Royal Government of Bhutan
Ministry of Health

Practical Guideline on Colposcopy & Treatment of Cervical Pre-cancer in Bhutan

National Cancer Control Program
Department of Public Health

UNFPA

CHUGAI
Roche Group

1st Edition: October 2024

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FOREWORD

Cervical cancer is the most common cancer and leading cause of cancer-related deaths among Bhutanese women, with an age-adjusted incidence rate of 19.5 per 100,000 and mortality rate of 7.8 per 100,000 from 2019-2022, as per the Population-Based Cancer Registry. However, it is preventable and curable with proper preventive measures in place, early detection and timely treatment.

Recognizing the need for public health interventions to reduce the burden of cervical cancer, Bhutan is committed to the global initiative towards achieving the ambitious target of elimination of cervical cancer by 2030. Achieving this goal requires strengthening cancer screening and treatment services. Key strategies, including gender-neutral HPV vaccination, HPV DNA testing for screening, increased public awareness, early diagnosis, and timely treatment, are expected to significantly reduce the cervical cancer burden in Bhutan.

Providing quality colposcopy and Loop Electrosurgical Excision Procedure (LEEP) or thermocoagulation services are essential to achieving these goals. Colposcopy is used as a triage method for screen-positive women, while LEEP and thermocoagulation is to treat cervical precancer in Bhutan. However, significant inter-observer and intra-observer variability has been noted in colposcopy performance, as well as in the execution of LEEP and thermocoagulation procedures. To address these challenges and ensure consistency, a practical guideline on colposcopy, LEEP and thermocoagulation has been developed.

This guideline aims to standardize the colposcopy, LEEP and thermocoagulation procedures among gynecologists in the country. I hope this guideline will ensure consistency and enhance the quality of colposcopy, LEEP and thermocoagulation services provided to Bhutanese women. This will ultimately contribute to the reduction of cervical cancer's impact in Bhutan.

Tashi Delek

Karma Jamtsho
Director
Department of Public Health

ABBREVIATIONS

AIS	: Adenocarcinoma in-situ
AWE	: Acetowhite
CGIN	: Cervical glandular intraepithelial neoplasia
CID	: Citizenship identity card number
CIN	: Cervical intra-epithelial neoplasia
CTZ	: Congenital transformation zone
DHIS	: District health information system
DNA	: Deoxy-ribose nucleic acid
ECC	: Endocervical curettage
ePIS	: Electronic patient information system
HIV	: Human immunodeficiency virus
HPV	: Human papillomavirus
HRT	: Hormone replacement therapy
HSIL	: High grade squamous intraepithelial lesion
IFCPC	: International federation of colposcopy and cervical pathology
IMB	: Inter-menstrual bleeding
JDWNRH	: Jigme Dorji Wangchuck National Referral Hospital
LBC	: Liquid based cytology
LEEP	: Loop electrosurgical excision procedure
LSIL	: Low grade squamous intraepithelial lesion
NCCP	: National cancer control program
OCP	: Oral contraceptive pill
OPD	: Outpatient department
PCB	: Postcoital bleeding
PMB	: Postmenopausal bleeding
SCJ	: Squamocolumnar junction
TIVA	: Total intra-venous anesthesia
TZ	: Transformation zone
UHID	: Unique health identification number
VIA	: Visual inspection of cervix with 5% acetic acid
VILI	: Visual inspection of cervix with lugol's iodine

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1. INTRODUCTION

Cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer death in women, with an estimated 604,000 new cases and 342,000 deaths worldwide in 2020 (Sung et al., 2021). Cervical cancer is the most commonly diagnosed cancer and leading cause of cancer death in women in Bhutan. As per the population-based cancer registry (PBCR) of Bhutan maintained at JDWNRH, the age-adjusted rate of incidence of cervical cancer was 19.5 per 100,000 women and age-adjusted rate of mortality was 7.8 per 100,000 women between 2019-2022.

Considering that cervical cancer is a significant health burden, Bhutan is committed to eliminate cervical cancer by 2030. As per the global strategy to eliminate cervical cancer, 90-70-90 targets must be met for the country to be on the path towards elimination of cervical cancer by 2030. This includes 90% of girls fully vaccinated with HPV vaccine by age of 15 years, 70% of women are screened with a high-performance test by 35 years of age and again by 45 years of age, and 90% of women identified with cervical disease receive treatment (Global strategy to accelerate the elimination of cervical cancer as a public health problem, 2020).

Furthermore, to address the cervical cancer burden, the population based cancer screening was initiated through the Health Flagship. As per the health flagship report, 90.8% of eligible women were screened using HPV DNA tests, and 92% of screen positive cases were treated with either thermocoagulation or loop electrosurgical excision procedure (LEEP). Colposcopy was done to triage screened positive cases as per the national cervical cancer screening guideline of Bhutan (National Cervical Cancer Guideline, 2021).

A study done on the performance of colposcopy at JDWNRH showed that the overall sensitivity, specificity, and accuracy of colposcopy to diagnose histologic CIN 2+ were 66.67% (95% CI 53.66, 78.05), 73.73% (95% CI 67.63, 79.23), and 72.24% (95% CI 66.79, 77.24) respectively (Dorji et al., 2022). In a study on use of LEEP to treat CIN in Bhutan, the margin positivity for HSIL was 36.4% (Tshering et al., 2024).

In an effort towards achieving the elimination target by 2030, provision of quality colposcopy services and performing quality LEEP/Thermo-coagulation across the country is felt as a need of the time. Since Bhutanese gynecologists are trained in colposcopy and LEEP/Thermo-coagulation from different countries, there is a need for a standard guideline.

With this practical guideline on colposcopy and treatment of cervical precancers, the quality of colposcopy and LEEP/Thermo-coagulation services across the country would be standardized. This will ultimately enhance the quality of the cancer screening and treatment in the country.

KEYPOINTS

Cervical cancer is the commonest gynecological cancer among Bhutanese women.

This practical guideline on colposcopy and LEEP/Thermo-coagulation is to improve the quality and standardized services across the country.

2. ANATOMY OF CERVIX

A normal cervix is approximately 4 cm in length and 3 cm in diameter. The size may vary with age and parity. It is considerably larger in parous women, and the cervix of a woman of reproductive age is larger than that of a postmenopausal woman. The intravaginal and supravaginal parts of the cervix are approximately equal in size. The endocervical canal is lined with glandular epithelium, and the ectocervix is lined with stratified squamous epithelium. The squamous epithelium meets the glandular epithelium at the squamocolumnar junction (SCJ). The external os of the cervix will nearly always be visible to the naked eye at speculum examination. The visible external lining of the cervix derives from the vaginal (squamous) epithelium. The endocervical or glandular epithelium is not usually visible to the naked eye at speculum examination. The intravaginal part of the cervix is surrounded by the vaginal fornices. These are the lateral, anterior, and posterior fornices and are where the vaginal epithelium sweeps into the cervix circumferentially (Prendiville & Sankaranarayanan, 2017).

2.1 Stroma

The stroma is made of fibromuscular tissue with vascular, lymphatic, and nerve supplies to the cervix. The cervical branches of the uterine arteries descend in the lateral aspects of the cervix at the 3 o'clock and 9 o'clock positions. The veins of the cervix run parallel to the arteries and drain into the hypogastric venous plexus. The lymphatic vessels from the cervix drain into the common iliac, external iliac, internal iliac, obturator, and parametrial nodes. The nerve supply to the cervix is derived from the hypogastric plexus (Prendiville & Sankaranarayanan, 2017)

The endocervix has extensive sensory nerve endings (both sympathetic and parasympathetic fibres), whereas there are very few in the ectocervix. Hence, procedures such as biopsy, thermal coagulation, and cryotherapy are relatively well tolerated in most women, although there is good evidence that local anaesthesia effectively prevents the discomfort of these procedures. Also, the cervix of a parous woman tends to have slightly less sensory appreciation, which may be due to damage to nerve endings during childbirth (Prendiville & Sankaranarayanan, 2017).

2.2 Squamous epithelium

The lowest level of cells in the squamous epithelium is a single layer of round basal cells with large dark-staining nuclei and little cytoplasm, attached to the basement membrane. The basement membrane separates the epithelium from the underlying stroma. The basal cells divide and mature to form the next few layers of cells, called parabasal cells, which also have relatively large dark-staining nuclei and greenish-blue basophilic cytoplasm. Further differentiation and maturation results in formation of the superficial layers of large flattened cells with small, dense, pyknotic nuclei and transparent cytoplasm. Overall, from the basal layer to the superficial layer, these cells undergo an increase in size and a reduction in nuclear size.

The cells in the intermediate and superficial layers contain abundant glycogen in their cytoplasm, which stains mahogany brown or black after the application of Lugol's iodine. Glycogenation of the intermediate and superficial layers is a sign of normal maturation and development of the squamous epithelium. Abnormal or altered maturation is characterized by a lack of glycogen production.

Mature squamous epithelium contains glycogen, it readily takes up Lugol's iodine (and is therefore Schiller test-negative). When epithelium does not take up Lugol's iodine, it is Schiller test-positive (Prendiville & Sankaranarayanan, 2017).

The maturation of the squamous epithelium of the cervix is dependent on estrogen, and if estrogen is lacking, full maturation and glycogenation do not take place. Hence, after menopause, the cells do not mature beyond the parabasal layer and do not accumulate as multiple layers of flat cells. Consequently, the epithelium becomes thin and atrophic. On visual examination, it appears pale, sometimes with subepithelial petechial haemorrhagic spots, because it is easily prone to trauma.

2.3 Columnar epithelium

The endocervical canal is lined with a single layer of columnar epithelium. On visual examination, it appears reddish, because the thin single-cell layer allows penetration of the stromal vascularity. It covers a variable extent of the ectocervix, depending on the woman's age and reproductive, hormonal, and menopausal status. The columnar epithelium forms multiple longitudinal folds protruding into the lumen of the canal, giving rise to papillary projections. It forms several invaginations into the substance of the cervical stroma, resulting in the formation of endocervical crypts (sometimes referred to as endocervical glands). The crypts may traverse as far as 5–6 mm from the surface of the cervix. These mucosal folds and crypts, gives the columnar epithelium a grainy or grape-like appearance on visual inspection. A localized overgrowth of the endocervical columnar epithelium may occasionally form cervical polyp.

Glycogenation and mitoses are absent in the columnar epithelium. Because of the lack of intracellular cytoplasmic glycogen, the columnar epithelium does not change colour after the application of Lugol's iodine or remains slightly discoloured with a thin film of iodine solution.

2.4 Squamocolumnar junction (SCJ)

The original SCJ lies in the endocervical canal. During childhood and around the menarche, the original SCJ is located at, or very close to, the external os (Figure 1). After puberty and during the reproductive period, the female genital organs develop under the influence of estrogen. Thus, the cervix enlarges and the endocervical canal elongates and the SCJ comes to lie on the ectocervix and becomes the new SCJ. In colposcopy terminology, the SCJ is this new SCJ.

The buffer action of the mucus covering the columnar cells is interfered with when the everted columnar epithelium is exposed to the acidic vaginal environment. This leads to the destruction and eventual replacement of the columnar epithelium by the newly formed metaplastic squamous epithelium. The metaplastic process starts at the original SCJ and proceeds centripetally towards the external os throughout the reproductive period and finally to the menopause. Thus, a new SCJ is formed between the newly formed metaplastic squamous epithelium and the columnar epithelium (Figure 1). As the woman passes from reproductive to perimenopausal life, the new SCJ moves towards the external os (Figure 1). From the perimenopausal period and afterwards, the atrophic cervix shrinks, and the new SCJ towards the

external os and into the endocervical canal. In postmenopausal women, the new SCJ is often invisible on visual examination, because it has become entirely endocervical.

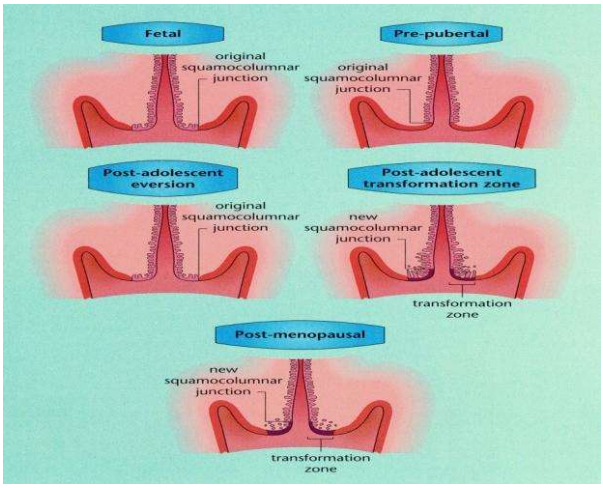


Figure 1. SCJ and formation of Transformation zone
(Source of image: Prendiville & Sankaranarayanan, 2017)

2.5 Squamous metaplasia

The physiological replacement of the everted columnar epithelium by squamous epithelium is called squamous metaplasia. The vaginal environment is relatively acidic during reproductive life and during pregnancy. The acidity is thought to play a role in squamous metaplasia. The columnar cells exposed are eventually replaced by metaplastic squamous epithelium. Initially, the irritation of exposed columnar epithelium by the acidic vaginal environment results in the appearance of sub columnar reserve cells, and these cells proliferate, producing reserve cell hyperplasia, and eventually become metaplastic squamous epithelium. Squamous metaplasia may progress at varying rates in different areas of the same cervix, and hence many areas of widely differing maturity may be seen in the metaplastic squamous epithelium with or without islands of columnar epithelium.

