NICE National Institute for Health and Care Excellence

NICE guidance

The TURis system for transurethral resection of the prostate

Medical technologies guidance

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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

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence. Using bipolar diathermy with TURis instead of a monopolar system avoids the risk of transurethral resection syndrome and reduces the need for blood transfusion. It may also reduce the length of hospital stay and hospital readmissions.

1.2 Using the transurethral resection in saline (TURis) system instead of monopolar transurethral resection of the prostate (TURP) results in an estimated saving of £71 per patient for hospitals that already use an Olympus monopolar system and an estimated additional cost of £20 per patient for other hospitals. However, there is some evidence of a reduction in readmissions with the TURis system compared with monopolar TURP. If this evidence is included, using the TURis system results in an estimated saving of £375 per patient for hospitals that already use an Olympus monopolar system and an estimated saving of £285 per patient for other hospitals.

2 The technology

Description of the technology

2.1 Transurethral resection in saline (TURis, Olympus Medical) is a bipolar electrosurgery system designed for use when surgical intervention is indicated for prostatic enlargement.

2.2 The TURis system consists of an Olympus generator, a resectoscope, which incorporates the TURis active working element and electrode, a telescope, an inner and outer sheath, a light guide cable, and a saline cable. The active and return electrode are contained within the resectoscope at the site of the operation, eliminating the need for a patient return electrode because TURis uses saline irrigation fluid to conduct electrical current within the resectoscope. The surgeon uses an endoscopic image to guide the electrode assembly through the urethra to the prostate. The electrode is then used to cut and coagulate prostate tissue and saline is used to flush the bladder free of resected prostate tissue and blood. Electrodes are available in different sizes and shapes (described as loop, button and roller) for cutting or coagulation and to take into account surgeon choice. Generally a loop is used to repeatedly cut out small chippings to create a wide channel through the prostate and a roller or button may be used to achieve haemostasis. The prostatic chippings are flushed out before inserting a urethral urinary catheter at the end of the procedure.

2.3 The components of the TURis system are covered by individual CE marks. The most recent of these was issued in 2013 for the TURis working element.

2.4 The list prices for the components of the TURis system for transurethral resection of the prostate (excluding VAT) are:

- £8905 for the resectoscope assembly (which includes the active working element, telescope, inner and outer sheath, light guide cable and saline cable).
- £14,681 for an ESG-400 Olympus generator.
- Single-use roller and loop electrodes are £156.67 and £126.67 respectively. Each TURis procedure uses 1 loop electrode and some procedures, typically 1 in 5, use an additional roller electrode.

The ESG-400 Olympus generator is usually provided at no cost as part of contractual arrangements with Olympus to purchase electrodes at list price.

2.5 The claimed benefits of the TURis system for transurethral resection of the prostate presented by the company were:

- Reduced risk of transurethral resection syndrome through the use of saline irrigation fluid.
- Reduced risk of postoperative blood transfusion because of intraoperative bleeding.
- A shorter length of stay in hospital due to a shorter surgical procedure and fewer intra- and postoperative complications.
- Earlier catheter removal time for improved patient comfort.
- A quicker procedure compared with monopolar transurethral resection of the prostate (TURP) so more men can be treated.
- Fewer complications during and after surgery resulting in lower readmission rates.
- Reduced costs (associated with postoperative blood transfusion, healthcare-associated infection, length of hospital stay, postoperative irrigation and a patient return electrode).
- The use of saline irrigation fluid is cheaper and more readily available than glycine.

Current management

2.6 The NICE guideline on lower urinary tract symptoms defines benign prostate enlargement as an increase in the size of the prostate gland because of benign prostatic hyperplasia, and states that about 50% of men with benign prostatic hyperplasia will develop benign prostatic enlargement. It recommends that surgery is offered only if voiding lower urinary tract symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate.

2.7 For surgical treatment of benign prostatic enlargement, the NICE guideline on lower urinary tract symptoms recommends the use of monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate or holmium laser enucleation of the prostate.

2.8 The NICE guideline on lower urinary tract symptoms also recommends some alternative options:

- Transurethral incision of the prostate (TUIP) can be offered as an alternative to other types of surgery to men with a prostate estimated to be smaller than 30 g.
- Open prostatectomy should only be offered as an alternative to other types of surgery to men with prostates estimated to be larger than 80 g.
- Other alternatives such as laser vaporisation techniques, bipolar transurethral vaporisation of the prostate or monopolar or bipolar transurethral vaporisation resection of the prostate should only be considered as part of a randomised controlled trial that compares these techniques with TURP.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for the transurethral resection in saline (TURis) system for transurethral resection of the prostate presented in the decision problem were:

- hospital length of stay
- procedural blood loss and blood transfusion
- time to removal of urinary catheter postoperatively
- transurethral resection syndrome
- readmission for repeat procedures
- duration of surgical procedure
- healthcare-associated infection
- quality of life
- device-related adverse events.

