NICE National Institute for Health and Care Excellence

NICE guidance

UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

Medical technologies guidance
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This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MTG26.

1 Recommendations

1.1 Evidence supports the case for adopting the UroLift System for treating lower urinary tract symptoms of benign prostatic hyperplasia. The UroLift System relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life.

1.2 The UroLift System is a minimally invasive procedure, which should be considered as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). It can be done as a day-case or outpatient procedure for people aged 50 and older with a prostate volume between 30 and 80 ml.

1.3 Cost modelling shows that the UroLift System is likely to be cost saving compared with standard treatments, because of reduced length of stay and procedure time. Over 5 years, if done as a day-case procedure, UroLift is estimated to save, per person:

- £981 compared with bipolar TURP
- £1,242 compared with monopolar TURP
- £1,230 compared with HoLEP.

  Cost savings are uncertain compared with transurethral water vapour therapy using Rezum and when UroLift is used for treating an obstructive median lobe.

Why the committee made these recommendations

The UroLift System inserts implants using a minimally invasive procedure. The implants hold obstructing prostate tissue away from the urethra so that it is not blocked. The aim is to relieve lower urinary tract symptoms such as difficulty urinating.

New clinical evidence available since the original guidance was published in 2015 shows

that UroLift relieves lower urinary tract symptoms for up to 5 years. It also shows that UroLift improves quality of life and avoids risk to sexual function.

Cost analyses suggest that using UroLift instead of TURP or HoLEP is likely to be cost saving. This is because UroLift is done as day surgery with reduced operating and recovery costs. Compared with Rezum, cost savings for UroLift are uncertain and depend on whether flexible cystoscopy is used before the procedure and the number of implants needed for UroLift. The additional implants needed when UroLift is used for obstructive median lobe treatment mean that there may be additional costs when compared with Rezum.

2 The technology

Technology

2.1 The UroLift System (Teleflex Inc.) is used to do a prostatic urethral lift, a procedure that relieves lower urinary tract symptoms. It uses implants to pull excess prostatic tissue away from the urethra so that it does not narrow or block the urethra. The system comprises 2 single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip with a needle-shaped probe attached. Each UroLift implant consists of a superelastic nitinol capsular tab (a piece of metal holding 1 side of the suture), a polyethylene terephthalate monofilament suture, and a stainless-steel urethral end-piece. The surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal). A fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored to the firm outer surface of the prostatic capsule, while the other is on the inside of the urethra. When the device is tightened, the prostatic tissue is pulled away from the urethra. This is repeated on the other lobe of the prostate. Typically, about 4 implants are used to widen the urethra. The procedure is done under local or general anaesthesia and usually as a day-case or outpatient procedure. Sometimes UroLift is done as an inpatient treatment depending on the person's circumstances. For example, if they have comorbidities or no home support.

Innovative aspects

2.2 Treatment with UroLift does not involve cutting or removing tissue. The implants can be partially removed, so the procedure is reversible, and people can have other surgical treatments later if needed. UroLift is less invasive than standard treatments and may reduce the need for postoperative catheterisation and catheterisation time. UroLift is a quick procedure that can be done as a day-case or outpatient procedure, so it may reduce the need to stay in hospital.

Intended use

2.3 UroLift is intended for treating symptoms caused by urinary outflow obstruction secondary to benign prostatic hyperplasia affecting the lateral and median lobes, in people aged 50 and older. This indication was updated in 2020. According to the UK instructions for use, UroLift should not be used if prostate volume is more than 100 ml or if people have a urinary tract infection. Clinical experts also advised that people need to be assessed on an individual basis to check if the procedure is suitable for them. This is because some clinicians may consider that other conditions, such as chronic urinary retention, are contraindications. The company states that UroLift treatment can be done under local anaesthetic, with light sedation if needed.

Costs

2.4 The cost of the UroLift System (comprising 1 delivery device and 1 implant) stated in the company's submission is £400 (excluding VAT).

