2024, Volume 24, August, Issue 04

AOGD BULLETIN

Shared Decision Making - Enhancing Women Emancipation

Theme
Contraception: Small Choices Big Impact

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AOGD Bulletin

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Message from the President

President

Dear AOGD members,

Namaskar

As we celebrate 77 years of glorious independence we must take a moment to remember the struggles of our freedom fighters and be inspired by their bravery.

A lot of women from both rural and urban backgrounds struggle daily for contraceptive needs to avoid the physical, financial and psychological burden of added pregnancy. The main requirement is consistent access to effective and affordable contraception. Some of the obstacles to this include health literacy, beliefs about side effects, conflicting cultural views and women at risk of unintended pregnancy. Our job as health care professionals is to ensure that patients are carefully guided about the available basket of contraception, their risks, and benefits along with the removal of misconceptions. In the current issue, we are talking about untouched aspects of Contraception which hopefully benefit you in practice as well as clinical knowledge.

Last month we ran a World Population Day campaign with the theme – Healthy timing and spacing of pregnancies for the well-being of mother and child. We advocate a three-armed approach- promoting modern methods of contraception, generating demand among postpartum and postabortal women and encouraging male participation. A lot of family planning activities with active community participation were conducted over the month in association with the Directorate of Family Welfare, Govt of Delhi.

We are continuing with our academic activities simultaneously in the form of webinars and CMEs– Post graduate fiesta last month was attended by more than 100 participants including students from other states. Our conference website is now live- www.aogdconference.com. The last date for abstract submission is October 15, 2024. A lot of national and international experts will be gracing the event. I would like to encourage all residents and colleagues for active participation to make this 46th annual conference a huge success.

Best wishes and happy reading!

Dr. Ashok Kumar MD, PhD, FICMCH, FICOG, FAMS
President, AOGD
Vice Chairperson, Elect, ICOG, an Academic Wing of FOGSI
National Corresponding Editor, Journal of Obstetrics & Gynaecology of India
Director Professor & Head
Department of Obstetrics & Gynecology,
Atal Bihari Vajpayee Institute of Medical Sciences &
Dr. Ram Manohar Lohia Hospital, New Delhi

Message from the Hon. Secretary

Hon. Secretary

Dear AOGD Members,

Warm greetings to all from AOGD secretariat at ABVIMS & Dr RML Hospital

Monsoons are here and so are the preparations for annual AOGD conference. The website is active and the abstract submission dates are out. Let's gear up for the mega event to be held from 22nd to 24th November 2024.

The preceding month has been quite eventful. World population day was observed with full vigour in various activities including online campaign, street plays, poster competitions, public counselling sessions, CMEs, etc. The theme for this year's world population day is "Empowering Youth for a Sustainable Future."

The current bulletin's theme is contraception. It is an opportunity to educate and generate public interest on the issues of family planning, gender equality, maternal and child health. The month of august will also see activities on the occasion of world breast feeding week. Women are pillars of the family, the community and the world. Let us try to empower our girls with knowledge to be able to decide for reproduction and family planning.

It is heartening to hear that the government will focus on HPV vaccination as announced in the current health budget. Sending our heartiest congratulations to all Indian sports persons who participated in the Paris Olympics. Let us all become a powerful force for positive change that will drive humankind forward towards inclusivity.

नारी अस्य समाजस्य कुशलवास्तुकारा अस्ति I

Woman is the perfect architect of society (Manusmriti).

Left to Right: *Dr. Vandana Agarwal, Dr. Neha Pruthi Tandon, Dr. Kamna Dutta and Dr. Geetanjali Nabiyal*

7th July 2024

PG Academic Fiesta At Mini Auditorium, LHMC - ABVIMS and RML Hospital

POSTGRADUATE - ACADEMIC FIESTA

Department of Obstetrics & Gynecology
Atal Bihari Vajpayee Institute of Medical Sciences &
Dr. Ram Manohar Lohia Hospital, New Delhi

Sunday 7th July, 2024 — Mini Auditorium, Lady Hardinge Medical College, New Delhi

Chairperson
Dr. Ashok Kumar

Coordinators
Dr. Reena Yadav & Dr. Vandana Agarwal

TIME	TOPIC	SPEAKER
08:30 AM - 09:00 AM: REGISTRATION		
09:00 AM - 10:00 AM Dummy & Doll	Pelvic Bone & Fetal Skull	Dr. Rekha Bharti (VMMC & SJH)
10:00 AM - 10:30 AM Competency Based Learning	Endometrial Sampling	Dr. Amita Gupta (Maharaja Agrasen Hospital, Dwarka)
10:30 AM - 10:45 AM	LAMP LIGHTING FOLLOWED BY TEA BREAK	
10:45 AM - 11:45 AM Case Discussion	Previous Caesarean	Students: Tirath Ram Shah Hospital Teachers: Dr. Kiran Aggarwal (LHMC) Dr. Nishi Makhija (Tirath Ram Shah Hospital) Dr. Kanika Jain (Sir Ganga Ram Hospital) Dr. Prassan Vij (St. Stephen's Hospital)
11:45 AM - 12:15 PM POMR	Oligohydramnios	Dr. Reema Bhatt (Amrita Hospital, Faridabad)
12:15 PM - 01:15 PM Counselling	A 38-year lady with history of GDM & Down's syndrome in previous pregnancy	Dr. Anubhuti Rana (AIIMS) Dr. Kamna Datta (ABVIMS & Dr. RMLH)
01:15 PM - 02:00 PM	LUNCH	
02:00 PM – 3:00 PM Case Discussion	Carcinoma Cervix	Students: LHMC Teachers: Dr. Amita Suneja (UCMS & GTB Hospital) Dr. Sharda Patra (LHMC) Dr. Satinder Kaur (Max Super Speciality Hospital, Vaishali) Dr. Neha Kumar (Amrita Hospital, Faridabad)
03:00 PM - 3:30 PM Problem Based Management	Fetal Hydrops at 22 weeks	Dr. Chanchal (Rainbow Hospitals)
3:30 PM - 4:00 PM Ultrasound Learning	Doppler study in FGR	Dr. Vatsla Dadhwal (AIIMS)
04:00 PM - 05:00 PM Case Discussion	Pelvic Organ Prolapse	Students: Sant Parmanand Hospital Teachers: Dr. Reena Yadav (LHMC) Dr. (Brigadier) R.D Wadhwa (SGT Medical College, Gurgaon) Dr. Anju Bala (Sant Parmanand Hospital) Dr. Neha Mishra (ABVIMS & Dr. RMLH)
5:00 PM	TEA	

11th July 2024

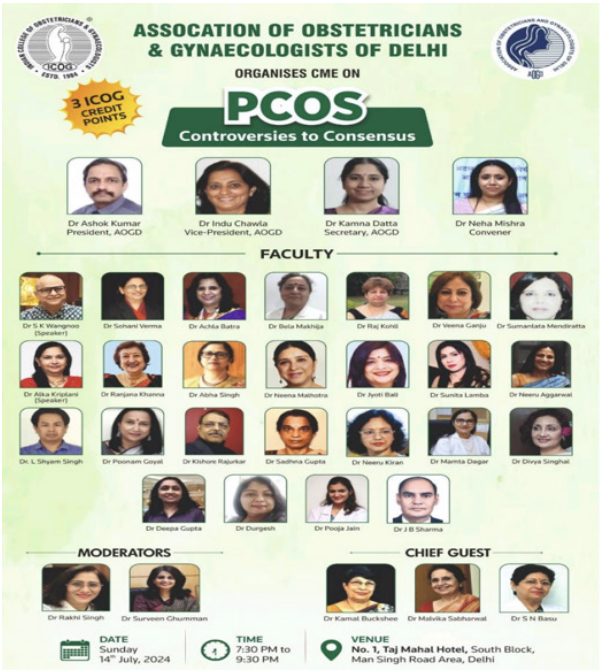
Happy Learning Masterclass Webinar Series, 200th episode in association with AOGD

13th July 2024

CME cum workshop on Ovulation Induction and IUI LHMC, Infertility and Reproductive Endocrinology subcommittee and SIG Early pregnancy, IFS

14th July 2024

PCOS – Controversies to Consensus organized by AOGD at Taj Mahal Hotel, Delhi



SCIENTIFIC AGENDA

TIME	TOPIC	
7:30pm - 7:35pm	Welcome Address	Dr Kamna Datta (Secretary, AOGD)
7: 35pm - 7:40pm	Lamp Lighting and Inauguaration	**Chief Guest:** Dr Kamal Buckshree, Dr Malvika Sabharwal, Dr S N Basu, Dr Indu Chawla

SESSION 1

TIME	TOPIC	SPEAKER
7:40pm - 8:00 pm	Metabolic Implications for life with PCOS and its management	**Speaker:** Dr S K Wangnoo
8:00pm - 8:10 pm	**Discussion**	**Chairpersons:** Dr Sohani Verma, Dr Achla Batra, Dr Beta Makhija, Dr Raj Kohli, Dr Veena Ganju, Dr Sumanlata Mendiratta

SESSION 2

TIME	TOPIC	SPEAKER
8:10pm - 8:30 pm	PCOS & Menstrual Management: Choosing the right regulator	**Speaker:** Dr Alka Kriplani
8:30pm - 8:40 pm	**Discussion**	**Chairpersons:** Dr Ranjana Khanna, Dr Abha Singh, Dr Neena Malhotra, Dr Jyoti Bali, Dr Sunita Lamba, Dr Neeru Aggarwal, Dr L Shyam

SESSION 3

TIME	TOPIC	SPEAKER
8:40pm - 9:20 pm	**Panel Discussion** PCOS,from Controversy to Consensus What is Current, What is New? **Moderators:** Dr Rakhi Singh, Dr Surveen Ghumman	**Experts:** Dr Alka Kriplani, Dr Ashok Kumar, Dr J B Sharma **Panelists:** Dr Poonam Goyal, Dr Kishore Rajurkar, Dr Sadhna Gupta, Dr Neeru Kiran, Dr Mamta Dagar, Dr Divya Singhal, Dr Deepa Gupta, Dr Durgesh, Dr Pooja Jain
9:30 pm	Vote of thanks followed by dinner	Dr Neha Mishra (Treasurer, AOGD)

14th July 2024

Webinar on Dealing with repeated pregnancy loss: evidence based management.

SIG Early pregnancy IFS Jammu chapter a/w Infertility and reproductive endocrinology subcommittee.

17th July 2024

Webinar on Breast cancer basics for Gynaecologists - Oncology subcommittee AOGD & Study of female breast committee, FOGSI.

24th July 2024

Webinar- Navigating the intricacies of GDM - Community Health and Public Awareness Subcommittee

Adolescent Health Committee

1. **Educational Talk at Kendriya Vidyalay Matiala School**
2. **Awareness talk on menstrual hygiene and anaemia at an Orphanage**

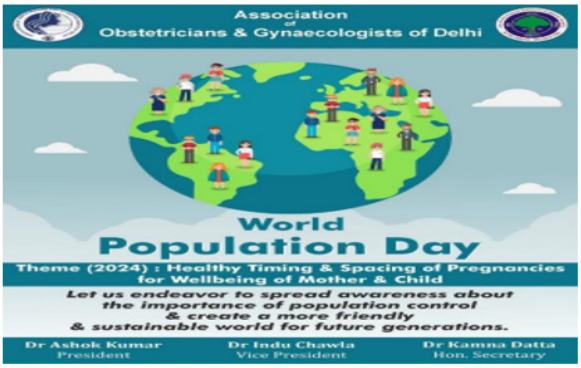
25th July 2024

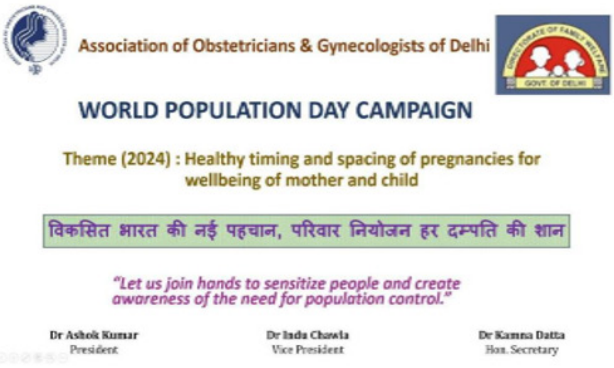
Colposcopy workshop Oncology Subcommittee at Safdarjung Hospital





WORLD POPULATION DAY ACTIVITIES



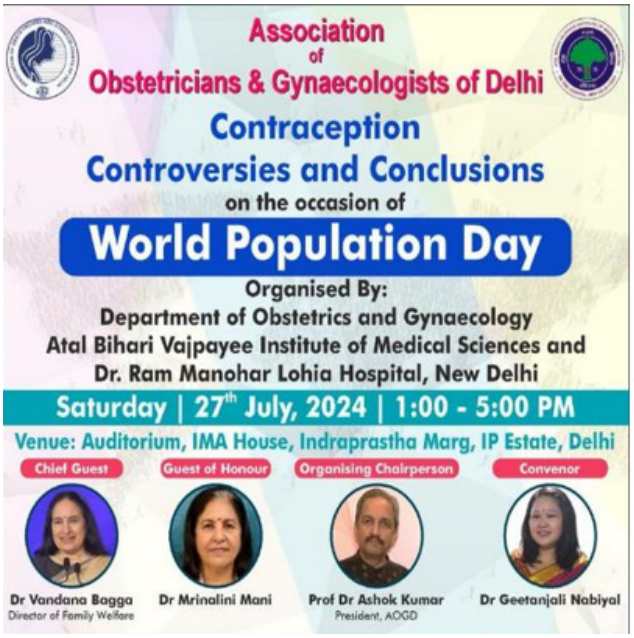






27th July 2024

CME on Contraception : Controversies and Conclusions by ABVIMS & Dr RML Hospital at IMA Headquaters on the occasion of world Population Day



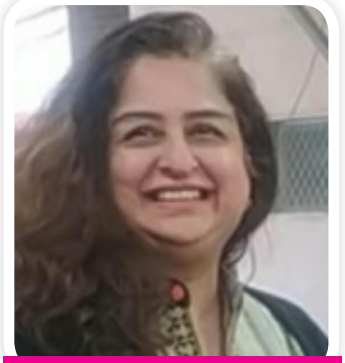
Time	Topic	Speaker
1:00 - 2:00 PM	Lunch	
2:00 - 2:30 PM	Welcome Address, Lamp Lighting	
2:30 - 3:15 PM	**Panel Discussion:** **Contraception in different age groups** **Panelists:** Dr Rachna Sharma, Dr Maruti Sinha, Dr Deepa Gupta, Dr Sumita Mehta, Dr Arpita Dey, Dr Priyanka Mathe	**Moderators:** Dr Yamini Sarwal, Dr Kashika
Chairpersons: Dr Jyoti Bali, Dr Anita Rajhoria, Dr Pinkee Saxena, Dr Jasmine		
3:15 - 3:30 PM	Clinical methods of first trimester MTP	Dr Ranjana Khanna
3:30 - 3:45 PM	Evolution of progestins	Dr Kamna Datta
3:45 - 4:20 PM	**I am the BEST ?** LNG_IUS : Dr Namita Chopra ANTARA: Dr Reetu Yadav IMPLANT : Dr Neha Mishra CENTCHROMAN: Dr Nilanchali Singh	**Experts:** Dr Jyoti Sachdeva, Dr Reena Yadav
4:20 - 4:30 PM	WPD Activities	Dr Preeti Sainia
Vote of Thanks		
High Tea		

Dr Ashok Kumar President | **Dr Indu Chawla** Vice President | **Dr Kamna Datta** Hon. Secretary

Forthcoming Events "for the month of August"

- 5th – CME on breastfeeding by AOGD RML under the aegis of FOGSI - RISHTA : ALL MOTHERS EVERYWHERE at India Habitat Centre, 1-5pm
- 6th – PPH workshop by AOGD with Safdarjung hospital, 2-5pm
- 1st – 7th – Breast Feeding awareness activities by community Health subcommittee
- 9th – CME- Erasing the blots : AUB to Endometriosis in adolescents by Adolescent subcommittee at Hotel Metropolitan 1.30-4pm
- 11th – Breast and cervical cancer awareness and prevention committee - Breast & Cervical Screening Camp for Free Paps smear, Mammography and HPV Vaccine in Vasant kunj
- 17th – CME- Enhancing caesarian section skills by QI subcommittee
- 23rd – Community health and Public Awareness Subcommittee - Visit to a Govt School
- 23rd – Preeclampsia: Updates in screening and management, Fetal medicine subcommittee, 6-8 pm

From the Editors Desk



Chief Editor

Monsoon greetings from the Editor's Desk

The editorial team is happy to share with you AOGD bulletin for month of August. This issue we are talking about untouched aspects of Contraception. Modern contraception is targeted to improve family planning by empowering women with more suitable options and including males in the process so that increased uptake will help curtail abortions and increase healthier families.

We found the following topics to be useful for discussion in this regard. The Medical eligibility criteria for contraceptive use (MEC) wheel is such an important document providing guidance about all forms of contraception that it is used worldwide by clinicians, policy makers and also the community workers. Contraception in adolescent and perimenopausal age group needs special attention since adolescents need to be guided about prevention of reproductive tract infections as well and old age women need targeted counselling keeping in mind associated co-morbidities. Among the innovative contraceptive methods we have touched about the single rod subdermal contraceptive which has been found to be safe and useful spacing method.

Unfortunately some aspects of emergency contraception are misunderstood, which leads to misdirected use and its vital to ensure guided prescription along with the correct media coverage about this aspect of public health as that is where the masses gain their knowledge from. Another less understood area is impact of well documented risk of failure in sterilization procedures. Since failed sterilization is a cause for litigation, every gynaecologist must inform all risks and complications prior to procedure and must also be well aware of negligence structure.

Hope you will find this issue enlightening and useful for practice. We look forward to any suggestions and feedback from you.

Dr. (Prof) Renuka Malik

Editor

Professor and Senior Consultant, ABVIMS & RML Hospital

Editorial Team: (Left To Right) Dr. Kanika, Dr. Preeti, Dr. Renuka, Dr. Kavita. (Second Row Left To Right) Dr. Seema, Dr. Niharika

Thought for the month: While we are free to choose our actions, we are not free to choose the consequences of our actions —Steven Covey

Association
of
Obstetricians & Gynaecologists of Delhi

HAPPY INDEPENDENCE DAY
15 AUGUST

Theme (2024) : Viksit Bharat

A day of pride and reflection, celebrating our hard-earned freedom, unity, and the vibrant spirit of our nation.

Dr Ashok Kumar	Dr Indu Chawla	Dr Kamna Datta
President	Vice President	Hon. Secretary

Navigating the Challenges: Addressing the Unmet Needs of Family Planning in India

Dr. Ashish Kale[1], Dr. Avir Sarkar[2], Dr. Prathamesh Lanjewar[3]

Chairperson, Family Welfare Committee, FOGSI; Director, Asha IVF Centers and Ashakiran Hospitals[1]
North Zone Coordinator, Family Welfare Committee, FOGSI; Assistant Professor, Department of Obstetrics and Gynaecology, Institute of Medical Sciences[2] Research Associate, Department of Obstetrics and Gynaecology, Institute of Medical Sciences[3]

INTRODUCTION

Contraception is a critical national health issue in India, despite notable advancements in family planning initiatives in recent years. The government is actively pursuing initiatives and policies to address the same. However, data from the National Family Health Survey (NFHS-5) conducted during 2019–20 indicates that approximately 9.4% of couples of reproductive age who wish to delay or avoid pregnancy do not have access to suitable contraceptive methods[1]. This article explores the surmounting problem of unmet need for contraception in India, detailing the current national status, potential causes of these unmet needs, and strategies for its improvement. It also discusses recent advancements, government initiatives, state-wise data, and the utilization of various contraceptive devices.

What is 'Unmet need for Family Planning'?

The term "unmet need for family planning" highlights the lacunae in women's reproductive goals and the usage of contraceptives. It specifically pertains to sexually active women who wish to avoid or delay pregnancy but are not using any form of contraception. This gap can lead to unintended pregnancies, which have significant repercussions for women's health, family welfare, and socio-economic development.

Defining Unmet need for Family Planning

Women of reproductive age (15-49) who are married or in a union and who have an unmet need for family planning x 100 / Total number of women of reproductive age (15-49) who are married or in a union.

Current Status

Currently, India has an overall unmet need for contraception estimated at 9.4%. While this represents a decrease compared to previous surveys, it highlights that a significant number of women still face barriers to accessing the contraceptives they need. The NFHS-5 has provided insights into unmet family planning needs among married women aged 15-49 years[1]. Initial results show a reduction in these needs across most states and Union territories, except Meghalaya. Overall, there has been substantial fulfilment of demands for family planning services and their impact on fertility in the majority of states.

Among the 17 states surveyed in NFHS-5 phase-1, Meghalaya topped the list of unmet needs, at 21.9 per cent in urban and 28.2 per cent in rural areas. Andhra Pradesh occupied the bottom-most place; it accounted for 5.2 per cent of unmet needs in urban areas and 4.4 per cent in rural areas. Andaman and Nicobar Islands and Jammu and Kashmir held the top and bottom positions among UTs. Andaman and Nicobar Islands accounted for 18.3 per cent of unmet needs in urban areas and 10.3 per cent in rural areas; Jammu and Kashmir had 6.1 per cent of unmet needs in urban areas and 8.4 per cent in rural areas (Figure 1).

