# THE INTERVENTIONALIST JOURNAL

### Contents

Volur	me 4 Number 1	March 2024
No.	Title	Page
Case	Report	
1.	ANGIOEMBOLISATION OF CREMASTERIC ARTERY	FOR SCROTAL
	HAEMATOMA FOLLOWING HERNIAL REPAIR	
	A.L.S. Fang, Z. Zainol Abidin, D. Balakrishnan, M.S. Norizan	1
Origi	inal Article	
U	THE EFFICACY OF REZUM WATER VAPOR THERAPY AMO	ONG MALAYSIAN
1.	MEN WITH LOWER URINARY TRACT SYMPTOMS AS	
	BENIGN PROSTATIC HYPERPLASIA	SOCIATED WITH
		aulagua ad Iguail A. Calaui
	F.Y. Lee, K.A. Mohd Ghani, A. Nurdin, C. L. K. Siang, N. Ibrahim, S. A. M	
	A.H. Jasmani, M.H. Mohd Rosli, M.F. Md Ibrahim	

# ANGIOEMBOLISATION OF CREMASTERIC ARTERY FOR SCROTAL HAEMATOMA FOLLOWING HERNIAL REPAIR

A.L.S. Fang<sup>1</sup>, Z. Zainol Abidin<sup>1\*</sup>, D. Balakrishnan<sup>1</sup>, M.S. Norizan<sup>2</sup>

#### \*Corresponding author:

Zakhirati Zainol Abidin, Department of Radiology, Sarawak General Hospital, Kuching, Malaysia.

Email: zakhirati@gmail.com

**DOI:** https://doi.org/10.32896/tij.v4n1.1-8

**Submitted:** 04.02.2024 **Accepted:** 15.03.2024 **Published:** 31.03.2024

#### **ABSTRACT:**

Cremasteric artery is a branch of inferior epigastric artery supplying the cremaster muscle and coverings of the cord. The possible consequence of injury to this artery is scrotal haematoma. We present a case of haemorrhage from unexpected cresmastric artery injury post-hernioplasty treated with angioembolisation. To the best of our knowledge, this has not been reported in literature.

A 66-year-old gentleman with a left indirect inguinal hernia underwent a left inguinal hernioplasty in our institution with no immediate complications. However, he presented to the emergency department the day after the procedure with complaints of rapidly worsening painful left scrotal swelling accompanied with symptoms of intestinal obstruction. Emergency laparotomy and re-do left hernioplasty was performed, revealing a strangulated inguinoscrotal hernia. Post-operatively, there was non-resolving scrotal swelling with a drop in the haemoglobin level; from 11.9g/dl to 8.5g/dl requiring packed cell transfusion. CT angiogram revealed active contrast extravasation from the left cremasteric artery. Angiographic run confirmed the finding and the left cresmatric artery was superselectively cannulated with a 1.9Fr microcatheter and embolization done with 0.5mm microcoil. Ultrasound scan 24-hour post-procedure showed patent proximal vessel. Clinically there was a reduction of the left scrotal swelling and the haemoglobin remained stable.

Cremasteric artery courses laterally deep into the fascia transversalis entering the cord deep to the internal spermatic fascia to supply the cremaster muscle and coverings of the cord. This course renders the artery to be prone for injury during procedure such as hernioplasty; one of the possible consequences is scrotal haematoma. This artery is usually small in caliber and its identification is important for efficient and effective treatment.

<sup>&</sup>lt;sup>1</sup>Department of Radiology, Sarawak General Hospital, Kuching, Malaysia

<sup>&</sup>lt;sup>2</sup>Department of Surgery, Sarawak General Hospital, Kuching, Malaysia

Angioembolisation is able to treat this injury with superior precision owing to its ability for localization and selective cannulation of the offending vessel.

**Keywords:** scrotal haematoma, cremasteric artery, embolisation

#### **INTRODUCTION:**

Cremasteric artery injury is a rare but potentially serious complication of hernioplasty surgery. The cremasteric artery is a branch of the inferior epigastric artery that supplies blood to the cremaster muscle and the coverings of the cord. If this artery is damaged during surgery, it can lead to a scrotal haematoma and other complications. In this case report, we present the unique case of a 66-year-old man who developed a haemorrhage from an unexpected cremasteric artery injury following hernioplasty surgery, which was successfully treated with angioembolisation. To the best of our knowledge, this case has not been reported in the literature.

