Autologous Fascial Slings: a clinical update

Dalia Saidan, Karen Guerrero

Author:
Dalia Saidan,
Subspecialty Registrar,
Urogynaecology, Queen Elizabeth University Hospital,
Glasgow, United Kingdom
Email:
daliasaidan@doctors.org.uk

Corresponding author:
Karen Guerrero
Subspecialist Urogynaecology Consultant,
Queen Elizabeth University Hospital,
Glasgow, United Kingdom
Email:
karen.guerrero@ggc.scot.nhs.uk

Abstract

Introduction
Autologous Fascial Slings (AFS) were first described by Aldridge in 1942. They are recommended as a treatment option for Stress urinary Incontinence (SUI) in women by NICE.

With rising concerns about mesh implants alternatives to Tension-Free Mid Urethral Tapes are gaining popularity.

In this article we aim to update our readers on recently published studies involving the use of AFS as an alternative to mid-urethral tapes, in the management of SUI in women

Method
A literature search of Cochrane Library, Embase and Pubmed was conducted, using the keywords: Autologous fascial slings, stress urinary incontinence slings, surgery, and tension-free vaginal tape.

Findings
We identified a number of case series, however only three comparative trials were found evaluating AFS to mid urethral tapes. One trial was found comparing AFS to Burch colposuspension. We plan to discuss these in detail highlighting key learning points.

Discussion
There is limited literature comparing AFS to other surgical procedures for SUI. Key advantages appear to be offered by AFS, such as better long-term outcomes. The procedure however does have a distinct complication profile, for example, a higher risk of voiding dysfunction.

Conclusion
There is a role for AFS in clinical practice, especially in women wishing a non-mesh surgical alternative for SUI. Patients need to be appropriately counselled of the potential benefits and risks to allow informed decision-making.

Introduction

Stress Urinary Incontinence (SUI) is a common condition affecting women. It can have a serious impact on quality of life, impacting physically, socially and psychologically on women's well being (1). There are various surgical treatment options described for women in whom conservative methods have failed, many of which are routinely available and recommended (1). Synthetic mid-urethral tape is the most commonly performed operation for incontinence world wide (2), having overtaken traditional procedures (such as Colposuspension and Fascial Slings).

With rising concerns recently about mesh implant use, (3) synthetic mid urethral tapes are under scrutiny. *The European review by the Scientific committee on Emerging and Newly Identified Health Risks (SCENIHR) published a report in December 2015(2). It supported the continued use of non-absorbable mesh for stress urinary incontinence, in the context of informed consent*. *The Scottish Government commissioned an Independent review into the use and safety of transvaginal mesh for pelvic organ prolapse and stress urinary incontinence, with an interim report released in October 2015(4). The interim report recommends robust clinical governance procedures but also includes the use of MDT for decision-making and again informed consent*. Concerns still continue however, including the risk of exposure, perforation of viscera and chronic pain (3) and therefore traditional alternatives to synthetic mid-urethral tapes are once again gaining popularity (5).

Aldridge first described Autologous Fascial Slings (AFS) in 1942(6). They are recommended as a treatment option for stress urinary Incontinence in women by NICE (1) yet uptake of them is low (7). An advantage of using AFS over synthetic material is that the risk of associated with the foreign body implant are essentially eliminated, as the patient's own tissues are used. However they also provide other advantages, as well as disadvantages, to mid-urethral tapes. The traditional Aldridge sling is done through a laparotomy via a "top down" approach, using two strips of fascia with maintained medial attachment. The lateral arms are passed inferiorly, retropubically. A vaginal incision is made and a tunnel is created around the bladder neck. The fascia is brought through the tunnel and sutured in the midline at the bladder neck (8)**.** This method has been modified to the less invasive, "Sling-On-a-String" (SOAS) technique (9). The operation involves harvesting of a shorter strip of autologous material, from the rectus fascia or fascia lata. This is less invasive as a consequence, which potentially makes this technique more favourable in clinical practice.

Aim

In this article we aim to update our readers on recently published Randomised Controlled trails (RCTs) involving the use of AFS surgery for SUI, reviewing available literature on AFS and their use in clinical practice

Methods

RCTs are level 1 evidence. They are regarded as the most rigorous way of assessing whether or not a cause and effect exists between a treatment and outcome (10). A literature search of Cochrane Library, Embase and Pubmed was conducted to identify RCTs involving the use of AFS for SUI in women, within 1996 and 2016. The keywords used were: Autologous fascial slings, stress urinary incontinence slings, surgery, tension-free vaginal tape and colposuspension.

