



Performance of Colposcopy for the Diagnosis of Histologic CIN2⁺ among Pap Smear Screen-Positive Women in a Camp Setting at Paro Hospital, Bhutan in 2021

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ABSTRACT

Objectives: Colposcopy camp is a way to reach colposcopy services in the community, reduce the burden on colposcopy centers, and reduce out-of-pocket expenses. This study assessed the sociodemographic profiles, colposcopy performance in diagnosing CIN2⁺, and cervical biopsy results among women who received colposcopy services during the colposcopy camp held at Paro Hospital, Bhutan, in 2021. **Materials and Methods:** This was a retrospective review of records of women with positive Pap smear screen who availed colposcopy services at Paro hospital, Bhutan, between August 30, 2021, and September 7, 2021. Data on sociodemographic characteristics, colposcopy, and histopathology diagnoses were retrieved from records maintained at the colposcopy clinic and the Department of Pathology and Laboratory Medicine, Jigme Dorji Wangchuck National Referral Hospital. Data entry and analysis were performed using SPSS version 25. **Results:** The mean age of study participants was 41 years (SD, 9 years). Among 84 women, 12 (14.3%), 31 (36.9%), and 41 (48.8%) had normal, low-grade lesion (LGL), and high-grade lesion (HGL) on colposcopy, respectively. Thirty-five (41.7%) underwent colposcopy-directed punch biopsy, and 33 (41.7%) underwent LEEP. The colposcopy sensitivity, specificity, and accuracy to diagnose histologic CIN2⁺ were 70.0 %, 56.82 % and 60.94 %, respectively. Whereas the sensitivity, specificity, and accuracy for the diagnosis of histologic CIN 2⁻ were 30.77 %, 56.86%, and 51.56 %, respectively. The overtreatment rate with LEEP was 69.7%. **Conclusion:** The performance of colposcopy to diagnose histologic CIN 2⁺ was better than the diagnosis of CIN2⁻, and the over-treatment rate was high in this colposcopy camp setting.

Keywords: Colposcopy; Pap smear; Uterine cervical neoplasm; Colposcopy camp; LEEP; See and treat; See, triage and treat

INTRODUCTION

Cervical cancer was the fourth most common cancer in women in terms of incidence and mortality with an estimated 604,000 new cases and 342,000 deaths worldwide in 2020 (Sung et al., 2021). It was the most frequently diagnosed cancer in Bhutan, and the leading cause of cancer deaths in women, with an age-standardized incidence rate of 14.4 cases, and mortality rate of 8.3 cases per 1,00,000 persons per year (ICO, 2016; Sung et al., 2021).

In line with the WHO, Bhutan aims to eradicate cervical cancer by 2030 through 90-70-90 triple strategies ("Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem," 2020). The conventional Pap smear was used as a cervical cancer screening tool for women aged 25-65

years in Bhutan since 2000 (Baussano et al., 2014). However, Pap smear was replaced by high performance human papillomavirus deoxyribose nucleic acid (HPV DNA) testing from January, 2022. WHO recommends HPV DNA testing as a primary screening tool for cervical cancer (WHO, 2013), and the single visit approach treatment (World Health Organization, 2014). ASCCP 2019 recommends management of screen positive women based on assessment of the immediate risk of cervical intraepithelial neoplasia 3+ (CIN3+)(Perkins et al., 2020). Through the Health Flagship Program by the end of 2023, Bhutan achieved 90-70-90 global targets of eliminating cervical cancer (Dorji et al., 2025).

Colposcopy is an important tool for triaging women with abnormal screen results regardless of any screening methods. Colposcopy helps in identifying the lesions, and making a decision on the timing and mode of treatment- either to

recommend follow-up, take a biopsy for histological diagnosis, or treat with ablative procedures or excisional procedures.

In Bhutan, women with abnormal Pap result underwent colposcopy examination. Colposcopy services are provided routinely in the colposcopy centers as well as in the communities or other health centers in the form of colposcopy camp. As of October 2022, Bhutan has eight colposcopy centers (Figure 2). People from other places need to travel to the nearest colposcopy centers to avail services.

