ABSTRACT

Objective: Total laparoscopic radical hysterectomy (TLRH) makes it difficult to resect adequate vaginal cuff according to tumor size and to avoid tumor spread after opening the vagina. Laparoscopic-assisted radical vaginal hysterectomy (LARVH) is associated with higher risk for urologic complications.

Methods: The vaginal-assisted laparoscopic radical hysterectomy (VALRH) technique comprises 3 steps: (1) comprehensive laparoscopic staging, (2) creation of a tumor-adapted vaginal cuff, and (3) laparoscopic transection of parametria. We retrospectively analyzed data of 122 patients who underwent VALRH for early stage cervical cancer (n=110) or stage II endometrial cancer (n=12) between January 2007 and December 2009 at Charité University Berlin.

Results: All patients underwent VALRH without conversion. Mean operating time was 300 minutes, and mean blood loss was 123cc. On average, 36 lymph nodes were harvested. Intra- and postoperative complication rates were 0% and 13.1%, respectively. Resection was in sound margins in all patients. After median follow-up of 19 months, disease-free survival and overall survival for all 110 cervical cancer patients was 94% and 98%, and for the subgroup of patients (n=90) with tumors ≤pT1b1 N0 V0 L0/1 R0, 97% and 98%, respectively.

Conclusion: VALRH is a valid alternative to abdominal radical hysterectomy and LARVH in patients with early-stage cervical cancer and endometrial cancer stage II with minimal intraoperative complications and identical oncologic outcomes.
high costs. Up to now, very few oncologic results are available; therefore, RRH is still under evaluation.

In Landoni’s 1997 randomized study, oncologic equality of radical hysterectomy and primary radiation for the treatment of patients with early cervical cancer was demonstrated. Since 1999, no new study has been conducted comparing chemoradiation and surgery. Careful and individual selection of patients to one of these treatment modalities is essential to avoid increased toxicity using both therapies. Only operative staging, best done by laparoscopy, can provide exact staging of disease and can help to identify patients who profit mostly from radical hysterectomy.

According to LeBlanc’s hint, we modified LARVH into VALRH (vaginal-assisted laparoscopic radical hysterectomy), which ideally combines advantages of vaginal and laparoscopic approaches after comprehensive staging. The present article describes the technique of VALRH together with operative and early oncologic results.

**METHODS**

**Patient Characteristics**

After obtaining Institutional Review Board approval, the prospectively maintained Gynecologic Service Database was used to identify all 122 patients who underwent VALRH between January 2007 and December 2009 at the Department of Gynecology at Charité University Berlin, Campi Benjamin Franklin and Mitte. Indications for VALRH were histologically proven cervical cancer (n=110) and endometroid endometrial cancer (n=12) after curettage. One patient requested to undergo radical hysterectomy type B in case of extensive CIN III lesion not completely resected by conization (Table 1).

| Table 1. Patient Characteristics |
|---------------------------------|
| Number of women 122             |
| Age 47 (27–82)                  |
| BMI (kg/m²) 24.9 (17.3–46.3)    |
| Parity 2 (0–6)                  |
| Histology (%)                   |
| Adenocarcinoma cervix 40 (32.8) |
| Squamous cell carcinoma cervix 67 (54.9) |
| Neuro-endocrine cervical carcinoma 2 (1.7) |
| CIN III 1 (0.8)                 |
| Endometrial cancer (diagnosed by D&C) 12 (9.8) |

The following parameters were analyzed: age, BMI, operating time, blood loss, node counts, and length of hospital stay, as well as time to spontaneous voiding of urine, intra- and postoperative complications.

**Surgical Technique**

Preoperatively, each patient underwent bowel preparation. Surgery was always performed with the patient receiving perioperative antibiotics (1.5g cefuroxime and 500mg metronidazole), general endotracheal anesthesia, and thrombosis prophylaxis. All patients consented to undergo radical hysterectomy using this new technique.

The VALRH consists of 3 parts: (1) laparoscopic staging including lymphadenectomy, to evaluate nodal status, and dissection of vesicocervical and vesicovaginal septum to evaluate tumor relation to adjacent organs, (2) vaginal creation of a tumor-adapted cuff, and (3) laparoscopic radical hysterectomy.