3.2 The company identified a total of 1116 studies in their database searches, and presented 24 studies in their submission as relevant to the decision problem. These included 14 randomised trials, not all of which were published in full or in English, with a total of 3032 patients (Abascal Junquera et al. 2006; Akman et al. 2013; Chen et al. 2009, 2010; Fagerstrom et al. 2010, 2011; Goh et al. 2009, 2010; Gulur et al. 2010a, 2010b; Michielsen et al. 2007, 2010a, 2010b; Rose et al. 2007) and 10 observational studies (Bertolotto et al. 2009; Fumado et al. 2011; Giulianelli et al. 2012; Ho et al. 2007; Jun Hyun et al. 2012; Lee et al. 2011; Michielsen et al. 2010c, 2011; Petkov et al. 2011; Puppo et al. 2009).

3.3 The External Assessment Centre considered the 14 randomised trials described in the submission. It established that the 3 randomised studies and 2 observational studies published by Michielsen reported on various stages and subgroups of the same study population. It also considered that the 2 papers from Fagerstrom were based on the same study population, and that the

4 conference abstracts (Goh et al. 2009, 2010; Gulur et al. 2010a, 2010b) were based on the same study population. Two studies were not published in English but have English abstracts (Abascal Junquera et al. 2006; Rose et al. 2007). The External Assessment Centre considered that, of these, only the Rose et al. (2007) paper contained pivotal results and it obtained a translation of the paper; the other was not considered pivotal. A literature search by the External Assessment Centre identified 2 further randomised studies (Geavlete et al. 2011; Ho et al. 2006). In total the External Assessment Centre considered that there were 10 unique randomised studies (1870 patients) relevant to the decision problem, 9 published as papers (including 2 foreign language papers with English abstracts) and 1 abstract.

3.4 The company presented 10 observational studies, 5 of which were published in full and 5 of which were abstracts only. The External Assessment Centre established that the Michielsen et al. (2010 and 2011) studies reported on subgroups from the randomised study by Michielsen et al. published in 2007. A literature search by the External Assessment Centre identified 1 additional observational study (Shum et al. 2014). The External Assessment Centre considered that there were 4 published papers and 5 abstracts describing relevant observational studies. It agreed with the company's conclusion that the outcomes reported from the observational studies were consistent with those from the randomised trials. The observational studies are summarised in the assessment report and are not considered further here.

Randomised trials: published papers

3.5 Akman et al. (2013) reported a Turkish study of 286 men (143 in each group) randomised to have either TURis or monopolar transurethral resection of the prostate (TURP) who were followed-up for 12 months. The mean procedure duration was 54.0 minutes for TURis and 58.7 minutes for monopolar TURP, p=0.03. The incidence of TUR syndrome was 0% for TURis and 1.5% for monopolar TURP (no p value reported). There was no statistically significant difference in the length of hospital stay for the TURis group compared with the monopolar TURP group (2.5 days compared with 2.7 days, no p value reported). The rate of blood transfusion was lower in the TURis group (2.4% compared with 6.2%) but the difference was not statistically significant (p=0.2). There were lower rates of clot retention (0.8% compared with 1.5%, p value not

reported) and mean time to catheter removal (2.4 days compared with 2.6 days, p value not reported) for TURis.

3.6 The Chen et al. (2009) study was done in China on 45 men with symptomatic benign prostatic hypertrophy and a large prostate gland, randomised to have either TURis or monopolar TURP. Results were analysed for 40 men, with reasons given for withdrawals. The results showed that average procedure duration was shorter in the TURis group compared with the monopolar TURP group (88 minutes compared with 105 minutes, p=0.001). No men in the TURis group had TUR syndrome, compared with a 5% rate (n=1/19) in the monopolar TURP group. Fewer men had a blood transfusion in the TURis group (4.8% compared with 15.5%, p value not reported). There was no statistically significant difference between groups in the time to catheter removal (2.5 days compared with 3.4 days, p=0.11). However there was a statistically significant reduction in length of hospital stay for the TURis group (3 days compared with 4.2 days, p=0.001).

3.7 Chen et al. (2010) reported a separate study of 100 men in China randomised to have either TURis or monopolar TURP. There was no statistically significant difference in procedure duration in the TURis group compared with the monopolar TURP group (59 minutes compared with 60 minutes, p=0.82) or weight of tissue resected (40 g compared with 38.9 g, p=0.31). No patient in either group had TUR syndrome. One man in the TURis group and 3 men in the monopolar TURP group needed a blood transfusion (2% compared with 6%, p=0.62).