The term “immature squamous metaplastic epithelium” is used when there is little or no stratification in this thin, newly formed metaplastic epithelium. Immature squamous metaplastic epithelium does not produce glycogen and, hence, does not stain brown or black with Lugol’s iodine. As the process continues, the immature metaplastic squamous cells differentiate into mature stratified metaplastic epithelium. For all practical purposes, this

resembles original stratified squamous epithelium. The more mature the metaplasia is, the more it will stain brown or black after the application of Lugol's iodine.

Certain oncogenic HPV types may infect the immature basal squamous metaplastic cells and, rarely, turn them into precancerous cells. The uncontrolled proliferation and expansion of these atypical cells may lead to the formation of an abnormal dysplastic epithelium, which may regress to normal, persist as dysplasia, or progress to invasive cancer after several years.

2.6 Transformation zone (TZ)

The TZ is that area of epithelium between original and new SCJ. Dynamic TZ is susceptible to HPV infection, whereby it may infect the basal layers of the epithelium in the TZ and, in a small proportion of cases, initiate the development of CIN. Most people will be infected with oncogenic HPV types early on in their normal sexual life, but the great majority will clear the infection without consequence. The TZ varies in its size and its precise position on the cervix, and it may lie partially or completely in the endocervical canal (Figure 2 and 3). In most women of reproductive age, the TZ is of type 1.

A type 1 TZ is completely ectocervical and is therefore fully visible.

A type 2 TZ is partially endocervical but is still fully visible. It may be shallow and within range of an ablative probe or may extend beyond reach of an ablative probe.

A type 3 TZ extends out of view up the endocervical canal, i.e., the squamocolumnar junction (SCJ), and is not fully visible

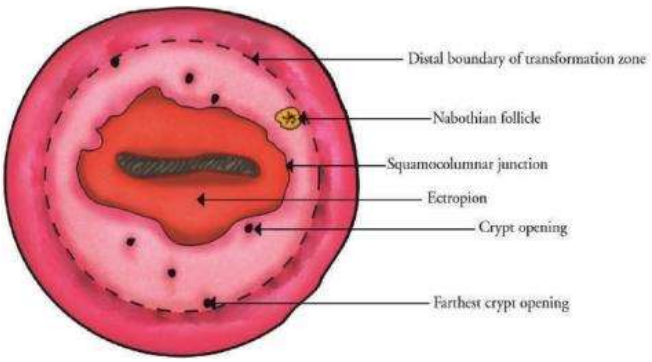


Figure 2. Transformation Zone.
(Source of image: Rivki et al., 2017)

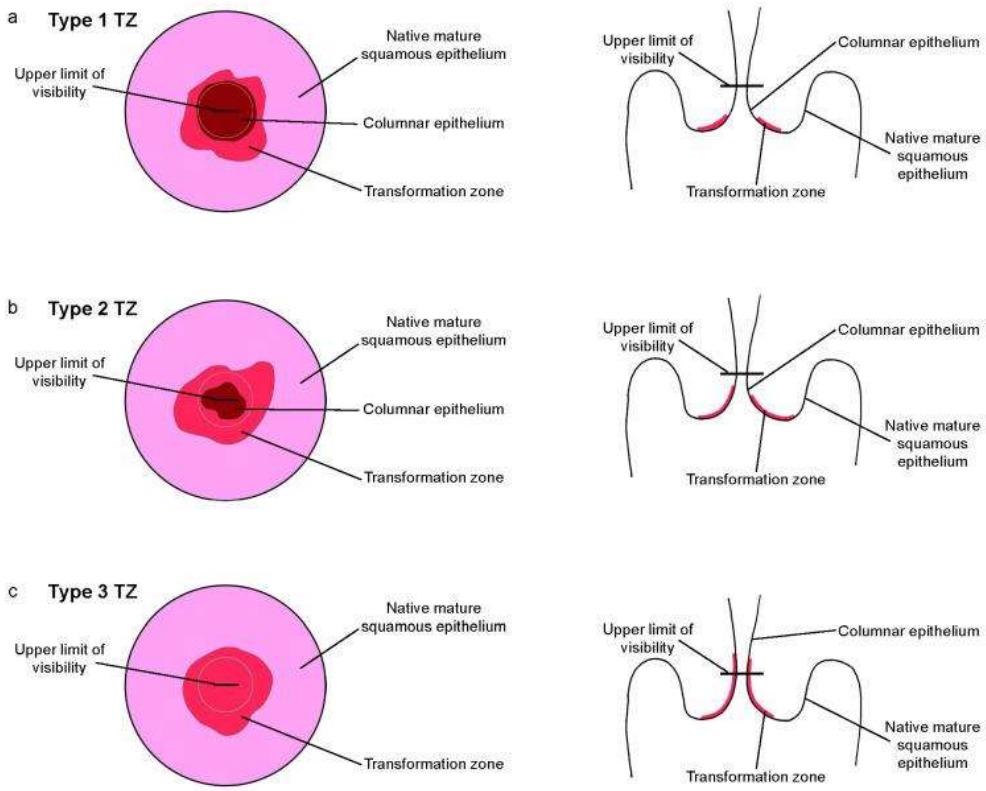


Figure 3. Types of TZ.
(Source of image: Prendiville & Sankaranarayanan, 2017)

2.7 Congenital transformation zone

During early embryonic life, the cuboidal epithelium of the vaginal tube is replaced by the squamous epithelium. This process is completed well before birth, and the entire length of the vagina and the ectocervix is normally covered by squamous epithelium. This process proceeds very rapidly along the lateral walls, and later in the anterior and posterior vaginal walls. If this process is arrested for some reason, or incomplete, the original SCJ will be located distal to the external os or may rarely be located on the vaginal walls, particularly involving the anterior and posterior fornices.

Clinically, The CTZ appears as a large oblong (lozenge-shaped) thin acetowhite area on the cervix often extending from the anterior to the posterior fornix of the vagina (Figure 4). At times it is very difficult to differentiate the CTZ from cervical premalignant lesions. In such cases, multiple biopsies are recommended. The condition is seen in 3–5% of young women undergoing colposcopy. No treatment is required, and the

changes disappear with age. However, it causes a diagnostic dilemma for the colposcopist.

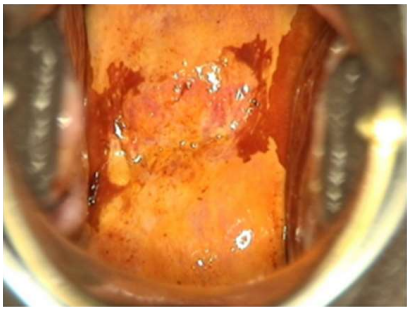


Figure 4. CTZ after application of acetic acid and lugols iodine. Note the extension of AWE to the anterior and posterior fornices
(Source of image: Atlas of Colposcopy: Principles and Practice, n.d.)

2.8 Ectropion or ectopy

Ectropion or ectopy is the presence of everted endocervical columnar epithelium on the ectocervix. It appears as a large reddish area on the ectocervix surrounding the external os (Figure 5). The eversion of the columnar epithelium is usually more pronounced on the anterior and posterior lips of the ectocervix. This is a normal, physiological occurrence. Occasionally ectropion maybe mistaken for erosion or ulcer. An ectropion may begin or become much more pronounced during pregnancy.

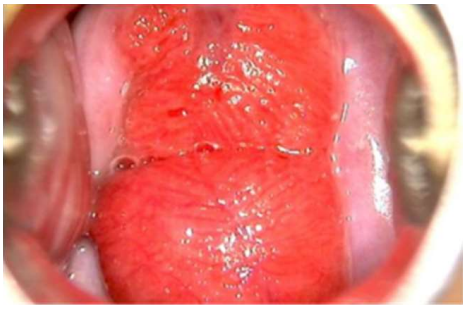


Figure 5. Ectropion with areas of immature squamous epithelium at 12 'o' clock position.
(Source of image: Prendiville & Sankaranarayanan, 2017)

2.9 Nabothian cysts

They are retention cysts that develop as a result of the occlusion of an endocervical crypt opening or outlet by the overlying metaplastic squamous epithelium. The buried columnar epithelium continues to secrete mucus, which eventually fills and distends the cyst.

KEY POINTS

Mature squamous epithelium contains glycogen, it readily takes up lugol's iodine (and is therefore Schiller test-negative). When epithelium does not take up lugol's iodine, it is Schiller test-positive.

In colposcopy terminology, the SCJ refers to the new SCJ.

Three types of TZ- I, II, and III.

Ectropion is a physiological change.

3. PATHOPHYSIOLOGY OF CERVICAL CANCER

Persistent infection of the cervix with high risk-human papillomavirus (HPV) has been established as a necessary (but not sufficient) cause for developing cervical cancer (Luiz, Manita and Portugal, 2016). This is characterized microscopically as a spectrum of events progressing from cellular atypia to various grades of dysplasia or cervical intraepithelial neoplasia (CIN) before progression to invasive carcinoma (Sankaranarayanan, 2003)

Cervical cancer is preceded by a long period of recognizable cytological and histological changes providing an opportunity for early detection by screening procedures (Nyirjesy, I., Holowaty, P., Miller, A. B., Rohan, T., & To, 1999). Several factors determine whether the infection will progress to CIN or carcinoma, the greatest of which is the HPV genotype causing the infection. Although there are approximately 100 subtypes of HPV, a small subgroup has a known association with cervical dysplasia and carcinoma (Massad et al., 2013). HPV 16 is the most carcinogenic and accounts for 55 to 60% of cervical cancers worldwide. HPV 18 is the second most carcinogenic and accounts for 10 to 15% of cervical cancer. Risk factors such as smoking, immunocompromised state, or HIV infection likely lead to persistence of HPV infection and an increased risk for the development of CIN (Sheng et al., 2000)

It is well established that infection of the uterine cervix with high-risk human papillomavirus (HPV) types needs to persist for many years or even decades before invasive cervical cancer develops. (Petry et al., 2018) About 80% of young women who become infected with HPV have transient infections that clear up within 12-18 months (Liaw et al., 2001)

HPV infection is believed to start in the basal cells or parabasal cells of the metaplastic epithelium. If the infection persists, integration of viral genome into the host cellular genome may occur. The normal differentiation and maturation of the immature squamous metaplastic into the mature squamous metaplastic epithelium may be disrupted because of expression of E6/E7 oncoproteins and the loss of normal growth control. This may then lead to development of abnormal dysplastic epithelium. If the neoplastic process continues uninterrupted, the early low-grade lesions may eventually involve the full thickness of the epithelium. Subsequently the disease may traverse the basement membrane and become invasive cancer (Sankaranarayanan, 2003). Refer to figure 6.

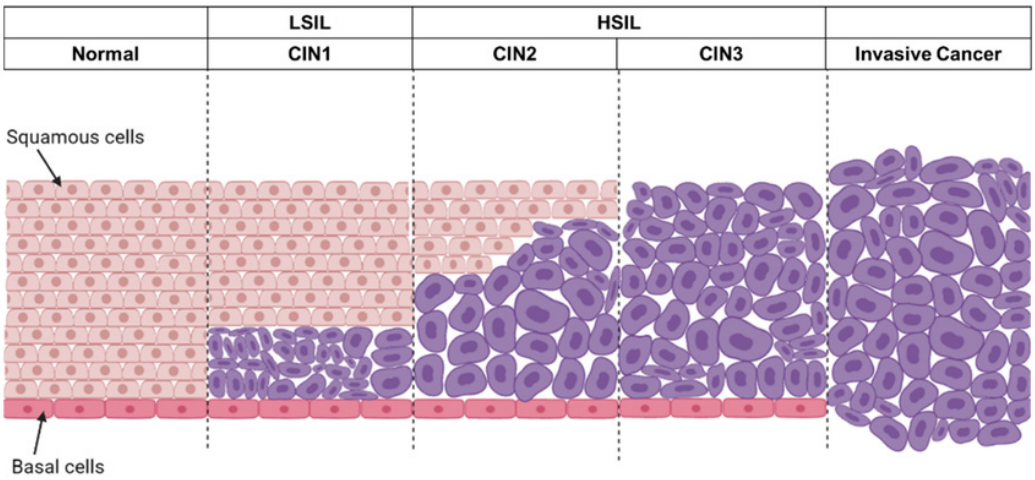


Figure 6: An overview of the progression of cervical cancer. Squamous cells are found in the outer part of the cervix. For Cervical intraepithelial neoplasia 1 (CIN 1) or Low-grade squamous intraepithelial lesion (LSIL), dysplasia occurs in the lower 1/3 or less of the epithelium. CIN2/3, also called high-grade squamous intraepithelial lesion (HSIL), has dysplasia in upper 2/3.
(Image source: Boon et al., 2022)

KEYPOINTS

Persistent infection with high-risk HPV infection is established as a necessary cause of cervical cancer

80% of HPV infection is transient, and clears within 12-18 months

The invasion of basement membrane with dysplastic cells turns in to an invasive cervical cancer.