Despite the mountainous terrain, the road connectivity has improved. However, people still face difficulties reaching the colposcopy centers, especially those from rural areas, due to numerous challenges, including high expenses, illiteracy and its associated problems, low awareness about the program, and a high rate of loss to follow-up. A study in Bhutan has shown that clients who are of older age, multiparous, are illiterate, and are housewives and residing in far-flung areas exhibit lower health seeking behavior (Baussano et al., 2017).

One effective solution to the above-mentioned limitation is to bring the colposcopy services to the communities. The community leaders and local health workers compile a list of women in need of colposcopy, and inform them about the availability of services. Doing so encourages the women to arrange for a group transportation facility, and they turn up for the services. Since the services are provided at the door step in one day, their burden on farming and livestock-care due to long distance travel to the colposcopy center is avoided. When such camps are conducted, women in the communities inform and encourage each other and come in groups, thereby increasing the clients' turnover.

Herein, we present the sociodemographic profiles, performance of colposcopy, and results of cervical biopsies (either loop electrosurgical excisional procedure (LEEP) or cervical punch biopsy) among women who availed colposcopy services during a colposcopy camp held at Paro hospital, Bhutan.

Materials and Methods

This was a retrospective review of records of women who underwent colposcopy, colposcopy directed cervical punch biopsy and LEEP procedures during the colposcopy camp conducted at Paro hospital. It was conducted between 30th August and 7th September 2021 by the colposcopy team from JDWNRH, Thimphu. The team consisted of one gynecologist, one colposcopy nurse and operation theatre staff (nurse anesthetist, operation theatre technician, and two scrub nurses). The colposcopist had more than 10 years of experience.

Patients with abnormal Pap smear results were called for colposcopy as per the national cervical cancer screening guidelines (Cervical Cancer Screening Manual 2014, 2014).

The portable video colposcope (proMISCOLpro 222DX-OZview) at 6-12 magnification was used. The standard steps described in the International Agency for Research on Cancer (IARC) manual of colposcopy were followed (Sellors & Sankaranarayanan, 2003), and the colposcopy findings were documented according to the International Federation for Cervical Pathology and Colposcopy (IFCPC) nomenclature, and Swede score calculated (Bornstein et al., 2012; Bowring et al., 2010). Swede score of 0-4 was categorized as low-grade lesion (LGL), 5-10 as high-grade lesion (HGL), and negative acetowhite as normal.

The colposcopy nurse explained about the procedure, potential discomfort, and the need for additional procedures such as biopsy, and LEEP, as well as possible complications of the procedure. Then, thumb imprint and written informed consent were obtained from all the patients who underwent the procedure. Women with LGL in colposcopy underwent colposcopy directed punch biopsies using either Kevorkian or Baby Tischler minibite biopsy forceps. Women with or above "atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion (ASC-H)" on Pap smear, and/or those with high grade lesion (HGL) on colposcopy underwent treatment with "Loop electrosurgical excisional procedures (LEEP)". Women who were unlikely to return for follow-up were treated with LEEP, irrespective of colposcopy result, at the discretion of the colposcopist.

LEEP was performed under total intravenous anesthesia (TIVA) as per the steps described in IARC manual of colposcopy and treatment of cervical intraepithelial neoplasia: a beginner's manual (Sellors & Sankaranarayanan, 2003).

The patients were educated about anticipated side effects, such as minimal blood stain discharge that may last for 4-6 weeks, to avoid sexual intercourse for 4-6 weeks, and a follow up schedule. Patients were advised to seek medical care if they experience complications such as high-grade fever lasting for more than two days, heavy vaginal bleeding, foul smelling yellowish-green vaginal discharge, and severe lower abdominal pain.

The detailed sociodemographic details, pap results, colposcopy diagnosis and types of procedures (Either punch biopsy or LEEP) were recorded in the colposcopy record register, which was transported and stored at the colposcopy clinic, JDWNRH.

The cervical tissue specimens obtained from the patients evaluated at the colposcopy camp were placed in 10% phosphate-buffered formalin, and transported to the Department of Pathology and Laboratory Medicine, JDWNRH. The slides were constructed from 3 mm sections of formalin-fixed paraffin-embedded (FFPE) blocks and stained with Mayer's Hematoxylin (HIMEDIA) and Eosin yellow (HIMEDIA) in the Sakura Tissue-Tek DRS 200 slide Stainer as per the standard operating protocol.

