

Med Pulse



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IN THIS ISSUE – UPDATE ON ANAESTHESIA
CENTCHROMAN – THE 'SAHELI' RETURNS!
GUIDE TO VISUAL INSPECTION OF CERVIX

Warm Greetings!

We move onward through the year 2016 with hope, apprehension and renewed efforts to deliver quality SRH services and improve the footfalls to our SDPs within limited resources.

As contraceptive technology and national policy has evolved over the last six decades, we have constantly endeavored to stay ahead in introducing and mainstreaming new and underutilized contraceptives for our beneficiaries. The announcement by the Ministry of Health and Family Welfare to introduce injectable DMPA, Progestin-only Pills and the indigenously developed non-hormonal oral contraceptive 'Centchroman' to expand the public sector 'basket' of contraceptives has indeed been a long awaited positive step to expand contraceptive choice. FPA India has the comparative advantage in providing technical support to partners and complement the efforts of the government in creating a demand for these methods as they reach the public health facilities.

While most of our clinic teams are quite familiar and comfortable by now with delivering injectable DMPA and PoPs, the Centchroman pill has not been part of our basket of services yet. A quick tutorial on this contraceptive is included in this issue of MedPulse. Please do read more and send us your queries, which we can address in the subsequent issues to enable a smooth introduction of this method through our SDPs.

Surgical and invasive procedures conducted in the RHFPCs tend to be more equal than other services because of the higher levels of skills involved in conducting these procedures and relatively higher inherent risks of procedure and anaesthesia. To ensure minimal adverse events within our SDPs around these procedures, it is advisable to follow guidelines and standards laid down by the Ministry of Health and Family Welfare in the updated reference manuals. Clinic teams of RHFPCs which also function as training Centres need to also familiarize themselves with the training modules and close gaps, if any in the protocols prescribed and practiced. A few pointers on updated anaesthesia protocols during Minilap Tubectomy procedure are included for your reference.

Prevention, early detection and management of cervical intraepithelial neoplasia is an important public health initiative to reduce the incidence of cervical cancer. Since the last few years, FPA India has built institutional capacity in a phased manner to introduce low resource screening methods like visual inspection by acetic acid and Lugol's iodine to screen clients for cervical cancer. A workshop was recently held in Mumbai to offer hands-on training to Medical Officers from four FPA India Branches to hone their skills in VIA/VILI and colposcopy as well as to orient them in Cryotherapy and LEEP (Loop Electrosurgical Excision Procedure). We have compiled some messages to improve screening skills based on our learnings during this workshop. This section has been reviewed by Dr. Geethanjali Amin, leading Mumbai Based Colposcopist and our Consultant and Chief Trainer for this workshop.

*Looking forward to your feedback and suggestions!
Happy reading!*

Analgesia and Anaesthesia for Female Sterilization procedures

The local anaesthesia has proven to be the most appropriate anaesthesia for female sterilization procedures both Minilap Tubectomy and Laparoscopic Tubal Occlusion and has allowed health institutions to provide sterilization services safely even in settings with limited resources. Although general and regional anaesthesia can be used safely and effectively for abdominal tubectomy and laparoscopic tubal occlusion, the number of unexpected and life-threatening complications related to general or regional anaesthesia is higher than the number associated with local anaesthesia (WHO, 1992). Thus, general and regional anaesthesia should be used only in settings that are properly equipped and staffed to provide such anaesthesia and to handle emergencies. Local anaesthesia is safer than general anaesthesia.

Pre-Medication

Reassurance and proper explanation of the procedure go a long way in allaying the anxiety and apprehension of the client. However, if needed, preferably Tablet Alprazolam (0.25 to 0.50 mg) or Tablet Diazepam (5 to 10 mg) can be given before the operation.

Sedation and Analgesia

The anxiolytic, sedative, light muscle relaxant and amnesic effect produced in the client following administration of sedation allow sterilization procedure to be performed smoothly under local anaesthesia. On the day of the operation, drugs for sedation and analgesia are to be given as shown in table below:

Drugs for Preoperative and Intra-operative Sedation and Analgesia

Approximate Weight/Build of client	Name of the Drugs (Dose)	Route and time of administration	Repeat Dose if required on the table**	Route and time of administration**
Thin (< 40 kg)	Pethidine 25 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
Average (40-50 kg)	Pentazocine 15 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pentazocine 15 mg	IV: 5 min prior to surgery
	OR			
Average (40-50 kg)	Pethidine 37.5 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
Well built (>50 kg)	Pentazocine 22.5 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pentazocine 15 mg	IV: 5 min prior to surgery
	OR			
Well built (>50 kg)	Pethidine 50 mg + Promethazine 25 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
Well built (>50 kg)	Pentazocine 30 mg + Promethazine 25 mg	IM: 30-45 min prior to surgery	Pentazocine 15 mg	IV: 5 min prior to surgery
	OR			

**Dosage according to body weight is: Pethidine 0.5 to 1 mg/kg, Pentazocine 0.5 mg/kg and Promethazine 0.3 to 0.5 mg/kg. A repeat dose (if required) is given slowly intravenously as Pethidine 10 mg or Pentazocine-15 mg, 45 minutes after the first dose. The drugs should be diluted with equal quantity of normal saline or distilled water before IV administration.

