Original Article

Vaginal-assisted Laparoscopic Sacrohysteropexy and Vaginal Hysterectomy with Vaginal Vault Suspension for Advanced Uterine Prolapse: 12-month Preliminary Results of a Randomized Controlled Study

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Abstract

Objective: Vaginal-assisted laparoscopic sacrohysteropexy (VALH) is a new modified form of uterine-sparing prolapse surgery using a combined vaginal and laparoscopic approach. We aimed to compare 1 year efficacy and safety of VALH and vaginal hysterectomy with vaginal vault suspension (VH + VVS) in the surgical treatment of apical pelvic organ prolapse (POP).

Materials and Methods: Women who requested surgical treatment for stage 2–4 symptomatic uterine prolapse were recommended to participate in one year-long randomized study between July 2017 and January 2019. POP Quantification (POP-Q) examination and validated questionnaires such as International Consultation on Incontinence Questionnaire Vaginal Symptoms (IVIQ-VS) survey, Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire Short Form (IIQ-7), and Patient Global Impression of Improvement (PGI-I) were recorded at baseline and 12 months after surgery. The main primary outcome measure was apical prolapse recurrence. Secondary results were duration of surgery, pain score, blood loss, postoperative hospital stay, and quality of life scores related to prolapse.

Results: There were 15 women in VALH and 19 women in the VH + VVS group. ICIQ-VS score, ICIQ-QOL, UDI-6, and IIQ-7 scores were improved for both groups. According to the PGI-I scores, 80% of subjects in the VALH group, and 100% in the VH + VVS group, were "very much better" or "much better" with their prolapse symptoms at their 1-year follow-up. There was no reoperation or operation-related complication in both groups.

Conclusion: VALH and VH + VVS have similar 1-year cure rates and patient satisfaction.

Keywords: Laparoscopy, sacrohysteropexy, uterin prolapse, vaginal hysterectomy

Introduction

Uterovaginal prolapse is a common and life-restricting condition experienced by women of different ages. Traditional surgical treatment for uterovaginal prolapse often includes vaginal hysterectomy (VH) and anterior or posterior colporrhaphy.[1] According to patient-specific therapies and the definition of surgical success as reported by patients, the option of preserving the uterus was preferable to performing a hysterectomy to treat apical pelvic organ prolapse (POP). According to the current literature comparing the results of uterus-sparing surgery to those of hysterectomy during

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POP repair, 36%–60% of women stated that they would prefer an intervention that preserves the uterus if there were comparable surgical results between the two approaches.[2,3]

Anatomical variables (isolated apical prolapse or multiple compartment prolapse), hormonal status (premenopausal, postmenopausal in hormone therapy, and postmenopausal without hormone therapy), and surgical approaches were compared in studies investigating the options of hysteropexy and hysterectomy. The multiplicity of different study designs using different techniques limits the generalization of their results. There is also only short-term follow-up data on uterine-sparing operations in POP cases.[4,5]

In an observational study covering >500 women who underwent laparoscopic sacrohysteropexy and were observed for up to 10 years, 94% reported that their prolapse was "very much" or "much" better.[6] In addition, in a study comparing VH with uterosacral ligament suspension and open sacrohysteropexy in 82 women, high apical prolapse success rates (95%) and subjective improvement results were reported. However, women in the sacrohysteropexy arm were more likely to have another surgery for prolapse within the 1st year of the index surgery.[7] To date, various techniques have been described for uterine-sparing prolapse surgery, including vaginal sacrospinous hysteropexy, transvaginal mesh kits, abdominal sacrohysteropexy, and laparoscopic uterine suspension through sling or mesh.

Until now, the results of modified uterine-sparing prolapse surgery using a combined vaginal and laparoscopic approach have been reported by Fayyad and Siozos in a series of 70 women with uterine prolapse.[8] However, there are no definitive data in the literature regarding the comparison of vaginally-assisted laparoscopic sacrohysteropexy (VALH) results to those of conventional VH. This study, therefore, aims to compare two surgical interventions for patients with POP.

