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Clinical Opinion

Re-evaluation of Sacrocolpopexy as a Gold Standard for Apical Genital Prolapse Correction

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ABSTRACT

Sacrocolpopexy (SCP) is the gold standard for apical and combined pelvic organ prolapse (POP) correction. The broad adoption of the technique has resulted in a large database regarding operative technique, advantages and success rates. This allows us to examine not only the outcome of SCP in terms of POP correction and patient satisfaction, but also the short and long term morbidity associated with the method in more detail. At closer look, procedure-induced morbidity is significant including chronic pelvic pain, de novo urinary incontinence, bowel dysfunction and mesh-associated complications. Besides SCP, there are several established as well as innovative methods for apical POP reconstruction surgery. They offer various beneficial aspects, such as uterus preservation, as well as avoiding the use of mesh material, thereby potentially decreasing long-term morbidity. In order to facilitate an objective evaluation of individual methods and to allow a meaningful analysis, we propose a simple equation to evaluate success in POP surgery. This equation would define overall success rate as result of anatomical / functional success rate minus procedure-related morbidity rate.

Keywords: *Abdominal sacrocolpopexy; apical prolapse; laparoscopic lateral suspension; laparoscopic sacrocolpopexy; pectopexy; pelvic organ prolapse; unilateral pectineal suspension.*

CLINICAL OPINION

Pelvic organ prolapse (POP) has a prevalence of 3-6% when defined by symptoms and up to 50% when based upon vaginal examination in parous women.[1] The initial treatment of POP is frequently nonsurgical, however most women will eventually ask for a surgical solution. The aim of surgical correction is the restoration of pelvic floor functional anatomy. The lifetime-risk of women undergoing surgery for POP repair has been estimated to be 11%, with a reoperation rate of 29% by the age of 79.[2]

POP reconstruction surgery should aim to improve patient quality of life with as little additional procedure related morbidity as possible. A growing data base on long-term sequelae of surgical POP correction, the introduction of new techniques as well as the current debate on the use of mesh implants imply the necessity for thorough analysis of our gold standard as well as potential alternatives. As the number of patients in need for POP surgery increases, perioperative and long-term morbidity following POP surgery gain increasing attention. Therefore, we need to look at our options not only regarding anatomical correction, but also in terms of fulfilling the patients' expectations to achieve excellent functional results. The aim of our work is to analyse sacrocolpopexy (SCP) with a closer look on success as well as morbidity and to assess alternatives for apical POP correction.

Defining Success in Pelvic Floor Surgery

Traditionally, failure after POP repair is defined by need for reoperation, recurrence of symptoms, or anatomic recurrence. The NIH Pelvic Floor Disorders Network has put forth a recommendation regarding clinically relevant criteria for defining success after POP surgery: no prolapse beyond the hymen, no vaginal bulge symptom, and no retreatment of POP. Absence of a vaginal bulge after POP surgery has a significant relationship with a patient's assessment of treatment success and Healthcare Related Quality of Life (HRQoL) while anatomic success does not directly correlate with QoL.[3]

Anatomical success rates decline as time passes. We still need to define the expectations for a successful repair over time, and how to judge a short-term, intermediate-term or long-term result. When looking at success after surgical POP repair, three main issues ought to be considered. The current literature is mainly focused on two of them, namely anatomical outcome and patient satisfaction with their prolapse correction. Using absence of prolapse beyond the hymen to define success after POP surgery, success rates are as high as 94%.[3]

In our opinion, the third issue to be addressed when defining success after POP surgery should be morbidity, including the rate of perioperative complications as well as long-term sequelae and re-operations. These outcome parameters have a great impact on physical and psychological well-being and ought to be weighed against the purely anatomical and subjective evaluation of the postoperative result. Pain and dyspareunia can cause significant problems. Mesh erosions cannot be simply attributed to surgical technique, since tissue aging is a significant factor in the increasing rate of mesh exposure over time. However, perioperative complications and long-term sequelae are still being reported separately when defining success rates in POP surgery.