#### **CASE PRESENTATION:**

A 66-year-old man with a left indirect inguinal hernia presented to our institution for left inguinal hernioplasty surgery. The patient had no significant medical history, and the surgery was performed under general anaesthesia without any complications. However, the following day the patient complained of rapidly worsening, painful left scrotal swelling and symptoms of intestinal obstruction.

An emergency laparotomy and re-do left hernioplasty were performed, revealing a strangulated inguinoscrotal hernia. The patient's post-operative course was complicated by non-resolving scrotal swelling and a drop in haemoglobin levels, from 11.9 g/dL to 8.5 g/dL, requiring a packed cell transfusion. The patient was initially treated with conservative measures, including elevation of the affected leg and scrotal support, but the swelling and bleeding persisted.

A CT angiogram was ordered to investigate the cause of the persistent swelling and bleeding and revealed large left scrotal haematoma secondary to active haemorrhage (Fig 1). Angiography of the left inferior epigastric artery was performed, and an active contrast extravasation from distal vessel that was the left cremasteric artery was seen. The left cremasteric artery was superselectively cannulated with a 1.9 Fr microcatheter (Carnelian; Tokai Medical

Products, Aichi, Japan) and embolised using a 0.5 mm microcoil (Hilal Embolization Microcoil; Cook Medical, Bloomington, Indiana) (Fig 2A,B). An ultrasound scan 24 hours post-procedure showed a patent proximal vessel (Fig 3). Clinically, there was a reduction in the left scrotal swelling and the haemoglobin levels remained stable. The patient was discharged from the hospital on post-operative day 5 with instructions to follow up with the surgeon in a week's time.

#### **DISCUSSION:**

Complications of inguinal hernia surgery include injury to bladder, bowel, vas deferens, and vasculature of the inguinal canal (1). Vascular injury during inguinal hernia repair usually presents as scrotal haematoma and can occur by damage to any of the following vessels: rectus muscle vessel, inferior epigastric vessels, venous plexus at the pubic symphysis, aberrant obturator vein, testicular vessels, and iliac vessels (1).

CT angiography should ideally be performed first, and the pelvic vasculature is studied to identify the offending vessel, in this case, the cremasteric artery.

The cremasteric artery is a small vessel that courses laterally deep into the fascia transversalis, entering the cord deep to the internal spermatic fascia to supply the cremaster muscle and coverings of the cord(2). This course makes the artery vulnerable to injury during procedures such as hernioplasty, which can lead to a scrotal haematoma(3). The cremasteric artery is typically small in caliber and its identification can be challenging, especially in cases where it is damaged and bleeding. Figure 4 illustrates the anatomy of the cremasteric artery.

Cremasteric artery injury is a rare complication of hernioplasty surgery, with only a few cases reported in the literature. The most common symptoms of cremasteric artery injury are persistent scrotal swelling and bleeding, which can occur immediately after surgery or several days later(4). In some cases, the bleeding may be concealed, making it difficult to diagnose(5). The management of cremasteric artery injury may vary

depending on the severity of the injury and the presence of other complications. Treatment options for cremasteric artery injury include surgical ligation of the artery, surgical repair of the damaged artery, and endovascular techniques such as angioembolisation (1,3).

Angioembolisation is a suitable treatment option due to its ability to accurately localise and selectively cannulate the offending vessel(1). It is also able to map the collateral vessels; in this case the testicular artery (a branch of the aorta) and artery to ductus deferens (branch of superior vesical artery)(1,2). This information is important in determining the safest level of embolisation (distal versus proximal) and the safest embolic agents to use. In view of the rich collateral supply in the inguinal canal and the scrotum, precise superselective catheterisation of the vessel until the point of haemorrhage and the utilisation of microcoils as the embolic agent of choice to protect the collaterals and to avoid complications, particularly testicular ischaemia. are recommended(1). Angioembolisation has several advantages over other treatment options, including its precision, minimally invasive nature and high success rate(1).

