THE EFFICACY OF REZUM WATER VAPOR THERAPY AMONG MALAYSIAN MEN WITH LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA

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ABSTRACT:
Purpose: This study investigates the efficacy and safety of Rezŭm water vapor in the management of Malaysian men with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).
Material and methods: A total of 60 men with symptoms of moderate to severe BPH were enrolled in pilot studies at Hospital Sultan Abdul Aziz Shah, Universiti Putra Malaysia. All patients were treated with transurethral delivery of water vapor. International Prostate Symptom Score (IPSS), quality of life (QoL), peak urinary flow (Qmax), postvoid residual, and International Index of Erectile Function (IIEF-5) were evaluated at 1 week and 1, 3, and 6-months post-treatment. Safety was also assessed.
Results and discussion: The mean age of our study population was 64.57 ± 9.37 years old with mean prostate volume of 59.98 ± 22.06 cc. Our findings revealed statistically significant improvements throughout the 6 months of follow-up for IPSS score (17.45 ± 6.10 score to 7.53 ± 4.28), the QoL scores (3.52 ± 1.19 to 1.53 ± 0.70) and the urinary flow rate, Qmax (9.74 ± 3.39 mL/s to 17.40 ± 5.92 mL/s). There was no significant difference ($p>0.05$) was observed in sexual function (IIEF-5 scores) when compared to preoperatively. No adverse events (AEs) related to endoscopic instrumentations were observed. Two cases of urinary retention were classified as procedure-related AE.
Conclusion: The Rezŭm water vapor therapy is safe and provides effective relief of symptoms and it should be considered as one of the treatment options in patients with LUTs associated with BPH especially for patients who are keen to preserve sexual function as part of the added benefit in this treatment modality.
Keywords: Benign prostatic hyperplasia, lower urinary tract symptoms, water vapor therapy

INTRODUCTION

Recently, a total of 94.0 million men aged 40 years and older were diagnosed with benign prostatic hyperplasia (BPH) in 2019 with a 70.5% increment as compared to prevalence in the year 2000. BPH is a urological disease that is characterized by the benign enlargement of the prostate gland due to the unregulated proliferation of stromal and epithelial cells within the transitional zone of the prostate (1). These changes, along with the inflammation, fibrosis, and alteration in the smooth muscle function, lead to the obstruction of the urethra (2,3). Chronic obstruction of the bladder outflow associated with BPH leads to lower urinary tract symptoms (LUTs) such as voiding dysfunction and storage symptoms, and these greatly affect the quality of life of the patients. Long-term untreated BPH conditions will lead to other possible complications such as chronic urinary retention, haematuria, bladder dysfunction, bladder stones, and kidney damage (4,5).

Medications such as 5-alpha-reductase inhibitors (5α-RIs) and phosphodiesterase-5 inhibitors are among the commonly prescribed drugs to reduce the tension on the urethra outflow and relax the muscle in the prostate. However, there is a growing concern that long-term use of these medications has neurocognitive implications that lead to an increased risk of diseases such as dementia and depression (6,7). Longer exposure to 5α-RIs such as finasteride also has been shown to increase the risk of persistent erectile dysfunction and is associated with worsening sexual function (8,9). In addition to drug intervention, a variety of promising surgical alternatives and minimally invasive therapies (MISTs) are currently available to treat BPH. Among them are transurethral resection of the prostate (TURP) and prostatic urethral lift (UroLift®).

Despite the improvement in BPH treatment, TURP remained the gold standard in treating BPH surgically by removing a section of the prostate gland to release the blockage using a resectoscope inserted through the urethra. However, the TURP procedure was reported to be associated with a risk of perioperative bleeding requiring transfusion and complications which include urinary tract infection, erectile dysfunction, retrograde ejaculation, transurethral resection syndrome, urinary incontinence, and urethral stricture (10,11). Alternatively, UroLift® therapy is considered a minimally invasive approach for treating BPH by permanently placing a non-absorbable suture consisting of a nitinol capsular tab, urethral endpiece, and adjustable non-absorbable filament to mechanically lift and hold the enlarged prostate tissue which will allow the widening of the urethra and subsequently increase urinary outflow (12). A recent study revealed that the patients treated using UroLift® therapy significantly improved the International Prostate Symptoms Score (IPSS) and increased their quality of life (QoL) as compared with TURP, suggesting that UroLift® therapy is an effective treatment for BPH patients with or without obstructive median lobes (OMLs) (13). This procedure works for men with a small- to intermediate-size prostate without the presence of median lobe obstruction, but not for individuals with a larger-sized prostate (>100 mL) (14). Despite the effectiveness of this method in providing rapid and durable relief of LUTs and preserving sexual function, several complications have been reported such as an encrusted implant, migration of implant into the bladder, and up to 13.5% of the patients received retreatment with additional implant and TURP or laser ablation after 5 years follow-up (15).

