

Laparoscopically-assisted radical vaginal hysterectomy with five years follow-up: a case control study

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Summary

Objective: To compare a novel surgical approach, laparoscopically-assisted radical vaginal hysterectomy (LARVH) with abdominal radical hysterectomy in women with cervical cancer, and to investigate whether selected women benefit from the minimally-invasive approach without high recurrence rate and complications. **Materials and Methods:** Forty women undergoing LARVH were included and compared with 40 women undergoing abdominal radical hysterectomy. The control group was matched for age and disease stage. Retrospective chart review was performed and patients were followed for an average of 2.5 years. **Results:** Blood loss was significantly increased in the control group (343.3 vs 606.3 ml, $p = 0.012$). Transfusions were given in 42.5% of women in the control group and 17.5% in the LARVH group. Mean operative time was longer in the control group (151 vs 240 minutes $p = 0.0001$). Mean nodal counts did not show a significant difference (27.3 in control vs 21.4 in LARVH, $p = 0.886$). Recurrence group was 7.5% at mean follow up of 30.1 months in LARVH group and in 30.8 months follow-up. **Conclusions:** The LARVH procedure was comparable in terms of safety (recurrence and complication rates) meanwhile LARVH showed minimally-invasive advantages in terms of blood loss, operative time, and shorter hospital stay.

Key words: Cervical carcinoma; Laparoscopic surgery; LARVH.

Introduction

The technical feasibility of laparoscopically-assisted radical vaginal hysterectomy (LARVH) as treatment for early-stage cervical cancer has been well-established through a series of retrospective reports [1-5]. These reports suggest that LARVH may have an intraoperative reduction in blood loss, transfusion requirement, and hospital stay, but surgical time may be prolonged. Furthermore, a growing evidence-based study indicates that adequate lymphadenectomy can be achieved laparoscopically. Indeed the inherent advantages of laparoscopic surgery, improved visualization of tissues, and magnification may improve accuracy of disease staging and lymphadenectomy [6, 7].

Laparoscopic management of cervical carcinoma was advocated by some authors as an alternative to open radical hysterectomy and pelvic node dissection. A number of case-control studies supported the hypothesis that preoperative morbidity, blood transfusion, and hospital stay can be reduced without compromising outcomes [8-10]. Pelvic lymphadenectomy, as an integral part of surgical management of cervical carcinoma, could be possibly achieved by laparoscopic approach.

This study aims to evaluate LARVH in terms of preoperative and postoperative complications, outcome (mortality and recurrence rates), and consumption of medical resources (hospital stay, operative duration). These parameters were compared with the standard open radical hysterectomy.

Materials and Methods

Between December 2003 and December 2008, 40 patients with cervical carcinoma of International Federation of Gynecology and Obstetrics (FIGO) Stage IA to IIA. The control group consisted of 40 open procedures, matched for age, stage of disease, and magnetic resonance imaging (MRI) outcomes, in the regional cancer center. This study was conducted in accordance with the declaration of Helsinki. This study was also conducted with approval from the Ethics Committee of Tumor Hospital of WuXi City affiliated to Soochow University. Written informed consent was obtained from all participants. All women in both groups underwent preoperative pelvic MRI scans and computed tomography (CT) scans. Results from two groups were compared for matching age and disease stage before operated by the same team over the same time period.

Date were collected retrospectively from the charts as follows: age, clinical stage, histopathological stage, blood loss, conservation of ovaries, duration of surgery, nodal counts, number of nodes involved, intraoperative complications, postoperative complications, hospitalization days, and recurrence of disease.

LARVH is performed through four-port laparoscopy with ligation of pedicles. Excision of the uterus, fallopian tubes, and ovaries was conducted when indicated and excision of parametria was carried out laparoscopically, with formation of vaginal cuff and extraction of specimen completed vaginally. Laparoscopic dissection of the ureteric tunnels and removal of pelvic node was performed within the same anatomical margins in the open procedure. Postoperative hospital stay was recorded.

Results were analyzed using SPSS software. Age, blood loss, hospital stay, duration of surgery, and node counts were compared with the two-tailed t-test.

