Rezum water vapour therapy for benign prostatic hyperplasia

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A new minimally invasive technique for managing benign prostatic hyperplasia provides real choice for patients. Here the authors describe the technique and discuss how it compares to the other established management options.

Rezum water vapour therapy uses convective rather than conductive heating to inject steam at low pressure into the prostate to destroy or ablate tissue[4]

The use of ablation techniques in medicine is not a new phenomenon. The targeted destruction of tissue in the absence of cutting has been used primarily in cardiology but also in dermatology, gynaecology and neurosurgery for decades.[1] In urology, ablation techniques are increasingly used to destroy areas of prostate cancer using energy sources such as cryoablation and high-intensity focused ultrasound.

In the treatment of benign prostatic hyperplasia (BPH) tissue, techniques such as transurethral needle ablation (TUNA) of the prostate and laser prostate ablation have been evaluated and trialed since the 1990s.[2] However, issues relating to high retreatment rates and irritative symptoms in the early postoperative period have led to a decline in the use of these techniques.[3] The injection of water vapour with the Rezum delivery system uses radiofrequency energy to heat up water droplets to 103 degrees Celsius. The delivered steam destroys the prostate tissue but does this by convective rather than conductive heating (common to previous interstitial treatments such as TUNA). Water vapour is uniformly dispersed at low pressure into the zone of the prostate into which it is injected, thereby destroying a predictable volume of tissue.

The management of symptomatic BPH is evolving and now includes several minimally-invasive therapies. These are an attractive option for men looking for a meaningful improvement in urinary symptoms without the risk of serious long-term adverse effects on sexual function and urinary control, coupled with a short hospital stay and early return to normal activities. This comes at a time when there is also a growing awareness of the not insignificant side-effects of the medications commonly prescribed for men with symptoms due to BPH; for example, the significant deterioration in sexual function that can be a result of treatment with 5-alpha-reductase-inhibitors.[5] Furthermore, the risk of a 5–10% deterioration in erectile function, and a 66% chance of drier ejaculation, following a transurethral resection of the prostate (TURP)[6] is understandably driving men to search for other options.

In this regard, laser surgical interventions are arguably a step in the right direction. The GreenLight XPS vapourisation technique has a lower risk of bleeding and adverse events, as well a shorter average hospital stay, when compared with TURP.[7] The Holmium laser enucleation of the prostate procedure also involves a shorter hospital stay, together with impressive amounts of tissue removal, and is certainly

equivalent with TURP and safer for those men with larger prostate glands.[8] For these reasons, most urologists with a sub-specialist interest in BPH have already incorporated a laser alternative to TURP into their routine BPH practice.

Rezum is a novel interstitial therapy for the treatment of symptomatic BPH and a welcome addition to the 'middle ground' recently occupied by Urolift and prostate artery embolisation. Rezum treatment involves injecting water vapour into the prostate tissue, thereby destroying or ablating the prostate tissue. The technique delivers convective water vapour thermal therapy transurethrally to ablate the transition zone of the prostate leading to an improvement in the lower urinary tract symptoms (LUTS) caused by BPH. It is important to understand that the water vapour remains confined to the zone of the prostate into which it is injected, thereby minimising the likelihood of causing collateral damage. Convection of the water vapour releases thermal energy that denatures cell walls leading to cell death. The ablated tissue is then resorbed by the body, reducing the volume of the prostate and increasing the calibre of the urethra, leading to a gradual improvement in LUTS over several weeks.

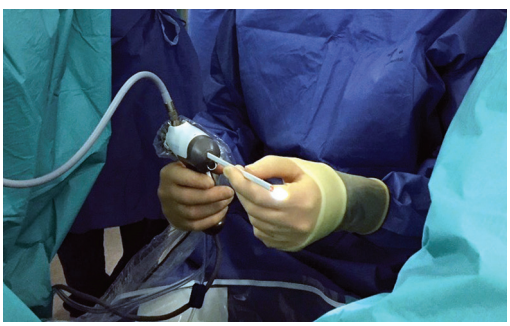

Figure 1. The Rezum handpiece

Figure 2. The Rezum generator

The procedure was first introduced to the UK in March 2017, but it has been a treatment option in countries such as Sweden and the US for almost five years. The three-year results from a prospective randomised US trial have demonstrated encouraging and durable results, with preservation of sexual function.[9] It is a quick procedure, taking from between 15 and 20 minutes, and can be performed under local anaesthetic.

Results

MRI studies have been undertaken at the Mayo clinic to assess the impact of convective thermal energy transfer within the transition zone of the prostate. After six months the transition zone volume had reduced by 38% and the ablated tissue lesions had more or less completely disappeared by three months after the procedure.[10] There have also been several case series published in the urological literature evidencing the clinical benefit of this technique.[11] Level 1 evidence comes from the PIVOTAL II study conducted by McVary and Roehrborn, which was a randomised, blinded controlled trial reporting results for 197 patients ≥50 years old from the USA, that showed significant improvements in International Prostate Symptom Score, quality of life and flow rate. Trial results showed that the improvement in BPH symptoms was maintained at three years,[9] along with preservation of sexual function, and the surgical retreatment rate was only 4.4% within the first three years of follow-up. No late-related adverse events or *de novo* erectile dysfunction were reported.

