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Extraperitoneal uterosacral suspension technique for post hysterectomy apical prolapse in 472 women: results from a longitudinal clinical study.

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Extraperitoneal uterosacral suspension technique for post hysterectomy apical prolapse in 472 women: results from a longitudinal clinical study.

Objectives

The study aims to evaluate the long-term results of the extraperitoneal uterosacral ligament suspension (bilateral) in women with apical prolapse following hysterectomy.

Design

Longitudinal clinical follow up conducted between June 2002 and December 2017.

Setting

Tertiary urogynaecology centre in Melbourne Australia.

Population: 472 women with symptomatic vault prolapse who underwent bilateral extraperitoneal uterosacral ligament suspension (EPUSLS). 61 %(287/ 472) of these patients had previously had a procedure for pelvic organ prolapse(POP).

Methods

Follow up using structured, standardized questionnaires and examination by POP-Q and Baden –Walker system pre-and post-operatively.

Main outcome measures

Objective and subjective outcome measures for pelvic organ prolapse were functional and anatomical results and surgical complications.

Results

Mean follow up duration was approximately 5 years. The objective success rate at vaginal cuff support was 89% (420/472). Only 4% needed revision surgery for vault recurrence. There was improvement in bladder, bowel and sexual symptoms after the procedure. Mesh exposure rate was 17% (of the 138 having mesh augmentation) with the majority of cases managed conservatively or with minor interventions. The ureteric injury rate was 1 % and mainly occurred in earlier cases. No women had buttock pain.

Conclusion

EPUSLS is an effective, suture based procedure for vault prolapse with few complications even on long term follow up. This technique avoids the need to open the peritoneum vaginally and has a low risk of ureteric injury and gluteal pain.

Funding: DK has received a research fellow grant through the Mercy Public Hospitals Inc.(MPHI) small research grants scheme for this study. There was no separate funding for the study.

Keywords Vaginal surgery; vault suspension; mesh.

Tweetable abstract:

Bilateral extraperitoneal USL suspension of vault is effective with low morbidity and high success rate.

Introduction

Vaginal vault or apical prolapse presents as a surgical dilemma and is described as the descent of the vaginal apex after hysterectomy [1,2]. The incidence is 0.2% to 43% [3–7]. The choice of abdominal or vaginal approach for surgery depends on previous surgery, factors such as age, activity level, length and capacity of the vagina, and sexual activity. Women with a short or narrow vagina and those having a concomitant abdominal surgery are often offered abdominal route [8]. Vaginal approach can consist of suture vault suspension utilizing uterosacral or sacrospinous ligaments. Vaginal mesh kits have been used for apical prolapse correction with some degree of success [9]. However, safety concerns and litigation has led to withdrawal of these products in Australia. Poor publicity and synthetic mesh complications including mesh exposure and pain has resulted in a significant consumer desire for native tissue repair alone.

High uterosacral ligament suspension (HUSLS) can be done vaginally, either extraperitoneally (not opening the peritoneal pouch) or intraperitoneally. Uterosacral ligament suspension (USLS) sutures are placed bilaterally below and posteriorly to the

ischial spine to suspend the vaginal vault. The vaginal intraperitoneal uterosacral suspension has been described in several reports as a fairly successful procedure [11]. In women who do not have an enterocele, accessing the pouch of Douglas can be challenging especially in the presence of scarring from prior surgery. Additionally, intraperitoneal USLS techniques performed laparoscopically or transvaginal have a high rate of ureteric injury, between 0% and 10.9% (12). The bilateral vaginal extraperitoneal uterosacral ligament vault suspension technique was described in 2008 by Dwyer and Fatton [13] and reported in a series of 123 patients with a mean follow-up of 2 years. There was a high success rates, low reoperation rates and ureteric injury rate of only 1.7%(14). This report from a larger sample size provides long term outcomes of this technique.

The RCOG guideline summarized that the evidence for high USLS as procedure of choice in women with apical prolapse is equivocal (15). The long-term follow up of safety and efficacy of this technique will improve the information available for surgeons and patients to make an informed decision about their operation.

