NICE advice

# PLASMA system with button electrode for electrovaporisation of the prostate

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## Summary

- The **technology** described in this briefing is PLASMA with an oval button electrode. It is used for bipolar transurethral vaporisation resection of the prostate (TUVP).
- The **innovative aspects** are that the button electrode vaporises prostate tissue rather than resects tissue, and it is intended to remove tissue at a faster rate. Vaporisation minimises bleeding and allows the endoscopic view to remain clear throughout the procedure.
- The intended **place in therapy** would be as an alternative to transurethral resection of the prostate (TURP) in people with benign prostatic hyperplasia that needs surgical intervention.

- The **main points from the evidence** summarised in this briefing are from 4 studies: 1 meta-analysis (consisting of 9 randomised controlled trials, 1 prospective non-randomised study and 1 retrospective study), 1 randomised prospective study and 2 retrospective studies, including a total of 2,171 patients with benign prostatic hyperplasia. They show that the PLASMA system with button electrode is as effective as TURP for people with benign prostatic hyperplasia and as effective as open prostatectomy for people with prostates larger than 80 g.
- **Key uncertainties** around the evidence are that there have been no studies done within an NHS context, so populations may not be applicable to NHS practice. Button electrode vaporisation has been used for small and large prostate sizes too, so transurethral incision and open prostatectomy may also be considered as comparators.
- **Safety issues** identified are blood in the urine, cramping in the bladder, frequent urination and a burning sensation.
- The **cost** of the TUVP procedure using the PLASMA button electrode is approximately £988 per procedure (excluding VAT). The cost of standard care is £972 per procedure (excluding VAT). The difference in cost is because of the difference in electrode cost.

# The technology

The PLASMA system (Olympus Medical) is a bipolar electrosurgery system, designed for use when surgical intervention is needed for prostatic enlargement. It consists of an Olympus high frequency generator (430 kHz plus or minus 20%), a resectoscope (which incorporates the PLASMA active working element and electrode), an endoscope, an inner and outer sheath, a light guide cable and a saline high-frequency cable. The active and return electrode are contained within the resectoscope at the operation site. This means a patient return electrode is not needed because PLASMA 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 electrodes are available in different sizes and shape (described as loop, button and roller). This review focuses on the button electrode. The button electrode hovers over the surface of the prostate and is used to vaporise prostatic tissue.

# Innovations

In common with other bipolar systems, the PLASMA system uses saline for irrigation instead of glycine, which is used in the monopolar transurethral resection of the prostate system. Using saline avoids transurethral resection syndrome, a serious adverse event. The button electrode is intended to offer more efficient vaporisation by removing tissue at a faster rate than other electrodes, such as loop and roller. Continuous haemostasis is provided during the procedure, which minimises bleeding. As tissue is vapourised and no individual chips are resected, the endoscopic view remains clear and unobstructed throughout the procedure.

# Current care pathway

Surgery is only offered to people with voiding lower urinary tract symptoms caused by an enlarged prostate if symptoms are severe, or if drug treatment and conservative management options have been unsuccessful or are not appropriate. The current surgical options are monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate, or holmium laser enucleation of the prostate, which is only offered at specialist centres. GreenLight XPS is also recommended as a treatment option for benign prostatic hyperplasia by photoselective vaporisation of prostatic tissue. For people with a prostate estimated to be smaller than 30 g, transurethral incision of the prostate may be used as an alternative to other types of surgery. Open prostatectomy is only offered to people with prostates estimated to be larger than 80 g. Minimally invasive surgical therapies are also used in clinical practice, such as prostatic urethral lift, water vapour therapy, prostatic urethral temporary implant and prostate artery embolism.

The following publications have been identified as relevant to this care pathway:

- NICE Pathway on lower urinary tract symptoms in men
- NICE's medical technologies guidance on GreenLight XPS for treating benign prostatic hyperplasia
- NICE's medical technologies guidance on the PLASMA system for transurethral resection and haemostasis of the prostate
- NICE's medical technologies guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

- NICE's medical technologies guidance on Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia
- NICE's interventional procedures guidance on prostate artery embolisation for lower urinary tract symptoms caused by benign prostatic hyperplasia
- NICE's interventional procedures guidance on prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia.

# Population, setting and intended user

The PLASMA bipolar electrosurgery system is intended to be used in adults with lower urinary tract symptoms, which happen because of benign prostatic hyperplasia. Surgery for benign prostatic hyperplasia is offered when symptoms are severe or if conservative treatment and drug interventions have been unsuccessful or are inappropriate. Procedures are commonly done in an inpatient setting, after which a hospital stay is normally needed, though day case is also achievable. Minimal training is needed for clinicians who are proficient in TURP to implement and safely use the PLASMA system.

