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ORIGINAL ARTICLE

Prospective evaluation of genital hiatus in patients undergoing surgical prolapse repair

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Abstract

Introduction and hypothesis Enlarged genital hiatus (GH) is associated with prolapse recurrence following prolapse repair. Perineorrhaphy is often performed to reduce GH. However, changes in GH between the time of surgery and follow up are poorly understood. Our primary aim was to compare the intra-operative resting GH at the conclusion of surgery with the resting GH 3 months post-operatively in patients who undergo perineorrhaphy. We hypothesized that the intra-operative resting GH would be sustained.

Methods Patients planning apical prolapse surgery were prospectively enrolled. Perineorrhaphy was performed at the surgeon's discretion. GH was measured pre-operatively in clinic, intra-operatively before and after surgery (resting), and 3 months post-operatively (resting and Valsalva).

Results Twenty-nine perineorrhaphy and 27 no perineorrhaphy patients completed 3-month follow-up. Groups were similar in age (63.9 y, SD 10.4), body mass index (28.3 kg/m^2, SD 5.2) and prior prolapse surgery (19.6%). Median (interquartile range) baseline Valsalva GH was larger in the perineorrhaphy group (4.5 (4 – 5.5) vs 3.5 (3 – 4) cm, $p < 0.01$). Median resting GH at 3 months was 0.5 cm less than end of surgery in the perineorrhaphy group ($p < 0.01$). The median change in GH between baseline and 3-month follow up was greater with perineorrhaphy (-1.5 vs -0.5 cm, $p < 0.01$). This difference was not seen in the sacrocolpopexy subgroup (-1.75 vs -1.5, $p = 0.14$; $n = 24$).

Conclusions Surgeons can be reassured that the intra-operative change in GH resulting from perineorrhaphy is sustained 3 months after surgery and similar to the more commonly measured preoperative to postoperative change in Valsalva GH.

Keywords Genital hiatus · POP-Q · Prolapse · Prolapse surgery · Perineorrhaphy

Introduction

The genital hiatus (GH) is defined as the distance between the middle of the external urethral meatus and the posterior midline hymen [1]. GH has been found to be an indicator for underlying pelvic floor muscle damage [2]. This value has been shown to be of significance in the evaluation of pelvic organ prolapse (POP) and a predictor of outcomes after surgical intervention [3]. Increased GH is associated with and predictive of apical vaginal support loss when GH is 3.75 cm or greater [4]. Additionally, an enlarged GH has been shown to be an independent risk factor for the future development of POP in parous women [5].

Surgeons commonly perform a perineorrhaphy during POP surgery in order to reduce the GH size [6]. However, the evidence to support this practice is lacking. Although there is evidence indicating a relationship between GH and POP, no such evidence demonstrates that surgical correction of GH is effective in the prevention of POP recurrence. In fact, some recent retrospective evidence suggests that perineorrhaphy may not be necessary [7, 8]. Moreover, there is a lack of understanding as to how the GH seen by the surgeon at the end of a POP surgery relates to the GH seen on physical exam at clinical follow up.

The goal of this study is to prospectively measure changes seen in GH peri-operatively in patients who undergo prolapse repair with and without perineorrhaphy and to determine if these changes are sustained 3 months post-operatively. Our primary aim was to compare the intra-operative

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resting GH at the conclusion of the procedure with the resting GH 3 months post-operatively in patients who undergo perineorrhaphy. The secondary aims were to (1) compare the change in GH seen intra-operatively with the change in GH seen between baseline and 3 months post-operatively in patients who undergo perineorrhaphy, (2) compare the change in GH seen at 3 months post-operatively in patients who do and do not undergo perineorrhaphy, and (3) to compare patient reported outcomes between those who do and do not undergo perineorrhaphy. We hypothesized that the intra-operative resting GH measured at the conclusion of the procedure is sustained at 3 months post-operatively in patients who undergo perineorrhaphy.