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence from the original guidance

Relevant evidence comes from 1 systematic review and 1 English language translation of an uncontrolled case series

3.1 In the original UroLift medical technologies guidance, the EAC considered:

- one systematic review summarising 9 studies (reporting outcomes for 452 to 680 people, depending on the outcome)
- one uncontrolled case series (reporting outcomes from 20 people).

The EAC identified no further evidence. The studies relevant to the decision problem in the scope were:

- nine studies in the systematic review including 2 papers on a randomised controlled trial (RCT; the LIFT study; McVary et al. 2014; Roehrborn et al. 2013) and 7 uncontrolled before-and-after studies (Cantwell et al. 2014; Chin et al. 2012; Delongchamps et al. 2012; McNicholas et al. 2013; Shore et al. 2014; Woo et al. 2011 and 2012)
- one English language translation of an uncontrolled case series (Abad et al. 2013).

For full details of the clinical evidence, see section 3 of the assessment report in supporting documentation.

There is no published comparison of UroLift with HoLEP

3.2 In the original guidance, there was no published evidence directly comparing the UroLift System with the comparator technologies highlighted in the scope. So, the EAC did an evidence synthesis of the outcomes in the UroLift studies. It compared them with those reported with transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) in a systematic review (Li et al. 2014). During the consultation period, initial results from the BPH6 RCT comparing UroLift with TURP became available.

UroLift improves symptoms of benign prostatic hyperplasia, but not as much as TURP or HoLEP

3.3 The EAC's evidence synthesis showed that both TURP and HoLEP were associated with greater improvements in International Prostate Symptom Score (IPSS) than UroLift at all time points. Overall changes within a 2-year period ranged from -17.34 to -19.7 with TURP and -17.68 to -20.88 with HoLEP, compared with -9.22 to -11.82 with UroLift. Maximum urinary flow (Q_{max}) and post-void residual improvements were also greater with TURP and HoLEP.

UroLift improves quality of life, but not as much as TURP or HoLEP

3.4 The EAC's evidence synthesis reported that the IPSS quality-of-life score improved by 2.22 to 2.48 points for people having UroLift treatment. However, this was less than the improvement after TURP (2.99 to 3.18 points) and HoLEP (2.64 to 3.24 points). An increase of 1 to 3 points is generally considered to represent a minimum important change.

UroLift does not damage sexual function

3.5 The EAC's evidence synthesis showed that sexual function is not negatively affected after using UroLift. In fact, small, statistically significant improvements

(0.3 to 0.4 points, based on combined sexual health scores reported in the meta-analysis) were reported. Changes in sexual function were poorly reported in the TURP and HoLEP studies, which made it difficult to accurately assess the effect of these technologies. Expert advice was that deterioration in sexual function was well described and seen in practice in some people having TURP or HoLEP.

New clinical evidence

New relevant evidence comes from 12 publications, including 2 RCTs, and 6 NICE shared learning case studies

3.6 For the guidance update, the EAC considered a total of 12 new studies (1,938 people) and 6 NICE shared learning case studies relevant to the decision problem in the scope. These were published after the original guidance was published. The scope for the guidance update included 1 additional comparator, Rezum. One study was found comparing Rezum with UroLift (Tutrone and Schiff, 2020), which was included in the EAC's evaluation of the evidence. The studies relevant to the updated scope were:

- two RCTs reported in 5 papers: The LIFT study (reported in Roehrborn et al. 2015, with Rukstalis et al. 2016 and Roehrborn et al. 2017 reporting trial follow-up data) and the full published results of the BPH6 study (reported by Sonksen et al. 2015; Gratzke et al. 2016)
- two non-randomised, comparative, prospective studies (Tutrone and Schiff 2020; Rukstalis et al. 2018)
- two non-comparative, prospective, multicentre studies (Sievert et al. 2019; Rubio et al. 2019)
- one retrospective non-comparative study (Bozkurt et al. 2016)
- one single-centre, single-surgeon retrospective note analysis (Bardoli et al. 2017)
- one retrospective multicentre chart analysis (Eure et al. 2019)

- six NICE shared learning case studies (Royal Devon and Exeter NHS Trust 2020; Northampton NHS Trust 2020; Norfolk and Norwich NHS Trust 2019; NHS Fife 2020; St Helens and Knowsley NHS Trust 2016; Frimley Park NHS Trust 2016).

