Original Article

Evaluation of 'See and Treat' Policy by Loop Electrosurgical Excision Procedure (LEEP) in Treating Cervical Intraepithelial Neoplasia (CIN)

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Abstract

Background: *Cervical intraepithelial neoplasia (CIN) is a pre-cancerous lesion of uterine cervix. "See and treat policy of CIN" – is a one-step procedure where evaluation and treatment of CIN cases are performed at the same sitting. In this policy, screen positive patients are referred to colposcopy and are treated with Loop Electrosurgical Excision Procedure (LEEP) or.* ***Objective:*** *Aim of this study was to evaluate the accuracy of colposcopy in diagnosis of CIN and also to determine the efficacy and safety of LEEP for the treatment of CIN.* ***Materials and methods:*** *This longitudinal study was performed at Obstetrics & Gynaecology department of Sir Salimullah Medical College & Mitford Hospital, Dhaka, Bangladesh, from July 2019 to June 2020. In this study, 30 patients were included according to selection criteria.* ***Results:*** *Most of the participants (50%) were in the 40-49 years old age group. Out of 30 participants, 16 (53.3%) had high grade CIN and 14 (46.7%) had low grade CIN on colposcopy. According to the biopsy report 26.7% had negative result whereas 13.3%, 46.7%, 10.0% and 3.3% had CIN I, CIN II, CIN III and micro invasive cancer respectively. During follow up, colposcopy revealed 93.3% to be normal, 3.3% had inflammation/infection and low-grade CIN each.* ***Conclusion:*** *A single visit approach using VIA, colposcopy followed by LEEP can help to reduce cervical carcinoma in a low resource country like ours though there is possibility of over-treatment in few cases.*

Keywords: *Cervical Intraepithelial Neoplasia; CIN; Loop Electrosurgical Excision Procedure; LEEP; See and Treat Policy.*

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Introduction

Cervical cancer is the most common malignancy in women of our country and a common cause of death due to genital malignancy. Since the introduction of cervical cytology screening with the Papanicolaou test (Pap test), a marked reduction has occurred in the incidence and mortality of cervical cancer.[1] Dysplastic or carcinoma in situ cells are noted in traditional pap smear preparation. Cervical intraepithelial neoplasia (CIN), formerly called dysplasia, means disordered growth and development of the epithelial lining of the cervix. There are various degrees of CIN; mild dysplasia or CIN I, moderate dysplasia or CIN II and severe dysplasia or CIN III.[2.] Colposcopy is in situ examination of the cervix with a low magnification (6-16 times) microscope. It evaluates vaginal part of the surface epithelium and the cervix including entire transformation zone[3].

Colposcopy followed by treatment at the same sitting ("see and treat") is an accepted norm for treating CIN as significant number of patients do not return for biopsy report/treatment. In a 'See and Treat' protocol, VIA positive patients referred for colposcopy can be treated with loop electrosurgical excision procedure (LEEP) during a single visit to the clinic. Especially in an underdeveloped country like ours, 'See and Treat' policy is very much acceptable as the patients with CIN are often dropped out. The strategy has become accepted internationally because of low cost and high compliance to the treatment.[4] Loop electrosurgical excision procedure (LEEP) is safe for evaluation and treatment of CIN with an acceptable and manageable surgical morbidity.[5]

