

## TO STUDY THE EFFICACY OF LOOP ELECTROSURGICAL EXCISIONAL PROCEDURE (LEEP) IN THE MANAGEMENT OF PRECANCEROUS CERVICAL LESIONS IN LOW RESOURCE SETTINGS

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### ABSTRACT

#### BACKGROUND

Large Loop Excision of the Transformation Zone (LLETZ) is a simple outpatient excisional procedure for transformation zone (TZ) of the cervix. Carcinoma in situ is the forerunner of invasive carcinoma of the cervix. Process of carcinogenesis starts at the transformation zone (TZ). LEEP is used for management of cervical intraepithelial neoplasia (CIN). It is a diagnostic and therapeutic procedure.

Objective- To study the efficacy of LEEP in the management of precancerous cervical lesions in low resource settings.

#### MATERIALS & METHODS

This study was done by performing Liquid Based Cytology (LBC) on 483 patients who attended the OPD of Obstetrics & Gynaecology Department in Rama Medical College, out of which 58 patients who had precancerous lesions on LBC underwent LEEP.

#### RESULTS

The incidence of pre-invasive cervical lesions in our study was 12%. The mean duration of the surgical procedure was 15±3 minutes. The only significant early post-surgical complication was bleeding which occurred in 2 patients. There were significant changes in the histopathological findings after LEEP.

#### CONCLUSION

LEEP is proved to be an effective management for the treatment of precancerous cervical lesions at our setting with minimal complications needing little training skills.

#### KEYWORDS

Cervical Cancer, LEEP (Loop Electrosurgical Excisional Procedure), Premalignant Lesions, Transformation Zone (TZ), Liquid Based Cytology (LBC).

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#### BACKGROUND

Cervical cancer is the commonest cancer cause of death among women with 86% of all the cervical cancer deaths occurring in developing countries.<sup>(1,2,3)</sup> Every year in India, 122,844 females are diagnosed with cervical cancer and 67,477 die from the disease.<sup>(4)</sup>

It is the second most common cancer in women aged 15-44 Years.<sup>(4)</sup>

The unique accessibility of the cervix to direct visual inspection & the longstanding nature of the premalignant lesions of cervix make carcinoma cervix a preventable disease. Several screening programs have been developed

that aim at detection of precancerous cervical lesions along with institution of effective treatment.

Various modalities of treatment have been evolved for regression of premalignant lesions. Ablative methods like cryotherapy, electrocautery, cold coagulation and electrocoagulation diathermy rely on accurate colposcopically directed biopsy diagnosis, because no tissue is available for histopathological confirmation & therefore are only therapeutic. On the other hand, excisional procedures like LEEP and Cone Biopsy are both diagnostic & therapeutic. LEEP [also known as large loop excision of the transformation zone (LLETZ)], utilises a thin electric wire to remove the entire transformation zone of the cervix.

A loop is a very thin stainless steel wire of 2-3 cm used for excision of transformation zone with blended current, (cutting & coagulation) with low voltage output is used, tissue up to the depth of 10 mm or more can be removed. Lesion must be localised by colposcopy and an appropriate size of loop should be selected. If ectocervical margin of excision is positive, repeat excision can be performed easily. If endocervical margin is positive for CIN, followup with cytology using Cytobrush or endocervical curettage is required.

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The present study aimed to evaluate the effectiveness of LEEP in treatment of various degrees of cervical dysplasias.

**MATERIALS & METHODS**

This was a prospective study conducted at the Department of Obstetrics and Gynaecology at Rama Medical College and Research Centre, Mandhana, Kanpur from September 2014 to March 2016. Total number of subjects included in the study were 58 out of 483 attending the OPD, who presented with one or more of following complaints of unhealthy discharge, intermenstrual or postcoital bleeding along with unhealthy or hypertrophied cervix on per-speculum examination. Exclusion criteria were pregnant females, age >65 or <18 years, unmarried females, and females who have had hysterectomy or did not give consent for the study. All 483 cases were screened for dysplasia using Liquid Based Cytology out of which 58 cases were selected for colposcopic examination on the basis of cervical cytology with CIN II in 23 patients, CIN III 14 patients and persistent CIN-I in 21 patients (even after 1 year of followup) (Table 1). Colposcopic grading was done using the newly introduced Swede score. Strander et al has devised a new scoring system, the Swede score, which includes lesion size as a variable. Swede Score of 8 or more had a sensitivity, specificity, positive and negative predictive values of 38%, 95%, 83% and 70% respectively for lesions where the final diagnosis was CIN II or higher.<sup>[5]</sup> The Swede score evaluation of scoring system was designed to improve the predictive value of colposcopy. All 58 cases were also subjected to human papillomavirus testing & HIV testing after proper voluntary counselling & testing.