Materials and methods

The study was conducted at the University of Iowa Hospitals and Clinics (Iowa City, IA, USA). The study protocol was approved by the University of Iowa institutional review board, and all subjects provided written informed consent. Patients scheduled for apical compartment prolapse surgery (uterosacral ligament suspension (USLS), sacrospinous ligament fixation (SSLF) and sacral colpopexy (SC)) were eligible for inclusion. Exclusion criteria included patients planning obliterative prolapse surgery (colpocleisis) and patients who were unable to provide consent in English. Baseline demographics, medical history, physical exam findings and Pelvic Floor Distress Inventory short form (PFDI-20) [9] were obtained from electronic chart.

The decision for performance of a perineorrhaphy was at the discretion of the surgeon. In general, all participating surgeons (CSB, KAK, JTK) usually consider a perineorrhaphy when the GH is 4 cm or greater at the time of the standard pre-operative pelvic organ prolapse quantification (POP-Q) exam in clinic [1]. The final decision for whether or not a perineorrhaphy was performed was made after the apical support procedure was complete. Additional POP and incontinence procedures were allowed. The details of the perineorrhaphy procedure were standardized. Two Allis clamps are placed on the hymen to the right and left of midline. The location of these clamps is chosen based on the size of desired reduction in GH. A stellate-diamond type incision is made extending from the distal posterior vaginal wall proximally to the perineal skin distally with the Allis clamps marking the lateral extent of the diamond (one triangle on the posterior vaginal wall and one triangle on the perineal skin). The vagina and skin outlined by the incision is sharply excised with care to leave behind as much tissue as possible. The vaginal epithelium is mobilized off the underlying connective tissues a short distance to mobilize the tissues of the perineal body. Similarly, the perineal skin is mobilized a short distance to further mobilize the tissues of the perineal body. Two to four 0 Vicryl (Ethicon Inc., Raritan, NJ, USA) sutures are used. The first suture(s) is placed through the bulbocavernosus muscle on each side. The second suture(s) is similarly placed through the superficial transverse perineal muscle on each side. The sutures are then tied down re-approximating the components of the perineal body. The subepithelial and skin layers are closed in a vertical orientation with a running 2-0 Velosorb Fast (Covidien, Dublin, Ireland) suture.

GH was measured in centimeters with a ruler as the distance between the middle of the external urethral meatus to the posterior midline hymen. GH was measured at 7 time points defined here:

1. Pre-operative Valsalva GH
2. Intra-operative resting GH before start of procedure
3. Intra-operative resting GH after procedure
4. Post-operative resting GH at 6 weeks
5. Post-operative Valsalva GH at 6 weeks
6. Post-operative resting GH at 3 months
7. Post-operative Valsalva GH at 3 months

The measurements with Valsalva were all part of a typical POP-Q exam [1]. The first intra-operative GH measurement (#2) was measured after induction of anesthesia with patient in the dorsal lithotomy position. The second intra-operative measurement (#3) was performed at the end of the case before reversal of sedation. The primary aim was evaluated by comparing the intra-operative resting GH after procedure (#3) with the post-operative resting GH at 3 months (#6). In other words, we sought to determine if the GH seen while under anesthesia at the end of the procedure would be reflective of the resting GH seen in clinic 3 months later.

The change in GH (ΔGH) was calculated as follows:

1. ΔGH_{io} = (intra-operative resting GH after procedure) – (intra-operative resting GH before procedure)
2. ΔGH_{3m} = (post-operative Valsalva GH at 3 months) – (pre-operative Valsalva GH)

Patient reported outcomes were evaluated with the PFDI-20 and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-IR) at the 3-month appointment [9, 10].

For comparison of baseline demographics, patient characteristics and results, t-test, Chi-square, Mann-Whitney U and Wilcoxon signed-rank were used as appropriate. For the primary aim, we planned to use a paired t-test to compare the "intra-operative resting GH after procedure" value to the "post-operative resting GH at 3 months" value. Assuming alpha=.05, a sample size of 27 could yield a power of 80% to detect a difference of .5 cm (Cohen's d=.5) between intra-operative and post-operative values. Therefore, 27 subjects

undergoing perineorrhaphy were needed. Assuming a loss to follow up rate of about 10%, 30 subjects were planned to be enrolled. An additional 30 subjects not undergoing perineorrhaphy were planned to be enrolled to evaluate the secondary aims. Paired analyses were repeated with Wilcoxon signed-rank test as data were not normally distributed.

