Australian Government
Department of Health and Aged Care

Urogynaecological mesh devices (mid-urethral slings)

Post-listing review report

Contents

Abbreviations 2
Overview 3
Items in scope for the review 3
Review process 4
Methodology 4
Comparative clinical effectiveness 4
Clinical practice guidelines and regulatory advice 5
Comparative cost effectiveness 5
Cost analysis 6
Key findings of the review 6
Comparative clinical effectiveness and clinical practice guidelines 6
Comparative cost effectiveness and cost analysis 6
Stakeholder consultation 7
Key recommendations 7
Conclusion and outcome of the review 7

Abbreviations

AR-DRG	Australian Refined Diagnosis Related Groups
ARTG	Australian Register of Therapeutic Goods
TGA	Therapeutics Good Administration
HTA	Health Technology Assessment
PL	Prescribed List
PLAC	Prostheses List Advisory Committee
POP	Pelvic Organ Prolapse
MSAC	Medical Services Advisory Committee
MUS	mid-urethral slings
NICE	The National Institute for Health and Care Excellence (UK)
MDHTAC	Medical Devices and Human Tissue Advisory Committee
RP-MUS	Retropubic mid-urethral slings
SUI	stress urinary incontinence
TO-MUS	Transobturator mid-urethral slings
TOR	Terms of Reference

Overview

Urogynaecological mesh devices have been the subject of regulatory review and safety monitoring in Australia due to concerns about adverse events related to their use. In November 2017, the Therapeutic Goods Administration (TGA) removed 2 types of urogynaecological mesh from the Australian Register of Therapeutic Goods (ARTG):

1. Urogynaecological mesh inserted through the vagina for pelvic organ prolapse (POP)
2. Single incision mini-slings for stress urinary incontinence.

Mid-urethral slings (MUS) for the treatment of stress urinary incontinence (SUI) continue to be approved for supply in Australia and are included in the Prescribed List (PL).

As these devices had not been subject to a Health Technology Assessment (HTA) through the Medical Services Advisory Committee (MSAC) or the former Prostheses List Advisory Committee (PLAC) (now called the Medical Devices and Human Tissue Advisory Committee, MDHTAC), a post-listing review of urogynaecological mesh devices was recommended by PLAC at its meeting on 12 May 2022.

The purpose of the review was to assess the comparative clinical effectiveness and cost-effectiveness of MUS for the treatment of SUI, and to inform decisions regarding the associated listings on the PL.

The department published information about the PL Post-Listing Review Framework and the 4 initial review topics PLAC agreed to, including urogynaecological mesh devices, on the PL Reforms website in July 2022.

Items in scope for the review

Retropubic (RP-MUS) and Transobturator (TO-MUS) were in scope for this review. The relevant PL billing codes are shown in Table 1.

Single-incision mini-slings are not currently approved for use in Australia and are not in scope for this review.

Table 1. Devices in scope

Device	Type	Sponsor	Billing Code	Benefit
Advantage	RP	Boston Scientific Australia Pty. Ltd.	BS402	$822
Obtryx II	TO	Boston Scientific Australia Pty. Ltd.	BS403	$822
Advantage Fit	RP	Boston Scientific Australia Pty. Ltd.	BS404	$822
GYNECARE TVT™: Device Tension Free Vaginal Tape / EXACT™ Continence System	RP	Johnson & Johnson Medical Pty. Ltd.	JJ070	$822

Device	Type	Sponsor	Billing Code	Benefit
GYNECARE TVT™ Obturator System	TO (inside-out)	Johnson & Johnson Medical Pty. Ltd.	JJ442	$822
GYNECARE TVT™ ABBREVO™ Continence System	TO (inside-out)	Johnson & Johnson Medical Pty. Ltd.	MN039	$822

Review process

The department engaged a Health Technology Assessment (HTA) group to undertake this focused HTA review in February 2023. The Terms of Reference (ToR) for the review were:

1. Review the evidence base for the comparative clinical-effectiveness and cost-effectiveness of mid-urethral slings for the treatment of stress urinary incontinence (SUI).
2. Review current clinical practice guidelines, HTA and advice from international regulators on the comparative clinical effectiveness and long-term safety of mid-urethral slings for SUI.
3. Based on the findings of ToR 1 and 2, provide a report to support the department's assessment of actions or policy initiatives for mid-urethral sling devices listed on the PL that are used for treatment of SUI.

