FOGSI FOCUS

INTRAUTERINE DEVICE

Editors-in-Chief:
Dr. Ritu Joshi
Dr. Hema Divakar

Guest Editors:
Dr. Nozer Sheriar
Dr. Mandakini Parihar

Reaching The Unreached
FOGSI 2010 INITIATIVE

The Federation of Obstetric & Gynecological Societies of India

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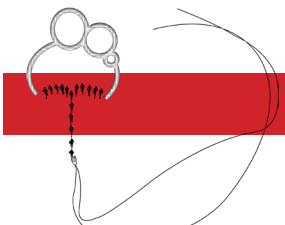
Ground Floor, Model Residency Tower,
605, Baburao Jagtap Road, Jacob Circle,
Mahalaxmi, Mumbai 400 011
Tel.:022-23021648/23021654/23021343
Email: fogsi@bom7.vsnl.net.in
Website : www.fogsi.org

First Edition: April, 2010

Edited by: Dr. Ritu Joshi, Dr. Hema Divakar

Designed by: The Pen & Mouse, mallika.badrinath@gmail.com

Printed at: The Executive Print Group, Bangalore



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Mahalaxmi, Mumbai - 400 011
Tel.:022-23021648/23021654/23021343
Email: fogsi@bom7.vsnl.net.in
Website : www.fogsi.org

From the Desk of Editors-in-Chief

Dr. Ritu Joshi

Dr. Hema Divakar

Dear FOGSIANS,

Every euphoric conversation about India ends in a whimper with questions like – 'Why can't you implement universal primary education?' 'Why do you still have child labour?' 'Why can't you have better infrastructure?' Somehow, it is difficult to reconcile India, a country with a rich ancient civilization and a modern high tech capability, with such questions.

A failure to Stabilize India's population is bringing forth significant implications for the future of Indian Economy and the impact on India's resources would be severe. We at FOGSI believe that we have the capability to face these challenges and the opportunity to transform our nation in the process. We appreciate the vision of our FOGSI President, Dr Sanjay Gupte, in getting us together to revisit the subject of "CONTRACEPTION" and sensitize us to do more and go beyond expectations to fulfill our responsible role as educators and healthcare providers for population stabilization. We dedicate this issue of FOGSI FOCUS on IUCD for this cause. We pledge our support in everyway that is possible.

Modern women and Modern lives drive individualized contraceptive expectations. Empowerment drives active involvement in individualized contraceptive choices Lifestyle of women have changed dramatically in recent years: Education and career Goals/ Relationship status/family planning/Access to information - Compel Changing needs from healthcare provider relationship to 'partnership'.

FOGSI-PSI partnership is one of its kinds that strengthens the advocacy, teaching and training and research in the field of IUCD.The Government of India is revisiting postpartum IUCD insertion programme and also expanding the usage of IUCD in our women. Everything you need to know on IUCD is captured by various authors in this issue of FOGSI FOCUS . We are grateful to all the contributors for their time and efforts.

Editors-in-Chief

Dr Ritu Joshi

Dr Hema Divakar

Guest Editors – FOGSI FOCUS on IUCD

It is our pleasure and privilege to be the guest editors for this important FOGSI FOCUS on IUCD - a subject that deserves priority and needs all our efforts to maximize the achievements.

The work and life of pioneers like Marie Stopes, Margaret Sanger and Annie Besant create a great impact for all involved in the field of reproductive revolution and especially use of Contraceptives. These pioneers have paved the way to universal access to birth control and are responsible for the empowerment of women today. Meeting the contraceptive need is an emergency and reproductive health is our priority. India was the first nation to establish a population strategy and we have to achieve the total fertility rate of 2.1 by 2010 as per the National Population Policy – 2000. Expanding methods and choices by introducing new methods in the program and partnership of Government, NGOs and the private sector is most essential.

The editors, Dr. Ritu Joshi and Dr Hema Divakar, have done an excellent work by covering every possible aspect from Demography to Research including the Knowledge Attitude Practices for IUCD. This FOCUS covers historical antecedents of modern IUCD contraceptives in a very interesting manner. This FOCUS certainly is a "must read" for all who are involved in Reproductive Health and Population Stabilization – the policy makers, health providers, practicing gynecologists, post graduates as well as the social scientists.

With warm regards

Dr. Nozer Sheriar Dr. Mandakini Parihar

FOGSI President Speaks

To the entire FOGSI Family…….

Greetings from the team of "Reaching the Unreached, FOGSI 2010 initiative".

It gives me great pride to bring forth the FOGSI focus on Intrauterine Contraceptive Device (IUCD). There is a constant ongoing development in the field of gynecology, especially contraception and all of us strive for results to be able to provide better healthcare to a woman. Constant updating of knowledge is fundamental. Many a practitioner due to busy schedule needs a focused capsule on a particular topic that he/she seeks and this focus offers just that.

I congratulate the editors-in-chiefs, Dr. Ritu Joshi and Dr. Hema Divakar for the concept and the contents of this concise and precise focus. It has been a hard work and dedication that is seen in the completion of this issue. I also congratulate the contributors who have used this platform judiciously and thank them for sharing their knowledge with all of us.

There are a lot of projects planned this year which I urge you all to actively participate in. The agenda for the year is "standardization, data collection, clinical research and safe practice." Remember FOGSI and all its endeavors are ours. FOGSI is us.

Warm regards,

Dr. Sanjay Gupte
President FOGSI 2010

Message from Dr C.N. Purandare, FOGSI President 2009

Dear FOGSIANS,

It gives me the great pleasure to present to all of you the FOGSI FOCUS on "IUCD".

It is a known worldwide fact that millions of women would prefer to avoid becoming pregnant either right away or ever, but are not using any contraception. IUCD has a great potential of being the modern, reliable contraceptive which can serve large number of women particularly in developing countries like India. The result of Copper 380 A with a 10 years lifespan will be known in 2013. However, so far the results are encouraging.

The aim of family welfare is to improve maternal and child health by reducing the number of children and spacing of the children and abortion should not be used as a contraceptive tool. The FOGSI and PSI have supported a wide range of efforts to improve the family planning and related reproductive health services.

The topics of this FOGSI FOCUS are very carefully selected and contributors are highly experienced and expert in the field of contraception.

I am sure that this issue of FOGSI FOCUS will make an interesting reading as well as throw light on the new developments in family welfare strategies and will serve as useful resource to all concerned whose mission is to reduce Maternal Mortality and Morbidity.

With warm regards,

Dr. C. N. Purandare
President – FOGSI 2009

Dr. Sheela V. Mane
Coordinator

Maternal mortality is a complex problem requiring complex responses. Nevertheless, every intervention must operate through one of 3 pathways: preventing pregnancy, preventing complications, or preventing death when obstetric complications occur.

From a policy perspective, the most efficient approach to prevention of mortality is to reduce unwanted pregnancies. If a women does not get pregnant, she will not die in pregnancy or childbirth. Because about 80 million women each year have unwanted pregnancies, preventing unwanted pregnancies is, without question, the single most effective means of preventing maternal death. Thus making family planning methods readily accessible, acceptable and affordable makes a significant impact on the absolute number of maternal deaths. Note, however, that it will not affect the maternal mortality ratio because the denominator for that measure is live births.