As a result of the COVID-19 pandemic and the associated precautions that were established at the University of Iowa, all in-person follow up visits that were not deemed medically necessary during this period by the subject's surgeon were cancelled. Subjects who had these visits cancelled were offered to reschedule a follow-up visit once normal clinical and research activities resumed. More subjects were lost to follow-up early in the enrollment period due to the pandemic. Therefore, 10 additional subjects were recruited to meet the desired sample size.

Results

Between November 2019 and January 2021, 70 patients were enrolled, and 56 (29 perineorrhaphy and 27 no perineorrhaphy) completed 3-month follow-up (Fig. 1). Groups were similar in age (63.9 y, SD 10.4), body mass index (28.3 kg/m^2, SD 5.2) and prior prolapse surgery (n = 11, 19.6%) (Table 1). Median baseline Valsalva GH was greater (4.5 vs 3.5 cm, p <0.01) and more apical descent (C: 1.5 vs -3.0 cm, p <0.01) was seen in the perineorrhaphy group (Table 2). Perineorrhaphy was performed less often in those who had sacrocolpopexy (8 (27.6%) vs 16 (59.3%), p = 0.02) compared to USLS and SSLF.

GH values at all study time points are outlined in Table 2 and depicted graphically in Fig. 2. In the perineorrhaphy group, the median (interquartile range: IQR) GH measured intra-operatively at the conclusion of the procedure was 3 cm (2.5 – 3.5), and the 3-month post-operative resting GH was 2.5 cm (2.5 – 3) (p <0.01, primary aim, Table 3). In other words, the resting GH seen at follow up measured about 0.5 cm less compared to the end of the procedure. A similar result was seen in the no perineorrhaphy group (Table 3). The median 3-month Valsalva GH in the perineorrhaphy group was 3 cm (2.5 – 3.5).

The median change in resting GH from beginning to end of surgery was equivalent to the median change seen in Valsalva GH between baseline (prior to surgery) and 3-month post-op (-1.5 vs -1.5 cm, p =0.52) in the perineorrhaphy group. The median change in Valsalva GH between baseline and 3-month follow up was greater with perineorrhaphy (-1.5 vs -0.5 cm, p <0.01). The magnitude of change in Valsalva GH between baseline and 3-month follow up is presented graphically as a function of baseline GH in Fig. 3. This change is negatively correlated with baseline GH (Spearman's rho -0.683, p < 0.01). In other words, larger reductions in GH are seen with larger baseline GH values. PFDI and PISQ-IR at 3 months after surgery were similar between groups (Table 3). Of the women who reported having intercourse on the PISQ-IR, there was no difference in the reporting of pain with intercourse as occurring sometimes, usually, or always (6 (42.8%) vs 2 (18.2%), p = 0.19).

The difference in median change in Valsalva GH between baseline and 3-month follow up that was seen between group was not seen in the sacrocolpopexy subgroup (-1.75 vs -1.5