Due to the TURP- and UroLift®-related complications, clinicians have considered offering Rezŭm water vapor thermal therapy to men with LUTs associated with BPH for the benefit of improving their QoL. It is a MIST medical procedure that delivers sterile water vapor to the targeted transition zone of prostate tissue and disperses into the interstitial space of the prostate The condensation process of the water vapour within the transition zone releases the stored thermal energy and causes denaturation of the cell membrane which leads to a reduction in the volume of prostatic tissue, and subsequently improves the LUTs symptoms (15).

Multiple clinical trial studies have suggested that Rezŭm is clinically effective in treating LUTs due to BPH with significant clinical improvement in IPSS, Qmax, and QOL while retaining their sexual functions (16-18). A recent randomized clinical trials study revealed that Rezŭm water vapour therapy significantly reduced the IPSS compared with UroLift® after 3 years of follow-up, suggesting that Rezŭm therapy provides a greater improvement in symptom relief (19). This technique, however, remains relatively novel in the local context as this treatment approach has never been used yet in Malaysia. All previous studies focused on the application of Rezŭm water vapor therapy among the Caucasian population. Hence, this study aims to evaluate the efficacy and safety of Rezŭm water vapor in the management of Malaysian men with LUTS associated with BPH.

METHODOLOGY

Study Protocol

From July 2021 to December 2022, 60 patients with symptomatic benign prostatic hyperplasia (BPH) were enrolled in this study. The study was performed following the ethical approval obtained from the Ethics Committee for Research involving Human Subjects of University Putra Malaysia (JKEUPM) (JKEUPM-2022-286). This study was conducted at Urology Clinic, Hospital Sultan Abdul Aziz Shah (HSAAS), UPM, Serdang, Selangor, Malaysia. Patients were considered eligible for this study if they met the following criteria: aged over 40 years, clinically indicated for surgical intervention with moderate to severe international prostate symptom score (IPSS), intolerable pharmaceutical side effect, desire of the patient to avoid taking daily medication, prostate volume 30 g and above, failure of medical therapy to sufficiently ameliorate bothersome lower urinary tract symptoms (LUTs) and large median lobe causing benign prostatic obstruction (BPO). However, patients with the following criteria were excluded from this study: patients who have active urinary tract infection (UTI) by culture, evidence of bacterial prostatitis or symptoms of epididymitis, presence of penile implant or urinary sphincter implant, presence of urethral stricture or bladder neck contracture, any cognitive disorder that interferes with or precludes direct and accurate communication with the study investigator, neurogenic bladder or sphincter abnormalities and presence of prostate or bladder cancer.

Patients who fulfilled the recruitment criteria and agreed to participate in this study were given a briefing about the study protocol by the investigator and the patient was then asked to sign the Informed Consent Form once they were agreeable. Patients will be informed that they are allowed to withdraw from this study at any point without obligation to explain the cause. During the outpatient review, the following tests were conducted: basic blood investigation for pre-operative assessment, urine FEME, urine culture and sensitivity, uroflowmetry and post-void residual volume (PVR), and flexible cystoscopy under local anaesthesia to assess the urethra, prostate, and bladder. Following that, patients were admitted at least a day before the procedure. On the day of admission, the patients were asked to answer a set of questionnaires. On the day of surgery, the patient underwent the procedure as per protocol with prophylactic antibiotics given during induction. The number of treatments required by the patient is based on the surgeon's assessment intraoperatively. After completion of the procedure, a 16F Foley's catheter was inserted and kept for 5-7 days up to the discretion of the surgeon. Two consultant urologists who had undergone training for the procedure performed the surgery. The duration of the surgery and any immediate post-operative complications were observed and documented. The patient was discharged on the following day with the following treatment: oral antibiotic for a week, oral analgesia (NSAID and paracetamol as needed), Foley's catheter, BPH medications for 1 month until review, and the antiplatelet or anticoagulant will be resumed if the patient is on before the procedure. The patient will be reviewed during the catheter removal, at 1 month, 3 months, and 6 months to assess patient progress with uroflowmetry and the questionnaires as mentioned.