3.8 The Fagerstrom et al. (2009 and 2011) studies were performed in Sweden on 202 men randomised to have either TURis or monopolar TURP. Results were analysed for 185 men, with reasons given for withdrawals. Results showed that there was no statistically significant difference between the TURis and monopolar TURP group in mean procedure time (62 minutes compared with 66 minutes, p not significant) or weight of tissue resected (27.3 g compared with 26.3 g, p not significant). No patient developed TUR syndrome in the TURis group, but 3 did so in the monopolar TURP group. A statistically significantly lower proportion of men in the TURis group had a blood transfusion (4% compared with 11%, p<0.01). Median time to catheter removal was the same in both groups (20 hours), and the length of stay in hospital was similar (51 hours compared with 52 hours). There was a statistically significant reduction in the

rate of readmission in the TURis group (n=5/98 compared with n=14/87, p<0.011).

3.9 The Geavlete et al. (2011) study involved 510 men in Romania who were randomised to 3 study arms (170 in each arm). Results are reported here for the TURis and monopolar TURP arms (340 patients), but not for the bipolar plasma vaporisation of the prostate arm which was considered to be outside the scope. Statistical analysis was performed on the difference between the 3 groups and is not reported here. The average procedure duration was 52.1 minutes in the TURis group and 55.6 minutes in the monopolar TURP group. No men had TUR syndrome in the TURis group compared with 3 men (1.8%) in the monopolar TURP group. In the TURis group 3 men (1.8%) needed a blood transfusion, compared with 11 men (6.5%) in the monopolar TURP group. In the TURis group 2 men (1.2%) had clot retention compared with 7 men (4.1%) in the monopolar TURP group. The mean time to catheter removal was 46.3 hours (range 36–72 hours) in the TURis group compared with 72.8 hours (range 48–96 hours) in the monopolar TURP group. In the TURis group length of stay in hospital was 3.1 days compared with 4.2 days in the monopolar TURP group.

3.10 The Ho et al. (2007) study was performed in Singapore on 48 men randomised to TURis and 52 men randomised to monopolar TURP. There was no statistically significant difference in mean procedure duration between the groups (59 minutes for TURis compared with 58 minutes for monopolar TURP) or in the weight of tissue resected (29.8 g TURis compared with 30.6 g monopolar TURP). There was a statistically significantly lower rate of TUR syndrome in the TURis group compared with the monopolar TURP group (0 men compared with 2 men, p<0.005). One patient in each group needed a blood transfusion. In the TURis group 3 men had clot retention compared with 2 men in the monopolar TURP group; this difference was not statistically significant.

3.11 The Michielsen et al. (2007) study recruited patients between January 2005 and June 2006 in Belgium. However, recruitment into the study continued until August 2009, leading to subsequent papers reported as randomised (Michielsen et al. 2010a, 2010b) and observational studies (Michielsen et al. 2010c, 2011). In total 550 patients were included in the study; 285 in the TURis group and 265 in the monopolar TURP group, but some outcomes were reported on smaller groups. There was no significant difference between the TURis group (n=263) and monopolar TURP group (n=255) in mean procedure duration (52.1 minutes

compared with 50.9 minutes, p=0.357) or mean weight of tissue resected (17.6 g compared with 19.2 g, p=0.173). TUR syndrome did not occur in the TURis group and occurred twice (0.8%) in the monopolar TURP group (p value not reported). In the TURis group (n=118) 4 men (3.4%) needed a blood transfusion compared with 1 patient (0.8%) in the monopolar TURP group (n=120, p=0.211). There was no statistically significant difference in mean length of hospital stay: 3.72 days in the TURis group (n=263) and 3.89 days in the monopolar TURP group (n=255, p=0.773). No patients in the TURis group (n=118) and 2 patients in the monopolar TURP group (n=120) needed a repeat procedure because of incomplete resection (p value not reported).

3.12 The Rose et al. (2007) study was published in German and the External Assessment Centre obtained an English translation. It included 38 men who had TURis and 34 men who had monopolar TURP (the remainder had treatment for bladder cancer) in Germany. Mean procedure duration was longer in the TURis group than in the monopolar TURP group (55 minutes compared with 35 minutes, p=0.005), but the mean weight of tissue resected tended to be greater in the TURis group (42 g compared with 31 g, p value not reported). No men had TUR syndrome in either group. The mean time to catheter removal was longer in the TURis group (64 hours compared with 49 hours, p value not reported) and the TURis group had a higher rate of readmission because of haemorrhage (n=4/38 compared with n=1/34, p value not reported).