For laparoscopic staging, the patient is placed in a deep Trendelenburg position (30°) with straight legs. After pneumoperitoneum is obtained, 5 trocars are placed: a 10-mm trocar through the umbilicus, an additional 10-mm trocar in the left medioclavicular line 2 fingers above the umbilicus, and three 5-mm trocars in the lower abdomen 2cm to 3cm below the umbilicus level bilaterally to the epigastric arteries and in the midline suprapubically. The intraabdominal pressure is maintained at 15mm Hg. After careful inspection of the abdominopelvic cavity to rule out intraabdominal spread, cytology is taken from the cul de sac. If present, adhesions are taken down.

Depending on tumor entity and FIGO stage, pelvic ± paraaortic lymphadenectomy is performed as previously described. In patients with proven cervical cancer, all removed lymph nodes are sent for frozen section. Dissection of the bladder up to the level of the ventral vaginal wall is done while waiting for frozen section results. In case of lymph node metastasis, the procedure is abandoned, and patients are referred for primary chemoradiation. Only if frozen section reveals tumor-free lymph nodes is the patient placed in a lithotomy position with extended legs for the vaginal part.

The aim of the vaginal part is to create a tumor-adapted cuff and to open vesicovaginal and rectovaginal spaces. According to tumor size, adequate length of the vagina is grasped with 6 straight clamps. A diluted solution of epinephrine-Xylocaine is injected under the vaginal mucosa for vasoconstriction followed by monopolar incision distally to the clamps. Vaginal cuff is now
closed with a continuous suture (Figure 1 B), and therefore the tumor is always covered to prevent spillage of cancer cells. With 6 serrated clamps, tension is brought on the closed vaginal cuff to open the vesicocervical and rectovaginal space as well as the cul-de-sac. The inferior part of the rectovaginal ligament is now transected bilaterally and the uterus can be pushed intra-abdominally after removal of the serrated clamps (Figure 1 C). The vaginal cuff is continuously sutured for hemostasis. Additionally, interrupted sutures are placed for later closure of the vagina (Figure 1 D). To preserve pneumoperitoneum, a wet surgical towel is placed into the vagina.

For the third part of VALRH, the patient is placed again into the Trendelenburg position with straight, slightly abducted legs. Now the parametrium is resected. As a result of the vaginal route, both bladder pillars and the starting point and end point of parametrial resection are easy to identify (Figures 2A and B). The operation starts by coagulation and transection of the uterine vessels at their origin from iliac internal vessels (Figure 2C). In case of salpingo-oophorectomy, infundibulopelvic ligaments are coagulated and cut. By pulling the vascular part of the cardinal ligament medially, the ureter is freed out of its tunnel up to the bladder entry. Now, the remaining part of the paracervix is identified, coagulated and transected under permanent visualization of the ureter. Plexus pelvics and splanchnic and hypogastric nerves are separated and preserved (Figure 3A and B). The suture of the closed vaginal cuff is easily identified and marks the endpoint of resection. The specimen is removed transvaginally, and the vagina is now closed using the preplaced interrupted sutures (Figure 4). Finally hemostasis is verified, and a suprapubic catheter and 2 drains are placed. The surgeon intraoperatively chooses, the radicality of parametrial resection in correlation to tumor size according type II (B) or III (C) radical hysterectomy. In 25 patients, parametrial resection was done with the da Vinci robotic system, in the others it was done by laparoscopy. No uterine manipulator

Figure 1. A. Creation of tumor-adapted vaginal cuff; B. Closure of the vaginal cuff with a continuous suture; C. Transsection of distal rectovaginal ligament after opening of cul-de-sac; D. Vaginal margin covered by a continuous suture. Six sutures are placed for later closure of the vagina. Uterus with closed vaginal cuff is pushed intraabdominally.
was used at any time. There are 3 gynecological oncology consultants in our unit. One of them would perform the operation with the assistance of one gynecologic fellow or resident, who took over sections of the operation, ie, opposite side of lymphadenectomy.

**Postoperative Course**

We left the suprapubic catheter in place until the patient was able to empty her bladder spontaneously with residual volume <50cc. All women received weight adapted low-molecular-weight heparin and a low-fat diet to reduce lipid concentration in the lymphatic fluid. Drains were removed if fluid was <100cc.

**Statistical Analysis**

Patient’s data, surgical outcome, and histologic results were extracted from medical charts. The postoperative follow-up was measured from the date of operation to the date of the last follow-up visit or death. Statistical analysis was performed using SPSS software (version 16.0). Overall survival (OS) and disease-free survival (DFS) were calculated according to Kaplan-Meier.

