General Section

Immediate and perioperative outcomes of polypropylene mesh in pelvic floor repair in a predominantly obese population

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Summary

This retrospective study was to identify perioperative and postoperative complications associated with use of polypropylene mesh for pelvic floor repair in a UK district general hospital in a predominantly obese population. The sample size was 27 women with data retrieved from records. Total mesh was used in 37.1%, isolated anterior mesh in 44.4%, and an isolated posterior mesh in 18.5%. There was a high incidence of obese (BMI kg/m² ≥ 30.0) women (66.67%). The highest recorded thus far. A high proportion of the women (44.4%) were also over the age of 65 years with attendant comorbidities. The age range was 45-77 years. Complications included mesh exposure (7.4%), catheterization at discharge (7.4%), bladder injury during dissection (3.7%) and recurrent prolapse (7.4%). In the carefully selected individuals, polypropylene mesh for prolapse repair appears to be a safe technique to correct pelvic organ prolapse. However, long-term follow-up is needed with further research.

Key words: Vaginal mesh; Pelvic organ prolapse; Predominant obesity; Immediate and perioperative morbidity.

Introduction

The first commercially available 'system' for transvaginal delivery of polypropylene mesh into the vesicovaginal and or rectovaginal plane to repair uterine and or vaginal prolapse was approved in 2004 by the Food and Drug Adminstration in the US. The system has been used in France for some time with data on follow-up being

This system has been shown to be able to provide similar results to abdominal sacral colpoplexy while precluding morbidities associated with laparotomy or prolonged laparoscopy. The system used is one of several commercially available kits which through the use of polypropylene mesh, combines apical support with reinforcement of either or both the anterior and posterior vagina.

The use of polypropylene mesh has been buttressed by the fact that the scarring and sclerosis produced by classical pelvic reconstructive surgery restores only 50% of the preoperative tissue strength [1-3].

There have been several studies examining the immediate postoperative sequelae. Further studies are compiling data on the long-term sequelae. However this study looked at outcomes in a predominantly obese cohort population.

Materials and Methods

This retrospective study was to identify perioperative and postoperative (3 months and 12 months) complications associated with use of polypropylene mesh for prolapse repair in predominantly obese patients in a UK district general hospital. The sample size included a total of 27 women between November

2006 and December 2008 and both practitioners were proficient in performing stress incontinence surgeries.

All patients had preoperative evaluation including history, physical examination and urine culture. Pelvic organ prolapse quantitative examination was a tool used in identifying degree of prolapse. The type of prolapse was identified based on definitions adopted by the International Continence Society [4]. Urodynamic evaluation was performed when indicated by

The polypropylene mesh repair procedures were carried out using the manufacturer's instructions [5]. A course of preoperative vaginal estrogen was offered on a need-to basis. All the women underwent general anaesthesia as this was the local protocol. This was also the case for excisions of persistent eroded mesh. Prophylactic antibiotics were given intraoperatively while a transurethral Foley catheter and gauze packing in the vagina were performed at the end of the procedure. The catheter and packing were left in for a period of 24 hrs. The women were discharged home without catheters on the second or third day. They were reviewed 8-12 weeks and 6 and 12 months later.

The primary outcome was deviation from a normal operative and postoperative course within 8-12 weeks of surgery. Complications seen during surveillance at 6 and 12 months in some of the women have also been included.

Complications were based on the Dindo scale of 0-5 based on therapeutic consequences of a complication. Grade I includes minor risk events not requiring therapy other than analgesics, antipyretics, antiemetics and antidiarrheal drugs while grade II includes events which require pharmacological treatment with drugs other than the ones listed for grade I complications. Interventions within grade III included the use of blood transfusions and total parenteral nutrition. This grade is subdivided into grade IIIa and IIIb. Grade IIIb required the need of general anesthesia.

Grade IV included life-threatening complications while grade V complications resulted in death [6].

Data was obtained from the review of patients' records. Results are presented as mean (range) for continuous variables and as percentages for categorical variables.

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Results

Another focus of this study was to examine if there was a difference in results in overweight and obese patients. The incidence of overweight and obese women in this population was 92.59%. There was a predominant percentage of obesity (BMI \geq 30) in this group (66.67%).

Most of the subjects were postmenopausal (88.88%) with a good percentage (51.85%) having had no previous hormonal replacement therapy. A good number of the women had previous pelvic organ prolapse repair (37.04%). Most women had grade II prolapse (66.67%). General anesthesia was utilized in all the cases.

Demographic and clinical details are in displayed in Table 1.

Table 1.— Demographic and clinical details of the study population.