	Urban	Rural
Andarnan & Nicobar Islands	18.3	10.3
Andhra Pradesh	5.2	4.4
Assam	9.9	11.1
Bihar	11.5	13.9
Dadra & Nagar Haveli and Daman & Diu	15.4	8.5
Goa	7.3	10.1
Gujarat	9.7	10.8
Himachal Pradesh	9.3	7.7
Jammu & Kashrmir	6.1	8.4
Karnataka	7.3	5.9
Kerala	13	12
Lakshadweep	13.6	7.6
Ladakh	11.5	7
Maharashtra	9.9	9.3
Meghalaya	21.9	28.2
Manipur	12.7	12
Mizoram	21.4	16.1
Nagaland	9.3	9.1
Sikkirn	18.2	8.2
Telangana	7.1	6.1
Tripura	4.7	9.6
West Bengal	5.2	7.8

Figure 1: Total Unmet Need among married women aged 15-49 years by place of residence, NFHS-5 (Phase-1). The chart includes 22 states and UTs surveyed in the first phase of NFHS-5

Unmet needs for family planning needs are evenly distributed between urban and rural areas across most Indian states, indicating consistent access and knowledge. Manipur has seen the largest decrease in unmet needs by 17.9% over the last five years. Maharashtra with just a 0.1% decline, while Meghalaya experienced a notable increase of 5.7% in unmet needs (Figure 2 and 3).

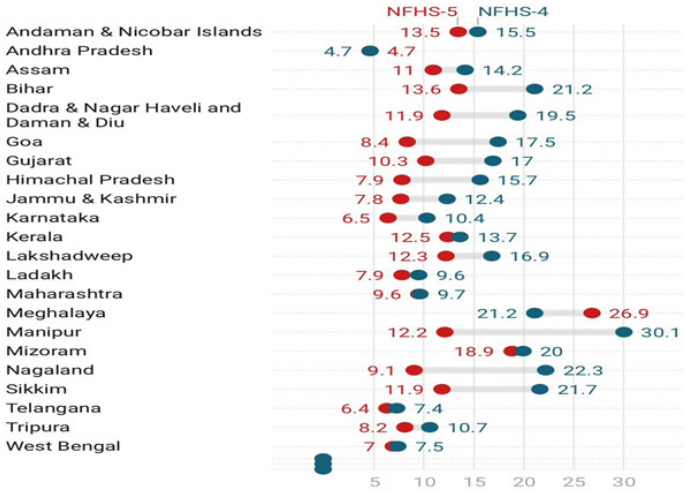


Figure 2: Total unmet needs among married women aged 15-49 years by states/UTs (Union Territory) of India, 2015-16 to 2019-20. Blue and Red circles, respectively, denote the values in the years 2015-16 and 2019-20.

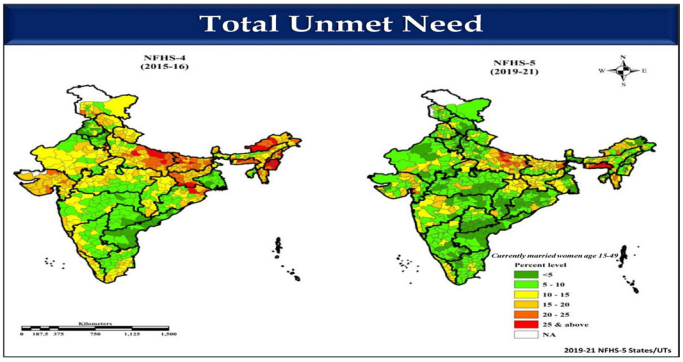


Figure 3: Percent distribution of currently married women aged 15–49 having unmet need for family planning in India, NFHS-4 (2015–2016) and NFHS-5 (2019–2021).

Factors Contributing to Unmet Need of Contraception and Implemented Strategies:

1. **Socio-economic Barriers-** Financial obstacles can be mitigated by subsidizing contraceptives and providing them free of charge under the National Family Planning Programme.
2. Non-engagement of Men- Involving men in discussions and decisions about family planning can reduce the burden on women. Promoting acceptance of newer male contraceptive methods, which are easier to use and have lower failure rates, is also crucial.
3. **Weak Supply Chain-** Ensuring high-quality contraception requires well-trained professionals. This can be achieved through social marketing and community distribution efforts via the Accredited Social Health Activist (ASHA) program.
4. **Low Accessibility of Contraceptives-** The Mission Parivar Vikas initiative, launched in 2016, targets high-fertility districts in seven states with significant unmet family planning needs, improving access to contraceptives.
5. **Lack of Knowledge and Education about Contraceptives-** Awareness campaigns and comprehensive sexual education should be provided, particularly to people of reproductive age, to enhance understanding and proper use of contraceptives.

Government Schemes

The government is actively working to address the unmet need for contraception through various initiatives and schemes[2]:

1. **Jansankhya Sthirata Kosh (JSK):** This registered society under the Ministry of Health and Family Welfare aims to promote population stabilization, small family norms, and provide contraceptive services.
2. **Introduction of newer contraceptive choices:** The Ministry of Health and Family Welfare has launched a new contraceptive option under the "Antara" program as a method of LARC. A non-hormonal contraceptive pill marketed by the name "Chhaya" has also become a preferred option across the country. To help improve the supply and distribution of the same, the Ministry has launched a new software called Family Planning Logistics Management Information System (FP-LMIS), designed to provide robust information on the demand and distribution of contraceptives to health facilities and the ASHAs.
3. **Mission Parivar Vikas (2016)-** This program targets high-fertility districts in seven states with significant unmet family planning needs. It aims to improve accessibility to contraceptives and ensure the provision of quality contraceptive services.
4. **Accredited Social Health Activist (ASHA) Program**: Community health workers promote contraceptive use and provide quality supplies directly to households through awareness campaigns, counselling services, supply distribution, follow-up, and support.
5. **National Family Planning Program:** This program provides free contraceptives at public health facilities. Recent advancements include the addition of newer methods such as injectables and implants, expanding the range of available contraceptive options.
6. **Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA):** This initiative offers antenatal care to pregnant women on the 9th of every month and provides counselling on contraception to prevent unplanned pregnancies.

7. **Family Planning (FP-2030):** Recently, to address the unmet needs of Family Planning in the country and to fulfil the FP-2030 commitment of expanding the basket of contraceptive choice, the Government of India has approved the introduction of subcutaneous Antara and single rod contraceptive Implants (Implanon NXT) into the basket of choice across various states.

Ministry of Health and Family Welfare Guidelines

The Ministry of Health and Family Welfare (MoHFW) has released updated guidelines to improve family planning services[2-5]. The Clinical Guidelines for Contraceptive Use outline detailed protocols for various contraceptive methods to ensure their safety and effectiveness. The Quality Assurance Guidelines focus on maintaining high standards in family planning services, covering proper counselling, method provision, and follow-up care. The Contraceptive Logistics Management Information System (CLMIS) aims to strengthen the supply chain for contraceptives, ensuring that all health facilities are well-stocked. Additionally, the Unplanned Pregnancy Guidelines provide comprehensive strategies to prevent unplanned pregnancies through better access to contraception, post-abortion care, and reproductive health education.

Statistics of State-Wise Contraceptive Usage and Their First Preference

While socio-economic disparities in unmet contraceptive needs exist, they are not substantial. However, notable differences are observed among various states, with some showing a high prevalence of contraceptive use. Additionally, the prevalence rate has increased in several states (Table 1).

Table 1: Different States with the CRP (Contraceptive Prevalence Rate) and the most common methods used

State/UT	Contraceptive Prevalence Rate (%)	Most Common Method
Andhra Pradesh	61.7	Female sterilization
Bihar	24.1	Condoms
Gujarat	62.5	Female sterilization
Haryana	60.4	Condoms
Karnataka	63.2	Female sterilization
Kerala	69.5	Female sterilization
Madhya Pradesh	51.9	Female sterilization
Maharashtra	65.5	Female sterilization
Punjab	68.6	Condoms
Rajasthan	51.6	Female sterilization
Tamil Nadu	70.2	Female sterilization
Uttar Pradesh	45.5	Female sterilization
West Bengal	71.8	Female sterilization
Delhi	56.5	Female sterilization

CONCLUSION

Women's education, occupation, and monthly family income are critical factors in contraceptive use. Free doorstep delivery of modern contraceptives, supported by nonprofits, is essential for effective reproductive and child health services. State governments should monitor family planning policies through regulatory bodies to reduce unmet needs. An education strategy is necessary to enhance awareness about contraception. Hospitals and nursing homes should establish dedicated departments with experienced professionals to guide couples in choosing suitable family planning methods.

India requires a comprehensive approach to deal with the unmet need for Family Planning that takes into account socio-cultural, economic, and health system factors. While substantial progress has been made, continued efforts are crucial to ensure all women and couples have access to the contraception they need to achieve their reproductive goals. By implementing thorough strategies and adhering to the latest guidelines, India can move closer to its family planning and reproductive health targets, ultimately improving the overall health and well-being of its population.

KEY POINTS

1. There is a large population that still has an unmet need for contraception.
2. Various contributing factors identified, need to be dealt with to address this unmet need of contraception.
3. Multiple programmes are introduced by the government to serve this unmet need.

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MEC Wheel India

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INTRODUCTION

Background

In an article in 1992 by Shelton et al, 'Medical barriers to access to family planning' six major types of barriers to contraceptive practices were described. Misguided contraindications, arbitrary eligibility criteria, process hurdles, service provision limited to physicians, bias of providers, and government-based regulatory restrictions on methods.[1] These barriers are the main reasons to restrict access to women, especially in rural areas in low-income countries or who often travel long distances for services only to learn that they did not qualify for the contraceptive method they were seeking. Before the 1990s medical advice was based on expert opinion which was biased and imprecise.

Many decision-makers fail to realise that the provider must tailor contraceptive options as per woman's needs and guide her in selecting the best method for her rather than advise the single best method.

With the popularity of evidence-based medicine, decisions are now guided by conclusions from scientifically rigorous research that help to improve clinical outcomes. The World Health Organization (WHO) published a document named 'Medical Eligibility Criteria (MEC) for contraceptive methods in 1996 (first edition) which provided guidance on the safety of contraceptive use under specific medical conditions or characteristics of the client. The document has been revised in the years 2000, 2004, 2009 and 2015 (fifth edition). The latest revision is upcoming soon in July 2024.[2]

Utility

The Medical Eligibility Criteria (MEC) define the safety of each contraceptive method determined by several considerations, primarily whether the contraceptive method creates additional health risks or worsens the medical condition, and whether the medical circumstance makes the contraceptive method less effective. The safety of the method should be weighed against the benefits of preventing unintended pregnancy. MEC help service providers in shortlisting safe & effective contraceptives for women with those medical conditions or characteristics.

DISCUSSION

WHO MEC Wheel

Based on the latest (fifth; 2015) edition of MEC, the WHO launched the MEC Wheel, a tool which can be used as a guide by service providers to initiate nine common contraceptives in women with medical conditions or certain relevant characteristics. The pdf version of the WHO MEC Wheel 2015 can be downloaded online from WHO's website (or from this link: https://iris.who.int/bitstream/handle/10665/173585/9789241549257_eng.pdf?sequence=1)

The WHO MEC Wheel 2015 enumerates recommendations for initiating use of nine common types of contraceptive methods:

1. Combined pills, COC (low dose combined oral contraceptives, with ≤ 35 µg ethinyl estradiol)
2. Combined contraceptive patch, P
3. Combined contraceptive vaginal ring, CVR
4. Combined injectable contraceptives, CIC
5. Progestogen-only pills, POP
6. Progestogen-only injectables, DMPA (IM, SC)/ NET-EN (depot medroxyprogesterone acetate intramuscular or subcutaneous or norethisterone enanthate intramuscular)
7. Progestogen-only implants, LNG/ETG (levonorgestrel or etonogestrel)
8. Levonorgestrel-releasing intrauterine device, LNG-IUD
9. Copper-bearing intrauterine device, Cu-IUD

In 2019 WHO launched an App, "WHO Contraception Tool" for contraceptive use initiation and continuation of 9 common methods included in MEC Wheel, which can be downloaded for both Android and iOS devices (from Playstore and iTunes respectively).

The MEC wheel only provides guidance for initiating contraceptive methods. Recommendations for the continuation of the method used, when a woman develops any medical condition while using the method, can be found in the Medical Eligibility Criteria for Contraceptive Use Guidelines.

MEC WHEEL - INDIA

While the WHO MEC wheel comes as a valuable tool and a practical guide to service providers, it does not include Chhaya (centchroman), a non-steroidal contraceptive pill used exclusively in India since 2017.[3]

This limitation was overcome when the MEC wheel for contraceptive use - India 2022 [Figure 1] was developed by the Family Planning Division, Ministry of Health and Family Welfare Government of India. It was adapted from the WHO MEC wheel for contraception use and is based on the MEC for contraceptive use 4th and 5th editions, 2009 and 2015 respectively. The wheel was launched on 27th July 2022, in New Delhi, India, during the National Family Planning Summit along with the unveiling of the India Family Planning 2030 vision document.

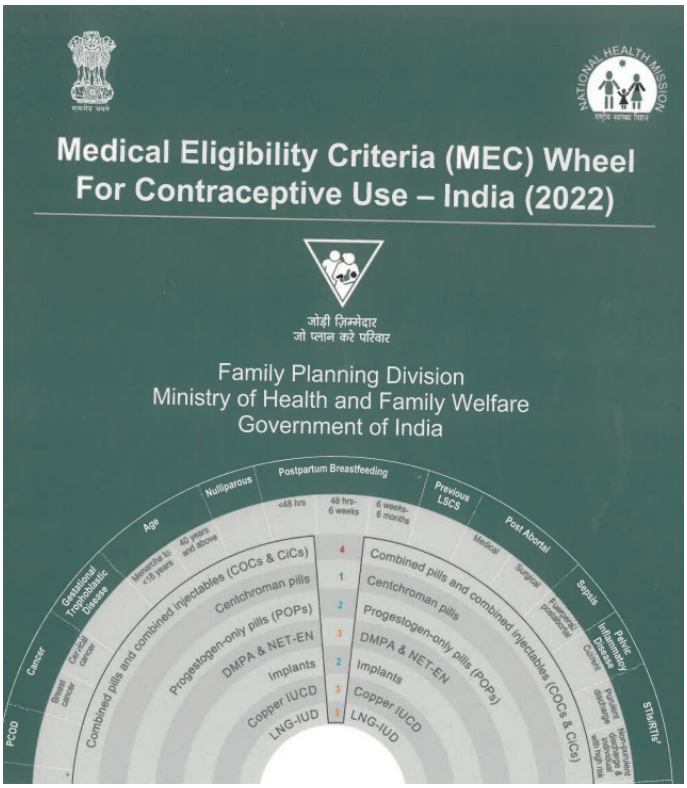

Figure 1: MEC Wheel India 2022

The wheel includes recommendations on the initiation of seven common types of contraceptives:

1. Combined pills (low dose combined oral contraceptive with < 35 microgram ethinylestradiol) and combined injectable contraceptive (COCs & CICs)
2. Centchroman pills
3. Progesterone-only pills (POPs)
4. Progesterone only injectables. DMPA (3 monthly injectables) and NET-EN (2 monthly injectables)
5. Progesterone implants
6. Copper bearing IUCD
7. Levonorgestrel intra uterine device (LNG-IUD)

The most unique aspect of MEC Wheel India is the inclusion of Tab Centchroman (Ormeloxifene), a reversible weekly oral contraceptive (half-life of about 168 hours), that was designed and developed at Central Drug Research Institute (CDRI), Lucknow. It is the only non-steroidal oral contraceptive in clinical use in the world today which was approved for marketing in 1991, under the brand name 'Saheli'. Since 2018, Centchroman has been provided free of cost to women in India by the government under the brand name *Chhaya*. It acts as a Selective Estrogen Receptor Modulator (SERM) and prevents implantation of the blastocyst in the endometrium. It has a high level of safety and is virtually free from side effects except for a delay in menstrual cycles in approximately 8% of users usually in the first three months.[4]

Centchroman is not recommended if the client has any of the following conditions:

- Polycystic ovarian disease
- Cervical hyperplasia
- Recent history of jaundice or liver disease
- Severe allergic state
- Chronic illness, like tuberculosis or renal disease[4]

How to use the Wheel

The wheel has specific medical conditions mentioned on the outer rim which matches up with the contraceptive methods shown on the inner disc. The inner disc is rotated to reveal the MEC categories for each specific medical condition in the viewing slot. There are 4 MEC categories. Categories 1 and 4 have clearly defined recommendations whereas categories 2 and 3 require greater clinical judgement. In general categories 1 and 2 means the method can be used and categories 3 and 4 means the method should not be used.

1. Category 1: YES: Use the method in any circumstance
2. Category 2: YES: Generally use the method
3. Category 3: NO: method not usually recommended unless other, more appropriate methods are not available or acceptable
4. Category 4: NO: Method not to be used

These MEC categories for specific medical conditions against each contraceptive method have been tabulated (Table I)

PREGNANCY CHECKLIST

On the cover of the wheel is a set of questions to rule out pregnancy before starting any method:

1. Did your last monthly bleeding start within the past 7 days (if the client is opting for IUCD this window maybe expanded to 12 days)?
2. Are you maintaining abstinence from sexual intercourse since your last monthly bleeding, delivery, abortion or miscarriage?
3. Have you been using a reliable contraceptive method consistently and correctly since your last period, delivery, abortion or miscarriage?
4. Have you had a baby in the last 4 weeks?
5. Did you have a baby of less than 6 months, are you fully or nearly fully breastfeeding and have you had no monthly bleeding since then?
6. Have you had a miscarriage in the past 7 days (if the client is opting for IUCD this window may be extended to 12 days)?

If the client answers yes to any one of the questions, then pregnancy is ruled out and the contraceptive method can be provided.

If the client answers no to every question, then ask her, if she has had regular cycles in the past and missed her periods this month?

- If she says no, then do a urine pregnancy test (UPT) and provide the chosen method if UPT is negative; in case of IUCD repeat UPT after 3-4 weeks of condom use/ abstinence and provide IUCD if UPT is still negative.
- If she says yes, delay the method till the next cycle; use a condom till then. Offer ECP in case of unprotected sex within the last 72 hours.

Notes to the conditions (TABLE 1):

1. >45 yrs = 2
2. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, declining to near baseline levels by 42 days postpartum.[5] Clinical studies demonstrate conflicting results regarding the effects of continuation of breastfeeding.
3. COCs, CICs, POPs, DMPA, NET-EN, and Implants can be initiated on the day misoprostol is given.
4. Cu IUCD and LNG-IUD to be inserted after ensuring complete abortion.
5. Cu IUCD and LNG-IUD is cat 2 after second-trimester abortion
6. Insertion of Cu IUCD or LNG-IUD during current infection (PID/ STI with purulent discharge) is cat 4. However, if a woman develops an infection While using LNG-IUD or Cu IUCD, give treatment and continue with the device.
7. If at an increased risk of STI or HIV advise condom use in addition to any other method.
8. If on ARV therapy= 2, except ritonavir-boosted ARVs=3 (Pharmacokinetics suggest decrease in COC and progestin levels with ritonavir-boosted Protease Inhibitors and ritonavir)
9. If not receiving ARV treatment and not clinically well, Cu IUCD and LNG-IUD = 3 due to increased risk of pelvic infections. For continuation of Cu IUCD and LNG-IUD, cat=2, but women should be closely monitored for pelvic infections.
10. COCs = 3; CICs= 2 (rifampicin reduces the effectiveness of COCs. But Rifabutin's effect on the metabolism of COCs are less than with rifampicin.[6] If a COC is chosen, preparation should contain minimum 30 µg EE.)
11. DMPA= 1; NET-EN= 2 (rifampicin or rifabutin reduces the effectiveness of POPs, NET-EN and LNG/ETG implants. However, DMPA is cat 1 as its effectiveness is not reduced.)
12. One survey suggests that rifabutin had no impact on the effectiveness of LNG-IUD (132).[7] If pelvic TB, Cu IUCD and LNG-IUD = 4
13. Use of certain anticonvulsants may decrease the effectiveness of COCs. If a COC is chosen, preparation should contain a minimum of 30 µg EE. Lamotrigine levels decrease significantly during COC use and increase significantly during the pill-free interval.[8]
14. For lamotrigine, POPs and implants =1. There are no drug interactions reported with progesterone-containing contraceptives and lamotrigine.[8]
15. COCs and heavy smoking (>=15 cigarettes/day) = 4 (due to increased risk of cardiovascular diseases like myocardial infarction); COCs and heavy smokers <35yrs= 2 (risk of cardiovascular diseases is less at a young age); COCs and light smoking= 2
16. Due to increased risk of stroke, acute MI, and peripheral arterial disease
17. Limited evidence suggests a small increased risk of cardiovascular events
18. For simple headaches most contraceptives can be used safely
19. To check for aura, ask 'Do you see a bright spot in your vision before bad headaches?'. If the condition develops while on POP, DMPA, NET-EN, Implants, or LNG-IUD, then switch on to a non-hormonal method.
20. Women with migraine with aura had an increased risk of stroke than those without aura.[9] Women with migraine on COCs are at 2–4 times higher risk of ischaemic stroke as compared to non-users with migraine.[9]
21. Migraine without aura and <35yrs, COCs and CICs= 2; Migraine without aura and >=35yrs, COCs and CICs= 3
22. Women with multiple risk factors: old age, smoking, hypertension, diabetes, obesity and dyslipidaemia. If stroke/IHD develops, while on POP, Implants, or LNG-IUD (only IHD), change to the non-hormonal method.

23. Prophylactic antibiotics are advisable for Cu IUCD and LNG-IUD.
24. If established on anticoagulant therapy = 2. No direct evidence on the use of POCs among women with DVT/PE on anticoagulant therapy. Although the risk of venous thrombosis with the use of POCs is inconsistent in otherwise healthy women, any increased risk is substantially less than that with COCs.[10]
25. If diabetes is complicated or for > 20 years: COCs, CICs, DMPA and NET-EN = 3-4.
26. Limited data is available for COC use during active hepatitis. Evidence suggests that COC use does not increase the rate or severity of cirrhotic fibrosis, or risk of hepatocellular carcinoma in women with chronic hepatitis.[11]
27. Centchroman is metabolised in the liver into active and inactive metabolites; the active metabolite (7-desmethyl centchroman) is responsible for the anti-implantation effect.
28. In mild cirrhosis, LNG-IUD= cat 2.
29. Presence of Antiphospholipid antibodies is associated with a higher risk for both arterial and venous thrombosis.
30. In severe anaemia, Cu IUCD = cat 2.
31. If a cavity is distorted or enlarged, should not use Cu IUCD or LNG-IUD. Continuation of use is cat 2.
32. If beta-hCG is persistently high or suspicion of local malignant disease Cu IUCD and LNG-IUD = 4.