LEEP was performed under local anaesthesia (Paracervical block), patients were put in dorsal lithotomy position and insulated Cusco’s speculum was used to spread apart the vaginal wall for proper visualisation of the cervix. Colposcopy was used to magnify the cervix during the surgery & tissue sent for histopathological examination. Roller ball was used to achieve haemostasis after the procedure followed by vaginal packing which was removed at the time of discharge. All cases were followed at 3 and 6 months using cytology and colposcopy to detect the presence or absence of residual or recurrent disease.

**RESULTS**

The incidence of pre-invasive cervical lesions at our institution was 12% (58/483), majority of the patients with high grade cervical lesions belong to lower socioeconomic group with higher parity (Table 2). In our study, human immunodeficiency virus (HIV) seropositivity was found in 8.62% (5/58), and HPV positivity was seen in 88% (51/58) of cases especially with high grade lesions. The mean duration of the surgical procedure and hospital stay were 15±3 minutes and 12±4 hours respectively. This reflects that LEEP is a relatively easier procedure which can be easily skilled by the physicians for the treatment of precancerous cervical lesions. Complete cervical wound healing was achieved in all the patients during the three month followup period. The only significant complication was early post-operative bleeding which was managed conservatively (Table 4).

Post-operative histology of 58 patients who under gone for LEEP revealed that out of 21 patients with CIN I in cytology, only 11 patients had mild dysplasia & 8 patients had

only chronic cervicitis without dysplasia after LEEP. 2 patients of CIN I shifted to CIN II, out of 23 patient of CIN II in cytology, 2 shifted to CIN III and 1 patient of CIN II shifted to microinvasive carcinoma, now 22 patients shows CIN II features. Out of 14 patients of CIN III in cytology, 3 patients shifted to microinvasive stage, now 13 patients show CIN III features and microinvasive carcinoma was present in 4 patients after LEEP (Table 3).

	No. of Pts.	%
Persistent CIN I	21	36.21%
CIN II	23	39.65%
CIN III	14	24.13%
<b>Total</b>	<b>58</b>	<b>100%</b>

**Table 1. Patients According to Distribution of Liquid Based Cytology CIN treated by LEEP**

This table shows the distribution of patients according to their histological findings of cervical smear by liquid based cytology, out of 58 patients, 21 patients showed persistent CIN I, 23 patients showed CIN II and 14 patients showed CIN III features.

Persistent CIN I	CIN II	CIN III
N=21	N=23	N=14

**Table 2. Sociodemographic Profile of the Patients with Pre-Invasive Cervical Precursors**

Parity			
PI	2 (3.44%)		
P2	8 (13.79%)	13 (22.41%)	5 (8.62%)
≥P3	11 (18.96%)	10 (17.24%)	9 (15.51%)

**Table A**

Age			
20-30 Years	6 (10.34%)	5 (8.62%)	
31-40 Years	12 (20.68%)	11 (18.96%)	6 (10.34%)
41-50 Years	3 (5.17%)	7 (12.06%)	8 (13.79%)

**Table B**

Socioeconomic Status			
Lower	14 (24.13%)	19 (32.75%)	10 (17.24%)
Middle	5 (8.62%)	3 (5.17%)	4 (6.89%)
Upper	2 (3.44%)	1 (1.72%)	--

**Table C**

HIV Seropositivity		3 (5.17%)	2 (3.44%)
HPV Seropositivity	16 (27.58%)	21 (36.20%)	14 (24.13%)

**Table D**

**This Table Shows the Distribution of Patients in Grades of Neoplasia According to their-**

- A. **Parity-** Mild dysplasia was present in low parity, high grade dysplasia was seen more in high parity females.
- B. **Age-** Low grade dysplasia was seen more in 20-30 years of age & high grade dysplasia was seen more in 30-50 years of age.
- C. **Socioeconomic Status-** High grade dysplasia was more seen in lower socioeconomic status & low grade dysplasia was more seen in higher socioeconomic status.

