The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Excellence in Women's Health

Position statement on midurethral slings

This statement has been developed by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG).

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1. Patient summary

Stress urinary incontinence (SUI) is an extremely common[1], burdensome and costly condition for women in Australasia, with a negative impact on a woman's quality of life. SUI is the type of urinary leakage associated with physical exertion, such as coughing, laughing and sneezing. SUI is caused by a weakness in the urethra or neck of the bladder, which means it cannot keep fully closed during exertion, allowing urine to escape.

Non-surgical, conservative measures such as pelvic floor muscle training and behavioural modifications are first line treatment options for SUI.[2] If these conservative treatments are not successful, surgery may be offered.

There are a number of different types of surgery for SUI. Midurethral sling (MUS) surgery is the most common surgery performed for SUI for women. A large number of studies have shown this surgery to be highly effective and improve women's quality of life overall.

There are three different insertion methods for these slings

- Retropubic (RPR) MUS: This is the oldest and most studied MUS. The incisions are in the vagina and just above the pubic bone.

- Transobturator (TOR) MUS: This sling has incisions in the vagina and in the groin area. Retropubic and Transobturator slings are considered 'Traditional' midurethral slings.

- Single incision (SIS) MUS: This is the newest and least studied MUS. The incision is in the vagina only. This sling is not currently approved for use by the TGA but may still be used in a clinical research trial setting for selected women.

These procedures have good success and safety profiles, however surgical failures and complications are possible. The different approaches have different risks and their use depends on patient factors and surgical experience. The type of MUS, risks and success rates should be discussed by the treating surgeon with any woman considering surgery. [3]

2. Summary of recommendations

Recommendation 1	Grade
Traditional MUS surgery is a recommended surgical procedure for SUI in routine cases. Traditional MUS is highly effective in the short and medium term for treatment of urinary stress incontinence. This recommendation is supported by the international Cochrane review Group on Urinary Incontinence. It is also supported by the European Safety Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR); to which a member of the Australian Therapeutic Goods Administration (TGA) contributed as an external advisor. [4] The MUS carries less risk than most other available major continence surgeries.[4,5]	(Grade A, Reference 3)
Recommendation 2	**Grade**
From 4 January 2018, Single Incision Slings (SIS) have been removed from the ARTG and should only be performed within the context of a properly conducted clinical. The use of currently available Single Incision Slings (SIS) have not yet demonstrated equivalence to traditional MUS. [6,7]	Consensus-based recommendation

3. Introduction

This position statement by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) supports the use of traditional mid-urethral slings (MUS) in the surgical management of female stress urinary incontinence (SUI). Mid-urethral slings are minimally invasive procedures developed in the early 1990s to treat female SUI. These slings are narrow, synthetic polypropylene tapes that are surgically placed beneath the middle part of the urethra to provide dynamic support to the urethra, preventing urinary leak during physical exertion. They have been shown to be "highly effective in the short and medium term with accruing evidence demonstrating their effectiveness long term".[3] This has resulted in MUS becoming the operation of choice in Europe, the United Kingdom, Australasia[8] and the USA[9] for treatment of SUI.

The USA Food and Drug Administration (FDA) released a white paper [10] and safety communications [11] regarding safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. A prolapse is where the pelvic organs bulge downwards giving rise to symptoms of an uncomfortable vaginal lump. Media attention on this totally distinct and separate issue of mesh use in women for pelvic organ prolapse (not stress urinary incontinence) has the potential to cause unnecessary confusion and fear in women considering MUS for treatment of stress urinary incontinence. RANZCOG strongly emphasises that the US FDA publications clearly state that traditional MUS were not the subject of their safety communication.