Results

Although there are 7242 thousand publications on SUI identified over this time period, we only identified 5 RCT's looking at AFS, although some have various follow-on publication of longer-term follow-up. We identified one trial comparing the traditional long slings with the modified 'sling on a string technique.' Three comparative trials were found evaluating AFS vs. mid urethral tapes. Additionally, we found one trial comparing AFS with Burch colposuspension.

Traditional Sling vs. 'Sling-on-a-Sling'

Guerrero et al (2007) (9) looked at the short, medium and long-term outcomes of the two techniques; long traditional sling vs. SOAS. 81 women (Group A) were randomized to have the full-length sling and 84 (Group B) were randomized to the modified SOAS. Primary outcomes were quality of life (QoL) scores, measured at 3months, 12months and 5years following both procedures. The Incontinence Impact Questionnaire (IIQ-7) {11} scores for Group A/ GroupB decreased from 1.91/1.85 at baseline to 0.65/0.72 at 12 months and 0.85/0.92 at +5 years. The Urogenital Distress Inventory (UDI-6) {11} scores decrease from 1.85/1.61 at baseline to 0.66/0.62 at 12 months and 1.22/1.08 at +5 years. This clearly showed a significant improvement in QoL in both treatment arms at all follow-up points. They used a strict definition of SUI and found that the incidence of recurrent SUI was 13% at 3 months, but increased over time with an incidence of 53% at +5 years.

Most importantly however they found no difference in success rates, either Qol scores or incidence SUI, between either Sling techniques at any follow-up point. The morbidity of the procedures was however different. The modified SOAS technique was quicker to perform. It was also associated with less post –operative pain and hospital readmissions due to post-operative complications. The authors therefore concluded that with no difference in efficacy, but a significant decrease in morbidity, that the SOAS should be the choice sling procedure.

Autologous Fascial Sling vs. Synthetic Mid Urethral Tapes

Three RCTs were found looking at AFS compared to synthetic mid urethral tape. Most were small and, arguably underpowered trials. Only 2 trials have published longer-term data (+ 1-yr). Wadie et al's (2005) (12) trial looked at 53 women having either a Retropubic Tension-free vaginal Tape (rpTVT) or AFS.

Follow-up was short term (12 months) with comparable outcomes: 92% cure rate with AFS and 92.9% with TVT. Amaro et al's 2009 trial (13) randomised 41 women to rpTVT or AFS. They also found no significant difference between AFS and TVT. Follow-up was only short-term. Cure rates were 71% vs. 75% at 1 month, 57% vs. 70% at 6 and 12 months and were 75% vs. 65% for AFS vs. rp TVT respectively. There were no statistical differences, however this sample size is realistically too small to detect any clinical or statistical difference in success rates. It was noted, however, that operative time was significantly longer with AFS.

Guerrero et al's published 2010 randomised control trial was designed as a powered trial to detect clinically and statistically significant differences between 3 types of retropubic slings: AFS – SOAS technique, rpTVT and Allograft Porcine Slings (Pelvicol™; Bard, Murray Hill, NJ, USA). The same standardised surgical technique was used for all 3 slings, therefore allowing direct comparison between sling materials and not surgeons or technique.

In the initial paper (14) 201 women with urodynamic stress urinary inco-

ntinence were randomised and assessed at baseline, 6 weeks, 6 months and one year after surgical treatment. The primary outcome measure was the patient reported improvement rate. The Pelvicol sling arm showed the lowest improvement rate, with only 72% of patients reporting improved symptoms at 6 weeks, with this falling to 61% and 22% at 6 months and 1year respectively. Pelvicol slings also demonstrated a statistically and *clinically* significant re-operation rate (porcine sling 19.5%, TVT and AFS 0%, p <0.0001, 95% CI) within 1-yr. Therefore, this arm of the study was suspended at interim analysis with Guerrero et al recommending that Pelvicol should not be used as a sling material for incontinence surgery.