The department consulted with affected sponsors and key stakeholders (Attachment A) at various intervals throughout the review process, including eliciting feedback on the draft review recommendations to inform the final report (refer 'Consultation with stakeholders' below).

The final report was provided to the department by the contracted HTA group in July 2023.

The recommendations of the final report were presented to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) for consideration and advice.

Methodology

Comparative clinical effectiveness

The research questions to focus the review of comparative clinical effectiveness were:

1. What is the comparative clinical effectiveness of mid-urethral slings compared to the use of colposuspension, pubovaginal sling (native tissue) or bulking agents for women with stress urinary incontinence?

2. What is the comparative clinical effectiveness of retropubic mid-rethral slings compared to transobturator mid-urethral slings for women with stress urinary incontinence?

These questions were assessed using a rapid review methodology. The approach to evidence identifications consisted of:

- search of HTA agency websites
- search for clinical practice guidelines
- targeted clinical evidence scan
- review of key documents supplied by the department
- review of responses from sponsors and stakeholders.

The comparators selected for this review were:

- Colposuspension (native tissue) – a surgical procedure whereby the neck of the bladder is lifted and suspended in position using synthetic stitches.
- Pubovaginal sling (native tissue) - an abdomino-vaginal surgery using the patient's own tissue to support the urethra, with an abdominal wall fixation site. This procedure may also be referred to as an autologous fascial sling, or (autologous) rectus fascial sling.
- Bulking agents- Urethral bulking refers to the injection of a substance into the urethral submucosa at the bladder neck.

Clinical practice guidelines and regulatory advice

Clinical practices guidelines, HTAs and regulatory advice were identified from the evidence search, including information provided by sponsors and stakeholders. Only those that are recent, comprehensive and/or from Australian jurisdictions were considered.

Comparative cost effectiveness

The research questions of the review were:

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1. What evidence is available on the cost-effectiveness of mid-urethral sling compared to the use of bulking agents, colposuspension or pubovaginal sling (native tissue) for women with stress urinary incontinence?

2. What evidence is available on the cost-effectiveness of retropubic mid-urethral sling compared to a transobturator mid-urethral sling for women with stress urinary incontinence?

Can any conclusions be drawn from the evidence base for these questions?

The evidence base was assessed following a literature review of existing comparative cost-effectiveness studies and an assessment of additional evidence provided by the department, sponsors and stakeholders.

A literature search was undertaken to identify published comparative economic evaluations that focus on surgical interventions for SUI including MUS. The economic evaluations included for assessment were cost-effectiveness analyses, cost-utility analyses, and cost-benefit analyses. Studies that included only comparative cost analyses were not included.

Cost analysis

The scope of this review included an analysis of the total cost of MUS implantation for SUI in the Australian health care setting, including the cost of the device, implantation procedure and associated resource use.

Findings

Comparative clinical effectiveness and clinical practice guidelines

The findings relating to the comparative clinical effectiveness of MUS are based predominately on the 2019 NICE Guideline Urinary incontinence and pelvic organ prolapse in women: management (NICE 2019).

The evidence base supports the place of MUS in the treatment of SUI, demonstrating comparable effectiveness to alternative surgical interventions. In international analyses, MUS is cost-effective based on lower procedure costs than alternative surgical interventions.

Of the 2 types of MUS devices listed on the PL, the evidence base appears to favour RP-MUS over TO-MUS and this is consistently recommended in clinical practice guidelines. However, a role for TO-MUS appears to remain in limited clinical circumstances.

