

# Genital hiatus measurements predict cuff prolapse risk in prolapse surgery

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## Ethics Committee Approval

The study was approved by the Istanbul Prof. Dr. Cemil Tascioğlu City Hospital Clinical Research Ethics Committee on 23/01/2020 with approval number 28.

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

## Conflict of Interest

No conflict of interest was declared by the authors.

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## Abstract

**Background/Aim:** Recognition and assessment of apical vaginal support defects remains a significant challenge in the evaluation and management of prolapse because there are no consensus or guidelines address the degree of apical support loss at which an apical support procedure should routinely be performed. The aim of this study was to evaluate whether preoperative genital hiatus (GH), perineal body (PB), and total vaginal length (TVL) are associated with prolapse recurrence after apical prolapse surgery.

**Methods:** Our cohort study included 98 patients who underwent vaginal hysterectomy apical suspension due to uterovaginal prolapse of grade 2 or higher according to Pelvic Organ Prolapse Quantification (POP-Q) staging between 2020 and 2021. Patients with a history of gynecologic malignancy, those who could not tolerate surgery or anesthesia, those who had previously undergone pelvic organ prolapse surgery, those with concomitant stress urinary incontinence, and those with abnormal cervical smear results were excluded. Patients were followed for 2 years at intervals of 3 months in the first year after the surgery. The last POP-Q was performed 24 months after surgical intervention. Surgical failure or recurrence was defined as apical descent greater than one third of the total vaginal length, anterior or posterior vaginal wall past the hymen, subsequent surgery, or bothersome vaginal bulge. Patients were given the Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire before surgery and 6 months postoperatively, and the severity of symptoms was compared between the groups with and without postoperative recurrence. Logistic regression (LR) analysis was performed to determine the factors affecting recurrence. Areas under the ROC curve were calculated as a differential diagnosis for the presence of recurrence, and the predictive value (cut-off) of variables was determined using sensitivity, specificity, positive predictive value, negative predictive value, and LR (+) values.

**Results:** While surgery was successful in 80 patients, genital relapse was seen in 18 patients. The mean preoperative perineal body was 3.05 (0.28) cm, mean preoperative GH was 3.9 (0.39) cm, and mean preoperative TVL was 8.54 (1.33) cm. The mean GH of the group with recurrence was significantly higher than the group without recurrence ( $P=0.004$ ). The mean preoperative POP-SS score was 15.14 (1.86), and the postoperative POP-SS score was 4.01 (3.74). The postoperative POP-SS score mean of the recurrence (+) group was significantly higher than the group without recurrence ( $P<0.001$ ). For the genital hiatus, the cut-off  $>4$  cm had a sensitivity of 61.11%, specificity of 76.25%, positive predictive value of 36.70%, negative predictive value of 89.70%, and LR (+) value of 2.57. For POP-SS Preop-Postop Change %, the cut-off  $<60$  had a sensitivity of 94.44%, specificity of 98.75%, positive predictive value of 94.40%, negative predictive value of 98.80%, and LR (+) value of 75.56.

**Conclusion:** Apical vaginal support loss is highly associated with genital hiatus size. In particular, according to all study definitions, a Pelvic Organ Prolapse-Quantification measurement genital hiatus of  $>4$  cm is a strong predictor of apical support loss. This simple measurement can be used to screen for apical support loss and further evaluate apical vaginal support before planning a hysterectomy or prolapse surgery.

**Keywords:** sacrospinous ligament fixation, pelvic organ prolapse, uterosacral ligament suspension

## Introduction

The herniation of the apical vaginal compartment through the vaginal introitus can result in the inclusion of either the bowel or uterus, which is indicative of either an enterocele or uterovaginal prolapse, respectively. The risk of undergoing pelvic organ prolapse (POP) surgery for a woman ranges from 11% to 19% in her lifetime [1]. The likelihood of surgical intervention increases with age [2]. Recognizing the association between the more common anterior wall prolapse and apical descent, many gynecologists still prefer vaginal hysterectomy (VH) with apical suspension as the preferred surgical approach for uterine prolapse [3]. A randomized controlled trial (RCT) showed that there is a high surgical failure rate of up to 35% within 2 years despite apical suspension [4]. The risk of reoperation for cuff prolapse after hysterectomy ranges from 4.6% to 18% [5].

