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ORIGINAL RESEARCH

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Efficacy and safety of cervical conization combined with neoadjuvant chemotherapy versus radical trachelectomy in early-stage cervical cancer treatment

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Abstract

This study evaluates the impact of cervical conization combined with neoadjuvant chemotherapy versus radical trachelectomy on treatment outcomes and patient safety in early-stage cervical cancer. Clinical data of 100 patients with early-stage cervical cancer treated at The First Hospital of Yulin City between January 2021 and January 2023 were retrospectively analyzed. According to different treatment methods, patients were divided into two groups: an experimental group (50 cases) receiving cervical conization (loop electrosurgical excision procedure, LEEP) combined with neoadjuvant chemotherapy, and a control group (50 cases) undergoing radical trachelectomy. Efficacy and safety were compared between the two surgical approaches. The overall efficacy rate was significantly higher in the experimental group than in the control group ($p = 0.046$). Additionally, the experimental group exhibited shorter surgical time, reduced hospitalization duration, and quicker return to first flatus compared to the control group ($p < 0.001$). The difference in postoperative complications rates between the two groups was not statistically significant ($p > 0.05$). Recurrence rates at six months and one year post-surgery did not significantly differ between the groups ($p > 0.05$). However, after three years, the experimental group had a significantly lower recurrence rate compared to the control group ($p < 0.05$). The combination of LEEP with neoadjuvant chemotherapy for early-stage cervical cancer demonstrates superior therapeutic efficacy, shorter surgical duration, and lower long-term recurrence rates compared to radical trachelectomy. This approach extends patient survival with a favorable safety profile, supporting its clinical adoption.

Keywords

Cervical conization surgery; Radical trachelectomy surgery; Neoadjuvant chemotherapy

1. Introduction

Cervical cancer ranks as a prominent gynecological malignancy, with an increasing incidence among younger women [1]. Early-stage cervical cancer typically presents without discernible symptoms; however, as the disease progresses, symptoms such as frequent urination, urgency, vaginal bleeding and leg pain or swelling may manifest. The potential for malignant transformation poses significant health risks to patients [2, 3]. Surgical resection, often combined with chemotherapy, constitutes the primary treatment modality for cervical cancer patients [4]. Studies have demonstrated the efficacy of early surgical intervention in controlling cervical cancer progression and achieving complete remission. While radical hysterectomy is recognized for its effectiveness, it compromises fertility in women [5]. The advent of minimally invasive surgical techniques has popularized the use of conization in managing early-stage cervical cancer, yielding favorable clinical outcomes while preserving fertility. Neoadjuvant chemotherapy (NACT) represents a novel approach wherein chemotherapy is administered prior to radiation or surgery. NACT can effectively curtail metastasis and reduce tumor size. Furthermore, NACT enhances immune responses, improves patient well-being, and aims to improve quality of life. However, research exploring the integration of chemotherapy with surgery in early-stage cervical cancer remains limited. Therefore, this study aims to compare the efficacy and safety of radical trachelectomy versus cervical conization with NACT in the management of early-stage cervical cancer.

2. Materials and methods

2.1 General information

Clinical data of 100 patients with early-stage cervical cancer treated at our hospital between January 2021 and January 2023 were retrospectively analyzed and divided into an experimental group (50 cases) and a control group (50 cases) based

on different treatment methods, as delineated in the patient selection flow chart (Fig. 1). The demographic and baseline characteristics of the participants are presented in Table 1, demonstrating comparability between the groups ($p > 0.05$).

The study inclusion criteria encompassed: (1) adherence to diagnostic criteria for early-stage cervical cancer; (2) suitability for surgical intervention; (3) confirmation of early-stage (stage Ia1/Ia2/Ib1) cervical cancer diagnosis; and (4) voluntary agreement to participate in the study by signing an informed consent form.

Exclusion criteria consisted of: (1) concurrent cardiovascular, liver, kidney or other significant organ disorders; (2) cognitive impairment or psychiatric conditions; (3) concurrent presence of other malignancies; and (4) concurrent infectious diseases or hematologic disorders.