# Costs

## Technology costs

The cost for TUVP or TURP using the PLASMA system with button electrode is estimated as £988, including consumables and length of stay. Costs are based on values taken from NICE's medical technologies guidance on the PLASMA system for transurethral resection and haemostasis of the prostate.

## Costs of standard care

The typical cost of a TURP procedure using the PLASMA system for resection and haemostasis is estimated as £972. This includes consumables and length of stay. Costs are based on values taken from NICE's medical technologies guidance on the PLASMA system for transurethral resection and haemostasis of the prostate.

## Resource consequences

The company has indicated that 114 NHS centres were using the PLASMA system in 2020, although this use would also include the loop and roller electrodes. Hospitals that do not currently have the Olympus infrastructure in place would need to purchase the specific equipment needed to use the system including the Olympus generator, endoscope, working element, light guide cable and saline cable. Advice from clinical experts suggests that minimal training would be needed for clinicians to implement and safely use the PLASMA system.

# Regulatory information

The PLASMA system is a CE-marked class IIb medical device for electrosurgery and endoscopic applications.

The potential side effects are:

- blood in the urine
- cramping in the bladder or an urgent need to urinate
- frequent urination, burning sensation.

# Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The following equality issues were identified during the development of this briefing: Benign prostatic hyperplasia is most common in people aged over 50. Some people may not identify as men but have a prostate. Sex, age and gender reassignment are protected characteristics under the Equality Act 2010.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process

and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

# Published evidence

Four studies are summarised in this briefing.

One meta-analysis of 1,690 people (Zheng et al. 2019) is included which compares outcomes for people with benign prostatic hyperplasia that had either button-type bipolar plasma vaporisation of the prostate (BPV) or transurethral resection of the prostate (TURP). The meta-analysis consists of 9 randomised controlled trials, 1 prospective non-randomised study and 1 retrospective study. There was also 1 randomised prospective study (Abdelwahab et al. 2019) and 1 retrospective study (Aboutaleb 2015) included which compared BPV with TURP. One further retrospective analysis (Giulianelli et al. 2019) comparing BPV with open prostatectomy in people with prostates larger than 80 g has been included in this briefing.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

# Overall assessment of the evidence

The evidence base for the PLASMA system with button electrode consists of several randomised controlled trials comparing the technology directly with other methods of procedure, mainly TURP. There are also several prospective and retrospective studies which commonly include a single arm of patients that had a procedure using the button electrode. As well as assessing the health-related outcomes after the procedure, there is a focus on the incidence of complications that are commonly seen with other interventions and the efficiency and safety of the surgical procedure itself. A major limitation of the evidence base is that there are no studies that have been done within a UK context, although some have been done at European centres. The PLASMA system is in use at centres throughout the UK with loop and roller electrodes, but it is unclear if the button electrode has been widely used by clinicians in NHS practice.

# Zheng et al. (2019)

## Study size, design and location

A meta-analysis of 11 studies (9 randomised-controlled trials, 1 prospective non-randomised study, 1 retrospective study) including 1,690 patients comparing short-term outcomes between button-type bipolar plasma vaporisation and transurethral resection for benign prostatic hyperplasia. Four studies were done in Romania, 2 in Egypt, 1 in Austria, 1 in Turkey, 1 in Hong Kong, 1 in China and 1 in Iran.

## Intervention and comparator

BPV, compared with TURP.

## Key outcomes

Efficacy data was quantified using the following outcomes: International Prostate Symptom Score (IPSS), maximum flow rate ($Q_{max}$), post-voiding residual (PVR) and quality of life. Differences between the 2 groups were represented by standard mean differences (SMD) with confidence intervals and odds ratios (OR) for dichotomous variables. Safety and tolerability data were also compared for both groups.

No significant differences in IPSS were seen at 1, 3 and 12 months across both groups. The TURP group had better 6-month IPSS than the BPV group (SMD=0.36 [0.08 to 0.63], p=0.01). The TURP group had better 1-month (SMD=-0.38 [-0.63 to -0.12], p=0.004), 6-month (SMD=-0.73 [-0.99 to -0.46], p<0.00001) and 12-month (SMD=-0.47 [-0.85 to -0.10], p=0.01) $Q_{max}$ than the BPV group. However, no significant difference was seen in 3-month postoperative $Q_{max}$. Postoperative values of PVR were significantly lower than preoperative values in both groups. The TURP group had a higher 3-month PVR (SMD=0.14, [-0.08 to 0.36], p=0.21) and lower 6-month PVR (SMD=1.18 [0.87 to 1.48], p<0.00001) compared with the BPV group. The 12-month PVR was similar. Quality of life estimates for TURP yielded better results than the BPV group at both 3 months (SMD=-0.24 [-0.48 to -0.01]) and 6 months (SMD=-0.62 [-0.91 to -0.33]).

