Department of Public Health and Family Welfare

NATIONAL HEALTH MISSION
GOVERNMENT OF MADHYA PRADESH

2021 TREATMENT MANUAL

MANAGEMENT OF

Cervical Precancer Using Cryotherapy, Thermal Ablation and LLETZ/LEEP Devices

FOR HEALTHCARE SERVICE PROVIDERS

ANNEXURE 21

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ANNEXURE 21

PREFACE

Cervical cancer is the second most common cancer among women in India. In 2020, around 1.24 lakhs women were diagnosed with the disease and around 77 thousand women died from the disease (Globocan 2020).

Under the National Program for Prevention and Control of Cancer, Diabetes, CVD, and Stroke (NPCDCS), cancer screenings including cervical cancer are to be conducted at all levels in the healthcare delivery system from sub-centers and above for early detection of common cancers. However, screening programs contribute to reducing prevalence and mortality from the disease only when successfully linked to high-quality treatment services. This manual has been drafted to build the capacity of healthcare service providers on the treatment of cervical precancer, thereby bridging the gap between screening and treatment and enabling continuum of care.

The objective of this manual is two-fold- firstly, it aims to orient program managers, state officials, and master trainers on conducting training for treatment of cervical precancer, and second, it aims to impart theknowledge and skill set for the treatment of cervical precancer to service providers.

There are four sections in the manual. The first section outlines the objective and the training materials included in the manual. The second section gives details about two different training modes for the treatment of cervical pre-cancer along with a detailed training schedule for each of the modes. The third section covers technical information on treatment along with an overview of cervical cancer and the anatomy of the cervix. The principle of treatment, eligibility criteria, steps-wise procedure, and post-treatment care and follow-up have been covered for each of the three treatment modalities – cryotherapy, thermal ablation, and LLETZ/LEEP in detail.

The fourth section of the manual includes annexures. The annexures include checklists for screening and treatment, image bank for enhancing interpretation and selection of treatment modality, session-wise training presentations, and safety precautions COVID-19 scenario. Representative samples of reporting, consent, and referral forms to be used at health care facilities have also been included.

This manual is designed as ready reference material service providers and will hopefully act as an effective tool in capacity building for the treatment of cervical precancer.

ACKNOWLEDGEMENT

We express our sincere gratitude to the Department of Health, Government of Madhya Pradesh and state senior leadership including Additional Chief Secretary, Department of Health and Family Welfare (DoHFW), Principal Secretary, Department of Health and Family Welfare (DoHFW), Principal Secretary, Department of Medical Education (DME), Commissioner, Directorate of Health Services, Commissioner, DME, Mission Director, NHM, Deputy Director NCD, NHM, Deputy Director MH, NHM for acknowledging the need for capacity building of health care workers for early screening of common cancers and providing constant support in the conceptualization of this Handbook to support the roll-out of population-based screening of common cancers under the NPCDCS program.

We acknowledge the valuable support that the Department of Health has provided by constituting an expert technical committee with Dr. Archana Mishra, DD MH, NHM, Dr. Ashish Saxena, DD NCD, NHM, Dr. Kavita N Singh, Professor and Head, Department of Obstetrics and Gynecology, NSCB Medical College, Jabalpur, Dr. Saritha Shamsunder, Senior Specialist in Obstetrics and Gynecology, VMMC and Safdarjung Hospital, Delhi, President ISCCP, Dr. Jyoti Bindal, Dean, MGM Medical College, Indore, and President AMPOGS, Dr. Madhuri Chandra, Former Professor, Gandhi Medical College, Bhopal, Dr. Shikha Ghanghoria, Surgical Pathologist and Professor, MGM Medical College, Indore, Dr.Ajay Halder, Associate Professor, Obstetrics and Gynecology, AIIMS, Bhopal, Dr. Jyoti Chauhan, Gynecologist, DH Sagar and CGM (Technical) MPPHSCL and DD Diagnostics DHS.

We are also thankful to Dr. Sarman Singh, Director, AIIMS, Bhopal for constituting a technical committee under the Government of India 6-district pilot initiative for screening and management of common cancers. Eminent members of the committee Dr. Saikat Das, Associate Professor of Radiation Oncology, AIIMS, Bhopal, Dr. Deepti Joshi, Additional Professor, Pathology and Lab Medicine, AIIMS, Bhopal, Dr. Vikas Gupta, Associate Professor, Otorhinolaryngology and Head - Neck Surgery, AIIMS, Bhopal, and Dr. Ajay Halder, Associate Professor, Obstetrics and Gynecology, AIIMS, Bhopal, provided technical guidance in the drafting of this handbook and we are thankful to them for their valuable feedback.

We acknowledge the support of Dr. Ruchi Pathak, Lead Medical Officer, Department of Preventive Medicine, Mahamana Pandit Madan Mohan Malviya Cancer Centre, Varanasi, and Dr. Archana Mishra, Associate Professor, Obstetrics and Gynecology at VMMC and Safdarjung Hospital, members ISCCP for providing valuable feedback in finalization of this Manual.

In drafting this Trainer's Manual, various documents, and publications by the Indian Council of Medical Research (ICMR), National Institute of Cancer Prevention and Research (NICPR), and Operational Guidelines on Cervical Cancer Screening and Management of Cervical Pre-Cancers were referred. Along with it, Training Manual on Cervical Cancer Screening using VIA by ICMR, Operational Framework for Management of Common Cancers by Ministry of Health and Family Welfare, Trainees' Handbook for Cervical Cancer Screening and Management of Cervical Pre-Cancers by World Health Organization and 'Colposcopy in Practical Gynecology' by Dr. Priya Ganesh Kumar and Dinesh Gupta were also referred. Additionally, images from WebMD website have been used.

We are extremely grateful to Unitaid and CHAI's Cancer Team for their contribution to enable us to move a step forward in achieving the overall objective of improving secondary prevention by improving the screening and treatment services for common cancers.

FOREWORD

मोहम्मद सुलेमान
Mohammed Suleman (IAS)

अपर मुख्य सचिव
लोक स्वास्थ्य एवं
परिवार कल्याण विभाग
मध्य प्रदेश सरकार

Additional Chief Secretary
Department of Public Health and
Family Welfare
Government of Madhya Pradesh
Bhopal (MP)
0755-2708890
acshealth@mp.gov.in

Government of Madhya Pradesh has been working dedicatedly to ensure the availability, affordability, and accessibility of healthcare services for every segment of its population. Through a dynamic approach the government is committed to strengthen the system to bravely face the emerging healthcare challenges including the recent Coronavirus pandemic.

With the changes in environment and lifestyle as the burden of Non-Communicable Disease (NCDs) and especially of common cancers is rapidly increasing, public health systems are being strengthened to provide preventive healthcare services including early screening and treatment. Under the purview of National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) public health facilities and service providers are being empowered for an effective last mile delivery of these services.

Under the program, to achieve the objective of population-based screening for the age group 30-65 years and reduce the incidence of common cancers, new Health and Wellness Centers are being established. Collaboration is being done with all the stakeholders for early diagnosis and management of common cancers by strengthening the existing healthcare systems in Madhya Pradesh.

I am thankful to the Expert Technical Committee constituted by National Health Mission, Department of Public Health and Family Welfare Madhya Pradesh for drafting this manual to help the service providers with knowledge & skills to accurately diagnose and treat the identified positive cases post screening. I am confident that this will aid in building a robust preventive cancer care system in the state of Madhya Pradesh.

Mohammed Suleman

FOREWORD

फैज़ अहमद किदवई
Faiz Ahmed Kidwai (IAS)

प्रमुख सचिव
लोक स्वास्थ्य एवं
परिवार कल्याण विभाग
मध्य प्रदेश सरकार

Principal Secretary
Department of Public Health and
Family Welfare
Government of Madhya Pradesh
Bhopal (MP)
0755-2708808
pshealth@mp.gov.in

Madhya Pradesh government is committed to provide quality health services to the citizens. To ensure this Primary Health Centres are being upgraded to Health and Wellness Centres and continuous efforts are being made towards strengthening the healthcare system.

Presently, non-communicable diseases pose a big challenge to public health. To address this, National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) is underway to reduce the burden of non-communicable diseases, under which, persons in the age group of 30-65 years are screened for common cancers and other NCDs. Deaths from common cancers that can be stopped by means of timely screening and treatment. According to GLOBOCAN- 2018 report, about 12 lakh new cases of cancer are reported every year, and about 8 lakh patients lose their lives from it. A third of those deaths are accounted by oral, breast and cervical cancer alone.

This Training Manual is drafted by the health department with the objective of helping trainers to equip the healthcare providers with necessary knowledge and skills to conduct accurate cancer screenings and guide those detected positive in the ablest manner.

I hope that this Manual, drafted under the guidance of expert committee constituted by the health department and AIIMS, will prove to be worthwhile for the service providers in early diagnosis and management of common cancers.

Faiz Ahmed Kidwai

FOREWORD

छवि भारद्वाज
Chhavi Bhardwaj (IAS)

मिशन संचालक
राष्ट्रीय स्वास्थ्य मिशन
मध्य प्रदेश सरकार

Mission Director
National Health Mission
Government of Madhya Pradesh
Bhopal (MP)
0755-4092503
mdnhm@mp.gov.in

The National Health Mission (NHM) has been working dedicatedly to make quality healthcare available, affordable and accessible for everyone, especially the most vulnerable sections with its rural and urban sub-missions.

In India, about 12 lakh new cases of cancer are diagnosed every year and 8 lakh people lose their lives to the disease. However, the healthcare system for conducting cancer screening and spreading awareness on common cancers continue to remain in poor state.

The Ministry of Health and Family Welfare (MoHFW), Government of India has launched the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) under NHM. The program is aimed at generating awareness, with a goal to screen 80% of the eligible population for NCDs in the next three years by enabling screening at primary health care level through our Health and Wellness Centres (HWCs) To achieve this goal, DoHFW, Government of Madhya Pradesh is working to address the gaps in healthcare system for services related to common cancers (oral, breast and cervical cancers). I am confident that this illustrative and descriptive Training Manual will go a long way in empowering the health care workers with appropriate information in identifying the possible cases of common cancers and provide appropriate guidance to positively screened patients.

I am also grateful to the expert technical committee for their support in drafting of this Manual for healthcare providers. This will go a long way in addressing the increasing burden of cancer in the state of Madhya Pradesh.

Chhavi Bhardwaj

LIST OF CONTRIBUTORS

1. **Dr. Shashi Thakur**
   MBBS, DGO Obstetrics and Gynecology, Diploma in Laparoscopic Surgery, PG diploma in Yoga and Meditation, Deputy Director, NHM

2. **Dr. Archana Mishra**
   MBBS, MD Obstetrics and Gynecology, Deputy Director, Maternal Health, NHM

3. **Dr. Ashish Kumar Saxena**
   MBBS, Deputy Director, NCD, NHM

4. **Dr. Madhuri Chandra**
   MDOBG, DNBOBG, FICOG, CMCL FAIMER Fellow, Former Professor and Unit Head, Obstetrics and Gynecology, Gandhi Medical College, Bhopal, ICOG: Governing Council Member

5. **Dr. Prof. Kavita N. Singh**
   MS PhD Obstetrics and Gynecology FICOG FICMCH, Professor and Head, Department of Obstetrics and Gynecology, NSCB Medical College, Jabalpur, Former Fellow Gyn Oncology and Colposcopy TMH Mumbai, RCC Trivandrum, & IACA Fellow RPCI Buffalo NY, Trainer Colposcopy IFCPC, FOGSI

6. **Dr. Saritha Shamsunder**
   MBBS MD, Obstetrics and Gynecology, Senior Specialist and Professor Obstetrics and Gynecology, VMMC and Safdarjung Hospital, Delhi, President ISCCP 2018-21

7. **Dr. Shikha Ghanghoria**
   Professor and Surgical Pathologist, MY Hospital, MGM Medical College and Government Cancer Hospital Indore, Consulting Surgical Pathologist, Aman Diagnostic, Indore, President Elect Indian Association of Pathologist and Microbiologist Madhya Pradesh Chapter

8. **Dr. Saikat Das**
   Associate Professor of Radiation Oncology, AIIMS, Bhopal

9. **Dr. Deepti Joshi**
   MBBS MD(Pathology), Additional Professor, Dept of Pathology and Lab Medicine, AIIMS, Bhopal

10. **Dr. Vikas Gupta**
    MBBS, MS, Additional Professor & I/C, ENT-Head & Neck Surgery, AIIMS, Bhopal

11. **Dr. Ajay Halder**
    MS Obstetrics and Gynecology, DNB Obstetrics and Gynecology, MNAMS, IGCS Fellowship in Gynecology Oncology (Montreal), Associate Professor, Dept of Obstetrics and Gynecology, AIIMS, Bhopal

TREATMENT OF CERVICAL PRECANCER

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SECTION - 1

General Guidelines for Training on Management of Cervical Precancer

Objective of Manual

Under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) of the Government of India, Madhya Pradesh is working towards secondary prevention of cervical cancer through strengthening screening and treatment services for cervical precancer. One of the key components of the program is the capacity building of healthcare staff for providing screening and treatment services.

The manual on 'Management of Cervical Precancer' is developed to –

1. Support program managers, master trainers, and the health department of states in conducting treatment trainings

2. Help healthcare service providers acquire knowledge and skills for treatment

To support training rollout, training materials including agenda for training sessions, knowledge assessment tools-pre and post-training, module-wise presentation to facilitate the training sessions, along with screening and treatment reporting formatsfor documentation of cases have been included in the manual.

For capacity building of healthcare staff, the manual includes detailed modules on treatment. These modules help trainees to learn about the underlying principle of treatment, selection of treatment modalities, step-by-step treatment procedure along with post treatment care and follow-up.The manual also contains screening and treatment checklist and SOPs that serves as ready reference to develop skills during screening and treatment procedures.

The manual also includes guidelines for providing treatment during COVID-19.

This manual builds upon the existing framework for 'Screening and Management of Cervical Cancer at Secondary Level Health Care Facilities' by Non-Communicable Disease Technical Advisory Group (constituted in 2016 by MoHFW).

Trainees and Batch Size

Trainees

- For ablative techniques (cryotherapy and thermal ablation) – Gynaecologists and lady medical officers from primary, secondary and tertiary level facilities can be trained[1]
- For excisional technique (LEEP)- Gynaecologists from secondary and tertiary level facilities should be trained

[1]*Source: Operational Framework for Management of Common Cancers, MoHFW*

Batch Size

Trainings for treatment of cervical precancer should be conducted in small batch sizes to ensure quality of training and engagement of trainees. It is also important to ensure that each trainee is exposed to sufficient number of cases for observation and practice under supervision during hands-on.

Ideal batch size for training should be between 8-10 service providers per batch.

Duration of Training

- For onsite training model, two days trainings covering theory and hands-on is required
- For hybrid training model (online + onsite), three days training covering theory and hands-on is required

Details of training models and sessions given in Section 2.

Training Material

The manual includes the following training material:
1. Session wise training schedule
2. Pre and post training knowledge assessment tools
3. Detailed modules on cervical cancer, anatomy of cervix, treatment of cervical precancer and infection prevention practices
4. Checklist for VIA screening (Annexure 1)
5. Checklist for management of screen positive women (Annexure 2)
6. Image bank for screening and treatment of cervical precancer (Annexure 3)
7. Session wise training presentations (Annexure 4)

SECTION - 2

Training Schedule

Training Models

A two days onsite training was envisaged for treatment of cervical precancer covering theory and hands-on component. However, due to the challenges posed by COVID-19 in conducting the trainings, original model was evolved to a hybrid model consisting of online theory sessions followed by hands-on training at a healthcare facility.

Schedule for both the models of training are given in this manual. In the onsite training model, theory and hands-on session are conducted in two consecutive days at a healthcare facility. In hybrid training model theory sessions are covered in online training spanning across 2 consecutive days followed by hands-on training at a healthcare facility. Summary of sessions and agenda for two training modes are given below-

Summary Of Sessions

Cervical Cancer and Anatomy of Cervix	Time (Minutes)	Time (Hours)
Theory	35	0.4
Sub-Total	**35**	0.4
Cryotherapy		
Theory	125	2.1
Hands-on	120	2
Sub-Total	**245**	**4.1**
Thermal Ablation		
Theory	95	1.6
Hands-on	90	1.5
Sub-Total	**185**	**3.1**
LLETZ/LEEP		
Theory	65	1.1
Hands-on	120	2
Sub-Total	**185**	**3.1**
Other Activities		
Discussion on Program Strategy	40	07
Pre and Post Knowledge Assessment	20	0.3
Recap/Open House/ Device Orientation/ Breaks	130	2.2
Sub-Total	**190**	**3.2**
Total	**840**	**14**

TRAINING SCHEDULE ONSITE MODEL

TRAINING SCHEDULE DAY - 1 THEORY SESSION

S. No	Topics	Time (Minutes)
1	**Session 1- Introductory Session**	
1.1	Opening Remarks and Program Strategy	10
1.2	Introduction of Trainers and Trainees	10
1.3	Pre-Training Knowledge Assessment	10
2	**Session 2- Introduction to Cervical Cancer and Anatomy of Cervix**	
2.1	Introduction to Cervical Cancer, Sign and Symptoms, and Strategies to Prevent Cervical Cancer, Importance of Counselling	15
2.2	Structure of Cervix- SCJ, TZ, Types of TZ	15
2.3	Precancerous Conditions of Cervix	10
3	**Session 3- Introduction to Cryotherapy**	
3.1	Treatment of CINs	5
3.2	Indications and Treatment by Cryotherapy	15
3.3	Setting up Cryosurgical Unit and Device Specific Troubleshooting	10
3.4	Equipment and Consumables for Cryotherapy	5
3.5	SOP for Cryotherapy and Cryotherapy Video	25
	Tea Break	**15**
4	**Session 4- Case Discussions**	**15**
5	**Session 5- Post Cryotherapy**	
5.1	Decontaminate Cryotherapy Unit	5
5.2	Side Effects and Complications, and Post-Treatment Care	20
5.3	Follow-up after Cryotherapy	5
5.4	Common Problems Encountered during Cryotherapy and their Management	10
6	**Session 6- Introduction to Thermal Ablation**	
6.1	Principles of Thermal Ablation	5
6.2	Orientation on Thermal Ablation Device and Device Specific Troubleshooting	10
6.3	Eligibility Criteria for Thermal Ablation	5
6.4	Instruments and Consumables Required, and SOP for Thermal Ablation	15
6.5	Post Treatment Advice, and Management of Treatment Complications	20
	Lunch Break	**45**
7	**Session 7- Case Discussions**	**15**

TRAINING SCHEDULE
ONSITE MODEL

S. No	Topics	Time (Minutes)
8	**Session 8- Treatment of Cervical Precancers by LLETZ/LEEP**	
8.1	Principles of LLETZ/LEEP	10
8.2	Orientation on LLETZ/LEEP Device and Device Specific Troubleshooting	10
8.3	Eligibility Criteria for LLETZ/LEEP	5
8.4	Instruments and Consumables Required, and SOP for LLETZ/LEEP	20
8.5	Post Treatment Advice, and Management of Treatment Complications	20
	Tea Break	**15**
9	Post-Training Knowledge Assessment	10
10	Open House	15
	Total	**420**

TRAINING SCHEDULE DAY - 2
HANDS-ON SESSION

S. No	Topics	Time (Minutes)
1	**Session 1- Hands-On Session**	
1.1	Opening Remarks	10
1.2	Orientation on Cryotherapy, Thermal Ablation and LLETZ/LEEP Device	30
1.4	Hands-On Session for Cryotherapy	120
	Lunch Break	**35**
1.6	Hands-On Session for TA/LLETZ/LEEP Device	210
1.7	Open House	15
	Total	**420**

TRAINING SCHEDULE
HYBRID MODEL

TRAINING SCHEDULE DAY - 1
ONLINE THEORY SESSION

S. No	Topics	Time (Minutes)
1	**Session 1- Introductory Session**	
1.1	Opening Remarks and Program Strategy	15
1.2	Introduction of Trainers and Trainees	10
1.3	Pre-Training Knowledge Assessment	10
2	**Session 2- Introduction to Cervical Cancer and Anatomy of Cervix**	
2.1	Introduction to Cervical Cancer, Sign and Symptoms, and Strategies to Prevent Cervical Cancer, Importance of Counselling	15
2.2	Structure of Cervix- SCJ, TZ, Types of TZ	15
2.3	Precancerous Conditions of Cervix	10
3	**Session 3- Introduction to Cryotherapy**	
3.1	Treatment of CIN	5
3.2	Treatment by Cryotherapy	10
3.3	Indications for Cryotherapy	10
3.4	Setting up Cryosurgical Unit and Device Specific Troubleshooting	10
3.5	Equipment and Consumables for Cryotherapy	5
3.6	SOP for Cryotherapy	15
4	**Session 4- Case Discussions**	**15**
5	**Session 5- Post Cryotherapy**	
5.1	Decontaminate Cryotherapy Unit	5
5.2	Side Effects and Complications	10
5.3	Post-Treatment Care	10
5.4	Follow-up after Cryotherapy	5
5.5	Common Problems Encountered during Cryotherapy and their Management	10
5.6	Cryotherapy Video	10
6	**Open House**	**15**
	Total	**210**

TRAINING SCHEDULE
HYBRID MODEL

TRAINING SCHEDULE DAY - 2
ONLINE THEORY SESSION

S. No	Topics	Time (Minutes)
1	**Session 1- Introductory Session**	
1.1	Opening Remarks	5
1.2	Revision of Cryotherapy	15
2	**Session 2- Introduction to Thermal Ablation**	
2.1	Principles of Thermal Ablation	5
2.2	Orientation on Thermal Ablation Device and Device Specific Troubleshooting	10
2.3	Eligibility Criteria for Thermal Ablation	10
2.4	Instruments and Consumables Required	5
2.5	Steps of Thermal Ablation	15
2.6	Post Treatment Advice	10
2.7	Management of Treatment Complications	10
3	**Session 3- Case Discussions**	30
4	**Session 4- Treatment of Cervical Precancers by LLETZ/LEEP**	
4.1	Principles of LLETZ/LEEP	10
4.2	Orientation on LLETZ/LEEP Device and Device Specific Troubleshooting	10
4.3	Eligibility Criteria for LLETZ/LEEP	5
4.4	Instruments and Consumables Required	5
4.5	Steps of LLETZ/LEEP	15
4.6	Post Treatment Advice	10
4.7	Management of Treatment Complications	10
5	**Post-Training Knowledge Assessment**	**10**
6	**Open House**	**20**
	Total	**210**

TRAINING SCHEDULE DAY - 3
HANDS-ON SESSION

S. No	Topics	Time (Minutes)
1	**Session 1- Hands-On Session**	
1.1	Opening Remarks	10
1.2	Orientation on Cryotherapy, Thermal Ablation and LLETZ/LEEP Device	30
1.4	Hands-On Session for Cryotherapy	120
	Lunch Break	**35**
1.5	Hands-On Session for TA/LLETZ/LEEP Device	210
1.6	Open House	15
	Total	**420**

PRE AND POST TRAINING KNOWLEDGE ASSESSMENT

Objective

To assess the knowledge of service providers before training (pre-test) and to assess the effectiveness of training (post-test).