Long-term follow-up of the gold standard, SCP, shows significant morbidity as well as the necessity of re-interventions. A recent analysis of the SALTO trial by Oudsheusen after a median follow-up time of 9.1 years revealed a re-intervention rate of 22.7% for laparoscopic sacrocolpopexy (LSC) and 26.3% for abdominal sacrocolpopexy (ASC) in a total of 39 patients available for follow-up. Mean time to surgical re-intervention was 41.2 months for LSC and 55.8 months for ASC. Two patients had surgery to remove mesh material owing to severe complications. There were an additional three mesh exposures as well as three suture exposures. Patient satisfaction rate was 57.9% for LSC and 58.8% for ASC. While composite outcome of success for the apical compartment was 78.6% for LSC and 84.6% for ASC, close to 25% of patients complained about overactive bladder and urinary incontinence.[4]

Studies have shown that the rate of mesh exposure was nearly six times lower when the uterus was preserved. Therefore, total hysterectomy has progressively been replaced by supracervical hysterectomy to reduce this risk.[5] In order to meet the expectations of women who increasingly prefer to keep their uterus, new techniques were established to allow for uterine preservation.[6,7] Furthermore, new methods have been developed to avoid application of mesh material.[7,8] These new options should be further evaluated to better understand potential advantages and disadvantages in comparison to our current gold standard.

After careful consideration of the available data, we suggest that with respect to overall satisfaction of the patient, anatomical and functional outcomes as well as procedure-related short and long-term morbidity should be addressed to define success after POP surgery (Figure 1). For further evaluation of patient collectives and discussion of outcome data, we therefore suggest to apply the following equation:

Overall success rate = Anatomical / functional success rate minus Procedure-related morbidity rate

The parameters for measuring each variable should be defined properly by scientific consensus and this would allow us to objectively measure and compare success after POP surgery respecting all relevant parameters.

Figure 1. Defining success after POP surgery
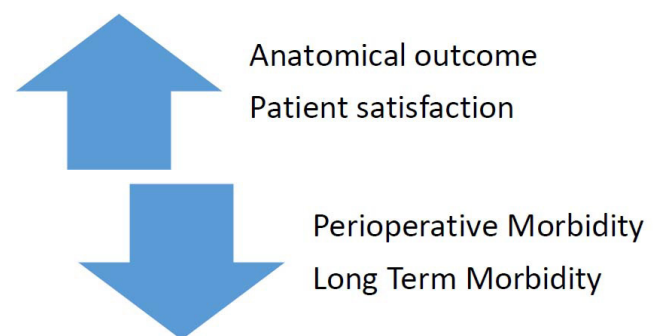
Success and Morbidity after Sacrocolpopexy

It has been shown that sufficient support of the vaginal apex is imperative in sustaining the structural integrity of the anterior and posterior compartments. Without adequate apical support, vaginal repairs run an increased risk of failure.[9] ASC has been the mainstay for apical POP repair since its first introduction by Lane et al. in 1962.[10] ASC can be performed as an open, laparoscopic, or robotically assisted method. It is the gold standard for women who wish a restorative repair of an apical or combined prolapse. The procedure typically uses a Y-shaped synthetic mesh, which is placed on the anterior and posterior aspects of the vagina and/or the cervix. The mesh is then typically attached to the anterior longitudinal ligament at the level of the sacral promontory.

ASC results in a high percentage of anatomical success. A comprehensive review by Nygaard et al. showed that 78% - 100% of patients had no apical prolapse postoperatively, and 58% to 100% had no prolapse at all.[11] In another systematic review conducted by Maher et al. it was shown that ASC is associated with a significantly lower risk of awareness of prolapse, recurrent prolapse on examination and repeat surgery for prolapse. The use of synthetic mesh was associated with superior anatomic outcomes when compared to cadaveric fascia.[9]

ASC may also be of benefit with respect to postoperative sexual function. It has been shown to conserve more vaginal length in comparison to vaginal approaches.[12] Several studies indicate that postoperative dyspareunia is significantly less with ASC compared to vaginal POP repair.[9,12] Another study, which evaluated postoperative sexual function following ASC, reported a "*relatively high*" sexual function score.[13] Based on these findings, sexually active patients or patients with shorter vaginal length may benefit from ASC over a vaginal POP repair.

