ORIGINAL ARTICLE

Incidence of vaginal erosion with different synthetic materials for suburethral sling in the treatment of Stress Urinary Incontinence: A systematic review

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ABSTRACT

Introduction:

The aim of this systematic review is to compare the vaginal erosion rates in different synthetic materials used in suburethral slings in Tension Free Vaginal Tape (TVT-O /TOT) procedures in management of female stress urinary incontinence.

Methods: PRISMA 2009 framework was adopted for study design. Scholarly literature search was done using MEDLINE, EMBASE, the Cochrane Library and Clinical Trials.gov using selected keywords. Five articles fulfilled the inclusion and exclusion criteria. Our main outcome of interest is to review the ideal properties of the suburethral sling, procedure of insertion and post-surgical complication following the sling insertion primarily vaginal erosion. Results were compared using one way-ANOVA test and independent T- test.

Results: Total of 1725 subjects were available for analysis in the five studies. Monofilament polypropylene constituted 92.5% of the total sample size from one study alone. Polyester (n= 16/51) causes higher incidence rate of vaginal erosion compared to monofilament polypropylene (31.4 vs., 4.7; p = 0.01). There was no difference in the vaginal erosion rate between monofilament polypropylene and multifilament polypropylene (4.7 vs, 14.1; p=0.055) as well as between multifilament polypropylene and polyester (14.1 vs, 31.4; p=0.068). Although there was a marginally lower rate of vaginal erosion in TVT-O over TVT, the difference was not significant. (5.6 vs., 6.4, p=0.468). Common presentations of vaginal erosion were vaginal discharge, perineal pain and dyspareunia.

Conclusion: Given the limited sample size, polyester sling material appears to cause higher rates of vaginal erosion. No difference in erosion rate was seen between TVT and TVT-O.

KEY WORDS:
Stress urinary incontinence, Mid-urethral sling, Synthetic material, vaginal erosion

INTRODUCTION

Stress urinary incontinence (SUI) is a common problem especially among older women worldwide and affects about 30% of menopausal women.[1] Specific treatment strategies include non-invasive management like pelvic floor training, weight reduction, local estrogen therapy, invasive surgical interventions like the suprapubic Burch colposuspension and the more acceptable minimally invasive vaginal procedures using tension free synthetic tapes (i.e., tension free vaginal tape insertion i.e., TVT and TOT or TVT-O).[2]

TVT was pioneered by Ulmsten and Petros as a mid-urethral sling and later this was modified so as to make the anatomical angle less arched by passing through to the obturator foramen i.e. TVT-O or TOT.[3-6]

Increasing use of the vaginal sling procedures using synthetic materials which are commercially produced as complete 'kits' has replaced harvesting for autologous materials. The Burch procedure is less popular in view of longer operating time and recovery period and longer hospital stay. The now popular minimally invasive TVT and TOT are not without risks as complications have been reported varying from technique related visceral injuries involving bladder, urethra, bowel and large vessel related to needle insertion to complications due to synthetic materials used in slings which include hematoma, infections, urinary obstruction, dyspareunia, abscess and vaginal erosions. Both host factors and synthetic materials have been implicated in the development of complications which are not uniformly reported in the literature. Other complications of these procedures like recurrence of SUI and postoperative voiding difficulties again are not reported uniformly so as to determine a cause –effect relationship.[3,8]

Mesh quality and its safety remains a contentious subject. Vaginal erosion is a known complication and this again lacks uniformity in the way they are reported in the literature. Erosion could be categorized as exposure, extrusion or perforation though the International Urogyaecological Association advice avoiding use the generic term 'erosion'. It would be prudent for clinicians to describe the complication and try to determine a probable cause as to its etiology. This can be difficult as alluded to above. Host

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factors like age, premorbid state, state of vitality of vaginal and endopelvic tissues and synthetic materials used need to be considered. The duration of follow up is also a determining factor. Follow up for cure rates and complication rates vary a great deal from months to more than a decade in some small series.

The safety and efficacy of commonly used synthetic materials have been studied and current views are that Type 1 monofilament and multifilament polypropylene are preferred because of their pore size (>75µm) which facilitate host-tissue growth better than Type II and III where the pore size is <10µm and <1µm respectively promoting bacterial growth leading to higher infection rates. An ideal synthetic sling material should be inert, sterile, non-carcinogenic and mechanically tough so as to reduce foreign body reaction and reduce the risk of 'vaginal erosion'.[2,3,7,8]

The aim of this focused systemic review is to compare erosion rates, as defined broadly above, arising from suburethral sling insertions for SUI between TVT or TOT (TVT-O) and the synthetic materials used in commercially available kits.