TABLE 1: MEC categories for specific medical conditions

MEDICAL CONDITION		COCs & CICs	Centchroman Pills	POPs	DMPA & NET-EN	Implants	Copper IUCD	LNG-IUD
Age	Menarche to <18 yrs	1	1	1	2	1	2	2
	40 yrs & more	2	1	1	1-2[a]	1	1	1
Nulliparous		1	1	1	1	1	2	2
Postpartum breastfeeding	<48 hrs	4[b]	1	2	3	2	1	2
	48 hrs- 6wk	4[b]	1	2	3	2	3	3
	6wk- 6 months	3	1	1	1	1	1	1
Prev LSCS		1	1	1	1	1	2	2
Post abortal	Medical	1[c]	1	1[c]	1[c]	1[c]	2[d]	2[d]
	Surgical	1	1	1	1	1	1[e]	1[e]
Sepsis (Puerperal/ Post-abortal)		1	1	1	1	1	4	4
Current PID		1	1	1	1	1	4[f]	4[f]
STIs/ RTIs[g]	Purulent discharge	1	1	1	1	1	4[f]	4[f]
	Non-purulent discharge & individual with high-risk	1	1	1	1	1	2	2
HIV/AIDS		1[h]	1	1[h]	1[h]	1[h]	2-3[i]	2-3[i]
TB	On rifampicin or rifabutin	2-3[j]	2	3[k]	1-2[k]	2[k]	1[l]	1[l]
Epilepsy	On anticonvulsants	3[m]	1	3[n]	1	2[n]	1	1
Smoking	>35 yrs	3[o]	1	1	1	1	1	1
Hypertension	<160/100	3[p]	1	1	2	1	1	1
	>160/100	4[p]	2	2[q]	3[q]	2[q]	1	2[q]
Headache[r]	Migraine with aura[s]	4[t]	3	2-3[s]	2-3[s]	2-3[s]	1	2-3[s]
	Migraine without aura[s]	2-3[u]	2	1	2	2	1	2
Cardio Vascular Disease	Stroke, IHD, multiple risk factors[v]	4	1	2	3	2	1	2
	Complicated valvular heart disease	3	1	2	2	2	2[w]	2[w]
Deep Vein Thrombosis	h/o DVT/PE, on anticoagulant, prolonged immobilization	4	1	2	2	2	1	2
	Acute DVT	4	3	3[x]	3[x]	3[x]	1	3
Diabetes Mellitus	Current	2[y]	1	2	2[y]	2	1	2
Liver Disease	Acute Viral Hepatitis	4[z]	4[aa]	1	1	1	1	3
	Cirrhosis/ Liver Tumor	4	4[aa]	3	3	3	1	3[bb]

SLE		4[cc]	3[cc]	3[cc]	3[cc]	3[cc]	1	3[cc]
Anaemia		1	1	1	1	1	1[dd]	1
Unexplained Vaginal Bleeding		2	2	2	3	3	4	4
Fibroid Uterus		1	1	1	1	1	1[ee]	1[ee]
PCOD		1	4	1	1	1	1	1
Cancer	Breast Cancer	4	2	4	4	4	1	4
	Cervical Cancer	2	2	1	2	2	4[ff]	4[ff]
Gestational Trophoblastic Disease		1	2	1	1	1	3-4[gg]	3-4[gg]

There are certain medical conditions where all the methods can be used (category 1 or 2) which are listed on the back of the wheel (Table II)

TABLE 2: medical conditions where all methods can be used

Reproductive Conditions	Medical Conditions	Other
Benign breast disease or undiagnosed mass	Depression	Adolescents
Benign ovarian tumours, including cysts	Epilepsy	Venous thromboembolism (VTE) family history
Dysmenorrhoea	HIV asymptomatic or mild clinical disease; WHO Stage 1 or 2	High risk for HIV
Endometriosis	Iron deficiency anaemia, sickle-cell disease and thalassaemia	Surgery without prolonged immobilization
History of gestational diabetes	Malaria	Taking antibiotics (excluding rifampicin/rifabutin)
History of high blood pressure during pregnancy	Mild cirrhosis	
History of pelvic surgery, including caesarean delivery	Superficial venous disorders, including varicose veins	
Past ectopic pregnancy	Thyroid disorders	
Past pelvic inflammatory disease	Tuberculosis (non-pelvic)	
Post-abortion (no sepsis)	Uncomplicated valvular heart disease	
Postpartum ≥ 6 months	Viral hepatitis (carrier or chronic)	

With few exceptions, all women can safely use emergency contraception (category 2 for h/o severe CVD, migraine and severe liver disease), barrier and natural/behavioural methods of contraception, including lactational amenorrhoea method.

CONCLUSION

Now the MEC has become an important document for practitioners and policymakers in family planning, as it provides the latest evidence-based recommendations for contraceptive use for women with various medical conditions. The WHO MEC wheel and the mobile App, 'WHO Contraception Tool' are excellent for quick reference and can be used even in a busy outpatient setting for robust contraceptive advice.

The inclusion of Chhaya in MEC Wheel – India allows all cadres of health workers in the country to help women choose the right contraceptive according to their medical condition or relevant medical characteristics. It is interesting to note that centchroman pills can be safely used (MEC 1 or 2) in the majority of medical conditions with only a few exceptions (MEC 3 or 4) like migraine with aura, acute DVT, liver diseases, SLE and PCOD.

KEY POINTS

1. WHO MEC document, wheel and mobile App are being used globally and guide family planning providers to adhere to evidence-based recommendations for contraceptive advice.
2. The main differentiating aspect of the Indian MEC wheel from the WHO MEC wheel is the inclusion of centchroman pill Chhaya.
3. Chhaya is an effective non-hormonal oral contraceptive which is suitable for use right from the immediate postpartum period and can be safely prescribed in most medical conditions.

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Contraception at Extremes of Reproductive Age

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INTRODUCTION

Contraception is an important part of women's health to avoid unwanted pregnancies. Thorough knowledge regarding available contraception is equally important for patients and clinicians. Different age groups have different needs when choosing contraception, be it adolescent and reproductive age group women.

Adolescent contraception

Our country has the largest generation of adolescents approximately 250 million and more young individuals with sexual and reproductive health needs.

It is a fact that sexual debut and activities start for them before acquiring knowledge & skills in self-protection against sexually transmitted infections and pregnancy. It is a fact that the majority of sexually active teenagers may not use any contraception and this is an area of potential unmet need. A very alarming 30% of new HIV infections are acquired in adolescence. Some of the reasons for poor health-seeking behaviour for adolescents are the fear of being judged for relationship decisions, lack of information, accessibility and affordability of contraceptive methods. At times the unexpected/unplanned nature of sexual activity leaves the couple exposed to the risk of unprotected sexual intercourse especially if there is no awareness regarding emergency contraception.[1]

As consultants we need to develop special skills: Ensure the young person and the partner are 18 years and more of age, provide information about the POCSO act and inform that sexual debut and activity before 18 years of age is a criminal offence in our country. Develop rapport & gain confidence. Identify sexual health & contraceptive needs, and assess compliance and affordability of the young person. Assess the risk of sexual exploitation, coercion, abuse, frequency of intercourse, partners and steadiness of relationships. Avoid time constraints & distractions during sessions. Offer the young person or couple the basket of choice of contraceptives and help towards choosing a contraceptive and provide method-specific counselling. Always offer dual protection against pregnancy and STI: Some examples are condoms plus oral contraceptive pills, condoms plus injectable methods, condoms during safe periods and willingness to use emergency contraception when needed and so on.

There are often doubts in the minds of practitioners regarding the relative safety of methods in younger women. All contraceptive prescriptions must follow the medical eligibility criteria by WHO 2015 and the MOHFW Wheel 2022. It is well established that all spacing methods are as safe as in adults including the intrauterine devices.[2] At any given time the basket of choices must offer barrier contraceptives, safe period and other natural methods, coital dependent methods e.g.: spermicides and foam tablets, short-acting methods like hormonal and non-hormonal contraceptive pills, the hormonal methods are the combined estrogen and progesterone contraceptive pills/rings/injections/ patches, progesterone only pills, long-acting methods like IUDs, LNG-IUD, injectable (Depot Medroxy Progesterone Acetate) contraceptive, etonogestrel implant and of course emergency contraceptive pills. Structured counselling efforts will help in dispelling myths and misconceptions and also increase the uptake of modern methods.

At all times we must also highlight the benefits of methods beyond contraception,[3] e.g., the non-contraceptive benefits of combined oral pills in this age group are: regular menstrual periods with less bleeding and so less anaemia, relief of dysmenorrhea and arrest progress of endometriosis. Fewer symptoms of premenstrual syndrome, in women with PCOS the definite relief of features of hyperandrogenism: acne, hirsutism and prevention of future metabolic syndrome.

Some method-specific disadvantages of OCP and other hormonal contraceptives must be known: no protection against sexually transmitted diseases, and need to be taken daily therefore, high compliance is needed. Irregular menstrual pattern (breakthrough bleeding) from lower dose pills and POP is a known fact and sometimes there can be headaches/depression. Also, the increased risk of cervical ectopy and chlamydial cervicitis: may be due to the sexual behaviour profile of pill users. Breast tenderness, nausea and vomiting can be experienced occasionally. We must carefully follow MEC criteria and avoid category 3 and

4 situations for pills, especially in cases with a history of arteriovenous thrombosis, hypertension, breast cancer and liver disease.

Contraceptive Access Programs for young people need to be developed in all healthcare delivery systems and providers must acquire higher skills and knowledge for the same.

Contraception for the Perimenopausal Woman

The contraception needs of a perimenopausal woman are complex for several reasons. At this age motivation to use a method becomes low as women have less libido, a false notion that advancing age protects from pregnancy, professional career challenges at maximum and a decline in energy accounting for poor health-seeking behaviour.

They also become prone to non-communicable diseases especially cardiovascular disease and gynecologic neoplasia and the choice of a safe method will require individualisation. Women who marry late also go through phases of contraception and family planning need ambivalence and remain unsure of seeking care on the matter. Nonetheless, the unmet need at this age requires an effective method, with minimum metabolic or endocrine effects, protects against all STIs, and preferably has favourable effects on bone health and menopausal symptoms.

In women with no independent cardiovascular risk factors, obesity, smoking, hypertension, diabetes, previous DVT etc, low-dose combined oral contraceptive pills may be offered with good benefits beyond contraception, to regularize cycles, relief of vasomotor symptoms if any and prevention of cancers. In women with the above CV risks and to eliminate user compliance issues, the LARC methods of injectable hormones, LNG-IUS, etonogestrel implants and Cu IUDS can be offered with high conviction for safety profile and efficacy, in some methods especially LNG-IUS is especially useful for prevention of endometrial hyperplasia and treatment of related heavy menstrual bleeding. A good example of such a woman is an obese, type 2 DM who has heavy menstrual bleeding.[4]

The biochemical characteristics of the premenopausal woman will play a role in her reproductive choices. The presence of irregular, heavy bleeding, climacteric symptoms, risk of osteoporosis and osteopenia and the fact that there is an increased risk for Bone demineralization, cardiovascular diseases and gynecologic neoplasia

In women of this age, who are not particular about fertility and have ambivalence about family planning, their need to be protected from unintended pregnancy is very high. They have high domestic responsibilities with adolescent children and have to care for ageing senior citizens in the family. Working women may have professional career challenges at maximum and suffer a decline in energy. Let us not forget the same age is susceptible to professional burnout and depression. The majority likely have to face the challenges of loss of sexual desire and other menopausal symptoms and thoughts about pregnancy will be very far from their minds. We need to alert them that the rising FSH values in response to declining follicular reserve in the ovaries can result in occasional ovulation and an accidental unintended pregnancy.

To be precise the Contraceptive for a Premenopausal woman must have the following characteristics;[5] effective, safe (no or minimal health risk), protect against STI and HIV, independent of compliance, no weight gain or negative metabolic effects. Preferably these should have additional benefits like climacteric symptoms, heavy menstrual bleeding, bone demineralization, perimenopausal depression etc.

Matching some of the methods to the above needs, we can easily identify the following benefits and nuances of the prescription of certain methods in this age group:

COMBINED ORAL CONTRACEPTIVES

It is very effective and is a good choice for women who already used CHC in the past with good outcomes, who have had no risk factors for cardiovascular disease or thromboembolism, and who need additional benefits from climacteric symptoms, heavy menstrual bleeding, protection against bone demineralization, perimenopausal depression and protection against endometrial and ovarian cancer. However, the decision to continue for a long period must be revisited periodically as it causes an age-dependent increase in thrombotic risk.

PROGESTERONE ONLY PILLS

This is one very versatile and effective but under-utilized method, that can be used in women for whom estrogen is contraindicated e.g. the woman with cardiovascular risk. There are additional benefits for climacteric symptoms and heavy menstrual bleeding. On the downside may lead to irregular bleeding and requires structural counselling for continuation, with no major health risks.

COPPER IUD

It is a long-acting reversible contraceptive and independent of compliance. It is suitable for women with cardiovascular risk / who wish for long-acting methods, and no additional needs, for eg, have no significant menopausal symptoms.

IMPLANON

Also a long-acting reversible contraceptive and independent of compliance. Suitable for women with cardiovascular risk who wish for a long-acting, efficient method with no weight gain or negative metabolic effects with additional benefits of protection against ovarian and endometrial carcinoma, and relief of dysmenorrhea. It may cause irregular bleeding in 20 % of acceptors who need skilled counselling and no cardiovascular risks.

DEPO PROVERA

It is a long-acting reversible contraceptive and no compliance is needed. Suitable for women with cardiovascular risk who wish for long-acting and have no risk factor for osteoporosis. Additional advantages are irregular bleeding, weight gain is reversible and reduction of bone mineral density can happen though it is reversible.

LNG- IUD

This is a long-acting reversible contraceptive and independent of compliance. Can be given to a woman with or without cardiovascular risk who wishes for a long-acting, effective method and doesn't require compliance. It has additional benefits in heavy bleeding (can even reverse endometrial hyperplasia), and menstruation-related symptoms and may cause attenuation of climacteric symptoms, which is still debatable. Irregular bleeding is a side effect.

CONCLUSION

Women in all age groups who are sexually active and not vasectomized or hysterectomised, do require birth control and must continue to use the method till one year after menopause as the risk of pregnancy persists till such time. Many women in all age groups have an unmet need for contraception which must be explored and understood and accordingly, the service should be provided.

KEY POINTS

1. Various types of contraception are available, but not all types are appropriate for all age groups.
2. The best method of contraception depends upon an individual's overall health, age, frequency of sexual activity, number of sexual partners, desire to have children in the future, and family history of certain diseases.
3. We need to ensure access to all their preferred contraceptive methods as per their requirement and other associated conditions.

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Monthly Clinical Meetings AOGD Calendar 2024-25

Date	Hospital
26th April, 2024	LHMC & Smt. Sucheta Kriplani Hospital
31st May, 2024	B L Kapoor Hospital
28th June, 2024	Apollo Hospital
26th July, 2024	Army Hospital (Research & Referral)
30th August, 2024	AIIMS Delhi
27th September, 2024	ESI, Basaidarapur Delhi
25th October, 2024	DDU Hospital
29th November, 2024	MAMC & LNJP Hospital
27th December, 2024	Sir Gangaram Hospital
31st January, 2025	VMMC & Safdarjung Hospital
28th February, 2025	UCMS & GTB Hospital
28th March, 2025	RML Hospital
25th April, 2025	LHMC & Smt Sucheta Kriplani Hospital

Single Rod Implant

Dr. Preeti Sainia

CMO-NFSG, Department of Obstetrics & Gynaecology, ABVIMS & RML Hospital

INTRODUCTION

Subdermal contraceptive implants have emerged as a significant innovation in family planning, providing long-term, reversible contraception. It is over three decades old and has evolved over the years from the 6-rod implant (LNG containing NORPLANT) to a single-rod implant. One of the newest medications in the hormonal contraceptive class is an etonogestrel implant (Implanon).[1] A single, small flexible thin rod is placed in the non-dominant upper arm and is replaced every three years. This offers women another option for preventing unplanned pregnancies.[1-3]

These implants release hormones that prevent pregnancy for several years, offering a reliable and low-maintenance option for women worldwide. This article explores the mechanisms, efficacy, benefits and side effects of subdermal contraceptive implants. We also review recent advancements and future directions in this field.

GENERAL INFORMATION

It comes in a sterile, preloaded disposable applicator with a needle for single use as shown in Fig 1

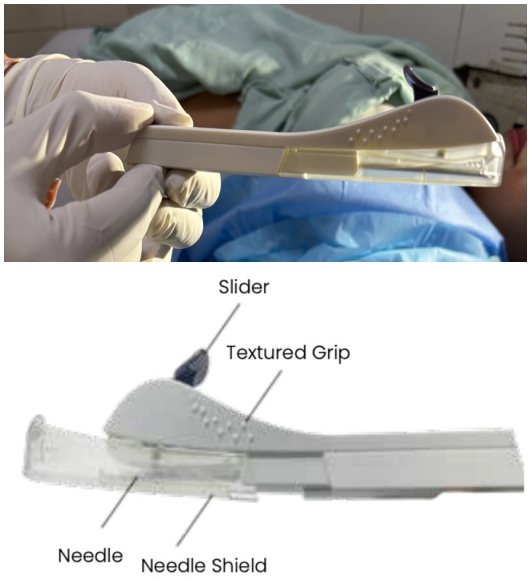


Figure 1: Applicator with preloaded Implant

The applicator consists of the following parts

1. **Needle shield/ Transparent protective cap**: The transparent protection cap covers the needle and is removed just before insertion.
2. **Textured area:** The rough dotted area on the applicator is for facilitating proper grip. The service provider needs to hold the applicator at this very point while inserting the Implant.
3. **Slider**: It is purple-coloured and lies on top of the applicator. Once the Implant is inserted, the slider is unlocked by pushing it slightly down and then pushed back to its full length.
4. **Bi-bevelled needle**: The needle is specially designed with two bevel points in front: One bevel point positions the needle to puncture the skin at a 30° angle and the other bevel point on the needle facilitates lifting of the skin after the needle has been inserted completely.

Etonogestrel, a synthetic biologically active metabolite of the synthetic progestin desogestrel,[1-3] binds with high affinity to progesterone receptors in the target organ

COMPOSITION

The single rod Implant is 4 cm long and 2 mm in diameter, with a core and skin, which contain active and inactive ingredients respectively, as shown in Fig 2

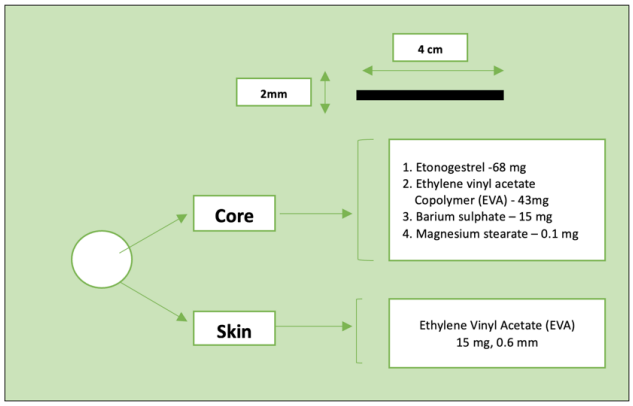


Figure 2: Composition of the implant

Active Ingredient: Etonogestrel (ENG; 68 mg) is placed in the core of the rod (a biologically active metabolite of Desogestrel and structurally derived from 19-Norethisterone), which binds with high affinity to progesterone receptors in the target organs.

Inactive Ingredients:

Core: Ethylene vinyl acetate copolymer (28% vinyl acetate, 43 mg), barium sulfate 15 mg and magnesium stearate 0.1 mg Core is surrounded by 0.6 mm ethylene vinyl acetate (EVA), which forms the skin of the Implant. The addition of barium sulfate to the core makes it radiopaque, making it easily detectable by X-ray or other imaging tools.[4]

Skin

Is composed of Ethylene vinyl acetate copolymer (15% vinyl acetate, 15 mg). The etonogestrel hormone, placed inside the core of the rod, is embedded in an ethylene vinyl acetate copolymer matrix.

After the insertion is done, rapid absorption of etonogestrel in circulation starts, and the ovulation-inhibiting action starts within an hour to one day (Table 2.1). Once the Implant is removed, the plasma level of etonogestrel falls quickly and there is an early return to fertility.

The week-wise absorption of etonogestrel is as follows (Table 1):

Table 1: Week-wise Absorption of Etonogestrel in Serum

Rate of Release of Etonogestrel	Serum Concentration
60-70 mcg/day by 6th week of insertion	>90 pg/ml reached in an hour to one day (ovulation inhibiting concentration)
30-40 mcg/day by the end of 2 years	472-1270 pg/ml maximum serum concentration (reached within 2 weeks)
25-30 mcg/ml by the end of 3 years	Serum concentration decreases to 156 pg/ml by the end of 3 years and falls to 20 pg / ml within 4 days of removal. Return to fertility is rapid with an implant.

SITE OF INSERTION

The Implant rod has to be placed away from major blood vessels, muscles and nerves to avoid potential injury.

The Implant rod should be inserted just under the skin on the inner aspect of the nondominant upper arm (Fig. 3) 8–10 cm proximal (towards the shoulder) to the medial epicondyle and 3–5 cm posterior to the sulcus/groove between the biceps and triceps muscles. In a woman with thin arms, it should be inserted as far from the sulcus as possible. It is recommended to measure and mark the insertion site before insertion. The site should be marked before insertion.

