UPDATE Pelvic floor disorders

Katherine L. Woodburn, MD
Dr. Woodburn is Female Pelvic Medicine & Reconstructive Surgery Fellow, Department of Obstetrics & Gynecology, Georgetown University School of Medicine/MedStar Washington Hospital Center, Washington, DC.

Cheryl Iglesia, MD
Dr. Iglesia is Professor and Division Director, Division of Female Pelvic Medicine & Reconstructive Surgery, Department of Obstetrics & Gynecology and Urology, Georgetown University School of Medicine/MedStar Washington Hospital Center. She serves on the OBG MANAGEMENT Board of Editors.

Dr. Iglesia reports receiving grant or research support from the Foundation for Female Health Awareness, made payable to MedStar Health; serving on the Advisory Boards for the NICHD Pelvic Floor Disorders Network, Patty Brisben Foundation, and Healthwomen.org; and being a contributer to UptoDate.

Dr. Woodburn reports no financial relationships related to this article.

doi: 10.12788/obgm.0121

Data on recent prospective studies for medical and surgical treatment of POP and SUI, along with a paradigm change for office-based pessary care and sexual health counseling

IN THIS ARTICLE

With the increasing prevalence of pelvic floor disorders among our aging population, women's health clinicians should be prepared to counsel patients on treatment options and posttreatment expectations. In this Update, we will review recent literature on surgical treatments for pelvic organ prolapse (POP) and stress urinary incontinence (SUI). We also include our review of an award-winning and practice-changing study on office-based pessary care. Lastly, we will finish with a summary of a recent Society of Gynecologic Surgeons collaborative systematic review on sexual function after surgery.

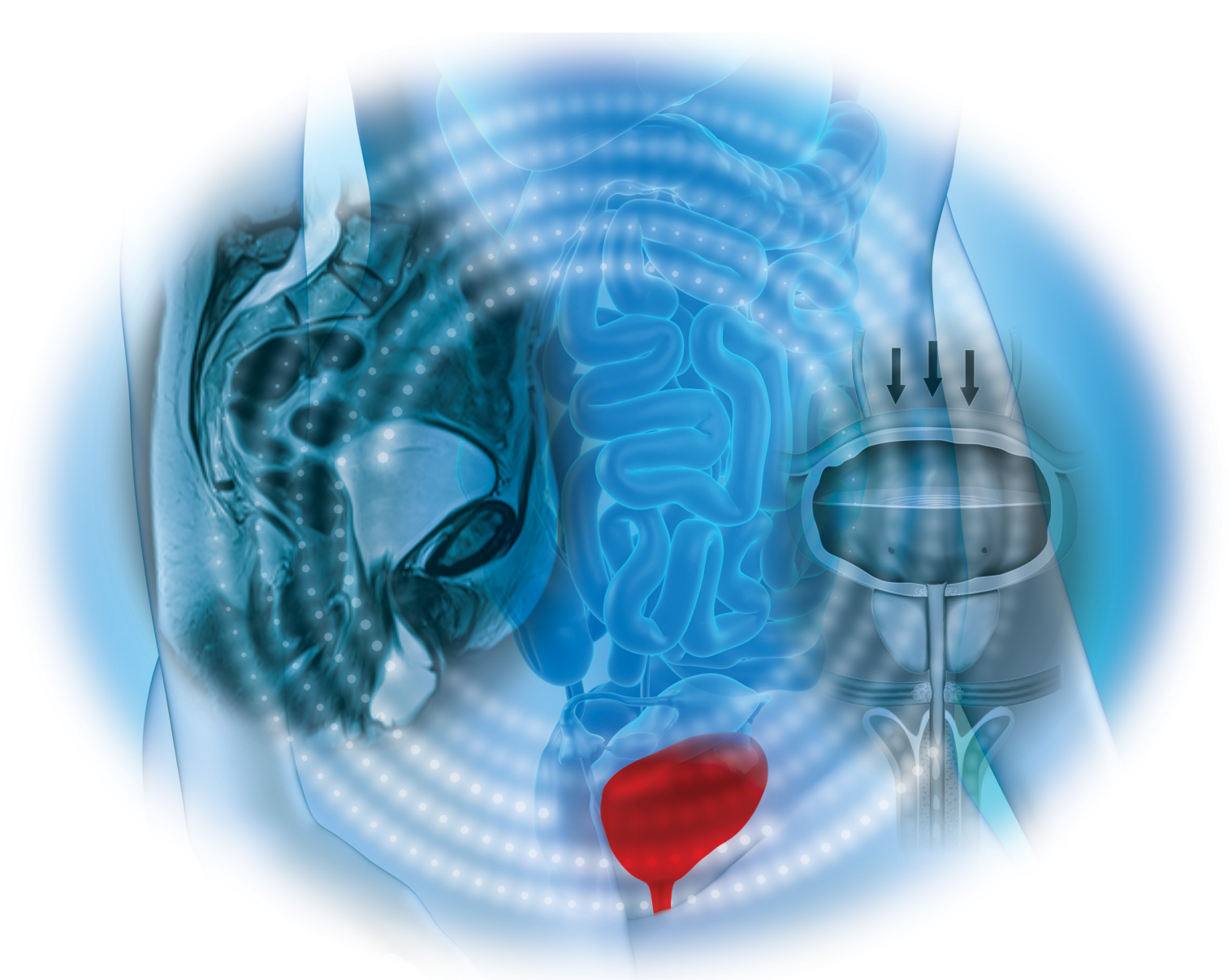
5-year RCT data on hysteropexy vs hysterectomy for POP