2.2 Therapeutic interventions

Positron Emission Tomography-Computed Tomography (PET-CT) was utilized to accurately determine the size, location and extent of tumor invasion, as well as to identify any metastases and their locations. Cervical cancer staging primarily follows the Tumor Node Metastasis (TNM) system based on the extent of invasion and lesion size: If the invasion is relatively small, less than 3 mm, it's classified as stage Ia1; if the depth of invasion is between 3–5 mm, it's classified as stage Ia2; when the invasion exceeds visible lesions, it may be classified as stage Ib.

All patients in the control group underwent radical trachelectomy. The procedure is as follows: First, the patient is positioned in the lithotomy position and administered general anesthesia. Using ultrasound to locate the surgical site, an abdominal incision is made to inspect the uterus and surrounding structures. PET-CT is used to check for pelvic lymph node metastasis. If metastasis is detected, a lymphadenectomy is performed. Surgical forceps are used to lift the peritoneum, pulling the broad ligament below the cervix to examine the uterine connective tissue. The uterine artery is isolated and bluntly dissected, and the uterus is ligated downward, freeing the upper end of the ureter and its connecting vessels outside the ureter. After opening the bladder, the rectal peritoneum is lifted, and both sides of the rectum are freed. The uterosacral ligaments, cardinal ligaments, and vaginal tissue 2–3 cm from the cervix are severed. An annular incision is made at the junction of the vaginal wall and the lower edge of the cervix, and the cervix is circumferentially resected at the uterine isthmus. The excised tissue is promptly sent to pathology for examination. The results are negative, an intrauterine contraceptive device is inserted, and the uterine body and vaginal stump are sutured. The abdominal cavity is then closed. Postoperatively, a gelatin sponge is used for hemostasis, and antibiotics are administered to prevent infection.