In this case, the patient developed a haemorrhage from an unexpected cremasteric artery injury following hernioplasty surgery, which was successfully treated with angioembolisation. The procedure involved superselectively cannulating the left cremasteric artery with a microcatheter and embolising it with a microcoil, resulting in a reduction in the left scrotal swelling and stabilisation of the haemoglobin levels.

#### **CONCLUSION:**

Cremasteric artery injury is a rare but potentially serious complication of hernioplasty surgery that can lead to scrotal haematoma and other complications. Accurate identification of the artery is important for efficient and effective treatment. In this case, angioembolisation was used to successfully treat the cremasteric artery injury, demonstrating the precision and effectiveness of this procedure in this setting. Further studies are needed to better understand the incidence and management of cremasteric artery injury following hernioplasty surgery.

#### **CONFLICTS OF INTEREST:**

The authors have no potential conflicts of interest to report regarding this presentation.

#### **FUNDING:**

This article did not receive specific funding.

#### **INFORMED CONSENT:**

Consent had been acquired from the patient's guardian for the publication of images and content.

#### REFERENCE

1. Sheikh A, Klyde D, Contractor S. Testicular artery hemorrhage after inguinal hernia repair. J Vasc Interv Radiol [Internet]. 2014;25(5):805–8. Available from:

http://dx.doi.org/10.1016/j.jvir.2013.12.003

- 2. Liu L. Applied anatomy of the scrotum and its contents. Scrotoscopic Surg. 2018;1–8.
- 3. Hebert J, Jagtiani M, Hsu A, Schmelzer D, Wolodiger F. Exploring a Third Confirmed Case of Hemoperitoneum following Open Inguinal Hernia Repair Caused by Sampson Artery Hemorrhage. Case Rep Surg. 2017;2017:1–3.
- 4. Gupta AK, Burgos MI, Santiago Rodriguez AJ, Lopez-Viego M, Ramseyer MM. Major Bleed Post Minimally Invasive Surgical Repair of Inguinal Hernia. Cureus. 2020;12(8):8–12.
- 5. Burnand K, Viswanath S, Kumar V, Chitale S. Acute spontaneous scrotal haematoma presenting with haemorrhagic shock: A case report. Ann R Coll Surg Engl. 2012;94(1):1–2.

## FIGURE LEGENDS:



Figure 1: CT Angiography showing contrast extravasation in the left scrotum.

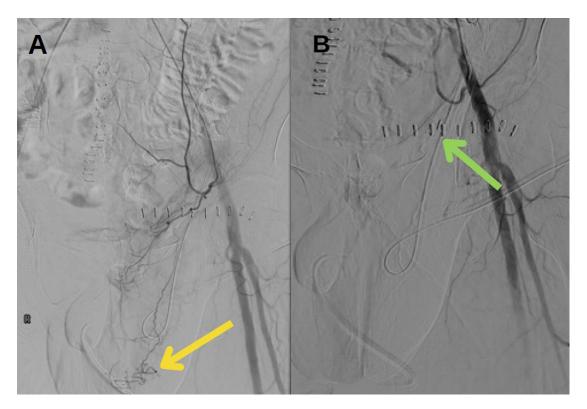


Figure 2: Left inferior epigastric run showing contrast extravsation from cremasteric artery (yellow arrow). Post-embolisation run shows obliteration of cremasteric artery with preservation of inferior epigastric artery (green arrow).

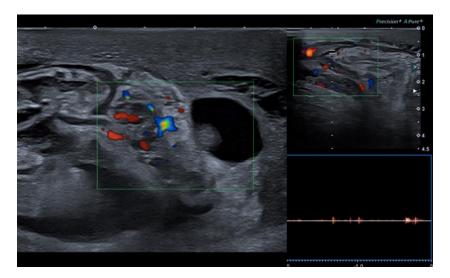


Figure 3: Ultrasound reassessment 24 hours post-embolisation. Images show patency of vessel proximal to the embolisation point.

