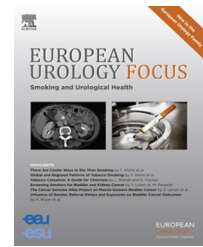


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Benign Prostatic Hyperplasia

Economic Value of the Transurethral Resection in Saline System for Treatment of Benign Prostatic Hyperplasia in England and Wales: Systematic Review, Meta-analysis, and Cost–Consequence Model

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Abstract

Context: Monopolar transurethral resection of the prostate (M-TURP) is the current UK surgical standard of care for benign prostatic hyperplasia, a condition estimated to affect >2 million men in the United Kingdom. Although M-TURP efficacy in prostate resection is established, potential perioperative complications and associated costs remain a concern.

Objective: To present up-to-date and robust evidence in support of bipolar transurethral resection in saline (TURis) as an alternative surgical option to M-TURP.

Evidence acquisition: A systematic review (SR) of electronic databases (up to 2015) for randomised controlled trials (RCTs) comparing TURis with M-TURP was conducted, followed by evidence synthesis in the form of a meta-analysis of hospital stay, catheterisation time and procedure duration, transurethral resection (TUR) syndrome, blood transfusion, clot retention, and urethral strictures. An economic analysis was subsequently undertaken from the UK National Health Service hospital perspective with costs and resource use data from published sources.

Evidence synthesis: The SR identified 15 good-quality RCTs, of which 11 were used to inform the meta-analysis. TURis was associated with improved safety versus M-TURP, eliminating the risk of TUR syndrome and reducing the risk of blood transfusion and clot retention (relative risks: 0.34 and 0.43, respectively; $p < 0.05$). TURis also reduced hospital stay (mean difference: 0.56 d; $p < 0.0001$). The economic analysis indicated potential cost savings with TURis versus M-TURP of up to £204 per patient, with incremental equipment costs offset by savings from reduced hospital stay and fewer complications.

Conclusions: The TURis system is associated with significant improvements in perioperative safety compared with M-TURP while ensuring equivalent clinical outcomes of prostate resection. The safety benefits identified may translate into cost savings for UK health services.

Patient summary: Our review of bipolar transurethral resection in saline, the new prostate resection technique, indicates that it offers equal efficacy while reducing complications and length of hospital stay.

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1. Introduction

Benign prostatic hyperplasia (BPH) is the most common cause of lower urinary tract symptoms (LUTS) in men [1] including high urinary frequency, nocturia, and urgency (storage symptoms), and weak or intermittent urinary stream, incomplete bladder emptying, and postmicturition dribbling (voiding symptoms) [2,3]. Prevalence of LUTS increases with age; approximately one-third of men aged >65 yr experience symptoms that negatively affect daily living [3]. Patients experience quality-of-life reductions that increase with symptom severity; 45–54% of patients with moderate to severe symptoms report anxiety and/or depression [4]. Treatment of BPH and LUTS places a considerable cost burden on health care services. In 2008–2009, estimated total UK annual drug therapy cost for BPH was >£69 million. Secondary care costs of treating BPH were estimated at £112 million per annum, £55 million attributable to BPH-related surgery [5].

In men with mild/moderate LUTS, current UK and European guidelines recommend conservative management involving watchful waiting with or without behavioural and dietary modification, or medication to control symptoms [3,6]. Surgical intervention is offered to patients with severe voiding symptoms presumed secondary to BPH or if first-line treatment is unsuccessful or considered inappropriate [3,6]. Transurethral resection of the prostate (TURP) is the most commonly used surgical procedure for endoscopic removal of excess prostate tissue in the treatment of BPH [7] and is recommended for prostate volumes of 30–80 g [6]. Other surgical interventions include laser vaporization, enucleation, and open prostatectomy, restricted to patients with estimated prostate sizes >80 g [3,8].

The most common perioperative complications of TURP are postoperative bleeding requiring transfusion (1–3% of patients) [9,10], clot retention (2–5% of patients) [11], urinary tract infection (4% of patients) [10], and urethral strictures (2–10% of patients) [11]. A further potential and possibly severe complication of TURP is systemic absorption of irrigation fluid [12]. Monopolar TURP (M-TURP), the system conventionally used for surgical treatment of BPH, uses a glycine, sorbitol, or mannitol solution as a nonconducting irrigation fluid [12]. Excessive systemic absorption of this solution during the procedure can result in transurethral resection (TUR) syndrome, reported to occur in 1.4% of procedures [10]. Symptoms of TUR syndrome include headache, bradycardia, abdominal distension, nausea and vomiting, confusion, and convulsions [13]. Untreated, it can lead to pulmonary or cerebral oedema or coma [13,14], or death in 0.2–0.8% of cases [15].

In England and Wales, an estimated 15 000 prostate resection procedures are performed annually [16]. Over the last 10 yr, use of M-TURP for surgical treatment of BPH has been challenged by the introduction of novel procedures including bipolar technology. Bipolar electrosurgical techniques, where both active and return electrodes are contained in the resectoscope, are currently the most extensively investigated alternative to M-TURP [17]. This

design means that no patient return electrode is required, enabling the use of a physiologic saline irrigation fluid. Because the saline is near isotonic with blood, the risk of TUR syndrome as a result of systemic uptake is minimised [17]. The fluid volume uptake should still be carefully monitored, especially in patients with cardiac or pulmonary conditions. A comparison of the efficacy and safety of these techniques was recently performed by Cornu et al [18]. Although it is acknowledged that bipolar TURP (B-TURP) offers a more favourable perioperative safety profile than M-TURP [6,19], there is currently no European consensus on its use.

The transurethral resection in saline (TURis) system uses a bipolar generator, where the energy creates a plasma corona at the electrode tip. The case for adopting TURis as a bipolar alternative to M-TURP was recently evaluated in the National Institute for Health and Care Excellence (NICE) medical technologies evaluation programme (MTEP). The evaluation resulted in publication of NICE medical technology guidance 23 (MTG23) in February 2015. It concluded that clinical and economic evidence supports the adoption of TURis for the surgical treatment of BPH [20]. The adoption of TURis is not anticipated to be associated with a steep learning curve given the similarity of the resection technique to M-TURP.

To incorporate recently published evidence for TURis versus M-TURP, we conducted an update to the original systematic review (SR), meta-analysis, and economic analysis presented in the manufacturer's MTEP submission. Preliminary results were presented at the 2015 World Congress of Urology [21].

2. Evidence acquisition

2.1. Methods

An SR was performed to identify clinical trials to form the basis of a meta-analysis. The results of the clinical meta-analysis form one part of our objective. They were also used as input for an economic analysis, the second part of our objective.

2.2. Systematic review of the clinical evidence

The SR was performed in line with guidance by the Centre for Reviews and Dissemination, University of York [22]. The detailed SR methodology, as well as results and quality assessment, is reported in the supplementary information for MTG23 [20]. We performed an update to the original search on April 20, 2015, limited to randomised controlled trial (RCT) publications from 2014 onwards. The output from this update was then combined with that from the original SR (Table 1).

2.3. Meta-analysis of the clinical evidence

Expert opinion solicited during development of the MTEP submission suggested that differences are most commonly observed between TURis and M-TURP in the incidence of

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