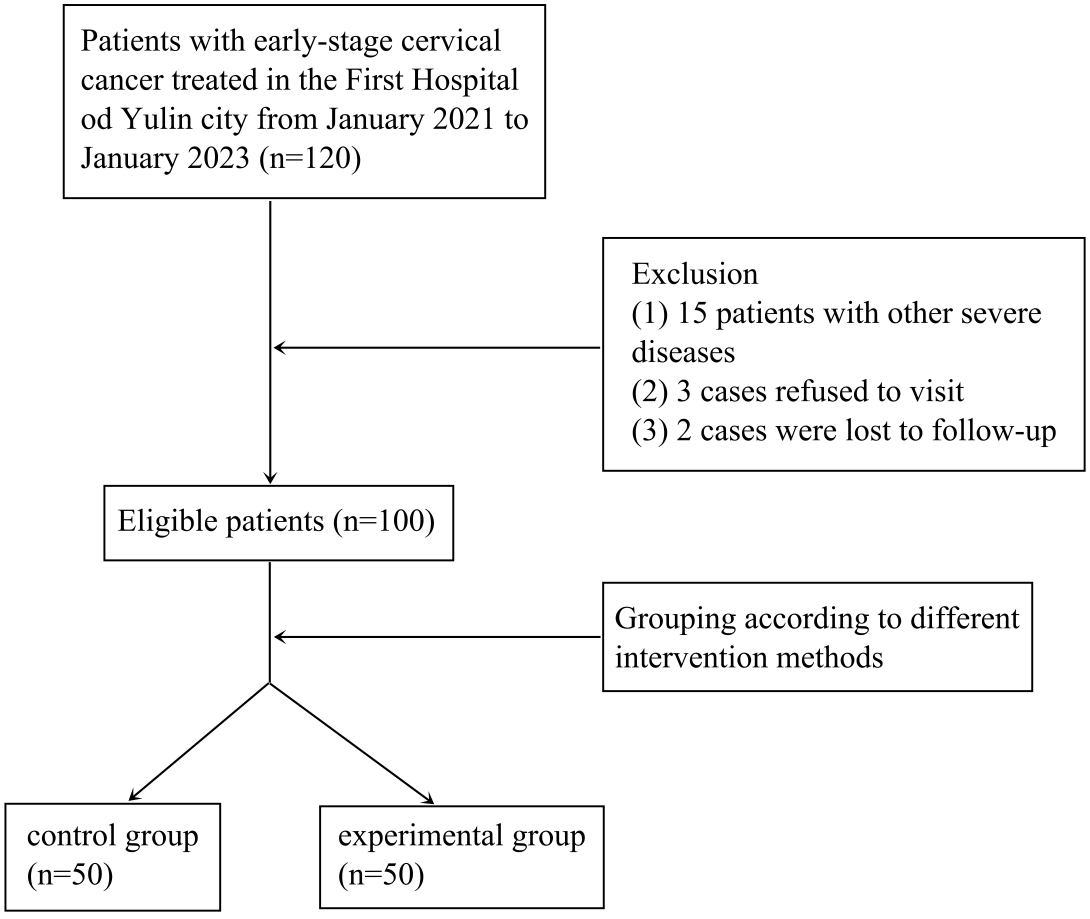

FIGURE 1. Flow chart of the study design and grouping.

TABLE 1. Comparison of general information between two groups.

Variables	Experimental group (n = 50)	Control group (n = 50)	t/χ^2	p
Age (yr)	41.32 ± 3.22	42.12 ± 3.29	1.229	0.222
Course of disease (mon)	2.10 ± 0.32	2.21 ± 0.44	1.430	0.156
Types				
Adenocarcinoma	10	12		
Squamous cell carcinoma	35	34	0.450	0.581
Others	5	4		
Periodization				
Phase Ia1	5	7		
Phase Ia2	27	26	0.418	0.377
Phase Ib1	18	17		
HPV infection				
Positive	30	28	0.164	0.685
Negative	20	22		

HPV: human papillomavirus.

In the experimental group, patients with stage Ia1 carcinoma only underwent conization of the cervix. Other patients received chemotherapy and conization. The details are as follows:

First, neoadjuvant chemotherapy was administered, consisting of paclitaxel and carboplatin. Liposomal paclitaxel (Nanjing Greenleaf Pharma Co. Ltd., Nanjing, Jiangsu, China, H20030357) for injection, typically dosed at 135–175 mg/m^2, was initially dissolved in 10 mL of a 5% glucose injection solution. It was then further diluted in 250–500 mL of the same solution for a 3-hour intravenous infusion. Similarly, Carboplatin injection (Qilu Pharmaceutical Co., Jinan, Shandong, China, H10920028) was dosed according to an area under the curve (AUC) of 5, administered once every three weeks, diluted in 10 mL of a 5% glucose injection solution, followed by additional dilution in 250–500 mL of the same solution for a 3-hour intravenous infusion. Pre-medication, administered half an hour before chemotherapy, included an intramuscular dose of diphenhydramine hydrochloride Injection (Tianjin Jinyao Pharmaceutical Co. Ltd., Tianjin, China, H12020617) at 20 mg per administration, once or twice daily; dexamethasone sodium phosphate injection (Hubei Tianyao Pharmaceutical Co. Ltd., Xiangyang, Hubei, China, H42020019) at a dose of 10 mg per administration, twice daily; and cimetidine injection (Guangdong Nan Guo Pharmaceutical Co. Ltd., Zhanjiang, Guangdong, China, H44024630) at 0.2 g per administration, twice daily. The treatment duration comprised two cycles, with each cycle lasting three weeks. Before surgery, oral antiemetics were given to prevent complications. After completing two cycles, conization of cervix was performed on the patients.

Subsequently, the experimental group underwent the loop electrosurgical excision procedure (LEEP): Patients were draped in a sterile fashion and positioned in lithotomy before receiving anesthesia. Disinfection of the vagina and cervix was performed, followed by the fully exposure of the cervical sites. Colposcopy was carried out to examine the cervix and identify the lesion site. Using a LEEP knife electrode, a circular resection from inside out was performed in a clockwise manner, with conical resection of the lesion site. The appropriate cutting degree was selected based on the severity of the patient's lesion. Electrocoagulation was employed to stop bleeding and flatten the wound. The excised tissue was sent to the pathology department for examination. The examination result was negative, the surgery was concluded. Similar to the control group, postoperative hemostasis was managed through the application of a gelatin sponge, accompanied by antibiotic prophylaxis.

