

Modified method of cervical conization with hybrid use of a cold knife and an electric knife for high-grade squamous intraepithelial lesions

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Abstract

Objective: To evaluate the feasibility and surgical outcome of the modified method of cervical conization with hybrid use of a cold knife and an electric knife.

Methods: A retrospective analysis of cervical conization for high-grade squamous intraepithelial lesions was performed between January 2020 and December 2020. Traditional cold knife conization and modified conization were used. The clinical characteristics and surgical outcomes were compared between these methods.

Results: Ninety-two patients with high-grade squamous intraepithelial lesions were included. Traditional conization was performed in 46 patients, and the modified method was used in 46 patients. There were no differences in clinical characteristics, such as age, menopausal status, and conization height, between the methods. Intraoperative blood loss with the modified method was significantly lower than that with traditional conization (27.6 ± 4.7 vs 51.3 ± 18.3 mL). Postoperative vaginal bleeding requiring emergent measures, such as prolonged gauze compression, sutures, or electrocautery, was significantly less with the modified method than with traditional conization (4.3% vs 17.4%). A median follow-up of 10.2 months showed no significant difference in persistence or recurrence between the methods.

Conclusions: The modified method of cervical conization with hybrid use of cold and electric knives may be a good alternative to traditional cold knife conization.

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Keywords

High-grade squamous intraepithelial lesion, cervical intraepithelial neoplasia, cervical conization, cervical dysplasia, cone biopsy, thermal damage

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Introduction

With the wide adoption of cervical cancer screening in China, the treatment of cervical cancer has shifted toward an early stage and precancerous cervical lesions.^{1,2} Consequently, cervical conization is increasingly performed in clinical practice. Although cervical conization is essential in the management of cervical precancerous lesions, it can cause some adverse consequences as follows. First, postoperative severe or persistent bleeding may occur with the requirement of emergent hemostatic measures, such as prolonged gauze compression, sutures, or electrocautery.³ Second, cervical canal adhesion and scar formation may occur with subsequent cervical stenosis.⁴ Third, adverse obstetrics outcomes, such as early spontaneous abortion or preterm labor, may also present after the procedure.^{5,6}

The method of cervical conization has been repeatedly modified to address these adverse consequences.⁷⁻⁹ Energy devices were introduced in this procedure because of their excellent coagulative effect. Advantages of the loop electrosurgical excision procedure (LEEP) are purported to be its low cost, reduced blood loss, and low incidence of postoperative morbidities, such as severe hemorrhage or cervical stenosis.¹⁰ However, thermal artifacts and fragmentation of specimens in this procedure may result in difficulty in pathological interpretation.^{11,12} Other variant modifications with only an electric knife or a pure cutting current or harmonic scalpel have

also been reported with reduced thermal artifacts¹³⁻¹⁵ Furthermore, because the extent of excised tissue is related to postoperative morbidities, the excised cone in LEEP and other procedures gradually transforms from a typical “cone” to a more shallow “coin” shape.^{16,17}

On the basis of these previous studies, we comprehensively modified our method of cervical conization with the aim of incorporating the advantage of the LEEP into the traditional procedure. The hybrid use of a cold knife and an electric knife was designed to address the thermal damage caused by the energy device and its adverse effect on pathological interpretation. This new method has been used in our department since June 2020. This study aimed to evaluate the feasibility and surgical outcome of the modified method of cervical conization with hybrid use of cold and electric knives.

Patients and methods

Enrollment of patients

In our hospital, the modified method of conization was introduced to replace traditional cold knife conization in June 2020. In this study, the medical records of all consequently hospitalized patients with high-grade squamous intraepithelial lesions (HSILs) between 1 January 2020 and 31 December 2020 were retrieved from the electronic medical record system and reviewed retrospectively. The inclusion

criteria consisted of the following: pathologically confirmed HSILs after biopsy under colposcopy; and no visible lesions in a pelvic examination. *In situ* adenocarcinoma and other lesions were excluded from the study. Approval of the study protocol was obtained from the Affiliated Women and Children's Hospital of Ningbo University (approval number: 2020-014). Because this study was retrospective, it did not require the patients' consent. All patients' details have been de-identified before the analysis to ensure privacy. The reporting of this retrospective cohort study conforms to the STROBE guidelines.¹⁸

Demographic data, such as age, marital status, and menopausal status, were collected from the medical records. Surgical and pathological data, such as the operation time and intraoperative complications, were collected from the surgical records and pathological reports. Data on intraoperative complications were also recorded after inquiry with the surgeons. The operating time was defined as the time from injection of vasopressin to tamponade with a gauze. The change in hemoglobin was defined as the level of hemoglobin before surgery minus the level of hemoglobin at day 1 after the operation.

Information on postoperative morbidities, such as cervical stenosis and oncological outcomes, were retrieved from the Ningbo municipal medical surveillance and sharing system. This modern system incorporates all medical information of patients who were treated within the city of Ningbo. This information was obtained via phone by our staff for patients who were not found in the system.