Health systems should maximize accessibility and emphasize that every opportunity should be seized to offer family planning; for example, when mothers bring children for immunization, they should be offered family planning at the same time and not asked to return at a later date or to a different location. The postpartum and postabortion periods are excellent windows of opportunity that should not be missed. It is more effective to discuss contraception at this point than to refer women to another health facility or to ask them to return at a later date. Human rights should be respected-meticulous attention to privacy, for example, and making family planning available to all including the young or unmarried.

This FOGSI Focus is designed to provide accurate and up-do-date information that will help clinic-based providers offer readily accessible, good-quality care.

Dr. Sheela V. Mane

From Population Services International...

Family planning is recognized as a significant health-improving and life-saving measure for mothers and newborns. Family planning can avert 30% of maternal deaths and play a significant role in helping India achieve maternal and child health related Millennium Development Goals.

An unmet need of 13% (NFHS III, 2005-06) in family planning in the country (meaning 13% of currently married women want to space their pregnancies or want to stop child-bearing entirely, yet do not use any family planning method) indicates that there is a demand for family planning in this country, which remains unfulfilled by existing family planning programs or services.

If we focus on use of various family planning methods in NFHS III, it is interesting to note that IUD use is lowest at 2%. Moreover, by going through NFHS I (1992-93), II (1998-99) and III, we find that use of IUD has remained constant at 2% since 1992.

While IUD use remains low in India, it is the second most popular contraceptive method worldwide, after sterilization, with nearly 153 million estimated IUD users in the world amounting to 13% of the world's women of reproductive age group. IUDs are widely used in large countries, like China and Egypt, as well as Vietnam.

IUDs are drawing new attention in many other countries. This new focus stems from high effectiveness of the IUD as a method of contraception—with 0.6–0.8% failure rate in the first year of use - combined with long duration of action of IUDs ranging from five to at least ten years for IUDs currently available. Coupled with the advantages of high effectiveness and long duration of action, there is considerable evidence suggesting that modern IUDs are also safe and quickly reversible. IUD can also act as an emergency contraceptive, if it is inserted within 5 days of unprotected intercourse.

Acknowledging the fact that 54% of IUD users receive the method from private providers, Population Services International (PSI) is working with a network of private qualified providers for making quality IUD services accessible and available for women in need, thus contributing to Government of India's (GoI) efforts of repositioning IUD as an important family planning method with high potential. PSI is an international non-profit, non-governmental organization registered under the Indian Societies Act and has been operating in India since 1988. FOGSI and PSI/India joined hands in the endeavor of increasing the acceptance and use of IUD in the country.

This is a matter of great pride for all of us that FOGSI, in consultation with PSI, decided to bring out this issue of FOGSI Focus on IUD. This issue of the journal intends to draw attention of all FOGSI members towards provision of quality IUD services, which can contribute significantly in changing the lives of many women of our country.

Dr. Jyoti Vajpayee
Senior Technical Advisor
Population Services International

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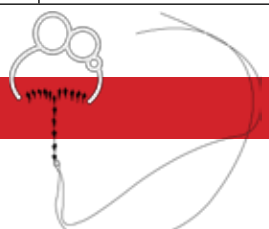


AUTHORS

Authors (in alphabetical order)

Prof Alka Kriplani
Professor, Head Unit II
Dept. of Obstetrics and Gynecology,
All India Institute of Medical Sciences, New Delhi
Vice President FOGSI 2009

Dr. Ashwini Bhalerao – Gandhi
Consultant Gynecologist
P. D. Hinduja Hospital & Medical Research Centre, Mumbai
Chairperson, Adolescent Health Committee of
FOGSI (2004-08)
Secretary, The Mumbai Obst. & Gynec. Society

Dr Atul Ganatra
Director, Dr. R. J. Ganatra's Nursing Home
Co-ordinator & Head, Dept. of Gynecology & Gynec Endoscopy
Wockhardt – Fortis Hospitals, Mumbai

Dr. Basab Mukherjee
Consultant Gynecologist & Obstetrician
Calcutta Medical Research Institute, Kolkata

Dr Bharti Dhorepatil
Founder Director, Pune Fertility Centre,
Head of Dept., Shree Hospital
Gen. Sec. POGS
Chairperson, Clinical Research Committee, FOGSI

Dr. N. Deepa Maheswari
Senior Resident
Dept. of Obstetrics and Gynecology,
All India Institute of Medical Sciences, New Delhi

Dr. Dilip Walke
Chairman,
Ethics and Medicolegal Committee,
FOGSI

Dr. Girija Wagh

Professor & Unit Chief, Bharati Vidyapeeth University Medical College, Pune
Hon. Consultant, Girija Hospital and Nursing Home, Kothrud
Joint Secretary FOGSI (2010)

Dr Hema Divakar

Consultant Obgyn, Bengaluru
Hon Secretary, ICOG
President, Karnataka State Obgyn Societies

Dr. Hrishikesh D. Pai

Consultant Gynecologist and IVF specialist: Lilavati Hospital, Mumbai,
Consultant Gynecologist: Fortis La Femme Hospital, Delhi, Chandigarh
Treasurer: FOGSI

Dr Jaideep Malhotra

Vice President FOGSI 2010
Director, Malhotra Nursing & Maternity Home Pvt. Ltd., Agra

Dr. Jyoti Vajpai

Senior Technical Advisor, PSI

Dr Madhuri Patel

Professor and HOD,
ESIC-PGIMSR MGM Hospital, Parel, Mumbai
Joint Secretary FOGSI, 2009,
Chairperson, Study on Female Breast Committee FOGSI

Dr. Mandakini Parihar

Director, Mandakini IVF Center, Mumbai.
Hon Associate Professor OBS.GYN K.J.Somaiya Medical College & Hospital, Mumbai
Jt. Secretary FOGSI 2003
Consultant, Wockhardt Hospital

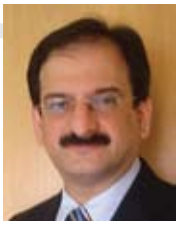
Dr Narendra Malhotra

Past President FOGSI 2008
Director, Malhotra Nursing & Maternity Home Pvt. Ltd., Agra

AUTHORS

Dr Neharika Malhotra
Hon. Consultant, Malhotra Nursing & Maternity Home Pvt. Ltd., Agra

Dr. Nozer Sheriar
Deputy Secretary General, FOGSI
Vice President, MOGS
Consultant, Breach Candy, Holy Family, Masina and Parsee General Hospitals



Dr Parag Biniwale
Chairman, Young Talent Promotion Committee, FOGSI

Dr. Parikshit D Tank
Hon. Clinical Associate, Nowrosjee Wadia Maternity Hospital, Mumbai
Consultant, Ashwini Maternity and Surgical Hospital, Center for Endoscopy and IVF

Dr. Prachi B Shitut
Sr. Registrar, Sion Hospital, Mumbai

Dr. Punit Bhojani
Lecturer, KJ Somaiya Hospital, Mumbai

Dr. Rajini Agarwal
Chairperson, Food & Drug Committee
Director, Dr. Ragini's Ob-Gyn Centre, Gurgaon

Dr. Rana Khan
Clinical Assistant,
P.D. Hinduja Hospital & Medical Research Centre, Mumbai

Dr. Rishma Dhillon Pai
Consultant Gynecologist – Lilavati & Jaslok Hospitals, Mumbai
First Vice President FOGSI 2010

Dr. Ritu Joshi
Hon. Consultant, Monilek Hospital & Reseach Centre
and Fortis-Escorts, Jaipur
Chairperson, Family Welfare Committee

