Loop Electrosurgical Excisional Procedure

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Loop electrosurgical excisional procedure, or LEEP, also known as loop diathermy treatment, loop excision of the transformation zone (LETZ), and large loop excision of the transformation zone (LLETZ), is a new technique for outpatient diagnosis and treatment of dysplastic cervical lesions. This procedure produces good specimens for cytologic evaluation, carries a low risk of affecting childbearing ability, and is likely to replace cryotherapy or laser treatment for cervical neoplasias. LEEP uses low-current, high-frequency electrical generators and thin stainless steel or tungsten loops to excise either lesions or the entire transformation zone. Complication rates are comparable to cryotherapy or laser treatment methods and include bleeding, incomplete removal of the lesion, and cervical stenosis. Compared with other methods, the advantages of LEEP include: removal of abnormal tissue in a manner permitting cytologic study, low cost, ease of acquiring necessary skills, and the ability to treat lesions with fewer visits. Patient acceptance of the procedure is high. Widespread use of LEEP by family physicians can be expected.

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The prevalence of premalignant cervical lesions is increasing in the United States.[1] This problem usually occurs in women of childbearing years.[1–5] Until recently, the choices for treatment of dysplastic cervical lesions included cryosurgery, electrocoagulation, laser vaporization or conization, knife conization, and hysterectomy. The first three are outpatient procedures and allow for the possibility of future pregnancies. Since these are ablative therapies, no tissue is sent for histologic inspection, however, thus raising the possibility of missing microinvasive or invasive cancer. Conization and hysterectomy produce tissue specimens with wide margins but require hospitalization with general anesthesia, and hysterectomy precludes future pregnancies. These latter procedures require considerable skill.

Recently, low-voltage, high-frequency, thin wire loop electrodes have been used to remove cervical lesions. The loop electrosurgical excisional procedure (LEEP) allows for outpatient treatment of cervical lesions that yields good specimens for pathologic evaluation and has a low risk of affecting childbearing ability.[6]

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Background

It is now generally accepted that all women who are sexually active or have reached 18 years of age should be followed with regular Pap smears to screen for squamous cell neoplasia of the cervix.[7] Colposcopy is performed when cytology indicates a squamous intraepithelial lesion (SIL) or possible invasive disease. If the entire transformation zone is adequately examined and biopsy confirms SIL, the lesions are usually ablated with cryotherapy or laser vaporization. Microinvasive disease is usually treated with conization or hysterectomy; invasive disease requires hysterectomy.

Physicians have experimented with high-frequency current for excisions since the 1940s. It was not until the mid-1960s in France, however, that Cartier began using small loops for biopsies and excisions to confirm SIL.[8,9] Prendiville experimented with larger loops with insulated crossbars and published his first paper on large loop excision of the transformation zone in 1989.[4] Since then, the procedure has become widely accepted throughout Europe.[9] The availability of modern high-frequency generators has accelerated the use of LEEP recently. Pioneers of LEEP in family practice include Eugene Felmar, who studied under Dr Cartier, and Drs Apgar, Wright, and Pfenninger.[10]

Loop electrosurgical excisional procedure has historically been called diathermy loop treatment, loop excision of the transformation zone (LETZ), and large

loop excision of the transformation zone (LLETZ), and these terms can still be found in the literature. Although several names are still in use, loop electrosurgical excisional procedure (LEEP) is becoming the preferred term in the United States.

LEEP makes use of low voltage and relatively high-frequency electric current. As the loop is introduced to the tissue, an arc occurs near the point of contact, rapidly heating the cells and causing them to explode into steam. The current is quickly dispersed to the grounding electrode without further tissue damage. This produces a clean cut with little coagulation artifact. The lesion (for diagnostic purposes) or entire transformation zone (for treatment purposes) can thus be removed, yielding a good specimen for pathologic evaluation. In the coagulation mode fulguration of tissue is produced with short bursts of high-peak voltage current. This mode is often used with a ball electrode to achieve hemostasis. Most modern units can combine the amount of cutting and coagulation currents in "blend modes."

