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Does Preoperative Resting Genital Hiatus Size Predict Surgical Outcomes?

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Short title: Resting GH and surgical outcomes

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Does Preoperative Resting Genital Hiatus Size Predict Surgical Outcomes? Abstract

Aim: To determine whether preoperative genital hiatus at rest is predictive of mediumterm prolapse recurrence.

Methods: We conducted a retrospective study of women who underwent native tissue prolapse surgery from 2002-2017 with pelvic organ prolapse quantification data including resting genital hiatus at one of three time points: pre-operatively, 6 weeks, and ≥1 year postoperatively. Demographics and clinical data were abstracted from the chart. Prolapse recurrence was defined by anatomic outcomes (Ba>0, Bp>0, and/or C≥-4) or retreatment. Descriptive statistics, bivariate analyses, and logistic regression analyses were performed.

Results: Of the 165 women included, 36 (21.8%) had prolapse recurrence at an average of 1.5 years after surgery. Preoperative resting genital hiatus did not differ between women with surgical success versus recurrence (3.5 cm (IQR 2.25, 4.0) vs 3.5 cm (IQR 3.0, 4.0), p=.71). Point Bp was greater in the recurrence group at every time point. Preoperative Bp (OR 1.24 Cl (1.06-1.45), p=.01) and days from surgery (OR 1.001 Cl (1.000-1.001), p<0.01) were independently associated with recurrence. Preoperative genital hiatus at rest and strain were significantly larger among women who underwent a colpoperineorrhaphy (rest: 4.0 (3.0, 4.5) cm vs 3.5 (3.0, 4.0) cm, p<0.01; strain: 6.0 (4.0, 6.5) cm vs 5.0 (4.0, 6.0) cm, p=.01).

Conclusions: Preoperative genital hiatus at rest was not associated with prolapse recurrence when the majority of women underwent colpoperineorrhaphy. Preoperative Bp was more predictive of short-term prolapse recurrence. For every 1 cm increase in point Bp, there is a 24% increased odds of recurrence.

Keywords: gynecologic surgical procedures, pelvic organ prolapse, pelvic organ prolapse surgery, pelvic reconstructive surgery, rectocele surgery

Introduction

Pelvic organ prolapse is common and carries a 6-18% lifetime risk of surgery.¹ An enlarged genital hiatus (GH), typically measured during Valsalva, is associated with development of prolapse,² presence of prolapse,³⁻⁵ and advancing severity of prolapse⁵ and is an established risk factor for recurrent prolapse.⁴⁻⁸ Surgical correction of an enlarged GH is associated with a reduced risk of prolapse recurrence at 12 months.⁹ However, not all women with an enlarged GH strain have an enlarged GH rest (Figure 1). Therefore, it is unclear whether an enlarged GH strain is due to prolapse filling the space created by an impaired hiatus or if prolapse dilates an otherwise normal hiatus.¹⁰

GH rest, which is also associated with prolapse,¹¹ may provide information about the status of the hiatus separate from the immediate dilating effect of the prolapse. Women with baseline impairment in resting GH closure may be at increased risk for prolapse recurrence, and furthermore, may benefit from a surgical procedure aimed at restoring the size of the GH. While GH rest is not routinely measured at all institutions, this measurement is routinely collected by providers at ours. Our primary aim was to determine if there is an association between preoperative GH rest and prolapse recurrence. Secondarily, we sought to identify other factors associated with prolapse recurrence.

Methods

We performed a retrospective cohort study of women who underwent native tissue prolapse surgery at a single tertiary center from July 2002-November 2017. Women were included if the surgeon was a Female Pelvic Medicine and Reconstructive Surgery specialist and if they had pelvic organ prolapse quantification (POP-Q) examination data at three time points: preoperatively, 6 weeks postoperatively, and at least one other visit ≥1 year postoperatively. Women were excluded if there were no

GH rest measurements available from any of the three time points or if they underwent a prolapse repair with mesh. The majority of prolapse procedures performed at our institution are native tissue prolapse repairs, therefore repairs using mesh were excluded due to small sample size. This study was deemed IRB exempt (HUM00150507), as it involved secondary research use of identifiable private information that only involved information collection and analysis. Informed consent was waived, as this is a retrospective review of existing data included in the standard care of patients; the results will not negatively or positively affect the patients or their offspring.