3.13 The Abascal Junquera et al. (2006) study was published in Spanish with an English abstract that had limited information on the statistical analysis. The External Assessment Centre considered that the study did not provide additional important data and the paper was therefore not translated. In this study 45 men were prospectively randomised, with 24 men having TURis and 21 men having a TURP procedure using a monopolar system. TURis was a slightly quicker procedure compared with monopolar TURP (39.7 minutes compared with 42.7 minutes) based on a similar resection weight (13 g for TURis compared with 12.6 g for monopolar TURP). The time to removal of the catheter was similar between the groups (2.92 days for TURis compared with 3.1 days for monopolar TURP, not statistically significant) as was the length of hospital stay (3.63 days for TURis compared with 3.67 days for monopolar TURP).

Randomised trials: abstracts

3.14 The Goh et al. (2009 and 2010); and Gulur et al. (2010a and 2010b) conference abstracts relate to the same multicentre study (country not reported). In this study, 210 men with benign prostatic obstruction were randomly allocated to TURis (n=110) or monopolar TURP (n=100). The study reported a similar procedure duration for TURis compared with monopolar TURP (38 minutes compared with 35 minutes, not statistically significant). There were no cases of TUR syndrome in the TURis group and 3 (3%) in the monopolar TURP group (p value not reported). Men in the TURis group tended to have a shorter time to catheter removal (48 hours compared with 52 hours, p=0.97), and a shorter hospital stay (90 hours compared with 103 hours, p=0.06) but neither result was statistically significant.

Meta-analysis of evidence

3.15 The company presented fixed-effect meta-analyses of the randomised studies for procedure-related outcomes between TURis and monopolar TURP for TUR syndrome, clot retention, procedure duration, time to catheter removal, length of hospital stay and procedural blood loss. The results are described in sections 3.17–3.22 with further details in the assessment report on pages 81–98. A summary of the results is presented in table 1.

3.16 The External Assessment Centre did not agree with the included studies used for some outcomes in the company meta-analyses. It did revised meta-analyses with changes in the selected studies, investigated additional outcomes and explored using either fixed- or random-effects methods. The results of the External Assessment Centre revised meta-analyses are shown in table 1.

Table 1 Results of company's meta-analyses and the External Assessment Centre revised meta-analyses (all fixed effects)

Outcome	Company's meta-analysis		External Assessment Centre's revised meta-analysis	
	Studies (n)	Relative risk for TURis (95% CI)	Studies (company studies)	Relative risk for TURis (95% CI)
TUR syndrome	6	0.28 (0.08 to 1.02)	6 (2)	0.18 (0.05 to 0.62)

Blood transfusion	3	0.36 (0.16 to 0.80)	6 (3)	0.35 (0.19 to 0.65)
Clot retention	2	0.63 (0.21 to 1.90)	5 (2)	0.55 (0.26 to 1.15)
	Studies (n)	**Mean difference for TURis (95% CI)**	**Studies**	**Mean difference for TURis (95% CI)**
Hospital stay (days)	3	−0.52 (−0.74 to −0.30)	2 (2)	−0.19 (−0.46 to 0.07)
Time to removal of catheter (days)	3	−0.23 (−0.38 to −0.08)	2 (2)	−0.09 (−0.25 to 0.06)
Procedure time (minutes)	4	−1.68 (−4.18 to 0.81)	5 (4)	−1.36 (−3.70 to 0.98)
CI, confidence interval; TURis, transurethral resection in saline; TUR, transurethral resection.				

3.17 The company included 6 studies presenting results assessing the risk of TUR syndrome (Abascal Junquera et al. 2006; Akman et al. 2013; Chen et al. 2010; Goh et al. 2010; Michielsen et al. 2011; Rose et al. 2007). The company applied a continuity correction to account for the zero event rate in all TURis arms, replacing nil values with 0.5. They found a non-statistically significant lower pooled relative risk in favour of TURis of 0.28 (95% confidence interval [CI] 0.08 to 1.02). The External Assessment Centre repeated the company's meta-analysis, excluding 4 studies: 3 studies in which there were no cases of TUR syndrome in either arm, and the results from the conference abstract by Goh et al. (2010). The External Assessment Centre added data from 4 randomised studies that the company did not include (Ho et al. 2006; Chen et al. 2009; Fagerstrom et al. 2011; Geavlete et al. 2011). This revised meta-analysis found a statistically significant effect in favour of TURis: relative risk 0.18 (95% CI 0.05 to 0.62, p=0.006), corresponding to a number needed to treat to prevent 1 case of TUR syndrome compared with monopolar TURP of 50.

3.18 The company's meta-analysis of trials presenting data on blood transfusion gave a pooled relative risk of 0.52 (95% CI 0.26 to 1.04) in favour of TURis based on 4 studies (Akman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011; Michielsen et al. 2007). The company re-ran this analysis, excluding Michielsen et al. (2007) because a higher proportion of procedures were carried out by trainee surgeons in the TURis arm of that study. This gave a pooled relative risk

of 0.36 (95% CI 0.16 to 0.80) in favour of TURis. The External Assessment Centre agreed with this approach and repeated the analysis, adding data from 3 further studies (Chen et al. 2009; Ho et al. 2006; Geavlete et al. 2011). The result was a statistically significant effect in favour of TURis with a relative risk of 0.35 (95% CI 0.19 to 0.65, p=0.0008). The External Assessment Centre calculated the number needed to treat to prevent 1 case of blood transfusion compared with monopolar TURP) as 20.