Genital hiatus (GH) is the measurement of the distance between the middle of the external urethral meatus and the posterior midline hymen [6]. GH has been identified as an indicator of underlying pelvic floor muscle damage [7] and has been shown to be significant in the evaluation of POP. It is a predictor of outcomes after surgical intervention [8]. When GH is 3.75 cm or greater, it is associated with and predictive of apical vaginal support loss [9]. An enlarged genital hiatus is an independent risk factor for the development of POP [10]. Here, we investigated whether preoperative genital hiatus is a predictor factor for prolapse recurrence after vaginal hysterectomy.

## Materials and methods

Between 2020 and 2021, a total of 98 patients who underwent vaginal hysterectomy + apical suspension due to uterovaginal prolapse with a POP-Q stage of grade 2 or higher were included in this prospective study. Eighteen patients were excluded from the study due to insufficient follow-up. Patients with a history of gynecologic malignancy, those who could not tolerate surgery or anesthesia, those who had previously undergone pelvic organ prolapse surgery, those with concomitant stress urinary incontinence, and those with abnormal cervical smear results were excluded. A detailed physical examination was performed after recording the demographic information of all patients included in the study. The ICS/IUGA documents provide a detailed description of how to perform the Pelvic Organ Prolapse Quantification (POP-Q) technique [11]. Six points are identified in the vagina during the POP-Q: Aa and Ba for the anterior vagina, Ap and Bp for the posterior vagina, and C and D for the cervix/vault; point D is excluded in women who have undergone a hysterectomy. The patient is instructed to strain, preferably in a lithotomy position, to achieve maximum POP. Three additional measurements are taken to provide a comprehensive assessment: the genital hiatus length, perineal body length, and total vaginal length [12]. GH is measured from the middle of the external urethral meatus to the posterior margin of the hymen, while TVL is the length of the vagina (in cm) from the posterior fornix to the hymen when Point C or D is in its fully normal position. PB is measured from the posterior margin of the hymen to the mid-anal opening. This preoperative assessment was conducted by two trained gynecologists who were not a part

of the initial surgical team. The Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire was administered to study participants twice: before surgery and six months after the operation. The Turkish version of POP-SS is a valid and reliable tool for Turkish women with POP [13]. The total score calculated by POP-SS is based on seven questions asked with a range of 0 to 28. A higher score indicates more severe prolapse symptoms—it reflects a greater frequency and variety of reported symptoms [14]. Various surgical treatments are available, and there are no guidelines to recommend the best. Patients scheduled for apical compartment prolapse surgery uterosacral ligament suspension (USLS), sacrospinous ligament fixation (SSLF), McCall's culdoplasty and Iliococcygeal Fascia Suspension (ICG) + Perineoplasty were eligible for inclusion.

In transvaginal hysterectomy with sacrospinous ligament fixation (SSLF), the patients who required uterine removal underwent TVH with sacrospinous ligament fixation per standardized requirements. Prior to closing the peritoneum, the uterosacral ligament and cardinal stumps were tied together in the midline. After closure of the peritoneum, unilateral SSLF of the right sacrospinous ligament was performed for all patients via a posterior approach. Finally, the non-absorbable sutures were tied to bring the vaginal vault back to the ligament. At our institution, common practices for TVH USLS include two sutures through each bilateral uterosacral ligament (permanent or delayed absorbable) for a total of four sutures. These are then attached to the vaginal cuff. Once the vaginal cuff has been suspended, any necessary anterior and posterior repairs are typically performed simultaneously.