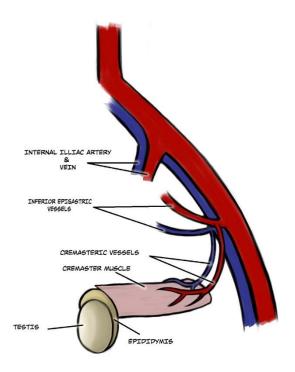


Figure 4: Illustration showing the origin of the cremasteric artery from the inferior epigastric artery.

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

F.Y. Lee<sup>1</sup>, K.A. Mohd Ghani<sup>1\*</sup>, A. Nurdin<sup>2,3</sup>, C. L. K. Siang<sup>1</sup>, N. Ibrahim<sup>4</sup>, S. A. Muhamad Jamil<sup>4</sup>, A. Sabri<sup>1</sup>, A.H. Jasmani<sup>1</sup>, M.H. Mohd Rosli<sup>1</sup>, M.F. Md Ibrahim<sup>1</sup>

#### \*Corresponding author:

Khairul Asri Mohd Ghani, Department of Urology, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor, Malaysia. Email: <a href="mailto:khairulasri@upm.edu.my">khairulasri@upm.edu.my</a>

**DOI:** https://doi.org/10.32896/tij.v4n1.9-20

**Submitted:** 16.02.2024 **Accepted:** 29.03.2024 **Published:** 31.03.2024

#### **ABSTRACT:**

**Purpose:** This study investigates the efficacy and safety of Rezum 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  $64.57 \pm 9.37$  years old with mean prostate volume of  $59.98 \pm 22.06$  cc. Our findings revealed statistically significant improvements throughout the 6 months of follow-up for IPSS score  $(17.45 \pm 6.10 \text{ score to } 7.53 \pm 4.28)$ , the QoL scores  $(3.52 \pm 1.19 \text{ to } 1.53 \pm 0.70)$  and the urinary flow rate, Qmax  $(9.74 \pm 3.39 \text{ mL/s to } 17.40 \pm 5.92 \text{ mL/s})$ . 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 Rezum 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

<sup>&</sup>lt;sup>1</sup>Department of Urology, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor, Malaysia

<sup>&</sup>lt;sup>2</sup>Department of Biomedical Sciences, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor, Malaysia

<sup>&</sup>lt;sup>3</sup>Laboratory of UPM-MAKNA Cancer Research (CANRES), Institute of Bioscience, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor, Malaysia

<sup>&</sup>lt;sup>4</sup>School of Mathematical Sciences, College of Computing, Informatics and Media, Universiti Teknologi MARA, Shah Alam, Selangor, Malaysia

#### 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 lead conditions will 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 (5α-RIs) and phosphodiesterase-5 inhibitors 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 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 nonabsorbable suture consisting of a nitinol capsular tab, urethral endpiece, and adjustable nonabsorbable 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 Rezum 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 Rezům water vapour therapy significantly reduced the IPSS compared with UroLift® after 3 years of suggesting that Rezum therapy follow-up, 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 Rezům water vapor therapy among the Caucasian population. Hence, this study aims to evaluate the efficacy and safety of Rezum 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 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 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 preoperative 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 completion intraoperatively. After of 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 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 the symptoms using standardized voiding 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 (12-16)dysfunction 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  $\pm$  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  $64.57 \pm 9.37$  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  $59.98 \pm 22.06$  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 Rezům water vapor treatment from  $9.74 \pm 3.39$ mL/s to 17.40  $\pm$  5.92 mL/s (p<0.01) (Table 1), indicating that the urine flows increased from  $70.92 \pm 79.39$  % to  $86.04 \pm 70.78$  % and  $95.72 \pm$ 80.62 % after 1 month, 3 months and 6 months of follow-up, respectively. Α 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  $17.45 \pm 6.10$  score to  $7.53 \pm 4.28$  score after 6 months of follow-up, indicating that the IPSS score was significantly improved from 27.94 ± 47.05% to  $54.07 \pm 27.25\%$  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 OoL scores significantly reduced from 3.52  $\pm$  1.19 to 1.53  $\pm$ 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  $123.40 \pm 65.34$  mL to  $40.92 \pm 71.37$  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. 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.

