An evidence-based pelvic organ prolapse care pathway optimizes shared decision making between patients and surgeons


1University of Texas at Austin Dell Medical School, Austin, TX, 2Albany Medical Center, Albany, NY

OBJECTIVES: Pelvic organ prolapse (POP) is common, with estimates that up to 4.9 million women will be diagnosed with POP by 2050. Evidence-based care pathways improve care standardization and patient outcomes. We created a standardized POP care pathway as a decision aid for our care team as a component of value-based care.

MATERIALS AND METHODS: Using a modified Delphi process, a multidisciplinary expert team reviewed existing guidelines and literature for POP diagnosis and treatment to reach consensus on care pathway definitions and components.

RESULTS: Our POP care pathway is seen in Figure 1. Entry occurs via an advanced practice provider (APPs) visit. Symptom and quality of life questionnaires as well as open-ended patient goals are used to guide patient-provider shared decision making. Initial evaluation includes measurement of post-void residual (PVR) and Pelvic Organ Prolapse Quantification (POP-Q) examination. Treatment choices of observation, pessary, pelvic floor physical therapy (PFPT) and surgery are presented to patients by APPs. Observation is offered for patients with normal PVR or less than Stage 3 POP. If POP is Stage 3 or 4, renal ultrasound and measurement of blood urea nitrogen and creatinine are recommended. Patients electing non-surgical management follow up by telehealth (preferred) or in-person visits as illustrated in Figure 1. Surgeon consultations are scheduled for patients desiring surgery. Surgical patients undergo urodynamics (UDS) or simple cystometry (SC) according to the UDS clinical pathway (Figure 2). SC is performed for patients with prolapse only, or prolapse with stress incontinence or mixed incontinence (MUI) with mild urge. UDS is ordered for patients with MUI with predominant or moderate urge. Postoperative follow up includes telehealth visits and minimizes in-person visits for women with uncomplicated postoperative courses. Patients with resolution of prolapse symptoms are graduated from clinic and return to their referring physician. The pathway is revised following publication of new compelling evidence.

CONCLUSION: We developed a POP care pathway to standardize care across a diverse provider group. APPs use this care pathway as a shared decision making tool for initial evaluation of patients with POP. This pathway serves as a component of value-based care and encourages team members to function at the top of their license (Figure 1).
aim for this systematic review was to examine validity evidence supporting or refuting FLS specifically as a high-stakes summative assessment tool in gynecology.

**MATERIALS AND METHODS:** We systematically searched for studies on FLS as an assessment tool in gynecology on January 30, 2019. We organized validity evidence for cognitive and manual skills portions based on validity elements of current validity framework.

**RESULTS:** From 1,971 citations identified 9 studies were included involving 319 participants. For the cognitive portion of the test, results were mixed in five studies in relationship with other variables category. For the manual portion of the test, most of the studies focused on relationships with other variables validity element with mixed findings. Concerning findings in the manual skills portion were the lack of transferability of skills to the operating room, limited mixed evidence for improvement in operating room performance, and worse performance by OBGYNs compared to other specialties. We were not able to find evidence supporting content, response process or consequences validity elements in either the cognitive or the manual skills portions of the test.

**CONCLUSION:** Validity evidence was mixed in relation with other variables category, but other validity evidence was lacking. Given the high-stakes use of this assessment, we suggest requiring further evidence and/or re-evaluating utilization of this test.

**DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS:**

Veronica Lerner: Nothing to disclose; Christopher Destephano: Nothing to disclose; Amanda Ulrich: Nothing to disclose; Esther Han: Nothing to disclose; Edgar LeClaire: Nothing to disclose; Grace Chen: Nothing to disclose.

**07 A novel, meshless method of vaginal colpopexy by sacrosphinic ligament fixation in the context of comprehensive repair of pelvic organ prolapse**

V. R. Lucente1, K. Baessler2, A. Polland3, S. A. Shobeiri1, J. D. Bertrand4, A. Garely6, M. Tuscher7, U. M. Peschers8, G. W. Davila9, E. Laron10, S. Molden11

1Institute of Female Pelvic Medicine, Allentown, PA, 2St. Joseph Krankenhaus, Berlin, Germany, 3Maimonides Medical Center, Brooklyn, NY, 4INOVA Women’s Hospital, Falls Church, VA, 5Walnut Hill Obstetrics and Gynecology Associates, Dallas, TX, 6South Nassau Community Hospital, Rockville Center, NY, 7Krankenhaus Waldfriede, Berlin, Germany, 8Isar Kliniken, Munich, Germany, 9Holy Cross Hospital, Fort Lauderdale, FL, 10Soroka Medical Center, Beer Sheva, Israel, 11The Female Pelvic Health Center, Newtown, PA

**OBJECTIVES:** Assess the safety and durability of EnPlace™ System as a minimally invasive treatment of uterine prolapse when used along with other surgical procedures for stress incontinence, cystocele, or rectocele.

**MATERIALS AND METHODS:** The study is a prospective, observational, single arm, international, multi-center study with 12-month follow-up in which 33 women > 35 years of age with pelvic organ prolapse (POP), defined as POP-Q C-point greater than -1 cm, were enrolled from 11 sites. Under anesthesia, EnPlace™ anchors were inserted bilaterally, transvaginally at the apex and deployed through the sacrospinous ligament. Two (pre-attached) sutures extend from each anchor and were tunneled behind the vagina and exited through a 1.5 cm para-cervical incision. The bilateral suture tails were passed through cervical stroma and tied to reduce the cervix to a normal position and suspend the uterus. Along with EnPlace, other vaginal, non-mesh surgeries were permitted, as needed, to provide comprehensive repair of POP.

**RESULTS:** Of the 33 women enrolled in this study, 6-month follow-up data are available for 23 patients. The women were post-meno-pausal (average age = 67.6 ± 10.1 years), and all complained of vaginal bulging. The nature of any additional surgery was reported in 17 patients: 4 patients had only the EnPlace sutures placed, and 2 patients had EnPlace and a mid-urethral sling, and 11 patients had one or more of the following: mid-urethral sling, anterior colporrhaphy, posterior colporrhaphy, perineorrhaphy and/or partial cervical amputation. The average time of the EnPlace procedure was 24 minutes, and blood loss attributed to the EnPlace procedure was minimal (< 5 ml on average). Anterior and posterior average pre-op Ba, Bp and C POP-Q scores were +0.5 cm, -0.6 cm, and +1.4 cm, respectively. At 6-month follow-up post-op, avg Bp- and C-point POP-Q scores were significantly more negative than baseline (P<0.02 for both comparisons). The average Bp-point was -2.4 cm and the C-point was -5.1 cm. Prolapse symptoms and C-point > -1 cm recurred in 4 of 23 patients at 6 months. There were 1 device related serious adverse event (SAE; rectal constriction), no procedure-related SAEs, and 1 unrelated SAE, and 1 device-related, 2 procedure-related and 3 unrelated AEs.

**CONCLUSION:** Results obtained previously demonstrated that the EnPlace™ System was safe and effective when used as a standalone procedure without concomitant repairs, and now, these results demonstrate that the EnPlace™ System is also an effective, minimally invasive procedure for treatment of uterine prolapse that can be used with other common POP repair procedures. Further follow-up is necessary to establish long term durability of the EnPlace procedure for POP when used with other common surgical POP procedures.