NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

1 Recommendations

1.1 Evidence supports the case for adopting the UroLift System for treating lower urinary tract symptoms of benign prostatic hyperplasia in the NHS. 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. It should be considered as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) as a day-case procedure for people who are 50 years and older with a prostate volume of less than 100 ml.

1.3 Cost modelling shows that the UroLift System is likely to be cost saving compared with standard treatments. 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 because of reduced length of stay and procedure time. Savings compared with transurethral water vapour therapy using Rezum are unclear because of uncertain assumptions in the cost modelling for that comparison. There is uncertainty about whether UroLift is cost saving

when treating benign prostatic hyperplasia with an obstructive median lobe because of the need for more UroLift implants.

Why the committee made these recommendations

The UroLift System inserts adjustable, permanent implants using a minimally invasive procedure. The implants hold excess 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 is unlikely to affect sexual function.

Cost analyses suggest that when UroLift is used instead of TURP or HoLEP, it is likely to lead to cost savings. This is because it 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. More implants are needed when UroLift is used for obstructive median lobe treatment, which means that additional cost may be incurred when compared with Rezum.

2 The technology

Technology

2.1 The UroLift System (NeoTract) is used to do a prostatic urethral lift, a procedure that relieves lower urinary tract symptoms. It uses adjustable, permanent 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 ensure that the urethra is widened. The procedure can be done under local or general anaesthetic on an inpatient or day-case basis.

Innovative aspects

2.2 Treatment with UroLift does not involve cutting or removing tissue. The implants are permanent but adjustable, 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 post-operative catheterisation and catheterisation time. UroLift is a quick procedure that can be done as a day case, 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 of 50 years and older. This indication was updated in 2020. UroLift should not be used if prostate volume is more than 100 ml, or if people have urinary tract infections, urethral conditions that prevent the delivery system being inserted into the bladder, urinary incontinence caused by an incompetent sphincter, or current gross haematuria. The company states that UroLift treatment can be done under local anaesthetic, without an anaesthetist present, with light sedation if needed.

Relevant pathway

2.4 The relevant NICE Pathway described in the decision problem for this technology is the NICE Pathway for managing lower urinary tract symptoms in men.

Costs

2.5 The cost of the UroLift System (comprising 1 delivery device and 1 implant) stated in the company's submission is £400 (excluding VAT). An average of 4 implants is used per procedure and so the typical cost per person is £1,600.

3 Evidence

Clinical evidence from the original guidance

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

3.1 In the original UroLift medical technologies guidance, the external assessment centre (EAC) considered 1 systematic review summarising 9 studies (reporting outcomes for 452 to 680 people, depending on the outcome) and 1 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:

- 9 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).
- 1 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.

There is no published comparison of UroLift with TURP and 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 and 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).

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. 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 data 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 Evidence 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:

- 2 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 BPH6 study (reported by Sonksen et al. 2015; Gratzke et al. 2016)
- 2 non-randomised, comparative, prospective studies (Tutrone and Schiff 2020; Rukstalis et al. 2018)
- 2 non-comparative, prospective, multicentre studies (Sievert et al. 2019; Rubio et al. 2019)
- 1 retrospective non-comparative study (Bozkurt et al. 2016)
- 1 single-centre, single-surgeon retrospective note analysis (Bardoli et al. 2017)
- 1 retrospective multicentre chart analysis (Eure et al. 2019)
- 6 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; NHS St Helens and Knowsley 2016; NHS Frimley Park 2016).

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

Long-term symptoms of benign prostatic hyperplasia significantly improved with UroLift

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 (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).

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).

Urinary flow and retention symptoms improve over time with UroLift

3.9 Maximum urinary flow (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, Eure et al. (2019) found that 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). Gratzke et al. (2016) reported that Incontinence Severity Index scores remained unchanged up to 2 years after treatment with Urolift.

3.11 TURP was reported to produce 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 when assessed using the International Index of Erectile dysfunction 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 significantly between UroLift and TURP (Sonksen et al. 2015; Gratzke et al. 2016) but was 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 there were no significantly greater improvements over time with Urolift compared with TURP (Sonksen et al. 2015; Gratze et al. 2016). In 1 study there was no significant difference in scores between people who had UroLift or Rezum at 30 days follow up (Tutrone and Schiff, 2020).

UroLift reduces the rate and duration of post-operative catheterisation compared with TURP and Rezum

3.14 In the TURP group 74% of people needed catheterisation for more than 24 hours compared with 45% of the UroLift group (Sonksen et al. 2015). In the UroLift group 57% of people compared with 87% in the Rezum group needed post-procedure catheterisation (Tutrone and Schiff, 2020).

