The Effect of Physiotherapy on Erectile Dysfunction Secondary to Prostatic Adenectomy: A Randomized Control Trial Study

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Purpose: The objective of this randomized controlled trial was to investigate the impact of manual therapy (friction massage) and pelvic floor muscle (PFM) training on erectile dysfunction (ED), pelvic floor muscle thickness, and blood flow in the penile arteries and veins in men who have undergone prostatic adenectomy (PA).

Materials and Methods: This study employed a randomized, double-blinded, controlled trial design. Forty patients participated and were divided into two groups: intervention and control (n=20 per group). The intervention group received 10 sessions of pelvic floor muscle training and manual therapy, while the control group solely underwent pelvic floor muscle training. The recovery rate was measured using the International Index of Erectile Function 15 (IIEF-15) questionnaire and Erection Hardness Score (EHS). Sonographic factors were assessed using simple and Doppler ultrasound.

Results: The intervention group exhibited significantly higher erectile function scores ($F(1,37)=158.04$, $P < 0.001$, $\eta 2$ $P = 0.810$) and a higher average total (IIEF-15) score (20.52) ($F(1,37)=136.76$, $P < 0.001$, $\eta 2$ $P = 0.787$) compared to the control group in the post-test assessment. Comparison between the two groups revealed an increase in ultrasonic parameters such as the thickness of the ischiocavernosus and bulbospongiosus muscles, maximum systolic velocity, and minimum diastolic velocity of the cavernosal artery in the intervention group. However, the maximum blood flow velocity in the posterior vein decreased.

Conclusion: PFM training and friction massage play a significant role in managing ED following PA, positioning them as the primary treatment approach for men experiencing ED post-prostatectomy.

Keywords: erectile dysfunction; friction massage; pelvic floor muscle training; physiotherapy; prostatic adenectomy.

INTRODUCTION

Erectile Dysfunction (ED) is defined as the inability to achieve or sustain an erection adequate for satisfactory sexual performance[1]. Erection, a complex event, necessitates the interplay between neurological and vascular responses[2]. ED is a prevalent condition among men, profoundly impacting intimate relationships, self-esteem, and quality of life[3-6]. A comprehensive international study involving 52,697 men aged 40 to 70 in several countries, including the United States, revealed that individuals with ED had notably lower physical and mental quality-of-life scores and health state utilities compared to those without ED (all $P < 0.001$)[6]. More than half of men within this age group experience partial ED, and approximately 10% face severe or complete ED[7]. The prevalence and impact of ED tend to rise with age, with recent research indicating a surprisingly high prevalence of ED in young men (8% among ages 20-30)[8]. This increased prevalence in young men may be attributed to psychological factors such as anxiety[8]. Men dealing with ED exhibit significantly higher rates of absenteeism (7.1% vs 3.2%), presenteeism (22.5% vs 10.1%), overall work productivity impairment (24.8% vs 11.2%), and activity impairment (28.6% vs 14.5%) compared to those without ED[6]. Persistent concern revolves around the functional outcomes in post-prostatic adenectomy (PA) for treating ED, significantly affecting the quality of life[9]. Additionally, the critical role of pelvic floor muscles (PFM) in managing urinary incontinence underscores their

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Table 1. Baseline characteristics of study participants.

	Total (n=40)	Group	
		Control (n=20)	Intervention (n=20)
Age (years)	54.18 (4.09)	53.65 (4.26)	54.70 (3.95)
Weight (kg)	77.70 (9.84)	77.95 (9.11)	77.45 (10.75)
Height (m)	1.74 (0.08)	1.75 (0.07)	1.73 (0.08)
BMI (kg/m^2)	25.85 (3.41)	25.65 (3.30)	26.06 (3.58)

crucial role in proper erectile function. Contraction of the ischiocavernosus and bulbocavernosus muscles elevates intracavernous pressure, thereby enhancing penile rigidity. The bulbocavernosus muscle compresses the deep dorsal vein of the penis, averting venous leakage during the erection process[2].

So far, various treatments have been used to treat erectile dysfunction which include physiotherapy and non-physiotherapy treatments, non-physiotherapy methods such as the use of stem cells[10] medication[11] and surgery[12]. Physiotherapy treatments have also been performed, for example, Hiroshi in a case-control study examined the effect of acupuncture on erectile dysfunction in diabetic men who did not respond to sildenafil[13]. Porta in a single-blind clinical trial study examined the effect of biofeedback on erectile dysfunction in men after prostatectomy[14]. Shendy investigated the effect of TENS in patients with erectile dysfunction due to incomplete spinal cord injury[15]. Fojeki in a double-blind clinical trial investigates the effect of low-power shockwave on idiopathic erectile dysfunction[16]. Dorey in a clinical trial study examined the effect of pelvic floor exercises on idiopathic erectile dysfunction[17].

Standard treatment options for erectile dysfunction comprise psychosexual counseling, medication (e.g., sildenafil and vardenafil), intracavernosal injections (papaverine or alprostadil), vacuum devices, and stem cell therapy[18-20]. Surgical implantation of penile prostheses becomes a viable option when other treatments prove ineffective[21,22]. Recent interest has surged in exploring the role of pelvic floor muscles as potential predictors for ED recovery in PA patients. Consequently, evaluating pelvic floor muscle (PFM) strength and thickness emerges as a crucial factor in identifying the risk of post-prostatectomy ED[20].