The BPV group had significantly fewer total complications (OR=0.52 [0.40 to 0.69], p<0.0001), lesser need for blood transfusion (OR=0.25 [0.09 to 0.69], p=0.005) and fewer haematuria (OR=0.27 [0.13 to 0.56], p=0.00004). No significant differences were found in postoperative urethral stricture, urinary incontinence, urinary retention, transurethral

resection syndrome, urinary tract infection, recatheterisation or retreatment. Seven of the included studies compared operative time. The findings indicated that the BPV group had shorter operative time (SMD=-0.15 minutes [-0.31 to 0.01], p=0.006), shorter catheterisation time (SMD=-0.96 days [-1.12 to -0.79], p<0.00001) and shorter hospitalisation time (SMD=-0.71 days [-0.89 to -0.53], p<0.00001).

### Strengths and limitations

The main strength of this meta-analysis is that it included 9 randomised controlled trials from 2010 to 2017. This study methodology is considered to be the gold standard when comparing medical interventions. Also, all of the studies used the Olympus technology specifically for BPV whereas previous studies compared earlier BPV systems. Compared with the previous meta-analysis assessing this technology, a larger number of efficacy and safety parameters were analysed. A limitation of the study is that most of the trials had a follow up of less than 12 months (2 studies had 3-month follow up and 4 studies had 6-month follow up) so only short-term efficacy and safety between BPV and TURP could be compared.

## Abdelwahab et al. (2019)

### Study size, design and location

Randomised prospective study analysing 89 patients with benign prostate hyperplasia who were seen between January 2013 and March 2014, with a follow up of 9 months. All procedures were done by a single surgeon in Egypt.

### Intervention and comparator

Olympus bipolar button vaporisation, compared with Olympus bipolar loop TURP.

### Key outcomes

There were 44 patients included in bipolar TURP and 45 patients in the vaporisation arm. The preoperative mean prostate volume (PV) and mean IPSS were equivalent in both groups. Vaporisation was associated with a significant increase in operative time (mean 81 minutes compared with 55 minutes), less blood loss (0.8% compared with 2.0% drop in haemoglobin, p<0.001), higher postoperative urinary frequency (80% compared with 50%, p<0.001), more haematuria with clots up to 4 weeks after surgery (20% compared with 2%,

p<0.001) and increased postoperative urethral stricture (11% compared with 0%, p<0.001). PV and IPSS were comparable across both treatment arms.

### Strengths and limitations

A strength of this study was that patients were randomised using simple randomisation, whereby consecutive patients had alternate surgical techniques. This prevents selection bias from clinicians affecting the results of the study. In this study, a significant limitation was that all surgeries were done by a single surgeon. Therefore, the success of surgery and investigated outcomes were highly dependent on the proficiency of the surgeon in relation to the 2 techniques employed. As TURP is already standard care, it may have been done more efficiently than button vaporisation; this could explain the significant increase in operative time with vaporisation. Patients were also informed about the type of surgery they had for the purposes of informed consent. This could potentially have influenced subjective reporting at time points after the procedure.

## Aboutaleb (2015)

### Study size, design and location

Retrospective study of 152 patients with benign prostatic hyperplasia that was treated between 2007 and 2013, with a short-term follow-up period of 3 months. All procedures were done by a single surgeon in Egypt.

### Intervention and comparator

Olympus BPV, compared with TURP.

### Key outcomes

TURP was done in 100 patients and BPV in 52 patients. The mean operative time was 53 minutes in the BPV arm and 62 minutes in the TURP arm and the indwelling catheter was removed after mean 2 days compared with 3 days. Patients in the BPV group were discharged after an average of 1 day compared with 3 days in the TURP group. Mean irrigation volume during surgery and postoperatively was significantly lower in terms of volume and hours in the BPV group. In the BPV group, 2 patients (3.8%) were noted with early complications, whereas in the TURP group 18 patients (18%) had early complications.

Short-term follow up at 3 months showed insignificant differences in IPSS, quality of life, and PVR between both groups compared with preoperative measurements, but highly significant (p=0.0001) improvements were seen in the BPV group for $Q_{max}$ and $Q_{ave}$ (average flow rate). Regardless of the technique used, results revealed highly significant improvements for patients in both groups for all outcomes after the procedure.

### Strengths and limitations

This study used a relatively large patient population for both arms. As with the previous study summarised, both the BPV and TURP procedures were done in a single centre by the same surgeon. This could be acknowledged as a strength because of the absence of inter-clinician variability. However, the success of surgery and investigated outcomes were highly dependent on the proficiency of the surgeon in relation to the 2 techniques employed. Preoperative data for the 2 groups showed insignificant baseline differences for all variables, except from age and PVR. The average age was lower in the BPV group, as was PVR. These 2 variables may have had an effect on the final outcomes. The relatively short follow-up time meant that long-term outcomes and adverse events could not be seen.