3.15 Catheterisation time after UroLift was statistically significantly less than with Rezum (1.2 days compared with 4.5 days; Tutrone and Schiff, 2020).

UroLift improves quality of life

3.16 Eleven studies measured quality of life, with 8 showing a statistically significant improvement up to 5 years after UroLift treatment.

3.17 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

3.18 One study (Sonksen et al. 2015) compared UroLift with TURP. It reported that 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

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

Case studies show that UroLift is beneficial in an NHS setting

3.20 All 6 NICE shared learning case studies suggested that UroLift was beneficial in an NHS setting, 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

3.21 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 trial, 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.

The EAC adjusts assumptions in the cost model

3.22 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

3.23 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 the length of 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; [redacted]; [redacted]; Royal Devon and Exeter NHS Trust 2020; Norfolk and Norwich NHS Trust 2019).

Surgery follow up is changed to a telephone consultation

3.24 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 for 20 minutes of band 6 nurse time.

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

3.25 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 consumables 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

3.26 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.

3.27 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

3.28 The 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 UroLift. However, the base-case model results showed that Rezum was cost saving when compared with UroLift. The key parameters that were changed in the current model were theatre time, length of stay and type of consultation after UroLift. If length of hospital stay was 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 symptomatic benefit and 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 which 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 distinction 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 choosing an appropriate 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, in which the follow-up period was only 30 days. The results 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 use of UroLift was supported by the evidence. But, deciding whether to use this technology 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 committee noted that some people have an obstructive median lobe. The clinical evidence for using UroLift for this population comprises only 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 is, in their experience, lower with UroLift than with other procedures. This

is 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. However, they considered that people should expect a failure rate of between 10% and 30%.

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 sedation

4.8 The clinical experts stated that in clinical practice, UroLift is done under either general anaesthesia or local anaesthesia with an anaesthetist present. They stated that the advantages of general anaesthesia are that the procedure can be done more quickly with less discomfort to the individual. When local anaesthetic is used, sedation and more time are needed to place the Urolift implants without causing unacceptable discomfort to the person. The clinical experts 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.

There are potential limitations for doing UroLift as an outpatient procedure

4.9 The clinical experts explained that they do not currently offer UroLift as an outpatient treatment. They expressed concerns about a lack of operational and recovery space in an outpatient environment and the increased potential for infection. The clinical experts stated that if these limitations were overcome, they would consider doing UroLift as an outpatient procedure but this is not current clinical practice.

There is uncertainty about the proportion of flexible cystoscopies carried out before a UroLift procedure

4.10 Two of the clinical experts stated that they used flexible cystoscopy routinely before deciding whether to offer UroLift. This allows them to see whether there is an obstructive median lobe and estimate the number of implants needed. They can 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 use flexible cystoscopy before UroLift because of the added time and cost implications. There is some 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

4.11 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 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 for all procedures considered

4.12 The committee was informed that 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 is 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

4.13 The clinical experts explained that TURP and HoLEP are unsuitable for some people with lower urinary tract symptoms, because of frailty or comorbidities. However, they considered that although UroLift is minimally invasive, it may be unsuitable for some people in poor health. Also, some people do not wish to have permanent implants. The clinical experts noted that the implants can sometimes leave traces on MRI scans, which may be confusing when people are being investigated for possible prostate cancer.

Equality considerations

People who identify as women have had UroLift

4.14 The committee was informed that 8 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.

Cost modelling overview

UroLift is cost saving compared with standard treatments

4.15 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 is estimated to save, per person, £981 compared with bipolar TURP, £1,242 compared with monopolar TURP and £1,230 compared with HoLEP. This is over a 5-year time horizon and if UroLift is done as a day-case procedure.

Follow up care for comparators affects UroLift's cost case

4.16 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 not clear which assumptions relating to follow up care most closely resembled routine NHS practice and concluded that this introduced some uncertainty in the cost case between UroLift and Rezum.

The number of implants used affects UroLift's cost case

4.17 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. 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 saving conclusions 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

4.18 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 was done to consider the use of flexible cystoscopy before UroLift treatment. It showed that Rezum was likely to be cost saving in this instance. However, there was uncertainty around whether only people being considered for UroLift would have flexible cystoscopy.

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

4.19 The committee noted that somewhere between 5% and 20% of people have an obstructive median lobe. It understood that not everyone with an obstructive median lobe would 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 for treatment of an obstructive median lobe included an average of 1.3 additional implants whereas the clinical experts believed the average 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

4.20 Further evidence to address uncertainties about the relative clinical and cost effectiveness of UroLift compared with Rezum, especially in an NHS setting, would be welcome.

4.21 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 technology 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 technology 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.

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