01 A randomized trial of sacral colpopexy, transvaginal mesh, and native tissue apical repair for post-hysterectomy vault prolapse

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OBJECTIVES: To compare the efficacy and safety of three post-hysterectomy apical repairs

MATERIALS AND METHODS: This randomized trial compared post-operative outcomes in women randomized to sacral colpopexy, transvaginal mesh, or native tissue followed for 36 to 60 months at 9 clinical sites. Anatomic evaluators remained masked to treatment assignment. Time to composite treatment failure (prolapse re-treatment, prolapse beyond the hymen, or prolapse symptoms) up to 60 months was evaluated with piecewise exponential survival models with alpha adjustment for 3 comparisons. Secondary outcomes measured every 6 months included patient-reported symptom-specific outcomes, functional efficacy and adverse events. Results from 36 months are reported since all participants completed this assessment.

RESULTS: 376 participants were randomized, 360 were treated (mean age, 66 years), and 296 (82%) completed planned study follow-up. Time to treatment failure (Figure 1) for transvaginal mesh was non-inferior to sacral colpopexy at the pre-determined hazard ratio margin of 1.93 (adjusted hazard ratio [HR], 1.05 [upper 1-sided 97% CL, 1.65, p=0.01). Statistical superiority over native tissue repair was seen with sacral colpopexy (adjusted HR, 0.57 [2-sided 99% CI, 0.33, 0.98], p=0.01) but not with transvaginal mesh (adjusted HR, 0.60 [2-sided 99% CI, 0.34, 1.03] p=0.02).

Maximum postoperative leading edge including POP-Q points Ba, Bp, and C at 36 months (mean, [95%CL]) was better in the sacral colpopexy (-1.4, [-1.6 to -1.1]) group compared to both the transvaginal mesh (-0.9, [-1.2 to -0.7], p=0.03) and native tissue groups (-0.6, [-0.9 to -0.4], p<0.001).

Perioperative outcomes and adverse events for sacral colpopexy, transvaginal mesh, and native tissue, respectively, included operative time in minutes (218, 128, 123), estimated blood loss in mL (104, 111, 96), mesh exposure (3%, 5%, N/A), urinary tract infections (31%, 53%, 49%), granulation tissue (4%, 7%, 15%), and suture exposure (5%, 3%, 14%).

At 36 months, all treatment arms showed sustained improvement over baseline in patient-reported outcomes (Figure 2) including pelvic floor and prolapse symptoms, urinary function, bowel function, sexual function, and quality of life, with notable differences between groups in the Pelvic Floor Distress Inventory (PFDI) subscales, Colorectal Anal Impact Questionnaire (CRAIQ), and Short Form Health Survey mental component. Notably, there were no differences in decision regret/satisfaction scale scores across treatment arms.

CONCLUSION: Among women seeking apical repair for post-hysterectomy vault prolapse, both sacral colpopexy and transvaginal mesh resulted in a lower composite failure rate compared to native tissue after a minimum of 36 months; however, only sacral colpopexy reached statistical significance. Results of safety and secondary efficacy outcomes varied. All three treatments resulted in sustained benefits for the majority of subjective outcomes.

Figure 1. Time to Composite Treatment Failure - Modified Intent-to-Treat Population

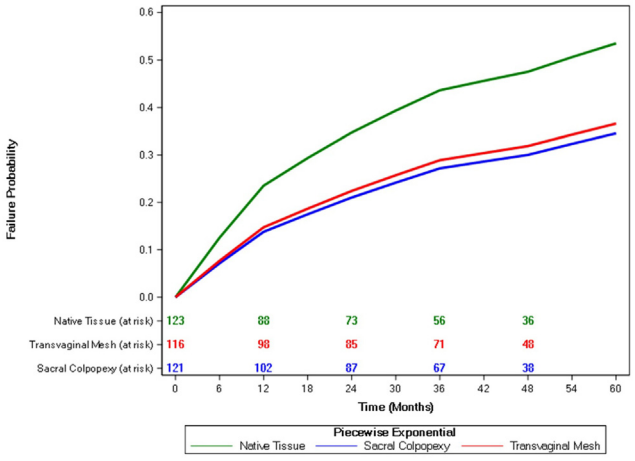

Figure 2. Patient-Reported (Secondary) Outcomes Change from Baseline[a] to 36 Months in Modified Intent-to-Treat Population

Outcome Adjusted mean (95% CI)	Native Tissue Repair (n=94)	Sacrocolpopexy (n=94)	Transvaginal Mesh (n=93)
Pelvic floor symptoms			
Pelvic Floor Distress Inventory (PFDI) score	-73.1 (-79.3 to -66.9)	-84.6 (-90.8 to -78.4)	-85.6 (-91.8 to -79.3)
Pelvic Floor Impact Questionnaire (PFIQ) score	-39.2 (-45.4 to -33.1)	-48.5 (-54.6 to -42.3)	-45.3 (-51.5 to -39.2)
Prolapse symptoms			
Patient Global Impression of Improvement (PGI-I, much better or very much better), No./total (%)[b]	79/91 (87%)	88/93 (95%)	84/89 (94%)
Pelvic Organ Prolapse Distress Inventory (POPDI) score	-36.9 (-39.8 to -34.1)	-39.0 (-41.9 to -36.2)	-40.4 (-43.2 to -37.5)
Pelvic Organ Prolapse Impact Questionnaire (POPIQ)	-18.6 (-20.7 to -16.6)	-20.2 (-22.2 to -18.1)	-19.3 (-21.4 to -17.3)
Urinary Function			
Urogenital Distress Inventory (UDI) score	-25.0 (-28.3 to -21.7)	-30.5 (-33.8 to -27.1)	-30.6 (-33.9 to -27.3)
Urinary Impact Questionnaire (UIQ) score	-15.4 (-18.3 to -12.4)	-18.5 (-21.4 to -15.5)	-18.0 (-21.0 to -15.1)
Bowel Function			
Colorectal Anal Distress Inventory (CRADI) score	-10.9 (-13.6 to -8.1)	-15.0 (-17.8 to -12.3)	-14.3 (-17.1 to -11.5)
Colorectal Anal Impact Questionnaire (CRAIQ) score	-5.4 (-7.9 to -2.9)	-9.9 (-12.4 to -7.4)	-8.1 (-10.6 to -5.6)
Sexual Function			
Pelvic Organ Prolapse Incontinence Sexual Questionnaire IUGA-Revised (PISQ-IR) average score among sexually active women	(n=37) 0.3 (0.2 to 0.5)	(n=41) 0.5 (0.3 to 0.7)	(n=44) 0.5 (0.4 to 0.7)
General Quality of Life			
Functional Activity Assessment Scale (FAS) score	3.4 (1.3 to 5.6)	5.8 (3.6 to 7.9)	4.9 (2.7 to 7.1)
Short Form Health Survey (SF-12) physical component score	3.9 (2.1 to 5.7)	3.5 (1.7 to 5.3)	3.2 (1.4 to 5.0)
Short Form Health Survey (SF-12) mental component score	1.0 (-0.8 to 2.8)	4.3 (2.5 to 6.1)	1.9 (0.1 to 3.7)
Decision Regret Scale[c]	1.4 (1.3 to 1.5)	1.2 (1.1 to 1.4)	1.3 (1.2 to 1.4)
Satisfaction with Decision Scale[c]	1.3 (1.2 to 1.4)	1.2 (1.1 to 1.3)	1.2 (1.1 to 1.3)

[a] Unless otherwise indicated results come from general linear models for repeated measurements adjusted for baseline outcome measure, pooled category (<65 and >= 65), intervention, visit, and interaction between intervention and visit, while modeling the within-participant correlations visits with an auto-regressive order 1.

[b] PGI-I results come from unstratified Fishers Exact tests.

[c] Decision Regret Scale and Satisfaction with Decision Scale are reported as score at 36 months (not change from baseline) from general linear repeated measurements adjusted for pooled site, age category (<65 and >= 65), intervention, visit, and interaction between intervention and visi modeling the within-participant correlations across visits with an auto-regressive order 1.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Shawn Menefee: Nothing to disclose; Holly E. E. Richter: Nothing to disclose; Deborah L. Myers: Nothing to disclose; Alison Weidner: Nothing to disclose; Pamela Moalli: Nothing to disclose; Heidi S. Harvie: Nothing to disclose; David D. Rahn: Nothing to disclose; Kate V. Meriwether: Nothing to disclose; Marie Fidela R. Paraiso: Nothing to disclose; Sonia Thomas: Nothing to disclose; Ryan

Whitworth: Nothing to disclose; Donna Mazloomdoost: Nothing to disclose.

02 Psychosocial predictors of change in sexual function after hysterectomy

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OBJECTIVES: Changes in female sexual function following hysterectomy have been noted in several studies and the impact on sexual function is a salient concern for many women undergoing the procedure. Yet controversy remains about which pre-surgical factors might be associated with post-surgical sexual function. Here we evaluate psychosocial predictors of change in sexual function following hysterectomy in a prospective study of pre-menopausal women.

MATERIALS AND METHODS: Women undergoing benign hysterectomy were prospectively recruited as part of an ongoing prospective observational cohort study evaluating pre-surgical predictors of post-hysterectomy outcomes on pain, quality of life, and sexual function. The Female Sexual Function Inventory (FSFI) was administered pre-surgically and six months following hysterectomy. Pre-surgical psychosocial assessments included validated measures of depression, sleep impairment, and emotional support, as well as the Relationship Assessment Scale (RAS) and the Connor Davidson Resilience (CDR) scale. Outcomes at six months were defined as 30% improvement, 30% worsening, or stable symptoms from pre-surgical FSFI scores and evaluated using multinomial regression models with the above psychosocial and clinical variables entered as predictors.

RESULTS: A total of 235 participants were evaluated. Prior to surgery, 75% of participants met impairment criteria (FSFI total score less than or equal to 26.55) and 80% six months post-surgery. Worsening sexual function was demonstrated by 16.2% of participants, stable symptoms by 66%, and improvement by 17.9%. Higher scores on the RAS and CDR scale were associated with a reduced likelihood of symptom worsening; each one-point increase on the RAS (range 7-35) was associated with a roughly 7% decrease in the likelihood of symptom worsening and each one point increase on the CDR scale (0-40) was associated with a roughly 8% decrease in the likelihood of symptom worsening (RAS OR: .933, 95% CI: .879, .991, $p = .023$; CDR scale OR: .922, 95% CI: .856, .992, $p=.031$). No other variables were associated with symptom worsening (all $p > .05$). Only baseline FSFI scores were associated with symptom improvement, such that higher scores on the FSFI prior to surgery, indicating better sexual function, were associated with less likelihood of symptom improvement (OR: .818, 95% CI: .768, .872, $p < .001$).