**RESULTS**

**Operative Data**

All 122 patients underwent VALRH without conversion to laparotomy. Type II (B) and type III (C) operations were performed in 82 and 40 patients, respectively. VALRH was combined with pelvic lymphadenectomy in 37, and with pelvic and paraaortic in 85 patients. Mean operating time was 300 minutes. Operation time was nearly identical for type B and C procedures. Duration of surgery differed significantly in 2 patients, one with infiltrative sigmoid endometriosis, who had to undergo simultaneously bowel resection (operating time 665 minutes) and one patient with a BMI of 46 (605 minutes). Learning curve increased over time, which can be seen in the operating times.

From 2007 to 2008, operating time decreased for VALRH Type II and III from 317 to 278 minutes and from 345 to 312 minutes, respectively. Between 2008 and 2009, operation times changed for Type II and III operations from 278 to 275 and 312 to 303. In all, operation times between 2007 and 2009 could be phased down 42 minutes for both types.
The mean number of lymph nodes harvested was 36 (range, 4 to 83) with 21 (range, 4 to 43) pelvic and 15 (range, 2 to 36) paraaortic lymph nodes. Additionally, 36 patients underwent the sentinel node harvesting prior to completion of the lymphadenectomy. One patient (cervical cancer pT1a2 N0 L0 V0 R0) refused complete pelvic lymph node dissection, and therefore only 4 sentinel lymph nodes were removed, which were tumor free on histology (Table 2).

Not a single intraoperative complication occurred, in particular, no bladder or ureter injury. Mean blood loss was 123cc (range, 10 to 400). One patient required blood transfusion due to stress-induced cardiomyopathy and 2 patients due to preoperative anemia on the demand of the anesthesiologist. Postoperative complication rate was 13.1% (Table 3). No patient required postoperative referral to a urogynecologist for postoperative bladder dysfunction, and only one patient needed >25 days to void her bladder adequately. Mean time to urine residuals <50ml was 7.9 days. Four patients had to undergo relaparoscopy, 1 due to lost drainage, 2 for suspected ileus (which could not be verified intraoperatively), and 1 for chyloperitoneum. Between 10 days and 40 days postoperative, 3 patients developed a ureterovaginal fistula, which was treated with ureteral stents without complication. Two of these patients underwent VALRH performed with the da Vinci robotic surgical system.

### Histologic Results

Parametrial and vaginal resection was in sound margins in all patients. Preoperatively, the extent of endometrial cancer to the cervical stroma was diagnosed through dilation and curettage in 12 patients but was confirmed postoperatively in only 2 patients. Cervical cancer was diagnosed preoperatively by biopsy or conization in 109 patients. One patient with extensive CIN III and R1 conization insisted on radical hysterectomy to get the highest possible oncologic safety. The majority of patients were found to have FIGO stage IB1 (75.5%). In 6 patients (5.5%), final pathology revealed parametrial involvement. Histological types were distributed as follows: squamous cell carcinoma 60.9%, adenocarcinoma 36.4%, and neuroendocrine carcinoma 1.8% (Table 4). Two patients underwent VALRH after neoadjuvant chemotherapy. In the final histopathological examination, 5/110 (4.5%) patients with cervical cancer had positive micrometastases/metastases undetected by frozen section. In 4/110 (3.6%) hysterectomy specimens, the preoperative diagnosis of negative lymphovascular space involvement (L0) had to be corrected postoperatively to L1.

### Adjuvant Therapy

Postoperative adjuvant therapy (radiation, chemotherapy, radiochemotherapy) was recommended for 30/122 patients (24.6%), 8 with endometrial cancer, and 22 with cervical cancer. Six patients with endometrial cancer stage ≥IA G2 underwent vaginal brachytherapy. One patient with endometrial cancer and a synchronous 4-cm Sertoli ovarian tumor (stage IA) received pelvic radiation. Pelvic
lymph node metastases on final histopathologic examination indicated chemoradiation in one young woman with endometrial cancer. Recommendation for adjuvant chemoradiation or chemotherapy was given for cervical cancer patients and proved high risk factors (N1, M1, stage IIB) or the combination of 2 intermediate risk factors (tumor size ≥4cm, LVSI, adenocarcinoma, G3, deep stromal invasion). In 2 of 22 patients, a neuro-endocrine tumor was found that was treated according to a multimodal protocol. In 6 and 4 patients, final histologic result revealed stage IIB or lymph node positivity and, therefore, need for adjuvant chemoradiation. Other reasons for chemoradiation were the combination of L1 and V1 in 3 patients, stage IIA and G3 in one patient, G3 and L1 in one patient, and L1 adenocarcinoma in another young patient.