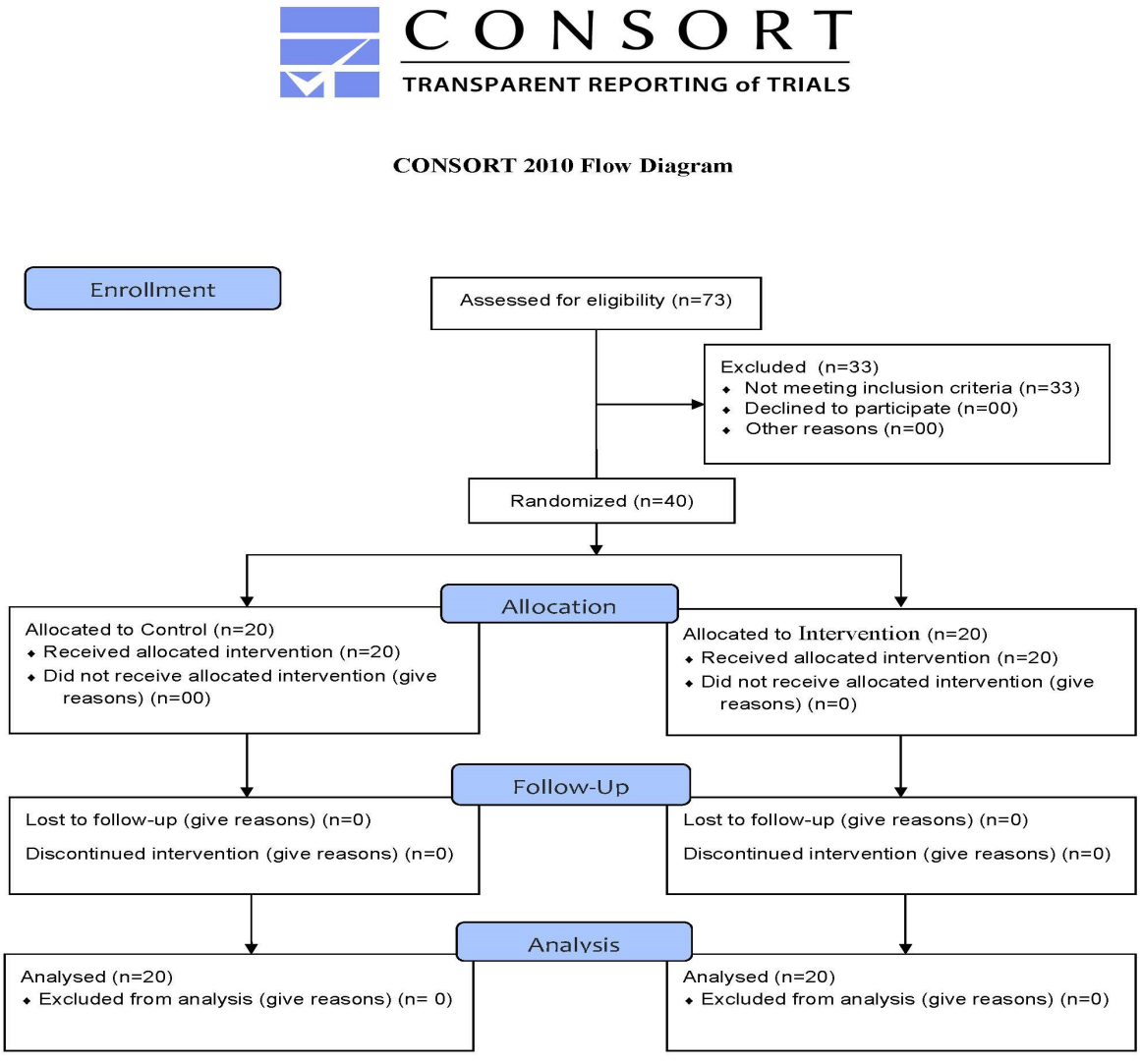

Figure 1. The CONSORT flow diagram of this study

Table 2. Evaluating the effect of pelvic floor myofascial release on treatment of male erectile dysfunction in post adenectomy