Dr. Sasikala Kola
Hon Consultant, Laxmi Clinic,
Hyderabad

Dr. Sheela V. Mane
Chairperson, Safe Motherhood Committee, FOGSI

Dr. Sheila Balakrishnan
Assoc Professor in O & G, Medical College Trivandrum
In charge of infertility clinic

Dr Sneha Bhuyar
Managing Director, Sukhakarta Hospital
Maternity, Surgical Nursing Home & Laproscopy Centre, Yavatmal

Dr Suchitra Pandit
Specialist in High risk pregnancy, adolescent and
menopausal Problems,
Pelvic Floor Surgery, Kokilaben Hospital, Mumbai,

Dr Sujata Misra
Associate Professor S.C.B.Medical College Cuttack
Chairperson, Medical Disorders in Pregnancy Committee,FOGSI
Academic Counsellor, Post graduate diploma in Maternaland child health

The Unmet Need Continues

Dr. Parikshit D Tank and Dr. Madhuri Patel

More than 100 million women in less developed countries, or about 17 percent of all married women, would prefer to avoid a pregnancy, but are not using any form of family planning. Demographers and health specialists refer to these women as having an "unmet need" for family planning—a concept that has influenced the development of family planning programs for more than 20 years.

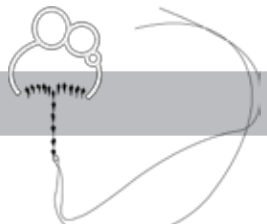
The concept of unmet need points to the gap between some women's reproductive intentions and their contraceptive behavior. In doing so, it poses a challenge to family planning programs: to reach and serve the millions of women whose reproductive attitudes resemble those of contraceptive users but who, for some reason or combination of reasons, are not using contraception. To reach out to women with unmet need, family welfare programs should focus on the extent of the unmet need, explore the reasons behind the unmet need and identify the subgroup of women who can be targeted for interventions.

Why is the unmet need a matter for concern?

Unmet need for contraception can lead to unintended pregnancies, which pose risks for women, their families, and societies. In less developed countries, about one-fourth of pregnancies are unintended—that is, either unwanted or mistimed (wanted later). One particularly harmful consequence of unintended pregnancies is unsafe abortion. This is a leading cause of maternal mortality in the developing world. In India, a woman dies every five minutes due to an unsafe abortion. In addition, unwanted births pose risks for children's health and wellbeing and contribute to rapid population growth in resource-strapped countries.

Measuring the unmet need

Today, the main tool for measuring unmet need is the Demographic and Health Survey (DHS), which has been conducted in 55 countries—often more than once. In the DHS, women ages 15 to 49 are asked whether they would like to have a child (or another child) and if so, how soon, or whether they would prefer not to have any (more) children. To derive a figure for unmet need, analysts link these responses with whether the women are able to become pregnant and whether they are currently using contraception. Combining the estimate of unmet need with data on current contraceptive use provides a picture of the total potential demand for family planning in a country. The data



generated from these surveys has some shortcomings such as exclusion of unmarried women who may have varying levels of sexual activity and exclusion of women using ineffective contraceptive methods. In spite of these, DHS remains the benchmark tool for assessing the unmet need.

Magnitude of the unmet need

Generally speaking, as countries develop, fertility declines with increasing contraceptive usage. The unmet need in developed countries is low. In most European countries, the unmet need is less than 10%. The unmet need may also be low in countries where the culture encourages women to have more children. For example, in Chad, though the average fertility is high (women have more than 6 children on average), the unmet need is only 4%. Comparatively, countries where the desire for a large family is reducing, but the effective distribution of contraceptive technology has not occurred represent areas where the unmet need is high. Countries such as Haiti, Nepal, Uganda have an unmet need over 30%.

India had a contraceptive prevalence rate of 48.3% in 2003. The unmet need was estimated as 15.8%. Of this, the unmet need for spacing births was 8.3% and for limiting births was 7.5%.

Exploring reasons for the unmet need

Women have unmet needs for a variety of reasons and usually it is a combination of a number of factors which brings about this situation. The reasons are complex and amorphous, often intertwined with cultural and religious beliefs. Some of the recurring themes for not using contraception are:

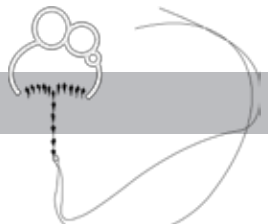
Perceived lack of exposure to pregnancy amongst couples who have intercourse infrequently or are breastfeeding or approaching menopause. These couples typically also have an ambivalent attitude towards becoming pregnant.

Opposition to family planning methods from women, their husbands or other members of the family.

Method related problems such as side-effects, cost and access facilities.

Lack of knowledge of contraception.

An interesting insight came up from the DHS questionnaires administered to men. There were significant differences from the women of the same country and culture. In general, men wanted more children than women and they wanted them earlier. This is an important issue that programs should address in order to avoid discord. A healthy dialog between couples, ensuring clear communication, could address this issue.



Characteristics of women with an unmet need

Women who have an unmet need are typically on the lower rungs of the socioeconomic ladder. Their levels of education are lower than their counterparts whose contraceptive needs are met. These women represent the unserved population in terms of many other indicators of health care in general. In order to understand the likelihood of the future usage of contraceptives amongst women with an unmet need, they are characterized by their previous usage of contraceptives if any and their intent of using contraception. Women who have used contraceptives in the past and have a positive intent of using them again are the most likely to have their unmet need fulfilled. These are typically women who are most likely to use contraception in the near future and the easiest to serve. On the other extreme, are women who have never used contraception in the past and have no positive intention of using a contraceptive but still wish to avoid pregnancy. This population is the least likely to adopt contraceptive practices. They are the most difficult to reach. The proportion of women with this characteristic varies with different populations. 54% of Indian women with unmet need fall into this category.

Using data on the unmet need

Survey data that is gathered from the DHS is an indicator and guideline for family planning programs. This data is a useful tool to identify the extent of the problem, the obstacles to reaching women and weaknesses in the service infrastructure.

Family planning programs can take some important steps to reduce the barriers that women face in their efforts to obtain contraceptive methods and services:

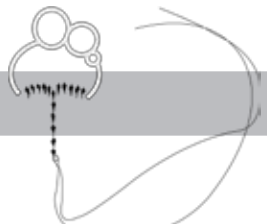
Women need to be counseled on the full range of available contraceptive methods so that they can choose the method that best matches their individual circumstances and intentions and can change methods when they need to.

Women who are postpartum, breastfeeding, or approaching menopause need counseling on their likelihood of becoming pregnant and on what family planning methods might be appropriate for them.

Women need correct information on contraceptive methods, especially on side effects and how to manage them.

Programs should work to improve interpersonal relations between clients and providers and to ensure periodic follow-up of clients to reduce the number of women who stop using contraception.

Programs should focus on men as well as women, creating an environment in which both sexes can seek services and encouraging men to discuss family planning with their wives.



Unmet need in the Indian scenario

India's population policy has resulted in the total fertility rate declining from 6 in the 1960s to 2.85 in 2003. This is undoubtedly a success but only a partial one. The sheer size of the population requires us to redouble our efforts and ensure replacement level fertility at the earliest.

In 2000 the contraceptive prevalence rate (CPR) among married women was 48.3%. Contraceptive use in India is characterized by:

The predominance of non-reversible methods, particularly female sterilization (about 35% of couples use female sterilization while only 3% of male partners are sterilized).