Further opinions from the European Commission and NHS Scottish review of current gynecological practice and of the literature regarding vaginal mesh have both supported the use of traditional MUS for stress urinary incontinence with both the RPR and TOR approaches demonstrating efficacy for the treatment of SUI with fewer adverse outcomes from MUS surgery than from other available continence surgeries such as colposuspensions and fascial bladder neck slings. [4,5]

The most recent of all the published reviews, the NHS Scottish review, does however note that the complications from each approach have different clinical implications. The risk of groin pain with the TOR approach can result in persistent groin and pelvic pain which may require the removal of the mesh. The Scottish review therefore recommended the RPR approach as routine surgery for SUI unless the RPR approach carried additional risks such as in women who had extensive abdominal surgery.[5] However, other reviews including the Cochrane review, European Commission and NICE guidance have not recommended one approach over the other at this stage. [3,4,7]

More recently there has been the introduction of single incision slings (SIS) or "mini-slings". These slings are also placed at the mid urethra with less dissection and a smaller length of mesh. The results of studies of these slings to date have not shown them to be as successful as traditional MUS. From 4 January 2018, the TGA have removed SIS from the ARTG. SIS are now only available in Australia via the Special Access Scheme and as part of a clinical trial. Until more robust data is available, RANZCOG recommends the use of single incision slings only within the setting of a properly conducted clinical trial or under strict institutional clinical governance such as a long-term prospective audit. [6,7]

In summary the different approaches to MUS include:

Retropubic MUS (RPR):

- Similar subjective and objective success rates in the short to medium term compared to TOR.[3]
- Higher success rates in women with intrinsic sphincter deficiency. (ie low midurethral closure pres-sures (MUCP) or low valsalva leak point pressure (VLPP)). These women have a higher rate of surgical failure especially with the TOR approach and the RPR is recommended in these women. [7,12]
- Higher rate of bladder perforation, major vascular/visceral injury, blood loss and longer hospital stay compared to TOR. [3] Therefore the TOR approach may be favored in women with extensive previous abdominal surgery or who are unable to cease anti coagulation.
- Higher rate of post-operative voiding dysfunction compared to TOR which may require surgical in-tervention. [3]
- Some evidence that success rate is higher in the longer term (>5 years) compared to TOR alt-hough further long term studies on the effect of these surgeries and how the insertion routes af-fect long term outcomes are required. [3]
- Less risk of groin pain compared to TOR. [3]
- Mesh exposure rate similar to TOR (approximately 2%).[3]

Transobturator MUS (TOR):

- Similar subjective and objective success rates in the short to medium term compared to RPR ex-cept in women with Intrinsic Sphincter Deficiency (ISD). ISD is confirmed on urodynamics when a low urethral pressure is found. [3]
- Less risk of bladder perforation compared to RPR however, intraoperative cystourethroscopy is rec-ommended as the consequences of not recognising this complication is serious.
- Less risk of blood loss and hematoma compared to RPR and may be considered in women who are unable to cease anti coagulation. [3]
- Less risk of visceral damage compared to RPR and may be considered in women who have had ex-tensive abdominal surgery previously. [3]
- Less risk of voiding dysfunction compared to RPR and may be considered if pre-operative void-ing is already compromised. However, consideration of not performing MUS or any continence surgery should be discussed as all continence surgeries will further compromise voiding function.

- Higher risk of groin pain at 12 months and beyond. This complication usually resolves by 6 weeks however in a small number of women this can result in persistent groin and pelvic pain which may require the removal of the mesh. Women who experience long term groin pain should be offered removal of mesh however complete removal of transobturator mesh can be difficult and in the longer term mesh removal is often incomplete.[5,7] These women may require a multi-disciplinary team care including physiotherapy with an experienced practitioner who can address pelvic pain symptoms and pain clinic team.

- Mesh exposure rate similar to RPR (approximately 2%).[3]

Single incision MUS (SIS):
SIS have been removed from the ARTG from 4 January 2018. As such, they may only be used in the context of a clinical trial.