		Control	Intervention	Adjusted mean difference (95% CI)a	F(1,37)	*P*	η2p
IIEF							
	Pretest	16.20 (1.77)	16.00 (1.59)				
	Posttest	21.60 (4.85)	42.00 (6.20)	20.52 (16.97 to 24.08)	136.76	< 0.001	0.787
EF							
	Pretest	6.35 (0.49)	6.45 (0.76)				
	Posttest	8.65 (2.46)	20.70 (3.45)	11.98 (10.05 to 13.92)	158.04	< 0.001	0.810
OF							
	Pretest	2.15 (0.37)	2.25 (0.55)				
	Posttest	2.95 (0.89)	5.90 (0.97)	2.87 (2.31 to 3.42)	109.81	< 0.001	0.748
SD							
	Pretest	2.20 (0.41)	2.25 (0.55)				
	Posttest	3.00 (0.92)	5.30 (0.86)	2.27 (1.72 to 2.83)	68.35	< 0.001	0.649
IS							
	Pretest	3.00 (0)	3.20 (0.70)				
	Posttest	4.70 (0.66)	8.50 (1.61)	3.71 (2.91 to 4.51)	88.14	< 0.001	0.704
OS							
	Pretest	2.00 (0)	2.00 (0)				
	Posttest	2.80 (0.52)	4.35 (0.75)	1.55 (1.14 to 1.96)	57.96	< 0.001	0.604
MTIC							
	Pretest	8.47 (0.25)	8.48 (0.33)				
	Posttest	8.86 (0.13)	9.46 (0.31)	0.60 (0.45 to 0.75)	62.63	< 0.001	0.629
CSAI							
	Pretest	98.55 (15.62)	89.00 (12.63)				
	Posttest	107.75 (13.17)	110.75 (12.96)	10.44 (5.65 to 15.22)	19.56	< 0.001	0.346
MTBS							
	Pretest	2.51 (0.26)	2.55 (0.24)				
	Posttest	2.98 (0.24)	3.44 (0.22)	0.44 (0.31 to 0.58)	43.74	< 0.001	0.542
CSAB							
	Pretest	39.60 (3.02)	38.00 (3.85)				
	Posttest	43.40 (3.27)	43.85 (2.74)	1.53 (0.25 to 2.80)	5.87	0.020	0.137
PSV							
	Pretest	42.20 (2.69)	42.75 (2.38)				
	Posttest	42.75 (2.71)	43.95 (2.01)	0.75 (-0.03 to 1.53)	3.84	0.058	0.094
EDV							
	Pretest	4.55 (0.51)	4.75 (0.55)				
	Posttest	4.55 (0.51)	4.90 (0.31)	0.23 (0.05 to 0.41)	6.56	0.015	0.151
PVDDV							
	Pretest	4.50 (0.51)	4.50 (0.51)				
	Posttest	3.00 (0)	3.00 (0)	NA	NA	NA	NA

Data are mean (SD), unless otherwise specified.
[a]Adjusted for pretest scores.
η2p values of 0.01-0.06, 0.06-0.14, and > 0.14 were considered as small, medium, and large effect size, respectively.
Abbreviations. IIEF: International Index of Erectile Function; EF: Erectile Function; OF: Orgasmic Function; SD: Sexual Desire; IS: Intercourse Satisfaction; OS: Overall Satisfaction; MTIC: Maximum Thickness of Ischiocavernosus; CSAI: Cross-Sectional Area of Ischiocavernosus; MTBS: Maximum Thickness of Bulbospongiosus; CSAB: Cross-Sectional Area of Bulbospongiosus; PSV: Peak Systolic Velocity; EDV: End Diastolic Velocity; PVDDV: Peak Velocity of the Deep Dorsal Vein.

Existing studies have highlighted physiotherapy as a noninvasive approach to normalize muscle tone, rectify structural disorders, optimize muscle contraction (strength and endurance), enhance neuromuscular coordination, and improve blood circulation[21]. Notably, PFM training is underscored in the literature as a pivotal physiotherapy intervention for ED in men. However, a notable research gap exists concerning the effects of friction massage on enhancing erectile function. The hypothesis of this study was that friction massage, by exerting mechanical pressure, is anticipated to augment soft tissue compliance, reduce passive and active stiffness, enhance blood flow, elevate soft tissue temperature, modulate neural excitability, and release penile spongy structures[17].

The primary objective of this present randomized control trial was to investigate the impact of manual therapy and PFM training on ED, pelvic floor muscle thickness, and the blood flow dynamics in the arteries and veins of the penis among men with PA. This study aims to bridge the knowledge gap by exploring the potential benefits of friction massage as a novel intervention in managing ED post-prostatectomy, thereby contributing to the development of more effective treatment strategies in this domain.

METHODS AND MATERIALS

Study Population: This study, conducted between June 2022 and August 2023, adopted a randomized, double-blinded, controlled trial design. A total of 73 patients aged between 45 to 60 years, experiencing ED and referred to the urology clinic of Emam Reza Hospital in Mashhad, Iran, were included. After a rigorous evaluation against specified criteria, 40 patients meeting the criteria were selected and allocated into two groups: intervention and control (n = 20 per group).

Inclusion and exclusion criteria: Inclusion criteria encompassed a body mass index <30 kg/m², age between 45-60 years, and ED persisting for at least six months secondary to PA. Conversely, exclusion criteria included a history of lumbar surgery, unstable medical or psychiatric disorders, neurological diseases aside from diabetic neuropathy, chronic hematological diseases, penile anatomical abnormalities, and non-responsiveness to phosphodiesterase 5 Inhibitors (PDE5Is). Patients already on PDE5Is underwent a 4-week washout period before being included in the study.

