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# Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse: The OPTIMAL Randomized Trial

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## ABSTRACT

Surgical correction of pelvic organ prolapse (POP) is a common procedure performed in the United States. The 2 most widely used vaginal procedures for correction of POP in women with stress urinary incontinence (SUI) are sacrospinous ligament fixation (SSLF) and uterosacral ligament suspension (ULS). No comparative studies have examined the efficacy and safety of these 2 procedures. Behavioral therapy with pelvic floor muscle training (BPMT) is an effective stand-alone therapy for pelvic floor symptoms in women with SUI and may be a logical adjunct to surgery. However, it is unknown whether preoperative BPMT improves prolapse outcomes after surgery.

The OPTIMAL study was a multicenter, 2 × 2 factorial, randomized trial designed to compare surgical outcomes of SSLF and ULS after vaginal surgery in women with prolapse and SUI. The trial also compared the effect of perioperative BPMT and usual care on surgical outcomes in this patient population. Women were treated at 9 US medical centers between 2008 and 2013. The 2-year follow-up rate was 84.5%. Women undergoing surgery for POP and SUI underwent 2 randomizations, the first to perioperative BPMT (n = 186) or usual care (n = 188), and the second to SSLF (n = 186) or ULS (n = 188). Participants were masked to their surgical group assignment, and study surgeons were masked to the physical therapy group assignment. The primary surgical outcome was success at 2 years defined as the following: (1) no apical descent more than one-third into vaginal canal or anterior or posterior vaginal wall decent beyond the hymen (anatomic success), (2) no bothersome vaginal bulge symptoms, and (3) no retreatment for prolapse. Primary outcomes for BPMT were evaluated at 6 and 24 months. The primary behavioral outcome at 6 months, urinary symptom scores, was assessed using Urinary Distress Inventory (range, 0–300, higher scores indicate worse condition). The

primary 24-month outcome, prolapse symptom scores, was assessed using the Pelvic Organ Prolapse Distress Inventory (range, 0–300) and anatomic success.

At 2 years, there was no significant difference between the 2 groups in surgical success rates (ULS, 59.2% [93/157] vs SSLF, 60.5% [92/152]); the unadjusted difference was 1.3%, with a 95% confidence interval (CI) of 12.2% to 9.6%, and an adjusted odds ratio of 0.9, with a 95% Cl of 0.6 to 1.5. There was also no difference between groups in serious adverse event rates (ULS, 16.5% [31/188] vs SSLF, 16.7% [31/186]; unadjusted difference 0.2% [95%CI, 7.7% to 7.4%] and adjusted odds ratio 0.9 [95% CI, 0.5–1.6]). With respect to behavioral intervention, perioperative BPMT did not produce greater improvements either in urinary scores at 6 months (adjusted treatment difference, 6.7; 95%CI, 19.7 to 6.2), or prolapse scores at 24 months (adjusted treatment difference, 8.0; 95%CI, 22.1 to 6.1), or anatomic success at 24 months.

These data show that there was no significant difference between ULS and SSLF for anatomic, functional, or adverse event outcomes 2 years after vaginal surgery in women with prolapse and SUI. Moreover, the finding that perioperative BPMT did not improve urinary symptoms or prolapse outcomes suggests that this behavioral intervention is unnecessary for routine care in most women undergoing such surgery.

## EDITORIAL COMMENT

(Clinical practices for vault suspension in patients with apical prolapse have traditionally been informed by surgeon comfort with the chosen technique or a perception of improved efficacy in certain scenarios. For instance, a surgeon treating a patient with severe or recurrent prolapse or a young patient might choose an abdominal sacral colpopexy with mesh over a vaginal approach because of evidence that it offers a lower risk of apical recurrence. Nonetheless, the vast majority (80%–90%) of apical suspension procedures done in the United States are done by a transvaginal route (Boyles SH, *Am J Obstet Gynecol* 2003;188(1):108–115). This means either clinicians treating prolapse are not comfortable offering sacral colpopexy, or they or their patients prefer it, for any of a variety of reasons including but not limited to patient comorbidities, perceived easier recovery of vaginal surgery, or avoidance of permanent mesh graft. (Certainly some of these vaginal procedures incorporate a permanent mesh graft anyway.) However, it is important to recognize that vaginal surgery is being done for apical prolapse despite evidence of less favorable apical durability when compared with sacral colpopexy. There are a few significant randomized trials of apical repairs, but each compared a vaginal to an abdominal (open or laparoscopic) technique.