The slides were then viewed under binocular light microscopy by the pathologists. The report was provided using the terminology of the WHO Classification of Female Genital Tumors, 5th edition (Höhn et al., 2021).

Data were retrieved from hard copy of patient's record maintained in the colposcopy clinic of JDWNRH into a data collection form which included all the study variables. The study variables included sociodemographic profiles, results of pap smear, indications of colposcopy, colposcopy diagnosis, and procedures (either punch biopsy or LEEP). The histopathology results were retrieved using patients' citizenship identity card number from the Department of Pathology and Laboratory Medicine, JDWNRH.

Descriptive statistical analysis was performed by using SPSS version 25 (IBM, Armonk, NY, USA). Performance of colposcopy is presented as sensitivity, specificity, and accuracy. P value <0.05 was considered statistically significant. The histopathology result was considered the gold-standard for calculating colposcopic performance. In the histology result, CIN II and III were considered as "CIN 2+", whereas atrophic change, chronic cervicitis, squamous metaplasia, cervical polyp and CIN I were considered as "CIN 2-". Overtreatment with LEEP was calculated with women with either normal or CIN 1 (numerator) divided by total women who had LEEP (Denominator).

Ethical clearance was obtained from the Research Ethics Board of Health, Ministry of Health, Bhutan (vide reference letter number REBH/Approval/2021/119 dated 12/10/2021). The waiver of consent was obtained. The confidentiality of study participants was maintained by removing all personal identifiers.

RESULTS

Sociodemographic details of the study population

In this review of records, a total of 84 women availed the colposcopy services provided at Paro during the reference period. The mean $\pm$ SD age of women was 41 ± 9 years. Seventy-nine women (94.0%) were residing in Paro district. Forty-eight (57.1%) did not have any form of education, 56 (66.7%) were housewives, 45 (53.6%) had a monthly family income less than Ngultrum 10,000. Their mean age at coitarche was 20 ± 4 years, and the mean age at first child birth was 22 ± 4 years. The majority of the women were multiparous (81%) (Table 1).

Indications and results of colposcopy, and procedures performed

ASCUS was the most frequent diagnosis of cervical Papanicolaou (Pap) test, comprising 44 (52.4%) of all diagnoses, followed by LSIL 13 (15.5%) and ASC-H 11 (13.1%). Seventy-five (89.3%) of the women underwent colposcopy due to abnormal result in Pap test. Colposcopy examination revealed low grade lesion (LGL) in 31 (36.9%) women, and high-grade lesion (HGL) in 41

Table 1: Distribution by sociodemographic profiles of women who availed colposcopy camp services at the colposcopy camp at Paro Hospital in 2021 (n=84)

Variables	Frequency (n)	Percentage (%)
Age in years (mean $\pm$ SD)	(41 $\pm$ 9)	
25-35	23	27.4 %
36-45	38	45.2 %
> 45	23	27.3 %
Residence		
Paro	79	94.0 %
Outside Paro (Thimphu)	5	6.0 %
Marital status		
Married	77	91.7 %
Divorced/widow/unmarried	7	8.3 %
Educational status		
No formal education	48	57.1 %
Educated	36	42.9 %
Occupation		
House wife	56	66.7 %
Civil servant	8	9.5 %
Farmer	11	13.1 %
Others	9	10.7%
Monthly income (in ngultrum)		
<11,000	45	53.6%
11,000-20,000	23	27.4%
>20,000	16	19.0%
Parity		
Nulliparous	2	2.4%
Primi	14	16.7%
Multiparous	68	81.0%
Age at coitarche (mean $\pm$ SD)	(20 $\pm$ 4)	
Age at first child birth (mean $\pm$ SD)	(22 $\pm$ 4)	

(48.8%) women. Intervention in the form of colposcopy guided cervical punch biopsy and LEEP was done in 35 (41.7%) and 33 (39.3%) women, respectively (Table 2).

Table 2. Distribution by Pap result, indication for colposcopy, colposcopy diagnosis and intervention among women who availed services during the colposcopy camp at Paro in 2021 (n=84).