Chart review was performed to extract data on demographics, medical and surgical history, pre- and postoperative POP-Q measurements, surgical information (date and type of procedures performed), and length of follow-up. POP-Q measures Aa, Ba, C, D, Ba, and Bp were performed during maximal Valsalva. GH and perineal body were measured both at rest and during maximal Valsalva. Total vaginal length was measured at rest. Surgical recurrence was defined as anatomical recurrence, based on POP-Q measurements (Ba>0 or Bp>0 or C>-4), 12 or retreatment with repeat surgery or pessary. Maximal prolapse size was the largest prolapse of any compartment (Ba, Bp, or C). All data were abstracted by study team members (P.S., C.C., S.S., W.H., and C.W.S.) and included a detailed review of all clinic visit notes and operative reports recorded in the electronic health record. Of note, the technique used for posterior colpoperineorrhaphy at our institution is standardized among all providers and is based on the technique described by Haylen et al. 13 Using this technique, the perineal gap (i.e., separation of the perineal membrane at the perineal body) is measured, and if ≥2.5 cm, a posterior repair is performed by 1) excising a triangular wedge of vaginal wall; 2) reattaching the separated ends of the perineal membrane, perineal body, and

bulbocavernosus muscles using a delayed absorbable suture; and 3) closing the vaginal incision using a dissolvable suture.

Demographic, surgical, and POP-Q examination data were compared between recurrence and success groups using bivariate analyses. Parametric data was reported as mean with standard deviation (SD) and non-parametric data was reported as median with interquartile range (IQR). Because of the possibility that colpoperineorrhaphy could affect hiatus size, demographic, POP-Q data, and recurrence status were also compared between women with and without this procedure at the time of their prolapse surgery. Using variables found to be statistically significant on bivariate analyses, logistic regression was performed to identify factors independently associated with prolapse recurrence and colpoperineorrhaphy. Student's t-test and Mann-Whitney U tests were used for continuous, non-parametric variables and Chi-square test was used for categorical variables. The statistical analyses were carried out using SPSS (version 25, IBM, Armonk, NY).

Results

Of the 165 women who were included in the analysis, the median follow-up time was 1.2 years (IQR 1.1, 2.3 years). Average age at the time of surgery was 59.2 ± 10.2 years and average BMI was 27.5 ± 4.9 kg/m². Median parity was 2.00 (IQR 2.0, 3.0) and 94.5% (n=156) were Caucasian. The majority of women underwent an apical suspension procedure (76.8%, n=125). Sixty-eight percent (n=113) of women underwent an anterior colporrhaphy and 77.6% (n=128) underwent a colpoperineorrhaphy. Thirty-six women (21.8%) had a prolapse recurrence: 31 had an anatomic recurrence only, one had both an anatomic recurrence and repeat surgery, one had both an anatomic recurrence and was fitted with a pessary, one was fitted with a pessary and had repeat surgery, and two had repeat surgery.

Table 1 shows demographics, comorbidities, and surgical procedures comparing women with surgical success versus recurrence. No statistical differences were found regarding age at time of surgery, age at most recent POP-Q clinical exam, BMI, parity, maximum preoperative prolapse size, or prior prolapse surgery. Medical comorbidities and surgical procedures were also not statistically different between groups. However, a larger proportion of women with surgical success underwent a colpoperineorrhaphy (80.6% versus 66.7%, p=.08), although this did not reach statistical significance.

Preoperative GH rest was similar in women who had a surgical success versus recurrence (3.5 (2.5, 4.0) vs 3.5 (3.0, 4.0), p=.71). However, at 6 weeks postoperatively, women with surgical success had a 3-fold greater reduction in hiatus size at rest compared to those with prolapse recurrence (1.5 cm vs 0.5 cm, p=.06). Women with prolapse recurrence had higher preoperative Bp measurements (0.0 (-1.0, 2.0) vs -1.0 (-2.0, 0.0), p=.02) but lower Bp measurements postoperatively (-2.0 versus -3.0, p=.01) compared to those with surgical success. Otherwise, preoperative POP-Q examination measurements did not significantly differ between women with surgical success versus recurrence (Table 2). Recurrence rates were similar between women with preoperative straining GH ≥4 versus <4 cm (77.4% vs 77.0%, p=.95). At the clinic visit ≥1 year after surgery, women with recurrence had significantly larger GH measures at rest and strain, as well as significantly lower Ba, Bp, and C points (Table 2).