Materials and Methods

In this study, the 1st-year results of a single-center, randomized controlled study of two parallel groups, conducted in the tertiary referral training and research hospital, were evaluated. The study included women who were admitted to our urogynecology unit for stage 2–4 symptomatic uterine prolapse between June 2017 and January 2019. The study was approved by our hospital's local ethics committee (approval number: 2018/23). This clinical trial was registered in ClinicalTrials.gov Protocol Registration and Results System (PRS) and given the code of NCT03436147 on February 10, 2018.

Requirements for participation were that the women be over 18 years of age with no desire to preserve fertility (subjects had completed childbearing or were practicing reliable contraception), have a normal size uterus (<10 cm) on examination or ultrasound, and agree to participate in principle. They were then given further information about the trial, and consent was sought either in an outpatient clinic or at the next visit for preoperative assessment. Exclusion criteria were: cervical elongation (surgeon's discretion), prior prolapse surgery, current foreign-body complications, increased risk or recent history of cervical dysplasia, chronic pelvic pain, significant uterine abnormalities, abnormal menstruation or postmenopausal bleeding within the previous 12 months, and a significantly enlarged fibroid uterus or concomitant medical problems precluding general anesthesia or the assumption of a steep Trendelenburg position. Written informed consent was obtained from all of the participants.

Participants were randomly assigned to either of two groups: Group A (VALH) or Group B (VH + VVS). The consolidated standard of reporting trials flow study diagram is presented in Figure 1. Simple randomization was performed by the distribution of blind envelopes in order to separate the patients into the groups; this randomization was performed before admission to surgery. Those who subsequently had a strong preference for either operation and consequently declined to continue in the study were excluded and not put through the randomization process.

Age, parity, body mass index (BMI), intraoperative blood loss, operation time, and postoperative hospital stay were recorded. Blood loss was assessed by the volume of blood and the weight of soaked pads. BMI was calculated as the weight (kg) divided by the square of the height (m^2).

Surgeries were performed under general anesthesia with the help of residents and one specialized urogynecologist. The VALH operation was initiated with conventional laparoscopy. Then, one 10 mm umbilical and two 5 mm lower abdominal trocars were inserted after obtaining sufficient pneumoperitoneum with a Veress needle (Ethicon Endo-surgery Inc., USA). Conventional laparoscopic 5 mm grasping forceps and scissors were used to perform the laparoscopic phase of the surgery. The peritoneum over the sacral promontory was incised [Figure 2a]. At the vaginal phase of the surgery, a semi-circular incision was made at the posterior cervicovaginal junction. Curved ring forceps were introduced through with blunt dissection over the right sacrouterine ligament to establish a tunnel toward to the incised opening over the sacral promontory. This step was visualized simultaneously via laparoscopy [Figure 2b]. A 15 cm × 3 cm, tailored, macroporous, nonabsorbable polypropylene monofilament mesh (15 cm–15 cm; Ethicon, Somerville, NJ, USA) was taken into the abdomen through