Variables	Frequency	Percentage
PAP smear result		
ASCUS	44	52.4%
ASC-H	11	13.1%
LSIL	13	15.5%
HSIL	7	8.3%
Others*	9	10.8%
Colposcopy Indications		
Abnormal pap	75	89.3%
Others**	9	10.7%
Colposcopy diagnosis		
Normal	12	14.3 %
LGL	31	36.9 %
HGL	41	48.8 %
Procedures performed		
No procedure	16	19.0 %
Cervical biopsy	35	41.7 %
LEEP	33	39.3 %

ASCUS, Atypical squamous cells of undetermined significance; ASC-H, Atypical squamous cells-cannot exclude a high-grade intraepithelial lesion; LSIL, low grade squamous intraepithelial lesion; HSIL, high grade squamous intraepithelial lesion; NILM, Negative for intraepithelial lesion or malignancy; LGL, Low grade lesion; HGL, High grade lesion; LEEP, Loop electrosurgical excisional procedures. *Others (2 cases): Bacterial vaginosis (1), Unsatisfactory (1), Repeated inflammation (2), NILM (5). **Others (8 cases): Post coital bleed (1), Repeated inflammation (2), Chronic pelvic pain (1), chronic PV discharge (1), unsatisfactory PAP (1), cervical polyp (2), Cervical growth (1)

Histology results

Out of 84 women involved in this study, 68 (81.0%) women received intervention (either cervical punch biopsy or LEEP).

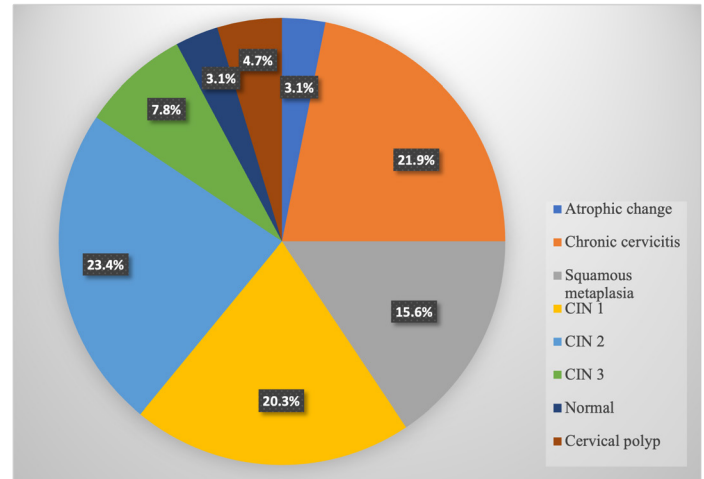


Figure 1. Distribution of histopathological diagnoses of the uterine cervix among women who underwent cervical biopsy/LEEP at the Colposcopy camp in Paro in 2021 (n=68).

The histopathological results of four cases were non-diagnostic due to inadequate/unsatisfactory specimens. The spectrum of histopathological diagnoses in the remaining 68 cases is illustrated (Figure 1)

Diagnostic performance of colposcopy

Evaluation of the performance of colposcopy in diagnosing histologic CIN2- and CIN2+ among 68 cases (Table 3). The sensitivity, specificity, and accuracy of colposcopy to diagnose histologic CIN 2- were 30.8 %, 56.9 %, and 51.6 %; and to diagnose histologic CIN 2+, were 70.0 %, 56.8 %, and 60.9% respectively.

Table 3. Performance of colposcopy to diagnose histologic CIN 2- and CIN 2+ in the camp setting (n=68)

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Histologic CIN2-	30.77	56.86	15.38	76.32	51.56
Histologic CIN2+	70.00	56.82	42.42	80.65	60.94

CIN 2+ included CIN II and III; CIN 2 included atrophic change, chronic cervicitis, squamous metaplasia, cervical polyp and CIN1; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value

Table 4. Distribution of histopathological diagnosis of women who underwent cervical punch biopsy and LEEP (n=68).