After controlling for age at surgery and days from surgery, preoperative Bp remained independently associated with prolapse recurrence (Table 3). Having had a colpoperine or rhaphy was not independently associated with prolapse recurrence.

Women who had a colpoperineorrhaphy had higher parity (2.0 (IQR 2.0, 3.0) vs 2.0 (IQR 1.0, 3.0), p=.02) and larger preoperative GH rest (3.5 vs 3.0, p=.002), GH strain (5.0 vs 4.0, p=.006), and POP-Q Bp (-1.0 vs -1.25, p=.003) compared to those who did not. Eighty-one percent (104/129) of women with surgical success underwent a colpoperineorrhaphy versus 19.4% (25/129) of women with recurrence (p=.08). Of the 129 women who underwent a colpoperineorrhaphy, GH measurements at rest were not statistically different between those with and without surgical success (3.5 (3.0, 4.0) vs 4.0 (3.0, 4.5), p=.12), nor were GH measures at strain (5.0 (4.0, 6.0) vs 6.0 (4.0, 6.0), p=.15). Preoperative factors independently associated with undergoing colpoperineorrhaphy were larger preoperative GH rest and parity (OR 2.08, CI 1.09-3.96, p=.03). Controlling for age at surgery, parity, and rectocele size, every 1 cm increase in size of GH rest conferred a 2-fold increased odds of having a colpoperineorrhaphy (OR 1.98, CI 1.26-4.51, p=.01).

Discussion

In this small retrospective study of women undergoing native tissue reconstructive prolapse surgery with the majority including a colpoperineorrhaphy, preoperative GH rest was not predictive of prolapse recurrence one year after surgery. Additionally, we did not find an association between preoperative GH strain and prolapse recurrence; however, recurrence was significantly associated with preoperative Bp size, with every 1 cm conferring a 24% increased odds of prolapse recurrence. Additionally, although 78% of women underwent a colpoperineorrhaphy, we also found that surgeons preferentially performed this procedure on women with larger preoperative GH rest and strain measurements.

This study adds new information about the status of the GH by investigating GH rest and its relationship to prolapse recurrence. We hypothesized that preoperative GH rest would be associated with prolapse recurrence, as GH rest is strongly correlated with GH strain, 10 which has consistently been shown to be associated with prolapse recurrence.^{6, 8, 9, 14, 15} However, we were unable to show an association between prolapse recurrence and preoperative GH rest or strain. One explanation for this difference may be related to the high colpoperineorrhaphy rate in the current study. Prior studies finding an association with preoperative GH size and recurrence performed posterior repair and perineorrhaphy at a rate of 0-35% compared to 78% in our current study. In addition, performing a concomitant colpoperine orrhaphy or perineorrhaphy at the time of native tissue prolapse repair⁹ has been associated with decreased odds of composite recurrence. Therefore, we think that the high rate of colpoperineorrhaphy in our population could account for a lack of association between GH rest or strain and composite recurrence. We therefore compared GH rest and strain measurements in women with recurrence versus success in only those who underwent a colpoperineorrhaphy as a part of their prolapse repairs. While differences in preoperative GH rest and strain measurements failed to reach statistical significance, a post-hoc power analysis showed we were underpowered and would need at least 51 women in each group to detect ≥0.5 cm difference between success and recurrence groups, with alpha=0.05 and power of 80%. Larger future studies are therefore needed to determine if preoperative GH measures are predictive of recurrence in a cohort of women who undergo colpoperineorrhaphy as a part of their prolapse repairs.

Advanced prolapse size in any vaginal compartment and Level III support defects,¹⁶ such as enlarged GH, are known risk factors for prolapse recurrence.^{17, 18} In our study, we found that a lower (more prolapsed) preoperative Bp measurement was independently associated with prolapse recurrence. The most common type of posterior vaginal wall support problem is at the level of the perineal body,¹⁹ which therefore represents a defect in Level III support. Findings from our study regarding the

association between lower posterior vaginal wall support and recurrence adds to the growing body of literature regarding Level III support defects and risk of recurrence even when colpoperineorrhaphy is performed. Further investigation on the underlying structural causes of Level III support defects and their association with prolapse recurrence is needed.