Materials and methods

This is a longitudinal clinical follow up conducted for four hundred and seventy-two consecutive women who had the EPUSLS(bilateral) for vault prolapse with symptoms with or without cystocele and recto-enterocele between June 2002 and December 2017 in our unit (Melbourne, Australia). The described index procedure was performed by the senior author (PD) as first surgeon or directly supervising a consultant urogynaecologist or urogynaecology subspecialty fellow.

We administer a standardized questionnaire and examination pro forma to all our patients before the procedure and for clinical follow up (usually at 6 weeks ,6 months and then annually post operatively). Prolapse was quantified by both the Baden-Walker halfway system and Pelvic Organ Prolapse Quantification(POP-Q) classification. Only patients with at least one follow-up appointment were included in this study. All patients were symptomatic from apical and/or other compartment prolapse. The core outcome set (COS) utilized definitions and terminology as described in the joint IUGA/ICS terminology document for reporting outcomes of surgical procedures for pelvic organ

prolapse (2) The senior author's (PD) EPUSLS technique has been reported in the literature [13,16]. Figures S1-S4 show the steps of this technique. Patients provided informed consent for the procedure. Statistical analysis was performed with Student's t test and Chi-square or Fisher exact test for quantitative and discrete variables respectively. Statistical significance level was defined as $p < 0.05$ (IBM SPSS Statistics 2015 ®).

Approval for the study was obtained from Mercy Hospital Ethics and Research Committee (HREC). There was no patient and public involvement in the setting up of the research project (Supplementary material). DK has received a research fellow grant through the Mercy Public Hospitals Inc. (MPHI) small research grants scheme for this study. There was no separate funding for the study. A portion of the findings of this study were presented in the IUGA 43rd Annual Meeting in Vienna, Austria (June 27-30, 2018).

Results

Baseline data:

Table 1 describes baseline data for the study population.

Peri-operative data

In terms of POP-Q, 329 women were stage III (70%) (table 3). One hundred and thirty-eight (29%) had mesh augmentation (Gynemesh® in 64 patients, Vypro® in 69 patients, Uphold kit in 5) and 108 had a concomitant midurethral sling (23 %) for urodynamically proven urinary stress incontinence. Table 2 and results (below) shows the proportion of patients having mesh augmentation concomitantly.

Intraoperative complications included 2 bladder injuries and 1 rectal laceration, which occurred during dissection, were recognized and repaired at the time of the operation. Three bladder perforations occurred with the mid-urethral sling procedure, and the trocar was re-sited.

There were 5 cases (1 %) of unilateral ureteric obstruction, three of which were noted in the first 100 cases. In these cases, the suture was taken out and re-sited. The technique was modified by routinely retracting the bladder and ureters antero-laterally with a Briesky retractor removing them from surgical field prior to placement of the uterosacral

sutures. This resulted in reduction of ureteral injury to two over the next 372 patients. As obstruction was recognized during procedure (routine cystoscopy with intravenous Indigocarmine dye in all cases) removal of the offending suture resolved the obstruction for all cases.

There was one death 10 days postoperatively (patient with severe cardio- pulmonary disease with grade four vault prolapse and a urethrovaginal fistula preoperatively). Twenty-one patients (4%) had blood loss more than 500 ml and 12 needed blood transfusions (2%). Twenty-nine women (6 %) required intermittent self-catheterization postoperatively. Seven readmissions occurred within 6 weeks following the procedure. These were for UTI (n=4), vaginal infection (n=1) and haematomas (n=2) which were managed conservatively. Average stay period in the hospital was 5 days (range 2–12days). Buttock pain did not occur. There was no reoperation required for suture removal for severe pain.

Follow-up details:

Mean follow up duration is 63.86 months (around 5 years). Number of patients followed up over 5 years post operatively was 269(57%). Ninety-two patients had only one follow-up appointment (at 6 week).