CONCLUSION: These findings support an underappreciated role for relationship satisfaction and psychological resilience in preventing worsening sexual function following hysterectomy. In contrast to other studies of sexual function post-hysterectomy, neither pre-surgical depression nor pelvic pain were significant predictors of change of sexual function after hysterectomy. This may be because a broader range of psychosocial factors were examined in the current study. Assessment of relationships and patient resilience may facilitate more accurate pre-surgical counseling on the likely impact of hysterectomy on sexual function.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Sara Till: Nothing to disclose; Andrew Schrepf: Nothing to disclose; Sarah Santiago: Nothing to disclose; Sawsan As-Sanie: Consultant, Myovant-Pfizer.

03 Effect of perineorrhaphy on female and male sexual function: a parallel-cohort study

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OBJECTIVES: Enlarged genital hiatus (GH≧6 cm) is common with advanced pelvic organ prolapse (POP) and may contribute to prolapse-associated sexual dysfunction. Perineorrhaphy narrows the GH to restore the normal vaginal axis and introital caliber in the setting of POP surgery. However, its impact on the sexual relationship in heterosexual couples is understudied. We aimed to characterize post-operative changes in sexual function of women with enlarged GH to examine the impact of perineorrhaphy on the sexual relationship of women and their male partners.

MATERIALS AND METHODS: This is a parallel-cohort study to a randomized controlled trial (RCT) including heterosexual women with a GH<6, POP≥stage 2, and undergoing vaginal reconstructive surgery. Women were dichotomized based on the preoperative GH (cm) with valsalva; women with GH>6 comprised the nested cohort for planned concomitant perineorrhaphy and women allocated to perineorrhaphy in the RCT with GH<6 comprised the control group. Sexual function was assessed at baseline and 6 months post-operatively. The Female Sexual Function Index (FSFI) was used to assess female sexual function; scores range from 2 to 36 and lower scores indicate higher sexual function. Participants' male partners completed the Index of Erectile Function (IIEF) questionnaire; scores range from 5-25 and lower scores indicate worse sexual function. Univariate analyses assessed differences in baseline demographic characteristics between groups. Paired t-test was applied to assess change in FSFI scores and IIEF scores at baseline to 6months between groups.

RESULTS: 79 women were enrolled; 22 with GH<6 randomized to perineorrhaphy and 35 with GH≥6 comprising the nested-cohort. Mean age and median vaginal delivery of participants was 57±13 years and 2, respectively. The mean total FSFI scores were similar between groups [19±10.4 and 21.3±9.2 at baseline and 20.2±10.6 and 22.6±8.7 at 6 month follow-up between GH≥6 vs GH<6, respectively]. The mean difference of total FSFI scores (baseline-6 month post-op) between groups was -0.26 [95% CI -3.53, 2.96] for GH≥6 and 1.34 [95% CI -2.89,-5.59] for GH<6, p=0.32, controlling for age and presence of vaginal atrophy. There were no significant differences between baseline and 6 month follow-up sub-scale scores of FSFI (arousal, satisfaction, pain, lubrication, orgasm, or desire). 15 male partners agreed to participate;12 completed baseline and 6 month follow-up. Baseline total IIEF scores were 62±10.8 and mean scores decreased to 53±20.8 at 6 months post-operatively. Scores worsened in all sub-scales including erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction.

CONCLUSION: Sexual dysfunction is common among women seeking surgical treatment with advanced stage prolapse, regardless of GH size. Perineorrhaphy may not impact female sexual function when performed concomitantly with vaginal reconstructive surgery. However, male sexual function may decline post-operatively in the presence of perineorrhaphy.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Candace Parker-Autry: Nothing to disclose; Robert E. Varner: Nothing to disclose; Holly E. E. Richter: Nothing to disclose.

04 The red bag problem: our unsustainable future in the operating room

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OBJECTIVES: Globally, healthcare creates enormous amounts of emissions. The US is responsible for 27% of healthcare emissions despite having only 4% of the world's population. We sought to reduce our economic footprint in the operating room (OR). The objective of this project was to reduce regulated medical waste (RMW) by properly sorting OR waste through education, staff buy-in, and a process change to one red RMW bag per room in line with our hospital policy.

MATERIALS AND METHODS: The first step of this project was to meet with environmental services (EVS) and the OR leadership to determine why so many RMW bags were being set up. We then sent a survey including an educational video to assess surgeons' and residents' knowledge and buy-in for properly sorting waste.

EVS was then brought to the OR to observe flow and agreed to move forward with a test of change. EVS and OR staff were trained on the new process. The criteria for what items belong in RMW were clarified and posted around the OR. This was implemented on one floor of our surgery center.

RESULTS: Our initial survey found that baseline knowledge was poor but buy-in was high, with 100% of respondents saying they would change their practice habits. After the test of change was implemented on just one floor of our OR's, percent RMW dropped from an average of 44% in the preceding 9 months to an average of 21.5%. The hospital was noted to have an average monthly savings of $7,930, with a projected saving of $95,000 in the next fiscal year.

CONCLUSION: We have found that RMW can be reduced by simple process changes that make using the solid waste bags easier. These changes are beneficial on multiple levels: reducing our carbon footprint, decreasing costs, and paving the way for other earth friendly initiatives. This process change was implemented on only one of our OR floors with great economic and financial success. Our next steps are to roll out this process to the other five OR floors, begin recycling for waste diversion, and develop a process for recycling batteries.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Clarissa A. Niino: Nothing to disclose; Catherine S. John: Nothing to disclose; Kelly Wright: Nothing to disclose.

05 Association between preoperative pelvic exam findings and locations of endometriosis

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OBJECTIVES: Endometriosis causes an inflammatory reaction, with likely irritation of certain nerve fibers. Nerve irritation can then contribute to localized and generalized pain. Lesions can occur anywhere in the pelvis. Prior studies have focused on whether symptomatology can diagnose endometriosis, finding that the association between symptoms and location of endometriosis is inconsistent. While there are physical exam findings suggestive of endometriosis, there is limited data investigating physical exam findings and location of endometriosis. This study investigated whether there is an association between preoperative physical exam findings and the location of pathology confirming endometriosis.

MATERIALS AND METHODS: This was a retrospective cohort study of all women with surgeries performed by MedSTAR Minimally Invasive Gynecologic Surgeons in Washington, DC from March 2018 through

Waste tonnage

	July	August	September	October	November	December	January	February	March	April*	May*	June*	July*
Solid Waste	27.88	26.04	23.81	29.75	24.84	25.61	22.98	23.68	12.20	42.35	30.63	31.67	37.83
RMW	19.11	16.33	15.74	19.56	21.40	34.21	10.13	14.26	28.24	10.58	10.32	9.83	7.51
Total	46.99	42.37	39.55	49.31	46.24	59.82	33.11	37.94	40.44	52.93	40.95	41.50	45.34
%RMW	41%	39%	40%	40%	46%	57%	31%	38%	70%	20%	25%	24%	17%

*Test of change implemented | RMW: Regulated Medical Waste.

Waste Cost

	July	August	September	October	November	December	January	February	March	April	May	June	July
Solid Waste	$5,349	$4,864	$4,671	$5,512	$5,086	$4,827	$4,932	$5,153	$5,727	$8,173	$6,024	$6,121	$6,698
RMW	$17,971	$16,654	$15,305	$17,538	$19,513	$32,297	$9,037	$12,909	$24,404	$9,886	$9,436	$9,269	$6,780
Total	$23,321	$21,519	$19,976	$23,049	$24,598	$37,124	$13,969	$18,062	$30,131	$18,060	$15,460	$15,390	$13,478

*Test of change implemented | RMW: Regulated Medical Waste.

March 2021 who were found to have pathological proven endometriosis. Our primary outcome was assessing the association between physical exam findings and intra-operative surgical findings. Chi-square and Fisher exact test was performed to calculate variables with a P<.05 based on bivariable analysis.

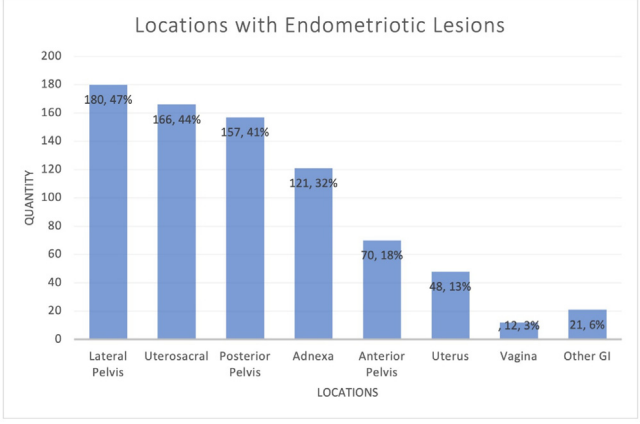
RESULTS: A total of 381 patients with endometriosis were assessed. There is a statistically significant association between levator ani tenderness, obturator tenderness, fixed uterus/ cervix, cervical motion tenderness, and vestibulodynia and the presence of endometriosis found in the lateral pelvis, posterior pelvis, and uterosacral ligaments (Figure 1). The most common sites for endometriotic lesions were noted in the lateral pelvis (47.2%), uterosacral ligaments (43.6%), and the posterior pelvis (41.2%) (Figure 2). Interestingly, there was no association between uterosacral ligament tenderness and uterosacral ligament endometriosis. However, uterosacral tenderness was associated with adhesions in the pelvis (p=.0341). Additionally, there was also an association between ovarian fossa tenderness and lateral pelvis endometriosis and uterosacral endometriosis, but not with posterior pelvis endometriosis.

CONCLUSION: Positive exam findings are associated with locations of pelvic and GI endometriosis lesions which can assist in surgical planning. The most common sites for endometriosis locations are the lateral pelvis, uterosacral ligaments and the posterior pelvis. Numerous physical exam findings correlate with endometriosis, but the specificity of a physical exam may be limited. Most patients with endometriosis had positive physical exam findings, however the location of the pain was not specific for the location of disease.