4. COLPOSCOPY

A colposcopic examination may be an easy or difficult procedure. It is easy for a properly trained colposcopist who is well equipped, and performing colposcopy on a relaxed and comfortable patient. In the absence of these ingredients, it will be a difficult procedure (6). It is easy to have a ***"quick look"*** at the cervix with colposcope. ***This is a mistake.*** A structured examination and documentation of specific findings, particularly the TZ type, and Swede score will result in the best care.

4.1 Indication of colposcopy

4.1.2 Screen positive cases [Human papillomavirus-deoxy ribose nucleic acid (HPV-DNA), Cytology, visual inspection of cervix with 5% acetic acid/visual inspection of cervix with Lugol's iodine (VIA/VILI)].

4.1.3 Suspicious-looking cervix.

4.1.4 Symptoms suggestive of cervical cancer (for e.g., postcoital bleeding (PCB), intermenstrual bleeding (IMB), postmenopausal bleeding (PMB), profuse foul-smelling vaginal discharges, etc.)

4.1.5 Follow up of patients who were treated for cervical cancer.

4.2 Pre-procedure counselling

Precancer is a concept that women often find difficult to understand. The association of the word "cancer" in "precancer" may predominate the patient's perception and to most women it may mean early cancer. So use of more client appropriate words, preferably, in Dzongkha or other relevant local dialect maybe preferable. The stress of having an abnormal screening test and a colposcopic examination is significant and, in this situation, a professional sympathetic care giver is immensely reassuring to most clients. As colposcopy is a low risk OPD procedure which is commonly performed and we might sometimes overlook the need for proper counselling. A woman who has not been properly counselled and is uninformed is more likely to be anxious, scared, and ultimately dissatisfied. Complications though not common, can occur during colposcopy and treatment of CIN. Counselling takes only a few minutes but can be rewarding for both the colposcopist and the clients.

Most colposcopy services have written information covering screening, investigation, and treatment. Written information is important but does not replace the need for face-to-face, open, and interactive counselling.

Colposcopy counseling, especially the first visit, by the healthcare providers is helpful for women in relieving anxiety (Pornsinsiriruck et al., 2023).

Besides counselling, anxiety associated with colposcopic examination appears to be reduced by a variety of interventions including playing music during colposcopy, and viewing the procedure on a TV monitor such as video colposcopy (Galaal et al., 2011).

Following should be discussed with the client:

- Maintain privacy.
- The HPV report/other reports/ other indications should be explained.
- The client should be encouraged to ask questions to clear misconceptions.
- A brief description of colposcopy and any other additional procedures that maybe required such as cervical biopsy, ECC and thermocoagulation.
- Information on procedure should also include information on measures taken to ensure privacy of the client during the procedure.
- Though complications are usually rare during colposcopy and related procedures, the possibility of some complications such as bleeding and infection should be explained to the client.
- If a biopsy has been taken, she should be given clear instructions, preferably in writing, as to how she will obtain the results of the biopsy.
- Further treatment and follow up plans should be clearly communicated.

4.3 Informed written consent

After the procedure has been explained to the client, written informed consent should be obtained by colposcopy nurse/ colposcopist. The written consent form ideally should include information about the colposcopic examination procedure and the common procedures performed, such as cervical punch biopsy, endocervical curettage and photography, and summarize the expected side effects (less serious and more frequent ones, as well as more serious but less frequent ones) that may occur. The standard consent form for colposcopy is in annexure 1.

4.4 Colposcopy steps

4.4.1 Explain the procedure to the client, and ensure that she understood it (Referred to section 4.2)

4.4.2 Obtain written informed consent (Referred to annexure 1)

4.4.3 Make equipment and consumables ready (Referred to annexure 4)

4.4.4 Obtain a relevant medical history including indication for colposcopy, parity, gynecological history (last menstrual period (LMP), oral contraceptive pill (OCP), hormone replacement therapy (HRT), sexually transmitted infection (STI), smoking, and human immune-deficiency virus/acquired immunodeficiency syndrome (HIV) status. LMP is useful to rule out pregnancy or confirm menopausal status.

4.4.5 Colposcopy nurse to check and document blood pressure (BP) and pulse rate (PR).

4.4.6 Ensure her to empty the bladder.

4.4.7 Colposcopy nurse should help the client to get onto the examining table and make her feel comfortable on the examination table, help her to undress and prepare for colposcopy.

4.4.8 Hands of the colposcopist should be washed thoroughly with soap and water/ thoroughly sanitize with alcohol-based hand sanitizer, and dried with clean hand towel or air dry.

4.4.9 New pair of sterile gloves need to be worn on both the hands.

4.4.10 Place her in the lithotomy position.

4.4.11 Place screen across the client to help her feel comfortable.

4.4.12 Inspect external genitalia for conditions such as growth, discharges, urinary incontinence, scar, etc.

4.4.13 Insert cusco speculum gently and position to fully visualize the cervix in a plane perpendicular to the colposcopic line of vision. Fix the speculum blades in an open position so that the speculum will remain in place with the cervix in view. Application of gel lubricant or warm water would facilitate smooth and comfortable insertion of speculum through the introitus. If the woman has a patulous vagina, it may be necessary to surround the speculum with condom or finger of large gloves (with its end cut off) or use of lateral vaginal wall retractor, so that the vaginal walls are held out of the line of vision.

4.4.14 Obtain specimens for laboratory examination, if necessary, such as endocervical swab and/ or high vaginal swab for culture/ microscopy.

4.4.15 Look for type of transformation zone, leukoplakia, warts, signs of infection, abnormal bleeding, cervical polyp, etc.

4.4.16 Apply normal saline and wait for one minute. The application of normal saline is an ideal way to inspect surface abnormalities such as leukoplakia, condylomata and the best way to examine the details of cervical capillaries and surface blood vessels. Otherwise, application of acetic acid and even lugol's iodine solution to the cervix can result in tissue swelling and consequent opacity, which in turn obscures some of the details of the vessels in the subepithelial tissues.). The distal and proximal borders of transformation zone should be identified again. Visualize under green/blue filter light.

4.4.17 Apply freshly prepared 5% acetic acid and wait for one minute: The two main purposes of applying acetic acid are first to conduct another inspection of the entire new SCJ and second, to detect and evaluate any areas of abnormal or atypical TZ. The acetowhitening effect of acetic acid develops gradually over the course of 60 seconds and the effect may fade after wards. Hence, acetic acid may be reapplied every 2-3 minutes during the examination. Use spray or direct application with cotton-soaked acetic acid.

4.4.18 Apply lugol's iodine solution. Normal squamous (both original and matured metaplastic) epithelial cells contain stores of glycogen that give a mahogany brown or nearly black stain when an iodine containing solutions, such as Lugol's, is applied. In contrast, normal columnar epithelium doesn't contain glycogen, and does not take up the iodine stain. Similarly, immature squamous metaplasia, inflammatory and regenerating epithelium, congenital TZ, condylomata either do not or only partially stain with iodine. In low to high grade cervical precancer, one would expect to see a range of staining from partially brown to mustard yellow, because they contain little or no glycogen. Also, the iodine test is very helpful for determining whether vaginal lesions are present.

4.4.19 If punch biopsy needs to be performed, take biopsy/s from the worst identified lesion (s) close to the SCJ (referred to chapter 5)

4.4.20 In order to control bleeding, apply Monsel's solution (paste) to biopsy site and remove the speculum (referred to section 5.5).

4.4.21 Perform bimanual examination to assess the cervical consistency, uterine position and size, and adnexal mass.

4.4.22 Help the client to get off from the examination table.

4.4.23 Tell the client about the importance of returning for further investigations and treatments.

KEYPOINTS

- The entire colposcopy procedure for one client should take about 15 minutes
- Proper counselling and informed written consent are required for colposcopy
- Every step of colposcopy should be followed
- Bimanual examination needs to be performed at the end of colposcopy
- Follow 2011 IFCPC terminology and swede score to document colposcopy finding
- Multiple punch cervical biopsies from dense acetowhite area to be taken under local anesthesia, and send in 10% formalin with a proper label
- If in doubt, second opinion should be sought from colleagues

4.5 Interpretation of colposcopy and calculation of swede score

Initially document colposcopy according to the IFCPC nomenclature (Referred to annexure 5), then the Swede score is calculated (Referred to annexure 6). Five characteristics are taken into consideration to assign a score of 0, 1, or 2. Images of different categories of findings of all five characteristics are shown below to improve the image recognition skills.

4.6 Vascular patterns

Vasculature will be easier to see with green or blue filter after cleaning away the cervical mucus with normal saline. These filters remove the background redness, thereby enhancing the image of the vessels, which will appear black. Two types of cappillaries apparent underneath the native

or original squamous epithelium: reticular or hairpin-shaped cappilaries. Reticular pattern is visible in thin epithelium, for example in women using oral contraceptive pills and postmenopausal women. Normal and atypical vasculature are shown in Figure 7a.

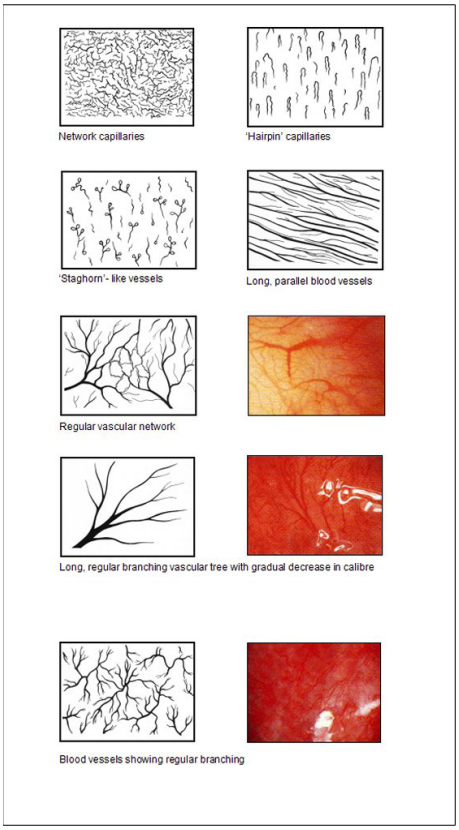


Figure 7a: Normal vascular pattern.

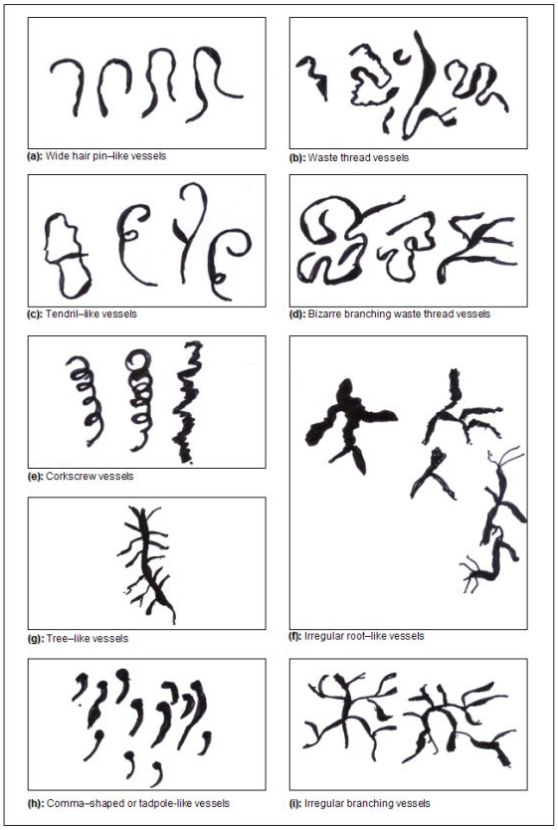
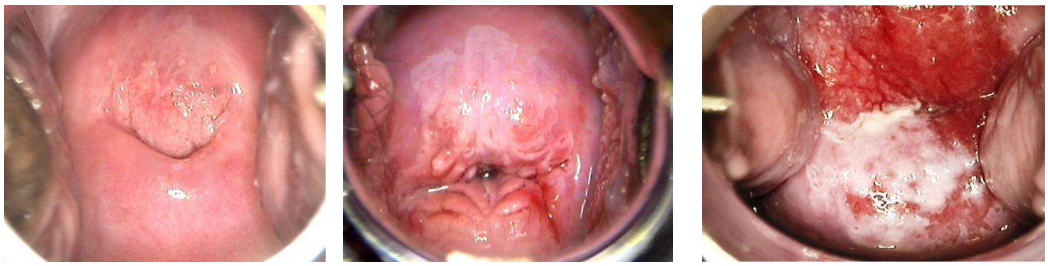