Results

From December 2003 until December 2008, 40 LARVHs were carried out for cervical carcinoma. All procedures were included in the study, including two cases converted to laparotomy due to ureteric injury and

bladder injury, which gave a conversion rate of five percent. Results of these two cases were included within the laparoscopic group. Over the same time period, 40 open radical hysterectomies with pelvic node dissection were identified and matched for age, clinical FIGO Stage, and histological results (Table 1).

Significant differences were found including the following: mean blood loss was significantly reduced in the LARVH group ($p = 0.012$) at 343.3 ml compared with 606.3 ml in the open group (Table 2). Seventeen women received blood transfusion in the open group, while seven women in LARVH group required blood transfusion, two of whom were converted to laparotomy. Duration of surgery differed significantly between the two groups (240 min in LARVH and 151 min in the open group, $p = 0.0001$). Postoperative stay was significantly longer in the open group, with a mean of 11.0 days (range 7-25) compared with 7.2 days (range 5-12) in LARVH ($p < 0.001$). No significant difference was found when comparing age, preoperative hemoglobin, and node counts. No women in the LARVH group had positive nodes, with five women in the open group having positive nodes (Table 2).

Recurrence rates were equal, with three recurrences in each group. Mean follow-up in the LARVH group was 30.8 months (range 6-60). Recurrence was found to be located in vault and pelvic sidewall in two patients with preoperative Stage IB in LARVH group. The other women developed lung metastases at 28 months follow-up postoperatively and was managed with chemoradiation and adjuvant radiotherapy, but died 40 months postoperatively (Table 3).

Discussion

This study lacked the power to prove that LARVH procedure was comparable to open radical hysterectomy in terms of complications and clinical outcomes, but provides further data to support LARVH. This procedure was not conducted in a randomized manner, which weakened the evidence power. The FIGO Stage in the LARVH group was not matched with that in the control group, which presented a lower Stage and might impact final outcomes. However, this is inevitable when learning a new complex technique. Mean follow up in this study was 30.8 months (range 6-60) in the LARVH group and 30.8 months (range 6-60) in the open group. Three recurrences resulted in each group (7.5%). Sites of recurrence were vault and pelvic sidewall in two women in LARVH group, one of which had a squamous cell tumor staged as pT1b1 histopathologically, with clean margins and no adjuvant treatment. Suspicious signs of recurrence were discovered by clinical examination 20 months postoperatively, which was confirmed by MRI, arising from right pelvic sidewall. The patient underwent chemoradiation and received surgery for resection of residual disease. The second recurrence case in the LARVH group was in a woman with adenocarcinoma pT1b1N0 who received adjuvant chemoradiation, and pulmonary metastatic disease was detected 28 months postoperatively on CT scan

Table 1. — Age, clinical FIGO Stage, and histological results.

	Open	LARVH
Median age years (range)	39.1 (28-57)	44.9 (30-61)
Stage I A2	6	12
Stage I B1	15	17
Stage I B2	13	9
Stage II A	6	2
Squamous	27	28
Adenocarcinoma	13	12

Table 2. — Comparison of hemoglobin, nodal counts, operative time, and hospital stay.

	Open	LARVH	<i>p</i> value
Blood loss (ml)	606.3	343.3	0.012
Mean operating time (minutes)	151	240	0.0001
Mean nodes retrieved (range)	27.3 (19-32)	21.4 (18-28)	0.886
Number of women with positive nodes	5	0	na*
Mean hospital stay	11.0	7.2	0.001

* na: not applicable.

Table 3. — Comparison of complications.

Complications	Open (n = 40)	LARVH (n = 40)
Pyrexia (requiring antibiotic therapy)	10	7
Bladder dysfunction (requiring ISC post-discharge)	8	7
Bowel dysfunction	2	0
Wound infection	2	0
Blood transfusion	17	7
Lymphoedema	9	1
Fistula formation	0	2
Bladder injury	0	1
Total	44	24

and treated surgically. The third recurrence in the LARVH group was adenocarcinoma staged as pT1b1N0 histopathologically, whose margins were clean and no adjuvant treatment was adopted. Suspicious signs of recurrence were discovered by clinical examination 30 months postoperatively, which was confirmed by MRI, arising from right pelvic sidewall, who underwent chemoradiation and resection of residual disease.