Time: 10 Minutes

1. All the statements about thermal ablation are true, except:

a. Ablative technique

b. Causes thermal destruction of tissue at 100–120°C

c. Multiple applications to cover a large lesion can be done

d. Requires anaesthesia

2. Woman is eligible for cryotherapy/thermal ablation if:

a. Entire lesion is visible on the ectocervix are occupies less than 75% of the cervix

b. Lesion occupies 90% of TZ

c. Extension on to vaginal wall

d. Suspicion of invasive cancer

3. Which of the following statements is false?

a. Mature epithelium evenly stains with Lugol's iodine

b. Dense acetowhite areas are seen after application of acetic acid on normal atrophic

c. Petechial haemorrhagic spots may appear after manipulation in postmenopausal women

d. SCJ recedes into the endocervical canal in post-menopausal women

4. **The following is a true statement for cryotherapy procedure:**

   a. 5–3–5 minute double freeze technique is used

   b. Pressure of refrigerant gas should be 40–70 kg/cm

   c. Ice ball is not formed at the end of the procedure

   d. Pull off cryotip immediately at the end of procedure

5. **Advantage of thermal ablation is:**

   a. Can treat lesions within the endocervical canal

   b. Electricity not required

   c. Tissue is obtained for confirmation of diagnosis

   d. No anaesthesia required

6. **Following are the warning signs for a woman to return to the health facility immediately after cryotherapy, except:**

   a. Foul-smelling or pus-coloured vaginal discharge

   b. Severe lower abdominal pain

   c. Fever for more than 38 °C

   d. Spotting or light bleeding

7. **Which of the following is a false statement about post-cryotherapy advice?**

   a. Complete abstinence for 4-6 weeks

   b. Report immediately if light bleeding occurs

   c. Use sanitary napkins for a few days after treatment

   d. Report if purulent vaginal discharge occurs

8. **Which of the following is not an indication for LEEP?**

   a. Glandular abnormality on punch biopsy

   b. Discordance between cytology, colposcopy and punch biopsy

   c. Treatment failure with ablative therapy

d. Cervical polyp

9. Which of the following is not a contraindication for LEEP?

a. Pregnancy

b. Severe local infection

c. Two months postpartum

d. CIN 3 with type 1 TZ

10. All the following are advantages of LEEP, except:

a. Can be performed under local anaesthesia

b. Tissue is available for histological evaluation

c. Small risk of adverse obstetric outcome

d. Outpatient procedure

Q. No	1	2	3	4	5	6	7	8	9	10
Answers	d	a	b	b	d	d	b	d	d	c

SECTION - 3

TRAINING MODULES

Module 1:	**Introduction to Cervical Cancer**
Module 2:	**Anatomy of Cervix**
Module 3:	**Introduction to Treatment of Cervical Precancer**
Module 4:	**Principle of Treatment by Ablative Methods**
Module 4.1:	**Cryotherapy for the Treatment of VIA Positive Lesion**
Module 4.2:	**Thermal Ablation for the Treatment of VIA Positive Lesion**
Module 5:	**Loop Electrosurgical ExcisionProcedure (LEEP) for the Treatment of VIA Positive Lesion**
Module 6:	**Infection Prevention during Screening and Treatment**

MODULE - 1
INTRODUCTION TO CERVICAL CANCER

Aim	To understand the cause, symptoms and strategies to prevent cervical cancer
Time	15 min
Material Required	Presentation
Qualifications of the Technical Resource	Gynecologist / PGMO

History of Cervical Cancer

Cervical cancer is caused by infection with Human Papillomavirus (HPV), which is a common sexually transmitted infection. Most people are infected with HPV shortly after the onset of sexual activity. HPV infects 80-90% of women in reproductive life. In more than 80% of women, the infection clears on its own within a year. It is only in a few women that the infection persists and may lead to the development of precancer or cervical cancer later in life. For cervical cancer to develop, it takes about 15-20 years after HPV infection in women with normal immune systems.

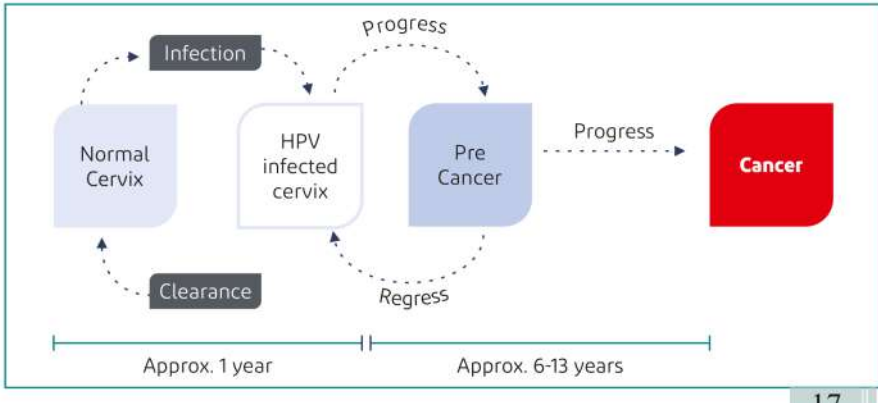
Invasive cervical cancer is preceded by a precancerous or intraepithelial stage, where screening techniques like cervical cytology, HPV DNA tests, and VIA can detect and treatment can be provided before CIN converts to an invasive stage.

Human Papillomavirus

Human Papillomavirus is a double-stranded circular DNA molecule. Over 100 types have been identified, most cause benign disease, but 15-20 can cause cancers like cervical, oral. and genital cancers. HPV type 16,18 cause 70% of cervical cancers and precancerous lesions.

There are 3 steps necessary for cervical cancer development

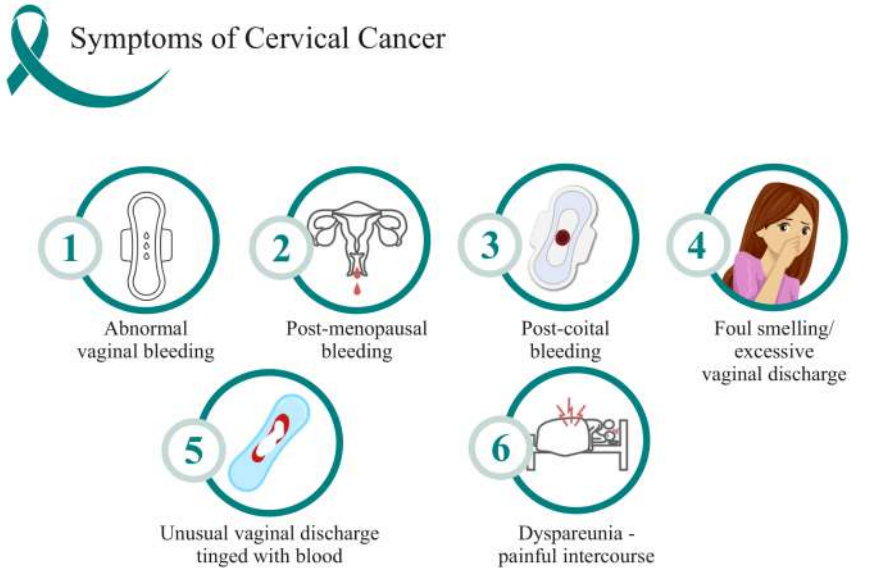
1. HPV Infection
2. Progression to Cervical Intraepithelial Neoplasia (CIN)
3. Invasive Cancer of Cervix



Pathogenesis: How does HPV cause cervical cancer?

Whenever there is cervical ectropion (prominent in puberty, pregnancy, OCP), there is a greater chance that the everted columnar epithelium will be exposed to high vaginal acidity, leading to the destruction of cells. This leads to proliferation of sub-columnar reserve cells with reserve cell hyperplasia and formation of metastatic, immature squamous epithelium and subsequently normal glycogen-containing mature squamous epithelium.

A virus replicates only inside the host cell. HPV has 2 oncoproteins namely E6 and E7 which when incorporated in host cell DNA prevent cell destruction and induce tumor formation. If there is persistent infection with HPV 16, 18 and 45 of the immature squamous epithelium of cervix the result is formation of atypical or dysplastic squamous epithelium.



✓ CIN and early stages of cervical cancer can be symptomless. Therefore, there is a great need for prevention, screening, early detection and treatment.

Strategies to Prevent Cervical Cancer

Primary Prevention	Secondary Prevention	Tertiary Prevention
➢ HPV vaccination ➢ ABC (Abstain, Be faithful, use Condoms), safe sex, male circumcision	➢ Screening for CIN - cytology, HPV DNA tests, VIA ➢ Treatment of cervical precancer	➢ Early detection and treatment of invasive cancer cervix

Point to Note

Cervical cancer is caused by infection with Human Papillomavirus (HPV) which is a common sexually transmitted infection

Common symptoms of cervical cancer are:

- ✓ Abnormal vaginal bleeding
- ✓ Post-menopausal bleeding
- ✓ Post-coital bleeding
- ✓ Foul smelling/excessive vaginal discharge
- ✓ Unusual vaginal discharge tinged with blood
- ✓ Dyspareunia - painful intercourse
- ✓ CIN and early stages of cervical cancer can be symptomless, therefore there is a great need for prevention, screening, early detection and treatment
- ✓ Up to 93% of cervical cancers are preventable[1]

[1] *Center for disease control and prevention (2019). Preventing Cervical Cancer in the 21st century*

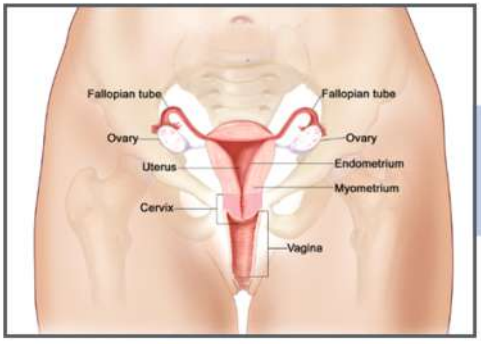
MODULE - 2
ANATOMY OF CERVIX

Aim:	To understand the structure of cervix, SCJ, TZ and CIN
Time:	30 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist / PGMO

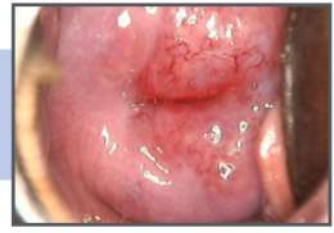
Structure of Cervix

Uterine Cervix: The cervix is the lower fibromuscular portion of the uterus. It consists of two parts -

The *portio vaginalis* (ectocervix) which projects into the vagina and the *supravaginal cervix* (endocervix). Between the external os and the internal os lies the cervical canal. The total length of cervix is 3-5cms and diameter 2.5cms. The endocervical canal varies in extent depending on the woman's age and her reproductive, hormonal and menopausal status.



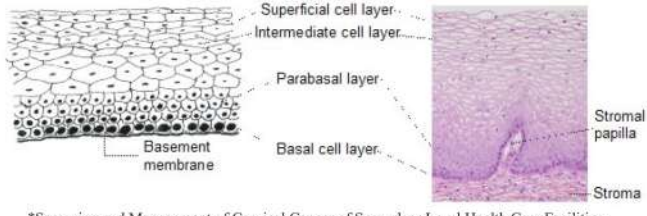
Structure of female reproductive system



Clinical Image of ecto cervix

Ectocervix is covered by stratified, non-keratinizing, glycogen-containing squamous epithelium. It appears opaque, pale pink in color. It consists of four layers of cells: basal, parabasal, intermediate, and superficial layers. From basal to superficial layers, cells undergo an increase in size & reduction in nuclear size, The intermediate and superficial cells contain abundant glycogen in their cytoplasm. The maturation of squamous epithelium depends on the hormone *estrogen.*

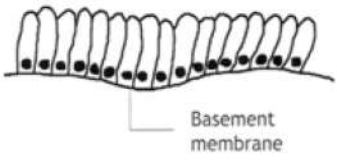
Microscopic Image of Stratified squamous epithelium (X20)

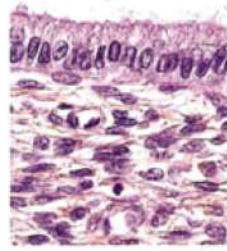


*Screening and Management of Cervical Cancer of Secondary Level Health Care Facilities

The endocervical canal is lined by mucin-secreting columnar epithelium. It consists of a single layer of tall cells with dark nuclei close to the basement membrane. It is a single thin velvety-red layer which allows the underlying vasculature to be seen. The mucosa is thrown into multiple longitudinal folds, protruding into the lumen of canal-forming crypts.

Columnar epithelium (X40)

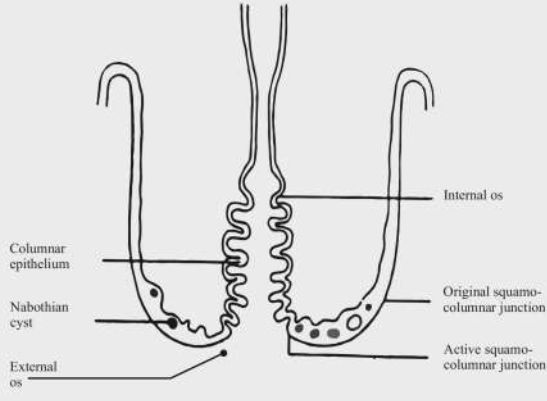




Source: https://screening.iarc.fr/colpochap.php

Squamocolumnar Junction or SCJ

Squamocolumnar Junction or SCJ appears as a sharp line with a step, due to the difference in height between squamous & columnar epithelium. The location of SCJ in relation to external os is variable & depends on age, hormone status, birth trauma, OCPs use, and pregnancy. Original SCJ visible during pre-menarche is located on or close to the external os. After puberty & during reproductive life, the cervix swells &enlarges and the endocervix elongates, leading to eversion of columnar epithelium on the ectocervix (ectropion). Thus, the original SCJ is located far from the external os.



Cross-section of the cervix and endo-cervix

Features of normal TZ

The proximal extent of the TZ is the new SCJ and is easy to identify. Tongue like projections of the thin newly formed metaplastic squamous epithelium is a feature of the normal TZ. Patent crypts appear as small openings on the normal TZ. Some of the crypts are blocked by the metaplastic epithelium, which leads to the formation of retention cysts known as nabothian follicles or cysts (as shown in image 1). Nabothian cysts appear as bluish or white cysts (pimples on the cervix) and are physiological. The crypt openings and nabothian cysts are features of normal TZ/ The position of the crypt opening or the nabothian cyst farthest from the SCJ helps to identify the outer limit of the TZ (as shown in Image 2).

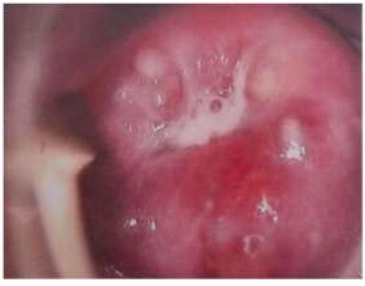


Image 1 - Nabothian cysts

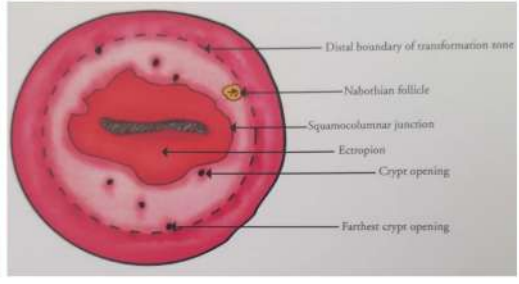


Image 2 - Transformation zone of the cervix

Changes in TZ during pregnancy and menopause

During pregnancy the cervix enlarges, becomes congested and the columnar epithelium extends to the ectocervix (ectropion). The SCJ is easily visible on the ectocervix (image 3).

During the perimenopausal period and after menopause, the cervix shrinks due to the lack of oestrogen, Due to shrinkage of the cervix, SCJ moves inside the endocervical canal from the external os. In post-menopausal, the SCJ is often invisible on visual examination. This is why screening for cervical cancer by VIA/VILI become difficult after menopause.

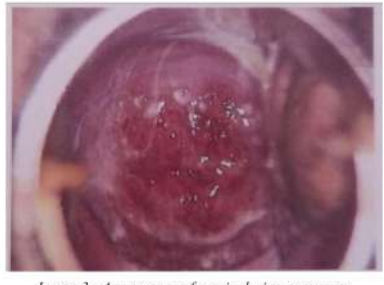
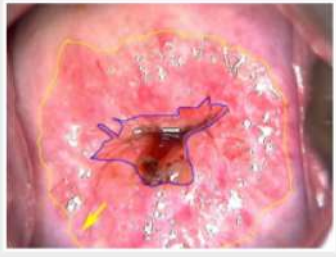


Image 3 - Appearance of cervix during pregnancy

Types of Transformation Zone (TZ)

Identification of type of transformation zone is critical to decide treatment modality for cervical precancer. Depending on the location and the visibility of the SCJ, the transformation zone (TZ) is categorized into type 1, type 2, or type 3.

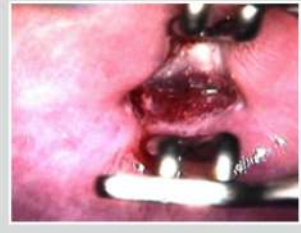
- **TZ Type 1: The SCJ is fully visible and is located at external os or on the ectocervix**



Type 1 transformation zone,
Blue line: SCJ
Yellow line: Distal extent of TZ
Yellow Arrow: Farthest crypt opening[1]

- **TZ Type 2: The SCJ is fully visible (with or without an endocervical speculum) and is located either fully or partially within the endocervical canal**

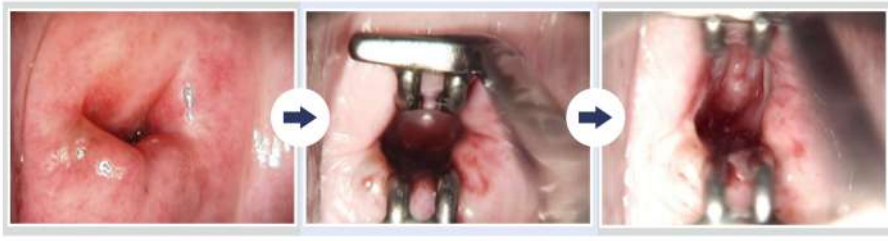
SCJ only partially visible



SCJ inside the endocervical canal

- **TZ Type 3: The SCJ is within the endocervical canal and is only partially visible or not at all visible, even using an endocervical speculum**

[1]*Source: Atlas of Colposcopy: Principles and Practice, IARC, WHO*



Atrophic cervix; the SCJ is not visible[1]

Endocervical speculum used to open the endocervical canal[1]

Even then, the SCJ is not fully visible[1]

Points to Note

- ✓ In a type 3 TZ, VIA may miss a CIN or cancer that may be hidden from view
- ✓ Ablative treatment is not indicated in a type 2 or type 3 TZ

What are the Precancerous Conditions of the Cervix?

Persistent HPV infection and unregulated divisions of the squamous cells of cervical epithelium lead to a pre-cancer condition known as cervical intraepithelial neoplasia (CIN), previously known as dysplasia. Depending on the severity of the abnormality and extent of involvement of the thickness of the squamous epithelium, the CIN lesions are graded into CIN 1, CIN 2, or CIN 3 (see image 1).

In CIN 1 (mild dysplasia), abnormal dysplastic cells are limited to the lower one-third of the epithelium. In CIN 2 (moderate dysplasia) and CIN 3 (severe dysplasia, stage O cervical carcinoma in situ), the cervical epithelial abnormalities extended up to the middle third and the upper third respectively.

[1]*Source: Atlas of Colposcopy: Principles and Practice, IARC, WHO*

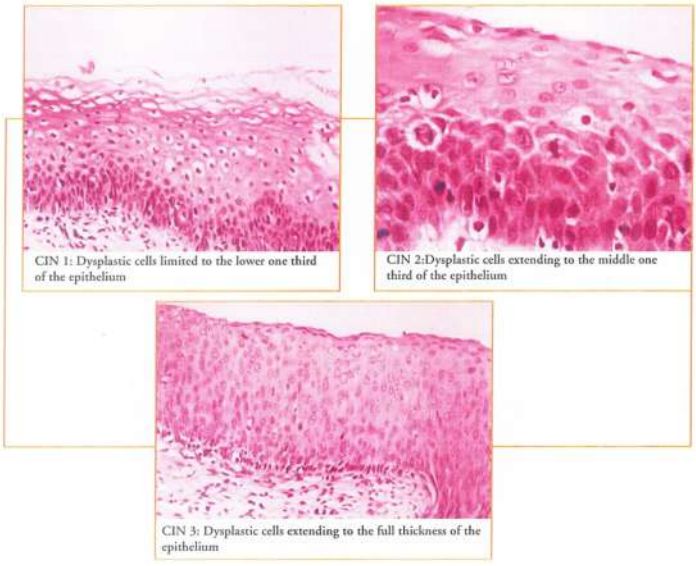


Image 1 - Grades of cervical intraepithelial

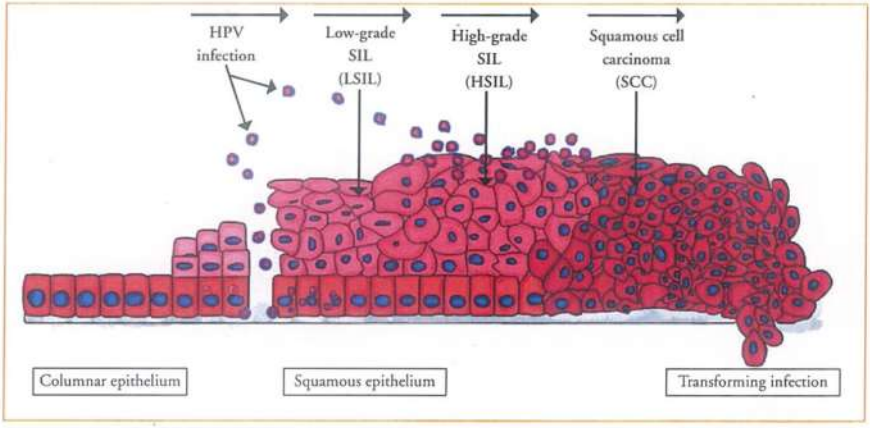


Image 2 - Grades of cervical intraepithelial

CIN lesions do not always progress to cancer and a good number of them may spontaneously regress. It has been estimated that the possibility of regression of CIN 1, CIN 2 and CIN 3 lesions are 57%, 43%, amd 32% respectively. While the CIN 1 lesions rarely progress to invasive cancer, the possibility of progression of CIN 2 or CIN 3 lesions are high unless treated. CIN 1 lesions are also known as low grade squamous intraepithelial lesions (LSIL) because of the low potential for progressions. CIN 2 and CIN 3 lesions are grouped together as high grade squamous intraepithelial lesions (HSIL) as a large number of them will progress if left untreated. The time interval between the HPV infection and the development of cervical cancer varies and is at least 10 years. (see image 2)

Precancerous lesions arising from the columnar epithelium are referred to as adenocarcinoma in situ (AIS). Cervical precancerous conditions do not cause any symptoms and are detected only by special tests.

Point to Note

- ✓ The cervix is the lower fibromuscular portion of uterus consisting of two parts, the *ectocervix* and the *endocervix*
- ✓ Between the external os and the internal os, lies the cervical canal
- ✓ Location of SCJ in relation to external os is variable & depends on age, hormone status, birth trauma, OCPs use, pregnancy
- ✓ The transformation zone is the region of the cervix, where columnar epithelium has been replaced and/or is being replaced by new metastatic squamous epithelium
- ✓ Cervical Intraepithelial Neoplasia (CIN) or preinvasive cancer is diagnosed, when dysplastic changes are limited to the epithelial lining and the basement membrane is intact
- ✓ CIN is classified into CIN 1, 2 & 3, depending on the depth of involvement of epithelium

MODULE - 3
INTRODUCTION TO TREATMENT OF CERVICAL PRECANCER

Aim:	To understand the management of screen positive woman and principal of cervical precancer treatment
Time:	15 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

Management of Women Positive on VIA Screening Test

In the population-based screening program, VIA is the test used for screening cervical cancer. All VIA positive women should be evaluated by gynaecologist and lady medical officer at the nearest health care facility. If the gynaecologist diagnoses it as the true VIA positive, the women should be advised to undergo either treatment or further confirmatory diagnosis.

Screen and Treat Approach

As mandated by Government of India (GoI) guidelines, VIA is adopted for cervical cancer screening because of the high cost of setting up cytology and HPV testing. Availability of immediate results in VIA provides an opportunity for treating the lesions in the same sitting which is called 'Screen and Treat' approach in which treatment decision is based on a screening test, and not on a histologically confirmed diagnosis of CIN. The treatment is provided soon or ideally immediately after a positive screening test.

The screen and treat approach enables early identification and treatment of precancerous lesions.