Figure 7b: Atypical vascular pattern

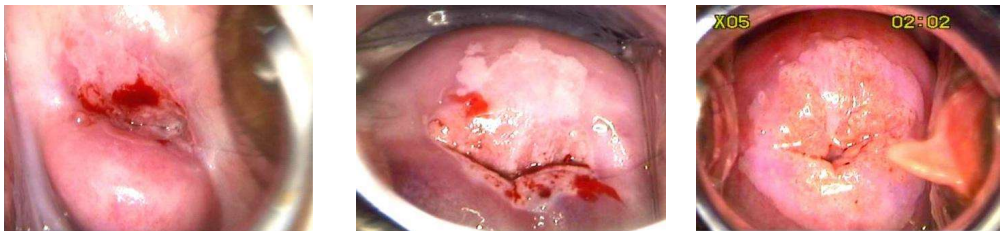
(Image source: Atlas of colposcopy: Principles and practice)

4.7 Application of 5% acetic acid



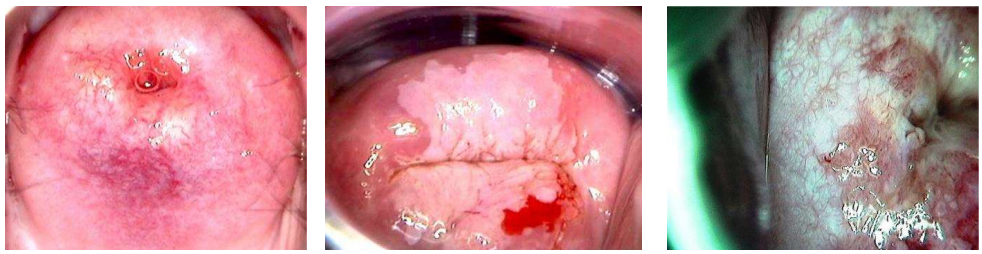
0: Zero or transparent | 1: Shady, Milky (not transparent, not opaque) | 2: Distinct, Opaque white

Figure 8: Density of acetic acid uptake
(Image source: Atlas of colposcopy: Principles and practice)



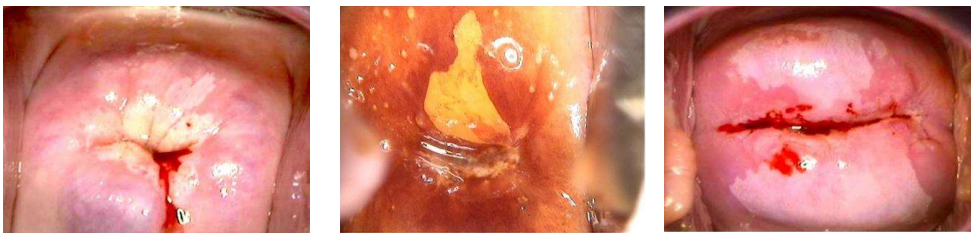
0: Diffuse or no margin | 1: Sharp but irregular, jagged, "geographical"; satellites | 2: Sharp and even; difference in surface level, including "cuffing"

Figure 9: Margin and surface of the lesion
(Image source: Atlas of colposcopy: Principles and practice)



0: Fine, regular | 1: Absent | 2: Coarse or atypical

Figure 10: Characteristics of blood vessels
(Image source: Atlas of colposcopy: Principles and practice)



0: < 5 mm | 1: 5-15 mm or spanning 2 quadrants | 2: > 15 mm or spanning 3-4 quadrants, or endocervically undefined

Figure 11: Size of lesion
(Image source: Atlas of colposcopy: Principles and practice)

0: Brown | 1: Faint or patchy yellow | 2: Distinct yellow

Figure 12: Result of application of Lugol's iodine
(Image source: Atlas of colposcopy: Principles and practice)

4.8 Features of invasive cervical cancer

- Growth or ulcer with necrotic areas
- Dull dense acetowhite area on the TZ; usually large
- Acetowhite area with raised well demarcated margins and the surface is elevated at places
- Atypical vessels (bizarre shapes, no definite branching patterns, unequal thickness along the stem, often raised from the surface, shiny and easily bleed at touch)
- Coarse mosaic, coarse punctuation or combinations of these
- Erosion of the surface that bleeds easily
- Uniform Iodine negative area

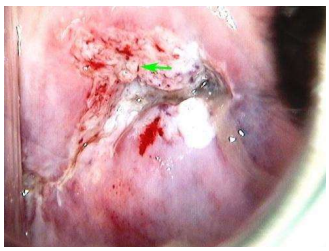


Figure 13: After AA: The surface of dense acetowhite area is irregular. Green arrow- irregular surface.

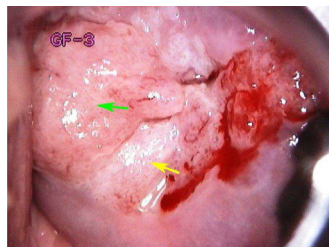


Figure 14: After AA: The columnar epithelium has become densely acetowhite with a sharp margin and an irregular surface. Yellow arrow: Dense acetowhite area, Green arrow: Irregular surface.

4.9 Ridge sign

Thick and elevated acetowhite area which is projected near the SCJ as the top of a wall or ridge.

Indicates the presence of a high-grade lesion

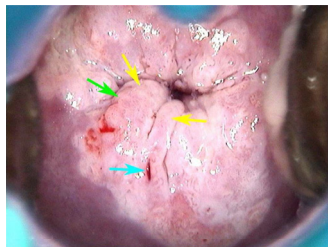


Figure 15: Ridge sign: A dense acetowhite area elevated near the external os, forming multiple ridges. Blue arrow: atypical vessels, Green arrow: Ridge, Yellow arrow: Ridges

4.10 Inner border sign

Low-grade and high-grade lesions may coexist, and there may be internal margins (borders) because of the abrupt change in the nature of a lesion or lesions. This is called a “lesion within a lesion” or the “inner border sign” and is a feature of high-grade neoplasia. The inner, more proximal lesion is more severe and of higher grade.

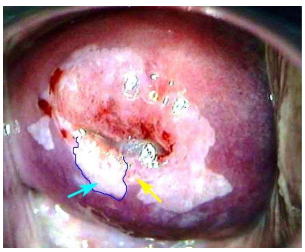


Figure 16: Inner border sign: a dense acetowhite lesion within a thinner acetowhite area. Blue arrow: Dense acetowhote area, Yellow arrow: Thin acetowhite area.

4.11 Rag sign

In high-grade lesions and invasive cancers, the epithelium tends to peel off easily. The eroded area is visible, and the peeled-off epithelium is seen to be hanging like rags. This phenomenon is usually iatrogenic, caused by overenthusiastic rubbing of the epithelium.

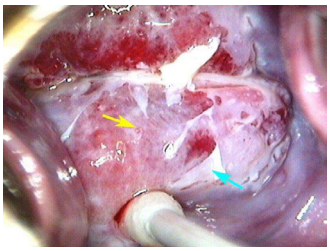


Figure 17: Rag sign: peeled-off epithelium from a large acetowhite area on the posterior lip of the cervix. Yellow area: erosion, Blue area: Peeled-off epithelium

KEYPOINTS

- Document colposcopy finding using 2011 IFCPC terminology and use swede score.
- Type of TZ can be identified during naked eye exam, after application of normal saline and 5% acetic acid.
- Multiple punch biopsies from dense acetowhite area under local anesthesia to be taken.

4.12 Post colposcopy counselling

- Inform the clients about the colposcopy findings, and the significance of positive results.
- When positive findings are detected, reassure the client that appropriate treatment for the condition is available, and arrangements will be made for that.
- Emphasize the importance of early treatment.
- If a biopsy was taken during colposcopy, information needs to be given to the woman when the biopsy report will be available.
- If she needs to clarify anything, encourage her to ask questions and respond with empathy.
- Provide necessary advices to take care of herself when she goes home;
  - » Advise her to abstain from sexual intercourse until she is free from discharges or bleeding if biopsy was taken.
  - » Tampons should not be used for one month.
  - » Avoid swimming or getting in to rivers, lakes etc. for 2 weeks.
  - » The client should be informed about the signs and symptoms that may occur due to complications. Eg: Active bleeding, serious cramping or lower abdominal pain, pus-like discharge, fever etc. If she experiences any of these, she needs consult gynecologist.

KEYPOINTS

- Sympathetic and informative post-colposcopy counseling is essential.
- Follow up plan is required whatever the colposcopy results with/out cervical biopsy.

4.13 Inflammatory lesions of cervix

Inflammatory conditions of the cervix are associated with excessive, usually malodorous, mucopurulent, seropurulent, or whitish discharge, red punctations, ulceration, and healing by fibrosis. Specific infections include:

4.13.1 Candidiasis

- May be asymptomatic
- Thick cheese-like discharge and pruritus of vulva and vagina

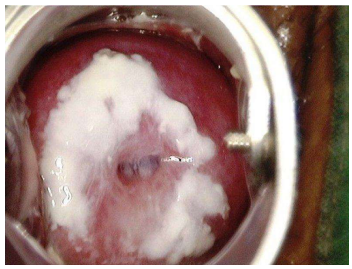


Figure 18: Typical appearance of candidiasis on high-power examination of the cervix

4.13.2 Trichomoniasis

- Intensely pruritic and offensive (fishy) discharge
- Frothy discharge- sometimes almost green, and quite profuse

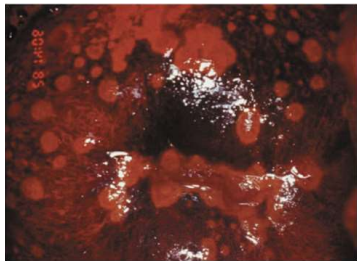


Figure 19: Leopard-skin appearance of vaginitis associated with a trichomoniasis infection

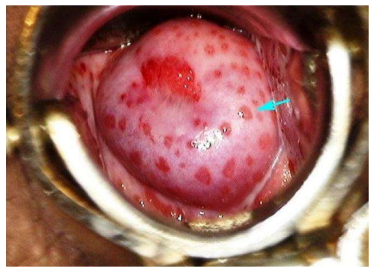


Figure 20: Multiple small ulcers cause straw berry appearance of the cervix, typically seen in trichomoniasis

4.13.3 Nonspecific cervicitis

The infected cervix is often tender on movement and is congested with prominent but normal branching blood vessels. Inflammation of the columnar epithelium can give cervix a beefy-red appearance.

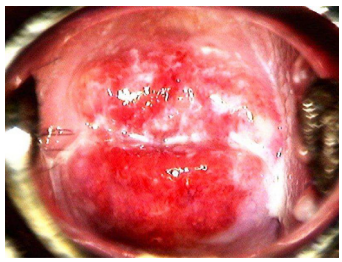


Figure 21: Nonspecific cervicitis

4.13.4 Atrophy

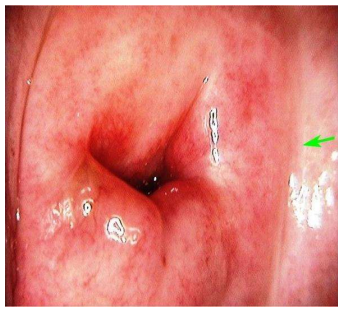


Figure 22: Speculum: Fornices are shallow due to atrophy of the cervix. The cervix looks pale. Blood vessels are visible through the thin epithelium.

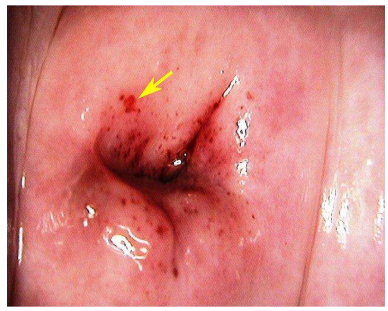


Figure 23: After application of normal saline: Subepithelial bleeding induced by manipulation, known as petechial spots. The SCJ is not visualised.

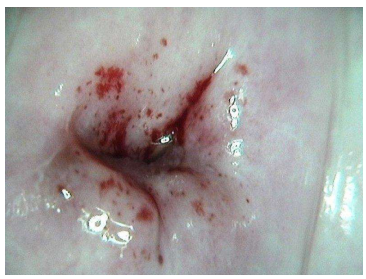


Figure 24: Green filter light: Subepithelial bleeding seen more prominently. No abnormal vessels seen.