Limited use of male-/couple-dependent methods.

High discontinuation rates.

Negligible use of contraceptives among both married and unmarried adolescents.

Less than 7% of married couples use officially accepted effective spacing methods (condoms, pills or intrauterine devices). This represents the segment which needs the maximum promotion. Couples need to be educated and awareness needs to be spread about these methods.

The IUCD in India

The IUCD has great potential of being the modern, reliable contraceptive that can serve the unmet need for a large number of Indian women. The program of IUCD use suffered a setback when it was introduced earlier due to lack of trained personnel and subsequently a poor result in terms of efficacy and side effects. These resulted in adverse publicity and put the brakes on an otherwise effective contraceptive method. The Copper T 380 A with a 10 year lifespan has been introduced with better training and support system. The results from the next DHS will be available in 2013 and should reflect changing patterns of contraceptive use in general and the IUCD in particular.

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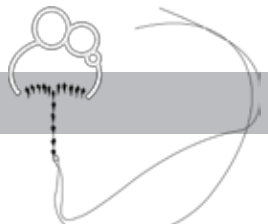


Historical Perspective To-Date

Dr. Sheila Balakrishnan

An intrauterine device is a long acting reversible contraceptive device placed inside the uterus. Previously it was also called a coil, due to the coil shaped design of the early devices. It is currently used by 100 million women over two thirds of whom are in China. Only 3% users are from India. According to popular legend, Arab traders inserted small stones into the uteri of their camels to prevent pregnancy during their long treks in the desert. This was probably the beginning of the IUCD- but whether fact or fiction we do not know. Precursors to the IUD were first marketed in 1902. Developed from stem pessaries (where the stem held the pessary in place over the cervix), the 'stem' on these devices actually extended into the uterus itself. Because they occupied both the vagina and the uterus, this type of stem pessary was also known as an intrauterine device. The use of intrauterine devices was associated with high rates of infection; for this reason, they were condemned by the medical community.

TYPES OF INTRAUTERINE DEVICES

Inert devices

These do not contain copper and include the Grafenberg ring, Ota ring, Margulies coil, Saf T coil and Lippes loop

Copper containing devices

Most of the T shaped devices have a plastic T frame wound around with pure copper wire or there may be copper sleeves. All the copper devices have a number which is the surface area of copper in sq mmm that the device proceeds. The first generation devices contained less of copper.

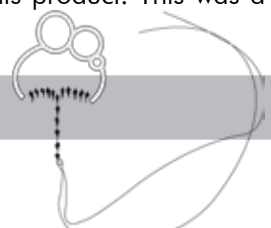
The second generation devices contain more of copper and the latest have copper on the sleeves as well.

Hormone releasing devices

These release progesterone and are also termed Intrauterine systems (IUS).

INERT DEVICES

The first intrauterine device (contained entirely in the uterus) was described in a German publication in 1909 by Richter, although the author appears to have never marketed his product. This was a silkworm catgut ring with a nickel and bronze wire. Dr Ernst



Grafenberg is usually credited as the first person to actually market these devices. He first reported the use of a silk ring and found a 3% pregnancy rate among 1100 women who used the ring. In 1930 he modified the ring by wrapping it in silver wire and reported a lower pregnancy rate of 1.6% among 600 women. Unknown to him this silver wire had been contaminated with copper, but this fact would be recognized only 40 years later!

In 1934 the Japanese physician, Tenrei Ota modified the Grafenberg ring by adding a supportive structure in the centre. This was in order to solve the problems of the high expulsion rates with the Grafenberg ring. But all these devices still had unacceptably high rates of infection. In addition their use, propogation and further development were kept stifled by the politics of the Second World War. Contraception was forbidden in the Nazist Germany as well as in its ally, Japan. Hence the western world did not come to know of all this work till the war ended. It was only in 1959 that Oppenheimer reported these rings in the American Journal of Obstetrics and Gynaecology.

The first plastic IUD was the Margulies coil or spiral and was introduced in the year 1958. It was quite large, causing discomfort to the users. In addition it had a hard plastic tail which caused discomfort to the male partners.

In 1962, Jack Lippes of Buffalo presented the Lippes loop at the first international conference on intrauterine devices in New York, which was organized by the Population Council. It was slightly smaller, had a single filament thread as tail and rapidly replaced the Margulies coil. It soon became the most widely prescribed IUD in the United States by the year 1970.Around this time the stainless steel single ring IUD was developed and used in China. But in 1993 the Chinese Government banned the production of the stainless steel IUD's because of very high (10%) failure rates.

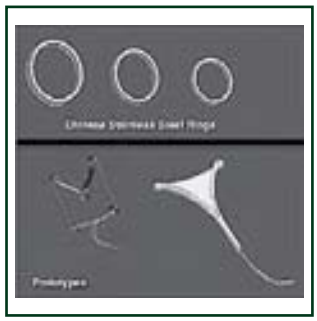


Fig 1.1 Lippes loop

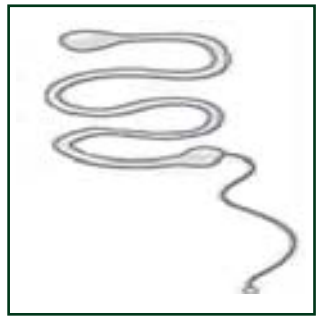
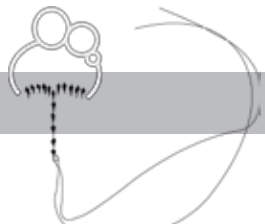


Fig 1.2 Other early devices

At around this time the Dalkon Shield was also becoming popular. This was manufactured by AH Robins Company and sold in the United States from 1971 to 1974. This was a very poorly designed device with a multifilament tail which became a pathway for bacteria to ascend resulting in pelvic inflammatory disease. 110 septic spontaneous abortions were



reported with the shield in place and 7 of them died. On June 28 1974 sales were suspended by Robins at the request of the FDA due to safety concerns. International sales were stopped in 1975. This had a lot of far reaching consequences. Many lawsuits were filed against the company and as a result all intrauterine devices fell into disrepute in the United States, which was the country where they were first developed. There was a virtual epidemic of sexually transmitted infections and pelvic inflammatory disease in the sixties and seventies. This was in reality due to the sexual revolution of the sixties and the failure to use protective contraception and not due to the intrauterine device alone. But unfortunately all this added to the unpopularity of the intrauterine device.

Fig 1.3 Dalkon Shield

COPPER CONTAINING DEVICES

It was James Zipper in Chile who first suggested that Copper had a local effect on the endometrium. He said that adding copper would increase the contraceptive efficacy. At around this time, Howard Tatum from the USA conceived the plastic T shaped IUD in 1968. He combined Zipper's suggestion of using copper and he developed the T shape to diminish uterine reaction to the structural frame. This was the birth of the first Copper T device. So there was a natural evolution from rings to coils and finally to the present day T shape of the intrauterine device. He found that the T shaped devices had less of pain and bleeding and also the expulsion rates were less. This was due to their similarity to the natural shape of the uterus.

First generation devices

These are the Cu 7, CuT 200, CuT 220C, Multiload Cu 250 and the Nova T. The CuT 200 was used previously in the National Family Planning Programme of India, but has now been replaced by the Cut 380A. The Nova T has a silver core to prevent fragmentation of the copper and thereby increase the lifespan. Most of these devices could only be kept for 3-4 years.

