NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

The PLASMA system for transurethral resection and haemostasis of the prostate

(update of MTG23)

The National Institute for Health and Care Excellence (NICE) is producing guidance on using the PLASMA system for transurethral resection of the prostate in the NHS in England. The medical technologies advisory committee has considered the evidence submitted by the company and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence (see the committee papers).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and resource savings reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on the PLASMA system for transurethral resection of the prostate. The recommendations in section 1 may change after consultation.

After consultation the committee will meet again to consider the evidence, this document and comments from the public consultation. After considering the comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England. For further details, see the medical technologies evaluation programme process and methods guides.

The key dates for this guidance topic are:

Closing date for comments: 9 October 2020

Guidance update panel: 21 October 2020

Details of the advisory committee are given in section 5.

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, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 The evidence supports the case for adopting the PLASMA system for bipolar transurethral saline resection and haemostasis of the prostate in the NHS. Clinical outcomes are the same as for monopolar transurethral resection of the prostate (mTURP), but PLASMA avoids the risk of transurethral resection syndrome and reduces the need for blood transfusion and the length of hospital stay.

1.2 The PLASMA system for prostate resection and haemostasis should be considered as an option for people with symptomatic benign prostatic hyperplasia when surgical intervention is indicated.

1.3 Cost modelling estimates that the PLASMA system is cost saving by £459 per procedure compared with mTURP for hospitals that already use an Olympus platform and £343 for those that do not. This assumes a reduced (2-day) length of stay with PLASMA and that 65% of procedures need a second electrode for haemostasis. Evidence suggests there are reduced readmissions with the PLASMA system compared with mTURP. This would increase cost saving to £534 for hospitals that already use an Olympus platform and £418 for those that do not.

Why the committee made these recommendations

The PLASMA system uses electrodes to cut out (resect) prostate tissue and stop any local bleeding afterwards (haemostasis). The electrodes are put into the prostate through the urethra (transurethral). It is a treatment for symptomatic benign prostatic hyperplasia.

The clinical evidence supports using the PLASMA system (which used to be called TURis) for TURP. Clinical outcomes are as good as for conventional mTURP but there is a lesser chance of serious complications. PLASMA also reduces the length of hospital stay. This means that the treatment costs are less than for conventional mTURP.

2 The technology

Technology

2.1 The PLASMA system (Olympus Medical) consists of an Olympus high frequency (430 kHz plus or minus 20%) generator, a resectoscope (which incorporates the PLASMA active working element and electrode), a telescope, 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. A loop electrode is used to repeatedly cut out small chippings to create a wider channel through the prostate (generator set to cut) and a roller or button electrode is used to promote haemostasis (generator set to coagulate). Electrodes are available in different sizes. A urethral urinary catheter is inserted at the end of the procedure.

Innovative aspects

2.2 In common with other bipolar systems, the PLASMA system uses saline for irrigation instead of glycine that is used in the mTURP system. Using

saline avoids transurethral resection syndrome, a serious adverse event. The PLASMA system has a range of electrodes. Of these, only the loop electrode for resection and the roller or button electrodes for haemostasis are in the scope of this guidance.

Intended use

2.3 The PLASMA system is a bipolar electrosurgery system designed for use when surgical resection and haemostasis is indicated to treat symptomatic benign prostatic hyperplasia.

Relevant pathway

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

Costs

2.5 The typical cost for a PLASMA procedure for resection and haemostasis is estimated as £972. This includes consumables and length of stay.

3 Evidence

Clinical evidence

3.1 All clinical evidence was reported when the technology was called TURis (transurethral resection in saline). Now it is called the PLASMA system.

Relevant evidence in original guidance comes from 10 studies and 1 meta-analysis

3.2 For the medical technologies guidance on TURis that this guidance replaces, the external assessment centre (EAC) considered 10 unique randomised studies (1,870 people) and 1 meta-analysis from the company. The studies relevant to the decision problem in the scope were:

- 8 papers (Akman et al. 2013; Chen et al. 2009; Chen et al. 2010; Fagerstrom el al. 2009; Fagerstrom et al. 2011; Geavlete et al. 2011; Ho et al. 2007; Michielson et al. 2007)
- 2 foreign language papers with English abstracts (Rose et al. 2007; Abascal Junquera et al. 2006)
- 1 multicentre study published in 4 abstracts (Goh et al. 2009; Gular et al. 2009; Gular et al. 2010a; Gular et al. 2010b).

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

PLASMA has equivalent clinical effectiveness to mTURP

3.3 All studies reported equivalent clinical effectiveness for resection of the prostate for PLASMA compared with monopolar transurethral resection of the prostate (mTURP).

