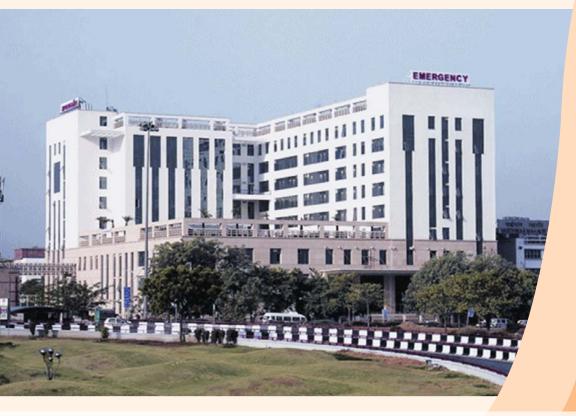




**Dedicated Issue:** "Revisiting Family Welfare Services"



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Vol.21, No.3; July, 2021



## Foreword



It gives me immense pleasure to write a Foreword for the July issue of AOGD Bulletin for 2021-22. Over the years we all have seen AOGD grow as a society and every bulletin brings fresh set of eyes to this wonderful academic platform. Even in the pandemic the association continues to grow by utilising virtual world to the full benefit of our knowledge. The informative webinars, illustrative e-CME s, exhilarating online panel discussions and more recently online public forums, all reflect the devotion and commitment of various Presidents, Vice Presidents, Scientific Committees and Editorial boards to keep AOGD at

par with international organisations even in these tough times when both physical and mental strength have taken a toll.

The monthly bulletin is a great learning platform not only for our young residents but also for senior professors to stay updated with latest evidence based practice. With the COVID cases coming to a decline and hospital work restarting, this bulletin, **"Revisiting Family Welfare Services"**, addresses an issue that has both clinical as well as immense social implications. The current issue on contraception and safe abortion is also in line with the Theme of AOGD for 2021-22: **"Promote Women's Health by Strong Will and Quality Skill"**.

It is up to us to ensure that women from all strata of society have access to all methods of contraception and abortion safely and effectively. Now when patients are coming back to hospitals, it's a great opportunity to revisit their contraceptive needs while simultaneously raising public awareness on these very pivotal issues. .......This issue aims to carry forward the AOGD mission of preserving women health.

V2 Shangar

Dr V L Bhargava Patron, AOGD

## From the President's Pen



#### Dear AOGD members

We started this month in a melodious way, as our members jubilated on the occasion of Doctor's Day. In this pandemic, a virtual *Antakshari* was a much needed break to take away the stress and strain of life.

Another matter to celebrate this month was the Government's nod to allow vaccination for pregnant and lactating women, though the programme is still to be rolled out. Meanwhile we must now campaign to make public aware about importance of COVID vaccination in

pregnancy.

As we celebrate World Population Day this month, we had a public forum on contraception which had a huge attendance and was appreciated a lot. It is our duty to spread awareness about family planning, right to health, gender equality, baby's health, child marriage, sex education, use of contraceptives, knowledge about Sexually Transmitted Diseases (STDs), etc. Let us all pledge that we will do our utmost to reaffirm the human right to plan a family. I urge all members to do public activities and tale help from AOGD if required.

In line with celebration of world population day this month, we bring to you this indispensible issue of bulletin on "*Revisiting Family Welfare Services*".

I hope you will enjoy reading this knowledge packed issue on Contraception and Safe Abortion.

*"Reproductive freedom is not just the ability not to have a child through birth control. It's the ability to have one if and when you want."* -Pamela Madsen

Ache

Dr Achla Batra President, AOGD (2021-2022)



## From the Vice-President's Pen



Dear colleagues and friends,

The monsoons are just around the corner and bring with them a certain romanticism. The month of July also brings along the World Population Day. This is a time to reflect on the impact of the swelling population on our planet; and for us gynecologists it adds the responsibility of making our family welfare services more patient centric, patient friendly and accessible especially in these challenging times when the rates of unsafe abortions have surged according to so many published reports.

To create awareness amongst the health care providers and the general population, AOGD has organized a plethora of activities. This dedicated issue which delves upon the contraceptive choices and safe abortion services is a must read for all of us. Hope you all find it useful in your daily practice.

COVID is still lurking around us, so continue to practice COVID appropriate precautions in your professional and personal lives. Stay Healthy and Safe!

"If we don't halt population growth with justice and compassion, it will be done for us by nature, brutally and without pity- and will leave a ravaged world". -Nobel Laureate Henry W. Kendall

Dr Jyotsna Suri Vice President, AOGD (2021-2022)

Apply For AOGD Membership Online, Go To Link https://in.eregnow.com/ticketing/aogdmembership

## From the Secretary's Desk



Warm greetings to all !

At the outset, I thank all our AOGD members for their constant appreciation and support for all our endeavours.

There has been a wonderful development in recent times, i.e. the government nod to the COVID vaccination in pregnancy and lactation. In our efforts to apprise all our members, clinicians and academicians about the latest evidence based knowledge, we held an online discussion with experts in the field which has been widely appreciated.

We have been continuing with our efforts and dedication towards public awareness about various health aspects. This month we conducted a public forum on "Updates in Contraception" in order to commemorate the **World Population Day** which was enthusiastically welcomed by general public and ASHA workers. To add to fruitful academic content in the "Population stabilisation fortnight" celebrations by the Directorate of Family Welfare, we are also organising a unique online quiz for all the postgraduates of Delhi later this month.

As regards this month's bulletin, the topic has been aptly chosen as **"Revisiting Family Welfare Services"** where we have tried to emphasize on the practical tips and latest evidence on Newer Contraceptives and Emergency Contraception. We have also covered the Abortion services prevalent in India in great detail especially in light of the latest amendments in the MTP Act including the post abortion care. I hope you all will find this third issue as informative and engaging as the previous ones.

Happy reading,

Dr Monika Gupta Secretary, AOGD (2021-2022)

## From the Editor's Desk



Greetings from the editorial team!

We are thankful to our readers for continuously encouraging us to do better. This month we celebrate the 'World Population Day' on 11<sup>th</sup> July hence we have chosen **"Revisiting Family Welfare Services"** as theme of our bulletin. We express our heartfelt thanks to Dr V L Bhargava for writing the foreword for our third issue of AOGD bulletin.

Incorrect and inconsistent use of contraceptives is responsible for the failure of contraceptives. Most eligible couples want to use contraception for prevention of

unplanned and unwanted pregnancies. The apprehension about complications is the most common reason for inconsistent use of contraceptive methods. It is important to address the needs of the client not only at the time of choosing contraceptive method but also during the ongoing use. If a woman suffers side effects from a particular method or is not being able to continue the usage due to poor compliance, it is important to help her choose another method and advise smooth transition to the method of her choice. The first article of this bulletin is on **Practical Tips to Ensure Effective Use of contraceptives. Newer Hormonal Contraceptives** are now available and they address the issue of non compliance due to need for daily administration or side effects of hormonal contraceptives. It is important to make women of reproductive age group aware of the over-the-counter availability of **Emergency Contraception.** 

Despite widespread availability of legal abortion services in India, the unsafe abortion rate continues to be high leading to maternal severe morbidity and mortality. Various amendments of original **MTP Act** 1971 have been done from time to time to improve legal abortion services. The protocols for providing skilled **Comprehensive Abortion Care during first and second trimester** have been formulated by Ministry of Health & Family Welfare, Government of India along with FOGSI. It is important to counsel women regarding need for **Contraception Immediately after Medical Termination of Pregnancy.** 

We hope this bulletin will help the readers provide skilled Family Welfare Services to the sexually active women of reproductive age group.

Looking forward for your valuable feedback and suggestions! Happy reading!

"...contraceptives are the greatest life-saving, poverty-ending, women-empowering innovation ever created." -Melinda Gates

KLO

Dr Rekha Bharti Editor, AOGD (2021-2022) editorsaogd2021@gmail.com



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## Contraception: Practical Tips to Ensure Effective Use

**Niharika Guleria<sup>1</sup>, Jyotsna Suri<sup>2</sup>** <sup>1</sup>Senior Resident, <sup>2</sup>Professor & Consultant, VMMC & Safdarjung Hospital

## Introduction

Universal access to high-quality and affordable contraceptive services is a fundamental human right and helps to prevent harmful effects of unintended pregnancies and abortions. Family planning providers play a key role in reducing this huge socio economic challenge for the global health community especially in developing countries. High quality counselling (detailed yet precise and objective) at the first visit, continued counselling during pregnancy and postpartum has the potential to reduce this unmet need of contraception. Since the literature on various contraceptive methods - their initiation, switching over, management of side effects or dosing errors- is vast; it becomes useful to have an abridged overview of the guidelines so that the health care provider is able to guide the client in choosing their method in a structured and easy way at the time of clinic visits. The WHO 2016 Selected Practice Recommendations is one of the cornerstones of WHO's comprehensive and uptodate content on family planning guidance. We have made an effort here to present it in a tabulated manner so as to ease the clinician as well as client s decision making at the time of family planning outpatient visits in a quick yet effective manner.

**Table 1:** The provider can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria

has not had intercourse since last normal menses

has been correctly and consistently using a reliable method of contraception.

within the first 7 days after normal menses.

within 4 weeks postpartum (for non-lactating women)

within the first 7 days post-abortion or miscarriage.

fully or nearly fully breastfeeding, amenorrhoeic, and less than six months postpartum

**Table 2:** MEC categories for contraceptive eligibility

Category 1	A condition for which there is no restriction for the use of the contraceptive method
Category 2 A condition where the advantages of using the method generally outweigh the theoretical or prove	
Category 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method
Category 4 A condition which represents an unacceptable health risk if the contraceptive method is used	

MEC criteria for various contraceptive methods can be accessed online using following links

To access WHO MEC criteria for various contraceptive methods go to -

https://www.who.int/reproductivehealth/publications/family\_planning/mec-wheel-5th/en/

Or to download WHO app for MEC criteria go to https://app-https://www.who.int/reproductivehealth/mec-app/en/

#### Table 3: Essential examination before providing method

	Cu IUD/LNG IUD	LNG Implants/POI/POP/COCs/ CVR/ Patch/CICs
Pelvic/genital examination	Yes	Consider <sup>\$</sup>
STI risk assessment	Yes	
BP screening		Desirable#

\$-Per speculum examination & Pap smear if eligible for screening; #Desirable- preferred but don't deny if unavailable. Combined oral contraceptives (COCs); Combined injectable contraceptives (CICs); combined contraceptive vaginal ring (CVR); Intrauterine device (IUD); Progestin only injectables (POIs); Progestin only pills (POPs); Sexually transmitted infections(STI)

### **Table 4:** Initiation of various contraceptive methods

	Cu-IUD	LNG IUD	LNG implants	ΡΟΙ	РОР	COCs/ CVR/ Patch	CICs
Having menstrual cycles	< 12 days- insert anytime >12 days- insert anytime if*	< 7 days- insert anytime >7days- insert anytime if*	<7days- insert >7days- insert if* + additional protection for next 7 days	<7days- give >7days- give if* + additional protection for next 7 days	<5days- initiate >5days- initiate if* + additional protection for next 2 days	<5days- initiate >5days- initiate if* + additional protection for next 7 days	<7days- give >7days- give if* + additional protection for next 7 days
Amenorrhoeic (non- postpartum)	insert anytime if*	insert anytime if*	insert if * + additional protection for next 7 days	give if * + additional protection for next 7 days	initiate if * + additional protection for next 2 days	initiate if * + additional protection for next 7 days	give if * + additional protection for next 7 days
Postpartum (PP)	<48 hrs- can be inserted including immediately post placenta removal 48hrs to <4 weeks - <i>MEC3</i> ≥ 4 weeks + ammenorrheic, BF or not - can be inserted if * Puerperal sepsis- <i>MEC4</i>	<48 hrs- can be inserted including immediately post placenta removal 48hrs to <4 weeks- <i>MEC3</i> ≥ 4 weeks + amenorrheic, BF or not - can be inserted if * Puerperal sepsis- <i>MEC4</i>	Breastfeeding <6 weeks- MEC2 >6 weeks • amenorrheic- insert. • cycles returned- insert as advised Non breastfeeding <21days- MEC1 ≥ 21days • amenorrheic- insert if* + additional protection for next 7 days • cycles returned- insert as advised	Breastfeeding <6 weeks- <i>MEC3</i> >6 weeks • amenorrheic- give. • cycles returned-give as advised Non breastfeeding <21 days- <i>MEC1</i> ≥ 21 days • amenorrheic- give if* + additional protection for next 7 days • cycles returned- give as advised	<6 weeks- <i>MEC2</i> >6 weeks • amenorrheic- initiate. • cycles returned- initiate as advised Non breastfeeding <21days- <i>MEC1</i> ≥ 21days • amenorrheic- initiate if* +	Breastfeeding <6 weeks- <i>MEC4</i> 6 weeks to 6 months- <i>MEC3</i> >6 months - initiate Non breastfeeding <21days- <i>MEC3</i> ≥ 21days- <i>MEC2</i> • amenorrheic- initiate if* + additional protection for next 7 days • cycles returned- initiate as advised	Breastfeeding <6 weeks- MEC4 6 weeks to 6 months- MEC3 >6 months - give Non breastfeeding <21days- not given ≥ 21days • amenorrheic- give if* + additional protection for next 7 days • cycles returned- give as advised
Post-abortion	T1 / T2 abortion- insert anytime Septic abortion- <i>MEC4</i>		insert immediately	give immediately	initiate immediately	initiate immediately	give immediately

\*if it is reasonably certain the woman is not pregnant (table 1); Breastfeeding (BF)

Previous Method	LNG IUD	LNG Implant/ POIs	POPs	COCs/ CVR/ Patch	CICs
Having     menstrual cycles	<7 days- Insert if* >7days- Insert if* + additional protection for next 7 days				
<ul> <li>Injectable</li> </ul>	At time of repeat injection	At time of repeat injection	At time of repeat injection	At time of repeat injection	At time of repeat injection
• Hormonal		With correct, consistent use or if*- Insert	With correct, consistent use or if *- Initiate	With correct, consistent use or if *- Initiate	With correct, consistent use or if *- Give
• Non hormonal		Insert if* And if >7 days since start of menses- additional protection for next 7 days	Initiate if * And if >5 days since start of menses- additional protection for next 2 days	Initiate if * And if >5 days since start of menses- additional protection for next 7 days	Give if * And if >7 days since start of menses- additional protection for next 7 days
• IUD		<7days of menses- Insert + remove IUD in same sitting >7days of menses- Insert if* • Sexually active in this cycle- remove IUD next cycle • Not sexually active in this cycle- remove & additional	<5days of menses- Initiate + remove IUD in same sitting >5days of menses- Initiate if* • Sexually active in this cycle- remove IUD next cycle • Not sexually active in this cycle- remove & additional	<5days of menses- Initiate + remove IUD in same sitting >5days of menses- Initiate if* • Sexually active in this cycle- remove IUD next cycle • Not sexually active in this cycle- remove & additional	<7days of menses- Give + remove IUD in same sitting >7days of menses- Give if* • Sexually active in this cycle- remove IUD next cycle • Not sexually active in this cycle- remove & additional
		protection for next 7 days	protection for next 2 days	protection for next 7 days	protection for next 7 days

**Table 5:** Switching from one method to another

\*if it is reasonably certain the woman is not pregnant (table 1)

#### Table 6: Management of complications in IUD users

Problem	Management		
Spotting	Common in 1st 3-6 months		
	NSAIDs (Ibuprofen or mefenamic acid)		
	Persistent/unacceptable/severe anemia-remove IUD		
Heavier or longer periods	Common in 1st 3-6 months		
	NSAIDs or Tranexamic acid		
	Don't use aspirin		
	Persistent/unacceptable/severe anaemia-remove IUD		
PID	Treat PID		
	Don't remove IUD unless patient desires		
	If removed, consider EC if she had unprotected intercourse		
Pregnancy	Exclude ectopic		
	Counsel about increased miscarriage and preterm delivery risk if retained and small risk of		
	miscarriage with removal		
	Strings visible- remove		
	Strings invisible- USG to localise & proceed accordingly		
Amenorrhea in LNG IUD user Reassure. If unacceptable, remove			
*Pelvic inflammatory disease (PID); Emergency contraception (EC)			

**Table 7:** Management of complications in Implant/ POI users

Problem	Management
Spotting or light bleeding	Common in 1st year of implant use or in first injection cycle Exclude gynaecological cause NSAIDs (mefenamic acid or valdecoxib) or low dose COCs/ethinyl estradiol If PID/STI- treat Persistent/treatment ineffective/ unacceptable-remove
Heavier or longer periods (>8days)	Exclude gynaecological cause NSAIDs or low dose COCs/ethinyl estradiol Persistent/treatment ineffective/ unacceptable-remove
Amenorrhea	Reassure. If unacceptable, remove

Table 8: Management of missed POPs

Having cycles (+/- breastfeeding) and missed ≥ 1 pill by >3hours*	Take 1 pill asap and continue rest Additional protection for 2 days
Amenorrheic + breastfeeding and missed ≥ 1 pill by >3hours	Take 1 pill asap and continue rest No additional protection if <6 months PP
Vomiting/diarrhea within 2 hours of taking pill	Take another active pill
Vomiting/diarrhea for 24 hours	Continue taking pill, if persists ≥ 2 days - follow missed pill protocol

\*For 75mcg desogestrel pill this time period is 12 hours

#### Table 9: Management of missed COCs

Missed 1 or 2 active pills or started 1 or 2 days late (30- 35mcg ethinyl estradiol)	Take active pill asap then continue taking pills at regular time If missed ≥ 2 in a row • take 1st missed pill then either continue rest missed pills or discard them • she may take both at same time or in same day		
Missed 3 or more active pills or started 3 days* (30- 35mcg ethinyl estradiol)	Take active pill asap then continue taking pills at regular time. If missed ≥ 2 in a row- same as above • Additional protection for 7 days • If missed in 1st week + unprotected sex- consider EC • If missed in 3rd week - finish current pack and discard inactive pills		

\*In case of pills containing upto 20mcg of ethinyl estradiol, same guidance for  $\ge$  2 missed active pills

Table 10: Management of dosing errors in patch/ring users

Table To: Management of dosing errors in patch/ring users				
Extension of 7 day patch free interval	Extension of 7 day ring free interval			
• If $\leq$ 48hours- apply new	<ul> <li>If ≤ 48hours- insert new</li> </ul>			
patch asap	ring asap , keep same ring			
Keep same patch change	change day			
day	• If >48hours- insert new			
• If >48hours- apply new	ring asap			
patch asap	Keep same ring change			
Keep same patch change	day Additional protection for			
day	·			
Additional protection for	7 days			
7 days	Unprotected sex in last 5			
Unprotected sex in last 5	days- consider EC			
days- consider EC				
Unscheduled patch	Unscheduled ring removal			
detachment	• If removed for $\leq$ 48hours-			
<ul> <li>If detached ≤ 48hours-</li> </ul>	reinsert asap			
apply new patch asap	Keep same ring change			
Keep same patch change	day			
day	<ul> <li>If removed for &gt;48hours-</li> </ul>			
<ul> <li>If detached &gt;48hours-</li> </ul>	reinsert asap			
apply new patch asap	Keep same ring change			
Keep same patch change	day			
day	Additional protection for			
Additional protection for	7 days			
7 days	<ul> <li>If in 1st week of ring use +</li> </ul>			
<ul> <li>If in 1st week of patch use</li> </ul>	unprotected sex in last 5			
+ unprotected sex in last 5	days- consider EC			
days- consider EC	<ul> <li>If in 3rd week of ring</li> </ul>			
• If in 3rd week of patch	use - omit ring free week			
use -omit patch free week	by finishing 3rd week			
by finishing 3rd week	use & starting new ring			
use & starting new patch	immediately			
immediately	,			
Extended patch use/	Extended Ring Use			
Delayed removal & re-	• If same used for upto			
application	28 days- no additional			
• If $\leq$ 48hours during week 1	protection, maximum			
to 3-apply new patch asap,	hormone free interval (HFI)			
keep same patch change	of 7 days can be taken			
day	• If same used for 28-35			
• If >48hours during week	days - insert new ring and			
2 to 3-apply replace	skip HFI, no additional			
patch asap. Additional	protection			
protection for 7 days	protection			
If delayed removal in week     A remove the patch, keep				
4- remove the patch , keep				
same patch start day				

#### Table 11: Follow up visits for various contraceptive methods

Cu IUD/LNG IUD	LNG Implants/POI	POP	COCs/ CVR/ Patch
After 1 st menses	No routine follow up needed	At 3 months	At 3 months
3-6 weeks post insertion	Any side effects	When ceases BF	Annual follow up
Any side effects	At time of removal	No annual follow up	Any side effects
At time of removal		Any side effects	

#### Table 12: Initiation of regular contraception after using EC

Post Cu-IUD	No additional contraceptive method
Post LNG/ combined ECPs	Can start any method immediately. If she doesnt return immediately then also she can start any method if* Additional protection for 2days (POPs) or 7 days (any hormonal method)
Post UPA ECPs	Can insert Cu-IUD immediately. Can insert LNG-IUD immediately if*. Can start any hormonal method on 6th day after taking UPA. If she doesnt start on 6th day, then she can start any method if* Additional protection for 2days (POPs) or 7 days (any hormonal method)

\*if it can be determined that she is not pregnant (table 1); Levonorgestrel containing emergency contraceptive pills(LNG ECPs); Ulipristal acetate containing emergency contraceptive pills (UPA ECPs)

## **Points To Remember**

- Prophylactic antibiotics are generally not recommended for IUD insertion
- 48 hours of POP use is necessary to achieve contraceptive effect on cervical mucus, this time duration is undetermined for LNG implants/ POIs / COCs
- ETG implant can be left in situ upto- 3 years; Sinoimplant - 4 years; Jadelle- 5 years (<80kg), 4 years (>80kg)
- Repeat DMPA injections given every 3 months; Repeat NET-EN injections given every 2 months. Repeat injection can be given upto 2 weeks early or 4(DMPA) / 2 (NET-EN) weeks late.
- Repeat CIC injections given every 4 weeks. Can be given unto 7 days early or 7 days late

- As emergency contraceptive, Cu-IUD can be inserted within 120 hours of unprotected intercourse; LNG-ECPs and combined ECP s ideally within 72 hours, can be inserted unto 120 hours; UPA ECPs more effective between 72-120 hours.
- Repeat pill needs to be taken if vomiting occurs within 2 hours of taking LNG/combined ECPs or 3 hours of taking UPA ECP

## **Suggested Reading**

- 1. WHO Medical eligibility criteria for contraceptive use.5th edition. 2015
- 2. WHO selected practice recommendations for contraceptive use. 3rd edition. 2016
- WHO Family Planning A global handbook for providers. 2018

## **Newer Hormonal Contraceptives**

#### Madhu Goel<sup>1</sup>, Kiranjeet Kaur<sup>2</sup>, Niharika Guleria<sup>3</sup>

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Table 2: Types of Patch

The newer hormonal contraceptives focus on alternate delivery mechanisms like transdermal patch, vaginal ring, implants or combined (E & P) injections. They obliterate the need for a daily pill and are highly effective when used consistently and correctly. The standard and tailored regimens for use of COC pills is shown in table 1.

