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RESEARCH ARTICLE

Rezūm™: yay or nay? From the patients' perspective: a patient reported outcome measure (PROM) study from a single UK centre

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Abstract

***Background*:** Rezūm™ steam ablation therapy is an effective minimally invasive surgical therapy for the treatment of symptomatic benign prostatic hyperplasia. The aim of this study was to assess the perception of this treatment from the patients' perspective at a single centre.
***Methods*:** A patient reported outcome measure (PROM) questionnaire was sent to 65 consecutive patients at least 6 months after undergoing Rezūm™ therapy. We evaluated changes in their prostate symptoms, quality of life (QoL) as well as new onset sexual dysfunction.
***Results*:** A total of 44 questionnaires were analysed with a response rate of 67.7%. Mean prostate volume was 62 mL in a mean population age of 68 years. There was a significant improvement in mean International Prostate Symptom Score and QoL scores ($P < 0.0001$). There was a higher rate of de novo sexual dysfunction noted as compared to other studies. Retreatment procedures occurred in 4.3% of patients, whilst 88.9% reported being medication free. Thirty-five (79.5%) respondents will recommend the procedure.
***Conclusions*:** This study highlighted that the beneficial effects of Rezūm™ observed clinically were also perceived positively by patients in a real-world setting, which is just as equally important.

Keywords: *BPH*; *PROMs*; *LUTS*; *Rezūm™*

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Benign prostatic hyperplasia (BPH) is the most common cause of lower urinary tract symptoms (LUTS) in men in the second half of life and may result in bladder outflow obstruction (BOO). The prevalence of symptomatic BPH increases with age; a meta-analysis has demonstrated an increase from 14.8% amongst men aged 40–49 years to 36.8% amongst those aged 70–79 years (1). These LUTS can be objectively assessed by the clinician with the aid of the International Prostate Symptom Score (IPSS), whilst BOO may be assessed with uroflowmetry and urodynamics using the Maximum Urinary flow Rate (Qmax) and Bladder Outflow Obstruction Index (BOOI). It must be noted that urodynamic studies are helpful in assessing appropriate patients for treatment, but this practice is not uniformly recommended prior to proceeding with surgical therapy, based on National Institute of Health and Care Excellence (NICE) Guidelines for the management of BPH (2).

There are multiple therapeutic options that depend on factors such as severity of symptoms, anatomical characteristics of the prostate, patient expectations as well as technical skills. These include lifestyle advice, watchful waiting, medical therapy and surgical therapy, and these have varying degrees of efficacy, invasiveness and effect on sexual function.

For decades, transurethral resection of the prostate (TURP) has been considered the gold standard worldwide in surgical therapy for LUTS secondary to BPH. Recently, however, the introduction of minimally invasive surgical therapies (MISTs) has helped to reduce surgical morbidity and enhance patient experience whilst providing strong and reproducible levels of efficacy.

The Rezūm™ (Boston Scientific, Marlborough, MA, USA) Transurethral Water Vapour Energy (WAVE) ablation therapy system, which is a relatively new MIST, utilizes convective radiotherapy to ablate obstructive prostatic tissue. Studies including an RCT and meta-analysis (3, 4) involving patients aged >50 year with an IPSS >13, maximum urinary flow rate (Qmax) <15 mL/s and prostate volume of 30–80 mL have shown that there was a significant improvement in LUTS with a retreatment rate of

4.4% at 5 years. It has also been shown that this treatment option has minimal adverse effects on sexual function, which offers a significant advantage to both medical and traditional surgical therapies such as TURP (5). However, very few studies have looked at the therapy from the patient's point of view. Our study objectively demonstrates outcome measures from the patient's perspective from a single centre in the UK.

Patients and methods

Patients diagnosed with symptomatic BPH based on their symptoms, IPSS scores, uroflowmetry and additional tests as appropriate were offered the Rezūm™ therapy as a minimally invasive procedure. It was carried out as a day case procedure under general anaesthesia by a single surgeon in a single centre in the UK.

The first Rezūm procedure was performed in July 2018, and consecutive procedures undertaken between July 2018 and March 2020 were included in this analysis.

Fig. 1. Rezūm Generator.

The Rezūm™ system works by the principle of convection. Water is converted into vapour, and when this vapour gets in contact with surfaces/tissue at a lower temperature, two things occur:

1. condensation takes place and the vapour/steam changes to water
2. the energy is released and transferred to the tissue, which heats up and denatures the cell membrane leading to cell death (6).