METHODS

The study was based on conventional approaches to systematic reviews. Literature search was carried out using four computerized databases i.e., MEDLINE, EMBASE, the Cochrane Library and Clinical Trials.gov. Studies done from 1st January 1990 till 31st July 2014 published in the English Language were extracted. Selection of articles were carried out based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2009) criteria. PICO was used for the eligibility criteria of our articles. The MeSH terms used were 'stress urinary incontinence', mid-urethral sling', synthetic material' and 'vaginal erosion'. Other terms used singly or in full sentences included 'suburetharal sling', 'TVT', TOT', TVT-O', polypropylene' polytetrafluoroetheylene' 'polyethylene tetraphtalate' and 'polyester'. We also reviewed the reference list in the articles for eligible studies fulfilling the inclusion criteria. Initially we analyzed the abstracts of articles and only randomized controlled trials, retrospective and prospective cohort studies which fulfilled the inclusion and exclusion criteria were included as shown in Fig.1

Inclusion Criteria:

i. Women with stress urinary incontinence who underwent sling procedures using either TVT or TOT/TVT-O
ii. Sling materials made from any one of these i.e., polypropylene, polytetrafluoroethylene (PTFE), polyethylene tetarphtalate or polyester

Exclusion Criteria:

i. Case reports
ii. Mixed urinary incontinence
iii. Direct intra-operative vaginal injury due to placement of sling
iv. Women undergoing concomitant surgery along with sling procedure e.g., pelvic organ prolapse

Two groups of researchers were involved i.e., Group A, two members and Group B, three members. The selected articles were equally distributed between the two groups for evaluation and data entry. Each group was to assess selected articles and summarise the following information:

i. Study design and year of publication
ii. Materials used for sub-urethral slings (polypropylene, PTFE, polyethylene tetraphtalate, polyester)
iii. Procedure employed in insertion of sub-urethral sling (TVT or TOT/TVT-O)
iv. Postoperative outcome focusing on vaginal erosion defined as any two or more of the following:
    - Palpable tape and vaginal discharge
    - Local pain, vaginal discharge and urinary infection
    - Dyspareunia due to tape placement
    - Protruding mesh detected at vaginal examination

After the first evaluation of articles by group A the articles were cross-checked with the other group (group B) for congruence, supervised by the lead author. Any non-agreement was resolved by discussion of with the lead author. Our main aim of interest were the 'ideal properties 'of the synthetic material used in tape, type of procedure employed i.e.. TVT or TOT/TVT-O, and postoperative complication so as to calculate the vaginal erosion rate. Final agreement for the objectives was reached by consensus.

Statistical Analysis:

A descriptive analysis is used as the mainstay of our research study design. The data obtained from the various sources were extracted and statistical analysis done with SPSS Statistics V 22. The mean score for vaginal erosion for each type of synthetic material was determined using the formula:
Mean score for vaginal erosion= Number of vaginal erosion cases /Number of synthetic materials used

Mean score of vaginal erosion for each type of procedure was determined by the formula:
Number of vaginal erosion/Number of procedures involved.

Vaginal erosion rate for each type of synthetic material as well as each procedure were then determined using the formula:
Vaginal erosion rate (%) = Means score of vaginal erosion X 100.

The difference between mean scores of vaginal erosion were then tested using Independent T-test when independent variables involved two levels and the one-way ANOVA (analysis of variance) test was used when independent variables involved three levels respectively. The statistical test of significance was fixed at $p<0.05$. Homogeneity of variance was tested using Leven's test and Welsh test was used in circumstances where assumption of homogeneity of variance was violated. Post hoc comparison using the Games Howel test was performed to test possible combinations of groups to determine where the significant differences are located. The mean score of vaginal erosion among the different synthetic materials as well as different procedures were plotted using bar charts representing the standard errors of mean respectively.

Table I: Characteristics of studies included in systematic review.