Association between endometriosis location and pre-op physical exam finding

	Levator Ani Tenderness		Obturator Tenderness		Ovarian Fossa		Fixed Uterus		Uterine Tenderness		Cervical Motion Tenderness		Uterosacral Ligament Tenderness		Vestibulodynia	
	n (%)	p	n (%)	p	n (%)	p	n (%)	p	n (%)	p	n (%)	p	n (%)	p	n (%)	p
Anterior Pelvis	33 (47%)	0.8631	23 (32.9%)	0.4292	31 (44.3%)	0.7568	9 (12.9%)	0.6911	26 (37.1%)	0.7015	24 (34.3%)	0.7656	16 (22.9%)	0.6071	24 (34.3%)	0.9318
Uterus	21 (45%)	0.7143	15 (31.3%)	0.7111	22 (45.8%)	0.9858	6 (12.5%)	0.8142	15 (31.3%)	0.2297	15 (31.3%)	0.8585	6 (12.5%)	0.9029	19 (39.6%)	0.4498
Vagina	9 (75%)	0.0734	5 (41.7%)	0.3251	6 (50%)	0.775	3 (25%)	0.1487	6 (50%)	0.4346	7 (58.3%)	0.0509	1 (8.3%)	1	6 (50%)	0.2588
Adnexa	51 (42%)	0.2782	31 (25.6%)	0.3244	64 (52.9%)	0.064	18 (14.9%)	0.1577	43 (35.5%)	0.323	38 (31.4%)	0.7825	13 (10.7%)	0.3616	39 (32.2%)	0.4859
Lateral Pelvis	106 (58.9%)	<.0001	76 (42.2%)	<.0001	107 (59.4%)	<.0001	30 (16.7%)	0.0026	79 (43.9%)	0.0745	86 (47.8%)	<.0001	19 (10.6%)	0.1716	84 (46.7%)	<.0001
Posterior Pelvis	86 (54.8%)	0.0051	55 (35%)	0.0296	81 (51.6%)	0.0649	25 (15.9%)	0.0233	55 (35%)	0.1673	61 (38.9%)	0.0239	23 (14.6%)	0.44	70 (44.6%)	0.0007
Uterosacrals	89 (53.4%)	0.0111	63 (38%)	0.0007	91 (54.8%)	0.0023	27 (16.3%)	0.0103	77 (46.4%)	0.0113	71 (42.8%)	0.0001	21 (12.7%)	0.8373	69 (41.6%)	0.0139
Other GI	9 (42.9%)	0.751	6 (28.6%)	0.966	9 (42.9%)	0.7697	4 (19%)	0.285	13 (61.9%)	0.0281	10 (47.6%)	0.1246	1 (4.8%)	0.3352	9 (42.9%)	0.4288
Other	9 (45%)	0.9109	8 (40%)	0.2646	10 (50%)	0.7091	3 (15%)	0.4908	7 (35%)	0.6951	8 (40%)	0.4542	4 (20%)	0.313	10 (50%)	0.1406
Adhesions	89 (44.7%)	0.5429	54 (28.1%)	0.766	91 (45.7%)	0.927	24 (12.1%)	0.715	85 (42.7%)	0.1389	59 (29.6%)	0.2354	19 (9.5%)	0.6341	65 (32.7%)	0.3776

* The percentage reflects the percentage of pts with endometriosis in stated location found to have stated physical exam finding



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06 Disparities in resident hysterectomy volume by trainee gender: a pilot study

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OBJECTIVES: Studies from ophthalmology and otolaryngology have demonstrated that female residents perform significantly fewer key procedures than male residents. Whether this phenomenon is present in the field of obstetrics & gynecology (ob-gyn) is unknown. Our primary aim was to compare the total number of hysterectomies logged between graduating male and female ob-gyn residents. Secondarily, we aimed to compare the number of each type of hysterectomy (abdominal, vaginal, and laparoscopic) logged as well as the observed vs. expected frequency of a male resident having the highest hysterectomy number in his class.

MATERIALS AND METHODS: This retrospective cohort study targeted residents who graduated from ACGME-accredited ob-gyn residency programs between the years 2009 and 2019. We distributed a REDCap survey to residency programs, through which respondents uploaded deidentified ACGME case logs annotated with resident gender and whether they took parental leave during their training.

A two-sided Student's t-test was used to compare mean hysterectomy numbers between male and female residents. A test of proportions was used to compare the observed vs. expected proportion of top-ranking residents (with regards to total hysterectomy number) that were male.

RESULTS: Thirteen programs contributed data from 908 residents - 791 (87%) were female and 117 (13%) were male. No residents were reported as other gender identities. 310 (34%) residents graduated from programs in the Northeast, 502 (55%) from programs in the South, and 96 (11%) from programs in the Midwest. 128 (14%) of residents took parental leave during their training, 483 (53%) did not, and this data was unavailable for 297 (33%) residents.

Male residents logged significantly more hysterectomies in total than female residents (126 ± 28 vs. 119 ± 26, p=0.008). This difference persisted when removing residents who took known parental leave. Male and female residents logged similar numbers of abdominal (51 ± 19 vs. 51 ± 21, p=0.95) and vaginal hysterectomies (22 ± 8 vs. 22 ± 8, p=0.96), but male residents logged significantly more laparoscopic hysterectomies (53 ± 25 vs. 46 ± 23, p=0.004).

Residents were ranked within each graduating class in order of total hysterectomies logged to control for the effect of graduation year and program. 579 (64%) residents graduated in a residency program class containing at least one male resident. Among these 579 residents, 117 (20%) were male and 462 (80%) were female, yet the resident with the greatest number of hysterectomies logged was male 32% of the time (p=0.007).

CONCLUSION: In our study cohort, male residents logged significantly more hysterectomies in total and more laparoscopic hysterectomies than female residents. They were also more likely than expected to have the highest hysterectomy number in their class. This raises concern for a fundamental disparity in the surgical training of female ob-gyn residents. Access to a wider cohort of case log data will help investigate this question more definitively.

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07 Women gynecologists receive lower press ganey patient satisfaction scores in a multi-center cross-sectional study

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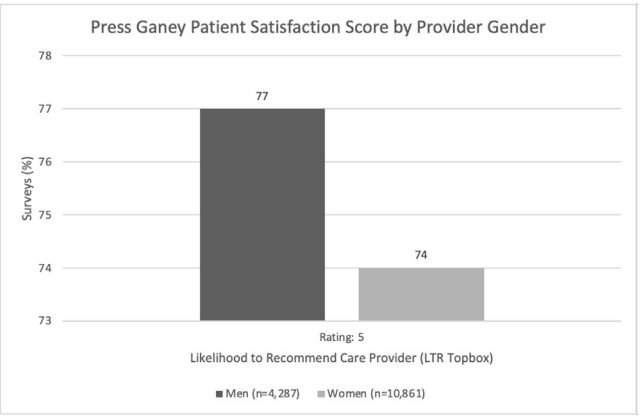
OBJECTIVES: The objective of this study was to examine the relationship between physician gender and patient satisfaction of outpatient gynecology visits as measured by the Press Ganey patient satisfaction questionnaires in a nation-wide, multi-center cohort. Previous published findings from a single institution demonstrated women gynecologists are significantly less likely to receive top scores when compared to their men counterparts. The study was limited to a single institution with a predominately white and privately insured population and may not have been generalizable to institutions with different patient demographics.

MATERIALS AND METHODS: This cross-sectional study analyzed 15,184 Press Ganey patient satisfaction surveys of 130 gynecologists linked to outpatient gynecology visits at 5 institutions from 2013 to 2020 including self-reported demographics and satisfaction. The primary outcome variable was likelihood to recommend care provider (LTR). LTR is evaluated on a 1-5 scale where a score of 5, Very Good, is commonly compared to a score of 1−4, due to the skewed distribution of LTR scores (the Topbox approach). Comparison of Topbox LTR scores was made using chi-square tests, and modeling of scores using generalized estimating equations (GEE).

RESULTS: The physician cohort was 72% women (n=10,861 surveys) and 28% men (n=4,287 surveys). Sixty-six percent of physicians were white, 16% Asian, and 18% were from race or ethnicities underrepresented in Medicine (URiM). In chi-square analyses, women physicians received an average Topbox score of 73.9% compared to 77.2% for men (p <0.0001). In the GEE model adjusting for race/ethnicity, patient and physician age, women gynecologists had significantly lower odds (17%) of receiving a top satisfaction score (OR 0.83; 95% CI 0.78-0.88; p <0.0001).

CONCLUSION: Women gynecologists are 17% less likely to receive top patient satisfaction scores when compared to their male counterparts on the basis of gender alone in a multi-center study of outpatient gynecology care. As patient satisfaction assessments become increasingly incorporated into provider evaluation, incentives, and measures of care quality, we ought to critically examine how biases may impact the patient satisfaction assessment process to avoid undue negative impacts on women gynecologists.



DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Laura Homewood: Nothing to disclose; Jonathan Altamirano: Nothing to disclose; Magali Fassiotto: Nothing to disclose; Mallory A. Stuparich: Nothing to disclose; Shana Miles: Nothing to disclose; Nicole M. Donnellan: Nothing to disclose; Julia Salinaro: Nothing to disclose; Amy Broach: Nothing to disclose; Lisa Rogo-Gupta: Nothing to disclose.

08 Uncovering disparities in compliance rates of nursing pain reassessment for obgyn patients at a large academic healthcare center

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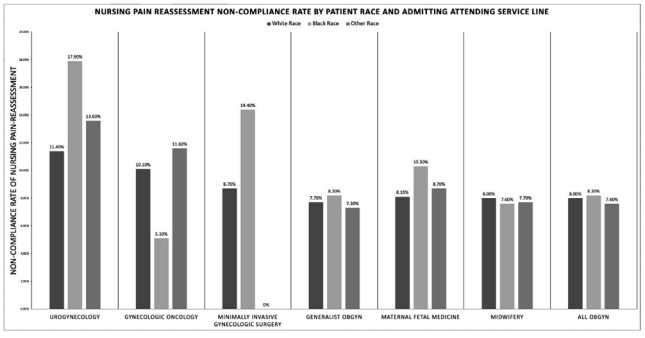
OBJECTIVES: Racial and socioeconomic disparities impact access to, delivery of, and patient perception of healthcare. When admitted to the hospital, most of a patient's time is spent interacting with nursing staff, and the greatest responsibility of direct care falls on the bedside nurse. This includes nursing reassessment of pain a metric that can be evaluated for compliance. Our objective is to evaluate for implicit biases by critically assessing racial and socioeconomic disparities in nursing pain reassessment compliance rates for OBGYN patients at our large, academic institution.