#### **FUNDING**

This study was supported by Boston Scientific Medical Device (Malaysia) Sdn. Bhd.

#### REFERENCE

- 1. Auffenberg GB, Helfand BT, McVary KT. Established medical therapy for benign prostatic hyperplasia. Urol Clin North Am. 2009 Nov;36(4):443-59, v-vi. doi: 10.1016/j.ucl.2009.07.004. PMID: 19942044.
- 2. McVary KT, Roehrborn CG, Avins AL, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. J Urol 2011; 185: 1793–803.
- 3. Bushman W. Etiology, epidemiology, and natural history of benign prostatic hyperplasia. Urol Clin North Am 2009; 36: 403–15.
- 4. Dixon C, Cedano ER, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Mynderse L, Larson T. Efficacy and Safety of Rezūm System Water Vapor Treatment for Lower Urinary Tract Symptoms Secondary Benign **Prostatic** to Hyperplasia. Urology. 2015 Nov;86(5):1042-7. doi: 10.1016/j.urology.2015.05.046. Epub 2015 Jul 26. PMID: 26216644.
- 5. Fusco F, Creta M, De Nunzio C, et al. Progressive bladder remodeling due to

- bladder outlet obstruction: a systematic review of morphological and molecular evidences in humans. BMC Urol 2018; 18: 15.
- Speakman MJ, Cheng X. Management of the complications of BPH/BOO. Indian J Urol. 2014 Apr;30(2):208-13. doi: 10.4103/0970-1591.127856. PMID: 24744522; PMCID: PMC3989825.
- 7. Welk B, McArthur E, Ordon M, Morrow SA, Hayward J, Dixon S. The risk of dementia with the use of 5 alpha reductase inhibitors. J Neurol Sci. 2017 Aug 15;379:109-111. doi: 10.1016/j.jns.2017.05.064. Epub 2017 May 31. PMID: 28716218.
- Pietrzyk B, Olszanecka-Glinianowicz M, Owczarek A, Gabryelewicz T, Almgren-Rachtan Kiguradze T, Temps WH, Yarnold PR, Cashy J, Brannigan RE, Nardone B, Micali G, West DP, Belknap SM. Persistent erectile dysfunction in men exposed to the 5α-reductase inhibitors, finasteride, or dutasteride. PeerJ. 2017 Mar 9;5:e3020. doi: 10.7717/peerj.3020. PMID: 28289563; PMCID: PMC5346286.
- 9. Fwu CW, Eggers PW, Kirkali Z, McVary KT, Burrows PK, Kusek JW. Change in sexual function in men with lower urinary symptoms/benign tract prostatic hyperplasia associated with long-term treatment with doxazosin, finasteride and combined therapy. J Urol. 2014 Jun;191(6):1828-34. doi: 10.1016/j.juro.2013.12.014. Epub 2013 Dec 14. PMID: 24342143.
- 10. Reich O, Gratzke C, Bachmann A, Seitz M, Schlenker B, Hermanek P, Lack N, Stief CG; Urology Section of the Bavarian Working Group for Quality Assurance. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. J Urol. 2008 Jul;180(1):246-9. doi: 10.1016/j.juro.2008.03.058. Epub 2008 May 21. PMID: 18499179.