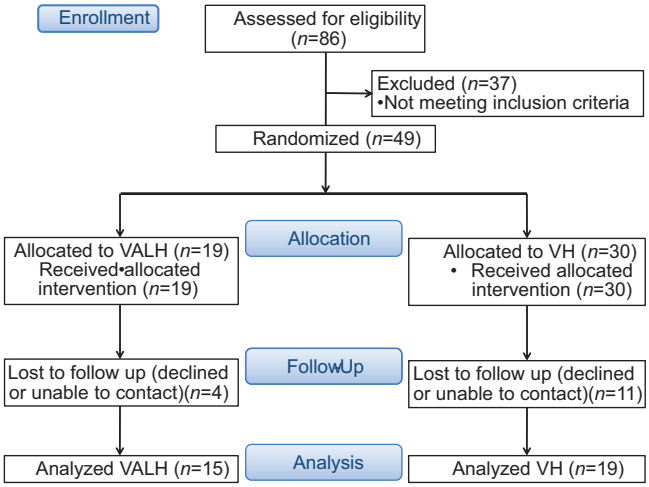

Figure 1: Consolidated standart of reporting trials (CONSORT) flow diagram

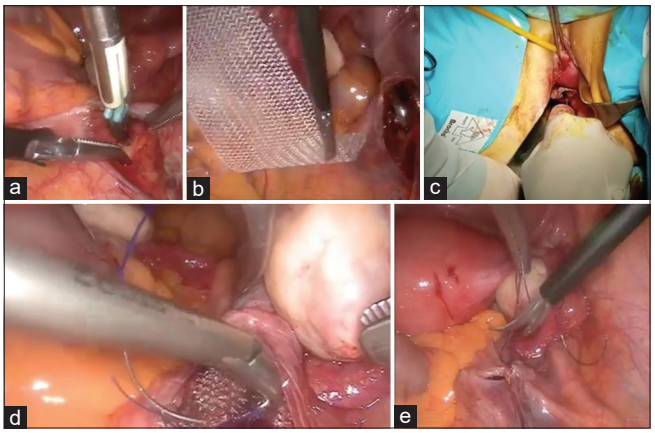

Figure 2: (a) Laparoscopic promontorium dissection, (b) laparoscopic visualization of creating a retroperitoneal tunnel through vaginal route via ring forceps, (c) mesh fixation to the posterior face of the cervix through vaginal route, (d) laparoscopic mesh suturing to the promontory, (e) laparoscopic suturing the peritoneal opening at the promontory level

the 10 mm trocar. When the ring forceps reached the incision at the promontory level, the tip of the mesh was grasped and pulled down through the retroperitoneal tunnel until it came to the posterior cervix. The mesh was fixed to the posterior face of the uterine cervix using nonabsorbable sutures through the vaginal route [Figure 2c]. The semicircular vaginal incision was closed with absorbable sutures (Vicyrl 1; Ethicon, Somerville, NJ, USA) after attaching the mesh to the cervix. Finally, after the uterine suspension was maintained with pushing the uterus to its normal position, the abdominal part of the mesh was sutured to the anterior longitudinal ligament at the sacral promontory with non-absorbable sutures using a laparoscopic technique [Figure 2d]. The excess part of the mesh was cut with scissors and removed from the abdomen through a trocar. The peritoneal incision at the promontory level was closed with absorbable sutures to cover the fixated mesh [Figure 2e].

The VH + VVS operation was initiated with a circumferential incision in the vaginal epithelium at the junction of the cervix. After the dissection of the vaginal epithelium, we entered the abdominal cavity along the anterior and posterior planes of the uterus. Uterosacral and cardinal ligaments, uterine vessels, broad ligaments, and utero-ovarian pedicles were classically identified, clamped, cut, and ligated with absorbable sutures (Vicryl 1; Ethicon, Somerville, NJ, USA). The uterosacral ligaments were attached with absorbable sutures to the vaginal vault after hysterectomy for vaginal vault support. Sacrospinous ligament fixation surgeries were also performed for patients whose vaginal vaults were <2 cm from the hymen after VH. Finally, the vaginal cuff was closed by a running locking stitch with absorbable sutures.

Additional concomitant surgeries, including anterior and posterior colporrhaphy and perineoplasty, were performed after apical suspension, as needed. Additional anti-incontinence surgeries were performed in accordance with the patient–surgeon interviews after preoperative evaluation, including urodynamic examination. In daily practice, we perform an urodynamic examination before surgery for patients who have advanced uterine prolapse with or without complaints of stress urinary incontinence. However, in this case, the participants who had a confirmed diagnosis of stress urinary incontinence or were diagnosed with occult stress incontinence in the urodynamic study had anti-incontinence surgery suggested to them. Tension-free vaginal tape surgery was performed by a separate anterior mid-urethral incision if needed.