PLASMA eliminates transurethral resection (TUR) syndrome

3.4 No cases of TUR syndrome were seen with PLASMA (Akman et al. 2013; Ho et al. 2007; Fagerstrom et al. 2009 and 2011; Gleavlete et al. 2011; Chen et al. 2009 and 2010).

PLASMA reduces bleeding

3.5 In the 3 studies where it was reported, fewer people needed a blood transfusion in the PLASMA group compared with mTURP. (Chen et al. 2009 and 2010; Geavlete et al. 2011).

PLASMA reduces length of hospital stay

3.6 The PLASMA system reduced the length of hospital stay in 2 studies (Chen et al. 2009; Gleavlete et al. 2011).

New relevant evidence comes from 2 studies in 3 publications, including 1 randomised controlled trial

3.7 For the guidance update, the EAC considered 2 new studies reported as 3 papers (156 people) relevant to the decision problem in the scope:

- a randomised controlled trial (2 publications: Komura at al. 2014 and 2015)
- a prospective observational study (non-randomised comparative study, Karadeniz et al. 2016).

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

PLASMA reduces the length of hospital stay

3.8 Hospitalisation time (mean days) was significantly higher in the mTURP group (3.4) compared with the PLASMA group (2.5), p=0.045 (Komura et al. 2014 and 2015).

PLASMA has been associated with an increased rate of urethral stricture

3.9 Komura et al. (2015) reported a rate of urethral stricture at 36 months. This was 4 out of 61 (6.6%) in the mTURP group and 12 out of 63 (19%) in the PLASMA group ($p<0.022$). Komura et al. (2015) also reported on the anatomical location of the strictures and the treatment. The incidence of urethral stricture was not reported in Karadeniz et al. (2016).

Cost evidence

The company provided an executable Excel model of a simple decision tree

3.10 For the guidance update, the EAC updated the parameters of the model from the company. For full details of the cost evidence, see the assessment report update. The company model assumed no change in length of stay for mTURP but a reduced length of stay with PLASMA.

3.11 The EAC contacted 3 professional experts and the company. They were asked to comment on whether the assumptions and parameters used in the original model were still valid for the update or whether there were any changes. There was no suggestion that assumptions on the cost of generators or single-use electrodes were invalid. One professional expert

advised that there was recent evidence that bipolar TURP was associated with higher rates of strictures and contractures compared with mTURP. See sections 3.12 to 3.15 for additional comments from the professional experts.

There is uncertainty about whether bipolar electrosurgery is standard care

3.12 Two professional experts indicated that most TURP procedures now use bipolar electrosurgery devices as standard care. The company advised that 100 NHS centres were using PLASMA in 2019, compared with 61 in 2015 (England, Scotland, and Wales). A third professional expert indicated that, in his opinion, bipolar should be seen as the 'gold standard' for electrosurgical TURP treatment. However, the experts also reported that other companies that make bipolar systems have been slow to develop reliable devices. This means that hospitals that rely on these companies have been slow to change from monopolar to bipolar TURP as their standard technique.

Blood transfusion rates and volumes may now be lower

3.13 Three professional experts stated that blood transfusion rates and volumes of blood given may be lower now. Two professional experts indicated that the haemoglobin threshold for starting blood transfusion had decreased from 80 g/L to 70 g/L. Or, it was restricted to patients who are symptomatic because of blood loss. Two professional experts advised that transfusion rates are very low, probably lower than the 5.8% used for monopolar TURP in the original model. Another indicated that 2.7 units of red blood cells used in the model seemed high and suggested that 1 to 2 units was more likely.

PLASMA is associated with better haemostasis

3.14 There is an overall indication that PLASMA is associated with better haemostasis than mTURP (based on lower blood transfusion rates and

increased use of coagulating electrodes). Therefore, a lower rate of admissions for haemorrhage would be expected for PLASMA.

Using PLASMA button electrode for vaporisation is out of scope for this guidance but using it for haemostasis is in scope

3.15 When used with the generator in cut mode, the PLASMA button electrodes cause transurethral vaporisation of the prostate (TUVP). This uses a plasma effect as an alternative to resection using a loop electrode. All 3 professional experts and the company considered this to be a separate procedure to PLASMA TURP. The evidence base is distinct and the clinical outcome values in the TURP model should not be transferred into a model of PLASMA TUVP compared with mTURP. Previously the model assumed that 22% of PLASMA resections also included using a roller electrode for haemostasis. All 3 professional experts and the company advised that using the button electrode for haemostasis (generator in coagulate mode) after loop resection is now relatively common. Two professional experts stated that they use the PLASMA button electrode for haemostasis after resection with a loop electrode. They suggested that this produces better haemostasis, therefore a lower risk of transfusion and higher chance of treatment as a day case. One professional expert stated that they suspected many of these cases unavoidably caused some vaporisation of prostate tissue, although the primary intention is haemostasis.