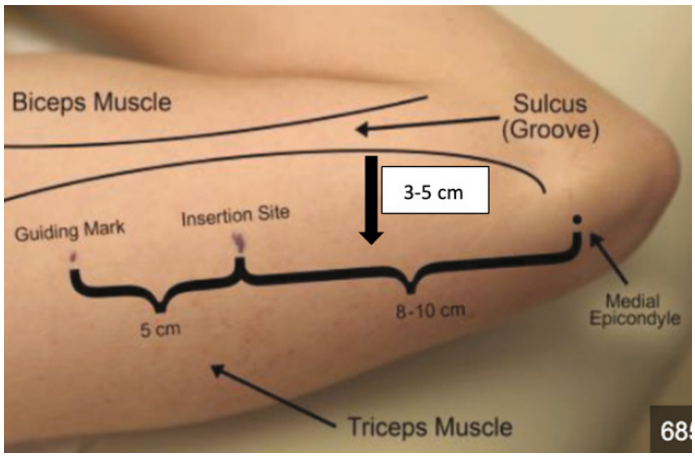


Figure 3: Site of insertion

Mechanism of Action

It acts by:

- Inhibiting Ovulation[5]
- Thinning the endometrial lining, making it unfavourable for Implantation of fertilized ovum.[6]
- Cervical mucus thickening, thereby preventing entry of sperms in the upper reproductive tract.[7]

STEPS OF INSERTION

The insertion tray should have the following material as shown in Fig 4

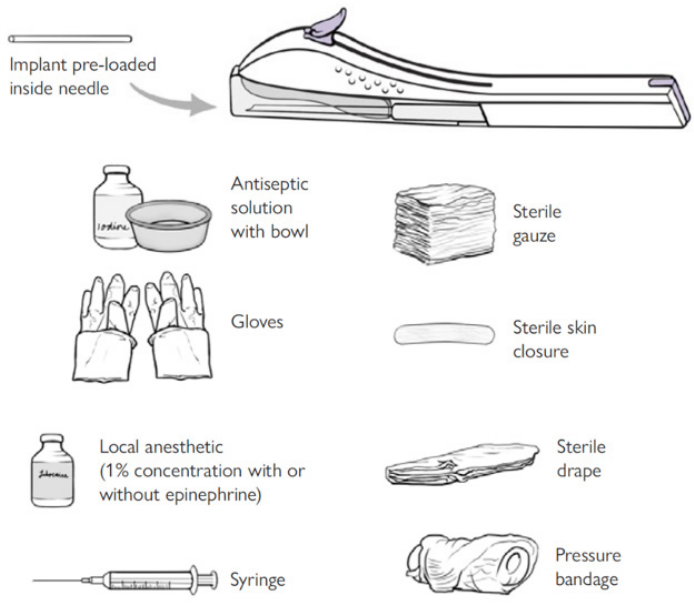
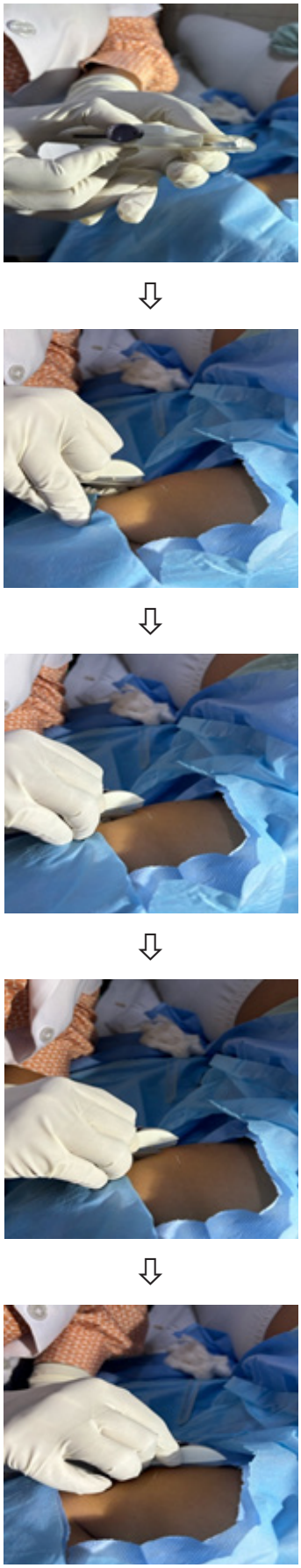


Figure 4: Material Required



STEPS OF INSERTION (FIG 5)

Mark points on the nondominant arm for insertion of rod, 8–10 cm from the medial epicondyle and 3–5 cm below the sulcus.

Clean and drape the woman's arm.

Inject 1–2 mL of 1% lidocaine just under the skin, at the insertion point and advancing up to 5 cm along the track of insertion.

Remove the sterile disposable applicator from blister pack using no touch technique. Always hold at the textured surface area. Verify presence of implant inside of needle visually and remove needle shield.

Provider should ensure that the insertion is subcutaneous and parallel to the arm.

Stretch skin near insertion site and puncture the skin with applicator at a 30^{o} angle and insert only the bevel of the needle.

Visualizing the needle, lower the applicator until it is parallel to the surface of skin and gently advance, lifting skin upwards to make sure that placement is superficial .

Insert entire length of the needle without using force. Visually verify that entire length of the needle has been inserted in the skin .

Hold the applicator in this position and press the purple slider downwards until it stops.

This action will retract the needle into the body of the applicator.

Gently remove applicator, this will leave the implant in place.

Palpate to check the implant is in place. Make the woman palpate the implant to confirm its presence.

Apply pressure bandage dressing to minimize bleeding and bruising.

Keep the patient under observation for 10 to 15 mins .

Explain the patient that she can take off the pressure bandage her self at home after 5 days and contact in case of excessive pain ,any swelling or bleeding at the site of insertion

Figure 5: Technique of insertion of Implant

POST-INSERTION CARE

- Make sure to observe the client for at least 15–20 minutes.
- Check the dressing for any soakage.
- Complete the facility records and registers.

No need for antibiotics

Follow-up Visits

There is no requirement for a routine return visit until it is time to replace the Implant. However, visits at 6 weeks and 3 months after insertion, are encouraged to review their client's menstrual pattern and address concerns if any.

Time of insertion

Insertion of an implant may occur at any time during the menstrual cycle as long as pregnancy is reasonably excluded.[8]

Appropriate timing for insertion in different situations (Table 2)

Table 2: Timing of insertion

Situations	Timing of Insertion
Having menstrual cycles	1. Can be inserted at any time of the month. 2. No need for a backup method If a client comes within 7 days after the start of menstruation. 3. If more than 7 days, a backup method will be required for the first 7 days after insertion.
In Postpartum client who is breastfeeding (a) < 6 months postpartum (b) > 6 months postpartum	1. May be started immediately after delivery irrespective of breastfeeding status. 2. May be started up to 6 months if a woman is fully or nearly fully breastfeeding and her monthly bleeding has not returned, without the need for a backup method. 3. In a partially breastfeeding woman, it may be started up to 6 months if menses have not returned and if it is reasonably certain that the woman is not pregnant. A backup method is required for the first 7 days after insertion. 4. May be started any time menses have not returned and it is reasonably certain that she is not pregnant. A backup method is required for the first 7 days after insertion. If her menses have returned, an Implant can be inserted as advised for women having menstrual cycles.
In postpartum clients not breastfeeding < 4 weeks postpartum > 4 weeks postpartum	any time without any need for a backup method 1. If her menses have not returned, insertion can be done anytime with a backup method for 7 days. 2. If her monthly bleeding has returned, an Implant can be inserted as advised for women having menses.
Post-abortion	1. Post-surgical abortion, it may be inserted Immediately or within 7 days after first or second-trimester miscarriage or abortion without the need for a backup method, If after 7 days use a backup method for the first 7 days. 2. After medical abortion it may be inserted as soon as 3rd day of medical abortion protocol.
Miscellaneous Situations After taking emergency contraceptive pill	May be started on the same day or any day after taking ECP if it is reasonably certain that the woman is not pregnant. The backup method is required for 7 days.
Switching from another method Non-Hormonal Hormonal	Cu IUCD – can be inserted immediately after Cu IUCD is removed. No backup is required. Switch from non-hormonal pills (Chhaya) – insertion can be done immediately while taking weekly pills (with correct use). Can shift immediately, if a woman has been using the hormonal method consistently and is reasonably sure that she's not pregnant. No backup method is required. Injectable contraceptives: The timing of the implant can be the same as the timing of the next injection. COC / POP: Can shift any day of the month, while she's on combined oral contraceptives (COCs) or progestogen-only pills (POPs). It should be inserted within 24 hours after consuming the last hormonal pill.

MEDICAL ELIGIBILITY CRITERIA FOR IMPLANT INSERTION

The implant can safely be placed in the presence of most of the physiological and medical conditions, but few conditions where implant falls in categories 3 and 4 and enumerated.

Category 3

1. Cases of severe liver disease (like cirrhosis, hepatocellular adenoma, malignant hepatoma)
2. Certain cases of Systemic Lupus Erythematosus (with positive antiphospholipid antibodies)
3. Ischaemic heart disease, stroke, migraine with aura.
4. Past history of breast cancer (with no evidence of disease for at least 5 years)
5. Unexplained vaginal bleeding
6. Acute Deep Vein Thrombosis/Pulmonary Embolism

Category 4

Current breast cancer presently is the only condition falling in cat 4

Benefits

1. Implants are safe and very effective and may be used by women of any age or parity if they are at risk of pregnancy.

2. Implant insertion is a walk-in procedure and once inserted, it is effective for 3 years.
3. No pelvic examination not required prior to use.
4. The implant does not interfere with sexual intercourse.
5. It is suitable for women who are not eligible for estrogen-containing contraceptives
6. It is acceptable for even those women who have blood pressure >160/100 mmHg, have diabetes >20 years of duration or have end organ damage or other vascular diseases
7. It is suitable for breastfeeding women and does not affect the quantity or quality of breast milk. It also does not affect the newborn and so can be initiated immediately after delivery
8. Implants are completely reversible with an early return to fertility.

Side-Effects

Side effects are minor but the patient needs to be counselled beforehand regarding the side effects to increase awareness and acceptability.

1. Menstrual changes including irregular bleeding, prolonged bleeding or amenorrhoea
2. Headache and dizziness
3. Weight gain
4. Acne
5. Mastalgia
6. Weight gain
7. Mood change or change in sex drive
8. Mild abdominal pain
9. Related to implant insertion, there may be pain, infection or abscess formation at the site of insertion.

REMOVAL OF IMPLANT

The removal usually takes 5–10 minutes, and the ease of removal is dependent correct insertion and competence of the service provider.

Indications

1. She is pregnant.
2. Wants to conceive.
3. After the 3-year duration of the Implant is over.
4. Wants the Implant removed for any reason.
5. Has problems with the method that bother her.
6. Wants to switch to another contraceptive method.
7. Medical condition which warrants removal.

Steps of Removal

1. Greet the patient explain the procedure to her and answer her queries.
2. Clean the upper arm where the Implant was inserted thoroughly with an antiseptic solution.
3. Wait for the antiseptic effect to set in.
4. Give local anaesthesia, lignocaine (1%) at the site of the incision, which is just below the distal end of the rod.
5. Push down the proximal tip of the rod, till a bulge may appear indicating the distal end of the rod.
6. From the distal tip of the rod, make a longitudinal incision of 2 mm towards the elbow along the line of the rod.
7. Gently push the proximal end of the rod toward the incision with a fingertip until the tip of the Implant is visible. Remove adherent tissue if any with blunt dissection.
8. Cover the puncture site with a sterile dressing and apply a pressure bandage.
9. Ensure that the rod is removed completely and show it to the client.

CONCLUSION

The etonogestrel implants are single rods containing ENG at a dose of 68 mg. Implants should be offered routinely as safe and effective contraceptive options for nulliparous women and adolescents. It is a safe and effective contraceptive option. The implant could be an effective and discrete alternative to the IUD in young girls, not requiring daily user action, and can be used if oestrogen is contraindicated To improve method satisfaction and continuation, patient counselling should include information on expected bleeding changes and reassurance that these changes are not harmful.

KEY POINTS

1. Implant is a small flexible rod, measuring just 4 cm, with a 2 mm diameter, that releases progestin hormone, which mimics the natural hormone in a woman's body.
2. It is inserted under the skin on the inner side of the upper arm by a **trained provider** and protects from unwanted pregnancy for 3 years.
3. It can be removed by a **trained provider** whenever the woman wants and can become pregnant without any delay. Return to fertility is quick.
4. The implant does not affect breast milk or the newborn infant and can be safely used by breastfeeding women immediately postpartum.
5. There may be some discomfort at the site during insertion or removal.
6. Harmless menstrual changes like irregular or prolonged bleeding and stoppage of the period may occur due to the effect of the method. The normal period is resumed after the stoppage of the method.

7. No protection from HIV/STIs. A barrier method needs to be used for protection against these infections.

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Emergency contraception: Myths and Misperception

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INTRODUCTION

Emergency contraception is used to prevent pregnancy after an unprotected or inadequately protected act of sexual intercourse. Though it is effective in preventing pregnancy up to 120 hours after unprotected intercourse, it is most effective in the first 24 hours. The U.S. Food and Drug Administration approved the first dedicated product for emergency contraception in 1998, yet numerous barriers exist to their usage to date. [(1)] While accessibility and affordability are broken barriers in current times, knowledge persists as a barrier across much of the world. This article thus focuses on the myths and misperceptions harbingering over the Emergency Contraception methods.

Modalities of Emergency Contraception

An unwanted pregnancy has emotional, social, and financial implications. Emergency contraception, by preventing an unwanted pregnancy, also prevents a consequent unsafe abortion. It thus stands to reason that more than a single modality of emergency contraception should be available. This, too, is one of the most considerable lacunae of knowledge amongst the reproductive age group, who are aware of only Emergency contraceptive pills. The modalities and their popular misperceptions are discussed below.

1. Emergency contraception pill (EC Pills)

   There are three types of EC pills.

   (a) Levonorgestrel containing EC pills: It is available in two 0.75 mg tablets/single 1.5 mg tablets. Its probable mechanisms include delay/inhibition of ovulation, thickening of cervical mucus, inhibition of fertilization, and interference with the transfer of egg/sperm/embryo. The ideal time is up to 72 hrs after an act of unprotected intercourse.

   (b) Combined EC pill (ethinyl estradiol and progestin) has a broader mechanism of action but is less effective.[(2)]

   (c) Ulipristal is another Emergency contraception pill. Ulipristal is a progesterone receptor modulator and can be taken up to 120 hours after unprotected intercourse. It is not a widely popular EC pill and is only available by prescription in India. Under the National Reproductive and Child Health Programme, Levonorgestrel (LNG) is advocated for EC Pills. This section deals with everyday, widespread myths amongst the population related to the same.

- *MYTH*: Besides side effects, like nausea, heavy bleeding, and cramps, regular use of emergency contraception may cause infertility
- *FACT*: While a routine contraceptive method should be opted for, rather than the repetitive use of EC Pill, it does not cause infertility
- *MYTH*: EC Pills are abortifacients
- *FACT*: EC Pills prevent conception rather than abortion.
- *MYTH*: EC pills can cause Birth Defects
- *FACT:* Levonorgestrel (1.5mg) is not associated with congenital anomalies
- *MYTH:* EC Pills require a doctor's prescription
- *FACT:* EC pills are over-the-counter drugs. LNG tablets can be taken as a single dose of 1 tablet of 1.5mg.
- *MYTH*: EC Pills cause weight gain
- *FACT:* The most common adverse events are short term and in the clinical trial by FDA included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), dizziness (11%), and breast tenderness (11%). Long-term side effects are rare.
- *MYTH*: EC pills cannot be taken more than once/ repeatedly
- *FACT*: It is best to use a regular method of contraception, but EC pills can be repeated in the same/ different cycles. Even in the same cycle, the EC pill taken today will not offer protection for future unprotected intercourse after a few days.

- *MYTH:* EC pills should only be taken MORNING AFTER unprotected intercourse
- *FACT*: EC pills should be taken as soon as possible. One must calculate 72 hours or three days from the first unprotected intercourse the woman has had during that particular menstrual cycle. The efficacy of levonorgestrel EC declines over time, from 98% if taken within the first 12 hours to 50% if taken within 120 hours of unprotected intercourse [3,4]
- *MYTH:* Obese women cannot take EC pill
- *FACT:* Emergency contraceptive pills were found to be less effective in obese women (whose BMI > 30 kg/m2), but there are no safety concerns. Obese women should not be denied emergency contraception when they need it. [5]

2. Intrauterine Device

Cu-T is an advocated emergency contraception method. Copper-containing intrauterine device, when used as an emergency contraceptive method, can be inserted within five days of unprotected intercourse. This method is appropriate for women needing highly effective, long-acting, and reversible contraceptive methods. Its mechanism of action involves creating a hostile uterine environment for sperm/pregnancy.

- *MYTH*: Cu-T is not an effective known method of emergency contraception
- *FACT*: When inserted within 120 hours of unprotected intercourse, CuT is more than 99% effective in preventing pregnancy. It is the most effective form of emergency contraception available. [5]
- *MYTH:* Cu-T, once inserted for emergency contraception, cannot be removed
- *FACT*: While it has long-term benefits and can continue as a routine method of contraception, the option to switch to another method/removal of CuT is still available with the user on an outpatient basis
- *MYTH:* Cu-T causes Pelvic Inflammatory Disease
- *FACT:* It is estimated that there may be less than 2 cases of Pelvic Inflammatory Disease (PID) per 1000 users as per WHO [6]
- *MYTH*: Risk of perforation / Expulsion is very high
- *FACT:* If inserted by a skilled medical partitioner, the rates of expulsion are meagre [7]

Emergency Contraception and Providers

While there are multiple myths amongst the general population, one must shed light on the lack of knowledge among providers, including gynaecologists. Studies bring to light several critical issues, including a lack of correct knowledge about EC Pills and myths and misconceptions about their effectiveness and contraindications, even among providers, including senior gynaecologists [1]. Among doctors, a strong tendency for the medicalization of EC Pills was observed, and it reflected in opposing continuation of EC Pills as the counter drug. While the use of EC Pills as an alternative to routine contraception by patients may be the reason for such tendencies, one cannot help but agree that they are still a better option than unsafe abortions or the unwanted population rise. Another misconception prevails that making emergency contraception more readily available promotes risky sexual behaviour and increases the rates of unintended pregnancy [8]. Literature suggests that ready access to emergency contraception is not associated with less hormonal contraceptive use, less condom use, or more unprotected sex [3,5]

When to Offer

One can offer emergency contraception to anyone seeking protection after a voluntary sexual act without contraceptive protection. Yet, a lot of doubts hover over the usage of Emergency contraception in some circumstances, and clarity amongst providers must exist, such as in cases of incorrect/inconsistent use of regular contraceptive methods. Failure of correct intake of routine contraception requires the practitioner to emphasize the role of emergency contraception as a backup method. (TABLE 1). Also, the role of emergency contraception in cases of sexual assault is paramount and the medico-legal responsibility of every Medical practitioner to ensure.

TABLE 1: Emergency contraception as a backup (*Source: WHO fact sheet on emergency contraception https://www.who.int/news-room/fact-sheets/detail/emergency-contraception*)

- Usage of emergency contraception must be advocated when:
  - (a) Condom breakage, slippage, or incorrect use;
  - (b) Three or more consecutively missed combined oral contraceptive pills or three days late during the first week of the cycle;
  - (c) more than 3 hours late from the usual time of intake of the progestogen-only pill (minipill) or more than 27 hours after the previous pill;
  - (d) more than 12 hours late from the usual time of intake of the desogestrel-containing pill (0.75 mg) or more than 36 hours after the previous pill;
  - (e) more than two weeks late for the norethisterone enanthate (NET-EN) progestogen-only injection;
  - (f) more than four weeks late for the depot-medroxyprogesterone acetate (DMPA) progestogen-only injection;
  - (g) more than seven days late for the combined injectable contraceptive (CIC);
  - (h) dislodgment, breakage, tearing, or early removal of a diaphragm or cervical cap;

(i) failed withdrawal (e.g., ejaculation in the vagina or on external genitalia);

(j) failure of a spermicide tablet or film to melt before intercourse;

(k) miscalculation of the abstinence period, or inability to abstain or use a barrier method on the fertile days of the cycle when using fertility awareness-based methods, or

(l) expulsion of an intrauterine contraceptive device (IUD) or hormonal contraceptive implant.

COMMON MISCONCEPTIONS

EC Pills: It should be clear that there have been no severe medical complications reported after Emergency contraception Pills. Doses of hormones are relatively small, and short exposure has no metabolic effects. The use of ECP is not associated with fetal malformations/ congenital disabilities, and it does not increase the risk of ectopic pregnancy. It can be taken at any time during the monthly cycle. Thus, a visit to the doctor can be avoided as it is available without a prescription, and a physical examination is not required. It can even be given to women for whom the use of hormonal contraceptive pills is contraindicated (small-short exposure). It can be used as many times as needed, although, as already mentioned, it is not a substitute for regular contraceptives. So, information about other forms of contraception and counselling about how to avoid future contraceptive failure should be made available to women who use emergency contraception, especially those who use it repeatedly. Suppose they visit a clinic for any doubts regarding emergency contraception while clearing the myths and advocating use. In that case, one must also advocate and press on regular contraception as the better route. It must be reiterated to women who continue to have sexual intercourse in the same cycle in which they have used oral emergency contraception that they are still at risk of unintended pregnancy.[9]

Cu-T: Another cavity that must be reiterated amongst gynaecologists is that intrauterine devices should also be offered more commonly for emergency contraception. The advantage is its imminent as well as prolonged nature of providing future contraception. In a 2010 survey of obstetrician-gynecologists, only 16% reported having recommended the use of the copper IUD for emergency contraception.[10] If suitable for the woman, the opportunity to provide a long-term method, such as an intrauterine device, must be utilized. Proper timing, selection of patient, and method of insertion must be ensured; women with any condition classified as MEC 3 or 4 (for example, with current PID, puerperal sepsis, unexplained vaginal bleeding, cervical cancer, or severe thrombocytopenia) should not be offered copper IUD for emergency purposes. IUD should also not be inserted for emergency contraception following sexual assault as the woman may be at high risk of a sexually transmitted infection. The WHO Medical eligibility criteria for contraceptive use states that IUD insertion may further increase the risk of PID among women at increased risk of sexually transmitted infections (STIs). While many women at increased risk of STIs can generally have an IUD inserted, some women at a very high likelihood of STIs should generally not have an IUD inserted without appropriate testing and after treatment.