Recurrence:

Over the study period, 113 patients (24%) experienced a prolapse recurrence with the leading prolapse at or beyond the introitus. Of these, 66 (14 %) patients required revision surgery for symptomatic prolapse recurrence, including 19 with a vault recurrence beyond the introitus (with or without anterior and /or posterior and /or enterocele recurrence) (19/472=4%) (table 4). Interval to recurrence needing surgery was from 6 months to 9 years (mean interval 3.41 years). Recurrences occurred at the previously operated compartment in 58 (58/113=51%) of patients. In the other 55 women, recurrences were in a non-operated compartment. On separately analyzing the apical compartment (vault +/- enterocele), 52 (19 needing surgery +33 not needing surgery) patients had a recurrence (11%) beyond the introitus yielding an objective success rate at cuff of 89 % (420/472).

Success rates:

Objective global anatomical success (leading point above 0 level on POP-Q) rate was 76%. (359/472) and 72 % patients (339/472) achieved the composite measure of success, ie asymptomatic, not needing revision POP surgery and leading point above level 0 (Table 3).

Outcomes between mesh augmented versus non-mesh groups:

These results have to be considered with caution due to the heterogeneity. Success rates and reoperation rates for recurrence are not significantly different between the 2 groups.

Mesh complications:

Rate of exposure of mesh was 17 % (23/138) with most detected in the first 6 months post procedure (14 women, 61%). The anterior compartment (13 women) and vaginal vault (10 women) were the most sites for exposure of mesh. Twelve women did not have any symptoms; 11 had a vaginal discharge, bleeding or pain with sexual intercourse which resolved after removal of exposed mesh. Overall, the exposed mesh was removed in 17 women and 6 had conservative management with vaginal oestrogen therapy.

Functional results

Two hundred and fifty-four patients (54%) were sexually active at baseline and 220 women (47%) were on follow up. Post operatively, 10 patients who were not sexually active before surgery participated in sexual intercourse post operatively without dyspareunia. Twenty-nine patients who were sexually active preoperatively ceased to be following surgery of which 8 cited partner impotence, significant pain with intercourse existent at baseline and unchanged post-operatively (6) and lack of sexual desire (15). One hundred and thirty-six (29%) patients reported dyspareunia at baseline and 29 (6%) on follow-up. 112 patients (82%) had resolution of pre-existing dyspareunia. Six women reported de novo dyspareunia.

Fifty-two women had stress urinary incontinence (SUI) post-procedure (including 24 with de novo SUI). Of these, SUI was treated surgically in 20 patients. Of the patients who had an operation at same time as EPUSLS, 5 had de novo voiding difficulty post operatively. Overall, 65 women (14%) reported urge symptoms on follow up, 41 of these experienced de novo symptoms. Seventy-five patients (16%) had subjective voiding difficulty - two needed urethral dilatation, one needed division of the sling.

Constipation and/or defecatory obstruction were reported by 40 % of the patients pre-operatively (188/472) at baseline and in 10% of the patients on follow up (46/472).

Thirteen patients reported flatal and/or faecal incontinence with unformed stool postoperatively: 4 had new onset faecal soiling, 2 patients had worsened flatal incontinence after surgery, 4 patients found that incontinence with unformed stool had improved following surgery, 3 patients had unchanged flatal incontinence post procedure. There was no report of sciatic or gluteal pain.

Discussion

Uterosacral ligament suspension for vault prolapse is practiced by less than 5% of gynaecologists in the UK [17]. However, the vaginal transperitoneal USLS is popular in the USA [11,12,18]. This study is the largest report of the extraperitoneal approach to USLS by vaginal route to treat vault prolapse.

Main findings

Complications of HUSLS include urinary tract or bowel injury, urinary tract infection, haemorrhage [11,12,18-20]. Suture erosion has been noted with permanent sutures. [18-20] Our transfusion rate of 2% is much lower than noted than literature [18]. We found that EPUSLS provides good long-term results with low recurrent prolapse rates and very low complication rates for treatment of post hysterectomy apical prolapse. Less than 5% of women had a middle compartment recurrence over the follow up period needed revision surgery. Over the mean 5-year follow-up period, the objective success rate is 76 %. These results compare similarly to the vaginal transperitoneal or other approaches viz. sacrospinous fixation [11,12,18-20] Trans-peritoneal USLS has been reported to achieve success rates of up to 94% to 100% [11,12,18-20].