Local Anesthesia

Skin sensitivity test for local anaesthetic agent (lignocaine) has no established predictive value for anaphylactic reaction. Therefore, it is not mandatory to perform a skin sensitivity test prior to infiltration of lignocaine.

The goal of local anesthesia is to achieve an anaesthetic field block that penetrates all layers of the abdominal wall, from the skin to the peritoneum. The three layers most sensitive to pain are the skin, the rectus fascia and the parietal peritoneum.

Each of these layers should be carefully infiltrated with local anaesthetic. Additionally, if required, dropping anaesthetic agents over the fallopian tubes reinforces the effect of the anesthesia as it decreases pain resulting from the manipulation of the tubes and also reduces postsurgical pain.

- Lignocaine is the recommended local anaesthetic and the recommended concentration is 1% lignocaine without adrenaline.
- The usual dose for local infiltration is 3 mg/kg body weight and onset of action is typically within three to five minutes, with the anaesthetic effect lasting up to 45 minutes.
- 2% lignocaine solution must be diluted to 1% using normal saline or sterile water for injection.
- Confirm the effect of anesthesia before surgery.
- Client must be continuously monitored during and after parenteral administration.
- Oral communication must be maintained with the client throughout the procedure.
- If required, an IV line is to be secured before the start of the procedure.

Following are the reasons why adrenaline (epinephrine) is not recommended:

- i. The vasoconstriction caused by adrenaline may mask bleeding in small blood vessels.
- ii. It is best to detect and control all bleeding during surgery to prevent formation of undetected hematomas later.
- iii. Adrenaline is dangerous, if accidentally injected intravascular.

Extracted from the Reference Manual for Female Sterilization Family Planning Division, MoHFW, November 2014

Centchroman (Ormeloxifene) Pills

Centchroman (Ormeloxifene) is a non-steroidal, non-hormonal once a week oral contraceptive pill. It acts as a selective estrogen receptor modulator (SERM). In some tissues/organs of the body, it has weak estrogenic action (e.g. bones) while in others it has strong anti-estrogenic action (e.g., uterus, breasts etc.)

Key Points

- Centchroman (Ormeloxifene) is safe and effective.
- Centchroman (Ormeloxifene) is safe for breast feeding women.
- Apart from prolongation of menstruation cycle in some women, it is not known to cause any side effects.
- One pill is taken twice a week for first three months, followed by once a week thereafter.

When to Start and How to Use Centchroman (Ormeloxifene)?

- For initiation of the Centchroman (Ormeloxifene), the first pill is to be taken on the first day of period (as indicated by the first day of bleeding) and the second pill three days later. This pattern of days is repeated through the first three months.
- Starting from fourth month, the pill is to be taken once a week on the first pill day and should be continued on the weekly schedule regardless of her menstrual cycle.

How to Increase Compliance of Centchroman (Ormeloxifene) Use?

- Assure every client that she is welcome to come back or ask question any time to the provider, if she has problems, wants another method, has any major change in health status or thinks that she might be pregnant.
- Encourage her to come back for more pills before her supply is finished.
- **Whenever client comes back to the provider ask:**
 - ✓ How she is doing with the method, whether she is satisfied and has any questions or anything to discuss.
 - ✓ Especially if she is concerned about bleeding changes. Give any information or help that she needs. Assure her that these changes get normalized with continuing usage.
 - ✓ If she often has problems remembering to take pills. If so, discuss ways to remember, making up for missed pills, ECP or choosing another method.
 - ✓ If there are major life changes that may affect her needs particularly plans for having children and STI/HIV risk, follow-up as needed.

How to Manage Side Effects, Missing of Pills?

- Centchroman (Ormeloxifene) causes delayed periods in few women. But this occurs in around 8% of users and usually in the first three months. The periods tend to settle down to a rhythm once the body gets used to the drug.
- Periods can get scanty over time in some women. Counsel and reassure her that some women using Centchroman (Ormeloxifene) have such problems. This is not harmful and will subside on its own.