Details of the surgical methods

The procedure of the modified conization is summarized as follows. (1) After general or regional anesthesia, the patient was placed in the high lithotomy position.

Diluted pituitrin (6 U pituitrin was diluted in 30 mL saline) was injected at 2, 5, 7, and 11 o'clock in patients with no contraindications, such as hypertension or heart disease. A 2% iodine solution was then used to delineate the contour of the lesion. (2) The external incision line of conization was 2 to 3 mm adjacent to the lesion. In alignment with the external incision line, a cold knife was used to incise the cervical stroma circumferentially with a depth of approximately 3 to 5 mm. The posterior semicircle was incised before the anterior semicircle to avoid blurred vision from bleeding. (3) After this circumferential incision was made, the cervix was picked up firmly by four Allis forceps at 12, 3, 6, and 9 o'clock and pulled outward. The cold knife was then replaced by an electric knife. Perpendicular to the cervical canal, the incision was continued deeper until near the inner surface of the cervical canal. (4) The direction of the incision was rotated at an angle of 90 degrees parallel to the cervical canal. The incision continued until the appropriate height of the cone was obtained. (5) The electric knife was replaced by the cold knife. The inverted mush-like specimen was then resected with the cold knife. (6) The standard Sturmdorf method was used to suture the residual cervix. In all patients, endocervical curettage was performed after removal of the cervical tissue to confirm whether there was residual dysplasia.

Follow-up

After the surgery, cytological tests and human papillomavirus screening were performed at 3, 6, 9, and 12 months within 1 year. Yearly examinations were then performed for at least 5 years. Once abnormal findings were suspected, colposcopy and biopsies were performed to confirm or obviate the suspicious lesions. In patients who presented with a confirmed HSIL or higher

lesion within the first 3 months after conization, the lesion was regarded as persistence of the earlier HSIL, even when the previous pathological examination reported a negative resection margin. In patients who presented with a confirmed HSIL or higher lesion more than 3 months after conization, the lesions were regarded as recurrence of the HSIL.

Statistical analyses

Quantitative data are presented as the mean with standard deviation. Qualitative data are shown as the absolute number and percentage. Student's *t* test or the χ^2 test was used for the comparison between groups as appropriate. A two-sided *P* value <0.05 was considered as significant. All analyses were performed using IBM SPSS Statistics 21.0 (IBM, Asia Analytics, Shanghai, China).

Results

During the study period, 92 patients were included in the final analysis. Traditional conization was used in 46 patients, and the modified method of conization was used in the other 46 patients. The mean age of the patients was 42.0 ± 6.9 years. Only 13 patients were menopausal. No

significant differences in demographic characteristics were found between the two methods (Table 1).

The duration of surgery with the modified method of conization was significantly less than that with traditional conization ($P < 0.001$) (Table 2). The intraoperative blood loss with modified conization was significantly lower than that with traditional conization ($P < 0.001$). The change in hemoglobin concentration was also lower in patients with modified conization than in those with traditional conization ($P = 0.004$). However, the conization height was not significantly different between the two methods. The pathological findings also indicated that the status of the surgical margin was not significantly different between the two methods.

No intraoperative complications occurred in our study. There was a significantly lower rate of postoperative complications with modified conization than with traditional conization (4.3% vs 19.6%, $p = 0.024$). Severe vaginal bleeding requiring emergent measures, such as prolonged gauze compression, sutures, or electrode cautery, was also significantly lower with modified conization than with traditional conization (4.3% vs 17.4%, $P = 0.044$). Only one patient with traditional conization

Table 1. Demographic characteristics of the two groups.

	Group with modified conization (n = 46)	Group with traditional conization (n = 46)	t or χ^2	P value
Age (years)	41.9 ± 6.3	41.9 ± 7.5	0.045	0.964
Parity			0.548	0.459
Nulliparous	5	3		
Parous	41	43		
Marital status			0.713	0.398
Single	2	4		
Married	44	42		
Postmenopausal	5	8	0.806	0.369
BMI (kg/m ²)	22.6 ± 1.8	22.8 ± 1.7	0.448	0.655

Values are mean \pm standard deviation or number.
BMI, body mass index.

Table 2. Surgical outcomes of the two groups.

	Group with modified conization (n = 46)	Group with traditional conization (n = 46)	t or χ^2	P value
Duration of surgery (minutes)	25.0 ± 3.4	32.3 ± 3.5	10.223	<0.001
Conization height (mm)	22.1 ± 3.8	21.8 ± 3.2	0.381	0.704
Intraoperative blood loss (mL)	27.6 ± 4.7	51.3 ± 18.3	8.491	<0.001
Changes in hemoglobin concentration (g/L)	4.13 ± 2.74	5.70 ± 2.33	2.955	0.004
Positive margin after conization	1	2	0.345	0.557
Positive margin status			–	–
Endocervical	0	1		
Basal	0	0		
Ectocervical	1	1		
Severe postoperative bleeding requiring intervention			4.039	0.044
Prolonged gauze compression	2	4		
Suture	0	2		
Electrocautery	0	2		
Blood transfusion	0	0	–	–
Cervical stenosis	0	1	1.011	0.315
Persistence/recurrence	1	4	1.903	0.168

Values are mean ± standard deviation or number.

complained of cervical stenosis. At a median follow up of 10.2 months, there was no significant difference in persistence or recurrence between the two groups (2.2% vs 8.7%).