If high-risk factors such as basal layer infiltration or vascular tumor infiltration were found after LEEP, further surgical intervention is necessary. During the surgical excision, the extent of removal had to exceed the visible tumor boundaries, which meant relatively extensive excision of the surrounding normal tissue was required, as these areas could also harbor infiltrating tumor cells. This approach aimed to prevent recurrence after surgery.

After the surgery, the patients underwent follow-up examinations, including routine physical assessments, specialized tests such as cytology (TCT) and human papillomavirus (HPV) DNA testing on residual vaginal tissue, pelvic magnetic resonance imaging (MRI) and pelvic ultrasonography. These follow-ups occurred every three months for three years to monitor for any recurrence of cervical cancer and to enable prompt intervention and treatment when necessary.

Treatment plans for cervical cancer recurrence depend on the patient's specific situation. If distant organ metastasis occurs after recurrence, further surgical treatment is not recommended. Concurrent chemoradiotherapy can be employed to reduce tumor burden and prolong survival. Symptomatic support therapies, such as analgesics and sedatives, may also be used. If the recurrent tumor remains localized in the pelvis, surgery can be performed again to address the local lesion, accompanied by chemoradiotherapy and targeted drug treat-

ments. For patients with compromised health, extensive recurrence, and prominent symptoms such as pain or abnormal bleeding, radiation therapy may be recommended to control cancer cell proliferation and extend survival. Chemotherapeutic agents such as cisplatin or carboplatin were administered under oncological supervision to eradicate cancer cells and provide treatment. Additionally, targeted medications such as gefitinib or erlotinib hydrochloride, which disrupt specific molecular pathways in cancer cells, may be prescribed under a physician's guidance. Immunotherapies, including nivolumab or pembrolizumab injections, may also be suggested by oncologists to enhance the immune response against cancer cells, thereby halting their dissemination.

Daily recommendations for patients included keeping warm to prevent colds, resting adequately to prevent fatigue, staying optimistic and managing stress levels. They were encouraged to maintain a nutritious diet consisting of protein, vitamins and essential nutrients, such as eggs and tomatoes, to fulfill dietary requirements, strengthen resilience, and support convalescence.

2.3 Observation indicators

(1) Clinical efficacy: Significant effect: No tumor-like lesions within six months post-treatment, complete disappearance of clinical symptoms. Effective: Reduced tumor-like lesions and improved clinical symptoms post-treatment. Ineffective: No improvement or worsening of the condition post-treatment. Total effective rate = significant effect + effectiveness percentage. (2) Clinical surgery indicators: Comparison encompassed the duration of surgery (from initiation to completion, including time for pathological tissue analysis), length of hospital stay, and time to first flatus post-surgery across both patient groups. (3) Postoperative complications: Recording and comparison of complications such as wound infections, urinary retention and diarrhea, vomiting and hair loss between both groups. (4) Recurrence monitoring: During the three-year post-surgery follow-up period for both cohorts, patients were scheduled to return to the hospital quarterly for evaluations to document any instances of disease recurrence. Recurrence was identified by the emergence of tumor metastases or local relapses within the pelvic region, adjacent structures, or regional lymph nodes, as confirmed *via* imaging modalities such as MRI, CT or colposcopy-directed biopsy, among others.

2.4 Statistical analysis

Data analysis was performed utilizing SPSS 22.0 statistical software (IBM, Armonk, NY, USA). Descriptive statistics, including means and standard deviations, were used to describe quantitative data, while *t*-tests were utilized for comparisons. Categorical data were described using percentages (%) and compared using chi-square tests, with a significance level set at $p < 0.05$ to indicate statistical significance.

3. Results

3.1 Comparison of treatment efficacy

The overall efficacy rate in the experimental group was significantly higher than that in the control group ($p = 0.046 < 0.05$), as shown in Table 2.

