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REVIEW

The dawn of minimal invasive surgical therapies for benign prostate hyperplasia in South Africa: water vapour energy ablation with Rezūm

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The challenges in managing the ever-increasing burden of patients with benign prostatic hyperplasia (BPH) in South Africa are diverse. Sexual and psychological side effects of current medical and surgical treatment options are contributing factors to some patients' unwillingness to undergo treatment. Severe shortages of urological theatre resources in the public sector lead to unacceptably long waiting lists for surgical management of BPH.

Minimal invasive surgical therapies (MIST) for BPH have the potential to address some of these challenges. The lack of availability of MIST options in South Africa has been hindering its integration into local BPH management strategies. Water vapour energy (WAVE) ablation with the Rezūm system has become the first urologist-administered MIST for BPH to be made available in South Africa. In this article we briefly review this new therapy's technique, mode of action, efficacy, and safety. We present the three-month outcomes of the first small Rezūm case series in Africa and discuss its potential application in addressing the challenges of BPH management in South Africa.

Keywords: Rezūm, water vapour therapy, BPH, South Africa, water vapour energy ablation

Introduction

The challenges in managing the ever-increasing burden of patients with benign prostatic hyperplasia (BPH) in South Africa are as diverse as everything else in this beautiful country. The longstanding three-tier approach of watchful waiting, medical therapies and surgical management is well ingrained into our collective BPH management plan. Transurethral resection of the prostate (TURP) and retropubic simple prostatectomy for larger prostates has been the gold standard treatment for the better part of the past century. With the advent of different laser technologies and techniques, came better safety profiles for patients. In the South African private sector, a variety of medical therapies have alleviated some of the surgical burden, but many patients' dissatisfaction with both medical therapy as well as current available surgical options provides a challenge that, in many instances, leads to equal frustration on the side of the patient and urologist. The sexual side effects (erectile, libido and ejaculatory) and the burden of taking lifelong medication discourages some patients from commencing or persevering with medical management. Recent studies have additionally identified potential psychiatric side effects, e.g. depression and anxiety, associated with finasteride usage in younger patients.[1] Similar sexual side effects, together with the need for anaesthesia, in-hospital stay and potential complications such as urinary incontinence, make current surgical options, for other patients, a bridge too far.[2]

In the overburdened South African public health sector, the sheer number of patients needing surgery has completely overwhelmed the limited theatre and hospital resources available. Factors that further compound BPH surgery waiting lists are the fact that these surgeries often compete for limited theatre resources against large volumes of more urgent oncological, stone and reconstructive surgery cases. This has led to waiting lists for BPH surgery at public hospitals of one to three years and the added burden of complications that accompanies long waiting times.

The need to fill the void in our BPH armamentarium between medical therapy and surgical treatment, which can address these challenges, has led to the development of various minimal invasive surgical therapies (MIST) for BPH over the past 15 years. Transurethral microwave therapy (TUMT), and transurethral needle ablation (TUNA) are both ablative techniques relying on conductive heat transfer. Its general uptake has been hindered by patient selection issues, inferior durability and higher than acceptable retreatment.[3] Prostatic urethral lift (PUL) and prostatic artery embolisation (PAE) has been described in numerous studies, including randomised controlled trials (RCTs) comparing them to standard surgical treatment.[4] Newer technologies, like convective water vapour energy (WAVE) ablation, the Rezūm system and iTind (temporary implanted nitinol device), have made their way into guideline documents with five-year and three-year data respectively, showing durable outcomes, but still lacking direct comparison to standard surgical management.[4] PAE has been available in South Africa since 2015 and requires a multidisciplinary team consisting of skilled interventional radiologists working in tandem with urologists. With the arrival of a second MIST for BPH in South Africa, in November 2021, WAVE ablation via the Rezūm system (Boston Scientific Corporation) has now become the first urologist-administered MIST option for BPH in the country.

Equipment, technique and mode of action

The Rezūm system consists of a generator that heats sterile saline through radiofrequency current into water vapour (steam), and a single-use delivery device that incorporates a standard rigid 30° cystoscope lens which allows delivery of the water vapour, under direct visualisation, to the prostatic urethra. Controls on the handheld delivery device allow for deployment of the snake-fang-like, 18-gauge, polyether ether ketone needle. Surgeon-controlled saline flushing assists with

visualisation and cools the prostate during treatments[5,6] (See Figure 1).

