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Cavitron Ultrasonic Surgical Aspirator in Laparoscopic Nerve-Sparing Radical Hysterectomy

A Pilot Study

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Objective: Pelvic autonomic nerve preservation during radical hysterectomy for cervical cancer has become a priority in recent years. This pilot study was undertaken to evaluate laparoscopic nerve-sparing radical hysterectomy (L-NSRH) using the Cavitron Ultrasonic Surgical Aspirator (CUSA) in women with cervical cancer.

Methods: Patients with stage IB1 or IIA1 cervical cancer underwent L-NSRH with pelvic lymphadenectomy. The patients were randomly assigned to receive L-NSRH using a CUSA (CUSA group; n = 24) or using other techniques (non-CUSA group; n = 21). Recovery of bladder function (indwelling catheter time and time to spontaneous voiding) blood loss, duration of hospital stay, lymph node harvesting, and postoperative complications were compared between the 2 groups. Patients were followed for up to 3 years to determine the maintenance of effect.

Results: All patients underwent L-NSRH successfully. Intraoperative blood loss was significantly less in the CUSA than in the non-CUSA group ($P = 0.005$). Length of hospital stay ($P = 0.006$) and indwelling catheter time ($P = 0.008$) were both significantly reduced in the CUSA group compared with that in the non-CUSA group. The spontaneous voiding rate 10 days postoperatively was 95.8% with CUSA and 85.7% with non-CUSA techniques. Two patients developed postoperative complications in the CUSA group as did 3 patients in the non-CUSA group. These were cases of lymphocyst formation or urinary tract infection.

Conclusions: Laparoscopic nerve-sparing radical hysterectomy using CUSA was safe and feasible in patients with cervical cancer. Our results provide initial evidence that L-NSRH using CUSA preserves pelvic autonomic nerve function.

Key Words: Cavitron ultrasonic surgical aspirator, Nerve sparing, Laparoscopy, Cervical cancer

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Cervical cancer remains the second most common malignancy and the second most common cause of cancer-related death in women worldwide.¹

Piver III radical hysterectomy is the standard surgery for the treatment of stage IB1 or IIA1 cervical cancer. During this procedure, the hypogastric nerve is often sacrificed as conventional surgical resection involves large areas of excision. This form of conventional radical hysterectomy damages pelvic autonomic nerves and may lead to impaired bladder function, defecation problems, and sexual dysfunction.^{2–4}

Ralph and colleagues⁵ report that rates of bladder dysfunction postsurgery are highly variable, and other workers suggest that incidence rates may be as high as 60%.⁶ In a study conducted by Ralph and colleagues, all patients developed

small, spastic bladders, and 68% had residual urine 14 days postoperatively. One year after the procedure, 17.5% of patients had bladder trabeculation, 62.5% had abnormal compliance, and 85% used abdominal straining to void. Some patients required an indwelling catheter, which severely affected quality of life.⁵

Pelvic autonomic nerve preservation radical hysterectomy is a new surgical approach that reduces the postoperative complications of radical hysterectomy such as bladder, rectum, and sexual dysfunction. Japanese gynecologists published the first English-language article for this procedure in the 1980s.⁷ Newer techniques of nerve-sparing radical hysterectomy have been shown to reduce postoperative bladder dysfunction.^{8–10}

One approach under investigation to improve postoperative bladder and rectum function while sparing the sympathetic hypogastric nerve is use of the Cavitron Ultrasonic Surgical Aspirator (CUSA).

Cavitron Ultrasonic Surgical Aspirator is a multifunctional instrument that is used to perform ultrasonic cavitation, stanching, debridement, and liposuction. The CUSA system absorbs cells with high water content (such as adipose tissue) and protects tissues with a high collagen content that have good elasticity. In this way, damage to healthy surrounding tissues is minimized. The system is currently used for liver and spleen resection, transplantation, and neurological surgery.¹¹

Studies evaluating use of the CUSA in laparoscopic pelvic autonomic nerve-sparing radical hysterectomy indicate that the technique preserves the hypogastric nerve, which may be beneficial to the postoperative recovery of bladder function and bowel function. However, CUSA is rarely used for laparoscopic pelvic autonomic nerve-sparing radical hysterectomy in China.

