal-Anal Distress Questionnaire 8 (CRADI-8), Urinary Distress Questionnaire 6 (UDI-6), and PFDI-20 significantly decreased after surgery in both groups (P<0.001). A comparison of scores between the two groups revealed that the reduction in PFDI-20 scores was significantly greater in the intervention group than in the control group (P<0.001). These results suggest that post-surgery radiofrequency treatment led to better improvement in PFDI-20 scores in the intervention group than in the control group. Additionally, the scores from the FSFI test significantly increased after the intervention compared to those before the intervention in both groups (P<0.001). Furthermore, a comparison of FSFI scores between the two groups showed that the increase in scores was greater in the intervention group than in the control group, and this difference was statistically significant (P<0.001).

The statistical analysis shows that the FSFI scores after intervention were significantly related to age (P = 0.002), but the total scores of the PFDI-20 were not

significantly related to age both before (P = 0.112) and after (P = 0.818) the intervention. These results indicate that FSFI scores showed better improvement at a younger age after the intervention.

4. Discussion

Advancements in technology have led to the emergence of fractional laser and radiofrequency techniques. These non-invasive thermal treatments are designed for women experiencing both aesthetic and medical symptoms due to vaginal atrophy and laxity. Research indicates that the careful administration of thermal energy to the vaginal wall and labia triggers biological responses in the vaginal skin layers. These responses include proliferation, neovascularization, and the formation of new collagen, which collectively contribute to symptom alleviation **(16)**. In this study, we assessed the effectiveness of postoperative radiofrequency treatment for POP using PFDI-20 and FSFI scores. The results indicated that the application of radiofrequency treatment resulted in a notable reduction in the scores of POPDI-6, CRADI-8, UDI-6, and the overall PFDI-20 following surgery, compared to the scores prior to surgery, as well as those in the control group. Furthermore, a significant enhancement in FSFI scores was observed post-surgery relative to pre-surgery values, with the augmentation being more substantial in the intervention group compared to the control group. These findings imply that the post-surgical radiofrequency treatment facilitated improvements in both PFDI-20 and FSFI scores.

Animal models have proven instrumental in elucidating the histological alterations associated with non-surgical restoration of the pelvic floor. However, clinical studies examining radiofrequency treatments remain relatively scarce **(17, 18)**. A significant obstacle to research in this area is the absence of a standardized instrument for assessing the strength of pelvic floor muscles and the laxity of the vaginal introits. A variety of potential measurement tools have been employed, encompassing caliper measurements, balloon devices (like the barista used for gauging esophageal strictures), and comparative photography. However, all these methods have been found to be either insufficient or inconsistent **(17)**. Most of the current clinical trials are focused on vulvovaginal rejuvenation and have yielded encouraging results, demonstrating improvements in factors like lubrication, vaginal laxity, and arousal, pain or without notable adverse events (including necrosis, ulceration, and scarring) **(16, 19, 20)**. A significant proportion of patients have expressed a high degree of tolerance towards in-office procedures, often describing the experience as a sensation of warmth. The procedures were executed without any complications or adverse reactions **(21)**.

