NICE advice

iTind for lower urinary tract symptoms caused by benign prostatic hyperplasia

Medtech innovation briefing
Published: 21 September 2022

www.nice.org.uk/guidance/mib306

Summary

- The **technology** described in this briefing is iTind. It is designed to treat people with lower urinary tract symptoms caused by benign prostatic hyperplasia.
- The **innovative aspects** are that it is a minimally invasive surgical treatment that does not involve a permanent implant, heating or removal of prostate tissue.
- The intended **place in therapy** would be as an alternative to surgical treatments including transurethral resection of the prostate or as an alternative to other minimally invasive surgical treatments.
- The **main points from the evidence** summarised in this briefing are from 3 studies (1 randomised controlled trial and 2 single arm studies) including a total of 326 people. The evidence suggests that iTind improves symptoms and quality of life and is associated with expected, short-term, mild, transient and self-resolving complications.

- **Key uncertainties** around the evidence are that the comparative study is sham controlled, there is limited UK NHS evidence, and there is a lack of comparative evidence compared with standard care in NHS pathways.
- **Experts advised** that the device is innovative and likely to produce patient and system benefits, but that it is unlikely to replace standard care. They also noted a need for long-term comparative evidence of any need for reintervention.
- The **cost** of iTind is about £1,208 per unit including the Foley catheter (excluding VAT). The cost of standard care (consumables only) is between £52 and £189 for transurethral resection of the prostate (TURP), £1,320 for UroLift, £1,384 for Rezum, £550 for Greenlight and £97 for holmium laser enucleation of the prostate (HoLEP; excluding VAT).

The technology

iTind (Olympus) is a temporary implanted nitinol device. Using local anaesthesia or light sedation, the folded device is inserted into the bladder under direct visualisation using a cystoscope. The device is opened in the bladder. The device is then pulled back and positioned in the prostatic urethra. Over the following days, the pressure applied by struts in the device creates areas of ischaemia in the prostatic urethra and bladder neck. This makes new longitudinal channels through which urine can flow. After 5 to 7 days, lidocaine gel and a flexible silicone Foley catheter are inserted into the urethra. Once the device is folded completely inside the Foley catheter, the Foley catheter is removed from the urethra. Insertion and removal of the device are both done as day case or outpatient procedures.

Innovations

The company says that iTind is a minimally invasive surgical treatment that can be delivered under local anaesthesia or sedation, as a day case or outpatient procedure, taking less than 20 minutes. They also note that it does not involve a permanent implant, heating or removal of prostate tissue and claims that sexual and erectile function is preserved. The company claims that the procedure is routinely catheter free, and people can go home once they have voided, usually a few hours after the procedure. The company also claims that the procedure preserves urinary continence and is suitable for treating people with high bladder necks.

Current care pathway

NICE's guideline on lower urinary tract symptoms in men describes current treatment options. Mild symptoms are usually managed conservatively. Medicines such as alpha blockers and 5 alpha-reductase inhibitors may also be used. If these treatments have not worked, there are several possible surgical options, including transurethral resection of the prostate, transurethral vaporisation, holmium laser enucleation, prostatic urethral lift implant insertion, prostatic artery embolisation and prostatectomy. Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.

Population, setting and intended user

iTind is designed to treat people who have lower urinary tract symptoms caused by benign prostatic hyperplasia.

Insertion and removal of the device are both done as day case or outpatient procedures by urologists. The company says that urologists undergo a training programme free of charge. This training involves a 1-day didactic course, either in person or online, followed by 4 to 6 iTind cases under supervision of a certified trainer.

Costs

Technology costs

The cost per patient is about £1,208 (excluding VAT).

- iTind device and removal snare: £1,200
- 22 Fr. single use Foley catheter: £7.50.

Costs of standard care

The cost of standard care depends on the procedure and is provided for consumables only.

- transurethral resection of the prostate: between £52.60 and £189.34

- UroLift (4 implants): £1,320
- Rezum: £1,384.

Experts suggested that bladder neck incision may also be a comparator as well as other laser methodologies such as HoLEP (£97.18) or Greenlight (£550).

Resource consequences

iTind is currently used in 2 NHS trusts.

The company claims that iTind is a rapidly deployable technology. It does not rely on buying capital equipment or ongoing maintenance costs. It can also be done as a day case or in an outpatient setting, avoiding the need for a theatre-based procedure, general anaesthetics or inpatient stay. The company claims that the ability to treat eligible patients as a day case will reduce pressure on inpatient beds and reduce disruptions from cancelled operations. It also claims it has significant benefits for overall urology services, freeing up operating theatre capacity and improving waiting list management.

The company says that a rigid cystoscope and surgical camera system are needed to insert the iTind device. The company assumes that all centres doing core urology will have these items because they are essential in routine urological practice.

Regulatory information

iTind is a CE marked class IIa medical device.

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.

iTind is intended for people with lower urinary tract symptoms caused by benign prostatic hyperplasia, which commonly affect men over 50. Some people may not identify as men but have a prostate. Age and gender are protected characteristics under the 2010 Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. 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

Three studies are summarised in this briefing, including a total of 326 people.