What makes Rezūm WAVE therapy such a unique treatment tool in our armamentarium is the fact that it can be done as an in-office or day-theatre procedure under local prostatic block, conscious sedation or anxiolytics coupled with oral/IV nonsteroidal anti-inflammatory drugs (NSAIDs).[5] The patient is placed in the lithotomy position and after a routine cystoscopy, the delivery device is placed over the 30° lens and inserted into the prostatic urethra. Visible, fixed markers on the tip of the delivery device are then used to measure the distance from the bladder neck to the verumontanum. Based on these measurements and the presence of a large posterior central or an obstructing middle lobe, the sites for delivery of the water vapour are planned. Deployment of the needle leads to a fixed depth of penetration (10 mm) into the prostatic transitional zone. Water vapour is dispersed circumferentially from the needle through 12 emitter holes and is delivered for a fixed period of nine seconds (automatically controlled by generator). The convective dispersion of energy, stored in the water vapour, along interstitial planes, assures equal spread of energy over the entire treatment field (each treatment creates a 1.5–2 cm defect).[5] This is in contrast to conductive energy dispersion that is used in TUNA and TUMT, where energy delivery is maximal at treatment point and exponentially decreases with increasing distance from this point.[6] Treatment is commenced 10 mm distal to the bladder neck, at 3'o clock and 9'o clock positions, and repeated distally at 10 mm intervals up to the verumontanum. The middle and lateral lobe prostatic protrusions into the bladder can be effectively targeted with injections 10 mm from the proximal edge of the protrusion.[5] This ability to treat the middle lobe has led to favourable comparisons to the PUL procedure, in which this is not possible.[7] The procedure takes no more than five to ten minutes to complete and a transurethral catheter is placed on discretion of the treating urologist. It is worth noting that in earlier studies more than half of patients needed catheterisation prior to discharge, with an average catheterisation duration of four days.[8]

Efficacy and safety

The pivotal Rezūm II randomised control trial, with final five-year data published in 2021, has provided us with good supporting evidence to advocate for firmly slotting Rezūm therapy into our continuum of BPH therapy options. In Rezūm II, a total of 196 patients were randomised in a 2:1 fashion between treatment (135 patients) and sham control arms (61 patients). Patients were included if they had prostate volumes between 30 and 80 cc and an IPSS score of > 12. The presence of a protruding middle lobe was not an exclusion factor. The final five-year results showed significant durability in the improvement of IPSS scores (22.0–11.1) and urinary flow (Qmax: 9.9–14 ml/s). Just as significant was the low surgical retreatment rate of 4.4% and medical retreatment rate of 11% at five years post procedure.[9]

Johnston et al. expanded the use of Rezūm to larger prostates, including patients that were catheter-bound and published their 12-month data for 210 patients in 2021.[10] They excluded patients in chronic urinary retention or "prohibitively large prostates". The cohort included 25 men with indwelling catheters or using intermittent catheterisation, of which only eight failed trial without catheter post-Rezūm.[10] Eredics et al. managed to achieve 78% catheter independency with Rezūm therapy performed in an ambulatory setting, under periprostatic block, in a cohort of elderly, multimorbid patients with urinary retention and catheter dependency (average catheter duration four months).[11] MIST that can be performed under local anesthaesia provides us with a potential answer to the longstanding challenge of what to do with the multimorbid or elderly patient that is catheter bound.

The safety profile of Rezūm, especially when it comes to the lack of ejaculatory side effects, is a major and underestimated draw card for patients. Numerous studies have reported on the preservation of sexual function after Rezūm therapy with preservation of antegrade ejaculatory function rates of 90–100% and no reports of de novo erectile dysfunction.[9,10,12,13] Rezūm also appears to be safe with most reported complications minor in nature (Clavien I–II). In the previously mentioned Rezum II trial, the most common complications were dysuria (16.9%), haematuria (11.8%), frequency or urgency (5.9%), acute urinary retention (3.7%), and suspected UTI (3.7%). All of these complications were resolved within 30 days.[9,14]