In this study, there was a trend toward a lower recurrence rate in women who underwent a colpoperineorrhaphy, but this did not reach statistical significance. We performed a post-hoc power analysis, which determined that to have a power of 80% with alpha 0.05, we would need a sample size of 156 patients in each group; therefore, we were likely underpowered to show a difference. This observed trend contrasts with a study by Sutkin et al, which showed that posterior repair at the time of native tissue prolapse repair was not associated with better surgical success. However, this study reported that the posterior repairs performed may not have included a perineorrhaphy and/or levator myorrhaphy, and the techniques to perform the posterior repair were likely heterogenous. The standardized use of this colpoperrineorrhaphy technique may help explain why our findings are different from prior studies.

Strengths of our study include that our institution collected data on GH rest, a relatively understudied variable, and that there was a consistent surgical technique used among all surgeons. Limitations of our study include our relatively small sample size due to missing POP-Q data, which likely contributed to us being underpowered to detect differences in GH rest measures between and colpoperineorrhaphy rates. Additionally, this was a retrospective study, which can lead to misclassification biases or missed data. Given there was no standardization for which patient received which procedure, there likely were selection biases, although it is a reflection of current practices by

board-certified urogynecologists. Finally, as we did not obtain subjective symptoms in all women, we could not include subjective outcomes.

In this medium-term follow-up retrospective study, we found that preoperative resting GH size is not predictive of prolapse recurrence when a colpoperineorrhaphy is commonly performed to normalize an enlarged GH. There was a trend toward a lower recurrence rate in women who underwent colpoperineorrhaphy, suggesting this may be important in correcting Level III support defects that lead to prolapse recurrence.

Further studies are needed to investigate the role of a colpoperineorrhaphy in preventing prolapse recurrence.

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Figure Legend

Figure 1. Differences in resting genital hiatus size in women with advanced pelvic organ prolapse

This figure shows that resting genital hiatus size can vary widely between women, despite a similar maximal prolapse size.

Table 1. Demographic characteristics and surgical procedures performed in women with surgical recurrence versus success

Variable	Surgical Recurrence (n=36)	Surgical Success (n=129)	p- value*
Patient Characteristics			
Age at surgery, years⁺	58.9 ± 9.3	59.5 ± 10.3	.75
Age at most recent POP-Q, years [†]	61.6 ± 9.5	61.0 ± 10.1	.76
BMI, kg/m² [†]	28.2 ± 5.8	27.2 ± 4.5	.37
Parity [‡]	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	.64
Maximum preoperative prolapse, cm [‡]	3.0 (2.0, 5.0)	3.0 (1.0, 4.0)	.07
Prior prolapse surgery	9 (30.0)	21 (16.3)	.23
Diabetes	1 (2.8)	13 (10.1)	.17
Smoker	2 (5.6)	3 (2.3)	.30
Constipation	5 (13.9)	19 (14.7)	.90
Surgical Procedures			
Vaginal hysterectomy	19 (52.8)	84 (65.1)	.18
Total abdominal hysterectomy	1 (2.8)	3 (2.3)	.88
Laparoscopic hysterectomy	1 (2.8)	5 (3.9)	.76
Sacrocolpopexy	3 (8.3)	9 (7.0)	.72
With hysterectomy	2 (5.6)	8 (6.2)	>.99
Without hysterectomy	1 (2.8)	1 (0.8)	>.99
Apical ligament suspension	21 (58.3)	91 (70.5)	>.99
Sacrospinous ligament suspension	7 (19.4)	35 (27.1)	.31
Uterosacral ligament suspension	14 (38.9)	56 (43.4)	.64
Anterior colporrhaphy	23 (63.9)	90 (69.8)	.53
Colpoperineorrhaphy	24 (66.7)	104 (80.6)	.08

TVT	5 (13.9)	33 (25.6)	.14
Manchester-Fothergil procedure	0 (0.0)	1 (0.8)	.60

Data presented as n (%) unless otherwise noted

^{*}P-values for age and BMI determined using student's t-test. P-values for all other continuous variables determined using Mann-Whitney U and Chi-square for categorical variables.

