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Direct, Easy & Educational Sacro-Spinous Ligament Fixation: A feasibility Study

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Abstract

Importance: Sacro-spinous Ligament Fixation (SSLF) is a versatile procedure for apical suspension in cases of pelvic organ prolapse (POP). However, done with traditional approach the learning curve is long. We present here an innovative approach (Dee-SSLF), that makes the procedure easy, with fewer complications and facilitates learning for the beginners.

Objectives: We analysed the surgical outcomes and complications of Dee-SSLF in our institute in the past two years. Study Design: This is a feasibility study conducted in a Urogynecological referral centre in India. We included 21 women with POP (including vault prolapse), who underwent surgical correction, with Dee-SSLF (as a stand-alone procedure, or as a part of the pelvic floor repair), over a span of two years. All these women were followed up 6 months post-surgery. The objective success rate was determined by recurrence of POP as per the ICS definition of vault prolapse.

Results: On follow up, we noted a significant improvement in all the subjective findings. The reduction in the vaginal bulge noted at 6 months post procedure was

highly significant (p value <0.01). None of the patients in our cohort had any serious intra operative complications – like visceral and/or vascular injuries. No peri-operative blood transfusions were given.

Conclusion: Dee-SSLF can be propagated as an innovative technique for an age- old procedure. It is an easy to perform and easy to learn technique, associated with good subjective and objective outcomes, with minimal complications.

Keywords: Pelvic Organ Prolapse, Vault Prolapse, Apical Suspension, Sacrospinous ligament fixation (SSLF)

Introduction

Sacrospinous ligament fixation (SSLF) is an established effective procedure for apical suspension in cases of pelvic organ prolapse (POP). Restoration of apical support with or without other defect repairs has been a well-recognized surgical modality in treating POP to minimize its recurrence. Apical suspension procedures are commonly used for the treatment of post hysterectomy vault prolapse (PHVP). There is also increasing evidence and recommendations to use it prophylactically for complete vaginal eversion, and paravaginal defect repair. (1).

Among the various approaches used for surgical restoration of apical support, abdominal sacro-colpopexy (ASC) and vaginal SSLF are the most performed procedures. ASC is considered as the gold standard in terms of efficacy. However, considering the factors like - mesh erosion, the cost of mesh, operative time, haemorrhage, wound infection, and gastrointestinal complications, SSLF is a better option for selected population. (2)

SSLF however, has its own limitations in terms of difficult approach to the limited operative space. This limited and difficult exposure of the surgical area puts nearby structures like rectum, pudendal nerves and vessels, sciatic nerve, and coccygeal plexus at risk of injury during the procedure. Moreover, this useful and versatile surgery has a long learning curve as acquiring the skill, while doing it under direct vision has been the only realistic option. It is very difficult for the surgical assistants and the on-floor trainees to learn, as the limited surgical field poses an absolute challenge for people other than the surgeon to have an adequate visual access to this limited space. (3)

Thus, over the last few years we have developed and copyrighted an innovative technique of SSLF to optimise the surgical outcome by direct visualization of the ligament under magnification. Suture passed directly through the ligament with the help of a suture capturing device (avoiding the need of holding the ligament with another instrument) under magnification with the help of a 30-degree laparoscopy camera, ensures safety. Display of the entire surgery on the laparoscopy monitor aids the learning of surgical assistants and the other trainees who are keen on the procedure.

In the present study we have analysed the surgical outcome of Dee-SSLF in our institute in past two years.

Material and Methods

This was a feasibility study conducted in a Urogynecology (Female Pelvic Medicine & Reconstructive Surgery) Referral Centre at a University teaching hospital, over a period of 2 years from January 2021 to December 2022. Institutional Ethics Committee approval was obtained (IEC: 150/2023).

Study Population: Women with POP (including vault prolapse), who underwent surgical correction, with Dee-SSLF (as a stand-alone procedure, or as a part of the pelvic floor repair), during the above-mentioned time

frame were recruited for the study. Those who agreed to be a part of the study by attending to a follow up visit after six months of surgery were included.