In the open group, there were three recurrences. One woman resulting in death had an adenocarcinoma staged as pT1b1 histopathologically with positive lymphovascular invasion but negative nodes and received adjuvant chemoradiation. Relapse was detected by clinical examination 16 months postoperatively. MRI revealed a four-cm lesion between bladder and rectum. She received further chemoradiation but died 26 months following detection of relapse. The second recurrence in the open group was adenocarcinoma pT1b1N0 with lymphovascular invasion, who received adjuvant radiotherapy. Recurrence was detected by clinical examination 17 months postoperatively. MRI demonstrated bilateral sidewall masses and right hydronephrosis. She received chemoradiation and adjuvant radiotherapy. Suspicious signs of recurrence

were discovered by clinical examination 30 months post-operatively, which was confirmed by MRI, arising from right pelvic sidewall. She underwent chemoradiation and surgical resection of residual disease.

As expected, morbidity of wound complications in the open group was high and two (5%) required antibiotic therapy. Bowel dysfunction requiring laxative treatment occurred in two women who had open surgery, while none occurred in the laparoscopic group. Bladder morbidity, as measured by the necessity for intermittent self-catheterization (ISC) at post-discharge, was equal in the two groups, and temporary for all women. It has been suggested that an inherently less radical parametric dissection in LARVH results in less bladder morbidity [2], but was not found in this study. Unsafe margins requiring adjuvant radiotherapy were reported in one woman in LARVH group and two women in open group. This indicates that the operative approach did not affect radical dissection in these women. One uretero-vaginal fistula was managed successfully by stenting of the affected ureter, which was the only ureteric complication. Reported rates for ureteric fistula in the literature range from one to three percent intraoperatively [11, 12] and relative ureteric injury rates were 0%-3.5% [12]. The incidence of which is up to 10% in published series [2], which was not compared with this study, as no cystotomies were performed. Complications in women in LARVH group were distributed throughout the series with no discernible pattern, suggesting that earlier cases had higher morbidity. Analyzing operative time across the series shows no downward trend and node counts in women in LARVH group show no correlation with increasing experience. It is possible that with greater numbers, a discernible improvement in surgical time and complication rate would occur, as in the prospective study of 200 women by Hertel *et al.* [1].

There are some women, for whom open surgery is more suitable. As observed by Roy *et al.* [10], a relatively new group of women, who wish to preserve fertility, benefited from the techniques of LARVH. Demand for this operation is likely to grow in the future, as published data re-confirm favorable obstetric outcomes and efficacy [13-15]. LARVH was applicable to radical trachelectomy with skills developed in surgeons, which may even be used for the management of two endometrial carcinoma stages. Published series imply that LARVH may be a valid alternative in endometrial carcinoma [16, 17], especially in obese women with co-morbidities. Tozzi *et al.* [18] found morbidity following LARVH decreased compared with open radical hysterectomy in women with BMI greater than 30, diabetics, hypertensives, and those with cardiorespiratory failure. They proposed that LARVH could be used for treatment of choice for all such women with endometrial carcinoma, a disease with significantly greater incidence than cervical carcinoma. This perhaps represents a paradigm shift for anesthetists as well as gynecologists.

This study provides further data to suggest that LARVH is a safe and alternative approach of open radical hysterectomy, by reducing operative complications without comprising the recurrence rate.

