

PE1517/H

NHS Lothian Letter of 21 June 2014

Andrew Howlett
Assistant Clerk
Public Petition Committee
The Scottish Parliament

21st June 2014

Dear Mr Howlett,

Thank you for the opportunity to provide a response to the Scottish Parliament Public Petition PE1517 on Polypropylene Mesh Medical Devices on behalf of NHS Lothian. We are fully aware of this petition and have watched the video session of the parliamentary petition group.

First of all, we would like to express our sincere sympathy to the women who have brought forward this petition and who have obviously been severely affected by complications of their surgery. As medical professionals, we endeavour to manage any complications of interventions in the best possible manner.

We share the concerns that some women may not have been comprehensively counselled prior to their surgery regarding potential outcomes, complications and alternative surgical and non-surgical options of management. In Lothian, we have introduced a comprehensive patient information leaflet for the synthetic mid-urethral sling (SMUS) procedure to treat stress urinary incontinence (also called tension-free vaginal tape (TVT)), which all patients receive when the procedure is offered. In addition, a further checklist detailing possible adverse events is completed when consent is taken. We fully support the efforts of the Short Life Working Group (SLWG) convened by the Deputy Chief Medical Officer at request of the Health Minister and the Scottish Government. The SLWG is issuing a standard patient information leaflet for SMUS, which is currently in the proof stage for publication, and is working on further leaflets for prolapse surgery.

The Scottish Pelvic Floor Network (SPFN), as a Scottish national body, has issued a statement (as attached) reinforcing the advice from the Royal College of Obstetricians and Gynaecologists (RCOG) and the British Society of Urogynaecology (BSUG) to adhere to the NICE guidelines in the management of stress urinary incontinence and pelvic organ prolapse. These specify that all suitable treatment options ought to be offered to women prior to undertaking and obtaining consent for surgery.

The SPFN statement proposes mandatory reporting of complications to the MHRA and encourages surgeons to regularly audit their outcomes. It fully supports the use of a national registry for all surgical procedures for incontinence and prolapse with or without the use of mesh devices, and urges Scottish health boards to facilitate this via the Caldicott Guardians. Use of such a registry would capture all procedures employing mesh devices including their postoperative complications, and would therefore make these specifically amenable to audit.

In Lothian, we concur with the SPFN statement and its proposals. We are also supportive of members of the SPFN who are actively involved in creating best available evidence for management of incontinence and prolapse. The SPFN has a pivotal role in leading high quality nationally funded and ethically approved research projects, currently investigating both surgical (SIMS Trial) and conservative (OPAL Trial) options for management of stress urinary incontinence. Patient reported outcomes and experiences are the primary outcomes assessed in both these clinical trials. The report of a large UK randomised controlled trial investigating the value of mesh in the management of prolapse (PROSPECT) is also currently in preparation. We agree with the petitioners that advice given to patients should be based on best available evidence from the results of independent research.

Due to best available evidence, we continue to support the use of SMUS in the management of stress urinary incontinence. We would like to highlight that, contrary to the proposal by the petitioners, there is a fundamental difference between the SMUS procedures for stress urinary incontinence and the transvaginal mesh (TVM) procedures for the management of prolapse. Although they are both made of the same synthetic material (Type 1 polypropylene), they differ significantly regarding the amount of mesh material used, the technique of insertion and the evidence for safety and effectiveness.

In Lothian, a total of 20-30 procedures have been performed using TVM for prolapse operations. After 2011, the use of TVM for prolapse was discontinued as a result of concerns over complications.

Over 2000 SMUS operations have been carried out in Lothian since 2001. Data from 2007-2013 on mesh removal suggest that <5 women required a partial removal and <5 women a total removal of mesh material following a SMUS procedure, with 1335 such operations being performed over the same period of time. These figures suggest a mesh specific complication rate of <1%, which is consistent with the medical literature.

We have not become aware of significant issues with chronic pain following the SMUS procedure. Over the years, probably less than 10 women have presented with this problem.

All surgical intervention carries risks of adverse events and unsatisfactory outcomes. Alternative surgical procedures for stress urinary incontinence (colposuspension / autologous fascial slings) do not utilize mesh but also use non-dissolvable suture material with associated risks. Risks common to all continence procedures such as difficulty with bladder emptying, irritable bladder symptoms, pain on intercourse have been reported to occur more commonly in the alternative procedures than in the SMUS procedures. As stated above, mesh specific complications following SMUS occur in <1% and certainly not at the frequency of 20% as quoted by the petitioners. Overall, evidence suggests that SMUS have the most favourable risk benefit profile of all continence procedures, and we therefore certainly do not support the ban of these devices.

Once again, we would like to emphasize that we aim to base our recommendations and advice to patients on the best available evidence from medical literature, high quality medical research focused on patient-reported outcomes and clinical expertise. Whilst we sincerely sympathize with the suffering of the petitioners, we do not support their quest for a generalized ban of a procedure, which has been demonstrated to be safe and effective over many years in the literature and in our experience.

We hope this is helpful to the Scottish Parliament Public Petitions Committee in making recommendations for future practice.

Yours faithfully,

Dr Julia Wilkens, Urogynaecologist

Dr Simon Nicholson, Urogynaecologist

Mr. Ammar Alhasso, Consultant Urological Surgeon in Female Urology,
Urodynamics and Reconstructive Urology

Mr. Laurence Stewart, Consultant Urological Surgeon in Female Urology,
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SCOTTISH PELVIC FLOOR NETWORK (SPFN) STATEMENT

THE USE OF SYNTHETIC MID-URETHRAL SLINGS FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

June 2014

“In line with the National Institute of Clinical Excellence Guideline CG171, the Management of Urinary Incontinence in Women, the SPFN supports the use of Synthetic Mid-Urethral Slings in surgical treatment of stress urinary incontinence in women wishing to proceed for surgical treatment after failure of the conservative treatment options. The SPFN also supports the current credible medical research in this field.”