Caruth **(22)** reported that the findings suggest therapy based on radiofrequency can be effectively and safely employed to address a variety of symptoms related to vaginal health, including sexual issues and urinary incontinence. The procedure was found to be safe and well-received by the patients. It was applicable to patients with both light and dark skin types. There were notable enhancements in all the treatment outcomes examined **(22)**. Alinsod **(23)** demonstrated that the application of radiofrequency to vulvovaginal tissue resulted in a reduction of orgasm time for 23 out of 25 patients by an average of 50%. The proposition was made that radiofrequency serves as a viable non-hormonal and non-invasive alternative for women experiencing challenges in achieving orgasm. This treatment method not only visibly firms female tissues but also seems to enhance local blood circulation, resulting in the tightening and hydration of the vagina. As a result, it improves appearance, increases self-confidence, and reduces performance anxiety **(23)**. The research conducted by Ghanbari et al **(24)** revealed that the levator muscle exhibits a certain degree of tonicity during contraction, as manually evaluated by an urogynecologist. Their findings indicated a growth in the maximum contraction of pelvic floor muscles, as determined through biofeedback. Furthermore, they observed improvements in pelvic floor distress following radiofrequency treatment, including symptoms related to POP, colorectal-anal distress, and urinary distress **(24)**. In a study by Lalji and Lozanova **(25)** non-invasive radiofrequency was used to treat stress urinary incontinence and vulvovaginal laxity. This approach results in improved symptoms and increased sexual satisfaction **(25)**. In a similar vein, another study found that radiofrequency was effective in alleviating fecal incontinence, enhancing the quality of life for up to 12 months without any delayed morbidity **(26)**. The findings of the present study suggest that the application of radiofrequency subsequent to POP surgery resulted in enhancements in the scores of POPDI-6, CRADI-8, UDI-6, and the comprehensive PFDI-20 in patients. Thus, the group that utilized radiofrequency treatment exhibited a greater decrease in scores compared to the control group.

Furthermore, research has indicated a correlation between the total vaginal length and enhanced female sexual function. However, no such correlation was found for the genital hiatus. In contrast, another study reported no association between vaginal measurements and sexual function. This suggests that additional therapeutic sessions may be necessary to improve POP quantification **(27, 28)**. The findings of the study suggest that radiofrequency has the potential to improve female sexual function in various aspects such as sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. This is consistent with prior research that has also identified the effectiveness of radiofrequency in enhancing sexual function **(28, 29)**. The use of radiofrequency technology with a warm endonym stimulates vaginal mucus, potentially leading to improved lubrication. Additionally, the use of cold endonyms or aerobics can aid in the contraction or relaxation of pelvic floor muscles during intercourse if

required (30, 31). A study conducted by Slongo et al (32) observed an enhancement in sexual function parameters following radiofrequency treatment. However, they reported no significant difference in total sexual function among the group that received combined radiofrequency with pelvic floor muscle training and the group that only received radiofrequency treatment (32). These findings align with previous studies that have also reported improvements in sexual function after radiofrequency treatment (25, 27). The study's outcomes suggest a notable enhancement in FSFI scores following surgery in comparison to the scores prior to surgery, across both groups. However, the group treated with radiofrequency exhibited a notably greater increase in FSFI scores than the control group.

Although this therapy shows promise, additional research is necessary to fully understand its benefits and drawbacks. The current research was constrained by the limited number of participants and the lack of a placebo-controlled methodology. The unique circumstances brought about by the COVID-19 pandemic have resulted in some women being unable to attend therapeutic sessions, leading to their exclusion from this study. The study did not evaluate potential psychological elements, like depression or anxiety that could potentially impact sexual function. It is suggested that subsequent studies should incorporate a more extensive participant pool and prolonged observation periods.

5. Conclusion

The findings of this study recommend that radiofrequency is an effective and safe method for pelvic floor repair. The results demonstrated a significant decrease in total PFDI-20 scores and an increase in FSFI scores post-surgery compared with preoperative values in both study groups. However, the group that received radiofrequency treatment showed a more significant improvement in both PFDI-20 and FSFI scores than the group that did not receive this treatment. These results indicate that postoperative radiofrequency therapy can effectively enhance the PFDI-20 and FSFI scores.

6. Declarations

Acknowledgments

We would like to thank all people who participate in this study.

Ethical Considerations

The study protocol underwent review and received approval from the Ethics Committee of Tehran University of Medical Sciences as part of its endorsement of the research project (No: IR.TUMS.IKHC.REC.1401.127). Furthermore, the study was officially registered with the Iranian Registry for Clinical Trials (code: IRCT20220906055897N1).

Authors' Contributions

Z. G. and M. D. P.: Data collection and Performed experiments. R. S. H. and F. S.: Performed experiments and Writing. T. E.: Data collection and Performed experiments. P. J.: Writing and editing article.

Conflict of Interest

The authors declare no conflict of interest.

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