3.2 Clinical surgical indicators

As shown in Table 3, the operation time, hospital stay, and time to first flatus were all significantly lower in the experimental group compared to the control group ($p < 0.05$). Additionally, within the control group, 10 patients were identified to have lymph node metastasis and subsequently underwent lymph node dissection, with an average of (15.21 ± 2.32) nodes dissected.

3.3 Postoperative complications

The difference in the complication rates between the two groups was not obvious ($p > 0.05$) (Table 4).

3.4 Postoperative recurrence

At the six-month post-surgery, both the experimental and control groups had a recurrence rate of 0.00%. Similarly, one year following surgery, there was no significant difference in recurrence rates between the two groups ($p > 0.05$). However, after three years post-surgery, the recurrence rate in the experimental group was found to be lower than that in the control group ($p < 0.05$), as illustrated in Table 5.

4. Discussion

Cervical cancer, a prevalent malignancy affecting women, is increasingly diagnosed at younger ages, significantly impacting reproductive health and functionality [6]. Despite prevention and screening efforts, cervical cancer maintains a high incidence rate among female cancers. The pathogenesis of cervical cancer is strongly linked to human papillomavirus (HPV) infection [7]. If left untreated, early-stage cervical cancer can progress to advanced stages, increasing the risk of metastasis and reducing the success of surgical interventions, posing a severe threat to patient life. Presently, surgery stands as the primary and most effective clinical treatment for early-stage cervical cancer [8]. Surgical removal of the lesion remains the preferred approach for patients with early-stage cervical cancer, despite conventional surgical methods resulting in significant trauma, prolonged recovery periods, and substantial impacts on patients' physical and emotional well-being [9].

While hysterectomy can effectively remove early-stage cervical cancer lesions, it can also cause significant trauma and damage to pelvic and adjacent neural tissue, leading to multiple postoperative complications that impede recovery [10, 11]. Advances in medical technology, such as cervical conization and radical trachelectomy, have led to the advent of promising alternatives. However, radical trachelectomy may harm female reproductive tissues and result in infertility [12, 13].

Cervical conization, also known as LEEP, has been demonstrated to be advantageous due to its precise targeting, straightforward technique, and reduced tissue damage. This method

TABLE 2. Comparison of treatment efficacy between two groups of patients (n (%)).

Group	n	Significant effect	Effective	Ineffective	Total effective rate
Experimental group	50	30 (60.00)	18 (36.00)	2 (4.00)	48 (96.00)
Control group	50	19 (38.00)	23 (46.00)	8 (16.00)	42 (84.00)
χ^2					4.000
p					0.046

TABLE 3. Comparison of clinical surgical indicators of the two groups ($\bar{x} \pm s$).

Group	n	Operative time (min)	Hospital stay (d)	First flatus time (h)
Experimental group	50	58.65 ± 2.32	10.04 ± 1.28	6.05 ± 1.39
Control group	50	86.34 ± 2.61	11.68 ± 1.53	8.37 ± 2.27
t	-	56.069	5.813	6.163
p	-	<0.001	<0.001	<0.001

TABLE 4. Comparison of postoperative complications between the two groups (n (%)).

Group	n	Incision infection	Uroschesis	Diarrhea	Vomiting	Hair loss	Total
Experimental group	50	1 (2.00)	1 (2.00)	0	1 (2.00)	2 (4.00)	5 (10.00)
Control group	50	1 (2.00)	2 (4.00)	1 (2.00)	3 (6.00)	0	7 (14.00)
χ^2							0.379
p							0.538

TABLE 5. Comparison of postoperative recurrence of two groups (n (%)).

Group	n	6 months after surgery	1 year after surgery	3 years after surgery
Experimental group	50	0	0	3 (6.00)
Control group	50	0	2 (4.00)	13 (26.00)
χ^2	-	1.010	0.510	7.441
p	-	0.315	0.475	0.006