3.19 For clot retention, the company's meta-analysis included 2 studies (Akman et al. 2013; Michielsen et al. 2007) and found a relative risk in favour of TURis of 0.63 (95% CI 0.21 to 1.90; not statistically significant). The External Assessment Centre re-ran the meta-analysis adding 3 further studies (Chen et al. 2010; Geavlete et al. 2011; Ho et al. 2006) giving a revised pooled relative risk of 0.55 (95% CI 0.26 to 1.15, p=0.11).

3.20 For length of hospital stay, the company conducted a meta-analysis on 3 trials presenting data on length of hospital stay (Akman et al. 2013; Chen et al. 2009; Michielsen et al. 2011) which revealed a pooled mean difference between the groups (TURis minus monopolar TURP) of −0.52 days (95% CI −0.74 to −0.30, p=0.0001). The External Assessment Centre examined the impact of the study by Chen et al. (2009), which was a source of significant heterogeneity and considered that it should be excluded. The External Assessment Centre calculated a pooled mean difference in length of hospital stay between the groups (TURis minus monopolar TURP) of −0.19 days (95% CI −0.46 to 0.07, p=0.16) which was not statistically significant.

3.21 The company included 3 randomised studies (Akman et al. 2013; Chen et al. 2009, Michielsen et al. 2010) in its analysis of mean time to removal of the urinary catheter and reported a significantly shorter time in favour of TURis of −0.23 days (95% CI −0.38 to −0.08). The External Assessment Centre excluded the Chen et al. (2009) study because it introduced significant heterogeneity to the analysis and presented a result based on 2 studies (Akman et al. 2013; Michielsen et al. 2010) which gave a non-statistically significant pooled mean difference (TURis minus monopolar TURP) for time to catheter removal of −0.09 days (95% CI −0.25 to 0.06).

3.22 The company's meta-analysis of trials presenting data for procedure duration included 4 papers (Akman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011;

Michielsen et al. 2010), and found a non-significant mean difference (TURis minus monopolar TURP) of −1.68 minutes (95% CI −4.18 to 0.81). The External Assessment Centre agreed with the exclusion of Michielsen et al. (2007) in the company's initial analysis but considered the addition of 2 further studies (Chen et al. 2009; Ho et al. 2006). After the External Assessment Centre explored the heterogeneity of the meta-analysis calculations, it presented a result based on 5 studies, which gave a non-statistically significant pooled mean difference in procedure time in favour of TURis of −1.36 minutes (95% CI −3.70 to 0.98, p=0.26).

3.23 The External Assessment Centre examined 3 further outcomes that were not included in the company's meta-analysis. For readmission because of haemorrhage, data from 3 randomised studies were used (Fagerstrom et al. 2011; Geavlete et al. 2011; Rose et al. 2007) and the result was a non-statistically significant lower rate for TURis, with a relative risk of 0.53 (95% CI 0.22 to 1.25, p=0.15). The External Assessment Centre also conducted a meta-analysis on urethral strictures and bladder neck contractures because this was highlighted as a potential concern with TURis by expert advisers. This analysis included 5 studies (Ackman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011; Geavlete et al. 2011; Michielsen et al. 2011) and found no statistically significant difference between the groups, with a relative risk of 1.08 (95% CI 0.70 to 1.69, p=0.72). The third additional outcome considered by the External Assessment Centre was repeat procedure because of incomplete resection. This analysis included 3 studies (Fagerstrom et al. 2011; Geavlete et al. 2011; Michielsen et al. 2011) and found no statistically significant difference between the groups: relative risk 0.76 (95% CI 0.42 to 1.40, p=0.38).

Committee considerations

3.24 The Committee considered that the evidence demonstrated the clinical equivalence of TURis and monopolar TURP for prostatic resection. The Committee noted there was evidence showing that the TURis system reduces the risk of TUR syndrome and reduces patients' need for blood transfusion as compared with monopolar TURP.

3.25 The Committee considered length of hospital stay derived from the meta-analyses by the company and by the External Assessment Centre. It discussed the rationale for excluding the Chen et al. (2009) study. The External

Assessment Centre confirmed that it excluded the Chen et al. (2009) study because it was the source of significant heterogeneity in the meta-analysis results. However, the External Assessment Centre stated that it did not differ in terms of methodological quality from the 2 included studies. The Committee noted that all the trials were based outside the UK and heard expert advice that local policies on healthcare reimbursement and hospital-specific catheter guidelines could have an effect on length of hospital stay. The Committee concluded that there was a possibility that TURis would result in shorter hospital stays, but that clinical trial data were inconclusive.