## Giulianelli et al. (2019)

### Study size, design and location

Retrospective study of 240 patients with benign prostatic hyperplasia with prostates heavier than 80 g that were treated between 2012 and 2013, with a long-term follow-up period of 36 months. All procedures were done by a single surgeon at a single centre in Italy.

### Intervention and comparator

Olympus BPV, compared with open prostatectomy.

### Key outcomes

Open prostatectomy was done in 111 patients, and 120 patients had BPV. Open prostatectomy needed significantly shorter operative time than BPV, with a weighted mean difference (WMD) of 41.5 minutes (p<0.05). Postoperative bladder irrigation time (WMD of 27.5 hours), catheterisation time (WMD of 38.14 hours) and hospital stay (WMD

of 16.82 hours) were significantly shorter in the BPV group compared with the open prostatectomy group ($p<0.05$). The reintervention rate at 3 years was 7.5% in the open prostatectomy group and 5% in the BPV group.

The following outcome measures were recorded at 1, 3, 6, 12, 18, 24, 30 and 36 months: IPSS score, quality of life, PVR and prostate-specific antigen (PSA). PV was measured at 6, 12, 24 and 36 months. During the follow-up period, there were no significant differences in terms of $Q_{max}$, quality of life, PVR, PSA and PV between the 2 groups at each time point. In the BPV group, significantly lower scores for IPSS were seen from 6 months to 36 months when compared with the open prostatectomy group ($p=0.001$).

### Strengths and limitations

This study compared BPV with open prostatectomy, which is the procedure most commonly used for prostates that are larger than 80 g. The inclusion of this study provides an insight into the outcomes of BPV compared with open prostatectomy in relation to this specific population. The major strength of this study was the follow-up period of 36 months, which allowed long-term efficacy and adverse event data to be captured. Also, no significant baseline differences were present between the 2 groups before the procedures. The same surgeon did all the surgeries and was considered adequately trained having already completed more than 300 procedures. The study authors recognised that the retrospective design of the study was a major limitation, and the use of a single centre means results depend on the enrolled population and cannot necessarily be extended to other populations.

## Sustainability

No sustainability claims have been made by the company.

## Recent and ongoing studies

Transurethral Vapor Enucleation Resection of the Prostate (TVERP), Bipolar TURis and HoLEP. ClinicalTrials.gov identifier: NCT04398420. Status: not yet recruiting. Indication: benign prostatic hypertrophy. Devices: TVERP, Bipolar TURis (transurethral resection in saline) and HoLEP (holmium laser enucleation of the prostate). Estimated study completion date: June 2024.

# Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 of the experts have used this technology before to do procedures.

## Level of innovation

All of the experts agreed that the technology provides a minor variation on an existing procedure, which is unlikely to alter the procedure safety or efficacy. One of the experts mentioned that the PLASMA system with button electrode is novel in that the prostate tissue is vaporised, rather than resected. Another expert explained that there is reduced risk of bleeding because the technology is targeted at people with a smaller prostate volume.

## Potential patient impact

Two experts stated that the PLASMA system with button electrode has a reduced complication profile and allows a shorter hospital stay. Also, the learning period for clinicians is likely to be fast because of similarities with TURP. The other expert said that TUVP has similar postoperative outcomes for patients compared with either TURP or open prostatectomy based on the evidence.

## Potential system impact

All of the experts agreed that there would be system benefits of adopting the PLASMA system with button electrode for vaporisation of the prostate, reducing the number of bed days and reattendance in emergency services. One expert said that there would be fewer complications needing management and shorter theatre time, resulting in increased theatre efficiency. Another expert stated that, compared with standard TURP and open prostatectomy, there would also be a reduction in catheterisation time.

## General comments

All of the experts outlined that the cost of the new procedure should be similar to standard care, adding that there may be an initial outlay for centres that do not already use the PLASMA system. The experts also explained that no extra staff would be needed and that minimal training from the company would be enough for clinicians who are already using PLASMA for TURP. One of the experts highlighted that there had been no mention of erectile dysfunction, which is a key patient concern when selecting the most appropriate procedure for benign prostatic hyperplasia.

# Expert commentators

The following clinicians contributed to this briefing:

- Mr Jeremy Nettleton, consultant urologist at Gloucestershire Hospitals NHS Foundation Trust. Produced a video for Olympus on day case TURP in June 2021.
- Miss Helena Burden, consultant urological surgeon at North Bristol NHS Trust. Carried out paid consultancy work for Olympus since 2020.
- Professor Ian Pearce, consultant urological surgeon at Manchester University NHS Foundation Trust. Did not declare any interests.

# Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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