The base case for PLASMA is cost saving with a 2-day length of stay for PLASMA and mTURP at sites with an existing Olympus system and cost incurring at other sites

3.16 For a 2-day length of stay for PLASMA and mTURP with an existing Olympus system, mTURP costs £1,196.60 and PLASMA costs £1,126.04. This is a cost saving of £70.56. For non-Olympus sites, mTURP costs £1,125.69 and PLASMA costs £1,145.49. This is a cost increase of £19.80. This original base case assumed 22% use of a second electrode.

The updated base case for PLASMA is cost saving with a 2-day length of stay compared with a 3.3-day length of stay for mTURP

3.17 For a 3.3-day length of stay with an existing Olympus system, mTURP costs £1,510.32. For a 2-day length of stay with an existing Olympus system, PLASMA costs £1051.42. This is a cost-saving of £458.91. For non-Olympus sites and a 3.3-day length of stay, mTURP costs £1,415.86. For non-Olympus sites and a 2-day length of stay, PLASMA costs £1,073.02. This is a cost saving of £342.84. In the updated base case, 65% of procedures needed a second electrode for haemostasis.

PLASMA is cost saving for a 1-day length of stay (day case)

3.18 For a 1-day length of stay (day case) for PLASMA and a 3.3-day length of stay for mTURP with an existing Olympus system, mTURP costs £1,510.32 and PLASMA costs £662.42. This is a cost saving of £847.91. For a non-Olympus site, mTURP costs £1,415.86 under these circumstances and PLASMA costs £684.02. This is a cost saving of £731.84. In this scenario, 65% of procedures required a second electrode for haemostasis.

PLASMA is cost saving for a 2-day length of stay when not using a second electrode for haemostasis

3.19 The EAC modelled an additional scenario with no second electrode. For a 3.3-day length of stay for mTURP and an existing Olympus site when no second electrode used for haemostasis, the cost is £1,510.32, and PLASMA costs £932.71 for a 2-day length of stay. This gives a cost saving of £577.61. For a 3.3-day length of stay for mTURP and a non-Olympus site with no second electrode, the mTURP cost is £1,415.86 and the PLASMA cost is £954.31 for a 2-day length of stay. This gives a cost saving of £461.55.

PLASMA is cost saving for a 2-day length of stay when a second electrode is used for haemostasis in 65% of procedures and all-cause admissions are reduced

3.20 The EAC modelled an additional scenario with 65% of procedures needing a second electrode and reduced all-cause admissions. For mTURP and an existing Olympus site when a second electrode is used for haemostasis in 65% of procedures, the cost is £1,621.25, and PLASMA costs £1,086.94. This is a cost saving of £534.34. For mTURP and a non-Olympus site when a second electrode is used in 65% of procedures, the mTURP cost is £1,526.79 and PLASMA costs £1,108.38. This gives a cost saving of £418.41.

4 Committee discussion

Clinical-effectiveness overview

Previous evidence about clinical outcomes is still relevant now the technology name has changed from TURis to PLASMA

4.1 The committee noted that the name change from TURis to PLASMA was not accompanied by any change to the technology. Therefore, they concluded that the previous evidence of equivalent clinical outcomes with mTURP is still relevant, and they saw no new contradictory evidence.

The evidence shows that PLASMA resection with a loop electrode is clinically effective

4.2 The committee discussed updated evidence on resection with PLASMA using the loop electrode and it concluded that the procedure is clinically effective. The professional experts advised that it is straightforward to switch from a loop to a roller or button electrode for haemostasis. The committee concluded from the published and expert evidence that using the button and roller electrodes is clinically effective for haemostasis after resection.

Using a PLASMA button electrode for vaporisation and the PLASMA system for other procedures such as incision and enucleation are not in the scope of this guidance

4.3 The professional experts advised that, in most cases after resection with loop electrodes, a separate roller or button electrode is needed to achieve haemostasis. They indicated that while this will inevitably result in some vaporisation of the prostate, this is not considered as a vaporisation procedure. The committee agreed that using the PLASMA button electrode for vaporisation of the prostate is not covered by the scope and so should therefore not be the subject of this assessment. It acknowledged that transurethral vaporisation of the prostate (TUVP) is not recommended in NICE's clinical guideline on management of lower urinary tract symptoms in men.

4.4 The committee agreed that using the PLASMA system for needle incision or enucleation is also out of scope for this evaluation.

Side effects and adverse events

Resection with the PLASMA system may increase the incidence of urethral strictures

4.5 The committee noted that 1 study reported an 19% incidence of urethral stricture after PLASMA treatment, compared with 6.6% for mTURP (Komura et al. 2015). The professional experts advised that this higher incidence did not reflect their own experience or practice. They informed the committee that they see urethral stricture in 5% or less of people who have treatment with PLASMA. The committee concluded that, based on the current evidence, it is difficult to be definitive about the incidence of urethral stricture after PLASMA. But, it was reassured that when this condition does develop, treatment is available.