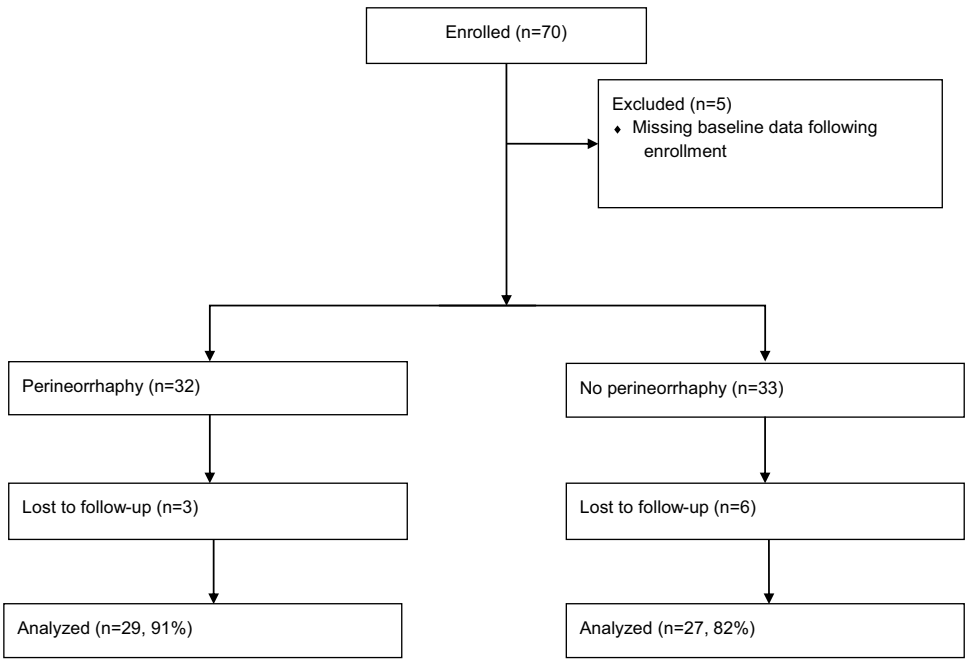

Fig. 1 Flow of participants

Table 1 Baseline patient characteristics

	Perineorrhaphy (*n*=29)	No perineorrhaphy (*n*=27)	*p*
Demographics and history			
Age, y (SD)	62.2 (12.8)	65.8 (6.7)	0.19
BMI, kg/m^2 (SD)	29.4 (5.3)	27.2 (4.9)	0.12
Current smoker, n (%)	5 (17.2)	3 (11.1)	0.51
Vaginal estrogen, n (%)	6 (20.7)	14 (51.9)	0.02
Vaginal parity, median (IQR)	3 (2-4)	2 (1-3)	0.11
Prior POP surgery, n (%)	6 (20.7)	5 (18.5)	0.83
Prior hysterectomy, n (%)	9 (31.0)	11 (40.7)	0.45
PFDI-20, mean (SD)	112.8 (59.1)	103.7 (68.9)	0.61
Procedures performed, n (%)			
Sacrocolpopexy	8 (27.6)	16 (59.3)	0.02
Laparoscopic sacrocolpopexy	7 (24.1)	14 (51.9)	0.03
Robotic sacrocolpopexy	0	2 (7.4)	0.14
Abdominal sacrocolpopexy	1 (3.4)	0	0.33
Hysterectomy	19 (65.5)	16 (59.3)	0.63
Laparoscopic hysterectomy	4 (13.8)	5 (18.5)	0.63
Robotic hysterectomy	0	1 (3.7)	0.30
Vaginal hysterectomy	15 (51.7)	10 (37.0)	0.27
Uterosacral ligament suspension	16 (55.2)	10 (37.0)	0.17
Sacrospinous ligament suspension	5 (17.2)	1 (3.7)	0.10
Anterior colporrhaphy	13 (44.8)	7 (25.9)	0.14
Posterior colporrhaphy	22 (75.9)	1 (3.7)	<0.01
Mid-urethral sling	9 (31.0)	6 (22.2)	0.41

Y = years; SD = standard deviation; BMI = body mass index; kg = kilogram; m = meter; IQR = interquartile range; POP = pelvic organ prolapse; PFDI-20 = Pelvic Floor Distress Inventory short form.

cm, $p = 0.14$; $n = 24$) (Table 4). This was not a planned, *a priori* analysis, and the study was not powered to detect differences in subgroups based on type of apical suspension. However, following analysis of the data, we saw distinct differences between those who had sacrocolpopexy and those who had uterosacral or sacrospinous ligament suspensions.

Discussion

In this prospective, observational study of women undergoing POP surgery, we found that the resting GH measured 3 months after surgery was about 0.5 cm less than when measured immediately following surgery while under anesthesia. This was true regardless of whether perineorrhaphy was performed. However, the median reduction in Valsalva GH between baseline and 3 months after surgery was about 1 cm greater in the perineorrhaphy group.