When looking at a surgical method for POP correction, perioperative and long-term risks also need to be considered (Table 1). Earlier studies have summarized the median complication rates as follows: cystotomy (3.1%), enterotomy or proctotomy (1.6%), and ureteral injury (1.0%). Median rates for postoperative events included urinary tract infection (10.9%), wound problems (4.6%), and haemorrhage or transfusion (4.4%). Mesh erosion was observed in 3.4% and varied depending on the materials used. Moreover, mesh erosion increased over time.[14]

Table 1. Median perioperative and longterm risks after ASC / LSC

Perioperative risks	Percent likelihood	Longterm risks	Percent likelihood
cystotomy	3.1 %[14]	de novo SUI	up to 50%[15,16]
enterotomy/proctotomy	1.6%[14]	secondary surgery: SUI	7.5%[17]
ureteral injury	1.0%[14]	scondary surgery: POP recurrence	4.2%[17]
urinary tract infection	10.9%[14]	mesh exposure	3.4%-10.5%[14,21]
wound problems	4.6%[14]	sacral roots/ hypogastric nerve damage	rare
haemorrhage/transfusion	4.4%[14]	spondylodiscitis	rare[18,19,20]

De novo stress urinary incontinence (SUI) is a significant drawback of the method. The incidence of postoperative SUI can be as high as 50% after LSC15 Similar rates were reported for ALC.[16] In the CARE trial, women without occult SUI were randomly assigned to groups of POP surgery with and without concomitant BURCH colposuspension. Two-year follow up showed that patients with concomitant BURCH colposuspension showed less SUI (32.0%) than patients who had not received a concomitant BURCH procedure (45.2%). The authors concluded that a prophylactic anti-incontinence procedure should be recommended at the time of SCP for stress-continent women who have a mobile urethra, as the incidence of de novo SUI is high.[16]

In patients without prophylactic incontinence surgery, secondary surgery is frequently performed placing a suburethral sling to cure the problem. In a retrospective cohort study after LSC, 7.5% of the patients needed reoperation for SUI, and this was the main indication for reoperation followed by POP recurrence in 4.2%.[17]

Promontory dissection may expose to potential life-threatening intraoperative vascular injuries, and sacral roots or hypogastric nerve damage. In newer studies, a few case reports of spondylodiscitis with consecutive lumbar vertebra bone erosion have been described.[18,19] Recent observations suggest that postoperative discitis has increased as more ASC procedures are performed using a minimally invasive technique. Durdag et al. described L5-S1 discitis 3 months following LSC, with likely contribution from penetration of the L5-S1 disk with sutures. The authors of this study recommended only using monofilament sutures to the depth of the anterior longitudinal ligament.[20]

Similar to other POP corrections, ASC success rates decline over time. In a review analysing the longer-term results of ASC, Nygaard et al. describe reduced success rates of around 70% - 75% after a 7-year follow-up. The extended CARE (ECARE) trial by year 7 showed probabilities of failure including POP, stress urinary incontinence (SUI), and urinary incontinence (UI) between urethropexy and no urethropexy groups of 0.27 and 0.22 for anatomic POP, and 0.29 and 0.24 for symptomatic POP. By this time, probability of mesh erosion was up to 10.5%. Interestingly, the same study found that 95% of patients did not seek retreatment for POP.[21] The reasons for this result remain speculative.

