National Institute for Health and Care Excellence

IP 1032 – Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Consultation Comments table

IPAC date: 14 November 2013

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Specialist adviser	**1.2**	The experience of clinicians with experience of this therapy suggests that patients can also be reassured that even if other standard treatments become necessary in the course of time, that the insertion of prostatic urethral lift implants will not interfere with or compromise those subsequent treatments. Â Several of us have had experience of TURP after [redacted] without any adverse effects. Â Others have performed laser procedures. Â The presence of the [redacted] devices in these circumstances has not caused problems	Thank you for your comment. Section 6 of the guidance has been changed.
2	Consultee 1 Specialist adviser	**1.4**	I agree. Many clinicians currently investigating this therapy do contribute to an international database (called "GUSTO") which will provide much of this important information	Thank you for your comment. We have been advised by the manufacturer that the GUSTO registry is open to UK clinicians but is restricted to the one device currently available for the prostatic urethral lift procedure. The manufacturer reports that there are no plans to release the data to groups such as NICE or FDA or publish the data.

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3	Consultee 1 Specialist adviser	**2.2**	the use of the term "antiandrogens" may confuse non specialists. Â That term is more commonly linked to direct blockers of testosterone binding as used in the treatment of prostate cancer. Â Why not use "5alpha reductase inhibitors" which is precisely the drug class I think you mean (and we use) for LUTS due to BPH?	Thank you for your comment. Section 2.2 of the guidance has been changed.
4	Consultee 2 Manufacturer	**3.1**	Suggested revision to Section 3.1 for accuracy and clarity because the rigid delivery device is used to displace the tissue and then the implants secure tissue in the displaced (retracted) position: The aim of insertion of prostatic urethral lift implants for lower urinary tract symptoms secondary to benign prostatic hyperplasia is to secure the prostatic lobes in retracted positions such that the lumen of the urethra is increased. The procedure is designed to cause less tissue injury than surgical resection or thermal ablation, and it is claimed to reduce the risk of complications such as sexual dysfunction and incontinence	Thank you for your comment. Section 3.1 of the guidance has been changed.

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5	Consultee 3 NHS Professional	**3.1**	As the rigid instrument itself is used to displace the prostatic tissue and the implants used to secure that dispacement an alternative to 3.1 might better read - 'The aim of insertion of prostatic urethral lift implants for lower urinary tract symptoms secondary to benign prostatic hyperplasia is to secure the prostatic lobes in retracted positions such that the lumen of the urethra is increased. The procedure is designed to cause less tissue injury than surgical resection or thermal ablation, and it is claimed to reduce the risk of complications such as sexual dysfunction and incontinence.'	Thank you for your comment. Please see response to comment 4.
6	Consultee 3 NHS Professional	**4.1**	Regarding the RCT described in section 4.1; a total of 19 centres in three countries (US, Canada, and Australia) participated in this study. This number of surgeons can only enhance the robustness of the data and may be worth including in the study description.	Thank you for your comment. It has been noted that the RCT included 19 centres in the relevant section in table 2 of the interventional procedures overview.
7	Consultee 3 NHS Professional	**4.1**	The RCT results through 12 months have been published. Â This 1 year data recording both improvements in AUASI and in maximum flow rate indicate a degree of durability of the PUL and would themselves warrant inclusion.	Thank you for your comment. The RCT reported comparative data at 3 months for primary efficacy endpoints and up to 1 year data for patients treated by prostatic urethral lift. For the AUASI and maximum flow rate outcomes at 1 year there were missing data (12% and 26%, respectively) and therefore this information was not included in the guidance. The outcomes are reported in the efficacy section of table 2 of the interventional procedures overview.

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8	Consultee 3 NHS Professional	**4.7**	Regarding the case series of 64 patients; it is important to record that the reported retreatment rate includes the first PUL procedures ever performed. Inevitably this means that the technique was not fully determined nor patient selection optimised thereby leading to a retreatment rate higher than demonstrated in the subsequent RCT. Given the level of evidence provided by the prospective, multi-centre RCT, I would suggest that 1) Section 4.7 be edited to focus primarily or exclusively on the retreatment rate demonstrated in the RCT or 2) a comment be included in Section 4.7 to specify that the 64 patient study included the first PUL procedures performed and thus the procedure was still under development.	Thank you for your comment. Table 2 of the interventional procedures overview notes that in the case series of 64 patients, 10 patients needing retreatment were in the first 25 patients treated by this procedure. The Committee considered this comment but decided not to change the guidance.
9	Consultee 3 NHS Professional	**5.5**	5.5 again describes complications as reported in one study. In the later, larger RCT, data relating to incontinence is also recorded and should be included. The risk of incontinence is a very important issue to patients. In the RCT, at 3 months 3.6% (5/140) reported urge incontinence after the PUL procedure with this figure dropping to less than 1% at 12 months (1/140). It is worth noting that 1.5% (1/66) described new urge incontinence in the sham arm.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