**Table 1:** Standard and tailored regimens for use of combined hormonal contraception (CHC)

Standard use	Period of CHC use	HFI
Tailored use	21 days (21 active pills or 1 ring, or 3 patches)	7 days
Shortened hormone-free interval (HFI)	21 days (21 active pills or 'l ring, or 3 patches)	4 days
Extended use (tricycling)	9 weeks (3 x 21 active pills or 3 rings, or 9 patches used consecutively)	4 or 7 days
Flexible extended use	Continuous use (≥21 days) of active pills, patches or rings until breakthrough bleeding occurs for 3-4 days	4 days
Continuous use	Continuous use of active pills, patches or rings	None

## **Transdermal Contraceptive Patches**<sup>1</sup>

**Transdermal contraception is as effective as COC** *pills* (Table 2)

	Ethinyl estradiol- norelgestromin (EE/N) patch	Ethinyl estradiol- levonorgestrel (EE/ LNG) patch
Commercial names	Xulane, Zafemy, formerly Evra	Twirla (approved by the US FDA in 2020)
Composition	35 mcg of EE and 150 mcg norelgestromin (the primary active metabolite of norgestimate; 60% higher compared with COC's of a similar dose	30 mcg of EE and 120 mcg of LNG per day; similar to COC's of the same dose
Area	14 cm <sup>2</sup>	28 cm <sup>2</sup>
Layers	Three	Five (innermost two layers contain the active ingredients)
Unintended pregnancy rates	<1 pregnancy / 100 woman year (HWY)	3.5, 5.7 and 8.6 /HWY for normal weight, overweight, and obese individuals, respectively

## Vaginal Contraceptive Rings<sup>2</sup>

The hormonal contraceptive vaginal rings offer the same benefits as the other CHCs but have the advantage that daily or weekly user compliance is not required. It can be the E/P releasing rings or Progesterone releasing vaginal rings. E&P rings are worn vaginally for three weeks and then removed for one week or discarded, Table 3.

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E/P releasing rings	Etonogestrel and Ethinyl Estradiol ring (ENG/EE, Nuvaring)	Segesterone and Ethinyl Estradiol ring (SA/EE, Annovera)
Area	54 mm in diameter and 4 mm in cross-section	56 mm in diameter and 8.4 mm in cross-section.
Composition	The outer ring is composed of both ethinyl estradiol (EE) and an ethylene vinyl acetate copolymer that contains crystals of ENG, the 3-keto-metabolite of desogestrel	2 internal channels: 1 channel with both SA and EE and the other channel with SA only
Hormone released	ENG an average of 120 mcg/day and 15 mcg/day of EE over 21 days of use	Approximately 150 mcg/day of SA and 13 mcg/day of EE over the 21-day use period
Availability in India	Yes	No

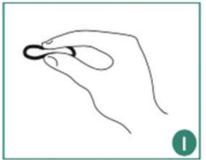
Table 3: Types of E & P Rings

Etonogestrel and Ethinyl Estradiol ring (ENG/EE, Nuvaring)	Segesterone and Ethinyl Estradiol ring (SA/EE, Annovera)
The concentration of EE is lower compared with other CHCs, reaches its peak ENG concentration once per cycle, within seven days of insertion.	The median T <sub>max</sub> of both hormones is approximately 2 hours after vaginal insertion; more constant approximately 96 hours after insertion.
No need for storage as it has to be discarded after 3 weeks	Does not require refrigeration for storage and not orally active so useful for lactating women
1 per 100 woman-years	3 per 100 woman-years
<ul> <li>If out of the vagina for &lt;3 hours- no additional steps. If out for &gt;3 consecutive hours-</li> <li>Week 1-2 of the cycle- reinsert as soon as possible + backup for 7 days</li> <li>Week 3 of the cycle- discard the ring. Restart options: Insert a new ring and begin a new three-week cycle. Back-up contraception or abstinence for 7 days. If the prior ring was in place for 7 consecutive days, leave the ring out for up to 7 days. During this ring-free time the woman may have her period. By day 7, insert</li> </ul>	<ul> <li>If expelled or removed for-</li> <li>Up to 2 hours- reinsert after washing with mild soap- water, then drying. No additional contraception is needed</li> <li>2 continuous hours or more, or &gt;2 cumulative hours (multiple episodes that add up to two hours), ring is cleaned and reinserted, and back- up for 7 consecutive days.</li> </ul>
contraception or abstinence for upto 7 days. The median time to ovulation is 19 days after ENG/	Women resume menses within six months of discontinuation of SA/EE ring.
	<ul> <li>Nuvaring)</li> <li>The concentration of EE is lower compared with other CHCs, reaches its peak ENG concentration once per cycle, within seven days of insertion.</li> <li>No need for storage as it has to be discarded after 3 weeks</li> <li>1 per 100 woman-years</li> <li>If out of the vagina for &lt;3 hours- no additional steps. If out for &gt;3 consecutive hours-</li> <li>Week 1-2 of the cycle- reinsert as soon as possible + backup for 7 days</li> <li>Week 3 of the cycle- discard the ring. Restart options: Insert a new ring and begin a new three-week cycle. Back-up contraception or abstinence for 7 days. If the prior ring was in place for 7 consecutive days, leave the ring out for up to 7 days. During this ring-free time the woman may have her period. By day 7, insert a new ring and begin a new cycle. Back-up contraception or abstinence for up to 7 days.</li> </ul>

*Effectiveness*- Typical use effectiveness is lower than that for methods that are less user-dependent (e.g. intrauterine contraception and implants).

choose a comfortable position. The sides of the ring are pressed together, and then it is inserted into the vagina as high as possible for comfort and to prevent it from falling out, Figure 1.<sup>3</sup>

Insertion and use -To insert, the woman should





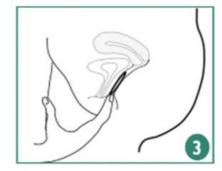


Fig 1: Insertion of Vaginal Ring

<b>Table 4:</b> Comparison between Contraceptive Patch and Ring
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	Transdermal Contraceptive Patches	Vaginal Contraceptive Rings
Mechanism of action⁴	<ul> <li>Inhibition of ovulation. Prevention of follicular maturation</li> <li>Progestin-related mechanisms include changes in cervical mucus, fallopian tube motility, and endometrial receptivity. Also have unfavourable effects on fertilization and implantation.</li> </ul>	Principle mechanism is inhibition of ovulation. Other include cervical mucus thickening, inhibition of sperm capacitation, and slowing of tubal motility.
Benefits	Improved compliance, useful for patients having difficulty swallowing pills, lower peak doses needed (avoid first-pass hepatic metabolism)	Improved compliance, regulation of bleeding, endometrial protection, and, in some women, reduction of dysmenorrhea and endometriosisrelated pain. <sup>5</sup>

	Transdermal Contraceptive Patches	Vaginal Contraceptive Rings
Side effects	topical problems (rare), unscheduled bleeding and spotting are reported by up to 18% of users in initial cycles of EE/N patch use, stabilize by approximately six months of use to 5 to 7% <sup>6</sup> , modest increased risk of VTE (compared to low-dose COCs) due to average overall EE concentration in EE/N patch users is 60% higher than in individuals who use a 35 mcg EE pill, although peak EE concentrations are 25% lower than in oral pill users. <sup>7</sup>	Breast tenderness and nausea is less compared to COCs. Vaginitis vaginal wetness, and leukorrhea are more compared with COCs. Compared with an extended cycle regimen of COCs, the traditional 28-day ENG/ EE ring cycle has a lower number of unscheduled bleeding days but a higher total number of bleeding/ spotting days. Acceptability of continuous use is high, even with unscheduled bleeding. <sup>8</sup>
Patient selection	Individuals desiring a reversible, non-event based method of contraception, having no contraindications to use of CHCs.	Same as for CHC, good option for adolescents, more private use than COCs and the transdermal patch.
Contraindications	Same as for other CHCs. In addition, both patches are contraindicated in patients with a BMI ≥30 kg/m <sup>2</sup> ; EE/N patch because of concern for increased risk of thromboembolism while EE/LNG patch has a lower efficacy in this population. Neither patch should be used in patients being treated for hepatitis C with combinations containing ombitasvir, paritaprevir, or ritonavir, with or without dasabuvir and should not be used in case of sensitive skin, exfoliative dermatologic disorders or skin hypersensitivity to any components. <sup>9</sup>	Same as for other CHCs.
Administration	Thorough medical history and a BP check. While breast examination and screening for sexually transmitted infections and cervical cancer are important but not necessary	Same as for other CHCs.
Initiation	<ul> <li>Regular method- first day start</li> <li>Sunday start method- on the Sunday following menses onset</li> <li>Quick start method- at the time of the initial office visit if pregnancy can be excluded. If initiated &gt;5 days from onset of menses, abstinence or back-up contraception for first 7 days of use.</li> <li>Postpartum- not earlier than four weeks postpartum.</li> <li>Postabortion- initiation depends on gestation at the time of termination or pregnancy loss.</li> <li>Switching from other contraceptives- Individuals switching from a CHC are advised to complete the existing cycle and then start the desired patch on the first day of the next cycle and stop the prior method. For individuals using Depo-Provera, the patch is started when the next injection should occur. Can be initiated on the same day that an intrauterine device or contraceptive implant is removed.<sup>3</sup></li> </ul>	Can be started anytime during the cycle once pregnancy has been reasonably excluded. If the date of last menses was more than 7 days prior with (ENG/EE) ring, more than 5 days prior (SA/EE) ring or is uncertain- back-up method is advised for the first seven days of ring use.
Application and duration of use	<ul> <li>Worn for 7 days to suppress ovulation, replaced on a weekly basis for two further weeks. The fourth week is patch-free to allow a withdrawal bleed. A new patch is then applied after seven patch-free days.</li> <li>Both patches can be applied to the buttock, abdomen, or upper torso (but not the breast as it might cause breast tenderness due to high local estrogen concentration). The EE/N patch can also be applied to the upper outer arm.<sup>2</sup></li> <li>Woman must press the sticky, medicated part against her skin for 10 seconds and run her finger along the edge to make sure it sticks.</li> </ul>	<ul> <li>Both the rings are left in place for three weeks followed by ring-free week to allow withdrawal bleeding.</li> <li>Women should periodically check to ensure the ring is in place.</li> <li>Ring should be inserted on the same day of the week that the old ring was removed the previous week</li> <li>The ring should not be removed during intercourse.</li> </ul>

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	Transdermal Contraceptive Patches	Vaginal Contraceptive Rings
Application and duration of use	<ul> <li>The patch will stay on even during work, exercise, swimming, and bathing.<sup>3</sup></li> <li>A different site is used each time a new patch is applied.</li> <li>Lotions and occlusive dressings should <i>not</i> be used at patch sites.</li> <li>Should always be changed or applied on the same day of the week.</li> <li>Switch should be made during the patch-free week.</li> </ul>	<ul> <li>The contraceptive ring can interfere with other female barrier contraceptives; diaphragm, cervical cap, or female condom and should be not be used for back-up contraception</li> <li>Tampons may be used</li> <li>Compatible with water based lubricants or spermicides but not with oil based</li> </ul>
Delay in beginning the patch or delayed insertion of ring	Delay in beginning the first patch in a cycle– If delayed beyond the scheduled start day, apply a patch asap + back-up for 7 days. The day new patch is applied becomes the new patch change day. Delay in beginning the second or third patch in a cycle– There is a 2 day period of continued release of adequate contraceptive steroid levels when the patch is left on for two extra days. If patch changed within this window, the patch change day remains the same, and no need for back-up but after this, risk for contraceptive failure increases. So back-up contraception advised for 7 days. Emergency contraception is advised in case of unprotected intercourse.	<ul> <li>For women who have delayed insertion of a new ring for</li> <li>&lt;48 hours- reinsert the ring immediately and remove it at the regular scheduled time. No additional contraception is needed.</li> <li>≥48 hours- immediately insert the ring + back up method of contraception.</li> </ul>
Delayed removal	Delay in removing the third patch in a cycle carries less risk than forgetting to remove the first or second patch. The user is instructed to remove the patch when she remembers and start the new patch on the usual start day. The patch change day is not altered.	If the ring has been in place >3 but ≤5 weeks, it is removed, and a new one is inserted after a 1 week ring- free interval. If the ENG/EE ring has been in place for >5 weeks, the old ring is removed, a new ring is inserted, and back-up for 7 days. If <i>unplanned</i> <i>removal or expulsion</i> of the contraceptive ring occurs, it may be rinsed and reinserted into the vagina.
Detached patch	<ul> <li>If a patch becomes partially or completely detached for</li> <li>&lt;24 hours-reapplied at the same location (adhesives or tape should <b>not</b> be used) or replaced with a new patch immediately.</li> <li>&gt; 24 hours-new patch should be applied, and this day of the week becomes the new patch change day.Abstinence or backup for 7 days</li> </ul>	Instructions for reinsertion timing and need for back-up contraception vary by ring type as discussed above. In the event of a <i>broken ring</i> , the broken ring should be removed and new ring inserted as it may slip out, but does not affect the efficacy.

## **Progesterone-Releasing Vaginal Ring<sup>3</sup>**

It continuously releases natural progesterone hormone and works by preventing ovulation. It is **safe and effective option for a woman**: who is 4-9 weeks postpartum, breastfeeding her baby at least 4 times per day, plans to continue breastfeeding and whose monthly bleeding has not returned.

*Effectiveness*- Failure rate is 1 or 2 pregnancies per 100 women years. There is no delay in return of fertility after use is stopped. It does not protect against STI.

Health benefits- no change in breast milk production

or composition; the method supports continued breastfeeding and healthy infant nutrition.

*Side effects-* spotting or irregular bleeding, low abdominal pain, breast pain and vaginal discharge

Insertion and Use- The woman places a flexible ring in her vagina, leaves it in place at all times, every day and night for 90 days. Four rings can be used, one after another, for approximately one year after giving birth. Each new ring should be started immediately after removal of the previous ring for greatest effectiveness. If the ring is out for >2 hours, put it back as soon as possible. If the ring is out for >24 hours, then put it back as soon as possible and a backup method is used for next 48 hours. For longer birth spacing, she can plan ahead to switch to another family planning method.

## **Combined Injectable Contraceptives,** CIC<sup>3</sup>

Also known as Monthly injections that contains both estrogen and progesterone. *Trade names* are MPA/  $E_2C$  (25 mg of medroxyprogesterone acetate and 5 mg of estradiol cypionate) as Ciclofem, Ciclofemina, Cyclofem, Cyclo-Provera, Feminena, Lunella, Lunelle and Novafem, and NET-EN/ $E_2V$  (norethisterone enanthate 50 mg plus estradiol valerate 5 mg) as Mesigyna and Norigynon, administered every 4 weeks. CICs are not available in India.

*Injection site*- 0.5 ml deep into the hip (ventrogluteal muscle), the upper arm (deltoid muscle), the buttocks (gluteal muscle, upper outer portion), or outer (anterior) thigh.

MOA- is similar to other CHC.

*Effectiveness*- When women have injections on time, failure is <1 pregnancy per 100 women using monthly injectables over the first year (5 per 10,000 women).

Return of fertility after stopping injections is in about 5 months. It does not provide protection against STIs.

Health benefits- Long-term studies of monthly injectables are limited but similar to those of COC's. Monthly injectables, however, do not pass through the liver first. Short- term studies have shown that monthly injectables have less effect than COCs on blood pressure, blood clotting, lipid metabolism, and liver function.

*Side effects-* infrequent bleeding, irregular or prolonged bleeding, amenorrhoea, weight gain, headaches, dizziness and breast tenderness. Cochrane systematic review of 12 trials concludes that CIC's resulted in less amenorrhea and discontinuation due to amenorrhoea or other bleeding problems than progesterone only injection.<sup>10</sup>

Patient selection- Individuals desiring a reversible, non-event based method of contraception and have no contraindications to use of estrogens or progestins constitute the initial population of potential users. Contraindications- are same as those for other CHCs.

Screening requirements- are same as for other COC's. Initiation-

- Normal menstrual cycles- within first 7 days
- 1<sup>st</sup> trimester abortion- within 5 days
- Non breastfeeding- after 4 weeks postpartum
- Breastfeeding- after 6 weeks postpartum
- Quick start- if it is reasonably certain that patient is not pregnant

*Next injection*- in 4 weeks or can be given up to 7 days early or late. If late by more than 7 days, she can receive her injection if not had intercourse since 7 days after the scheduled date of her injection or has used backup method.

## Implants

The etonogestrel implant is a single-rod progestin for long-acting reversible contraception in women. It does not contain estrogen, and so can be used throughout breastfeeding and by women who cannot use methods with estrogen. A specifically trained provider performs a minor surgical procedure to place it. The insertion site is marked on upper inner aspect of the patient's nondominant arm 8 to 10 cm (3 to 4 inches) above the medial epicondyle and overlying the triceps muscle to avoid nerve and vessel injury. One mark is made where the rod will be inserted and a second mark is made a few centimetres proximal to the first to serve as a direction guide. The implant should be inserted subdermally.<sup>11</sup>

- *Jadelle*: 2 rods containing levonorgestrel, highly effective for 5 years
- *Implanon NXT (Nexplanon):* 1 rod containing etonogestrel, labelled for up to 3 years of use (a recent study shows it may be highly effective for 5 years). It can be seen on X-ray.
- *Levoplant (Sino-Implant (II)):* 2 rods containing levonorgestrel. Labelled for up to 4 years of use.

*Nexplanon* is available in India. It consists of a 40 mm X 2 mm semirigid plastic (ethylene vinyl acetate) rod containing 68 mg of the progestin etonogestrel (the 3-keto derivative of desogestrel). Etonogestrel is slowly released, initially at 60 to 70 mcg/day, decreasing to 35 to 45 mcg/day at the end of the first year, to 30 to 40 mcg/day at the end of the second year, and then to 25 to 30 mcg/day at the end of the third year and beyond.

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## **Emergency Contraception**

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Emergency contraception (EC) methods are important female-controlled contraceptive methods which can be used to prevent pregnancy after an act of unprotected sexual intercourse (UPSI). The proper use of EC can significantly decrease unsafe abortions.