Results between rpTVT and AFS however were more positive. At 6months, TVT and AFS had comparable improvement rates, 92% and 95% respectively, with results sustained at 1 year, 93% vs. 90%. The main difference between AFS and TVT was a longer operating time and hospital stay with AFS. Otherwise AFS and TVT were comparable in all outcomes. The only available long-term data on AFS came from this trial with the 10-year follow up data published by Khan et al in 2015 (15). 162 women (80.6%) were available for follow up at +10-yrs. Between 12 months and 10 years, there was a reduction in success rate from 93% to 73% (p = < 0.05) in the TVT and from 90% to 75.4% (p = < 0.05) in the AFS group was noted.

The re-operation rate for persistent SUI was 3.2% in the TVT arm, while none of the patients in the AFS arm required further intervention. None of the studies showed a statistically significant difference in intra-operative complications between AFS and TVT. One of the concerns about AFS is the long-term voiding dysfunction and the increased risk of long-term Clean Intermittent Self Catheterisation (CISC) rates. In Guerrero et al's paper, there is a statistically significant increase in CISC with AFS at 6-weeks post operatively; in later follow up, however, there was no statistically significant differences in CISC between the groups. Whilst this study suggested limited differences between TVT and AFS, it concluded that there was evidence that 'dry' rates for AFS were higher than TVT, and AFS should be offered as an alternative procedure to TVT.

Autologous Fascial Sling vs. Colposuspension

One trial was found comparing AFS to Burch colposuspension. The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) trial is a multicentre trial by first published by Albo et al in 2007 (16). 665 women with stress urinary incontinence requiring surgical treatment were randomly assigned to Burch colposuspension (329) or traditional AFS (326). 79% of these (520) completed follow up. The primary outcome was success in terms of overall urinary-incontinence measures: a negative pad test, no urinary incontinence (as recorded in a 3-day diary), a negative cough stress test, no self-reported symptoms, and no retreatment for the condition. They also assessed postoperative urge incontinence, voiding dysfunction, and adverse events.

At 24 months following surgery was AFS shown to be more effective than Burch colposuspension in the overall treatment of stress urinary incontinence (66% vs. 49% success rate) (p<0.001). Brubaker et al published the 5-year follow up study looking at the long-term data following this trial (17). This found that overall continence was higher in the AFS group compared to the Burch colposuspension group (30% vs. 24%) and that satisfaction was also higher in the AFS group (83% vs. 73%). The re-operation rate was lower in the AFS group compared to the colposuspension group (2% vs. 12%), (p<0.0001).

Chai et al (2009) analysed the complications of AFS and Burch Colposuspension (18), as highlighted in the SISTEr trial. AFS was associated with an increased risk of adverse events (AE) and serious adverse events (SAE). Serious adverse events included wound complication requiring surgical intervention, infections requiring operative drainage, haematomas requiring operative drainage, extrusions of vaginal sutures or mesh from abdominal sacrocolpopexies requiring operative removal, and pelvic abscesses. Adverse events included reported GI problems such as abdominal pain, and ileus. The most common adverse events were bladder related, such as urinary retention and cystitis.

The risk of developing cystitis up to 6weeks post operatively was increased in the AFS group and the risk of cystitis was increased further if the patient required intermittent self catheterisation (17% in Burch colposuspension and 23% in AFS). Concomitant surgery significantly increased the risk of serious adverse events. This trial however used the traditional AFS technique, and not the lower morbidity SOAS technique

Discussion

Many women worldwide have benefitted from stress incontinence surgery with a significant positive impact on their quality of life (5). *Informed consent is not just explaining an operation to the patient; it also includes informing the patient and offering alternatives, such as autologous fascial slings.* There is limited literature comparing AFS to synthetic mid urethral tapes or colposuspension. Most trials are underpowered, with short-term follow-up and have to be interpreted with caution. There are, however, some larger, powered trials with good long-term follow-up we can use to help us with our clinical practice.

It is important to consider from these not just success rates but also the different complication profiles of colposuspension, synthetic and autologous slings when deciding on what might be the 'best' operation. All are potential treatment options (1). In the studies that are available, there appears to be no statistical significance in short-term outcomes in terms of success of procedures AFS compared to synthetic tapes. Better efficacy is seen with AFS compared to colposuspension. Compared to Colposuspension, AFS (16) offered much better short and long term success rates, although at the cost of increased morbidity. They however performed traditional slings. Difficulties with AFS include inadequate length or poor quality of the tissue (2). Complications are due to the harvesting technique, which leads to longer operative time and hospital stay. Furthermore there is the risk of wound complications, such as infection and pain. There is also the negative cosmetic impact of a scar on the abdomen or thigh. To try and minimise these, the SOAS technique was developed.