It is important to note that no thermal effects occur outside the targeted treatment zone (7). Heating from room temperature of 21 to >100°C requires >80 kcal/litre with this thermal energy being provided by the radiofrequency generator (Fig. 1).

A single use handheld device with a retractable 18-gauge polyetheretherketone (insulated plastic) needle (Fig. 2) inserted under transurethral endoscopic guidance via a cystoscope then delivers the vapour into the target prostatic tissue within a 9 sec cycle. The retractable needle has multiple emitter holes to enable controlled and uniform vapour dispersion. The vapour delivered into the prostatic tissue is at slightly above interstitial pressure, convectively driving the water vapor through tissue interstices. During each 9 sec treatment, 0.42 mL of radio frequency heated sterile water vapour at 103°C is convectively delivered into 37°C prostate tissue, increasing the temperature of tissue within each treatment area to approximately 70°C+, which results in irreversible protein denaturation and immediate cell death.

To keep the urethra and shaft of the device cool, there is a constant flow of room temperature (20–25°C) saline flush when the needle is deployed.

The sites for injection are determined at cystoscopy. The total number of vapour treatments in each prostate lobe is determined according to the length of the prostatic urethra

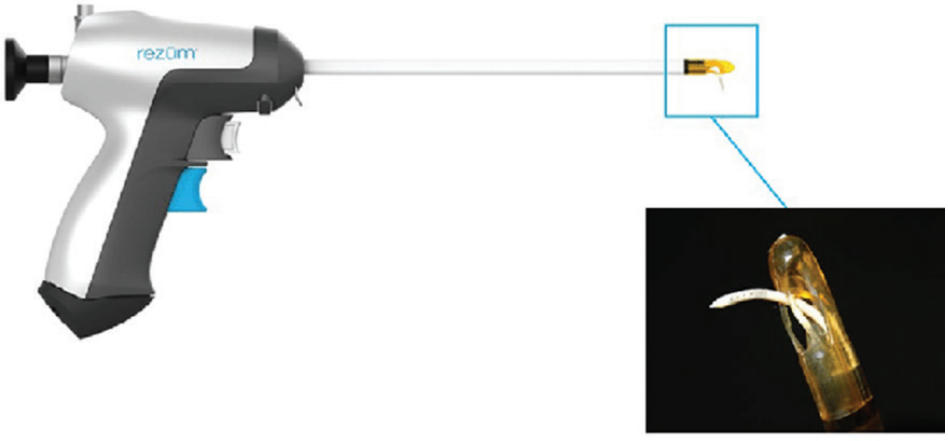

Fig. 2. Rezūm™ handpiece showing retractable needle with multiple emitter holes.

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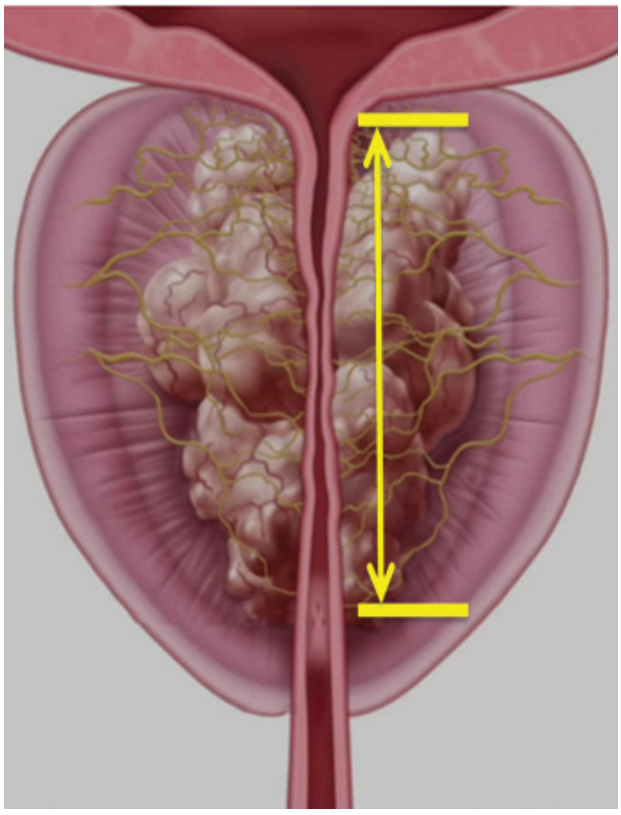

Fig. 3. Estimating prostate length.