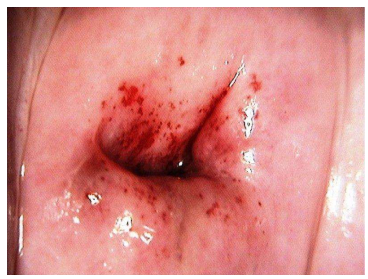


Figure 25: After acetic acid: The SCJ is not visible. NO acetowhite area.

(Image source: Atlas of colposcopy: Principles and practice)

KEYPOINTS

- Inflammatory lesions are not confined to the transformation zone. It may mimic cervical precancer or cervical cancer.
- A biopsy will sometimes be necessary to discriminate between infection and cervical precancer or cervical cancer.

4.14 COLPOSCOPY DOCUMENTATION

Colposcopic examination should be performed in a systematic and structured way, which documents the adequacy of the examination, the type and size of the transformation zone, and the degree of abnormality as reflected in an objective diagnostic scoring system 2011 IFCPC (Referred to annexure 5) and interpreted using the swede score (Referred to annexure 6).

High-quality patient management requires meticulous documentation of the woman's medical record. The results of consultations, examinations and treatments must be recorded electronically on ePIS and DHIS 2 tracker capture. Comprehensive documentation should include a photo (up loaded in ePIS) or drawing of the cervix (included in the colposcopy record form). To standardize the annotations used on the drawing, the following colors should be used:

- SCJ outline ➜ **black line**
- Acetowhite ➜ **blue shade**
- Biopsy site ➜ **"X" with red color**

Description of abnormalities should be in line with the 2011 IFCPC terminology (referred to annexure 5).

5. CERVICAL BIOPSY

A Townsend cervical punch biopsy forceps (Figure 26) is used for this procedure to collect tissue samples from the cervix. Taking multiple biopsies (2 – 4 biopsies) from different areas of the cervix is recommended (Nam et al., 2010)(Perkins et al., 2020).

Figure 26: Townsend cervical punch biopsy forceps.

(Image source: https://urlshort.app/MLQDTP)

5.1 Purpose of cervical biopsy

- To confirm the presence of a pre-cancerous lesion (CIN) or cervical cancer
- To evaluate a suspicious vaginal or cervical lesion identified during a pelvic examination
- To monitor women receiving conservative treatments for pre-cancerous lesions
- Post treatment follow-up

5.2 Timing of punch biopsy

Punch biopsy should be performed a week after the end of menstruation because menstrual blood will obscure the view of the cervix. It is performed during colposcopy if indicated.

5.3 Questions to be asked from the woman before performing cervical punch biopsy

- Whether the woman is pregnant
- Any allergies to medications
- Any bleeding disorder or taking anticoagulant or antiplatelet drug
- Advise the woman not to apply vaginal creams or medications for 24 hours before the procedure
- Empty her bladder before the procedure

5.4 Procedure of the colposcopic-directed punch biopsy

- Before cervical punch biopsy, use lidocaine spray on the cervix to reduce the pain associated with the procedure (Mongkolmafai et al., 2024).
- Low power magnification of the colposcope is used to obtain a panoramic view of the cervix.
- Take biopsy from the area with maximum disease severity, closest to the squamocolumnar junction.
- Take multiple directed punch biopsies (2 – 4 biopsies)
- The posterior cervical lip is sampled first to prevent obscuring due to bleeding.
- Biopsy forceps is placed straight over the lesion to be biopsied.
- The opened biopsy forceps is positioned in such a way that the fixed jaw end of the forceps is placed within the cervical os.
- When a biopsy is taken from the posterior lip, the biopsy instrument handles are held upside down.
- Cervix need to be pushed backwards with the open biopsy forceps as much as possible in order to prevent slipping of the forceps from biopsy site.
- Forceps handles are squeezed together immediately to take biopsy
- Open the jaws of the forceps to release the specimens directly into the container containing 10% formalin solution
- Send all the biopsy specimens in one container with proper labeling
- Hemostasis is achieved by applying Monsel's solution using swab stick for 30 - 60 seconds.
- Endocervical curettage may be performed after colposcopy-directed biopsy if;
  - » SCJ is not completely visible (TZ 3).
  - » Lesion extends into the endocervical canal.
- Endocervical curette specimen should be sent in a separate container in 10% formalin solution

5.6 Complications of punch biopsy

- Bleeding for up to a week after the procedure
- Infection
- Mild cramping
- Vaginal soreness
- Dark vaginal discharge for 1- 3 days

5.7 Advices to be given to the patient after cervical punch biopsy

- Avoid strenuous activities for 8 – 24 hours.
- Avoid sexual intercourse, douching, and tampons for one week.
- Mild cramping after a biopsy is normal and can take painkillers.
- Slight bleeding may also be normal after biopsy and use sanitary napkins rather than tampons.
- Inform the doctor immediately if heavy bleeding (more than the menstrual bleeding) or foul smelly vaginal discharge lasting for more than 2 days

5.8 Endocervical curettage (ECC)

ECC should be performed using an endocervical curette under local anesthesia (Figure 27), and send the specimen in a separate container containing 10% formalin.

Figure 27: Endocervical curette
(Image source: https://fondby.com/3iZpT)

5.9 Procedures

Curette the entire 360-degree endocervical canal from cranial to caudal movement.

5.10 Perform ECC for patients (Massad et al., 2023):

- When the squamocolumnar junction is not fully visualized at colposcopy (TZ 3)
- Acetowhite extending inside the endocervical canal
- AIS

KEY POINTS

- Multiple cervical biopsies to be performed under local anesthesia, and send in one container with proper labelling.
- ECC to be performed under local anesthesia covering 360-degree of endocervical canal, and send in a separate container.

6. TREATMENT OF CERVICAL PRECANCER

The treatment of cervical precancer depends on the grade of the disease. The treatment options for cervical precancer fall into two categories: ablative (thermo-coagulation) and excisional procedure (LEEP).

6.1 LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP)

Loop electrosurgical excision procedure is the term used to describe excision of the transformation zone. The procedure is performed using a low-voltage diathermy loop of thin wire with a blended current under local anesthesia / total intravenous anesthesia (TIVA). It has both therapeutic and diagnostic benefits.

6.1.1 The eligibility criteria for LEEP (Prendiville and Sankaranarayanan, 2017)

- Confirmed CIN on cervical biopsy.
- Lesions should be clearly seen and if the lesion extends into the endocervical canal (extension should be <1 cm)
- No evidence of PID
- Postpartum >3 months
- Blood pressure should be controlled

6.1.2 Indications of LEEP (Prendiville and Sankaranarayanan, 2017) (WHO, 2017)

- AIS
- CIN I lesions persistent beyond two years.
- CIN II OR III lesions
- CIN lesions that cannot be treated by ablative procedure
- CGIN
- CIN lesions in those previously treated with ablation.
- HSIL with type 3 TZ and no visible lesions in colposcopy
- ECC showing glandular abnormality.

6.1.3 LEEP procedures

- Counseling and obtain written inform consent (referred to annexure 2) and ensure the fulfilment of eligibility criteria.
- Place the patient in lithotomy position.
- Apply a screen across the patient.
- With all the necessary equipment ready on a trolley and with a trained assistant present, introduce an appropriately sized insulated suction speculum and expose the cervix.
- Use lateral vaginal wall retractor in patulous vagina (referred to annexure 4).
- Adjust the speculum so that the cervix is visualized clearly.
- The procedure should start with adequate infiltration of local anesthetic. Avoid 3 and 9 o'clock positions (Referred to figure 28).
- Use a dental syringe or spinal needle to infiltrate 2% lignocaine with adrenaline subepithelially.
- After infiltration of local anesthetic, the diathermy ground plate is attached to the patient and suction pipe to the suction tube on the anterior blade of the speculum and activate the suction machine.
- Select and set the appropriate power setting on the ESU in blend mode (45:45)
- Select the appropriate size of the loop depending on the lesion size.
- Apply Lugols iodine to delineate the lesion margin.

- The un-activated loop is introduced and held a millimeter off the entry point for resection (without touching the cervix).
- The loop electrode should be activated just before making contact with the epithelium. Use the cutting button (yellow button) in the diathermy hand piece.
- The entry point should be 1-2 mm away from the outer limit of the lesion delineated by lugol's iodine.
- The TZ should be resected in a single pass as far as possible from either 3 o'clock or 9 o'clock position or from posterior to anterior.
- Resection from the anterior to the posterior should be avoided as the bleeding may obscure the surgical field.
- Diathermise the circumferential margin (360 degree) after excision.
- The 12 o'clock position should be suture marked on the specimen and immersed in a container containing 10% formalin solution (within 30 mins).
- Specimen obtained with multiple passes (fragmented specimens) should be anchored in anatomical position (orientation of specimen) before sending for histopathological examination OR send fragmented specimens in a separate container labelled clock wise.
- Hemostasis is achieved with a ball electrode using fulguration. Activation of current (fulguration mode) with coagulation button on hand piece without touching the surface (1-2 mm away) leads to fulguration. Touching the surface causes charring of the cervix.
- Hemostasis can also be achieved by packing with Monsel-soaked gauze.
- Suturing may be required if the hemostasis is not achieved with the above two methods/if there is profuse venous/arterial bleeding at the onset.
- Before removing the speculum, blood or iodine should be cleaned from the posterior fornix.
- The procedure should be documented.
- The patient should be counseled about the procedure and the follow-up information.

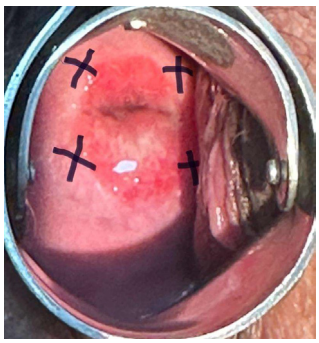


Figure 28: Common cervical sites of local anesthetic agents' administration at 2, 4, 8 and 10 O'Clock positions

6.1.4 Post-treatment advice to patients:

The patient information leaflet should be given to all patients, and explained verbally before the patient leaves the hospital (Referred to annexure 8)

6.1.5 Complications of LEEP

- Bleeding
- Infection
- Cervical incompetence and stenosis (late complications)

6.1.6 Types of LEEP

The type of excision depends on the type of TZ as well as the nature and extent of the lesion.

6.1.6.1 Type 1 LEEP

Type 1 excision is adequate for CIN 2/3 lesions provided the transformation zone is type 1 (SCJ is fully visible on the ectocervix) (Figure 29). The acetowhite inner margin should be fully visible. In type 1 excision, the endocervical canal is excised minimally.

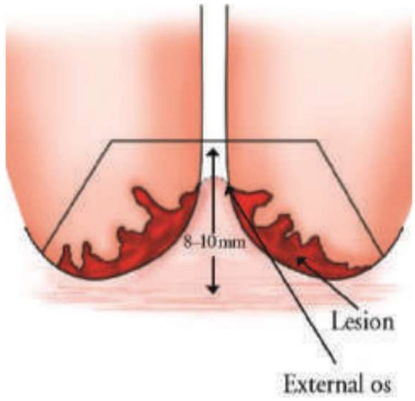


Figure 29: Showing type 1 LEEP

6.1.6.2 Type 2 LEEP

Type 2 excision is done for CIN 2/3 lesions extending into the endocervical canal (Figure 30). The upper margin of the lesion should be visualized clearly. Type 2 excision is done for the type 2 transformation zone and the endocervical component should be included.

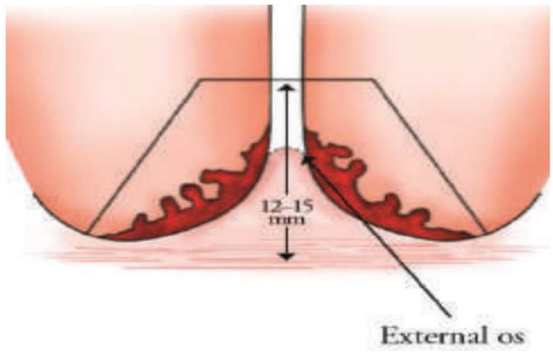


Figure 30: Showing type 2 LEEP

6.1.6.3 Type 3 LEEP

A type 3 excision is done for CIN2/3 lesions with a type 3 transformation zone and glandular lesions (Figure 31). It involves the excision of the endocervical canal (1.5 to 2 cm) as the upper limit of the lesion is not visible. Type 3 excision might require TIVA. If it is not possible to perform Type III LEEP, perform additional top hat excision. The proximal margin of top hat specimen should be suture marked.

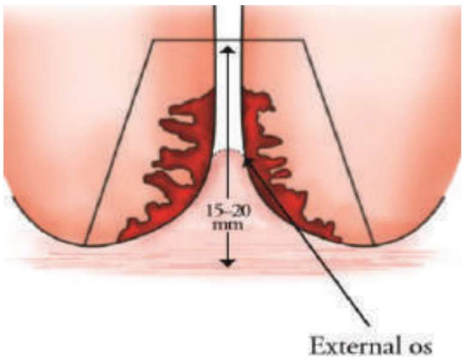


Figure 31: Showing type 3 LEEP.