Fig 1.4 Cu 7

Fig 1.5 CuT 200

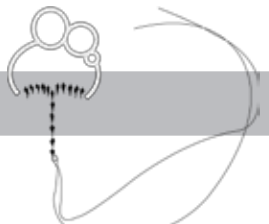


Fig 1.6 CuT 220

Fig 1.7 Multiload Cu 250

Fig 1.8 Nova T

Second generation devices

These devices have more of copper and hence are more effective and can be kept longer. Some have copper only in the stem. Examples are the Multiload Cu375, Nova T 380, UT 380, UT3 380 Short and the Neo Safe 380. Some of the newer second generation devices have in addition, copper in the sleeves as well. They are the most effective and long lasting ones. The most popular one is the Cu T 380A which is currently available all over India as part of the National Family Planning Programme. It can be kept for upto 10 years and can be considered a reversible alternative to sterilisation. The Cu T 380 Ag has a silver core which increases lifespan. The Cu T 380 Slimline is very popular in the United Kingdom. Here the copper sleeves are flush at the ends of the horizontal arms. This is in order to facilitate easy loading and insertion. The Cu Safe 300 is made from a more flexible plastic and is slightly smaller than the Cu T 380 A. The major difference is that the ends of the transverse arm have sharply bent ends that are adapted to the uterine cavity. The advantage is that removal for pain and bleeding is slightly less. The performance of most of the second generation devices which have copper on the sleeves as well is almost comparable to the Cu T 380 A.

Fig 1.9 Multiload Cu 375

Fig 1.10 Nova T 380

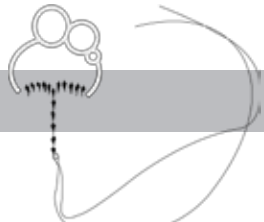


Fig 1.11 CuT 380 A

Fig 1.12 CuT 380 Slimline

HORMONE RELEASING IUD's

These are also called Intrauterine Systems in some countries including the UK. Progestasert was the first one to be developed in the year 1996. But it had a lot of disadvantages. The failure rate was 2% which was unacceptable and it had to be replaced annually. In addition the rate of ectopic gestation was also increased. Due to all these problems, it was withdrawn from the market in 2001.

Fig 1.13 Progestasert

The next hormonal device to be marketed was the Levonorgestrel releasing intrauterine system (LNG-IUS) or Mirena in the year 1990. It releases about 20 µgm of levonorgestrel per day. It was approved for 5 years but is effective upto 10. Its efficacy is almost equal to that of the CuT 380 A. In addition it decreases the menstrual blood loss and so can be used as an alternative to hysterectomy in women with heavy periods.

Fig 1.14 Mirena

RECENT DEVELOPMENTS

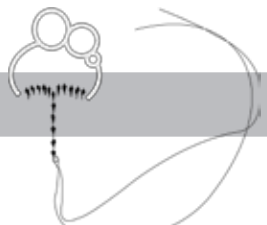
Low dose IUS

Low dose Mirena or MLS is another recent addition which delivers only 10 µgm daily. Femilis is another low dose intra uterine system developed by a Belgian company.

Frameless devices

Gynefix (also called Flexigard 330 or CuFix PP 330) is a new frameless device. It consists of a loop that holds six copper sleeves strung on a surgical nylon thread knotted at one end. The knot is pushed into the myometrium with a notched needle and held in place by a suture to the uterine fundus. Insertion is difficult, but the expulsion rates are low. The efficacy is comparable to the Cu T 380 A

Fig 1.15 GyneFix



The Fibroplant levonorgestrel intrauterine system is another frameless device which is also hormone releasing. It is anchored to the fundus of the uterus like the Gynefix and releases about 14 μgm of levonorgestrel per day.

Ombrelle

The Ombrelle 250 and 380 were designed in France where they are popular. As the name suggests, the umbrella like shape ensures a fundus seeking action when the uterus contracts. In addition they have a spring like action to resist expulsion at the isthmus. The efficacy is good and expulsion and side effects are claimed to be less.

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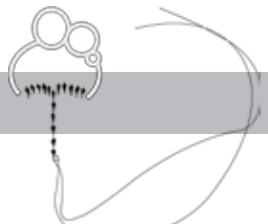


Indian Public Health Context

Dr. Ashwini Bhalerao – Gandhi & Dr. Rana Khan

India is presently the second most populous country in the world, and with the rising trend in birth rate may soon be on the top of the list (1,2,3). This inspite that it was the Indian government which was one of the first in the world to formulate a National Family Planning Programme way back in 1952, which was later expanded to encompass maternal and child health, family welfare, and nutrition. The Third five year plan (1961-66) redefined the definition of family planning "the very centre of planned development" from 'clinic approach' to more vigorous 'extension education approach' and 'small family norm'. A separate department for family planning was set up in 1966.The first National population policy came up in 1976. However after the disastrous forcible sterilization campaign in 1976, the Ministry of Family Planning was renamed as Family Welfare.

In 2000, the National Population Policy advocated a holistic, multisectoral approach towards population stabilization, with no targets for specific contraceptive methods except for achieving a national average total fertility rate (TFR) of 2.1 by the year 2010 (3,4). This resulted in a shift in implementation from centrally fixed targets to target free dispensation through decentralized, participatory approach.

The contraceptive prevalence rate (CPR) among married women in the year 2000 was 48.3% (5,6). Contraceptive use in India is characterized by:

- Predominance of non-reversible methods, particularly female sterilization
- Limited use of male-/couple-dependent methods
- High discontinuation rates; and negligible use of contraceptives among both married and unmarried adolescents

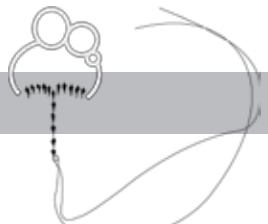
Three out of four users rely on sterilization in India, overwhelmingly female sterilization (7,8,9). Sterilization accounts for roughly 85% of all modern contraceptive methods used. Less than 7% of currently married women use the officially sponsored spacing methods (pills, IUD and condoms) (7,8). One of the major obstacles in usage of spacing methods, is that the access to quality health services is limited in both urban and rural areas. Only 37% of rural women live in a village with a primary health centre or sub-centre. Important sub¬groups such as adolescents are neglected or under-served.

The public sector provides five contraceptive methods – female sterilization, male sterilization, the IUD, oral contraceptive pills and condoms (6). These contraceptives are supplied through the government's network of health care facilities and with the assistance of NGOs. There is also a good social marketing programme of condoms and oral contraceptives.