Originally LEEP was performed using small loops (5 × 5 mm), but these required multiple passes to remove large lesions, which damaged the tissue specimens. As experience and equipment improved, larger loops and blending of cutting and coagulation currents were introduced and have become accepted practice.

Efficacy and patient acceptance of LEEP compare favorably with other methods of treatment. Studies indicate that LEEP is 90% to 98% effective in treating SILs.[2–4,11,12] This compares with 81% to 95% for cryosurgery,[13–19] and 91% to 94% for laser.[8,20] LEEP is also a well-tolerated procedure, with 85% of patients reporting no discomfort. Most patients who do report discomfort indicate that the degree of pain is mild.[3,8] Pregnancy rates after LEEP are comparable to laser therapy and better than rates for conization.[6]

For these reasons, LEEP is gaining acceptance in the United States.[21] The procedure is relatively simple, and the skills required to perform LEEP can be easily learned by family physicians who are proficient in colposcopy.

Materials

Electrosurgical generators used for LEEP are identical to ones used in laparoscopic and urologic surgery. The alternating current output ranges between 100 and 4000 KHz. At frequencies of greater than 100 KHz, cellular membrane depolarization does not occur, so there is no associated shock or muscular contraction. The relative cutting power is proportional to the amount of current measured in watts.

Most loops have an insulated shaft and crossbar to prevent accidental thermal injury. Common loop sizes range from 1 × 1 cm to 2.0 × 1.5 cm (Figure 1). The stainless steel or tungsten wire of the loop is approximately 0.2-mm thick. Ball electrodes ranging from 3 mm to 5 mm are used for fulguration. The probe is a monopolar output, and requires the use of a ground electrode pad. A pad's large area disperses the current so that no injury or discomfort occurs.

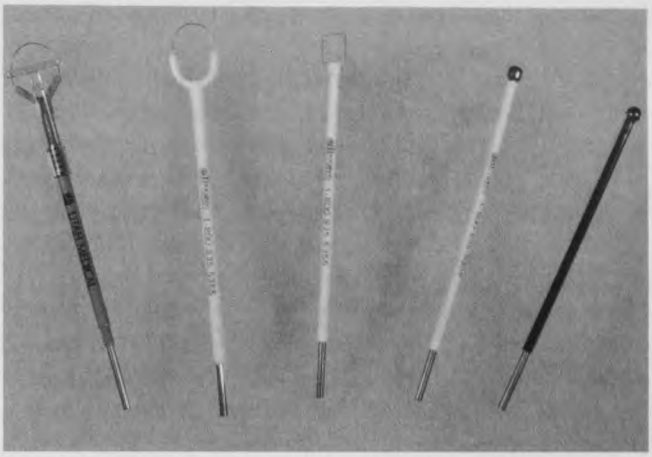

Figure 1. Typical LEEP loops and ball electrodes. The first two loops on the left are for biopsy or transition zone removal, the middle loop is used for deeper excision of the cervical os in LEEP cones, and the two ball electrodes are used for fulguration.

Smoke evacuators consisting of suction devices with filters are used to eliminate the steam or smoke generated during the procedure. Often the smoke evacuator is a separate unit, but some LEEP units now have them built in. Operators should use submicron particle masks because live virus particles have been found in similar plumes from lasers.[22]

Technique

The cervix is first evaluated colposcopically with a 5% acetic acid solution. Lugol's solution may also be applied to aid in visualizing the lesion, especially if intracervical anesthesia is used. A return electrode is attached to the patient (usually a disposable adherent grounding pad placed on the upper leg). Anesthesia is obtained with 2 to 10 mL of 1% to 2% lidocaine with 1:200,000 epinephrine. The lidocaine can be applied perilesionally, intracervically in each quadrant of the cervix, or in a pericervical block at the 3 o'clock and 9 o'clock positions.