On the day of the operation, the allocation was confirmed, and appropriate consent was obtained for the given surgical procedures. VH and laparoscopic hysteropexy were combined with anterior and/or posterior repair at the surgeon's discretion at the time of the operation. Each participant was initially followed-up with in the clinic at 1 week, 1 month, 3 months, and 1 year postsurgery as part of the departmental procedure. Postoperative pain scores were evaluated 24 h after surgery by a visual analog scale score. Uterovaginal prolapse was assessed again using the International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) questionnaire and the POP Quantification (POP-Q) system by another researcher, and then the operator. During interviews, further questions were asked regarding postoperative recovery, current urinary symptoms, and satisfaction with the operation. Subjective surgical outcome was measured using the Patient Global Impression of Improvement (PGI-I), which is a validated global index of response to prolapse surgery consisting of a seven-point scale upon which patients may compare their preoperative and postoperative conditions (with 1 being "very much better" and 7 being "very much worse").[9] The

PGI-I scale was evaluated 1 year after surgery with each of the patients.

The participants' prolapse symptoms, and their impacts, were evaluated both before and 1 year after surgical treatment. A subjective assessment of the prolapse was made using the ICIQ-VS.[10] Objective assessment of POP was performed during a Valsalva maneuver using a Sims' speculum, and the frequently-used POP-Q scale was evaluated.[11] Patients were also asked to complete the Urogenital Distress Inventory Short Form (UDI-6) and the Incontinence Impact Questionnaire Short Form (IIQ-7). The UDI-6 and IIQ-7 are accepted as validated questionnaires that are useful in the assessment of urogenital symptoms and disease-specific quality of life.[12]

The measure for the primary outcome was treatment failure, defined as recurrent apical prolapse that required surgery within the 1st year after initial surgery. The secondary outcome measures were changed in anatomy quantified by POP-Q and symptoms quantified using the ICIQ-VS questionnaire scores for prolapse, quality of life, and PGI-I, UDI-6, IIQ-7 scores. Other secondary outcome measures were operation time, pain score, blood loss, and postoperative hospital stay.

Data analysis was performed with SPSS (version 20.0; Chicago, IL, USA). Data were analyzed using descriptive statistical methods (mean, standard deviation, median, frequency, rate, minimum, and maximum). One sample Kolmogorov–Smirnov test was performed to analyze the distribution of the data. For group comparisons of parameters with quantitative data showing normal distribution, Student's *t*-test was used, whereas a Mann–Whitney U test was used for comparing other parameters not showing normal distribution. A $P < 0.05$ was considered statistically significant.

Results

A total of 86 patients with stage 2–4 symptomatic uterine prolapse, who were seen over the period of 1 year (between January 2018 and January 2019), participated in the current study, 49 of whom were recruited. Enrollment and randomization are summarized in Figure 1. The demographic characteristics and clinical data of the study population are presented in Table 1. There were no significant differences among the VALH group and the VH + VVS group vis-à-vis age (56.26 ± 0.27 vs. 57.84 ± 0.56, $P = 0.88$, respectively), parity (3.0 ± 1.25 vs. 3.5 ± 2.71, $P = 0.88$, respectively), or BMI (30.39 ± 3.46 vs. 29.65 ± 4.50, $P = 0.603$, respectively). There was no significant difference in mean pain score and the mean number of nights spent in the hospital between both groups. The mean estimated blood loss was significantly less in the VALH group (76.66 ml) compared to the VH + VVS group (142 ml) ($P = 0.001$). Although the mean duration of total operation time was longer in the VALH group than in the VH + VVS group, the difference was not statistically significant ($P = 0.376$).

Concomitant urogynecological procedures performed for the VH + VVS group were: posterior colpoperineorrhaphy (58%), anterior colporrhaphy (84%), perineorrhaphy (78%), tension-free vaginal tape (21%), and sacrospinous fixation (74%). Concomitant procedures carried out in the VALH group were: posterior colpoperineorrhaphy (33%), anterior colporrhaphy (53%), and perineorrhaphy (33%) [Table 1]. Four patients underwent tension-free vaginal tape surgery due to urodynamically confirmed stress urinary incontinence. Of the remaining 30 patients, three were given an occult incontinence diagnosis according to urodynamic study, but they did not accept anti-incontinence surgery. Neither patients who had occult incontinence without incontinence surgery nor the four patients who had tension-free vaginal tape surgery had any complaints of stress urinary incontinence during the follow-up period.