Amongst the intrauterine devices, Lippe's loop was the first to be introduced in family planning programme way back in 1965 (9,11). It is a double S shaped device made of polyethylene, non toxic & non tissue reactive .However it was not well accepted by Indian women, as side effects like menorrhagia & dysmenorrhoea were very commonly encountered. Even the expulsion rate was relatively high .This led to the introduction of the Copper intrauterine device in Indian family planning programme (10). It is inserted by 'withdrawal method' as opposed to the 'push in' method used in case of Lippes loop and hence has lesser complications. It is supplied free of cost to all the State / UTs for insertion at the PHCs, Sub-centres and Hospitals by trained Medical Practitioners / Health Workers. The earlier version of Cu – T 200 'B' (IUDs)has now been replaced by Cu-T 380-A from 2002-03 onwards, which provides protection for a longer period (about 10 years) as against Cu-T 200 'B' which provides protection for about 3 years only. (7)

Many studies have analysed the misperceptions mostly among rural women related to female anatomy and contraceptive methods such as the IUD (12,13,14). Most rural women did not know where the IUD is inserted in the body, what it does, or how it works. They had limited understanding of the relationship between the reproductive and gastrointestinal systems. They expressed fear that the IUD could ascent into their chest or be lost in the abdomen. Other commonly expressed concerns were that the IUD causes heat, could lead to loss of weight & energy, and that when in place, the woman's partner could become stuck during sexual intercourse and would require a physician's intervention !!! During the initial years, women who came to the dispensary to have an IUD removed attributed any and every physical problem they were experiencing to the device, and insisted upon removal despite extensive reassurance.

In recognition of these concerns, the IUD service programme was modified in 1991 (Phase II) (15,16) wherein, the government launched an expanded programme of information through community group meetings and individually with women at the time of antenatal visits. Through slides and pictures, women were shown the entire female reproductive and gastrointestinal tract, as well as the location of the IUD. Women who came for an IUD insertion were also first shown the entire process of IUD insertion using a plastic model. This demonstration allayed women's above mentioned fears and misconceptions. In addition, IUD 'acceptors received counselling on all possible problems associated with the method such as initial discharge, bleeding and pain, and were also encouraged to visit the clinic for treatment if any of these problems arose.



Inspite of all these efforts, IUD is still underused in the Indian Family Planning Program and repositioning it will have several advantages (12,13,14).

It increases choice for a long-acting and safe contraceptive to achieve optimal birth interval of 3-5 years; especially in postpartum and post abortion women.

With the Copper T-380A, a woman can protect herself against pregnancy for up to 10 years.

This is particularly attractive for those couples who have achieved their desired family size but do not want to adopt a permanent method like sterilization.

The IUD is a highly effective contraceptive method (pregnancy rate < 1%) and does not require constant attention.

It does not interfere with intercourse and there is a quick return of fertility once woman stops using the method.

As the IUD can be used for at least 10 years, its use will be less expensive than most temporary methods.

This is an important consideration for countries where contraceptive security is an issue, such as with the Ministry of Health and Family Welfare (MOHFW). (17)

The private sector has the liberty of using the latest available options and therefore enjoys a better patient response. The newer intrauterine devices like Multiload and Hormone releasing devices (Levonorgestrel intrauterine system LIS) are better accepted.

The collective wisdom from various projects trying to increase use of IUD, list several factors as pre-conditions for the success of the IUD program. (15, 16, 17) It includes technical and counseling skill upgradation of health care providers, mechanisms for follow-up and resolving supply constraints to meet the demand. In addition, the general program emphasis on sterilization and gives no incentive to health care providers to promote IUD or other spacing contraceptive methods. In such an environment, it is not surprising that usage of temporary (spacing) methods is only 10.2 percent and that for IUD only 1.8 percent. However, more recently, Ministry of Health and Family Welfare (MOH & F W) has set up committees at the Ministry level to look into the overall strategy to strengthen Information Education and Communication (IEC) to promote spacing methods, particularly, repositioning of IUD thus increasing its acceptance and continuation. (16, 17)

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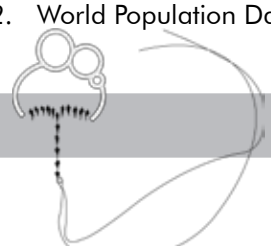

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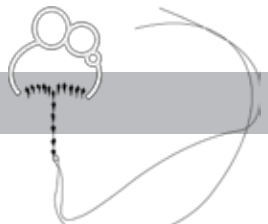


Modern Intrauterine Device

Dr. Mandakini Parihar & Dr. Rajini Agarwal

"Family Planning could bring more benefits to more people at less cost than any other single technology now available to the human race."

UNICEF Report

Introduction

We currently have over 6300 million people on planet Earth, and this number rises each year by around 80 million. In addition, almost 50% of the pregnancies that occur worldwide are unplanned, and hence the need for contraceptive awareness and newer more acceptable contraceptives is the need of the hour. It is as effective method of preventing pregnancy. When it's removed, fertility returns immediately. Intrauterine methods with their appropriate default state and excellent "forgetability" are likely to be demographically more successful than others. Continuation rates are higher than any hormonal method. 160 million women use IUCD for contraception, (15% of the world's women of reproductive age) making it the most popular method of reversible contraception.

Table1: The 3rd and 4th Generation IUCD

- Mirena
- Cu-T 380A
- Frameless IUCD
  - Gynefix
  - Fibroplant

The levonorgestrel-releasing intrauterine system (LNG-IUS) - Mirena

The levonorgestrel-releasing intrauterine system (LNG-IUS) consists of a plain Nova-T device with a silastic reservoir attached to the vertical arm. The silastic reservoir is impregnated with levonorgestrel and is covered with a rate-limiting silastic membrane. The steroid reservoir contains 52 mg of levonorgestrel mixed with polydimethylsiloxane, and it is covered with a membrane of the same material to control the release rate, which is initially 20 mg per 24 hours. The device is currently approved for a lifetime of 5 years. (1, 2) The IUS (Intra Uterine System) is a unique method of contraception combining the main benefit of the pill - effective birth control - with the main appeal of sterilization ''forget-ability'. Unlike the pill, you don't have to remember to take it every day. Unlike sterilization, it is a fully reversible method. The IUS also has an advantage over the Copper IUD (Intra Uterine Device) because it tends to make periods lighter and shorter which the Copper IUD does not.

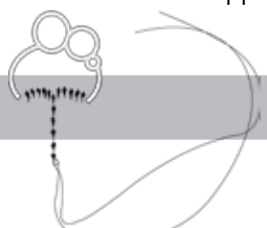


Table 2: Mechanism of Action (2, 3, 4, 5)

- Strong suppression of the endometrium - antiproliferative action
- Prevention of Fertilization
- Cervical mucus becomes thick, scanty, and impermeable
- Stimulate glycodelin A (GdA) in the endometrium and hence inactivate sperm.
- Impairs sperm migration by endometrial suppression and changes in the cervical mucus and uterotubal fluid

Insertion of Mirena

Training is necessary for the insertion of Mirena because it is different form that of other intrauterine devices (IUDs). Mirena has its own inserter and its use needs practice. Correct fundal placement of the device is necessary to deliver the steroid over the whole endometrial tissue to suppress all the endometrium. This is essential for most therapeutic indications.

The device is enclosed within the insertion tube during passage through the cervical canal. The side arms of the device are released when the tip of the tube has passed the inner os of the cervical canal. It takes about 15 to 30 seconds before the arms start to open, and then the device is slowly and gently lifted to the fundus. The unfolded arms prevent perforation and the correct position in the fundus is achieved. This way insertion is safe and there is no need to use sonography afterward.

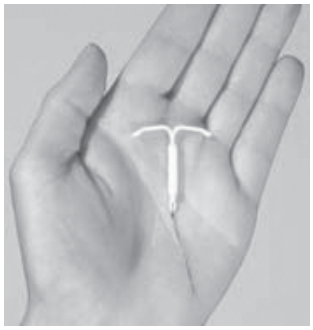


Fig 1: Mirena

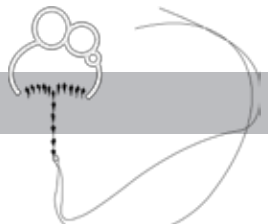
Irregular Uterine Bleeding and oligomenorrhoea and amenorrhoea

After insertion up to 25% of women will experience oligoamenorrhoea, so this needs to be explained as appositive advantage of the product. Importantly, even among the amenorrhoeic LNG-IUS user the plasma estradiol is in the normal range for fertile women.