For treatment of SIL lesions, a loop should be chosen to allow excision of the entire transformation zone in one or two passes without major risk of contact to the vaginal side wall. A plastic or coated speculum is

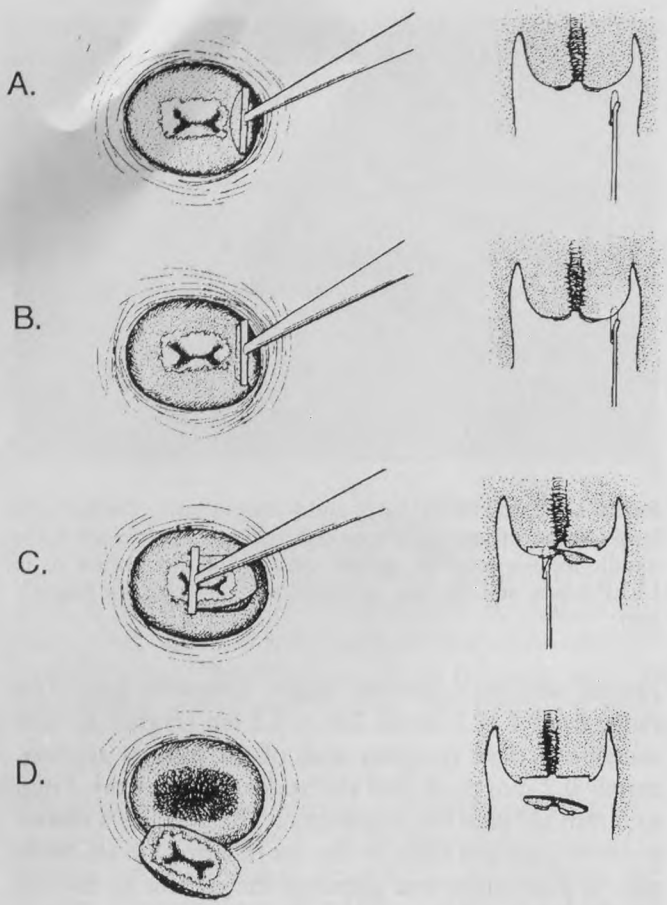

Figure 2. LEEP Procedure. A. Current is applied before the loop touches the cervix. B. The loop is introduced and moved perpendicularly. C. The cut is made in one smooth continuous motion. D. A specimen for histology is produced.

recommended because contact with a metal speculum will cause discomfort (but usually no burn because of the large surface area). The amount of current used depends on the generator and the loop size. A blend mode is most commonly used for cutting, with a setting of 35 to 55 watts. A coagulation setting of 40 to 55 watts is typical.

The loop is attached to a pencil-shaped base that is controlled with a finger switch or foot switch. To excise tissue, the loop is placed a few millimeters above the cervix and about 5 mm lateral to the lesion or edge of the transformation zone. Current is applied before the loop contacts the cervix. If current is applied after contact is made, significant thermal injury will occur and the quality of the cut will be poor. The loop is pushed into the tissue to a depth of 5 to 8 mm. Then it is drawn slowly through the tissue until the loop is approximately 5 mm past the edge of the transformation zone. It is then removed perpendicularly (Figure 2). The average cutting time is approximately 5 to 10 seconds. The excision should be done in a single, smooth motion using continuous current. Stopping the current before the excision is completed causes extensive thermal injury and may damage the loop. Many practitioners apply superficial fulguration to the entire crater. Monsel's solution may also be applied to the bed and may reduce late bleeding.[12] This usually produces excellent hemostasis.

LEEP conization (also known as the "cowboy hat" procedure) can be used when a lesion extends into the endocervical canal. The cervix is anesthetized as above, except that if intracervical anesthesia is used, an additional 0.5 to 2 mL of lidocaine is infiltrated at 6 o'clock and 12 o'clock around the os to a depth of approximately 1 cm. The external os and distal endocervical canal can be excised to 9 to 10 mm, usually with a 10 mm × 10 mm loop or square electrode. The rest of the transformation zone can then be excised in the usual manner. Some physicians advocate removing the external transformation zone first and then excising the os. With either method, the result is similar to a cold knife conization performed in the operating room.