Nager CW, Visco AG, Richter HE, et al; National Institute of Child Health and Human Development Pelvic Floor Disorders Network. Effect of sacrospinous hysteropexy with graft vs vaginal hysterectomy with uterosacral ligament suspension on treatment failure in women with uterovaginal prolapse: 5-year results of a randomized clinical trial. Am J Obstet Gynecol. 2021;225:153.e1-153.e31. doi: 10.1016/j.ajog.2021.03.012.

The Pelvic Floor Disorders Network conducted a multisite randomized superiority trial comparing sacrospinous hysteropexy with mesh graft to vaginal hysterectomy with uterosacral ligament suspension for POP.

Study details

Postmenopausal women who desired surgery for symptomatic uterovaginal prolapse were randomly assigned to sacrospinous hysteropexy with polypropylene mesh graft using the Uphold-LITE device (Boston Scientific) versus vaginal hysterectomy with uterosacral ligament suspension. Participants were masked to treatment allocation and completed study visits at 6-month intervals through 60 months. Quantitative prolapse POP-Q exams were performed and patients completed multiple validated questionnaires regarding the presence; severity; and impact of prolapse, urinary bowel, and pelvic pain symptoms.



JANULLA/MEDICALSTOCKS/ISTOCK /PAUL BIRIS/MOMENT/GETTY IMAGES PLUS

Results

A total of 183 postmenopausal women were randomized, and 156 (81 hysteropexy and 75 hysterectomy) patients completed 5-year follow up with no demographic differences between the 2 intervention groups. Operative time was statistically less in the hysteropexy group (111.5 min vs 156.7 min). There were fewer treatment failures (a composite including retreatment for prolapse, prolapse beyond the hymen, and/or bothersome bulge symptoms) in the hysteropexy than in the hysterectomy group (37% vs 54%, respectively) at 5 years of follow up. However, most patients with treatment failure were classified as an intermittent failure, with only 16% of hysteropexy patients and 22% of hysterectomy patients classified as persistent failures. There were no meaningful differences between patient-reported outcomes. Hysteropexy had an 8% mesh exposure risk, with none requiring surgical management.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This study represents the highest quality randomized trial design and boasts high patient retention rates and 5-year follow up. Findings support further investigation on the use of polypropylene mesh for POP. In April of 2019, the US Food and Drug Administration halted the selling and distribution of vaginal mesh products for prolapse repair given the lack of safety outcomes, concerns about mesh exposure rates, and possible increased rates of pelvic pain and adverse events. This study invites pelvic reconstructive surgeons to revisit the debate of hysteropexy versus hysterectomy and synthetic mesh versus native tissue repairs. The 8% mesh exposure rate represents a challenge for the future design and development of vaginal implant materials, weighing the balancing of improved long-term efficacy with the safety and complication concerns.

CONTINUED ON PAGE 26

CONTINUED FROM PAGE 21

Preliminary 12-month data for a single-incision sling for surgical management of SUI

Erickson T, Roovers JP, Gheiler E, et al. A multicenter prospective study evaluating efficacy and safety of a single-incision sling procedure for stress urinary incontinence. J Minim Invasive Gynecol. 2021;28:93-99. doi: 10.1016/j.jmig.2020.04.014.

In this industry-sponsored study, researchers compared a novel single-incision sling to currently available midurethral slings for SUI with 12-month outcomes and adverse event details. However, results are primarily descriptive with no statistical testing.

Study details

Patients were eligible for inclusion in this prospective, nonrandomized cohort study if SUI was their primary incontinence symptom, with confirmatory office testing. Exclusion criteria included POP greater than stage 2, prior SUI surgery, plans for future pregnancy, elevated postvoid residuals, or concomitant surgical procedures. The single-incision Altis (Coloplast) sling was compared to all commercially available transobturator and retropubic midurethral slings. The primary outcome of this study was reduction in 24-hour pad

weights, and secondary outcomes included negative cough-stress test and subjective patient-reported outcomes via validated questionnaires.