ICIQ-VS, ICIQ-QOL, UDI-6, and IIQ-7 scores improved for both groups with no statistically significant difference between groups within preoperative and postoperative 12-month scores [Table 2]. According to the PGI-I scores, 80% of patients in the VALH group, and 100% in the VH + VVS group, were "very much better" or "much better" with their prolapse symptoms at their 1-year follow-up.

In addition, there was no significant mean difference in POP-Q parameters or point C levels between the two groups at the 1-year follow-up. The mean difference in total vaginal length was significantly higher in those who underwent VALH. There were no major intraoperative complications, and no vaginal mesh exposure or any other mesh-related complications were observed in either group during the 1-year follow-up period. In addition, there were no repeat operations for either study group during this period.

Discussion

Our study demonstrated that both the VALH and VH + VVS procedures had similar 1-year cure rates and satisfaction scores (adjusted by objective assessment); thus, the optimal treatment of advanced uterine prolapse is still unclear. A study in the United Kingdom confirmed that VH with uterosacral suspension is the most common procedure performed for uterine prolapse.[13] However, due to increasing morbidity and mortality with the hysterectomy procedure, as well as an increasing desire to preserve fertility, uterine-preserving approaches were described a few decades ago.[14,15]

With the development of endoscopic surgery over the years, laparoscopic uterine suspension techniques have begun

to be defined. Endoscopic approaches afford recognized advantages, including rapid recovery, quick hospital discharge, less adhesion formation, and better-magnified visualization of the anatomy during surgery. In the literature, one of the laparoscopic techniques for suspension of the uterus using the rectus sheath had insufficient results.[16] Other laparoscopic techniques – uterosacral plication and hysteropexy– were reported to have an 80% success rate.[5] Recently, the technique of laparoscopic hysteropexy through mesh replacement from the upper part of the cervix to the sacral promontory was described.[17] In addition, conventional laparoscopic sacral hysteropexy procedures were described to have similar anatomic results, excellent patient satisfaction, and improved quality-of-life scores.[18] Laparoscopic hysteropexy techniques are being modified with data on these successful results.

Fayyad and Siozos aimed to report the results of a modified laparoscopic hysteropexy technique using vaginal dissection, mesh replacement, and fixation of the mesh to the sacral promontory via laparoscopic view. Results showed that their technique was free from any increased risk of vaginal shortening or narrowing.[8] The study also showed that total vaginal length was significantly higher in women who had undergone VALH. Rahmanou *et al*. reported that estimated blood loss was significantly less in their VALH group, but that the mean duration of operation was much less in the VH group.[19] The study also showed that estimated blood loss was significantly less in the VALH group as compared to the VH + VVS group. We speculate that this result is largely due to the known advantages of laparoscopic techniques with regard to blood loss. However, there was no significant difference concerning the duration of total operation time among the two groups in our study. Both operations showed comparable levels of safety, with similar postoperative pain scores and the number of nights in the hospital, and a study showed that there were no differences in ICIQ-VS scores between VALH and VH + VVS groups.[19] Furthermore,

Table 1: Patients demographics and surgical data of the study population

	VALH (*n*=15)	VH+VVS (*n*=19)	*P*
Age (years)	56.26±0.57	57.84±0.56	0.06
Parity	3.0±1.25	3.5±2.71	0.88
BMI (kg/m^2)	30.39±3.463	29.65±4.506	0.603
Mean duration of total operation, min (range)	93.66 (60-135)	84.21 (15-155)	0.376
Mean pain score 24 h postoperatively, scale 1-10 (range)	4.26±1.17 (2-7)	3.47±1.57 (1-6)	0.190
Mean number of nights in hospital	2.53 (2-4)	2.05 (1-3)	0.075
Mean estimated blood loss, mL (range)	76.66 (20-250)	142 (50-250)	0.001
Concomitant urogynaecology procedures, *n* (%)			
Posterior colpoperineorrhaphy	5 (33)	11 (58)	0.160
Anterior colporrhaphy	8 (53)	16 (84)	0.53
Perineorrhaphy	5 (33)	14 (78)	0.020
Tension-free vaginal tape	0	4 (21)	0.62
Sacrospinous fixation	0	14 (74)	<0.001