		Cervical punch biopsy	LEEP	Total
Histopathology diagnosis	Non-neoplastic	15	16	31
	CIN I	6	7	13
	CIN II/III	10	10	20
	Unsatisfactory	4	0	4
Total		35	33	68

DISCUSSION

In this study involving the review of records of colposcopy performed in the camp setting among 84 women, the sensitivity, specificity and accuracy of the colposcopy to diagnose histologic CIN 2+ were 70.0%, 56.8%, and 60.9% which is lower than the colposcopic performance of senior colposcopists at the colposcopy clinic of JDWNRH (Dorji et al., 2022). The colposcopist involved in the Paro colposcopy camp was one of three senior colposcopists who participated in the aforementioned study (Dorji et al., 2022). The difference in the colposcopy performance is probably attributable to the difference is the colposcopy machines used (proMIS COLpro

222DX-OZview in the current study versus EDAN C3A in the aforementioned study). The World Health Organization (WHO) recommends using freshly prepared 3-5% acetic acid to be used for colposcopy, and disposing of any remaining dilutions at the end of the day (WHO Technical Guidance and Specifications of Medical Devices for Screening and Treatment of Precancerous Lesions in the Prevention of Cervical Cancer, 2020). However, 3-5% acetic acid was prepared one day in advance of starting the colposcopy camp and the same batch was used for one week. This probably might have contributed to the lower performance of colposcopy. In an attempt to improve the quality of colposcopy, the recently endorsed standard guideline on colposcopy in Bhutan recommends use of 5% acetic acid, which has to be prepared freshly on the day of colposcopy (Practical Guideline on Colposcopy & Treatment of Cervical Pre-Cancer in Bhutan, 2024)

The single-visit approach of either “screen and treat” or “see and treat” reduces loss of follow-up, had a similar overtreatment rate as compared to conventional multiple-visit management, and it had demonstrated benefits in low-resource countries (Sankaranarayanan et al., 2007; Vet et al., 2012). In this study, the “screen, triage and treat” with LEEP has effectively treated 30.3% (10 out of 33) of cases with HSIL. The overtreatment rate in this study was approximately 70% which is

Location of Colposcopy Centres of Bhutan, 2022

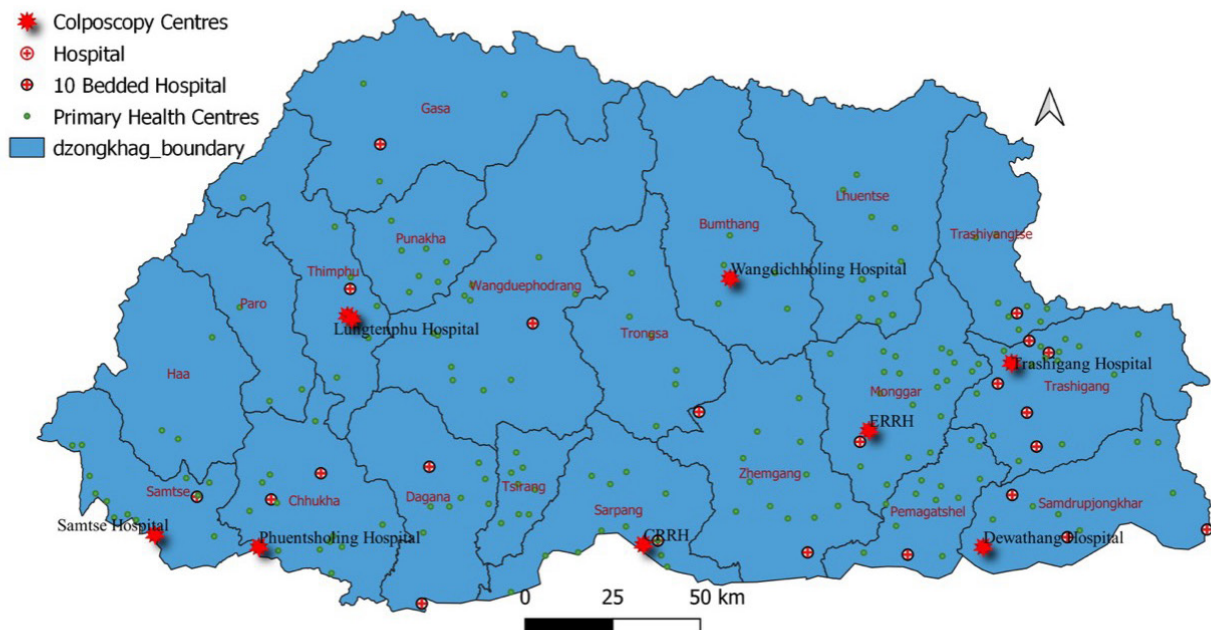


Figure 2. Map of Bhutan showing the colposcopy centres (in pink asterisk) as of 2022