Therefore, the comparative clinical effectiveness, long-term outcomes and clinical practice guidelines are all consistent with the care pathway as specified by the Australian Commission for Safety and Quality in Health Care.

Analysis of departmental Casemix data for PL billings indicated that RP-MUS were used predominantly, with TO-MUS used in lower volumes. This was noted to be broadly consistent with the clinical evidence base and clinical practice guidelines.

Comparative cost effectiveness and cost analysis

Although cost-effectiveness analyses from other jurisdictions may have limited applicability to the Australian setting, 4 modelled economic studies that compared MUS to alternative surgical interventions all found MUS to be cost-effective. Most of the included economic studies found that cost-effectiveness was driven by the cost of the device itself or the device procedure and were limited by the extrapolation of effectiveness and complication rates over the long-term.

In considering the cost of the MUS procedure in the Australian setting, the main costs are for the device ($822 PL benefit) and the procedure, which has a total MBS cost of $1,287. Additional costs may include pre-surgical tests such as urodynamic analysis and post-surgical pharmaceutical costs. Estimates of hospital costs are uncertain as there is no specific Australian Refined Diagnosis Related Groups (AR-DRG) for the procedure.

Stakeholder consultation

The draft report outlining the proposed recommendations of the review was circulated for consultation with affected sponsors and key stakeholders between 2 June 2023 and 7 July 2023.

Noting that the recommendations suggested no change to existing listings and benefits, no major concerns were raised by stakeholders with the draft report. Two issues of note were identified during consultation:

1. There was a suggestion to consider listing RP-MUS and TO-MUS separately due to the variance in surgical technique for insertion of the 2 devices that require specific training. As the purpose of the PL is benefit setting, and RP-MUS and TO-MUS perform similar clinical functions, the recommendation that these items continue to be listed in a single group has been maintained. There was no evidence to support differential benefits, and it is considered that simplicity of the PL is a primary consideration during reform and as such, it is preferred to group like products together where possible.
2. Although evidence suggests there is a clinical preference for RP-MUS, there is a need to retain TO-MUS for some patients for whom this is the most suitable (or only) option. It was noted that a formal post market surveillance tool or registry would be a useful tool to monitor these devices.

The Australasian Pelvic Floor Procedure Registry provides data related to mid-urethral slings and this was considered in the HTA group's report, though sample sizes remain small. Ongoing post market surveillance applies to these devices and falls under the remit of the TGA as the regulator of medical devices, and, is therefore out of scope for the purposes of this review.

Recommendations

- Continue to list both RP-MUS and TO-MUS devices on the PL.
    - As both approaches are for similar clinical indications and both types of devices have similar technical characteristics there is no justification for listing them in separate groups.
    - MUS is likely to be cost-effective at the current benefit based on a lower expected procedure cost than the comparators, with similar effectiveness. The annual cost to the PL in 2021-22 was $833,000. No evidence was identified to support a change to the current benefit.
- Monitor and respond appropriately to any changes in regulatory advice from the TGA regarding the safety and performance of MUS devices
- Continue to monitor utilisation data for RP-MUS and TO-MUS devices to ensure use aligns with clinical recommendations in favour of a RP-MUS approach.

Conclusion and outcome of the review

The HTA final report was considered by the MDHTAC at its September 2023 meeting. MDHTAC supported the recommendations made in the HTA report, with no concerns raised.

Following MDHTAC's consideration, the Delegate confirmed support for the reviews' key findings and MDHTAC's advice to retain existing listings and associated benefits for all urogynaecological mesh devices currently listed on the PL.

It was further agreed that the department will consider how it may progress the 2 additional policy recommendations raised by the HTA Group as part of the review in the future, namely: monitoring and responding to relevant regulatory advice from the TGA; and monitoring PL utilisation data.

No further action was required to finalise the outcome of this review, which formally concluded in October 2023.

Outcome of the post-listing review

To retain existing listings and associated benefits for all urogynaecological mid-urethral sling devices currently listed on the Prescribed List.