Several retrospective studies have examined the relationship between GH and the presence of anatomic and symptomatic prolapse [4, 11]. Retrospective studies report a conflicting association between increased GH and prolapse recurrence after surgery [3, 8, 12]. Similar to our study, these retrospective studies are limited by the fact that surgeons performed perineorrhaphy at their own discretion. Some surgeons perform perineorrhaphy on all cases, some on none, and most choose only certain patients for perineorrhaphy [13]. Ostensibly, the goal of a perineorrhaphy is to reduce the GH and restore level 3 support [6, 14]. However, the change in GH that actually does or does not occur with perineorrhaphy has previously not been well described. This is the first study providing a detailed analysis of the perioperative changes in GH that occur in patients undergoing apical prolapse surgery with and without perineorrhaphy. Furthermore, we were able to directly compare GH measurements performed in the operating room (which are resting, or non-Valsalva measurements) with resting GH measurements taken during postoperative visits, which we added to the typical POP-Q examination performed.

Our results support the assertion that perineorrhaphy is associated with a post-operative reduction in GH. Furthermore, the results should reassure surgeons that the GH they see at the conclusion of a case will be sustained 3 months later. However, our study also demonstrated a reduction in GH when apical POP surgery is performed even without perineorrhaphy. Similarly, Carter-Brooks *et*

Table 2 POP-Q (Pelvic Organ Prolapse Quantification) measurements at all study time points. GH, PB and TVL are measured in positive centimeter (cm) values. All other points are measured in positive or negative cm relative to the hymen. All values are measured with maximal Valsalva except for TVL and values denoted as "resting". Intra-op values are measured with the patient under general anesthesia

	Perineorrhaphy (*n*=29)	No perineorrhaphy (*n*=27)	*p*
Baseline, cm, median (inter-quartile range)			
GH	4.5 (4 – 5.5)	3.5 (3 – 4)	<0.01
PB	3 (3 – 4)	3 (2.5 – 3.5)	0.04
TVL	9 (8 – 10)	9 (9 – 9)	0.08
Aa	0 (-0.5 – 1)	1 (0 – 2)	0.59
Ba	2.5 (1 – 4.5)	1.5 (0 – 2)	0.09
C	1.5 (-2.5 – 4)	-3 (-4 – -1)	<0.01
D	-1 (-6 – 1)	-5 (-7 – -4)	0.03
Ap	-1 (-1.5 – 0)	-1.5 (-2 – -1)	0.10
Bp	0 (-1 – 3.5)	-1 (-2 – -0.5)	<0.01
Intra-operative, before surgery			
GH (resting)	4.5 (4 – 5.5)	4 (3.5 – 4)	<0.01
PB (resting)	3.5 (3.5 – 4.5)	3.5 (3 – 4)	0.22
Intra-operative, after surgery			
GH (resting)	3 (2.5 – 3.5)	3 (2.5 – 3.5)	0.43
PB (resting)	4.5 (3.5 – 5)	3.5 (3 – 3.5)	<0.01
3-month post-op			
GH	3 (2.5 – 3.5)	3 (1 – 5)	0.20
GH (resting)	2.5 (2.5 – 3)	2 (2 – 3)	0.08
PB	4 (3.5 – 4)	3 (3 – 3.5)	<0.01
PB (resting)	3.5 (3.5 – 4)	3 (2.5 – 3.5)	<0.01

al [7] found that perineorrhaphy may not be necessary for reduction of GH. Interestingly, the postoperative change in GH in the subgroup of patients undergoing sacrocolpopexy was smaller than that seen in those undergoing vaginal native tissue apical suspensions, and the change in GH was not significantly greater in those who had perineorrhaphy vs. no perineorrhaphy. These results further suggest that the change in GH seen after surgery is not solely related to perineorrhaphy. However, these subgroups were small and our study was not powered to identify these differences. Most importantly, whether performance of perineorrhaphy reduces the risk of prolapse recurrence remains unknown, and this should be the focus of future research.

Perineorrhaphy may also be associated with additional risk of complications such as introital narrowing and dyspareunia [15]. Among sexually active women, there was more frequent reporting of pain with intercourse in the perineorrhaphy group in this study (6 (42.8%) vs 2 (18.2%), p=0.19). While this difference did not reach statistical significance, the study was not specifically powered to evaluate this outcome. Also, we do not have pre-operative PISQ-IR data for comparison.