higher than those reported from other low-income countries (Sankaranarayanan et al., 2007; Vet et al., 2012). This could be due to misdiagnosis of cervicitis as HGL on colposcopy which is evidenced by 48.4% with normal histology result among 33 women who had LEEP treatment. Considering the low complication rate of LEEP and high likelihood of loss to follow up among village folks, over treatment of cervicitis with LEEP seems acceptable in Bhutan's context.

Among women who underwent cervical biopsy, 28.6 % (10 out of 35) had HSIL who will need treatment with either LEEP or cryotherapy. As majority of study participants is illiterate (57.1%), loss of follow up is highly likely. The 2019 ASCCP consensus guideline recommends immediate treatment using an excisional procedure without previous biopsy as a preferred option in non-pregnant women 25 years or older with an estimated immediate risk of CIN 3+ of 60% or greater (Perkins et al., 2020).

Service providers faced challenges while conducting such camps. At the technical level, biopsy forceps were too large for smaller lesions, thus preventing the correct biopsy of the lesion. In addition, the LEEP procedure, which is done under total intravenous anesthesia (TIVA) as per the national protocol requires observation of patients after the operation. This leads to putting stress on the limited colposcopy centers (Figure 2), such as the beds. Such challenges affect the service delivery, e.g. only a limited number of LEEP procedures can be performed in a single day. A randomized trial has shown that the LEEP performed under local anesthesia is equally tolerated and offers procedure-related and patient-reported benefits over general anesthesia (Rezniczek et al., 2020).

With the introduction of HPV DNA testing with reflex cytology including self-sampling as national cervical cancer screening program, the health seeking behavior towards cervical cancer screening might improve. Our screening guideline is in line with the WHO recommendation of screen, triage and treat including self-sampling for HPV DNA test (WHO Guideline for Screening and Treatment of Cervical Pre-Cancer Lesions for Cervical Cancer Prevention, Second Edition. Geneva: World Health Organization, 2021).

With the insight gained from this retrospective study, colposcopy camp services are beneficial for the rural communities and should be expanded widely. In cases of HGL on colposcopy, LEEP should be continued in the camp setting until we have enough manpower and public literacy to avail multiple visit services. We also recommend studies to cover cost-benefit analysis, public perception, patients' satisfaction level, and issues and challenges. Such studies could be useful for promoting and enhancing colposcopy services, as well as investments in manpower and equipment, among others. In order to curb the menace of cervical cancer and achieve the global elimination target 2030 ("Global Strategy to Accelerate the Elimination of

Cervical Cancer as a Public Health Problem," 2020), colposcopy camps should be continued in Bhutan.

Strength

This is the first study in Bhutan that provides a baseline data on colposcopy camp services in Bhutan, and way forward. There is no interobserver variation in this study as the colposcopy and histopathology examination performed by a gynecologist and a pathologist respectively.

Limitation

This study being a retrospective review involving a small sample size is the major limitation. The findings of this study can't be generalizable to the rest of colposcopy camps conducted across Bhutan, as different colposcopists with varying years of experience perform colposcopy. Other limitation was that the margin status of LEEP specimen were not studied, and we have no data on outcome of management of those women who had cervical biopsy and has HSIL on histopathology. This is because, review of records for the purpose this study was done within six months of colposcopy. In Bhutan, follow up HPV DNA is usually recommended in 12 months as per the Practical Guideline on Colposcopy & Treatment of Cervical Pre-Cancer in Bhutan (Practical Guideline on Colposcopy & Treatment of Cervical Pre-Cancer in Bhutan, 2024).

Acknowledgement

We are thankful to Kinley Dorji, Research Officer, Ministry of Health, Thimphu, Bhutan for generating the Bhutan map showing colposcopy centers.

Declaration of interest

There is no conflict of interest involved for this study

Financial disclosure

There is no budget involved in this study.

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