Studies	Types of studies	Intervention	Types of synthetic material used	Sample size	Number of patients with vaginal erosion (%)	Symptoms of vaginal erosion	Period of presenting symptoms of vaginal erosion	Management
Kokanali M, et al 2014[9]	Retrospective cohort study	TVT (n=566) TOT (n=873)	Monofilament polypropylene (TVT®)	1439	TVT- 20 (3.5%) TOT- 41 (4.7%)	- Palpable tape - Vaginal discharge/ bleeding - Dyspareunia - Asymptomatic (Tape extrusion found in vaginal examination)	N.R	N.R
Kaelin-Gambirasio I, et al 2009[10]	Prospective cohort study	TOT	Monofilament polypropylene (TVT-O® & Aris®)	157	TVT(O)- 3 (5.4%) Aris - 11 (10.9%)	- Tape extrusion - Abscess - Dyspareunia - Perineal pain - Obturator abscess	Mean=11 months (Range 1 - 37 months)	N.R
Domingo S, et al 2005[11]	Prospective cohort study	TOT	Multifilament polypropylene (Uratape®)	43	5 (11.6%)	-Vaginal discharge - Perineal pain - Abscess	Mean = 9 months (Range 2 – 19 months)	Partial (n=1) or complete (n=4) sling removal
Siegel A, et al 2005[12]	Retrospective cohort study	TVT	Multifilament polypropylene (Intravaginal slingplasty IVS®))	35	6 (17.1%)	- Vaginal discharge - Pelvic pain - Dyspareunia - Sling extrusion - Pelvic mass	Mean = 9 months (Range 2 -15 months)	Complete sling removal (n=6)
Govier F, et al 2005[13]	Prospective cohort study	TVT	Silicone-coated polyester (Lift®)	51	16 (31.4%)	- Sling extrusion - Vaginal discharge/ bleeding	Mean = 5 months (range 2 - 7 months)	Complete sling removal (n=13) Partial sling removal (n=3)

TVT- tension-free vaginal tape; TOT- transobturator tape; N.R- not reported.
Aris,TVT, TVT-O, Uratape, IVS, Lift - Trade name for synthetic material

Table II: Pooled data of types of material and procedures

Types of synthetic material	Number, N_1 (n = 1725)	Number of vaginal erosion, N_2 (n =102)	Mean score of vaginal erosion, $\frac{N2}{N1}$	Vaginal erosion, rate $\frac{N2}{N1}$ x100%
Types of synthetic material				
Monofilament polypropylene	1596	75	0.047	4.7
Multifilament polypropylene	78	11	0.141	14.1
Polyester	51	16	0.314	31.4
Procedure				
TVT	652	42	0.064	6.4
TOT	1073	60	0.056	5.6

RESULTS

Our search initially identified 283 studies. However, 256 were excluded as these studies included surgical procedures for treatment of stress urinary incontinence in women without the use of TVT or TOT/TVT-O, utilization of non-synthetic materials for sub-urethral sling procedure or there was no mention of the incidence of vaginal erosion rates. Of the remaining 27 studies, 22 were excluded because they were case reports, small sample size or the use of sub-urethral slings no longer in use, leaving with five analyzable studies that met the inclusion and exclusion criteria.

Table I summarizes the characteristic of each study included in this review which consists of three prospective and two retrospective studies. Total number of subjects was 1725. However, 1439 of these subjects came from one study (i.e., Kokanali et al.) and this was a retrospective study. All studies used either TVT or TOT/TVT-O. The synthetic materials used in sub-urethral slings were monofilament polypropylene or multifilament polypropylene polyester. The rate of vaginal erosion pertaining to each material was calculated for each study respectively.

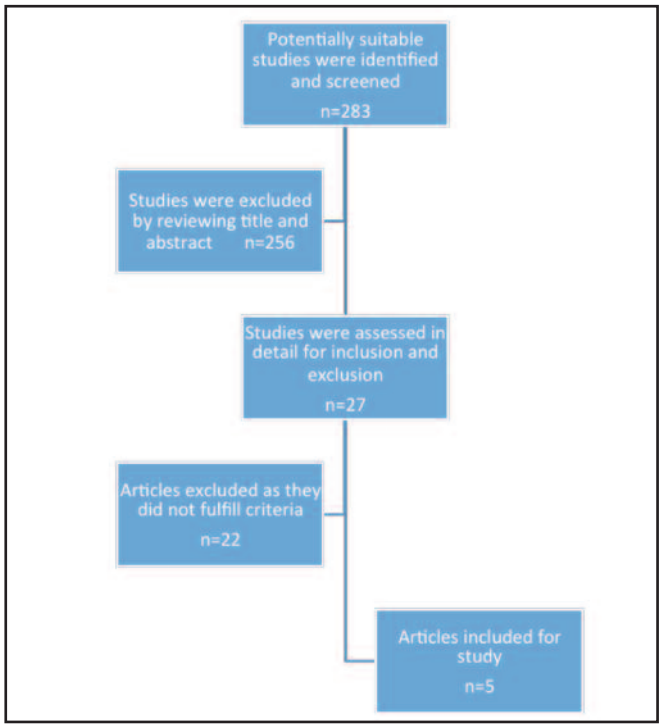

Fig. 1: Study selection flow chart.