Strengths and limitations

Our study fills the research gap for long term results on a safer and reliable alternative to transperitoneal HUSLS. One drawback of the study is the large proportion of concomitant procedures. This can be a possible source of confounding effect. Defective vaginal support may occur in any of the three compartments, apical, anterior and posterior. Large cystocele and enterorectocele frequently have significant loss of apical support. For this reason, we chose anatomical results at the middle compartment as the primary endpoint. Success / recurrence in other compartments should be interpreted with caution due to the

heterogeneity of concomitant procedures and in view of the fact that some patients had mesh augmented repair of one or the other compartment.

A major proportion of the subjects in this study had grade 3 or more vault prolapse. Objective success at the apex was 76%. There was no significant difference between the mesh and no-mesh group. Bilateral EPUSLS is a safe and successful procedure for the surgical management of vault prolapse. The advantage of this technique is that the pelvic cul-de-sac does not need to be opened and there is a lower risk of visceral injury. The risk of recurrence of anterior wall compartment is much less compared to sacrospinous fixation (discussed below). Urinary, bowel and sexual functions are significantly improved following the procedure. Earlier studies have emphasized upon anatomical outcomes. These studies have reported POP-Q stages I or 0 as success [23]. Subsequent research showed that descent distal to the hymen may be a more accurate predictor of bulge symptoms [24, 25]. In line with these, we have looked at anatomical objective measures and patient reported outcomes including functional symptoms. Our mean follow-up duration over the study period is around 5 years with about 43% patients lost to follow up beyond 5 years. The study is conducted in a single centre and all procedures performed / supervised by a single surgeon, which can potentially introduce significant bias, however this factor also allowed for standardization of this technique.

Interpretation in the light of other evidence

The recent Cochrane review [26] included three RCTs comparing Abdominal sacrocolpopexy (ASC) with SSF. Post operatively ASC had lower rates of recurrence, stress incontinence and dyspareunia. Patient satisfaction, prolapse symptoms and reoperation rates for prolapse were similar. SSF had a lesser operative time, and patients returned earlier to daily activities. A review of observational studies on SSF reported long-term success rates of 78–100% [27]. A recent trial [28] has compared HUSLS (n=188) with SSF (n = 186) in women with vault prolapse and SUI. The 2-year results showed similar success rates (HUSLS 59.2% vs. SSF 60.5%), similar incidence of serious

adverse events rates and prolapse scores at 2 years. Neurogenic pain was higher in the SSF group with a reported incidence of 12.4%.

SSF may not be suitable where vaginal length is short or where there is pre-existing dyspareunia [9,29]. Ipsilateral gluteal pain has been reported in as high as 15% of patients [30]. It also results in deviation of the posterior vaginal axis increasing the risk of recurrent cystocele [29,30,31]. Roughly half of the recurrences occur at a non-operated and previously well supported compartment.

There is no strong evidence to support routine use of mesh for apical prolapse. In our experience, native tissue repair provided good correction of prolapse in the index procedures. The commonest complication in our series is exposure of mesh in 17% of those who had it placed. This is higher than the systematic review by Feiner et al [33] but comparable to the 17.3% rate reported by Hiltunen et al [32] and lower than Hlaska et al (20%) [33]. Nevertheless, majority of cases of exposures were dealt with conservatively or by minor procedure. Since the FDA warnings [34,35] on mesh complications and following our interim audit of surgical outcomes, we no longer use mesh in the reinforcement of repairs during EPUSLS.

Bilateral EPUSLS was our first line surgical procedure for vault prolapse except in sexually active younger women when there was vaginal foreshortening, when a sacrocolpopexy would usually be offered. However, patients are increasingly requesting the avoidance of synthetic mesh either vaginally or abdominally.