- 11. Rassweiler J, Teber D, Kuntz R, Hofmann R. Complications of transurethral resection of the prostate (TURP)--incidence, management, and prevention. Eur Urol. 2006 Nov;50(5):969-79; discussion 980. doi: 10.1016/j.eururo.2005.12.042. Epub 2006 Jan 30. PMID: 16469429.
- 12. Bardoli AD, Taylor WSJ, Mahmalji W. Can the UroLift prostatic implant device treat the symptoms of benign prostatic hypertrophy, avoid sexual dysfunction and reduce hospital TURP waiting times? A single centre, single surgeon experience and review of the literature. Aging Male. 2017 Sep;20(3):192-197. doi: 10.1080/13685538.2017.1336531. Epub 2017 Jun 13. PMID: 28609136.
- 13. Eure G, Rukstalis D, Roehrborn C. Prostatic Urethral Lift for Obstructive Median Lobes: Consistent Results Across Controlled Trial and Real-World Settings. J Endourol. 2023 Jan;37(1):50-59. doi: 10.1089/end.2022.0324. Epub 2022 Sep 9. PMID: 35876440; PMCID: PMC9810349.
- 14. Pushkaran A, Stainer V, Muir G, Shergill IS. Urolift minimally invasive surgical BPH management. Expert Rev Med Devices. 2017 Mar;14(3):223-228. doi: 10.1080/17434440.2017.1296762. Epub 2017 Mar 8. PMID: 28270016.
- 15. Roehrborn CG, Barkin J, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Cantwell AL, McVary KT, Te AE, Gholami SS, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Herron S, Rashid P, Rukstalis DB. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813. PMID: 28646935.
- 16. Dixon CM, Rijo Cedano E, Mynderse LA, Larson TR. Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezūm(®) system: evaluation of acute ablative capabilities in the human prostate. Res Rep Urol. 2015

- Jan 30;7:13-8. doi: 10.2147/RRU.S74040. PMID: 25674555; PMCID: PMC4321608.
- 17. McVary KT, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, Cowan BE, Cantrill CH, Mynderse LA, Ulchaker JC, Larson TR, Dixon CM, Roehrborn CG. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. May;195(5):1529-1538. 2016 doi: 10.1016/j.juro.2015.10.181. Epub 2015 Nov 22. PMID: 26614889.
- 18. Mynderse LA, Hanson D, Robb RA, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Cedano ER, Woodrum DA, Dixon CM, Larson TR. Rezūm System Water Vapor Treatment for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia: Validation of Convective Thermal Energy and Characterization Magnetic Resonance Imaging and 3-Dimensional Renderings. Urology. 2015 Jul;86(1):122-7. doi: 10.1016/j.urology.2015.03.021. Epub 2015 May 16. PMID: 25987496.
- 19. Elterman D, Shepherd S, Saadat SH, Alshak MN, Bhojani N, Zorn KC, Rijo E, Misrai V, Lajkosz K, Chughtai B. Prostatic urethral lift (UroLift) versus convective water vapor ablation (Rezum) for minimally invasive treatment of BPH: a comparison of improvements and durability in 3-year clinical outcomes. Can J Urol. 2021 Oct;28(5):10824-10833. PMID: 34657655.
- 20. Leigh Gilpin, David Zekan, Bryce Baugh, Apexa Patel, Stacie A Deslich, Samuel Deem, Ryan Fitzwater, Joshua Lohri, James Tierney, Nathan E Hale. Evaluating the Efficacy of Employing Local Anesthetic Prostatic Blocks During Rezum Procedure. Cureus. 2022 Sep; 14(9): e29598. doi: 10.7759/cureus.29598. PMID: 36321018

**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) <sup>†</sup>	$9.74 \pm 3.39$	$15.09 \pm 5.35$	$16.65 \pm 5.36$	$17.40 \pm 5.92$
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 (%)		$70.92 \pm 79.39$	$86.04 \pm 70.78$	$95.72 \pm 80.62$
International Prostate Symptom So	core (IPSS)			
PSS score #	$17.45 \pm 6.10$	$11.58 \pm 6.90$	$9.40 \pm 5.01$	$7.53 \pm 4.28$
N (paired value)	60	60	60	60
P value		0.001	0.001	0.001
Number of patients with clinically		45 (86.7%)	57 (95.0%)	57 (95.0%)
significant improvement				
Change (%)		$-27.94 \pm 47.05$	$-43.37 \pm 28.84$	$-54.07 \pm 27.25$
Quality of life (QoL)				
QoL score #	$3.52 \pm 1.19$	$2.37 \pm 1.21$	$1.83 \pm 0.85$	$1.53 \pm 0.70$
N (paired value)	60	60	60	60
P value		0.001	0.001	0.001
Post Void Residual (PVR)				
· · ·				
PVR value #	$123.40 \pm 65.34$	$38.68 \pm 29.04$	$55.48 \pm 67.53$	$40.92 \pm 71.37$