Side Effects and their Management

While the patient may not come to seek emergency contraception, they may visit outpatient clinics with side effects (albeit uncommon) of the emergency pills. Any false conception among doctors must not blind the same management. If vomiting occurs within two hours of taking the dose of ECPills, advise to repeat the total dose to be given. Women with irregular bleeding and spotting after taking ECPills should be counselled that this is normal. They must be reassured that there is nothing to worry about and that it should not be confused with menses. ECPills do not necessarily lead to menstruation immediately (a common misconception among users of ECPs); most women will have their menstrual bleeding on time or slightly early or 2-3 days later than the expected date. If menstruation is delayed beyond one week from the scheduled date, tests must be conducted to exclude the possibility of pregnancy. In about 10-15% of women, emergency contraceptive pills change the amount, duration, and timing of the next menstrual period. These effects are usually minor and do not warrant any treatment. Side effects such as breast tenderness, headache, dizziness, and fatigue are not typical and do not generally last more than 24 hours. Paracetamol, Aspirin, or Ibuprofen tablets can be safely recommended for breast tenderness and headache. If Cu-T is used as emergency contraception, proper counselling before and after insertion must be provided. Follow-up advice, known side effects, and rare complications are pre-informed. Advice to seek healthcare if missed period/ abnormal uterine bleeding/ discharge per vaginum/pain abdomen/discomfort/expelled Cu-T is re-iterated.

Fighting Barriers

There are a lot of religious myths and barriers in society as well. Some communities lack a nearby facility or clinician willing to provide emergency contraception. In other communities, hospitals, clinics, and pharmacies that are religiously affiliated might present a further barrier to access. [8] One way to overcome this is to reiterate to healthcare workers (ASHA, ANM, MPHCW, etc.) who often contact the general population to spread the right message.

Limitations

Like all methods of contraception, emergency contraception also has its limitations. One must not miss the opportunity to counsel about the same. As well-informed gynaecologists, we must warn the patient that the closer she is to ovulation

at the time of unprotected intercourse, the higher the pregnancy risk and the lower the efficacy of the ECPs. The failure of emergency contraception to prevent pregnancy beyond the time frame of the efficacy window (72-120 hours) following unprotected intercourse while offering contraception is to be explained to those who report late. Knowledge of risks/possibility of failure is as important as awareness about modalities of emergency contraception among the population.

CONCLUSION

Emergency contraception remains an essential and only effective method after unprotected intercourse for pregnancy prevention. Although progress has been made toward improving access, barriers remain, and myths prevail. Obstetricians–gynaecologists and other healthcare providers should contribute to eliminating these. The goal should be to ensure all women and girls at risk of unwanted pregnancy have access to and correct knowledge of emergency contraception. Access and expertise to emergency contraception form a strong domain as they strive to ensure sexual and reproductive health in society continues.

KEYNOTES

1. Emergency contraception can be used at any time during the menstrual cycle after unprotected intercourse.
2. It may be useful for up to 5 days but is most effective if used within 24 hrs of unprotected intercourse.
3. EC; by preventing an unwanted pregnancy, also prevent a consequent unsafe abortion.

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AOGD Risk Management Support (ARMS) Group

One of the ways to ensure stress-free work environment and optimal patient care is mutual support among professional colleagues. An advisory group was set up last year so that they can be contacted if any of us is caught in a complex clinical dilemma/dealing with aggressive clients or is apprehensive about how to document or effectively troubleshoot a potential problem. The same group will continue to provide timely advice and is led by

Convener – Dr. Vijay Zutshi – 9818319110

Co-convener – Dr. Aruna Nigam – 9868656051

We invite suggestions from all members regarding functioning of this cell which will guide us forming the SOPs. Please mail to aogd.ucmsgtbh2023@gmail.com

Understanding Implications of Sterlization Failure

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INTRODUCTION

Sterilization is a crucial procedure that plays a significant role in family planning and population stabilization. Sterilization refers to surgical procedures intended to permanently prevent reproduction. In women, it commonly involves tubal ligation, where the fallopian tubes are cut, tied, sealed, or a combination of these methods to prevent eggs from meeting sperm. In men, sterilization involves a vasectomy, where the vas deferens, which carry sperm, are tied and resected.

Despite being highly effective, sterilization procedures are not infallible. The failure rate for female sterilization ranges from 0.1% to 0.4% in India (HMIS data 2022-23).[1] These rates vary with the type of approach to the fallopian tubes, the technique used to achieve discontinuity, the expertise of the surgeon, and sometimes the anatomy of the pelvic organs or difficulty in approaching the tubes due to anatomical variations or previous surgeries. While these rates are low, given the large number of female sterilizations performed, the absolute number of failures can be significant, leading to various implications in clinical practice and program management.

For male sterilization, the quoted failure rate is around 0.15% in India (HMIS data 2022-23).[1] As vasectomy is a less frequently performed procedure, this adverse event is extremely rare. Nonetheless, it has its potential implications.

GLOBAL SCENARIO

Female sterilization is the most commonly used contraceptive method, with 23 per cent of contraceptive users globally (219 million) opting for it.[2] In contrast, male sterilization accounts for just 2 per cent of total contraceptive users (17 million) (WHO). It is noteworthy that the high global prevalence of female sterilization is largely due to its extensive use in India, which accounts for 48 per cent of women who use this method across the world.[3]

Sterilization failure rates are often calculated as crude rates or using the Pearl Index (failure rates per 100 woman-years). Although female sterilization is a highly effective permanent method of fertility control, pregnancy can still occur in approximately 1 in 200 cases, according to international sources.[4] In the first year after tubal sterilization, the estimated failure rate ranges from 0.1% to 0.8%.[5]

Several retrospective and prospective studies have reported failure rates concerning female sterilization. The US multicenter CREST study (Collaborative Review of Sterilization) recruited 10,685 women undergoing sterilization between 1978 and 1987 and prospectively followed the cohort for up to 14 years. The overall 10-year cumulative probability of pregnancy was 18.5 per 1000 procedures computing a % failure rate of 1.85%.[6]

A Canadian study retrospectively analyzed the Quebec health insurance database, encompassing 311,960 female sterilizations from 1980 to 1999. The 10-year cumulative probability of pregnancy was 8.4 per 1000 procedures (0.84%), considerably lower than the US study.[7] Here, failures were often due to faulty techniques or misidentification of the fallopian tubes.

NATIONAL SCENARIO

The scenario in India regarding sterilization failure is complex and has significant implications for the country's population growth and reproductive health. Despite being a widely used method of family planning, sterilization has shown a notable failure rate in India. Based on the HMIS 2022-23 data, approximately a 0.68 % failure rate was reported nationwide.[1]

The National Family Planning Program has emphasized enough on improving the quality of services related to sterilization procedures. Quality initiatives include the release of standard reference manuals, provision of specifications for equipment, use of quality-tested commodities like Fallope rings, and most importantly, providing indemnity to surgeons and compensation for failed procedures. Well-defined institutional mechanisms have been established for quality assurance. Development of standards for training, the establishment of criteria for empanelment of service providers, and accreditation of

service delivery points are some such mechanisms which have been put in place. Quality circles at facility level and Quality Assurance Committees at district and state oversee the quality at respective levels and contribute to achieving primary and secondary prevention of sterilization failure. The program also includes the accreditation of private facilities rendering sterilization services. The Revised Compensation Scheme of 2007 and the Family Planning Indemnity Scheme of 2016 have been strategically introduced. Monitoring plays a crucial role in improving the quality of services and reducing adverse event rates.

Different states in India face varying challenges contributing to the current failure rate, aside from the inherent and unavoidable fraction of the overall data. These challenges include pressure to complete procedures within a specified time, operator skills, equipment or commodity issues, and non-adherence to standards. In this context, the roles of standard operating procedures (SOPs), adherence to reference manuals, ownership by senior administrators and experienced surgeons, and teamwork by counsellors, OT staff, and capacity builders are all crucial.

DELHI SCENARIO

Delhi has made significant strides as far as the overall progress in family planning is concerned over the years. As per the Sample Registration System (SRS) 2020, the TFR(Total Fertility Rate) in Delhi is 1.4, down from 1.9 in 2012. This sustained low TFR reflects the effective implementation of family planning initiatives, including sterilization.[4] The CPR (Contraceptive Prevalence Rate) has seen a significant increase, from 54.9% in 2016-17 (NFHS-4) to 76.4% in 2019-21(NFHS-5).[3] One-fourth of this is contributed by sterilization(mainly female sterilization). There has been a notable decrease in the total unmet need for family planning, from 15.0% in 2016-17 to 6.1% in 2019-21 with unmet need for permanent methods as low as 4. This reflects increased awareness and accessibility of contraceptive methods, including sterilization.

The State and district quality assurance committees(SQAC and DQAC) have regularly been issuing guidelines based on causes of failure commonly featured in reviews of cases. These preventive actions have contributed towards the reduction and sustenance of failure rates in Delhi-currently standing at 0.2%. Out of these, approximately 45% happen within a year of the procedure and 33% happen after 3 years.[1]

IMPLICATIONS OF STERILIZATION FAILURE

Whenever there is an adverse/undesirable/ unexpected event in the medical profession, it has multiple repercussions. Moreover, when sterilization procedures fail, there are serious implications for individuals, spouses/ partners, families, communities and health systems too. This article explores the implications of sterilization failure presenting the challenges, consequences, and possible solutions.

Medical Implications

1. **Reproductive Health:** The most immediate medical implication of sterilization failure is the unintended pregnancy which in turn brings along its aftermath. It is also an established fact that among women who conceive after tubal ligation, the likelihood of an ectopic pregnancy is higher which can be life-threatening if not treated promptly. As such, the woman facing the issue of unintended pregnancy post sterilization is stuck with a situation where either she has to undergo a termination of pregnancy or carry an unplanned baby. Both carry inherent risks. Again, the person facing a failed procedure has to go in for a post-abortion or post-partum contraception, whereby, if she chooses a repeat sterilization, the procedure carries higher chances of complications due to technical difficulties and if she opts for temporary methods, they may bring side effects or insecurity. The solution lies in good counselling, smooth indemnity procedure and management of the unintended pregnancy in a respectful and professional attitude.
2. **Psychological Impact:** The psychological impact of an unintended pregnancy following sterilization failure can be profound. Women and couples may experience a range of emotions, including shock, disbelief, anger towards a counsellor or service provider, anxiety, and distress. The expectation of no longer needing to worry about contraception is shattered, leading to potential trust issues with healthcare providers and the medical system. The comprehensive counselling of such couples needs to address these issues also. The service provision must be more flexible and extra time may be devoted to counselling and facilitation. This approach should include extended sessions of counseling and follow-up care to address any ongoing concerns, thus bringing back their trust in the health systems. In another scenario where termination is not acceptable due to cultural, family norms or personal ethics.

Social Implications

1. **Family Dynamics:** Unintended pregnancies can significantly alter family dynamics. Families who have planned their size and resources around the belief that they would not have more children may find themselves strained financially and emotionally. A pregnancy resulting from failure of male sterilization can invite suspicion of infidelity which in turn can be devastating until managed with due sensitivity. Also, where any one partner has been the soul or driving force in decision-making for sterilization, he or she may be left alone to figure out the next step. This would obviously be more true for female sterilization. After all, it is way more common and pregnancy affects women.

2. **Social Stigma:** In some communities, there may be social stigma attached to sterilization failure. Women, in particular, may face judgment or blame, regardless of the shared responsibility for contraception. This can lead to social isolation and stress.
3. **Economic Burden:** The economic burden of raising an additional child can be substantial, especially for families with limited resources. Each child (however unplanned he/she may be) comes with a parent's dreams, the fulfilment of which entails high cost, especially in the current economic situation of the ever-increasing index of dearness. The cost of potential additional medical procedures to rectify the failed sterilization or manage complications arising from it is also a concern for couples who decide to terminate the pregnancy. The ongoing cost of temporary methods, if adopted in place of re-sterilisation compounds the issue.

Legal Implication

Sterilization failure can lead to legal actions against healthcare providers if negligence is proven in a court of law. In India, beneficiaries have the right to seek compensation for medical negligence. If a sterilization procedure fails, affected individuals can file claims for the cost of rearing the unintended child and compensation for emotional distress and other damages. Legal implication revolves around informed consent and adherence to standards. Healthcare providers must ensure that sterilization acceptors are fully informed about the potential risks and failure rates associated with sterilization. Inadequate counselling or failure to provide complete information can be grounds for legal action.

While the failure rates documented in literature do protect the surgeon in a court of law, thorough documentation related to the entire process flow involved in carrying out the procedure is essential. Good counselling notes, consent in the standard format, and detailed and preferably illustrated OT notes are crucial. The management of failure must be done with great diligence, care, empathy, and compassion. Good post-failure counselling, facilitation of filing of claims as per timelines (90 days), and managing the unplanned pregnancy can go a long way in increasing the satisfaction level and confidence of the affected couple thus averting litigation. As such, as per the Family Planning Indemnity Scheme (FPIS), the empanelled surgeons complying with all standards are indemnified for up to four cases per year concerning expenditure on court cases, if any.

Implications of the program

1. **Loss of trust in method or system:** While a satisfied client can motivate several others and benefit them as well as the program performance, a dissatisfied, regretful or frustrated acceptor can do great harm to the program through negative publicity. This can have long-term consequences on the reproductive health of women. The solution again lies in good counselling both at the time of the initial procedure and at the time of managing the adverse event of failure. Good follow-up care can also help detect the adverse event well in time before it impacts the individual and becomes tougher to manage. Here, linking workers with their constant contact with the couples can play a role in early detection and referral.
2. A high failure rate is also a **financial burden on the program** as per the family planning indemnity scheme introduced by the Ministry of Health and Family Welfare, Govt. of India. All failures at accredited facilities are covered under the scheme and are to be compensated at the rate of Rupees 60,000 (30,000 each from National Health Mission funds and state funds). Hence, if the quality of services especially technique and skill is compromised, the burden of the scheme cost can strain both budgets. A benchmark has been kept under NHM, that is, the quantum of funds sanctioned is estimated and provisioned at the rate of 1 case per 600 cases performed by the state. Thus, more frequent reporting of failures beyond 1:600 will put a higher burden on the State health budget - not only to compensate at the rate of Rs.30,000 per case but also the exceeding expenditure beyond the sanctioned amount (GOI Policy).

   Ever since the scheme (FPIS) was introduced as guided by the directives of the Hon'ble Supreme Court of India, the number of litigations has dropped significantly. Such cases had a potential risk of judgment going in favour of the plaintiff, especially in cases where documentation was found to be inadequate.
3. There is yet another angle to the negative impact on the program. Service providers and program implementers **facing litigation for failure of the procedure often get demotivated** and start refraining from offering and performing sterilization procedures which not only impinges upon the reproductive health rights of their clients but also reflects as a drop in performance indicators related to sterilization. Here, while indemnifying the surgeons is a welcome policy, surgeons/ facilities belonging to both public and private sectors must own up to the responsibility of providing necessary medical support to the couple reporting with sterilisation failure.

CONCLUSION

In conclusion, the issue of sterilization failure in India including Delhi has wide-ranging implications across medical, psychological, social, and legal domains. Although the failure rates may be low, the consequences for the affected individuals and families can be deeply impactful. To address this issue effectively, several key measures need to be implemented. First and foremost, continuous monitoring of sterilization procedures, especially during

the initial few procedures of practice is crucial. Double-check by identification of fimbrial ends, confirmation by histopathology (open procedures), and additional eyes (assistants/senior colleagues/anaesthetists) can minimize wrong structure ligation. Regular evaluation and assessment of surgical techniques, equipment, and protocols can help identify and rectify any potential shortcomings, thereby curtailing the risk of failure. Quality assurance programs should be organized engaging the administrators of the accredited facilities and empanelled service providers or those potentially eligible for empanelment to ensure that all sterilization procedures meet the highest standards of safety and effectiveness.

Comprehensive pre- and post-operative counselling should also be an integral part of the sterilization process. Educating individuals about the procedure, its potential risks, and available alternatives can help them make informed decisions. Additionally, providing post-operative support and counselling can assist individuals in coping with any emotional or psychological challenges that may arise from a failed sterilization. All these can avert psychological and legal implications arising out of sterilization failure.

By implementing these comprehensive measures, our country including Delhi has been addressing the issue of sterilization failure effectively, thus mitigating its medical, psychological, social, legal and programmatic implications. Further strengthening the measures related to comprehensive counseling, quality assurance, continuous monitoring and strong legal frameworks will not only minimize the occurrence of failures but also provide the necessary support to those affected.

KEY POINTS

1. Despite being a widely used method of family planning in India, tubal sterilisation has a notable failure rate.
2. Quality circles at the facility level and quality assurance committees at the district and state level contribute to primary and secondary prevention of sterilisation failure.
3. There have been medical, social and legal implications due to sterilisation failure.
4. Good pre and post-procedure counselling can prevent many negative implications.
5. Good follow-up care after the failure of sterilisation helps in detecting and managing adverse events well in time.

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MTP Amendment Act, 2021

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INTRODUCTION

There is an overwhelming trend towards liberalization of laws about abortion, worldwide. Over the past thirty years, about 60 countries have liberalized their abortion laws. India has been at the forefront amongst most of the countries in this extremely pertinent subject of human reproductive rights. The Medical Termination of Pregnancy (MTP) Act was legislated in India in 1971. Fifty years later, the MTP Amendment Act, of 2021 was passed. It is an evolutionary landmark addressing the challenges posed by about 15.6 million abortions which are managed on a yearly basis in India.

MTP Law in India

In India, about 48.1 million pregnancies occur yearly of which, almost fifty per cent are unintended and about one-third comprise of abortions.[1] India is one of the first nations to legislate a law on abortion. The Government of India formulated the MTP Act on 10th August; 1971. This was a progressive act allowing termination of pregnancy up to 20 weeks period of gestation for a wide range of indications. It also provided protection to registered practitioners if they adhered to prescribed protocols.[2]

The MTP Amendment Act No. 64, 2002 and MTP Amendment Rules, 2003 was the first amendment after the legislation of the MTP Act which was passed in 1971. It ensured better facilitation and implementation of the abortion law with improved access in the private sector.[3] The important amendment points are as follows:

- 'Lunatic' term was replaced by 'mentally ill person.' She is someone who needs treatment for a mental disorder besides mental retardation.
- The District level committee was given the power to recognize the centers where MTP can be conducted. It is comprised of a chief medical officer or a District health officer who acts as the chairperson.
- The concept of punishment in the form of rigorous imprisonment lasting for two years, extendable till seven years was introduced.
- Centers conducting MTP in the first trimester were segregated from the ones conducting MTP in the second trimester. Their registration process was simplified.
- Early medical abortion was made accessible by allowing prescription from an RMP. It can be performed in a clinic with a notional access to an approved centre.[4]

MTP Amendment Act, 2021

However, in a historic move, there were some very pertinent amendments made to the MTP Act. The Lok Sabha approved the MTP Amendment Bill on 17th March 2020. The changes were made for the empowerment of women by making safe abortion accessible to all. The MTP Amendment Act was notified on 25th March 2021 by the Ministry of Law and Justice through the official gazette.[5] Its salient features were:

- Opinion of a single Registered Medical Practitioner is required for conducting abortions up to 20 weeks of gestation in cases of minors, rape survivors, unmarried women, and in cases of incest.
- Extension of MTP limit was done up to 24 weeks. Opinion of two RMPs is required in case of abortion from 20 to 24 weeks.
- MTP can be done at any gestation in case of severe congenital anomalies. The decision needs the approval of the Medical Board, required to be set up by the state.
- Confidentiality of the woman undergoing medical termination of pregnancy has to be maintained.

Indications for Medical Termination of Pregnancy

(A) Up to 20 weeks gestation:

1. If the continuation of pregnancy shall cause danger to her life
2. If the continuation of pregnancy shall cause any grave injury to her physical/mental health
3. Rape
4. Substantial risk such that if the child was born, he/she would suffer from a physical or mental abnormality and be seriously handicapped
5. Failure of contraceptive method.

(B) Between 20 – 24 weeks of gestation:

1. Victims of incest/rape survivors
2. Minors
3. In case of a change in the marital status during pregnancy (widowhood/ divorce)
4. Major physical disability as per the Rights of Persons with Disabilities Act, 2016
5. Mentally ill person including one suffering from mental retardation
6. Substantial congenital malformation incompatible with life or if the child is born, it may suffer from physical/mental abnormality and might be seriously handicapped.
7. Pregnancy in humanitarian settings like disaster/ emergency situations.

(C) Beyond 24 weeks of gestation:

Substantial congenital malformation incompatible with life or if the child is born, it may suffer from physical/mental abnormality and might be seriously handicapped.

Sex selection is not an indication for conducting MTP according to law.

Eligibility for performing MTP?

Only a Registered medical practitioner under the MTP Act is allowed to perform abortions. He/she should fulfil the following criteria:

1. Should hold a medical qualification as defined in the Indian Medical Council Act, 1956.
2. His/her name must be in the State medical register.
3. He/she should have the required experience or training in the field of Obstetrics and gynaecology as stated in the MTP Rules.
4. In case of rape beyond 24 weeks of gestation, the only recourse is through a Writ Petition.

