



Safety of Mesh for Stress Urinary Incontinence: Fighting the Hype

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Abstract

Mesh surgery for the management of Stress Urinary Incontinence (SUI) has been used effectively and safely since the 1990's. Despite this, the Therapeutic Goods Association of Australia (TGA) has recently issued a ban on Single Incision Sling (SIS) devices due to a reported increase in post-operative complications. However, SIS devices have been found to have similar efficacy and safety profiles compared to mesh devices that have not been removed from the market. In addition to this, the Food and Drug Administration (FDA) has not issued a ban on any mesh product for SUI, linking the increase in mesh related complications to surgery for pelvic organ prolapse (POP). Mesh surgery via sling devices for SUI has been and continues to be a "gold standard" operation to manage the pathology. The purpose of this commentary is to discuss the successful use of mesh in SUI surgery and highlight the efficacy and safety profile of SIS devices.

Keywords: Stress Urinary Incontinence, Mesh Surgery, MiniArc, Single Incision Sling Surgery, Pelvic Organ Prolapse, Mesh Ban, Therapeutic Goods Administration

Abbreviations: TGA= Therapeutic Goods Administration of Australia, SUI = Stress Urinary Incontinence, POP = Pelvic Organ Prolapse, MUS = Midurethral Sling, SIS = Single Incision Sling, UDS = Urodynamics Studies, CST = Cough Stress Test, QoL = Quality of Life, FDA = US Food and Drug Administration

1. INTRODUCTION

The media-lead "vaginal mesh controversy" has prompted the Therapeutic Goods Administration of Australia (TGA) to ban many mesh products, some of which have been used effectively in the treatment of stress urinary incontinence (SUI) for many years. As justification, a recent Australian consumer group survey was highlighted, which documented more than 700 women complaining of mesh induced side effects such as incontinence, severe chronic pain, problems with walking, dyspareunia and marriage breakdown[1]. Whilst patients who have experienced unrelenting complications as a result of vaginal mesh surgery deserve our empathy, support and help, it is critical that blame is not

shifted upon all mesh-related products. The purpose of this commentary is to discuss the successful use of mesh in SUI surgery and highlight the efficacy and safety profile of SIS devices.

2. COMMENT

In urogynaecology, the TGA mesh ban primarily affects surgeries used to correct Pelvic Organ Prolapse (POP) and SUI. These two conditions are distinctly different pathologies that ought to be discussed and evaluated as separate entities[2]. Each surgery carries its own success and complication rates that cannot be combined to determine the effectiveness of mesh surgery as a whole. Despite this, the TGA has withdrawn

several mesh products from the Australian market in response to complications associated with POP. This has resulted in several effective 'gold standard' mesh-based devices for SUI being excluded from surgical practice.

SUI has effectively been managed via insertion of devices known as a Midurethral slings (MUS) since the 1990's [3]. Approximately a decade later, sling insertion was the most frequently performed incontinence surgery in Australia. The procedure has an 80-90% success rate and low serious complication rates (<1%) when compared to other urinary incontinence surgeries [2, 3]. Rates of sling division/excision and mesh erosion associated with MUS were 1-6% and 1-3% respectively [2, 4]. Despite the success and safety associated with MUS, there are several possible complications such as bladder perforation and neurovascular injury that can severely affect a woman's quality of life post-surgery. In order to reduce the incidence of these significant complications, Single Incision Sling (SIS) devices were introduced into the market. These devices have been shown to be effective in managing SUI, compared to older methods, and are associated with a decreased incidence of complications [2, 5-7]. The evidence for both SIS and MUS show that both surgical methods are efficacious with low rates of complications, when used by the appropriately trained surgeon, in the appropriate patient, for the appropriate pathology.

SIS products have also been extensively studied, with the majority of the literature showing comparable success rates to MUS of 80-90% [2, 4, 8]. A recent Cochrane review into the safety of MUS and SIS showed mesh erosion rates of 2.4% and 2.1% respectively [4]. The evidence available showed good health outcomes for patients treated with SIS, but only presented findings ranging from 6 months to 3 years. Our study and a more recent study by Lo et al., (2018) are the only known studies that have followed up patients for 5 years, providing an insight into the long-term success of the procedure. In our study, 88 women were reviewed after mid-urethral Miniarc sling placement for SUI by a single surgeon in 2001. Six weeks' post-op, patients underwent urodynamic studies (UDS), cough stress test (CST) and completed a quality of life (QoL) survey. This was then followed by a QoL survey 5 years' post-op, focusing on development of complications and overall satisfaction with the treatment. The operation was deemed successful

if a patient reported a >7/10 score in satisfaction with the surgery.