The objective of this study was to compare the outcomes in Chinese patients with cervical cancer undergoing laparoscopic nerve-sparing radical hysterectomy (L-NSRH) with or without CUSA.

MATERIALS AND METHODS

Patients

All patients provided consent to participate in the trial after the study procedures as well as possible benefits and/or risks was explained to them in lay language. Participation was voluntary, and subjects were allowed to drop out at any given time. The study was reviewed and approved by the local ethics committee.

This open label randomized study included patients with International Federation of Gynecology and Obstetrics¹² stage IB1 or IIA1 cervical cancer with systemic pelvic lymph nodes who were assessed for laparoscopic nerve-sparing radical hysterectomy (L-NSRH) at the Second Hospital of Shanxi Medical University between June 2011 to June 2013.

Patients were excluded from the study if they had received radiotherapy or chemotherapy before surgery. None of the patients had a history of chronic diseases of urinary system or intestinal tract before surgery and none had bowel or bladder dysfunction. Patients with complications likely to affect surgery were also excluded.

Women with serious pelvic adhesions and those with heart conditions that contraindicated laparoscopic surgery were referred for laparotomy.

Cases where laparoscopic surgery was not nerve sparing because there was a close relationship between the tumors and surrounding nerves were excluded from the outcome evaluation.

In this prospective study, sample size was calculated as described below, based on our previous experience. In the non-CUSA group, postoperative indwelling catheter time is generally 9 ± 2 days. Assuming a lost to follow-up of 10% or less, we considered $\alpha = 0.05$ and $\beta = 0.20$ in a unilateral design, and found at least 22 cases would achieve the desired statistical strength. Patients were randomized at a ratio of 1:1 and assigned to the CUSA group and non-CUSA group, respectively.

Surgical Procedure

The patients were divided into 2 groups using a random number table. The laparoscopic nerve-sparing radical hysterectomy with pelvic lymphadenectomy was performed in 2 groups with or without the CUSA system. In all patients, the objective of the operation was to achieve Piver III radical hysterectomy surgery resection range.¹³

The first step of the procedure was lymph node dissection. The CUSA system (SonoSurg USU; Olympus) was used to grind, emulsify, and absorb the adipose tissue surrounding lymph nodes. It was then used to isolate all associated structures (and expose the nerves and major blood vessels). The procedure facilitated identification and preservation of the hypogastric nerve, the inferior hypogastric plexus (pelvic plexus), and the bladder branch.

Surgery was undertaken by the same physicians (2 senior surgeons, 2 associate senior surgeons, and 2 attending physicians) throughout the study.

Bladder Function

All patients received an indwelling Foley catheter (latex double lumen catheter, FR14; Suzhou Weikang Medical Instrument Co, Ltd, China) for 7 days. Postoperative indwelling catheter time was used to assess bladder function. After the catheter was removed, the onset of spontaneous voiding was recorded, and the postvoiding residual volume (PVR) was assessed. The catheter was inserted again if self-voiding did not occur or PVR was greater than 100 mL. Bladder function was considered normalized when patients urinated to their satisfaction, reported spontaneous voiding, and had a PVR less than 100 mL.

Postvoid residual urine volume in the sonolucent area of the bladder was measured by ultrasound. Postvoiding residual volume (milliliter) was assessed as length (millimeter) \times width (millimeter) \times thickness (millimeter)/2000.

Intraoperative and Postoperative Assessment

Operation time was assessed from the time of the first incision to the time of completing the final sutures.

Estimated blood loss was calculated as the difference between the weight of the wet blood-soaked gauze (gram) and the weight of wet gauze (gram)/1.050 + volume in the

aspiration bottle (liquid volume in the bottle minus volume of normal saline used during surgery in millimeter).