Raymond Lee of the Mayo Clinic described the technique used for vaginal hysterectomy with McCall's culdoplasty [15]. Following vaginal hysterectomy, one or two internal McCall's sutures were inserted utilizing Vicryl-1. The external McCall's sutures were positioned anterior cephalad to the internal McCall's sutures and inserted through the posterior vaginal wall. The suspension technique utilizing the fascia of the iliococcygeus muscle (ICG) was initially developed by Inmon in 1963 for patients in whom identification of the uterosacral ligament was challenging or inadequate to provide support to the vaginal vault. Shull et al. further modified the technique in 1993 [16]. Its development aimed to prevent potential vessel and nerve injuries linked to SSLF. The technique of initial pararectal dissection in ICG is comparable to that in SSLF except for the suture site for attaching the vaginal vault. ICG involves using the fascia of the iliococcygeus muscle, which is located just below the ischial spine and lateral to the rectum where there are fewer major nerves and vessels. Perineorrhaphy with native tissue was performed as follows: Depending on the size of the vaginal outlet, a transverse incision is made at the musculocutaneous border of the posterior hymen followed by removal of a triangular posterior epithelial flap. The procedure usually involves recto- and enterocele repairs or repairs of other compartments based on individual defect patterns. The tissues proximal and distal to the hymen are included depending on intraoperative findings. Proximal to the hymen, one to three deep interrupted sutures are used to approximate the perirectal connective fascia tissue over the distal part of the rectocele, depending on the size of the vaginal outlet and the extent of the

posterior compartment defect. Levator plication is not performed. The bulbocavernosus muscles are re-approximated with one or two sutures where they deviate. In most cases, re-approximation of the transverse perineal muscles may be appropriate. Finally, the skin is trimmed and closed. All surgeries were performed by five surgeons. Patients were followed up for 2 years at intervals of 3 months in the first year after the surgery. The last POP-Q was performed 24 months after surgical intervention. During each follow-up visit, all patients were examined for any recurrence or de novo urinary incontinence. Pelvic examination was performed under maximum strain to assess for recurrence. Surgical failure or recurrence was defined as apical descent greater than one-third of the total vaginal length, anterior or posterior vaginal wall past the hymen, subsequent surgery, or bothersome vaginal bulge.

In this study, ethical approval was obtained from the Istanbul Prof. Dr. Cemil Tascioglu City Hospital Clinical Research Ethics Committee on 23/01/2020 with approval number 28. In addition, written permission was obtained from the institutions where the research was conducted. All patients gave informed consent. The study was conducted in accordance with the Principles of the Declaration of Helsinki.

**Statistical analysis**

Statistical analyses in this study were performed using NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program.

Descriptive statistical methods (mean, standard deviation, median, interquartile range) were used, and the distribution of variables was examined by the Shapiro-Wilk normality test. A paired t-test was used for the evaluation of variables and showed normal distribution in pre-op and post-op assessments. Independent t-tests were used for comparison of binary groups. The Wilcoxon test was used to evaluate variables that did not show normal distribution in pre-op and post-op assessments. The Mann Whitney U test was used for the comparison of binary groups. A Chi-squared test was used to compare qualitative data. Logistic regression analysis was performed to determine the factors affecting the presence of recurrence. The areas under the ROC curve were calculated for differential diagnosis in the presence of recurrence, and the variables' prediction (cut off) value was determined by sensitivity, specificity, positive predictive value, negative predictive value, and LR (+) values. The results were evaluated at the significance level of  $P < 0.05$ .

**Results**

The mean age of the 98 patients included in the study was 62.5 (10.05) years, the mean gravidity was 5.18 (3.17). The mean parity of the patients was 4.12 (2.89), the mean body mass index (BMI) was 27.88 (3.63), the mean number of normal deliveries was 4.09 (2.93), the mean preoperative perineal body length was 3.05 (0.28), the mean preoperative genital hiatus was 3.9 (0.39), and the mean preoperative total vaginal length was 8.54 (1.33). Demographic and patient data are summarized in Tables 1 and 2, and the POP-Q parameters between relapse (+) and relapse (-) groups are summarized in Table 3.

Table 1: Baseline patient characteristics

	Mean (SD)
Age	62.5 (10.05)
Gravidity	5.18 (3.17)
Parity	4.12 (2.89)
Height	161.3 (5.83)
Weight	72.32 (8.31)
BMI	27.88 (3.63)
NSD	4.09 (2.93)
CS	0.13 (0.47)
Perineal Body	3.05 (0.28)
Genital Hiatus	3.9 (0.39)
POP-Q	2.58 (0.75)
Aa	0.13 (2.24)
Ba	2.06 (3.87)
C	1.29 (3.44)
Ap	-0.59 (1.9)
Bp	1.02 (3.01)
TVL	8.54 (1.33)

SD: Standard Deviation, TVL: Total Vaginal Length, POP-Q: Pelvic Organ Prolapse Quantification, BMI: Body Mass Index, NSD: Normal Spontaneous Delivery, CS: Cesarean Section

