UPDATE Pelvic floor dysfunction

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Updates on new data on alternative management options for urinary incontinence, medical optimization prior to prolapse surgery, and long-term outcomes for prolapse repair with transvaginal mesh

Knowledge of the latest evidence on the management of pelvic floor disorders is essential for all practicing ObGyns. In this Update, we review long-term outcomes for a polyacrylamide hydrogel urethral bulking agent for the treatment of stress urinary incontinence (SUI) that presents a viable alternative to the gold standard, midurethral sling. We review the new recommendations from the American Urogynecologic Society (AUGS) regarding the administration of anticholinergics, highlighting a paradigm shift in the management of overactive bladder (OAB). In addition, we present data on a proposed threshold glycosylated hemoglobin A_{1c} (HbA_{1c}) level for patients undergoing pelvic organ prolapse (POP) surgery that may help reduce the risk of perioperative complications. Finally, we consider new evidence on the long-term efficacy and safety of transvaginal mesh for repair of POP.

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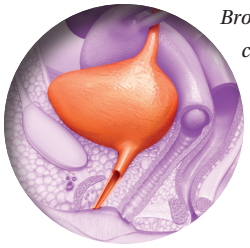
Periurethral injection with polyacrylamide hydrogel is a long-term durable and safe option for women with SUI



Brosche T, Kuhn A, Lobodasch K, et al. Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence. Neurourol Urodyn. 2021;40:502-508. doi:10.1002/nau.24589.

Urethral bulking agents are a less invasive management option for women with SUI compared with the gold standard, midurethral sling. Treatment with a polyacrylamide hydrogel (PAHG; Bulkamid)—a nonparticulate hydrogel bulking agent—showed long-term efficacy and a favorable safety profile at 7 years' follow-up.

Study details

Brosche and colleagues conducted a retrospective cohort study that included women with SUI or stress-predominant mixed urinary incontinence (MUI) who underwent

transurethral PAHG injections for primary treatment of their incontinence symptoms. The study objective was to evaluate the long-term efficacy of PAHG based on patient satisfaction. Treatment safety was a secondary outcome.

Pad counts and validated questionnaires were used to determine treatment effectiveness. Additional data on reinjection rates, perioperative complications, and postoperative complications also were collected.

Long-term outcomes favorable

During the study time period, 1,200 patients were treated with PAHG, and 7-year data were available for 553 women. Of the 553 patients, 67% reported improvement or cure of their SUI symptoms when PAHG was performed as a primary procedure, consistent with previously published 12-month data. There were no perioperative complications. Postoperative complications were transient. Short-term subjective prolonged bladder emptying was the most common complication and occurred in 15% of patients.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

PAHG injection is a durable and safe alternative for the treatment of stress urinary incontinence in women who are not candidates for or who decline treatment with alternative methods, such as a midurethral sling.

New society guidance on the use of anticholinergic medications for the treatment of OAB

AUGS Clinical Consensus Statement: Association of anticholinergic medication use and cognition in women with overactive bladder. Female Pelvic Med Reconstr Surg. 2021;27:69-71. doi:10.1097/SPV.0000000000001008.

In 2021, AUGS updated its consensus statement on the use of anticholinergic medications for the treatment of OAB. This action was in response to growing evidence that supports the association of anticholinergic medications with long-term cognitive adverse effects, including cognitive impairment, dementia, and Alzheimer disease.

Here, we summarize the most recent modifications, which differentiate the updated statement from the preceding consensus document published in 2017.

Updated AUGS recommendations

- If considering anticholinergic medications, counsel patients about the risk of cognitive adverse effects and weigh these risks against the potential benefits to their quality of life and overall health.
- Use the lowest possible dose when prescribing anticholinergics and consider alternatives such as β_3 agonists (for example, mirabegron or vibegron).
- Avoid using anticholinergic medications in women older than age 70. However, if an anticholinergic must be used, consider a medication that has low potential to cross the blood-brain barrier (for example, trospium).

WHAT THIS EVIDENCE MEANS FOR PRACTICE

For patients who are unresponsive to behavioral therapies for OAB, medical management may be considered. However, the risks of anticholinergic medications may outweigh the benefits—especially for older women—and these medications should be prescribed with caution after discussing the potential cognitive adverse effects with patients. β_3 agonists should be preferentially prescribed when appropriate. Consider referral to a urogynecologist for discussion of third-line therapies in patients who prefer to forego or may not be candidates for medical management of their OAB symptoms.