A Medical Board should be constituted in every State and Union territory by notification in the Official Gazette. It consists of a gynaecologist, a paediatrician, and a radiologist. It shall co-opt other specialists as may be required on a case-to-case basis.

As per the Government of India's suggestions:

- Medical Board may be formed under the Chairmanship of the Department Head of the concerned hospital.
- A senior officer from administration may be included for interdepartmental coordination.

The functions of the Medical Board shall be:

- To examine all the reports of the woman who requests MTP.
- To provide an opinion regarding the acceptance or rejection of an abortion request in a prescribed format.
- To ensure that MTP is carried out after proper counselling and that all safety precautions are followed.

Training and experience required by the RMP

- The RMP should have a post-graduate degree or diploma in the field of Obstetrics and Gynecology.
- House surgeon for six months in Obstetrics and Gynecology.
- At least one year of experience in a hospital which has all the required facilities should be present.
- The practitioner should have assisted an RMP in 25 cases, of which he /she should have conducted at least 5 MTPs independently at a place approved by the government. Such a person is allowed to conduct only first-trimester MTPs.

Drugs for medical method of abortion can be prescribed by an RMP till nine weeks of gestation at an OPD clinic which is linked to an approved site. The certificate for the same must be displayed in the OPD clinic.

Places where MTP is performed

It can be done at one of the two sites:

- Primary, secondary, and tertiary care hospitals approved by the Government.
- A private clinic which has been approved by the Government or District committee.

The medical method of abortion up to a nine-week scan is prescribed from OPD clinics that are not approved as MTP-certified sites but have an established referral linkage to an MTP-certified site. The clinic must display a certificate to the effect of the owner of the certified site.

All the records of MTP must be maintained for medical methods of abortion also like the consent form, admission register, RMP opinion form and monthly report form. The District Level Committee which is appointed by the Government is responsible for the approval or suspension of a place.[6]

District-level committees are made of three to five members. The Chief medical officer or the District health officer is the Chairperson. One member must be a gynaecologist/ anaesthetist or a surgeon. The rest are members of the local medical profession, Panchayati Raj and NGOs. At least one member should be a woman. The committee is formed for the tenure of two calendar years. The NGO member is appointed for two terms or four years.

Infrastructure Requirement for sites

It varies depending on the period of gestation till which MTP can be carried out at the centre.

For First trimester MTP- The site should have:

- A gynaecology examination table or a labour table
- Equipments to perform resuscitation as well as sterilization
- Emergency drugs including intravenous fluids notified by the Government

- Back-up facility for the emergency treatment of shock.
- Facility for the transportation of the patient

For MTP beyond 12 weeks- The site should have:

- Operation table for conducting surgery
- Instruments for performing surgery
- Equipment related to anesthesia administration
- Equipment for resuscitation and sterilization surgery
- Emergency drugs and intravenous fluid
- Facility for the transportation of the patient

Consent for MTP

- If the woman is 18 years or above, only her consent is required, irrespective of her marital status.
- If she is less than 18 years old or is mentally ill, then the consent of the guardian is required. A certificate from the psychiatrist stating her unsound mental status is also required. 'Guardian' refers to a caretaker who is willing to be responsible for the woman.

Spouse/Partner's consent is not mandatory.

Mandatory documents for MTP under the MTP Act:

There are eight forms to be filled for medical as well as surgical MTP.[7]

1. Form "A" – It is the application form for approval of a place under clause (B) of section 4. Public sector sites that have the required infrastructure, do not need separate approval. All private sites need approval from the District Level Committee before starting abortion services.
2. Form "B"- Certificate of approval should be conspicuously displayed in a place where it is easily visible.
3. Form "C" - The client must fill and sign consent form "C" before the procedure. If the client is a minor, the guardian should sign it. If the client is mentally ill, a certificate from a psychiatrist is required. The legal guardians can provide consent.
4. Form "D"- A medical board should be constituted for MTP beyond 24 weeks. Form "D" should be signed, for congenital anomalies incompatible with life.
5. Form "E"- Should be filled by two RMPs for 20-24 weeks of gestation. The categories may be prescribed by rules under MTP Amendment Act, 2021.
6. Form "I"- Should be filled by one RMP for up to 20 weeks.
7. Form "II"- a reporting form which must be sent to the district authorities every month.
8. Form "III" –The owner of the hospital must maintain a register in the prescribed format of Form III. The admission register shall be a secret document. The information contained in it is confidential. All columns mentioned by the MTP Act should be included in the register.

All documents should be maintained and preserved as per guidelines. Consent should be sealed after the procedure. Information cannot be divulged to anyone unless asked by a court of law.

PENALTY FOR VIOLATION OF MTP ACT

In the following cases, the penalty is charged for the violation of the MTP Act:

- MTP conducted by a person who is not an RMP under the MTP Act.
- MTP conducted at a place not approved by the Government.
- Mandatory documents like consent, monthly reports and other medical records are not maintained as stated in the Law.
- The RMP shall not reveal the details of the woman undergoing MTP to anyone except to a person authorized by law. In case of violation of confidentiality, the RMP shall be punished with imprisonment up to one year, or fine, or both. The imprisonment is for two to seven years if MTP is performed by an uncertified person or it is done at an unapproved site.

If MTP is done by a RMP to save the woman's life i.e. in good faith, it will not be treated as an offence even if it was done at an unapproved site or by a provider who does not have all the legal requirements provided, the person reports to the Chief Medical Officer of the district on the same day or the next working day.

Comparison of the Two MTP Acts

	MTP Act, 1971	MTP Amendment Act, 2021
Indications (Contraceptive failure)	Applies only to married women	Irrespective of marital status
Gestational Age limit	20 weeks for all indications	• Up to 24 weeks in case of rape • After 24 weeks in the presence of substantial congenital anomalies
Requirement of opinion	• One RMP till 12 weeks • Two RMPs from 12 to 20 weeks	• Only one RMP till 20 weeks • Two RMPs from 20 to 24 weeks • Beyond 24 weeks, approval of the Medical Board is required, (for severe congenital abnormality or on court orders)
Gestational age limit for using Medical methods of abortion	Till 7 weeks	Till 9 weeks
Penalty in case of breach of confidentiality	Fine up to Rs 1000	Rigorous imprisonment of 1 year and or a fine

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Obituary

Dr. Bengali Majhi

(1959-2024)

Dr Bengali Majhi, a true gentleman, was born in 1959. He did his graduation and post graduation from VSS medical college, Orissa. During his initial service at he played a vital role in establishment of the department at BJRM hospital followed by Baba Saheb Ambedkar Hospital. He then served at RML hospital from where he superannuated in March 2024. He was an excellent clinician, surgeon and administrator. He was always appreciated for his calm, friendly, composed and helpful nature. His humble personality and selfless attitude made him popular among all. His tragic and sudden demise was a shock to one and all. He is survived by his wife Dr Meenakshi Hembram and daughter Ms Tusupriya Kisku and son in law Mr Ajay Mardi. We will cherish his gentle spirit and his extraordinary contributions and his memories will always stay with us.

On behalf of all AOGD members we express our heartfelt condolence to the family and pray to God to give them strength to bear the loss.

AOGD FAMILY

1. Primary Infertility with Endometrial Cancer: Providing A Ray of Hope: A Case Report

Dr. Prasad R Lele[1], Dr. Bikram Bharadwaj[2], Dr. Neha Tomar[3]

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ABSTRACT

Background

Endometrial cancer is the fifth most common gynaecological cancer.

Typically associated with post-menopausal women, it is increasingly diagnosed in younger women, 5% of EC – in< 40 years of age where fertility is a concern in treatment. Survival outcome is good with the standard treatment.

Case report

This case report discusses a 31-year-old nulligravida who, during the evaluation for primary infertility, was diagnosed with endometrial carcinoma. Despite her diagnosis, the patient expressed a strong desire to conceive. Consequently, ovum retrieval was performed, and she was started on high-dose progestins. After six months of medical treatment, a repeat endometrial biopsy revealed an excellent response, showing only focal atypia. Given this favourable outcome, the high-dose progestin therapy was continued for an additional three months.

Conclusion

Endometrial cancer in young women presents unique challenges and requires a personalized approach. Early diagnosis and appropriate management strategies can greatly improve outcomes and quality of life. Multidisciplinary care, considering both oncologic control and fertility preservation, alongside robust psychosocial support, is essential for holistic patient care. Further research is needed to optimize treatment protocols and understand the etiological factors contributing to the rise in endometrial cancer cases among younger women.

KEYWORDS

Endometrial cancer, young women, fertility preservation, progestin therapy, hysterectomy, psychological support, early diagnosis, conservative management

INTRODUCTION

Endometrial carcinoma is the most prevalent gynaecological cancer in developed regions but is rising in incidence in developing countries. The incidence of endometrial cancer in young women is rising, attributed partly to increasing obesity rates and genetic predispositions (e.g., Lynch syndrome). In younger women, often below 40 years, the condition presents unique challenges due to fertility concerns and the typically late diagnosis. Younger patients typically exhibit a more favourable prognosis but require approaches that consider fertility preservation and long-term health impacts. Medical management of endometrial carcinoma in young patients often involves high-dose progestin therapy, especially for those desiring fertility preservation. This approach can induce regression of the tumour and allow for future fertility treatments. Regular monitoring through endometrial biopsies is essential to assess treatment response and guide ongoing management.

Case Presentation

A 31-year-old nulligravida, married for 8 years and cohabitated for 3 years. As she was keen to conceive she got herself evaluated for primary infertility. She had regular menstrual cycles. Her past medical and surgical history was non-contributary. On general examination, she was moderately built with a BMI of 22 kg/m2. The patient's vital were stable, and abdominal & pelvic examination revealed no abnormalities She was subjected to further evaluation in the form of transvaginal ultrasound showed thickened endometrium, suggestive of a polyp. Subsequently, she underwent diagnostic laparoscopy & hysteroscopic polypectomy. During diagnostic laparoscopy her uterus, B/L fallopian tubes and ovaries were normal. However, to our surprise, the final histopathological diagnosis report yielded an unexpected diagnosis of endometrial carcinoma. Once she was diagnosed with carcinoma endometrium she reported to our centre. To complete the evaluation of carcinoma endometrium, an MRI pelvis and CECT abdomen, pelvis and thorax was done. MRI Pelvis- Uterus normal size, ET- 19 mm, endo-myometrial surface normal, junctional zone normal, myometrium normal, endocervix

and vagina normal, B/L ovaries normal. CECT(Abdomen and Pelvis)- normal Scan except for the possibility of endometrial hyperplasia. No mesenteric, pelvic and retroperitoneal lymphadenopathy and no Ascites. Male factor evaluation was done which came out to be normal. A review of slides and blocks was done at our centre and also from TMC Mumbai which again showed well-differentiated endometrioid endometrial adenocarcinoma. Since she was keen to conceive she was counselled about the possibility of medical treatment and the chance of progression/relapse during treatment. Once she consented to medical treatment a multidisciplinary tumour board was convened at our centre. Following a thorough discussion, the board recommended completing a genetic evaluation, ovum retrieval and starting her on high-dose progestin. The genetic evaluation came negative for germline BRCA and HNPCC syndrome. Ovum retrieval was done at our centre. Initial Management - given the desire for fertility preservation, and the low-grade nature of the tumour, conservative management with progestin therapy was initiated. The patient received oral medroxyprogesterone acetate (MPA) 60 mg thrice daily for 3 months then increased to 100mg for the next 3 months. Follow-up endometrial sampling after 6 months showed a very good response with focal cytological and architectural atypia seen in endometrium.

Future plan: The patient will be administered high-dose progesterone for a duration of three months. Following this period, a repeat biopsy will be performed. If two consecutive biopsies return negative for carcinoma, the patient will be referred to the ART centre. After the patient's family-building goals are achieved, definitive surgery will be done.

Discussion

Types of Endometrial Cancer: Two subtypes of endometrial cancer are recognized: Type I Endometrial Cancer (Endometrioid Endometrial Carcinoma): Occurs in approximately 80% of cases, secondary to hyperestrogenism, and typically affects patients aged 55-65 years old. Type II Endometrial Cancer (Non-Endometrioid Endometrial Carcinoma) comprises 20% of cases, occurs secondary to endometrial atrophy, and typically affects women aged 65-75 years old. Our patient was diagnosed with Type I endometrial cancer.

Risk Factors and Epidemiology

In young women, risk factors for developing endometrial cancer include obesity, smoking, higher insulin levels, type II diabetes, hypertension, and early menarche. A BMI of >30 is considered the greatest individual risk factor for early-onset endometrial cancer. Additionally, it is associated with Lynch syndrome and polycystic ovarian syndrome. Race has been associated with the early onset of endometrial cancer, with young black women more likely to be diagnosed with endometrial carcinoma. Tissue sampling more commonly demonstrates poorly differentiated and non-endometrioid subtypes in black women. Five-year survival rates are significantly better in young white women compared to their black counterparts, with survival rates for stage IB tumour at 90.6% for white women and 81.5% for black women, and for stage III cancer, at 75.1% for white women and 63.3% for black women[1].

Clinical Presentation: Investigation into endometrial carcinoma often follows abnormal vaginal bleeding. In postmenopausal women, this is more easily identifiable, while in premenopausal women, abnormal menstrual cycles with long or heavy bleeding may prompt further evaluation. Symptoms may include vaginal discharge, lower abdominal or pelvic pain, dyspareunia, or dysuria. Interestingly, some young women with endometrial cancer are incidentally diagnosed during hysteroscopic examinations during reproductive procedures.

Radiological Diagnosis: Initial radiological investigations involve transvaginal and transabdominal ultrasound. Transvaginal ultrasonography is especially useful for evaluating endometrial thickness. In postmenopausal women, an endometrial thickness greater than 4 mm (or greater than 8 mm if on tamoxifen or hormone replacement therapy) should prompt tissue sampling. In premenopausal women, endometrial thickness varies with the menstrual cycle, typically not exceeding 16 mm. Other sonographic signs include a heterogeneous and irregular appearing endometrium with evidence of a mass or fluid collection. Further radiological examinations include contrast-enhanced CT for assessing metastasis and contrast-enhanced MRI for evaluating local extension within the pelvis. MRI is preferred for determining the FIGO stage due to its superior visualization of myometrial invasion compared to CT. Nuclear imaging modalities, such as PET/CT, may be employed for distant metastasis evaluation in advanced cases.

Pathology Diagnosis: Microscopic evaluation of endometrial carcinoma demonstrates confluent glands lacking stroma with cribriform configurations. Pathology reports typically comment on tumour grade, myometrial, serosal, lymphovascular, cervical stromal, ovarian, and fallopian tube invasion. Histological FIGO staging is used based on the architecture of the tumour, with stages I-II having a better prognosis compared to stage III. Endometrioid endometrial cancer subtypes frequently exhibit PTEN gene mutations. Additionally, genes like KRAS and CTNNB1 (beta-catenin) are also altered in type I cancer. In contrast, non-endometrioid endometrial subtypes are associated with mutations in the p53 gene, leading to a poorer prognosis. Immunohistochemical changes in type II carcinoma include alterations in cyclin E and p16. Younger women with endometrial cancer, specifically those under the age of 40, show a significantly higher incidence of synchronous ovarian cancer compared to women aged 41-60, with rates of 9.2% versus 0.7%, respectively[2].

Treatment: The standard surgical treatment for endometrial cancer typically includes hysterectomy with bilateral salpingo-oophorectomy, with or without lymphadenectomy. Adjuvant chemotherapy and/or radiotherapy are commonly administered, often utilizing

a combination of paclitaxel, doxorubicin, and a platinum-based agent. The application of genomic and molecular analysis can facilitate the identification of more effective and individualized treatment regimens. In young women with endometrial carcinoma, fertility-preserving treatments are often considered. However, the literature indicates limited efficacy for conservative management. Uterine preservation is generally only recommended for cases of FIGO stage IA endometrial cancer. This approach is usually combined with high-dose progestogen therapy, such as systemic medroxyprogesterone acetate or levonorgestrel intrauterine systems, administered for 6-12 months, with complete remission observed in 80%-90% of patients. Metformin has also been used in obese patients due to its beneficial effects on insulin resistance and weight loss. A meta-analysis of women undergoing fertility-sparing treatment for atypical hyperplasia and endometrial cancer reported a 12-month remission rate of 78.0%, a 12-month recurrence rate of 9.6%, and a successful pregnancy rate of 32%[3]. In our patient's case, cervical stromal invasion precluded the possibility of conservative treatment.[4]

Follow-up care for endometrial cancer involves periodic cross-sectional imaging, including CT, MRI, or PET/CT scans. Additionally, the tumour marker cancer antigen 125 (CA-125) may be measured at diagnosis and during follow-up to monitor for recurrence, particularly in advanced cases characterized by lymph node metastasis, extra-uterine disease, or deep myometrial invasion. However, this tumour marker was not assessed in our case. Approximately 4-20% of patients with endometrial cancer experience regional recurrence, with higher recurrence rates in those initially presenting with locally advanced disease, most commonly within the first two years post-treatment.

Discussion on Psychosocial Impact: The psychological impact of a cancer diagnosis and the potential loss of fertility are profound, necessitating comprehensive supportive care. Individual and group counselling can play a crucial role in addressing body image issues, future planning, and emotional well-being.

Research and Future Directions: Further research into molecular profiling and personalized medicine may enhance our understanding of endometrial cancer in young women, leading to targeted therapies with improved efficacy and reduced side effects. Investigating the role of lifestyle interventions, such as weight management and diet, in reducing recurrence risk is also crucial.

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2. Fetal Hydro Pod-Out A Saviour

Dr. Prasad R Lele[1], Dr. Gunjan Rai[2], Dr. Divya Bojja[3]

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ABSTRACT

Alloimmunization, often called Rh-isoimmunization, was first described in Rh-negative women with Rh-positive. Fetus, but it can occur with many other blood type incompatibilities. It is a condition that may occur during pregnancy when there is an incompatibility between the mother's blood type and the fetus's blood type. During pregnancy, red blood cells from the fetus can cross the placental border, and there is the formation of antibodies. Those antibodies can cross back through the placenta and destroy fetal RBCs, causing fetal anaemia. This is called hemolytic disease of the fetus.

Still, fetal anaemia due to red cell allo-immunization in Rh iso-immunised pregnancy is the leading cause of intra-uterine blood transfusion. However, intra-uterine transfusion can be considered in severe fetal anaemia for any other reason like Parvo B 19 viral infection. Access to the umbilical vein also helps in the transfusion of platelets in allo-immune thrombocytopenia and injection of drugs to the fetus, like anti-arrhythmic drugs in fetal arrhythmia. Ultrasound-guided access of the umbilical vein is typical for all types of intrauterine transfusion.

KEYWORDS

Rh isoimmunization, Intrauterine transfusion, Phototherapy, Exchange transfusion

INTRODUCTION

Maternal Rhesus (or red cell) iso-immunization occurs when a pregnant woman develops an immunological response to a paternally derived red blood cell antigen (D) foreign to the mother and inherited by the fetus. The antibodies may cross the placenta, bind to antigens present on the fetal erythrocytes, and cause hemolysis. Hemolysis of the erythrocytes causes anaemia in the fetus and, if severe, may result in oedema, hydrops fetalis, and even fetal death. Hemolytic disease of the fetus/neonate can also be caused by other antigens of the Rh blood group system (the Rh blood system consists of the C, c, D, E, e, and G antigens - there is no d antigen) and by the so-called 'irregular antigens' of the non-rhesus blood group system such as Kell, MNS, and Kidd[1]. Therefore, the term red cell or Rhesus alloimmunization is more commonly used.

Onset of fetal anaemia

Hemolytic disease of newborns was one of the most common causes of early neonatal death before 1960. Preterm delivery followed by exchange transfusion were the only treatments available until the 1960s. Freda and colleagues performed open fetal surgery, transfusing the fetus using a vein in the exteriorized leg[2]. A breakthrough was the development of per-cutaneous intra-peritoneal transfusion under X□ray guidance by Sir William Liley[3]. However, hydropic fetuses did not take up the transfused blood from the peritoneal cavity very well. In addition, the technique was not feasible before 27 weeks gestation[4]. In the 1980s, Sir Charles Rodeck introduced the method of intravascular transfusion by needling the umbilical artery under direct fetoscopic guidance[5]. Shortly afterwards, Jens Bang in Denmark and Ferdinand Daffos in France pioneered fetal blood sampling under ultrasound guidance. In the last two decades, their approach has been used worldwide as a technique for intrauterine transfusions[6,7].

Diagnosis of fetal anaemia

This patient who has been transferred to our center was followed with MCA PSV at our Obstetrics unit, and values were tallied with the standard chart as per the period of gestation. The patient had an MCA PSV of more than 1.5 MoM. Patients with MCA PSV values less than 1.0 MoM and between 1-1.29 MoM can be called up after two weeks for repeat sonography for MCA PSV, but patients who have values between 1.29-1.5 MoM can be called up after a week only for repeat MCA PSV. Along with MCA PSV monitoring, the fetus was also screened for any sequel of iso-immunization in the form of cardiomegaly and ascites/ hydrops. Weekly ultra-sonographic evaluation is essential for early detection of fetal hydrops when MCA PSV is between 1.29 -1.5 MoM or above. When fetal Hb% drops below 5g/dl, features of hydrops develop. So hydrops is a sign of severe fetal anaemia and is usually associated with adverse neonatal outcomes. The first sign of hydrops due to fetal anaemia is ascites, which initially starts as a rim of fluid around the abdomen and pericardial effusion, practically always in conjunction with cardiomegaly. If the cardio-thoracic ratio is 0.6 or above, it is called cardiomegaly. Skin oedema develops later, and pleural effusions are signs of advanced disease. Even increased placental thickness and poly-hydramnios were looked for in the sonography of such fetuses. Some severely hydropic anaemic fetuses may even develop oligohydramnios. Fetal movements are sometimes remarkably regular despite severe anaemia. A CT ratio of more than 0.6 is a diagnostic of fetal cardiomegaly, and a thin rim of fluid in the fetal abdomen of more than 3 mm suggests that the development of ascites and fluid in more than one body cavity implies hydrops.