KEY POINTS

- The amount of peri- and post-LEEP bleeding is reduced with adequate infiltration of local anesthesia and hemostasis is more easily achieved.
- Treatment by LEEP aims to excise the entire TZ to an adequate depth.
- To minimize the coagulating diathermy effect on the specimen and the wound, a blend mode should be used.
- If not able to perform Type III LEEP, perform additional top hat resection.

6.1.7 Follow-up after LEEP for HSIL

- HPV testing at 12 months is recommended regardless of the margin status of the excisional (LEEP) specimen.
- If the repeat HPV test at 12 months is negative, repeat the HPV test in another 12 months. If 2 tests are negative, 5 yearly HPV tests for at least 25 years.
- If the repeat HPV test at 12 months is positive, colposcopy with biopsies/ECC should be performed. If the report is HSIL irrespective of margin status, go for repeat excision. If re-excision is not desirable or feasible, a hysterectomy is recommended (Figure 32)

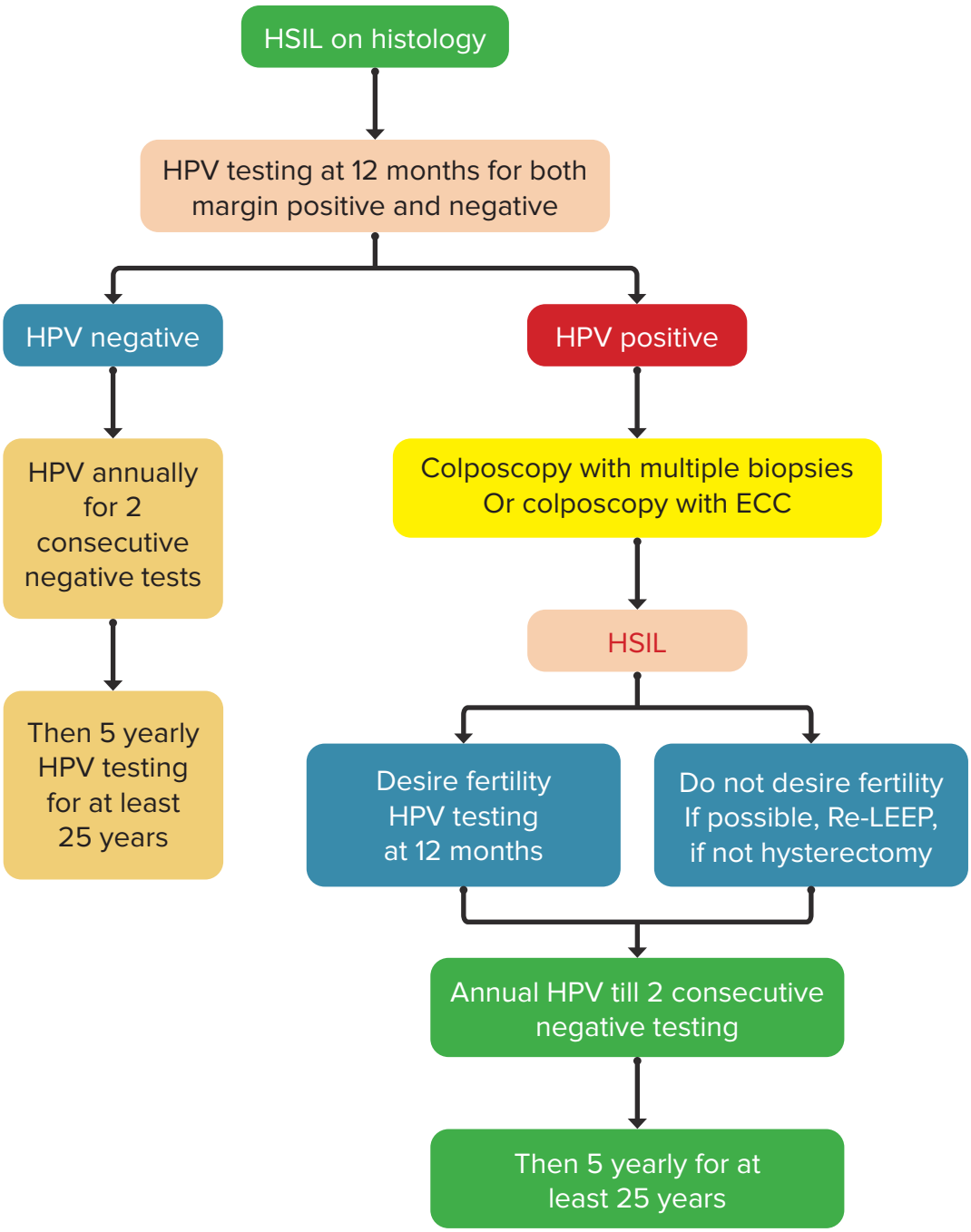


Figure 32: Flowchart showing follow-up of HSIL on histology (Perkins et al., 2020)

6.1.8 Follow-up after treatment for LSIL

- Repeat HPV testing annually for 2 times and for two consecutive negative results, then followed by 5 yearly HPV tests for at least 25 years (Perkins et al., 2020) (Figure 33).

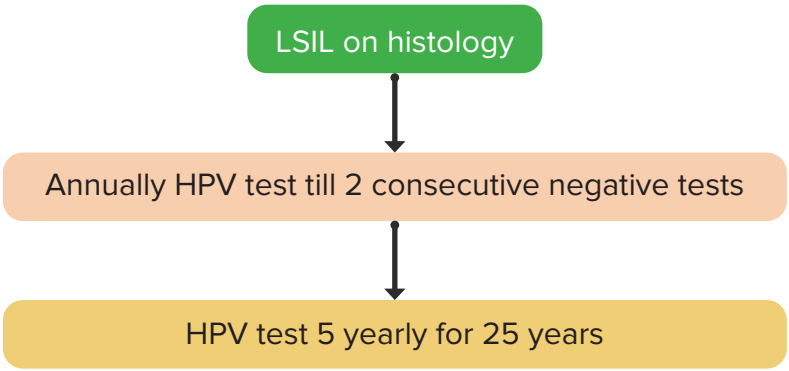


Figure 33: Flowchart showing follow-up for LSIL on histology

6.1.9 Follow-up of AIS after LEEP (Figure 34)

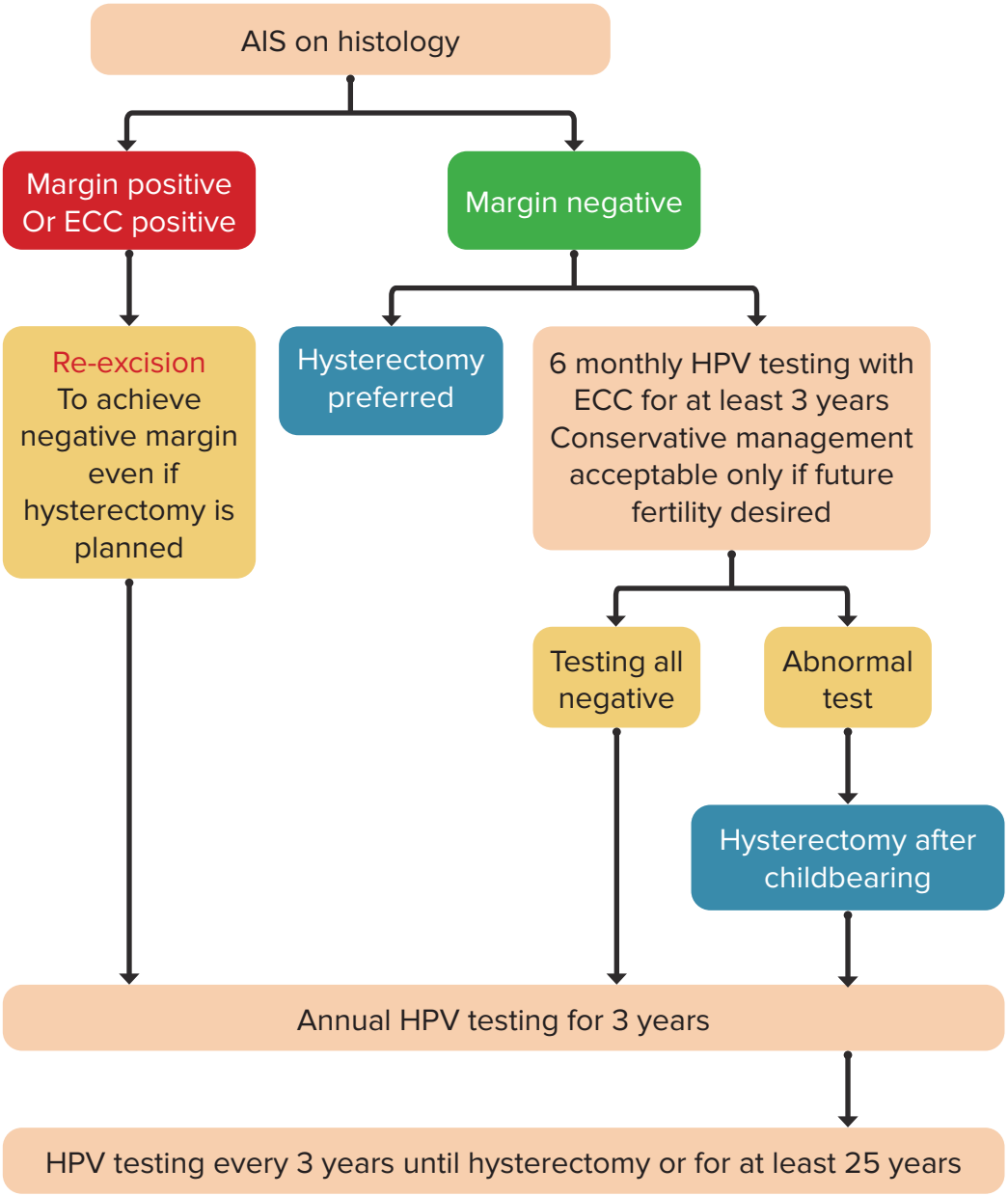


Figure 34: Flowchart showing follow-up for AIS on histology
(Perkins et al., 2020)

6.2 THERMAL COAGULATION

This destructive or ablative procedure is performed using a thermal coagulation machine (Figure 35) which involves heating the probe electrically to a temperature of 100–120 °C. At that temperature, the

intracellular water reaches boiling point and the cells get necrosed. It achieves tissue destruction to a depth of 4–7 mm. It is a useful technique to be used in remote regions with poorly equipped facilities. It is easy to learn and perform, and the procedure takes less than 2 minutes to complete.

Figure 35: Thermal coagulation machine

6.2.1 Eligibility criteria

- The TZ is fully visible,
- The whole lesion is visible and it does not extend into the endocervix
- The lesion is type 1 TZ
- The lesion is type 2 TZ where the probe tip will achieve complete ablation of the SCJ epithelium, i.e., where it can reach the upper limit of the TZ. Sometimes the SCJ can be seen high in the canal but a probe tip would not reach it.

6.2.2 Contraindications

- Suspicious of invasive or glandular lesion
- The TZ is not fully visible because it is endocervical (Type 3 TZ)
- It is a Type 2 TZ where the SCJ is out of reach of the probe tip

6.2.3 Procedure (Prendiville and Sankaranarayanan, 2017)

- Counsel and get informed written consent from the patient
- Confirm the eligibility criteria for destructive therapy (Table 2).
- No prophylactic antibiotic is required (WHO, 2019)

- Check equipment status required for the procedure (clean probe, temperature gauge functional)
- Place the patient in a bed and apply a bed screen across the patient, then place in the lithotomy position
- Insert appropriate size speculum
- Apply 5% AA or Lugols iodine to delineate the site, size and endocervical extension of CIN lesions.
- Take multiple cervical biopsies from the doubtful area of the cervix and place them all in one container with 10% formalin
- Apply probe to the transformation zone on the cervix and ensure good contact with the cervical epithelium
- Ensure vaginal walls are not in contact with the probe
- Activate the thermal coagulation probe, and simultaneously start the stopwatch
- Ensure temperature 100 °C and maintain it for 20 seconds (Prendiville and Sankaranarayanan, 2017)(WHO, 2019)
- If the transformation zone is larger than the thermal coagulation probe head, apply the probe for further 20 seconds to untreated areas, overlapping with the previously treated area (as many applications as needed to cover the entire TZ in overlapping fields).
- Deactivate the thermal probe first, then only withdraw the probe
- Then decontaminate the probe (Referred to annexure 3)

6.2.4 Complications of thermal coagulation

A few cases of mild cramps or pain and heat sensation in the vagina are reported (Peters, 2019)

1. Watery vaginal discharge
2. Heavy/malodorous vaginal discharge
3. Mild vaginal bleeding
4. Cervical infection
5. Cervical stenosis
6. Fever
7. PID
8. Vasovagal reaction

6.2.5 Follow-up of HPV positive with normal colposcopy finding

HPV annually till 2 consecutive negatives, then 5 yearly screenings with HPV (Perkins et al., 2020)

7. HISTOPATHOLOGY

7.1 Specimen accessioning (Prematilleke et al., 2021)

Sample accessioning refers to the process of accepting the samples in the histopathology laboratory and entering the sample data in the ePIS, and generating a UHID/barcode number. The UHID/ barcode number helps to track the specific sample

7.2 Requisition form

All the samples are accompanied by a requisition form containing the following patient information (Lester et al., 2016).