One study is a randomised controlled trial comparing iTind with sham. The other 2 studies are single arm studies. One of the single arm studies has multiple publications for 1-year (Porpiglia et al. 2019), 2-year (Kadner et al. 2020) and 3-year (Amparore et al. 2020) follow up and is summarised as 1 study.

There are further studies that are not summarised here including 1 study with 2 publications for 1-year and 3-year follow up (Porpiglia et al. 2015; Porpiglia et al. 2018) on the first generation Temporary Implantable Nitinol Device (TIND) and 1 narrative review (De Cillis et al. 2022) that summarised all the studies linked in this section. There is also a further long-term follow-up abstract published with data up to 79 months post treatment (Amparore et al. 2022).

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

Overall assessment of the evidence

The evidence for the technology is of low to moderate methodological quality. There is limited UK NHS evidence, and in the randomised controlled trial a sham was used as the comparator. Some of the evidence is on the TIND, which was the previous version of iTind. The evidence suggests that iTind improves symptoms and quality of life and is associated with expected, short-term, mild, transient and self-resolving complications. Evidence on more comparative long-term patient outcomes would be beneficial.

Chughtai et al. (2020)

Study size, design and location

A randomised controlled trial in 175 men with symptomatic benign prostatic hyperplasia in the US and Canada.

Intervention and comparator

iTind (second generation) compared with sham (18F silicon Foley catheter).

Key outcomes

A total of 175 men were randomised to either the iTind group (n=118) or the sham group (n=57). At 3 months, 78.6% of men in the iTind group showed a reduction in 3 or more points in the international prostate symptom score (IPSS) compared with 60% in the sham group (p=0.029). At 12 months, the iTind group reported a 9.25 point decrease in IPSS (p<0.0001), a 3.52 ml/s increase in peak urinary flow rate (p<0.0001) and a 1.9 point improvement in IPSS quality of life (p<0.0001). Adverse events were typically mild and transient in 38.1% of patients in the iTind arm and 17.5% in the control arm, most were Clavien-Dindo grade 1 or 2. No new ejaculatory or erectile dysfunction was reported.

Strengths and limitations

This study showed that iTind provided a sustained improvement in lower urinary tract symptoms during the 12-month study period while preserving sexual function. Limitations included loss to follow up at the 3-month visit (29% in the iTind group compared with 30% in the sham group) and limited generalisability because of the strict inclusion criteria. Unblinding happened at 3 months. The study was sponsored by Medi-Tate Ltd. The corresponding author is a consultant for Medi-Tate Ltd, Olympus, Boston Scientific and Medeon Bio.

Amparore et al. (2020)

Study size, design and location

Prospective, single arm, multicentre study in 81 men with lower urinary tract symptoms

secondary to benign prostatic obstruction in Italy, Switzerland, the UK, Spain and Hong Kong.

Intervention and comparator

iTind (second generation), no comparator.

Key outcomes

At 3 years of follow up, data was available for 50 participants. Significant improvements from baseline ($p<0.001$) were found for IPSS score (58.2%), quality of life (55.6%), maximum urinary flow rate (114.7%) and post void residual urine (85.4%). These improvements in outcomes remained significant compared with the baseline values in the intention-to-treat analysis ($p<0.001$). All iTind implantations were successful with no intraoperative complications and with a median visual analogue scale pain score of 4. Participants were discharged without a catheter on the same day of the implantation. During the 12-month follow up, 2 patients (2.4%) required further medical therapy and 2 patients (2.4%) required transurethral resection of the prostate, while 10 patients were lost to follow up (12.3%). No adverse events were recorded between 12 months and 36 months. Sexual function was stable throughout the 3-year follow up, with no reports of sexual or ejaculatory dysfunction. No participants had alternative treatments between 24 months and 36 months.

Strengths and limitations

This paper reports the 3-year results from this study. Kadner et al. (2020) reported 2-year results and Porpiglia et al. (2019) reported 1-year results. The authors concluded that this study showed that iTind showed a significant and durable reduction in symptoms and improvement in functional outcomes and quality of life at 3-year follow up. Limitations include the lack of a control arm and potential selection bias because the study excluded people with a prostate volume of more than 75 ml and with post void residual urine of more than 250 ml. Fifty participants (62%) completed the 3-year follow up.

De Nunzio et al. (2020)

Study size, design and location

Prospective, single arm multicentre study in 70 men with symptomatic benign prostatic

hyperplasia in Italy and Spain.

Intervention and comparator

iTind (second generation), no comparator.

Key outcomes

Significant improvements from baseline ($p<0.01$) were found for IPSS (-12.7), IPSS quality of life (-2.2) and peak flow rate (4.6 ml/s). No significant changes in post void residual urine were found. At 6 months, erectile and ejaculatory function, and urinary continence were preserved in all 70 men and significantly improved according to the male sexual health questionnaire for ejaculatory dysfunction (MSHQ-EjD; $p<0.01$). Overall, 75 complications were detected in 70 patients. The most common complications (Clavien-Dindo grade 1) were transient haematuria (18.6%), dysuria (17%), urgency (12.8%), pain (11.4%), transient urinary incontinence (8.4%) and frequency (7%). Acute urinary retention occurred in 3 people (4.2%), 2 with the device in situ and one 12 hours after the device was removed. Only 1 patient presented a Clavien-Dindo grade 3 complication (1.4%), specifically gross haematuria presenting a few days after iTind removal in a patient with a large prostate (80 g), needing endoscopic fulguration.