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Clinical characteristics				
Mean age (range)	61.78 (45-77)			
Mean body mass index kg/m² (range)	29.8 (22-37)			
Mean hospital stay (range)	3.07 (2 -5)			
Mean estimated blood loss (range)	105.56 (50-250)			
Menopausal status (%)				
Premenopausal	11.11			
Postmenopausal	51.85			
Postmenopausal + HRT	37.04			
Preoperative stage of prolapse (%)				
Stage II	66.67			
Stage III	29.62			
Stage IV	4.71			
Previous hysterectomy	62.96			
Previous surgery for POP	37.04			

POP: pelvic organ prolapse.

Concomitant procedures, carried out in four of the cases included anterior vaginal wall repair, posterior vaginal wall repair, bladder neck buttressing and tension-free vaginal tape insertion (TVT). Total mesh was used in ten cases, anterior mesh in 12 cases while five women had posterior mesh insertion.

Mean age was 61 years with average hospital stay about three days and the average BMI being 29.8. Mean operative time was 87.48 minutes with average blood loss being 105.56 ml. The above figures were comparative with other studies examined [7, 8].

Mesh exposure was seen in 7.4% of cases at 12 weeks follow-up in our study. This was managed by excision under general anesthesia due to personal requests and reluctance to continue with topical estrogen; 7.4% went home catheterized as a result of urinary retention following a urinary tract infection; 7.4% presented with a recurrent prolapse within the 12-week postoperative period. There was also another case of recurrent prolapse following a bout of respiratory problems three months postoperatively. There was resolution of a case of mesh erosion which presented 12 months later with the use of topical estrogen cream.

A case of a promptly repaired bladder injury during dissection was seen. There was no bladder perforation with trocar insertion.

Table 2. — Type of complication in relation to type of repair done.

Complications	Total (10)	Anterior (12)	Posterior (5)	Freq (%)	Morbidity grade
UTI	1	1	0	7.4	II
Intraoperative injury	1	0	0	3.7	I
Recurrent POP	1	1	0	7.4	IIIb
Rec POP+Resp Infection	0	1	0	3.7	IIIb
Mesh exposure	0	1	1	7.4	III
Mesh erosion					
(12 months later)	0	1	0	3.7	II

POP: pelvic organ prolapse.

There was also *no incidence of hematoma or rectal injury*. No hemorrhage of more than 250 ml was recorded.

Table 2 reflects type of complication in relation to type of repair done.

Discussion

Polyprolene mesh is the most commonly used synthetic graft material used in prolapse repair surgery. Mesh exposures, erosions, infections and sinus tract formation are the most often encountered complications described [9].

In a predominantly obese population, surgical complications are bound to be on the increase. It was interesting to observe different types of morbidities seen in this subgroup of women. All the complications were found in overweight and obese women. The complications seen in the overweight group included two cases of urinary tract infection, one of intraoperative bladder injury, one of recurrent prolapse and one of mesh erosion. The obese and very obese group had two cases of mesh exposure, one case of recurrent prolapse, and one case of recurrent prolapse following respiratory infection.

The Dindo morbidity scale grades complications based on invasiveness of the successful treatment module. The common complications were recurrent prolapse (7.4%) and urinary tract infection (7.4%).

A significant number of the recurrent prolapses were from the group with a history of recurrent prolapse (37.04%). One had a conservation of cervix following a previous laparoscopic subtotal hysterectomy while the other had conservation of the uterus due to personal requests despite contrary counselling and advice. There was one presentation of a rectocele following an anterior mesh insertion three months later following a bout of respiratory infections.

Reasons for prolapse recurrences are varied and include:

- 1) Changes in stability of the pelvic floor after surgery. This has been identified by the study done by Clark *et al*. [10] which revealed a 40% incidence of recurrence post-operatively at another site.
- 2) A greater likelihood of recurrent prolapse has also been associated with age < 60 yrs and preoperative pelvic organ prolopse quantification stage 3 or 4 [3]. These characteristics were evident in this group of recurrent prolapse.

3) Inherent weak native tissues, the use of which have led to treatment failures [7]. As there was a significant number of repeat procedures for recurrence (37.04%), this may be a contributing factor.

Of the patients, 7.4% went home catheterized as a result of retention from urinary tract infection. This figure was well below the median rate of 10.9% reported after abdominal sacral colpopexy [11].

The visceral injury made during dissection was promptly repaired and a catheter was left in for a period of ten days under antibiotic cover. She was a 77-year-old woman with no previous history of hormone replacement therapy resulting in atrophic vaginal tissues. A cystogram carried out thereafter was normal.

There was no bladder perforation with trocar insertion. The rate of visceral injuries is comparative to a previously published rate of 4.0% during Prolift insertion [12] although it is higher than the 0.2% rate reported for transobturator techniques of midurethral sling placement [13]. There was also no incidence of haematoma or rectal injury. No hemorrhage of more than 250 ml was recorded. These results were better or comparative to other studies [7, 8].