Discussion

This study showed that our modified method of conization may be used as a safe alternative to traditional conization in patients with an HSIL. This modified method of conization had a significantly lower intraoperative blood loss and a lower rate of severe postoperative bleeding without interfering with pathological interpretation than traditional conization.

Severe bleeding, mainly postoperatively, is a major complication of cervical conization^{14,19} The low occurrence rate of severe bleeding with modified conization may be due to the following factors. First, the modified method combines the advantages of using electro-surgical and cold knives.

An electronic knife coagulates small blood vessel simultaneously when incising.¹³ With less bleeding during incising, a clear surgical field can be maintained, which in turn facilitates a precise incision, and consequently, less bleeding. Second, the purposeful manipulation of the cervix and the change in the cone shape may also be important factors. With the change in the cone shape, the cervix had an externally convex contour. Therefore, a suture could fully compress the residual cervical tissue. Several previous studies have also shown that this change in the cone shape significantly reduced the risk of intra- and postoperative bleeding.^{7,16,20,21}

Any surgical procedure involving the cervix, including conization, has the potential to cause cervical incompetence, which subsequently leads to abortion or preterm delivery during the following pregnancy.^{5,22} Kigure et al. reported that more conservative conization, such as shallow coin-shaped conization, could achieve favorable

obstetric outcomes.¹³ A smaller amount of the cervical stroma was excised with our modified method, which may be a better alternative in young patients with the desire of future fertility.

A thermal artifact remains the main concern of the LEEP. Bittencourt et al. reported that severe artifacts occurred in 22.8% of their patients.²³ The hybrid use of cold and electric knives in our method was designed to address the thermal artifact caused by the energy device and its adverse effect on pathological interpretation. The cold knife was used at the external and internal margin of the specimen of conization. Therefore, the status of the surgical margin in a pathological examination can be appropriately determined. In this way, the advantages of both cold and electric knives were incorporated.

The LEEP is also limited by a predetermined geometry based on the loop size. Repeated excisions with a poor-fitted loop present difficulty for pathological examinations. No fragmentation of specimens occurred with our modified method of conization. Additionally, the surgeon could adjust the shape of the cone to better excise the transformation zone of the cervix. In postmenopausal patients, the conization height should be greater to prevent the omission of higher located lesions in the cervical canal.⁴ In patients with a younger age, the conization should be broad-shaped, but does not need to have a great height. In cases of invasive cancer or glandular disease, such as adenocarcinoma *in situ*, the width and height of the conization should be sufficient to obtain favorable outcomes.²⁴

The inpatient setting of our modified method requires more medical expenditure than the outpatient setting in the LEEP. However, we consider that our method is important for improving the technique of cervical conization. We could easily add a cold knife in the outpatient setting in the

future. There is the possibility that we can further abandon suturing and adopt electrocautery after the excision of specimens for hemostasis in our method. In the present study, conization was performed in an inpatient setting to evaluate the feasibility and safety of this procedure, and to observe the intra- and postoperative course. Because no severe complications were observed, this modified procedure may be performed in an outpatient clinic under local cervical anesthesia in the future.

The highlights of our modified conization can be briefly summarized as follows. (1) In the first and last periods, the cold knife was used to obviate the possible burning effect of the electronic knife, which can have adverse effects on the pathological diagnosis. (2) In the interim period, an electronic knife was used to decrease the blood loss and make the surgical field dry and clear. (3) A reversed mushroom-like or coin-shaped specimen was incised instead of the standard cone-shaped specimen. (4) The cervix had a convex contour remaining, which facilitated suturing. The residual cervix tissue was fully compressed to achieve hemostasis.

The limitations of our study are that it was a non-randomized, retrospective study with only a small number of patients included. A prospective, randomized, controlled study with a larger size is necessary to confirm the efficacy of this modified method of conization. Additionally, the obstetrical outcomes were not compared in our study because of the short follow-up. One possible drawback of our study is the possibility of deep invasion at the basal margin. However, patients requiring cervical conization are supposed to be in the precancerous stage or early stage of cervical cancer in most circumstances. The risk of deep invasion in the basal margin was low in this group of patients. In our study, no case of a positive basal margin was observed. However, a preoperative examination with magnetic resonance

imaging should be used to evaluate the possible deep invasion of cervical carcinoma.

In conclusion, our modified method of conization may be safely performed as an alternative in selected patients. This method does not require special instruments and can be easily learned by gynecologic surgeons. However, to draw firm conclusions and detect other possible beneficial or adverse consequences of this modified method, further observations and randomized, controlled trials need to be performed.

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Author contributions

Weifeng Zhang conceived, designed the study, interpreted the data, and wrote and revised the manuscript. Yi Lin conducted the study, interpreted the data, and revised the manuscript.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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