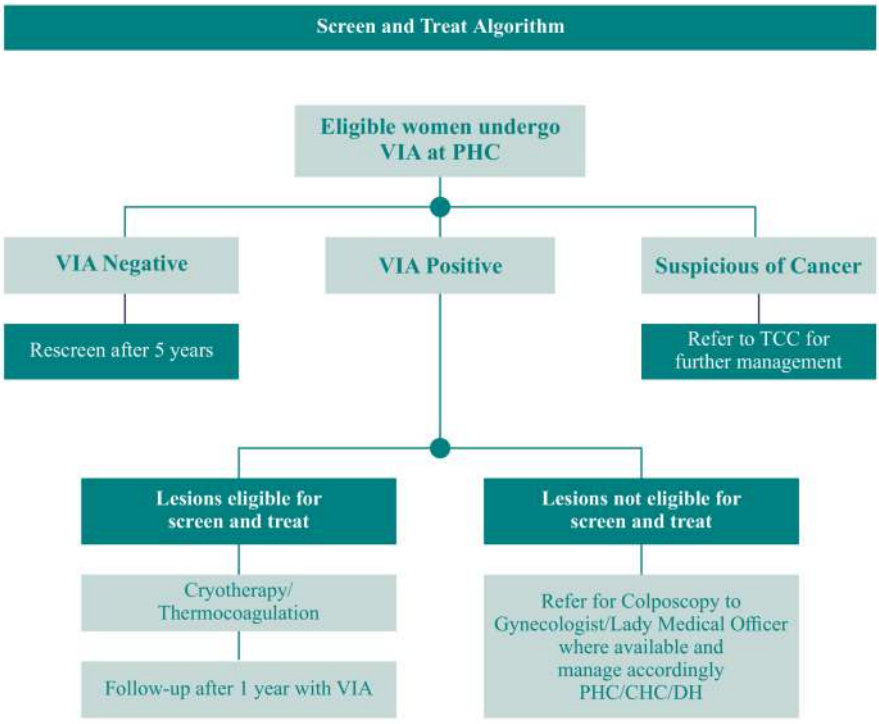


Figure 1: Screen and Treat Algorithm at Health Care Facility

Treatment of Cervical Intraepithelial Lesions

Cervical premalignant lesions may be treated by either ablative or excisional techniques. Ablative techniques use either cold injury (cryotherapy) or heat injury (thermal ablation) to destroy the abnormal epithelium of the transformation zone of the cervix. The most widely used excisional technique is large loop excision of the transformation zone (LLETZ), also known as the loop electrosurgical excision procedure (LEEP), in which the entire abnormal transformation zone (TZ) is removed using a metallic wire powered by an electrosurgical unit.

Source: GoI module on "Screening and Management of Cervical Cancer at Secondary Level Health Care Facilities"

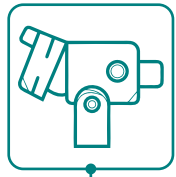
Whereas excisional techniques can be used to treat all cervical premalignant lesions, ablative techniques are suitable only for lesions that fulfil certain selection criteria. Ablative techniques are simpler and have fewer complications compared with excisional techniques. **In a screen-and-treat programme, every VIA positive woman should be assessed for the suitability of the lesion for ablative treatment.**

Principles of treatment of cervical intraepithelial neoplasia (CIN) are-

1 **The decision about treatment may be based on the outcome of the:**

1. Screening Test

✓ All screen-positive women should be treated



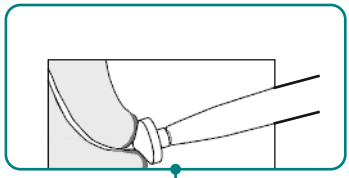
2. Colposcopy Diagnosis

✓ All women suspected to have high-grade CIN should be treated

3. Histopathology Diagnosis

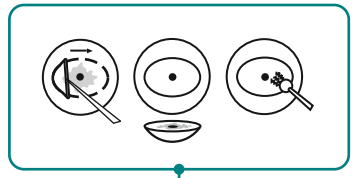
✓ Confirmed CIN cases should be treated

2 **Whatever the decision-making process is, the treatment of cervical precancer involves either of the two types of technique:**



1. Ablative Techniques

✓ Cryotherapy
✓ Thermal Ablation



2. Excisional Techniques

✓ LLETZ/LEEP

3	➢ The entire transformation zone undergoes HPV-induced clonal change and is at risk of developing CIN ✓ **Therefore, the whole transformation zone (TZ) should be treated (ablated or excised), irrespective of the size of the lesion**
4	➢ High-grade CIN lesions often extend into the crypts present in the TZ. The depth of the crypts can be up to 5 mm ✓ **During ablative treatment, the tissue destruction must extend up to 7–8 mm to ensure complete clearance of disease**
5	➢ **Low-grade lesions/ CIN1 lesions should be treated when follow-up is not guaranteed**
6	➢ **CIN2 and CIN3 lesions should always be treated except in very young women (younger than 25 years)**
7	➢ **The decision to treat a CIN lesion may be based on -** ✓ Colposcopic findings **("see and treat")** without waiting for histological verification ✓ For VIA or HPV positive result, without colposcopic or histological verification **("screen and treat")** in situations where these diagnostic services are not available

Aim:	To understand eligibility criteria for ablative treatment and role of Lugol's iodine in treatment
Time:	30 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

Eligibility Criteria for Ablative Treatment

Ablative treatment (cryotherapy/thermal ablation) can be used to treat an abnormal transformation zone provided the following criteria are fulfilled:

1. SCJ Visibility: The squamocolumnar junction (SCJ) should be fully visible and should be on the ectocervix or at the external os

2. Location of the Lesion: If there is a visible lesion, it should be on the ectocervix without any extension to the endocervix or to the vagina

3. Size of the Lesion: If there is a visible lesion, it should not occupy more than 75% of the ectocervix

4. Suspicion of Invasive Cancer: There should not be any suspicion of invasive cancer

5. Size of Cryoprobe: The size of the lesion should be such that it can be fully covered by the tip of the largest cryotherapy probe **(applicable for cryotherapy only)**

The steps to determine eligibility for ablative treatment require addressing the following questions-

S.No.	Question	Eligible for Ablative Treatment
1	Is the SCJ fully visible?	**Yes**
2	Is the SCJ located on the ectocervix or at the external os?	**Yes**
3	Does the size of the lesion occupy less than 75% of the ectocervix?	**Yes**
4	Does the lesion extend to the vagina and/or to the endocervix?	**No**
5	Is there any suspicion that the lesion could be an invasive cancer?	**No**
If cryotherapy is being used, an additional question to answer is -		
6	If the tip of the largest cryotherapy probe can adequately cover the entire transformation zone?	**Yes**

Examples - Determining Eligibility Criteria for Ablative Treatment

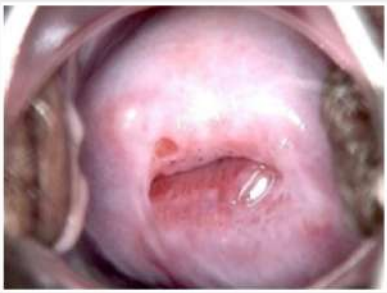


Figure 2: Cervix before application of acetic acid. Nabothian cyst at 10 o'clock position and multiple crypt[1]

One minute after application of 5% acetic acid

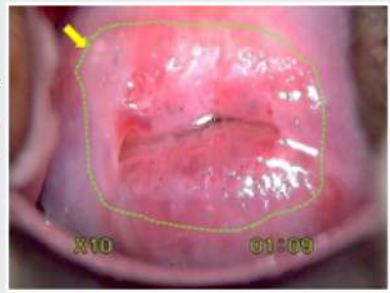


Figure 3: Cervix after application of 5% acetic acid-VIA positive: The lesion can be treated by ablation, because –

- *SCJ is fully visible at the external os*
- *Lesion occupies less than 75% of the ectocervix*
- *No suspicion of invasive cancer*
- *Lesion does not extend to vaginal or endocervical canal*

Original SCJ (green line) and nabothian cysts (yellow arrow)[1]

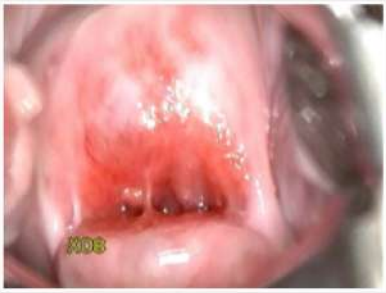


Figure 4: Cervix before application of acetic acid. SCJ fully visible[1]

One minute after application of 5% acetic acid

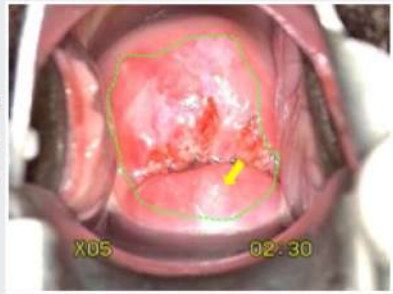
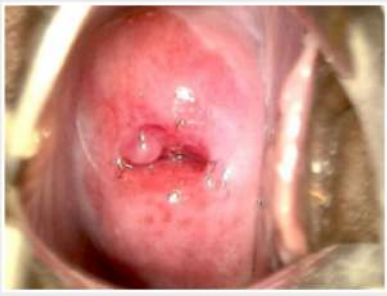


Figure 5: Cervix after application of 5% acetic acid-VIA positive: The lesion can be treated by ablation, because –

- *SCJ is fully visible at the external os*
- *Lesion occupies less than 75% of the ectocervix*
- *No suspicion of invasive cancer*
- *Lesion does not extend to vaginal or endocervical canal*

Original SCJ (green line) and nabothian cysts (yellow arrow)[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*



One minute after application of 5% acetic acid

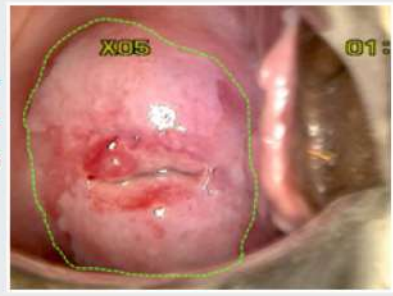
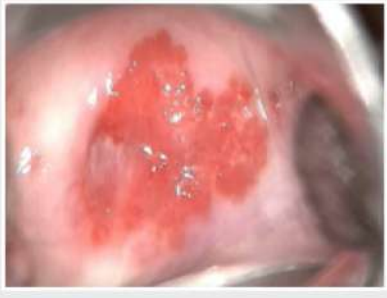


Figure 6: Cervix before application of acetic acid. A Nabothian cyst is partially covering the SCJ[1]

Figure 7: Cervix after application of 5% acetic acid- VIA positive: The lesion is not eligible for ablative treatment, because-

- *Lesion occupies more than 75% of the ectocervix*
- *Extends to the vagina*

Original SCJ (green line)[1]



One minute after application of 5% acetic acid

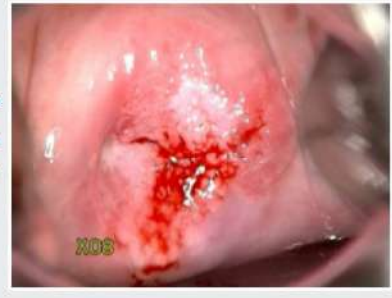


Figure 8: Cervix before application of acetic acid. The SCJ is not entirely visible[1]

Figure 9: Cervix after application of 5% acetic acid- VIA positive: The dense acetowhite area is not very big, however, the presence of surface bleeding and the irregularity of the surface raise the suspicion of invasive cancer. The lesion is not eligible for ablative treatment –

- *Suspicion of invasive cancer*[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

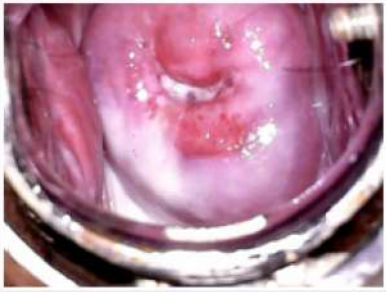


Figure 10: Cervix before application of acetic acid. Cervix inflammed and covered with purulent[1]

One minute after application of 5% acetic acid

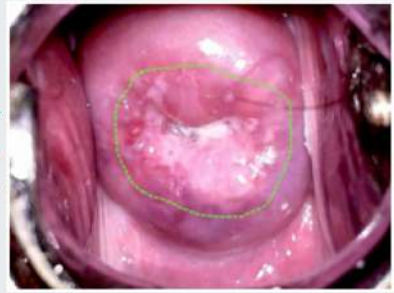


Figure 11: Cervix after application of 5% acetic acid- VIA positive: The lesion is not eligible for ablative treatment –
Acetowhite area extending inside endocervical canal
Original SCJ (green line)[1]

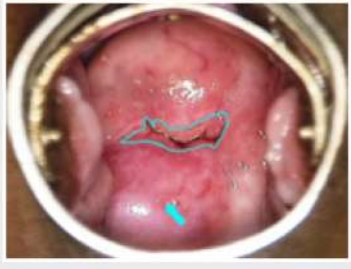
Points to Note

- ✓ Ablative treatment should not be performed in presence of active acute infection of cervix
- ✓ The patient should be advised appropriate antibiotics to treat infection and recalled for treatment after the course of antibiotics is complete

[1]Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment

Role of Lugol's Iodine in Identifying the Transformation Zone for Treatment

Application of Lugol's iodine may help to better delineate VIA positive lesions and guide treatment. The strong colour contrast between the normal cervical epithelium, which stains with Lugol's iodine, and the abnormal epithelium, which does not take up Lugol's iodine, helps to demarcate the outer margin of the lesion before treatment of cervical neoplasias by ablative or excisional methods in a screen-and-treat setting. **Iodine stains the glycogen-containing normal epithelium to dark brown, while the neoplastic epithelium, in which the abnormally dividing cells do not produce glycogen, remains unstained.** The normal epithelium appears dark mahogany brown, whereas the diseased epithelium is visible as areas appearing bright yellow or mustard yellow. The sharp contrast between the abnormal epithelium and the normal epithelium enables much better delineation of the abnormal transformation zone that needs to be treated.



After application of Lugol's Iodine

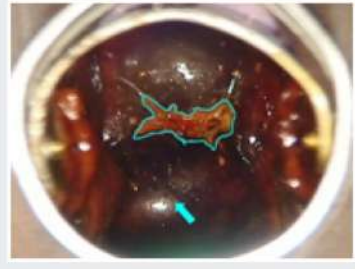
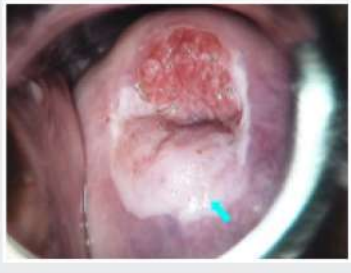


Figure 12: Normal mature squamous epithelium remains pink after application of acetic acid
Squamous epithelium (blue arrow), SCJ (blue line)[1]

Figure 13: After application of Lugol's iodine, normal squamous epithelium appears dark mahogany brown
Squamous epithelium (blue arrow), SCJ (blue line)[1]



After application of Lugol's Iodine

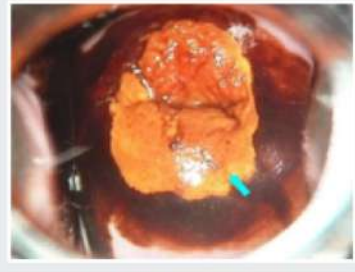


Figure 14: Dense acetowhite area in the TZ after application of acetic acid (histopathology: HSIL-CIN3)
Acetowhite area (blue arrow)[1]

Figure 15: The acetowhite area does not take up iodine and appears bright mustard yellow after application of Lugol's Iodine
Iodine negative area (blue arrow)[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

Points to Note

- ✓ Iodine uptake areas are always considered normal
- ✓ Iodine non-uptake areas are visible in several non-neoplastic conditions, such as atrophic epithelium, inflammation, squamous metaplasia, and healing and regenerating epithelium
- ✓ An iodine negative area due to CIN or invasive cancer is usually uniformly bright yellow and is always located within the transformation zone

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

Steps for Applying Lugol's Iodine to the Cervix

1. After completing the assessment with acetic acid, take a dry cotton swab and wipe out the excess acetic acid solution present on the posterior blade of the speculum
2. Gently paint the whole cervix with a small cotton swab dipped in Lugol's iodine solution
3. **The colour change is visible immediately; there is no need to wait**
4. The acetowhite area does not take up iodine stain and appears mustard yellow, and the normal squamous epithelium is stained dark brown
5. Delineate the outer margins of the iodine non-uptake areas, and reassess whether the lesion occupies less than 75% of the ectocervix
6. The columnar epithelium is not stained with Lugol's iodine and retains its original red colour

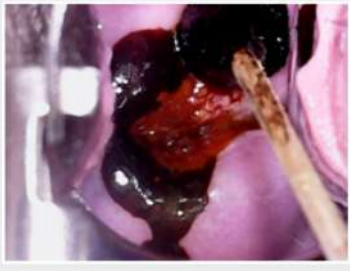


Figure 16: Painting the ectocervix with a small cotton swab soaked in Lugol's iodine[1]

After application of Lugol's Iodine

Figure 17: Lugol's iodine provides colour contrast and sharply delineates the area to be treated
Iodine negative area (blue arrow)[1]

Point to Note

- ✓ Application of Lugol's iodine should be done after completing the assessment with acetic acid, because the iodine stain covers all other features, including acetowhiteness of the epithelium

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

Use of Lugol's Iodine for Pre-Treatment Assessment

VIA positive women who are eligible for treatment by ablative methods in a screen and treat setting can be further assessed after application of Lugol's iodine before treatment. However, this assessment is not mandatory and should be practised only in settings with a regular supply of Lugol's iodine solution.

1. Assessment of the size of the lesion

Assessment of the size of the lesion tends to be more precise after application of Lugol's iodine, because of the strong colour contrast between the normal area and the abnormal area. Strong colour contrast after application of Lugol's iodine provides a better approximation of the percentage of the cervix occupied by the abnormal epithelium. **Lesions that occupy less than 75% of the ectocervix are eligible for treatment by ablation.**

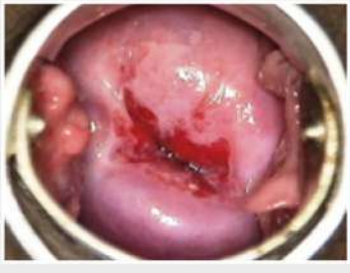


Figure 18: Acetowhite area on the anterior lip located in the TZ, attached to the SCJ (histopathology: LSIL-CIN1)[1]

Figure 19: Lugol's iodine sharply delineates the margins and helps in assessing the size of the lesion. This lesion occupies less than 75% of the ectocervix[1]

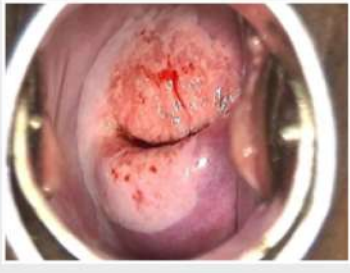


Figure 20: The dense acetowhite area occupies more than 75% of the ectocervix (VIA positive). It is not suitable for treatment by ablation[1]

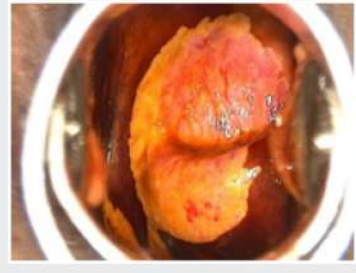


Figure 21: The acetowhite area appears mustard yellow. The strong colour contrast sharply delineates the abnormal area, which occupies more than 75% of the ectocervix. Such large lesions are not suitable for treatment by ablation[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

2. Assessment of the margins of the lesion

Sometimes the margins of thin acetowhite lesions are not obvious, and this may give rise to dilemmas in deciding on the area to be treated. In such situations, the colour contrast produced by Lugol's iodine assists in easy identification of the margins of the lesions and thereby helps in determining the extent of the area for treatment.

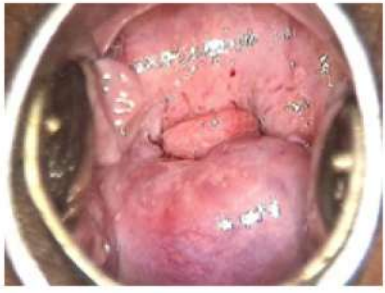


Figure 22: The peripheral margins of the thin acetowhite areas on the anterior and posterior lips are indistinct, making it difficult to assess the precise area for treatment (histology: LSIL-CIN1[1]

Figure 23: After application of Lugol's iodine, the margins of the lesion become obvious. The contrast between the yellow abnormal epithelium and the brown normal epithelium precisely identifies the area for treatment[1]

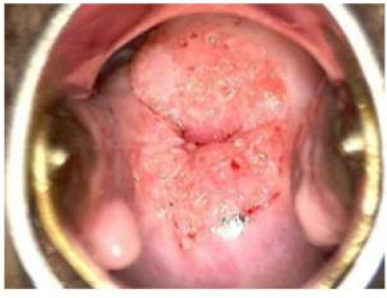


Figure 24: The thin acetowhite area at the 10 o'clock position has an indistinct outer margin (histopathology: LSIL-CIN1)[1]

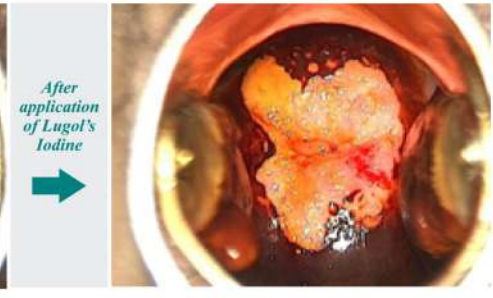


Figure 25: Lugol's iodine provides a strong colour contrast and sharply delineates the margins of the lesion and the area to be treated[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

3. Assessment of the size of the probe for ablative treatment

Selection of the appropriate size of the probe for cryotherapy or thermal ablation for treatment of the abnormal area on the cervix can be made easy by application of Lugol's iodine to the cervix. **Because the margins of the lesion are sharply delineated by the colour contrast produced by Lugol's iodine, the area to be treated becomes prominent.** This helps in choosing a suitable size of the probe that will adequately cover the abnormal area.

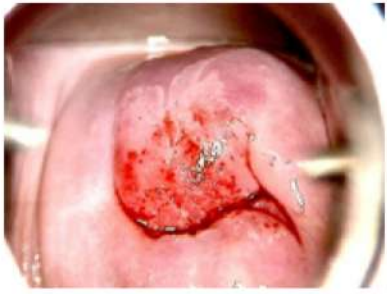


Figure 26: A thin acetowhite area is seen in the TZ on the anterior lip (histopathology: LSIL-CIN1)[1]

Figure 27: After application of Lugol's iodine, the treatment area is well demarcated by the colour contrast. The area can be treated by using a large flat cryotherapy probe or by 1–2 overlapping applications of a thermal ablation probe[1]

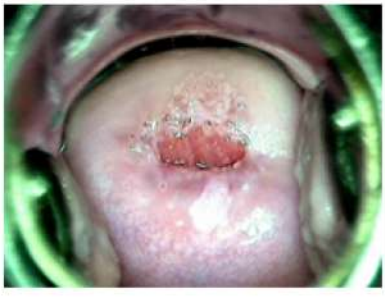


Figure 28: Thin acetowhite areas are seen on the anterior and posterior lips within the TZ (histopathology: LSIL-HPV changes)[1]

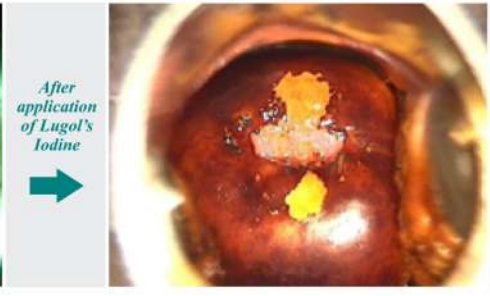


Figure 29: Thin acetowhite areas are seen on the anterior and posterior lips within the TZ (histopathology: LSIL-HPV changes)[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

4. Assessment of the number of applications of the selected probe:

Sometimes the shapes of lesions are such that they cannot be effectively covered by a single application of the largest cryotherapy probe. **Such lesions are best treated by multiple, overlapping applications of a small thermal ablation probe.** When performing treatment by multiple applications, delineation of the outer margins of the lesion can become tricky. In such circumstances, the colour contrast produced by Lugol's iodine helps in correctly determining the peripheral margins of the lesions, which can otherwise be missed during treatment.