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HbA_{1c} levels > 8% may increase complications risk in urogyn surgery

Ringel NE, de Winter KL, Siddique M, et al. Surgical outcomes in urogynecology—assessment of perioperative and postoperative complications relative to preoperative hemoglobin A1c—a Fellows Pelvic Research Network study. Female Pelvic Med Reconstr Surg. 2022;28:7-13. doi:10.1097/SPV.0000000000001057.

Diabetes mellitus is a known risk factor for complications following surgery. Adoption of an HbA_{1c} level threshold for risk stratification before urogynecologic surgery may help improve patient outcomes.

Study details

Ringel and colleagues conducted a multicenter retrospective cohort study that included women with diabetes mellitus who underwent prolapse and/or SUI surgery between 2013 and 2018. The aim of the study was to identify a hemoglobin A_{1C} threshold that would help predict increased risk for perioperative complications in women undergoing pelvic reconstructive surgery. Demographics, preoperative HbA_{1C} levels, and surgical data were collected.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Women should be medically optimized before undergoing surgery and, while this study was restricted to urogynecologic surgery patients, it seems reasonable to assume that a similar HbA_{1c} threshold would be beneficial for women undergoing other gynecologic procedures. Appropriately screening patients and referring them for early intervention with their primary care clinician or endocrinologist may improve surgical outcomes, especially in women with an HbA_{1c} level > 8%.

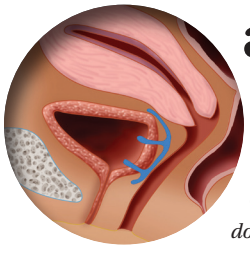
Complication risks correlated with higher HbA_{1c} threshold

The study included 807 women with HbA_{1c} values that ranged from 5% to 12%. The overall complication rate was 44%. Sensitivity analysis was performed to compare complication rates between patients with varying HbA_{1c} levels and determine a threshold HbA_{1c} value with the greatest difference in complication rates.

The authors concluded that women with an HbA_{1c} level ≥ 8% showed the greatest increase of perioperative complications. Patients with an HbA_{1c} ≥ 8%, compared with those who had an HbA_{1c} < 8%, had a statistically significantly increased rate of overall (58% vs 42%, P = .002) and severe (27% vs 13%, P< .001) perioperative complications.

After multivariate logistic regression, the risk of overall complications remained elevated, with a 1.9-times higher risk of perioperative complications for women with an HbA_{1c} ≥ 8%.

Success is similar for TV mesh and native tissue repair



Kahn B, Varner RE, Murphy M, et al. Transvaginal mesh compared with native tissue repair for pelvic organ prolapse. Obstet Gynecol. 2022;139:975-985. doi:10.1097/AOG.0000000000004794.

The distribution of vaginal mesh kits for the repair of POP was halted by the US Food and Drug Administration (FDA) in 2019. However, concerns have been raised

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about the measures used by the FDA to justify pulling these devices from the market. A cohort study compared 36-month outcomes between women who underwent prolapse repair with newer generation transvaginal mesh versus native tissue repair.

Study details

In a nonrandomized prospective multicenter cohort study, Kahn and colleagues compared outcomes in women with POP who underwent native tissue repair or transvaginal mesh repair with the Uphold LITE vaginal support system. The study's objective was to compare the safety and efficacy of native tissue and transvaginal mesh prolapse repairs at 36 months postoperatively.

Treatment success was measured based on composite and individual measures of anatomic and subjective success, need for retreatment, and the occurrence of adverse events. Quality of life (QoL) measures also were obtained using validated questionnaires. Intention-to-treat and per-protocol analyses were performed.

Composite success rate was higher for mesh repair

A total of 710 patients were screened for eligibility (225 received transvaginal mesh and 485 received native tissue repair). Transvaginal mesh placement was found to be significantly superior to native tissue repair for composite success (84% vs 73%, $P = .009$) when prolapse within the hymen (that is, Ba and/or C < 0 on the Pelvic Organ Prolapse Quantification System) was used to define anatomic success.

Adverse events were similar between transvaginal mesh and native tissue repair groups, with most adverse events occurring within the first 6 months. The mesh exposure rate was 4.9%. Of the 13 incidents of mesh exposure, 4 patients required surgical intervention and 1 incident was considered a serious adverse event. QoL measures demonstrated improvement without any statistically significant differences between the treatment cohorts. ●

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This study established the superiority and safety of newer generation transvaginal mesh used for the treatment of pelvic organ prolapse. Women who received newer generation transvaginal mesh can be reassured that the prolapse recurrence rates are low and that adverse events related to their mesh are rare—even when compared with those of native tissue repair. Patients also may be reassured that most adverse events would have occurred within 6 months of the initial prolapse repair surgery.