Learning Curve

Although LSC has been performed for nearly 30 years and is considered the gold standard for the correction of apical prolapse, it still poses a challenge to master the operative technique. Therefore, the number of surgeons becoming proficient in this technique is limited. Claerhout in Belgium evaluated the learning curve of LSC and found that it takes around 60 procedures to ensure anatomical success and limit the risk of complications. Operative time decreased rapidly after the first 30 procedures and reached a steady state after 90 procedures.[22] A structured program could further reduce this learning curve.[23] With robotic surgery, the realization of laparoscopic sutures has been simplified, potentially helping to shorten the learning curve. However, studies on this subject report relatively similar numbers of 50 to 75 operations required before mastering the technique.[24]

Evaluation of New Concepts

There is increasing interest in alternative POP repair procedures aiming at reasonable anatomical and functional outcomes with lower perioperative and long-term risks. New concepts may allow to preserve the uterus in the absence of uterine pathology, and / or to avoid the application of mesh material. Some options may help to reduce operation times, contributing to fast recovery of the patients, and/or shorten the learning curve by a standardized surgical approach. We will discuss some promising techniques currently used as alternatives to SCP.

LAPAROSCOPIC LATERAL SUSPENSION (LLS)

Laparoscopic lateral suspension (LLS) with mesh is an alternative technique for apical POP repair. The mesh is attached to the vesico-vaginal fascia and to the isthmus uteri with non-absorbable or absorbable threads. A tension free subperitoneal passage is created for the lateral arms, which are directed above the anterior superior iliac spine and fixed to the peritoneum to create a relatively physiological vaginal angulation.[25] LLS has been shown to respect the physiologic axis of the vagina on MRI.[26]

LLS lowers perioperative risks by avoiding sacral promontory preparation. Recent studies show similar anatomical and functional outcomes to LSC, with the advantage of better preserving the vaginal axis. Moreover, LLS is well suited for preserving the uterus.

Therefore, the method was suggested to be used as a complementary option for LSC, since LLS adapts particularly well to hysteropexy, and SCP remains a better option for vaginal vault prolapses. Dissection of the promontory can be challenging in obese patients, or in the case of vascular anatomical variations, and lateral suspension may represent a safer alternative.

PECTOPEXY

Pectopexy is a surgical procedure to correct apical prolapse using a mesh prosthesis consisting of a distinct type of mesh material called polyvinylidenfluoride (PVDF). Laparoscopic mesh-supported pectopexy has been introduced by Banerjee et al. in 2011.[27] It was first developed to overcome the difficulties of POP repair in adipose patients.

Similar to SCP it is an operative method designed primarily for apical prolapse repair, however in contrast to SCP, pectopexy uses the lateral parts of the iliopectineal ligaments on both sides for a bilateral mesh fixation of the descended structures. The mesh is attached

to the anterior or posterior cervix with intact uterus or to the cervical stump after supracervical hysterectomy. In its original description, a pre-cut one size fits all mesh is used.

Pectopexy offers some advantages when compared to SCP, since the pelvis is not divided by mesh material, and bowel manipulation is not needed to complete the procedure. Furthermore, preparation of the sacrum is not necessary. Pectopexy has been increasingly added to the spectrum of pelvic floor reconstruction worldwide.[28,29] Recently, laparoscopic pectopexy was compared to LSC in a retrospective review. The overall complication rates were 6.0% for pectopexy and 16.5% for LSC, the difference was not significant. The rates of recurrent prolapse were similar for both methods. Pectopexy was often used in more complex patients. The authors suggested pectopexy as an alternative for vaginal vault support in patients who have contraindications to SCP.[30]

POP REPAIR WITH AUTOLOGOUS SEMITEN-DINOSUS TENDON TRANSPLANT

Since the use of synthetic mesh for prolapse and incontinence surgery has been increasingly questioned, attempts have been made to replace mesh by autologous material. To this end, semitendinosus tendon from the popliteal fossa has been used as a mesh replacement. The feasibility of this approach was demonstrated both for sacrocolpopexy[8] and for pectopexy.[31] Initial data from a multicenter trial show stable results in terms of fixation of the apical compartment in cervicosacropexy after 6 months.[32]

UNILATERAL PECTINEAL SUSPENSION (UPS)

Based on the principle to use a lateral fixation point within the pelvis, we have previously established unilateral pectineal suspension (UPS) as a novel, minimal invasive, mesh free suspension technique for isolated or combined apical POP correction fulfilling a broad range of quality criteria. UPS provides mesh-free midline uterus suspension using a single non-absorbable suture to attach the anterior cervix to the lateral part of the iliopectineal ligament in five defined steps.[7] Similar to LLS, the method respects the physiological direction and angulation of the vaginal axis. Reliable apical fixation is effectively accomplished in all POP stages, including stage 4 total prolapse.