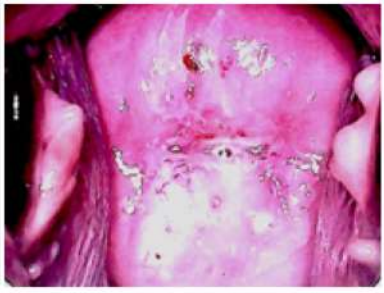


Figure 30: The TZ is large, with multiple acetowhite areas arising from the SCJ and extending outwards (histopathology: LSIL-CIN1)[1]

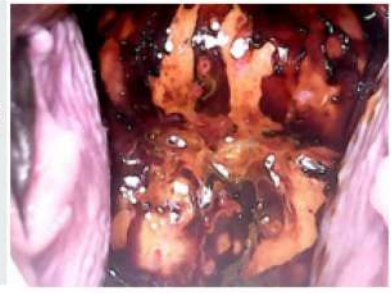


Figure 31: Application of Lugol's iodine sharply demarcates the peripheral margins. The abnormal area can be treated with precision by multiple, overlapping applications of a thermal ablation probe[1]

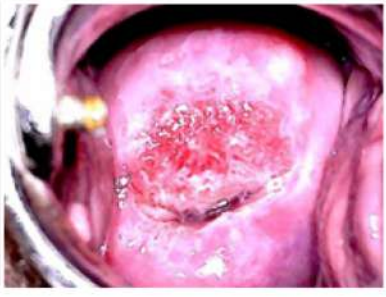


Figure 32: The TZ is large, with acetowhite areas extending outwards from the SCJ (histopathology: LSIL-CIN1)[1]

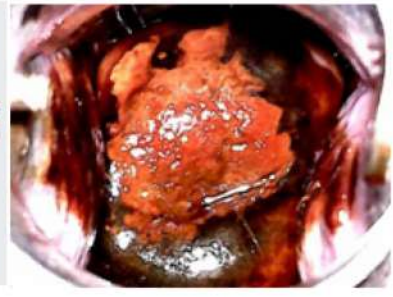


Figure 33: Lugol's iodine sharply defines the peripheral margins, allowing precise and complete treatment by multiple, overlapping applications of a thermal ablation probe[1]

[1]*Source: Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment*

MODULE - 4.1
CRYOTHERAPY FOR TREATMENT OF VIA POSITIVE LESION

Aim:	To learn about cryotherapy as treatment modality for cervical precancer
Time:	120 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

CRYOTHERAPY FOR THE TREATMENT OF VIA POSITIVE LESION

Principle of Treatment by Cryotherapy

Cryotherapy is an ablative technique for treatment of ectocervical lesions. It uses the freezing effect of compressed refrigerant gases like nitrous oxide (N_2O) or carbon dioxide (CO_2) to destroy the abnormal TZ of the cervix. The compressed gas is delivered on to the surface of ectocervix through cryoprobes made up of highly conductive metals (like silver or copper). The flow of gas through the narrow aperture of the cryoprobe and its subsequent release on the surface of the ectocervix produces a significant drop in temperature. This causes severe damage to cells by crystallization of water and denaturation of proteins inside the cells. **The ectocervix has sparse sensory nerve endings, as a result an ectocervical procedure like cryotherapy does not require any anaesthesia.**

Indications for Cryotherapy

VIA positive women are eligible for cryotherapy if-

1. Entire lesion is visible on ectocervix
2. Lesion is not extending to the endocervical canal or to vagina
3. Lesion is occupying less than 75% of the ectocervix
4. Lesion should be adequately covered by largest cryoprobe
5. There should be no evidence or suspicion of cancer or glandular abnormality
6. Woman should not be pregnant at the time of treatment
7. Woman should not be menstruating at the time of treatment
8. If the woman has recently delivered, she is at least 3 months post-partum
9. Woman should not have pelvic inflammatory disease (PID) at the time of treatment
10. Endocervical canal is normal and there is no evidence of glandular dysplasia

Knowing the Cryotherapy Unit

Cryotherapy equipment (a cryosurgical unit) consists of a handle grip (cryogun) with a trigger mechanism that is attached to the cryoprobe on one side and the connecting hose on the other side to transmit gas from

the gas cylinder. The hose is connected to the cylinder with a connector and a pressure gauge. The cryoprobe or the cryoshaft has a cryotip made of highly conductive metal. The protrusion of the nipple of the cryotip should not exceed 5 mm.The gas from the cylinder passes through the hose, the cryogun, and the probe (or shaft) to the cryo tip. The tip is applied to the cervix, and the cervix is frozen as the gas is released to the atmosphere. The detailed description of each part is given below-

Table 1: Parts of cryotherapy unit along with their functions and uses[1]

S.No.	Name of Part	Function	How to Use
1	Hand Unit	Allows and controls the flow of gas into the cryoprobe	Slip the cryoprobe over the nozzle of the hand unit and secure by tightening
2	Trigger	Controls the flow of gas through the hand unit	Press to allow flow of gas and release to stop flow
3	Handle Grip	Part of the hand unit that is held by the operator	Hold the handle grip during the entire procedure
4	Cyroprobe	Delivers the refrigerant on to the surface of the cervix and has two parts – cryotip and cryo shaft	Apply the cryoprobe connected to the hand unit on the TZ of the cervix for freezing effect
5	Cryotip	Metal tip of the cryoprobe that covers the surface of the cervix and induces the freezing effect	Select the cryotip of appropriate size and shape and press it onto the cervix without touching the vagina
6	Cryo Shaft	Part of the cryoprobe that attaches the cryotip to the hand unit	
7	Gas Conveying Tube	Connects the hand unit to the pressure gauge and allows the gas to flow	The flexible tube remains connected
8	Pressure Gauge	Monitors the pressure of gas flowing to the hand unit. It has an indicator and three colour zones – yellow, green and red.	On opening the gas cylinder if the indicator moves to: Green zone – gas pressure is adequate Yellow zone – pressure too low Red zone – gas pressure is too high
9	Gas Cylinder Connector	Attaches the gas cylinder to the cryotherapy unit	Insert the inlet of the connector into the slot of the gas cylinder valve. Tighten the attachment by screwing in the tightening knob of the connector
10	Washer or O-rings	Prevent leakage of gas from the system. Washers need to be replaced if they become defective, causing leakage of gas	Make sure that the washers are fitted in between the cryoprobe and hand unit and also between the gas cylinder connector and the cylinder

[1]*Source: WHO, 2017, p.102-103, Training of health staff in VIA, HPV detection test and cryotherapy*

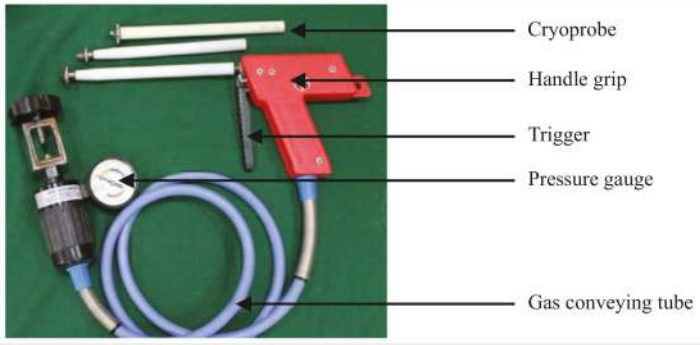


Figure 34: Cryotherapy Unit

Setting up the Cryotherapy Unit

- Check the washer before attaching the cryoprobe to the handle grip (cryogun). Replace the washer if it is broken
- Select the appropriately sized cryoprobe, depending on the size of the transformation zone, and attach it to the handle grip (avoid using the probes with endocervical extension)

Figure 35: Attaching Cryoprobe to Cryogun

- Connect the cryotherapy machine to the gas cylinder and tighten the valve
- Open the gas cylinder so that the gas can flow into the handle grip through the hose. Check the gas pressure indicated on the pressure gauge
- The ideal gas pressure required to perform the cryotherapy procedure is 40–70 kg/cm2
- **On opening the cylinder and during the cryotherapy procedure, the indicator of the pressure gauge should be in the green zone.** A needle positioned in the yellow zone indicates low gas pressure, and in the red zone indicates high gas pressure. In either case, cryotherapy should not be started or should be discontinued
- Large gas tanks (> 15 litre capacity) should be used for the procedure if possible

Figure 36: Cryotherapy Gas Cylinder

Equipment and Consumables required for Cryotherapy Procedure

Equipments	Consumables
➢ Examination table ➢ Light source ➢ Cusco's speculum ➢ Sponge holding forceps ➢ Cryosurgery unit with adequate gas supply • Cryogun • Cryoprobes • Gas conveying tube • Pressure gauge • Gas cylinder connector	➢ Disposable gloves ➢ Cotton swabs for wiping the cervix ➢ Normal saline solution ➢ Lubricant jelly ➢ Dilute acetic acid (5%) solution (freshly prepared) ➢ Lugol's Iodine

Steps of Performing Cryotherapy Procedure

Table 2: Steps for performing cryotherapy procedure

S. No.	Activity
Pre-Cryotherapy tasks	
1	Counsel the woman, ensure that the woman has understood the procedure and **obtain informed written consent**
2	Ensure that woman has emptied her bladder
3	Check the pressure inside the gas tank. It should be in the green zone as indicated in the pressure gauge of most of the cryotherapy models
Doing the procedure	
4	Insert the appropriate size speculum gently and expose the cervix properly
5	Apply freshly prepared 5% acetic acid to outline the abnormality and wait for a minute, followed by Lugol's iodine to delineate the limits of the lesion
6	**If the lesion is positive and eligible for treatment with cryotherapy-**
7	Choose an appropriate size cryoprobe that adequately covers the lesion.Attach the probe to the handle grip (cryogun)
8	Wipe the cryotip with saline or lubricant, to ensure adequate thermal contact
9	Apply the cryoprobe tip at the external os of the cervix
10	**Ensure that the vaginal wall is not in contact with the cryoprobe or you may cause a freezing injury to the vagina**
11	Release the gas by pressing the trigger on the cryogun and hold it for 3 minutes
12	You will observe the ice forming on the tip of the cryoprobe and on the cervix

Figure 37: Ice crystals forming on the cryotip[1]

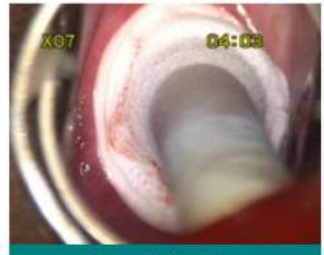
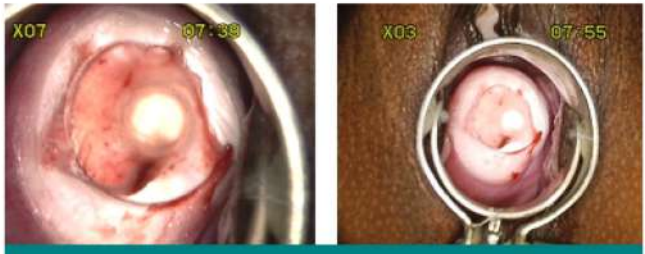


Figure 38: Rim of ice around the cryotip[1]

[1]*Source: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index=62&e=,0,1,2,3,8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111*

S. No.	Activity
13	When the frozen area extends 4–5 mm beyond the edge of the cryoprobe, freezing is adequate. This will ensure cryonecrosis occurs down to 5 mm of depth
14	Release the trigger and allow thawing for 5 minutes. **Repeat freezing for 3 more minutes**
15	After second freezing, allow time for thawing. **Do not pull cryoprobe till it comes out on its own**
16	The cervix will have a white crater, which indicates that the cervix is properly frozen  *Figure 39: Crater on the cervix after removal of cryotip*[1] [1]*Source: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index=62&e=,0,1,2,3, 8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111*
17	Gently remove the cryoprobe and remove the speculum after careful inspection of the cervix
18	Examine the cervix for bleeding. If bleeding is noted, apply Monsel's paste. Do not pack the vagina
Post procedure tasks	
19	Ask the woman to continue lying down for 5 minutes before letting her get up
20	Document treatment completion in individual case record form
21	Provide her the date for next follow up and emphasize on the importance of it. Also, ask the woman to report in case she experiences any adverse reaction/effect or has discomfort other than the ones explained
22	After use, the probe tip should be wiped with 60-90% ethyl or isopropyl alcohol and then cleaned well with boiled water and disinfected and kept dry. After the procedure is completed, the cryogun, tubing, pressure gauge and gas tank should be de-contaminated by wiping with cotton soaked with 60-90% ethyl or isopropyl alcohol

Possible Side Effects

- Cryotherapy is a safe procedure with no significant operative morbidity. The possible side effects and complications are

Common Side Effects

1. 

A little discomfort or cramping in the lower abdomen during and after the procedure

2. 

Watery vaginal discharge for 4–6 weeks

3. 

Vaginal pain if the probe with the ice ball touches the vaginal walls

Rare Side Effect

1. 

Pelvic infection, requiring antibiotics and supportive treatment

2. 

Excessive bleeding, requiring hospital admission or blood transfusion (extremely rare)

3. 

Stenosis of the cervix - late complication (extremely rare)

- Some women may feel light-headed if they get up from the table immediately after the procedure. **Ask the woman to continue lying on the bed for 5 minutes after the procedure, to avoid this side effect**

Post-Treatment Care

1. Provide a sanitary pad to the woman

2. Inform woman that she may experience excessive watery discharge for up to 4-6 weeks. **She should not get worried about it**

3. The woman should be advised not to have sexual intercourse for 4–6 weeks

4. Avoid douching or use of tampon for 4-6 weeks

5. **If the woman develops any of the below-mentioned symptoms, she should be asked to report it and seek medical advice**

   a. Fever with temperature higher than **100.4 degree Fahrenheit** lasting for more than 48 hours

   b. Severe lower abdominal pain

   c. Foul-smelling or pus-like discharge

   d. Bleeding for more than two days or bleeding with clots

6. 

   The woman should be advised regarding the follow-up schedule, ask the woman to return for follow-up after 3 and 12 months of treatment

Point to Note

- ✓ Antibiotics are not routinely prescribed after cryotherapy. Paracetamol tablets may be given for 1 or 2 days for pain relief

Follow-up after Cryotherapy

- Healing takes place during the first six weeks after cryotherapy. Granulation tissue is present in the wound during the first 2-3 weeks after cryotherapy (Figure 40:(b)), which is followed by re-epithelialization of the surface. Normally, the wound is totally healed within 6-8 weeks of treatment. The appearance of the cervix 3 months and 12 months after cryotherapy is shown in Figure 40:(c), 40:(d) below-

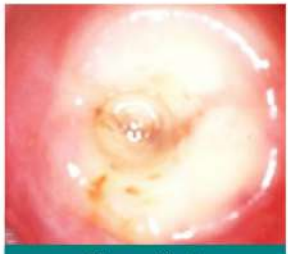


Figure 40: (a)
The ice ball on cervix immediately after cryotherapy[2]

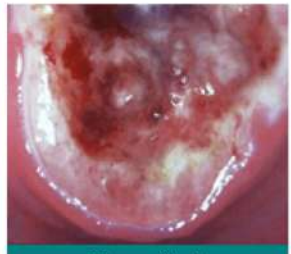


Figure 40: (b)
Appearance after 2 weeks of cryotherapy[2]

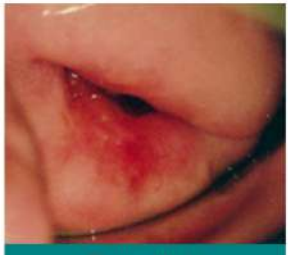


Figure 40: (c)
3 months after cryotherapy[2]

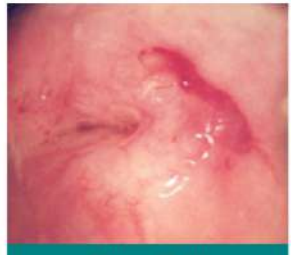


Figure 40: (d)
1 year after cryotherapy[2]

- The next check-up should be done after 3 and 12 months of the treatment, when the woman may have the VIA screening test originally performed or a direct colposcopic examination
- **If there is a persistent lesion at follow-up, it is preferable to excise the lesion**

[2]*Source: Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual, Edited by J.W. Sellors and R. Sankaranarayanan*

Decontaminate Cryotherapy Unit

After treatment the cryo probe should be sterilized before re-using it. This can be done by following these simple steps-

1. Decontaminate by wiping with ethyl alcohol 60–90%

2. Dip the probe in clean water

3. Scrub any visible biological matter on the probe tip with a cotton swab and wash with clean water

4. Clean the probe in any one of the following chemicals:
   - ✓ 0.5% chlorine solution or 2% glutaraldehyde for 20 minutes
   - ✓ 6% hydrogen peroxide solution for 30 minutes

4. Rinse the probe thoroughly with sterile water or tap water

5. Air-dry or dry it with a sterile cloth

6. Clean the cryoprobe shaft and the rest of the cryotherapy unit by wiping with cotton or clean cloth soaked in 60–90% ethyl or isopropyl alcohol

7. Make sure that the inside hollow part of the cryoprobe is completely dry before the next use (water inside the probe may freeze and the probe could crack, thus interfering with proper treatment)

Common Problems Encountered during Cryotherapy and their Management

Table 3: Common problems encountered during cryotherapy and their management

Problems	Reason	Suggested Solution
Gas stops flowing	Gas tank is empty	Arrange for a new gas cylinder
	Nozzle is blocked by impurities in the CO_2 gas	Dip the tip of the nozzle in a small bowl of water and flush it by pressing the trigger of the cryogun until the blockage is cleared
Gas leakage from the hand unit	The washer/O-ring is either missing or is broken	Change washer/O-ring (usually provided by the manufacturer in the cryo unit) and put in a new appropriately sized washer
Pressure gauge indicator is in the yellow zone	Inadequate gas in the cylinder	Stop performing cryotherapy and change the gas cylinder
Difficulty in exposing the cervix	Laxity of vaginal walls	➢ Put a condom or the cut finger of a glove on the speculum ➢ Insert lateral vaginal wall retractors ➢ Use a wooden spatula to push away vagina from between the blades of the speculum

Points to Note

- ✓ Cryotherapy is an ablative method for treatment of ectocervical precancerous lesions
- ✓ It uses the freezing effect of compressed refrigerant gases – N_2O/CO_2
- ✓ Cryotherapy destroys the TZ by crystallization of water and denaturation of proteins
- ✓ The entire lesion should be visible on the ectocervix, fully covered by the cryoprobe, occupying less than 75% of ectocervix with no suspicion of cancer
- ✓ Watery discharge or spotting can occur until 6 weeks after cryotherapy
- ✓ Complete abstinence should be followed for 6 weeks after the procedure
- ✓ **Follow-up is recommended after 3 and 12 months of treatment**

  The woman should report immediately if she has any of the following symptoms:

  - Foul smelling discharge, fever of more than 100.4 degree Fahrenheit
  - Heavy vaginal bleeding or severe lower abdominal pain occur within 4 weeks of treatment

- ✓ **Anaesthesia is not required**

MODULE - 4.2
THERMAL ABLATION FOR TREATMENT OF VIA POSITIVE LESION

Aim:	To learn about thermal ablation as treatment modality for cervical precancer
Time:	90 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

Thermal Ablation for the Treatment of VIA Positive Lesion

Principle of Treatment by Thermal Ablation

Thermal ablation is a safe and acceptable procedure used as an alternative to cryotherapy for treatment of VIA positive lesions. **A probe heated to 100°C- 110°C destroys the abnormal lesions by direct contact the of the ectocervix (destructive therapy) and does not require anaesthesia.** Multiple applications of the probe are feasible with thermal ablation. Hence, unlike cryotherapy, the technique is not limited by the disparity between the size of the lesion and that of the probe.The rest of the principles and indications for treatment by thermal ablation is the same as those for cryotherapy.

Indications for Thermal Ablation

	VIA positive women are eligible for thermal ablation, if-
1	Entire lesion is visible on ectocervix
2	Lesion is not extending to the endocervical canal or to vagina
3	Lesion is occupying less than 75% of the ectocervix
4	There should be no evidence or suspicion of cancer or glandular abnormality
5	Woman should not be pregnant at the time of treatment
6	Woman should not be menstruating at the time of treatment
7	If the woman has recently delivered, she is at least 3 months post-partum
8	Woman should not have pelvic inflammatory disease (PID) at the time of treatment
9	Endocervical canal is normal and there is no evidence of glandular dysplasia

Point to Note

✓ Indications for treatment with thermal ablation are same as cryotherapy

Equipment and Consumables required for Thermal Ablation

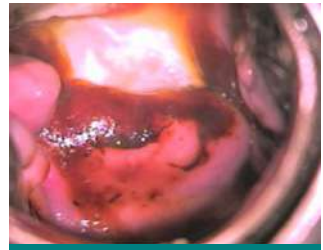
Equipments	Consumables
➢ TA Unit *(as shown in the figure 41)* ➢ Examination table ➢ Light source ➢ Cusco's speculum ➢ Sponge holding forceps	➢ Disposable gloves ➢ Cotton swabs for wiping the cervix ➢ Normal saline solution ➢ Dilute acetic acid (5%) solution (freshly prepared) ➢ Lugol's iodine ➢ Lubricant jelly ➢ 0.5% chlorine solution

Figure 41: Thermal Ablation (TA) Unit

Steps for Performing Thermal Ablation Procedure

Table 4: Steps for performing thermal ablation procedure

S. No.	Activity
Pre-Thermal Ablation Procedure tasks	
1	Counsel the woman, ensure that the woman has understood the procedure and **obtain informed written consent**
2	Ensure that woman has emptied her bladder
3	**No anaesthesia is required for thermal ablation**
Doing the procedure	
4	Expose the cervix gently using the cusco's speculum
5	Focus light source for clear visualization of cervix
6	Moisten the cervix with a saline-soaked cotton swab, for good thermal conduction
7	Apply 5% acetic acid on cervix for 1 minute to outline the abnormality and identify- ➢ Squamocolumnar junction ➢ Limits of the lesion ➢ TZ and area to treat
8	Application of 5% acetic acid to be followed by application of Lugol's iodine to delineate the limits of the lesion
9	Apply the probe to the TZ so that the centre of the tip is on the external os
10	Maintain the temperature at 100°C constantly
11	Keep the probe in contact with the TZ for 20-45 seconds *(Treatment time may differ for different models. Please refer to device-specific instruction manual)*
12	Withdraw the probe from the cervix after 20-45 seconds; a crater will be visible
13	Typical duty cycle of thermal ablation: ➢ 8 seconds of heat up ➢ 20-45 second of treatment ➢ 10 seconds to cool down *(Duty cycle may differ for different models. Please refer to device-specific instruction manual)*

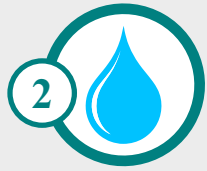
S. No.	Activity
	  *Figure 42: (a)Thermal ablation device probe applied to the cervix* *Figure 42: (b) Appearance of the cervix after thermal ablation*[3] [3]*Source: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index=62&e=,0,1,2,3, 8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111*
14	If the entire TZ is not covered by a single application, apply the probe to another part of the cervix and treat for 20-45 seconds (up to 5 overlapping applications can be made - may differe for different models)
15	Switch off the machine once the applications are complete
16	Remove the probe carefully so that the probe does not touch the vaginal walls
17	Remove the speculum gently
Post procedure tasks	
18	Ask the woman to continue lying down for 5 minutes before letting her get up
19	Counsel the woman and give appropriate follow-up advice
20	Document treatment completion in individual case record form
21	Provide her the date for next follow up and emphasize on the importance of it. Also, ask the woman to report in case she experiences any adverse reaction/effect or has discomfort other than the ones explained
22	Disinfect the probes and device

Possible Side Effects

- The possible side-effects and complications of the thermal ablation procedure are the same as those for cryotherapy
- **The duration of vaginal discharge is usually shorter with thermal ablation**

Thermal ablation is well tolerated. However, following symptoms may be experienced rarely:

Mild pelvic pain



Watery discharge, spotting or light bleeding for 2-4 weeks

Other side effects are rare

Post-Treatment Care and Follow-up

- Provide a sanitary pad
- The woman should be told that she may experience excessive watery discharge for up to 2- 4 weeks. She should not get worried about it
- Instruct the woman to abstain from intercourse for 6 weeks
- Avoid douching or use of tampon for 6 weeks
- Inform her of possible complications and ask her to return immediately if she notes:
  - Fever with temperature higher than 100.4 degree Fahrenheit lasting for more than 48 hours
  - Severe lower abdominal pain
  - Foul-smelling or pus-like discharge
  - Bleeding for more than two days or bleeding with clots
- Ask the woman to report for follow up after 3 months and 12 months of treatment