Methodology

As per the unit protocol, patients posted for surgery were admitted a day prior. Detailed history entailing specific urinary, fecal, and sexual functions was recorded. A thorough physical examination including Pelvic Organ Prolapse-Quantification (POP-Q) was documented. Anesthetic clearance and medical fitness were sought prior to the surgery.

Surgical technique (Dee-SSLF): The surgery is performed under spinal anaesthesia. To approach the sacrospinous ligament (SSL) an incision is made in the middle third of the posterior vaginal wall after infiltration with diluted adrenaline in normal saline (1: 200,000). Sharp followed by blunt dissection by sweeping the finger medially is done to reach the ischial spine on the right side. This mobilizes the rectum medially. Upon entering the space, the ischial spine is identified. With further blunt dissection medially, the SSL is palpated. SSL is a fan shaped structure that exists within the body of the coccygeus muscle. It attaches medially to the sacrum and laterally to the ischial spine.

Blunt dissection is continued to ensure that the rectum is retracted medially, and the ligament is adequately exposed. Once this surgical space has been accessed, three long bladed retractors are placed. The first one is placed infero-laterally, parallel to the SSL. The second and third retractors are positioned supero-medially and infero-medially respectively to help retract the rectum. Now an assistant introduces a 10 mm, 30-degree laparoscope standing behind the operating surgeon. Thus, the procedure is performed under direct visualisation and displayed on the laparoscopic monitor, putting the operating team at ease. The other observers also tend to understand and learn better.

The suture carrier device along with the ligature is used and the first suture is placed 2 cm lateral to the ischial spine. We use either of the two devices: 1) First Pass Mini, Suture Passer (Smith & Nephews) 2) Knee Scorpion Suture Passer (Arthrex). These devices are easily available in Indian/ Asian markets as they are widely and frequently used in knee arthroscopic procedures. The second suture is placed 1cm medial to the first. These sutures are then brought out and held with different (curved and straight) artery forceps for easy identification of lateral and medial sutures. Other planned ancillary procedures like hysterectomy or anterior colporrhaphy are then performed. After this, one end of both the SSL sutures is anchored to the vaginal apex taking a bite in it with the help of the needle attached at the suture end. The posterior vaginal wall incision is then closed. Finally, the SSL sutures that have been anchored to the apex of the vagina are tied individually, pulling up the apex of the vagina to the SSL (pulley stitch). (Figure 1) (Video 1: attached as supplementary materiel)

Vaginal packing with a betadine-soaked gauze was done at the end of the procedure which was removed after 6-8 hours. Urinary catheter was kept in situ for around 24 hours.

Patients were advised normal diet and ambulation from the second post operative day and were discharged on the third day of surgery.

All these patients were followed up after 6-8 weeks as per the routine institutional protocol. Those who agreed for participation in the study were invited for a follow up visit after 6 months following the surgery. Systematically their symptom recovery and complaints were documented in a pre-set format. Following which, they underwent a pelvic

examination that included POP-Q. The objective success rate was determined by recurrence of POP, as descent of the vaginal cuff below a point that is 2 cm less than the total vaginal length above the plane of the hymen, as defined by the International Continence Society (ICS). (4) Entire data was collated, analyzed, and compared.

Statistical Analysis

The data were managed on Microsoft excel spreadsheet (version 2007, Microsoft Corp, Seattle, Washington) and analysed using SPSS for Windows (release 16.0, SPSS Inc, Chicago IL, USA). Patient characteristics were reported as median (IQ range) or frequency (percent), as appropriate. To compare, Mc Nemar test and Wilcoxon singed rank test were used, and significant results were demarcated. P value of <0.05 was considered significant, and <0.01 was considered highly significant.

