National Institute for Health and Care Excellence

IP1555 Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia

IPAC date: 14/06/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Neotract	**Title**	General comments 1. Description of the procedure As pointed out by one of the Specialist Advisors, the current description of this procedure as 'water vapour ablation' confuses it with another procedure under evaluation for treating BPH – 'water jet ablation', which uses high pressure water rather than steam. The confusion this may cause is illustrated by the fact that one of the Specialist Advisors has commented on the water jet ablation procedure, not the procedure that is the subject of the current consultation. 'Steam' would be a better way to describe water vapour.	Thank you for your comment. The committee considered your comment but decided not to change the title of the guidance. The following committee comment has been added to the guidance in section 3.7: '' *The committee noted that this procedure is also known as transurethral water vapour thermal ablation or transurethral steam ablation*.''
2	Consultee 1	**3.1**	2. Evidence review	Thank you for your comment.

	Company Neotract		The literature review appears not to include a recent retrospective single centre review of 129 patients treated with the Rezum system [Mollengarden D et al. Convective radiofrequency water vapor thermal therapy for benign prostatic hyperplasia: a single office experience. Prostate Cancer Prostatic Dis. 2017 Dec 27. doi: 10.1038/s41391-017-0022-9. Epub ahead of print]. This study is particularly relevant as regards to the summary of efficacy and safety in the IPG Consultation Overview: • Infection [page 10, IPG Consultation Overview] o The rate of UTI following the procedure was 17% [Mollengarden et al 2017] • Urinary Retention [page 10-11, IPG Consultation Overview] o 100% patients underwent post-operative drainage, either with a catheter for a mean of 4.4 days (range 1- 26 days) or prostatic stent for 19 days (range 1 - 51 days). Following catheter or stent removal, 14% of patients had episodes of urinary retention. [Mollengarden et al 2017] • Urinary Incontinence [page 11, IPG Consultation Overview]	The Mollengarden (2017) paper was retrieved by our update literature search and the study has been added to Table 2. The efficacy and safety sections of the overview have also been updated accordingly. The Mollengarden (2017) paper is a retrospective case series of 129 patients with a maximum follow-up of 6 months. The committee decided not to change the main recommendations.

			o The rate of incontinence following the procedure was 3.9%. [Mollengarden et al 2017] • Ejaculatory problems [page 11, IPG Consultation Overview] o 3% of patients experienced erectile dysfunction. [Mollengarden et al 2017] o 3% of patients experienced retrograde ejaculation. [Mollengarden et al 2017] • Vesical catheterisation [page 11, IPG Consultation Overview] o 100% patients underwent post-operative drainage, either with a catheter for a mean of 4.4 days (range 1- 26 days) or prostatic stent for 19 days (range 1 - 51 days).	
3	Consultee 1 Company Neotract	**3.1**	o Also omitted from the Consultation Overview was the post-operative catheterisation rate in the RCT, which was reported to be 90% for a mean of 3.4 days (no range given). [McVarty and Roehrborn 2017] • Prostate volume [page 9, IPG Consultation Overview] o Prostate volume was reduced by 17% and 14% at 6 months, determined by TRUS or	Thank you for your comment. In the Mc Vary (2016b) paper it says: *''Catheterization immediately after the procedure was performed at the discretion of the treating physician. A total of 90.4% (122 of 135) of treatment subjects were catheterized for a mean 3.4 ± 3.2 days. Of these, 68% (83 of 122) were discretionary and 32% (39 of 122) were due to an unsuccessful voiding trial before discharge.*

			PSA respectively. [Mollengarden et al 2017] Reoperation o 2.3% of patients required a secondary BPH surgery during 4–12 months of follow up. [Mollengarden et al 2017]	*In the control group 19.7% (12 of 61) were catheterized for a mean of 0.9 ± 0.8 days."* These results have been added to Table 2 and the Safety summary section of the overview has been updated accordingly.
4	Consultee 1 Company Neotract	**2.2**	Specific comments on the Consultation document Section 2.2. Prostatic artery embolisation should not be included as this is not routinely offered by the NHS and is not recommended by NICE	Thank you for your comment. NICE has recently updated its guidance on Prostate artery embolisation for lower urinary tract symptoms caused by benign prostatic hyperplasia (IPG 611) in April 2018 and it says: ‘*'Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."* The committee considered this comment but decided not to change the guidance.
5	Consultee 1 Company Neotract	**2.2**	The sentence about prostatic urethral lift should appear at the end of this paragraph, after the sentence about the potential complications of the more traditional surgical procedures. As per NICE guidance, prostatic urethral lift is not associated with the same complications as (TURP), transurethral vaporisation, and HoLEP.	Thank you for your comment. Section 2.2 of the draft guidance has been changed as follows: ‘' Mild symptoms are usually managed conservatively. Drugs may also be used, such as alpha blockers and 5-alpha-reductase inhibitors. If other treatments have not worked, there are a range of surgical options that may be considered including transurethral resection of the prostate (TURP), transurethral vaporisation,

				holmium laser enucleation, insertion of prostatic urethral lift implants, prostatic artery embolisation or prostatectomy (see the NICE guideline on lower urinary tract symptoms in men). Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.''
6	Consultee 1 Company Neotract	**2.3**	"Transurethral water vapour ablation is usually done as day-case surgery using local anaesthetic, and sometimes sedation." It is important to point out that this procedure almost exclusively requires a peri-prostatic block, administered transrectally via ultrasound probe.	Thank you for your comment. Section 2.3 of the guidance has been changed as follows: ''Transurethral water vapour ablation is usually done as day-case surgery using local anaesthetic including a peri-prostatic block, and sometimes sedation. A device similar to a rigid cystoscope is advanced into the prostatic urethra. Under direct visualisation, a retractable needle is inserted into the prostate and water vapour (at a temperature of about 103 degrees centigrade) is delivered for 8 to 10 seconds. At the same time, saline irrigation is used to cool and protect the surface of the urethra. Conductive heat transfer disrupts cell membranes in the prostate, leading to rapid cell death. The needle is retracted and repositioned several times so that thermoablation can be repeated in different areas of the gland, including the median lobe. The aim is to reduce the size of the prostate, leading to improvement in lower urinary tract symptoms 1 to 3 months after treatment, without impairing sexual function.''

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