

Rezūm and Benign Prostatic Hyperplasia (BPH)

This information has been provided to help answer the questions you may have with regards to your enlarged prostate and the Rezūm procedure that is being offered to you. It explains what Rezūm is, what treatment options are available, and what you can expect if you choose to undergo a Rezūm procedure.

We will ask you to sign the consent form before the procedure if you decide to go ahead with surgery.

What is BPH?

Benign prostatic hyperplasia (BPH) with associated lower urinary tract symptoms (LUTS) is a common medical condition in older men. The incidence of BPH has been estimated to increase from 50% (5 out of 10 cases) among men between the ages of 50 and 60 years, to 90% (9 out of 10 cases) for men older than 80 years of age. In 2016, it is estimated that up to 3 million men in the UK have lower urinary tract symptoms associated with BPH.

Traditional treatment or management options have included making life-style changes for mild symptoms. For men with more severe symptoms or complications of prostate enlargement, such as urinary infections or a complete stoppage (urinary retention), medication and surgical procedures such as TURP or laser prostatectomy may be considered..

What other treatment options are available?

- **Life-style changes and reassurance:** For men with concerns about prostate cancer and mild symptoms, reassurance and advice regarding food and drinks is usually all that is required. This “watch and wait” approach is employed for many men diagnosed with BPH. Treatment usually occurs once the symptoms of bladder outlet obstruction and bladder irritability interfere significantly with quality of life. Traditionally, the primary objective of treatment has been to alleviate uncomfortable LUTS that result from prostatic enlargement.
- **Medication:** For many men, medications such as alpha blockers are the first line approach to control mild-to-moderate symptoms of BPH. These symptoms include frequent urination and getting up at night as well as a deterioration in the flow of urine often with hesitancy and sometimes with a feeling of incomplete emptying. Choosing the correct medical treatment for BPH symptoms is often complex and ever changing.

Disadvantages of medication

Many men begin medical therapy but have:

- Inadequate or short-lived improvement in their symptoms and quality of life;
- Undesirable side-effects, such as light headedness and sexual problems, that lead to them stopping medication;
- Increasingly, men do not want to commit to a lifetime of taking tablets, particularly as they are often taking other medication and there can be concerns relating to interactions between these.
- Remembering to take the tablets can also be an issue.

The most effective way of treating troublesome symptoms due to BPH is still not entirely clear, but many men take medication for several years before going on to have surgery. Increasingly, minimally invasive surgical treatments are being offered to men with moderate symptoms, a reluctance to take/continue medication and a desire to return to normal activities quickly.

Minimally invasive procedures

These include:

- Transurethral microwave thermotherapy (TUMT) and Transurethral needle ablation using radiofrequency thermotherapy (TUNA).
- The use of implants called UroLift[®] to retract enlarged prostate tissue is gaining popularity but not all prostates are suitable for this procedure, as it depends on the size and shape of the prostate gland.

Endoscopic surgery

The removal of prostate tissue is called a prostatectomy and when there is benign (non-cancerous) prostate tissue causing a blockage, most, or all, of the prostate is removed one way or another, in order to allow urine to flow more easily from the bladder.

For men with severe BPH symptoms, including retention of urine, transurethral resection of the prostate (TURP) has been the gold standard for a long time but increasingly men are looking at the alternatives. These include laser enucleation (Holep) or vaporization (PVP using the 180W greenlight laser). These technologies remove or vapourise prostate tissue by laser and may be done as a day case.

Disadvantages of surgery

With all surgical procedures there are complications, side effects and risks. One study showed that 13.5% men needed unplanned readmission to hospital following a TURP procedure.

Other recognised side effects include:

- Retrograde ejaculation (dry ejaculation);
- Erectile dysfunction (impotence);

- Urethral strictures or scarring;
- Bleeding (occasionally requiring a blood transfusion);
- Urinary infection (UTI).

Surgery will also involve a hospital stay of several days (usually 3 days after TURP) and it is often 6 weeks before patients can return to normal activities and regular exercise.

Rezūm treatment

What is Rezūm?

Rezūm uses steam energy to remove the particular part of the prostate that enlarges and causes symptoms due to BPH. Rezūm involves a portable radiofrequency (RF) generator and a delivery device that is introduced into the body via the urethra (the tube connecting the bladder to the outside world) (transurethral approach). It is guided to the correct position using a camera on the end of the delivery device (similar to a scope).

Radiofrequency energy from the generator travels to an inductive coil in the delivery device to heat up a controlled amount of water outside of the body, converting the water into vapour or steam. The thermal energy created outside the body is delivered into the prostate tissue through a tiny needle with emitter holes to ablate (remove) the targeted obstructive prostate tissue that causes BPH. The procedure takes approximately 3-7 minutes and can be performed as day surgery. No radiofrequency energy is delivered into the body.

Throughout the procedure saline (salty water) is running into the urethra through the scope to help ensure better views and to prevent the urethra from overheating.