  For full details of the clinical evidence, see section 3 of the assessment report update in supporting documentation.

UroLift significantly improves long-term symptoms of benign prostatic hyperplasia

3.7 In 7 studies there were statistically significant improvements in symptom severity (IPSS score) and in 4 studies there were improvements in Benign Prostatic Hyperplasia Impact Index (BPHII) score up to 5 years after the UroLift procedure. These studies were Roehrborn et al. 2015; Bozkurt et al. 2016; Rukstalis et al. 2016; Bardoli et al. 2017; Roehrborn et al. 2017; Sievert et al. 2018; Eure et al. 2019 and Rubio et al. 2019; Rukstalis et al. 2018.

UroLift improves symptoms of benign prostatic hyperplasia compared with TURP and Rezum

3.8 Compared with TURP, people having UroLift reported smaller improvements in IPSS scores up to 12 months after the procedure (Sonksen et al. 2015; Gratzke et al. 2016). Compared with Rezum, people having UroLift reported greater improvements in IPSS scores at 30 days after the procedure (Tutrone and Schiff, 2020).

UroLift improves urinary flow and retention symptoms over time

3.9 Q_{max} improved up to 5 years after UroLift treatment in most studies (Roehrborn et al. 2015; Bozkurt et al. 2016; Rukstalis et al. 2016; Roehrborn et al. 2017; Sievert et al. 2018; Rubio et al. 2019; Rukstalis et al. 2018). However, in Eure et al. (2019) Q_{max} decreased up to 6 months after the procedure and no significant difference

in Q_{max} was reported by Bardoli et al. (2017).

3.10 In 4 studies there was a statistically significant improvement (up to 12 months) in post-urination residual volume (Bozkurt et al. 2016; Rukstalis et al. 2016; Bardoli et al. 2017; Sievert et al. 2018). In Gratzke et al. (2016) Incontinence Severity Index scores remained unchanged up to 2 years after UroLift treatment.

3.11 TURP produced greater improvements in Q_{max} and post-urination residual volume up to 24 months after the procedure compared with UroLift (Sonksen et al. 2015; Gratzke et al. 2016).

UroLift does not negatively affect sexual function

3.12 In most studies, the UroLift procedure did not result in statistically significant changes in erectile dysfunction. This was assessed using the International Index of Erectile Function and the Sexual Health Inventory for Men (SHIM) questionnaires (Bozkurt et al. 2016; Rukstalis et al. 2016; Rubio et al. 2019). However, in people with obstructive median lobes, there were improvements in both measures up to 12 months after the procedure (Rukstalis et al. 2018). The amount of change in SHIM scores did not differ much between UroLift and TURP (Sonksen et al. 2015; Gratzke et al. 2016) but was statistically significantly better with UroLift than Rezum (Tutrone and Schiff, 2020).

3.13 In 5 studies, Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) scores after UroLift and other treatments were reported. In 2 of these, there were improvements over time after UroLift (Roehrborn et al. 2015; Rukstalis et al. 2018). In 2 other studies improvements over time with UroLift compared with TURP were not statistically significant (Sonksen et al. 2015; Gratze et al. 2016). In 1 study the difference in scores between people who had UroLift or Rezum was not statistically significant at 30 days follow up (Tutrone and Schiff, 2020).

UroLift reduces the rate and duration of postoperative catheterisation compared with TURP and Rezum

3.14 After TURP 74% of people needed catheterisation for more than 24 hours compared with 45% after UroLift (Sonksen et al. 2015). After UroLift 57% of people needed post-procedure catheterisation compared with 87% after Rezum (Tutrone and Schiff, 2020). Catheterisation time after UroLift was statistically significantly shorter than with Rezum (1.2 days compared with 4.5 days; Tutrone and Schiff, 2020).