Table 2: Characteristics of women studied in this analysis

		Relapse (-) n=80		Relapse (+) n=18		P-value
Age	Mean (SD)	63.19 (9.88)		59.44 (10.48)		0.154*
Operation	VAH+Culdoplasty	22	27.50%	3	16.67%	0.391+
	VAH+Iliococcygeal Fascia Suspension + Perineoplasty	24	30%	5	27.78%	
	VAH+USLS	21	26.25%	4	22.22%	
	VAH+SSLF	13	16.25%	6	33.33%	
Gravidity	Mean (SD)	5.19 (3.28)		5.17 (2.68)		0.904†
Parity	Mean (SD)	4.1 (3)		4.22 (2.46)		0.488†
BMI	Mean (SD)	27,64 (3.51)		28.91 (4.06)		0.182*
NSD	Mean (SD)	4.06 (3.03)		4.22 (2.46)		0.471†
CS	Mean (SD)	0.14 (0.47)		0.11 (0.47)		0.678†
De Novo Urinary Incontinence	Absent	75	93.75%	12	66.67%	0.001+
	Present	5	6.25%	6	33.33%	
Groin Pain	Absent	74	92.50%	14	77.78%	0.062+
	Present	6	7.50%	4	22.22%	
Dyspareunia	Absent	79	98.75%	15	83.33%	0.003+
	Present	1	1.25%	3	16.67%	

\*Independent t test † Mann Whitney U test, SD: Standard Deviation, BMI: Body Mass Index, NSD: Normal Spontaneous Delivery, CS: Cesarean Section, VAH: Vaginal Hysterectomy, USLS: Uterosacral Ligament Suspension SSLF: Sacrospinous Ligament Fixation

Table 3: Preoperative POP-Q parameters between relapse (+), relapse (-) groups

		Relapse (-) n=80	Relapse (+) n=18	P-value
POP-Q	Mean (SD)	2.53 (0.69)	2.83 (0.92)	0.113*
Aa	Mean (SD)	0.05 (2.24)	0.5 (2.28)	0.457†
Ba	Mean (SD)	1.91 (3.83)	2.72 (4.1)	0.437†
C	Mean (SD)	1.33 (3.18)	1.11 (4.54)	0.555†
Ap	Mean (SD)	-0.6 (1.85)	-0.56 (2.18)	0.925†
Bp	Mean (SD)	1 (2.89)	1.11 (3.58)	0.903†
TVL	Mean (SD)	8.66 (1.35)	8 (1.09)	0.065*
Perineal Body	Mean (SD)	3.04 (0.26)	3.07 (0.35)	0.748*
Genital Hiatus	Mean (SD)	3.85 (0.35)	4.14 (0.48)	0.004*

\*Independent t test † Mann Whitney U test, SD: Standard Deviation, POP-Q: Pelvic Organ Prolapse Quantification, TVL: Total Vaginal Length

The average preoperative POP-SS score for the patients was 15.14 (1.86), and the postoperative POP-SS score was 4.01 (3.74). There was no statistically significant difference in the average preoperative POP-SS score between the groups with and without recurrence ( $P=0.870$ ). However, the postoperative POP-SS score in the group with recurrence was significantly higher than in the group without recurrence ( $P<0.001$ ).

Regression analysis used the variable of genital hiatus to determine the factors affecting the presence of recurrence. There was a statistically significant increase in recurrence with an increase in preoperative genital hiatus measurement ( $P=0.008$ ).

In the differential diagnosis of recurrence, the area under the ROC curve was 0.705 (0.604-0.771) for the variable of GH, and 0.947 (0.882-0.982) for the variable of percentage change in POP-SS ( $P=0.01$ ). For genital hiatus, a cut-off value

of >4 cm yielded a sensitivity of 61.11%, specificity of 76.25%, positive predictive value of 36.70%, negative predictive value of 89.70%, and LR (+) value of 2.57. For POP-SS Preop-Postop % Change, a cut-off value of <60 yielded a sensitivity of 94.44%, specificity of 98.75%, positive predictive value of 94.40%, negative predictive value of 98.80%, and LR (+) value of 75.56. Sensitivity and specificity analysis for GH and POP-SS percentage change are summarized in Table 4.

