Long-term efficacy and complications of a multicentre randomised controlled trial comparing Retropubic and Transobturator Mid-Urethral Slings: a prospective observational study.

Wael Agur[1]

[1]University of Glasgow

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Letter to Editor: Long-term efficacy and complications of a multicentre randomised controlled trial comparing Retropubic and Transobturator Mid-Urethral Slings: a prospective observational study.

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Congratulations to the authors on publishing a robust long term follow up of a randomised controlled trial on the use of mesh tapes for the treatment of stress urinary incontinence in women.

With regard to safety, the authors report the risk of moderate to severe pain as 14% (17/121) and describe it as '*uncommon*' . Such description does not appear in line with the 2015 Guidance on Obtaining Consent from the Royal College of Obstetricians & Gynaecologists (1). According to the Guidance, a 14% risk is '*very common* ' and carries the colloquial equivalent of '*one in a family* '.

The risk of all-severity chronic pain was not directly mentioned in the paper, but it appears to be 17.5%. If this figure is correct, the team looking after the NHS Patient Information Leaflet (2) on mesh tape surgery would consider updating the risk of chronic pain. Currently, it is '*common*' after transobturator tape and '*uncommon* ' after the retropubic tape. The authors' conclusion on the importance of careful counselling could not be overemphasised.

A key finding of the long-term study is the loss of the recognised and significant short-term difference in chronic pain between the two mesh procedures. Most shorter-term trials, and subsequently their systematic reviews (3), had consistently favoured the retropubic procedure over its transobturator variant when chronic pain is considered.

In addition, many shorter-term trials(3) reported higher risk of voiding dysfunction with the retropubic tape, giving surgeons the impression of it being more obstructive than the transobturator variant. How would the authors explain the loss of such significant differences in their long-term study and also the more bothersome OAB symptoms in the transobturator group?

With regard to efficacy, the difference in the primary outcome (Patient Global Impression of Improvement, PGI-I) was not significant, suggesting a similar overall effectiveness of the two procedures at 12 years. Using*cure* as a study outcome, however, led to the conclusion of superiority of the retropubic procedure. Most relevant qualitative studies had confirmed that improving, rather than curing, incontinence may be adequate for many women(4). Therefore, the authors' application of a slightly different outcome that carries a strict definition of cure may have unnecessarily disadvantaged the transobturator variant.

Finally, the authors appear to confidently extrapolate the mostly favourable results from the patient-reported PGI-I scores to indicate satisfaction. As a marker for clinical improvement, the PGI-I scores may or may

not directly correlate with overall *satisfaction* with the surgical procedure, which is a wider concept that extends to safety matters amongst others.

Offiah & Freeman study is indeed a landmark that is expected to change Clinical Guidelines and to influence the national discourse on continence mesh surgery in the UK and beyond.

References

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