Several factors have been reported to be associated with the prevalence of High-Grade CIN and cancer in general population. These high risk factors are: younger age of marriage that is younger age at the first intercourse, high parity, multiple sexual partners, long term use of oral contraceptive, tobacco smoking, infection of high-risk type of Human Papilloma Virus (HPV) and low cellular immune response.[6-8] The clinical management of CIN I lesions may take one of the following courses: (i) Immediate treatment or (ii) follow up of the women and then treat if the lesion is persistent or progressive after 18 to 24 months. Multiple techniques have been used for the treatment of CIN II and III. These include ablative methods (e.g., cryotherapy, laser vaporization, electrocautery, diathermy and cold coagulation) as well as excisional methods (e.g., LEEP, laser conization and cold knife conization) and hysterectomy[9]. The loop electrosurgical excision procedure (LEEP) is currently one of the most used approaches to treat high grade cervical squamous intraepithelial lesion confirmed on Colposcopy[10]. It is performed by using a wire loop through which an electric current is passed at variable power settings. Various shapes and sizes of loop can be used depending on the size and orientation of the lesion[11]. Electrosurgical current applied to tissues can have three effects on the tissues: desiccation, cutting and fulguration, depending on the power setting and the waveform of the current used. The aim of LEEP is to remove the lesions and the transformation zone entirely and then the retrieved tissue is sent to the histopathological laboratory for examination[12]. This procedure has many advantages including low cost, high success rate and ease of use. The procedure can be done in an office setting and usually requires a local anesthetic[13].

Aim of this study was to evaluate the accuracy of colposcopy in diagnosis of CIN and to determine the efficacy and safety of LEEP for the treatment of CIN.

Materials and methods

This longitudinal study was performed at Obstetrics and Gynecology department of Sir Salimullah Medical College & Mitford Hospital, Dhaka, Bangladesh, from July 2019 to June 2020. Total 30 samples were taken, among whom LEEP were performed. The samples were selected by purposive sampling technique. All cases were diagnosed by colposcopy. Each participant was briefed individually on the study's purpose and procedure. After obtaining informed consent, the women were interviewed by the researcher herself for the purpose of collection of data. The collected data were systematically analyzed using SPSS software. Results were presented as mean ± standard deviation (SD) for quantitative variables and as absolute frequencies and percentages for categorical variables. Comparison was done by Chi-Square test.

The accuracy of colposcopy was evaluated by colposcopy findings with the histopathology report from excised specimen.

The efficacy of LEEP was assessed through histopathology reports, which included grading the severity of CIN and determining whether CIN was present or absent.

Patients' privacy and confidentiality were maintained by giving physical privacy, taking informed written consent and maintaining confidential records.

Results:

In this longitudinal Study, 30 patients were included according to selection criteria. Analyses were done and the result is presented in the following tables and figures.

Table I: Demographic profile or the patients

Age group (years)	Frequency	Percent
30-40	5	16.7
40-49	15	50
>49	10	33.3
Education	**Frequency**	**Percent**
literate	6	20
Primary	12	40
Secondary	8	26.7
Higher secondary and above	4	13.3
Occupation	**Frequency**	**Percent**
Housewife	28	93.3
Service	2	6.7
Monthly family income (in Taka)	**Frequency**	**Percent**
5000-10000	10	33.3
10000-15000	9	30
>15000	11	36.7

Table II: Distribution of patients according to parity

Parity	Frequency	Percent
2	6	20.0
3	5	16.7
>3	19	63.3

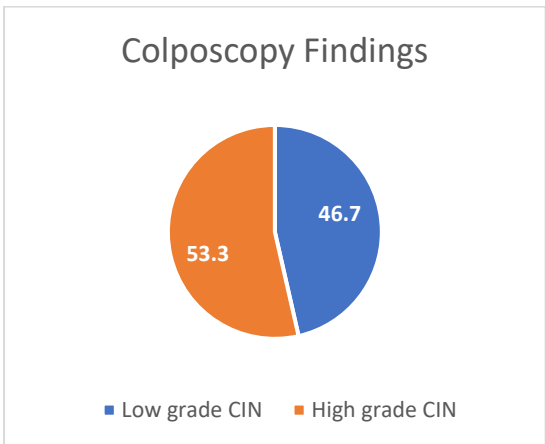

Figure-1: Pie chart for colposcopy findings.

Figure -1 shows colposcopy findings, out of 30 participants, 16 (53.3%) had high grade CIN and 14 (46.7%) had low grade CIN.