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10	Consultee 3 NHS Professional	**5.7**	5.7 describes results only from the smaller initial study; in the RCT, of the 140 patients assigned to the PUL procedure there was NO reported incidence of de novo ejaculatory or erectile dysfunction. This is an important aspect of the potential benefits of the PUL procedure compared to standard surgical approaches and indeed alpha blocker therapy, and should be mentioned.	Thank you for your comment. The relevant section in table 2 of the interventional procedures overview states that there were no reports of erectile dysfunction or retrograde ejaculation reported in the study.
11	Consultee 3 NHS Professional	**6**	I would agree that patients will be attracted to this procedure if keen to avoid the substantial risks of ejaculatory disorder that may occur following standard surgical options. It is also likely that some patients will prefer a minimally invasive surgical option to chronic drug therapy either because they don't enjoy the concept of taking medication on a daily basis or because of low grade side effects. I might also suggest that the PUL procedure also offers a surgical solution that offers a reliable rapid return to normal activity, including work; this usually being within 7 days in my experience. I would take issue however with the initial statement that suggests that the PUL procedure is not likely to offer permanent relief of symptoms. One could level this claim against any of the more recognised surgical options; all suffer with a re-operation or symptomatic failure rate. Interestingly, there is not a great deal of published data on this front and, in particular, long term randomised data is lacking. Permanent relief is impossible to guarantee therefore. It would therefore seem reasonable to suggest that ' the longevity of relief of symptoms is unclear.....'	Thank you for your comment. Section 6.1 of the guidance has been changed.

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12	Consultee 1 Specialist Adviser	**6**	This comment by the committee is opinion and and may be correct but there is no data to prove the case either way. Â All current treatments have a significant failure rate. Â We reviewed this issue in Roehrborn C, McNicholas T. The management of prostatic obstruction: How to determine the best options? Eur Urology Supplmnts. 2003;2(8):13-9. The risk of treatment failure with a-blocker was 48% for patients with relatively “ideal” prostate volumes of < 40 cc and 72% for those with prostate volumes > 40 cc (p = 0.0002) [de la Rosette JJ et al.: Long-term risk of re-treatment of patients using alpha-blockers for lower urinary tract symptoms. J Urol 2002;167:1734–1739.] The condition progresses in many men. Even the most effective therapies with the longest likely duration of effect have shorter effect if applied to the wrong candidates or if applied with errors of technique. I would suggest Â “The Committee recognised that, in common with most available treatment options, implantation of prostatic urethral lift implants is not likely to offer permanent relief of symptoms” The US RCT includes 4 years follow up to provide durability data.	Thank you for your comment. Section 6.1 of the guidance has been changed. The references cited by the consultee do not evaluate efficacy or safety of prostatic urethral lift. It is unclear if the RCT the consultee refers to is the RCT which is included in table 2 of the interventional procedures overview (Roehrborn (2013): reporting 1 year outcomes; protocol calls for follow-up on an annual basis to 5 years).

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13	Consultee 1 Specialist Adviser	General	I did not have much else to add but would have pointed out that the consultation describes some outcome data from the very earliest patient study rather than the latest data from bigger studies with rigorous methodology and using the current and final version of the technology.	Thank you for your comment. Where possible, larger studies or studies with longer or more complete follow-up are included in the efficacy section of the guidance. Key safety outcomes identified in studies (irrespective of study design) are included in the safety section of the guidance. In table 2 of the overview it will be clarified if the study includes patients from earlier cohorts.
14	Consultee 1 Specialist Adviser	Notes	My affiliations etc are on record with NICE.	Thank you for your comment. The specialist adviser has declared a personal pecuniary interest (consultancies or directorships, fee-paid work and shareholdings) in the specialist adviser form.
15	Consultee 3 NHS Professional	Notes	I am National Primary Investigator for the BPH-6 study; a randomised multi-centred, multi national study comparing TURP vs the [redacted] device.	Thank you for your comment.

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