✔ Post treatment care and follow up for thermal ablation is same as cryotherapy

Decontaminate Thermal Ablation Unit

After treatment by TA, the probe should be sterilized thoroughly before re-using it. Steps to sterilize are as follows-

1. Decontaminate by wiping with ethyl alcohol 60–90%

2. Dip the probe in clean water

3. Clean any visible biological matter on the probe tip with a cotton swab and wash with clean water

4. Soak the probe in any one of the following chemicals:
   - ✓ 0.5% chlorine solution or 2% glutaraldehyde for 20 minutes
   - ✓ 6% hydrogen peroxide solution for 30 minutes

5. Rinse the probe thoroughly with sterile water or tap water

6. Air-dry or dry it with a sterile cloth

7. Clean the probe and the rest of the thermal ablation unit by wiping with cotton or clean cloth soaked in 60–90% ethyl or isopropyl alcohol

Treatment Complications and their Management (for Cryotherapy and Thermal Ablation)

Table 5: Treatment complications and management for cryotherapy and thermal ablation

Side Effects	Management
Cramping during treatment	➢ Counsel the woman before the procedure to expect some degree of cramping during and after the procedure ➢ Cramping can be reduced by giving a mild analgesic like paracetamol orally half an hour before treatment ➢ Analgesics can be given after the procedure if the woman complains of persistent pain
Vaginal pain due to inadvertent touching of the vagina with a heated probe	➢ Make the woman lie down for about 30 minutes ➢ Give her analgesic tablets like paracetamol or ibuprofen ➢ Reassure her and make sure she is feeling all right before letting her go
Vaginal discharge (profuse, watery)	➢ Reassure the woman that this is expected after treatment ➢ Ask her to use sanitary napkins for comfort
Acute pelvic inflammatory disease	➢ Send swab from vaginal discharge for culture, if feasible ➢ Start empirical treatment with antibiotics ➢ Give supportive treatment
Spotting/light bleeding	➢ Reassure the woman that this is expected after treatment ➢ Ask her to use sanitary napkins for comfort

Source: WHO, 2017, p.114-115, Training of health staff in VIA, HPV detection test and cryotherapy

Points to Note

- ✓ Thermal Ablation is an ablative method for treatment of ectocervical precancerous lesions
- ✓ It uses metallic probes heated to 100–110 °C
- ✓ Typical duty cycle of thermal ablation:
  - ***8 seconds of heat up***
  - ***20-45 seconds of treatment***
  - ***10 seconds to cool down***
- ✓ Thermal ablation causes thermal destruction of the cervical tissue
- ✓ The entire lesion should be visible on the ectocervix, occupying less than 75% of the ectocervix, with no suspicion of cancer
- ✓ Watery discharge or spotting can occur until 4-6 weeks after cold coagulation
- ✓ Complete abstinence should be maintained for 6 weeks after the procedure

Follow-up is recommended after 3 and 12 months of treatment

- ✓ The woman should report immediately if any of the following symptoms occur within 4 weeks of treatment:
  - Foul smelling discharge
  - Fever of more than 100.4 degree Fahrenheit
  - Heavy vaginal bleeding or severe lower abdominal pain
- ✓ Anaesthesia is not required
- ✓ Do not perform ablative therapy if the patient is -
  - ***Menstruating at the time of the procedure***
  - ***Pregnant (to be treated after 6 weeks of childbirth/abortion)***
  - ***Suffering from any genital tract infection (treat the infection before the procedure)***

MODULE - 5
TREATMENT OF CERVICAL PRECANCER USING LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE (LLETZ/LEEP)

Aim:	To learn about LLETZ/LEEP as treatment modality for cervical precancer
Time:	60 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

Principle of Treatment by LLETZ/LEEP

LLETZ/LEEP is an excisional method of treating cervical intraepithelial neoplasia (CIN). In this procedure, a wire loop electrode powered by an electrosurgical unit is used to remove the entire transformation zone (TZ) along with the lesion. The heat from a high voltage electrical arc between the operating electrode and tissue allows the operator to cut by vaporizing the tissue. A blend of cutting and coagulation current is used. The excision of the TZ treats the abnormality effectively and provides a specimen for detailed histological evaluation. The width of the loop ranges from 10 mm to 20 mm and the depth ranges from 10 mm to 15 mm. The appropriate size of the loop is chosen to achieve adequate depth and width of the cut depending on the size and position of the lesion. Since the disease can extend along the crypts of the TZ and the average depth of a crypt is 5 mm, the extent of excision should be at least 8 mm to 10 mm to get an adequate disease-free margin.

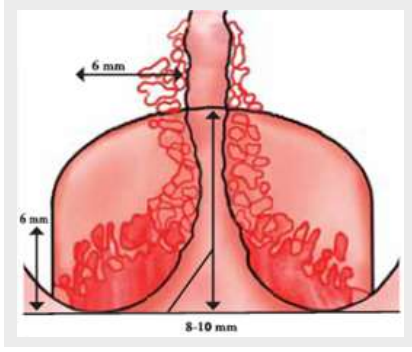


Figure 43: Extent of excision necessary to treat CIN lesions[4]

- A wire loop electrode powered by an electrosurgical unit (ESU) is used to resect the transformation zone along with the lesion
- It is important to remove the entire transformation zone (not just the lesion) along with an adequate length of the endocervix to ensure at least 2–3 mm of tumour-free margin and removal of the full depths of the crypts in the transformation zone

[4]*Source: WHO, 2017, p.124, Training of health staff in colposcopy, LEEP and CKC*

- Depending on the type of transformation zone and the length of the endocervix removed, the excision can be of type 1, type 2, or type 3. Type 1 excision is adequate for a purely ectocervical lesion, whereas type 3 excision is required if the endocervical extent of the lesion is not visible or if LEEP is performed for glandular abnormalities or microinvasive cancer

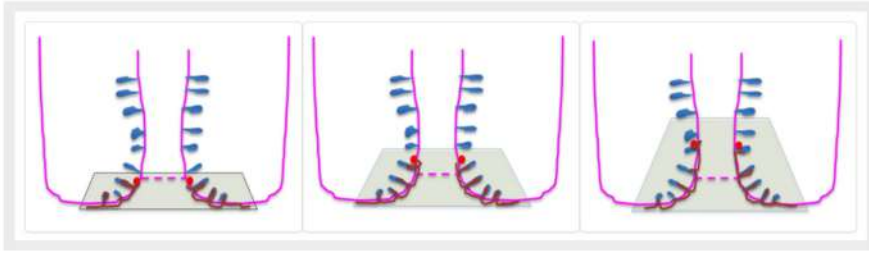


Figure 44: Types of Excision (Type 1, Type 2, Type 3)[4]

- **The cervical tissue is cut as the heat from the electrical arc between the fine wire (active electrode) and the cervix vaporizes the tissue. Therefore, the loop should not be forced into the cervix; rather, it should be guided to melt the tissue (like a hot knife in butter). Bending of the loop will result in a shallow cone**
- A blend of cutting and coagulation current is used. The wattage required varies from machine to machine, but it should be started at 40 W coagulation and 40 W cutting current and gradually increased if necessary
- The width of the loop ranges from 10 mm to 30 mm, and the depth ranges from 10 mm to 20 mm. The appropriate size of the loop should be selected to achieve an adequate depth and width of cut depending on the size and the position of the lesion. Loops that are too small should not be used, because there will be charring of the tissue
- Ideally, the transformation zone should be removed as a single piece of tissue. However, a bigger lesion may require multiple passes of the loop to remove the transformation zone in pieces. The central part of the lesion should always be excised first
- The tissue removed must be subjected to histopathological examination to determine the severity of the disease and whether the margins of the cone are free of disease

[4]*Source: WHO, 2017, p.124, Training of health staff in colposcopy, LEEP and CKC*

Indications for LLETZ/LEEP

Eligibility Criteria for LLETZ/LEEP	
1	CIN1 lesion that is persistent beyond 2 years
2	CIN2 or CIN3 lesions
3	CIN lesions that cannot be treated by cryotherapy/thermal ablation
4	Cervical glandular intraepithelial neoplasia (CGIN) (adenocarcinoma in situ) (cold-knife conization preferred)
5	Microinvasive cancer (cold-knife conization preferred)
6	Cytology ASC-H or HSIL with a type 3 transformation zone and no visible lesion on colposcopy
7	Persistently abnormal cytology in the absence of any lesion visible on colposcopy
8	VIA or HPV positive lesions that cannot be treated by cryotherapy (only in settings where the screen-and-treat algorithm is practised)
9	Cytology and/or endocervical curettage shows glandular abnormalities

Contraindications for LLETZ/LEEP

1 **Pregnancy**

2 **Less than 3 months postpartum/abortion**

3 **Severe infection/ inflammation of cervix**

Equipment and Consumables required for LLETZ/LEEP

Table 6: Equipment and Consumables for LLETZ/LEEP

Equipments	Consumables
➢ Examination table with leg support ➢ Focusing white light for examination ➢ Smoke evacuator with tubing for attachment to speculum ➢ Colposcope ➢ Electrosurgical unit (with patient return electrode, hand switch or foot operated switch) ➢ Loop/ball electrodes ➢ Insulated self-retaining speculum with smoke extraction channel ➢ Sponge holding forceps ➢ Lateral vaginal wall retractor ➢ Kidney tray ➢ Syringe for injecting local anaesthetic (dental syringe preferred)	➢ Gloves (sterile/gloves after high-level disinfection/disposable) ➢ Sterile cotton swabs, cotton swab sticks ➢ Normal saline ➢ Freshly prepared 5% acetic acid ➢ Lugol's iodine ➢ Monsel's paste ➢ Local anaesthetic (1 or 2 % lignocaine) with or without 1:100 000 epinephrine ➢ Lubricant jelly ➢ Vials containing 10% formaldehyde ➢ Chlorine solution (0.5%) or 2% glutaraldehyde

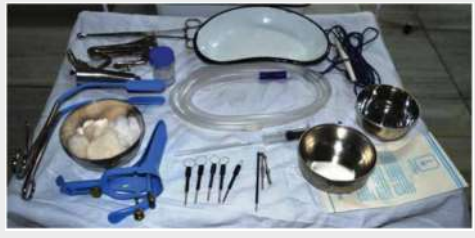


Figure 45: LLETZ/LEEP Tray

Points to Note

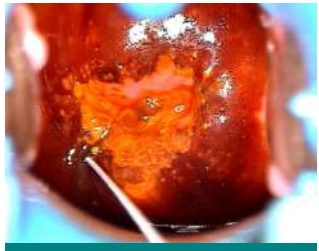
- ✓ The smoke generated must be sucked out either by a smoke evacuator (preferred) or by a suction machine attached to the smoke extraction channel
- ✓ An insulated speculum is preferred but not essential. Regularly check the insulated speculum for any damage to the insulation coating
- ✓ An insulated lateral vaginal retractor may be used if the lateral vaginal walls are patulous and obstruct the view. However, it causes discomfort to the patient. **A non-lubricated condom (with its end cut off) stretched around the speculum can also hold back the vaginal walls away**
- ✓ In most cases the procedure can be performed under local anaesthesia. Regional or general anaesthesia is required if:
  - The lesion is large and/or extends to the vagina
  - Exposure is difficult
  - The woman is uncooperative

Steps for Performing LLETZ/LEEP Procedure

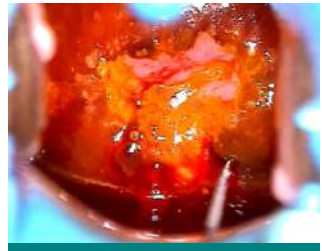
Table 7: Steps for performing LLETZ/LEEP Procedure

S. No.	Activity
Pre-LLETZ/LEEP counselling	
1	Counsel the woman
2	Explain to the woman why the treatment is recommended and describe the procedure
3	Tell her about the side effects she may expect and the alternatives to LLETZ/LEEP
4	Patiently listen to her problems and concerns and respond to her queries
5	Ensure that the woman is not pregnant
6	**Obtain written informed consent for LLETZ/LEEP**
Getting ready	
7	Check that instruments, supplies, colposcope, LLETZ/LEEP unit are available and ready to
8	Check that the ESU and the smoke evacuator are ready for use
9	Check that the woman has emptied her bladder
10	Help her onto the examining table, help her to undress and drape her
11	**Place a reusable patient return electrode under her buttocks or on her thigh and connect it to the ESU. Ensure electrode has been sanitized before and after use**
12	Wash hands thoroughly and air dry them
13	Put on new examination or high-level disinfected surgical gloves
14	Arrange instruments and supplies on a high-level disinfected tray or container
Doing the procedure	
15	Insert an appropriately sized insulated speculum with smoke extraction channel and fix blades so that the entire cervix can be seen clearly
16	Connect the smoke evacuator tubing to the insulated speculum
17	Place a lateral vaginal wall retractor, if required
18	Manipulate colposcope to focus clearly on the cervix

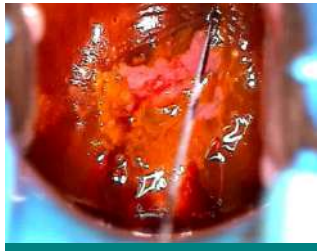
S. No.	Activity
19	➢ Apply 5% dilute acetic acid and identify ➢ Squamocolumnar junction ➢ TZ and area to treat ➢ Limits of the lesion
20	**Apply Lugol's iodine to delineate the lesion clearly**
21	Inject a local anaesthetic agent (5–7 mL of 1% lignocaine with adrenaline) into the stroma of the ectocervix (just beneath the epithelium) in a ring pattern at the periphery of the lesion. **Avoid the 3 o'clock and 9 o'clock positions, because you may encounter a branch of the descending cervical artery**



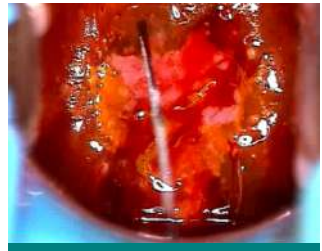
(a) Step 1: injecting the local anaesthetic at the 8 o'clock position just below the epithelium



(b) Step 2: injecting the local anaesthetic at the 4 o'clock position



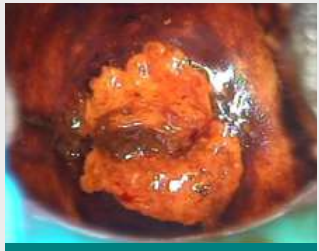
© Step 3: injecting the local anaesthetic at the 2 o'clock position



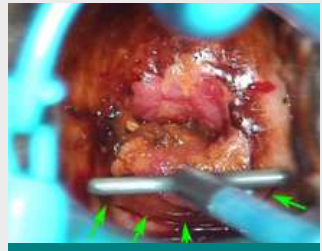
(d) Step 4: injecting the local anaesthetic at the 11 o'clock position

Source: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index =73&e=,0,1,2,3,8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111

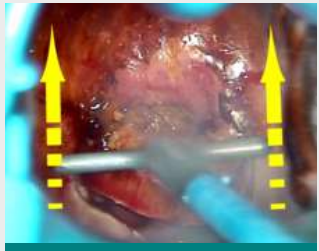
S. No.	Activity
22	Set the power setting of the ESU to a blend of 40-50 watts of coagulation and 40-50 watts of cutting currents (Wireless, battery-operated devices have automatic pre-set voltage)
23	Select an appropriately sized loop depending on the size and endocervical extent of the lesion so as to remove the lesion with minimum number of passes
24	Introduce the loop into the tissue 2–3 mm outside the outer margin of the lesion (either left or right or lower margin, but not the upper margin) and activate the ESU by pressing the cutting switch **Treatment by LLETZ/LEEP- Direction of cutting: from below upwards**



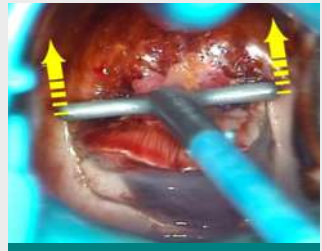
(a) Apply Lugol's iodine to delineate the lesion; note that the long axis of the lesion extends vertically



(b) Apply Lugol's iodine to delineate the lesion; note that the long axis of the lesion extends vertically

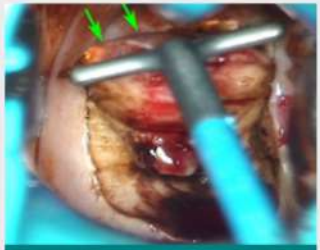


(c) Continue moving the loop upwards slowly and steadily

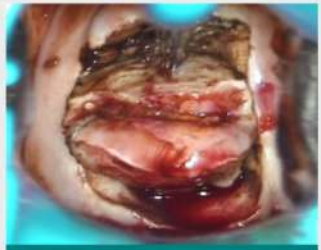


(d) Use the full depth of the loop to cut across the endocervical canal

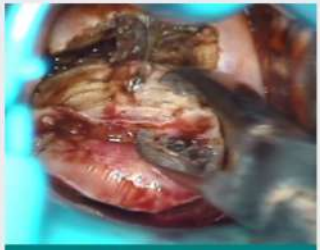
Source of images: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index =74&e=,0,1,2,3,8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111



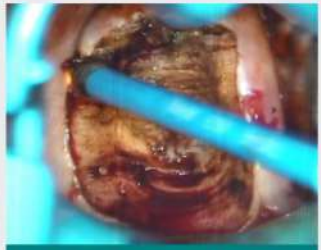
(e) Take the loop out from a point just beyond the lesion (or the transformation zone) on the anterior lip



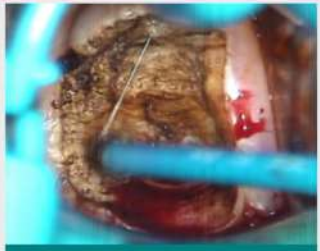
(f) The excised cone with the lesion will be free transformation zone) on the anterior lip



(g) Pick up the cone with a pair of forceps



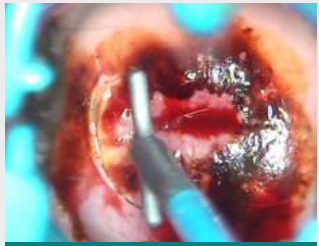
(h) Start cauterizing the margin of the cavity unless there is any obvious major bleeding



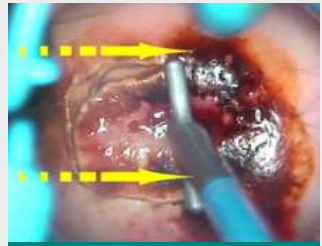
(I) Cauterize the base of the cavity starting from the anterior lip and gradually moving towards the posterior lip

Source of images: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index =74&e=,0,1,2,3,8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111

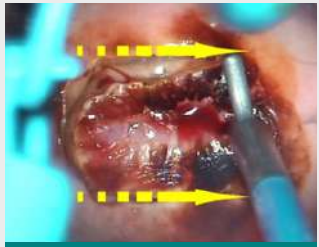
Treatment by LLETZ/LEEP- Direction of cutting: from one side to other



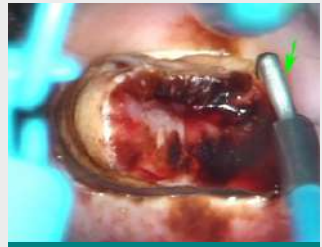
(a) Place the loop just beyond the lesion (or the transformation zone) on the side convenient to you and activate the cutting switch; note that the long axis of the lesion extends horizontally



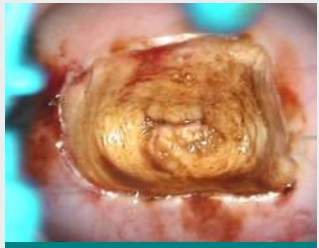
(b) Continue moving the loop towards the opposite side slowly and steadily



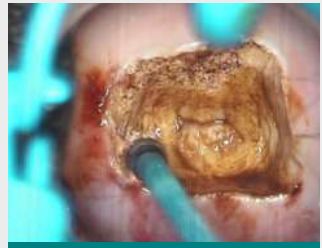
(c) Use the full depth of the loop to cut across the endocervical canal



(d) Take the loop out from a point just beyond the lesion (or the transformation zone) on the opposite side



(e) Very little bleeding is encountered if the diathermy settings are right and the procedure is done slowly



(f) Start cauterizing the margin of the cavity and move towards the centre

Source of images: International Agency for research on Cancer (IARC), WHO, https://screening.iarc.fr/atlascolpodetail.php?Index =74&e=,0,1,2,3,8,10,15,19,30,31,43,46,47,60,61,68,73,83,88,89,93,96,102,105,111

S. No.	Activity
25	**Direct the loop gradually into the cervix until the cross bar nearly comes in contact with the epithelial surface**
26	**Guide the loop parallel to the surface of the cervix across the endocervical canal till the opposite outer margin of the lesion is reached**
27	Gradually withdraw the loop and, as soon as it is out of the tissue, release the switch to stop the ESU
28	Remove the excised tissue with a pair of forceps
29	Fulgurate the defect on the cervix with a ball electrode using the pure coagulation current from the ESU to control the bleeding
30	If necessary, use multiple passes to remove the lesion entirely
31	Remove blood and clots from vagina and smear Monsel's paste on the treated area
32	Remove return electrode. Remove speculum and place in 0.5% chlorine solution for 10 min
33	Help the woman to get up from examination table and sit comfortably
34	Send the excised tissue for histopathological examination
Post-LLETZ/LEEP tasks	
35	Dispose-off the swabs and other disposable items in appropriate disposal bags

36	• Sanitize patient return electrode
	• Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out:
	  • If disposing-off the gloves, place in leak-proof container or plastic bag
	  • If reusing surgical gloves, submerge in 0.5% chlorine solution for 10 minutes for decontamination

37	Wash hands thoroughly with soap and water and air dry them
38	Ensure that the woman is not having any discomfort or bleeding
39	**Advise her about post-treatment care and follow-up instructions**
40	Document the treatment done in the reporting register form along with the follow-up plan

Possible Complications of LLETZ/LEEP

- **Primary Haemorrhage:** Excessive bleeding may occur during LLETZ/LEEP if -
- Cervix is congested and hypertrophied,
- The transformation zone is large, and the lesion extends too far laterally
- Moving the loop through the cervix too quickly or interrupting the excision midway also induces more bleeding
- Rarely, the loop may injure the lateral vaginal wall, resulting in profuse bleeding

- **Management Approach**

S.no.	Complications	Management
1	**Excessive bleeding during the procedure**	➢ Add adrenaline to the local anaesthetic ➢ Use higher coagulation current for a large, congested cervix ➢ Complete the procedure in a single smooth, slow, deliberate motion of the loop through the cervix
2	**Loop stops cutting midway**	➢ Withdraw the loop to see whether it is intact ➢ If the loop is intact, increase the cutting current by 5 W and try again through the original incision ➢ Gradually increase the cutting current until the loop starts working
3	**Excessive bleeding after the procedure**	➢ Take a piece of dry gauze on a sponge-holding forceps, and press the wound ➢ Get an assistant to help you ➢ Remove the piece of gauze and try to identify the source of heavy bleeding under colposcopy- usually it is a spurting artery ➢ Use the gauze on the forceps to dry the area with one hand and the diathermy with the ball electrode with the other hand and try to cauterize the vessel ➢ Increase the coagulation current to 50 or 60 W ➢ **Once the major bleeding is controlled** ➢ Systematically cauterize the entire wound, starting from the periphery of the anterior lip ➢ After haemostasis is secured, loosen the blades of the speculum and check whether new bleeding points appear becauseof the release of pressure
4	**If there is bleeding but no obvious source of bleeding seen on the cervix**	➢ Check the lateral vaginal walls for tears ➢ A tear on the lateral vaginal wall needs to be stitched with a polyglactin suture

		➢ Remove the self-retaining speculum and introduce the anterior and posterior vaginal retractors ➢ Expose the injury and infiltrate with a local anaesthetic agent ➢ Apply interrupted or continuous stitches to stop the bleeding ➢ Rarely, stitches are required to stop bleeding from the cervix

- **Secondary Haemorrhage:** The woman may return after a few days complaining of heavy bleeding with passage of clots

- **Management Approach**
- The woman should be assessed and resuscitated appropriately.
- The vagina should be cleared of all clots, and a tight vaginal pack should be applied. Antibiotics should be started or changed. Removal of the pack after 24 hours usually stops the bleeding in most cases.
- If bleeding persists, the woman should be moved to the operating theatre for exploration, preferably under general anaesthesia. Bleeding points should be secured by deep stiches with a polyglactin suture and with diathermy.