EC methods can be used in following circumstances-UPSI in a women not using any contraceptive method; UPSI from Day 21 after childbirth (unless the criteria for lactational amenorrhoea are met); UPSI from Day 5 after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophastic disease (GTD); and after sexual assault

EC should also be used when regular contraception has been compromised or has not been used correctly

- More than 3 hours late from the usual time of intake of the progesterone only pill or i.e. 27 hours after the previous pill
- More than 12 hours late from usual time of intake of the desogestrel containing (0.75mg), i.e. more than 36 hours after the previous pill
- More than 2 weeks late for the norethisterone enanthate (NET-EN) progesterone only injection
- More than 4 weeks late for the depot medroxyprogesterone acetate (DMPA), progesterone only injection
- Dislodgement, breakage, tearing or early removal of a diaphragm or cervical cap
- Failed withdrawal method (e.g. ejaculation in the vagina or on external genitalia)
- Failure of a spermicidal tablet or film to melt before intercourse
- Miscalculation of the abstinence period or failure to abstain or use a barrier method during the fertile days of the cycle when using fertility awareness based methods
- Expulsion of an Intrauterine device (IUD) contraceptive or hormonal contraceptive implant

## **Types of EC Available Are**

#### Oral

• Combined oral contraceptive pills (COC), Yuzpe Method: It is less effective and less well-tolerated than the progestin-only method. Only used if other methods not available.

- Levonorgestrel pills (LNG): It is recommended to be used as EC within 72 hours or within 96 hpurs. Its efficacy as EC after 96 hours is not proved. It is part of Government program as 'I' Pill containing 150 µg levonorgestrel.
- Uliprestal Acetate (UPA): UPA is approved by FDA as EC but not by DGCI and in India its use as EC is off label. It has better efficacy than LNG. A recent meta-analysis of two randomized clinical trials published in Lancet showed UPA to have a 42% lower pregnancy risk than LNG if taken within 72 hours and 65% lower pregnancy risk than LNG if taken within the first 24 hours following UPSI. When taken beyond 72 hours, significantly more pregnancies were prevented with UPA than with LNG.<sup>1</sup> Side effects are mild and similar to those seen with LNG. UPA is not recommended for a woman who has severe asthma managed with oral glucocorticoids.
- *Mifepristone*: It is not available in the dose required for EC. It is not approved by FDA for use as EC.

#### Intrauterine Contraceptive Device (IUCD)

- **Copper Intra uterine devices (Cu IUD):** It is most effective method of EC but least acceptable. The main side-effects are increased menstrual bleeding and menstrual disturbances.
- Levonorgestrel intrauterine device (LNG 52 IUD): Containing levonorgestrel 52 mg (LNG 52) is highly effective and provide EC and long-term contraception in one treatment.

#### **Effectiveness**

The risk of pregnancy following placement of a copper IUD is 0.1% i.e. Cu-IUD reduces the risk of pregnancy after UPSI by more than 99%. It is effective from preovulatory phase to 5 days after ovulation.

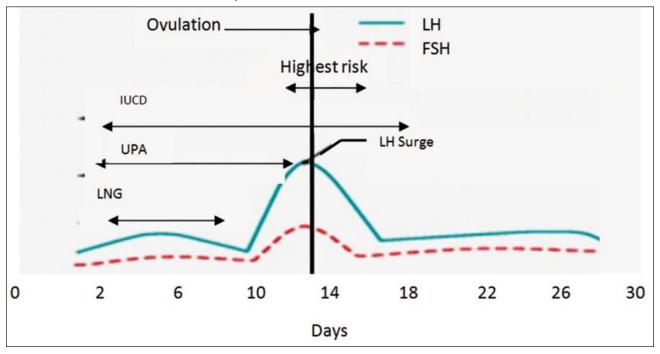
Oral EC are effective only prior to ovulation and ineffective if administered after ovulation.

LNG-EC is most effective within 72 hours of UPSI. They are effective till beginning of LH surge Pregnancy rate of 2.6% has been reported with use at any time of menstrual cycle.<sup>1</sup>

#### Table 1:

Name	Class	Timing of use after UPI	MOA	Preparation
Yuzpe Method	Combined oestrogen & progesterone EE 100 μg & 0.5 mg LNG (or equivalent doses)	Within 120 hours	Prevents ovulation	No separate preparation required <b>High dose pills</b> : Ovral G (50 µg EE & 500 µg Norgestrel) or Duoluton L (50 µg EE & 250 µg LNG): 2 pills as soon as possible and 2 pills 12 hours after 1 <sup>st</sup> dose. <b>Low dose pill</b> containing 30 µg EE: 4 pills as soon as possible and 4 pills 12 hours after 1 <sup>st</sup> dose.
Levonorgestrel	Progestogen	Within 72 hours	Delays follicular development when administered before the level of luteinizing hormone increases.	75 μg LNG: 2 pills 12 hours apart or 2 pills stat 150 μg LNG: Single pill taken as soon as possible
Ullipristal	Selective progesterone receptor modulater	Within 120 hours	Inhibits follicular rupture even after the level of luteinizing hormone has started to increase	30 mg single dose (6 tablets of 5 mg)
Mifepristone	Ante Progesterone	Within 120 hours	Prevents ovulation; may also disrupt luteal phase events and endometrial development	25-30 mg single dose
Cu IUCD	Copper containing intrauterine device	Within 120 hours	Inhibition of fertilisation by its toxic effect on sperm and ova. Prevention of implantation by local endometrial inflammatory reaction	IUCD retained until pregnancy excluded (e.g. onset of next menstrual period) or can be kept for ongoing contraception

## Time of Cycle when various EC are most effective



UPA-EC has been demonstrated to be effective when taken up to 120 hours after UPSI. They are effective even after beginning of LH surge. The overall pregnancy rate after administration of UPA-EC has been reported to be about 1–2%.

Mifepristone is more effective than the Yuzpe method and likely more effective than LNG at the low-dose range (<25 mg) and the mid-dose range (25 to 50 mg). Pregnancy rate 0.9%.<sup>1</sup>

## **Factors Affecting Efficacy of Oral EC**

**Body weight-** LNG EC was found to be less effective with body mass index of >26 kg/m<sup>2</sup> or weight >70 kg. A double dose (3 mg) of LNG-EC is recommended for these women.

For UPA EC, women >85 kg or with a BMI >30 kg/  $m^2$  were found to have lower effectiveness, doubling dose has not been advocated

**Drug Interaction-** In women taking enzyme inducing drugs like efavirenz, rifampin, or the antiseizure medications carbamazepine and phenytoin, the efficacy of oral EC is reduced. A double dose (3 mg) of LNG-EC is recommended if a woman is taking an enzyme-inducing drug. For UPA again there is no recommendation of doubling the dose

UPA EC- Efficacy is reduced if woman is taking progesterogen containing drugs before taking UPA EC. Progesterone containing pills should not have been taken 7 days prior to taking UPA-EC and should be avoided for 5 days after taking UPA-EC as it interferes with the UPA's ability to block ovulation.

## **Side Effects of Oral EC**

Headache, nausea and dysmenorrhoea are side effects common to both UPA-EC and LNG-EC and have been reported in around 10% of users. If vomiting occurs within 3 hours of taking oral EC, a repeat dose should be given.

### Contraception After EC (Table 2)

After oral EC, the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent UPSI. It is essential that women are made aware of this risk and advised regarding ongoing contraception

A gap of 5 days is mandatory before hormonal contraception containing progesterone can be started after UPA because progesterone will decrease efficacy of UPA which is a progesterone antagonist. IUCD can be continued as long term reversible contraceptive method if women wishes.

### Multiple use of EC in same cycle

Both Ulipristal acetate and LNG can be given multiple times in the same menstrual cycle but need not to be taken more than once every 24 hours if multiple episodes of unprotected intercourse occur within this timeframe. Because UPA and LNG interact with one another, the same regimen that had already been used (whether LNG or UPA) should be repeated if EC is needed again within a five-day period.

Frequent and repeated ECP use may be harmful for women with conditions classified as medical eligibility criteria category 2, 3, or 4 for combined hormonal contraception or Progestin-only contraceptives. Frequent use of emergency contraception can result in increased side-effects, such as menstrual irregularities, although their repeated use poses no known health risks.

#### EC in Breastfeeding women

- LNG-EC has no adverse effects on breastfeeding or on the infants.
- Breastfeeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA-EC.

Contraception	LNG	UPA	сос	Mifepristone	Back up non hormonal contraception/ Abstinence after initiation
Non hormonal	Immediate	Immediate	Immediate	Immediate	none
Progesterone only	Immediate	After 5 days	Immediate	Immediate	2 days
СОС	Immediate	After 5 days	Immediate	Immediate	7 days
Progesterone Inj/ Implants	Immediate	After 5 days	Immediate	Immediate	7 days
IUCD	Immediate	Immediate	Immediate	Immediate	None

Table 2: Initiation of contraception after EC

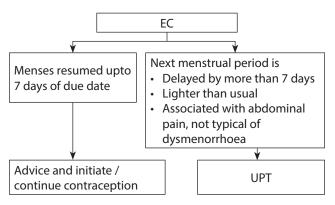
- Breastfeeding women have a higher relative risk of uterine perforation during insertion of intrauterine contraception than non-breastfeeding women.
- However, the absolute risk of perforation is low. Insertion of a Cu-IUCD is relatively contraindicated between 48 hours and 28 days after delivery.

#### **Choice of EC**

The best and most effective EC is Copper IUCD and can be inserted up to 5 days after the first UPSI in a natural menstrual cycle, or up to 5 days after the earliest likely date of ovulation (whichever is later).

LNG– EC can be used within 72 hours of UPIS and if a women presents more than 72 hours but up to 5days. It is not effective after the ovulation period so if a women request EC in post ovulatory period, the only option is Cu IUCD. If she is not a suitable candidate for IUCD or refuses, she should be offered immediate quick start of suitable hormonal contraception with follow-up pregnancy testing. If woman is not sure of dates then also EC can be prescribed followed by regular quick start contraception.

## **Follow Up Care**



**Effect on Pregnancy:** Pregnancy may exist prior to taking EC, EC may fail, or pregnancy can result from intercourse after using EC. EC has no known adverse effects on pregnancy and is not associated with increased risk of congenital anomalies or ectopic pregnancy should pregnancy occur.

### **Important Points**

Emergency contraception prevents pregnancy after an unprotected intercourse. Pregnancy is the only absolute contraindication to EC use. Cu IUD is most effective method of emergency contraception. LNG IUDs are effective but its use as EC has not been studied. Ulipristal acetate is most effective oral method for EC but it is not approved by DCGI. Progesterone should not be taken 7 days prior and 5 days after administration of UPA. EC do not increase the risk of teratogenicity or ectopic pregnancy.

### **Suggested Reading**

- 1. Mittal S. Emergency contraception-Potential for women's health. Indian J Med Res 2014; Suppl S1:45-52.
- 2. Guidelines for Administration of Emergency Contraceptive Pills by Health Care Providers. November 2008. Family Planning Division, Ministry of Health and Family Welfare.
- Emergency contraception [Internet]. World Health Organization. World Health Organization; 2018 [cited 2018Feb1]. Available from: http://www.who.int/ mediacentre/factsheets/fs2
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- 5. FSRH Guideline Emergency Contraception. UK: Faculty of Sexual & Reproductive Healthcare; December 2017

## Medical Termination of Pregnancy Act: Old and New

### Nishi Choudhary<sup>1</sup>, Zeba Khanam<sup>2</sup>, Sujata Das<sup>3</sup>

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While formulating policies related to abortion, policymakers seldom take into account a woman's right to determine her fertility. Though medical termination of pregnancy (MTP) has been legalized in India since 1971, widespread access to MTP services is still missing. This is especially true for rural India. Unsafe abortions are a significant yet preventable cause of maternal mortality and morbidity in India. Women who undergo unsafe abortions may suffer long-term morbidity that significantly affects their reproductive health. Ensuring comprehensive abortion care (CAC) services are now an integral component of the efforts made by the Government of India to bring down maternal mortality and morbidity in the country. Since no contraception is one hundred percent effective, safe abortion care becomes all the more important part of reproductive services.

The Indian Penal Code (IPC) was enacted by the British colonial government in 1860. It was declared that inducing an abortion amounted to culpable homicide and that any person performing it would be subjected to imprisonment for three or more years and/or payment of a fine. The only exception to the code was that the abortion was performed to save the life of a woman. Several hundreds of women succumbed to illegal abortions each year. This penal code was changed in Britain in 1967, but ironically, not in India until the year 1971. The Medical Termination of Pregnancy (MTP) Act enacted in 1971 governs the provision of abortions in India. It was enforced to safeguard the health of a mother undergoing an abortion and the interest of a doctor performing the procedure on her. It also offers legal protection to a practitioner if he/she adheres to and fulfils all the requirements of this Act.

### **MTP act- The Development Processes**

*MTP Act:* is passed by both houses of parliament and receives assent by the President

*MTP Rules:* are made by the Central Government and passed by the parliament; notified in the official gazette

MTP Regulations: are made by the state government

and passed by the state legislature.

The legal frame work of the act is divided into three sub-categories:

- *The MTP act* It lays down when & where pregnancies can be terminated and it grants the powers to make rules to Central Government, and power to frame regulations to the State Governments.
- *MTP rules* It lays down who can terminate the pregnancy, the training requirements, approval process for the place where MTP is done and more.
- *MTP regulations* It lays down forms for opinion and maintenance of records and regulates custody of forms and reporting of cases.

**Legal abortion** is defined as termination of pregnancy by an approved registered medical practitioner (RMP) for approved conditions and gestational age, and at an approved centre while complying with the other requirements of the MTP rules and regulations.

### **Objectives of the MTP Act, 1971 are:**

- To liberalize provisions of termination of pregnancy.
- To protect the RMP who performs an abortion as per the provisions of this act.
- To keep the record of a woman undergoing an MTP a secret.

## Conditions under which A Pregnancy can be Terminated Under The MTP Act include:

- *Therapeutic or medical indications*: Where the pregnancy is risk to the life of the pregnant woman or of grave injury to her physical or mental health.
- *Eugenic indications*: Where there is a substantial risk of a child being born with serious physical or mental abnormalities to be handicapped for life.
- *Humanitarian indications*: In cases of pregnancy as a result of rape.
- Socio-economic indications: Where pregnancy results from failure of contraception method/ an

unwanted child or the pregnancy poses a grave injury to maternal mental health.

Sex selection is not an indication for pregnancy termination under the law.

# Amendments in the MTP Act and Rules (2002 and 2003)

#### Key features of the amendments are:

- Decentralization of the MTP site approval to district level through the formation of District Level Committees (DLCs) as regulatory bodies.
- Laying down of details of *composition and tenure of DLCs* and process of MTP site approval.
- Requirement for being *certified as an MTP provider*.
- Infrastructure and equipment requirements for *sites providing first and second-trimester* MTPs are defined and separated.
- Imprisonment of two to seven years, if an uncertified provider performs an MTP procedure or if the procedure is done in an unapproved site.

#### Implications of the amendments:

- It simplifies registration of sites, which can now be done at district level.
- Providers can get their sites approved for providing abortions under the MTP Act and thereby come under the protective cover of the MTP Act.
- Approved providers can provide medical abortions from their clinic, as long as they have an access to an MTP approved referral site.
- Offers potential to increase number of approved sites, which would enable women to access safe abortion services.
- Effective implementation to help bring all abortions within the legal frame work.

## **MTP Rules**

#### Who can Perform MTP

- Only an RMP who possesses a recognized medical qualification as defined in the Indian Medical Council Act, 1956 can perform an MTP.
- Opinion of the RMP is to be put on the record in prescribed Form I.
- For termination of pregnancy for **up to 12 weeks** of gestation:
  - A practitioner who has assisted a RMP in 25 cases of MTP, of which at least 5 were performed independently by him/her in a hospital

established or maintained or a training institute approved for this purpose, by the Government.

- Opinion of one RMP is sufficient.
- For termination of pregnancy **up to 20 weeks of gestation**:
- A practitioner who holds a post-graduate degree or diploma in Obstetrics and Gynaecology.
- A practitioner who has completed six months' house job in Obstetrics and Gynaecology.
- A practitioner who has at least one-year experience in the practice of Obstetrics and Gynaecology at a hospital which has all the facilities for MTP.
- A practitioner registered in state medical register immediately before commencement of the Act with an experience in practice of Obstetrics and Gynaecology for a period not less than three years.
- Opinion of two RMPs is mandatory.

## **Requirements for Approval of a Place for Conducting MTP**

## For sites approved to perform MTP **up to 12 weeks of** gestation

- A gynecological examination /labor table.
- Instruments for performing abdominal or gynecological surgery.
- Resuscitation and sterilization equipment.
- Drugs and parental fluid.
- Back up facilities for treatment of shock.
- Facilities for transportation.

## For sites approved to perform MTP **up to 20 weeks of** *gestation*

- All requirements for performing MTP up to 12
   weeks *plus*
- Operation table and instruments for performing abdominal or gynaecological surgery.
- Anaesthetic equipment, resuscitation equipment and sterilization equipment.
- Drugs & parental fluids notified for emergency use, notified by Government of India from time to time.

#### Places where MTP can be Performed

- Government hospitals, nursing homes, or centres approved by the Director of Health Services (DHS) or Chief Medical Officer (CMO) of the district.
- Places approved by the Government or a District Level Committee (DLC) constituted by that Government with the Chief Medical Officer (CMO)

as the Chairperson of the Committee

- DLC would consist of not less than three and not more than five members, including the Chairperson (CMHO), as the Government may specify from time to time.
- Details of the composition and tenure of the DLC includes:
  - One member of the DLC is a gynaecologist/ surgeon/anaesthetist.
  - One member is from the local medical profession, non-governmental organizations (NGOs), and the Panchayati raj institution (PRI) of the district.
  - At least one member of the DLC shall be a woman.
  - Tenure of the committee- Two calendar years.
  - The tenure of NGO members shall not be more than two terms.

#### Approval process of a place for MTP involves:

- Filing an application in Form A addressed to the Chief Medical Health Officer (CMHO).
- Within 2 months of receiving application, the CMHO verifies or inspects the place if it is suitable for a safe and hygienic MTP. The CMHO may call for information, report to the committee for unsafe and unhygienic conditions at a proposed centre. The committee may suspend or cancel approval of the centre after giving the owner an opportunity of representation. The owner in these circumstances may reapply to the committee after making rectifications and improvements. In cases of suspension, the place is represented as 'nonapproved'.
- In cases of approval, CMHO shall recommend the approval to the committee.
- The committee will consider the application and recommendations and may approve and issue certificate of approval in Form B within 2 months of inspection. In case a deficiency is found, the certificate shall be issued within 2 months of the deficiency being rectified.

#### Consent

- Written consent of women is needed. Husband's consent is not required. In the case of a minor (<18 years old) or a mentally retarded girl, written consent from her parents or legal guardian is required.
- In case of a minor seeking an abortion under the Protection of Children from Sexual Offences

(**POCSO**) Act, 2012 section 3(4) and rule 9, reporting of the case should be done to the appropriate authorities (either the local police or special juvenile police) or the concerned authority in the hospital responsible for medico-legal cases.

- Consent on Form C is mandatory.
- Consent taken on any other paper is not valid.
- Consent should be informed and written.

### **MTP Regulations**

The MTP regulations cover

- 1. Forms required for making opinion, admission register and reporting of MTPs.
- 2. Custody of forms.
- 3. Prevention of disclosure of information.

#### **Opinion Forms**

- Opinion of one or two approved RMPs according to the gestational age of pregnancy.
- The provider(s) is required to certify his/her opinion in Form I.

#### **Record Keeping**

Absolute confidentiality of records has to be maintained. It is mandatory to keep the following records under the MTP Act:

- **1. Form C** (Consent Form): To be signed by the woman herself/guardian.
- **2. Form I** (Opinion Form): Opinion of RMP, also mentioning the indication of MTPs.
- **3. Form II**: Head of the hospital or owner of the place should send a monthly statement of cases to the CMO of the district in this form.
- 4. Form III (Admission Register): An approved site should maintain case records in Form III. This register is kept for five years from the date of the last entry of the cases. It should be kept in safe custody and not be opened for inspection by any person except under the authority of law.

## **Reporting and Custody of Records**

- All documents (patients' consent, the certified opinion recorded under the above provisions and the intimation of termination of pregnancy) should be put in a sealed envelope to the head of the hospital or owner of the approved place by the RMP. Safe-custody of the same should also be maintained by the former.
- A weekly statement of cases of medical termination

of pregnancy should be sent to the Chief Medical Officer by the head of the hospital or the owner of the approved place.