Table 4: Sensitivity and specificity analysis for GH and POP-SS Change %

	Criterion	Sensitivity%	Specificity%	PPV%	NPV%	LR (+)
Genital Hiatus	>4	61.11	76.25	36.7	89.70	2.57
POP-SS Change (%)	<60	94.44	98.75	94.4	98.80	75.56

## Discussion

In patients presenting with apical prolapse, recurrence of prolapse can occur despite suspension operations. It is unclear which patients may develop recurrence. Here, prolapse recurrence was 2.57-fold more common in patients with a genital hiatus measurement greater than 4 cm versus those with a measurement of less than 4 cm. We previously showed that urogenital hiatus prolapse was increased in women with POP versus those without, but the Baden Walker classification system was used instead of the POP-Q examination; therefore, the PB measurements were not reported in that study [17]. We found no difference in PB and TVL between the groups with and without recurrence. Similarly, a study of 1037 women evaluated POP severity based on levator hiatus size and function. Prolapse severity was positively correlated with GH but not with PB [18]. Another study found that a GH measurement above 3.75 cm was strongly associated with apical prolapse [9]. Numerous studies have shown that an enlarged pre- and/or postoperative GH is associated with an increased risk of recurrent prolapse following repair surgery [19]. Publications also exist that associate GH size with prolapse symptoms and severity of discomfort [20]. We found that the likelihood of recurrence in a patient with a preoperative-postoperative POP-SS score change percentage value of >60 was 75.56 times higher than in a patient with a value of <60.

Early postoperative genital hiatus measurements <4 cm have been associated with long-term success without increasing dyspareunia in surgeries involving apical suspension such as USLS and robotic sacrocolpopexy [21]. Another study has associated both preoperative and postoperative enlarged GH with increased surgical failure after SSLF [22]. In a randomized controlled trial comparing suspension surgeries for apical prolapse, there was no significant difference in surgical failure rates between USLS and SSLF [23].

HUSLS had better outcomes in a study comparing high uterosacral ligament suspension (HUSLS) and McCall's culdoplasty for vaginal cuff suspension, [24]. In our study, there was no superiority observed in terms of surgical success for USLS, SSLF, ICG fascia fixation, and McCall's culdoplasty. Similar studies in the literature have shown that transvaginal repair using native tissue procedures is safe and effective for correcting vaginal vault prolapse after hysterectomy [25]. Surgeons frequently perform perineorrhaphy during POP surgery

to reduce GH size [26]. However, evidence supporting this practice is lacking. Although there is evidence showing a relationship between GH and POP, there is no evidence that surgically correcting GH is effective in preventing POP recurrence [27]. Some publications suggest that perineorrhaphy may not be necessary [28]. In contrast to the aforementioned studies, a different study discovered that incorporating perineorrhaphy in POP repair resulted in Level III support as indicated by decreased genital hiatus size [29]. Here, there was no significant difference in surgical failure rate between adding perineoplasty to ICG fascia fixation and other apical prolapses; however, the correction of the genital hiatus or the reduction of its measurements does not ensure the maintenance of the apical correction. It is not possible to establish a cause of recurrence or that only taking care to reduce the genital hiatus can guarantee the maintenance of the apical correction. The pathophysiology of recurrence is complex, and other factors may be involved with the need for further studies with long-term follow-up.

Similar studies in the literature have shown that the diagnosis of prolapse is preceded by a larger GH, and the risk of prolapse differs significantly depending on the GH values [30]. This cohort did have a few limitations. While we followed women for up to 2 years, this duration of follow up may be insufficient to accurately predict outcomes many decades from surgery. The strengths of this study include its prospective nature, standardized methods for collecting medical history, and POP-Q examinations. All POP-Q values were collected by two individuals who were well trained in obtaining POP-Q measurements.

Although there is still no definitive proof of a causal link between GH size and prolapse, these results imply that a larger GH is a crucial factor in predicting future prolapse risk.

## Conclusion

Apical vaginal support loss is highly associated with genital hiatus size. In particular, according to all study definitions, a Pelvic Organ Prolapse-Quantification measurement genital hiatus of >4 cm is a strong predictor of apical support loss. This simple measurement can be used to screen for apical support loss and further evaluate apical vaginal support before planning a hysterectomy or prolapse surgery.

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