Other Complications

S.no.	Complications	Management
1	**Vaginal discharge**	➢ Most patients have minimal vaginal discharge for 2–3 weeks after the procedure ➢ After a week, the discharge usually becomes heavier and may be bloodstained. This may persist for about 2 more weeks. Patients should be counselled beforehand
2	**Pelvic inflammatory disease**	➢ Rarely, the woman may have pelvic inflammatory disease, characterized by lower abdominal pain and foul-smelling vaginal discharge with or without fever
3	**Cervical stenosis**	➢ Stenosis of the external os is seen in 2–3% of cases during follow-up
4	**Premature rupture of membranes and preterm labour**	➢ Excision of large transformation zones or type 3 excision is associated with a higher risk of premature rupture of membranes and preterm labour in subsequent pregnancies

Post-Treatment Advice

- **Inform the woman about the expected symptoms like watery discharge or blood-stained discharge for about 4 weeks**

- **Advise her to use sanitary napkins, as required, to avoid staining of clothes**

- **Advise her to avoid sexual intercourse for about 6 weeks (or to use condoms if sexual intercourse cannot be avoided)**

- **Advise her to NOT use vaginal tampons or douche for about 6 weeks**

- **Advise her to attend for check-up after 1 month when the histology report would be available. Histopathology report should be carefully evaluated-**
  - Cases with invasive cancer on histopathology should be appropriately managed or referred
  - Women with a positive margin on the LLETZ specimen need individualized management
  - Those with CIN 2, CIN 3, microinvasive cancer, or glandular disease on the inner margin (endocervical and stromal) need evaluation for repeat LLETZ or hysterectomy
  - Those with CIN detected on the ectocervical margin of the cone need follow-up only

- **Those with persistent disease at first follow-up after 8–12 months need a repeat excision after carefully ruling out invasive cancer**

- **Advise her to report back if she has any of the following symptoms within 4 weeks of treatment:**

Fever with temperature higher than 100.4 degree Fahrenheit lasting for more than 48 hours

Severe lower abdominal pain

Foul-smelling or pus-like discharge

Bleeding for more than two days or bleeding with clots

Decontaminate LLETZ/LEEP Unit

There are various kinds of instruments used in LEEP. These include insulated instruments, plastics and cords, and metallic instruments. Each requires different cleaning and decontamination solutions depending on the material of which it is made:

1. **Insulated Instruments:** These include speculums, vaginal wall retractors, pick-up forceps, tenaculum, or any other insulated metallic instrument:
   - Insulated instruments should be cleaned thoroughly with a soft brush and soapy water,and then rinsed at least thrice, with clean water and air drying. DO NOT use bleach (chlorine solution) to decontaminate
   - After cleaning, sterilize these instruments using an autoclave
   - The insulated speculum and other insulated instruments used for LEEP may also be disinfected with glutaraldehyde solution. The manufacturer's instructions must be precisely followed because these solutions are corrosive and failure to follow correct procedure will cause instruments to degenerate over time

- Do not leave the instruments in a disinfectant solution for more than two hours
- Rinse-off all traces of the disinfectant solution with sterile water
- Inspect the instrument insulation frequently before and after each use for cracks, nicks, cuts, and depressions which may decrease the effectiveness of the insulation and may lead to electric burn or shock when in contact with a charged electrode
- Avoid contact with sharp instruments
- Always verify that metal is not visible underneath the insulation coating

2. **Metallic Instruments:** These include speculums, vaginal wall retractors, pick-up forceps, tenaculum, or any other insulated metallic instrument:
   - Fully submerge used instruments in a container filled with 0.5% chlorine solution for only 10 minutes
   - After 10 minutes, clean instruments with a brush and soapy water (wearing examination gloves), then rinse at least thrice with clean water and dry properly
   - After cleaning, these instruments may be autoclaved

3. **Rubbers and Plastics:** Electrical cords, hand switches and smoke evacuator tubes can be decontaminated with 0.5% chlorine:
   - Submerge them in a plastic container filled with 0.5% chlorine solution for 10 minutes
   - After 10 minutes, clean them with a brush and soapy water (wearing examination glove)
   - Rinse items at least thrice with clean water and dry properly
   - After decontamination, place them in high-level disinfection solution (glutaraldehyde) for 20–90 minutes
   - Pack items and place in a clean and dry place for storage

Common Problems Encountered during LLETZ/LEEP and their Solutions

Table 8: Common problems encountered during LLETZ/LEEP and their solutions

Problems	Reason	Suggested Solution
Difficult exposure of the cervix	➢ Laxity of vaginal walls	➢ Put a non-lubricated condom or the cut finger of a glove on the speculum ➢ Insert lateral vaginal wall retractors
Patient feels pain during cutting	➢ Inadequate infiltration of local anaesthetic ➢ Poor contact with patient return electrode (dispersive plate)	➢ Inject sufficient local anaesthetic ➢ Adjust patient return electrode (dispersive plate) so as to establish a complete electrical circuit and prevent electrical burns to the patient

Loop does not cut properly/ gets stuck while cutting	➢ Inappropriate power setting of the diathermy machine	➢ Choose the power setting that is appropriate for that particular diathermy machine. Ideally this should be predetermined, and the machine set accordingly before starting the procedure. Increase the cutting power gradually, 5W each time, till the loop starts excising the tissue smoothly
Field of vision in obscured due to smoke	➢ Smoke evacuation system malfunctioning	➢ Check the smoke evacuator tube and change if necessary

Source: WHO, 2017, p.128, Training of health staff in colposcopy, LEEP and CKC

Routine Maintenance Procedures and Safety Precautions for the Electrosurgical Unit used for LLETZ/LEEP

- The safety and effectiveness of electro surgery is dependent, to a large degree, upon the skill of the user. The user should read, understand and follow the operating instructions supplied with the electrosurgical unit and should have adequate knowledge of the principles and use of such systems
- Electrosurgery should not be done in the presence of flammable gases, flammable liquids or flammable objects in oxygen-enriched atmospheres or in the presence of other oxidizing agents
- The electrical cord of the electrosurgical unit should be connected to a properly grounded receptacle. Extension cords and/or adapter plugs should be avoided
- Old or worn accessories should not be used
- Safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests. The equipment should be decontaminated at the end of the day and kept properly covered to avoid dust.

MODULE - 6
INFECTION PREVENTION DURING SCREENING AND TREATMENT

Aim:	To understand about infection prevention practices during screening and treatment
Time:	30 min
Material Required:	Presentation
Qualifications of the Technical Resource	Gynecologist

Infection Prevention During Screening

Why is prevention of infection important?

Infection prevention is of paramount importance in all health interventions specially in cervical cancer screening as instruments come in contact with body fluids and secretions. The spread of infection can occur if proper precautions are not taken to prevent transmission of microorganisms from an infected person or a contaminated object to another person. All microorganisms, including normal flora, can cause infection or disease. Normal flora may cause infection when introduced into an area of the body where they are not normally found.

How to prevent spread of infection?

As healthcare professionals are frequently exposed to potentially infectious materials, it is mandatory that appropriate infection prevention procedures are practiced to reduce the risk of infection transmission. The following are standard universal precautions of infection prevention:

- Washing hands before and after examining each client
- Wearing gloves when touching broken skin, mucous membranes, blood or other body fluids, soiled instruments, gloves and medical waste
- Disinfecting instruments after use
- Disposal of waste as per standard guidelines
- Safe work practices; environmental cleanliness
- All equipment/instruments (speculum forceps, biopsy forceps, endocervical curette, anterior vaginal wall retractor) must be decontaminated and cleaned by autoclaving or disinfected by boiling (high level disinfection or HLD)

How to process instruments for cervical cancer screening

Several steps are involved in reducing the risk of infection transmission from used instruments and other items to healthcare workers and clients. The basic steps for processing instruments, surgical gloves and other items are as follows:

1. Decontamination is the first step in handling soiled surgical instruments and other items to make objects safer for handling by healthcare staff. Immediately after use, the instruments and other items should be placed in a 0.5% chlorine solution for 10 minutes (Fig. a). This step rapidly inactivates microorganisms like hepatitis B virus, hepatitis C virus and HIV and makes items safer to handle. Surfaces of the procedure table and parts of any equipment/ instrument that may have come in contact with body fluids should also be decontaminated by wiping them with 0.5% chlorine solution or 90% ethyl alcohol before reuse.

2. Cleaning refers to scrubbing the instruments with a brush (an old tooth brush works well), using detergent and water to remove blood, other body fluids, organic material, tissue and dirt (Fig. b). In addition, cleaning greatly reduces the number of microorganisms (including bacterial endospores) on items. Items should be thoroughly rinsed with water to remove detergent residue, which can interfere with chemical disinfection. Wear utility gloves while cleaning. All staff should be careful to protect their eyes from splashing contaminated water.
3. Sterilization eliminates all microorganisms (bacteria, viruses, fungi, and parasites), including bacterial endospores, from instruments and other items. Sterilization should be performed on any item or instrument that comes in contact with the bloodstream or tissues under the skin. It can be performed using steam (autoclaving), dry heat, or chemicals
4. High level disinfection (HLD) is the process that eliminates all microorganisms (including bacteria, viruses, fungi, and parasites), but does not reliably kill all bacterial endospores, which cause diseases such as tetanus and gas gangrene. HLD is suitable for instruments and items that come in contact with broken skin or intact mucous membranes. If sterilization is not available, HLD is the only acceptable alternative.

Processing of instruments after use for infection prevention

a) Decontamination in 0.5% chlorine solution

b) Cleaning by scrubbing with brush

c) Sterilization in autoclave

d) Chemical sterilization

Process of HLD

HLD by boiling: Boiling is a simple method of HLD that can be performed in any location that has access to clean water and a source of heating. Using this method, instruments and other items are submerged in a covered pot or boiler and the water is heated for 20 minutes after it reaches boiling point . Use instruments immediately or keep them in a covered, dry, high-level disinfected container. (The container used for drying the instruments can be used for storage only if there is no water in the bottom of the container). These instruments can be stored for 7 days if the container remains tightly covered and for 24 hours if the lid of the container is opened.

Steps of HLD by boiling

- Submerge the cleaned instruments in water contained in a covered pot or boiler
- Boil the water for 20 minutes. Timing should begin when the water is at a rolling (bubbling) boil. All items should be submerged (totally covered) in water
- Do not add or remove any item after the water begins to boil
- After boiling for 20 minutes, remove the boiled items using high-level disinfected forceps and place them in a high-level disinfected container
- Allow the items to cool and air dry

HLD by boiling

A guide to processing instruments used in cervical cancer screening

Instruments/consumables	Process required	Suggested procedures
Vaginal speculum, biopsy forceps, endocervical curette, endocervical speculum, vulsellum forceps, insulated speculum, vaginal side-wall retractor	Decontamination, cleaning followed by sterilization or HLD	Autoclaving or HLD by boiling
Colposcope, LEEP equipment, cryotherapy equipment, cryo gas cylinder, cold coagulator with probe, examination table, halogen lamp, instrument trolley, trays	Decontamination	Wipe with ethyl alcohol

How to decontaminate various surfaces in cervical cancer screening

The surface of equipment like the cryotherapy unit, focusing lamp, patient examination table, etc. should be regularly decontaminated as these come in contact with body secretions and blood in screening clinics. Decontamination is done by wiping the surfaces with 0.5% chlorine solution or 60–90% ethyl or isopropyl alcohol or iodophores. The examination table should be decontaminated after each patient examination to prevent transmission of infection from one patient to another or to healthcare providers.

SECTION - 4

ANNEXURES

Annexure - 1

Checklist for VIA Screening

Objective: The checklist is designed to enhanceVIA interpretation skillset of service providers. Service providers are expected to fill the checklist for initial 15-20 cases which ensures that they are well acquainted with the interpretation framework.

Table 1:Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics			
Characteristics of acetowhite patches	**Observations of Acetowhite lesion**	**Observation (Y/N)**	**Remarks**
Speed of appearance	Appeared immediately and stayed for more than a minute		
Colour Intensity	Opaque/Dull/Cloudy White, not transparent, or pinkish white		
Colour uniformity	Distinct white patch on cervix, not blending with rest of the cervix		
Borders and demarcations	Distinctly clear and sharp/ raised margin		
Location	Close to or arising from SCJ/ close to external os if SCJ is not visible/ in the TZ		
VIA Result	1. VIA Positive 2. VIA Negative 3. Suspicious for Invasive Cancer		

Before VIA

1. *Only when New SCJ and transformation zone are clearly identifiable the results of VIA screening are acceptable*
2. *Presence of cauliflower growth, irregular surface that bleeds on touch are indications of suspicious of invasive cancer*

After VIA

3. *If all the observations are YES then lesion is VIA positive else it is VIA negative*
4. *Thick, dense large acetowhite areas with raised margin that may bleed on touch are suspicious for invasive cancer*

Annexure - 2

Checklist for Management of Screen Positive Women

Objective: The checklist is designed to help service providers in identifying cases for pre-cancer treatment and to decide treatment modality (ablative or excisional). Service providers are expected to fill the checklist for initial 15-20 cases which ensures that they are well acquainted with the framework to identify treatment eligibility and decide on treatment modality.

VIA Positive

- If colposcopy is planned before treatment refer table 2 for reporting colposcopy findings
- If treatment is planned basis VIA screening interpretation, refer table 3 for deciding treatment modality

Table 2:Colposcopy reporting Using Swede Score

S. No.	Parameter	Feature	Score	Score Allotted basis Observation
1	Aceto-White Uptake	Zero or transparent	0	
		Thin, Milky	1	
		Distinct	2	
2	Margin and Surface	Zero or diffuse	0	
		Sharp but irregular, jagged, geographical, satellites	1	
		Sharp and even, difference in surface levels including cuffing	2	
3	Vessels	Fine, regular	0	
		Absent	1	
		Coarse or atypical vessels	2	
4	Iodine Staining	<5 mm	0	
		5–15 mm or two quadrants	1	
		>15 mm or three to fourquadrants or endocervically undefined	2	
5	Lesion Size	Brown	0	
		Fainty or patchy yellow	1	
		Distinct yellow	2	
			Total	

Interpretation of Swede Score

Score	Interpretation
0-4	Normal/Low-grade CIN
5-6	High Grade CIN, Non-Invasive
7-10	High grade/suspected of invasive cancer

- Depending on colposcopic appearance of cervix, biopsy (if needed) followed by treatment with ablation excision can be performed on the same visit

Table 3: If the interpretation is VIA Positive from screening and suggestive of CIN from colposcopy, answer following question to decide treatment modality for CIN

S. No.	Questions	Answers (Y/N)	Treatment by Cryo/TA	Treatment by LEEP
1	Is the SCJ fully visible and located on the ectocervix or at external OS (Type TZ-1,2)?		Yes	If the criteria for Cryo/TA is not met and there is no sign of invasive cancer, treat using LEEP
2	Does the lesion occupy less than 75% of the ectocervix?		Yes	
3	Is the size of lesion adequately covered by the cryotip? (Answer only in case of cryotherapy)		Yes	
4	Lesion does not extend to the vagina or to the endocervix		Yes	
5	There is no suspicion of invasive cancer		Yes	
6	There are no signs of inflammatory infections on the cervix		Yes	

VIA Negative

- Explain the meaning of negative result to the woman and ask her to get rescreen after 5 years

Suspicious of Invasive Cancer

- Take biopsy sample from the abnormal area and decide next steps basis biopsy result

Annexure 3 - Image Bank for Screening and Treatment

Cervix BEFORE application of 5% acetic acid

Fig: 1.1

Yellow arrow: Columnar epithelium

Green arrow: Squamous epithelium

The cervix is exposed adequately. No abnormal discharge is seen

Cervix AFTER application of 5% acetic acid

Fig: 1.2

Blue line: SCJ

Green line: Outer limit of TZ

Green arrows: Acetowhite epithelium

The SCJ becomes prominent. A thin acetowhite area with sharp but irregular margins is visible at the 12–2 o'clock position

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

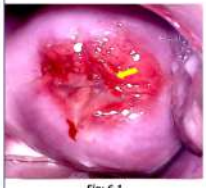


Fig: 6.1

Yellow arrow: Columnar epithelium

Red columnar epithelium is visible around the externalos.

Cervix AFTER application of 5% acetic acid

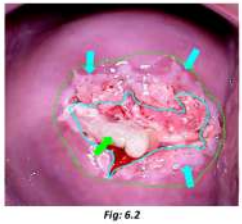


Fig: 6.2

Blue line: SCJ

Blue arrows: Acetowhite areas

Green arrow: Mucus

Green line: Outer limit of TZ

Thin acetowhite areas with irregular margins are seen on the anterior lip (at the 10-1 o'clock position) and the posterior lip (at the 4 o'clock position

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear, raised margin
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal* ***(The thick white mucus plug at the external os should not be mistaken for an acetowhite area)***

Cervix BEFORE application of 5% acetic acid

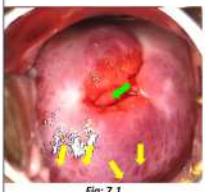


Fig: 7.1

Green arrow: Polyp

Yellow arrows: Strawberry appearance

A few red patches are visible on the posterior lip, giving rise to strawberry appearance of the cervix.

Cervix AFTER application of 5% acetic acid

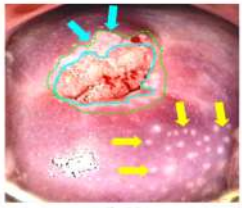


Fig: 7.2

Blue line: SCJ
Blue arrow: Acetowhite area
Yellow arrows: Scattered white dots
Green line: Outer limit of TZ

A thin acetowhite area with irregular margins and attached to the SCJ is seen on the anterior lip (at the 10–12 o'clock position). The multiple scattered white dots on the posterior lip are due to cervicitis

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Opaque/Dull/Cloudy White-
Margins and Demarcations-	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as-*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal (Thin AW areas near external os are due to squamous metaplasia)*

Cervix BEFORE application of 5% acetic acid

Fig: 9.1

Blue line: SCJ

The "fish mouth" appearance of the external os in a parous cervix.

Cervix AFTER application of 5% acetic acid

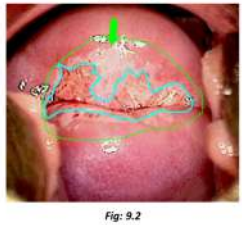


Fig: 9.2

Blue line: SCJ

Green arrow: Acetowhite area
Green line: Outer limit of TZ

A thin acetowhite area with irregular margins and arising from the SCJ is seen at the 12 o'clock position.

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Opaque/Dull/Cloudy White-
Margins and Demarcations-	Distinctly clear margin
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as-*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

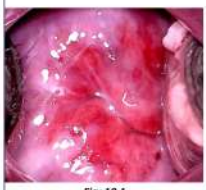


Fig: 10.1

The cervix is covered with mucoid discharge.

Cervix AFTER application of 5% acetic acid

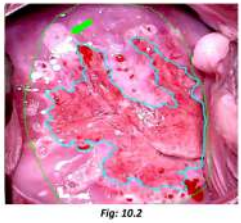


Fig: 10.2

Blue line: SCJ

Green arrow: Acetowhite area
Green line: Outer limit of TZ

Large ectropion pushing the SCJ far out on the ectocervix. A thin acetowhite area with a well defined margin and attached to the SCJ is seen on the anterior lip at the 11 o'clock position.

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	*Lesion eligible for ablative treatment as* ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal (Thin AW areas near external os are due to squamous metaplasia)*

Cervix BEFORE application of 5% acetic acid

Fig: 11.1

The cervix is covered with mucoid discharge.

Cervix AFTER application of 5% acetic acid

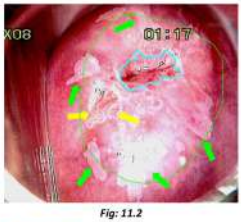


Fig: 11.2

Blue line: SCJ
Green arrows: Acetowhite area
Green line: Outer limit of TZ
Yellow arrows: Islands of columnar epithelium

Multiple thin milky white areas with geographical margins and detached from the SCJ are visible on both the anterior and posterior lips. A thin acetowhite area with distinct and regular margin is at 4 o'clock position

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive** *(AW areas outside TZ are not VIA positive and do not require treatment. In this case AW lesion with well defined margin attached to SCJ is VIA positive)*
Management	*Lesion eligible for ablative treatment as* ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

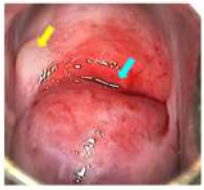


Fig: 1.1

Blue arrow: Columnar epithelium

Yellow arrow: Nabothian cyst

Hypertrophied cervix. A nabothian cyst is present at the 10 o'clock position

Cervix AFTER application of 5% acetic acid

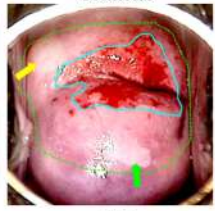


Fig: 1.2

Blue line: SCJ
Green line: Outer limit of TZ
Green arrow: Acetowhite epithelium with distinct margin
Green line: Outside limit of TZ
Yellow arrow: Nabothian cyst
The white area at the 6 o'clock position is opaque and has a smooth well-defined outer margin. It is difficult to assess continuity with SCJ

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive** (Thin acetowhite area is on the TZ though the continuity with SCJ is not very distinct. The case should be considered as VIA-positive due to the features of the acetowhite area. Application of Lugol's iodine would have helped to delineate the complete lesion better)
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

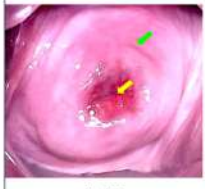


Fig: 1.1

Yellow arrow: Columnar epithelium

Green arrow: Squamous epithelium

The ectocervix is covered by pink squamous epithelium. Red columnar epithelium is seen around the external os

Cervix AFTER application of 5% acetic acid

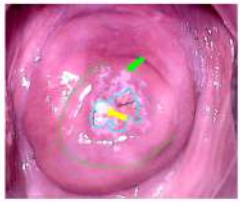


Fig: 1.2

Blue line: SCJ

Green arrow: Acetowhite epithelium
Green line: Outer limit of TZ

Yellow arrow: Mucus

Thin acetowhite areas with irregular margins are visible at the 12 o'clock position, abutting the SCJ and within the TZ

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Distinctly clear margin, not blending with rest of the cervix
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal* ***(The thick white mucus plug at the external os should not be mistaken for an acetowhite area)***

Cervix BEFORE application of 5% acetic acid

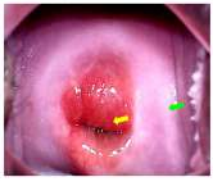


Fig: 1.1

Cervix AFTER application of 5% acetic acid

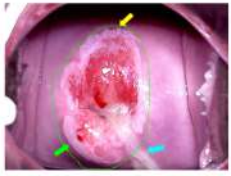


Fig: 1.2

Yellow arrow: Columnar epithelium

Green arrow: Squamous epithelium

The columnar epithelium is visible as a red patch around the external os.

Green arrow: Sharp margin
Green line: Outer limit of TZ
Yellow arrow: Irregular margin
Blue arrow: Mucus
A dense acetowhite area with sharp margins is present at the 7–8 o'clock position. Transparent acetowhite areas with irregular margins are present on the anterior lip at the 10-1 o'clock position. Thick mucus is seen close to the external os on the posterior lip

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Sharp and regular
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal* ***(The thick white mucus plug at the external os should not be mistaken for an acetowhite area)***

Cervix BEFORE application of 5% acetic acid

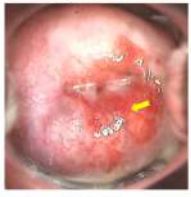


Fig: 1.1

Cervix AFTER application of 5% acetic acid

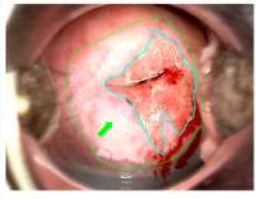


Fig: 1.2

Yellow arrow: Columnar epithelium

The cervix is covered with normal mucoid discharge. The central red patch is columnar epithelium

Blue line: SCJ
Green arrow: Acetowhite area
Green line: Outer limit of TZ

A dense acetowhite area attached to the SCJ is present at the 6–9 o'clock position. Bleeding on the columnar epithelium is due to injury caused during examination

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque/Dull/Cloudy White
Margins and Demarcations	Sharp and regular
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, in transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

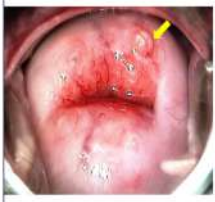


Fig: 5.1

Yellow arrow: Nabothian cyst
The blister-like swelling at the 2 o'clock position is a nabothian cyst.