Thermal treatment procedures

The operative procedure for water vapor thermal therapy was performed as previously reported under general anesthesia (4). Water vapor thermal therapy uses the principles of convective heat transfer to the cell membrane of the targeted tissue in the prostate leading to instant cell death. This system comprises of radiofrequency generator with a single-use transurethral delivery device which was incorporated into a 4mm 30-degree cystoscopy lens. The radiofrequency current is then applied to an inductive coil heater producing thermal energy in the form of water vapor (steam). This water vapor was delivered through a retractable needle via emitter holes in the transurethral device that is injected into the transitional zone of the prostate which rapidly and uniformly disperses through the tissue interstices leading to cell necrosis and subsequently increases the luminal diameter of the urethra.

Study clinical assessment

For the primary outcome measures, the subjects were assessed for the mean improvement in the voiding symptoms using the standardized questionnaire of International Prostate Symptom Score (IPSS). The IPSS questionnaire consists of a total of seven questions related to BPH symptoms. The secondary outcome was also measured in this study by assessing the subject's quality of life associated with voiding symptoms, erectile and ejaculatory functions using the IPSS-QoL score, and International Index of Erectile Function -5 (IIEF-5), respectively. The obtained IPSS-QoL score was categorised into seven categories which include delighted, pleased, mostly satisfied, mixed, mostly dissatisfied, unhappy, and terrible. The IIEF-5 questionnaire consists of five questions and the total scores were categorized into severe erectile dysfunction (1-7 scores), moderate erectile dysfunction (8-11 scores), mild-moderate erectile dysfunction (12-16 scores), mild erectile dysfunction (17-21 scores), and no erectile dysfunction (22-25 scores). The urine flow rate and post-void residual urine volume (PVR) were also assessed using the uroflowmetry and transabdominal sonography of the bladder, respectively. These outcomes were measured in the standardised protocol by the qualified and trained urologist before the procedure (baseline) and follow-up assessment at 1,3 and 6 months after the procedure.

Statistical analysis

The obtained data were analysed using Statistical Package for the Social Sciences (SPSS) version 27. A paired-t test was used to determine the significant difference between the baseline and follow-up assessments. The obtained data were presented as mean ± standard deviation (SD) with a p-value less than 0.05 was considered significant.

RESULTS AND DISCUSSION

This study was designed to evaluate the effectiveness of water vapor thermal therapy of the prostate among Malaysian men with lower urinary tract symptoms (LUTs) associated with benign prostatic hyperplasia (BPH). A total of 60 patients presented with BPH with a mean age of 64.57 ± 9.37 years old were enrolled in this study. The majority were Malay ethnicity (83.4%), Chinese (10%), and Indian (6.6%). The mean prostate volume of the patients evaluated was 59.98 ± 22.06 cc. Out of that, 10 patients had prostate volume of >80cc. The majority (83.30%) of them received general/regional anesthesia during the procedure.

The results in this study demonstrate that the Rezum therapy is an effective treatment option for LUTs secondary to BPH. Our findings outline an improvement in the mean of urinary flow rate (Qmax) throughout the 6 months of follow-up after Rezŭm water vapor treatment from 9.74 ± 3.39 mL/s to 17.40 ± 5.92 mL/s ($p<0.01$) (Table 1), indicating that the urine flows increased from 70.92 ± 79.39 % to 86.04 ± 70.78 % and 95.72 ± 80.62 % after 1 month, 3 months and 6 months of follow-up, respectively. A significant improvement in Qmax was observed in patients after 3 months ($p<0.022$) and 6 months ($p<0.009$) of follow-up as compared with 1-month follow-up. However, no further significant improvement in Qmax was observed after 6 months ($p=0.146$) of

follow-up as compared with 3 months of follow-up.

