

LLETZ PROCEDURE IN AN OUTPATIENT SETTING: APPLICABILITY AND COST-EFFECTIVENESS

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Summary

We present the applicability and cost-effectiveness of the large loop excision of the transformation zone (LLETZ) procedure in outpatient settings – anesthesia, postoperative pain, postoperative stay, and complications such as intraoperative bleeding, early postoperative bleeding, infection, late cervical canal stenosis, spotting, incomplete epithelialization, inadequate colposcopy). From Jan 1, 2017, to Jul 31, 2021, 189 patients underwent LLETZ at Medical Center "Prof. Kornovski". The methodology includes the indications for performing the LLETZ procedure, the preparation of the patients, a description of the procedure, tools, technical parameters, the operation technique, and the postoperative period. We present the duration of the procedure; analgesics in terms of intraoperative bleeding; postoperative pain; postoperative stay; early postoperative complications (bleeding, infection); late postoperative complications (stenosis of the cervical canal, incomplete epithelialization, spotting before menstruation, and inadequate colposcopy). The LLETZ procedure is applicable in outpatient practice with low intra- and postoperative complications and minimum stay. Two main factors determine its cost efficiency in outpatient practice: the use of local anesthesia instead of general anesthesia requiring an anesthesiologist, anesthesiology nurse, anesthetic for short-term venous anesthesia, and the daily cost for an occupied bed – a financial factor in-hospital care versus the lack of daily cost per occupied bed in outpatient care.

Keywords: large loop excision of the transformation zone, cost-effectiveness, infection, bleeding, local anesthesia, stenosis

Introduction

The treatment of precancerous changes in the cervix is the basis of secondary prevention of cervical cancer and is part of most national programs to prevent the disease. It includes destructive and excisional techniques. The indications for treatment are determined by the degree of development of precancerous lesions and the degree of penetration of the atypical area (lesion) into the cervical canal. Excisional

techniques are recommended for high-grade precancerous lesions, utterly invisible lesions, or their spread into the cervical canal [1]. The most commonly used excision techniques are electroconization, scalpel conization, laser conization, and electrical loop excision (LLETZ – large loop excision of transformation zone). The latter is characterized by minimal blood loss, high efficiency, low cost, low incidence of complications, and the possibility to perform in an outpatient setting [2-5].

Aim

We present the applicability and cost-effectiveness of the LLETZ procedure in outpatient settings – anesthesia, postoperative pain, postoperative stay, complications such as intraoperative (bleeding), early postoperative (bleeding, infection), and late (cervical stenosis, spotting, and incomplete epithelialization, inadequate colposcopy).

Materials and Methods

Clinical subjects

From Jan 1, 2017, to Jul 31, 2021, 189 patients underwent large loop excision of the transformation zone (LLETZ) at Medical Center “Prof. Kornovski”. Their distribution by age, parous status, and menopausal status are presented in Tables 1, 2, and 3.

Table 1. Distribution of patients by age

20 – 30 years of age	37 (19,5%)
30 – 40 years of age	91 (48,2%)
40 – 50 years of age	50 (26,5%)
50 – 65 years of age	11 (5,8%)

Table 2. Distribution of patients by parous status

Parous	144 (76,2%)
Non-p0 arous	45 (23,8%)

Table 3. Distribution of patients by menopausal status

Perimenopause	177 (93,7 %)
Postmenopause	12 (6,3%)

We present the indications for performing the LLETZ procedure, the preparation of patients, a description of the procedure, tools, technical parameters, the operation technique, and the postoperative period.

General indications for excision techniques [1]

1. The lesion had penetrated the cervical canal, and colposcopy or biopsy evaluation was impossible (unsatisfactory colposcopy).
2. Repeated cytology with suspicion of invasion without colposcopic findings.
3. Suspicion of an invasive lesion by colposcopy, cytology, or biopsy.
4. Abnormal glandular lesion confirmed by cytology or colposcopy.
5. Cytology presented a more objective finding than colposcopy or forceps biopsy.

Patient preparation

The procedure was performed before the 15th day of the menstrual cycle. Two days before it, the patient inserted one pessary of Arilin 1000 mg in two consecutive evenings.