The primary strength of this study is prospective collection of resting and Valsalva GH at multiple time points before, during and after surgery. Subjects also completed validated questionnaires. Limitations include a modest sample size and only 3 months of follow-up. Further, similar to all prior studies evaluating perineorrhaphy and GH, perineorrhaphy was performed at surgeon discretion. Thus, we do not know to what degree surgeon decision-making has on the differences (and lack of differences) seen between groups.

In conclusion, intra-operative resting GH measured after perineorrhaphy is about 0.5 cm greater than the resting GH at 3 months after surgery. Surgeons can be reassured that the intra-operative change in resting GH resulting from perineorrhaphy is sustained at the 3-month postoperative visit and is similar to the more commonly measured preoperative to postoperative change in Valsalva GH.

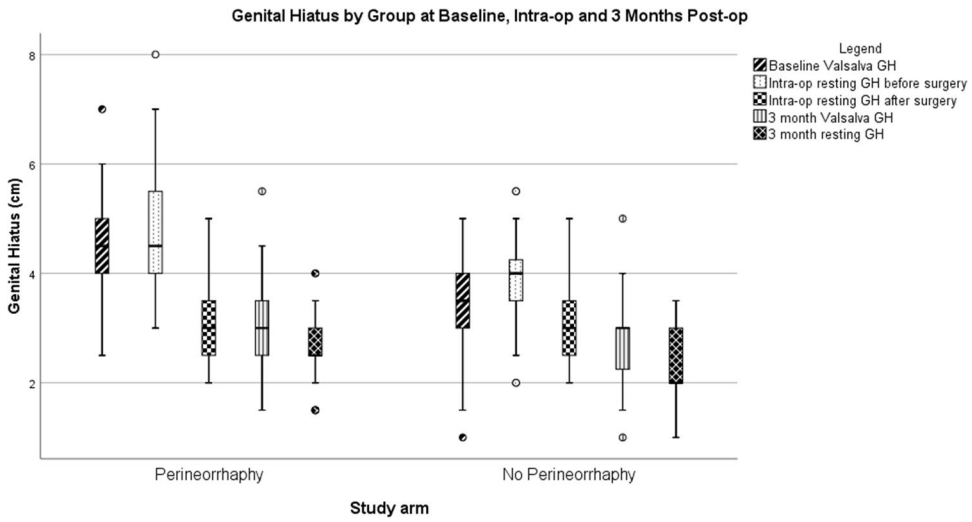

Fig. 2 Median genital hiatus (GH) is shown at each study time point and separated by study arm (perineorrhaphy or no perineorrhaphy). cm = centimeter.

Table 3 Primary and secondary outcomes

	Perineorrhaphy (n=29)	p (within group)	No perineorrhaphy (n=27)	p (within group)	p (between groups)
Comparing intra-op GH after surgery to 3-month post-op resting GH, median (interquartile range)					
Intra-operative GH after surgery	3.0 (2.5 – 3.5)	<0.01*	3.0 (2.5 – 3.5)	<0.01	
3-month resting GH	2.5 (2.5 – 3.0)		2.0 (2.0 – 3.0)		
(3-month resting GH) – (Intra-operative GH after surgery)	-0.5 (-1.0 – 0.0)		-0.5 (-1.0 – -0.5)		0.10
Comparing change in resting GH intra-op with change in Valsalva GH between baseline and 3-month post-op, median (interquartile range)					
ΔGH_{io}	-1.5 (-2.5 – -1.0)	0.52**	-1.0 (-1.5 – 0.0)	0.48	
ΔGH_{3m}	-1.5 (-2.0 – -1.0)		-0.5 (-1.5 – 0.0)		<0.01**
3-month post-op questionnaires, mean (SD)					
PFDI-20	23.2 (25.9)		19.9 (25.8)		0.63**
PISQ-IR	43.4 (10.3)		41.3 (9.8)		0.46**

GH = genital hiatus. ΔGH_{io} = Change in GH between before and after surgery while under anesthesia. ΔGH_{3m} = Change in GH between baseline Valsalva GH and 3-month post-op Valsalva GH. PFDI-20 = Pelvic Floor Distress Inventory short form. PISQ-IR = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire. *Primary aim. **Secondary aims.