Our findings also revealed a significant improvement in the IPSS score of the patients from 17.45 ± 6.10 score to 7.53 ± 4.28 score after 6 months of follow-up, indicating that the IPSS score was significantly improved from 27.94 ± 47.05% to 54.07 ± 27.25% after 6 months of follow up with a significant improvement was observed after 3 ($p<0.008$) and 6 ($p<0.001$) months of follow up as compared with 1 month follow up. A significant improvement in IPPS score was also observed after 6 months ($p<0.001$) of follow-up as compared with 3 months of follow-up (Table 1). In line with the IPSS score, the QoL scores significantly reduced from 3.52 ± 1.19 to 1.53 ± 0.70 after 6 months of follow-up, indicating that the QoL among the patients is significantly increased after being subjected to water vapor thermal therapy. At 6 months of follow-up, most of the patients (93.7%) are satisfied with their QoL after undergoing Rezum water vapor thermal therapy. (Figure 1).

From our findings, 41.7% of the patients (n=25) were categorized as having good PVR values. Intervention with water vapor thermal therapy among these patients significantly reduced the PVR value from 123.40 ± 65.34 mL to 40.92 ± 71.37 mL after 6 months of follow-up as compared to the pre-operative value. However, no significant difference ($p>0.05$) was observed in the reduction of the PVR value in different months of follow-up. No significant difference ($p>0.05$) was observed in the IIEF-5 scores after 1, 3, and 6 months of follow-up as compared with pre-operative IIEF-5 scores (Table 1; Figure 2).

The safety of the Rezum therapy was confirmed in this study. Two patients (3.3%) had failed trial of void at 1 week due to suspected urinary tract infection (UTI) and successful removal of catheter thereafter the infection was treated. There were 7 patients (11.7%) reported to have light hematuria post procedure, however not requiring bladder irrigation. Most of the adverse events reported were classified as Clavien Dindo Grade I. Majority of the patients reported to have irritative symptoms which includes urinary frequency, urgency, and dysuria, which were transient and self-limiting for 4-6 weeks. In our study appeared that the sexual function was not adversely affected by the treatment. This is an added benefit to individuals who had significant LUTs symptoms secondary to BPH and who want to have voiding symptom resolution and preserve sexual function.

Rezum therapy is a minimally invasive procedure suitable for patients who are at high risk for general/regional anaesthesia and unsuitable for prolonged operative time. In this cohort of patients, we have a total of 10 patients (16.7%) who underwent this procedure under IV sedation. Most patients reported the maximal pain was during the delivery of steam into the prostatic tissue with a mean pain score reported 4. The procedure performed in this group of patients was uneventful. Based on the small number of our patients being performed under local anaesthesia suggest that it is reasonable to perform this procedure under local anaesthesia. It has been reported in the previous study that Rezum therapy can be done under IV sedation without local anaesthetic prostatic block as it has no significant effect on patient-reported pain (20). The minimally invasive nature of this procedure coupled with its favourable safety profile makes it an attractive alternative for individuals seeking relief from BPH-related symptoms.

CONCLUSION

In conclusion, the results of this study suggest that Rezum water vapor therapy represents a promising therapeutic option for men with lower urinary tract symptoms associated with BPH, offering a minimally invasive and effective approach to improving their quality of life. Continued research and long-term studies will be crucial in further establishing the role of Rezum therapy in the comprehensive management of benign prostatic hyperplasia.

LIMITATIONS

The sample size of our cohort was small, hence we were not able to draw a conclusion that represents Malaysian populations. This study also had a short

follow-up period which is crucial in assessing the sustainability of treatment effects and any delayed adverse events. Given the specific demographic of Malaysian men, cultural and ethnic factors may influence treatment outcomes differently than in other populations. Acknowledging and addressing these limitations in future research can contribute to a more robust understanding of the efficacy of Rezum Water Vapor Therapy among Malaysian men with lower urinary tract symptoms associated with BPH.

CONFLICTS OF INTEREST

The authors have declared no conflicts of interest.

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TABLE LEGENDS:

Table 1: Paired outcomes measures after Rezum water vapor thermal therapy through 6 months.