Other assessments included the number of harvested lymph nodes, evacuation time, and incidence of postoperative complications.

Follow-up

Patients were followed-up postoperatively every 3 months for 2 years, every 6 months for 1 year, and then once a year. Each follow-up visit included assessments to determine patient voiding after discharge, measure residual urine, and determine the recovery of bladder void function. The follow-up visit also included a physical and pelvic examination, vaginal cytology, ultrasound examination, chest x-ray, and squamous cell carcinoma antigen detection to determine the presence or absence of tumor recurrence and metastasis.

Statistical Analysis

Statistical analysis was performed using SPSS (version 13.0) software (IBM). The quantitative data were presented as mean (SD). The numeric data were presented as rate or ratio. Student *t* tests were used to compare the means in the 2 groups. The differences between proportions were compared with the χ^2 test. Values of *P* < 0.05 were considered statistically significant.

RESULTS

Study Population

A total of 54 patients were screened, and 48 patients were included in the study. Of the 24 patients randomized to CUSA, 24 patients received L-NSRH. Two of the 24 patients randomized

to the non-CUSA required laparotomy. Another subject had a close relationship between the tumor and surrounding nerve tissue. The remaining 21 patients in this group received L-NSRH and were included in the outcome evaluation (Fig. 1).

The patients' demographic characteristics are listed in Table 1. The mean (SD) age in the CUSA group was 48.21 (10.28) years, and the mean (SD) body mass index (BMI) was 24.50 (3.30) kg/m². The mean (SD) age in the non-CUSA group was 48.33 (8.12) years, and the mean (SD) BMI was 23.92 (2.75) kg/m². There were no significant differences detected between the 2 groups in terms of age, BMI, menopausal status, International Federation of Gynecology and Obstetrics stage, or histological type (*P* > 0.05).

Surgical Outcomes

All patients underwent L-NSRH successfully. The mean (SD) operation was 148.04 (18.26) minutes in the CUSA group and 158.1 (22.24) minutes in the non-CUSA group (Table 2). The mean (SD) intraoperative blood loss for was 114.17 (35.25) mL in the CUSA group and 151.43 (49.63) mL in the non-CUSA group. There were no cases of recurrence or metastasis.

The mean (SD) number of lymph nodes was 23.54 (4.41) in the CUSA group and 23.00 (4.68) in the non-CUSA group.

There were no significant differences between the 2 groups in terms of operation time (*P* = 0.103) or the numbers of harvested intraoperative lymph nodes (*P* = 0.692); however, intraoperative blood loss (*P* = 0.005) and length of hospital stay (*P* = 0.006) were both significantly shorter in the CUSA group than in the non-CUSA group (Table 2).

Twenty-three patients (95.83%) in the CUSA group were voiding spontaneously with a PVR less than 100 mL within