Conclusions

The EPUSLS is a safe and reliable technique with high success rates and low reoperation rates for surgical management of PHVP even without mesh reinforcement.

Practical recommendations

There will be an ongoing need for both the vaginal and abdominal approaches to provide the best outcomes depending on patient characteristics, expectations and surgeon experience.

Research recommendations

Further prospective comparative studies are needed to compare the effectiveness and safety of this procedure to the other procedures for surgical management of vault prolapse.

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Disclosure of Interests

DK has received a research fellow grant from Mercy Public Health Inc. (MPHI) for this study. PD, ET, LS have nothing relevant to disclose. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to Authorship

DK: Ethics application, data collection, analyses, manuscript writing

PD: Conceived the study idea, overall supervision of study, manuscript writing, proof reading.

ET: Data Collection, proof reading

LS: Contributed to recruitment, assisted with data collection ,proof reading .

Details of Ethics Approval

The study has received full ethical approval from the HREC (Ref: RI 16/76 -13.12.2016)

Funding

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TABLE CAPTIONS:

Table 1 : Patient Characteristics

Table 2 : Index POP surgery

Table 3 : Comparison of results with or without concomitant mesh augmentation

Table 4 : Recurrences needing repeat surgery for POP

Table 1 :Patient Characteristics

Demographic	Mean(/range)	Number /percentage (n=472)
Age (years)	69.49 years (45 -86 years).	
Parity	3 (0–8)	
Weight (kg)	69.91 (48–98)	
Body mass index	27.47 (19–36)	
Menopause		443/93%
HRT		143/30 %
Prior hysterectomy		
Abdominal		283 (60%)
Vaginal		189 (40%)
Previous surgery for POP		287(61%)
Vaginal repair		244(52%)
Abdominal repair		19(4%)
Both		14(3%)

Table 2 :Index POP surgery

Index POP procedure	Number of patients	Percentage (n=472)	Notes
EPUSLS +anterior repair	124	26%	48 patients had mesh augmentation 56 patients had enterocele sac dissection
EPUSLS +anterior repair+posterior repair	208	44%	50 patients had mesh augmentation 47 patients had enterocele sac dissection 9 patients had levator plasty
EPUSLS +posterior repair	140	30%	40 patients had mesh augmentation 50 patients had enterocele sac dissection 18 patients had levator plasty
108 patients had concomitant mid-urethral slings (23%) Anal sphincter repair(n=2), Repair of urethrovaginal fistula existing preoperatively (n=2) , Haemorrhoidectomy (n=3)			

Table 3 Comparison of results with or without concomitant mesh augmentation

Mesh versus no mesh	Mesh repair (n=138)	No mesh repair (n=334)	P
Perioperative data			
Mean Age (years)	65.79	71.01	NS
Median parity	3	3	NS
Menopause	124(90%)	319(95%)	0.03
HRT	41(34%)	102(29%)	NS
Previous hysterectomy (abdominal)	77(56%)	206(62%)	NS
Previous hysterectomy (vaginal)	63(46%)	126(38%)	NS
Previous POP surgery	101(73%)	186(56%)	0.0004
Previous SUI surgery	69(50%)	32(10%)	0.0001
Preop POP-Q			
Stage 1	7(5%)	16(5%)	NS
Stage 2	34(25%)	66(20%)	NS
Stage 3	108(78%)	221(64%)	0.01
Stage 4	14(10%)	6(2%)	0.001
Mean follow up	68.11 months	62.10 months	0.07
Recurrences (>=stage 2)	30(22%)	83(25%)	NS
Further surgery for recurrence	19(14%)	47(14%)	NS

Table 4 : Recurrences needing repeat surgery for POP

Compartment	Number of patients	Percentage (n=472)
Vault recurrence (with or without anterior and /or posterior and /or enterocele recurrence)	19	4%
Anterior recurrence only; no vault or posterior or enterocele recurrence	14	3%
Posterior recurrence only ;no anterior or vault or enterocele recurrence	33	7 %

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