- MTP performed has to be reported to the Director of Health Services of the State on a prescribed MTP form.
- An admission register should be maintained for recording details of women undergoing MTP. The register should be preserved for 5 years from the end of the calendar year it relates to.
- In case of litigation, records need to be preserved till the final disposal of the litigation.

## **Offenses and Penalties**

- Termination of pregnancy by any person at an unapproved place or termination of pregnancy by any person other than RMP would be liable for imprisonment of not less than 2 years that may be extended up to 7 years.
- Any contravention of the requirement of recordkeeping would invite a fine extending one thousand rupees.

## **Words of Caution**

- Ectopic pregnancy to be ruled out.
- Anti- D injection to the patient if the latter has a Rh-negative blood group.
- Manage a partial or complete molar pregnancy accordingly.
- Valid consent to be taken.
- MTP to be practiced only at a registered place.
- All the provisions of the MTP act 1971 should be complied with.
- RU-486 use should also comply with the provisions of the MTP act.

In case of termination of an early pregnancy of up to seven weeks using Mifepristone (RU486) and Misoprostol as per the CAC 2018 guidelines, an RMP may prescribe these drugs at his/her clinic. In such cases, patients should have access to a place approved for terminating pregnancies under the MTP Act.

## The MTP (Amendment) Act, 2021

With the passage of time and advancement in medical technologies such as ultrasonography and genomics, the MTP Act of 1971 has become inadequate in safeguarding the rights of women.

Prenatal diagnosis of a large number of foetal disorders emphasizes the need for raising the upper limit of gestational age for terminating pregnancies. Given the steady increase in writ petitions seeking termination of pregnancy in cases of severe foetal abnormalities, the concerned medical professionals have been representing the Ministry of Health and Family Welfare to amend the MTP Act and bring it in line with the international thinking. The MTP Act 2021 notified in the Gazette of India on 25th March 2021, contains significant amendments to the MTP Act of 1971.

- The Law proposes requirement of opinion of one RMP (instead of two or more) for termination of pregnancy up to 20 weeks of gestation (fetal development period from the time of conception until birth).
- It introduces the requirement of opinion of two RMP for termination of pregnancy between 20 to 24 weeks of gestation.
- It has also enhanced the gestational age limit for 'special categories' of women which includes sexual assault survivors, victims of incest, and other vulnerable women like differently-able and minors.
- It also states that the 'name and other particulars of a woman whose pregnancy has been terminated shall not be revealed', except to a person authorized in any law that is currently in force. Whoever contravenes such provisions shall be punishable with imprisonment which may extend to one year, or with fine, or both.
- In case of any substantial foetal anomaly, the upper gestational age limit of termination shall not apply to the termination of pregnancy, where such termination is necessitated by the diagnosis of any of the substantial foetal abnormalities, by a Medical Board, as specified in the Act.
- The Medical Board shall consist of the following: One Gynaecologist, one Paediatrician, one Radiologist or a Sonologist, and such other number of members as may be notified in the Official Gazette by the State Government or Union territory, as the case may be.

## Conclusion

The foremost objective of legalizing abortion through the MTP act is to provide women with quality and safe abortion care which is sensitive to their needs of easy accessibility and affordability.

Modifications	Old MTP Act	New MTP Act	Impact of Amendments	
Opinion of provider	MTP up to 12 weeks gestation- Opinion of one provider is required	MTP up to 20 weeks gestation- Opinion of one RMP is required	This will increase number of facilities that are eligible to provide MTP till 20 weeks	
	MTP from 12 weeks to 20 weeks gestation- Opinion of two providers is required	MTP beyond 20 weeks up to 24 weeks gestation- Opinion of two RMPs is required	gestation	
Gestational age limit in vulnerable group	MTP beyond 20 weeks is permitted only to save life of a pregnant woman	Increased upper limit of pregnancy termination from 20 to 24 weeks for sexual assault survivors, victims of incest, and other vulnerable women like differently-able and minors	This will reduce court cases and unsafe abortions in vulnerable group	
Gestational age limit in case of substantial foetal anomalies	Termination of such pregnancies is permitted only up to 20 weeks	For such cases, upper gestation limit will not apply. Decision will be taken by a Medical Board or as will be prescribed under the Rules of this Act.	This will reduce court cases and unsafe abortions in women with substantial fetal anomalies.	
Condition of failure of contraception	MTP under this clause is applicable only for married women or her husband	MTP under this clause will be extended for any woman or her partner	This will increase access of unmarried women to safe and legal abortion	

## Salient Features of MTP (Amendment) Act, 2021

Important Note: MTP Act, 2021 will come in force only after the Rules & Regulations are laid down.

## **Suggested Reading**

- Ministry of Home Affairs, Government of India. The Indian Penal Code, 1860. New Delhi: MoHA; 1860 [cited 2021 Feb 22]. Available from: https://ncib.in/pdf/indian-penalcode.pdf.
- Khanna AK, Prabhakaran A, Patel P, Ganjiwale JD, Nimbalkar SM. Social, Psychological and Financial Burden on Caregivers of Children with Chronic Illness: A Crosssectional Study. Indian J Pediatr. 2015 Nov;82(11):1006-11.
- Sedgh G, Bearak J, Singh S, et al. Abortion incidence between 1990 and 2014: global, regional, and subregional levels and trends. Lancet. 2016 Jul 16;388(10041):258-67. doi: 10.1016/S0140-6736(16)30380-4. Epub 2016 May 11.

- 4. Medical Termination of Pregnancy Act, 1971. http://www. egazette.nic.in/Write Read Data/ 1971/E-1383-1971-0034-61647.pdf
- 5. Comprehensive Abortion Care: Provider's Manual, April 2014. http://nhm.gov.in/images/pdf/programmes/ maternal health/guidelines/CAC\_Trainers\_Manual.pdf.
- 6. Clinical Practice Handbook for Safe Abortion, WHO 2014. http://apps.who.int/iris/bitstream /10665 /97415/1/ 9789241548717\_eng.pdf
- Handbook on Medical Methods of Abortion, MoHFW 2016. http://nhm.gov.in/images/pdf/programmes/ maternal-health/guidelines/MMA\_Handbook.pdf
- 8. Ministry of Law and Justice, Govt of India.. The Medical Termination of Pregnancy (Amendment) Act 2021, no 8 of 2021. The Gazette of India. CG-DL-E-26032021-226130. March 25, 2021. https://egazette. nic.in/WriteReadData/2021/226130.pdf

## Medical Termination of Pregnancy in First Trimester

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Maternal mortality ratio (MMR) for India is 113/ 100000 live birth; out of which 8% is due to unsafe abortion.<sup>1</sup> This makes unsafe abortion to be the third leading cause of maternal death in our country. Factors contributing to unsafe abortion include lack of awareness that abortion is legal, gender discrimination, lack of qualified providers for safe abortion.

## **Medical Termination of Pregnancy Act<sup>2</sup>**

The Medical Termination of Pregnancy (MTP) Act was introduced in 1971. It is the framework for provision of safe and legal abortion services of MTPs in our country. The act allows termination of pregnancy by a Registered Medical Practitioner (RMP), up to 20 weeks gestation for a broad range of indications. The MTP Act offers protection to a practitioner if she/ he adhere to and fulfils all the requirements under this act.

## **Amendments in the MTP Act and Rules**

The MTP Act and Rules were amended in 2002, 2003 and 2021. The MTP (amendment) act 2021 has been passed by both houses of the Parliament in March 2021 but shall come into force only after Central and State Government notify the Rules and Regulations.

Abortion may be classified into various categories depending upon nature and circumstances under which it occurs. It may be either spontaneous or induced. The first trimester is generally considered to consist of the first 12 weeks or, by some experts, as the first 14 weeks of pregnancy. Throughout this document, gestational age is defined in both weeks and days.<sup>3</sup> Number of days or weeks since the first day of the woman's last normal menstrual period (LMP) in women with regular cycles (for women with irregular cycles, the gestational age may need to be determined by physical or ultrasound examination).

Termination of pregnancy should be performed after obtaining a valid consent, by approved person at approved place with mandatory documentation for MTP procedures under the MTP Act.

In case of a woman over 18 years of age, married/

unmarried, only her consent is required to terminate pregnancy. **Spouse consent is not mandatory.** In case of a minor (less than 18 years) or an intellectually disabled person, the consent of a guardian (caretaker) is required.

## **Steps of First trimester Abortion**

**Step 1: Pre-abortion**<sup>4</sup>- First step in legal abortion involves counselling of the woman, to allow her to make her own decisions about whether to have an abortion and what method to choose. Confirmation of pregnancy status, determination of intrauterine location and gestational duration are the other targets of this step. It also provides an opportunity to discuss future use of contraception. Physical examination for general health assessment, abdominal examination and bi-manual examination for confirmation of intrauterine pregnancy and to rule out genital tract infection is done.

The following laboratory tests are done when available, or may be performed on the basis of individual risk factors, findings on physical examination and available resources: Pregnancy test if pregnancy is unconfirmed; haemoglobin (Hb) or haematocrit for suspected anaemia; urine albumin and sugar levels, Rhesus (Rh) testing, where Rh-immunoglobulin is available for Rh-negative women; HIV testing/counselling; STI screening and cervical cancer screening (usually performed during the pelvic examination); other laboratory tests as indicated by medical history (kidney or liver function tests, etc.); diagnostic ultrasound, if indicated, to confirm pregnancy dating or the location of the pregnancy.

**Step 2: Abortion**<sup>5</sup>- There are two methods of abortion proposed for terminating the pregnancy in first trimester. They are medical and surgical method. Selection of method depends upon period of gestation, qualification of trained practitioner, availability of infrastructure, feasibility of patient to follow up in outpatient department, method of contraception accepted and planned during post abortal period.

## Medical Method of Abortion (MMA) in First Trimester<sup>6</sup>

As the title suggests, medical method is a nonsurgical method of termination of pregnancy using combination of drugs. A combi-pack of mifepristone and misoprostol (one tablet of mifepristone 200 mg and four tablets of misoprostol 200 mcg each) has been approved by the Central Drugs Standard Control Organisation, Directorate General of Health Services in December 2008, for the medical termination of pregnancy up to nine weeks (63 days) of LMP. **However, Government of India has approved for medical abortions for up to 49 days of gestation.** *A combination of mifepristone and misoprostol has a success rate of 95- 99% for early abortions.* 

## **Mechanism of Action**

Mifepristone is a derivative of norethindrone with anti-progestin action. It binds to progesterone receptors in the endometrium and decidua, resulting in necrosis and detachment of products of conception (POC). It also softens the cervix and causes mild uterine contractions. Mifepristone sensitizes the uterus to the effect of prostaglandin.

Misoprostol is a prostaglandin E1 analogue which binds to myometrial cells, causing strong myometrial contractions and cervical softening and dilatation. This leads to the expulsion of conceptus from the uterus. It is stable at room temperature and well absorbed from the gastro-intestinal tract and vaginal mucosa. Being selective for PGE1 receptors, there are no significant effects on bronchi and blood vessels, minimising its side-effects, as compared to other prostaglandins.

# Indications, Contraindications and Special Precautions

*Indications:* All women with an intrauterine pregnancy, who wish to get their pregnancy terminated within nine weeks of LMP, and are willing to make three visits (two visits with home administration of misoprostol).

## **Advantages of MMA<sup>7</sup>**

- Safe procedure with high percentage of success rate in early pregnancy offers more privacy
- Feasible with minimum technical assistance
- Less overall complication rate. No risk of cervical or uterine injury

- No instrument and anaesthesia required, hence less invasive
- No effect on future fertility, if standard protocol followed

## Limitations of MMA<sup>5</sup>

- Generally three visits are required (if misoprostol is administered at home, a minimum of two visits required)
- Whole process takes longer time and duration of bleeding can be 8-13 days. However, the bleeding decreases as soon as the POC expulsion process is complete
- Drugs used for termination may have side-effects
- Potential risk of foetal malformation in cases where pregnancy continues due to the failure of MMA
- Woman should be ready for surgical evacuation in case of failure of the method or excessive bleeding and should be within accessible limits of the appropriate healthcare facility providing emergency care.

## **Contraindications**

Medical method of abortion is contraindicated in women with: Confirmed or suspected ectopic pregnancy or undiagnosed adenexal mass, as mifepristone or misoprostol cannot treat ectopic pregnancy; Anaemia (haemoglobin <8gm %); Uncontrolled hypertension with BP >160/100mm Hg; Chronic adrenal failure; severe renal, liver or respiratory diseases; uncontrolled seizure disorder; Glaucoma; Inherited porphyria.

## **Summary of Tasks for 3 Visits**

Visit	Day	Tasks
1 <sup>st</sup>	1	<ul> <li>200mg Mifepristone oral;</li> <li>Anti D 50 mcg, if Rh negative (give 300 mcg if 50 mcg is not available</li> </ul>
2 <sup>nd</sup>	3	<ul> <li>400mcg Misoprostol sublingual/buccal/ vaginal/oral</li> <li>Analgesics (Ibuprofen)</li> <li>Antiemetic</li> <li>Offer contraception</li> </ul>
3 <sup>rd</sup>	15	<ul> <li>Confirm and ensure completion of abortion</li> <li>Offer contraception, if not already done so</li> </ul>

## Tasks for Day 1/Day of Mifepristone Administration

For provider- Take detailed history, rule out contraindications and do general counselling &

MMA specific counselling. Discuss contraceptive options with woman, complete physical and pelvic examination; obtain informed consent in Form-C; Fill in Form I; Record investigations; Tablet Mifepristone 200 mg, to be take normally; Complete MMA followup card; Give contact address and phone number for any emergency; Give 180 tablets of Iron and Folic Acid; Give 2 packets of sanitary napkins; and Record details in Admission Register

Instructions to the woman- Explain what to expect after taking tablet Mifepristone; She must return for Misoprostol administration after two days (unless the service provider decides for home administration of Misoprostol); She may have pain and bleeding during these two days; Take tablet Ibuprofen to relieve the pain; Avoid intercourse or use barrier method, such as condoms; Report to the center/ provider in case of excessive bleeding/ acute abdominal pain; and Record any experience of side effects on the MMA on follow up card

#### Tasks for day3/Day of Misoprostol Administration

*Provider's task*- Note bleeding/ pain or other side effects after tablet Mifepristone; Give two tablets of Misoprostol (400mcg)sublingual/ buccal/ vaginal/ oral; Observe her for four to six hours in the clinic; Prescribe tablet Ibuprofen for pain relief; Bi-manual examination just before discharge from the facility; Anti emetic and anti-diarrhoeal drugs could be prescribed; Explain what to expect after taking Misoprostol; Oral Contraceptive Pill can be started, if chosen as a contraceptive method.

Instructions to the woman- Lie in bed for 30 minutes after vaginal insertion of Misoprostol; She can have side effects such as nausea, vomiting, diarrhoea, headache, fever, dizziness, fatigue; Avoid intercourse till bleeding stops; Use clean sanitary napkins and avoid tampons and douche; and avoid going out of station till third visit

She should report in case of: No bleeding 24 hours after Misoprostol intake; Excessive bleeding, i.e. soaking two or more thick pads per hour for two hours continuously; Fever more than 24 hours after Misoprostol administration; Return for follow-up on the 15<sup>th</sup> day; Keep filling the MMA follow-up case

#### Tasks for Day15/Follow Up Visit

Provider's task and instructions to the woman-

- Note history of bleeding/ pain in abdomen/ expulsion of POC.
- · Pelvic examination to rule out continuation of

pregnancy. USG, if indicated.

• Reiterate contraceptive counselling and services

### **Side Effects**

Main side effects are pain, fever, diarrhoea, bleeding per vaginum and pelvic infection. All the above symptoms are relieved after giving symptomatic relief. Ibuprofen is the choice of analgesic for pain relief.

### **Post MMA Contraception**

Hormonal methods, whether combined (estrogen and progestogen) or progestin-only, can be started on the day of the Misoprostol administration (day 3) or day 15 of the MMA regimen. Injectable hormonal methods like Depot Medroxy Progesterone Acetate (DMPA) can also be started on day 3 or 15 of the MMA regime. IUCD can be inserted after confirmed complete abortion, provided the presence of infection is ruled out on day15. Condoms can be used as soon as she resumes sexual activity after abortion.

Tubal ligation can be done after the first menstrual cycle. However, if desirous of concurrent tubal ligation, vacuum aspiration is preferred Vasectomy, if chosen, can be done independent of the procedure.

# Surgical Method of Termination of Pregnancy in First Trimester

**Termination of** pregnancy in first trimester by surgical method is done by Vacuum aspiration method. It is a method by which the contents of the uterus are evacuated through a cannula that is attached to a vacuum source. The term 'vacuum aspiration' includes both Manual Vacuum Aspiration and Electric Vacuum Aspiration. It is a safe and simple technique for the termination of pregnancies up to 12 weeks of gestation/ uterine size with the efficacy of 98%. It is the surgical method of preference over dilatation and curettage due to less complication.

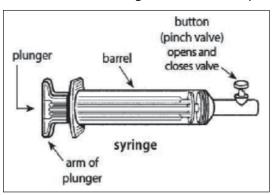


Fig 1: Manual vacuum aspiration syringe

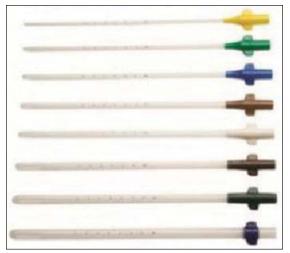


Fig 2: Karman's cannula

## Indications for Using Vacuum Aspiration

Vacuum aspiration can be used for: Induced abortion of up to 12 weeks gestation/uterine size.

It can also be used for: Incomplete abortion of up to 12 weeks gestation/uterine size; Missed abortion; Hydatidiform Mole of up to 12 weeks gestation/ uterine size; Removal of decidua with surgical management of an ectopic pregnancy

# Contraindications for Vacuum Aspiration

- Presence of acute cervical, vaginal or pelvic infection. The procedure should only be done under peri-operative antibiotic cover
- Suspicion of perforation (from a previous interference in the present pregnancy).
- Suspicion of ectopic pregnancy

## **Procedure**

Pre-procedural care involves reassessment and confirmation of diagnosis. Informed consent for the procedure is must. Shaving of perineum is not an essential requirement before evacuation.

A dose of oral analgesic/antispasmodic should be given an hour before the procedure and misoprostol 400 mcg vaginally or sublingually 3 hours before the procedure is given for cervical dilatation. Single dose of prophylactic antibiotic such as oral Ampicillin/ Azithromycin 1gm and Metronidazole 800 mg is administered. In non-lactating women, Doxycycline 100 mg BD for 7 days may be given in place of Ampicillin/Azithromycin.

## **Manual Vacuum Aspiration (MVA)**

MVA is done as an outpatient or an office procedure. Woman is laid on table with empty bladder in Lithotomy position. Bimanual examination findings are confirmed. Posterior wall of vagina is depressed using Sim's speculum and anterior lip of cervix held using allis forceps. Paracervical block is given using 1% Lignocaine (10 mL) at 4, 8 and 12 o' clock position. Cervix is dilated using Hegars dilator. Cannula as suited to uterine size is introduced inside till middle of uterine cavity. The two varieties of plastic cannulae are available for use with an MVA aspirator and EVA, the disposable single-use cannula (Karman) & autoclavable reusable cannula (Easy Grip). It is available in sizes ranging from 4 to 12. Preferred cannula size depends upon uterine size.

In MVA procedure, a handheld plastic aspirator providing a vacuum source is attached to a cannula and activated to suction out the uterine contents. The cannula is moved up, down and rotated within the uterine cavity (360 degrees). After appreciating the signs of complete evacuation, (by no more products being sucked out, gripping of the cannula by contracting uterus, grating sensation and appearance of bubbles in the cannula) vacuum is released before withdrawing the cannula. Post procedure repeat bimanual examination should be done to confirm status of cervix and uterine size. Post procedure check curettage is not essential if grating sensation is achieved during curetting.<sup>4</sup> The aspirated contents are examined. MVA aspirators are essentially of two types: single-valve (also referred to as the menstrual regulation [MR] syringe) and double-valve aspirators.4

**In Electric Vacuum Aspiration (EVA),** electric pump or suction machine attached to a cannula is used to evacuate uterine contents. It is available and preferred in centralised settings with higher caseloads. Pressure of the suction is raised to 400-600 mm Hg. Suction bottle is inspected for the product of conception and blood loss.

Immediately in post procedure period, vitals of woman are checked, blood loss is evaluated and abdominal pain is assessed.