3.26 The Committee discussed readmission to hospital after resection and noted that this outcome was not included in most of the clinical trials. However, it noted a non-statistically significant lower rate of readmission because of bleeding for TURis compared with monopolar TURP in the data from 3 trials included in a meta-analysis. The Committee also noted that the readmission rate reported in the Fagerstrom et al. (2011) study showed a statistically significant reduction in the TURis group compared with the monopolar TURP group (n=5/98 compared with n=14/87, $p<0.011$). In addition, it heard expert advice based on experience of the use of TURis in the NHS, which suggested that there was indeed a reduction in readmissions due to bleeding seen in clinical practice. Based on the evidence, the Committee concluded that it was plausible that TURis would result in lower readmission rates, although the evidence was not definitive.

3.27 The Committee considered the other outcomes from the meta-analysis and noted no statistically significant differences between TURis and monopolar TURP in procedure time, time to catheter removal, the incidence of clot retention and incidence of urethral stricture or bladder neck contracture.

4 NHS considerations

System impact

4.1 The company proposed that using the transurethral resection in saline (TURis) system would not result in changes to the current pathway or involve additional system resources. The External Assessment Centre agreed with these assumptions.

4.2 The company and the External Assessment Centre did not identify any special additional training needs for a switch to the TURis system from monopolar transurethral resection of the prostate (TURP). The Committee received expert advice that confirmed that little training is needed for surgeons who are already performing monopolar TURP procedures.

Committee considerations

4.3 Based on the evidence from the company and the External Assessment Centre and on expert advice, the Committee was satisfied that using the TURis system could produce benefits for patients and for the NHS and would be relatively easy to introduce, with minimal additional training requirements.

4.4 The Committee noted that the costs of adopting the TURis system were different depending on whether hospitals were already using Olympus systems. The company stated that 40–45% of UK hospitals would already have access to a component of the Olympus systems. The Committee concluded that it was important to consider both scenarios in the cost analysis.

4.5 For hospitals that currently use monopolar equipment for TURP, expert advice to the Committee was that most would wish to change to bipolar systems when their monopolar equipment needs replacing.

4.6 The Committee noted the advice that surgeons who are already skilled at performing TURP with monopolar equipment would need very little training to use the TURis system. It concluded that additional training would not be a significant consideration in the adoption of this technology.

5 Cost considerations

Cost evidence

5.1 The company presented 3 published economic studies on surgical procedures for prostate enlargement, 2 of which reported costs for bipolar transurethral resection of the prostate (TURP) compared with monopolar TURP. The External Assessment Centre identified 1 other observational study. The studies came from different healthcare systems (Japan, India and Singapore) where care pathways vary from those in the NHS. In addition, it was not clear whether patients had received treatment with the transurethral resection in saline (TURis) system and the studies did not directly compare monopolar and bipolar systems. The economic studies are summarised in the assessment report and are not considered further here.

5.2 The company submitted a de novo cost analysis comparing the cost consequences of procedures using the TURis system and a monopolar TURP system. The time horizon of the model was a non-defined short time period designed to capture procedure-related complications. Costs were modelled from an NHS perspective and a discount rate of 3.5% per year was applied. The population included in the model was men having surgical intervention for prostate enlargement. The model adopted a cost-minimisation approach based on an assumption of no difference in the efficacy of TURis and monopolar TURP in terms of resection weight or completeness of resection. The model included the cumulative costs associated with the initial surgical procedure, complications resulting from the procedure and the need for reoperation or readmission. The sensitivity analysis also included clot retention and the need for reoperation in the event that the initial procedure was stopped before completion.

5.3 The company's model contained 3 clinical parameters: length of hospital stay, rate of blood transfusion and rate of TUR syndrome. The company used 0.52 days (95% CI 0.30 to 0.74) for reduction in the length of hospital stay, from a meta-analysis of 3 studies. The reduction in the rate of blood transfusion was taken as 0.36 (95% CI 0.16 to 0.80) from a meta-analysis of 3 studies. The rate of TUR syndrome was taken as zero for TURis patients and 1.14% (95% CI 0.30 to 1.98) for monopolar TURP from a meta-analysis of 6 studies. Full details are in section 9.4.3 of the company's submission.

