IUGA
international urogynecological association

THREE COUNTRIES BAN THE USE OF VAGINAL MESH IN PROLAPSE SURGERY

IUGA: THE OFFICIAL NEWSLETTER Volume 12, Issue 4, 2017, Released January 19, 2018

Sharif Ismail, Consultant Obstetrician and Gynaecologist/ Subspecialist Urogynaecologist, Brighton and Sussex University Hospitals, NHS Trust & Honorary Senior Lecturer, Brighton and Sussex Medical School, United Kingdom.

The use of vaginal mesh in surgery for pelvic organ prolapse has been banned in Australia, New Zealand, and the United Kingdom.

The Australian Therapeutic Goods Administration (TGA) concluded that the benefits of transvaginal mesh for pelvic organ prolapse do not outweigh its risks to patients on the basis of its review of the latest international studies as well as an examination of the clinical evidence for each product supplied in Australia. The TGA also considered that there is inadequate scientific evidence to show that the risks of single incision mini-slings for stress urinary incontinence are outweighed by their benefit. The ban on vaginal mesh for pelvic organ prolapse and single incision (mini) slings for urinary stress incontinence in Australia comes into effect on 4 January 2018.

New Zealand Medicines and Medical Devices Safety Authority (Medsafe) declared it would remove vaginal mesh for pelvic organ prolapse. The New Zealand Health Minister went further to ban the surgical mesh for any pelvic operations – including both urinary incontinence and prolapse.

In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) concluded in December 2017 that current evidence on the safety of vaginal mesh repair of anterior or posterior vaginal wall prolapse shows serious, but well-recognised, safety concerns and that evidence of its long-term efficacy is inadequate in quality and quantity such that it should only be used in the context of research. Although the institute does not regulate medical devices, this conclusion amounts to a de facto ban on vaginal mesh use for pelvic organ prolapse (see joint RCOG/BSUG statement at http://bit.ly/2BBL3zZ). This does not cover abdominal mesh surgery for pelvic organ prolapse, and mesh can be used to treat stress urinary incontinence.

The NICE conclusion followed the Scottish Mesh Report (released in March 2017), a cross-party campaign to the Houses of Parliament in London in October 2017 to push for a suspension of mesh use and full inquiry, and the BBC documentary “The Operation That Ruined My Life” which showed that tension-free vaginal tape (TVT-secure) was only tested on 31 women before it was licensed for use.

The implications for this ban, which may spread to other countries, are two-fold. First, for Urogynaecologists looking after patients, they must comply with the new regulations. They will need to provide full information to enable informed consent and offer other treatment options, such as fascial repair, sacrospinous fixation as well as abdominal, laparoscopic and robotic surgery. Local guidelines and patient information leaflets will need to be updated. Patients having complications related to mesh

surgery will need to be looked after by multidisciplinary teams in centres with relevant expertise. Second, for the profession as a whole, the role of patient pressure groups and politicians in reaching this ban should not pass unnoticed. Traditionally, the profession was trusted to look after patients and ensure that only safe and effective treatment is offered to them. The principle of self-regulation, through research and audit, needs to be strengthened; as such a move should have come from the medical profession in the first instance. The search for safe and effective mesh continues through proper scientific research.