- Patient name/age/CID/mobile number.
- Brief clinical history (Hormonal/ menstrual/contraceptive) with diagnosis/differential diagnosis.
- Imaging finding if any.
- HPV/ LBC result.
- Colposcopy finding.
- Type of procedure: Cervical biopsy, LEEP (Type I, II, III), ECC.
- Location of the lesion (Clock face sutured marked).
- Name of the surgeon with BMHC number.

7.3 Container (Prematilleke et al., 2021)

1. All tissue submitted for histopathological examination must be in a container having:

Leak proof with a well-fitting/screw cap lid
Unbreakable

Large enough to hold the specimen and adequate volume of fixative

Multiple cervical biopsy samples can be sent in one container

Figure 36: Ideal container

The container/s should be kept ready with fixative to assure direct transfer of specimens to the container immediately after removal.

The following should be clearly and indelibly stated on each container label

- Patient name and age
- UHID/CID/mobile number
- Anatomical site and exact location (clockwise)
  - » The information on the specimen container should match with the information provided. in the requisition form.
  - » The label should be firmly attached to the container.
  - » Labelling or writing on the lid should be avoided.
  - » ***Never pre-label specimen containers.***

KEYPOINTS

- The information in the specimen label should correlate with the information given in the histopathology request form.
- The label should be firmly attached to the specimen container.
- Labelling or writing on the lid should be avoided.
- Never pre label specimen containers.

7.3 Fixation/ Fixative (Suvarna, Layton and Bancroft, 2018)

- Fixation is an initial step in cells or tissue processing for microscopical examination in histopathology. The aim of fixation is to protect the tissue from microorganisms, minimization of all enzymatic and other metabolic activities, prevention from decomposition, putrefaction, and autolysis, as well as hardening and strengthening the tissue as much as possible to minimize damage. During this procedure, the semi-fluid state of the cell or tissue converts to hardened specimens where their original states are preserved
- Ideal fixative: 10 % neutral buffered formalin. In our set up, we use 10% formalin
- Cold ischemic time: The time from removal of the tissue from the body to the time the specimen is placed in fixative. Place the tissue in the formalin as soon as possible or at least before 30 minutes (Neumeister et al., 2012).

7.4 Preparation of 10% Formalin (1 liters)

1. Add 100 ml of concentrated formalin in 900 ml of tap water and mix well.
2. Date of preparation to be recorded every time a new solution is prepared.

7.5 Safety issues while preparing 10% formalin

As formaldehyde fumes are toxic and carcinogenic

1. Use PPE such as gloves, mask, goggles, and apron while preparing formalin
2. Formalin fixatives should be prepared in a well-ventilated room

7.6 Grossing (Lester et al., 2016)

7.6.1 Colposcopic biopsy: Describe color, number of fragments, size and submit as such if ≤ 2mm and if ≥ 2mm, submit entirely in 2-3 mm thickness of block.

7.6.2 Loop Electrosurgical Excision Procedure (LEEP) (Goldblumn et al., 2017)

- Orientation marker.
- Specimen description: color, consistency, shape.
- Measurement: number of pieces, maximum dimension, length of canal, diameter of ectocervix.
- Macroscopically visible lesion: absent/ present.
- Inking of the specimen is not necessary, if the cauterized margins are easily identified on gross examination. However, ink the margin if uncertain. Section serially from 12 O` clock position at 2-3 mm thickness and submit in entirety.

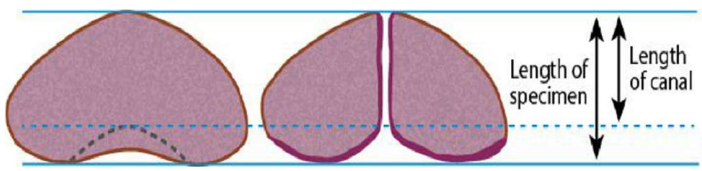


Figure 37: Measurement of LEEP biopsy.
(Image source: Jenkin IK, Newman M, Anderson L, 2017)

7.7 Microscopy (Darragh et al., 2012)

7.7.1 Reporting for cervical intraepithelial neoplasia (CIN)

- Low grade squamous intraepithelial lesion (LSIL): CIN I, p16 negative CIN II
- High grade squamous intraepithelial lesion (HSIL): p16 positive CIN II, CIN III, CIS:
- Margin status.

7.7.2 Synoptic reporting for invasive tumor (Crothers et al., 2023)

- Tumor site.
- Tumor size: Greatest dimension in cm.
- Histologic type.
- Histologic grade.
- Depth of stromal invasion: Specify in (mm).
- Horizontal extent of stromal invasion: Specify in (mm): (Not applicable in larger tumor that can be measured grossly).
- Lymphatic and / or Vascular Invasion.
- Margin status: endocervical/ ectocervical/both/deep margin.

7.8 Immunohistochemistry (Jenkin IK et al., 2017)

In the diagnosis of cervical precancer lesions, p16 and Ki67 immunohistochemistry is beneficial;

- Where there is diagnostic uncertainty for an HSIL (eg cervicitis, difference in opinion between pathologists).
- Where morphology is CIN2.

In the case of tissue artefact hindering accurate assessment of specimen margins. P16 may assist in clarifying margin status by highlighting an area of HSIL or AIS. Caution is however advised in interpretation of IHC in tissue affected by artifact. Ki67: Increased proliferation index compared with LSIL.

KEYPOINTS

- Adequate clinical information, type of procedure and tissue orientation to be provided by the gynecologist.
- Mandatory use of 10% formalin as a fixative with adequate volume in appropriate container.
- p16 and Ki67 IHC is recommended in categorizing CIN 2 in to either LSIL or HSIL
- Pathologist signing out an invasive gynecological cancer histopathology to inform the concerned gynecologist/gyne-oncologist, so ensure that the proper treatment is/are provided to the clients.

8. MONITORING AND EVALUATION FOR COMPLIANCE OF THE PROCEDURE

For any systematically conducted program, monitoring and evaluation is essential to have information on services provided, procedures performed, pathological conditions treated and number of women attended. For this purpose, a colposcopy and LEEP details can be extracted from ePIS. The National Cancer Control Program (NCCP), Ministry of Health will collect information and maintain record on biannual basis. The colposcopy nurse/ colposcopist will be responsible for reporting on colposcopy and the gynecologists/scrub nurse will report on LEEP procedures in the ePIS. There will be an annual supervision and monitoring conducted by colposcopy nurses and onco-gynecologists using the checklist (Referred to annexure 7) for internal quality assurance purposes.

KEY POINTS

- NCCP will be responsible for spear heading quality control of colposcopy and LEEP services
- The supervision and monitoring of colposcopy and LEEP services will be conducted on annual basis for quality control purposes and to maintain standard practice across the country

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ANNEXURE-1:

CONSENT FOR COLPOSCOPY AND PUNCH BIOPSY

PROPOSED PROCEDURE

Colposcopy is a diagnostic examination that permits a clinician to examine the cervix, vagina, and vulva under magnification to determine the cause of abnormal findings from previous HPV screening. The colposcopic examination will assist the clinician in determining or finding an abnormal area that is visible. In order to establish the degree of abnormality and to assist in the type of treatment, one or more biopsies may be taken. A cervical biopsy is a small sample of tissue that is obtained from the surface of the cervix after applying a local anaesthetic spray. An endocervical curettage yields a small sample of tissue removed from inside the opening in the cervix. After analysis of tissue specimens, the laboratory provides a diagnosis for guidance in possible treatment.

BENEFITS

- Minimally invasive.
- Will assist in treatment and further management.

RISKS

I understand that during or after the procedure one or more of the following might occur:

- May have some vaginal bleeding or discharge if a cervical biopsy was taken.
- Small risk of infection.

LIMITATIONS

No examination or test is 100% accurate, and that no 100% guarantee can be made as to the correctness of diagnosis.

DECLARATION

- I understand that a single colposcopic examination might not explain my problem, and that additional examinations and testing might be recommended.
- If any staff member is injured or exposed to my blood or other body fluid then I give my consent to a sample of my blood being collected for the purpose of testing for infectious diseases, such as Hepatitis B, C and HIV, after proper counseling.

I acknowledge that I have been informed about the procedure, I have read and or understood the above information and I give my consent to the proposed procedure.

Client's name and signature/ thumb print:
Date:
Witness' name and signature:

ANNEXURE 2:

CONSENT FORM FOR LEEP

PROPOSED PROCEDURE

This means removing tissue from the cervix using a hot wire. A speculum is placed in the vagina. A 5% dilute acetic acid solution is painted onto the cervix to show areas of cervix to be removed using the wire loop. The wire seals small blood vessels as the tissue are removed, controlling minor bleeding. The tissue removed is then sent for histopathological examination. The procedure may be done under a local anesthesia or short general anesthesia.

BENEFITS

I understand the benefits such as;

- Minimally invasive procedure
- Quick recovery.
- Effective for treating cervical precancer (success rate up to 95%).

RISKS

I understand that the LEEP has the following limitations:

- May have some vaginal bleeding or discharge for a few days after the procedure.
- May have some abdominal cramps while the procedure is happening (if done under local anesthesia).
- Will have a blackish per vaginal discharge while the wound heals.
- May have a small risk of local infection, and this can cause a foul-smelling discharge (incidence is around 1.6%).
- There is a small risk that you may find it difficult to become pregnant or to carry the pregnancy to term.

DECLARATION

- I understand that resected tissues will be sent for histological examination.
- If any staff member is injured or exposed to my blood or other body fluid then I give my consent to a sample of my blood being collected for the purpose of testing for infectious diseases, such as Hepatitis B, C and HIV after proper counseling.

I acknowledge that I have been informed about the procedure, I have read and or understood the above information and I give my consent to the proposed procedure.

Client's name and signature/ thumb print:
Date:
Witness' name and signature:

ANNEXURE 3:

INFECTION PREVENTION PRACTICES

The purpose of infection prevention practices is to prevent transmission of microorganisms from an infected person or a contaminated object to another person.

Hand washing

- Wash hands with soap and water, or use alcohol hand rub before each examination.
- After removing the gloves, hands need to be washed thoroughly with soap and water

Decontamination

- Once the colposcopy /thermos-coagulation /LEEP procedure is completed, contaminated objects need to be disposed in a leak-proof container.
- Instruments and other items should be submerged in 0.5% chlorine solution for 10 minutes before health staff handles or cleans it.
- After decontamination, wash the instruments with detergent soap.
- Dispose sharps in the sharp box (Needle, blades).
- Send the leak proof container/plastic bags for proper disposal/ incineration.
- Change mackintosh in each client after every procedure.

Instruments	Different surfaces
0.5% chlorine solution for 10 minutes	0.5% chlorine solution
90% ethyl alcohol	

Cleaning

- Reduces number of microorganisms (including bacterial endospores)
- Rinse thoroughly with running water to remove detergent residue

While cleaning	- Wear utility gloves - Scrub instrument with detergent - Use soft brush to clean instrument - Rinse with running water

Sterilization

Eliminates all microorganisms including bacterial endospores.