5.4 The equipment costs for the TURis system included capital costs and the consumable costs of the electrodes. The Olympus generator was assumed to be provided without cost. It was assumed that each hospital would need 3 complete TURis systems. The capital costs differed between hospitals that used Olympus monopolar TURP systems and those that did not since some of the components are interchangeable. The company took these costs from Olympus data on file. For hospitals with Olympus monopolar systems, the cost of purchasing a TURis system included 3 working elements and 3 saline cables at a cost of £8800. Hospitals not using Olympus equipment would additionally need 3 each of the following: a telescope, an inner sheath, an outer sheath and a light guide cable at a total cost of £26,715. These capital elements were assumed to have a mean working life of 7 years at 150 procedures a year. This resulted in a capital cost per patient of £9.68 for hospitals using Olympus systems and £29.13 for other hospitals.

5.5 The estimated cost of electrodes for each TURis procedure was based on 1 single-use loop electrode and in 22% of procedures an additional single-use roller electrode.

5.6 For monopolar TURP the company assumed that hospitals have an existing system and so capital costs were not considered. The cost of electrodes for a monopolar TURP procedure was estimated to be 50% of the TURis electrode costs; this came to £80.57 per procedure.

5.7 The company included a £1848 cost for TUR syndrome, assuming an additional 2 days in a high-dependency unit and 2 days in a general ward. The company based the cost of a blood transfusion on an estimate used in a study by Varney et al. (2003), which was £920.40.

5.8 The results of the company's base case stated that the average total cost per patient of using the TURis system was £1043.57 for hospitals using Olympus systems and £1063.01 for hospitals not using Olympus systems, compared with £1177.20 for a monopolar TURP system. TURis therefore reduced costs for hospitals using Olympus systems by £133.63 per procedure and for hospitals not using Olympus systems by £114.19 per procedure.

5.9 The results of one-way probabilistic and threshold analyses done by the company suggested that these results were robust. The key drivers of the

savings in the company's cost model were the reduction in the length of hospital stay and the cost of monopolar consumables.

5.10 The External Assessment Centre considered the company's basic model structure to be appropriate. The External Assessment Centre revised the cost model parameters based on its meta-analyses results and so used a zero difference in the length of hospital stay between TURis and monopolar TURP; a relative risk of blood transfusion for TURis compared with monopolar TURP of 0.35; and a relative risk of TUR syndrome for TURis compared with monopolar TURP of 0.18.

5.11 The External Assessment Centre considered that the company's costs for blood transfusion overestimated the true costs because several components were included that would not typically be needed. The External Assessment Centre estimated the cost of a blood transfusion to be £329, based on the cost of 2.7 units of red blood cells.

5.12 The External Assessment Centre could not find a rationale for the company's assumption that the cost of monopolar electrodes was 50% of the cost of the TURis electrode. Based on advice from the clinical experts, the External Assessment Centre assumed that all monopolar TURP procedures, in both Olympus and non-Olympus cases, involved both a loop and a roller electrode. The External Assessment Centre considered that hospitals using Olympus systems obtained the generator on loan and paid the list price for monopolar TURP consumables (£137.75). Hospitals not using Olympus systems have the option to purchase a non-Olympus electrosurgery unit generator, incurring a higher initial cost but allowing the purchase of monopolar electrodes at a lower price from NHS Supply Chain, saving money over the lifetime of the electrosurgery unit. The External Assessment Centre used a price of £66.84 for hospitals not using Olympus systems (based on the price of generic monopolar TURP consumables [£56.84] from NHS Supply Chain and a £10 per procedure electrosurgery unit cost).

5.13 The results for the base case in the External Assessment Centre's revised model found a total cost per TURis procedure in hospitals using Olympus systems of £1183.99 and in other hospitals of £1203.44. The total costs for a monopolar TURP were £1196.60 for hospitals using Olympus systems and £1125.69 for other hospitals. TURis was cost saving for hospitals using Olympus systems by

£12.60, but added costs of £77.75 for other hospitals. The savings are driven by a reduction in risk of TUR syndrome and blood transfusion.

5.14 The External Assessment Centre reported an additional scenario involving readmissions for all causes, based on data from the Fagerstrom et al. (2011) study. The rate of readmission (all causes) for TURis was 5.1% and for monopolar TURP was 16.1%, giving a relative risk for TURis of 0.31, p=0.011. The External Assessment Centre estimated the cost of a readmission (all causes) as £2781, based on the NHS reference cost 2012/13 code LB20D. Results obtained when readmission from all causes was included in the model revealed that TURis saved £319.62 per procedure for a hospital with an existing Olympus monopolar TURP system and £229.27 per procedure for other hospitals.

5.15 The External Assessment Centre calculated a further revision to the model at the request of the Committee, with a change to the mean difference in hospital stay from zero to 0.19 days in favour of TURis, based on the External Assessment Centre's meta-analysis. The results for the recalculated base case in the External Assessment Centre's revised model found a total cost per TURis procedure in Olympus centres of £1126.04 and in non-Olympus centres of £1145.49. The total costs for a monopolar TURP were £1196.60 for a hospital using Olympus systems and £1125.69 for other hospitals. TURis was cost saving for a hospital using Olympus systems by £70.55, but added costs of £19.80 for other hospitals.