Sample size

At first, the sample size calculation was done for an

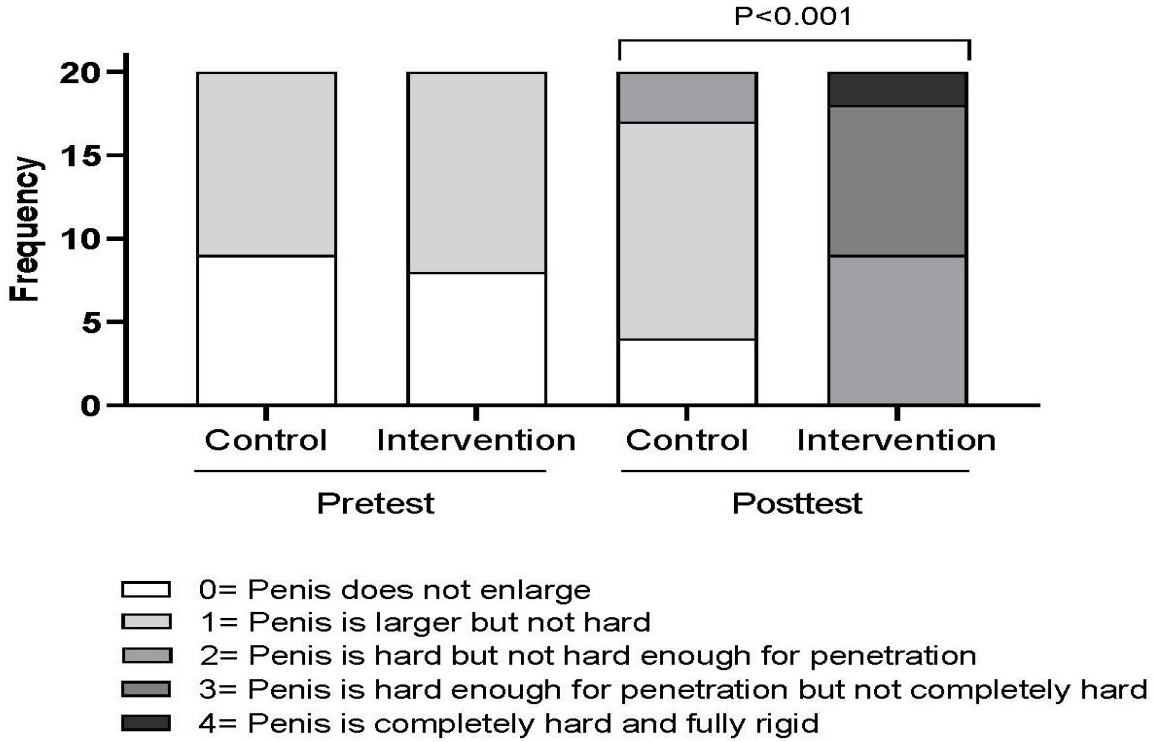

Figure 2. Distribution of EHS between control and intervention groups
Note. Distribution of 5-point ordinal scale between groups were compared using the Cochran-Armitage test for trend.

independent samples t-test using G*Power version 3.1.9.2 [23]. Since we planned to incorporate the pretest scores in the analysis using analysis of covariance (ANCOVA), we multiplied this number by a design factor of (1- ρ2), where ρ is the correlation coefficient between the pretest and posttest scores[24]. With an effect size of 0.8 (Cohen's d) for IIEF total score, a power of 0.8, a two-sided alpha value of 0.05, and using r = 0.6 to account for the correlation between pretest and posttest scores, 17 subjects would be required in each group.