Patients should be instructed to refrain from sexual intercourse, douching, or tampon use for 2 to 4 weeks. A discharge can be expected for 2 to 3 weeks, and may last up to 6 weeks. The patient should report any significant bleeding. A follow-up Pap smear with or without colposcopy should be scheduled for 4 to 6 months.

Indications for Treatment

The indications for LEEP treatment of exocervical lesions are the same as for cryotherapy. Any biopsy-proven CIN lesion can be treated with LEEP. Note that human papillomavirus (HPV) infection without evidence of dysplasia should not be treated with LEEP.[10]

Some centers are performing LEEP conizations for diagnosis and treatment of lesions that extend into the cervical canal, when the colposcopy is inadequate, or when the endocervical curettage is positive. Some physicians are also using LEEP conization for microinvasive disease, but this is not generally accepted at present.

General contraindications include clinically apparent invasive carcinoma, bleeding disorders, and pregnancy (except possibly with highly experienced practitioners).

Complications

Burns are always a possibility when working with electric current. Burns in the vaginal vault are usually due to poor visualization or operator inexperience. There is also a risk of burns through alternate grounding sites or under the pad owing to poor return electrode contact. Most of the

last two types have been eliminated with modern return electrode monitoring that cuts off the current to the loop if normal grounding is disrupted.

When excising the transformation zone with the LEEP procedure, perioperative bleeding is rare, especially with the use of fulguration or Monsel's solution.[3,4,8] Bleeding is significantly less than with laser therapy.[8] Significant late bleeding has also been reported in 4.3% of patients who had LEEP therapy.[3,4,8,11,12,23] Most did not require hospitalization and were treated with vaginal packing or suturing. This compares well with bleeding rates for laser therapy, which range from 1.5% to 7%,[6,20,24,25] and for cryotherapy, which are usually less than 1%.[15] Infection has also been reported in 0.5% to 2% of patients.[4,24]

Incomplete removal of the lesion when excising the transformation zone is another potential risk. Positive margins have been reported in up to 15% of patients.[23] There are some data that indicate the recurrence rate in patients with positive margins is low (around 25%), possibly owing to the fulguration of the bed after excision.[23]

LEEP conization has been found to have a higher complication rate than LEEP excision of the transformation zone. Perioperative bleeding has been observed in 0% to 2% of patients. Late bleeding has been reported in 6% to 14% of patients treated with LEEP conization.[23,24] This correlates with early LEEP studies that showed that bleeding rates were higher with deeper excisions.[3]

A less common complication found in larger studies was cervical stenosis (0.5% to 1.3% of cases), which was found mainly in patients with deep removal of extensive lesions.[3,12] Incompetent cervix and sterility are included in informed consent by some practitioners for theoretical reasons, but there are no published clinical data to support this, and we do not include them. Most experts feel cold knife cone or laser cone is preferable to LEEP in known microinvasive or invasive disease. LEEP is contraindicated in invasive disease, and its safety in pregnancy has not been established.

Advantages

A major advantage of LEEP is the removal of abnormal tissue while providing an adequate specimen for pathologic study. Confirming complete removal of the lesion by observing specimen margins essentially eliminates the risk of missing microinvasive cancers. In spite of the removal of tissue, the transformation zone heals, leaving a normal appearance in the vast majority of patients that allows for normal long-term cytologic and colposcopic follow-up.[3]

LEEP also offers the advantage of being an outpatient procedure performed under local anesthesia. Treatment of even advanced lesions can be accomplished with the complete removal of the transformation zone. This result is comparable to knife conization as described by several authors.[3,4,8,11,23,24]

Several studies show that colposcopy-directed biopsy may underestimate the severity of cervical lesions between 14% and 25.5% of the time when compared with LEEP specimens.[2,5,26–28] There is also evidence that microinvasive carcinoma has been missed on directed biopsy[2,4,5,29,30] and ablative therapies.[14,24,31,32] Underestimation of severity can lead to improper use of simple ablative therapy with the possibility of not eradicating the cancer. LEEP virtually eliminates this risk because it allows for histologic examination and complete removal of the tissue. It is comparable to laser conization for removal of tissue.[33]

Cost is another major consideration. The LEEP unit usually costs $3000 to $7500. This expense is much less than laser equipment (between $50,000 and $80,000).[21] The cost of maintaining laser equipment may exceed $5000 per year. LEEP also saves the costs of hospitalization and anesthesia in some cases. By improving diagnostic accuracy, LEEP may avoid the human loss and financial costs incurred when microinvasive cancer is not detected.