So, USG can be used to diagnose fetal anaemia based on the above parameters. Treatment modalities at this juncture with the patient are either to undergo intrauterine blood transfusion to prolong the gestation or deliver the fetus immediately and later manage the newborn with either exchange transfusion or IVIg & phototherapy or only observation if there are no signs of fetal anaemia.

When to go for Intra –uterine transfusion in such cases

As in all surgical procedures clinicians perform, the technical details are only part of the clinician's skills. The correct indication and timing are significant, especially in invasive procedures in obstetrics, in which any complication is potentially lethal for the fetus. Careful identification of individual fetuses at risk for anaemia requiring intrauterine transfusion can be picked and treated within time. However, not all fetuses in allo-immunized pregnancies develop severe anaemia. A serial assessment of signs of anaemia, such as rising MCA PSV, cardiomegaly, or hydrops, is necessary to enable timely intervention. The goal and the challenge are to transfuse only in case of severe anaemia but before the fetus develops hydrops. Survival after intrauterine transfusion in hydropic fetuses is significantly lower than in non□hydropic fetuses[8]. Several studies have shown that hydrops only grows when the fetal hemoglobin drops to levels 6–7 SD below the mean for the gestational age. Ideally, a transfusion is given when MCA PSV is more than 1.5 MoM and before the appearance of fetal ascites. In such cases, one can transfuse a relatively large amount of O□negative doubly irradiated donor blood, which is not haemolysed by the red cell antibodies. The subsequent transfusion can then be given several weeks later. Further, we will discuss when to transfuse next.

How much blood volume to transfuse: The volume of packed cells to be given (V) was calculated using the formula (Moise et al., 1997)

V = FPV (Hct target–Hct first sample) Hct donor blood,

FPV (fetoplacental blood volume) = 1.046 + (0.14x ultrasound estimated fetal weight (g))

Technique of transfusion: At our hospital, we get O-negative, doubly irradiated,leucodepleted blood, and it has to be transfused within 12 hrs of issue. Ideally, intrauterine transfusion should have a team, and each team member should know their responsibility, and it requires

a good quality ultrasound machine. We have a designated team in OT, and each member is briefed repeatedly for orientation of the job to which they have been assigned. The most effective and common site for transfusion is the umbilical vein at the insertion site of the umbilical cord at the placenta. If we try in free loops, the chances of a tear of the umbilical cord are high.

Before starting the procedure, we should know the placental location. If the placenta was anterior, the fetus was not paralyzed in our center. Still, in the case of others where the placenta is posterior, the fetus was paralyzed before transfusion by pancuronium or vecuronium so that the fetus does not disturb the ongoing procedure.

The Fetal Medicine Specialist puts the needle in the fetal umbilical vein at the insertion site under ultrasound guidance. One assistant, usually the second gynaecologist, connects the three-way connector, and two more assistants are detailed for pushing blood. The fetal medicine specialist who inserted the needle stabilizes the needle when the blood is being moved, and he continuously monitors the fetal heart rate for any distress during the procedure. One assistant is detailed to assist with the various medications and syringes, and another assistant helps to perform the on-site blood tests and calculations.[9,10] In general, fetal blood transfusions, including all preparations, take 40–60 min and can be carried out as an outpatient procedure or with an overnight stay. We discharge the patient either the same evening or the following day of IUT.

Instruments required: USG machine with Doppler, 20 Gauze spinal needle for fetal paralysis, 22 Gauze spinal needle for insertion in umbilical vein, ten 10 ml syringes for pushing blood, 50 cm three-way connector.

Fetal paralysis

The fetus was not paralyzed where the placenta was anterior but usually done in the case of the posterior placenta using diluted pancuronium or vecuronium (intramuscular in the thigh), depending upon the availability.

CASE REPORT

32-year-old G5P3L2 A1, with POG of 24 weeks 04 days, referred from a service Hospital as a case of Rh Isoimmunized pregnancy with ICT titer of 1:512. She had one Intrauterine Fetal death and one second trimester missed abortion at 20 weeks in 2022. The cause for this mishap was not precisely known as the patient did not undergo Obstetrics Ultrasound, but history was indicative of Hydrops fetalis, a cause of Intrauterine demise. An obstetric Ultrasound done at our hospital was suggestive of Fetal Scalp oedema, pleural effusion, and fetal ascites, indicative of fetal Hydrops fetalis due to Rh Isoimmunization. The patient underwent five Cycles of Intrauterine transfusion at our Centre (Table 1). After the fourth Intrauterine transfusion, Ultrasound features of hydrops fetalis disappeared as the Hb% of the fetus improved. Even after tocolysis, she underwent preterm vaginal delivery at 34 weeks 01 day and delivered a newborn of 2.13 kg. The neonate underwent intense monitoring and phototherapy in the NICU. At last, she was discharged with a healthy baby.

DISCUSSION

Each Rh isoimmunised pregnancy should be offered an ICT titer, and when it is above the critical titer of 1:16, the patient should be monitored with MCA PSV after 16 weeks. When MCA PSV has become more than 1.5 MoM, she should be offered intrauterine transfusion. If MCA PSV is not rising above 1.5 MoM, monitoring should be continued with MCA PSV, and delivery should be advised at 36 to 37 weeks if MCA PSV values are within the normal range. Where ICT titer is very high in early pregnancy, IVIG can be given to postpone intra-uterine transfusion at a later gestation.

Table 1: Showing results of pre and postintrauterine transfusion

POG	Date	Pretransfusion Hct	Pretransfusion MCA PSV	Post Transfusion HCT	Post Transfusion Mca Psv
24 Wks 4 Days	08 Nov 2023	9(Hb 3 gm%)	62.5	14	57(11 Nov 2023)
25 Wks 01 Days	12Nov 2023	10.8	60	20.7	54
25 Wks 05 Days	16 Nov 2023	18	56	25	50
26 Wks 06 Days	24 Nov 2023	22	52	33.6	48
28 Wks 6 Days	06 Dec 2023	25.7	50	43.5	45
31 Wks 1 Day	22 Dec 2023	34.1	48	49	42

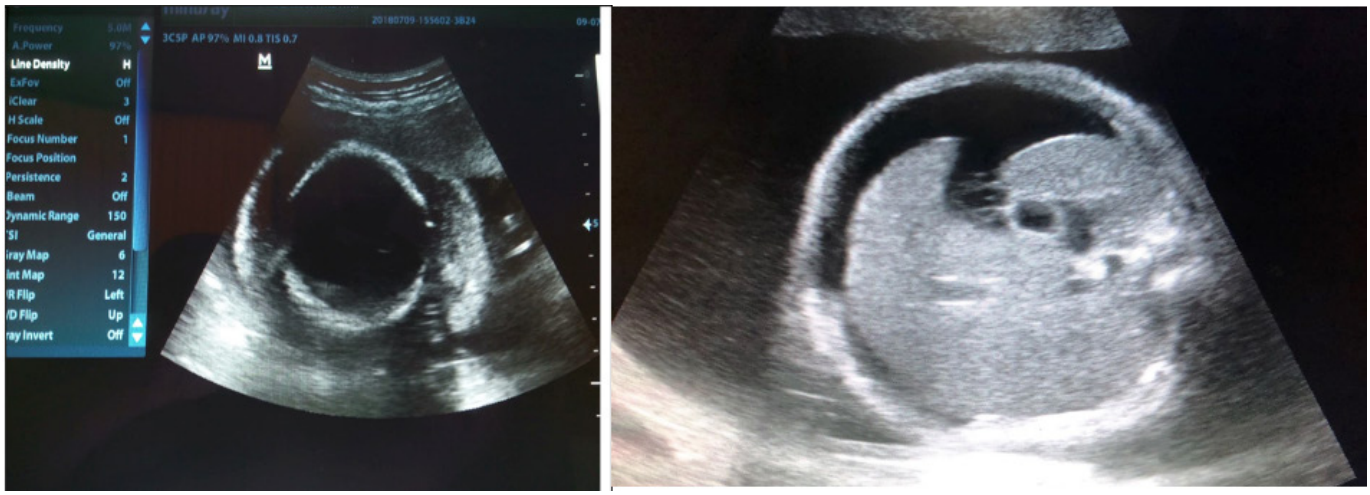

Figure 1: Gross fetal scalp oedema and ascites

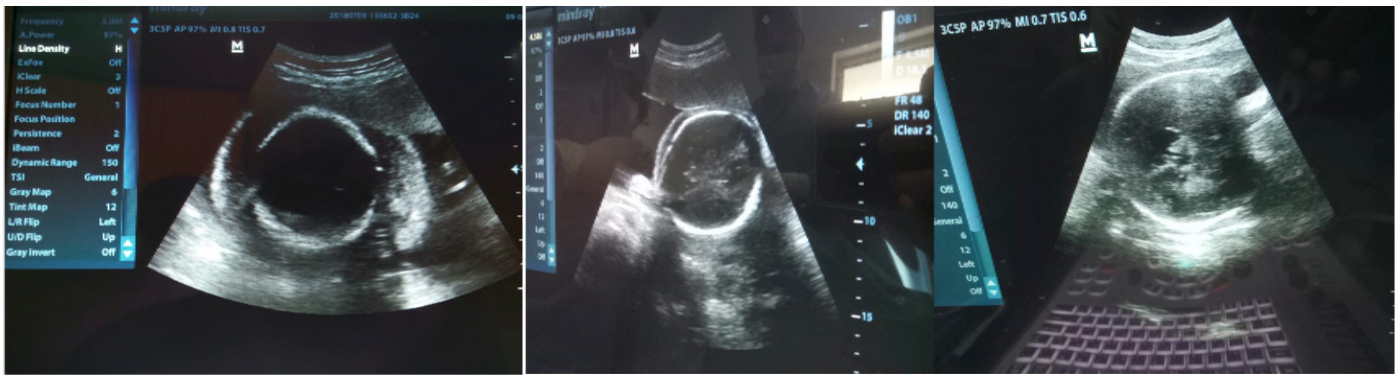

Figure 2: Gradually resolved scalp oedema

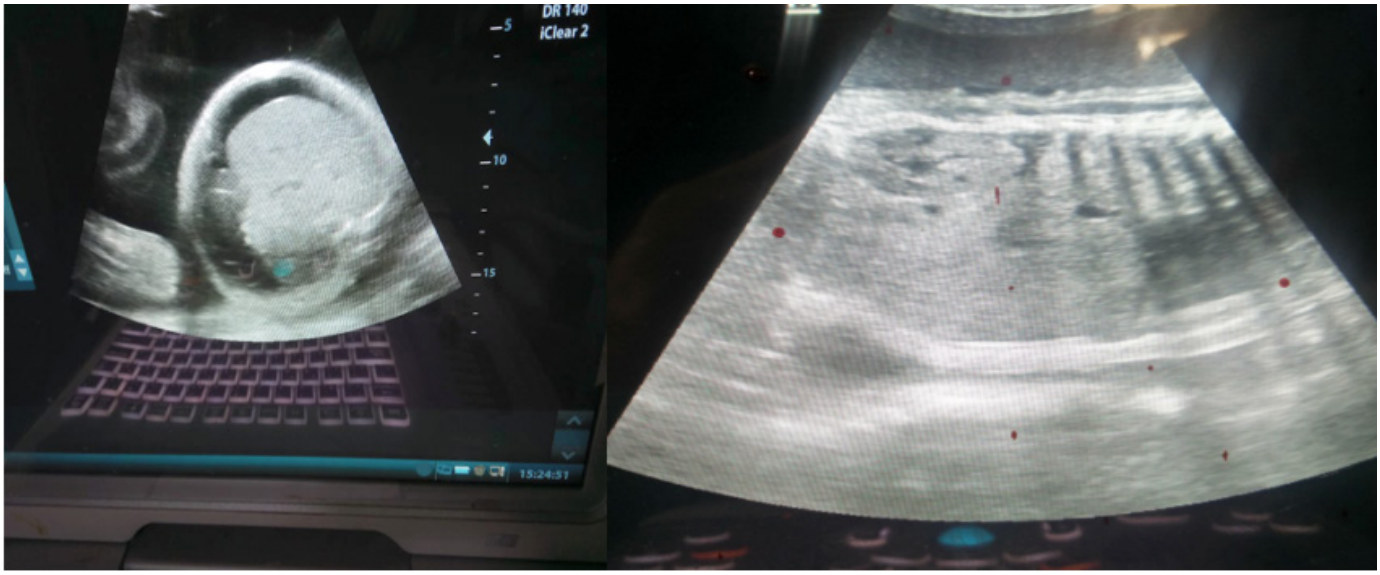

Figure 3: Gradually resolved Ascites

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3. Sequential Embryo Transfer: A Way Forward in Cases of Repeated Implantation Failure in an IVF Cycle

Dr. Prasad R Lele[1], Dr. Nikita Naredi[2], Dr. Ipsita Sahoo[3]

Consultant and HOD Obs Gyn & ART[1], Sr. Adv. Obs Gyn & ART[2], Senior Resident Obs Gyn & ART[3] AHRR

ABSTRACT

The best time of endometrial receptivity is the missing part of the implantation puzzle in patients with recurrent in vitro fertilization (IVF) failure. Sequential embryo transfer (ET) extends the availability time of embryos on the implantation window. The study aimed to evaluate the improvement of pregnancy rate in sequential (two-step) frozen-thawed embryo transfer (FET) on day 3/day 5 in individuals in 21 patients who suffer from repeated IVF failures. Clinical pregnancy rates were significantly higher in the sequential (two-step) FET group (71.4%). Two patients (9.5%) had multiple pregnancies (twins) and one patient (4.76%) had a chemical pregnancy. Hence, the sequential transfer of frozen-thawed embryos on day 3/ day 5 was more effective than regular day 5 for patients suffering from repeated IVF failure.

KEYWORDS

Sequential embryo transfer, implantation, FET, embryos

Introduction and Case Report

Recurrent implantation failure is the main challenge in assisted reproductive technology (ART) practice. Implantation of the embryo is the end product of a series of complex processes which require high-potential embryos, good endometrial receptivity and ultimately effective interaction between the embryo and the endometrium.[1] Synchronised communication between a receptive endometrium and functional embryo is indispensable for successful implantation.[2] Conventionally, cleavage stage embryos were transferred on day 3; however, nowadays there has been a change to day 5 transfer. Sequential embryo transfer gives benefits of both day 3 as well as day 5 transfers in the same cycle, giving better outcomes in patients suffering from infertility.[3]

We carried out a case series on 21 women with repeated IVF failures (previous two implantation failures) who underwent sequential embryo transfer between Jan 2024 to May 2024 at the Assisted Reproductive Technology Centre of a tertiary-level hospital. Institutional ethics committee clearance was taken for the above study. All patients underwent a baseline transvaginal sonography on Day 2/3 of menses and if endometrial thickness (ET) was less than 4 mm, they were started on tablet estradiol valerate 2 mg TDS for 12 days to prepare endometrium. Once the ET was more than 7.5 mm, progesterone supplementation was started. The frozen-thawed embryos (cleavage stage 8 cell and blastocyst) were transferred to hormone replacement therapy-prepared endometrium in these patients. Pregnancy was detected by positive serum beta hCG report (value >

50 miu/ml) on day 18 and the gestational sac was localized by transvaginal ultrasonography on day 21. The primary outcomes were clinical pregnancy and implantation rates. The secondary outcomes were early pregnancy loss and multiple pregnancies.

In this case series, the demographic profile of the 21 patients is shown in Figure 1 and Figure 2. PCOS was the most common cause of infertility in our study population as shown in figure 3. Out of 21 patients who underwent FET, 15 patients became pregnant with positive beta hCG values. Clinical pregnancy rates were significantly higher in this sequential (two-step) FET group (71.4%). Two patients (9.5%) had multiple pregnancies (twins) and one patient (4.76%) had a chemical pregnancy. The data of Beta hCG and TVS findings is tabulated in Table 1 below.

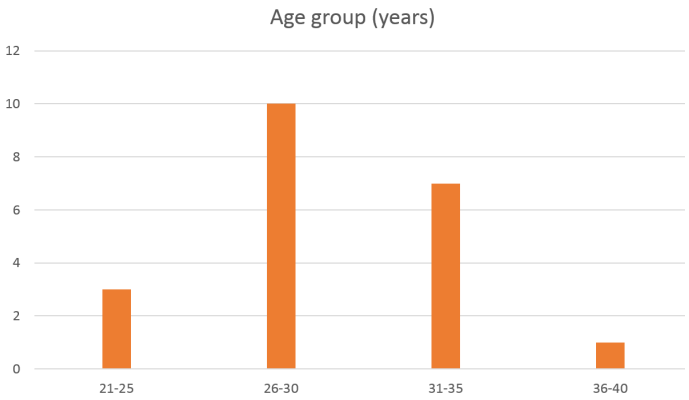

Figure 1: Age profile of study population

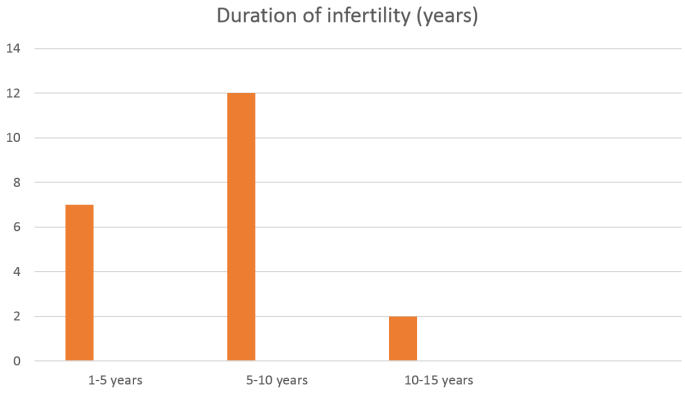

Figure 2: Duration of infertility (years) of study population

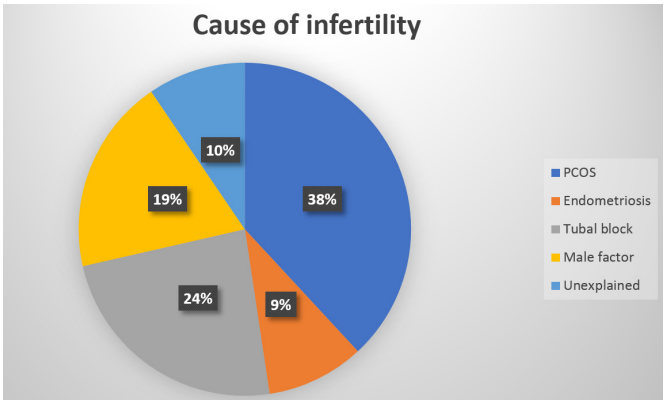

Figure 3: Cause of infertility of study population

Table 1: Beta hCG and TVS findings of the study population

Sr. No. of patient	Beta hCG (mIU/ml)	Pregnancy Positive/Negative	TVS finding
1	2540	Positive	SIUGS
2	1104.2	Positive	SIUGS
3	2600.2	Positive	TWINS
4	569.3	Positive	SIUGS
5	1461	Positive	SIUGS
6	< 2.0	Negative	—
7	84.69	Positive	Chemical pregnancy
8	< 2.0	Negative	—
9	546.3	Positive	SIUGS
10	1385	Positive	SIUGS
11	1425	Positive	SIUGS
12	628.3	Positive	SIUGS
13	< 2.0	Negative	—
14	< 2.0	Negative	—
15	4527	Positive	TWINS
16	574.7	Positive	SIUGS
17	978.9	Positive	SIUGS
18	< 2.0	Negative	—
19	996	Positive	SIUGS
20	467.8	Positive	SIUGS
21	< 2.0	Negative	—

DISCUSSION

The best time of endometrial receptivity is the missing part of the implantation puzzle in patients with recurrent in vitro fertilization (IVF) failure. There are various treatment plans and strategies to meet the best endometrial timing for implantation. However, the lack of synchronization of the good quality embryo with the patient's individual "window of implantation" is the hypothesis for most IVF failures so far. Sequential embryo transfer (ET) theoretically extends the availability time of embryos on the window of implantation.

In this approach, embryos are transferred into the uterus at different stages of development, typically over two separate procedures during a single menstrual cycle. This strategy aims to mimic the natural implantation process more closely, potentially enhancing the success rate for patients with repeated implantation failures.[4] By transferring embryos at different stages, the likelihood of at least one embryo implanting may be increased. Also transferring embryos on different days can better align the varying receptivity of the endometrial lining, which may improve the chances of successful implantation.[5]

Among the 21 cases, 15 patients conceived making a pregnancy rate of 71.4 %. These results are in concordance with the study by Palshetkar et al[1] where the implantation rate was 60.66% and Salehpour et al[2] where the implantation rate was 52.94%. Out of the 15 patients who conceived,

14(93.3%) were clinical pregnancies and one (6.66%) was a chemical pregnancy. No case of ectopic pregnancy was detected. Out of the 14 clinical pregnancies, 12 (85.71%) were singleton gestation and 2 (14.2%) were twins.

From our case series, we concluded that sequential embryo transfer improves implantation rates as compared to conventional cleavage stage or blastocyst transfer in patients with repeated implantation failures. However, the limitation of this case series is patients could not be followed up to find out live birth rate. Also, prospective studies with larger sample sizes are required to validate our study results.