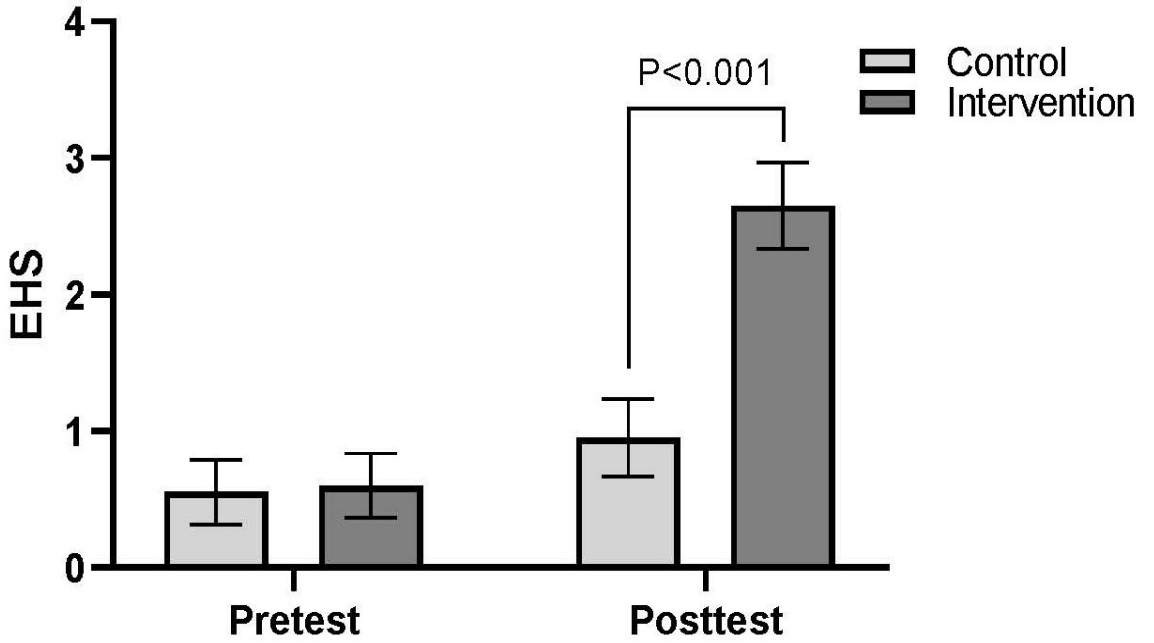

Figure 3. The effect of treatment on the EHS (erection hardness score)
Data are mean and 95% confidence interval (95% CI).
P-value calculated using ANCOVA adjusted for baseline values.

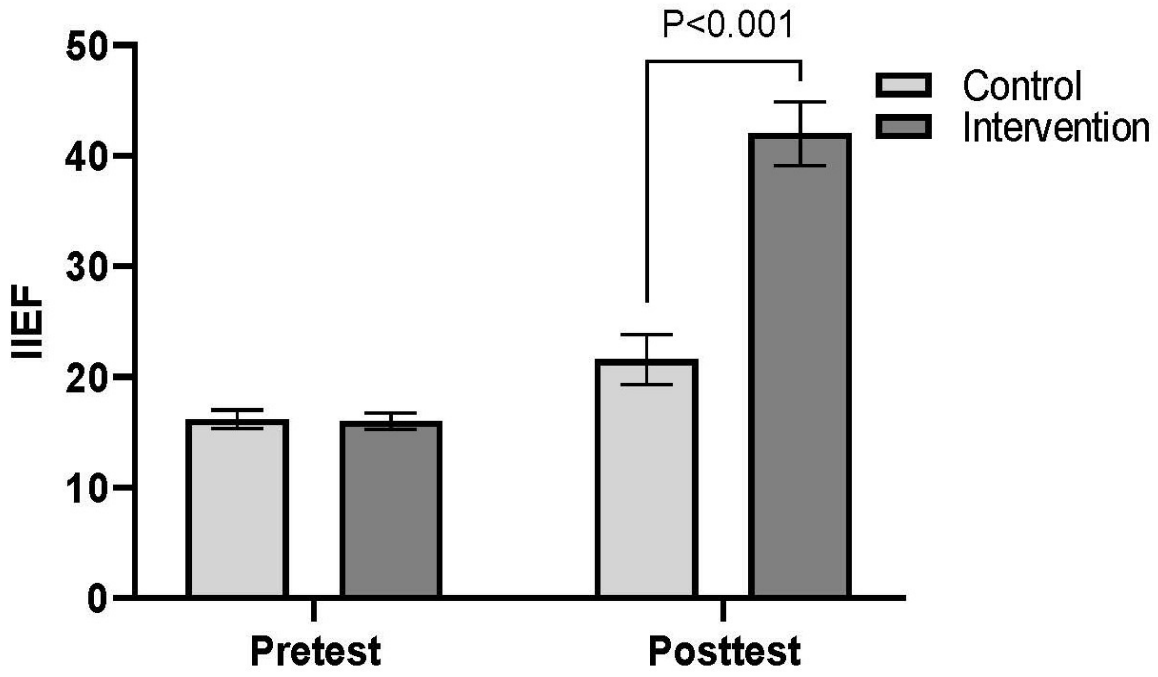

Figure 4. The effect of tratment on the IIEF (International Index of Erectile Function)
Data are mean and 95% confidence interval (95% CI).
P-value calculated using ANCOVA adjusted for baseline values.

Taking into account a potential drop-out rate of 15%, 20 subjects were enrolled in each group.
Randomization: The randomization followed a simple individual-based method. Patients' names were recorded in Excel software, and random numbers were assigned to each person using the Rand function. The first 20 patients were designated for the intervention group, while the subsequent 20 formed the control group.
Blinding: This study was Double-blind. 1- Participants: In the case group, the application of the manual technique was performed in a real way, while in the control group, only a superficial touch was performed and the therapeutic exercise component was performed in the same way in both. 2- Data Analyzer: The data analyzer used code to analyze the data in such a way that it was unaware of its content.
Procedures: Patients were presented with a consent form to read and sign. Subsequently, comprehensive patient examinations were conducted, capturing essential data such as age, weight, height, and gender, recorded in individual patient files (**Table 1**). Following this, patients completed the IIEF-15 questionnaire and erection hardness score (EHS).
Table 1
Then by using the image, the basic anatomy of the pelvic floor structures and how each of these structures plays a role in erection was taught to the patients. Then, the treatment process (PFM training and friction massage) was explained for each group. The PFM training (therapeutic exercise) was performed in the same way for both groups, but the application of friction massage was performed in a real way in the intervention group, while in the control group, only a superficial touch was performed.