5.16 The External Assessment Centre calculated a revised result based on the meta-analysis results for the reduction in readmissions associated with TURis, including data from the Fagerstrom et al. (2011) study at the request of the Committee. The results showed TURis was cost saving by £375.02 per procedure for a hospital with an existing Olympus monopolar TURP system and by £284.66 for other hospitals.

Committee considerations

5.17 The Committee agreed with the External Assessment Centre's conclusions that the published economic studies did not contain relevant evidence. It also agreed with the revisions suggested by the External Assessment Centre in terms of the costs of the consumables and blood transfusion costs. It heard expert opinion that patients having a blood transfusion may also have an increased length of

stay in hospital and it noted that this was not included in the model. The Committee considered it was quite likely that TURis could be cost saving, but noted the uncertainties in the External Assessment Centre and company meta-analyses for length of hospital stay. At the draft guidance meeting the Committee considered that the cost model should include the 0.19 days difference in the length of hospital stay in favour of TURis compared with monopolar TURP. Results from the revised model showed that TURis saved around £71 per patient for hospitals that already use Olympus systems and has an additional cost of around £20 per patient for other hospitals (see section 5.15). The Committee concluded that, although uncertainty remained in the cost model, the use of the TURis system is likely to generate cost savings compared with the monopolar TURP system.

5.18 The Committee noted that the data available to estimate differences in readmission rates between TURis and monopolar TURP were limited in quantity, but it received expert advice that a reduction in readmissions was likely if TURis was used, instead of monopolar TURP. From the results of the External Assessment Centre's scenario analysis based on the Fagerstrom et al. (2011) study it considered that it was plausible there would be cost savings for hospitals with TURis, attributable to fewer readmissions, whether or not the hospitals were already using Olympus equipment.

6 Conclusions

6.1 The Committee concluded that the evidence demonstrated that the transurethral resection in saline (TURis) system was of equivalent efficacy to the monopolar system for transurethral resection of the prostate (TURP). It noted the important clinical advantages of TURis are reducing the risk of TUR syndrome that exists with monopolar TURP and reducing the need for blood transfusion. The Committee considered that it is plausible that TURis will also reduce length of hospital stay and reduce readmissions after surgery, although the evidence on these outcomes was limited.

6.2 The Committee accepted the External Assessment Centre revised model and sensitivity analyses and judged that, although uncertainty remained in the cost model, the use of the TURis system is likely to generate cost savings compared with the monopolar TURP system. It acknowledged that cost savings would be easier to achieve in hospitals that currently use Olympus monopolar systems. The Committee concluded that the case for adoption of the TURis system for transurethral resection of the prostate was supported by the evidence.

Andrew Dillon
Chief Executive
February 2015

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

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

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Ms Susan Bennett
Lay member

Dr Keith Blanshard
Consultant Interventional Radiologist, University Hospitals of Leicester NHS Trust

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Dr Fiona Dennison
Consultant Obstetrician and Gynaecologist, University of Edinburgh

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Adviser

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner, University of Liverpool

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Dr Rory O'Connor
Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Brian Selman
Managing Director, Selman and Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson
Director of Devices, Medicines and Healthcare Products Regulatory Agency

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

Dr Amber Young
Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Paul Dimmock
Technical Analyst

Bernice Dillon
Technical Adviser

Neil Barber and Ian Pearce
Lead Expert Advisers

Shaheen Hamdy
Non-Expert MTAC Member

Andrew Cleves and Grace Carolan-Rees
External Assessment Centre Representatives

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Cedar:

- Cleves A, Morgan H, Poole R et al. The TURis system for transurethral resection of the prostate, June 2014

Submissions from the following company:

- Olympus Medical

The following individuals gave their expert personal view on The TURis system for transurethral resection of the prostate by providing their expert comments on the draft scope and assessment report.

- Mr Neil Barber, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Andrew Dickinson, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr John McGrath, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Ian Pearce, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Mark Speakman, British Association of Urological Surgeons (BAUS) – clinical expert

The following individuals gave their expert personal view on the TURis system for transurethral resection of the prostate in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Mr Neil Barber, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Andrew Dickinson, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr John McGrath, British Association of Urological Surgeons (BAUS) –clinical expert
- Mr Ian Pearce, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Mark Speakman, British Association of Urological Surgeons (BAUS) – clinical expert
- Hannah Winter, Prostate Cancer UK – patient expert

About this guidance

This guidance was developed using the NICE medical technologies guidance process.

It has been incorporated into the NICE pathway on lower urinary tract symptoms in men, along with other related guidance and products.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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