Outcome measure	Baseline	1 month	3 months	6 months
Peak urinary flow rate (Qmax)				
Qmax (mL/s) ‡	9.74 ± 3.39	15.09 ± 5.35	16.65 ± 5.36	17.40 ± 5.92
N (paired value)	60	60	60	60
P value		**0.001**	**0.001**	**0.001**
Number of patients with clinically significant improvement		52 (86.7%)	57 (95.0%)	56 (93.3%)
Change (%)		70.92 ± 79.39	86.04 ± 70.78	95.72 ± 80.62
International Prostate Symptom Score (IPSS)				
IPSS score #	17.45 ± 6.10	11.58 ± 6.90	9.40 ± 5.01	7.53 ± 4.28
N (paired value)	60	60	60	60
P value		**0.001**	**0.001**	**0.001**
Number of patients with clinically significant improvement		45 (86.7%)	57 (95.0%)	57 (95.0%)
Change (%)		- 27.94 ± 47.05	- 43.37 ± 28.84	- 54.07 ± 27.25
Quality of life (QoL)				
QoL score #	3.52 ± 1.19	2.37 ± 1.21	1.83 ± 0.85	1.53 ± 0.70
N (paired value)	60	60	60	60
P value		0.001	0.001	0.001
Post Void Residual (PVR)				
PVR value #	123.40 ± 65.34	38.68 ± 29.04	55.48 ± 67.53	40.92 ± 71.37

Outcome measure	Baseline	1 month	3 months	6 months
N (paired value)	25	25	25	25
P value		**0.001**	**0.001**	**0.001**
Number of patients with clinically significant improvement		21 (84.0%)	17 (68.0%)	20 (80.0%)
Change (%)		- 59.0 ± 43.21	- 50.47 ± 75.03	- 68.06 ± 38.10
International Index of Erectile Function-5 (IIEF-5				
IIEF score [#]	14.26 ± 4.98	14.47 ± 4.87	14.53 ± 4.98	14.68 ± 4.61
N (paired value)	53	53	53	53

Outcome measure	Baseline	1 month	3 months	6 months
Peak urinary flow rate (Qmax)				
Qmax (mL/s) [ǂ]	9.74 ± 3.39	15.09 ± 5.35	16.65 ± 5.36	17.40 ± 5.92
N (paired value)	60	60	60	60
P value		**0.001**	**0.001**	**0.001**
Number of patients with clinically significant improvement		52 (86.7%)	57 (95.0%)	56 (93.3%)
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Outcome measure	Baseline	1 month	3 months	6 months
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Quality of life (QoL)				
QoL score [#]	3.52 ± 1.19	2.37 ± 1.21	1.83 ± 0.85	1.53 ± 0.70
N (paired value)	60	60	60	60
P value		0.001	0.001	0.001
Post Void Residual (PVR)				
PVR value [#]	123.40 ± 65.34	38.68 ± 29.04	55.48 ± 67.53	40.92 ± 71.37
N (paired value)	25	25	25	25
P value		**0.001**	**0.001**	**0.001**
Number of patients with clinically significant improvement		21 (84.0%)	17 (68.0%)	20 (80.0%)
Change (%)		- 59.0 ± 43.21	- 50.47 ± 75.03	- 68.06 ± 38.10
International Index of Erectile Function-5 (IIEF-5)				
IIEF score [#]	14.26 ± 4.98	14.47 ± 4.87	14.53 ± 4.98	14.68 ± 4.61
N (paired value)	53	53	53	53
P value		0.589	0.593	0.380

Values are presented as mean ± standard deviation (SD).
The p-value is calculated based on the comparison of the value after follow-up with the value obtained from pre-operative or baseline.
ǂ Increase indicates improvement.
[#] Decrease indicates improvement.
% changes were calculated based on the following formula = [(post-operative - pre-operative) ÷ pre-operative] x 100.
The p-value is calculated based on the comparison of the value with the baseline.

FIGURE LEGENDS:

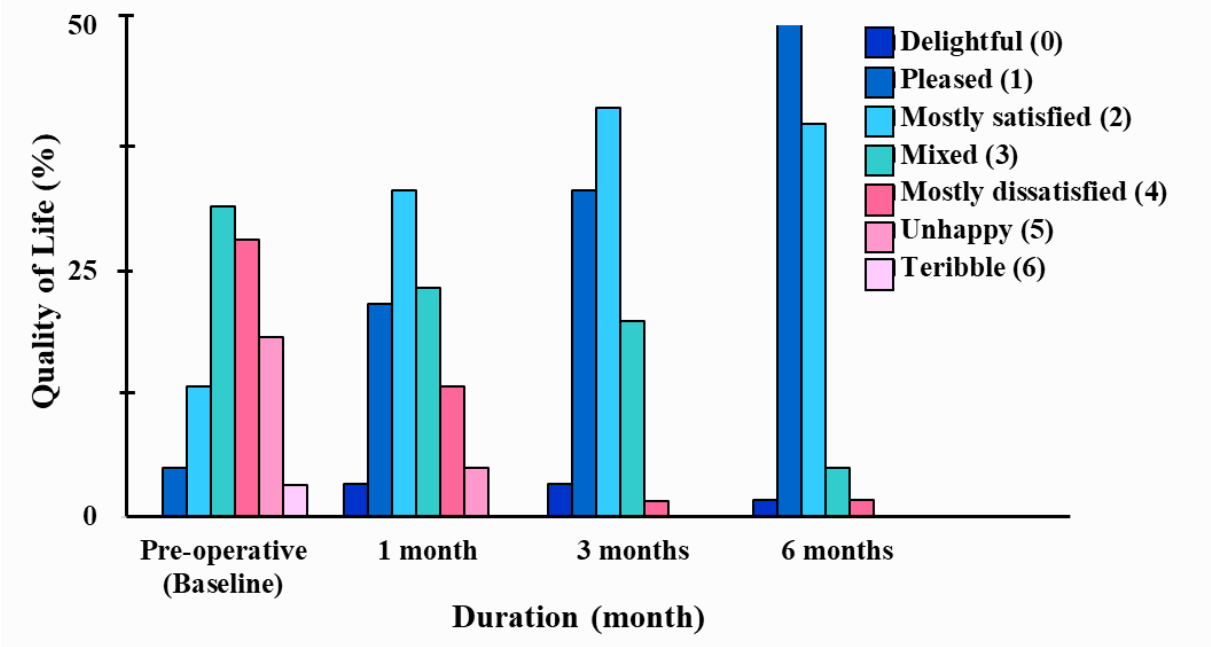

Figure 1: Quality of Life (QoL) of the patients after being subjected to water vapor thermal therapy with 6 months of follow-up.

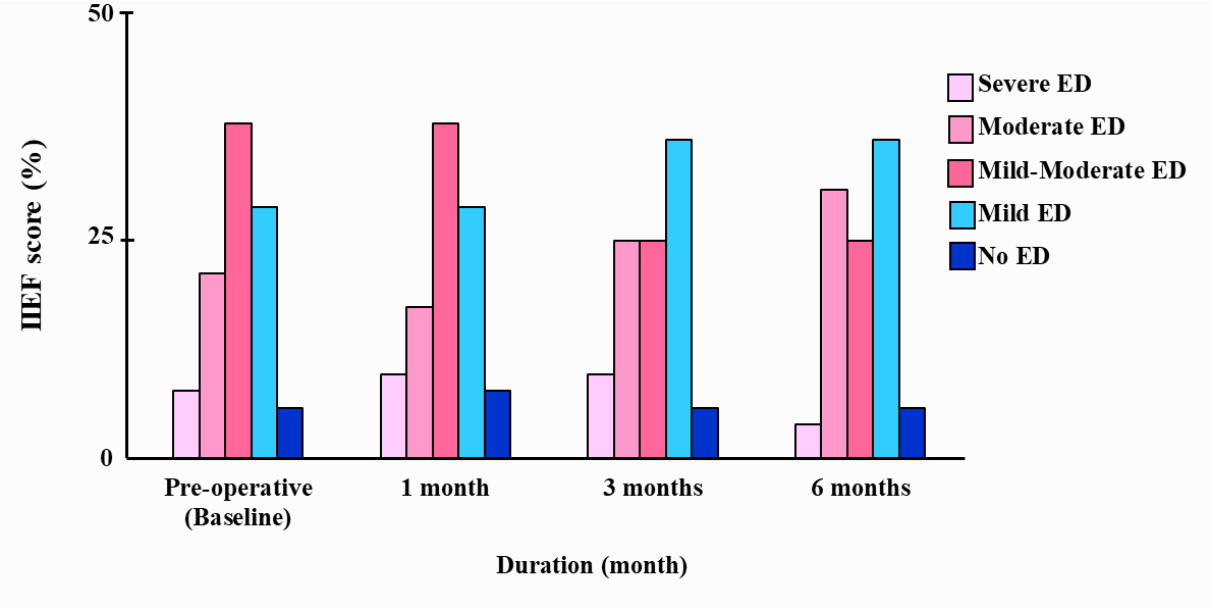

Figure 2: International Index of Erectile Function-5 (IIEF-5) of the patients after being subjected to water vapor thermal therapy with 6 months of follow-up.