Several other studies have reported similar improvements in LUTS due to BPH without a negative impact on sexual function at 1–2 years.[12,13] Early results from the UK were reported at the British Association of Urological Surgeons meeting in 2018 and are due to be presented at the European Association of Urology meeting in 2019. Rezum treatments in the UK have also received positive feedback from patients (see Box 1).

How is it performed?

A Rezum treatment is delivered using a handpiece and a radiofrequency generator (see Figures 1 and 2). The procedure can be performed in an operating theatre or procedure room under general or local anaesthetic (usually a urethral lignocaine gel), combined with sedation in selected cases. Each injection of steam takes nine seconds to deliver and is placed into the prostatic transition zone in a systematic fashion, with the number of injections corresponding to the overall volume of the prostate and its endoscopic appearance. The larger and more occlusive the prostate, the more injections the patient should receive to ensure an efficacious procedure. Importantly, while thought needs to be given to the size of the gland, the shape of the gland is not an issue – and this includes the presence of a median or middle lobe.

Once the injections have been completed, a urethral catheter is placed for between three to five days to allow the inevitable postprocedural swelling of the prostate to settle. The patient will usually be able to go home on the day of the procedure, regardless of the type of anaesthetic used. From our own personal experience we have achieved a 97% same-day discharge rate.

Who should have Rezum?

The ideal patient for Rezum would be a man with moderate or severe LUTS due to BPH, with a gland volume

Box 1. Patient feedback

`Since [the procedure], I am only getting up once a night now, and sometimes going right through… overall, an amazing treatment done quickly and efficiently.` AW, 71

`I was really pleased not to need a big operation. I had the procedure on a Thursday and by Saturday I was well enough to walk 10 miles. I was back to work on Monday and there have been no real side-effects. I think it could make a real difference to a lot of people.`
DL, 63

Key points

- Rezum therapy for benign prostatic hyperplasia (BPH):
  - Is an alternative to medication and other BPH surgical options
  - Unlikely to affect sexual function
  - Is a quick, day-case procedure
  - Improves urinary symptoms
  - Can be performed with local anaesthetic and sedation
  - Should be considered for men with BPH symptoms
- Both surgical and medical treatments of BPH, along with conservative management, should be discussed with the patient to allow them to make an informed choice

ranging from between 30–80mL. Patients with large glands (183mL has been reported), catheters and those who have previously had BPH surgery have all had their results reported in the literature.[14] Rezum can also be used to treat patients with an obstructive median lobe. Rezum particularly suits patients aiming to preserve their erectile and ejaculatory function, so younger, sexually active men are a group that may seek it out over and above other BPH treatments. At the other end of the scale, elderly and comorbid patients, or those with significant caring responsibilities, may value the unique ability of Rezum to be carried out under local anaesthetic. The avoidance of general anaesthetic means patients with comorbidities who are not considered fit for general anaesthetic can still have BPH therapy.

Similarly, those with caring responsibilities can drive immediately and will not have to spend time away from a loved one. Therefore, while we would argue that patients with very large glands or a history of infection or retention might be suited to other treatment modalities, Rezum is appropriate for the majority of BPH patients.

Rezum seems to occupy a niche in the BPH treatment armamentarium in that it is a truly minimally invasive procedure that can be performed under local anaesthetic and as a day case. It sits in the middle between medical and surgical treatment and gives patients a true choice.

NICE approval

In August 2018, NICE released a Medtech Innovation Briefing – which is the first step of the NICE process – providing urologists in the UK with a summary of the indications, alternative treatments and evidence for Rezum.[15] The briefing also provided costings for practitioners and hospitals wishing to introduce Rezum into their clinical practice. The NICE approval allows Rezum to be considered for treatment of men with BPH against the current standard of care, and explains that cost savings may be produced against TURP should the day case rate be high.

Conclusion

Rezum water vapour therapy is a welcome addition to the expanding portfolio of minimally invasive treatment options for BPH. Any urologist who is serious about the treatment of this common condition will need to incorporate at least one of these options into their repertoire. This, in turn, will improve the quality of the patient interaction, thereby enabling the patient to make an informed choice about which procedure is best for them. Patients should no longer have to choose between a TURP and a tablet. Rezum has the potential to do well in the UK given the need for a procedure that is quick and easy to perform with reliable same day discharge. However, further studies will be required to assess its potential in patients with larger glands and in urinary retention, as well as high-risk patients and those on anticoagulation.

We predict that the proportion of men receiving medication before consideration of surgical intervention will contract over the next decade, given the attractive range of minimally invasive therapies now available

Declaration of interests

Richard Hindley has received payments from Kenomed and Boston Scientific for proctoring and teaching surgeons the Rezum procedure

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