The generator has a number of safety features to ensure proper heating and thermal ablation of the targeted prostate tissue, while protecting the urethra during treatment. Thermocouples in the delivery device monitor temperatures to ensure consistent delivery of thermal energy into the ablation region. The length of the vapour needle is fixed and the operator controls all functions of the device. Placement of the vapour needle within the prostate is done under direct visualisation through the telescopic lens, which is in the urethra inside the prostate.

Benefits

Symptom improvement following the procedure is gradual. During the clinical study significant symptom improvement was seen in just two weeks in some cases but responses to the treatment vary.

Data shows this procedure:

- Improves urinary flow rate by on average 50% (5 out of 10).
- Improves quality of life scores.
- May treat patients on certain anticoagulation medication.
- The results last at least 4 years.
- Can be carried out as a day case procedure (no hospital stay).

- Can be performed under local anaesthesia and or sedation. General anaesthetic may be recommended for some patients.

Side effects

Rezūm has been proven to reduce urinary symptoms for many men who have been diagnosed with an enlarged prostate or benign prostatic hyperplasia (BPH).

As a minimally invasive procedure, Rezūm has demonstrated fewer side effects compared to those typically seen with surgical therapies, but as with any interventional procedure, some of the following side effects may temporarily occur:

- Painful urination.
- Blood in urine.
- Blood in semen.
- Frequent urination.
- Inability to urinate or completely empty the bladder.
- Need for short-term catheterisation.

Most of these events resolve within three weeks of the procedure, but there is a possibility some of these effects may be prolonged. Please talk with your doctor about ways to potentially minimize the effects of these risks. Patients have found that the following options may help relieve discomfort during the short-term healing process:

- Take a mild pain medication such as Tylenol[®].
- Try a warm bath or sitting on a hot water bottle.
- Eliminate caffeine, chocolate, and alcohol from your diet.

What approvals does Rezūm have?

The Rezūm System received CE Mark on 8 July 2013 and FDA clearance for use in the USA on 27 August 2015.

What is the evidence for benefits of Rezūm?

There have been several clinical studies undertaken on the benefits of the Rezūm System and we can give you details if you would like to review them.

What happens next?

If, after reading the various options, you wish to go ahead with the Rezūm treatment, you will be sent a letter giving you the date and time of your procedure and also for a pre-operative assessment if a general anaesthetic is going to be used. If you have not already done a flow test, this will be performed as well as completing some questionnaires. If you are on blood thinners, you may be asked to stop taking them for a period prior to your treatment but this will be advised at your pre-op assessment. If you are having the procedure under a general anaesthetic (ie you are asleep) then you will be sent fasting instructions on when to stop eating and drinking, which you must follow.

What happens on the day?

Even though it only takes a few minutes, you will probably be at the hospital some time before and after the procedure, again depending on the type of anaesthetic used. If everything goes smoothly you will be discharged home the same day.

On arrival in the Day Surgery Department you will be shown to a room and asked to undress from the waist down and put on a hospital gown. The urologist (doctor) will come to talk to you about the procedure and will ask you to sign a consent form if you wish to go ahead.

Antibiotics will be given directly into your vein in theatre. You will then be accompanied to theatre where the procedure will take place.

The treatment

If you are having a general anesthetic you will be sent to sleep.

If you are having local anesthetic it will be administered around your prostate gland with the use of an ultrasound probe via your back passage. This may feel a bit uncomfortable, but the more relaxed you are the easier it will be.

The Rezūm equipment is then passed through the urethra using plenty of anaesthetic gel, which may momentarily sting. After a quick inspection of the bladder, the treatment will begin.

After the procedure a catheter will be left in your bladder for a few days as the prostate readjusts to the treatment and the swelling subsides.

When can I go home?

After your procedure, you will be reviewed by a member of the urology team who will discuss the operation, any specific requirements for you at home and a plan for your aftercare.

A date will be given to you to return for the catheter removal as well as instructions for the care required whilst at home.

It is normal to have some pain or discomfort after the procedure and we advise you to take regular painkillers, following the dosage instructions, to help keep it under control.

Return to work as soon as you feel comfortable, depending on your job. If in doubt please check with your urologist and ask the nurses for a certificate, before you are discharged if you need one.

Follow up appointment

When you attend for catheter removal, the catheter will be removed and then when you are ready you will be asked to pee and if the nurse is happy with the results you will be discharged.

If there are any problems you may require a further period of catheterisation or be taught how to do it yourself (intermittent self catheterisation).

Recovery

Within a few days you will be able to resume normal activities and should notice improvements within two weeks, although it may be three months before the full benefit is evident. Blood may be visible in the urine and ejaculation fluid for a few weeks

Resuming sexual activity

We recommend you avoid ejaculation for 6-8 weeks following the procedure.

Where can I get more information?

NHS Website: www.nhs.uk

NHS 111

www.royalberkshire.nhs.uk

This document can be made available in other languages and formats upon request.

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