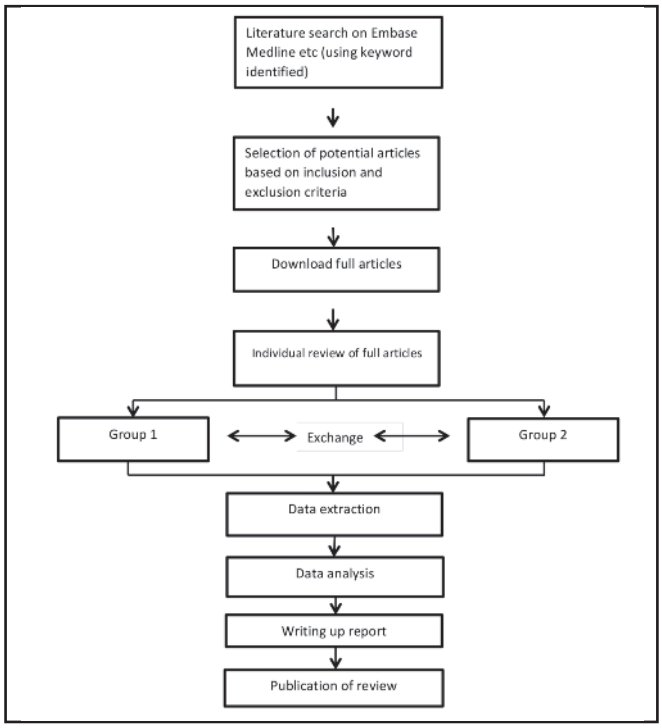

Fig. 2: Study Design.

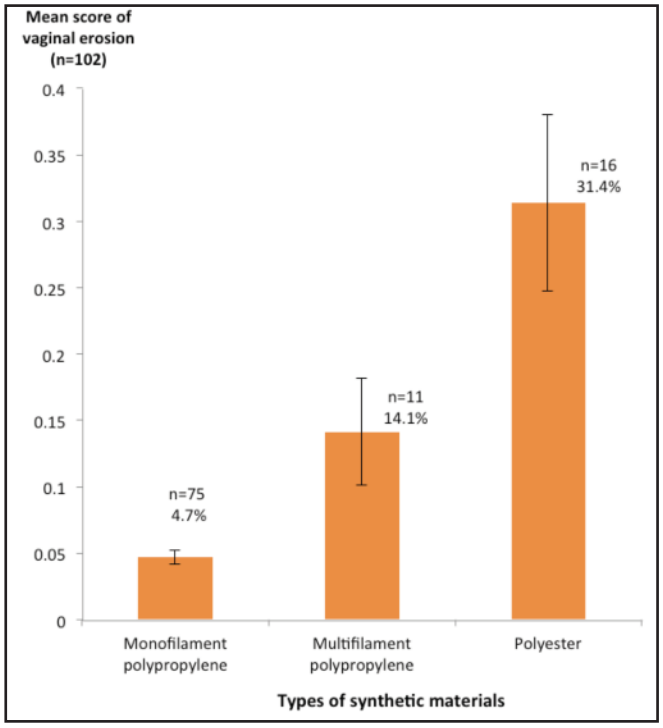

Fig. 3: Vaginal erosion among different synthetic materials in suburethral sling
n = Number of vaginal erosions in each synthetic material
Figure in percentage represents vaginal erosion rate in each synthetic material
Error bars represent standard error of mean

