

The MASTER trial: artificial urinary sphincter versus male sling

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The MASTER trial is the first randomised controlled trial comparing the artificial urinary sphincter and the male sling – both treatments for urinary incontinence in men who have had prostate surgery.

Around one in five men who undergo prostate surgery for cancer or benign disease end up leaking urine as they walk around, cough or do physical activity. This ruins the quality of these men's lives, lowers their self-esteem, can stop them working and damages their personal relationships.

The established therapy is a surgical intervention in which an artificial urinary sphincter (AUS) device is inserted to control their incontinence. A newer and less invasive surgery, the male sling, has also been developed and is available. However, the sling has not been properly evaluated to modern standards. In fact, NICE has said that it should not be used except in high-quality research in comparison against the AUS.¹

The number of men needing surgery for this type of incontinence is set to rise as a result of the improvements in detecting early prostate cancer using PSA testing. Therefore the effectiveness and definitive costs of any new treatment must be assessed to inform NHS on the best treatment strategy.

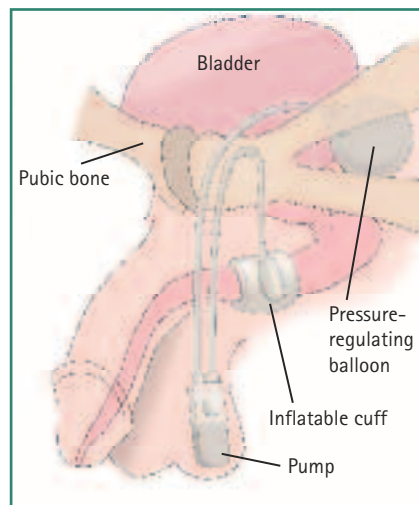


Figure 1. Artificial urinary sphincter

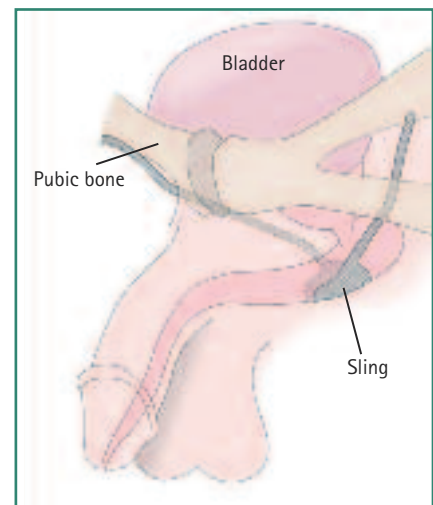


Figure 2. Male synthetic sling

The MASTER trial (Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial) will compare the advantages and disadvantages of the AUS and male sling operations. This will be done by considering two primary outcomes:

- the clinical effectiveness of implanting the male sling versus the AUS in terms of patient-reported incontinence at 12 months
- the cost-effectiveness measured in quality-adjusted life-years at 24 months.

This will determine whether men can be confidently informed about whether implantation of the male sling gives equivalent effectiveness for cure of incontinence compared to the standard AUS.



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MASTER is the first randomised controlled trial comparing the AUS and the male sling and is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme and sponsored by North Bristol NHS Trust. The trial will randomise 360 eligible men to the two treatment arms. To be eligible for the trial, men must have agreed, in discussion with their urologist, to have surgery for stress incontinence resulting from prostate surgery; and be willing to be randomised.

Men will be ineligible if they:

- have had previous male sling or AUS surgery
- have unresolved bladder-neck contracture or urethral stricture after prostate surgery
- do not consent to be randomised (but these men are eligible for the follow-up cohort)
- have insufficient manual dexterity to operate the AUS device
- are unable to give informed consent or complete trial paperwork.

Both operations in the MASTER trial involve a surgical procedure to implant a plastic (prosthetic) device designed to stop or reduce urine leakage (Figures 1 and 2). The AUS has been used for almost 40 years, during which time the device has been updated to make use of new materials and to improve both its effectiveness and its safety. The male sling has been used for the past 3–5 years. Both operations require a hospital stay for 1 or 2 days.

ARTIFICIAL SPHINCTER

The AUS has three parts connected to each other. There is a circular inflatable

cuff placed around the urethra and a pressure-regulating balloon to keep the cuff inflated. The cuff keeps the urethra closed so no urine leaks except when voiding. When the man wants to pass urine he squeezes a small pump placed in the scrotum. This action empties the cuff so that urine can flow; the cuff refills automatically over 2 or 3 minutes.

The balloon and the pump are put in through an incision in the groin. The balloon is placed in the space under the muscles of the abdominal wall and the pump is placed in the scrotum. The cuff is placed around the urethra through a cut in the skin behind the scrotal sac but in front of the back passage.

After surgery, the cuff is left deflated, meaning that it does not work at once. This is to allow any swelling from the operation to settle down. Three to six weeks after surgery, the sphincter is activated.

MALE SLING

The male sling supports the urethra and puts it in a more natural position to allow the sphincter muscles to function more normally to control urine leakage.

The male sling is a permanent plastic tape that is placed under the urethra through a small cut in the skin behind the scrotal sac but in front of the back passage. The two ends of the sling are passed under the urethra and out through the pelvic area into the upper thigh on each side. It is then tightened just enough to lift and partially compress the urethra. The sling can work immediately, although

The MASTER trial

The MASTER trial is a collaborative UK-wide randomised controlled trial and includes the 26 main centres that are responsible for treating men with incontinence after prostate surgery. MASTER is being run by the Centre for Healthcare and Randomised Trials based at the University of Aberdeen. The trial funding commenced in September 2013 and is currently open to recruitment around the UK. If you are interested in receiving further information about the trial, please contact the trial office at master@abdn.ac.uk or 01224 438096

it may take a few weeks to reach its best performance. The sling has a passive mode of action, meaning that the man is able to pass urine normally when he is ready to void.

Declarations of interest

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REFERENCE

1. NICE. *The management of lower urinary tract symptoms in men*. Clinical guideline 97, May 2010. www.nice.org.uk/guidance/cg97/resources/guidance-lower-urinary-tract-symptoms-pdf