By: Our Medical Expert

In response to the article:

ARTICLE - EUROPEAN UROLOGY JOURNAL - SYNTHETIC VAGINAL TAPES - PROPOSALS FOR IMPROVED REGULATION

Direct Link:

http://www.europeanurology.com/article/S0302-2838(11)00868-2/fulltext

It is a very good article and demonstrates that the profession is beginning to recognise the problem. It does call for a National Register. This is a major step forward. The BAUS and the BSUG would not produce such an article unless they had serious concerns.

There are, however, many more questions and points that need to be considered:

1. The paper describes the MHRA meeting. Will the MHRA now put the article or a warning notice on their website? This has now been done please click to read www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-M-Z/Syntheticvaginaltapesforstressincontinence/index.htm >>>

2. I have been in contact with the MHRA and they are keen to set up a National Register. Although the BAUS and BSUG should promote such a Register, it is essential that there is input from those who do not have a vested interested in promoting this surgery.

3. The article states that the MHRA know that there has been considerable under-reporting. They state 42 reports in 2010. If you look at the suggested problems to be reported, then I would say that there are probably at least 42 such problems per year in each large hospital!

4. There is no suggestion that a Register should be retrospective. However, these devices have been in use for 15 years and there is a need to address those already affected. This could be achieved by launching a national recall letter to patients similar to the recent practice with metal hip joints.

5. The article does not deal with the use of mesh for vaginal prolapse. This is important as the FDA has effectively banned its use except in clinical trials. This use of mesh has become quite widespread in the UK. Should the MHRA issue a warning , similar to the FDA, about this use?

6. The article does not really deal with one of the major problems i.e. lack or sufficient information to obtain valid consent prior to the operation and lack of detailed explanation about the potential serious side-effects and the discussion of alternative management options. This is very important because it is one of the main complaints heard from patients who ask why they were not properly informed about the risks.

7. The article does deal with training and competence but does not make sufficient recommendations about the need for multi-disciplinary urology – uro/gynaecology teams to deal with difficult cases and to manage those affected by serious complications. There are still too many surgeons working on their own especially in the private sector.

8. The article does not deal with the exaggerated success claims made by some surgeons on their private practice websites. These websites often quote unproven personal subjective figures which are way above the published objective results in published journals. The article also does not deal with the unfortunate tendency for some surgeons to ' pass the buck ' when faced with complications of their surgery.

9. Finally, the European Urology Journal is not widely read among urologists in the UK and I doubt if many UK uro/gynaecologist's ever look at it. A statement from the MHRA, BAUS and BSUG via the Royal Colleges and NICE or NPSA would be more widely seen. It should be mentioned in the BMJ News Section. Certainly, every UK NHS Trust Clinical Governance Lead, Medical Director and Women's Health and Urology Clinical Directors should see this article.