Description of the procedure (equipment and tools)

The anesthesia was local, using 10 mL of 2% Lidocaine solution. Multiple punctures (closer and farther from the cervical canal, deeper and shallower) were made with a 1 ml insulin syringe. The cervicovaginal branches were avoided (at 3 and 9 o'clock) to reduce the risk of vegetative reactions such as noise in the ears and dizziness. A mandatory scarification test with Lidocaine was performed prior to anesthesia. RR, heart rate, and saturation were monitored. The operation began with disinfection of the vagina with Braunol, colposcopy with acetic acid (5%), or Lugol's solution and loop choice. SURTRON electrosurgical unit (cutting mode: cutting 100W and coagulation 60W; coagulation mode – SOFT 100W 60W) and a smoke evacuation device were used.

The procedure began with cutting from left to right and simultaneous powerful aspiration of the smoke from the altered area outlined with Lugol's solution.

Coagulation was included simultaneously with the cutting mode. In extensive lesions

of the exocervix, the lesion's periphery was additionally cut to a clean cut with a smaller loop. In lesions going to the cervical canal, the top of the resection surface was excised with a smaller and thinner loop. After the operation, the resection surface was coagulated with a spherical electrode.

In case of continued bleeding from the wound surface after coagulation with a spherical electrode, we applied the following algorithm:

1. Radiofrequency bipolar coagulation (Figure 1) and bipolar coagulation (Figure 2).



Figure 1. Radiofrequency coagulation generator (radio-frequency knife)



Figure 2. Bipolar radiofrequency coagulation

In case of no success in controlling the bleeding, we moved on to the next step, including applying a hemostatic mesh (Surgicel-Ethicon) and pressing with a swab for a few minutes.

In case of failure:

2. Sterile vaginal tamponade was applied for 1 – 1.5 hours.

In case of failure:

3. If bleeding occurred after tamponade

removal, another tamponade was applied to the vagina for 24 hours, and Dicynon 3 x1, p. per os for several days was administered.

The postoperative period (monitoring and recommendations)

Included observing the patient for bleeding and pain for 1 hour after the procedure. For postoperative analgesia we used Dexofen sachet per os. If genital bleeding was detected, the vagina and cervix were examined with a speculum. In case of vascular bleeding, we applied radiofrequency bipolar coagulation, and in case of diffuse bleeding – surgical+/-vaginal tamponade. Postoperatively, antibiotics and antifungals were administered, and abstinence from sexual intercourse, physical exertion (lifting over 10 kg), and sports for one month were recommended. After restoring sexual life, using a condom for three months (until the first check-up) was recommended.

Results and Discussion

Duration of the procedure

The duration of the LLETZ procedure was in the range of 25-40 minutes (average 30 minutes). It included the time for disinfection, colposcopy, local infiltration anesthesia, the operation itself, and hemostasis, if necessary. It took between 7 to 10 minutes to aspirate Lidocaine into insulin syringes (1 mL) and anesthesia infiltration at ten cervix points. An intraoperative complication like bleeding, though rare in the patients of the current series, was also a factor that significantly prolonged the procedure due to the application of individual measures to control it according to the described algorithm. Cai et al. reported an LLETZ duration of 15.7+/-9.8 minutes [2].

Anesthesia

According to the described method, local anesthesia ensured a smooth course of the procedure. It was performed on 182/189 patients (96.2%). The only subjective feeling of the patient was warmth during the procedure. The absence of vasomotor symptoms (tinnitus, dizziness) was achieved by avoiding anesthetic infiltration in the area of the cervicovaginal branches of a. uterina (3 and 9 o'clock) Venous anesthesia was performed in 7/189 patients (3.8%). The indications for venous anesthesia

were allergy to Lidocaine on the scarification test (3 patients) and patients' choice of general anesthesia (4 patients). According to the UK NHS Cervical Screening Program (NHSCSP), recommendations for cervical screening are that the LLETZ procedure is performed under local anesthesia in >80% of cases [3]. However, there are few publications in the literature on the subject. Yap et al. applied local anesthesia to 105 patients undergoing an outpatient LLETZ procedure. They reported no postoperative pain and a smooth operation [4]. Borbolla et al. published perioperative and histological results, including the type of anesthesia in 465 cases of LLETZ for four years (2005 – 2009) [3]. Of these patients, 33% underwent LLETZ under general anesthesia, and the rest – under local anesthesia. According to the authors, the type of anesthesia did not affect the course and safety of the procedure, postoperative complications, and histological results (affecting the resection lines by the dysplastic process).