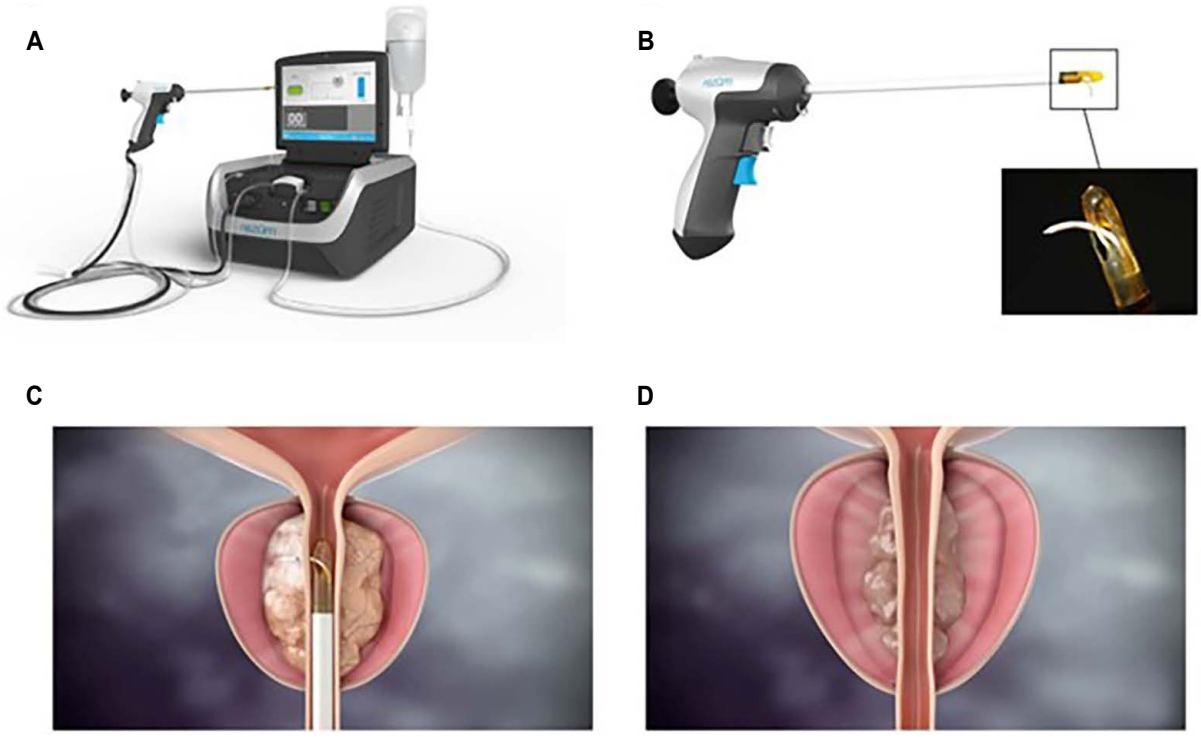
Tygerberg experience with initial five cases

The first five Rezūm therapy cases were performed at Tygerberg Academic Hospital urology day-theatre complex in November 2021. The average age of the patients was 65.4 years with an average prostate volume of 41 cc. None of the patients were catheter-dependent prior to procedure and the indication in all five cases was failure of medical treatment. Due to this being the first case series, we decided to conduct all procedures under general anaesthesia. The longest procedure time was eight minutes and transurethral catheters (TUC) were inserted after conclusion. The patients were all discharged two hours after their procedures with TUC in situ, and a script for NSAID analgesia, alpha-blockers and a seven-day course of antibiotics. All five patients' catheters were removed on Day 7, after which one patient required replacement of TUC on Day 11, after taking oxybutinin. A catheter was replaced for a further five days, after which it was successfully removed. At three-month follow-up all patients showed significant improvement in IPSS (24–11.4), QoL score (3.2–1.6) and Qmax (9.4–12.8). These results, although only a case series, mimic the findings of the larger studies' findings at three-month follow-up.

How should we approach Rezūm therapy in BPH?

The late Prof. Chris Heyns used to reprimand us for the heedless use of the phrase "game-changer". Time alone will tell whether Rezūm therapy will live up to this label that many, including myself, would cautiously want to bestow on it. It is hard not to get excited about the potential of this new addition to our BPH therapy arsenal to address a significant number of the challenges mentioned in the introduction. In the public sector, the potential for Rezūm to bring about significant changes to our TURP waiting lists, by circumventing the biggest of all our resource constraints – theatre-time and bedspace – is that of a game-changer.

As with most new technologies, the cost-comparison with established treatment is a factor that needs to be carefully looked



A. Complete Rezūm delivery system including generator and single-use handset
B. Close-up of tip of delivery device and it's deployable needle
C. Diagram illustrating delivery of vapour into prostate transitional zone
D. Atrophy of adenoma takes place over next three months

Figure 1: The Rezūm system

into. In initial cost analysis and comparisons conducted by the local team from Boston Scientific in collaboration with Tygerberg urology department, the increased cost of the new technology is offset by the savings in theatre time, in-patient hospital costs and decreased need for consumables. These costs can be further reduced once the procedure is done in-office, as is the practice in many centres.

It is the opinion of many MIST experts that Rezūm and its comrades in this treatment category are not intended to replace the well-proven surgical modalities like TURP, laser vapourisation or enucleation, but rather to provide us with another effective tool to create a continuum of treatment options for BPH management: starting at watchful waiting and lifestyle modifications all the way through to surgical therapies. This will enable the urologist to better individualise treatment for patients and assist us in tackling the diverse challenges of BPH management in South Africa.

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