Intervention

How to apply friction massage: The friction massage technique was used on the ischiocavernosus, bulbospongiosus muscles and the spongy structure of the penis. Since the spongy structures of the penile tissue are oriented in different directions, the force must be applied in different directions equally and so, lengthening and release occurs in all directions. Friction massage was applied by index finger of the therapist from the origin of the ischiocavernus and bulbospongisus muscles to the end of these muscles in a circular manner and in the up and down directions. This technique should be performed at a slow speed so that it takes ten seconds to draw a circle. Then therapist continues the release technique towards the end of the penis. This technique was applied for 10 minutes.
How to perform pelvic floor training exercises: The patients performed six sets of exercises every day in such a way that they did 10 fast contractions of the pelvic floor muscles (for one second) and 10 slow contractions of the pelvic floor muscles (for 10 seconds) with equal rest time between the contractions[25]. Then, the patients were taught how to pull up the testicles in front of the mirror or in the position of all fours. They were also taught how to retract the penis (selective strengthening of the ischiocavernus muscle). The total exercise time was 10 minutes[25]. All patients performed these exercises every day for one month as home exercises. Patients in the intervention group received 10 sessions of friction massage and patients in the control group only did their exercises. EHS and IIEF15 indicators and ultrasound factors were measured once before and once after the treatment (after the final session). In this study, manual techniques and exercises were taught by one person and data analysis of EHS index and IIEF questionnaire was done by another person.

Outcome measures

There were two main group of outcome measures: 1-

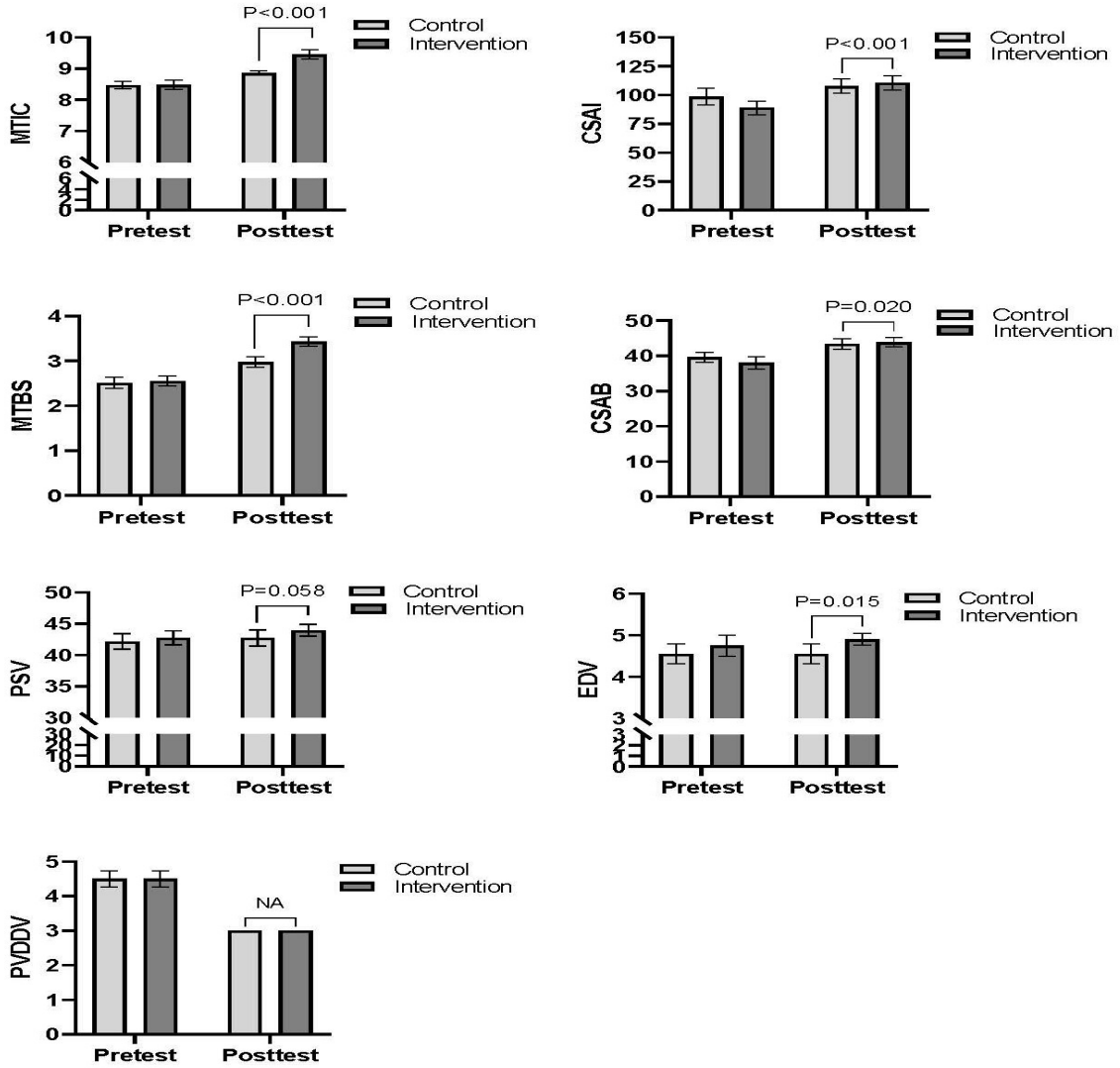

Figure 5. The effect of treatment on the outcome variables
IIEF: International Index of Erectile Function; MTIC: Maximum Thickness of Ischiocavernosus; CSAI: Cross-Sectional Area of Ischiocavernosus; MTBS: Maximum Thickness of Bulbospongiosus; CSAB: Cross-Sectional Area of Bulbospongiosus; PSV: Peak Systolic Velocity; EDV: End Diastolic Velocity; PVDDV: Peak Velocity of the Deep Dorsal Vein.
Data are mean and 95% confidence interval (95% CI). NA: Not Applicable.