The use of the cervix as a stable fixation structure provides excellent pelvic floor support. For the cervical fixation a running suture of 3-4 stitches has been suggested, because this spreads the tension away from a single fixation point. As opposed to bilateral fixation UPS unilateral suspension avoids tension on the suspended structures and allows for physiologic pelvic floor mobility. The tension-free principle of the UPS concept leads to a physiologic midline repositioning of the cervix. This can be easily demonstrated intraoperatively from the abdominal and the vaginal side.[33,34] The procedure avoids dissection along the ureter as well as bowel manipulation. The uterus can be preserved unless uterine pathology warrants hysterectomy. UPS can be combined with additional vaginal and abdominal procedures for the correction of POP and / or SUI during the same or a subsequent procedure.

Short-term results of a retrospective outcome analysis have been published and showed 93.6% treatment success as measured by a defined composite endpoint for the entire cohort. No complications or conversions were observed.[35] Furthermore, our clinical follow-up showed absence of de novo SUI. We assume that the concomitant tension-free repositioning of the urethra due to the physiologic restoration of the vaginal axis could avoid the appearance of de novo SUI.

The reduction of variability provided by the standardized 5-step procedure shows a fast learning curve and is easily adoptable for teaching and training purposes.

SUMMARY AND CONCLUSION

SCP is considered the gold standard for apical and combined prolapse repair. It results in stable apical fixation and low recurrence rates. However, there is a price to be paid. Increasing evidence reveals significant long-term morbidity in terms of de novo incontinence, bowel disorders, dyspareunia and pelvic pain. Mesh application on the vagina in the presence of chronic prolapse-induced changes of skin and tissue texture can cause mesh-related complications such as contraction or mesh perforation.

Furthermore, rare but significant complications such as osteomyelitis of the os sacrum occur occasionally as the method is broadly established.

SCP is often combined with supracervical hysterectomy to facilitate application of the Y-shaped mesh, even in the absence of uterine pathology. The increasing tendency to preserve a healthy uterus leads to a dilemma indicating the organ's removal. Furthermore, the issue of uterus morcellation and retrieval of the uterus pose an extra challenge.

There is a significant learning curve, and due to the complex nature of the procedure, operation times are usually in the range of 150-180 min.

In view of these significant disadvantages of SCP, it is mandatory to carefully examine feasible alternatives for individual indications. Apical repair can be efficiently achieved using alternative fixation points. LLC as well as pectopexy have proven to be reasonable alternatives for mesh-supported hysteropexy or cervicopexy.

With respect to the existing international need for mesh-free alternatives due to increasing restrictions, a promising method for sufficient mesh-free apical repair has been recently proposed by the introduction of UPS. It allows for anatomical POP repair with a very advantageous overall profile of anatomical success and reduced morbidity.

The recent implementation of low morbidity innovative methods for POP reconstruction surgery should be thoroughly evaluated in future studies in order to improve quality of patient care. A new equation to evaluate success in POP surgery is proposed to define overall success rate as a result of anatomical / functional success rate minus procedure-related morbidity rate.

CONFLICT OF INTEREST

Both Dimitrios Bolovis and Cosima Brucker hold a contract with Intuitive Surgical for proctoring and teaching using Da Vinci robotic systems. Both authors declare that they have no other relevant financial or non-financial interests to disclose.

CONDENSATION

Analysis of the procedure-induced morbidity of sacrocolpopexy and discussion of well-established and novel alternative approaches.

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