BMI: Body mass index, VALH: Vaginally-assisted laparoscopic sacrohysteropexy, VH: Vaginal hysterectomy, VVS: Vaginal vault suspension

Table 2: Pelvic organ prolapse quantification and international consultation on incontinence questionnaire for vaginal symptoms scoring pre- and post-operatively and comparing the mean difference between the groups

	VALH (*n*=15)			VH+VVS (*n*=19)			*P*
	Preoperative	Postoperative 12 months	Mean difference	Preoperative	Postoperative 12 months	Mean difference	
ICIQ-VS	20.93	7.13	−13.80	22.63	4.84	−17.78	0.251
ICIQ-QOL	6.20	2.33	−3.86	7.36	1.73	−5.63	0.39
POPQ –C	2.73	−5.8	−8.53	2.42	−4.57	−7.0	0.142
TVL	9.17	8.77	−0.26	9.18	8.11	−1.07	<0.001
Ba	2.80	−0.80	−3.60	2.32	−1.57	−3.89	0.766
Bp	−1.13	−2.67	−1.50	−1.36	−2.31	−0.94	0.458
UDI-6	5.53	2.80	−2.73	6.0	3.52	−2.47	0.461
IIQ-7	4.40	1.73	−2.66	7.0	2.68	−4.31	0.24

VALH: Vaginal assisted laparoscopic sacrohysteropexy, VH: Vaginal hysterectomy, VVS: Vaginal vault suspension, ICIQ-VS: International consultation on incontinence questionnaire for vaginal symptoms, ICIQ-QOL: :International consultation on incontinence questionnaire for vaginal symptoms quality of life score, POP-Q: Pelvic organ prolapse quantification, UDI-6: Urogenital distress inventory short form, IIQ-7: Incontinence impact questionnaire short form, TVL: Total vaginal length

we reported that the 1-year data for ICIQ-VS and QOL assessments were similar between the two groups.

Uterine prolapse repair can worsen urinary incontinence and unmask urethral sphincter weakness.[20] However, previous studies show up to 40% recovery from urinary incontinence after prolapse surgery.[21] In this study, this conflict was analyzed through validated questionnaires investigating urinary symptoms. This study further showed that UDI-6 and IIQ-7 scores improved for both groups with no difference between VALH and VH + VVS groups. We also detected the coexistence of prolapse and stress incontinence in four cases, which was managed through tension-free vaginal tape surgery.

In our clinic, we avoid additional vaginal urogynecological operations as much as possible during VALH procedures because, in our experience, restoring apical prolapse support tends to also correct cystocele and rectocele. We also suppose that additional vaginal surgeries with VALH may increase morbidity and risk of vaginal dysfunction or infection. However, if additional vaginal surgery is required during patient follow-up, then we prefer to perform these operations. In a randomized controlled study comparing laparoscopic hysteropexy and VH, it was reported that the number of concomitant urogynecology surgeries were significantly higher in the VH group and at the end of the first year, significantly more repeat vaginal repairs are required posthysteropexy (10%).[19] In this study, although higher numbers of concomitant vaginal surgeries were performed in the VH + VVS group, we did not find any difference between the two groups in terms of the need for additional vaginal surgery; we attribute this to our limited number of patients.

The strengths of this study are its prospective, randomized nature, the different surgical applications for conducted questionnaires, the fact that all operations were carried out by the same surgeon, and its evaluation of life quality scores in addition to primary surgical outcomes. However, our study had some limitations as well. First, our sample size was relatively small. Second, the follow-up period is limited up to 12 months; the study needed a longer follow-up duration.

Conclusion

VALH is a safe, minimally invasive, and effective surgical alternative to VH + VVS. At 1 year, the VALH and VH + VVS groups had similar cure rates and satisfaction scores, and zero recurrence rates. However, there is a need for subsequent studies with larger study populations and longer follow-up periods. Data studies also are required as a further guide to the most efficacious mode of surgery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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