References

- [1] Hertel H., Kohler C., Michels W., Possover M., Tozzi R., Schneider A.: "Laparoscopic-assisted radical vaginal hysterectomy (LARVH): prospective evaluation of 200 patients with cervical cancer". *Gynecol. Oncol.*, 2003, 90, 505.
- [2] Jackson K.S., Das N., Naik R., Lopes A.D., Godfrey K.A., Hatem M.H., Monaghan J.M.: "Laparoscopically assisted radical vaginal hysterectomy vs radical abdominal hysterectomy for cervical cancer: a match controlled study". *Gynecol. Oncol.*, 2004, 95, 655.
- [3] Steed H., Rosen B., Murphy J., Laframboise S., De Petrillo D., Covens A.: "A comparison of laparoscopic-assisted radical vaginal hysterectomy and radical abdominal hysterectomy in the treatment of cervical cancer". *Gynecol. Oncol.*, 2004, 93, 588.
- [4] Morgan D.J., Hunter D.C., McCracken G., McClelland H.R., Price J.H., Dobbs S.P.: "Is laparoscopically assisted radical vaginal hysterectomy for cervical carcinoma safe? A case control study with follow up". *BJOG*, 2007, 114, 537.
- [5] Pomel C., Atallah D., Le Boueded G., Rouzier R., Morice P., Castaigne D., Dauplat J.: "Laparoscopic radical hysterectomy for invasive cervical cancer: 8-year experience of a pilot study". *Gynecol. Oncol.*, 2003, 91, 534.
- [6] Nezhat F., Yadav J., Rahaman J., Gretz H., Gardener G.J., Cohen C.J.: "Laparoscopic lymphadenectomy for gynecologic malignancies using ultrasonically activated shears: analysis of first 100 cases". *Gynecol. Oncol.*, 2005, 97, 813.
- [7] Querleu D.: "Laparoscopically assisted radical vaginal hysterectomy". *Gynecol. Oncol.*, 1993, 51, 248.
- [8] Sardi J., Vidaurreta J., Bermudez A., di Paola G.: "Laparoscopically assisted Schauta operation: learning experience at the gynecologic oncology unit" Buenos Aires University Hospital. *Gynecol. Oncol.*, 1999, 75, 361.
- [9] Hertel H., Kohler C., Michels W., Possover M., Tozzi R., Schneider A.: "Laparoscopic-assisted radical vaginal hysterectomy (LARVH): prospective evaluation of 200 patients with cervical cancer". *Gynecol. Oncol.*, 2003, 90, 505.
- [10] Roy M., Plante M., Renaud M.C., Tetu B.: "Vaginal radical hysterectomy versus abdominal radical hysterectomy in the treatment of early-stage cervical cancer". *Gynecol. Oncol.*, 1996, 62, 336.
- [11] Spiritos N.M., Eisenkop S.M., Schlaerth J.B., Ballon S.C.: "Laparoscopic radical hysterectomy (type III) with aortic and pelvic lymphadenectomy in patients with stage I cervical cancer: surgical morbidity and intermediate follow up". *Am. J. Obstet. Gynecol.*, 2002, 187, 340.
- [12] Steed H., Rosen B., Murphy J., Laframboise S., De Petrillo D., Covens A.: "A comparison of laparoscopic-assisted radical vaginal hysterectomy in the treatment of cervical carcinoma". *Gynecol. Oncol.*, 2004, 93, 588.
- [13] Plante M., Renaud M.C., Hoskins I.A., Roy M.: "Vaginal radical trachelectomy: a valuable fertility preserving option in the management of early stage cervical cancer. A series of 50 pregnancies and review of the literature". *Gynecol. Oncol.*, 2005, 98, 3.
- [14] Plante M., Renaud M.C., Roy M.: "Radical vaginal trachelectomy: a fertility preserving option for young women with early stage cervical cancer". *Gynecol. Oncol.*, 2005, 99, 143.
- [15] Boss E.A., van Golde R.J., Beerendonk C.C., Massuger L.F.: "Pregnancy after radical trachelectomy: a real option?". *Gynecol. Oncol.*, 2005, 99, 152.
- [16] Eltabbakh G., Shamonki M.I., Moody J.M., Garafeno L.L.: "Laparoscopy as the primary modality for the treatment of women with endometrial carcinoma". *Cancer*, 2001, 91, 378.
- [17] Zapico A., Fuentes P., Grassa A., Arnanz F., Otazua J., Cortes-Prieto J.: "Laparoscopic-assisted vaginal hysterectomy versus abdominal hysterectomy in Stages I and II endometrial cancer: Operating data, follow-up and survival". *Gynecol. Oncol.*, 2005, 98, 222.
- [18] Tozzi R., Malur S., Kochler C., Schneider A.: "Analysis of morbidity in patients with endometrial cancer: is there a commitment to offer laparoscopy?" *Gynecol. Oncol.*, 2005, 97, 4.

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