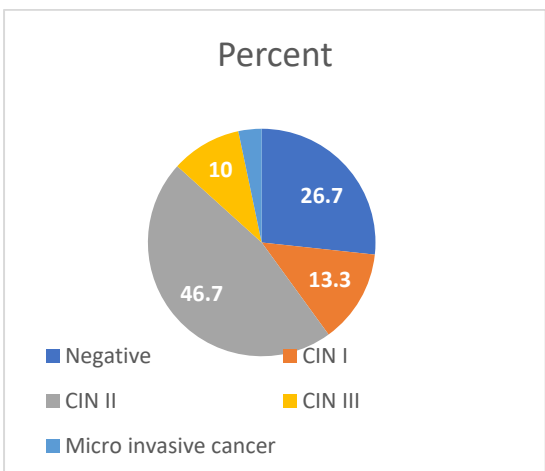

Figure 2: Pie Chart shows patients according to Biopsy Report.

Figure 2 shows the biopsy reports. According to the biopsy reports 26.7% had negative results whereas 13.3%, 46.7%, 10.0% and 3.3% had CIN I, CIN II, CIN III and Micro invasive cancer respectively.

Table-4: Distribution of patients according to post procedure complications of LEEP.

Post procedure complications	Frequency	Percent
No complication	20	66.7
Pain	2	6.7
Vaginal discharge	2	6.7
Vaginal bleeding	4	13.3
Fever	1	3.3
Vaginal discharge & pain	1	3.3
Total	**30**	**100.0**

Most of the patients (66.7%) had no complication. Among the patients who had complications, 13.3% patients had vaginal bleeding while other complications were pain (6.7%), vaginal discharge (6.7%), fever (3.3%) and vaginal discharge with pain (3.3%).

Table-5: Distribution of patients according to Colposcopic findings during follow-up.

Colposcopic findings during follow up	Frequency	Percent
Normal	28	93.3
Inflammation/Infection	1	3.3
Low grade CIN	1	3.3
Total	**30**	**100.0**

During follow up, colposcopy revealed 93.3% as normal, 3.3% inflammation/Infection and low-grade CIN.

Table-6: Association of Colposcopic findings with age group.

Age group (yrs.)	Low grade CIN	High grade CIN	Total	Chi-Square	P Value
30-40	5 (35.7%)	0 (0%)	5 (516.7%)	7.098	.029
40-49	6 (42.9%)	9 (56.2%)	15 (50.0%)		
>49	3 (21.4%)	7 (43.8%)	10 (33.3%)		
Total	**14(100.0%)**	**16 (100.0%)**	**30 (100%)**		

Low grade CIN (42.9%) as well as High grade CIN (56.2%) were highest in the age group of 40-49 years which was significant statistically.

Discussion

Cervical cancer is a major public health problem in many developing countries, and the absolute burden will increase in future if effective prevention measures are not undertaken. Most of the study subjects (50%) were in the age group of 40-49 years. In study by Nessa, conducted in two periods, the mean age (34.2±8.5 and 35.5±9.26 years) of the women was similar in both periods. In that study, 52 (28.7%) were found in <29 year` age group, 89 (49.2%) were in 30-39 years`, 40 (22.1%) were in ≥ 40 years` and 45 (25.4%) were in <29 years` age group, 74 (41.8%) were in 30-39 years`, 58(32.8%) were in ≥ 40 years` in respective period[14]. In another study by Kirby TO was done including 26 women were aged 30-59 years` group, 28 women were aged 20-70 years` group, the mean age of the patients were 26 years`(range 19-45 years`)[15]. All are consistent to the present study. In this study, about forty percent of patients completed primary education. Majority of the participants (93.3%) were housewives. More than one third of patients had monthly family income above 15000 taka. In another study by Nessa, illiterate was 33 (18.2%) and completed primary education were 84 (46.4%) and secondary education and above 64 (35.4). About occupation, Housewives were 166 (91.7%). Regarding Monthly family income, 36 (19.9%) had monthly income 10000 taka[14]. All those were like this study. More than fifty percent of patients had the history of first coitus before the