MATERIALS AND METHODS: This is a retrospective cohort study of patients admitted for OBGYN care at our large, regional hospital from September 2017 - March 2021. Nursing pain reassessment encounters were identified using Tableau, and de-identified patient and hospital encounter information was extracted from the medical record. Compliance rates were analyzed based on patient race, ethnicity, BMI, age, and insurance type. Continuous variables were summarized using quantiles and assessed with Wilcoxon rank test; categorical variables were presented as percentages and assessed with $\chi 2$ with $p<0.05$ conferring statistical significance.

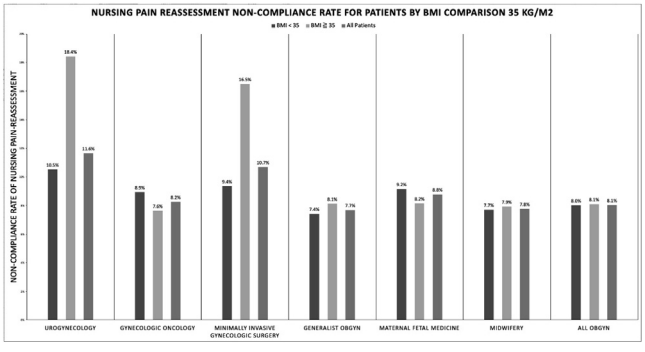
RESULTS: A total of 153082 nursing pain reassessment encounters were collected from 12109 hospital admissions of 11180 patients. Graph 1 shows the non-compliance rates broken down by patient race and admission service line. Nursing pain reassessment non-compliance rates were higher in the Black patient group than the White group for all service lines except Gynecologic Oncology and Midwifery; this difference was only statistically significant in Maternal Fetal Medicine (<0.01) and Minimally Invasive

Gynecologic Surgery (<0.01). Graph 2 shows non-compliance rates for patients with BMI <35kg/m^2 and those with BMI ≧35kg/m^2. Non-compliance was significantly higher in the group with class II obesity or greater for the service lines of Urogynecology (0.02), Minimally Invasive Gynecologic Surgery (<0.01) and General OBGYN (0.02). Significant differences were also noted based on patient age and insurance provider within service lines.

CONCLUSION: Clinically and statistically significant differences were noted in nursing pain reassessment compliance rates based on patient demographics, including greater non-compliance for Black patients and patients with class II obesity or greater. These differences were more marked in the patients admitted under Urogynecology and MIGS, though this may be attributed to an overall lower number of patients within these service lines. Quality improvement studies such as this must be performed at all levels of healthcare to investigate, uncover, and reform implicit biases that result in inferior care and contribute to the hesitation of many patients of marginalized communities to trust and seek medical attention.



Graph 1



Graph 2

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Shivani M. Murarka: Nothing to disclose; Edwin W. Holt: Nothing to disclose; Zhiguo Zhao: Nothing to disclose; Mary V. Baker: Nothing to disclose; Ukpebo R. Omosigho: Nothing to disclose; Rony A. Adam: Nothing to disclose.

09 Somatic and autonomic nerve distribution of the urethra, periurethral tissue, and anterior vaginal wall: an immunohistochemical study in adult female cadavers

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OBJECTIVES: Procedures such as retropubic sling placement and sacrocolpopexy may disrupt nerve fibers in the retropubic space and anterior vagina, though knowledge of neuroanatomy in this region is limited. Our objective was to characterize the density and distribution of autonomic and somatic nerves in the periurethral tissue and anterior vaginal wall.

MATERIALS AND METHODS: En bloc pelvic sections were harvested from female cadavers 24 hours from death. Axial sections were made at the midurethra (just proximal to the perineal membrane), proximal urethra (urethrovesical junction), and upper trigone (level of ureteric orifices) to the lateral boundary of the arcus tendineus fascia pelvis. Anatomic subregions of periurethral and vaginal tissue were denoted as middle, medial and lateral (Figure). Double immunofluorescent staining was performed using antibodies against Beta III tubulin (βIIIT), a global axonal marker, and myelin basic protein (MBP), a myelinated nerve marker. Multichannel fluorescent images were taken on a Zeiss Axioscan.Z1 slide scanner. Anatomic regions were manually annotated in Zeiss Zen Blue Lite. Threshold-based automatic image segmentation distinguished areas stained with βIIIT and MBP alone and double positive regions. Autonomic and somatic nerve density was calculated as percentage of the region area stained with βIIIT antibodies alone, and with both βIIIT and MBP antibodies or MBP alone, respectively. T-tests compared nerve density between regions.

RESULTS: Six cadavers, aged 22-73, were examined, including 5 nulliparas. Average autonomic nerve density was greater than somatic density in all regions. The highest total nerve density was in the medial periurethral tissue at the level of the midurethra (0.97% total, 0.78% autonomic and 0.19% somatic). The second highest total density was in the middle anterior vaginal wall at the midurethra (0.92% total, 0.87% autonomic and 0.05% somatic). Somatic nerve density was significantly higher in the medial (0.19% v. 0.02%, p =0.008) and lateral (0.13% v. 0.04%, p=0.027) regions of periurethral tissue compared to corresponding regions in the anterior vagina at the level of the midurethra.

CONCLUSION: Nerve density was highest at the level of the midurethra in the medial periurethral tissue and mid-vagina. This likely reflects the path of distal inferior hypogastric plexus fibers supplying the urethra and pudendal nerve fibers supplying urogenital sphincter complex muscles. Interestingly, the highest autonomic density was in the middle segment of the distal vagina, the location of midurethral sling placement, which may explain symptoms of voiding and sexual disfunction after incontinence surgery. Avoidance of trocar, suture or mesh placement, and extensive dissection in close proximity to the medial and dorsal aspects of the urethral wall may prevent these adverse outcomes.

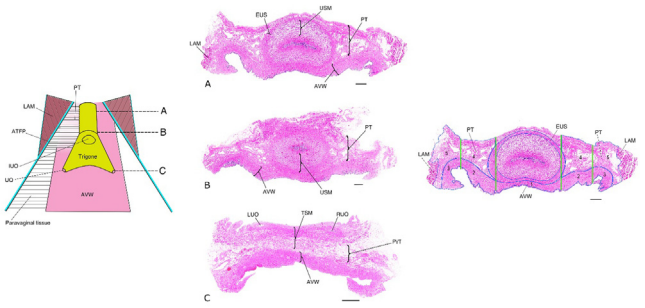

Figure. Left panel is schematic representation of the levels examined, A, midurethra; B, urethrovaginal junction; C, upper trigone. Middle panel displays Hematoxylin and Eosin (H&E) staining corresponding to levels A, B, and C. Right panel is representative H&E with outlined regions individually analyzed for somatic and autonomic nerve density, 1, middle anterior vagina; 2, medial anterior vagina; 3 lateral anterior vagina; 4, medial periurethral tissue; 5, lateral periurethral tissue. Key anatomic structures are labeled. ATFP, arcus tendineus fascia pelvis; AVW, anterior vaginal wall; EUS, external urethral sphincter; IUO, internal urethral opening; LAM, levator ani muscle; PT, periurethral tissue; PVT, perivesical tissue; TSM, trigone smooth muscle; UO, ureteric orifice; USM, urethral smooth muscle. Scale bars for A and B are 2mm and C is 5mm.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Erryn E. Tappy: Nothing to disclose; Denise Ramirez: Nothing to disclose; Abby Stork: Nothing to disclose; Kelley Carrick: Nothing to disclose; Jennifer Hamner: Nothing to disclose; Marlene Corton: Nothing to disclose.

10 Postoperative patient removal of urinary catheters: a randomized controlled trial

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OBJECTIVES: Patient removal of postoperative catheters at home offers an important alternative to standard office catheter removal. Our primary objective was to compare postoperative urinary retention rates in the early postoperative period between home and office catheter removal; secondary outcomes included pain, difficulty, satisfaction, likelihood to use again, and healthcare utilization.

MATERIALS AND METHODS: We conducted a non-blinded, randomized controlled, non-inferiority trial of women undergoing surgery for stress incontinence and prolapse from 3/2021 to 6/2022. Exclusion criteria were preoperative voiding dysfunction (PVR >150 mL) and need for prolonged postoperative catheterization. Participants discharged with indwelling catheters due to a failed void trial were randomized 1:1 to home or office removal on postoperative day 3. For home removal, participants were instructed to remove catheters at 7am and to drink 2 glasses of water. If they had difficulty voiding 5 hours after catheter removal, they came to the office for a void trial. Our primary outcome was rate of early postoperative urinary retention, defined as confirmed retention after home removal or a failed office void trial (PVR > half voided volume). Secondary outcomes were assessed at a 2-week call. Healthcare utilization (telephone calls and office visits) related to catheter issues was also assessed. At 80% power and α=0.05, we needed 100 participants (50 per group) to detect a non-inferiority margin of 11%.

RESULTS: Among 117 participants, home (n=59) and office (n=58) removal groups were similar in age (60 vs 61 years, p=0.67), BMI (29 vs 30, p=0.71) and POP-Q stage 3/4 (p=0.52), respectively; slings were more common in the office group (45.8% vs 77.6%, p<0.001). For our primary outcome, there was no difference in early postoperative retention rates (10.2% home vs 22.4% office, p=0.07). A logistic regression confirmed that removal method (OR 0.43, 95% CI 0.2, 1.3) was not associated with early retention when controlling for age, BMI, sling, diabetes or anticholinergics. For secondary outcomes, the home removal group was more likely to report "No pain" (p=0.02) and "Very likely" to use this method again (p=0.004) (Table). There were no differences in difficulty or satisfaction between groups. Number of nursing calls was not different (p=0.66); however, number of office visits was higher in the office group (median 0 (0,1) vs 1(1,1), p <0.001).

CONCLUSION: Postoperative patient removal of catheters at home was non-inferior to office removal when comparing early urinary retention rates. Participants in the home removal group had fewer office visits, reported low pain, low difficulty, and high satisfaction.

	Home (n = 59)	Office (n = 58)	P-value
No pain (vs a little, some, a lot, a whole lot)	43 (75.4%)	30 (53.6%)	0.02
Not difficult (vs a little, somewhat, very, extremely)	55 (96.5%)	51 (91.1%)	0.23
Very satisfied (vs not at all, slightly, somewhat)	54 (94.7%)	48 (85.7%)	0.11
Very likely to use again (vs not at all, slightly, somewhat)	53 (93.0%)	40 (72.7%)	0.004

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Amy L. Askew: Nothing to disclose; Ijeoma Agu: Nothing to disclose; Samantha L. Margulies: Nothing to disclose; Michelle Schroeder: Nothing to disclose; Katie LeCroy: Nothing to disclose; Elizabeth J. Geller: Grant and unpaid consultant, Boston Scientific; Marcella Willis-Gray: Nothing to disclose; Christine Chu: Nothing to disclose; AnnaMarie Connolly: Nothing to disclose; Jennifer M. Wu: Nothing to disclose.