UroLift improves quality of life

3.15 Eleven studies measured quality of life, with 8 showing a statistically significant improvement up to 5 years after UroLift treatment. Quality-of-life scores for people having UroLift were statistically significantly better than for people having Rezum (Tutrone and Schiff, 2020). In Sonksen et al. 2015 and Gratzke et al. 2016 there were no statistically significant differences between quality-of-life scores after TURP and UroLift at up to 12 and 24 months, respectively.

UroLift reduces the length of hospital stay compared with TURP

3.16 In 1 study (Sonksen et al. 2015) hospitalisation times were reduced for UroLift (time to discharge 1.0 days) compared with TURP (1.9 days).

UroLift is effective for treating benign prostatic hyperplasia with an obstructive median lobe

3.17 One small study (Rukstalis et al. 2018) including 45 people described the clinical effectiveness of using UroLift in people with an obstructive median lobe. UroLift reduced BPHII and IPSS scores of symptom severity and improved sexual function (MSHQ-EjD score), quality-of-life measures and urological outcomes (Q_{max} values). The changes were statistically significant.

Case studies show that UroLift is beneficial when used in the NHS

3.18 All 6 NICE shared learning case studies suggested that UroLift was beneficial when used in the NHS, resulting in improved IPSS and quality-of-life scores, reduced surgery times and reduced hospital stay. In 1 case study, the use of either general or local anaesthetic was compared, and no statistically significant differences were reported in IPSS, quality-of-life and pain scores after the procedure (NHS Fife, 2020).

Cost evidence

The company's updated cost model is based on the original model but Rezum is a comparator and median lobe treatment is included

3.19 The company updated the original economic model to include Rezum as a comparator and median lobe treatment. Clinical parameters for UroLift were based on the LIFT study, using 5-year post-procedure data (Roehrborn et al. 2017). The original guidance was based on clinical parameters from the same trial at 1 and 2 years after the procedure (Roehrborn et al. 2013 and 2014). For full details of the cost evidence, see section 4 of the assessment report update in the supporting documentation.

The EAC adjusts assumptions in the cost model

3.20 The EAC updated some of the model's parameters, including the cost of incontinence to cover the 5-year time horizon, the consumables costs for TURP procedures and the NHS reference costs.

The updated costs include a reduced number of implants used per surgery and reduced theatre time

3.21 The overall cost of UroLift was reduced by £200 per surgery because of adjustments in the number of devices implanted and the duration of surgery. The

number of implants per surgery was reduced from 4 to 3.5 and theatre time was decreased from 30 minutes to 14 minutes based on submitted audit data. These data were collected from NHS trusts over the past 3 years for 552 people who had treatment. The findings were supported by local audits carried out in NHS trusts and described in NICE shared learning case studies (NHS Fife 2020; Natarajan 2020; Dhanasekaran 2020b; Royal Devon and Exeter NHS Trust 2020; Norfolk and Norwich NHS Trust 2019).

Surgery follow up is changed to a telephone consultation

3.22 Changing the follow up for UroLift surgery from a face-to-face consultation to a telephone consultation reduced the cost by £72.33 per consultation. This was based on an EAC cost of £37.00 for 20 minutes of band 6 nurse time.

Costs increase for bipolar TURP, monopolar TURP and HoLEP compared with the original guidance

3.23 In the model update the costs of bipolar TURP and monopolar TURP increased compared with the original guidance. This was because of an increase in consumable costs for bipolar TURP, and to a lesser extent for monopolar TURP. The cost of managing incontinence was also applied to the whole population who have treatment instead of only when treatment has failed.

The revised EAC base-case analysis shows that UroLift is cost saving when compared with all comparators

3.24 The EAC's revised base-case analysis showed that when UroLift is done as an outpatient procedure, UroLift is cost saving, per person, by:

- £121 compared with Rezum
- £1,006 compared with bipolar TURP
- £1,267 compared with monopolar TURP and

- £1,255 compared with HoLEP.

  When UroLift is done as a day-case procedure, it is cost saving, per person, by:

- £96 compared with Rezum
- £981 compared with bipolar TURP
- £1,242 compared with monopolar TURP and
- £1,230 compared with HoLEP.

  The EAC concluded that UroLift is cost saving compared with monopolar TURP, bipolar TURP and HoLEP in the base case and in the company's and EAC's scenarios.