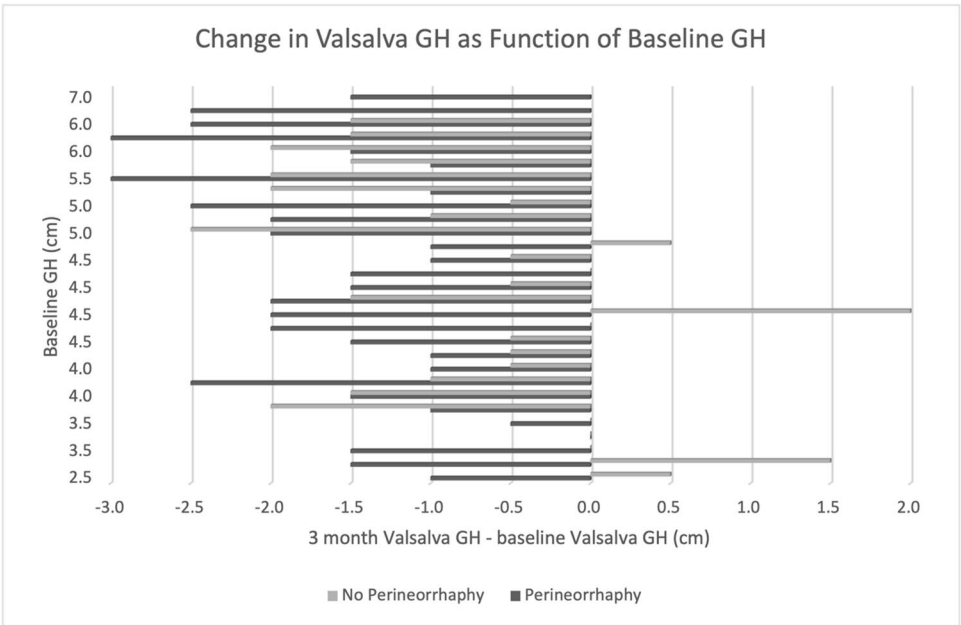

Fig. 3 Graph demonstrates the magnitude of change in Valsalva genital hiatus (GH) between baseline and 3 months after surgery as a function of baseline GH. cm = centimeter

Table 4 Primary and secondary outcomes analyzed separately for patients undergoing sacrocolpopexy and non-sacrocolpopexy (uterosacral or sacrospinous ligament suspension)

	Only sacrocolpopexy					Only non-sacrocolpopexy				
	Perineorrhaphy ($n = 8$)	p (within group)	No perineorrhaphy ($n = 16$)	p (within group)	p (between groups)	Perineorrhaphy ($n = 21$)	p (within group)	No perineorrhaphy ($n = 11$)	p (within group)	p (between groups)
Comparing intra-op GH after surgery to 3-month post-op resting GH, median										
Intra-operative GH after surgery	3 (2.5 – 3.75)	0.50*	2.5 (2.5 – 3)	0.43		3 (2.5 – 3.5)	<0.01*	3.5 (2.75 – 3.75)	<0.01	
3-month resting GH	3 (2.75 – 3)		2 (2 – 3)			2.5 (2 – 3)		2.5 (1.75 – 3)		
(3-month resting GH) – (Intra-operative GH after surgery)	0 (-0.75 – 0.25)		-0.5 (-1 – 0)		0.32	-0.5 (-0.5 – 0)		-1 (-1.25 – -0.5)		0.03
Comparing change in resting GH intra-op with change in Valsalva GH between baseline and 3-month post-op, median (interquartile range)										
ΔGH_{io}	-2.5 (-3 – -1.5)	0.19**	-1 (-1.75 – -0.5)	0.69		-1.5 (-2 – -1)	0.75**	-0.5 (-1 – 0)	0.10	
ΔGH_{3m}	-1.75 (-2.5 – -1.25)		-1.5 (-2 – -0.5)		0.14**	-1.5 (-2 – 1)		0 (-0.5 – 0.25)		<0.01**

GH = genital hiatus. ΔGH_{io} = Change in GH between before and after surgery while under anesthesia. ΔGH_{3m} = Change in GH between baseline Valsalva GH and 3-month post-op Valsalva GH. *Primary aim. **Secondary aims.

Declarations

Conflicts of interest None

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