[†]Mean ± SD

[‡]Median (IQR)

POP-Q=Pelvic Organ Prolapse Quantification System; TVT=tension-free vaginal tape

Table 2. Preoperative, 6 Weeks Postoperative, and most recent POP-Q in women with surgical recurrence versus success

	Preope	Preoperative			stoperative		Most Recent (≥	1 year Post-op)	
Variable	Recurrence N=36	Success N=129	p- value	Recurrence N=36	Success N=129	p- value	Recurrence N=36	Success N=129	p- value
Days before surgery	59 (36, 90)	63 (42, 98)	.48						
Days after surgery				41 (38, 46)	41 (36, 45)	.47	594 (414, 1557)	428 (409, 658)	.01
POP-Q, cm									
Ва	2.0 (0.0, 4.0) n=36	2.0 (2.0, 4.0) n=129	.50	-2.0 (-3.0, -1.0) n=35	-2.0 (-3.0, -2.0) n=129	.10	.5 (-1.0, 2.0) n=35	-1.5 (-2.0, -1.0) n=129	<.001
С	-2.0 (-5.0, 4.0) n=35	-2.0 (-4.0, 2.0) n=126	.82	-8.0 (-9.5, -6.0) n=35	-8.0 (-9.0, -7.0) n=123	.41	-6.5 (-7.5, -3.0) n=35	-7.0 (-8.5, -6.0) n=129	<.001
Вр	0.0 (-1.0, 2.0) n=21	-1.0 (-2.0, 0.0) n=127	.02	-2.0 (-3.0, -2.0) n=36	-3.0 (-3.0, -2.0) n=127	.01	-1.0 (-2.0, 1.0) n=36	-2.0 (-3.0, -1.0) n=129	<.001
GH, rest	3.5 (2.5, 4.0) n=31	3.5 (3.0, 4.0) n=91	.71	3.0 (2.5, 3.0) n=19	2.0 (2.0, 3.0) n=38	.07	3.0 (2.5, 4.0) n=19	2.5 (2.0, 3.0) n=51	.01
GH, strain	5.0 (4.0, 6.0) n=31	5.0 (4.0, 5.5) n=123	.42	3.0 (2.5, 3.5) n=34	2.5 (2.0, 3.0) n=116	.31	4.0 (3.0, 5.0) n=34	3.0 (2.0, 3.5) n=116	<.001
PB, rest	3.0 (2.5, 3.0) n=25	3.0 (3.0, 4.0) n=107	.33	3.0 (2.5, 4.0) n=10	3.0 (2.5, 4.0) n=16	.96	4.0 (3.0, 4.0) n=10	3.0 (2.5, 4.0) n=14	.14
PB, strain	3.0 (2.5, 3.0) n=11	3.0 (2.5, 4.0) n=49	.37	3.0 (3.0, 4.0) n=34	3.5 (3.0, 4.0) n=123	.99	4.0 (3.0, 4.0) n=34	3.0 (3.0, 4.0) n=117	.09
TVL	10.0 (9.0, 11.0) n=34	10 (9.0, 10.0) n=124	.20	9.0 (8.0, 10.0) n=35	9.0 (8.0, 10.0) n=123	.46	9.0 (8.0, 10.0) n=35	9.0 (8.0, 10.0) n=121	.45
D	-6.0 (-8.0, -2.0) n=23	-7.0 (-6.0, 4.0) n=104	.96	-9.0 (-11, -7.5) n=11	-9.0 (-10.0, -8.0) n=11	.83	-7.0 (-9.0, -3.0) n=11	-8.0 (-9.0, -7.5) n=24	.12

Data presented as Median (IQR)
POP-Q=Pelvic Organ Prolapse Quantification System

Table 3. Logistic Regression for factors associated with surgical recurrence

Variable	Odds Ratio	Confidence Interval	р
Age at surgery	1.003	.96-1.05	.88
Days after surgery when POP-Q performed	1.001	1.00-1.001	.01
Preoperative Bp	1.24	1.06-1.45	.01
Posterior colpoperineorrhaphy performed	0.53	.21-1.38	.20

POP-Q=Pelvic Organ Prolapse Quantification System



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