Vol. 5 Issue 1 (Sep 2016)

HSA Health Sciences Authority

MEDICAL DEVICE Alert

Safety of Transvaginal Surgical Meshes

Transvaginal surgical meshes have been used widely for urogynaecologic procedures, including repair of pelvic organ prolapse (POP) and relief of stress urinary incontinence (SUI). However, there have been global reports of serious complications associated with the use of these devices. As these devices are also registered in Singapore for use in POP or SUI, this article serves to highlight issues associated with their use and to encourage reporting of their adverse events (AE) to HSA for safety monitoring.

Use of transvaginal surgical meshes in POP and SUI

POP is a condition where the ligaments and fascia surrounding the vagina break down, leading to herniation of the surrounding pelvic organs, such as the bladder, uterus and the rectum, into the vaginal canal. Possible causes of POP include vaginal childbirth and menopause. POP may negatively impact the quality of life by causing pelvic discomfort and interfering with sexual, urinary, and defecatory functions, as well as other daily activities. SUI occurs when physical activities such as coughing, sneezing, jumping or lifting heavy objects exerts pressure on the bladder, resulting in incontinence.

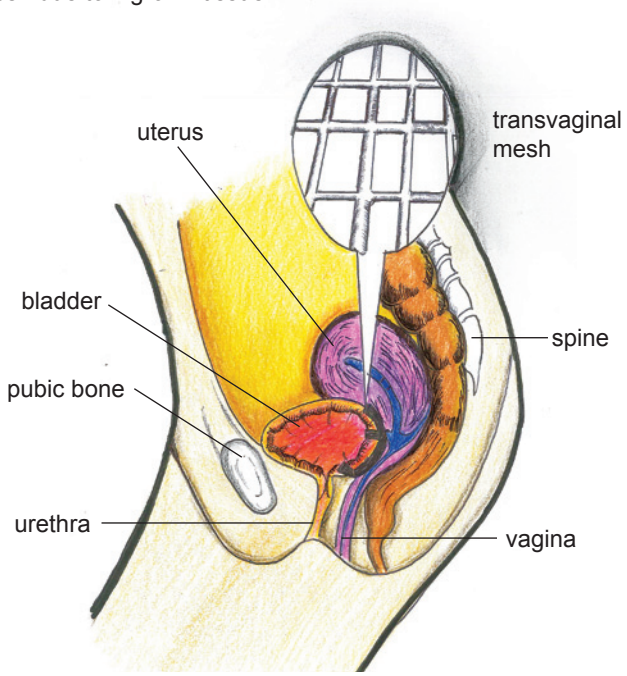
When conservative, non-surgical treatment options such as lifestyle changes and physical therapy are insufficient, surgical options may be required to repair POP or relieve SUI. These include repair with stitches or the patient's tissues (traditional non-mesh surgeries), and placement of meshes abdominally or vaginally (transabdominal or transvaginal mesh surgeries) to strengthen and support the organs. Based on a study conducted in the US, women have an estimated 11% lifetime risk of undergoing such surgeries to repair POP or SUI.[1]

Transvaginal meshes were initially embraced as a less invasive solution for POP or SUI compared to traditional non-mesh and transabdominal mesh surgeries. Transvaginal meshes are woven materials inserted vaginally to create a sling-like structure under organs needing support and are anchored by sutures or other devices to muscles or ligaments. With time, tissues grow in and fill the pores of the mesh, keeping it stable. The sling, in turn, maintains the correct position of the affected organ.

Complications associated with the use of transvaginal surgical meshes

From 2005 to 2010, the United States Food and Drug Administration (US FDA) received close to 4,000 reports of complications and injuries related to surgical mesh surgeries for POP and SUI, including death.[2] This prompted a systematic review by US FDA, which concluded that the transvaginal meshes appeared to have no advantage over traditional non-mesh surgeries for POP repair and instead, were associated with complications such as pain, erosion of the mesh into the vaginal tissue, organ perforation, bleeding, dyspareunia, urinary problems and infections. Transvaginal meshes also appeared to result in higher rates of mesh complications compared to transabdominal meshes for POP repair.