How to Manage Missed Pills?

- Take a pill as soon as possible after it is missed.
- If pill is missed by 1 or 2 days but lesser than 7 days, the normal schedule should be continued and client needs to use a back-up method (e.g. Condoms) till the next period starts.
- If pill is missed by more than 7 days, client needs to start taking it all over again like a new user that is twice a week for 3 months and then once a week.

If Period is missed with Centchroman (Ormeloxifene)

With Centchroman (Ormeloxifene), occasionally the menstrual cycle may get prolonged in some users. The contraceptive makes the periods lighter and the interval longer, which is not harmful and can actually be helpful for anemic women, as user loses lesser amount of blood. However, if periods are delayed by more than 15 days, pregnancy needs to be ruled out.

[Ref:-http://nrhm.gov.in/images/pdf/programmes/familyplanning/guidelines/Reference_Manual_Oral_Pills.pdf](http://nrhm.gov.in/images/pdf/programmes/familyplanning/guidelines/Reference_Manual_Oral_Pills.pdf)



A Quick Guide to Visual Inspection of Cervix to Screen for Precancerous Lesions

Expert review of this section with responses to frequently asked questions by Dr. Geethanjali Amin, Consultant Obstetrician, Gynecologist and Colposcopist, Mumbai

The pathway to prevent cervical cancer deaths is simple and effective. If the precancerous changes in cervical tissue (which can linger for years) are identified and successfully treated, the lesions will not develop into cervical cancer. Treating the abnormal, dysplastic tissue also seems to protect women from developing cervical cancer in the future.

Given the difficulty of ensuring high-quality cytology-based services in many settings, there is significant interest in new approaches to screening for precancerous lesions. Of these, visual inspection of the cervix is a promising option, especially for low-resource settings.

Approach to clinical diagnosis

- Unaided visual inspection of the cervix, referred to as "Down staging" by WHO. It involves looking at the cervix during a speculum examination to detect early stage cancer.
- Unaided visual inspection of the acetic acid treated cervix.
- Unaided visual inspection of the Lugol's Iodine treated cervix.

Visual Inspection with Acetic Acid

- Acetic acid causes reversible coagulation or precipitation of the nuclear proteins & cytokeratins.
- Areas of dysplastic epithelium undergo maximum coagulation due to high content of nuclear protein.
- The acetowhite appearance is also seen in other situations where there is increased nuclear protein e.g.: Immature squamous metaplasia, Congenital Transition Zone, Healing & regenerating epithelium, Leukoplakia & Condyloma.

Visual Inspection with Lugol's iodine (VILI)

- Squamous epithelium contains glycogen, whereas precancerous lesions and invasive cancer contain little or no glycogen.
- Iodine is glycophilic and is taken up by the squamous epithelium, staining it mahogany brown or black.
- Columnar epithelium, immature metaplasia and inflammatory lesions, Precancerous lesions and invasive cancer have little or no glycogen so does not take up stain and appear yellow, partial uptake or no colour change at all.

Instruments and materials required for VIA/VILI examination

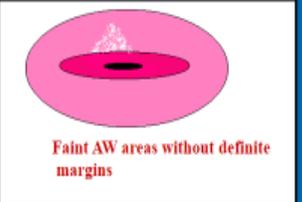
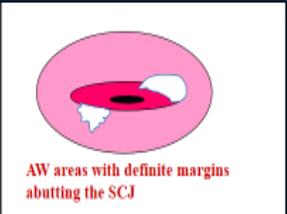
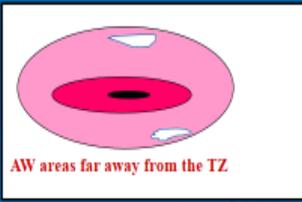
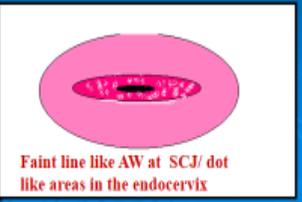
Examination table
 Bivalve self-retaining speculum
 Good light source
 Examination Gloves
 Cotton Swab Sticks
 5% freshly prepared acetic acid
 Lugol's iodine

VIA and VILI as the evidence and experience to date are the most promising tests since both have been tested in large recent cross sectional and randomized control trail in developing countries and show promise as alternatives to cytology where resources are limited and either no screening program exists or an existing program functions poorly.

For effective cervical cancer prevention program, it must consist of a package of education, screening and treatment services that reach the majority of at risk women. Implementing any one of these elements without the others will not result in a substantial positive impact.

VIA/VILI are entirely subjective tests; so adequate & ongoing training is essential for health care providers to make an accurate assessment.