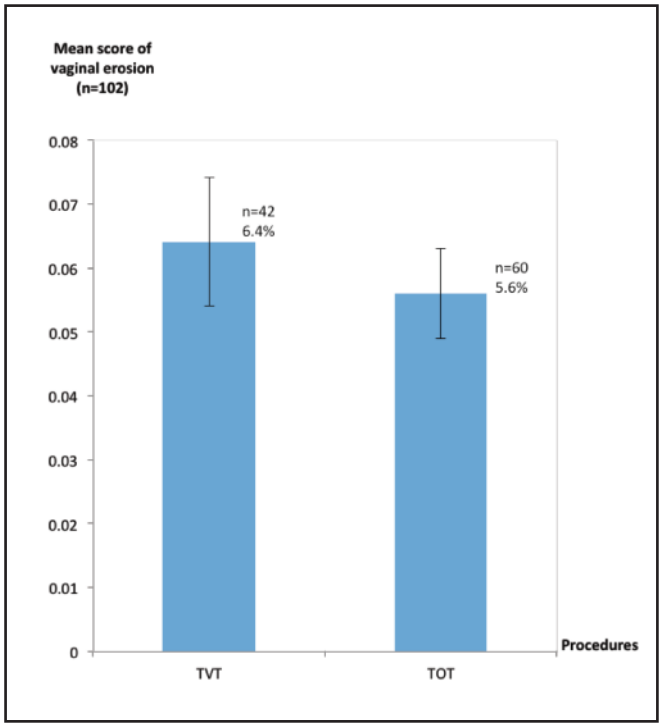

Fig. 4: Rate of vaginal erosion for TVT and TOT
n = Number of vaginal erosions in each synthetic material
Figure in percentage represents vaginal erosion rate in each procedure.
Error bars represent standard error of mean.

We noticed a wide spectrum of severity of vaginal erosions; most patients had little to no trace of vaginal erosion but a number of them reported vaginal discharge or vaginal bleeding, vaginal pain after insertion, localized abscess, pelvic mass, dyspareunia, palpable tape or tape extrusion observed at vaginal examination. The mean duration of presenting symptoms of vaginal erosion after placement of sling ranged from 5-11 months. Sling removal for vaginal erosion was either partial or complete.

The sample size of procedures and types of synthetic materials used for sling procedures as well as number of vaginal erosion for each procedure are shown in Table I. Table II shows the pooled data of number of vaginal erosions occurring with respect to the types of synthetic materials and procedures involved derived from Table 1. Bar charts based on results shown in Table II are shown in Fig. 3 & 4.

A one-way ANOVA was conducted to compare the vaginal erosion rates among different synthetic material used in sub-urethral slings. There was a statistically significant difference in the vaginal erosion rate ($p<0.05$) among the synthetic material used ($p=0.01$). The assumption of homogeneity of variance showed Levene $(2,1722) = 95.972$; $p=0.0$ proving that the assumption was violated as there was statistical difference. Robust test of equality of means (Welsh Test) showed that there was a significant difference among the three types of materials used ($p=0.00$). Post hoc comparisons using the Games Howel test indicated that the mean score for the polyester (mean=0.314±0.469; standard error of mean=0.066) was significantly different compared to monofilament polypropylene (mean =0.047±0.212; standard error of means =0.005; $p=0.01$). However, the vaginal erosion rate of multifilament polypropylene (mean=0.141±0.35; standard error of mean=0.04) did not significantly differ from monofilament polypropylene ($p=0.055$) and polyester ($p=0.068$). These results are shown in Figure 3. The bar chart with error bars represent standard error that illustrate the mean score of vaginal erosions among monofilament polypropylene, multifilament polypropylene and polyester. Considered together, these results indicate that vaginal erosion rates are higher in the polyester group compared to polypropylene (31.4% vs., 4.7%) when used in both TVT and TOT/TVT-O procedures. This is mentioned with caution as the sample size in the polyester group is small.

An independent student T test was conducted to compare the vaginal erosion rates between TVT and TOT/TVT-O procedures as treatment for stress urinary incontinence. There was no statistically significant difference in the mean vaginal erosion rates between TVT and TOT/TVT=O (mean =0.064±0.246, standard error of mean =0.010 vs., mean =0.056±0.230; standard error of mean= 0.007; $p=0.468$) respectively.

Fig. 4 shows a bar chart representing standard error to illustrate the mean score of vaginal erosion rates between TVT and TOT/TVT=0 ; there were no significant difference between the two types of procedure. The prevalence of postoperative vaginal erosion rates in women who underwent sub-urethral sling procedures in the studies evaluated between October 2001-October 2013 was 5.9% (59/1000).

DISCUSSION

The majority of literature on stress urinary incontinence focuses on comparing the surgical techniques for the treatment of stress urinary incontinence in women with little data regarding the types of synthetic material used for the sling.