11 Assessment of patient satisfaction with home versus office foley catheter removal placed for urinary retention after female pelvic floor surgery: a randomized controlled trial

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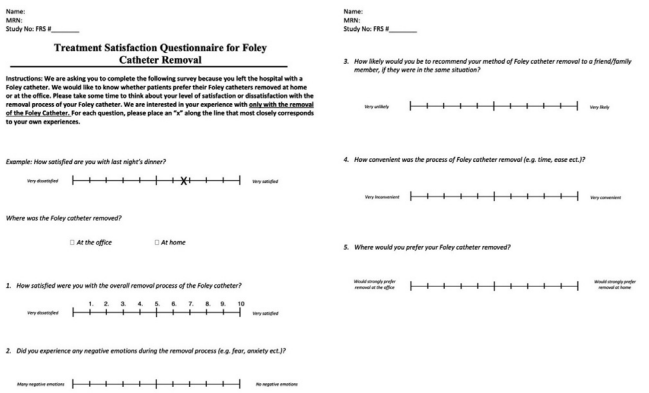
OBJECTIVES: To assess patient satisfaction with location of Foley catheter removal placed for urinary retention after urogynecologic surgery.

MATERIALS AND METHODS: Female patients over the age of 18 with urinary retention after undergoing surgery for urinary incontinence and/or pelvic organ prolapse were eligible for this randomized controlled study. Patients requiring post-operative Foley catheter reinsertion after failed voiding trial were approached for participation and were randomly assigned for home versus office removal at 2-4 days after discharge. Those randomized to home removal were educated prior to discharge and given written instructions, a voiding hat, and a 10 mL syringe. Voiding >150 mL was considered passing. An office nurse called the afternoon day of removal, and patients were asked to come into the office if unsuccessful. Patients

randomized to the office had their bladder backfilled with 300 mL of normal saline (or significant urgency of urination if threshold not reached) prior to Foley removal. Urinating >50% of instilled volume was considered passing. All patients received a visual analogue scale survey (Figure 1), created to assess patient satisfaction, the primary outcome, and four secondary outcomes. A sample size of 40 participants per group was needed to detect a 10mm (10%) difference in satisfaction with 80% power and an alpha of 0.05. 10% loss to follow up was included. Baseline characteristics were compared, including urodynamic parameters, perioperative indices, and patient satisfaction.

RESULTS: Of the 78 women enrolled in the study, 38 (48.7%) removed their catheter at home and 40 (51.3%) during an office visit. Median and interquartile range (IQR) for age, vaginal parity, and body mass index (BMI) were 60 (49-72) years, 2 (2-3), and 28 (24-32) kg/m2, respectively. The two groups did not differ significantly in age, vaginal parity, BMI, history of prior surgery, or type of procedures performed (including hysterectomy and midurethral sling). Patient satisfaction was comparable between the groups with a median score (IQR) of 95 (87-100) for home removal and 95 (80-98) for office removal (p=0.52). Initial pass rates also did not differ significantly between home (83.8%) versus office (72.5%) removal (p=0.23). 6/38 (15.8%) of patients in the home removal group were evaluated in the office due to inadequate voiding parameters. No one required emergent evaluation for inadequate voiding. Within 30 days postoperatively, a lower proportion of patients in the home removal group (8.3%) had urinary tract infection, compared to patients in the office removal group (26.3%) (p=0.04).

CONCLUSION: In patients with urinary retention after urogynecologic surgery, there is no difference in satisfaction with regards to location of Foley catheter removal when comparing home and office.


Name:
MRN:
Study No: FRS #_____

Treatment Satisfaction Questionnaire for Foley Catheter Removal

Instructions: We are asking you to complete the following survey because you left the hospital with a Foley catheter. We would like to know whether patients prefer their Foley catheters removed at home or at the office. Please take some time to think about your level of satisfaction or dissatisfaction with the removal process of your Foley catheter. We are interested in your experience with only with the removal of the Foley Catheter. For each question, please place an "x" along the line that most closely corresponds to your own experiences.

Example: How satisfied are you with last night's dinner?

Very dissatisfied — Very satisfied

Where was the Foley catheter removed?

□ At the office □ At home

1. *How satisfied were you with the overall removal process of the Foley catheter?*

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 Very satisfied

2. *Did you experience any negative emotions during the removal process (e.g. fear, anxiety ect.)?*

Many negative emotions — No negative emotions

Name:
MRN:
Study No: FRS #_____

3. *How likely would you be to recommend your method of Foley catheter removal to a friend/family member, if they were in the same situation?*

Very unlikely — Very likely

4. *How convenient was the process of Foley catheter removal (e.g. time, ease ect.)?*

Very inconvenient — Very convenient

5. *Where would you prefer your Foley catheter removed?*

Would strongly prefer removal at the office — Would strongly prefer removal at home

All patients were surveyed with a visual analogue scale, "Treatment Satisfaction Questionnaire for Foley Catheter Removal" (Figure 1), created to assess patient satisfaction (the primary study outcome) and four secondary outcomes. A sample size of 40 participants per group was needed to detect a 10mm (10%) difference in satisfaction with 80% power and an alpha of 0.05.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Patrick Popiel: Nothing to disclose; Christina Swallow: Nothing to disclose; Jennie E. Choi: Nothing to disclose; Keisha Jones: Nothing to disclose; Xiao Xu: Nothing to disclose; Oz Harmanli: Nothing to disclose.

12 Output force and force ratio of laparoscopic graspers: an evaluation of ergonomics

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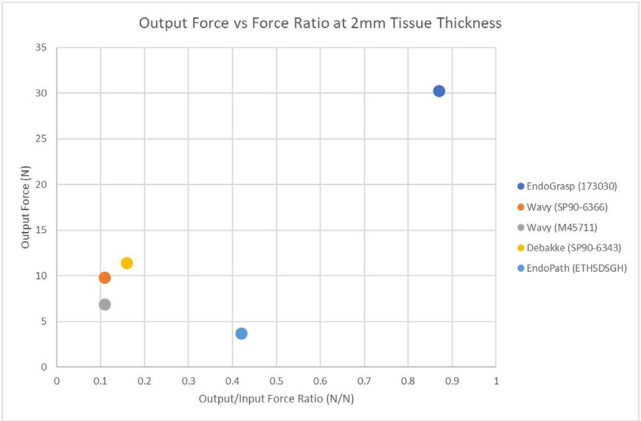
OBJECTIVES: "Surgeon's thumb," or thenar paresthesia, can result from prolonged or excessive grip force during laparoscopy. This is particularly relevant in gynecology, where procedures involving enlarged uteri or fibroids are common. Though this method of injury is well known, there is a paucity of data to guide surgeons in selecting more efficient, ergonomic instruments. This study compares the ratio of applied tissue force and required surgeon input in a sample of common laparoscopic graspers, with the goal of providing quantitative data applicable to surgical ergonomics and surgeon instrument choice.

MATERIALS AND METHODS: Laparoscopic graspers with varied ratcheting mechanisms and tip shapes were evaluated. Brands included Snowden-Pencer, Covidien, Aesculap and Ethicon. A kocher was used as an open instrument comparison. Flexiforce A401 thin-film force sensors were used to measure applied forces. Data was collected and calibrated using an Arduino Uno microcontroller board with Arduino and Matlab software. Single handed, complete closure of each device's ratcheting mechanism was performed three times. Maximum required force in Newtons (N) was recorded and averaged. The average applied force was measured with a bare sensor and the same sensor between two different thicknesses of LifeLike BioTissue.

RESULTS: The most ergonomic grasper was identified by the highest ratio of output force compared to required surgeon input. The kocher required an average input force of 33.66N, with its highest output ratio of 3.46 (112N output). The Covidien EndoGrasp was the most ergonomic, with an output ratio of 0.96 on the bare force sensor (31.4N output) and an average input force of 37.9N. The Snowden-Pencer wavy grasper was the least ergonomic, with an output ratio of 0.07 when applied to the bare force sensor (5.9N output) and the highest average input force of 85.9N. All graspers except for the EndoGrasp had improving output ratios as tissue thickness and subsequent grasper contact area increased. Input force in excess of that provided by the ratcheting mechanisms did not increase output force in a clinically significant amount for any of the instruments evaluated.

CONCLUSION: Laparoscopic graspers vary widely in their ability to provide reliable tissue force without requiring excessive input by the surgeon, and a point of diminishing returns exists when surgeon input exceeds that of the capability of ratcheting mechanisms. Output force and force ratio can be used as quantitative measures of the efficiency of laparoscopic instruments. Providing users with this type of data could allow for easier identification of the most ergonomic instrument for the desired application.



DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Emily Olig: Nothing to disclose; Madhuri Reddy: Nothing to disclose; Sara Wilson: Nothing to disclose.

13 Crowd-sourced assessment of laparoscopic surgical skills for ob/gyn residents

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OBJECTIVES: This study sought to understand how unbiased crowd-sourced assessment of residents' laparoscopic skills compares to the current faculty assessment of residents' laparoscopic skills in an OB/GYN residency program.

MATERIALS AND METHODS: Residents from a single academic OB/GYN residency program were recruited to partake in this prospective educational intervention study. Individual performance videos were recorded and uploaded to the Crowd-Sourced Assessment of Technical Skills (CSATS) database where they were analyzed. Formal written feedback reports from the CSATS system were sent to the residents after each uploaded case. After completion of the video submission/feedback portion of the study, all residents were asked to complete a survey addressing satisfaction, timeliness, and utility of the CSATs feedback method overall and in comparison to the residency's traditional attending feedback and to the standard written feedback through an existing evaluation platform.

