Document Date: 10.01.2020

NCT: NCT03436147

Vaginal-assisted laparoscopic sacrohysteropexy (VALH) and vaginal hysterectomy+vaginal vault suspension (VH+VVS) for advanced uterine prolapse: 12-month preliminary results of a randomized controlled study

Materials and Methods

In this study, the first-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).

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 (CONSORT) 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 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 towards to the incised opening over the sacral promontory. This step was visualized simultaneously via laparoscopy (Figure 2b). A 15x3 cm, tailored, macroporous, non-absorbable polypropylene monofilament mesh (15cm-15 cm; Ethicon, Somerville, NJ, USA) was taken into the abdomen through the 10 mm trocar. When the ring forceps reached the incision at 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 non-absorbable 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 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 less than 2 cm from the hymen after vaginal hysterectomy. 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 a 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. Vaginal hysterectomy 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 one week, one month, three months, and one year post-surgery as part of departmental procedure. Postoperative pain scores were evaluated 24 hours after surgery by a visual analog scale (VAS) score. Uterovaginal prolapse was assessed again using the International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) questionnaire and the Pelvic Organ Prolapse 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 one year after surgery with each of the patients.

The participants' prolapse symptoms, and their impacts, were evaluated both before and one year after surgical treatment. A subjective assessment of the prolapse was made using the ICIQ-VS.[10] Objective assessment of pelvic organ prolapse 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 first 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.

Statistical analysis

Data analysis was performed with SPSS (version 20.0; Chicago, IL). 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, while a Mann–Whitney U test was used for comparing other parameters not showing normal distribution. A p value of less than .05 was considered statistically significant.