High pressure saturated steam sterilization	- Temperature between121-132 degree Celsius at a pressure of 106 kPa (15 lb/inch2) • unwrapped instruments-20minutes • wrapped instruments-30 minutes
Chemical sterilization	• 2-4% Glutaraldehyde for 8-10 hours • 10% Formaldehyde for 24 hours

Steps of HLD by chemical agents

- Soak all cleaned instruments for 20 minutes in correct dilution of selected chemical agent:
  - » 2% Glutaraldehyde solution
- Remove using high-level disinfected cheatle forceps or gloves
- Rinse well with boiled water and air dry/dry with sterile cloth

Use promptly or store for up to 24 hours in high-level disinfected and covered container

Length of safe storage for sterile pack

Wrapping	Closed Cabinet	Clean Open Shelves
Single-wrapped muslin (2 layers)	1 week	2 days
Double-wrapped muslin (2 layers each)	3 weeks	2 weeks

Processing of instruments

Instruments/ consumables	Process required	Suggested procedure
Vaginal speculum, biopsy forceps, endocervical curette, endocervical speculum, vulsellum forceps, insulated speculum,	Decontamination, cleaning followed by sterilization or HLD	Autoclaving
Colposcopy, Cold coagulator/thermo coagulator with probe, LEEP equipments, examination table, instrument trolley, trays	Decontamination	Wipe with ethyl alcohol
Thermocaogulator probe	Decontamination	• Wipe with ethyl alcohol • Rinse with running water and dry • Sterilize at 120 degree centigrade
Suction tubing, cautery hand piece	Decontamination	Plasma Autoclaving
Loop/ball electrodes	Decontamination	• 2-4% Glutaraldehyde for 8-10 hours • 10% Formaldehyde for 24 hours

Colour coding & type of container for disposal of bio-medical wastes

Green waste bin	Red waste bin	Red waste bin	Sharp box
General waste	Infectious waste	Only infectious used gloves	Needle, blades, ampules

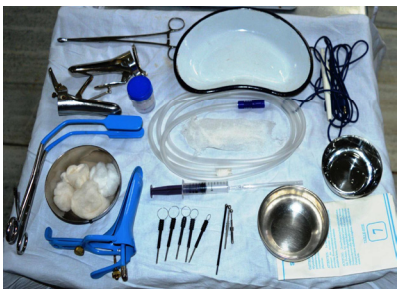
ANNEXURE 4:

INSTRUMENTS/EQUIPMENT'S REQUIRED FOR COLPOSCOPY

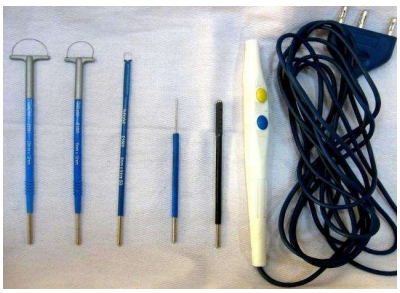
Instruments/equipment's	Consumables required
• Examination table • Focusing Light • Colposcope • Colposcopy Instrument tray containing: » Trolly » Mayo table » Kidney tray » Galipot » Long non-toothed forceps » Self-retaining vaginal speculum (Cusco's) » Sponge-holding forceps » Endocervical speculum » Endo-cervical curette » Cervical Punch biopsy forceps (e.g. Tischler / Townsend biopsy forceps) » Cheatle forceps	• Gloves (sterile and clean) • Cotton swabs • Culture swab sticks • Gauze, cotton and vaginal pack (sterile) • Normal saline • Acetic acid (5%) solution (freshly prepared) • Lugol's iodine • Monsel's solution/paste • 10% formalin • Lubricant jelly • HVS swab • Waste disposal bag • Case record forms/consent form • Histopathology forms • Register • Treatment card • 0.5% Chlorine solution • Glutaraldehyde • Foot drapes/ screen • Mackintosh • Plastic apron • Hand towels

Instruments/equipment's for LEEP

Instruments/equipment's	Consumable required
• OT table • Ceiling lighting for procedure • Insulated speculum with smoke evacuator • suction machine with suction tubing for attachment to speculum • Diathermy machine(with patient plate, hand switch and foot plate) • Loop/ball electrodes • Insulated self-retaining Speculum with smoke extraction channel • Gallipot • Sponge holding forceps • Plain thumb forceps • Syringe for injecting local anaesthetic (Dental syringe, needle, cartridge) • Cheatle forceps • Trolly • Mayo table	• Gown(sterile) • Gloves (sterile) • Hand towels (Sterile) • Cotton swabs (sterile cotton and gauze) • Stirrup • Hole towel (sterile) • Leggings (sterile 1pair) • Normal saline • Betadine 10% • Freshly prepared 5% acetic acid • Lugol's iodine • Monsel's solution/paste • Local anesthetic (1 or 2 % xylocaine/ lidocaine) with or without 1:100,000 epinephrine • Vials for sampling containing 10% Formaldehyde • Waste disposal bags (green, red) • Sharp box • Chlorine solution (0.5%) or 2% Glutaraldehyde • Histopathology form • Register book

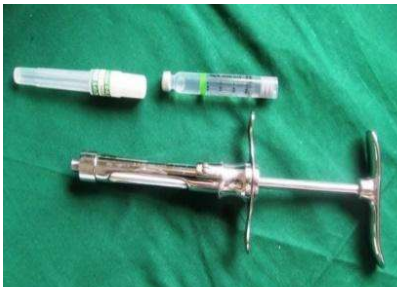


LEEP instruments



Loop electrodes

Insulated speculum



Dental syringe and cartridge

ANNEXURE 5:

2011 IFCPC COLPOSCOPIC TERMINOLOGY OF THE CERVIX

IFCPC Colposcopic terminology of the cervix	
Section	**Pattern**
General assessment	Adequate or inadequate; if inadequate, for what reason (e.g. cervix obscured by inflammation, bleeding, scar) Squamocolumnar junction visibility: completely visible, partially visible, not visible Transformation zone types 1, 2, 3
Normal colposcopic findings	Original squamous epithelium: mature, atrophic Columnar epithelium; ectopy/ectropion Metaplastic squamous epithelium; Nabothian cysts; crypt (gland) opening Deciduosis in pregnancy

<table>
<tr><td rowspan="3">Abnormal colposcopic findings</td><td colspan="2">General Principles</td></tr>
<tr><td>Location of the lesion:
• Inside or outside the transformation zone
• By the “clock position”

Grade 1 (minor)
• Fine mosaic; fine punctation
• Thin acetowhite epithelium
• Irregular, geographical border</td><td>Size of the lesion:
• Number of cervical quadrants the lesion covers
• Size of the lesion as a percentage of the cervix

Grade 2 (major)
• Sharp border; inner border sign; ridge sign
• Dense acetowhite epithelium
• Coarse mosaic; coarse punctation
• Rapid appearance of acetowhitening
• Cuffed crypt (gland) openings</td></tr>
<tr><td>Non-specific
• Leukoplakia (keratosis, hyperkeratosis); erosion
• Lugol’s staining (Schiller test): stained or non-stained</td><td></td></tr>
<tr><td>Suspicious for invasion</td><td colspan="2">Atypical vessels
Additional signs: Fragile vessels, irregular surface, exophytic lesion, necrosis, ulceration (necrotic), Tumour or gross neoplasm</td></tr>
<tr><td>Miscellaneous findings</td><td>Congenital transformation zone Condyloma
Polyp (ectocervical or endocervical)
Inflammation</td><td>Stenosis
Congenital anomaly post-treatment consequence
Endometriosis</td></tr>
<tr><td>Excision treatment types</td><td colspan="2">Excision types 1,2,3</td></tr>
</table>

Excision specimen dimensions	Length: the distance from the distal or external margin to the proximal or internal margin Thickness: the distance from the stromal margin to the surface of the excised specimen Circumference (optional): the perimeter of the excised specimen
IFCPC, International Federation of Cervical Pathology and Colposcopy	

ANNEXURE 6:

SWEDE COLPOSCOPIC SCORE

	0	1	2	Score
Acetowhite area	Zero or transparent	Shady, milky (not transparent, not opaque)	Distinct, opaque white	
Margin/ Surface	Diffuse	Sharp but irregular, jagged, “geographical” satellites	Sharp and even, differences in surface level, including “cuffing”	
Vessels	Fine regular	Absent	Course or atypical	
Lesion size	<5 mm	5-15mm or 2 quadrants	>15 mm or 3-4 quadrants/ endocervical undefined	
Iodine staining	Brown	Faint or patchy yellow	Distinct yellow	
Total score (Maximum 10)				

INTERPRETATION OF SWEDE SCORE

Over all swede score	Colposcopic prediction of probable histology
0-4	Low grade lesion/Normal/CIN I
5-6	High grade lesion/CIN 2/CIN 3
7-10	High grade lesion/CIN 3/Suspected cancer

ANNEXURE 7:

CHECKLIST FOR SUPERVISION AND MONITORING OF COLPOSCOPY AND LEEP PROCEDURES

Regarding colposcopy and punch biopsy			
1. Availability of logistics a. Freshly prepared 5% acetic acid b. Lugol's iodine c. Monsel's solution/paste d. Normal saline e. Punch biopsy forceps f. Endocervical curette g. Cusco speculum h. Swab sticks/cotton ball/vaginal pack i. Hand towels j. Gulli pot	Yes	No	Any remarks
2. Are the universal precautions followed? a. Handwashing/hand sanitization b. Wearing of sterile gloves c. Decontamination of beds, colposcope and instruments d. Wearing apron/face mask e. Availability of 0.5% chlorine solution f. Separate buckets for waste disposal			
3. Pre-requisites a. Was the counseling done? b. Was the written informed consent obtained? c. Was there patient privacy? d. Were the colposcopy record form and register maintained?			

4. Are the steps of colposcopy followed? 1. Steps of speculum insertion 2. Application of normal saline and waiting for one minute 3. Application of acetic acid and waiting for one minute 4. Application of Lugol's iodine			
5. Was the post-procedure counseling done?			
6. Was the specimen labelling done properly?			
7. Regarding punch biopsy a. Was local anesthesia used? b. Was the biopsy taken from dense acetowhite area? c. Were multiple biopsies taken and sent in same container? d. Were ECC sent in a separate container?			
Regarding LEEP			
1. Availability of logistics a. Lugol's iodine/5% acetic acid b. Loop electrodes of different sizes and cautery hand piece c. Insulated cusco with suction tube/ machine			
2. Was the counselling done? 3. Was the written informed consent taken?			

4. LEEP procedure a. Was lithotomy position done correctly? b. Check insulated speculum intactness/ damages? c. Did the surgeon apply Lugol's iodine/5% AA to delineate the lesion margin? d. Did surgeon apply local anesthesia correctly? e. Did the surgeon follow aseptic precautions? f. Did the surgeon choose right diathermy setting? g. Was the diathermy plate/pad applied properly? h. Did the surgeon identify type of TZ and nature of lesion? i. Did surgeon remove specimen in one piece? j. Was fulguration done to achieve hemostasis? k. Was the circumferential margin diathermised? l. Did the surgeon orient the tissue (suture at 12'O clock position)? m. Was the histopathology form filled correctly and specimen properly labelled?			

ANNEXURE 8:

PATIENT INFORMATION SHEET (POST LEEP, THERMO-COAGULATION, TAH)

Name:

Age: HPV-DNA number:

Date of surgery: Anesthesia type:

Indication:

Name of surgeon:

What is expected after LEEP/ Thermocoagulation/ TAH	What to do after LEEP/ Thermocoagulation/ TAH	Signs for which you need to see a doctor
• No symptoms • Mild abdomen pain • Water discharge for 2-4 weeks	• Avoid sexual intercourse for one month • Do HPV tests in 12 months • Collect histopathology report in 4-6 weeks and consult a gynecologist • Do not use tampon or douching	• Fever lasting more than 2 days • Severe pain in abdomen lasting more than 4 hours • Vaginal bleeding lasting more than 2 days or the bleeding is heavier than your menstruation or clots come out • Purulent and foul smelling vaginal discharge

ANNEXURE 9:

PREPARATION OF 5% ACETIC ACID, LUGOL'S IODINE SOLUTION, AND MONSEL'S PASTE

5% dilute acetic acid

Ingredients	Quantity
1. Glacial acetic acid	5 ml
2. Distilled water	95 ml

Preparation of 100 ml of 5% acetic acid: Carefully add 5 mL of glacial acetic acid into 95 mL of distilled water and mix thoroughly.

Storage: Unused acetic acid should be discarded at the end of the day.

Label: 5% dilute acetic acid

Note: It is important to remember to dilute the glacial acetic acid, because the undiluted strength causes a severe chemical burn if applied to the epithelium.

Note: The fresh 5% acetic acid should be prepared on the day of procedure.

Lugol's iodine solution

Ingredients	Quantity
1. Potassium iodide	10 g
2. Distilled water	100 ml
3. Iodine crystals	5 g

Preparation:

A. Dissolve 10 g of potassium iodide in 100 mL of distilled water.
B. Slowly add 5 g of iodine crystals, while shaking.
C. Filter and store in a tightly stoppered brown bottle.

Storage: 1 month

Label: Lugol's iodine solution. Use by (date of expiry)

Monsel's paste

Ingredients	Quantity
1. Ferric sulfate base	15 g
2. Ferrous sulfate powder	A few grains
3. Sterile water for mixing	10 ml
4. Glycerol starch	12 g

Preparation

Take care: The reaction is exothermic (emits heat).

1. Add a few grains of ferrous sulfate powder to 10 mL of sterile water in a glass beaker. Shake.
2. Dissolve the ferric sulfate base in the solution by stirring with a glass stick. The solution should become crystal clear.
3. Weigh the glycerol starch in a glass mortar. Mix well.
4. Slowly add ferric sulfate solution to glycerol starch, constantly mixing to get a homogeneous mixture.
5. Place in a 25 mL brown glass bottle.
6. For clinical use, most clinics prefer to allow enough evaporation to give the solution a sticky, paste-like consistency that looks like mustard. This may take 2–3 weeks, depending on the environment. The top of the container can then be secured for storage. If necessary, sterile water can be added to the paste to thin it.

Note: This preparation contains 15% elemental iron.

Storage: 6 months

Label: Monsel's paste Shake well External use only Use by (expiry date)