There is uncertainty as to whether UroLift is cost saving compared with Rezum

3.25 The UroLift economic model was compared with the model used in NICE's medical technologies guidance on Rezum. The committee concluded that there were too many uncertainties to draw firm conclusions about the costs of using Rezum compared with the costs of using UroLift. However, the Rezum base-case model results showed that Rezum was cost saving when compared with UroLift. The key parameters that were changed in the UroLift model were theatre time, length of stay and type of consultation after UroLift. If length of hospital stay were the same for Rezum and UroLift, Rezum would be cost saving compared with UroLift. However, the EAC's sensitivity analysis concluded that UroLift was only cost saving compared with Rezum if theatre time for the procedure was less than 16.7 minutes.

4 Committee discussion

Clinical-effectiveness overview

UroLift is effective with sustained clinical benefits, and the procedure is minimally invasive

4.1 The committee concluded that UroLift is clinically effective, with sustained relief of lower urinary tract symptoms up to 5 years after treatment. It is implanted using a minimally invasive procedure. The clinical experts confirmed that in their practice, UroLift is an effective treatment that is well tolerated.

The UroLift procedure avoids the development of sexual dysfunction

4.2 The committee concluded that there was no evidence to suggest the UroLift procedure increases the risk of developing sexual dysfunction. The clinical experts explained that during the procedure there is no resection or ablation of prostate tissue. This is an important difference between UroLift and other invasive treatments for benign prostatic hyperplasia. Therefore, the committee considered that the reduced incidence of sexual dysfunction with UroLift, compared with comparator treatments, was plausible.

The person's preference is important in choosing an appropriate treatment for benign prostatic hyperplasia

4.3 The clinical experts explained that there are several invasive treatments for managing benign prostatic hyperplasia symptoms when drug treatment has not worked. Also, they explained that treatment is guided by what the person prefers because there is no definitive evidence that one treatment is better than another for all clinical outcomes. The committee noted that the updated evidence allowed

direct comparison of UroLift with transurethral resection of the prostate (TURP). This evidence suggested that although the improvement in lower urinary tract symptoms may be greater after TURP the incidence of sexual dysfunction was lower with UroLift. The clinical experts explained that people for whom UroLift is considered suitable are also able to have Rezum treatment. The committee noted that there is only 1 study comparing Rezum with UroLift, with a follow-up period of 30 days. This showed that UroLift was better than Rezum for the short-term relief of lower urinary tract symptoms and for improving erectile dysfunction, but any comparative benefits beyond 30 days were uncertain. The committee concluded that the evidence supported the use of UroLift. But, deciding whether to use UroLift or other technologies should be guided by clinical expertise and counselling for the person having the procedure.

The evidence for using UroLift for people with an obstructive median lobe is limited but shows promising clinical effectiveness

4.4 The clinical evidence for using UroLift for people with an obstructive median lobe consisted of 1 small study of 45 people with a 12-month follow-up period. The results showed a statistically significant improvement in lower urinary tract symptoms and quality of life after UroLift without the development of sexual dysfunction. The clinical experts explained that they have successfully used UroLift to treat an obstructive median lobe. The committee concluded that the evidence was limited but promising for using UroLift to treat an obstructive median lobe.

Side effects and adverse events

Urinary tract infection is not a common complication after UroLift

4.5 The urinary tract infection rate after UroLift was 2.9% (Roehrborn et al. 2013). The clinical experts explained that the risk of urinary tract infection was, in their experience, lower with UroLift than with other procedures. This was likely to be because of the reduced need for urinary catheterisation after the procedure.

The treatment failure rate is low with UroLift

4.6 The clinical experts explained that UroLift has a good success rate in adequately relieving lower urinary tract symptoms, with an early failure rate of less than 5%. However, they considered that people may need further treatment, for example if the prostate enlarges further, so should expect a reintervention rate of up to 20%. The clinical evidence from the LIFT study showed a 13.6% reintervention rate at 5 years after the procedure. This reintervention rate was used in the economic model for UroLift.