The following tasks should be undertaken before the woman is discharged from the facility: assessment and documentation of the woman's vital signs at discharge; contraceptive counselling with contraceptive provision when requested. Other reproductive health issues addressed are: anaemia, reproductive tract infections (RTIs), HIV, domestic violence, cancer screening.

Provide medications and instructions: Pain management with analgesics, NSAIDs (for example, Ibuprofen); Antibiotic therapy, as appropriate; Injection Anti-D (50mcg) to Rh negative women. Haematinic (IFA tablets) are given for at least three months. Woman is instructed to resume normal diet on the same day. Activities are restricted for the next three days and vaginal douching and intercourse is avoided until a week or till bleeding stops.

# Conditions that Require Immediate Attention and Treatment

Significant decline in physical condition may occur as reflected in vital signs. Dizziness, shortness of breath or fainting, may be caused by internal or external blood loss. Fainting may be due to anxiety or transient vasovagal reaction. Severe vaginal bleeding may occur, some post-procedure bleeding is expected, but the amount of bleeding should decrease over time. Excessive bleeding may be a sign of retained POC, lack of normal uterine tone, cervical laceration or other complications. Severe abdominal pain or prolonged cramping may be a sign of uterine perforation or post-abortal hematometra.

Woman is advised to follow up after 2 weeks after medical abortion. After a vacuum aspiration procedure, schedule the follow-up visit within one to two weeks, because problems are most likely to occur during this period.

## **During the Follow-Up Visit<sup>7</sup>**

Assess the physical status, vital signs and bleeding pervaginum: Inquire about fever, pelvic or abdominal

pain or cramps. Determine whether symptoms of pregnancy, such as nausea and breast tenderness have decreased or continued, in order to rule out continuing pregnancy. Discuss about contraceptive choices if not already chosen by the woman.

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## Comprehensive Abortion Care: Second Trimester Termination of Pregnancy

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Under IPC 1860, terminating a pregnancy was a criminal offence. There are different rules and regulations with regard to allowing abortions, in different countries of the world. In India, **the Medical Termination of Pregnancy Act, 1971 which was later amended in December 2002,** offered protection to a practitioner if he/she adhered to and fulfilled all requirements under the MTP Act 1971. The MTP Act 2021 has been notified in the Gazette of India on 25th March 2021 and contains significant amendments to the MTP Act of 1971.

Abortion is legal when the criteria laid in the act regarding person performing procedure, place where it is performed and indications of abortion are fulfilled. For 2<sup>nd</sup> trimester MTP, place of abortion should be equipped with OTs for performing abdominal or gynaecology surgery, anaesthesiologist and anaesthetic equipment.

Second trimester abortion covers the period between 12-20 weeks of gestation. Late diagnosis of pregnancy and detection of GCA in level II scan play a major role in need for second trimester abortion. 9-11% of all induced abortions occur in second trimester; however these abortions are responsible for two thirds of all major complications.

No contraceptive is 100% effective and therefore, safe abortion services are important. Appropriate pre and post abortion counselling, plays an important role. Documentation in FORM I, II, III and C have to be completed before the procedure. Woman's identity is hidden and is referred in all documentation by serial number given in FORM III.

### **Pre-Procedure Assessment**

It includes confirmation of gestational age by LMP, per-abdominal, per-vaginal examination and ultrasound; patients' history; identification of comorbidities; general physical examination; informed consent; and essential investigations (haemogram, urine routine examination, blood group). Pre anaesthetic check up is mandatory as patient may require hysterotomy. Contraception counselling is necessary.

Additional recommendations: inpatient care; prophylactic antibiotics to be given to all before performing any surgical procedure<sup>1</sup> and injection Anti D (300micrograms) to be given to all Rh negative women immediately after abortion or within 72 hours.

## Different Methods of Second Trimester Pregnancy Termination

#### I. Medical Methods of Abortion (MMA)

Use of mifepristone and misoprostol is presently not an approved method of second trimester abortion by DCGI India. However *clinical practice handbook for safe abortion, WHO 2014 & the comprehensive abortion care training and service delivery guidelines(GOI)* recommend it as a safe and effective method of termination of second trimester pregnancies.

Before starting the medical method written informed consent specifically stating need for surgical method including hysterotomy should be taken

**Gestation limit:** 12-20 weeks, upper limit will be increased from 20 weeks to 24 weeks for special categories of women once MTP Act 2021 comes into force.

Misoprostol: is a synthetic analogue of Prostaglandin E1, and causes myometrial contractions by interacting with C specific receptors on myometrial cells. It causes cervical ripening by decreasing total collagen content, increasing collagen solubility and increasing collagenolytic activity. This results in the expulsion of uterine contents. It can be given by different routes i.e. sublingual; oral; vaginal; rectal. Following oral administration, plasma misoprostol level increases rapidly achieving peak values at 30 minutes and decline rapidly by 120 minutes remaining low thereafter. While the vaginal application of misoprostol results in slower gradual increase, attaining maximum concentration at 70-80 minutes with values detectable even after 6 hours.

*Mifepristone:* is a synthetic steroid (an antiprogestin RU 486) and a Progesterone Receptor Modulator. *In early pregnancy, it causes decidual breakdown by blockade of uterine progesterone receptors, which leads to detachment of blastocyst resulting in decrease in HCG production. This in turn decreases the progesterone secretion from the corpus luteum which further accentuates decidual breakdown.* It also has both antiglucocorticoid and anti-androgenic actions. Peak plasma concentration is attained 90 minutes after oral administration; t1/2 is 20-40 minutes. It is metabolised in the liver.

*Teratogenicity:* includes Sirenomelia, Mobius and Poland syndrome and various limb abnormalities. *Mifepristone & Misoprostol regime (WHO Regime* 2014; 98% effective)

200 mg oral mifepristone followed 36–48 hours by 400 mcg misoprostol orally. If no effect 400mcg misoprostol vaginal or sublingual repeated every three hours, upto five doses (including the first dose) OR

200mg oral mifepristone followed 36-48 hours later by 800 mcg misoprostol vaginally. If no effect after 12 hours 400mcg misoprostol vaginal or sublingual repeated every three hours, upto five doses (including the first dose)

#### Misoprostol alone regime (WHO Regime 2014;75-90% effective)

Misoprostol is used for cervical priming as well as inducing uterine contractions; 400mcg, vaginal or sublingual, every 3 hours, upto5 doses.

#### FIGO 2017 regime

*For 13-20 weeks gestation:* misoprostol 400mcg vaginal/buccal/sublingual every 3 hours upto 5 doses (cervical priming with mifepristone preffered if available)

During the MMA process, placenta should be expelled within two hours of foetal expulsion. If the placenta remains in the uterus, one of the following options is used: Sublingual/buccal/ rectal misoprostol, 400mcg *OR* high doses oxytocin regimen for two hours, such as 20 units in 500ml normal saline, run at 50ml/hr intravenous.

Pain can be relieved with ibuprofen 400mg to all women undergoing the termination with medical methods with the first dose of misoprostol and then subsequently every six to eight hours. Paracetamol is not effective for pain relief during the process of MMA. Contraindications of medical methods: are Anemia (haemoglobin <8 gm%); Uncontrolled hypertension with BP >160/100 mmHg; Cardiovascular diseases such as angina, valvular disease and arrhythmia; Coagulopathy or women on anticoagulant therapy; Chronic adrenal failure or current long term use of systemic corticosteroids; Severe renal, liver or respiratory disease; Uncontrolled seizure disorder; Inherited porphyria; Allergy or intolerance to mifepristone or misoprostol or other prostaglandins.

#### II. Surgical Methods of Abortion

#### Dilatation & Evacuation

It is a safe and effective surgical technique for late gestation and where skilled experienced providers are available. Not commonly used method in India. D & E requires preparing and dilating the cervix and evacuating the uterus using vacuum aspiration and ovum/sponge holding forceps.

Gestation limit: It can be safely done upto 13-16 weeks, Efficacy is 98% (For pregnancy termination between 16-20 weeks surgical procedure should be done under USG guidance)

Cervical Preparation/Dilatation is recommended for all women undergoing the termination of pregnancy over 12-14 weeks as it decreases the risk of cervical injury and uterine perforation. Methods used for priming are- Misoprostol: 400 microgram to be given vaginally/sublingually 3-4 hours before the procedure (1 additional dose of 400 microgram can also be given). Laminaria tent: It is not easily available. It can lead to infection particularly if introduced without proper care and left in cervix for too long. They are made up of hygroscopic materials, which swell up by absorbing cervical and vaginal secretions and gradually dilate and soften the cervix and also stimulate uterine contractions. Gradual dilatation by graded metal/plastic dilators: this is not a recommended procedure for cervical dilatation and should only be done in absence of other techniques.

*Evacuation:* is done after achieving the desired level of cervical dilatation by one of the above methods. Uterine suction evacuation is usually done with 12, 14 or 16 mm cannula.

Additional uterotonics agents are given in case of incomplete evacuation: Misoprostol 400-600 micrograms orally or sublingual, or

Prostaglandins, PGF2 alpha 250 micrograms intramuscular, or Injection oxytocin 20 units in 500ml NS or RL at 50 ml/hr.

*Hysterotomy:* It is opted for in cases of failure with other methods or in presence of other associated gynaecological conditions.

#### III. Miscellaneous Methods

Few agents are used to stimulate uterine contractions but available data regarding their safety is limited. These agents include (i) hyperosmolar urea injected intra-amniotically or extra-amniotically (ii) prostaglandins analogues administered parenterally or intra- or extraamniotically. But these are no longer used because of risk of prolonged duration of abortion and risk of infection while the currently used agents like misoprostol are more effective with lesser duration of abortion procedure.

Ethacridine lactate: Extra amniotic instillation of Ethacridine lactate has a direct oxytocin effect on the myometrium and is highly safe with efficacy of around 95%. It is contraindicated in women with renal disease and low lying placenta. 10ml/ weeks of gestation is instilled with maximum dose of 150ml. Under aseptic precautions, a foley's catheter 14-16 F is inserted intracerviacally, 2.5 cm beyond the internal os and inflated with 30cc distilled water or normal saline. The required quantity of dye is injected with a syringe and catheter is clamped. After six hours, an oxytocin drip is started at 10 units in 500ml and is titrated according to uterine contractions. Once the cervix is 5-6 cms dilated, foetus is usually expelled followed by placenta and membranes. Antibiotics coverage and vital monitoring has to be done regularly during the whole procedure. If termination fails once, ethacridine lactate can be instilled again after 24 hours. If it fails twice, surgical method is considered.

### **Special Circumstances**

- Uterine anomaly (uterine septa; bicornuate uterus; uterus didelphys – Medical method is preferred. Surgical evacuation if needed should be done under ultrasound guidance.
- 2. Prior uterine scar- Misoprostol is not an absolute contraindication but in a systematic review, the risk of uterine rupture among women with prior caesarean delivery with misoprostol was 0.28% whereas the risk in women without prior caesarean was 0.04%. Uterine rupture risk

increases with the number of prior uterine scar, advancing gestational age, increasing gravidity and uterine anomalies.

- Placental localisation should always be done before planning the abortion procedure so as to rule out placenta previa, scar site pregnancy or placenta accreta spectrum.
- Different methods for abortion in case of prior uterine scar include: use of mifepristone only, 200mg 8 hourly upto 6 doses; Foleys induction followed by oxytocin augmentation with upto 16 mIU/min, titrated according to uterine contraction; Cervical ripening with mifepristone followed by cerviprime; or Hysterotomy, if the above methods fail.
- 3. Multifetal gestation- It is managed in the same way as singleton pregnancy, though patients might confront a higher risk of uterine atony and hemorrhage due to greater uterine size.

### Important Points to be Followed in Case of MTP in Women with Various Medical Conditions

*Heart Disease*: Termination of pregnancy should be performed in hospital where all emergency support services are available.

- Multidisciplinary team should include the cardiologist, an anaesthesiologist, and the obstetrician.
- Proper counselling about risk to mother should be explained and informed consent taken.
- Incidence of post abortal endometritis is 5-20% in women who haven't received endocarditis prophylaxis; therefore peri abortal antibiotics should be given.

Abortion by hysterotomy is preferred in the second trimester. Medical abortion with mifepristone and misoprostol can also be done. Both mifepristone and misoprostol have minimal cardiovascular effects. But procedure is prolonged and close monitoring is required.

*Hypertension*: avoid use of ergometrine for the treatment of postabortal atony and bleeding.

*Seizure Disorder*: usual dose of antiepileptic to be taken on the day of abortion.

Anaemia: haemoglobin should be at least 8 gm% for MTP. If haemoglobin is less than 7 gm%, then MTP should be done after blood transfusion or if 3 weeks delay is feasible IV iron can be given. *Diabetes*: blood sugar values should be monitored strictly and maintained in the normal range during the process to avoid ketoacidosis.

Asthma: PGE2 and PGE1 can be used.

#### **Complications & Management**

*Excessive haemorrhage*: Bleeding may result from uterine atony, retained products of conception, perforation or cervical laceration. Lacerations may occur during cervical dilation or cervical injury during foetal passage.

*Uterine Perforation:* should be suspected if patient complaints of abnormal or excessive abdominal pain; has tachycardia, hypotension, Shock, abdominal distension, shoulder pain, nausea or vomiting, or abdominal x ray shows air in the abdomen.

Resuscitate with intravenous fluids, blood and antibiotics; check haematocrit and arrange adequate blood products; complete the evacuation under direct visualization, laparoscopic guidance if perforation is by dilator or ovum forceps, otherwise do laparotomy and assess damage to pelvic organs; repair the defect with complete bowel exploration to rule out bowel injury; monitor the patient postoperatively.

Infection and Sepsis: Infection in women can be caused by micro-organisms introduced into the cervix and uterus or more commonly by bacteria growing in retained foetal or placental products. Patient may present with septic shock. Patient is stabilised with IV fluids, blood, vasopressors and broad-spectrum antibiotics, followed by evacuation of the uterus for retained products of conception. *Anaesthesia Complication:* Rarely a woman may have anaesthetic complication due to anaesthesia used during the procedure.

#### **Postabortal Contraception**

A woman should wait at least 6 months before trying to conceive again as it reduces the chances of low birth weight baby, premature birth and maternal anaemia. Fertility returns within 2 to 3 weeks after a second trimester abortion or miscarriage.

WHO Medical Eligibility Criteria for Contraception in Second Trimester Abortion

Condition	COCs	POCs	DMPA	Implants	Barrier	IUCD	FAM
					Method		
Second	1	1	1	1	1	2	1
trimester							
MTP							

All these contraceptive methods can be used immediately after the abortion procedures.

Female Sterilisation: Laparoscopic ligation should not to be done after second trimester abortion because there are chances of injury to the fallopian tubes as the tubes are oedematous and possibility exists of slipping of the rings from the tubes or cutting the tubes, leading to the failure of the tubal ligation procedure.

#### **Suggested Reading**

- 1. Comprehensive Abortion Care (Training And Services Delivery Guidelines) *Second Edition* 2018 Mininstry of Health and Family Welfare Government of India
- Provider's Manual. Comprehensive Abortion Care 2014. Ministry of Health and Family Welfare Government of India
- 3. Safe Abortion: Technical And Policy guidance for health Systems Second Edition World Health Organization 2012
- 4. Comprehensive Abortion Care (Training And Services Delivery Guidelines) 2010 Ministry of Health And Family Welfare Government of India

## Contraception after Medical Termination of Pregnancy

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Post abortion family planning is the use of contraception or other family planning methods while managing abortion or before return of fertility following an abortion. In India, abortions account for 8% of maternal mortality in of which 90% of deaths are due to unsafe abortions.<sup>1</sup> Post abortion contraceptives can prevent unintended pregnancies and save women from morbidity and mortality caused by abortion associated complications.

All contraceptive methods should be offered immediately after or during an abortion as 83% of women ovulate within 8 days or at first cycle following an abortion.<sup>2</sup> Apart from this it was found that more than 50% of women are sexually active within 2 weeks after an abortion which can lead to unintended pregnancies.<sup>3</sup>

Women have been shown to be most motivated for contraception immediately after an abortion. Also, many women do not return for follow-ups following an abortion. Hence counselling in post abortive period plays a major role. Women should be counselled that a safe and induced abortion will have no impact in future fertility and there is no difference in return of fertility after medical or surgical abortion. Both partners should have full involvement in the decision making of any intervention in abortion.

#### **First Trimester**

Oral pills- According to WHO MEC (medical eligibility criteria for contraceptive use), combined hormonal contraception (pills, patch and ring) and progestin only pills (POP) can be started immediately after an abortion or on the same day as the abortion. Studies have shown that immediate start following medical or surgical first trimester abortion does not affect the outcome of the abortion or duration of post abortion bleeding.<sup>4</sup> However it will effectively prevent ovulation in the next cycle and hence decrease the risk of another unintended pregnancy. Also it is estimated to reduce vaginal bleeding, shorten recovery period for menstruation, reduce risk of complications and increase endometrial thickness 2 to 3 weeks after abortion.<sup>5</sup> Hence combined pills and progesterone only pills can be started on day 3

(misoprostol day) of a medical abortion but within 5 days of post abortion to avoid need for back up barrier methods. If started later, an additional barrier method should be used for 7 days with COC and for 2 days with POP.<sup>6</sup>

Use of combined vaginal contraceptive ring immediately after first-trimester medical or surgical abortion was not associated with any serious adverse effects or infections during three cycles of post abortion follow-up. However hormonal uptake in vaginal epithelium may be reduced due to heavy bleeding.<sup>7</sup>

*Centchroman (ormeloxifene)*- marketed as Saheli or chhaya is a non-steroidal, non-hormonal oral contraceptive drug. It is found to be quite effective contraceptive and favourable to women due to its weekly dosing schedule. It has been recommended after abortion since it is non hormonal and hence has no side effects.<sup>8</sup> It can be started immediately after a first trimester surgical abortion and on 3<sup>rd</sup> day after a medical abortion.<sup>1</sup>

Long acting reversible contraception (LARC) such as intrauterine contraceptive device (IUD) and implants are found to be highly effective in post abortal contraception. It is especially beneficial for women who have lower compliance with daily pill regimen. According to WHO MEC category for IUD insertion following first trimester abortion is MEC 1 provided there is no evidence of infection. Insertion should not be delayed as women may not return for the scheduled insertion. Infection should be ruled out before insertion and in case of medical abortion it is advised to be inserted on day 15 so that it is confirmed that abortion process is complete<sup>1</sup> or it can be inserted within 7 days of abortion if completion confirmed by ultrasound. Since medical abortion may take longer to complete (and if there is doubt about completeness of abortion), it is better to use COC or condom and insert IUD in next menstrual cycle. Expulsion rates are not increased if the IUD insertion is done at one week following the medical abortion versus at 3-4 weeks follow-up. Earlier insertion of the LNG-IUD was found to reduce bleeding after medical abortion.9 Hence IUD was

found to be highly effective in women of young age who require long term contraception.

Implants can be inserted soon after abortion or during first two weeks following medical abortion. In a study conducted for comparison of outcome between immediate and delayed insertion showed no difference in complications among the two. However immediate insertion led to higher rates of implant insertion as fewer women came on scheduled days for follow up insertion and hence had reduced risk of unintended pregnancy and abortion in subsequent 6 months.<sup>8</sup>

Injectable contraceptives DMPA or Progestogen-only injection- can be started on the day of misoprostol administration (day 3) or soon after abortion<sup>1</sup>. Studies have shown that DMPA is safe and effective following spontaneous or surgical abortion firsttrimester<sup>10</sup> but still further evidence is needed. If the first injection is delayed for more than 7 days, then additional contraceptives (barriers or condoms) need to be used.<sup>1</sup> There is no study yet to recommend DMPA at the time of mifepristone administration. Also since mifepristone is a progesterone receptor antagonist which binds with high affinity to the progesterone receptor it may interact with the progestin in the DMPA hence not recommended.<sup>2</sup>

#### **Barrier Methods**

Male and female condoms both can be used immediately after abortion, unless contraindicated. Sponges and diaphragms are not recommended to be used soon after abortion because of presence of vaginal bleeding, and fitting may change following an abortion. Their use is recommended 6 weeks after abortion.

#### **Permanent Sterilization**

According to Royal College of Obstetrics and Gynaecology (RCOG) there is higher failure rate of sterilization when performed at the time of abortion and RCOG medicolegal committee recommends against it.<sup>11</sup> Women who wish to have concurrent sterilization still, are advised for surgical evacuation over medical abortion. For women opting for medical abortion it is better to do tubal sterilization done after next cycle and until then she is advised to use alternative methods. However according to Govt. of India guidelines post abortion female sterilization can be performed through minilap tubectomy procedure as well as laparoscopic procedures concurrently or within 7 days after first trimester abortion.<sup>1</sup>

#### **Second Trimester**

According to WHO, combined oral pills can be started immediately after a second trimester abortion. However in pregnancy risk of venous thromboembolism increases with gestational age and is around twofold during the second trimester of pregnancy and abortion. Therefore immediate start of COC requires careful balance of risks and benefits after second trimester abortion.