Only one patient (0.9%) underwent vaginal brachytherapy based on surgical result (close margin of 5-mm vaginal). Individual procedures were performed in 2 patients: 1 patient with cervical cancer stage IB2 was treated by neoadjuvant chemotherapy and underwent postoperative chemoradiation, and another patient received brachytherapy only due to grading of 3. In one patient with ovarian metastasis, 6 cycles of platen-based chemotherapy were administered. Two patients denied recommended chemoradiation.

**Follow-up**

After a mean follow-up of 19 months (range, 4 to 40), the total recurrence rate in the entire cohort was 6.7% (8/120), for cervical cancer patients 6.4% (7/110), and for endometrial cancer 8.3% (1/12), respectively. DFS and OS for
all 110 cervical cancer patients are 93.5% and 98.1%, for the subgroup of patients (n=90) with tumors ≤pT1b1 N0 V0 L0/1 R0, 96.7% and 97.8%, respectively.

**DISCUSSION**

Radical hysterectomy is the operative standard procedure in patients with early cervical cancer, and the recommended operation in stage II endometrial cancer. Today, a broad spectrum of open,\textsuperscript{33-35} total laparoscopic,\textsuperscript{5,7-12,16,18-20,24-26} laparoscopic-assisted vaginal,\textsuperscript{1,4,6,13-15,17,22} and robotic\textsuperscript{7,11,21,26-29} techniques are described. Operative data of these different techniques are summarized in Table 5. Recently published studies comprise 7 to 400, 8 to 200, 8 to 317, and 7 to 80 patients for ARH, LARVH, TLRH, and RRH, respectively (for literature see Table 5). There are 3 main criteria to use to evaluate and compare different techniques of radical hysterectomy: (1) possibility to triage patients and therefore avoid combined use of operation and chemoradiation, (2) complication rate, and (3) oncologic outcome. Our intent was to modify previously used LARVH into VALRH to reduce a high urologic complication rate with similar oncologic results.

Operative staging including pelvic ± paraaortic lymphadenectomy is the key step to differentiate patients who benefit from radical surgery from those who are better treated by primary chemoradiation.\textsuperscript{30} TLRH, RRH, LARVH, and VALRH offer the possibility to start with lymph node dissection (± sentinel node) and frozen section. However, frozen section was not routinely used in all centers. We strictly have abandoned radical hysterectomy in cases of positive lymph nodes. However, frozen section was not accurate in 4 of 110 (3.6%) patients with cervical cancer in our series. Bader et al\textsuperscript{36} reported a false-negative rate for frozen sections of 17%.

Most published retro- or prospective studies on radical hysterectomy include cervical cancer patients with stages IA1 L1 – IIA (B) and only a few higher stages (Table 5). This was in concordance with our study population. Conversion rates are described as up to 5%, 10%, and 14% for RRH, TLRH, and LARVH, respectively. None of our planned VALRH-procedures had to be converted to the open approach. ARH, LARVH, and our new technique of VALRH are done without any manipulator to create an adequate vaginal cuff, whereas nearly all TLRH and RRH require a manipulator or sponge in the vagina. Creation of a vaginal cuff by the transvaginal approach seems to be easier and avoids any tumor distribution due to manipulator use. With the described technique of VALRH, we were able to resect tumor always in sound vaginal margins in contrast to some studies of ARH, TLRH, and RRH where up to 20% of positive vaginal margins are reported had to be considered (Table 5).

Blood loss in our study was low compared to that in ARH and LARVH and in the lower range of TLRH and RRH. Therefore, transfusion was given to only 3 patients, where it had not been caused by intraoperative blood loss. Operation time of 300 minutes in our cohort is longer than the average time for ARH, TLRH, and RRH (Table 5). However, one must consider that 85 of 122 (69%) of our patients also underwent paraaortic lymph node dissection with a duration of approximately 60 minutes. The majority of radical hysterectomies reported in the literature are combined with pelvic lymph node dissection exclusively. Subsequently, the mean number of harvested lymph nodes (n=36) in our cohort is in the upper range of all described studies and often higher than in open surgery (Table 5).