(Fig. 3) and the need to treat the median lobe. The aim of this was to create overlapping continuous ablation of the prostate along the length of the prostatic urethra (Table 1).

At the end of the procedure, patients were fitted with a urethral catheter that was generally removed at 5–7 days post-operatively (Table 2).

Over 1–3 months, the ablated tissue is resorbed by the body. All patients were typically reviewed at an 8-week appointment post-operatively with further reviews if they had ongoing urinary symptoms.

They were then sent a questionnaire at least 6 months post-operatively to assess their Patient Reported Outcome Measures (PROMs) (Appendix 1). This amounted to 65 questionnaires being sent out.

Data on patient demographics, prostate volume (either estimated or from imaging), IPSS, quality of life (QoL) scores, post-procedure retrograde ejaculation (RE), erectile dysfunction (ED), urinary incontinence (UI), need for and type of retreatment, current medication use and level of satisfaction were recorded and analysed.

Results

Of the 65 questionnaires distributed, 44 were returned amounting to a 67.7% response rate being achieved. Follow-up period ranged from 10 to 28 months post-procedure with a mean of 18.1 months.

Table 1. Showing estimated number of treatments based on prostatic urethra length mapping

Distance Bladder Neck to Veru	Estimated treatments per Lobe
< 2.0 cm	1–2
2.0–3.0 cm	2–3
> 3.0 cm	3–4

Table 2. Showing procedure steps

Rezūm procedure steps
Set up device and prime with pre-treatment vapour cycle
Carry out initial cystoscopy
Measure distance from bladder neck to verumontanum to map out treatment plan (Fig. 3). Vapour treatments should be placed 1 cm from bladder neck and 1 cm apart
Treat as per treatment plan
Insert catheter

The mean age was 68 years with a range of 51–91 years. The mean prostate volume was 62.0 ± 20.7 mL. Two patients had a prostate volume of more than 80 mL (100 and 111 mL, respectively).

The mean pre-procedure IPSS was 20.64 (7–33), which dropped to a mean post-procedure IPSS score of 8.07 (1–29) with a statistically significant reduction ($P < 0.0001$, 95% CI: 10.11 to 15.03). A higher impact was noticed in the voiding domain scores of the IPSS (Table 3).

QoL also significantly improved reducing from 4.66 pre-procedure to 1.68 post-procedure ($P < 0.0001$, 95% CI: 2.49 to 3.47). Thirty (68.2%) respondents had QoL scores ≤2, whilst three (6.8%) reported being unhappy (QoL 5). None evaluated QoL as being terrible (QoL 6) (Figure 4).

De novo ED, RE (ejaculatory dysfunction) and UI were reported in 10, 10 and 0%, respectively, post-operatively (Fig. 5). Most (88.9%) patients reported being medication free. Seven (15.9%) reported dissatisfaction post-procedure, whilst 35 (79.5%) patients would recommend the procedure to others. Some comments included 'amazing change in quality of life', 'delighted' and 'absolute success'. Only two patients (4.5%) had undergone further procedures (one TURP and one repeat Rezūm™).

Discussion

Rezūm therapy is a viable treatment option for men with LUTS secondary to BPH. Our study showed comparable results to other studies evaluating outcomes of Rezūm as we demonstrated a significant improvement in IPSS and QoL scores (8–10). It was not surprising to see a higher impact noticed in voiding domains scores of the IPSS as storage symptoms are notoriously difficult to treat. We also had similar retreatment rates (4.5%) to the Rezum pivotal study (4.4%) (3). Incidentally, two patients with a

Table 3. Patient responses to individual IPSS items

IPSS item	0	1	2	3	4	5
Incomplete emptying	26	7	4	5	0	2
Frequency	11	13	9	4	4	3
Intermittency	22	11	8	1	0	2
Urgency	15	11	8	5	3	2
Weak stream	14	15	6	3	5	1
Straining	35	2	3	2	2	0
	None	1 time	2 times	3 times	4 times	5 times
Nocturia	9	13	11	8	1	2

IPSS, International Prostate Symptom Score.

