

Original Research

# The Effect of Tamponade on Postoperative Bleeding after Electrical Loop Excision of the Transformation Zone (LLETZ)

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#### **Abstract**

**Background**: This two-armed clinical audit aimed to evaluate the effectiveness of vaginal tamponade in reducing postoperative bleeding after large loop excision of the uterine cervix's transformation zone (LLETZ). **Methods**: We included patients after LLETZ with and without vaginal tamponade in this clinical audit analysis. In January 2021, we stopped performing routine postoperative vaginal tamponade after LLETZ, intensively monitored the occurrence of bleeding 30 days after the procedure, and analyzed the clinical audit. We compared the data with the clinical audit from 2016, when we performed routine postoperative tamponade in all patients. The primary outcome of our analysis was to evaluate the effect of vaginal tamponade on reducing the incidence of postoperative bleeding, necessitating secondary intervention. The secondary outcome was the occurrence of postoperative infection necessitating antibiotic treatment. All patients in the study signed written consent to analyze their data for quality control. **Results**: A total of 301 patients (132 patients with and 169 patients without postoperative tamponade) were included in the study and were similar regarding baseline characteristics. Postoperative bleeding occurred in 16 (5.3%) patients of both groups and was more prevalent in patients with vaginal tamponade compared to patients without the tamponade, although the difference was not statistically significant (6.1% vs 4.7%, respectively, p = 0.616). Postoperative infection occurred in 8 (2.7%) patients of both groups, and the incidence was similar in both groups (3.0% vs 2.4%, respectively, p = 0.734). **Conclusions**: According to our results, routine tamponade after LLETZ does not help reduce the incidence of postoperative bleeding.

Keywords: LLETZ; postoperative bleeding; vaginal tamponade; postoperative infection; surgery; conization

## 1. Introduction

High-grade (HSIL) and low-grade squamous intraepithelial lesions (LSIL) are premalignant lesions of the uterine cervix, typically located in the transformation zone between the endocervix, which is covered by the glandular epithelium, and the ectocervix, which is covered by the squamous epithelium. They are diagnosed by colposcopy with biopsy and histopathological examination [1].

The most common treatment of cervical intraepithelial lesions is excision or ablation of the cervical transformation zone. Large loop excision of the transformation zone (LLETZ), which has been in use for three decades, is currently the golden standard with over a 90% success rate [1–3]. It can be performed under local or general anesthesia and usually as an outpatient procedure. Although the procedure is simple and uncomplicated, perioperative complications can occur with an overall complication rate of 9.5% [4].

Early complications are those that develop within 14 days after the procedure [4]. Most common are bleeding,

pain, vaginal discharge and infection [5,6]. Serious complications such as bowel injury, laceration of uterine artery and abdominal bleeding are rare, with an incidence of 0.6% [4]. Late complications associated with the procedure are premature birth, late miscarriage and cervical stenosis [7].

The most common complication after LLETZ is vaginal bleeding. The incidence is slightly lower compared to cold-knife conization, namely 0–8% [8]. Although bleeding is usually similar to menstrual bleeding, heavier bleeding can occur and could be associated with larger specimen size or can be also present in women who undergo intense or prolonged exercise in the post-operative period [9].

Commonly, bleeding intensifies around the 10th day after the procedure, indicating that the wound is healing [4]. Since bleeding is the most common complication, obtaining sufficient haemostasis during and after the procedure is essential, which can be achieved through good surgical technique. To decrease the occurrence of bleeding, lidocaine or vasoconstrictive agents can be injected directly into the site of the excision, or electrocoagulation can be used. In

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rare cases, haemostatic sutures or absorbable hemostats are placed directly to the cervix after the excision. In our region, it has been common practice to use immediate postoperative vaginal tamponade as a preventive measure against postoperative bleeding. However, our experience and published data have also shown that patients who undergo tamponade often report discomfort, pain, and dysuria [4].

There is little data regarding the effect of vaginal tamponade after LLETZ. Therefore, our two-armed clinical audit in two separate periods in patients who underwent LLETZ for preinvasive cervical lesion aimed to evaluate the effectiveness of tamponade after LLETZ and its role in preventing postoperative vaginal bleeding.

## 2. Materials and Methods

A single-center, two-armed clinical audit in two separate periods included all consecutive patients who underwent LLETZ for cervical intraepithelial lesions. LLETZ was indicated according to our national guidelines [10]. With all patients, LLETZ was done as an out-patient procedure. The first group (Group 1), which was retrospectively analyzed, underwent the procedure from January to June 2016. In this group, all patients had vaginal tamponade after the procedure. The second group (Group 2), which was prospectively followed and closely monitored, underwent the procedure without the use of tamponade in the same period of 2021.

The primary outcome of this clinical audit was to evaluate the effect of vaginal tamponade on reducing the incidence of postoperative bleeding, necessitating secondary intervention, such as revisiting the hospital and cauterization of bleeding sites on the remaining cervix with silver nitrate, ball tip electrocoagulation under local anaesthesia or gauze packing. The secondary outcome was the occurrence of infection necessitating antibiotic treatment.

The inclusion criterium was LLETZ in women aged 18 to 75. Exclusion criteria were cold-knife conization, missing data, missing informed written consent or participation in any other ongoing clinical trial.