**Table 5.** Literature Review and Comparison of Different Techniques of Radical Hysterectomy

| Technique | Stages | Blood loss (cc) | Transfusion (%) | Non in sano (R1)-resection (%) | OR-time (minutes) | Intra-operative complications (%) | Lymph node number | Postoperative complications (%) | Conversion rate (%) |
|-----------|--------|----------------|----------------|-----------------|----------------|------------------------|-----------------|--------------------------|-----------------|
| TLRH      | IA1 L1-IIIB\textsuperscript{12,25} | IA1 L1-III\textsuperscript{15,33} | 55–400\textsuperscript{18} | 1–23\textsuperscript{23,24} | 0–17.7\textsuperscript{25} | 92–371\textsuperscript{10,25} | 0–11.8\textsuperscript{18} | 10–34\textsuperscript{16} | 5.1–40\textsuperscript{5,9} | 0–10.24 |
| ARH       | IA1-L1-III\textsuperscript{15,33} | 221–2000\textsuperscript{1,2,26} | 8 [gtl] 50\textsuperscript{20,3} | 1.4–21.4\textsuperscript{7,35} | 4–12.5\textsuperscript{7,9} | 95–391\textsuperscript{35} | 4–12.5\textsuperscript{6,35} | 12–46\textsuperscript{6,35} | 4.7–40\textsuperscript{5,9} | 0 |
| VALRH     | — | — | — | 4.7–40\textsuperscript{5,9} | 4.7–40\textsuperscript{5,9} | 4.7–40\textsuperscript{5,9} | 4.7–40\textsuperscript{5,9} | 4.7–40\textsuperscript{5,9} | 4.7–40\textsuperscript{5,9} | 0 |
| RRH       | VALRH Own Data | — | — | — | — | — | — | — | — | — |

| Technique | — | Conversion rate (%) | — | — | — | — | — | — | — |
|-----------|--------|-----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| VALRH     | VALRH Own Data | — | — | — | — | — | — | — | — |
| IA1 L1-IIA | — | — | — | — | — | — | — | — | — |
| 123       | 50–300\textsuperscript{26,29} | 272–666\textsuperscript{13,22} | 0–7.5\textsuperscript{21} | 7 [gtl] 50\textsuperscript{14,15} | 0–15.6\textsuperscript{7,27} | 129–434\textsuperscript{28,29} | 0–14\textsuperscript{26} | 13–32\textsuperscript{7,26} | 3%–59%\textsuperscript{7,29} | 0–14%\textsuperscript{4,22} |
| 0.2 Surgical-related (0%) | — | — | — | — | — | — | — | — | — |
| 300       | — | — | — | — | — | — | — | — | — |
| 0         | — | — | — | — | — | — | — | — | — |
| 13.1      | — | — | — | — | — | — | — | — | — |
| 0         | — | — | — | — | — | — | — | — | — |
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Intraoperative complications were observed in 4% to 12.5%, 0% to 11.8%, 5.9% to 13.2%, and 0% to 14% in ARH, TLRH, LARVH, and RRH, respectively. Interestingly, there was not one intraoperative complication in our study. Also, the postoperative complication rate in our study (13.1%) is in the lower range of published data (Table 5). In particular, urologic intra- and postoperative complications are significantly lower compared to those in LARVH1 or TLRH. Because 2 of 3 ureterovaginal fistulae in our series are associated with the use of the da Vinci, we believe that this reflects the fact that we did not pass the learning curve completely with our robotic skills. A frequent reported postoperative complication of RRH, vaginal dehiscence, which is described in 3.1% to 21%, occurred partially in only 1 of our patients (0.8%) and was treated conservatively.

Adjuvant therapy was recommended to 24.6% of all our patients. After exclusion of 8 patients with endometrial cancer, 2 patients with neuroendocrine cervical tumors (multimodal therapy), and 4 undetected lymph node metastases, the rate of adjuvant therapy decreased to 12.7%. This percentage is in our opinion an acceptable range with the philosophy of avoiding combined treatment of radical hysterectomy and chemoradiation, compared with other studies where adjuvant therapy was performed in 30% up to 63% of patients.4,6,7,29

Oncologic data are difficult to compare, because of different follow-up intervals and various oncologic cornerstones. Summarizing data from open, laparoscopic, laparoscopic-vaginal, and robotic series, recurrence rates vary between 0% and 13%, DFS between 82% and 100%, and OS between 89% and 100%. Despite a relatively short follow-up of 19 months, our DFS rate of 94% and OS rate of 98% is promising. However, longer follow-up is mandatory to confirm these data.

CONCLUSION

Our new technique of VALRH is an oncologically valid alternative to ARH, LARVH, TLRH, and RRH in patients with cervical cancer <1B2 and endometrial cancer stage II with low blood loss and a minimal intraoperative complication rate. During the vaginal part of the operation, it is always possible to create an adequate vaginal cuff and therefore to avoid tumor spillage and disregard the use of any manipulators. Further studies comparing this new technique with other types of radical hysterectomies are necessary to underline the promising results of our single-institutional series.

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