Cervix AFTER application of 5% acetic acid

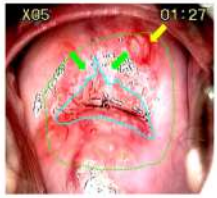


Fig: 5.2

Blue line: SCJ
Green line: Outer limit of TZ
Green arrows: Acetowhite epithelium
Yellow arrow: Nabothian cyst
The location of the nabothian cyst helps to identify the outer limit of the TZ. A tongue shaped thin acetowhite area with irregular margins is seen on the anterior lip at the 12 o'clock position

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Thin acetowhite area
Margins and Demarcations	Distinct, well defined margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

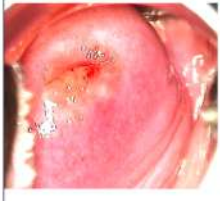


Fig: 6.1

Parous cervix. No abnormal discharge is seen

Cervix AFTER application of 5% acetic acid

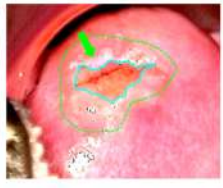


Fig: 6.2

Blue line: SCJ
Green arrow: Acetowhite epithelium
Green line: Outer limit of TZ
The SCJ is fully visible. A thin acetowhite area with irregular margins is seen at the 10–12 o'clock position

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Thin acetowhite area
Margins and Demarcations	Distinct, well defined margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

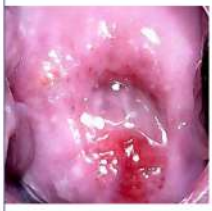


Fig: 7.1

Copious curdy white discharge is present.

Cervix AFTER application of 5% acetic acid

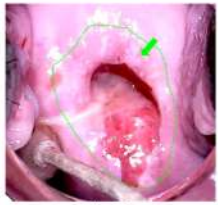


Fig: 7.2

Green arrows: Acetowhite areas
Green line: Outer limit of TZ
The mucus is pushed to one side to visualize the SCJ. Thin acetowhite areas with feathery margins are visible at the 1 o'clock position

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Thin acetowhite area
Margins and Demarcations	Distinct, clear but irregular margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Type of Transformation Zone : **Type 1**

Cervix BEFORE application of 5% acetic acid

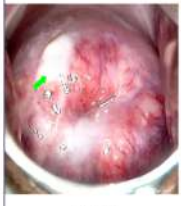


Fig: 8.1

Green arrow: Curdy white discharge
The cervix is covered with copious curdy white discharge suggestive of candidiasis.

Cervix AFTER application of 5% acetic acid

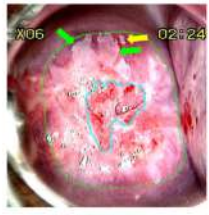


Fig: 8.2

Blue line: SCJ
Green arrows: Thin acetowhite epithelium
Green line: Outer limit of TZ
Yellow arrow: Satellite lesion
Acetic acid clears the discharge, and the SCJ becomes fully visible. Thin acetowhite areas with geographical margins are present at the 12 o'clock position. A small satellite lesion is seen at the 1 o'clock position, located away from the SCJ)

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Thin acetowhite area
Margins and Demarcations	Distinct, clear margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Type of Transformation Zone : **Type 1**

Cervix BEFORE application of 5% acetic acid

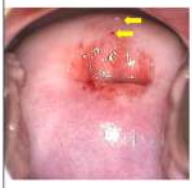


Fig: 11.1

Yellow arrows: Nabothian cysts
The cervix appears normal. Nabothian cysts are present at the 12 o'clock position

Cervix AFTER application of 5% acetic acid

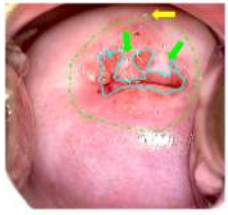


Fig: 11.2

Blue line: SCJ
Green line: Outer limit of TZ
Green arrows: Acetowhite epithelium
Yellow arrow: Nabothian cyst
Thin acetowhite epithelium with tongue-shaped projections is seen in the TZ at the 11 o'clock and 1 o'clock positions

Type of Transformation Zone : **Type 1**

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Thin acetowhite area
Margins and Demarcations-	Distinct, clear margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion eligible for ablative treatment as-*** ✓ *SCJ fully visible on ectocervix* ✓ *Lesion occupy less than 75% of ectocervix* ✓ *No Suspicion of invasive cancer* ✓ *Lesion do not extend to vagina or endocervical canal*

Cervix BEFORE application of 5% acetic acid

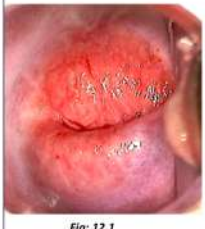


Fig: 12.1

The cervix appears normal.

Cervix AFTER application of 5% acetic acid

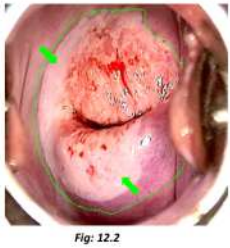


Fig: 12.2

Green arrows: Dense acetowhite area
Green line: Outer limit of TZ
A large dense acetowhite area with well defined margins is seen on both the anterior and posterior lips, occupying more than 75% of the ectocervix.

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Opaque, dull, cloudy white
Margins and Demarcations-	Distinct, clear margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion not eligible for ablative treatment as-*** ✓ *SCJ not visible* ✓ *Lesion occupy more than 75% of ectocervix*

Cervix BEFORE application of 5% acetic acid

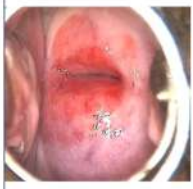


Fig: 12.1

The cervix appears normal.

Cervix AFTER application of 5% acetic acid

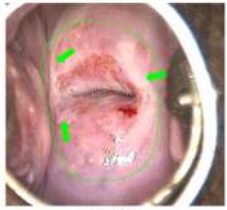


Fig: 12.2

Green arrows: Dense acetowhite area
Green line: Outer limit of TZ
Dense acetowhite areas are present on both the anterior and posterior lips. The lesion extends into the endocervical canal.

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque, dull, cloudy white
Margins and Demarcations	Distinct, clear margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion not eligible for ablative treatment as*** ✓ *SCJ not visible* ✓ *Lesion occupy more than 75% of ectocervix* ✓ *Lesion extend into the endocervical canal*

Cervix BEFORE application of 5% acetic acid

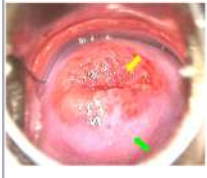


Fig: 12.1

Yellow arrow: Columnar epithelium

Green arrow: Squamous epithelium

The ectocervix is covered by pink squamous epithelium. Red columnar epithelium is seen around the external os

Cervix AFTER application of 5% acetic acid

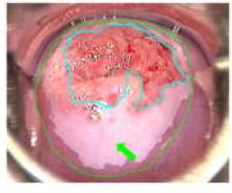


Fig: 12.2

Blue line: SCJ

Green arrow: Acetowhite area
Green line: Outer limit of TZ

The SCJ is fully visible. A dense acetowhite area with sharp margins and attached to the SCJ is present on both the anterior and posterior lips

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation
Speed of Appearance	Appeared immediately and stayed for more than a minute
Colour Intensity	Opaque, dull, cloudy white
Margins and Demarcations	Distinct, regular and sharp margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location	Arising from SCJ, In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion not eligible for ablative treatment as*** ✓ *Lesion occupy more than 75% of ectocervix*

Cervix BEFORE application of 5% acetic acid

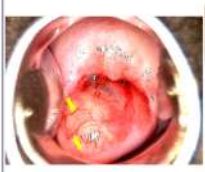


Fig: 12.1

Yellow arrows: Prominent blood vessels on nabothian cyst

A large nabothian cyst is present on the posterior lip. On closer inspection, the blood vessels appear prominent on the surface of the cyst

Cervix AFTER application of 5% acetic acid

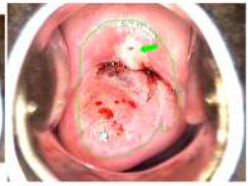


Fig: 12.2

Blue line: SCJ

Green arrow: Acetowhite area
Green line: Outer limit of TZ

A dense acetowhite area with sharp margins is present at the 12 o'clock position, with extension into the endocervical canal. The SCJ is not visible

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Opaque, dense, cloudy white
Margins and Demarcations-	Distinct, regular and sharp margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	In transformation zone, close to external os(SCJ not visible)
VIA Result	**VIA Positive**
Management	***Lesion not eligible for ablative treatment as-*** ✓ *Lesion extend into the endocervical canal*

Cervix BEFORE application of 5% acetic acid

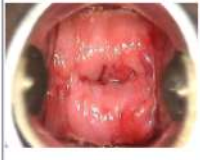


Fig: 12.1

No abnormal discharge is seen

Cervix AFTER application of 5% acetic acid

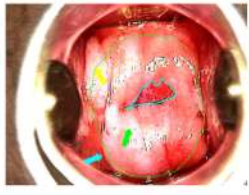


Fig: 12.2

Blue line: SCJ
Blue arrow: Raised margin
Yellow arrow: Extension to vagina
Green arrow: Dense Acetowhite area
Green line: Outer limit of TZ
A large dense acetowhite area with raised margins is visible. On the anterior lip the lesion is seen extending towards the vaginal wall

Were acetowhite patches visible on the cervix after application of 5% acetic acid? if yes, observe characteristics

Characteristics of Acetowhite Lesions	VIA Interpretation-
Speed of Appearance	Appeared immediately and stayed for more than a minute-
Colour Intensity-	Opaque, dense, cloudy white
Margins and Demarcations-	Distinct, regular and sharp margins
Colour Uniformity	Distinct white patch on cervix, not blending with rest of the cervix
Location-	In transformation zone
VIA Result	**VIA Positive**
Management	***Lesion not eligible for ablative treatment as-*** ✓ *Lesion extending into the vagina (yellow arrow)*

Annexure 4 - Presentations for Training

Introduction to Cryotherapy

Table of Content

Topics	Time (minutes)
Treatment of CINs	10
Section 1 – Treatment by Cryotherapy	30
Section 2- SOP for Cryotherapy	30
Section 3 – Post Cryotherapy	45
Cryotherapy Video	20
Open House	15
Total	**150 (2.5 hours)**

Treatment of Cervical Intraepitelial Neoplasia (CIN)

Cervical premalignant lesions can be treated either by an ablative method (cryotherapy or thermal ablation) or by excision, depending on certain criteria

Principles of treatment of cervical intraepithelial neoplasia (CIN)-

1. The entire transformation zone undergoes HPV-induced clonal change and is at risk of developing CIN. Therefore, the whole TZ should be treated (ablated or excised), irrespective of the size of the lesion
2. High-grade CIN lesions often extend into the crypts present in the TZ. The depth of the crypts can be up to 5 mm. During ablative treatment, the tissue destruction must extend up to 7–8 mm to ensure complete clearance of disease
3. Low-grade lesions/CIN1 lesions should be treated when follow-up is not guaranteed
4. CIN2 and CIN3 lesions should always be treated except in very young women (younger than 25 years)
5. The decision to treat a CIN lesion may be based on colposcopic findings ("see and treat") without waiting for histological verification
6. Ablative or excisional treatment can be performed for VIA- or HPV -positive women without colposcopic or histological verification ("screen and treat") in situations where these diagnostic services are not available

3

Section 1 – Introduction to Cryotherapy

Learning Objectives

1. Understand Principle of cryotherapy
2. Identify eligibility criteria for treatment with cryotherapy
3. Describe all the parts of a cryotherapy unit
4. Identifying requirements for cryotherapy at health facility

4

Treatment by Cryotherapy - Principle

- Cryotherapy is an ablative technique for treatment of ectocervical lesions
- It uses the freezing effect of compressed refrigerant gases like nitrous oxide (N_2O) or carbon dioxide (CO_2) to destroy the abnormal TZ of the cervix
- The compressed gas is delivered on to the surface of ectocervix through cryoprobes made up of highly conductive metals (like silver or copper)
- When the gas is applied to the cervix, the tissue temperature is reduced to minus 20 °C, causing permanent damage to the epithelial cells
- The ectocervix has sparse sensory nerve endings. As a result, an ectocervical procedure like cryotherapy does not require any anesthesia

5

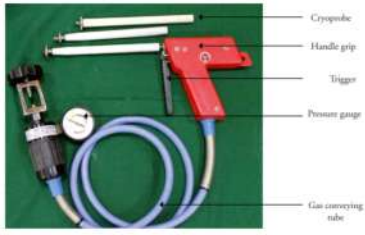
Indications for Cryotherapy

VIA test-positive women are eligible for Cryotherapy/Thermal ablation if –

1. Entire lesion is visible on ectocervix
2. Lesion is not extending to the endocervical canal or to vagina
3. Lesion is occupying less than 75% of the ectocervix
4. The size of the lesion should be such that it can be covered by the tip of the largest cryotherapy probe
5. There should be no evidence or suspicion of cancer or glandular abnormality
6. Woman should not be pregnant at the time of treatment
7. Woman should not be menstruating at the time of treatment
8. If the woman has recently delivered, she is at least 3 months post-partum
9. Woman should not have pelvic inflammatory disease at the time of treatment
10. Endocervical canal is normal and there is no evidence of glandular dysplasia

Cryosurgical Unit

- Cryotherapy equipment consists of a **handle grip (cryogun)** with a trigger mechanism that is attached to the **cryoprobe** on one side and the connecting hose on the other side to transmit gas from the gas cylinder
- Hose is connected to the cylinder with a connector and a **pressure gauge**.
- In some equipment, the cryogun is replaced by a **cryoshaft**
- Cryoprobe or the cryoshaft has a cryotip made of highly conductive metal. The protrusion of the nipple of the cryotip should not **exceed 5 mm**



7

Setting up Cryosurgical Unit (1/2)

- Check the washer before attaching the cryoprobe to the handle grip (cryogun). Replace the washer if it is broken
- Select the appropriately sized cryoprobe, depending on the size of the transformation zone, and attach it to the handle grip (avoid using the probes with endocervical extension)

- Connect the cryotherapy machine to the gas cylinder and tighten the valve
- Open the gas cylinder so that the gas can flow into the handle grip through the hose. Check the gas pressure indicated on the pressure gauge

8

Setting up Cryosurgical Unit (2/2)

- The ideal gas pressure required to perform the cryotherapy procedure is 40–70 kg/cm2
- On opening the cylinder and during the cryotherapy procedure, the indicator of the pressure gauge should be in the green zone. A needle positioned in the yellow zone indicates low gas pressure, and in the red zone indicates high gas pressure. In either case, cryotherapy should not be started or should be discontinued
- Large gas tanks (> 15 litre capacity) should be used for the procedure if possible

9

Equipment and Consumables for Cryotherapy

- Examination table
- Light source
- Cusco's speculum
- Disposable gloves
- Cotton swabs for wiping the cervix
- Normal saline solution
- Dilute Acetic acid (5%) solution (freshly prepared)
- Lugol's Iodine
- Cryosurgery unit with adequate gas supply
  - Cryogun
  - Cryoprobes
  - Gas conveying tube
  - Pressure gauge
  - Gas cylinder connector

10

Section 1 – Introduction to Cryotherapy

Learning Outcomes

1. Cryotherapy is an ablative method for treatment of ectocervical precancerous lesions
2. It uses the freezing effect of compressed refrigerant gases – N_2O/CO_2
3. Cryotherapy destroys the TZ by crystallization of water and denaturation of proteins
4. The entire lesion should be visible on the ectocervix, fully covered by the cryoprobe, occupying less than 75% of ectocervix with no suspicion of cancer

11

Section 2 – SOP for Cryotherapy

Learning Objectives

1. Perform the technique of cryotherapy following the correct steps
2. Follow infection prevention practices during cryotherapy

12

SOP for Cryotherapy

- Counsel the woman, ensure that the woman has understood the procedure and obtain informed written consent
- Ensure that woman has emptied her bladded
- Re-evaluate the lesion and ensure that:
  - The lesion is completely in ectocervix, without extension to endocervix and/or vagina
  - The lesion does not extend to more than 75% of the cervix
  - The lesion can be fully covered by the largest cryotip
  - The lesion does not have any features suspicious of cancer
- Check the pressure inside the gas tank. It should be in the green zone as indicated in the pressure gauge of most of the cryotherapy models
- Insert the speculum gently and expose the cervix properly
- Apply 5% acetic acid to outline the abnormality and wait for a minute, followed by Lugol's Iodine to delineate the limits of the lesion
- Choose an appropriate size cryoprobe that adequately covers the lesion. Attach the probe to the handle grip (cryogun)

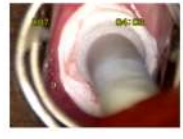
13

SOP for Cryotherapy

- Wipe the cryotip with saline or lubricant, to ensure adequate thermal contact
- Apply the cryoprobe tip at the external os of the cervix
- Ensure that the vaginal wall is not in contact with the cryoprobe or you may cause a freezing injury to the vagina
- Release the gas by pressing the trigger on the cryogun and hold it for 3 mins

- You will observe the ice forming on the tip of the cryoprobe and on the cervix

- When the frozen area extends 4-5 mm beyond the edge of the cryoprobe, freezing is adequate. This will ensure cryonecrosis occurs down to 5 mm of depth

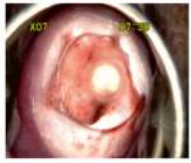


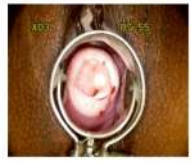
- Release the trigger and allow thawing for 5 minutes. Repeat freezing for 3 more minutes
- After second freezing, allow time for thawing. **Do not pull cryoprobe till it comes out on its own**

14

SOP for Cryotherapy

- The cervix will have a white crater, which indicates that the cervix is properly frozen





- Gently remove the cryoprobe and remove the speculum after careful inspection of the cervix
- Examine the cervix for bleeding. If bleeding is noted, apply Monsel's paste. Do not pack the vagina
- Ask the woman to continue lying down for 5 minutes before letting her getting up
- Document treatment completion in individual case record form
- Provide her the date for next follow up and emphasize on the importance of it
- After use, the probe tip should be wiped with 60-90% ethyl or isopropyl alcohol and then cleaned well with boiled water and disinfected and kept dry
- After the procedure is completed, the cryogun, tubing, pressure gauge and gas tank should be de-contaminated by wiping with cotton soaked with 60-90% ethyl or isopropyl alcohol

15

Section 2 – SOP for Cryotherapy

Learning Outcomes

1. Informed and written consent should be obtained for cryotherapy

2. Check that cryotherapy instruments and gas tanks are ready for use before procedure

3. Apply 5% dilute acetic acid and identify:
   - SCJ
   - TZ and area to treat
   - Limits of the lesion

4. Take precautions so that the cryoprobe tip does not inadvertently touch any part of the vagina

5. Check for adequate pressure (40–70 kg per cm2) in the gas tank, indicated by the green zone in most models of the equipment

6. Inspect the cervix to ensure that the ice ball forming on the cervix extends outside the rim of the cryoprobe by 4–5 mm

7. Advise about post-treatment care and follow-up instructions

8. Complete the documentations to record the treatment

16

Section 3 – Post Cryotherapy

Learning Objectives

1. Correctly decontamination all equipment post cryotherapy
2. Recognize probable treatment complications
3. Offer appropriate management of complications
4. Perform appropriate follow-up after treatment

17

Decontaminate Cryotherapy Unit

After treatment by cryotherapy, the cryo probe should be sterilized thoroughly before re-using it. This can be done by following these simple steps-

- Decontaminate by wiping with ethyl alcohol 60–90%
- Dip the probe in clean water
- Scrub any visible biological matter on the probe tip with a cotton swab and wash with clean water
- Soak the probe in any one of the following chemicals:
  - 0.5% chlorine solution for 20 minutes
  - 2% glutaraldehyde for 20 minutes
  - 6% hydrogen peroxide solution for 30 minutes
- Rinse the probe thoroughly with sterile water
- Air-dry or dry it with a sterile cloth Clean the cryoprobe shaft and the rest of the cryotherapy unit by wiping with cotton soaked in 60–90% ethyl or isopropyl alcohol

Make sure that the inside hollow part of the cryoprobe is completely dry before the next use (water inside the probe may freeze and the probe could crack, thus interfering with proper treatment)

18

Side Effects and Complications

Cryotherapy is a safe procedure with no significant operative morbidity. The possible side-effects and complications are-

- A little discomfort or cramping in the lower abdomen during and after the procedure
- Watery vaginal discharge for 4–6 weeks
- Pelvic infection, requiring antibiotics and supportive treatment – rare
- Excessive bleeding, requiring hospital admission or blood transfusion – extremely rare
- Stenosis of the cervix (late complication) – extremely rare
- Vaginal pain if the probe with the ice ball touches the vaginal walls

Some women may feel light-headed if they get up from the table immediately after the procedure. Ask the woman to continue lying on the bed for 5–10 minutes after the procedure, to avoid this side-effect

19

Post-Treatment Care

- Provide a sanitary pad
- The woman should be told that she may experience excessive watery discharge for up to 4 weeks. She should not get worried about it
- Instruct the woman to abstain from intercourse for 6 weeks
- Avoid douching or use of tampon for 6 weeks
- Inform her of possible complications and ask her to return immediately if she notes any of the following:
  - Fever with temperature higher than 38 °C lasting for more than 48 hours
  - Severe lower abdominal pain
  - Foul-smelling or pus-like discharge
  - Bleeding for more than two days or bleeding with clots
- If the woman develops any of the above-mentioned symptoms, she should be asked to report it and seek medical advice
- The woman should be advised not to have sexual intercourse for 6 weeks, or until the watery discharge disappear completely
- The woman should be advised regarding the follow-up schedule

Point to note: Antibiotics are not routinely prescribed after cryotherapy. Paracetamol tablets may be given for 1 or 2 days for pain.