LLETZ was performed with a KLS Martin Maximum (KLS Martin Group, Tuttlingen, Germany) with loops ranging from 10 mm to 20 mm. The excision was performed under local or general anesthesia using a monopolar current with a cut frequency set to 100-150 W with additional monopolar coagulation and was performed by experienced surgeons dedicated to treating diseases in gynecological oncology. Procedures were all done by five different surgeons, all specialist in gynecological oncology for at least 5 years and at least 50 LLETZ procedures per year. After the procedure, in the first group (in 2016), a vaginal tampon made from cotton measuring 6, 8 or 10 cm in length was inserted in the vagina and patients were instructed to remove it by themselves the following morning. All patients were instructed to monitor bleeding or vaginal discharge after the procedure. In case of heavy bleeding, defined as needing

to change sanitary pads every 1 to 2 hours or vaginal infection, defined as unpleasant vaginal discharge with odor, we instructed the patients to visit our outpatient clinic. We used the similar research protocol as described in one of our previous articles [6]. The follow-up was 30 days postoperatively.

We obtained written informed consent forms from the patients who agreed to the use of their medical records for quality control and statistical data analysis.

Statistical analysis was performed using SPSS Statistics software 25.0 (IBM, Armonk, NY, USA). Descriptive statistics were calculated on basic patient characteristics. Pearson's chi-square/Fisher's exact tests were used to compare categorical data between groups. Statistical significance was set at a p-value < 0.05.

#### 3. Results

Using our research criteria, we identified 301 consecutive patients who underwent LLETZ in the selected periods. Group 1 consisted of 132 (43.9%) patients and Group 2 of 169 (56.1%) patients. Of all cases, 290 (96.3%) were performed under local anesthesia and 11 (3.7%) under general anesthesia.

The treatment groups were comparable regarding baseline characteristics such as age (39.2  $\pm$  12.4 years vs 41.8  $\pm$  12.1 years; p-value = 0.054) and type of anesthesia used (general vs local; 4.5% vs 3.0%; p-value = 0.543).

There were no statistically significant differences regarding postoperative bleeding or infection (6.1% vs 4.7%; p-value = 0.616, and 3.0% vs 2.4%; p-value = 0.734, respectively) (Table 1). None of the patients with bleeding were re-operated. They were all managed in an outpatient setting using local coagulation agents. Also, none of the patients with infection were readmitted. All were managed in an outpatient setting using oral empiric antibiotics.

#### 4. Discussion

In our study, 5.3% of patients experienced postoperative bleeding that needed secondary intervention, which is comparable to results from other studies (0–8%) [11]. The incidence of postoperative bleeding was actually higher in patients with tamponade (6.1% vs 4.7%; p = 0.616), although the difference was not statistically significant.

There is a lack of studies about the significance and effectiveness of postoperative vaginal tamponade, which was traditionally used with cold-knife conization. After the introduction of LLETZ, some studies showed that it is associated with a smaller incidence of postoperative bleeding [12], although data are inconsistent [13]. Along with the progress made in surgical technique and equipment, we have found that the use of hemostatic and antibacterial agents can further decrease the likelihood of moderate to severe bleeding occurring 14 days after the procedure. While the literature has described the use of Chitosan tampon, we do not rely on this particular method [14]. However, there is



Table 1. Complications, as sorted in two groups.

	Group 1	Group 2	Overall	p value
	n = 132	n = 169	n = 301	
Postoperative bleeding: Yes [Number (%)]	8 (6.1%)	8 (4.7%)	16 (5.3%)	0.616
Postoperative infection: Yes [Number (%)]	4 (3.0%)	4 (2.4%)	8 (2.7%)	0.734

no convincing data regarding the routine use of basic vaginal tampons.

Postoperative infection with vaginal discharge requiring intervention occurred in 2.7% of patients. There was a slight increase in infection after using tamponade (3.0% vs 2.4%; p=0.734). However, the difference was not significant. We know that genital pathogens are not an important cause of postoperative bleeding necessitating secondary intervention after LLETZ [3], but the role of vaginal tamponade on the incidence of postoperative inflammation should be confirmed in larger studies.

The study's strengths are that the same team of surgeons performed all the procedures, and that perioperative technique and postoperative follow-up were the same in both groups. Patients also had our team's support throughout the 30 days postoperative period. In addition, our study was the first to evaluate the preventive effect of tamponade on postoperative bleeding after LLETZ.

There are also some limitations of our work. Firstly, it was retrospective and designed as a clinical audit. Additionally, there was a 5-year gap between observing groups, and the number of participants and postoperative complication rates was relatively small, which may have increased the risk of verification bias. Also, we did not check the volume of the removed tissue or the remaining cervical length, which could have impacted on the outcomes.

## 5. Conclusions

Our results show that vaginal tamponade after LLETZ does not decrease postoperative bleeding necessitating secondary intervention. Moreover, based on data from literature patients with tamponade often experience discomfort, more severe pain and feel unable to urinate. These facts support the decision to avoid tamponade, so this finding will likely have practical implications. We believe routine postoperative tamponade or use of hemostats is not necessary since the low number of events. Intraoperative and postoperative measures for reducing bleeding complications should be used individually in a case-to-case scenario.

## Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## **Author Contributions**

Conceptualization, AC and MP; data curation, formal analysis, investigation, writing – original draft preparation, AC, ET, TS, ŽM, AD, JK and LAM; writing – review, editing and supervision, AC, TS, MP and ET. All authors contributed to editorial changes in the manuscript. All authors have read and agreed to the published version of the manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work

## **Ethics Approval and Consent to Participate**

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Local Ethics Committee of University Medical Centre Maribor (approval number: UKC-MB-KME-14/23). Written informed consent was obtained from all the participants.

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#### **Conflict of Interest**

The authors declare no conflict of interest.

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