Centchroman is safe and effective and can be immediately started after a second trimester abortion.<sup>1</sup> If there is delay for more than 7 days, backup contraception is required.

IUD when inserted immediately after a second trimester abortion carries higher risk of expulsion and risks increases with gestational age and uterine size. However, this risk may be compensated by the advantage of immediate insertion as these women may not turn up on scheduled follow up. There are no definitive studies of IUD insertion following second trimester medical abortion. Besides, infection has to be ruled out before IUD insertion.

According to WHO, diaphragm or cervical cap after a second trimester abortion have high rate of expulsion. Hence, it is recommended to be used six weeks after abortion.<sup>12</sup>

Injectible contraceptives like DMPA can be used immediately after a second trimester abortion. Delay of more than 7 days will require additional backup method.<sup>1</sup>

Permanent tubal sterilization can be done after second trimester abortion. However Laparoscopic tubal occlusion is not recommended after second trimester abortion in view of risk of injury to adjacent structures like uterus and tubes.<sup>1</sup>

Post-	CHC	POP	DMPA	Implant	IUD-	IUS	TL
abortion	(Oral,			(ETG)	Cu	-LNG	
	vaginal,						
	Patch)						
1st	1	1	1	1	1	1	1
trimester							
2nd	1	1	1	1	2	2	1
trimester							

## WHO Medical Eligibility Criteria for Contraceptive Use after Abortion

1-condition with no restriction in use of contraceptive method, 2- condition in which advantage of using contraceptive method outweighs the theoretical or proven risks

### Conclusion

Abortions, spontaneous or safely induced have no impact on future fertility. Women should be offered all types of contraception and counselling at the time of abortion, as motivation among women for contraception use is highest immediately after the abortion. Counselling plays a major role in preventing complications associated with unsafe abortions. Immediate start of LARC which includes IUD and implants have been found to be most effective in preventing unintended pregnancies following an abortion. However, choice of contraception should be decided by her in consultation with the treating physician based on condition of the woman and her choice.

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## Self-Administration of Abortion Pills and Their Implications

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#### Abstract

Objective: To evaluate the effect of unauthorized self-medication of over the counter (OTC) abortion pills. Methods: This was a prospective observational study done over a period of six months on a total of 300 women of 15 to 49 years' age group who presented to the Gynaecology emergency and outpatient clinic of a tertiary care centre situated in North India. The demographic features of the participants, acquisition methods for the medicine, need for the drug acquisition, gestational age at drug intake, the time interval between the drug intake and first presentation to the hospital, the presenting complaints, and the final interventions were noted for analysis. Results: The majority of the women were multiparous (88%). Most of them presented within 14 days of drug intake. Almost all of the women procured these pills OTC from nearby pharmacies without a valid prescription. A maximum number of women took the pills between 7-9 weeks (48.8%). Unprotected intercourse and unplanned pregnancy were common reasons for intake of these pills. 7.7% of women presented with hemorrhagic shock, 2% with sepsis, 13% required blood transfusion, 0.7% were admitted in ICU, and 71.4% required additional medical or surgical interventions. Laparotomy for ruptured ectopic pregnancy was done for 5% women. There was one (0.3%) maternal death. Main outcomes were need for additional medical measures or surgical interventions, need for blood transfusion, development of sepsis, maternal morbidity, or mortality. Data was analyzed by using SPSS software 21.0. Conclusion: Unauthorized self-medication of over the counter (OTC) abortion pills is hazardous to the women's health. The use of regular contraception should be encouraged in women of reproductive age group and availability of safe abortion services should be ensured.

**Keywords:** Over-The-Counter, medical abortion, self-medication, MTP pill, abortion pill, MTP

#### Introduction

Globally one-tenth of women who die annually from unsafe abortion belong to developing countries.<sup>1</sup> In

India, 67% of abortions are unsafe abortions and every year seven million women need hospitalization for the same.<sup>2</sup> Unsafe abortion practices bring huge financial and health burden to a nation.

The World Health Organization (WHO) defines Medical abortion as 'the usage of pharmacological drugs to terminate a pregnancy'. It further defines unsafe abortion as a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking minimal medical standards or both.<sup>3</sup>

Medical termination of pregnancy (MTP) was legalized in India by an act passed by the Indian Parliament in 1971, which also laid down certain regulations and pre-requisites for medically terminating a pregnancy. The MTP Act, allows prescription and administration of Mifepristone and Misoprostol only by a gynaecologist or a registered medical practitioner and up to 49 days since the first day of the Last Menstrual Period (LMP).<sup>4</sup> The WHO and GOI along with Federation of Obstetrician and Gynaecologists Societies of India (FOGSI) have formulated guidelines mandating preabortion work up in a woman seeking a medical abortion. WHO recommends medical abortion up to 63 days from the first day of the LMP.<sup>5</sup> USFDA and Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services has approved Anti-progesterone Mifepristone (RU486) and prostaglandin Misoprostol for medical abortion up to 63 days. In optimal settings and safe hands, the success rates of medical abortion may reach up to 93-98%.<sup>6,7</sup>

Despite the availability of such clear guidelines on the implementation of safe abortion practices, the Over-The-Counter (OTC) availability of abortion pills in India has led hundreds of Indian women to consume these drugs without a valid prescription. Their use is so pervasive that some women would even consider this as a method for birth spacing.<sup>8</sup> This study aimed to evaluate the implications of this very self-administration of abortion pills in Indian women.

#### **Materials and Methods**

In a prospective observational study done over 6 months' period, 300 gravid women of the reproductive age group (15 to 49 years) who presented to the Gynaecology emergency or outpatient clinic with a history of self-administration of abortion pills were recruited. 'Self-administration' was defined as 'unsupervised intake of abortion pills by the woman herself, which was procured OTC without a valid prescription. Exclusion criteria were supervised prescribed intake of medical abortion drugs.

Demographic profiles (age, marital status), obstetric parameters (parity), drug acquisition source, the reason for drug administration, the time interval between drug intake and presentation to the hospital, gestational age at administration, the drug regimen consumed by the woman, and presenting complaints were recorded. Primary outcomes were need for additional medical measures and surgical interventions. Secondary outcomes were the need for blood transfusion, development of sepsis, maternal morbidity, or mortality. Data was entered in Microsoft excel and analyzed by using SPSS software 21.0.

#### **Results**

A total of 300 women were recruited. More than one third of women (39%) belonged to 20-25 years of age followed by 20-30 years and 30-35 years, 33% and 16% respectively. Majority of women were married and only 12% were unmarried. Most of them had at least one living child (88%), Table 1.

Table 1: Age and Parity of Women in Stud
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	Number (n)	Percentage (%)			
Age (years) distribution of the women					
≤19 years	15	5			
20-25	117	39			
26-30	99	33			
31-35	48	16			
>36	21	7			
Parity of women	` 				
Nullipara	36	12			
Multipara	264	88			

Lack of regular contraception was the most common reason for drug acquisition and intake. The majority of the pills were procured by the woman's partner followed by self-procurement, 80.1%, and 12% respectively. In all cases, pills were brought OTC from the local pharmacies. The most common gestational age of drug intake was between 7 to 9 weeks (48.8%). The most common period for presentation to the hospital was 1-2 weeks after the drug intake (35%), Table 2.

Table	2:	Cause	of	Drug	Intake,	Source	of	Acquisition,
Gestati	ona	al Age a	at D	rug In	take, and	d Time Ir	nter	val between
Drug In	ıtak	ke and F	res	entatio	on to hos	pital		

Parameters	Number (n)	Percentage (%)				
Reason for drug intake						
Family or social pressure	6	2				
Conceived during lactational amenorrhea	75	25				
Failure to use emergency contraception	103	34.3				
Lack of regular contraception	116	38.7				
Source of acquisition						
Self	36	12				
Relative	24	7.9				
Partner	240	80.1				
Gestational age at drug intake						
<7 weeks	75	25				
7-9 weeks	146	48.8				
9-12 weeks	64	21.2				
>12 weeks	15	5				
Time interval between drug intake and presentation to hospital						
< 1 week	66	22				
1-2 week	105	35				
2-3 weeks	84	28				
3-4 weeks	27	9				
>4 weeks	18	6				

85.9% of the women presented with bleeding per vaginum. Sepsis was evident in 2% of the women. One third (32.7%) of women had additional medical abortion pills in the form of Misoprostol or Mifepristone. 38.7% of the women who had failed medical abortion required an additional surgical evacuation of the retained products. 5% of women were diagnosed with ectopic pregnancy and underwent laparotomy. One of these women had chronic ruptured ectopic pregnancy with dense bowel adhesions requiring difficult dissection. 7.7 % of women presented with hemorrhagic shock and 0.7 % developed multi-organ failure requiring Intensive Care Unit (ICU) care. There was one maternal death secondary to septic shock (0.3%), Table 3.

Parameters	Number (n)	Percentage (%)
<b>Clinical features at presentation</b>	้า	
Bleeding per vaginum	258	85.9
Pain abdomen	12	4
Fainting attacks	12	4
Severe pallor	12	4.1
Signs and symptoms of sepsis	6	2
Interventions		
Additional medical methods (misoprostol/mifepristone) required	98	32.7
Failed medical method needing dilation and evacuation or suction evacuation of the retained products	116	38.7
Ectopic pregnancy requiring laparotomy	15	5
Haemorrhagic shock /severe anaemia requiring blood transfusion	23	7.7
Blood transfusion given overall	39	13
Sepsis	6	2
Intensive care unit admission	2	0.7
Maternal death	1	0.3

**Table 3:** Clinical Features at Presentation and VariousInterventions Undertaken

### Discussion

Unsafe abortion is defined as the termination of pregnancy which is self-induced/performed by a person/institute devoid of requisite expertise or which is performed in an environment not fulfilling a basic minimum medical standard or both.

The MTP act of India, allows only a gynaecologist or a registered medical practitioner to prescribe abortion pills to a woman seeking termination of pregnancy on grounds that the continuation of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to physical or mental health and/or there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.<sup>4</sup> It also mandates maintaining the anonymity of the woman undergoing MTP.

Ministry of Health & Family Welfare, Government of India gives clear directives on evaluating the women for a basic pre-abortion work-up. These women should be mentally sound and should be ready to follow up on at least three occasions. A woman who is undergoing medical abortion must understand the risks and benefits associated with the procedure. She must be thoroughly counselled regarding the warning signs and asked to seek urgent care when the need arises. However, when a patient self-procures and consumes these drugs, she misses on these important aspects and may land in a hazardous health situation. The MTP act was called into action to bring checks to the rising number of unsafe and criminal abortions and to reduce severe maternal morbidity and maternal mortality in India. However, despite the act in place and its amendments from time to time, the rate of unsafe abortions in India is still on the rise. A most important factor to this rise is the OTC availability of abortion pills. Other contributing factors may include ignorance of the women towards contraceptive choices, illiteracy, and a desire to maintain secrecy about abortion.

A total of 300 patients presented to us with a history of self-administered abortion pill intake during six months study period. That makes a monthly average of 50 women. These figures are alarming. According to Singh S et al. the actual number of data on selfprescribed consumption of abortion pills might be extremely high secondary to non-reporting of such cases.<sup>9</sup> The authors further reported that among 48.1% of pregnancies which were studied, the rate of abortion was 47 for every one thousand pregnancies in women of 15 to 49 years' age group. The unintended pregnancy rate per thousand women was 70.1%. Among 81% of medical abortions, 90% were done outside the health care facility.

It is reported that women from all backgrounds whether rural or urban self-administer abortion pills from time to time.<sup>10,11</sup>

In our study, self-administered abortion pill intake was more common in multigravidae (88%). This was in line with the findings of Sarojini et al.<sup>12</sup> The most common presenting complaints in our study were bleeding per vaginum and pain abdomen. This was also similar to that reported by other authors.<sup>12,13</sup>

Most of the abortion pills were acquired by the women's partner. Kumar et al. found that partner advice on consuming medical abortion drug intake is very common in India.<sup>14</sup> Local pharmacies were the main source of drug procurement. This was similar to the reports from previous studies.<sup>10,15,16</sup> Incomplete information about the drug regimen from such pharmacies led to improper drug intake at the wrong gestational age and late presentation to hospitals in the majority of the women. 48.8 % of

the women consumed pills at the wrong gestational age. Such a high percentage of improper drug intake was also reported by Nivedita et al. (75%) and Aggarwal et al. (60%).<sup>11,15</sup>

Many women developed severe morbidity and one of these died. Additional medical methods for abortion were required in 32.7% of the women. Medical management failed in 38.7% of women where surgical evacuation of products of conception had to be done. 5% of women were diagnosed with ectopic pregnancy. Attempts to confirm an intrauterine pregnancy before attempting medical abortion were not carried out in any of these women. 13 % of women required blood transfusion, 0.7 % of women required ICU care, and 2 % of women developed sepsis. Our findings were in line with those reported by Sukhwinder et al. and Rajal et al. The latter also reported one maternal mortality after a ruptured ectopic pregnancy.<sup>8,9</sup> Sarojini et al. reported 2 maternal mortalities. One was due to irreversible hemorrhagic shock and the other was secondary to septicemia after self-administered abortion pill.<sup>12</sup> The results of these study along with the present study clearly indicates untoward outcomes of self-administered abortion pills.

Limitations of our study included small sample size and the nature of the study design. More research into this topic might further aid in highlighting the adverse implications of OTC availability of abortion pills and their wides pread unsupervised consumption by women with unintended pregnancies.

#### Conclusion

Self-medication with abortion pills may have dire consequences to a woman's health. Regulatory authorities should formulate and implement strict laws against the OTC availability of these drugs. These should be made available only through health care facilities and administered only under medical supervision. A thorough pre-abortion work-up of the woman should be mandatory to rule out an ectopic or a molar pregnancy. Health care providers should propagate the benefits of regular contraceptive use to all sexually active women in the reproductive age group and make them aware of the emergency contraception pill and safe abortion services.

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## Awareness and Practice of LNG Only Emergency Contraceptive Pill Among Women Undergoing Medical Termination of Unwanted Pregnancy

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#### Abstract

Objective: To find the awareness and practice of LNG only emergency contraceptive pill among women attending a tertiary care hospital for termination of pregnancy. Material and Methods: A cross-sectional study conducted in the Obstetrics and Gynaecology department of Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi on 240 women attending family welfare outpatient department for medical termination of pregnancy. A self-administered open-ended and multiple response questionnaire was provided and the responses regarding demographic information, previous abortions, use of regular contraception and the awareness of emergency contraception were collected. Results: Majority of these women were between 18-30 years of age, had previous live issues and belonged to lower socio-economic class. 82.1% of them never used any kind of contraceptives and 94% had an unplanned and unwanted pregnancy. 90% women had lack of knowledge regarding LNG ECP, remaining 10% knew about it through TV or friends but didn't use it. Significant factors associated with knowledge regarding LNG ECP were educational status of both partners, profession of the woman and past usage of contraceptive. Majority of them chose one of the offered contraceptives for future use. Conclusion: Most of the women attending hospital for medical termination of pregnancy, were unaware of emergency contraception and those who knew, did not use it.

**Keywords:** MTP, Emergency contraception, EC, post coital pill, LNG pill, Abortion

#### Introduction

An unwanted or unplanned pregnancy has its own impact on physical and mental well-being of a woman. Abortion plays a crucial role in the reproductive health of Indian women. The standard practice norms are set by the Medical Termination of Pregnancy Act in 1971, still many women turn to unqualified persons which endangers the maternal health. A study by Yokoe R et al. showed 4.8% pregnant women hade abortion during 2007-2011, of which 67.1% had unsafe abortion and 0.3% maternal death were related to this.<sup>1</sup> They also reported that the abortion rate is higher in younger age group.

The burden of unwanted pregnancy and unsafe abortion can be reduced by educating the women and make them aware about availability and use of regular and emergency contraception (EC). EC is intended for emergency use following unprotected intercourse, contraceptive failure or misuse (such as forgotten pills or torn condoms), rape or coerced sex. WHO and Government of India recommend levonorgestrel pill for emergency contraception.

Levonorgestrel-only Emergency Contraceptive Pills (LNG-only ECPs) are available in India since 2001. It was introduced under Family Welfare Programme during 2002-03 and over-the-counter access to LNGonly ECPs was approved in 2005.<sup>2</sup> LNG-only ECPs are the hormonal contraceptives that provide women a chance to prevent unwanted pregnancy after unprotected intercourse. 1.5 mg of levonorgestrel taken within 72-120 hours of coitus can prevent pregnancy in cases of unprotected intercourse or mishaps during regular contraception. The failure rate is 1%. ECP has been included in the ASHA kits to address the issue of unwanted pregnancy at the community level. Emergency contraceptive are described as cost-effective form of "contraceptive first aid".3

Open discussions on media about the availability and safety of ECP have been a major source of awareness among the general population. A study done in 2016 concluded that there is lack of awareness and certain misconceptions about the use of EC even among the gynecologists, which has resulted in underutilization of EC.<sup>4</sup>

This study was conducted to evaluate and awareness regarding availability and usage of LNG ECP in these women, know about their attitude and practice of this method of contraception.

### **Material and Methods**

A cross-sectional study conducted in the Obstetrics and Gynaecology department of Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi on 240 women attending family welfare outpatient department for medical termination of pregnancy. Women undergoing MTP for medical reasons and due to congenital malformations in the foetus were excluded from the study. A self-administered open-ended and multiple response questionnaire was provided to the women who came to the Family Welfare Out Patient Department for Medical Termination of Pregnancy (MTP) and were willing to participate in the study. The responses were noted and data regarding demographic information, previous abortions, use of regular contraception and the awareness of emergency contraception were collected. The different methods of contraception accepted post abortion by the MTP cases were also recorded.

## **Statistical Analysis**

The data analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage (%). Chi square test was applied to find out the association between factors. P value of <0.05 is taken as significant.

### **Results**

Out of 240 women included in the study, 92% were less than 30 years of age. Majority (92.2%) were multigravida and had previous abortion (87.5%), Table 1. Most of the participants had never used any contraception (82.1%). Of the contraceptive users most common method used was barrier contraception (53%). Contraception failure was the reason for MTP in only 6.25% women and 50% of these women were using barrier contraception.

Table 1: Demographic characteristics of study population

Demographic characteristics	Percentage	
	Number (N=240)	(%)
Age (Years)		
18-30	221	92
>30	19	8
Religion		
Hindu	203	84.6
Non-hindu	37	15.4
Gravida		
Primigravida	18	7.8
Multigravida	222	92.2
Previous history of abortion		
Present	30	12.5
Absent	210	87.5
Live issue		
Present	214	89.2
No live issue	26	10.8
Socio-economic status		
Lower class	172	71.7
Upper/middle class	68	28.3
Education of the woman		
Illiterate	165	68.8
12 <sup>th</sup> pass	19	8
Graduate	4	0.2
Postgraduate	52	22
Education of the husband		
Illiterate	168	70
12 <sup>th</sup> pass	37	15.4
Graduate	8	3.3
Postgraduate	27	11.3
Profession of the woman		
Housewife	209	87.1
Semiskilled	0	0
Skilled	6	2.5
	25	10.4

The most common source of information regarding LNG-ECP was Television, Table 2.

Table 2: Source of knowledge regarding LNG ECP

Source of knowledge	Number (N=240)	Percentage (%)
No knowledge	218	90.84
Through television but not used	13	5.41
Through friends but not used	6	2.5
Through doctor but not used	3	1.25

Various factors significantly associated with the knowledge of LNG ECP were Education of women and her husband, profession of women and past use of contraception, Table 3.

These women were counselled regarding use of regular contraception after this abortion. Majority of women (89.2%) chose one of the offered methods of contraception. Most women had insertion of copper intrauterine device along with abortion.

<b>Table 3:</b> Association of different parameters with knowledge
of LNG ECP

Parameters	p value (<0.05 is significant)
Age	0.255
Religion	0.21
Gravida	0.507
Previous history of abortion	0.401
Live issue	0.868
Socio-economic status	0.197
Education of the woman	0.001
Education of husband	0.0012
Profession of woman	0.0012
Past use of contraception	0.007

#### Discussion

Unsafe abortion is a preventable cause of maternal morbidity and mortality. Medical termination of pregnancy is legal in India but still a large number of women have unsafe abortions. It sometimes is more difficult for the younger age group of women to seek MTP.