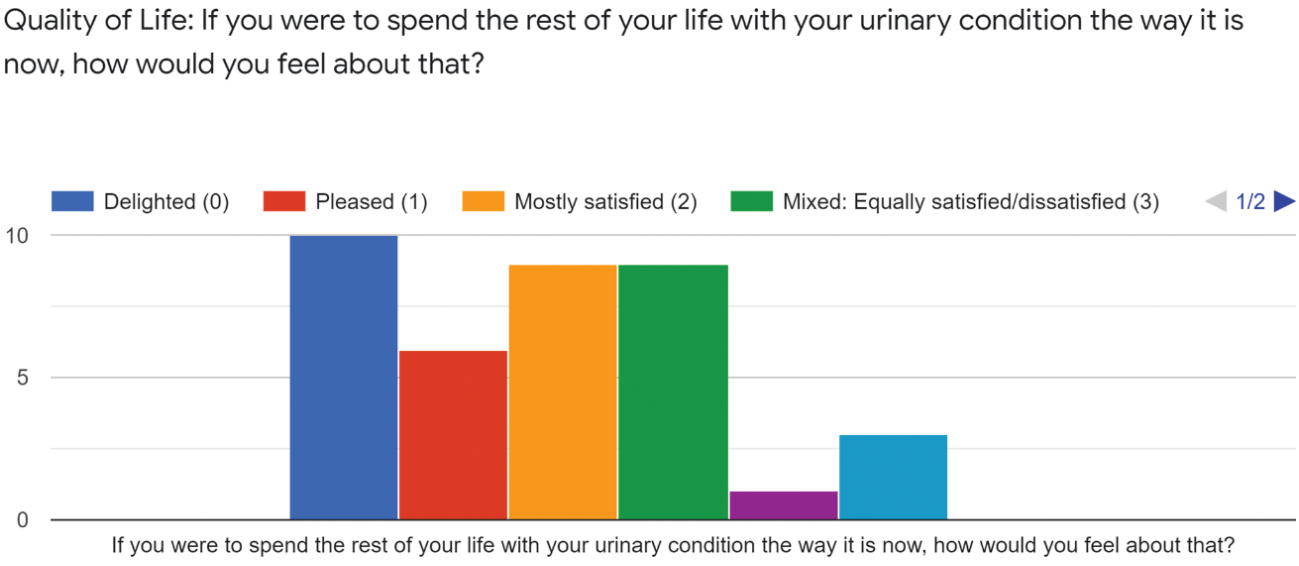

Fig. 4. Quality of life (QoL) scores from respondents.

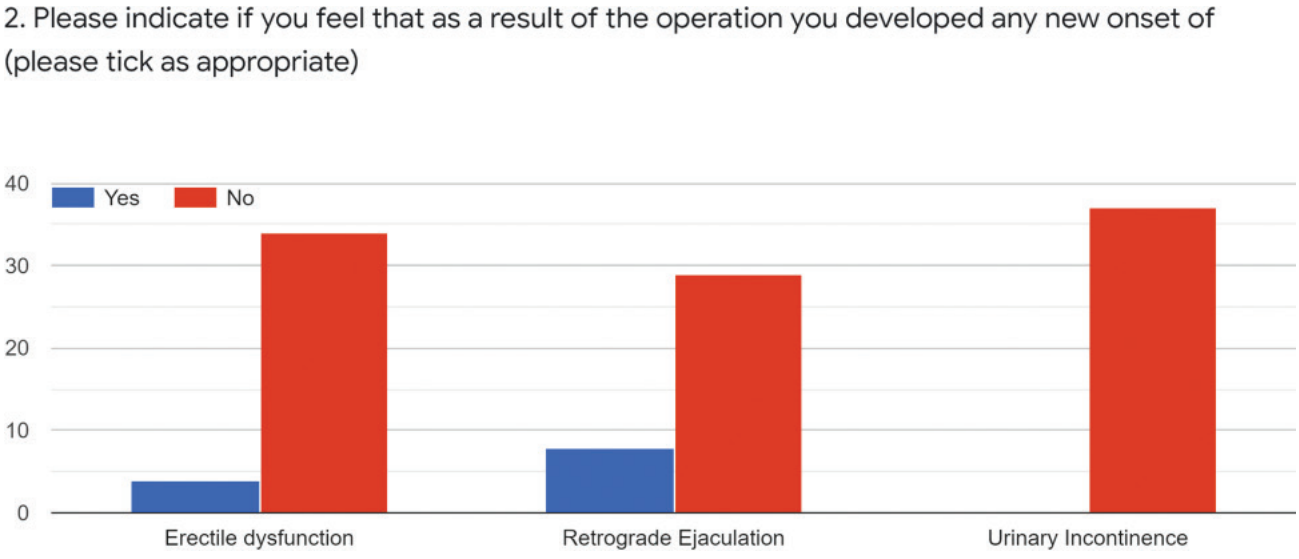

Fig. 5. Highlighting de novo sexual dysfunction and urinary incontinence (UI).