Strengths and limitations

This study suggested that iTind significantly improves symptoms, quality of life and urinary flow, and preserves erectile and ejaculatory function at 6-month follow up. Limitations include a lack of a control arm, short follow up, no full use of the MSHQ questionnaire and lack of urodynamic data. The authors concluded that further comparative studies with longer follow up are needed. The study was sponsored by Medi-Tate. The authors declared that they had no conflict of interest. The company note that this is a preliminary report which will be followed up at 36 months on the whole 200 patient cohort.

Sustainability

iTind is a single use device and cannot be recycled. The iTind device should be disposed of safely according to local regulations.

Recent and ongoing studies

- Prostate Resection versus Minimally Invasive Surgery Evaluation Trial- PREMISE trial. NIHR. Status: active. Indication: men who are being considered for surgical intervention to treat their lower urinary tract symptoms. Devices: iTind, Rezum and UroLift compared with TURP. Country: UK. Expected completion date: February 2028.
- A Randomized, International Study to Assess the Safety of iTind Compared to TURP (MT-08). ClinicalTrials.gov identifier: NCT04757116. Status: not yet recruiting. Indication: benign prostatic hyperplasia. Devices: iTind; procedure: TURP. Country: US. Expected completion date: October 2023.
- Study to Assess the Efficacy of the iTind in Subjects With Symptomatic BPH (MT-06). ClinicalTrials.gov identifier: NCT03395522. Status: active, not recruiting. Indication: benign prostate hyperplasia. Devices: iTind. Countries: Australia, Austria, France, Italy, Spain and Switzerland. Expected completion date: April 2025.

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 experts were familiar with the technology and 2 have used this technology before.

Level of innovation

Two experts said that the technology and its approach is innovative. One said that this is because it is a temporary device that makes 3 longitudinal incisions through pressure necrosis, remodelling the bladder neck and prostatic urethra and aiming to relieve the bladder outlet obstruction. Two experts said that it is novel but of uncertain safety and efficacy. One said that it is not novel because it has been in use in and out of trials for over 6 years.

Two experts were not aware of any competing technologies, with 1 saying that any competitors have a different mode of action. One expert said that, because it is a minimally invasive option, it can be compared to UroLift or Rezum.

Potential patient impact

All experts agreed that iTind has minimal side effects. Further patient benefits included no risk of negative impact on sexual function, no need for a permanent implant and that it can be done as a day case. All experts suggested patient groups that would particularly benefit from this technology. These included people who were unfit for general anaesthesia and people who did not want to accept the potential risks of impact on sexual or ejaculatory function, catheterisation or risk of incontinence.

One expert noted that about 20,000 bladder outlet cases are done in the UK and said that the exact proportion that would be eligible for iTind needs to be defined. Another expert said that about 10% to 20% of men presenting with LUTS caused by benign prostatic hyperplasia that needed surgical intervention would be eligible for iTind per year.

Potential system impact

Experts agreed that the technology has the potential to change the current pathway and lead to shorter waiting times. This is because the procedure takes less time, there is no need for specialist equipment or to use a theatre, minimal training is needed, and side effects are minimal.

Two experts agreed that iTind costs less than TURP. One said it may cost the same or less than Rezum or UroLift.

One expert said that no change in the existing facilities is needed because all the equipment used for iTind is available in all urology units. Two experts clarified that treatment rooms need to be available, plus lithotomy stirrups, a cystoscope and fluid for insertion.

Two experts noted that the company provides a training programme and support in the form of observing and then doing the procedure. One expert said that there is no formal training pathway in place and that this needs to be clearly documented.

General comments

All experts agreed that iTind is an alternative to the already existing treatment options and is unlikely to replace standard care.

None of the experts raised issues with the usability of iTind. However, they noted several issues that could prevent this technology being adopted in the NHS. These included cost, if it is not done as a day case or outpatient procedure, and the lack of a strong evidence base. One expert noted that longevity and reintervention rate always remain a question for minimally invasive surgical therapies including UroLift and Rezum.

One expert said that further research is needed, including a large multicentre randomised controlled trial. Another expert noted that the long-term efficacy needs to be proven against other minimally invasive treatment options.

Expert commentators

The following clinicians contributed to this briefing:

- Neil Barber, consultant urological surgeon, Frimley Health NHS Foundation trust. Did not declare any interests.
- Toby Page, consultant urologist, Newcastle upon Tyne Hospitals NHS Foundation Trust. Did not declare any interests.
- Iqbal Shergill, consultant urological surgeon, Wrexham Maelor Hospital, Betsi Cadwaladr University Health Board. Did not declare any interests.

Development of this briefing

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

ISBN: 978-1-4731-4731-7