Results

A total of 21 patients were included in the study. Baseline demographic characteristics are shown in Table 1. Sixteen patients (76.2%) had a previous hysterectomy, and had come with a vault prolapse, and underwent Dee-SSLF. Five patients (23.8%) came with uterovaginal prolapse who underwent a vaginal hysterectomy with/without pelvic floor repair, along with Dee- SSLF.

Subjective Outcome

Most of the patients in our cohort presented with the chief complaint of a vaginal bulge. The second most common complaint was related to the anterior compartment defect (Table 2). On follow up, we noted a significant improvement in all the subjective findings. The reduction in the vaginal bulge noted at 6 months post procedure was highly significant (p value <0.01). One patient in our study cohort complained of reappearance of vaginal bulge at 6 months follow up. All urinary complaints like- urinary frequency, urge and stress urinary incontinence (SUI), showed an improvement. The improvement in SUI was noted as statistically significant (p <0.05). It must be noted, that 6 women out of the study group were diagnosed with SUI during their evaluation and underwent a mid-urethral sling surgery as a part of the comprehensive surgical procedure. They were comfortable and symptomatically better at the time of follow up after 6 months. Anal symptoms decreased after the procedure and the reduction noted in anal straining was statistically significant (p<0.05).

Among the women who were sexually inactive prior to the procedure, 57.1% declared that this was due to vaginal bother. Only 9.5% women were sexually active prior to the procedure, and at the time of the follow up after 6 months, 47.6% of the women in the study group resumed sexual activity. This improvement was found to be highly significant (p<0.01), as per the statistical analysis.

Objective Outcome

As per the POP-Q classification, at the time of presentation, two women had stage II, 13 had stage III and 6 had stage IV prolapse. The pre- and post-operative comparison of POP-Q is summarized in Table 3. At 6 months follow up, no patient had more than stage II prolapse. The median change in POP-Q score for the point which represents the cervix/ vault changed from +3 to -6 at 6 months' follow up and the total vaginal length was well preserved.

Recurrence was noted in 2 patients when they were examined after 6 months post-procedure (9.5%). One of them preferred treatment with vaginal ring pessary and the other was asymptomatic and thus, did not want any further treatment.

Complications

None of the patients in our cohort had any serious intra operative complications – like visceral and/or vascular

injuries. No peri-operative blood transfusions were given. The median time of Dee-SSLF was 22 (18-30) minutes. There were no readmissions at any given point in time. Recurrence was noted in 2 patients when they were examined after 6 months of the procedure (9.5%). (Table 4)

Discussion

In the present study we found that the innovative technique of SSLF was efficacious in both subjective and objective parameters at 6 months' follow up. Somewhat similar laparoscopic demonstration of a single case has been presented earlier. (5) Unlike our technique, in that presentation a regular needle holder was used to pass the sutures through the ligament. This study is the first in Scientific English Literature to present a collective data of 21 women along with their follow up.

Apical suspension plays a pivotal role in the management of POP. Not only for the management of PHVP, apical suspension has also been recommended as an ancillary procedure during surgical reconstruction of the pelvic floor in cases of stage III/IV uterovaginal prolapse with or without hysterectomy.Present guidelines also recommend apical suspension as the procedure of choice for paravaginal defect repair. (1)

Based on its high efficacy ASC is considered as the gold standard procedure for apical suspension. However, it has its own risk and complications, related to entry into the peritoneum and use of mesh to anchor the vaginal vault with anterior longitudinal ligament. Kurt Richter described SSLF as a vaginal approach to apical prolapse in 1968 (6 years after Lane described ASC). (6) It soon became popular because of its multiple advantages of being minimally invasive, with no abdominal incision, no peritoneal entry, lesser blood loss, shorter operative time, faster recovery and better cosmetic satisfaction. SSLF saw a second peak in its popularity, recently following the reclassification of vaginal surgical mesh to the highest risk class of devices (class III) by the American Food and Drugs Administration (FDA). This has led to many surgeons and researchers developing an interest in making the technique easier and more effective. (7) The classical technique described by Richter uses dissection and direct visualization of the SSL. Placement of fixation suture under direct vision in this restricted target area is technically challenging. (6) To address this problem of restricted field and limited access associated with the classical open technique, various suture carrier devices have been introduced, over the years. (8) A newer advancement in this technique has been the concept of closed SSLF, wherein the surgeon palpates the SSL vaginally and anchors the suture through the vagina blindly, without surgical dissection of the target space down to the ligament. (9)

The anterior approach of SSLF, has been developed to facilitate with an exaggerated anterior compartment defect.