Diagnostic-Therapeutic LEEP

A final but important advantage is that some patients can be diagnosed and treated in a single visit. The so-called diagnostic-therapeutic LEEP or DT-LEEP (also known as "see and treat") may offer several advantages over therapeutic LEEP (T-LEEP) after directed colposcopic biopsy. It is indicated only in patients with evidence of dysplasia (not isolated HPV lesions) on Pap smear cytology with visible colposcopic lesions. It should not be used when colposcopic findings are equivocable or suggestive of invasive cancer. The diagnosis and therapy can be done in one clinic visit with one pelvic examination. This approach eliminates the need for the patient to return for the results of directed biopsy before receiving treatment. DT-LEEP can decrease patient discomfort, the number of visits, cost, and perhaps most important, the number of patients lost to follow-up who do not receive treatment and thus increase their risk of cancer. Patient anxiety while awaiting laboratory results and anticipating treatment may also be eliminated with DT-LEEP.

Bigrigg et al[11] studied DT-LEEP in 1000 patients. They found a high level of patient acceptance. Their complication rate was low (0.6% had bleeding) and they found five cases of unsuspected microinvasive cervical cancer. They found the procedure was both clinically effective and cost-effective. They also noted that "all patients treated in a single visit preferred this approach to the alternative." Other researchers have had similar experience.[8,34]

The major concern with this approach is that the procedure may be performed on patients who do not need it. Approximately 10% to 22% of patients could be treated unnecessarily (including HPV lesions without a SIL).[2,3,35] The morbidity and mortality from the possibility of missing more advanced disease (3% in the first study) must be weighed against the potential morbidity of the procedure, which has been shown to be low. Also, attention must be given to the fact that some studies show a poor correlation between directed biopsy and abnormal histologic findings, which is eliminated with DT-LEEP. The psychological impact on the woman and her family of having continuing abnormal findings and the ensuing anxiety this provokes must be taken into account.[35]

Implications for Family Practice

With the low cost of equipment and the ease of mastery, LEEP should be an excellent procedure for the practicing family physician. Basic technique can be taught in a conference setting in 1 day, and this training could be incorporated into existing colposcopy workshops for family physicians. With a relatively low cost for a state-of-the-art LEEP unit, it is cost-effective for even infrequent use.

It is also possible that widespread use of LEEP will result in a higher standard of care for patients. It can allow for fewer visits to work up and treat cervical lesions, and can lower the danger of patients being lost to follow-up. The risk of missing microinvasive disease and incomplete excision of lesions can also be decreased. LEEP conization requires little additional training, is safe, and allows for outpatient treatment of patients with inadequate colposcopies. Patients can also benefit from being able to get their care from their own family physician. Continuity of care can thus be increased for these patients, and the costs can be controlled.

The field of LEEP treatment of cervical dysplasia is still developing. The American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists have not as yet taken a stand on the use of LEEP in clinical practice. When they do, it could change the patterns of LEEP use in the future. Some family medicine residencies are starting to incorporate LEEP training into their colposcopy training. The AAFP and family medicine residency programs will need to support teaching efforts in the future if widespread training is to be available.

Conclusions

LEEP is a new diagnostic and therapeutic modality for the treatment of SILs. The low cost of setup and ease of use lends itself well to use by family physicians. Patient acceptance of the procedure is high, and cure rates and complication rates are comparable to those of similar treatment methods. Widespread use of LEEP by family physicians can be expected in the future.

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