

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The TURis system for transurethral resection of the prostate

1 Technology

1.1 *Description of the technology*

Transurethral resection in saline (TURis, Olympus Medical) is a bipolar electro-surgery system designed for use when surgical intervention for prostate enlargement is indicated. The TURis system consists of the ESG-400 Olympus generator (including power cable and trolley); the resectoscope which incorporates the TURis active working element, PRO 12° 4 mm telescope, PRO inner sheath, PRO 26FR outer sheath, and electrodes (loop, roller and button); a light guide cable; and ESG-400 saline cable. The bipolar design means a patient return electrode is not required; instead TURis uses saline irrigation fluid to conduct electrical current locally from the loop (the active electrode) to the resectoscope.

The surgeon uses the active working element to position the electrode in order to conduct resection. The electrode is the only consumable element of the system, and it carries the current through the resectoscope, delivering it to the patient tissue site. The electrode is used for cutting, coagulation and/or vaporisation of tissue using the conductive irrigation fluid (saline). Electrodes are available in different sizes and shapes (described as loop, button and roller) to accommodate different anatomies and morphologies; the choice is made by the individual surgeon.

1.2 Regulatory status

The TURis system received a CE mark in April 2012 for electrosurgery and endoscopic applications.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Reduced risk of transurethral resection (TUR) syndrome through the use of a saline irrigation fluid.
- Reduced risk of post-operative blood transfusion due to intraoperative bleeding.
- A shorter surgical procedure leading to fewer intra and post-operative complications and a lower level of hospitalisation.
- Earlier catheter removal time for improved patient comfort.

The benefits to the healthcare system claimed by the sponsor are:

- A quicker procedure compared to monopolar TURP so more patients can be treated.
- Fewer complications during and after surgery resulting in lower re-admission rates.
- Reduced costs associated with post-operative blood transfusion, healthcare-associated infection, shorter length of stay, reduced post-operative irrigation and no patient return electrode required.
- The use of saline irrigation fluid is cheaper and easier to access than glycine.

1.4 Relevant diseases and conditions

The TURis system is intended for use when transurethral resection of the prostate (TURP) is indicated for treatment of prostate enlargement (also known as benign prostatic hyperplasia (BPH)). Benign prostate enlargement (BPE) is the most common cause of lower urinary tract symptoms (LUTS) in men. Around 60% of men who are aged 60 or over have some degree of prostate enlargement. The cause of prostate enlargement is unknown, but it is

thought to be linked to changes in hormone levels in a man's body due to ageing. BPH affects quality of life in around 40% of men in their fifties and 90% of men in their nineties. It is unusual in men younger than 45 years and affects men from black ethnic groups more than white men.

TURP is a common surgical intervention for adults with LUTS presumed secondary to BPH, when first line treatments such as medication fail to control symptoms. This is estimated to occur in around 1 in 10 patients with BPH. BPH, marked by obstructive LUTS, may cause complications such as severe urinary tract infections, urinary retention or renal failure. LUTS voiding symptoms are the most common and include weak or intermittent urinary stream, straining, hesitancy, terminal dribbling and incomplete emptying. Although LUTS do not usually cause severe illness, they can considerably reduce a man's quality of life, and may point to serious pathology of the urogenital tract. Approximately 15,000 TURP procedures are carried out each year in England and Wales.

Transurethral resection (TUR) syndrome is a rare, but potentially fatal complication of TURP surgery. Recent large observational studies have demonstrated an incidence rate for TUR syndrome of between 0.78% and 1.4%. During monopolar TURP glycine is used to clear the urethra of blood and debris. When glycine is absorbed into the bloodstream, it can cause a potentially dangerous build-up of fluid in the circulation, leading to fluid overload and hyponatraemia. TUR syndrome varies in its severity depending on how early it is identified, the type of irrigation fluid used, and the amount of irrigation fluid that is absorbed during surgery. If it is identified during surgery, this can lead to TURP being terminated before completion. Post operatively mildly symptomatic patients may require observation in a high dependency unit until symptoms pass, while those with severe hyponatraemia require treatment with hypertonic saline and risk residual neurological damage or death.

1.5 Current management

NICE Clinical Guideline 97, CG97 (May 2010), Lower urinary tract symptoms (LUTS), recommends that surgery is offered only if voiding LUTS symptoms are severe; or if drug treatment and conservative management options have been unsuccessful or are not appropriate. For management purposes, the guideline defines BPE as an increase in the size of the prostate gland due to BPH, and states that around 50% of patients with BPH will develop BPE.

For surgical management of voiding LUTS presumed secondary to BPE, CG97 recommends the use of monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). HoLEP should only be performed at a centre specialising in the technique, or with mentorship arrangements in place.

CG97 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 TUVP or monopolar or bipolar transurethral vaporisation resection of the prostate (TUVRP) can be offered as part of a randomised controlled trial.