Mesh exposure rate (7.4%) was relatively high in this study as compared to 4% in a post mesh insertion study involving the use of Prolift [7] or 3.7% in an abdominal sacral colpoplexy study [14]. However a recent review has shown rates to be between 4.6-10.7% [15]. The overall surgical intervention to correct mesh exposure was 7.4% and this was due to hospital protocol and personal requests. The case of mesh erosion occurred 12 months later in a postmenopausal woman and was possibly due to estrogen deficiency as this erosion resolved with the use of vaginal estrogen therapy. The rates of mesh exposure and erosion could be due to the high mean age in our cohort (61.78 yrs) and the present hospital protocol of intermittent use of preoperative vaginal estrogen on a need-to basis as opposed to a mandatory preoperative course.

Limitations of this study included the relatively small sample size and a retrospective design encouraging bias. This was reduced by data analysis from consecutive consultation notes identified on the computer records. Our findings are particular for women who are overweight or obese with a significant percentage of recurrent prolapse, adding more data regarding safety and complications of mesh pelvic floor repair systems. There appeared to be a high incidence of certain complications. Alterations in practice have been made to reduce these complications, i.e., use of preoperative vaginal estrogen therapy. We hope also to build on our areas of success via an on-going assessment of these women with the aim of following them up to 24 months postoperatively.

Conclusion

In carefully selected individuals, polypropylene mesh for prolapse repair appears to be a safe technique to correct pelvic organ prolapse. However, long-term follow-up is needed. Further research should be directed towards well-conducted and adequately powered randomized controlled trials.

References

- [1] Whiteside J.L., Weber A.M., Meyn L.A., Walters M.D.: "Risk factors for prolapse recurrence after vaginal repair". Am. J. Obstet. Gynecol., 2004, 191, 1533.
- [2] Cosson M., Boukerrou M., Lambaudie E., Lobry P., Crepin G., Ego A.: "Biomechanics of stress distribution and resistance of biological tissues: why use prostheses for the cure of genital prolapse?". J. Gynecol. Obstet. Biol. Reprod. (Paris), 2003, 32, 329.
- [3] Brenner J.: "Mesh materials in hernia repair". In: Schumpelick V., Wantz G.E. (eds.): "Inguinal Hernia Repair. Expert Meeting on Hernia Surgery". St Moritz, 1994, Karger, Basel, 1995, 172.
- [4] Bump R.C., Mattiasson A., Bo K., Brubaker L.P., Delancey J.O., Klarksov P. et al.: "The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction". Am. J. Obstet. Gynecol., 1996, 175, 10.
- [5] Manufacture's Instructions for Use guide: Gynecare Prolift Pelvic Floor Repair System: Surgical technique. Gynecare/Ethicon, Somerville, NJ, 2004.
- [6] Dindo D., Demartines N., Clavien P.A.: "Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey". Am. Surg., 2004, 240, 205.
- [7] Fatton B., Amblard J., Debodinance P., Cosson M., Jacquetin B.: "Transvaginal reapir of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)-a case series multicentric study". *Int. Urogynecol. J.*, 2006, 18, 743.
- [8] Alperin M., Sutkin G., Ellison R., Meyn L., Moalli P., Zyczynski H.: "Perioperative outcomes of the Prolift pelvic floor repair systems following introduction to a urogynaecology teaching service". *Int. Urogynecol. J. Pelvic Floor Dysfunct.*, 2008, 19, 1617.
- [9] Lo T.-S., Wang A.C.: "Abdominal colposacropexy and sacrospinous ligament suspension for severe uterovaginal prolapse: a comparison". J. Gynecol. Surg., 1998, 14, 59.
- [10] Clark A.L., Gregory T., Smith V.J., Edwards R.: "Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence". Am. J. Obstet. Gynecol., 2003, 189, 1261.
- [11] Nygaard I.E., McCreery R., Brubaker L., Connolly A., Cundiff G., Weber A.M. et al.: "Abdominal sacrocolpoplexy: A comprehensive (review)". Obstet. Gynecol., 2004, 104, 805.
- [12] Altman D., Falconer C.: "Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair". Obstet. Gynecol., 2007, 109 (2 pt 1), 303.
- [13] Sung V.W., Schleinitz M.D., Rardin C.R., Ward R., Myers D.L.: "Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis". *Am. J. Obstet. Gynecol.*, 2007, 197, 3.
- [14] Culligan P.J., Blackwell L., Goldsmith L.J., Graham C.A., Rogers A., Heit M.H.: "A randomized controlled trial comparing the fascia lata and the synthetic mesh for sacral colpopexy". *Obstet. Gynecol.*, 2005, 106, 29.
- [15] Feiner B., Jelovsek J.E., Maher C.: "Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review". *BJOG*, 2009, 119, 1.

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