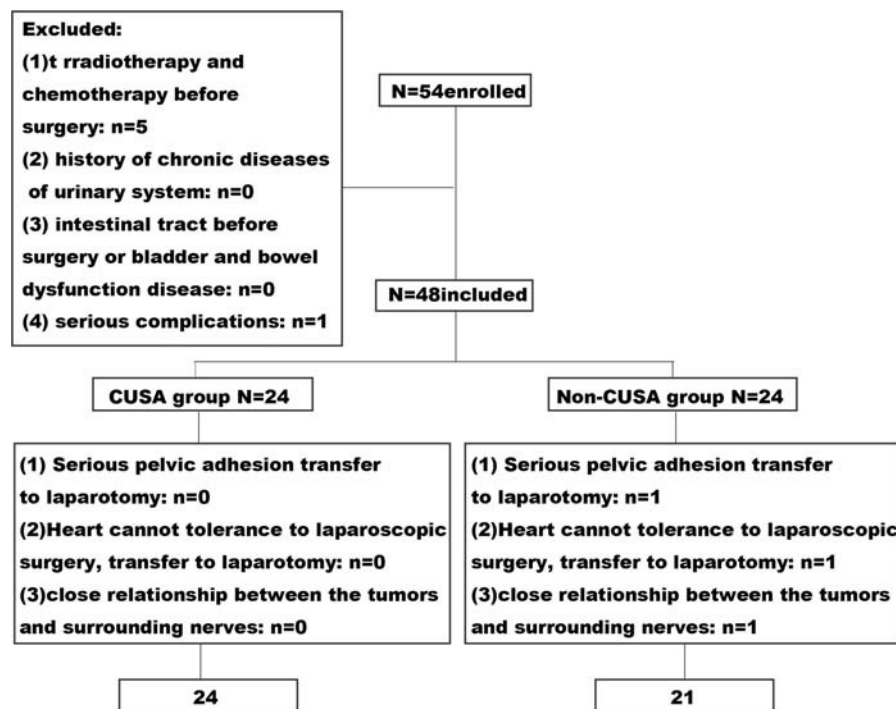


FIGURE 1. Flow chart.

TABLE 1. Patients' demographic characteristics of 2 groups

	CUSA (n = 24)	Non-CUSA (n = 21)	P
Age, mean (SD), y	48.21 (10.28)	48.33 (8.12)	0.964
BMI, mean (SD), kg/m ²	24.50 (3.30)	23.92 (2.75)	0.531
Postmenopausal, n (%)	7 (29.17)	7 (33.33)	0.507
Disease characteristics			
Histotype, n (%)			
Squamous	24	21	
Adenocarcinoma	0	0	
Grade, n (%)			0.467
1–2	19 (79.16)	14 (66.67)	
3–5	5 (20.83)	7 (33.33)	
Stage, n (%)			0.565
Stage IB	21	19	
Stage IIA, <4 cm	3	2	
HPV positive, n (%)	21 (87.5)	18 (85.71)	0.6
Parameters of radicality			
Parametrial width, mean (SD), cm	3.56 (0.26)	3.60 (0.25)	0.58
No. nodes yielded, mean (range)	23.54 (4.41)	23 (4.68)	0.692
Vaginal cuff length, mean (SD), cm	3.57 (0.21)	3.65 (0.23)	0.221
Follow-up, mean (range), mo	19.67 (4.77)	16.86 (4.76)	0.966

10 days after surgery. The other patient recovered their ability to void spontaneously within after 14 days. In the non-CUSA group, 18 patients (85.71%) were voiding spontaneously after 10 days and 3 after 14 days.

Postoperative indwelling catheter time was significantly shorter in the CUSA group compared with that in the non-CUSA group ($P = 0.008$; Table 2). No significant difference was detected between the 2 groups in terms of the postoperative evacuation time ($P = 0.871$).

There were no cases of damage to blood vessels or important organs during the procedure. All patients had negative surgical margins. Lymph node positivity was apparent in 1 patient in the CUSA group and in 2 patients in the non-CUSA group.

As shown in Table 2, 5 (20.83%) and 4 (19.05%) cases in CUSA and non-CUSA groups, respectively, received postoperative adjuvant radiotherapy, indicating a nonstatistically significant difference ($P = 0.590$). Pelvic external irradiation concurrently with chemotherapy was used in all these cases.

Follow-up

All patients were followed up. The median follow-up time was 23 months (range, 11–28 months).

Two patients developed postoperative complications in the CUSA group (a lymphocyst and a urinary tract infection), and 3 patients developed complications in the non-CUSA group (1 lymphocyst and 2 cases of urinary tract infections).