Until the OPTIMAL trial described here, there has been no randomized trial comparing 2 vaginal techniques. Published studies and trials describing outcomes after transvaginal surgical treatment of vaginal or uterovaginal prolapse are widely available but consist primarily of case series or cohorts for either SSLF or, more recently, ULS. Some 22 published studies with sample size of 50 or more subjects undergoing SSLF are available. These studies describe success rates that vary greatly according to the definition of success used, but generally describe a 70% to 90% 2- to 3-year success rate with rates of reoperation of less than 10%. Perhaps because of the relatively dorsal and often right-sided retroflexion of the vaginal apex with SSLF, anterior compartment recurrences are most common. Concern about these features led many surgeons in the United States to adopt the ULS as a go-to transvaginal apical repair, despite the fact that only about 7 poorly controlled retrospective studies described its use. These studies describe an 82% to 96% anatomic success rate but also a 1% to 11% risk of ureteral injury. (For details of the literature existing regarding these 2 procedures, an excellent summary is Maher C, *Cochrane Database Syst Rev* 2013;4:CD004014.)

A randomized trial of surgery for prolapse provided a good opportunity to also test the efficacy of perioperative pelvic floor physical therapy as well. There is good evidence that BPMT improves symptoms of a variety of pelvic floor disorders, with little or no risk. Evidence of its efficacy in the perioperative period is very limited, however, with poorly described interventions or limited postoperative follow-up. This makes studying BPMT in this setting very attractive, but testing both these interventions in 1 study is legitimate only if any effect of the surgical vault suspension technique were to be independent of any effect from whether a subject performed BPMT per protocol or was assigned to usual perioperative care.

The investigators designing the OPTIMAL trial assumed this would be the case and used a factorial design with 2 independent randomizations, allowing them to obtain level I data for both the surgical (SSF vs ULS) and physical therapy (BPMT vs usual care) interventions. Women entering into the study had to have stage 2 to 4 POP by the POP quantification system measures, with descent of the cervix or apex at least one-half way into the vagina, and symptoms of bulge. All women had to demonstrate SUI and have plans to undergo a midurethral sling procedure to treat the incontinence. This criterion helped to standardize the postoperative support of the distal anterior vaginal wall and isolated the surgical effect on the patient's prolapse to the apex support from the SSF or ULS, and any anterior colporrhaphy. The study was powered to detect a 15% difference between surgical success rates, defined using a composite outcome as described above. Two-year follow-up was high at 84.2%, and CONSORT data of subject progression through the study period are clearly described in the full manuscript.

Study findings are remarkably consistent, with no significant differences found between SSLF versus ULS for the primary composite outcome at 24 months, nor were there any differences between postoperative symptom scores or prolapse at 24 months between BPMT and usual care groups. Surgical success rates at 24 months were about 60% in both groups, relatively lower than previously reported studies of SSLF or ULS, but this is likely because of the rigorously defined composite outcome that was used to define surgical success. Symptoms of vaginal bulge postoperatively (one of the elements of the primary composite outcome) were present in only about 20% of subjects in both groups, and this is notable because absence of bulge has been cited in multiple studies as the outcome most consistently associated with patient satisfaction.

The authors did report detecting some unexpected interactions between the 2 interventions; for instance, women who received ULS and also BPMT had more apical vaginal descent postoperatively than did women receiving SSLF and BPMT. The reasons for this finding are unclear, but they emphasize the potential risks of a factorial design.

The clinical implications of this study are not necessarily generalizable to all women having prolapse and incontinence surgery. For instance, while the study does not support additional benefits for women with prolapse and SUI embarking on a program of BPMT in the perioperative period, it does not mean that a woman who does not plan surgery or who develops new symptoms postoperatively would not benefit from pelvic floor therapy. Similarly, it does not mean SSLF and ULS procedures are equivalent in all clinical settings. Nonetheless, it is reasonable to use SSLF or ULS in specific circumstances and anticipate similar outcomes with regard to prolapse. For instance, for a patient with posthysterectomy vaginal vault prolapse, in whom intraperitoneal entry may be difficult, it would be reasonable to routinely perform SSLF. It may be reasonable to routinely perform ULS in the context of hysterectomy for uterovaginal prolapse where the peritoneum is already open. The OPTIMAL study also provides rigorous documentation of outcomes for these 2 commonly performed procedures, facilitating comparisons to other methods of vault suspension such as current transvaginal mesh procedures and sacral colpopexy. Hopefully, more such studies will be soon in progress to inform clinicians counseling patients with prolapse.—ACW)