Primary outcome measures were EHS and IIEF-15. 2-Secondary outcome measures including measurement of muscle thickness through simple sonography, and also investigation of penile hemodynamics through an intracavernous injection of vasoactive drug by using Pharmaco-penile Duplex Sonography (PPDS) method were done. All these measurements were performed using a Samsung WS80 device made in Korea with a Linear probe (7-12 MHz) with a frequency of 11 MHz which was performed in two dimensions. This type of sonography is valid and reliable[26]. Parameters include: MTIC: Maximum Thickness of Ischiocavernosus; CSAI: Cross-Sectional Area of Ischiocavernosus; MTBS: Maximum Thickness of Bulbospongiosus; and CSAB: Cross-Sectional Area of Bulbospongiosus were measured by using simple sonography. For Doppler sonography, 5 mg of papaverine was injected into the patient's penis and Peak systolic velocity (PSV), end-diastolic velocity (EDV), and peak velocity of the deep dorsal vein (PVDDV) were measured at the base of the penis.

Ethics Approval and Consent to Participate: The Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran, granted ethical approval for this study (Ethics Code: IR.SBMU.RETECH.REC.1400.714). All participants were adequately informed about the study's objective and the voluntary nature of participation. This RCT was registered at www.irct.ir (Trial Registration Number: IRCT20210809052123N1).

Statistical analysis

In this study, categorical variables are presented as numbers (percentages) and continuous variables are presented as mean (standard deviation (SD)). Trends in 5-points ordinal score of EHS were investigated by the Chi-square test. ANCOVA was used to compare the groups after controlling for pretest scores. Partial eta squared ($\eta 2p$) was used to represent effect size (for the group comparisons), where 0.01-0.06, 0.06-0.14, and

> 0.14 represented small, medium, and large effects, respectively. Data analysis was performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA), and error bar graphs were depicted using GraphPad Prism, Version 8.0.1 (GraphPad Prism Software Inc., San Diego, CA, USA). All statistical tests were two-sided and a *P*-value less than 0.05 was considered statistically significant.

RESULTS

Participants characteristics

The flow of participants through the trial is in Figure 1. A total of 73 men were screened and 40 men underwent randomization. Of these, follow-up data were available for all men to be included in the intention-to-treat analysis (Figure 1). The demographic and clinical characteristics of the men are presented in **Table 1**. The mean age of the participants was 54.18 (SD = 4.09) years and the mean BMI of the participants was 25.85 (SD = 3.41) kg/m2. Demographics and clinical characteristics were well balanced between control and intervention groups. **Figure 1**

Results of Primary Outcomes

As presented in Table 2, the intervention group showed significantly higher erection function scores when compared with the control group at posttest assessment (F(1,37)=158.04, $P < 0.001$, $\eta 2$ $P = 0.810$). The effect size, calculated using partial eta squared, was 0.810, which is considered to be large.

Table 2

EHS

Figures 2 and 3 show the status of participants in the control group and the intervention group according to the 5-point ordinal scale of EHS at pretest and posttest assessment. The EHS score in the intervention group was significantly higher than that of the control group at posttest (*P* for trend < 0.001).

Figure 2

(IIEF-15)

After adjusting for pretest scores, men in the intervention group scored on average, 20.52 (95% CI: 16.97 to 24.08) points higher on the IIEF total score than men in the control group at the posttest assessment (F(1,37)=136.76, $P < 0.001$, $\eta 2$ $P = 0.787$). The effect size, calculated using partial eta squared, was 0.787, which is considered to be large. The same results were also obtained for all the IIEF subscales (Figure 4).

Results of Secondary outcomes (Figure 5)

(MTIC)

As presented in Table 2, the intervention group showed significantly higher MTIC scores when compared with the control group at posttest assessment (F(1,37) = 62.63, $P < 0.001$, $\eta 2$ $P = 0.629$). The effect size was 0.629, which is considered to be large.

(CSAI)

After adjusting for pretest scores, men in the intervention group scored, on average, 10.44 (95% CI: 5.65 to 15.22) points higher on the CSAI than men in the control group at the posttest assessment (F(1,37)=19.56, $P < 0.001$, $\eta 2$ $P = 0.346$).

(MTBS)

At posttest measurement, the intervention group showed higher MTBS when compared with the control group (F(1,37) = 43.74, $P < 0.001$, $\eta 2$ $P = 0.542$).

