Canadian Urological Association
Position statement on the use of transvaginal mesh

July 2016

Blayne Welk
Western University

Kevin Carlson
University of Calgary

Richard Baverstock
University of Calgary

Stephen Steele
Queens University

Greg Bailly
Dalhousie University

Duane Hickling
University of Ottawa

Introduction

- Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are common conditions that can have a negative impact on a patient's quality of life. An estimated 1 in 5 women will undergo surgical treatment for one of these problems in their lifetime.[1]
- Based on the successful use of synthetic mesh in other surgical fields, transvaginal mesh procedures were developed to treat both SUI and POP. The initially reported advantages associated with transvaginal mesh procedures included a reduced operative time, shorter hospital stay, and quicker patient recovery. In addition, these procedures were initially thought to provide a more consistently effective and durable surgical result.[2]
- In the mid-1990s, transvaginal synthetic mesh sling procedures for SUI were developed. In these procedures, surgeons place a long narrow strip of mesh under the urethra in a tension free manner using trocars passed via the retropubic or transobturator route. In principle, these slings are meant to provide a backboard of support which allows for appropriate urethral coaptation during activities that increase intraabdominal pressure such as cough, sneeze, laugh or physical exertion.
- Transvaginal mesh kits for prolapse were developed in the early 2000's to reduce compartmental pelvic prolapse by recreating normal pelvic floor supports via placement of a square or trapezoidal sheet of mesh with securing arms beneath the vaginal wall with the aid of specialized designed trocars.
- Health Canada issued a Notice to Hospitals in 2010 (and updated in 2014) regarding the use of transvaginal mesh for the treatment of female SUI and POP. The statement regarding the use of transvaginal mesh for prolapse states that there may be a higher rate of complications compared to traditional operations which do not use synthetic mesh. The statement regarding the use of transvaginal mesh for prolapse and stress incontinence specified that these procedures may lead to complications which may not be fully correctable with additional surgery, and that surgeons should have adequate training in transvaginal mesh, and be familiar with the device warnings and techniques.[3]
- Regulatory warnings, media interest, and high profile stories of patient complications have led to widespread awareness of the potential negative aspects of transvaginal mesh. Often the distinction between the different procedures involving transvaginal mesh is not clear, leading to confusion among patients.[4]

Regarding the use of transvaginal mesh for female SUI

- An extensive body of literature supports the routine use of full length transvaginal retropubic or transobturator mesh slings for SUI. This procedure is the most common SUI procedure, is appropriate for almost any patient with SUI and is the most commonly performed SUI procedure in North America. Studies have suggested that these procedures are generally as effective, or sometimes more effective than traditional SUI operations.[5]
- Very rare, but serious complications such as injury to other structures during trocar passage, intraoperative placement or post-operative migration of the mesh into the urethra or bladder, and vaginal or pelvic pain have been reported. These outcomes may not be fully correctable even with additional surgery.[6] Serious adverse events such as ureteral injury, fistula, pelvic pain, and wound complications requiring reoperation can also occur with traditional non-mesh based SUI procedures.[7]
- Transvaginal mesh slings should not be used in women with urethral diverticulum, urethrovaginal fistula, urethral injury or prior transvaginal mesh complication (such as pain, or mesh erosion).
- Numerous organizations support the use of full length midurethral mesh slings for SUI including American College of Obstetricians and Gynecologists, The American Urogynecologic Society, The International Urogynecological Association, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, and the American Urology Association.
- When a transvaginal SUI procedure is offered to a patient, she must be informed of potential procedure-specific and mesh-specific complications. The 2014 Health Canada Advisory should be disclosed to patients. Surgeons performing these procedures should be adequately trained in SUI surgery, and specifically trained in the sling technique they use. They should be capable of recognizing, diagnosing and treating potential mesh-related complications associated with their procedure.
- Further evidence is required before a statement applicable to non-full length transvaginal mesh sling (such as the shorter “mini-slings”) can be made.