age of 15 years. Majority of the patients (63.3%) were married for more than 29 years group followed by 20% for 10-19 years group and 16.7% for 20-29 years group respectively. In the study by Nessa was found that 59 (32.6%) were married ≤ 15 years`,22 (12.2%) were nullipara, para≥3 were 90 (50.8)[14]. But, in this study, all the patients were multipara, among them 19 (63.3%) had more than 3% parity. So it indicates age and multiparty are risk factors for developing CIN. Adequate treatment of CN is vital for the success of cervical screening in preventing cervical cancer. Out of 30 participants. 16 (53.3%) had high grade CIN and 14 (46.7%) had low grade CIN. According to the biopsy report 26.7% had negative result whereas 13.3%, 46.7%, 10.0% and 3.3% had CIN I, CIN II, CIN III and Micro invasive cancer respectively. The following side effects were observed like mild pain or mild cramps during or after treatment in 252(2.1%) women, malodorous excessive vaginal discharge following treatment in19 (1.6%); mild bleeding or spotting in nine (0.7%), delayed bleeding from the biopsy site in three (0.2%), and fever in two (0.2%) women in kriby TO et al. studies[15].During follow up, colposcopy revealed 93.3% to be normal, 3.3% had inflammation/infection and low grade CIN each. Only 2 (6.7%) patients had developed invasive cancer subsequently, rest was out of recurrence. In a study by R. Sankaranarayanam et al.`s among 885(86.3%) VIA-negative women at follow-up evaluation was done and 789 were cured, CIN1 was present in 87 cases, CNI2- 3 were in 9 cases. Among 141 (13.7%) VIA-positive women; 35 were cured; CIN1 was in 92 cases, CIN2-3 were in 12 cases, invasive cancer was in 2 cases. Age and area of lesion did not affect cure rate[17]. In a study by Numnum TN et al. showed that of the 51 patients who underwent LEEP, 4 had no evidence of CIN (8%), 4(8%) had CIN 1, 18(35%) had CIN 2 and 25 (49%) has CIN 3. 16% had over treatment[17]. In current study, 26.7% had negative result whereas 13.3%, 46.7%, 10% and 3.3% had CIN II, CIN III and microinvasive cancer respectively. So over treatment of some cases were found in all discussed cases. This is the only drawback of this "See and Treat" policy. All stages of CIN were high in the age group of 40-49 years. Highest number of both Low-grade CIN 7(50.0%) and High-grade CIN 12(75.0%) belonged in >29 years' age group. It was statistically significant. In the study by Nessa, during the first period (n= 181), 50 (27.6%) woman received treatment; among them 48 (26.5%) had LEEP and two (1.1%) had hysterectomy. Thirty-nine (21.5%) women with high-grade CIN did not come back to have follow-up and treatment. During follow-up, 177 women were diagnosed as having high-grade CIN by colposcopy. Of those, 129 (72.9%) had LEEP 118(91.5%) at first visit and 11 (8.5%) received treatment within six months of diagnosis. During the follow-up, more women (72.9%) availed treatment than the first period (26.5%)[16] and the difference was statistically significant (0.000). It is evident that from Nessa's study[16] (in Bangladesh), a good number of cases did not come for follow up. So "See and Treat" policy should be adopted in developing countries like ours.

Conclusion

A single visit approach using VIA, colposcopy followed by LEEP can help to reduce cervical carcinoma in a low resource country like ours though there is possibility of over-treatment in few cases. High acceptability to avail 'See and treat' protocol was seen among women attending colposcopy clinics.

Recommendations

Cervical cancer is the most common malignancy in Women of our country and a common cause of death due to genital malignancy. Though the government of Bangladesh (GOB) is developing cervical cancer screening program but still now most of the women are away from this service. So, more policy should be implemented to raise cervical awareness program among mass population and high acceptability to avail "see and treat" protocol in treating Cervical Intraepithelial

Neoplasia. LEEP facilities are available in only few tertiary hospitals. To serve mass population, more LEEP machines should be supplied to the District Hospitals and at least to all Medical College Hospitals.

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