(CSAB)

At posttest measurement, the intervention group showed higher CSAB scores when compared with the control group (F(1,37) = 5.87, $P = 0.020$, $\eta 2$ $P = 0.137$). The effect size was 0.137, which is considered to be medium.

(PSV)

At the posttest measurement, there was no statistically significant difference in PSV between control and intervention groups (F(1,37) = 3.84, $P = 0.058$, $\eta 2$ $P = 0.094$).

(EDV)

At the posttest measurement, results of the ANCOVA showed a significantly higher EDV scores for the participants in the intervention group compared to the men in the control group after adjusting for the pretest scores (F(1,37) = 6.56, $P = 0.015$, $\eta 2$ $P = 0.151$).

(PVDDV)

Due to non-variability of the PVDDV at posttest, the ANCOVA could not be performed.

Evaluating the effect of manual therapy on treatment of male erectile dysfunction in post Adenectomy (**Table 2**). Figure 3. Figure 4.Figure 5.

DISCUSSION

Sexual health is one of the most important aspects of human's life and has a direct impact on the quality of life and marital relationships. Therefore, any investigation and research in this field is valuable. The purpose of this RCT study was to evaluate the effectiveness of manual therapy (friction massage) and PFM training on ED, PFM thickness, and amount of blood flow in the arteries and veins of the penis in men with PA.

The results of this study showed significantly higher EHS and IIEF-15 total score in the intervention group when compared with the control group. The MTIC and MTBS and also the PSV and EDV of the cavernosal artery had increased, but the PVDDV had decreased in the intervention group.

In recent years, clinical studies have been developed to evaluate the efficacy of PFM training in improving the sexual function of post-prostatectomy patients. There are some systematic reviews (Perez et al., 2018), (de Lira et al., 2019; Oh et al., 2020) which have important methodological limitations. They include studies that are not randomized clinical trials (RCT) or not assess directly ED as an outcome. In the last systematic review, de Oliveira Xavier (2022) investigated the quality of the available evidence on the use of PFM training in improving the sexual function of men after prostatectomy. In this study, 4 RCT ((Kannan et al., 2019), (Feng et al., 2020), (Wong et al., 2020), (Nicolai et al., 2021) were evaluated[27].

Friction massage is one of the most important manual techniques in the field of physiotherapy[28]. According to the literature, friction massage has been used in many cases of pelvic floor disorders such as pelvic pain[29]. This type of treatment can also be used as an adjunct treatment in the discussion of ED. In the literature, we could not find any study related to the friction massage in patients with ED. That is why the focus of this study was on the implementation of friction massage for the treatment of ED in patients with prostatectomy.

In this study, both objective and subjective measure-

ment tools were used. In previous studies, only subjective tools such as the IIEF-15 questionnaire and the EHS index were used to evaluate the data while in this study for a more detailed and better examination of the subject, objective tools such as Doppler and simple ultrasound were used to measure the thickness of the PFM, and also to estimate the penile blood flow[30].

Analysis of different factors of questionnaires (EHS and IIEF-15) include erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction which indicates that the erection rate has increased significantly in the intervention group. The mechanism of erection is by increasing the entry blood flow into the cavernous tissue of the penis and also reducing blood outflow from penile tissue. Also, contraction of the ischiocavrenus muscle causes more blood entry into the penis, and contraction of the anterior fibers of the bulbospangius prevents more blood out flow[31]. According to this mechanism, increasing the strength of these muscles can be effective in improving erectile function. The strength of these two muscles depends directly on the thickness of these muscles[32]. Sonographic evaluations including MTTIC, CSAI, MTBS, and CSAB confirm that the thickness of both muscle (ischiocavrenus and bulbospangius) has increased significantly in intervention group.

The majority of authors suggest that penile fibrotic changes during the postoperative period of erectile silence may account for the reduced extensibility and volume of the cavernous structures in patients with radical prostatectomy[33]. According to the study of Awwad et al. (2005), decrease in penile extensibility is because of penile tissue stiffness and abnormal corporal compliance (loss of elasticity of the tunica albuginea) [34]. The tunica albuginea forms a thick fibrous coat to the spongy tissue of the corpora cavernosa and corpus spongiosum of the penis. The application of friction massage can produce mechanical pressure, which is expected to increase soft tissue compliance, release muscle connective tissue[35], decrease passive and active stiffness, increase blood flow, increase soft tissue temperature, and change neural excitability[22]. According to our hypothesis, friction massage can improve EF according to the aforementioned effects of friction, and the results of present study by using Doppler ultrasound confirmed our hypothesis. Increasing PSV and EDV indicates more and faster blood entering the penile tissue, and decreasing PVDDV indicates a decrease in more blood outflow in the intervention group. Analysis of different factors related to ultrasonic evaluation (Simple and Doppler ultrasonography) confirms the results of questionnaires.

CONCLUSIONS

Sexual health is a pivotal aspect of human's life that deserves substantial attention. The findings of this study underscore the significant role of pelvic floor muscle training and friction massage as cost-effective, easily learned by physiotherapists, side-effect-free, and accessible interventions in enhancing erectile function post-prostatic adenectomy. Consequently, these approaches should be regarded as primary modalities for addressing erectile dysfunction.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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