Urinary incontinence (UI) is a common symptom that can affect women of all ages, with a wide range of severity and nature. While rarely life-threatening, UI may seriously influence the physical, psychological, social and sexual wellbeing of affected individuals.

The National Institute for Health and Care Excellence (NICE) first published guidance on the management of urinary incontinence in women in 2006 and updated guidance (clinical Guideline CG171) was published in September 2013. This guidance is supported by two sets of interventional procedures guidance:

- surgical repair of vaginal wall prolapse using mesh (IPG267)
- sacrocolpopexy using mesh for vaginal vault prolapse repair (IPG283).

The Medical Healthcare products Regulatory Agency (MHRA) commissioned York University to review the published literature on the most frequently reported adverse events in light of concerns expressed by patient groups about procedures using synthetic implants (tension-free vaginal tape, TVT and polypropylene mesh) to treat UI. York University Health Economics Consortium reported in 2012 on the rates of common adverse events associated with TVT for the treatment of urinary incontinence (UI), and mesh for pelvic organ prolapse (POP).

In summary the report confirmed;

- that adverse event rates associated with the various surgical techniques using TVT for UI are generally in the range 1–3% (9% for deterioration in sexual function for one technique); and
- adverse event rates for surgical techniques using vaginal mesh for POP are in the range 2–6% for most outcomes, but 14–15% for deterioration in sexual function.

Actions

Who: All NHS organisations providing surgical management of urinary incontinence and pelvic organ prolapse.

When: As soon as possible but no later than 31 July 2014

- Organisations must confirm compliance by 31 July to: DU.Inbox@wales.nhs.uk
- Ensure the investigation and management of all patients requiring surgical management of UI and POP follows NICE guidance
- Consent: ensure all consenting processes comply with up to date evidence and risk management at all levels from individual, local NHS and also at UK level. Consent forms, consent guidance and patient information are available from NHS Scotland, the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons (BAUS) and should be given to all patients well in advance of the surgery.
- Surgery for insertion or removal of TVT or mesh: demonstrate that any surgery for insertion or removal of TVT
The report concluded that interpretation of these findings was not straightforward as many patients experience symptoms such as sexual problems before surgery, and rates of adverse events for surgery not using implants are believed to be as high as or higher than those using implants. Further information was felt to be required and an ongoing trial looking at evidence of the relative safety of prolapse repairs using native tissue repair and mesh implants is due to report in 2014.

A letter to Medical Directors in NHS Wales was issued in January 2013 regarding surgical management of UI and POP. This letter drew attention to the York University report recommendations and the need for compliance with existing NICE and professional guidance on the safe and appropriate use of these devices.

In response to these earlier concerns, the MHRA, working with professional associations – the British Society for Urological Gynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) – and the Scottish Government, developed a range of materials for clinicians and patients, including patient information leaflets, and questions which patients should ask their surgeons when considering surgery. These are available on the Scottish Government and MHRA websites.

The MHRA’s current view is that for the vast majority of women, mesh and tape implants are a safe and effective operation, but as with all surgery, there is an element of risk. While a small number of women have experienced adverse effects, the current evidence shows that when these products are used correctly they can help with the very distressing symptoms of these conditions and as such the benefits can still outweigh the risks.

The MHRA acknowledges that there is considerable under reporting of complications, so continues to encourage voluntary reporting of adverse incidents relating to medical devices, by all health care workers, as well as carers, patients and members of the public.

NICE guidelines recommend that all surgeons undertaking any TVT or mesh procedures should maintain careful audit data and submit their outcomes to national registries such as the BSUG65 or BAUS76 databases.

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4 www.scotland.gov.uk/Publications/2014/06/2806/downloads
6 www.bsug.net
7 www.baus.org.uk/Sections/femaleresearch-and-audit
8 www.mhra.gov.uk
9 www.patientsafety.wales.nhs.uk/patient-safety-incidents