utilizes a high-frequency electrosurgical unit to excise lesions with minimal bleeding, thereby facilitating postoperative recovery [14, 15]. Initially used in breast cancer treatment, neoadjuvant chemotherapy (NACT) has been extended to gastrointestinal and head and neck cancers through subsequent research. During the 1990s, NACT was investigated as a preoperative management strategy for cervical cancer and demonstrated notable efficacy. Paclitaxel, a chemotherapy agent, contains natural anti-tumor properties effective against various malignancies, including uterine, ovarian and breast cancers [16]. Additionally, carboplatin, which is associated with relatively few side effects, can impede tumor growth. Our study findings indicate a significantly higher overall efficacy rate in the experimental group compared to the control group, suggesting that combining cervical conization with NACT could be effective in treating early-stage cervical cancer. This combination achieves more comprehensive removal of lesioned tissue and minimizes remaining tumor tissue compared to radical trachelectomy alone. A key factor in the NACT regimen is its use of carboplatin before surgery, as carboplatin targets specific components of DNA, namely pyrimidine and purine bases, effectively blocking DNA synthesis. Furthermore, in conjunction with paclitaxel, this therapeutic approach disrupts tumor cell division and growth, reducing tumor volume and optimizing the timing for surgical intervention.

Preoperative reduction of tumor cell viability and prevention of intraoperative dissemination enhance safety and overall treatment efficacy. Radical trachelectomy, involving extensive removal of uterine tissues and nerves, results in more substantial bodily trauma, increased intraoperative bleeding, and prolonged wound healing times. LEEP, conducted under colposcopic guidance, enhances the surgical visual field and facilitates precise localization of lesion tissue while minimizing damage to important pelvic ligaments and adjacent fascia, thereby preserving pelvic structural stability and integrity to the highest degree. This increased precision results in reduced blood loss and less extensive surgical incisions and trauma, often eliminating the need for postoperative suturing and significantly shortening surgery duration. Patients are able to ambulate sooner postoperatively, expediting recovery and promoting enhanced restoration of cervical function. Additionally, colposcopic assistance enables a more thorough excision of lesional tissue, effectively reducing residual tumor burden. Consequently, the combined approach of conization and chemotherapy yields improved outcomes in managing of early-stage cervical cancer.

In this study, the clinical surgical indicators of the experimental group were superior to those of the control group,

indicating less surgical trauma and shorter recovery times. Additionally, the complication rate of the two groups were not significantly different, underscoring the high safety and positive significance of this surgical treatment in preventing postoperative complications in early cervical cancer patients. Recurrence rates at six months post-surgery were nil for both groups, indicating no immediate difference in efficacy. At one-year follow-up, the recurrence rate was 4% in the control group and 0.00% in the experimental group; however, this difference was still not sufficiently significant. After three years, the experimental group demonstrated a lower recurrence rate compared to the control group, indicating that chemotherapy combined with surgery significantly reduces recurrence. These findings support that NACT can notably diminish the presence of vascular tumor thrombus and pelvic lymph node metastasis by reducing tumor cell viability, thereby limiting intraoperative dissemination and enhancing the eradication of micro-metastatic foci, which ultimately decreases postoperative lymph node metastasis [17]. Pelvic lymph node metastasis is a critical risk factor for the prognosis and recovery of cervical cancer patients. Postoperative metastasis can drastically reduce the 5-year survival rate, sometimes to approximately 50%. Thus, mitigating the incidence of pelvic lymph node metastasis can substantially enhance survival quality. Moreover, NACT significantly increases tumor cell sensitivity to adjuvant radiotherapy, minimizing radiation-induced damage to the ovaries and vagina, enhancing the effectiveness of subsequent treatments, and improving the tumor-free quality of life. Despite these promising findings, this study had some limitations. Due to the small sample size, these findings may be subject to bias. Therefore, future studies with larger and multicenter cohorts are needed to validate these results.

5. Conclusions

In conclusion, the combination of cervical conization with neoadjuvant chemotherapy in the treatment of early-stage cervical cancer was found to be highly effective. This approach significantly reduced serum tumor marker levels, improved clinical symptoms, accelerated postoperative recovery, minimized complications, and demonstrated promising safety and efficacy. These findings indicate that this combined approach has the potential to improve patient outcomes.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

HL—designed the study and carried them out; supervised the data collection, analyzed the data, interpreted the data. HL and RG—prepared the manuscript for publication and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of the First Hospital of Yulin City (Approval no. 2019013-1). Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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