Serious adverse events are reduced by using the PLASMA system compared with mTURP

4.6 The committee considered the incidence of serious adverse events, including transurethral resection (TUR) syndrome and blood transfusion with bipolar and monopolar TURP, during the production of MTG23. The committee noted that the evidence shows that the PLASMA system reduces the risk of TUR syndrome and reduces the need for blood transfusion compared with mTURP. The committee considered that these original conclusions about adverse events are still relevant and that there is no new data that would contradict their previous conclusions.

Relevance to the NHS

The PLASMA system and mTURP are used in the NHS

4.7 The committee heard that use of the PLASMA system for resection of the prostate has increased in the NHS over the last 5 years, with the number of centres offering this treatment rising from around 60 to over 110. The professional experts advised that the use of bipolar TURP is superseding mTURP. But, uptake across the UK is variable, and bipolar TURP is not yet established as standard care. The professional experts advised that mTURP is still used in people with small prostates when prolonged procedures are unlikely and when the incidence of TUR syndrome is likely to be low. The committee concluded that PLASMA and mTURP are both used in the NHS.

Collecting real-world evidence during post-market surveillance is encouraged

4.8 The committee encouraged the collection of real-world clinical data on PLASMA. They considered that this would represent good clinical practice and routine post-market surveillance.

Cost-modelling overview

PLASMA can be used with a reduced length of stay

4.9 The committee heard that PLASMA is now more expensive than it was when the original guidance was published. This is because of increased costs for components of the PLASMA system, including consumables, and increased inpatient day costs. However, the professional experts advised that PLASMA can now be used with a shorter length of stay. They stated that the length of stay for mTURP had not changed and so 3.3 days was still correct. Assumptions about length of stay for PLASMA were contained in the original model, that is, reduced by 0.19 days compared with mTURP. Accounting for this and the increase in the cost of PLASMA, the treatment would be cost incurring if applied in this way. However, with a reduction in length of stay to 2 days, the technology becomes cost saving. There are even more cost savings when treatment is given as a day case. The professional experts advised that a plausible and conservative length of stay with PLASMA in their practice is 2 days. One professional expert advised that he does the procedure as a day case in most of his patients. The committee concluded that PLASMA can be used with a reduced length of stay compared with mTURP.

PLASMA can be used with existing compatible equipment to save costs

4.10 The committee agreed that sites that already have compatible Olympus equipment for mTURP would be able to use some of this equipment for PLASMA. This could result in greater cost savings for these sites. However, the committee also noted that for sites where purchase of Olympus equipment would be needed for PLASMA treatment to be offered, cost savings would still be possible.

A second electrode is often needed to stop bleeding (haemostasis)

4.11 The professional experts advised that a second electrode is needed to achieve haemostasis in most cases. The EAC modelled this in a scenario

of 65% of procedures. It advised that PLASMA is still cost saving under these circumstances.

A urinary catheter is used after treatment with PLASMA and mTURP

4.12 The professional experts advised that a urinary catheter is used after PLASMA and mTURP and that for day-case surgery with PLASMA, the catheter is removed after discharge from hospital in a community setting. The EAC estimated that the cost of catheter placement was included in the procedure costs. The cost of removal of the catheter at an outpatient appointment with a single healthcare professional is £68 (NHS tariff). The cost of removal in community care during a 1-hour appointment is £84 for a band 7 healthcare professional. The EAC advised the committee that neither of these costs for catheter removal would negate the cost savings for PLASMA compared with mTURP.

Main cost drivers

Length of stay was the main cost driver

4.13 The length of stay was the main driver of cost savings in the model. The committee discussed with professional experts using the PLASMA system for day-case surgery. One professional expert advised that PLASMA was used routinely for day-case TURP in his centre, but the experts acknowledged that this is not the case in all centres. The experts agreed that day-case use of PLASMA is possible, especially in people with low risk.

Cost savings

The PLASMA system is cost saving with reduced length of stay

4.14 The committee considered an updated base case and 4 additional scenarios presented by the EAC in the assessment report update (sections 3.16 to 3.21 of this guidance).

4.15 It agreed that reduced length of stay for the PLASMA system compared with mTURP was plausible. The committee also agreed that even when a second electrode is used to achieve haemostasis, cost savings are still possible with PLASMA because of the reduced hospital stay.

Equalities

4.16 People over 80 years old, especially those with frail health and comorbidities, have been found to have an increased risk of complications after TURP. However, the effectiveness of TURP is the same as in younger people.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technology advisory committee which is a standing advisory committee of NICE.

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

The minutes of the medical technology advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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