Table 3: Advantages of the IUCD (3,5,7,8,9,10)

Contraceptive advantages

a. SAFE : Mortality estimated at less than 1 in 500.000
b. Highly effective
c. Fewer accidental pregnancies
d. Can be used in the interval period or After an abortion
e. Sexually convenient



f. Forgettable memory not required after successful insertion
g. long acting
h. Continuation rates high--long duration of use:
i. Reversible
j. Immediate return of fertility after removal

Other health benefits like

k. Reduction of menstrual blood loss and duration of loss
l. Better iron balance
m. Better quality of life
n. Reduction of dysmenorrheal
o. Reduced risk of PID and endometritis
p. Reduced risk of ectopic pregnancy
q. Reduced abortions
r. Less endometriosis ??

Table 4: CHECK-LIST – indications for use of LNG-IUS (MIRENA) (5, 9, 10)

Any patient desirous of contraception
Ideally one who has had atleast one child but can be used in nulliparous too
Normal uterine cavity
Patient with menorrhagia
Patient with severe dysmenorrhoea
Adenomyosis
Small intra-mural fibroids

Table 5 RED TAG : Contra-indication for use (2, 4)

Evidence of active pelvis inflammatory infection
Evidence of active cervical or vaginal infection
Sub-mucous fibroids
Pregnancy
Undiagnosed vaginal bleeding

Copper 380A

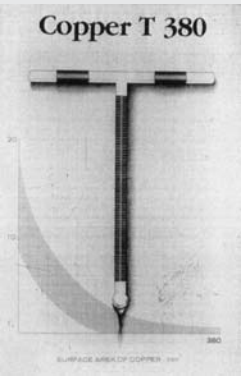
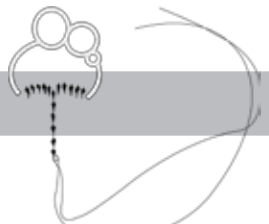


Fig. 2. The copper T 380A IUD

The copper T 380A intrauterine device (IUD) is a T-shaped device composed of a polyethylene frame measuring 36 mm by 32 mm with 176 mg of electrolytic copper wire wrapped around its vertical stem and two copper sleeves of 68.7 mg of copper, placed on each of the horizontal arms, for a total surface area of 380 ± 23 mm2 of copper. The device has a monofilament polyethylene string tied at the base of the stem to create two tail strings that aid in monitoring device's position and in its removal. The frame contains barium sulfate to permit radiographic visualization. The copper



T 380A IUD is Food and Drug Administration (FDA)-approved for 10 years of use, although clinical studies indicate high efficacy for at least 12 years and perhaps as long as 20 years. (11, 12, 13)

Efficacy

The cumulative 5-year pregnancy rate is between 0.3–0.6% for the copper T 380A IUD. The copper T 380A IUD is the most effective copper-bearing IUD in the world. The 10-year cumulative pregnancy rate for the copper T 380A is 1.9–2.2%. Because IUCD's act their efficacy is maintained even in women with Class III obesity. (11, 13)

Contraindications

The copper T 380A IUD is not appropriate for women with copper allergies and is not recommended for women with copper storage defects (Wilson's disease). Labeling states that the copper T 380A IUD should not be used by women at high risk for sexually transmitted infections; however, in that situation, concurrent condom use may enable IUD use. A recent retrospective study of women with a history of STDs or active infections showed that both the IUCs were safe and effective. HIV-infected women are also appropriate candidates for IUCs. (13, 14)

Expulsion

Expulsion rates are highest in the first few months after placement and depend on insertion technique and timing of placement within the menstrual cycle. Overall, first-year expulsion rates with the copper T 380A are 5.7% among all users and 2.3% among parous women. After the first year, expulsion rates decline.

4th Generation Frameless IUCD

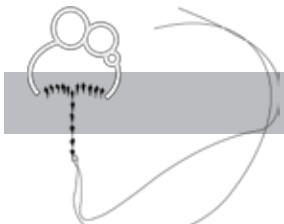
These IUCD are not yet in clinical use.

The frameless IUD—made without the plastic T-shaped frame common to most other types of IUDs—consists of several copper cylinders tied together on a string. It is anchored one centimeter deep into the fundus (top) of the uterus. This design is intended to cause less pain and bleeding than framed devices. (15, 16, 17)

Fig: 3 Frameless IUCD

GyneFix, the newest frameless IUD, was introduced in Europe in the early 1990s, following 15 years of research to improve ease of insertion and attachment to the uterine wall. It is also available in China and through Marie Stopes International programs in Latin America, Asia, and Africa. Its developer plans to apply for US FDA approval.

Small, non-comparative studies demonstrate promising results for GyneFix in minimizing menstrual blood loss and discontinuation. Randomized controlled trials involving



GyneFix have not yet provided clear support for the benefits expected and the expulsion rates have been higher than found in early clinical trials.

The frameless IUD requires an entirely different insertion technique than the framed IUD, and the level of skill required to insert them is high. Providers face difficulty with insertion even with the use of a new inserter mechanism, introduced by the developer to simplify insertion. The frameless IUD is less likely to be expelled when inserted by an experienced provider

Another frameless IUD in development, FibroPlant-LNG, releases the progestin levonorgestrel. Based on the design of the GyneFix IUD, it too is anchored into the fundus of the uterus. FibroPlant-LNG delivers 14 μg of levonorgestrel daily and prevents pregnancy for at least three years. Initial studies suggest that FibroPlant-LNG would be highly acceptable and may reduce bleeding. (15, 16, 17)

CONCLUSIONS

The newer IUCD offer one of the most effective methods for reversible contraception. A correctly inserted IUCD prevents fertilization, and extra-uterine pregnancies are therefore also avoided. The return of fertility is immediate after removal. The initial counseling of the users must include information on the charges likely to occur in the bleeding pattern, in particular the adaptation period lasting 3-6 months. 160 million women use IUCD for contraception, (15% of the world's women of reproductive age) making it the most popular method of reversible contraception. Intrauterine contraceptives (IUCs) provide top tier contraception that is convenient, long term, cost effective and rapidly reversible. Their efficacy compares favorably with permanent sterilization.

"Technology made large populations possible and large populations today make technology indispensable"

Joseph Krutch

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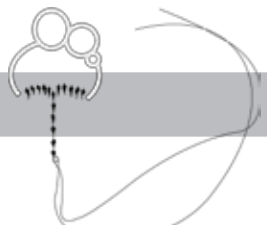

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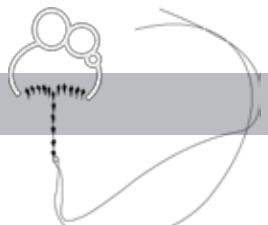


Types & Technical Specifications

Dr. Jyoti Vajpai

Earlier IUDs

Precursors to IUDs were first marketed in 1902. Developed from stem pessaries (where the stem held the pessary in place over the cervix), the 'stem' on these devices actually extended into the uterus itself. Because they occupied both the vagina and the uterus, this type of stem pessary was also known as an interuterine device.