Relevance to the NHS

UroLift is an option for treating lower urinary tract symptoms caused by benign prostatic hyperplasia in the NHS

4.7 A clinical expert confirmed that UroLift is widely used in the NHS since the publication of the original NICE guidance. However, there are now other minimally invasive procedures available to treat the condition in the same population, such as Rezum.

NHS considerations overview

UroLift can be done using general anaesthesia, or local anaesthesia with or without sedation

4.8 The clinical experts stated that in clinical practice, UroLift is done under either general anaesthesia or local anaesthesia (with or without sedation). The method of anaesthesia is tailored to the needs of the person having the procedure. If light sedation is needed with local anaesthesia, the clinical experts emphasised that it is important to have an appropriately trained professional, other than the surgeon, monitoring the person during and after the procedure. They also explained that doing flexible cystoscopy in the outpatient clinic to plan treatment is a good opportunity to assess tolerance and suitability for doing the procedure

under local anaesthesia.

UroLift can be done as an outpatient procedure if appropriate facilities are available

4.9 The clinical experts explained that they do not currently offer UroLift as an outpatient treatment themselves but were aware that some clinicians do. UroLift procedures are offered in a small number of NHS trusts with outpatient facilities equipped for implant procedures and with recovery space to monitor people after the procedure. The clinical experts stated that if such facilities were available in their own centres they would also consider doing UroLift as an outpatient procedure.

Consider prostate volume when assessing whether UroLift is suitable

4.10 There is limited clinical evidence on using UroLift for prostates over 80 ml in volume. The clinical experts confirmed that in their own practice, they consider UroLift is most appropriate for prostates under 80 ml. They explained their experience that if UroLift is done on prostates over 80 ml, more implants are needed. Also, the results are not likely to be as good and symptoms may recur. Clinical decision making is best supported by measuring prostate size objectively using transrectal ultrasound or MRI, but it can also be estimated from preoperative cystoscopy.

The proportion of flexible cystoscopies routinely carried out before a UroLift procedure is uncertain

4.11 Two of the clinical experts stated that they did flexible cystoscopy routinely before deciding whether to offer UroLift. This allowed them to see whether there is an obstructive median lobe and estimate the number of implants needed. They could also assess whether there are any other conditions, including bladder stones or bladder cancer, which might affect whether the procedure is done. One

expert stated that they do not routinely do flexible cystoscopy before UroLift because of the added time and cost implications. There is uncertainty about the proportion of flexible cystoscopies routinely carried out before the procedure.

The procedure time and length of hospital stay for UroLift can vary

4.12 The clinical experts agreed that on average, the UroLift procedure takes 10 to 15 minutes per person to do. However, they noted that this does not take into account variations in time taken for the administration of local or general anaesthetic or for changeover time between procedures. The clinical experts also noted that the length of hospital stay can vary. This is because of local hospital procedures, the time taken to recover from the anaesthetic and for the person to empty their bladder (a requirement for leaving hospital).

Telephone follow up is routinely used

4.13 Telephone follow up by a nurse was now routine with UroLift, Rezum, TURP and holmium laser enucleation of the prostate (HoLEP). People having Rezum, TURP or HoLEP also need to have a trial period without the urinary catheter in place, but the clinical experts explained that this was usually done in the community. The clinical experts also explained that people may return a few months after their procedure for objective tests to assess clinical outcomes such as flow rate and International Prostate Symptom Score.

UroLift is a minimally invasive procedure but may not be suitable for everyone

4.14 The clinical experts explained that TURP and HoLEP are unsuitable for some people with lower urinary tract symptoms, because of frailty or comorbidities. Although UroLift is minimally invasive, they considered that it may be unsuitable for some people in poor health and those who do not wish to have implants in their bodies. The decision to use UroLift should be made on an individual basis.

The clinical experts noted that the implants can sometimes leave traces on MRI scans, which may be confusing if people are being investigated for possible prostate cancer. But if the radiologists interpreting the scans are aware that the person has UroLift implants, this should not be a problem.