RESULTS: A total of 16 residents submitted 65 videos of operations. Of the 16, six (37.5%) submitted five or more videos and ten (62.5%) submitted 1-4 videos. Overall comparison of CSATS to faculty evaluation scored a 3.25 (3 meaning CSATS and faculty evaluations are equivalent). Residents found that CSATS response time was slower than receiving in person feedback from faculty with a mean score of 2.81 (3 meaning equivalent response times). When comparing CSATS to the standard feedback form, residents felt strongly that CSATS was superior to the standard form for both surgical skill feedback and procedure evaluation, with both categories receiving a mean top score (mean: 5.0 "CSATS is far superior"). While residents agreed that CSATS was thorough and could help with laparoscopic skills (mean scores 3.88 and 3.62, respectively), they are not exercising laparoscopic skills more or less based on CSATS feedback (mean score: 3.0, "I exercise the same as before"). When comparing response from residents with low volume (1-4 submitted videos) CSATS to high volume (>4 videos) CSATS feedback, there were no statistical differences for any of the questions. Overall, residents reported satisfaction with CSATS evaluation with a mean score of 4.13. Residents report that there may be an adjunctive role for CSATS as a standard tool for laparoscopic evaluation with an average score of 4.06 and no statistical difference in low volume compared to high volume.

CONCLUSION: Residents were generally satisfied with CSATS as a form of feedback, both in timeliness and as an overall feedback tool. The majority found it was comparable, but not superior, to the traditional real-time and in-person feedback. They did strongly feel that it was superior to the standard feedback form and agreed that this should be implemented as a standard tool for evaluation.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Bayley Clarke: Nothing to disclose; Nicholas Hazen: Nothing to disclose; James Robinson: Nothing to disclose; Jovana Tavcar: Nothing to disclose.

14 Risk adjusted outcomes of abdominal surgery with gynecologic vs general surgeons

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OBJECTIVES: In response to persistent bias and systematic devaluation of gynecologic surgery, we aimed to assess differences between general and gynecologic surgeons' risk-adjusted postoperative outcomes using a national surgical database.

MATERIALS AND METHODS: We queried the 2019 National Surgical Quality Improvement Program (NSQIP) database for all primary abdominal procedures with at least 100 occurrences performed by either a general surgeon or gynecologist. Cases were divided into laparoscopic or open, based on CPT coding. Surgeries performed in an emergent setting, for hernia repair or with a documented preoperative wound or soft tissue infection were excluded. We selected adverse outcomes related to undergoing intrabdominal surgery that were not specific to general surgery or gynecologic procedures (unplanned postoperative readmission, reoperation and mortality) along with four measures of wound integrity (superficial surgical site infection (SSI), deep or organ space SSI, wound disruption/dehiscence, and readmission with an incisional hernia (ICD-10-CM K43.0-43.2)). Multivariable logistic regression compared outcomes controlling for potential confounding patient and case characteristics.

RESULTS: A total of 386,711 cases were identified, with 77.1% performed by general surgeons. Power analysis demonstrated >99% power to detect a 0.1% difference in the rarest outcome (hernia readmission) between groups. Notably, there were differences in population characteristics, with gynecologic patients having a lower ASA class (Chi-Square P<0.001) and higher proportion of individuals with an independent functional status (99.0 vs 97.8%, P<0.001). Gynecologic patients were also younger (mean(95%CI) 46.6(46.5, 46.7) vs 55.4(55.3, 55.5)) and had a higher BMI (31.4(31.3, 31.4) vs 30.5(30.5, 30.6)). Table 1 demonstrates the results of the bivariate and multivariate comparisons adjusting for these baseline population differences along with associated P-values and confidence intervals.

CONCLUSION: Our analysis found no evidence of worsened outcomes associated with intrabdominal surgery with a gynecologic surgeon and found higher odds of complications among those undergoing surgery with a general surgeon. We implore medical leaders to not only challenge explicit and implicit gender bias manifest within their specialties, but also to dismantle systems that devalue women's health care and reinforce stereotypes regarding relative provider skills.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Douglas Luchristt: Nothing to disclose; Cheryl Iglesia: Nothing to disclose; Kimberly Kenton: Nothing to disclose; Jocelyn J. Fitzgerald: Nothing to disclose.

15 Pelvic floor muscle training versus radiofrequency for women with vaginal laxity: randomized clinical trial

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OBJECTIVES: To compare the effect of radiofrequency (RF) and pelvic floor muscle training (PFMT) on the treatment of women with vaginal laxity (VL).

MATERIALS AND METHODS: A prospective, parallel, randomized clinical trial, including women aged ≥ 18 years, with a complaint of VL assessed by direct question (yes/no) and classified by questionnaire (VL Questionnaire), from February 2020 to December 2021 in a tertiary hospital. Two groups (RF − Wavetronic 6000 Megapulse Fraxx and PFMT) were evaluated at baseline, 30 days, and six months follow-up (RF: 3 sessions 4 weeks apart; PFMT: 12 individual sessions for 12 weeks). The primary endpoint was the indication of improvement in symptoms of VL through the Global Response Assessment (GRA). Secondary outcomes were changes in questionnaire scores (FSFI, FSDS-R, ICIQ-SF, ICIQ-VS), in the modified Oxford Scale, and in the quantification of pelvic organ prolapse (POP-Q). Analysis was intention-to-treat based.

RESULTS: After recruiting 167 participants, 87 were included (RF n=42; PFMT n=45), with homogeneous clinical and sociodemographic characteristics. The type of sexual intercourse (p=0.486), duration of VL (p=0.941), perception of VL (p=0.681), and type of VL complaint (p=1.000) did not differ between groups and between follow-up periods. All questionnaires (Table 1) showed improvement ($p<0.05$) in their total scores and scales for both groups and follow-ups. The GRA was not statistically different between the groups (p=0.138) and follow-ups. On physical examination, POP-Q showed significant improvement in points Aa, Ba at 30 days follow-up and Aa, Ba, and Ap ($p<0.001$) at six months follow-up in the PFMT group and in points C (p=0.004) and D (p=0.043) at 30 days follow-up and at point C (p=0.028) at six months follow-up in the RF group. PFM strength significantly improved in the RF (p=0.006, 30 days; p=0.049, six months) and PFMT ($p<0.001$, both follow-ups) groups, with a significant gain in the PFMT group.

CONCLUSION: Both RF and PFMT improved sexual, vaginal, and urinary symptoms 30 days and six months follow-ups. Although the PFMT group showed greater gains in PFM strength and POP-Q, the groups did not differ in the GRA at 30 days and at six months follow-ups.

Table 1. Assessment of women of vaginal laxity using questionnaires by treatment group (ITT analysis).

Questionnaire/ Scores	Radiofrequency (n=42)				PFMT (n=45)			
	Baseline	30 days Follow-up	p-Value	6 Months	p-Value	Baseline	30 days Follow-up	p-Value	6 Months	p-Value
FSFI										
Desire	3.01 ± 1.16	3.77 ± 1.13	**0.001**	3.80 ± 1.13	**0.001**	3.41 ± 1.26	3.87 ± 1.12	**0.007**	4.04 ± 1.00	**0.001**
Arousal	3.39 ± 1.23	4.23 ± 1.34	**0.001**	4.00 ± 1.14	**0.001**	3.73 ± 1.26	4.43 ± 1.07	**0.001**	4.49 ± 1.06	**0.001**
Lubrication	4.06 ± 1.30	4.94 ± 1.23	**0.001**	4.61 ± 1.15	**0.002**	4.52 ± 1.34	5.00 ± 1.09	**0.011**	4.97 ± 1.03	**0.012**
Orgasm	3.56 ± 1.44	4.50 ± 1.38	**0.001**	4.46 ± 1.29	**0.001**	3.91 ± 1.44	4.39 ± 1.47	**0.005**	4.58 ± 1.38	**0.001**
Satisfaction	4.15 ± 1.36	4.83 ± 1.07	**0.001**	4.70 ± 1.34	**0.031**	4.04 ± 1.45	4.68 ± 1.31	**0.001**	4.91 ± 1.18	**0.001**
Pain	4.26 ± 1.58	4.95 ± 1.19	**0.001**	4.92 ± 1.16	**0.001**	4.86 ± 1.26	5.32 ± 1.20	**0.010**	5.33 ± 1.02	**0.005**
Total Score	22.42 ± 6.71	27.21 ± 5.93	**0.001**	26.50 ± 5.49	**0.001**	24.48 ± 5.80	27.68 ± 5.58	**0.001**	28.32 ± 5.20	**0.001**
ICIQ – Vaginal Symptoms										
Vaginal Symptoms	17.07 ± 7.19	10.67 ± 7.79	**0.001**	10.17 ± 8.17	**0.001**	13.83 ± 7.89	7.23 ± 7.15	**0.001**	9.82 ± 8.91	**0.001**
Sexual Matters	25.98 ± 20.31	15.98 ± 10.18	**0.001**	15.64 ± 10.27	**0.001**	26.69 ± 21.59	11.77 ± 17.28	**0.001**	14.20 ± 16.62	**0.001**
Quality of Life	6.24 ± 3.51	3.07 ± 3.39	**0.001**	3.67 ± 3.75	**0.001**	5.29 ± 3.54	2.37 ± 3.38	**0.001**	4.16 ± 5.30	**0.002**
Q.4 – Vaginal Laxity	2.38 ± 0.79	1.31 ± 0.90	**0.001**	1.33 ± 1.00	**0.001**	2.06 ± 0.84	1.06 ± 1.06	**0.001**	1.36 ± 1.09	**0.001**
FSDS-R	24.74 ± 15.13	15.88 ± 13.46	**0.001**	16.71 ± 14.34	**0.001**	28.42 ± 14.74	17.42 ± 13.97	**0.001**	16.33 ± 14.23	**0.001**
ICIQ-Short Form	8.45 ± 7.13	4.31 ± 5.32	**0.001**	4.60 ± 5.59	**0.001**	10.16 ± 6.36	5.64 ± 6.77	**0.001**	5.87 ± 6.57	**0.001**

ITT: Intention to treat; Wilcoxon test; PFMT: Pelvic Floor Muscle Training; FSFI: Female Sexual Function Index; ICIQ: International Consultation on Incontinence Questionnaire; Q.4: Question number 4; FSDS-R: Female Sexual Distress Scale – Revised;

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Luiz G. Oliveira Brito: Nothing to disclose; Glaucia M. Pereira: Nothing to disclose; Cristiane M. Almeida: Nothing to disclose; Natalia Martinho: Nothing to disclose; Kleber C. Andrade: Nothing to disclose; Cassia R. Juliato: Nothing to disclose.

16 Decreasing utilization of vaginal hysterectomy: an analysis by candidacy for vaginal approach

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OBJECTIVES: Although vaginal hysterectomy (VH) is recommended as the preferred approach for benign hysterectomy whenever feasible, the rate of VHs performed is declining. It is unclear whether the number of appropriate candidates for VH is a contributing factor. We sought to assess trends in hysterectomy routes by patients who are likely and unlikely candidates for a vaginal approach using two independent surgical registries.