2 Reasons for developing guidance on the TURis system for patients requiring a TURP procedure

The Committee recognised that TURis may offer benefits to patients and the healthcare system. It considered that the target population in the evaluation should be people with BPH, rather than those with bladder tumours, for whom

the system is also indicated, because the majority of the evidence related to this indication.

The Committee also recommended that the evaluation should take into account the resource impact of adopting TURis in centres which are currently using the common components of the Olympus TUR systems (such as the Olympus electro-surgery generator) and those which are not.

	Draft scope issued by NICE	
Population	Adults with lower urinary tract symptoms (LUTS) presumed secondary to benign prostatic hyperplasia (BPH), in whom surgical intervention, mostly commonly a TURP, is indicated	
Intervention	TURis system	
Comparator(s)	Monopolar TURP system	
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> • Hospital length of stay • Procedural blood loss and blood transfusion requirement • Time of removal of urinary catheter post-operatively • TUR syndrome • Re-admittance for repeat procedures • Duration of surgical procedure • Healthcare associated infection • Quality of life • Device-related adverse events 	
Cost analysis	<p>The comparator is a monopolar TURP system</p> <p>Cost models should consider 2 scenarios for the adoption of the TURis system:</p> <ul style="list-style-type: none"> - Hospitals which are currently using the Olympus TURP system in a monopolar configuration. - Hospitals which are not currently using the Olympus TURP system in a monopolar configuration. <p>Cost models should take into account the use of a combination of different electrode type, based on a typical case mix.</p> <p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p>	
Subgroups to be considered	Individuals with prosthetic lower limbs or cardiac pacemakers	
Special considerations, including those related to equality	None identified	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No

	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE guidance

Published

- Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE interventional procedure guidance, IPG475, January 2014. Available from: <http://guidance.nice.org.uk/IPG475>
- Lower urinary tract symptoms secondary to benign prostatic hyperplasia: tadalafil. NICE Evidence summary: new medicine, ESNM18. Available from: <http://www.nice.org.uk/mpc/evidencesummariesnewmedicines/ESNM18.jsp>
- Prostate Artery embolisation for Benign Prostatic Hyperplasia. NICE interventional procedure guidance, IPG453, April 2013. Available from: <http://guidance.nice.org.uk/IPG453>
- Tadalafil for the treatment of symptoms associated with benign prostatic hyperplasia. NICE technology appraisal guidance, TA273, January 2013. Available from: <http://guidance.nice.org.uk/TA273>
- Lower urinary tract symptoms in men pathway. NICE Pathway. October 2012. Available from: <http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men>
- Lower urinary tract symptoms, The management of lower urinary tract symptoms in men. NICE Clinical guideline, CG97, May 2010. Available from: <http://www.nice.org.uk/cg97>
- Laparoscopic prostatectomy for benign prostatic obstruction. NICE interventional procedure guidance. IPG275, November 2008. Available from:

<http://publications.nice.org.uk/laparoscopic-prostatectomy-for-benign-prostatic-obstruction-ipg275>

- Holmium laser prostatectomy. NICE interventional procedure guidance, IPG17, November 2003. Available from:
<http://www.nice.org.uk/guidance/IPG17>
- Transurethral electrovaporisation of the prostate. NICE interventional procedure guidance, IPG14, October 2003. Available from:
<http://www.nice.org.uk/guidance/IPG14>

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

None identified

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association for Perioperative Practice
- British Association of Day Surgery
- British Association of Urological Surgeons
- British Prostate Group
- British Uro-oncology Group
- PSA Prostate Cancer Support Association
- Royal College of Surgeons of England
- The Association for Perioperative Practice
- The College of Operating Department Practitioners

4.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association for Perioperative Practice
- British Association of Day Surgery
- British Association of Urological Surgeons
- British Prostate Group
- Royal College of Surgeons of England
- The Association for Perioperative Practice
- The College of Operating Department Practitioner

4.2 Patient organisations

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary:

- Action on Bladder Cancer
- Bladder and Bowel Foundation
- Bladder Cancer Support UK
- BME cancer communities
- Cancer Black Care
- Cancer Equality
- Cancer Voices
- Cancer52
- CancerHelp UK
- Everyman
- Helen Rollason Cancer Charity
- Macmillan Cancer Support
- Men's Health Forum (MHF)
- Orchid Cancer Appeal
- Prostate Cancer Network (PCaSO)
- Prostate Cancer Support Scotland (PCSS)
- Prostate Cancer UK

- Prostate Help Association (PHA)
- Rarer Cancers Foundation
- Tackle prostate cancer
- Tenovus

The following patient organisations have been alerted to the availability of the draft scope for comment:

- Black Health Agency
- Equalities National Council
- Ethnic Health Foundation
- Everyman
- Gay Men's Health Charity
- Men's Health Forum
- Muslim Health Network
- Prostate Cancer Support Scotland (PCSS)
- Prostate Cancer UK
- Prostate Help Association (PHA)
- South Asian Health Foundation
- Tackle prostate cancer
- Working with men