Emergency contraceptives are used when there is unprotected intercourse or inadequately protected intercourse. Of all the ECs available, LNG ECPs are safe, effective with limited side effects and are available over the counter. Their limited use in our country is a matter of concern. The present study was undertaken on 240 women presenting to hospital for medical termination of pregnancy, to find out the awareness and reason for non usage of LNG-ECP.

In few studies done to evaluate the knowledge, attitude and practice of EC among the gynaecologist, the lack of proper knowledge and misconception regarding the EC were prevalent even among this category of health care workers.<sup>4,5</sup> Although all the participants knew that LNG can be used as EC, 84% of them were not offering it routinely. The common concerns were that EC is not safe and it is a kind of abortion. Some had the apprehension that couples may discontinue regular contraception use if EC is easily available. A study done in Nepal among the community pharmacy practitioners showed that those with more than 10 years of experience had good knowledge regarding dispensing ECPs. Many of them thought that dispensing it without

prescription may increase sexual promiscuity, unsafe sex and repeated use.<sup>6</sup>

All pregnancies in our study group were unplanned and 94% were unwanted. Most women were below 30 years of age, multigravida, belonging from lower socio-economic class with no previous history of use of contraception. The major void was in the knowledge regarding availability, usage and benefits of emergency contraception, LNG ECPs in particular.

A study by Kumar R et al. in 2015 evaluated the knowledge, attitude and practice of emergency contraceptives among women of reproductive age in a district of north India. They found that 44.6% females of the study population had heard about EC pills and only 20% had ever used EC pills. Near about 41.9% shows positive attitude towards EC Pills, main source of information was mass/media.<sup>7</sup>

Another target population should be the adolescents and the teenage girls, who find it difficult to seek MTP when required and use of routine contraception is also not practiced in them. A study done in US showed that 82% pregnancies in girls aged 15-19 years of age are unplanned and unwanted.<sup>8</sup> The benefits of EC, in addition to preventing unintended pregnancy, also extend to related consequences of adolescent motherhood, including premature birth, stunted educational and vocational opportunities, decreased rates of high school completion, increased welfare dependence and future poverty rates, decreased psychological functioning, and decreased employment stability. If these girls are provided with the knowledge and taught about the right practice to use ECs it will give them a second chance to avoid unwanted pregnancies. However, in India use of EC among minors (<18 years of age) is not promoted due to the POCSO act.

A study by Rivet D et al. also showed that majority of participants were aware of emergency contraception, only 52% reported ever using it. Most participants (89%) planned to use contraception in the future.<sup>9</sup> So, motivating these women for regular contraception after MTP is important. Also, they should be made aware of emergency contraceptives as the last chance to prevent unwanted pregnancies.

In our study the women who knew about EC did not use it in the current pregnancy. Despite of advertisement in various media, easy availability in terms of OTC sale and free supply under Government of India, Family Welfare Programme, couple are not usig it. We need to strengthen the education and counselling programme for the couple, provide regular training to health care providers and reaching to the pharmacists to optimize the use of this beneficial tool. It should also be available in the basket of choice offered to a woman considering contraception.

#### Conclusion

Most women with unwanted pregnancies attending hospital for medical termination of pregnancy lack awareness about Levonorgestrel emergency contraceptive pill. The practice of LNG-ECP pill is also poor among these women.

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## **Journal Scan**

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## Salpingectomy Versus Tubal Ligation for Sterilization: A systematic review and metaanalysis

Kerry Mills, Greg Marchand Katelyn Sainz Ali Azadi, Kelly Ware, Janelle Vallejo Sienna Anderson, et al.

Am J Obstet Gynecol 2021 Mar;224(3):258-265.e4.

**Objective:** Following strong evidence and major organizations recommending salpingectomy over tubal ligation. A systematic review and metaanalysis was performed comparing the intraoperative attributes and complication rates associated with these two procedures.

**Data Sources:** PubMed, the Cochrane Library, EMBASE and clinical trials registries without time or language restrictions, were searched. The search was carried out in February 2020. Database searches revealed 74 potential studies, of which 11 were examined at the full-text level. Of these, six studies were included in the qualitative analysis and five studies were included in the meta-analysis.

**Study Eligibility Criteria:** Randomized controlled trials comparing salpingectomy with tubal ligation in women seeking sterilization were included. Studies that also had at least one outcome listed in the PICOTS were included. Articles were excluded if they did not meet the inclusion criteria or if data were not reported *and* the authors did not respond to inquiries.

**Study Appraisal and Synthesis Methods:** Abstracts and full-text articles were assessed by two authors independently using the blinded coding assignment function or EPPI-Reviewer 4. Conflicting selections were resolved by consensus. The quality of included studies was determined using the Cochrane Collaboration tool for assessing the risk of bias in randomized trials. Two authors independently assessed the risk of bias for each study; disagreements were resolved by consensus.

**Results:** There were few differences between the procedures, with no differences in most important clinical outcomes (AMH, blood loss, length of

hospital stay, pre- or post-operative complications, or wound infections). A single study reported a reduced rate of pregnancies with salpingectomy (RR = 0.22, 95% CI: 0.05, 1.02), but this did not reach statistical significance (p = 0.05).

**Conclusions:** Salpingectomy is as safe and efficacious as tubal ligation for sterilization, and may be preferred, where appropriate, to reduce the risk of ovarian cancer.

**Strengths and Limitations:** As stated, the quantity and quality of data comparing the 2 procedures limited the analysis. This resulted in the relatively small sample size of the included studies and the limited number of outcomes reported. Furthermore, although this study did not show many significant differences in the reported complications, one cannot rule out the possibility that a larger study may bring to light other adverse events that were not reported in the available literature. The main strength of this analysis is the novelty of the approach, because to the best of authors' knowledge, no previous authors had set out to compare these procedures with a formal analysis.

### **Contraception and Ectopic Pregnancy Risk: A prospective observational analysis**

#### Schultheis P, Montoya MN, Zhao Q, Archer J, Madden T, Peipert JF

Am J Obstet Gynecol. 2021 Feb;224(2):228-229.

**Objective:** To estimate the rates of ectopic pregnancy in women stratified by contraceptive method used and compare these rates to participants using no contraceptive method or condoms. Authors hypothesized that women using highly to moderately effective contraceptive methods (intrauterine device (IUD), implant, injectable contraception, and oral contraceptives (OCs), patch, or ring) would have a lower rate of ectopic pregnancy than women using no method or condoms.

**Study Design:** This is a secondary analysis of the Contraceptive CHOICE Project (CHOICE), a prospective cohort study of 9,256 participants,

who were provided the contraceptive method of their choice at no cost and followed for 2-3 years duration. Reported incident ectopic pregnancy during actual use of the contraceptive method was collected during follow-up telephone surveys. Authors estimated the incidence of ectopic pregnancy by each contraceptive method category: copper IUD, levonorgestrel IUD, implant, depot medroxyprogesterone acetate (DMPA), and one combined category consisting of OCs, contraceptive patch, and vaginal ring. The control or referent group included women using no method or condoms. Inclusion and exclusion criteria followed that of the CHOICE Project.<sup>1</sup> Percentage of ectopic pregnancies was calculated using number of ectopic pregnancies divided by number of pregnancies (intrauterine and ectopic, method specific) and multiplied by 100. Ectopic pregnancy rates per 1,000 womenyears were calculated using number of ectopic pregnancies divided by the total length of method use and multiplied by 1,000.<sup>2</sup> Cox proportional hazard models calculated the hazard ratio (HR) for ectopic pregnancy in each contraceptive method compared to no method or condoms.

Results: Participants provided 20,381 women-years of follow-up with 13 ectopic pregnancies identified. Follow-up rates were 93.5%, 84.1%, and 78.9% at 1, 2, and 3 years, respectively. Seven participants in the no contraception/barrier group had an incident ectopic pregnancy. There were 6 contraceptive users who reported an incident ectopic pregnancy; 4 levonorgestrel IUD users, one copper IUD user, and one OC user. Rates of ectopic pregnancy per 1,000 women-years were: no method/condoms 6.90; levonorgestrel IUD 0.50; copper IUD 0.46; OCs/ patch/ring 0.22; implant 0; and DMPA 0. Use of the levonorgestrel IUD (HR 0.06, 95% confidence interval (CI) 0.02 to 0.23), copper IUD (HR 0.08, CI 0.01 to 0.62), OCs/patch/ring (HR 0.04, CI 0.01 to 0.37) reduced the risk of ectopic pregnancy compared to no method/ condoms. Participants choosing implant and DMPA contraception had no reported ectopic pregnancies. Given the small number of ectopic events, authors reported only the unadjusted HR.

**Conclusion:** Women using the levonorgestrel IUD, copper IUD, DMPA, implant, and OCs/patch/ring had a significantly lower risk of ectopic pregnancy compared to women using no contraception or barrier methods of contraception.

**Strengths and Limitations:** The CHOICE Project is one of the largest prospective cohort

studies to investigate contraceptive use and ectopic pregnancy rates across multiple forms of contraception. This study covers a wider range of contraceptive methods than previous studies, and the forms of contraception included in this study are more contemporary than currently included in the prior literature. One limitation of this work is that the incidence of ectopic pregnancy was low across all methods. This is not unexpected with over 75% of the cohort using a highly effective method and having a low risk of contraceptive failure. Additionally, recall bias is a possible limitation in defining ectopic pregnancy by using telephone call follow-up surveys and patient self-report.

# Combined Hormonal Contraception and COVID-19

#### lñaki Lete

*Eur J Contracept Reprod Health Care 2021 Apr;26(2):128-131.* 

**Aim:** This article reviews the possibility of using combined hormonal contraception during the COVID-19 pandemic.

Methods: narrative review.

**Results:** The factors that protect women from the severity of the disease are analysed, as well as the risk factors for the use of this type of contraception, especially related to the increased risk of a thrombotic event in patients affected by the disease. Finally, the information available on the guidelines for action in patients with COVID-19 using combined hormonal contraception is collected.

**Conclusions:** We can continue to prescribe and use hormonal methods with EE.

**Comment:** Authors found no evidence of a possible increased risk of VTE in CHC users suffering from COVID-19. The mechanisms by which VTE occurs in CHC users appear to be different from the mechanisms by which VTE occurs in COVID-19 patients. There are no published data on the possible summative effect of the two risk factors. *The recommendations made for continuing the use, abandonment or change of contraceptive method in women with COVID-19 or at risk of being infected by SARS-CoV-2 reflect the opinions of expert groups, but are not based on scientific work designed to such aim. Authors identified a retrospective study in which it was observed that women who used CHC orally were less infected with SARS-CoV-2 than those who did* 

not use it. There is some evidence of the therapeutic role of oestradiol in the most severe stages of the disease, but the possibility of continuing to use CHCs with low doses of non-oral ethinylestradiol or with 17 beta oestradiol orally has not been explored. Clinical studies are needed to analyse the VTE safety of low-dose non-oral ethinyl oestradiol preparations or oestradiol preparations in patients with COVID-19. In conclusion, according with the Italian Society of Contraception the prescription and use of hormonal methods with EE can continue.

## **Events Held in June, 2021**

- 1. A Webinar on "Trials and Tribulations with Hysteroscopy" was held under the aegis of the Endoscopy Subcommittee of AOGD on 3<sup>rd</sup> June, 2021.
- 2. Virtual Annual Conference of Delhi Gynaecology Endoscopists Society was held in association with IAGE and AOGD on 4<sup>th</sup> and 5<sup>th</sup> June, 2021.
- 3. A Webinar on "APH, Anticipate, Prepare and Handle" was held under the aegis of DGF outer Delhi and the AOGD Safe Motherhood Subcommittee on 8<sup>th</sup> June, 2021.
- 4. A CME on "Optimizing Outcomes of LSCS" was held under the Happy Learning Master Class Webinar Series, in association with AOGD on 8<sup>th</sup> June, 2021.
- 5. A CME on "The Thyroid Gland- from Adolescent to Menopause" was organized by the Endocrinology Subcommittee of AOGD on 10<sup>th</sup> June, 2021.
- 6. A dialog with President AOGD Dr Achla Batra was organized on the digital platform Zoom WOW India on the 13<sup>th</sup> of June, 2021.
- 7. A Workshop on "Metabolic Women's Health" was organized by the FOGSI Safe Motherhood Committee in collaboration with AOGD on 15<sup>th</sup> June, 2021.
- 8. A Teleconsultation on "Medico-Legal Aspects" was held on 16<sup>th</sup> June, 2021 by the QI committee of AOGD.
- 9. A Panel discussion on "A to Z of GDM" was organized jointly by the Multidisciplinary Subcommittee of AOGD, NARCHI, and DGF South West on 19<sup>th</sup> June, 2021
- 10. A Webinar on "Investigations in Infertility and Adjuvants in Male and Female Infertility" was organized on 22<sup>nd</sup> June, 2021 by the Infertility Committee of AOGD.
- 11. A Webinar on "Contraception" was organized by AOGD and Directorate of Family Welfare, GOVT. of NCT of Delhi on 23<sup>rd</sup> June to commemorate World Population Day.
- 12. A Webinar on "Endoscopy in COVID Era- Evidence, Practice, Innovations" was organized on 24<sup>th</sup> June, 2021 by the Endoscopy Subcommittee of AOGD.
- 13. A Virtual AOGD Monthly Clinical Meeting was held on 25th June 2021 by AIIMS, New Delhi.
- 14. A Webinar on "Cosmetic Gynae" was held on 30<sup>th</sup> June, 2021 by the Urogynae Subcommittee of AOGD.

## Forthcoming Events for July 2021

S.No.	Date	Event	Time
1	1 <sup>st</sup>	"Antakshari Competition" by the Rural Health Subcommittee AOGD to celebrate Doctor's Day	4:00-6:00 pm
2	3 <sup>rd</sup>	Webinar on "High-Risk Pregnancy" organized by the IMA-SDB in association with AOGD to celebrate Safe Motherhood Week	5:00-7:00 pm
3	3 <sup>rd</sup>	Public Forum on "Contraception Awareness" by AOGD in Association with Directorate of Family Welfare	4:00-6:00 pm
4	6 <sup>th</sup>	"Anaemia" organized by the IMA-SDB in association with AOGD in celebration of the Safe Motherhood Week	5:00-7:00 pm
5	7 <sup>th</sup>	"Impact of COVID and Endocrinopathies on Pregnancy" organized by the IMA-NDB in association with Reproductive Endocrinology & Safe Motherhood Subcommittees AOGD to celebrate Safe Motherhood Week	2:45-4:00 pm
6	7 <sup>th</sup>	"Infamous Obstetrical Triad- Recognition & Action" by the Safe Motherhood Subcommittee of AOGD	4.45-7:00 pm
7	8 <sup>th</sup>	"Current updates in Antenatal & Postnatal Management of Rh Isoimmunisation" by Foetal Medicine and Genetic Subcommittee	4:00-6:00 pm
8	9 <sup>th</sup>	"Adolescent Endometriosis- An Incessant Problem" (Searching for solutions) by Endometriosis Subcommittee AOGD & DGFS	3:00-5:00 pm
9	10 <sup>th</sup>	Public Forum "Adolescent Menstrual Problems" by Adolescent Health Subcommittee AOGD, DGFS, WOW	4:00-6:00 pm
10	10 <sup>th</sup>	"Management of Abnormal Cervical Screening- A Common Clinical Dilemma" by DGFS & Oncology Subcommittee	2:00-3.30 pm
11	10 <sup>th</sup>	"PCOS & Infertility" by NARCHI Delhi and Endocrinology Subcommittee of AOGD	5:00-6:00 pm
12	12 <sup>th</sup>	Doctors Forum "COVID Vaccination in Pregnancy- Ask the Experts"	4:30-5:30 pm
13	13 <sup>th</sup>	"Vitamin D & Women's Health" by Multidisciplinary Subcommittee AOGD & DGFS	3.30-4:30pm
14	13 <sup>th</sup>	Series "All about PCOS" Part I by Adolescent Health subcommittee AOGD	5:00-7:00 pm
15	14 <sup>th</sup>	"Urological Injuries during Caesarean & Gynae Surgeries and Fistula Repair" by Urology Subcommittee AOGD	4:00-6:00 pm
16	16 <sup>th</sup>	"Comprehensive Abortion Care: Bridging the Gap" by the Safe Motherhood Subcommittee of AOGD	2:00-4:00 pm
17	18 <sup>th</sup>	"Recurrent Pregnancy Loss: Dilemmas & Solutions" by Reproductive Endocrinology & Foetal Medicine and Genetic Subcommittee	5:45-8:00 pm
18	20 <sup>th</sup>	Series "All about PCOS" part II by Adolescent Health Subcommittee AOGD	5:00-7:00 pm
19	21 <sup>st</sup>	"Demystifying Thyroid disorder in Women" FOGSI Endocrinology committee & Reproductive Endocrinology Subcommittee AOGD	3:00-5:00 pm
20	21 <sup>st</sup>	Quiz "Contraception" AOGD in Association with Directorate of Family Welfare	11:00 am onwards
21	22 <sup>nd</sup>	Series "Basic Gynae Endoscopy" by Endoscopy Subcommittee AOGD & IAGE	6:00-8:00 pm
22	23 <sup>rd</sup>	"Jaagriti Ek Pehel" by IMA-SDB under aegis of AOGD to celebrate World Population Day	5:00-7:00 pm
23	24 <sup>th</sup>	"Menopause" by AOGD under aegis of Indian Menopause Society, Delhi Chapter	4:30-6:30 pm
24	25 <sup>th</sup>	"Infertility and IVF" by Reproductive Endocrinology Subcommittee AOGD & DGF Outer Delhi	10:00-12:00 am
25	27 <sup>th</sup>	Series "All about PCOS" part III by Adolescent Health Subcommittee AOGD	5:00-7:00 pm
26	28 <sup>th</sup>	CME on "Role of Oral Contraceptives in Womens Reproductive Health" by Multidisciplinary Committee	5:00-6:00 pm
27	30 <sup>th</sup>	Monthly Clinical Meeting by Sitaram Bhartia Hospital	4:00-5:00 pm
28	31 <sup>st</sup>	Master Class "Gestational Trophoblastic Disease" by Oncology Subcommittee AOGD	6:00-8:00 pm

## **Events held under the aegis of AOGD in June 2021**



Trials and Tribulations with Hysteroscopy





Annual Conference of Delhi Gynaecological Endoscopists' Society



CME on "Optimizing Outcomes of LSCS"



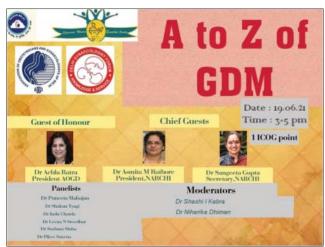
CME on "The Thyroid Gland- from Adolescent to Menopause"



Webinar on "Contraception"



Workshop on "Metabolic Women's Health"



Panel discussion on "A to Z of GDM"



"Investigations in Infertility and Adjuvants in Male and Female Infertility"



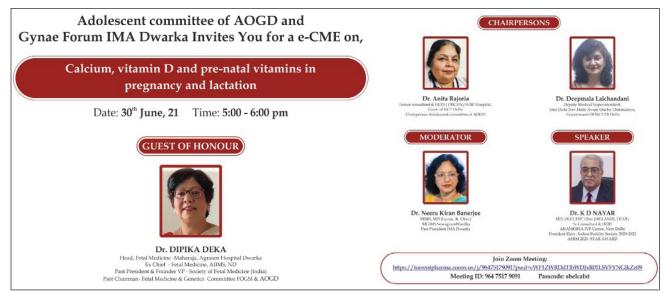
Webinar on "Endoscopy in COVID Era- Evidence, Practice, Innovations"



Virtual AOGD Monthly Clinical Meeting at AIIMS



Webinar on "Contraception"



Webinar on "Cosmetic Gynae"

## Proceedings of Virtual AOGD Monthly Clinical Meeting held at All India Institute of Medical Sciences, New Delhi on 25<sup>th</sup> June, 2021

### Journey of Procreation in Cloacal Exstrophy: Defying all Odds

#### Swati Tomar, Garima Kachhawa, Reeta Mahey Anju Singh, Neerja Bhatla

Mrs X, 26-year-old woman  $G_{3}P_{0+0+2+0}$  with 4 months amenorrhea presented to outpatient department for routine antenatal care. She was a known case of cloacal exstrophy with history of continuous dribbling of urine and involuntary passage of stools since birth. She was married for last 8 years. Her first two conceptions ended in first trimester missed abortions which were managed medically. Examination of respiratory, cardiac and neurological systems was unremarkable. Abdominal examination showed a complete absence of umbilicus and lower anterior abdominal wall. On local examination, the dorsal bladder mucosa was exposed with dribbling of urine seen from both ureteric orifices and urethral meatus was absent. Pubic rami were widely separated with a bifid clitoris. Labia majora were also widely separated. The distal part of rectum, anal canal and anal opening were exposed and there was no definitive anal sphincter. A small vaginal opening around 4 cm in length was present on extreme left side which was anteriorly placed and deviated towards the midline. A small cervix was felt at the tip of the finger. The vaginal opening on the right side was hypoplastic.