Equality considerations

People who identify as women have had UroLift

4.15 Eight people who identify as women have had UroLift treatment. One of these procedures was done in the NHS. The clinical experts stated that doing a UroLift procedure in people who have had gender reassignment surgery did seem possible. Gender reassignment is a protected characteristic under the Equality Act 2010.

Cost modelling overview

UroLift is cost saving compared with standard treatments

4.16 The external assessment centre (EAC) revised the company's base case and showed that UroLift remained cost saving compared with the standard treatments, TURP and HoLEP. The committee accepted the EAC's conclusions. It noted that using UroLift was estimated to save, per person, £981 compared with bipolar TURP, £1,242 compared with monopolar TURP and £1,230 compared with HoLEP. This was over a 5-year time horizon and if UroLift was done as a day-case procedure.

Follow-up care for comparators affects UroLift's cost case

4.17 Further analysis was done to look at the use of telephone follow up for all treatments and a trial without a catheter in the community for Rezum. UroLift remained cost saving when all treatments had a telephone follow up instead of an

outpatient appointment. Rezum and UroLift were cost neutral when there was a trial without a catheter in the community, instead of as an outpatient, after Rezum. The committee considered that it was unclear which assumptions on follow-up care most closely resembled routine NHS practice. It concluded that this introduced some uncertainty in the cost case between UroLift and Rezum.

The number of implants used affects UroLift's cost case

4.18 The economic analysis included an assumption that an average of 3.5 implants were used per person with UroLift treatment. The clinical experts thought this was an underestimate and that an average of 4 implants was more appropriate, with a range of between 2 and 6 implants depending on prostate size. There was a learning curve associated with accurately judging the number of implants needed and usually after 15 to 25 procedures a surgeon can confidently do this. The committee acknowledged that the economic model was sensitive to the cost and number of implants used. But varying the number of implants used was unlikely to affect the cost savings when compared with TURP and with HoLEP. It concluded, however, that the cost case compared with Rezum was less certain if the number of implants varied. The clinical experts commented that this may mean that using UroLift for smaller prostates, with no obstructive median lobe, might be cost saving when compared with Rezum.

It is uncertain whether UroLift is cost saving compared with Rezum

4.19 UroLift (if done as an outpatient procedure) was cost saving in the base case by £121 compared with Rezum for everyone who had treatment, over a 5-year time horizon. However, the EAC's sensitivity analysis showed that Rezum would be cheaper if several parameters were changed individually, including:

- if the procedure time was the same for both procedures
- if the average number of UroLift implants exceeded 3.61.

Further economic analysis showed that Rezum was likely to be cost saving if

flexible cystoscopy was done before UroLift treatment. However, there was uncertainty around whether only people being considered for UroLift would have flexible cystoscopy. The clinical experts stated that they sometimes use flexible cystoscopy in assessing suitability for procedures other than UroLift.

The cost case for UroLift when treating an obstructive median lobe is uncertain because of the increasing number of implants

4.20 Between 5% and 20% of people with lower urinary tract symptoms of benign prostatic hyperplasia have an obstructive median lobe, which may not be identified before the procedure. The committee discussed that having an obstructive median lobe made UroLift's potential case for cost savings for the full population uncertain. The base case assumed that 5.3% of people have an obstructive median lobe, which means on average, 1.3 additional implants per procedure. The clinical experts stated that in their practice, the average is more likely to be 2 additional implants. This led to increasing uncertainty in the cost case for UroLift compared with Rezum. Rezum's cost is not affected by the presence of an obstructive median lobe.

Further research

The efficacy of UroLift compared with Rezum needs further research

4.21 Further evidence to address uncertainties about the relative clinical and cost effectiveness of UroLift compared with Rezum, especially in the NHS, would be welcome. This should include:

- exploring long-term clinical outcomes and reintervention rates after UroLift
- assessing the suitability of UroLift for prostates larger than 80 ml and for those with an obstructive median lobe.

This evidence could be generated by collating UK registry data and including

the number of implants used, the length of the procedure and procedural outcomes.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Charlotte Pelekanou and Harriet Unsworth
Technical analyst and senior technical analyst

Christopher Pomfrett
Technical adviser, research commissioning

Victoria Fitton
Project manager

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Accreditation