Complication rates from treatment of SUI with mesh slings were reported to be lower than their use in POP.[3] However, in comparison to traditional non-mesh surgeries, the use of mesh slings in transvaginal SUI repair introduces an additional risk of mesh extrusion into surrounding tissue.[4] When complications do arise, multiple surgeries may be required to remove the embedded mesh due to ingrown tissue.



Picture illustration of the use of transvaginal mesh in pelvic organ prolapse

International regulatory actions

The regulatory agencies in the US, Australia and Canada have issued safety recommendations to healthcare professionals and patients on the use of urogynaecological surgical meshes in order to mitigate their risks, in particular when used for POP repair.[5, 6, 7] Advisories have been issued to healthcare professionals on the potential complications with the use of transvaginal meshes, to encourage them to inform patients of these risks and to get informed consent for the use of these meshes. Implant surgeons were also advised to receive adequate training and garner sufficient experience before performing transvaginal mesh implant procedures. In January 2016, US FDA issued orders to manufacturers to strengthen data requirements for transvaginal mesh for POP repair by reclassifying their medical device risk class from moderate to high risk, as well as to require these devices to go through the more rigorous premarket approval (PMA) review route prior to being allowed market access. This is in contrast to the previous shorter approval route under 510K, which is based on evidence of equivalence to a predicate device.[8] The orders will require manufacturers to address existing safety concerns associated with the transvaginal meshes, including severe pelvic pain and organ perforation, and to demonstrate their safety and effectiveness through the PMA pathway.

Local situation and HSA's actions

HSA has been closely monitoring the safety and performance of transvaginal mesh implants supplied in Singapore and the international developments. HSA had also consulted local clinical experts regarding the safety of transvaginal meshes for POP repair. The outcome of HSA's assessment is that there are circumstances where the benefits of use of transvaginal meshes in POP may outweigh their risks, such as in patients with severe or recurrent prolapse or when alternate treatments have been deemed unsuitable.

HSA has required that locally registered transvaginal meshes for POP repair are accompanied with patient information guides. These guides contain background information on POP and its treatment options, the complications associated with transvaginal mesh procedures, the intended use of the mesh and their expected AEs. The guides will aid healthcare professionals in explaining the procedure to their patients so that they can make an informed decision on the use of these meshes.

As transvaginal meshes intended for SUI are likely to have similar associated risks, HSA is reviewing the current labelling and product information accompanying these meshes for their adequacy in highlighting associated concerns. Healthcare professionals will be updated on any local recommendations upon completion of HSA's review of the benefit-risk profile of transvaginal meshes.

Call for adverse event reporting

Healthcare professionals are strongly encouraged to report any AEs related to the use of transvaginal mesh implants to the Vigilance and Compliance Branch at Tel: +65 6866 3538, Fax: +65 6478 9069, or report online at *http://www.hsa.gov.sg/ae_online*.

References

1. *Am J Obstet Gynecol. 2003; 189(5): 1261-67*
2. *http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf*
3. *Indian Journal of Urology. 2012; 28(2): 129-53*
4. *http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/ucm345219.htm*
5. *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm*
6. *http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php*
7. *https://www.tga.gov.au/behind-news/results-review-urogynaecological-surgical-mesh-implants*
8. *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm479732.htm*

Editor-in-Chief:
A/Prof. Chan Cheng Leng, BSc (Pharm) Hons

Editorial team:
Dr Lakshmidevi Balakrishnan, PhD, RAC
Adena Lim, Bsc (Pharm) Hons, MPharm
Peck Li Fung, BSc (Pharm) Hons
Dr Sethuraman Rama, PhD, RAC
Wong Woei Jiuang, BSc (Pharm) Hons

Drawing and illustration:
Choong Chih Tzer

Please send your enquiries, comments and suggestions to:

Vigilance and Compliance Branch,
Health Products Regulation Group,
Health Sciences Authority
11 Biopolis Way, #11-01,
Helios, Singapore 138667

Tel: (65) 6866 3538
Fax: (65) 6478 9069

Website: http://www.hsa.gov.sg
Email: HSA_productsafety@hsa.gov.sg