Results

A total of 184 women were enrolled in the Altis group and 171 in the comparator other sling group. Symptom severity was similar between groups, but more patients in the comparator group had mixed urinary incontinence, and more patients in the Altis group had intrinsic sphincter deficiency. The Altis group had a higher proportion of "dry patients," but otherwise the outcomes were similar between the 2 groups, including negative cough-stress test and patient-reported outcomes. Two patients in the Altis group and 7 patients in the comparator group underwent device revisions. Again, statistical analysis was not performed.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Single-incision slings may reduce the risk of groin pain associated with transobturator slings and may be a good option for patients who desire less mesh burden than the traditional retropubic slings or who are not good candidates. This trial suggests that the Altis single-incision sling may be similar in outcomes and adverse events to currently available midurethral slings, but further, more rigorous trials are underway to fully evaluate this—including a US-based multicenter randomized trial of Altis single-incision slings versus retropubic slings (ClinicalTrials.gov Identifier: NCT03520114).

FAST TRACK

Initial results indicate that the Altis single-incision sling is similar in outcomes to currently available midurethral slings; more data are coming

Office-based pessary care can be safely spaced out to 24 weeks without an increase in erosions

Propst K, Mellen C, O'Sullivan DM, et al. Timing of office-based pessary care: a randomized controlled trial. Obstet Gynecol. 2020;135:100-105. doi: 10.1097/AOG.0000000000003580.

For women already using a pessary without issues, extending office visits to every 6 months does not increase rates of vaginal epithelial abnormalities, according to results of this randomized controlled trial.

Study details

Women already using a Gelhorn, ring, or incontinence dish pessary for POP, SUI, or both were randomized to continue routine care with office evaluation every 12 weeks versus the extended-care cohort (with office evaluation every 24 weeks). Women were excluded if they removed and replaced the pessary themselves or if there was a presence of vaginal epithelial abnormalities, such as erosion or granulation tissue.

Results

The rate of vaginal epithelium erosion was 7.4% in the routine arm and 1.7% in the extended-care arm, meeting criteria for non-inferiority of extended care. The majority of patients with office visits every 24 weeks

WHAT THIS EVIDENCE MEANS FOR PRACTICE

As there are currently no evidenced-based guidelines for pessary care, this study contributes data to support extended office-based care up to 24 weeks, a common practice in the United Kingdom. During the COVID-19 pandemic, with reduced health care access, these findings should be reassuring to clinicians and patients.

preferred the less frequent examinations, and there was no difference in degree of bother due to vaginal discharge. There was also no difference in the percentage of patients with unscheduled visits. The only factors associated with vaginal epithelium abnormalities were prior abnormalities and lifetime duration of pessary use.

How can we counsel patients regarding changes in sexual activity and function after surgery for POP?

Antosh DD, Dieter AA, Balk EM, et al. Sexual function after pelvic organ prolapse surgery: a systematic review comparing different approaches to pelvic floor repair. Am J Obstet Gynecol. 2021;2:S0002-9378(21)00610-4. doi: 10.1016/j.ajog.2021.05.042.

A secondary analysis of a recent systematic review found overall moderate- to high-quality evidence that were no differences in total dyspareunia, de novo dyspareunia, and scores on a validated sexual function questionnaire (PISQ-12) when comparing postoperative sexual function outcomes of native tissue repair to sacrocolpopexy, transvaginal mesh, or biologic graft. Rates of postoperative dyspareunia were higher for transvaginal mesh than for sacrocolpopexy.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This systematic review further contributes to the growing evidence that, regardless of surgical approach to POP, sexual function generally improves and dyspareunia rates generally decrease postoperatively, with overall low rates of de novo dyspareunia. This will help patients and providers select the best-fit surgical approach without concern for worsened sexual function. It also underscores the need for inclusion of standardized sexual function terminology use and sexual health outcomes in future prolapse surgery research.

Study details

The Society of Gynecologic Surgeons Systematic Review Group identified 43 original prospective, comparative studies of reconstructive prolapse surgery that reported sexual function outcomes when comparing 2 different types of POP procedures. Thirty-seven of those studies were randomized controlled trials. Specifically, they looked at data comparing outcomes for native tissue versus sacrocolpopexy, native tissue versus transvaginal mesh, native tissue versus biologic graft, and transvaginal mesh versus sacrocolpopexy.

Results

Overall, the prevalence of postoperative dyspareunia was lower than preoperatively after all surgery types. The only statistical difference in this review demonstrated higher postoperative prevalence of dyspareunia after transvaginal mesh than sacrocolpopexy, based on 2 studies. When comparing native tissue prolapse repair to transvaginal mesh, sacrocolpopexy, or biologic grafts, there were no significant differences in sexual activity, baseline, or postoperative total dyspareunia, de-novo dyspareunia, or sexual function changes as measured by the PISQ-12 validated questionnaire. ●