- D. **HIV & HPV Seropositivity-** 5 patients were found to be HIV positive and 51 patients were HPV Positive.

Grade	n	%
Cervicitis without dysplasia	8	13.79%
CIN I	11	18.96%
CIN II	22	37.93%
CIN III	13	22.41%
Micro Invasive Car	4	6.89%

**Table 3. Distribution of Patients with respects to Post-operative Histology Patient treated by LEEP; N=58 Post-operative Histology**

This table shows the histological changes in cytology of cervical smear after LEEP, out of 58 patients, 8 patients showed normal cytology with no dysplasia, 11 patients showed CIN I features, 22 patients showed CIN II and 13 patients showed CIN III features, 4 patients were presented with microinvasive carcinoma.

Complications	N	%
Early postop bleeding	2	3.44%
Pelvic Inflammatory disease	1	1.72%
Cervical Stenosis	1	1.72%
Residual Disease	Nil	0%

**Table 4. Complication of LEEP**

This table shows the complications of LEEP, most important early post-operative complication was bleeding per vaginum in 3.44% of patients, PID was seen in 1.72% and cervical stenosis was seen in 1.72% of patients.

## DISCUSSION

Majority of the patients who underwent LEEP in our series were in the age group of 30-40 Years (Table 2), which was slightly lower than the other studies,<sup>(5,6,7,8)</sup> this difference might be due to early age of marriage & completion of family at an early age in our country, predisposing the patients to development of precancerous cervical lesions at an early age. In our series, majority of the patients belonged to lower socioeconomic group. A meta-analysis of social inequality and the risk of cervical cancer showed a 100% increased risk in the low social class categories for the development of invasive cervical cancer.<sup>(9)</sup>

Human Papilloma Virus (HPV) prevalence among cervical cancer patients in India has varied from 87.8% to 96.67%.<sup>(10,11,12,13)</sup> Our study also showed a strong correlation between HPV seropositivity for 16 & 18 and pre-invasive cervical lesions in 88% cases.

HIV infection was seen in 8.62% of patients in our study. Several studies have found that HIV infected females are at higher risk of cervical precancerous lesions than those without infection with Odds Ratio (OR) in the range of 4.1 to 11.<sup>(14,15)</sup> Indeed it is thought that the immune impairment due to HIV infection will lead to the persistence of HPV infection which increases the risk of precancerous lesions of the cervix.<sup>(16)</sup> The mean duration of the surgical procedure in our study was 15±3 minutes and the duration of hospital stay

was 12±4 hours, which was comparatively similar to the study conducted by Ngowa et al.

The study showed that there was change in the severity of dysplasia obtained after LEEP preceded by colposcopy when as compared to cytology alone as 4 patients were identified to have microinvasive carcinoma which was missed by liquid based cytology (LBC) alone. Also 8 were identified to have only chronic cervicitis without any degree of dysplasia after LEEP. Excisional treatment methods such as LEEP have the advantage of providing tissue specimens for histopathological diagnosis thereby reducing the possibility of incomplete eradication of precancerous cells.

The limitation of this study was the small sample size which constitutes a selection bias. However, the merit of this study was to provide an idea about the feasibility of the treatment of CIN by LEEP in low resource settings.

Complication rate in our study was 6.8% but no residual disease was observed at 3 & 6 months followup. The rate of early postoperative bleeding was 3.4% in our study which was similar to the 4.9% & 5.4% reported by other authors.<sup>(17,18)</sup>

In developed countries, management of precancerous cervical lesions has shifted from use of inpatient surgical methods to use of outpatient approaches. In developing countries; however, clinicians still opt aggressive approaches such as conization or hysterectomy, therefore LEEP has been introduced as an outpatient procedure which can successfully be done in our settings.

## CONCLUSION

From our study we conclude that LEEP is a simple, feasible & effective management strategy for treatment of precancerous cervical lesions as it has both diagnostic & therapeutic importance. It may be considered as a suitable alternative to cold knife conization or hysterectomy for younger females who are yet to complete their families. However, adequate training is essential to ensure proper treatment.

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