MATERIALS AND METHODS: We performed a retrospective cohort study of patients who underwent vaginal, abdominal, or laparoscopic hysterectomy between 2017-2020 in two surgical registries with chart-abstracted hysterectomy data: the National Surgical Quality Improvement Program (NSQIP) database and the Michigan Surgical Quality Collaborative (MSQC). Patients undergoing hysterectomy for a primary diagnosis of benign uterine pathology, dysplasia, abnormal uterine bleeding, pelvic floor disorder, or pelvic pain based on International Classification of Diseases codes were eligible for inclusion; patients undergoing hysterectomy for malignancy, endometriosis, adnexal indications, or other indications were excluded. Based on an algorithm developed to guide surgical approach, patients were deemed likely VH candidates if they were parous, had no history of pelvic or abdominal surgery, and had a uterine weight < 280 gm on pathology. Average annual changes in the proportion of likely VH candidates and route of hysterectomy were assessed using linear regression and trends were compared.

RESULTS: A total of 81,194 patients in NSQIP and 16,910 patients in MSQC met inclusion criteria. Of these patients in NSQIP and MSQC, 14,278 (17.6%) and 4,068 (24.1%) were deemed likely VH candidates, respectively. Among likely VH candidates, the proportion who underwent VH was 34.1% and 29.2%; among unlikely VH candidates, it was 13.8% and 10.6%, respectively. There was a decrease in the overall proportion of VH in both datasets (NSQIP:

-1.2%/year, p<0.01; MSQC -0.5%/year; p=0.02). This decreasing trend was more pronounced among likely VH candidates (NSQIP: -1.9%/year, p<0.01; MSQC -1.5%/year, p=0.04) compared to unlikely VH candidates (NSQIP: -1.1%/year, p<0.01; MSQC -0.2%/year, p=0.53); the difference reached statistical significance in the NSQIP dataset (p<0.01) but not the MSQC dataset (p=0.08). There was no significant change in the proportion of likely VH candidates in the NSQIP dataset (p=0.33) while a decrease of -0.7%/year was identified in the MSQC dataset (p=0.02).

CONCLUSION: The proportion of VH performed for eligible indications decreased between 2017-2020 in two independent surgical registries. This negative trend was present and more pronounced among patients who were likely candidates for VH based on favorable parity, surgical history, and uterine weight. These trends are important to consider, as they may have implications on preservation of vaginal surgery skills, surgical training, and outcomes.

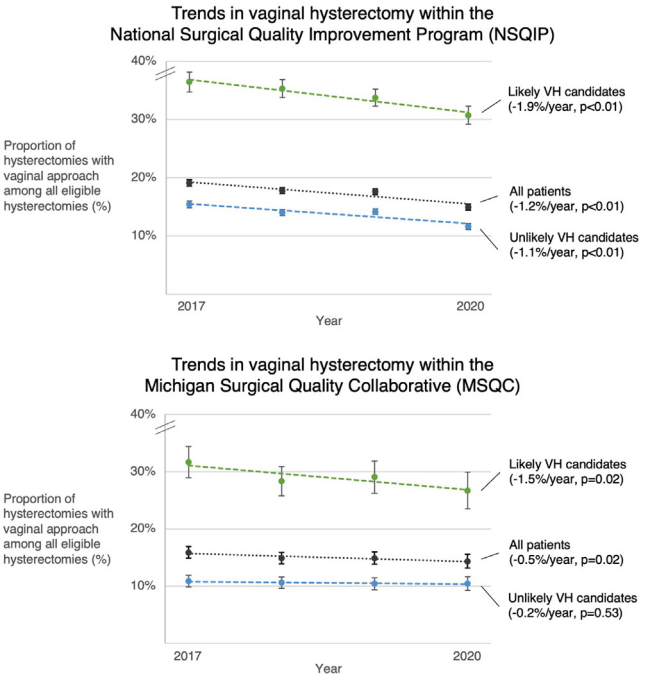

Figure 1. Trends in the proportion of vaginal hysterectomy (VH) among patients undergoing hysterectomy for benign uterine pathology (eg, fibroids), dysplasia, abnormal uterine bleeding, pelvic floor disorder, and pelvic pain. Top graph shows trend within the National Surgical Quality Improvement Program (NSQIP) registry; bottom graph shows trend within the Michigan Surgical Quality Collaborative (MSQC) registry. Within each independent registry, patients are stratified by likely or unlikely candidates for vaginal approach based on parity, history of prior pelvic or abdominal surgery, and uterine specimen weight. Trend percentages represent the predicted change in the proportion of vaginal hysterectomy with each successive year. Error bars represent 95% confidence intervals.

Schmitt JJ, et. al. Prospective Implementation and Evaluation of a Decision-Tree Algorithm for Route of Hysterectomy. Obstet Gynecol. 2020 Apr;135(4):761-769.

Figure 2. Reference for prospective algorithm developed to determine optimal route of hysterectomy based on history of laparotomy, uterine size, and vaginal access.

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17 Bladder instillations versus onabotulinumtoxina injection for bladder pain syndrome: a randomized trial

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OBJECTIVES: To compare efficacy of bladder instillations and intradetrusor onabotulinumtoxinA injection for bladder pain syndrome.

MATERIALS AND METHODS: Patients with clinical criteria for bladder pain syndrome, O'Leary-Sant (OLS) questionnaire scores ≥ 6, and desiring procedural management were randomized to instillations or onabotulinumtoxinA. The primary outcome was differences in OLS scores at 2 months posttreatment between groups. Secondary outcomes included sexual function, physical/mental health status, pain, patient satisfaction, treatment perception, and retreatment rates.

RESULTS: This is an interval analysis of 45 patients (22 instillation, 23 onabotulinumtoxinA) in an ongoing trial. There were no differences in demographic or clinical characteristics between groups. From baseline to 2 months posttreatment, OLS scores decreased in both groups (Interstitial Cystitis Symptom Index (ICSI) -6.3 (CI -8.54, -3.95), p<.0001; Interstitial Cystitis Problem Index (ICPI) -5.9 (CI -8.18, -3.57), p<.0001). At 2 months posttreatment, patients in the onabotulinumtoxinA group had lower OLS scores versus those in the instillation group respectively (ICSI 5.9±4.8 vs 9.6±4.5, p=.006; ICPI 5.7±5.4 vs 8.0±4.2, p=.048). Differences in OLS scores between groups were not maintained at 6 months. The majority of remaining questionnaires showed improvement from baseline to 2 months, though not statistically significant. Patient satisfaction, perceived treatment convenience, or willingness for retreatment did not differ between groups.

CONCLUSION: Both onabotulinumtoxinA injection and bladder instillations are effective for patients with bladder pain syndrome with clinical improvement at 2 months. The recent American Urologic Association algorithm equalizes treatment options, including oral medications, instillations, and procedures. Our early findings suggest that intradetrusor onabotulinumtoxinA injection may be more effective than bladder instillation therapy.

2 Month Post-Treatment Outcomes

Questionnaire scores	Bladder instillation therapy (BIT) N=22	Intradetrusor onabotulinumtoxinA injection N=23	p-value	Group Differences (2 months - Baseline) (95% CI)	p-value
OLS (0-36)					
ICSI (0-20)	9.6 ± 4.5	5.9 ± 4.8	.006[a]	-6.3 (-8.54, -3.95)	<.0001[a]
ICPI (0-16)	8.0 ± 4.2	5.7 ± 5.4	.048[a]	-5.9 (-8.18, -3.57)	<.0001[a]
FSFI (pain) (0-6)	2.4 ± 2.5	3.1 ± 2.5	.824	1.0 (-0.169, 2.07)	.091
FSDS-R (0-52)	18.6 ± 19.1	19.6 ± 19.6	.674	-6.6 (-16.82, 3.57)	.186
SF-12 (0-100)					
PCS	45.1 ± 11.2	43.6 ± 11.4	.717	2.7 (-2.71, 8.15)	.303
MCS	41.7 ± 10.5	47.5 ± 9.1	.223	0.2 (-2.95, 3.25)	.920
VAS (0-10)	3.2 ± 2.9	3.3 ± 3.0	.960	-0.3 (-2.02, 1.39)	.701

Data are mean ± standard deviation unless otherwise specified. BIT: bladder instillation therapy; OLS: O'Leary-Sant questionnaire; ICSI: Interstitial Cystitis Symptom Index; ICPI: Interstitial Cystitis Problem Index; FSFI: Female Sexual Function Index, pain subset; FSDS-R: Female Sexual Dysfunction Scale-Revised; SF-12: Short-Form 12; PCS: Physical Component Score; MCS: Mental Component Score; VAS: visual analog scale Group differences at 2 month timepoint were calculated via matched pairs analysis. a Statistically significant

Figure 2. Longitudinal O'Leary-Sant (OLS) Questionnaire Scores

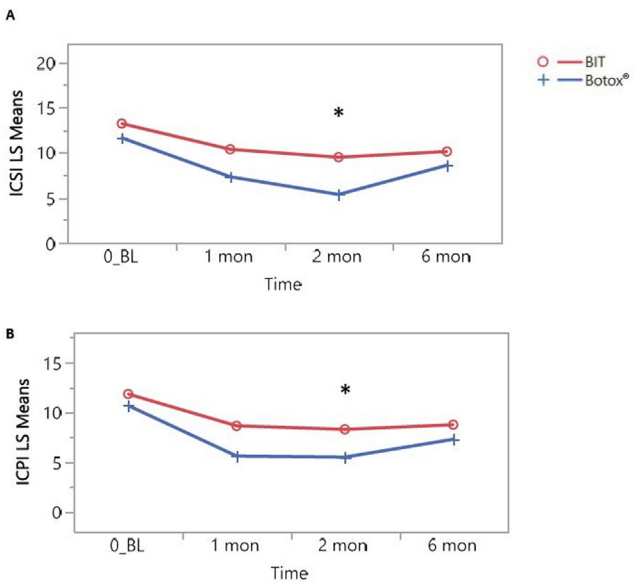

Figure 2. A graphical representation of the mean O'Leary-Sant (OLS) subscale scores (Interstitial Cystitis Symptom Index [ICSI]; Interstitial Cystitis Problem Index [ICPI]) between patients who received bladder instillation therapy (red) and intradetrusor BOTOX® injection (blue) across all time points (baseline, 1, 2 months, 6-9 months post-treatment). Longitudinal differences within groups were calculated using the repeated measures ANOVA test.