From this review we deduce that polyester sling appears to be associated with a higher incidence rate of vaginal erosion compared to monofilament polypropylene. However , we are severely limited by the number of studies (i.e. five only) that we have been able to include in this systematic review with only one study by Govier F et al (2005) which reported on silicone coated polyester. Though this was a prospective study, the sample size was small (n=51). Current literature relates mechanisms of vaginal erosion to variations in the mechanical properties of synthetic materials used in the sling. Generally, vaginal erosion is said to be related to poor incorporation and decreased ingrowth of sling material into the surrounding vaginal and endopelvic tissue. Consequently subclinical infection results resulting in poor wound healing which subsequently leads to erosion of the vaginal epithelium. The type of filament in the mesh plays a pivotal role in determining the overall function of sling material with regards to durability, tensile strength and foreign body reaction. Multifilament such as Lift® (polyester) and Uratape® (polypropylene) have 'small interstices' which can easily harbor micro-organisms while preventing access of key immune cells such macrophages and fibroblasts leading to local infection and risk of vaginal erosion of the tape.[1,14] This observation is supported by Siegel A et al. who showed that multifilament composition of mesh sling predisposes to higher rates of vaginal extrusion due to high rate of defective vaginal wound healing.[12]

Monofilament polypropylene used in TVT®, TVT-O® and Aris® constitutes single polypropylene filaments that have relatively larger pore size (75-100µm). Larger pore size is associated with lower rate of vaginal erosion since infection rates are reduced with the entry of macrophages and leukocytes, facilitating vascular and tissue ingrowth into the sling material.[2,3,8] Pore size of these dimensions provides large space for collagen deposition; which aids in promoting tissue incorporation. As a result of this there is good integration of the sling onto the surrounding tissue literally 'fixing it in to place'.[7,15,16] On the other hand , sling material with smaller pore size (<10µm), such as multifilament polypropylene and multifilament polyester, may allow micro-organisms which are approximately 1µm in size to enter the mesh but the larger macrophages and lymphocyte measuring 50µm are prevented from entry.[8,11,17] Apart from that, ingrowth of fibro-collagenous tissue are affected leading to proper mesh integration.[7]

Weave type of the sling material is yet another property that needs consideration as loose knitted mesh is frequently associated with increased elasticity and porosity facilitating the sling material to integrate well into the surrounding vaginal tissue.[18,19] On the other hand, non-knitted mesh is stiff and inelastic which affects 'conformation to the surrounding tissue' compared to knitted mesh described above.[18] Another factor that affects integration into biological tissues is additives or coating on the sling material. As pointed out in Govier's study, use of silicone coating on the

sling material such as polypropylene and polyester, is associated with higher rates of vaginal erosion. Smoothening of the surface by silicone-coating 'effectively closes the pores of mesh decreasing tissue ingrowth while inducing an inflammatory response'. These factors affect adversely, incorporation of the mesh into the surrounding tissues.[7,17,20] Incorporation of silicone, antibiotics and collagen have 'protected the slings from erosion, extrusion and subsequent sling excision'.[20] Govier's argument in incorporating silicone coats is that partial or complete removal of silicone coated polyester sling is easier when vaginal erosion or complications arise as fibrosis is less complete in these cases.[13]

Table III summarizes the currently used synthetic materials used in TVT and TOT. [2,7,8,17-19,21,22] This systematic review shows the common presentations of vaginal erosion are vaginal discharge, perineal pain and dyspareunia.[9,13,18] However, there were patients who presented without any overt symptoms as reported by Kokanali M et al. In these patients, mesh erosion was discovered through vaginal examination and cysto-urethroscopy.[9] Obturator abscess is a rare presentation.[5] Dyspareunia is one of the symptoms in vaginal erosion and it impacts negatively on the quality of life, with a reduction in satisfaction rate overall.[10]

Risk factors related to vaginal erosion are classified into three categories: impact of patient demography, material used in sling and surgical technique. Older age, diabetes mellitus, high body mass index, smoking and previous vaginal surgery for incontinence increase the risk of mesh erosion.[9,23,24] Older women, especially after menopause, have lower collagen content and have increased collagenase activity. Co-morbid factors mentioned weaken incorporation of sub-urethral sling into the endovaginal and vaginal tissues. Surgical incision length exceeding two centimeters at the vagina increases the risk of vaginal erosion. This may be related to greater vaginal vascular damage and poor wound healing.[9,15] Kaufman et al., reported that frequent sexual activity in young women increases the risk of mesh erosion in their review.[25] Preoperative optimization of co-morbids, weight reduction and improvement of vaginal mucosa with estrogen may need to be evaluated in future studies as to decreasing vaginal erosion rates.