Some surgeons believed that the accessibility and visualization were better through the anterior approach of SSLF. Studies have reported a comparable outcome in both the approaches. (10–12) Thus, the approach to access the operative space may be chosen as per the surgeon's discretion.

Recently single-port laparoscopic SSLF *via* the natural vaginal cavity (SvNOTES) has also been tried to improve the success rate of SSLF, with lesser blood loss and fewer complications. On comparison with the conventional SSLF technique, SvNOTES was found to be a safer minimally invasive surgical approach. However, the operative time was doubled from a mean of 30 ± 15 min

in conventional approach to 60 ± 15 min in SvNOTES. (13)

The continuous innovation in this field reflects the still unfulfilled need of an ideal SSLF procedure with high efficacy & low complication rates combined with technical ease of learning and teaching.

We have described here a preliminary feasibility study of an innovative technique of SSLF: Dee-SSSLF, which is Direct, Easy and Educational. It restores the essence of the classical technique described by Richter of direct visualization of SSL. Direct visualization with magnification helps in perfect placement of sutures that minimizes complications related to injury of pudendal nerve and vessels (laterally), rectum (medially) and sciatic nerve (superiorly). As we use a ligature carrier device, it avoids the need to hold the ligament with another instrument, thus preventing tethering of its fibers, leading to a stronger bite and less failure rates. Display of entire procedure on the monitor helps not only the operating surgeon but also the assistants and fellow trainees to understand the procedure in a step-wise fashion. This helps them learn and gives them the skill and confidence to perform the procedure by shortening the learning curve.

Conclusion

Keeping in mind the growing need of surgical management of prolapse in the future Dee-SSLF can be propagated as an innovative technique for an age old procedure. It is an easy to perform and easy to learn technique, associated with good subjective and objective outcomes, with minimal complications.

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Legend Figure

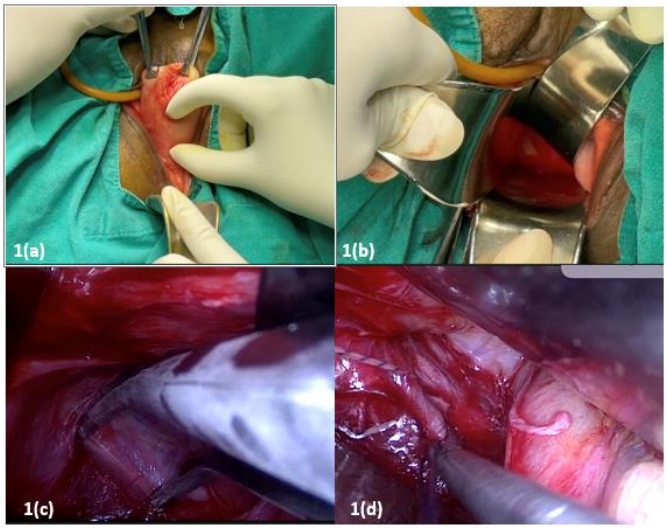

Figure 1: Intraoperative crucial steps of Dee-SSLF, 1(a) planning the incision in the middle third of posterior vaginal wall, 1(b) Retraction of the surgical space with the help of three long bladed retractors, 1(c) Visualisation of the Sacro-spinous Ligament (SSL) under magnification in the laparoscopic monitor, 1(d) Two bites of sutures taken in the SSL with the help of a suture capturing device under magnification.