*Significance at p< .05.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Eva K. Welch: Nothing to disclose; Katherine L. Dengler: Nothing to disclose; Angela DiCarlo-Meacham: Nothing to disclose; Joy Wheat: Nothing to disclose; Carissa Pekny: Nothing to disclose; Jason Aden: Nothing to disclose; Christine M. Vaccaro: Nothing to disclose.

18 Body mass index and surgical diagnosis of endometriosis: do obese patients experience an operative delay?

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OBJECTIVES: To quantify time to diagnosis of endometriosis by diagnostic laparoscopy for patients of varying body mass index (BMI).

MATERIALS AND METHODS: Retrospective chart review of all women ages 14-51 receiving a primary laparoscopic diagnosis of endometriosis at an academic tertiary hospital from January 2017 to December 2020. CPT codes were used for medical record identification.

RESULTS: One hundred fifty-two patients met inclusion criteria, including 67 (44%) normal or underweight patients, 44 (29%) overweight patients, and 41 (27%) obese patients.

Obese patients had a significantly longer delay from gynecologic presentation to diagnostic laparoscopy (18.4 months, IQR 3.1-42.8) compared to overweight patients (9.0 months, IQR 2.5-23.2) or normal and underweight patients (3.8 months, IQR 1.1-17.0) (Kruskal-Wallis test, p=0.02). Obese patients underwent laparoscopy at an older age (median age 35, IQR 28-42) compared to normal or underweight patients (median age 31, IQR 24-39), with a trend toward significant (Mann Whitney t-test, p=0.07). Overweight

and obese patients visited the emergency department more frequently, though the trend was not significant (Chi-square test, p=0.14).

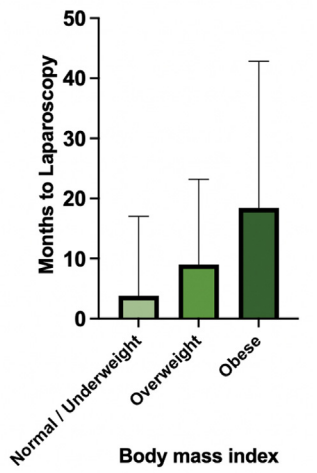
Medical management (including non-steroidal anti-inflammatory drugs, progestins, combined estrogen-progestins, gonadotropin releasing hormone agonists/antagonists, and pelvic floor physical therapy) by BMI class did not differ by total number or therapy type used pre-operatively (Kruskal-Wallis test, p=0.59, p=0.55, respectively). No difference was seen in additional medical indications for laparoscopy based on BMI (Chi-square test, p=0.40).

Intra-operatively, there were no significant differences in risk by BMI. No cases were converted to laparotomy. One case involved an organ injury (cystotomy during hysterectomy) in an obese patient (Fisher's exact test, p=1.00). Overweight and obese patients had a higher Mallampati score (Chi-square test, p<0.01); however, there were no differences in number of intubation attempts (Kruskal-Wallis test, p=0.44), and no anesthetic complications or post-operative respiratory complications occurred in any cases.

Post-operatively, one wound complication occurred in an overweight patient (Fisher's exact test, p=1.00). No venous thromboembolisms occurred within thirty days of surgery. No differences were observed in rates of repeat laparoscopy for endometriosis within three years by BMI (Fisher's exact test, p=1.00).

CONCLUSION: Obese patients undergo an approximate 14-month delay in surgical diagnosis of endometriosis compared to normal and underweight patients. Obese patients may undergo laparoscopy at an older age and visit the emergency department more frequently, though our findings are limited by sample size. Our data may highlight provider biases in diagnosing endometriosis, based on prior studies that inversely associate BMI with rates of endometriosis.

Figure 1. Time to surgical diagnosis of endometriosis by body mass index



DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Melissa A. Markowitz: Nothing to disclose; Molly Doernberg: Nothing to disclose; Howard J. Li: Nothing to disclose; Yonghee Cho: Nothing to disclose.

19 Effects of vaginal estrogen on pelvic floor disorder symptoms in postmenopausal women with prolapse undergoing surgery

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OBJECTIVES: To determine the effects of vaginal estrogen (compared to placebo) on stress and urgency urinary incontinence (SUI, UUI), urinary frequency, sexual function/dyspareunia, and vaginal atrophy symptoms and signs in postmenopausal women with symptomatic prolapse.

MATERIALS AND METHODS: This was a planned ancillary analysis of a randomized, double-blind trial including women with ≥stage 2 apical and/or anterior vaginal wall prolapse scheduled for transvaginal native tissue apical repair at 3 US sites. The intervention was 1g conjugated estrogen (CE) vaginal cream (0.625mg/g) or identical placebo (1:1), inserted nightly for 2wk, then 2x/wk for ≥5 weeks preoperatively and continued 2x/wk for 1yr postoperatively. At baseline and after ≥5 weeks of cream use, participants answered questions about SUI, UUI, and urinary frequency (UDI-6); sexual health questions including dyspareunia (PISQ-IR); and atrophy-related symptoms (dryness, soreness, dyspareunia, discharge, itching; each scored 1-4, 4 being *quite-a-bit* bothersome). Masked examiners assessed vaginal color, dryness, and petechiae (each scored 1-3, total range 3-9, with 9 being most estrogenized-appearing). Data were analyzed by intent-to-treat and "per-protocol" (i.e., those adherent with ≥50% of expected cream use, per before/after weights).

RESULTS: Of 199 women randomized (mean age 65y), 187 contributed baseline and preoperative data. Characteristics were similar between groups. Total UDI-6 scores showed minimal change from baseline to time of preop (Table). For those with at least moderately bothersome baseline SUI (n=32 CE, n=21 placebo), 16(50%) and 9(43%) showed improvement, respectively, from baseline to preop (P=0.78). Likewise, 43% and 31% showed improvement in UUI symptoms (P=0.41), and 41% and 26% showed improvement in urinary frequency (P=0.18). There was minimal change in PISQ-IR among sexually active women (Table); dyspareunia rates did not differ between CE and placebo at the preop visit. The max score for most bothersome atrophy symptom (among those with baseline bother) improved more with CE, but not significantly (Table). However, on exam, among adherent participants, objective signs of atrophy were significantly more improved with CE (+1.54 vs. +0.79 points, P=0.018).

CONCLUSION: Five or more weeks of CE (vs. placebo) cream application in postmenopausal women with symptomatic prolapse did objectively improve atrophy appearance at time of surgery but did not significantly improve SUI, UUI, frequency, sexual function, dyspareunia, or atrophy symptoms.

	CE (n=102)		Placebo (n=97)			
	Baseline	Preop	Baseline	Preop	Mean Difference (95% CI)	P-value
Urogenital Distress Inventory-6						
Adjusted mean (SE)	40.2 (2.7)	38.2 (2.7)	38.1 (2.8)	37.7 (2.8)	-1.6 (-8, 4.8)	0.515
PISQ-IR, sexually active women						
Adjusted mean (SE)	3.16 (0.10)	3.13 (0.10)	3.23 (0.10)	3.12 (0.10)	0.07 (-0.18,0.33)	0.468
Vaginal Atrophy Symptom, max score, among those with baseline bother						
Adjusted mean (SE)	3.21 (0.14)	2.74 (0.15)	2.85 (0.14)	2.67 (0.15)	-0.29 (-0.88,0.30)	0.211

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: David D. Rahn: Research support: provision of study drug, Pfizer, Inc.; Holly E. E. Richter: Nothing to disclose; Vivian Sung: Nothing to disclose; Jessica Pruszynski: Nothing to disclose.

20 A randomized trial comparing perioperative pelvic floor physical therapy to current standard of care in transgender women undergoing vaginoplasty for gender affirmation: the flower trial

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OBJECTIVES: To compare the effectiveness of postoperative pelvic floor physical therapy (PFPT) with no PFPT in transgender women undergoing vaginoplasty.

MATERIALS AND METHODS: This was a randomized double-blind trial of transgender women undergoing vaginoplasty surgery by one gynecologic surgeon. Patients were excluded if they had undergone previous PFPT or if they were scheduled for a no-depth vaginoplasty. Once enrolled, patients were randomized to one of two groups: no PFPT or PFPT. Patients randomized to PFPT were further randomized to postoperative PFPT alone versus pre- and postoperative PFPT. Subjects completed the following questionnaires at baseline and at 12 weeks: CRAD-8, UDI-6, PFIQ-7. At 12 weeks, subjects underwent vaginal length measurement and completed the PGI-I and a VAS scale (0-10) assessing reported ease of vaginal dilation and pain with dilation. Ease of dilation was the primary outcome measured in this study. We determined that 17 subjects in each arm were needed to detect a difference of 2 (+/-1) points between the two groups with 80% power and a significance level of 0.05. We planned to recruit 20 subjects to each arm, for a total of 40 subjects.

RESULTS: Forty-one subjects were enrolled and 12-week data were available for 37 subjects (20 PFPT, 17 no PFPT). The mean age and BMI of this cohort was 31 ±13 years and 24.9 (±4.0) kg/m^2, respectively. Subjects were on hormone therapy for a median of 39 (20-240) months and 5 (13.5%) patients had undergone previous orchiectomy. There were no differences in patient characteristics between the PFPT and no PFPT groups. There were no intraoperative complications. The following postoperative complications were recorded: vaginal stenosis/stricture (3), vulvar hematoma (1), wound dehiscence (1). At 12 weeks, the median vaginal length was 12.5 (10-16) cm, reported ease of dilation (0-10) was 7.3 (±1.6) and pain with dilation (0-10) was 2.4 (±1.7). There were no differences in these outcomes between the groups. There were also no differences in pelvic floor symptoms. One patient randomized to the no PFPT group experienced significant difficulty with dilation at 8 weeks and was crossed over to PFPT which resulted in significant improvement in her symptoms. When the PFPT group was subanalyzed, there were no differences between those who underwent postoperative PFPT alone versus pre- and postoperative PFPT with the following exception: patients who underwent both pre-and postoperative PFPT reported higher easier of dilation (8.0 vs 6.6, p=0.02).

CONCLUSION: At our center, where patients undergoing vaginoplasty receive extensive postoperstive dilation teaching, adding routine postoperative PFPT did not improve outcomes. However, PFPT may be used as needed for patients struggling with dilation. The role of preoperative PFPT should be further explored.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS: Cecile Ferrando: author, UpToDate; Kavita Mishra: Nothing to disclose; Frances Grimstad: Nothing to disclose; Natalie Weigand: Nothing to disclose; Cameron Pikula: Nothing to disclose.