Post-op cystoscopy showed that no intraoperative complications were encountered and all patients were discharged on the day of the procedure. Evaluation of the CST and QoL surveys showed a 61.7% objective success. However, 75% of patients were free from SUI and 79% reported that they were satisfied with the surgery. The 5 year surveys reported that 42.4% of patients were free from SUI and 66.7% were better than they had been prior to the operation. Subjectively, 68.2% of patients were satisfied with the surgery. These findings are supported by Lo et al., (2018), who reported a subjective cure rate of 80% and an objective cure rate of 84.7% in their 5 year retrospective study of 85 patients.

Even though there is clear evidence supporting the success rates of both MUS and SIS, the TGA has issued a ban on SIS devices which has prompted medical device companies to voluntarily remove other mesh products from the Australian market. The TGA, in a 2017 report, stated that *"risks to patients associated with the use of mesh products as single incision minislings for the treatment of stress urinary incontinence are outweighed by their benefits"*. This statement does not appear to be supported by current evidence. Recent studies have all documented that SIS devices have a similar efficacy to transobturator and retropubic sling devices with the same, if not less, associated complications [6, 8-15]. The only evidence that exists which supports the inferiority of SIS devices has been linked to one device known as the TVT-Secure. A Cochrane Review by Nambier et al. (2017) demonstrated that this device was associated with higher incidences of vaginal mesh exposure, bladder/urethral exposure and operative blood loss. As a result of these findings, the TVT Secure was removed from the market [16]. However, the negative performance of one device cannot warrant all SIS devices being included under the same ban as POP mesh devices, which have been associated with significantly higher complication rates.

The increased POP-related mesh complication rates could be attributed to a host of reasons. Around its advent, the vaginal mesh was readily available to all surgeons and interest in mesh surgery became so great that the FDA had approved more than 100 mesh products for SUI and POP between 2002-2011 [17]. This was a critical error, as mesh started being used in higher

frequencies, often for the wrong patient and for the wrong pathology, to increase positive surgical outcomes. Unsurprisingly, the incidence of complications such as vaginal mesh erosion, pain, infection, urinary problems, bleeding and organ perforation in POP are encountered in up to 10% of patients, which is significantly greater than the complication rate associated with SIS surgery [18].

Despite the higher incidence of complications associated with POP repair, sling mesh surgery remains the 'gold standard' for the management of women suffering from SUI. The negative media attention that has grouped SIS mesh surgery and POP together has resulted in a cycle of misinformation, leading to the removal of many SUI mesh products from the Australian market without a proper evidence-based reason. The FDA, recognising the success and low complication rates for SUI has not banned any products and has only issued a warning for mesh repair for POP[18]. Despite this, the TGA, appearing to disregard the plethora of literature demonstrating the efficacy of SIS surgery continue to enforce the ban on many devices that are being used successfully with a high safety profile for the management of SUI. The evidence that supports this reason is non-existent, with the majority of randomised control trials reporting significant success and safety of using sling surgery [4-9, 13]. Our study further supports the existing literature, providing a 5year follow-up of patients receiving surgery with the MiniArc single incision system.

The main study limitation is that the population were from a single setting and were operated on by a single surgeon, hence the results may not represent the success of SIS devices in the general population or with other surgeons. This is particularly relevant to the author's study, as success rates could have been affected due to the learning curve associated with recent introduction of the SIS device into the surgeons practice. This could explain the difference in success rates between this study compared to others such as Lo et al. (2018), who reported greater success rates. Despite this difference, the success rate of the procedure by a surgeon who had only recently started using the MiniArc, highlights the potential that the device has in managing SUI in the future

3. CONCLUSION

Mesh slings have been effectively and safely used in SUI surgery since the 1990's. SIS devices were developed as an improvement to the

traditional MUS sling in order to avoid the rare, but serious complications of MUS insertion such as neurovascular injury and bladder perforation. Although the efficacy of the devices was initially affected by the learning curve associated with the new surgical technique, the majority of recent literature have documented that SIS devices are as effective and safe in the management of SUI as transobturator and retropubic MUS devices. Despite the success of SIS devices, the TGA has issued a ban on all of these products due to safety concerns, without clear evidence-based justification. Regardless of the legislation, surgeons should act in the best interests of their patients and it is acknowledged that further research is needed to firmly establish the safety of SIS devices to ensure the best outcomes for patients are achieved. It is hoped that the TGA will take note of the myriad of successful clinical trials regarding SIS surgery and take positive steps to reduce the constraints of the ban. This will allow SIS surgery to be more thoroughly investigated, ensuring that patients have the safest and most effective surgical options for the management of SUI.

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Citation: Mr Kaveshan Pather, Professor Ajay Rane, Dr Harsha Ananthram, Dr Mugdha Kulkarni. *Safety of Mesh for Stress Urinary Incontinence: Fighting the Hype*. *ARC Journal of Urology*.2018; 3(1):15-18. doi:dx.doi.org/10.20431/2456-060X.0301004.

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