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 their 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 severe chronic pain with retropubic Tension-free Vaginal Tape (TVT) as 4.8% (3/63) and describe it as '*uncommon'*. Such description does not appear to agree with the Guidance on Obtaining Consent from the Royal College of Obstetricians & Gynaecologists (1). According to the Guidance, a 4.8% risk is '*common*' and carries the colloquial equivalence of '*a person in street*'.

For both procedures, retropubic and transobturator, the risk of moderate to severe pain is 14.0% (17/121). According to RCOG Guidance(1), such risk is '*very common*' and carries the colloquial equivalence of '*a person in family*'. While the risk of all-severity chronic pain was not directly mentioned in the paper, it appears to be 18.2% (22/121). If this figure is correct, do authors recommend updating the national Patient Information Leaflet on continence mesh surgery(2)? Currently, the Leaflet describes the risk of chronic pain as '*uncommon*' after the retropubic procedure and '*common'* after its transobturator variant. 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 groin pain is considered.

In addition, many shorter-term trials(3) reported a higher risk of voiding dysfunction with the retropubic procedure, giving surgeons the impression of it being more obstructive than its 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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4. Robinson, D; Anders, K; Cardozo, L; Bidmead, J; Dixon, A; Balmforth, J; Rufford, J. What Do Women Want? Interpretation of the Concept of Cure. Journal of Pelvic Medicine and Surgery: November 2003 - Volume 9 - Issue 6 - p 273-277.