20

Follow-up after Cryotherapy

- The woman may be advised to come back for a checkup after 1 month to exclude infection or other complications
- No screening or speculum examination or colposcopy should be done
- The biopsy report, if available, should be reviewed. In a screen-and-treat programme, this follow-up visit is often omitted
- The next check-up should be done after 8–12 months, when the woman may have the screening test originally performed or a direct colposcopic examination
- If there is a persistent lesion at follow-up, it is preferable to excise the lesion, although cryotherapy may be repeated if the usual criteria for cryotherapy are fulfilled

21

Common Problems Encountered during Cryotherapy and their Management

Problems	Reason	Suggested soluton
Gas stops flowing	Gas tank is empty	Arrange for a new gas cylinder
	Nozzle is blocked by impurities in the CO_2 gas	Dip the tip of the nozzle in a small bowl of water and flush it by pressing the trigger of the cryogun until the blockage is cleared
Gas leakage from the hand unit	The washer/O-ring is either missing or is broken	Change washer/O-ring (usually provided by the manufacturer in the cryo unit) and put in a new appropriately sized washer
Pressure gauge indicator is in the yellow zone	Inadequate gas in the cylinder	Stop performing cryotherapy and change the gas cylinder
Difficulty in exposing the cervix	Laxity of vaginal walls	• Put a condom or the cut finger of a glove on the speculum • Insert lateral vaginal wall retractors • Use a wooden spatula to push away vagina from between the blades of the speculum

22

Section 3 – Post Cryotherapy

Learning Outcomes

1. Watery discharge or spotting can occur until 4 weeks after cryotherapy
2. Complete abstinence should be followed for 4 weeks after the procedure
3. Follow-up is recommended after 1 year of the treatment
4. The woman should report immediately if she has any of the following symptoms:
   - foul smelling discharge
   - fever of more than 38 °C
   - heavy vaginal bleeding or severe lower abdominal pain occur within 4 weeks of treatment

23

Introduction to Thermal Ablation

Table of Content

Topics	Time (minutes)
Treatment of CINs	10
Section 1 – Treatment by Thermal Ablation	10
Section 2- SOP for Thermal Ablation	15
Section 3 – Post Thermal Ablation	15
Thermal Ablation Video	5
Open House	10
Total	**65**

Treatment of Cervical Intraepitelial Neoplasia (CIN)

Cervical premalignant lesions can be treated either by an ablative method (cryotherapy or thermal ablation) or by excision, depending on certain criteria

Principles of treatment of cervical intraepithelial neoplasia (CIN)-

1. The entire transformation zone undergoes HPV-induced clonal change and is at risk of developing CIN. Therefore, the whole TZ should be treated (ablated or excised), irrespective of the size of the lesion
2. High-grade CIN lesions often extend into the crypts present in the TZ. The depth of the crypts can be up to 5 mm. During ablative treatment, the tissue destruction must extend up to 7–8 mm to ensure complete clearance of disease
3. Low-grade lesions/CIN1 lesions should be treated when follow-up is not guaranteed
4. CIN2 and CIN3 lesions should always be treated except in very young women (younger than 25 years)
5. The decision to treat a CIN lesion may be based on colposcopic findings ("see and treat") without waiting for histological verification
6. Ablative or excisional treatment can be performed for VIA- or HPV -positive women without colposcopic or histological verification ("screen and treat") in situations where these diagnostic services are not available

3

Section 1 – Introduction to Thermal Ablation

Learning Objectives

1. Understand Principle of Thermal Ablation
2. Identify eligibility criteria for treatment with Thermal Ablation
3. Identifying requirements for Thermal Ablation at health facility

4

Treatment by Thermal Ablation - Principle

- Thermal ablation is safe and acceptable procedure, alternative to cryotherapy
- A probe heated to 100°C- 110°C destroys the abnormal lesions by direct contact of the ectocervix (destructive therapy)
- Multiple applications of the probe to ectocervix are feasible with thermal ablation
- The ectocervix has sparse sensory nerve endings. As a result, an ectocervical procedure like thermal ablation/cryotherapy does not require any anesthesia

Since multiple applications of probe are possible, unlike cryotherapy, the technique is not limited by the disparity between the size of the lesion and that of the probe

5

Indications for Thermal Ablations (Same as Cryotherapy)

VIA test-positive women are eligible for Cryotherapy/Thermal ablation if –

1. Entire lesion is visible on ectocervix
2. Lesion is not extending to the endocervical canal or to vagina
3. Lesion is occupying less than 75% of the ectocervix
4. The size of the lesion should be such that it can be covered by the tip of the largest cryotherapy probe
5. There should be no evidence or suspicion of cancer or glandular abnormality
6. Woman should not be pregnant at the time of treatment
7. Woman should not be menstruating at the time of treatment
8. If the woman has recently delivered, she is at least 3 months post-partum
9. Woman should not have pelvic inflammatory disease at the time of treatment
10. Endocervical canal is normal and there is no evidence of glandular dysplasia

Equipment and Consumables for Thermal Ablation

Equipment

- TA Unit
- Examination table
- Light source
- Cusco's speculum
- Sponge holding forceps

Consumables

- Disposable gloves
- Cotton swabs for wiping the cervix
- Normal saline solution
- Dilute Acetic acid (5%) solution (freshly prepared)
- Lugol's Iodine
- Lubricant jelly
- 0.5% chlorine solution

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Section 1 – Introduction to Thermal Ablation

Learning Outcomes

1. TA is an ablative method for treatment of ectocervical precancerous lesions
2. A probe heated to 100°C- 110°C destroys the abnormal lesions by direct contact
3. Multiple application of TA probe to ectocervix are possible
4. The entire lesion should be visible on the ectocervix, occupying less than 75% of ectocervix with no suspicion of cancer

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Section 2 – SOP for Thermal Ablation

Learning Objectives

1. Perform the technique of Thermal Ablation following the correct steps
2. Follow infection prevention practices during Thermal Ablation

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SOP for Thermal Ablation

- Counsel the woman, ensure that the woman has understood the procedure and obtain informed written consent
- Ensure that woman has emptied her bladded
- Re-evaluate the lesion and ensure that:
  - The lesion is completely in ectocervix, without extension to endocervix and/or vagina
  - The lesion does not extend to more than 75% of the cervix
  - The lesion does not have any features suspicious of cancer
- Check that instruments, supplies and light source are available and ready to use
- Expose the cervix gently using the cusco's speculum
- Focus light source for clear visualization of cervix
- Moisten the cervix with a saline-soaked cotton swab, for good thermal conduction
- ***Apply 5% acetic acid on cervix for 1 min to outline the abnormality and identify-***
  - Squamocolumnar junction
  - Limits of the lesion
  - TZ and area to treat
- Application of 5% acetic acidto be followed by application oflugol's iodine to delineate the limits of the lesion

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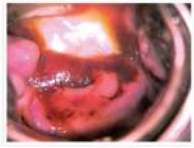
SOP for Thermal Ablation

- Apply the probe to the TZ so that the centre of the tip is on the external os
- ***Maintain the temperature at 100°C constantly***
- The formation of small bubbles around the probe indicates that thermal coagulation is taking place
- Keep the probe in contact with the TZ for 45 seconds
- Withdraw the probe from the cervix after 45 seconds; a crater will be visible



- If the entire TZ is not covered by a single application, apply the probe to another part of the cervix and treat for 45 seconds (up to 5 overlapping applications can be made)
- Switch off the machine once the applications are complete

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SOP for Thermal Ablation

- Remove the probe carefully so that the hot probe does not touch the vaginal walls
- Remove the speculum gently
- Ask the woman to continue lying down for 5 minutes before getting up
- Counsel the woman and give appropriate followup advice
- Document treatment completion in reporting register
- Provide her the date for next follow up and emphasize on the importance of it

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Section 2 – SOP for Thermal Ablation

Learning Outcomes

1. Informed and written consent should be obtained for Thermal Ablation
2. Check that TA unit and other equipment and consumables are ready for use before procedure
3. Apply 5% dilute acetic acid and identify, followed by application of lugol's iodine prior to treatment:
   - SCJ
   - TZ and area to treat
   - Limits of the lesion

4. Apply the probe to the TZ so that the centre of the tip is on the external os, maintain the temperature at 100 °C constantly
5. Take precautions so that the probe tip does not inadvertently touch any part of the vagina
6. Advise about post-treatment care and follow-up instructions
7. Complete the documentations to record the treatment

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Section 3 – Post Thermal Ablation

Learning Objectives

1. Recognize probable treatment complications
2. Correctly decontamination all equipment post TA procedure
3. Offer appropriate management of complications
4. Perform appropriate follow-up after treatment

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Side Effects and Complications

Thermal Ablation is a safe procedure with no significant operative morbidity. The possible side-effects and complications are (same as cryotherapy) -

- A little discomfort or cramping in the lower abdomen during and after the procedure
- Watery vaginal discharge for 2-4 weeks (shorter duration than cryotherapy)
- Pelvic infection, requiring antibiotics and supportive treatment – ***rare***
- Excessive bleeding, requiring hospital admission or blood transfusion – ***extremely rare***
- Stenosis of the cervix (late complication) – ***extremely rare***

Some women may feel light-headed if they get up from the table immediately after the procedure. Ask the woman to continue lying on the bed for 5–10 minutes after the procedure, to avoid this sideeffect

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Post-Treatment Care

- Inform the woman that she may have watery vaginal discharge (that can be blood-stained also) for about 4 weeks
- Advise her to use sanitary napkins to avoid staining her clothes
- Advise the woman to avoid sexual intercourse for about 4 weeks
- Advise her not to use vaginal tampons for 4 weeks
- Ask the woman to report to the health facility if she suffers from any of the following symptoms within 4 weeks of treatment:
  - fever with temperature >38 °C with chills and rigors
  - foul smelling purulent vaginal discharge
  - severe lower abdominal pain/cramps
  - vaginal bleeding for more than 2 days or with clots (except during expected time of menstruation)
- Inform the woman that she should return for follow-up after 1 year

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Decontaminate TA Unit

After treatment by TA, the probe should be sterilized thoroughly before reusing it. Steps to sterilize are as follow

- Decontaminate the probe by wiping with ethyl alcohol 60-90%
- Dip the probe in clean water
- Scrub any visible biological matter on the probe tip with a cotton swab and wash with clean water
- Soak the probe in any one of the following chemicals:
  - 0.1% chlorine solution for 20 minutes
  - 2% glutaraldehyde for 20 minutes
  - 6% hydrogen peroxide solution for 30 minutes
- Rinse the probe thoroughly with sterile water
- Air-dry or dry it with a sterile cloth Clean the probe shaft and the rest of the TA unit by wiping with cotton soaked in 60 90% ethyl or isopropyl alcohol

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Follow-up after Thermal Ablation

- The woman may be advised to come back for a checkup after 1 month to exclude infection or other complications
- No screening or speculum examination or colposcopy should be done
- The biopsy report, if available, should be reviewed. In a screen-and-treat programme, this follow-up visit is often omitted
- The next check-up should be done after 8–12 months, when the woman may have the screening test originally performed or a direct colposcopic examination
- If there is a persistent lesion at follow-up, it is preferable to excise the lesion, although TA/cryotherapy may be repeated if the usual criteria for TA/cryotherapy are fulfilled

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Treatment side effects/complications during TA and their Management

Side Effect	Management
Cramping during treatment	• Counsel the woman before the procedure to expect some degree of cramping during and after the procedure • Cramping can be reduced by giving a mild analgesic like paracetamol orally half an hour before treatment • Analgesics can be given after the procedure, if the woman complains of persistent pain
Vaginal pain due to inadvertent touching of the vagina with a heated probe	• Make the woman lie down for about 30 minutes • Give her analgesic tablets like paracetamol or ibuprofen • Reassure her and make sure she is feeling all right before letting her go
Vaginal discharge (profuse, watery)	• Reassure the woman that this is expected after treatment • Ask her to use sanitary napkins for comfort
Acute pelvic inflammatory disease	• Send swab from vaginal discharge for culture, if feasible • Start empirical treatment with antibiotics • Give supportive treatment
Spotting/light bleeding	• Reassure the woman that this is expected after treatment • Ask her to use sanitary napkins for comfort

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Advantages and Limitations of Thermal Ablation

Advantages	Limitations
Effective in treating CIN	Destruction leaves no tissue sample for confirmatory diagnosis
No anesthesia or hospitalization required	Difficult to determine the exact amount of tissue destroyed
No noise/smoke/smell of burning tissue during treatment	Expensive equipment
Multiple applications to cover a big lesion is possible	
Does not require continuous supply of refrigerants	
Short treatment time	
Associated with few side effects and complications	
Easy sterilization of the probe	
Easy portability as equipment is light weight	

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Section 3 – Post Thermal Ablation

Learning Outcomes

1. Watery discharge or spotting can occur until 4 weeks after TA
2. Complete abstinence should be followed for 4 weeks after the procedure
3. Follow-up is recommended after 1 year of the treatment
4. The woman should report immediately if she has any of the following symptoms:
   - foul smelling discharge
   - fever of more than 38 °C
   - heavy vaginal bleeding or severe lower abdominal pain occur within 4 weeks of treatment

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Introduction to LLETZ/LEEP(Large Loop Excision of the Transformation Zone)

Table of Content

Topics	Time (minutes)
Section 1 – LLETZ/LEEP Principle	10
Section 2- SOP for LLETZ/LEEP	15
Section 3 – Post LLETZ/LEEP	15
LLETZ/LEEP Video	15
Open House	10
Total	**65**

2

Section 1 – Introduction to LLETZ/LEEP

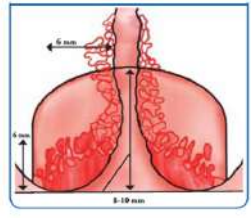
Learning Objectives

1. Understand Principle of LLETZ/LEEP
2. Identify eligibility criteria for treatment with LLETZ/LEEP
3. Identify requirements for LLETZ/LEEP at health care facility

3

Treatment by LLETZ/LEEP- Principle

- LLETZ/LEEP is an excisional method of treating CIN
- A wire loop electrode powered by an electrosurgical unit is used to remove the entire TZ along with the lesion
- Heat from a high voltage electrical arc between the operating electrode and tissue allows the operator to cut by vaporizing the tissue
- Excision of the TZ treats the abnormality effectively and provides a specimen for detailed histological evaluation
- Width of the loop ranges from 10 mm to 20 mm and the depth ranges from 10 mm to 15 mm
- Appropriate size of the loop is chosen to achieve adequate depth and width of the cut depending on the size and position of the lesion
- Since the disease can extend along the crypts of the TZ and the average depth of a crypt is 5 mm, the extent of excision should be at least 8 mm to 10 mm to get an adequate disease-free margin

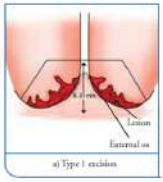


Extent of excision necessary to treat CIN lesions

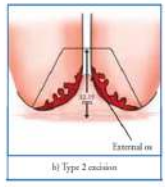
4

Types of Excision

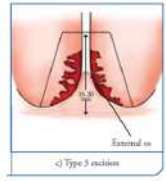
The type of excision depends on the type of TZ and the extent and nature of the lesion



- **Type 1 excision:** Involves excision of Type 1 TZ
- Doesn't include much of the endocervical canal
- *Type 1 excision is adequate for CIN 2/3 lesions if the SCJ is fully visible on the ectocervix*



- **Type 2 excision:** Involves excision of Type 2 TZ
- Includes endocervical component of the TZ depending on the extent of the lesion inside the endocervical canal
- *Type 2 excision is indicated if there is a CIN 2/3 lesion extending to the endocervical canal and the upper margin of the lesion is clearly visible*



- **Type 3 excision:** Involves excision of Type 3 TZ
- Involves a significant amount of the endocervical canal is excised (1.5 cm to 2 cm) as the upper limit of the TZ or the lesion is not visible
- *Type 3 excision is required for CIN 2/3 lesions with Type 3 TZ or glandular lesion or micro invasive cancer*

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Indications for LLETZ/LEEP

1. CIN of any grade
2. Lesions not amenable to treatment by ablative techniques
3. Discordance between the cytology, colposcopy and punch biopsy, especially if a high-grade disease is suspected
4. High grade squamous intraepithelial lesion (HSIL) on cytology; colposcopy normal with Type 3 TZ
5. Glandular abnormality on cytology, punch biopsy or endocervical curettage
6. Treatment failures (after ablative or excision procedure)
7. Woman should not be pregnant at the time of treatment
8. If the woman has recently delivered, she is at least 3 months post-partum
9. No Severe infection/inflammation of cervix

6

Equipment and Consumables for LLETZ/LEEP

Equipment

- LEEP Unit
- Smoke evacuator with tubing for attachment to speculum
- Colposcope
- Examination table
- Light source
- Cusco's speculum
- Sponge holding forceps

Consumables

- Normal saline solution
- Dilute Acetic acid (5%) solution (freshly prepared)
- Lugol's Iodine
- Lubricant jelly
- Monsel's paste
- Local anaesthetic (1 or 2 % lignocaine) with or without 1:100 000 epinephrine
- Vials containing 10% formaldehyde
- 0.5% chlorine
- Syringe for injecting local anaesthetic (dental syringe preferred)
- Disposable gloves
- Cotton swabs for wiping the cervix

LLETZ/LEEP Unit

Section 1 – Introduction to LLETZ/LEEP

Learning Outcomes

1. To perform the LLETZ/LEEP procedure a wire loop electrode powered by an electro-surgical unit is used to remove the entire TZ along with the lesion

2. LLETZ/LEEP can be used to treat CIN of any grade, lesions not amenable to treatment by ablative techniques, the cervix with discordant cytology, colposcopy and punch biopsy reports especially if high grade disease is suspected or there is suspected glandular abnormality

3. Contraindications to LLETZ/LEEP include pregnancy, severe infection/inflammation of the cervix and less than 3 months postpartum

Section 2 – SOP for LLETZ/LEEP

Learning Objectives

1. Perform the technique of LLETZ/LEEP following the correct steps

2. Follow infection prevention practices during LLETZ/LEEP

SOP for LLETZ/LEEP (1/4)

S. No	Activity
Pre-LLETZ/LEEP counselling	
1	Counsel the woman
2	Explain to the woman why the treatment is recommended and describe the procedure
3	Tell her about the side effects she may expect and the alternatives to LLETZ/LEEP
4	Listen to her problems and concerns and respond to her queries
5	Ensure that the woman is not pregnant
6	**Obtain written informed consent for LLETZ/LEEP**
Getting ready	
7	Check that instruments, supplies and colposcope are available and ready to use
8	Check that the ESU and the smoke evacuator are ready for use
9	Check that the woman has recently (not more than 30 minutes previously) emptied her bladder
10	Help her onto the examining table, help her to undress and drape her
11	**Place a reusable patient return electrode under her buttocks or on her thigh and connect it to the ESU. Sanitize patient return electrode before and after use**
12	Wash hands thoroughly and air dry them
13	Put on new examination or high-level disinfected surgical gloves
14	Arrange instruments and supplies on a high-level disinfected tray or container

11

SOP for LLETZ/LEEP (2/4)

Doing the procedure	
15	Insert an appropriately sized insulated speculum with smoke extraction channel and fix blades so that the entire cervix can be seen clearly
16	Connect the smoke evacuator tubing to the insulated speculum, place a lateral vaginal wall retractor, if required
17	Adjust colposcope to focus clearly on the cervix
18	Apply 5% dilute acetic acid and identify - Squamocolumnar junction, TZ and area to treat, Limits of the lesion
19	**Apply Lugol's iodine to delineate the lesion clearly**
20	Inject a local anaesthetic agent (5–7 mL of 1% lignocaine with adrenaline) into the stroma of the ectocervix (just beneath the epithelium) in a ring pattern at the periphery of the lesion. Avoid the 3 o'clock and 9 o'clock positions, because you may encounter a branch of the descending cervical artery

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SOP for LLETZ/LEEP (3/4)

Doing the procedure	
21	Set the power setting of the ESU to a blend of 50 watts of coagulation and 50 watts of cutting currents
22	Select an appropriately sized loop depending on the size and endocervical extent of the lesion so as to remove the lesion with minimum number of passes
23	Introduce the loop into the tissue 2–3 mm outside the outer margin of the lesion (either left or right or lower margin, but not the upper margin) and activate the ESU by pressing the cutting switch
24	**Direct the loop gradually into the cervix until the cross bar nearly comes in contact with the epithelial surface**
25	**Guide the loop parallel to the surface of the cervix across the endocervical canal till the opposite outer margin of the lesion is reached**
26	Gradually withdraw the loop and, as soon as it is out of the tissue, release the switch to stop the ESU
27	Remove the excised tissue with a pair of forceps
28	Fulgurate the defect on the cervix with a ball electrode using the pure coagulation current from the ESU to control the bleeding
29	If necessary, use multiple passes to remove the lesion entirely
30	**Remove blood and clots from vagina and smear Monsel's paste on the treated area**
31	Remove return electrode. Remove speculum and place in 0.5% chlorine solution for 10 minutes
32	Help the woman to get up from examination table and sit comfortably

13

SOP for LEEP (4/4)

Post-LEEP tasks	
33	Dispose-off the swabs and other disposable items in appropriate disposal bags
34	Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out: • If disposing-off the gloves, place in leak-proof container or plastic bag. • If reusing surgical gloves, submerge in 0.5% chlorine solution for 10 minutes for decontamination
35	Wash hands thoroughly with soap and water and air dry them
36	Check to be sure the woman is not having any discomfort or bleeding
37	**Advise her about post-treatment care and follow-up instructions**
38	Document the treatment done in the case record form along with the follow-up plan

Section 2 – SOP for LLETZ/LEEP

Learning Outcomes

1. Informed and written consent should be obtained for LLETZ/LEEP
2. Check that LLETZ/LEEP unit and other equipment and consumables are ready for use before procedure
3. Apply 5% dilute acetic acid and identify, followed by application of lugol's iodine prior to treatment:
   - SCJ
   - TZ and area to treat
   - Limits of the lesion
4. During the procedure, direct the loop gradually into the cervix until the cross bar nearly comes in contact with the epithelial surface
5. Guide the loop parallel to the surface of the cervix across the endocervical canal till the opposite outer margin of the lesion is reached
6. Advise about post-treatment care and follow-up instructions
7. Complete the documentations to record the treatment

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Section 3 – Post LLETZ/LEEP

Learning Objectives

1. Recognize probable treatment complications
2. Correctly decontamination all equipment post LLETZ/LEEP
3. Offer appropriate management of complications
4. Perform appropriate follow-up after treatment

Side Effects and Complications

- Excessive bleeding during or immediately after surgery (usually can be controlled by diathermy, fulguration and/or by applying Monsel's paste)
- Secondary haemorrhage due to post-operative infection
- Post-operative infection/PID (characterized by presence of foul-smelling yellowish discharge or blood mixed discharge and/or fever and/or pain. Appropriate management with antibiotics and other anti-inflammatory medicines is indicated)
- Cervical stenosis
- Cervical incompetence
- Premature rupture of membranes and pre-term labour in subsequent pregnancies

Management of Secondary Haemorrhage after LLETZ/LEEP

- Admit for observation
- Appropriately resuscitate if heavy bleeding
- Coagulate bleeding points using ball electrode
- Apply Monsel's paste
- Apply tight vaginal pack if bleeding still persists and remove after 24 hours
- Start antibiotics
- In rare cases, cervical stitches are required to control bleeding

Post-Treatment Care

- Inform the woman about the expected symptoms like watery discharge or blood-stained discharge for about 4 weeks
- Advise her to use sanitary napkins, as required, to avoid staining of clothes
- Advise her to avoid sexual intercourse for about 6 weeks (or to use condoms if sexual intercourse can not be avoided)
- Advise her to use vaginal tampons or douche for about 6 weeks
- Advise her to attend for check-up after 1 month when the histology report would be available
- Advise her to report back if she has any of the following symptoms within 4 weeks of treatment:
  - fever for more than 2 days;
  - foul smelling purulent vaginal discharge;
  - severe lower abdominal pain/cramps;
  - vaginal bleeding heavier than menstrual bleeding;

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Follow-up after LLETZ/LEEP

- Histopathology report of the excised specimen should be carefully evaluated to see whether there is any suggestion of invasive cancer and whether the margins are positive (affected by CIN)
- Cases with invasive cancer on histopathology should be appropriately managed or referred
- Women with a positive margin on the LEEP specimen need individualized management
  - Those with CIN 2, CIN 3, microinvasive cancer, or glandular disease on the inner margin (endocervical and stromal) need evaluation for repeat LEEP or hysterectomy
  - Those with CIN detected on the ectocervical margin of the cone need follow-up only
  - Those with persistent disease at first follow-up after 8–12 months need a repeat excision after carefully ruling out invasive cancer

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Maintenance and Safety Precautions for LLETZ/LEEP

- User should read, understand and follow the operating instructions supplied with the electrosurgical unit
- Electrosurgery should not be done in the presence of flammable gases, flammable liquids or flammable objects in oxygen-enriched atmospheres or in the presence of other oxidizing agents
- Old or worn accessories should not be used
- Safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge and practical experience to perform these tests
- The equipment should be decontaminated at the end of the day and kept properly covered to avoid dust

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Common Problems Encountered during LLETZ/LEEP and their Management

Problems	Reason	Suggested solution
Difficult exposure of the cervix	• Laxity of vaginal walls	• Put a non-lubricated condom or the cut finger of a glove on the speculum • Insert lateral vaginal wall retractors
Patient feels pain during cutting	• Inadequate infiltration of local anaesthetic • Poor contact with patient return electrode (dispersive plate)	• Inject sufficient local anaesthetic • Adjust patient return electrode (dispersive plate) so as to establish a complete electrical circuit and prevent electrical burns to the patient
Loop does not cut properly/ gets stuck while cutting	• Inappropriate power setting of the diathermy machine	• Choose the power setting that is appropriate for that particular diathermy machine. Ideally this should be predetermined, and the machine set accordingly before starting the procedure • Increase the cutting power gradually, 5W each time, till the loop starts excising the tissue smoothly
Field of vision is obscured due to smoke	• Smoke evacuation system malfunctioning	• Check the smoke evacuator tube and change if necessary

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Advantages and Limitations of LLETZ/LEEP

Advantages	Limitations
Simple outpatient procedure	Requires more skill than ablative techniques
High efficacy	Small risk of bleeding during and after the procedure
Tissue available for histological evaluation	Small risk of adverse obstetric outcome
Can be performed under local anaesthesia	
Minimal complications	

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Notes

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