Based on the analysis of the five studies that we have included, although there was a marginally lower rate of erosion in TOT versus TVT, the difference was not significant (p=0.468). A meta-analysis comparing sling erosion between retropubic versus obturator mid-urethral slings by Schimpf M et al. demonstrated lower rates of sling erosion, need to return to the operating room for treatment of sling erosion, groin or leg pain, and vaginal perforation in the retropubic procedure as compared to the obturator approach.[26] Another meta-analysis by Latthe et al., showed that the incidence of mesh erosion is higher in TOT compared to TVT.[27] A probable explanation for this may be that vaginal sulcus trauma may be more in TOT.[28] Both these observations contradict our results. This may be due to small sample size in our study and the potentially biased data in the retrospective studies with one study having the major number of patients. Larger properly designed prospective studies stratifying for the variables stated above with regards to host factors , material used in sling and defined complications of sub-urethral sling are needed to show any significant difference and to influence clinical practice.

Conventional approaches to management of mesh vaginal erosion may be conservative in the immediate postoperative stage. However when there are persistent symptoms or there is infection and or extrusion of the sling material, it should be surgically removed. Application of estrogen cream to the surgical site at time of surgery is suggested to promote healing of the vaginal epithelium. In patients with vaginal erosion after polyester mesh procedure, Latthe recommends conservative office treatment if the erosion is less than 5 mm and excision of the mesh with 2-layer repairs only if 6 to 30 mm of the tape is exposed.[27] Such guidelines may be cautiously followed based on patient's acceptance of any disability and known information on superiority of materials used in the sling. Domingo et al. and Govier et al. advocate complete removal of tape as the mainstay of treatment for mesh erosion based on the fact mesh erosion is partially due to mesh infection and it is near impossible to completely treat infection with antibiotic therapy. Further observational studies are required as to which approach is to adopt as best practice.[8,11,13]

Implications for clinical practice

Though our study indicates that polyester in sling is associated with higher vaginal erosion rates compared to the other two studied, we need more robust studies with larger sample size stratified for the factors mentioned above. Definitions for vaginal erosion should be standardized and reporting of adverse events should be part of quality assurance in units employing sub-urethral sling. Clearly there are divided opinions in treating vaginal erosions and if all 'foreign bodies' be removed in the presence of vaginal erosions. This is yet another area for quality studies.

Limitations

There are a few limitations in this systematic review. Firstly, the studies reviewed in our paper were non-randomized controlled trials. Hence, there is potential bias in the results reported. Our review includes retrospective studies lending to inherent limitations in the information derived. A few studies did not clearly separate the statistics of vaginal erosion post-surgery in TVT and TOT procedures. This made it not possible to be include such studies in our review resulting in smaller sample size. In addition, studies on polyester used as the main component in a mid-urethral sling were scarce; only one study met our criteria for this review. Apart from that. we found the lack of availability of studies on other types of synthetic material. Hence, our review could be biased due to the information discrepancy of each material analyzed.

CONCLUSION

Given the limited sample size, polyester as a sling material is associated with higher vaginal erosion rate; probably due to small interstices affecting macrophage entry leading to increased infection rates. In contrast monofilament polypropylene had lower complication due to larger pore size. Tensile strength, pore size and host factors appear to

influence incorporation of sub-urethral slings into biological tissues. Our review did not show any significant difference between TVT and TOT with regards to erosion rates. With increasing popularity of TVT and TOT there is a need for properly designed randomized controlled trials to assist practicing clinicians in adopting appropriate sling material and surgical technique in applying slings for stress urinary incontinence.

CONFLICT OF INTEREST

None declared. The authors are not involved in the commercial purchase or use of any other of the sling materials mentioned in this review.

ACKNOWLEDGEMENT

This study was approved by the Joint Committee on Research and Ethics, International Medical University , Malaysia (IMU). We gratefully acknowledge a small fund made available by IMU for conducting this study. We would also thank Ms Natashya bte Mohd Nizar , librarian at the Clinical School , IMU for assistance in obtaining the full text articles for this systemic review.

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