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> RECORD FOR THE OLDEST PATIENT OPERATED IN THE WORLD OF 107 YEAR OLD
> RECORD FOR THE LARGEST UTERUS REMOVED LAPAROSCOPICALLY OF 9.5 KG

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DAY 1 - SATURDAY, AUG 10, 2024

WE HAVE PLANNED A "SURGICAL BONANZA" WHERE MORE THAN 25 SURGERIES WILL BE RELAYED LIVE FROM SUNRISE HOSPITAL TO HOTEL HYATT REGENCY BHIKAJI CAMA PLACE NEW DELHI FROM 08:00 AM TO 08:00 PM.

DAY 2 - SUNDAY, AUG 11, 2024

8.30 AM TO 4.30 PM - "CONFERENCE CME AND SOCRATIC SEMINAR" AT HOTEL HYATT REGENCY NEW DELHI (OVAL BANQUET)

4.30 PM TO 5.00 PM- VALIDECTORY

REGISTRATION FEES DETAILS

REGISTRATION FEES:- RS 9,500/-
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ACCOMPANYING PERSON :-SAME AS ABOVE
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(LETTER FROM HOD IS COMPULSORY)

PLANNED SURGERIES

ENDOMETRIOSIS OT

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> LAPAROSCOPIC EXCISION OF BLADDER NODULE
> LAPAROSCOPIC EXCISION OF DIAPHRAGMATIC NODULE
> LAPAROSCOPIC EXCISION OF SCIATIC NERVE ENDOMETRIOSIS

ONCO & ADVANCED OT

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Journal Scan

Dr. Aarti Jeenwal
Assistant Professor
ABVIMS & RML Hospital

Migration of Intra-Uterine Devices

Victoria Verstraeten,[1,2] Karlien Vossaert,[2] Thierry Van den Bosch[1]
[1]Obstetrics & Gynaecology - UZ Leuven Gasthuisberg, Leuven, Belgium;
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BACKGROUND

The intrauterine device (IUD) is a widely used contraceptive method. This type of contraception belongs to the family of long-acting reversible contraceptives (LARC) and is among the methods with the highest contraceptive effectiveness. The two most used types are the copper intrauterine device (Cu-IUD) and the levonorgestrel intrauterine device (LNG-IUD). These methods offer 99.2% and 99.8% effectiveness, respectively, in preventing pregnancy. Possible complications from IUDs include failed insertion, pain, vasovagal reaction, infection, abnormal bleeding, and expulsion. Uterine perforation and migration of the IUD are rare complications occurring in approximately 1– 2 per 1000 insertions. The most common sites of migration are the intestine, bladder, and omentum. The purpose of the study was to systematically review all case reports and case series on IUD migration, published between December 2002 and December 2022. The review indicates that about half of these patients present with pain and that a third are completely asymptomatic. It was found that the preferred method for removing the migrated IUD is laparoscopy. Generally, there are no lasting injuries after the removal of the migrated IUD, but occasionally, severe complications have been reported. Healthcare providers should be vigilant about this rare complication, especially in cases of painful insertion or the presence of other risk factors for perforation. When uterine perforation is diagnosed, it is advisable to remove the IUD to prevent severe complications.

MATERIALS AND METHODS

The purpose of our review was to identify randomized clinical trials, case reports and systematic reviews regarding migrated IUDs. A systematic search was performed on several electronic databases (Medline/Pubmed, Cochrane and ScienceDirect). The search terms and MeSH terms used were "Intrauterine device migration", "Intrauterine device perforation", "Uterine perforation" and "Intrauterine device". All articles in Dutch, French, English, or Spanish between 2002 and 2022 that described complete uterine perforation or migration of an IUD were included.

The selection of articles was performed by one author (VV). The study was completed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[7] The following data were collected from each case: demographic data, including age and parity, clinical symptoms at presentation, the specific type of IUD, length of time between IUD placement and diagnosis of perforation, location of the perforated IUD, method of IUD removal, and reported complications.

RESULTS

936 articles were studied, of which 119 articles were included in the review. All included articles were case reports or case series. Within these 119 articles, 165 cases of IUD perforation were identified. The average age of the patients was 39 years, ranging from 19 to 74 years. Parity was mentioned in only 60% of the cases, of which 68% were multiparous (median: 2). The time between IUD placement and diagnosis of perforation ranged from one week to 42 years (median: 3.75 years). Patients presented with various clinical symptoms, with pain and urological complaints being the most common. (Table 1)

Approximately 31% of the patients were completely asymptomatic at the time of diagnosis. The type of IUD was specified in 59% of the cases, with two-thirds being Cu-IUDs and one-third LNG-IUDs. (Table 2)

In half of the cases, the IUD could be removed laparoscopically. Other removal methods included cystoscopy, laparotomy, and

colonoscopy. In some cases, multiple techniques were combined during a single procedure. Most migrations did not result in serious complications. Four cases of abscess formation, seven cases of complex adhesions, eighteen cases of bladder lithiasis, and four cases requiring partial bowel resection were described. Occasionally, other serious complications were reported, such as small bowel obstruction, urosepsis, hydronephrosis, the need for partial gastrectomy, the need for partial cystectomy, and even nephrectomy.

CONCLUSION

IUDs are a widely used contraceptive method worldwide due to their high effectiveness and reliability. IUDs require only a single insertion procedure for long-term use. The contraceptive effect of IUDs is not dependent on user compliance, gastrointestinal function, or the user's weight. Therefore, the Pearl index is the same for perfect use and normal use. Complications of the IUD include failed insertion, pain during and after insertion, vasovagal reaction during insertion, infection, abnormal bleeding, expulsion, and uterine perforation.[4] The risk of IUD expulsion within five years of placement is approximately five per cent and is highest in the first year of use, immediately after abortion, and in the postpartum period. Expulsions are more common in women under 25 years of age, with the use of copper IUDs compared to LNG-IUDs, and in women who have given birth fewer than two times. Uterine perforation and migration of an intrauterine device (IUD) are rare and often late-detected complications. Clinicians need to be aware of the risk factors and possible symptoms of this condition. A routine follow-up after IUD placement is recommended. If an IUD is not visible on ultrasound, it should not be automatically interpreted as "expelled" but further imaging should be conducted. Although the chance of permanent damage to the patient after an IUD perforation is small, it is not non-existent. Gynaecologists must remain vigilant, especially shortly after placement, to prevent later serious damage to visceral organs due to IUD migration.

The personal experience of female obstetricians and gynaecologists with contraceptive use influences the guidance and prescription of contraceptive methods: a web survey

The personal experience of female obstetricians and gynaecologists with contraceptive use influences the guidance and prescription of contraceptive methods: a web survey

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The European Journal of Contraception & Reproductive Health Care Volume 29, 2024 - Issue 4

OBJECTIVE

To evaluate the influence of the personal experience of female obstetricians and gynaecologists (Obst/Gyns) who utilise contraceptive methods on the provision of these methods.

METHODS

An anonymous online web-based survey was carried out with female Obst/Gyns. The instrument contained questions about their current and previous contraceptive methods use, factors that influenced the choice and satisfaction with the ongoing method, as well as the occurrence of adverse events. They were also asked whether the experience of any adverse events influenced their decision to prescribe any particular contraceptive method.

RESULTS

476/9000 (5.3%) female Obst/Gyns answered the survey. The most common contraceptive in use was the 52-mg levonorgestrel-intrauterine device (52-mg LNG-IUD) (34%), followed by non-long-acting Reversible Contraception hormonal methods (21.2%). More than half of the respondents (57.6%) reported having some adverse effects and 18.7% reported that the personal experience of an adverse effect with the use of a contraceptive method influenced the prescription of that method.

CONCLUSION

Half of female Obst/Gyns encountered adverse events linked to contraceptive usage. Additionally, almost one-fifth believe that their encounter with adverse effects from a contraceptive method impacts their decision to prescribe the same method.

EDITOR'S COMMENT

Almost one-fifth of the female obstetrics and gynaecologists who answered the online survey reported that the personal experience of an adverse effect with the use of a contraceptive method influenced the prescription of that method.

Assessing the impact of hormonal contraceptive use on menstrual health among women of reproductive age – a systematic review

Assessing the impact of hormonal contraceptive use on menstrual health among women of reproductive age – a systematic review

Shayesteh Jahanfar, Julie Mortazavi, Amy Lapidow, Cassandra Cu, Jude Al Abosy, Hartman Ciana, Katherine Morris, Meredith Steinfeldt, Olivia Maurer, Jiang Bohang, Rajkumari Anjali Oberoi & Moazzam Ali
The European Journal of Contraception & Reproductive Health Care, 1–31.

BACKGROUND

Contraceptive methods are well-established in their ability to prevent pregnancy and increase individual agency in childbearing. Evidence suggests that contraceptives can also be used to treat adverse conditions associated with menstruation, including abnormal and prolonged uterine bleeding, heavy menstrual bleeding, painful menstruation, endometriosis, uterine fibroids, and premenstrual dysphoric disorders.

This review investigates the effects of contraceptive techniques such as contraceptive pills, and long-acting reversible contraceptives (e.g. intrauterine devices, implants) on menstrual morbidity.

METHODS

Over ten databases with no geographical boundaries were searched from inception until October 2023. Study designs were one of the following types to be included: parallel or cluster randomised controlled trials, controlled clinical trials, controlled before and after studies, interrupted time series studies, cohort or longitudinal analyses, regression discontinuity designs, and case-control studies. Ten team members screened the papers in pairs with a Kappa score of more than 7, and Covidence was used. Conflicts were resolved by discussion, and the full papers were divided among the reviewers to extract the data from eligible studies.

RESULTS

Hormonal contraceptives are considered a well-tolerated, non-invasive, and clinically effective treatment for abnormal and prolonged uterine bleeding, heavy menstrual bleeding, painful menstruation, endometriosis, uterine fibroids, and premenstrual dysphoric disorders. Our studies investigating quality of life or well-being in women with heavy menstrual bleeding, endometriosis, or uterine fibroids have found improvements in all dimensions assessed.

CONCLUSIONS

Hormonal contraceptives significantly reduce pain, symptom severity, and abnormal bleeding patterns associated with women who suffer from heavy menstrual bleeding, endometriosis, and uterine fibroids.

EDITOR'S COMMENTS

Hormonal contraceptives significantly reduce pain, symptom severity, and abnormal bleeding patterns associated with women who suffer from heavy menstrual bleeding, endometriosis, and uterine fibroids. Findings can inform clinical practice and policy decisions to ensure that women have access to safe and effective contraceptive options that promote both reproductiveand non-reproductive health

News Flash

Dr. Jaya Chawla

Professor

Department of Obstetrics and Gynaecology, ABVIMS & Dr RMLH

Allocation to Health and Family Welfare Department 87,656.90 Cr INR

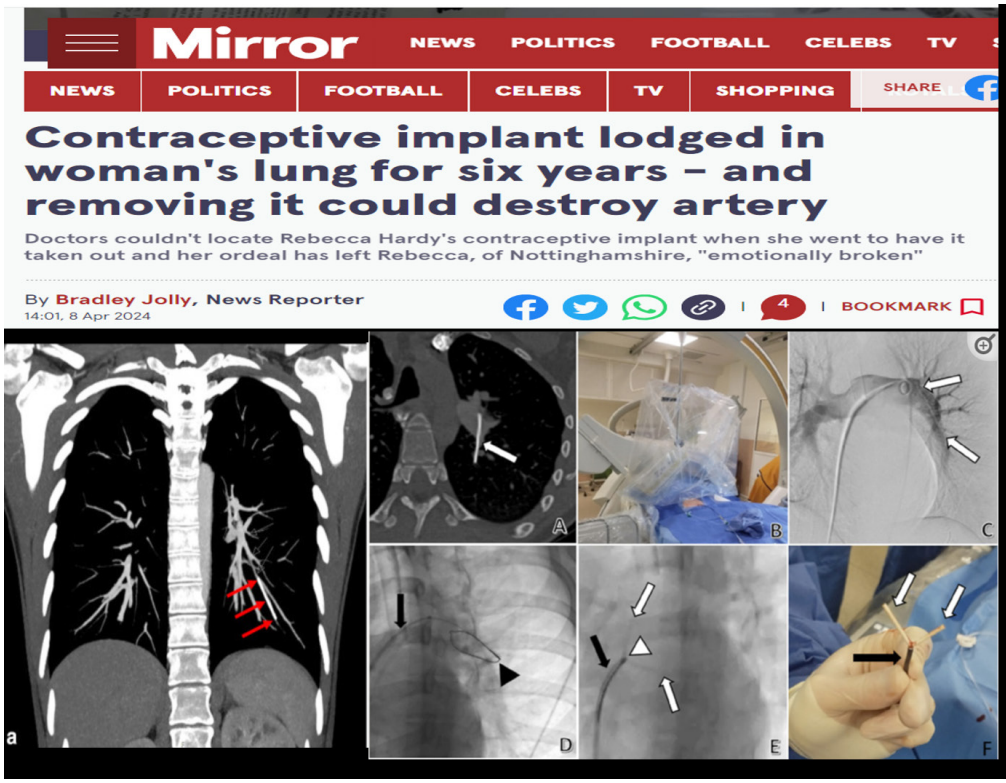
AB PM-JAY receives an escalated allocation of 7,300 Cr INR

Customs duty removed on 3 anti-cancer drugs, trastuzumab deruxtecan, osimertinib, and durvalumab.

Reduced on X ray equipment and digital detectors

US FDA has on July 23, 2024 approved an orally disintegrating combined hormonal pill, FEMLYV for general use. The pill which contains norethindrone acetate 1 mg and ethinyl estradiol 20 micrograms has to be placed on the tongue until completely disintegrated, followed by intake of 140 ml of water. The preparation comes as a set of three blister packs each containing 24 green active pills and 4 white inert pills. It has to be taken at the same time every day.

The preparation has received approval after being thoroughly studied in clinical trials that included 583 women in 3565 treatment cycles in which a total of 5 pregnancies were encountered when the women did not use any other mode of contraception. The pill which acts by suppressing ovulation has a pearl index of 1.82 (95% CI, 0.59-4.25) per 100 women years. It is yet to be approved for women more than 35 years of age. All contraindications of COCs apply to this preparation including smoking, history of thromboembolic disorders, or breast carcinoma to name a few.



Lost & found ! The implant that travelled to the lung!

Dr Jaya Chawla

The Daily Mail on April 5 and the Sun on April 3, 2024 published a strange news. A German lady, from Nottinghamshire, a mother of two, had gotten an implant inserted in her arm for contraception. The following years she could not locate the same in the usual site. Worried she sought medical attention but was reassured that it was just a 'deep implant'!

Three years later when she went again to get the device removed the doctor couldn't find the device in the arm as expected. However, the chest radiograph and the CT clearly showed it to be in the subsegmental branch of the left pulmonary artery! The story doesn't fall short of being called a gynaecologic parallel for a Steven Spielberg movie, isn't it? However, the real thrill is yet to come.

The doctors at the contraceptive team referred the case to cardiothoracic endovascular surgeons who did a thoracotomy and gained access to the segment of the pulmonary artery distal to the implant but due to endo-vascularisation it was dangerous. So, the decision for segmental resection was taken. The procedure could be accomplished uneventfully and the patient is subsequently doing fine. (Wali A et al. BJR Case Rep. 2021)

Another similar case reported by a French team (Grange R et al. CVIR Endovasc. 2024), employed the endovascular route to the pulmonary artery entering through the right femoral vein via the inferior vena cava. Here the catheter was sent past the implant in the vessel under fluoroscopic after confirming that there was no thrombosis in the region. Subsequently, a snare was deployed to retrieve the foreign body. The entire procedure had a fluoroscopic procedure lasting 60 minutes and using radiation exposure of 261mGy.

This news article aims to reflect upon the fact that half-baked news can be potentially harmful and jeopardise the acceptance of a largely successful method of birth control. Amalgamating the scientifically published case reports along with the news that was hugely publicised by a large number of newspapers helps keep things in the right perspective.

Snitch Snatchers

Dr. Preeti Sainia
CMO NFSG
Department of Obstetrics and Gynaecology, ABVIMS & RML Hospital

1. All are high focus states except
   A. Kerala B. Uttar Pradesh
   C. Bihar D. Madhya Pradesh
2. Gynefix is an example of
   A. Oral hormonal contraceptive
   B. Oral nonhormonal contraceptive
   C. Frameless IUCD
   D. Contraceptive implant
3. In case a woman is switching from an oral hormonal method to dmpa which of the following is true
   A. DMPA can be started immediately if she has been using the hormonal method correctly and consistently and reasonably sure of non-pregnant status
   B. can be started immediately with a backup method for the first 7 days
   C. after the next period
   D. none of the above
4. The dose of subcutaneous MPA is
   A. 105 mg/ml B. 104 mg/ml
   C. 104 mg/0.65Ml D. 150 mg/ml
5. Elcometrine is the active ingredient in which subdermal implant
   A. Norplant B. Nestorone
   C. Sino implant II D. Norplant 2 (jadelle)
6. The etonogestrel containing subdermal implant has a core and a skin, besides etonogestrel, all are ingredients of the core except
   A. Ethylene Vinyl Acetate (EVA)
   B. Barium Sulphate
   C. Magnesium Stearate
   D. Polylactic Acid
7. Rate of release of etonogestrel in the single rod implant, by the end of 3 years is
   A. 25–30 mcg/day B. 30–40 mcg/day
   C. 60–70 mcg/day D. none of the above
8. A claim will fall within the "family planning indemnity scheme" only if the beneficiary files the claim with the disc
   A. Within 120 days from the occurrence of the event of death/ failure/complication
   B. Within 30 days from the occurrence of the event of death/ failure/complication
   C. Within 60 days from the occurrence of the event of death/ failure/complication
   D. Within 90 days from the occurrence of the event of death/ failure/complication
9. Window period for progesterone-only pills is
   A. 5 hrs B. 5 days
   C. 3 hrs D. 24 hrs
10. Which state has the lowest fertility rate
   A. Manipur B. Kerala
   C. Meghalaya D. Jharkhand

Answer Key to Quiz 3, July 2024

1. Testicular
2. 46 XX
3. All of the above
4. Prophase I
5. Kallmans syndrome
6. Uterine artery PI > 3
7. 1.7 mm/day
8. Klinefelters syndrome
9. Endometrial scratching
10. IUI with ovarian stimulation

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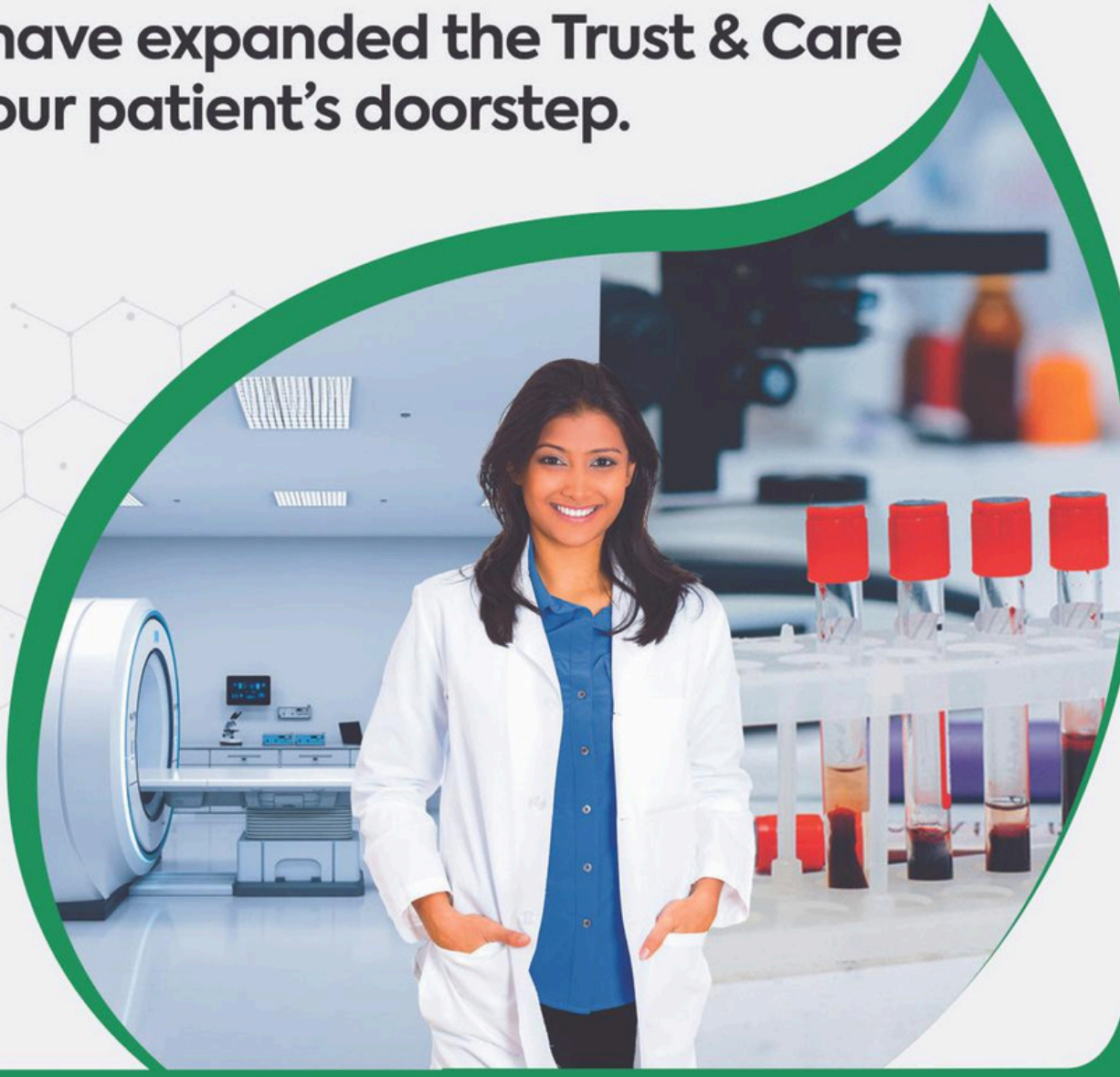

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