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		21 (84.0%)	17 (68.0%)	20 (80.0%)
significant improvement				
Change (%)		$-59.0 \pm 43.21$	$-50.47 \pm 75.03$	$-68.06 \pm 38.10$
International Index of Erectile Fund	ction-5 (IIEF-5			
IIEF score #	$14.26 \pm 4.98$	$14.47 \pm 4.87$	$14.53 \pm 4.98$	$14.68 \pm 4.61$
N (paired value)	53	53	53	53
Outcome measure	Baseline	1 month	3 months	6 months
Peak urinary flow rate (Qmax)				
Qmax (mL/s) <sup>†</sup>	$9.74 \pm 3.39$	$15.09 \pm 5.35$	$16.65 \pm 5.36$	$17.40 \pm 5.92$
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 (%)		$70.92 \pm 79.39$	$86.04 \pm 70.78$	$95.72 \pm 80.62$
International Prostate Symptom Sco	ore (IPSS)			
IPSS score #	$17.45 \pm 6.10$	$11.58 \pm 6.90$	$9.40 \pm 5.01$	$7.53 \pm 4.28$
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%)

Outcome measure	Baseline	1 month	3 months	6 months
Change (%)		$-27.94 \pm 47.05$	- 43.37 ± 28.84	- 54.07 ± 27.25
Quality of life (QoL)				
QoL score #	$3.52 \pm 1.19$	$2.37 \pm 1.21$	$1.83 \pm 0.85$	$1.53 \pm 0.70$
N (paired value)	60	60	60	60
P value		0.001	0.001	0.001
Post Void Residual (PVR)				
PVR value #	$123.40 \pm 65.34$	$38.68 \pm 29.04$	$55.48 \pm 67.53$	$40.92 \pm 71.37$
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 (%)		$-59.0 \pm 43.21$	$-50.47 \pm 75.03$	$-68.06 \pm 38.10$
International Index of Erectile Fu IIEF score # N (paired value)	nction-5 (IIEF-5) 14.26 ± 4.98 53	$14.47 \pm 4.87$ 53	$14.53 \pm 4.98$ $53$	$14.68 \pm 4.61$ 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.

‡ Increase indicates improvement.

<sup>#</sup> 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:

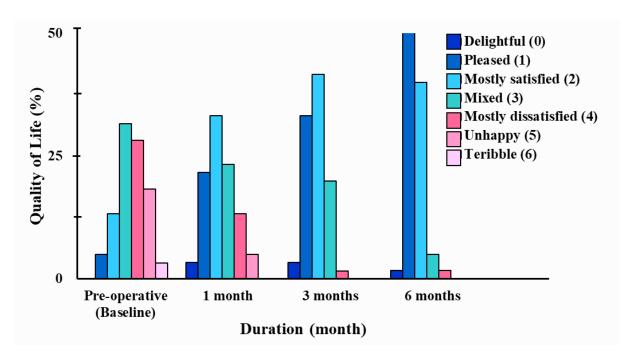


Figure 1: Quality of Life (QoL) of the patients after being subjected to water vapor thermal therapy with 6 months of follow-up.

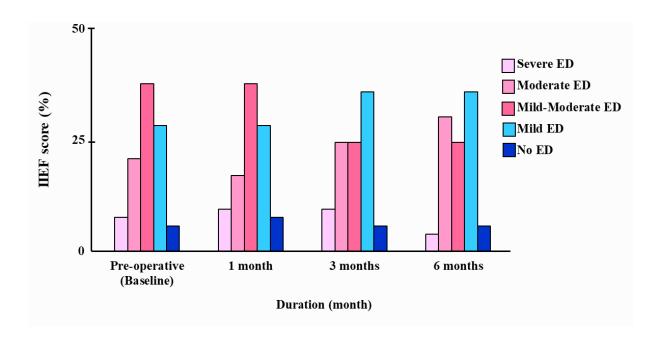


Figure 2: International Index of Erectile Function-5 (IIEF-5) of the patients after being subjected to water vapor thermal therapy with 6 months of follow-up.