The SOAS seems to offer same result as traditional sling, but with lower morbidity (9). SOAS appears comparable in morbidity with potentially higher dry rates even to mid urethral slings at 10 years. Perhaps by moving to SOAS procedure we are able to achieve this improved success rates compared to TVT & colposuspension, with more acceptable morbidity. Synthetic slings such as synthetic retropubic tapes or transobturator tapes offer the advantages of shorter operating times; using synthetic material negates the need to harvest tissue and the complications associated with this.

The increased initial morbidity of AFS procedures compared to TVT may be acceptable to patients in view of potential success rates and no mesh complications. As both SOAS and colposuspension

involve a similar abdominal incision it could be argued that initial morbidity would be similar anyway. Obesity and poor tissue quality (for example post irradiation) increases the risk of exposure and perforation of synthetic mesh (2). Complications due to harvesting autologous fascial slings are increased in women who are obese, or have impaired healing, for example in diabetic patients (2). Therefore, patient selection is essential, as well as robust counseling about the benefits and risks of each procedure. Ultimately this information is about patient choice. We need to discuss options with our patients and have the surgical tools available to us to deliver to them the best treatment possible.

Conclusion

Key advantages appear to be offered by AFS, such as better long-term outcomes. The procedure however does have a distinct complication profile, which includes a potentially higher risk of long-term voiding dysfunction. There is a role for AFS in clinical practice, especially in women wishing a non-mesh surgical alternative for SUI. Patients need to be appropriately counselled of the potential benefits and risks to allow informed decision-making.

References

1) Urinary incontinence in women: management. NICE September 2013 Clinical guideline [CG171]

2) Opinion on the safety of meshes used in urogynaecological surgery; Scientific committee on emerging and newly identified health risks, 2015.

3) Mesh in Gynaecological surgery, the use of. (Scientific impact paper No 19), RCOG, 2010

4) The Scottish Independent review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse.

5) Bang S-L, Belal M. Autologous pubovaginal slings: back to the future or a lost art? *Research and Reports in Urology*. 2016; 8:11-20. doi: 10.2147/RRU.S96957.

6) Aldridge A. Transplantation of fascia for the relief of urinary stress incontinence. Am J Obstet Gynecol 1942; 44:398–441.

7) Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study. *The Lancet , Volume 0 , Issue 0 ,*

8) Insertion of biological slings for stress urinary incontinence in women NICE January 2006 Interventional procedures guidance [IPG154]

9) Guerrero K, Watkins A, Emery S, et al. A randomised controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up. Int Uro- gynecol J Pelvic Floor Dysfunct 2007; 18:1263–70

10) Sibbald Bonnie, Roland Martin. Understanding controlled trials: Why are randomised controlled trials important? BMJ 1998; 316 :201

11) Uebersax JS,WymanJF, Shumaker SA, et al. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn. 1995; 14:131–9

12) Wadie, Bassem S. et al. Autologous Fascial Sling vs. Polypropylene Tape at short-term follow up: a prospective

randomized study. The Journal of Urology, Sept 2005; 174:990 - 993

13) Amaro, Joao L. et al. Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial. *Int. braz j urol*, Feb 2009; 35: 60-67,

14) Guerrero K, Emery S, Wareham K, et al. A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence. BJOG. 2010; 117: 1493-1503

15) Khan ZA, Nambiar A,et al. Long-term follow-up of a multicenter randomised controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women. *BJU Int*. 2015; 115:968–977.

16) Albo, ME et al. Burch Colposuspension versus fascial sling to reduce urinary stress incontinence. *New England Journal of Medicine*. 2007 May 24;356:2143-55

17) Brubaker, L et al. "Five Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence." *The Journal of urology*. 2012.187.4: 1324–1330.

18) Chai TC, Albo ME, Richter HE, et al. Complications in Women Undergoing Burch Colposuspension Versus Autologous Rectus Fascia Sling for the Treatment of Stress Urinary Incontinence. *The Journal of urology*. 2009;181(5):2192-2197. doi:10.1016/j.juro.2009.01. 019.

Conflicts of Interest
None