Obstetric examination revealed an enlarged uterus corresponding to 20 weeks of gestation deviated to left side. Foetal anomaly scan revealed a normal viable foetus corresponding to 19 weeks of gestation in left horn of the didelphic uterus. Routine investigations revealed moderate anaemia which was corrected by injectable ferric carboxymaltose as she was intolerant to oral therapy. Ultrasound abdomen showed normally situated left kidney with mild hydroureteronephrosis and right pelvic kidney. At 33 weeks' gestation, she went into spontaneous preterm labour. Antenatal steroids (dexamethasone 6 mg 12 hourly) and tocolysis with nifedipine were administered but she did not respond. Emergency caesarean section was performed in view of malformed pelvis and breech presentation. Prior

to caesarean section, both ureteric orifices were identified and catheterized by infant feeding tubes. The abdomen was opened by left paramedian vertical incision keeping short of the exposed bladder. The rectus sheath and muscle were very thin and deficient and the left gravid horn was completely shifted to the left. A vertical incision was made in the upper part of the lower segment and a healthy male baby weighing 1602g was delivered as breech. Baby needed ICU care for 72 hours. Both baby and mother were discharged in good condition after 3 weeks.

**Discussion:** Cloacal exstrophy is a rare complex congenital birth defect which occurs due to abnormal development of the cloacal membrane during the embryonic period. It is the most severe form of the group of anomalies called bladder-exstrophy–epispadias complex (BEEC), as the lower abdominal wall is congenitally deficient. It occurs in approximately 1 in 200,000 to 1 in 400,000 live births with a male predominance. As reproductive function is preserved pregnancy is reported in previously operated cases. Only 5 cases of successful pregnancies have been reported in women with corrected cloacal exstrophy. To the best of our knowledge this is the first report of a successful pregnancy in an uncorrected case of cloacal exstrophy.

#### Foetal Intervention with International Collaboration, Administrative Support and Social Services to the Rescue of an Unborn Foetus

Sharma KA, Pandey H, Singh N, Garg D Choudhary P, Shainy P, Kandpal S, Dadhwal V, Rana A

The Rh blood group system in humans is known to cause haemolytic disease of foetus and newborn (HDFN). We report a rare case (1<sup>st</sup> reported case in India) of successful outcome of HDFN due to anti Rh 17 in a woman with D - - phenotype which is characterized by the absence of C, c, E, e antigens and overexpression of D antigens. Globally, previously there are only 18 reported cases of Rh D-- in pregnancy, out of which, 8 had successful outcomes.

She is 27 year old female,  $G_8P_4L_0A_3$  with bad obstetric history of previous 4 intra-uterine demises between 28-36 weeks and history of eclampsia in one pregnancy. She was diagnosed with this rare blood group during her 6<sup>th</sup> pregnancy at 23 weeks period of gestation when she developed foetal hydrops and severe maternal anaemia. Her blood was incompatible with all blood groups. At that time she was referred to our institution and workup for rare blood groups (Bristol laboratory, UK) confirmed this Anti Rh 17(D--) status. Then she received plasmapheresis and delivered a macerated hydropic baby.

In current pregnancy, patient reported at 19 weeks with foetal anaemia. Initially she received 2 cycles of intravenous immunoglobulin but despite that the foetus developed hydrops at 21 weeks. Procuring this rare blood for intrauterine transfusion (IUT) was the biggest challenge for which international rare donor panel was contacted. Nearest compatible donors were identified in Japan. Even though blood was available free of cost, each instalment of transport cost was around 2000 USD. With the help of hospital administration and due diligence from the medical social officers, funds were arranged. Appropriate import permits were taken.

The patient received 6 IUT's, first at 21+6 weeks and the 6<sup>th</sup> at 28+1 weeks. Steroid cover was given at 28 weeks. At 31 weeks, the foetus developed nonreassuring non-stress test and a preterm caesarean section was done. Preoperative autologous blood transfusion was performed for the patient due to non-availability of blood for the mother. The baby received surfactant, 1 cycle of partial exchange transfusion and 6 cycles of phototherapy. Baby was discharged in stable condition day 29 of birth.

This case was successfully managed with a close collaboration between foetal medicine, transfusion medicine and the neonatology team. Establishing a rare blood group registry in developing nations can help in managing such cases with relative ease.

#### A Case of ITP Gone Rogue in Pregnancy: Challenge Embraced

#### Tarang Preet Kaur, Seema Singhal, Vatsla Dadhwal Anubhuti Rana, Akanksha Gupta, Neena Malhotra

Refractory immune thrombocytopenia (ITP) in pregnancy is clinically challenging for obstetricians and haematologists. First-line treatment includes corticosteroids, intravenous immunoglobulin (IVIG). Novel drugs, Romiplostim & Eltrombopag (thrombopoietin receptor agonist) which form second line treatment do not have well controlled trials in pregnancy and have been rarely used. Splenectomy is usually kept as the last resort and is preferably done in second trimester. We report a rare case of refractory ITP in pregnancy where sequential pharmacological management including novel agents followed by splenectomy were used.

А 30-year-woman,  $G_{5}P_{1}L_{1}A_{3}$ , with diamniotic dichorionic twins at 24+3 weeks gestation, Rh negative (non-immunized) was diagnosed with severe ITP. Medical management including high dose steroids and IVIG could only cause transient improvement. Her platelets remained in the range of 5000-10,000/cumm. In view of limited evidence, after multidisciplinary deliberations and patient counselling, a trial of novel agents like TPO receptor agonist was given after counselling. She received multiple platelets transfusion (98 RDPs and 1 SDP). At 35 weeks, in view of FGR and poor biophysical profile LSCS along with splenectomy was performed. The intra-operative and post-operative course was uneventful and both babies had no evidence of thrombocytopenia. Maternal Platelet counts again dropped to 30,000/mm<sup>3</sup> on post op day4- and oral Eltrombopag was tried which showed a favourable response. She was discharged in stable condition with platelet count between -40 50,000/mm<sup>3</sup> on post-operative day 15.

Splenectomy in pregnancy or during caesarean section is rarely reported. From our institution, Mahey et al (2013) have reported similar case where splenectomy was conducted at 38 weeks along with caesarean section.

## **Quiz Held at Monthly Clinical Meeting**

#### Niharika Guleria<sup>1</sup>, Rekha Bharti<sup>2</sup>

<sup>1</sup>Senior Resident, <sup>2</sup>Professor, VMMC & Safdarjung Hospital

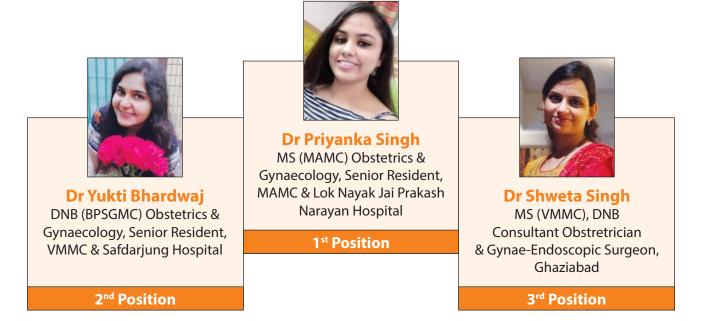
- 1. Prophylactic antibiotics should be administered
  - a. Within 60 min prior to start of surgery
  - b. On the OT table
  - c. At the time of anaesthesia
  - d. At the time of incision
- 2. Extension of rectus sheath incision beyond the rectus muscle can traumatize following nerve
  - a. Iliohypogastric
  - b. Ilioinguinal
  - c. Both a & b
  - d. None of the above
- 3. During Caesarean delivery, changing gloves before MRP reduces risk of endometritis

a. True b. False

- 4. Which of the following needle is best suited for suturing large superficial wounds
  - a. 1/2 circle
  - b. 3/8 circle
  - c. 5/8 circle
  - d. none of the above
- 5. Negative pressure dressings are best used for
  - a. Large defects with clean granulating base
  - b. wounds with malignant tissue
  - c. Ischemic wounds
  - d. Actively discharging infected wounds

Answers			
Q. 1- a	Q. 2- c	Q. 3- b	
Q. 4- b	Q. 5- 1		

## Winners of the Monthly Clinical Meeting Quiz, June Issue 2021



## Annexure: COVID-19 Vaccination for Pregnant Women

Sumitra Bachani<sup>1</sup>, Jyotsna Suri<sup>2</sup>, Pratima Mittal<sup>3</sup>

<sup>1</sup>Associate Professor, <sup>2</sup>Professor, <sup>3</sup>Professor & Head of Unit, VMMC & Safdarjung Hospital

### **COVID-19 and Pregnancy**

Most pregnant women with COVID 19 may have asymptomatic or mild disease. Compared with pregnant women without COVID-19, those with symptomatic COVID19 are at increased risk of adverse pregnancy outcomes, including admission to the Intensive care unit, iatrogenic preterm birth, pre-eclampsia-like symptoms, operative intervention and death. Additionally the fetus is at risk of perinatal morbidity(hypoxia) and mortality. WHO recommends vaccination in pregnant women as the benefits of vaccinating the pregnant woman outweigh the potential risks, such as pregnant women at high risk of exposure to COVID-19 and those with comorbidities that place them in a high-risk group for severe COVID-19 disease. Pregnant women with certain conditions have greater risk of severe illness from COVID-19 such as pre-existing medical conditions (Hypertension, Diabetes), chronic respiratory conditions (COPD, Asthma, Cystic Fibrosis), Homozygous sickle cell disease, on immunosuppression therapies (enough to significantly increase risk of infection), dialysis or advanced chronic kidney disease, congenital or acquired heart disease and organ transplant recipients.

### **Benefits Outweigh The Risks**

Based on the recommendations from National Technical Advisory Group on Immunisation (NTAGI) and an important role played by FOGSI recommendations and expert opinions the MoHFW has approved vaccination of pregnant women against COVID-19. Information related to COVID-19, the impact of the disease on pregnancy and data related to COVID-19 vaccines are rapidly evolving. Women comprise nearly 48% of the population between 18 to 45 years of age. The intent is to weigh risk versus benefit on individualised basis, so that a pregnant woman can take an informed decision. This decision is based on the woman's understanding that the risk of infection and/or morbidity from COVID-19 outweighs the yet undescribed risk of being vaccinated during pregnancy.

In India, at present three vaccines are available which have received approval for restricted use in emergency situation. One of them is Covaxin and other two are Covishield and Sputnik V. Covaxin is an inactivated virus vaccine manufactured in India by Bharat Serum while Covishield is a viral vector based vaccine manufactured by the Serum Institute and uses a harmless non replicating Adenovirus as a vector to carry the DNA which enters the host cell nucleus and induces mRNA formation which is similar to the Corona virus mRNA. These two vaccines are heat stable and can be kept at 2-80 C. The vaccines induce the host to form antibodies against the viral spike protein by carrying the inactivated virus or inducing the formation of the protein in the host cell. Sputnik V has been manufactured in Russia and carries the gene component of corona virus which induces the spike protein formation in the host which in turn activates the immune response. Since the genetic martial carried by it is fragile the vaccine has to be stored at - 180 C.

The mRNA vaccines manufactured in the USA by Pfizer and Moderna carry the extremely fragile corona virus mRNA hence they need to be stored at very low temperatures from -50 to -150 C. Moderna mRNA 1273 has been approved for emergency use in India and may be available in a few months. Its unpunctured vials may be stored in the refrigerator between 2° to 8°C for up to 30 days which will be beneficial in the Indian climate. Although any of the the vaccines do not guarantee absolute protection from COVID 19 but the rationales of vaccination are : To reduce the risk of infection as it is a public health problem.

- To reduce the risk of severe acute morbidity and mortality from the infection.
- To prevent long term effects of infection.
- To prevent transmission to other individuals.

### **Counselling and Time of Vaccination**

A pregnant woman who opts for vaccination, could be vaccinated at any time of the pregnancy. However it will be beneficial to get fully vaccinated within the first 28 weeks as then the woman is protected in the third trimester which is seen to be associated with more severe disease of COVID 19. To help pregnant women make an informed decision to be vaccinated, they should be provided with information about the risks of COVID-19 infection in pregnancy, the benefits of vaccination, along with the likely side effects of vaccination.

There are several points at which interface of the pregnant woman and the front line workers (FLW) occurs and where pregnant women could be counselled. These include household visits by frontline workers, Antenatal checkup at health facility, outreach immunization sessions, Village Health and Nutrition Days (VHNDs), Urban Health and Nutrition Days (UHNDs), visits by pregnant women for other reasons to COVID-19 Vaccination Centers (CVCs). During the counselling, the FLW or vaccinator (if the women reaches the CVC directly and has guestions related to COVID 19 vaccination) should explain to the pregnant women the potential risks of COVID-19 on their health or that of the baby, benefits of vaccination, potential side effects and precautions they need to take following vaccination. If a woman contracts COVID 19 during pregnancy its recommended to vaccinate her in the immediate post partum period provided she fulfils all other criteria. Pregnant women may also be exposed to COVID-19 vaccine before the woman knows she is pregnant. It is not recommended to perform testing for pregnancy prior to vaccination and delaying pregnancy or terminating pregnancy because of vaccination.

### **Vaccination Side Effects**

Based on current knowledge, experts believe that COVID -19 vaccines are unlikely to pose a risk to the pregnant person or foetus. Like any medicine a vaccine may have side effects which are normally mild. After getting the vaccine, she can get mild fever, pain at injection site, or feel unwell for 1-3 days.

The long-term adverse effects and safety of vaccine for foetus and child is not established yet. Very rarely, (one in 1-5 lakh persons) the beneficiary may after COVID 19 vaccination, experience some of the following symptoms within 20 days after getting the injection which may need immediate attention: Shortness of breath (difficulty in breathing), chest pain, pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf), small pinpoint haemorrhages (petechial) or bruising of the skin beyond the vaccination site, persistent abdominal pain with or without vomiting, seizures in the absence of previous history of seizures with or without vomiting, severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache),weakness/ paralysis of limbs or any particular side of the body, persistent vomiting without any obvious reason, blurred vision/ pain in eyes, any other symptom or health condition which is of concern to the recipient or the family.

## **Contraindications to Vaccination**

As for the general population, pregnant women should avoid vaccination in the following conditions: Anaphylactic or allergic reaction to the previous dose of COVID-19 vaccine.

Anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, fooditems etc.

Vaccine is temporarily contraindicated in the following conditions:

Diagnosed COVID-19 infection – defer for 12 weeks from infection or 4 to 8 weeks from recovery Active COVID-19 infection.

COVID-19 infection treated with anti-COVID-19 monoclonal antibodies or convalescent plasma.

### **Guidelines Recommendations**

WHO recommends use of recombinant vaccine in pregnant women, provided the benefits of vaccination outweigh the potential risk and does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

International Federation of Gynaecology and Obstetrics (FIGO) believes that risk-based approach to immunisation might be of disadvantage to the pregnant woman.

The Royal College of Obstetricians and Gynaecologists (RCOG) states that pregnant women should be offered the vaccine as the general population.

The American College of Obstetricians and Gynecologists (ACOG) states that pregnancy testing should not be required prior to receiving vaccine and may be administered to the people who may consider future pregnancy. Women under age 50 including pregnant women can receive any

COVID-19 vaccine. However, they should be aware of the rare risk of thrombosis with thrombocytopenia syndrome after receipt of mRNA vaccines.

Countries such as Australia, Canada, Israel, Singapore, United Kingdom and United State of America are vaccinating pregnant women with COVID-19 vaccines.

## Post Vaccination Appropriate Behaviour

Pregnant woman and her family members should continue to practice COVID appropriate behaviour: wearing double mask, frequent hand washing, maintaining physical distance, and avoiding crowded areas, to protect themselves and those around from spreading the SAR-CoV-2 infection.

### Are You Ready for Vaccination?

All pregnant women need to register themselves on Co-WIN portal or may get themselves registered onsite at the COVID-19 vaccination centre. The process of registration for pregnant women remains same as of the general population and as per the latest guidance provided by MoHFW from time to time.

### **Suggested Reading**

1. Wei SQ, Bilodeau-Bertrand M, Liu S, Auger N. The impact of COVID-19 on pregnancy outcomes: a systematic review and meta-analysis. CMAJ. 2021 Apr 19;193(16):E540-E548. doi: 10.1503/cmaj.202604. Epub 2021 Mar 19. PMID: 33741725; PMCID: PMC8084555.

- Outcomes of Neonates Born to Mothers with Coronavirus Disease 2019 (COVID-19) – National Neonatology Forum (NNF) India COVID-19 Registry; early online version, Indian pediatrics
- 3. https://www.mohfw.gov.in/pdf/Operational Guidance for COVID19 vaccination of Pregnant Woman.pdf
- https://www.mohfw.gov.in/pdf/COVID 19 Vaccine OG 111 Chapter16.pdf
- https://www.mohfw.gov.in/pdf/GuidancedocCOWIN2. pdf
- 6. https://www.heart.org/en/coronavirus/coronavirusquestions/questions-about-covid-19- vaccination
- 7. SAGE guidance for the development of evidence-based vaccination-related recommendations. Geneva: World Health Organization; 2017.
- 8. Interim Clinical Considerations for Use of COVID -19 Vaccines Currently Authorized in the United States; Centers for Disease Control and Prevention; https://www. cdc.gov/vaccines/Covid -19/info-by-product/clinicalconsiderations.html#pregnant
- 9. Royal College of Obstetricians and Gynecologists (RCOG). COVID -19 vaccines, pregnancy and breastfeeding. [Online]. https://www.rcog.org.uk/en/guidelinesresearch services/coronavirus-Covid -19-pregnancy-and -womens -health/ Covid -19-vaccines-andpregnancy/ Covid -19-vaccines-pregnancy-and-breastfeeding/
- Sarwal Y, Sarwal T, Sarwal R. Prioritizing pregnant women for COVID-19 vaccination. Int J Gynaecol Obstet. 2021 Jul 6. doi: 10.1002/ijgo.13816. Epub ahead of print. PMID: 34227102.
- 11. https://www.fogsi.org/wp-content/uploads/covid19/ fogsi-statement-on-covid-vaccination-in-pregnancyand-bf.pdf.





#### Block your dates for 43<sup>rd</sup> Annual Conference 2021 to be held on 20<sup>th</sup> - 21<sup>st</sup> November, 2021

## **Calendar of Virtual Monthly Clinical Meetings 2021-22**

28 <sup>th</sup> May, 2021	B L Kapoor Hospital
25 <sup>th</sup> June, 2021	All India Institute of Medical Sciences
30 <sup>th</sup> July, 2021	Sitaram Bhartia Hospital
27 <sup>th</sup> August, 2021	Army Hospital (Research & Referral)
24 <sup>th</sup> September, 2021	Deen Dayal Upadhyay Hospital
29 <sup>th</sup> October, 2021	PGIMSR & ESI Hospital
21 <sup>st</sup> - 23 <sup>rd</sup> November, 2021	43 <sup>rd</sup> Annual Conference
26 <sup>th</sup> November, 2021	MAMC & Lok Nayak Jai Prakash Narayan Hospital
31 <sup>st</sup> December, 2021	Sir Ganga Ram Hospital
28 <sup>th</sup> January, 2022	ABVIMS & Dr Ram Manohar Lohia Hospital
25 <sup>th</sup> February, 2022	UCMS & Guru Tek Bahadur Hospital
25 <sup>th</sup> March, 2022	VMMC & Safdarjung Hospital
29 <sup>th</sup> April, 2022	LHMC & Smt. Sucheta Kriplani Hospital
27 <sup>th</sup> May, 2022	Apollo Hospital



Block Your Dates

# Advanced Hysteroscopy Training Course 7<sup>th</sup> & 8<sup>th</sup> August, 2021 Time: 4:00 - 6:00 PM (IST)

Anatomy Of The Uterine Cavity -Landmarks For Intra Uterine Surgery

Hysteroscopic Myomectomy -What's New

**Ashermans - The Basics** 

Hysteroscopic Management Of Isthmocoele - The Old And What's New

Hysteroscopy In Pregnancy-The Unchartered Territory And Its Applications

Ashermans - Interesting Cases ( Videos) And Their Management- Tips And Tricks

IISE - (Impaired Inflammatory State Of The Endometrium) A New Concept And Its Applications

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