4. Discussion and recommendations

Informed Patient Consent:

1. All women should be recommended to consult a pelvic floor physiotherapist and/or continence nurse advisor for pelvic floor exercises and bladder retraining as first line of treatment.[2]

2. Women who fail conservative treatments can be offered continence surgery including traditional MUS.

3. Prior to proceeding with surgery, urodynamic study should be considered to exclude other causes of urinary incontinence and exclude voiding dysfunction. However, the evidence regarding improvement in outcomes after urodynamic studies is lacking.[13]

4. Individual patient needs and preferences must be taken into account. Patients must have adequate opportunity to make informed decisions in partnership with heath care professionals.

5. Success rates for obese women who undergo MUS are significantly lower compared to women of normal BMI and weight loss strategies should be discussed pre and post operatively with these women.[14]

6. Success rates must be discussed with women considering surgery including the different success rates associated with each MUS route.

7. Complications must be discussed with women considering surgery including the different complications associated with each MUS route. Discussion must include bleeding, damage to the bladder and urethra, bowel and major vessel perforation. Voiding difficulties which may require catheterisation, loosening or even division of the sling at a later stage which may result in recurrent SUI.[15] Denovo urge incontinence or worsening of pre existing over active bladder symptoms can occur. Sling insertion can cause pain and dyspareunia and with the TOR, groin pain can occur. This is usually short lived but may become intractable. [3] In some women these long term adverse outcomes have had severe effects on everyday activities and their quality of life. [5] The mesh is a permanent material that can result in mesh exposure and infection which may occur soon after surgery or many years later. This can result in the need for mesh removal which may be difficult, may have complications and may not completely resolve chronic pain or other adverse symptoms.

Surgical Training:

1. As with all surgical procedures, adequate supervised training should be obtained in the particular surgical technique and device to be performed. Studies show a learning curve for all urogynaecological procedures and surgical complication rates are higher during this time. MUS surgery should only be undertaken by those regularly carrying out MUS surgery. [7,16,17]

2. Surgeons should demonstrate experience and expertise to perform intraoperative cysto-urethroscopy to evaluate for bladder and urethral integrity, and this is recommended practice for insertion of all types of MUS.

3. Surgeons should demonstrate knowledge of the management of intra and post-operative complications of MUS surgery.

4. Surgeons need to be aware of the surgical complications of MUS including the different risks of the various approaches. The RPR approach of MUS carries a higher risk of bladder, visceral and vascular injury during insertion and voiding dysfunction post operatively while the TOR approach of MUS has a higher risk of groin pain and reoperation for SUI in the longer term.[3] The TOR approach has a higher risk of failure in women with ISD and the RPR approach should be performed in these women. [7,12] The TOR approach is more appropriate if there is the risk of intra-abdominal organ injury due to extensive abdominal surgery.[5]

Monitoring of efficacy and safety:

1. As for all surgical procedures, regular clinical audit is a powerful tool for monitoring of efficacy and safety. To aid monitoring it is encouraged that surgeons performing MUS log their MUS outcomes onto a recognised database or registry and advise regulatory bodies of adverse events. [4,7]

2. All gynaecologists should be aware of and be encouraged to make full use of the ability to report adverse events from mesh surgery to the Australian Therapeutic Goods Administration at: www.tga.gov.au The link appropriate to reporting problems with a medical implant is: http://www.tga.gov.au/safety/problem.htm

3. In New Zealand, this is should be done to the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). The link is: http://www.medsafe.govt.nz/safety/report-a-problem.asp

5. Conclusion

There is robust evidence to support the use of traditional MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated surgical procedure for female stress urinary incontinence. [3, 4, 7] In Australia and New Zealand, the MUS has become the operation of choice for female SUI. RANZCOG supports the use of traditional MUS for surgical treatment when conservative treatment has been unsuccessful.

There are different risks and long term outcomes from different surgical approaches which need to be discussed and tailored to each individual woman.

Surgeons who perform MUS need to be aware of the risks and benefits of each approach and appropriately trained to perform these surgeries and manage the possible complications.

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Appendix A Full Disclaimer

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