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prostate volume >80 mL received the procedure with good outcomes. This has also been documented in the study by Whiting et al. with 18% of their study population having a prostate volume >80 mL (11).

The strengths of our study lie in the procedure being undertaken by a single surgeon, thereby reducing inter-operator bias as well as the evaluation of Rezūm therapy from the patients' point of view in addition to assessment of clinical outcomes. Our study, therefore, highlighted that Rezūm therapy is largely perceived positively by our cohort in terms of patient-reported outcomes, all within a real world setting with most respondents stating they would recommend the procedure.

We, however, recorded higher rates of de novo sexual dysfunction following the procedure compared to other studies. This might have been mitigated by the administration of the International Index of Erectile Function (IIEF-5) questionnaire both before and after the procedure to assess this objective and rule out covert sexual dysfunction prior to the procedure. Further review and refinement of the procedure in regards to ideal placement of the injections, especially in glands with certain characteristics, may help to predict instances with more favourable outcomes and reduction of unwanted sexual dysfunction.

Conclusion

It is now well established that Rezūm therapy is a viable MIST, which should be part of every urologist's armamentarium in the surgical management of BPH. It has been demonstrated here that the benefits of Rezūm observed in the pivotal Rezūm study are transferable to a real-world population. It should be noted that PROMs are an objective assessment of patients' perspectives, which gives a powerful perspective in its own right.

In the real-world setting, our study shows that patients appreciate that Rezūm therapy has good efficacy in improving symptoms and decreasing medication utilization for patients with BPH. The reported rates of ED and retrograde ejaculation/ejaculatory dysfunction in this study, however, merit further evaluation, preferably by prospective evaluation.

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Appendix 1

Patient reported outcome questionnaire for Rezum.

16/11/2020

Dear Mr.

The Rezum (Trans-urethral water(steam)) vapourisation of the prostate is a relatively new minimally invasive procedure used to treat men with lower urinary tract symptoms secondary to benign prostate enlargement.

Thank you for choosing to undergo your recent Rezum (Trans-urethral water(steam)) vapourisation of the prostate procedure under my care.

You are one of the first consecutive 65 patients who had this procedure performed by me between July 2018 and March 2020.

I am conducting a clinical audit of outcomes of this procedure. I, therefore, need your help please. I assure you that this exercise is being conducted in the strictest confidence, and none of your personal/clinical information will be divulged to any third party. I will involve one member of my junior medical staff and one medical student to assist me with this clinical audit project. The reason for this exercise is to collate 'real world' patient reported outcome measures (PROMs) to add to clinical scientific information about this procedure. It could, therefore, be of use in helping me and other urologists treat future patients.

Please assist with the following questions as well as the attached International Prostate Symptom Score (IPSS) questionnaire.

NB: Please don't worry if you don't remember the exact date of your procedure as I, of course, have that information.

Thank you for your kind assistance.
Kind Regards,
Mr Adebanji Adeyoju
Consultant, Urological Surgeon.

1. Please indicate the date you had your procedure:
2. Please indicate if you feel that as a result of the operation you developed any new onset of (please circle as appropriate);

   Erectile dysfunction? Yes No

   Retrograde ejaculation? Yes No

   Urinary incontinence? Yes No
3. Have you had any further surgery for lower urinary tract symptoms?

   Yes No

   If yes, what operation?

   And when?
4. Are you currently taking any medication for lower urinary tract symptoms?

   Yes No

   If yes, what medication(s) are you taking?
5. How satisfied are you with the overall outcome you have experienced?

   a) Extremely dissatisfied b) Dissatisfied

   c) Neither satisfied nor dissatisfied d) Satisfied

   e) Extremely satisfied
6. Would you recommend this procedure to a friend or family member?

   Yes No

   If no, please could you elaborate why?

   Any specific feedback?

Kindly post back this sheet and the accompanying IPSS symptom questionnaire.

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