Australian Government
Department of Health
Therapeutic Goods Administration

Urogynaecological surgical mesh complications

TGA urges reporting of adverse events

2 August 2016

As part of its ongoing monitoring of the safety of urogynaecological surgical meshes, the TGA is urging consumers and health professionals to report any adverse events experienced in association with these medical devices.

The TGA believes that adverse events involving these devices are most likely under-reported and that some patients may not realise that their symptoms are associated with an adverse event.

Urogynaecological meshes (sometimes known as transvaginal meshes and supplied in a variety of forms including 'sling', 'tape', 'ribbon', 'mesh' and 'hammock') are used to treat a variety of conditions affecting women - most commonly pelvic organ prolapse and stress urinary incontinence. Pelvic organ prolapse occurs when a woman's pelvic muscles weaken and the pelvic organs - including the bladder, rectum and uterus - drop into the vagina.

The TGA has been monitoring surgical meshes since 2008 and has continued to publish information (/behind-news/results-review-urogynaecological-surgical-mesh-implants) for the public and health professionals.

From July 2012 to 1 June 2016, the TGA received 99 adverse events reports involving urogynaecological surgical meshes. The most frequently reported adverse events were pain and erosion.

Reports by consumers and health professionals to the TGA provide important information, building a picture of the safety profile of a product and assisting with our safety monitoring program. A list of adverse events associated with urogynaecological meshes is published in the ‘Additional information’ section below.

Consumers and health professionals are encouraged to report problems with medical devices. The most convenient method for most people to report is via the TGA's online form (https://apps.tga.gov.au/prod/mdir/udir03.aspx). A hard-copy form (/form/report-medical-device-adverse-event-medical-device-user) can also be downloaded. Further information on what to report and how

we use these reports can be found on the TGA's Incident Reporting and Investigation Scheme (IRIS) (/medical-device-incident-reporting-investigation-scheme-iris) webpage.

Additional information

Adverse events that may be associated with urogynaecological meshes include:

- punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair)
- transitory local irritation at the wound site
- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- as with all foreign bodies, mesh may potentiate an existing infection
- over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction
- acute and/or chronic pain
- voiding dysfunction
- pain during intercourse
- neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area
- recurrence of incontinence
- bleeding including haemorrhage, or haematoma
- seroma
- urge incontinence
- urinary frequency
- urinary retention
- adhesion formation
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient’s partner during intercourse
- mesh migration
- allergic reaction
- abscess
- swelling around the wound site

- recurrent prolapse
- contracture
- scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- granulation tissue formation.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices (/reporting-problems). Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS) (/medical-device-incident-reporting-investigation-scheme-iris).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Category: Alert/Advisory, Medical devices safety
Tags: urogynaecological surgical mesh implants
URL: https://www.tga.gov.au/node/729620 (https://www.tga.gov.au/node/729620)