Sounding Board

EDITORIAL

NEUROUROLOGY & URODYNAMICS

TOTAL TAPE BAN: NOT THE ANSWER!¹

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On 10th July, 2018, it was announced that all mid-urethral slings (MUS – known commonly and defined¹ as “tapes”) for stress urinary incontinence (SUI) would be suspended (“paused”) in England for at least nine months². This appears to follow sustained public criticism by patients in regard to complications. An extension of this measure to Northern Ireland appears likely. It comes after the suspension of continence tapes for use in Scotland in 2014³, a ruling (reportedly) reversed in March

2017⁴. The English ban brings to reality the scenario addressed in an article published below in this journal's current issue "What if there were no tapes"⁵. At the time of preparation, the article was semi-speculative in response to regulatory changes and restrictions on all mesh and certain tapes (those without sufficient scientific evidence) in Australasia^{6,7}.

The article examines the significant benefits of tapes over a full range of alternate surgeries for SUI. It concludes⁵: "In the haste for some countries to severely restrict or abandon the use of tapes for SUI, authorities should be cognizant that they are leaving their incontinence sufferers and the clinicians who treat them with overall inferior surgical treatment options. The experience of many clinicians with any of these alternate options might be little or none. The inherent danger to patients with surgeons returning to these options may be far greater than leaving in use, tapes of proven efficacy and safety". The proviso would be that the surgeons would be appropriately qualified and have sufficient ongoing experience in SUI surgery using tapes. It is to be noted that, on 2013-2014 figures, 24 tapes are inserted in England for each alternate continence procedure⁸. Re-learning traditional procedures would be a challenge for most surgeons with variable "learning curve" morbidity.

We recognise that it is undesirable that women should be left with ongoing and difficult-to-treat pain issues, if this was a significant consideration in the English decision. An extensive Cochrane review⁹ of transobturator (side-to-side through the obturator space) tapes showed 2-21%⁹ of women developed significant post-surgical groin or limb pain. Seklehner et al¹⁰ reported neurological symptoms (groin or thigh pain or associated neurological symptoms) were nearly three times more common after the transobturator tapes than the retropubic tapes and occurred in 9.5% of those having obturator MUS's. As the management of groin pain after transobturator tapes is challenging, the surgery to totally remove the tapes is difficult and the outcomes unpredictable¹¹⁻¹³, women need to be fully informed prior to considering the transobturator tapes.

A total ban on all tapes will, however, leave incontinence sufferers (13-45% of an adult female population¹⁴ or 40% persistent after childbirth¹⁵ with up to 20% requiring surgery¹⁶) and their surgeons with no “first-line” minimally invasive surgical option.

What then, are the regulators’ respective stances internationally (outside of England) with regards to pelvic floor prostheses? The position in *Australia and New Zealand* since early 2018 has been similar: a clear distinction has been made between tapes for SUI and “mesh” for pelvic organ prolapse (POP). Transvaginal mesh will be unavailable whilst the range of “tapes” will be limited to those with sufficient scientific evidence of safety and efficacy^{6,7}. The Australian Commission on Quality and Safety in Health Care have completed their review of tapes for SUI¹⁷ and have preferenced towards retropubic mid-urethral slings for SUI over the transobturator tapes based on the data presented above. This seems an appropriately measured response and allows an avenue for change in the pathway as evidence and data matures. The so called “mini-slings” are excluded due to the lack of quality data. New surgical accreditation guidelines have been introduced dependent on surgical volume and training amongst other criteria.

With regards to *North American* regulators, the U.S. Food and Drug Administration (FDA)¹⁸ in July 2011 re-classified transvaginal mesh used specifically for POP as “high risk” whilst maintaining tapes used for SUI as “low risk”. They state on their website that “The safety and effectiveness of multi-incision slings (tapes) is well-established in clinical trials that followed patients for up to one-year.” The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)¹⁹, American Urogynecologic Society (AUGS)¹⁹, supported by other professional bodies, and the American Urological Association (AUA)²⁰ released position statements strongly supporting the FDA decision in regard to tapes for SUI.

In a recent development (June 2018), the FDA²¹ re-classified the manual surgical instruments used in most pelvic floor surgical prostheses from Class I to Class II, requiring much greater evidence of their

safety and efficacy for substantial equivalence in premarket notification. Distribution of those tapes involved²² has stopped, temporarily withdrawing them from the market.

In 2010, Health *Canada*²³ issued a Notice to Hospitals (NtH) alerting surgeons about complications associated with transvaginal mesh use for SUI and POP and continue to monitor complications of these procedures. Thus, neither mesh nor tapes are currently banned in North America.

In 2015, the *European Commission*²⁴ enquiry on the safety of surgical meshes supported the use of tapes for women seeking surgery for SUI. They qualify this by stating that health professionals must be appropriately trained in the procedure.

We maintain the view expressed in our article⁵ regarding the safety and efficacy of retropubic tapes in experienced surgical hands and their superiority over other continence procedures and we are fully supportive of audited practice. Banning all continence tapes we believe is regressive and “not the answer”: it limits the choices for women seeking surgical relief for SUI whilst exposing them to possible additional morbidity and poorer outcomes associated with alternative options.

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