Intraoperative bleeding (abnormal intraoperative bleeding)

Abnormal intraoperative bleeding has been defined as bleeding after the end of the operation that cannot be controlled as described in the algorithm and requires vaginal tamponade for 24 hours. In our series of patients, such bleeding was reported in 4 of 189 patients (2.1%) due to HSIL, suspicion of invasive cancer, and the size and depth of the excised area of the cervix, respectively. One of the advantages of the LLETZ procedure over conization (scalpel and electroconization) is the lower morbidity, including bleeding, during the operation and the possibility of performing it in an outpatient setting. In support of this thesis, Brun et al. performed a comparative analysis of complications after scalpel conization, electroconization, and LLETZ [5]. The lowest incidence of bleeding after LLETZ was 2%, similar to that reported in the present study, while after scalpel and electroconization, it was 8% and 5%, respectively [5]. The measures described above are crucial for reducing the incidence, including bipolar radiofrequency coagulation. Monsel's solution for hemostasis (compression of the wound surface with a swab soaked in Monsol's solution) has been

the subject of several studies [6-9]. According to one of them, Monsel's solution reduces the risk of postoperative bleeding after LLETZ but does not prevent the occurrence of severe intra- or postoperative bleeding. The authors of this study concluded that its routine application after cauterization of the resection surface was unnecessary [6]. Another randomized study compared Monsel's solution to spherical electrode coagulation in bleeding control during and after LLETZ without distinguishing between the two methods [7]. Martin-Hirsch PP et al. analyzed different approaches to limit cervical bleeding after cervical intraepithelial neoplasia (CIN) surgery [10]. According to them, combining adrenaline with a local anesthetic has an excellent hemostatic effect, in contrast to hemostatic sutures, which lead to cervical stenosis and unsatisfactory colposcopy. The use of tranexamic acid has a good effect on scalpel and laser conization to prevent secondary bleeding. However, it does not reduce the risk of primary bleeding and blood loss [10].

Postoperative pain

Reporting pain in the follow-up period after the LLETZ procedure required NSAIDs analgesia (Dexofen sachet p.o.), which proved necessary for 6 of 189 patients (3.1%). Therefore, local anesthesia provides a smooth and painless operation and adequate analgesia in the postoperative period. Similar results have been reported by other authors [4].

Postoperative stay

The postoperative stay of patients after the LLETZ procedure was 1 hour for local anesthesia cases (182 of 189 patients) and 4 hours – for cases of venous anesthesia (7 of 189 patients). The primary purpose of monitoring in the postoperative period was analgesia, if necessary, and monitoring for postoperative bleeding. The length of the postoperative stay proves that the LLETZ procedure is suitable for use on an outpatient basis.

Early postoperative complications

They are defined as complications occurring up to 1 month after the procedure, e.g., bleeding from the surgical wound and infection of the wound surface of the cervix. We observed

bleeding from the operative wound in 2 of 189 patients (1%). The bleeding was due to non-compliance with the postoperative recommendations (weight lifting or physical labor). According to the algorithm described above, its treatment is radiofrequency bipolar coagulation (in a bleeding vessel), surgical (in diffuse bleeding), and tamponade as a last resort. The incidence reported in the literature for postoperative bleeding ranges from 2% to 23.9% [2,5]. In the present study, the low incidence of intra- and postoperative bleeding was due to the characteristics of the loops used (thickness and strength) and the mode of simultaneous cutting and coagulation of the generator. This approach ensured a bloodless operation, although it took longer, leading to frequent thermocoagulation changes in the cone. During the procedure, a large amount of smoke was released, which had to be aspirated with a powerful smoke evacuation device to avoid interrupting the operator's eye contact with the operating field.

Infection of the wound surface, clinically manifested by the appearance of purulent fluoride with a foul odor, was found in 1 of 189 patients (0.5%). The low frequency was due to preoperative preparation of vaginal secretions and postoperative antibiotic administration. Some authors have reported an incidence of 0.8% to 14% [11] due to this complication after LLETZ. However, a series of patients with a 28% incidence of wound infection have been described in the literature [2].

