Communication with Medsafe

Following the pelvic mesh discussions and recent regulatory announcements by Medsafe, the joint communication below has been sent to Medsafe on behalf of RANZCOG and UGSA.

Joint response from RANZCOG and UGSA

Dear Medsafe,

We are writing in response to the regulatory action notice issued 11/12/2017.
We note that the impetus for this action was the recent Therapeutic Goods Administration (TGA) notice of regulatory action in Australia dated 28 November 2017[1] and data available internationally.

The TGA categorises mesh for use in urogynaecological surgery based on surgical use and anatomical site of placement, Tables 1,2 and 3.

1. To support the urethra, as mid urethral slings, for the treatment of stress urinary incontinence.

These can be further divided into placement via a:

- transoburator route
- retropubic route
- single incision route (minisling)

2. To treat pelvic organ prolapse(POP) via vaginal implantation.
3. To treat pelvic organ prolapse (POP) via abdominal implantation.

The TGA considered all mesh products for the treatment of POP (Table1) in legal use in Australia. The TGA withdrew the approval for transvaginal mesh for the treatment of POP. This withdrawal was because of the lack of evidence that mesh augmentation via a vaginal route improved subjective outcomes, whilst having a higher reoperation rate than native tissue surgery for primary repairs. Internationally the outcomes of the Scottish inquiry, SCENIHR and national bodies such as NICE and the IUGA concur with these conclusions.

The TGA also withdrew approval for minislings, this withdrawal was also because of lack of

evidence of efficacy. Both vaginal mesh and single incision 'minislings' are the subject of ongoing FDA 522 studies. We support the withdrawal of these products until evidence regarding efficacy and safety is well established.

The TGA report supports the continued use of meshes implanted via an abdominal route clarifying that it cannot be implanted vaginally. We support this finding. Sacralcolpopexy for women with advanced or recurrent POP has level 1 supporting evidence for its efficacy and safety.

All women undergoing surgery should be counselled with regard to evidence based surgical risks and outcomes. We welcome the TGA recommendation to strengthen the preoperative counselling and information available to patients and surgeons.

Table 2 relates to products discontinued since 2013.

Table 3 relates to urogynaecological mesh products which will remain approved as of Jan 4 2018.

The two categories available are.

1. Mesh for POP via abdominal implantation.
2. Retropubic mesh midurethral slings to treat stress incontinence.
   These will be approved with "Conditions of inclusion: additional precautions must be included in Instructions for use and labelling, from 11 August 2017.

We support the extra information and safety precautions recommended by the TGA and would support a similar request from Medsafe.

We recognise the need for ongoing work in the areas of informed consent for patients, the credentialing of surgeons to perform these procedures and the robust monitoring of outcomes and complications from these procedures.

We support the implementation of a database for patients undergoing mesh based procedures and have an established database within the UGSA for this purpose.

Mid urethral slings are recognised internationally as an effective and safe treatment for SUI, We recognise the importance that suitably trained surgeons with expertise in placement and the management of potential complications perform these procedures. This will result in a minimisation of risk.

The withdrawal of mid urethral slings as a treatment option would be against the international standards of management for SUI. A withdrawal of MUS would increase the burden of morbidity associated with SUI faced by many New Zealand women who would be unfit for traditional surgeries such as the Burch colposuspension. Because of the overwhelming evidence in favour of the use of MUS, traditional surgical techniques have not been taught in recent years. Thus, surgical skills in the traditional less effective surgeries for stress incontinence are only available to a minority of older New Zealand trained surgeons, leaving a big skills gap.

You have already received correspondence from our colleagues at the Urology society of Australia and New Zealand. We share and wholeheartedly endorse the views expressed in their submission, that approval for mid-urethral slings and mesh placed abdominally for prolapse continue to be approved for use in New Zealand, as they are in Australia.

References:

1. TGA actions after review into urogynaecological surgical mesh implants
2. The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report Monday, March 27, 2017
3. NICE guidelines
4. SCENIHR
5. AUGS