Regarding the use of transvaginal mesh for POP

- The currently available literature does not support the routine use of transvaginal mesh for prolapse repair. This recommendation does not apply to the use of transabdominal mesh used during a minimally invasive or open sacrocolpopexy.
- Although fewer women have symptomatic prolapse after transvaginal mesh repair compared to traditional repairs, the magnitude of this difference is small.[8] In addition, women have an over 2-fold higher risk of additional surgery, primarily from the unique risk of mesh removal or revision. The treatment of these complications is often technically challenging, and may not fully correct the associated symptoms.[9] Studies from both Canada and United States suggests that the use of transvaginal mesh procedures for POP is becoming less common.[10,11] Placement of transvaginal mesh may still be indicated in select cases, for example in the setting of recurrent prolapse where an abdominal sacrocolpopexy is contraindicated.
- Other organisations have also suggested that the routine use of transvaginal mesh for prolapse repair is not warranted (such as the Royal College of Obstetricians and Gynaecologists and the British Society of Urogynaecology and the American College of Obstetricians and Gynecologists), and the US Food and Drug Administration has classified transvaginal mesh used for prolapse as a high risk device and has required additional safety studies within the next 3 years.
- When a transvaginal prolapse procedure is offered to a patient, she must be informed of potential procedure-specific and mesh-specific complications, and the rationale for the use of mesh should be explained to the patient. The 2014 Health Canada advisory should be disclosed to patients. Surgeons performing these procedures should be adequately trained in pelvic floor reconstructive surgery, including the use of specific transvaginal synthetic mesh prolapse kits. They should be capable of diagnosing and treating potential mesh-related complications associated with their procedure.

References

1. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol*. 2014;123(6):1201-1206. doi:10.107/AOG.0000000000000286.

2. Brophy MM, Klutke JJ, Klutke CG. A review of the tension-free vaginal tape procedure: outcomes, complications, and theories. *Curr Urol Rep*. 2001;2(5):364-369.

3. Surgical Mesh - Complications Associated with Transvaginal Implantation for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse - Notice to Hospitals - Recalls & alerts - Healthy Canadians Website. www.healthycanadians.gc.ca. http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php. Published May 13, 2014.

4. Brown LK, Fenner DE, Berger MB, et al. Defining patients' knowledge and perceptions of vaginal mesh surgery. *Female Pelvic Med Reconstr Surg*. 2013;19(5):282-287. doi:10.1097/SPV.0b013e31829ff765.

5. Schimpf MO, Rahn DD, Wheeler TL, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *YMOB*. 2014;211(1):71–e27. doi:10.1016/j.ajog.2014.01.030.

6. Daneshgari F, Kong W, Swartz M. Complications of mid urethral slings: important outcomes for future clinical trials. *J Urol*. 2008;180(5):1890-1897. doi:10.1016/j.juro.2008.07.029.

7. Albo ME, Richter HE, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med*. 2007;356(21):2143-2155. doi:10.1056/NEJMoa070416.

8. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev*. 2016;2:CD012079-CD012079. doi:10.1002/14651858.CD012079.

9. Menchen LC, Wein AJ, Smith AL. An appraisal of the Food and Drug Administration warning on urogynecologic surgical mesh. *Curr Urol Rep*. 2012;13(3):231-239. doi:10.1007/s11934-012-0244-2.

10. Kelly EC, Winick-Ng J, Welk B. Surgeon Experience and Complications of Transvaginal Prolapse Mesh. *Obstet Gynecol*. 2016;128(1):65-72. doi:10.1097/AOG.0000000000001450.

11. Sedrakyan A, Chughtai B, Mao J. Regulatory Warnings and Use of Surgical Mesh in Pelvic Organ Prolapse. *JAMA Intern Med*. December 2015:1-2. doi:10.1001/jamainternmed.2015.6595.