Dear SPFN Member,

This statement is issued in response to the recent media attention regarding the use of transvaginal mesh (TVM) for treatment of pelvic organ prolapse (POP) in women; this has later extended to include the use of synthetic mid-urethral slings (SMUS) for treatment of stress urinary incontinence (SUI). The Scottish Health Minister has recently announced, without discussion with health professionals, the decision to suspend the use of TVM and SMUS throughout NHS Scotland.

The above has led to increasing concerns to women awaiting surgical treatment for SUI and POP. There are also concerns at senior management level in some health boards about potential increase in litigations. Legal liability for individual health boards has been largely related to the adequacy of pre-operative counselling and provision of information to patients.

The SPFN emphasizes that patients should be provided with the appropriate information and counselling regarding procedure-related risks, outcomes, and alternative treatment options. This will enable patients to make an informed choice regarding their treatment and fully consider the implications of different surgical and non-surgical options available. The SPFN stresses that the information given to patients should be based on the best available medical evidence, rather than anxieties arising from media attention and/or from litigations.

The SPFN has been working with the Scottish Government and representatives of the mesh-injured women within a Short-Life Working Group (SLWG) that started in 2013; a comprehensive patient information leaflet on SMUS has recently been produced. Pathways for management of POP and management of TVM complications will be available from the SLWG later this year. The SPFN recommends to its members the use and implementation of these documents.

In providing evidence for best practice, it is most important to recognize the fundamental differences between (a) SMUS used for treatment of SUI and (b) TVM used in POP surgery. Although they are both made of the same synthetic material (Type 1 polypropylene mesh), they vary significantly regarding the volume of mesh used, the mode of insertion and the availability of supporting evidence for their safety and effectiveness. An overwhelming wealth of medical evidence supports the use of SMUS as a first line surgical treatment for SUI in women wishing to proceed to surgery after failure of conservative management. The current robust medical evidence¹⁻³ shows that SMUS are both safe and effective minimal invasive procedures with similar efficacy and significantly less rates of peri-operative morbidity and earlier recovery, compared to the alternative surgical procedures such as Burch Colposuspension (open and laparoscopic) and

autologous slings. The FDA⁴ has recently proposed to reclassify TVM for treatment of POP to level III i.e. high-risk procedures. FDA clarified that the reclassification does not apply to SMUS for SUI or mesh for other indications, such as abdominal sacrocolpopexy and hernia.

In line with the National Institute of Clinical Excellence (NICE) Guideline CG171 “The Management of Urinary Incontinence (UI) in Women”³, the SPFN supports the use of SMUS for surgical treatment in women with SUI. Implementation of the NICE guideline has been specifically supported in a letter by the Medical Director NHS England in December 2013; supported and co-signed by the President of the Royal College of Obstetricians & Gynaecologists (RCOG), the chairmen of the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS). Similarly, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)⁵ and the American Urogynaecological Society (AUGS) jointly with the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)⁶ have issued position statements in March 2014, supporting the use of SMUS in treatment of SUI in women based on the best available evidence. Most recently, the International Urogynaecology Association (IUGA) has also drafted a similar statement.⁷

The SPFN proposes that MHRA reporting of complications should be made mandatory. The SPFN also encourages its members to regularly audit the results of the surgical procedures performed for SUI and POP, preferably using a national registry (BSUG/BAUS), and to discuss the audit results during their annual appraisal. The Health Boards in Scotland are urged to facilitate the introduction of national registries to routine practice.

The SPFN continues to lead the way in creating the best available evidence for surgical and conservative treatment options for SUI and POP in women, through high quality nationally funded and ethically approved research projects. The SPFN currently leads 2 large multicentre HTA-funded clinical trials in the field of UI in women: (a) The “SIMS Study” investigating the best type of SMUS to be performed in women with SUI. The SIMS trial aims to assess if a “mini-sling” with 50% less mesh volume, robust anchoring mechanism and performed with less invasive surgery can lead to improved outcomes in women undergoing surgery for SUI; (b) The “OPAL Study” investigating the optimal regime for pelvic floor exercises and biofeedback for non-surgical treatment of SUI in women. Patient-reported outcomes, complications, and effect on patients’ urinary symptoms and quality of life are the main end points of both studies emphasizing that patients’ experience and satisfaction are at the centre of SPFN-led medical research. Many units in the UK are recruiting centres for both trials; the SPFN recommends that eligible patients are offered to participate and welcomes the Health Minister’s decision to exempt approved medical research (SIMS Study) from the decision of mesh suspension.

The SPFN will continue to (a) support healthcare professionals in managing their patients with SUI and POP according to the best available clinical evidence, and (b) empower patients with high quality medical information that would enable them to make an informed decision regarding their treatment options.

Kind Regards
SPFN Steering Committee

References:

1. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub2.
2. Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspension, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. Eur Urol. 2010; 58: 218-238
3. <http://www.nice.org.uk/CG40>
4. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm395192.htm
5. <http://www.ranzcog.edu.au/media/statements/1355-ugsa-ranzcog-supports-the-use-of-mid-urethral-slings-in-the-surgical-management-of-female-stress-urinary-incontinence.html>
6. <http://www.augs.org/guidelines-statements>
7. <http://www.iuga.org/?page=slings>