Late postoperative complications

They include cervical canal stenosis, inadequate colposcopy, incomplete epithelialization, and spotting before menstruation. Such complications are reported by the patient or detected at the first follow-up examination after LLETZ.

Cervical stenosis was found in 4 of 189 patients (2.1%). It is defined as making it difficult or impossible to take cytology from the cervical canal. It occurs in menopausal patients and cases of deep excision of the cervical canal (more than 2 cm). Cervical stenosis is one of the complications and adverse effects of surgical interventions used to treat cervical precancers. It makes cytology impossible or very painful, and thus the follow-up of patients with high-grade precancerous lesions and carcinoma

colli uteri in situ becomes risky and unreliable. Therefore, hysterectomy is recommended in postmenopausal patients diagnosed with HSIL and carcinoma colli uteri in situ after LLETZ. It can lead to dysmenorrhea, oligomenorrhea, and primary or secondary infertility in young women. Therefore, in young women with incomplete reproductive functions and high-grade endocervical lesions, compromise in radicality (concerning the cone tip) is an option to avoid this complication. Different surgical techniques lead to different incidences of cervical stenosis. According to one study, electroconization leads to stenosis in 27% of cases, scalpel conization in 8%, and LLETZ in 3% [5]. El-Nashar et al. found that the LLETZ procedure was less likely to lead to cervical stenosis than scalpel conization [12]. Baldauf et al. compared the LLETZ procedure with another surgical technique for treating cervical precancerous lesions, i.e., laser conization concerning the occurrence of postoperative stenosis. The study was large, including 277 patients undergoing LLETZ and 255 – laser conization. The authors identified the factors leading to stenosis: age > 50 years, endocervical lesion, and the height of the removed cone > 2 cm. Laser conization led to stenosis in 10.2%, while LLETZ – in 4.3% of the cases [13,14]. In addition, according to the authors, plastic surgical treatment of stenosis led to re-stenosis in most cases. Lin et al. offered dilatation of the cervical canal at 3, 5, and 8 weeks following the LLETZ procedure to prevent cervical stenosis [15].

Inadequate colposcopy was reported in 15 of the 189 patients (7.9%). Oncolposcopy, the boundary between the simple columnar epithelium and stratified squamous epithelium had entered the cervical canal and remained unevaluated in these cases. Follow-up for these patients was based on endocervical cytology, especially the COBAS test.

Incomplete epithelialization was found in 10 of 189 patients (5.3%). During colposcopy, it was found that the wound surface was not covered with multilayered squamous epithelium and looked like a “red spot” (erythroplakia). According to some studies, 90% of the wound surface regenerates in 6 months [16, 17].

Pre-cycle spotting was reported as a complication in 11 of 189 patients (5.8%). It

is usually due to easily bleeding vessels at the cervix site where the electrical loop had passed (Fig. 3). It is not considered a complication, though it is one of the reported consequences of the LLETZ procedure that tends to decrease and disappear over time. If this condition was of great concern to the patient, cryodestruction or CO2 laser vaporization was recommended.

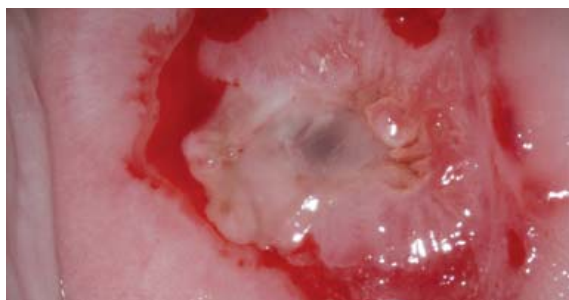


Figure 3. Bleeding vessels from the loop with which LLETZ was performed

Conclusion

The LLETZ procedure is applicable in outpatient practice with a low incidence of intra- and postoperative complications and minimum stay. Two main factors determine its cost-effectiveness in outpatient practice: the use of local anesthesia instead of general anesthesia, which requires an anesthesiologist, anesthesiology nurse, anesthetic for short-term venous anesthesia, and the daily cost for an occupied bed – a financial factor in hospital care versus the lack of daily cost per occupied bed in outpatient care.

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