Outcome of VIA

Outcome of VIA Score 1: VIA Negative		Outcome of VIA Score 2: VIA Positive	
 <p>Streak like AW areas in the TZ</p>	 <p>Faint AW areas without definite margins</p>	<p>➤ Sharp, distinct, well defined, dense (opaque/ dull white/ oyster white) acetowhite areas with or without raised margins, closer to SCJ in the TZ are scored as positive.</p>	 <p>AW areas with definite margins abutting the SCJ</p>
 <p>AW areas far away from the TZ</p>	 <p>Faint line like AW at SCJ/ dot like areas in the endocervix</p>	<p>➤ Invasive cancer is scored when there is a clinically visible ulceroproliferative growth on the cervix which bleeds on touch</p>	 <p>AW area with definite margin jutting into both endo & exocervix</p>

Sources: R. Sankaranarayanan, RamaniS. Wesley. A practical manual on visual screening for cervical neoplasia (IARC technical publication No 41)

Frequently Asked Questions on Cervical Cancer Screening

1. What is the minimal age to screen asymptomatic clients?
Sexually active female client can be screened from the age of 25 years (This is keeping in view that women seeking services in FPA India SDPs, are mostly married/sexually active by the age of 25 years).
2. How frequently should clients who are screened 'negative' be followed up for repeat screening?
Once in 3 years.
3. Can we diagnose HPV clinically by conducting VIA/VILI? Is it essential to send the client for a confirmatory test? If not, what should our approach be towards such a client?
This is not necessary. You can just say VIA/VILI + or (which may have HPV cases). Only VIA/VILI positives should be sent for Pap smear or colposcopy, whichever facility is available. Conducting HPV tests in low resource settings is not cost-effective in the current scenario.
4. How soon should a client with a cytology report "Atypical squamous cells of undetermined significance" (ASCUS) be asked to undergo repeat cytology? Can any other confirmatory test be advised as a protocol?
ASCUS cases should be treated for infection, if there is focus of infections. Repeat Pap smear can be done in 6 months. Persistent ASCUS or cytology report of ASC-H should go for immediate Colposcopy.
5. If the provider is not sure of VIA/VILI findings can she do a Pap smear during the same visit to confirm findings? What should the time gap between VIA/VILI and Pap smear collection should be if it is done in the same visit? Is it ok to collect Pap smear from iodine stained cervix?
No. Client should be called after three days for Pap smear as stained cervical tissues can give false findings.
6. What is the preparation for Cervical Cancer Screening tests?(visual screening tests)
 - Don't conduct the tests if the client is menstruating.
 - Client should be counselled well for the test
 - Not to douche for 2 days before the tests.
 - To avoid sexual intercourse for 2 days before the test.
 - To avoid using tampons or birth control foams, jellies, or other vaginal creams or vaginal medicines for 2 days before the test.

Quick Clinical Reference Chart for Visual Inspection with Acetic Acid (VIA)

VIA NEGATIVE



No definite acetowhite area



Acetowhitening of the mucus on columnar epithelium



Mucus plug



Nabothian cysts



Polyp



Acetowhite area far away from SCJ

VIA POSITIVE



Well-defined, acetowhite lesions touching the SCJ or close to the os

Acetowhitening on the entire cervix

CANCER



SCJ: Squamocolumnar junction

Source: R. Sankaranarayanan, Ramani S. Wesley. A practical manual on visual screening for cervical neoplasia (IARC technical publication No 41) Available from: press@iarc.fr (IARC/Press)

Acetowhitening of growth on the cervix

Acetowhitening of growth on the cervix; partly obliterated by bleeding



Quick Clinical Reference Chart for Visual Inspection with Lugol's iodine (VILI)

VILI NEGATIVE



Black squamous epithelium. No colour change in columnar epithelium. No yellow areas



Patchy, cotton wool, scattered yellow areas indicating immature squamous metaplasia and inflammation



'Satellite' yellow areas away from SCJ



Pepper-like yellow areas due to inflammation away from SCJ



Pepper-like scattered yellow spots all over the Cx due to inflammation. No iodine uptake in the polyps



Leopard like appearance due to scattered yellow areas

VILI POSITIVE



Well-defined yellow area touching the SCJ in the upper lip

Circum-orificial, large yellow areas extending into the canal

CANCER



SCJ: Squamocolumnar junction

Source: R. Sankaranarayanan, Ramani S. Wesley. A practical manual on visual screening for cervical neoplasia (IARC technical publication No 41) Available from: press@iarc.fr (IARCPress)

Dense, thick, irregular yellow coloration of the growth on the Cx