TABLE 2. Outcomes between 2 groups

	CUSA (n = 24)	Non-CUSA (n = 21)	P
Postsurgical outcomes			
Postoperative indwelling catheter time, mean (SD), d	7.13 (0.61)	9.00 (3.24)	0.008*
Postoperative evacuation time, mean (SD), d	2.44 (0.51)	2.47 (0.52)	0.871
Adjuvant radiotherapy (with or without chemotherapy), n (%)	5 (20.83)	4 (19.05)	0.590
Postoperative complications, n (%)	2 (8.30)	3 (14.28)	0.435
Surgery-related outcomes			
Operative time, mean (SD), min	148.04 (18.26)	158.1 (22.24)	0.103
Estimated blood loss, mean (SD), mL	114.17 (35.25)	151.43 (49.63)	0.005*
Hospital stay after surgery, mean (SD), d	6.92 (1.56)	8.67 (2.46)	0.006*

Indicates there was a significant difference between the CUSA group and the non-CUSA group.

DISCUSSION

Nerve-sparing laparoscopic techniques including laparoscopic radical hysterectomy (L-RH) have been shown to achieve similar results to open surgery, and its feasibility and safety have been widely recognized.^{14–16} A meta-analysis of 20 individual studies concluded that NSRH was associated with a reduced incidence of intraoperative complications in comparison with conventional radical surgery. The incidences of urinary incontinence or frequency and constipation were also less frequent with NSRH, and there were no adverse effects on survival or sexual function.¹⁷

The results of the present study using CUSA demonstrated that all patients successfully completed the standard operation by laparoscopy, and major blood vessels and organs were not damaged during the surgery. There were no significant differences in the operation time in the CUSA group and non-CUSA group but blood loss in the CUSA group was greater than that of patients in the non-CUSA group. A similar number of lymph nodes were harvested in both groups consistent with the foreign and domestic reports.

A number of other researchers have compared laparoscopic nerve-sparing radical hysterectomy with non-nerve-sparing surgery. These studies indicate that indwelling catheter time of the laparoscopic nerve-sparing radical hysterectomy was shorter than that with the nonreserved nerve surgery.¹⁴ In addition, the results of urodynamic tests were significantly better.¹⁸ Studies performed by Yong et al¹⁴ reported a mean indwelling catheter time of 10.6 (2.7) days in laparoscopic surgery patients, compared with 17.2 (4.2) days in the non-nerve-sparing surgery group.

Despite these advantages, conventional laparoscopic instruments cannot meet the requirement of avoiding nerve damage.

Autonomic nerves are not easily identified and can be damaged by electrical equipment. New clinical electrosurgical instruments are constantly being introduced to overcome this problem. These include the Pk scalpel, the Biclamp, and the Ligasure; they reduce electrical nerve injury, compared with devices that separate and identify nerves,¹⁹ but to date no clinically significant advantage have been demonstrated.

Other strategies have been implemented to help the surgeon protect the hypogastric nerve, pelvic splanchnic nerve plexus, and the bladder branch. These include marking the nerve with blue dye²⁰ or the use of intraoperative electrical stimulation.²¹

We have used CUSA in our hospital to perform laparoscopic nerve-sparing radical hysterectomy since 2011. The use of CUSA has helped identify the hypogastric plexus and its branches (above the iliac vessels and on the both sides of the rectum). Cavitron Ultrasonic Surgical Aspirator exposes the parabladder and pararectal spaces, allowing successful separation of the uterosacral ligament (USL). It also preserves the inferior hypogastric and pelvic plexus in the lateral part of the USL. Cavitron Ultrasonic Surgical Aspirator also facilitates identification of the uterine deep vein and the pelvic plexus located beneath the USL and exposes the tissue between the paravaginal space and bladder side space, which in turn preserves the bladder branch.

Limitation of this study should be considered. The results of this small pilot study conducted in a single center require confirmation in larger multicenter randomized studies.

CONCLUSIONS

Our results suggest that CUSA used for laparoscopic nerve-sparing radical hysterectomy was safe and feasible. The technology was simple and easy to operate, without special training. Use of the suction device clearly exposed the surgical field, allowed selective crushing of tissue edges, and provided continuous perfusion. Protection of autonomic nerves even in relatively obese patients was associated with improved postoperative bladder function. Cavitron Ultrasonic Surgical Aspirator was also effective at removing lymph nodes.

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