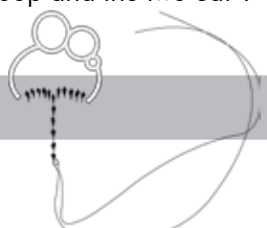
The first intrauterine device (contained entirely in the uterus) was described in a German publication in 1909. In 1929, Dr. Ernst Gräfenberg of Germany published a report on an IUD made of silk suture. In 1930, Dr. Gräfenberg reported a lower pregnancy rate using an improved ring wrapped in silver wire. Unknown to Dr. Gräfenberg, the silver wire was contaminated with 26% copper but copper's role in increasing IUD efficacy would not be recognized until nearly 40 years later.

In 1934, Japanese physician Tenrei Ota developed a variation of the Gräfenberg ring that contained a supportive structure in the center. The addition of this central disc lowered the IUD's expulsion rate.

The first plastic IUD, the Margulies Coil or Margulies Spiral, was developed by Lazer Margulies in 1960, at Mt Sinai Hospital in New York City. It was the first plastic device with a memory, which allowed the use of an inserter and reconfiguration of the shape when it was expelled into the uterus. However, The Coil was a large device sure to cause cramping and bleeding, and its hard plastic tail proved risky and uncomfortable for the male partner. The various devices developed in the 1960s were made of plastic (polyethylene), impregnated with barium sulfate so that they would be invisible on an X-Ray

In 1962, the Population Council organized the first international conference on IUDs in New York City. It was at this conference that Jack Lippes of Buffalo presented experience with his device, which fortunately had a single filament thread as a tail. The Margulies Coil was rapidly replaced by the Lippes Loop, which quickly became the most widely prescribed IUD in the United States in the 1970s.

Many other devices came along but with the exception of the four sizes of the Lippes Loop and the two Saf T Coils, they had limited use.



The stainless steel single-ring IUD was developed in the 1970s and widely used in China because of low manufacturing costs. Stainless steel devices using springs were designed to compress for easy insertion, but the movement of these devices allowed them to embed in the uterus making them too difficult to remove e.g. the Majzlin Spring.

Figure 1: Dalkon Shield

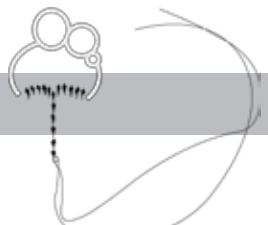
The Dalkon Shield was introduced in 1970. Within 3 years, a high incidence of pelvic infection was recognized. The multifilamented tail (hundreds of fibers enclosed in a plastic sheath) of the Dalkon Shield provided a pathway for bacteria to ascend, protected from the barrier of cervical mucus. Although sales were discontinued in 1975, the large number of women with pelvic infections led to many lawsuits against the pharmaceutical company, tainting all IUDs in the eyes of the media and public. Changes in sexual behaviour in the 1960s and 1970s, and failure to use protective contraception (condoms and oral contraceptives), led to an epidemic of sexually transmitted infections (STIs) and pelvic inflammatory disease (PID), for which IUDs were held partially responsible.

Dr. Howard Tatum, in the USA, conceived the plastic T-shaped IUD and shortly thereafter Dr. Jaime Zipper, in Chile, introduced the idea of adding copper to the devices to improve their contraceptive effectiveness. It was found that copper-containing devices could be made in smaller sizes without compromising effectiveness, resulting in fewer side effects such as pain and bleeding. T-shaped devices had lower rates of expulsion due to their greater similarity to the shape of the uterus. (1)

Second-generation copper-T IUDs , introduced in the 1970s, had higher surface areas of copper, and for the first time consistently achieved effectiveness rates of greater than 99%.

Categories of the Modern IUD

- There are three broad categories of intrauterine contraceptive devices: inert or unmedicated devices, copper-based devices, and hormonally-based devices that work by releasing a progestogen.
- In the United States, there are two types of intrauterine contraceptive devices or IUD available: the copper Paragard and the hormonal Mirena.
- In the United Kingdom, where ten types of copper-containing IUDs are available, the term IUD only refers to inert or copper-containing devices. Hormonal intrauterine contraceptives are considered a different form of contraception and are distinguished with the term intrauterine system or IUS.



Inert or Unmedicated IUDs

Un-medicated devices include the plain plastic devices and stainless steel rings, without addition of any medication. The Lippes loop, made of plastic (polyethylene) impregnated with barium sulfate is still used throughout the world (except the U.S.).Flexible stainless steel rings are still used in China but not elsewhere.

Copper IUDs

Most non-hormonal medicated IUDs have a plastic T-shaped frame that is wound around with pure electrolytic copper wire and/or has copper collars (sleeves).

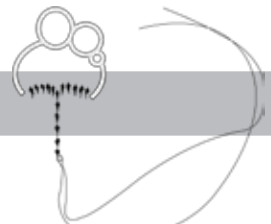
The addition of copper to the IUD was suggested by Jaime Zipper of Chile, whose experiments with metals indicated that copper acted locally on the endometrium. Howard Tatum combined Zipper's suggestion with the development of the T shape to diminish the uterine reaction to the structural frame and produced the Copper T.

The first copper IUD had copper wire wound around the straight shaft of the T, the T Cu 200 (200 sq mm of exposed copper wire), also known as Tatum T. Tatum's reasoning was that the T shape would conform to the shape of the uterus in contrast to the other IUDs that required the uterus to conform to their shape. Furthermore, the copper IUDs could be much smaller than simple inert plastic devices and yet provide effective contraception. The addition of copper to the IUD and reduction in the size and structure of the frame improved tolerance, resulting in fewer removals for pain and bleeding. Two of the first Copper IUDs , wound with 200 to 250 sq mm of copper wire, are still available (except in the U.S) – in the form of the T Cu 200 and Multiload 250

The Nova T is similar to the T Cu 200, containing 200 sq mm of copper. However the Nova T has a silver core to the copper wire, flexible arms and a large flexible loop at the bottom to avoid injury to the cervical tissue. The silver core has also been shown to prevent breaking of the wire. The arms of the frame hold the IUD in place near the top of the uterus. There was some concern that the efficacy of Nova T decreased after 3 years in World Health Organization data; however, results from Finland and Scandinavia indicate low and stable pregnancy rates over 5 years of use.

The Cu 7 with a copper wound stem was developed in 1971 and quickly became the most popular device in the U.S. Both the Cu 7 and Tatum T were withdrawn from the US market in 1986.

IUD development continued however, with addition of more copper, leading to the T Cu 380 A with copper wound around the stem plus a copper sleeve on each horizontal arm. The 'A' in T Cu 380 A is for arms, indicating the importance of the copper sleeves. The more modern copper IUDs contain more copper and part of the copper is in the form of solid tubular sleeves, rather than wire, increasing efficacy and lifespan. This



group of IUDs is represented in the U.S. by the T-Cu 380 A (the Paragard) and in the rest of the world by T Cu 220 C, the Nova T and Multiload 375. The Paragard T 380a is 32 mm (1.26") in the horizontal direction (top of the T), and 36 mm (1.42") in the vertical direction (leg of the T).

The T Cu 380 A is a T shaped device with a polyethylene frame holding 380 sq mm of exposed surface area of copper. The pure electrolytic copper wire wound around the 36 mm stem weighs 176 mg, and copper sleeves on the horizontal arms weigh 66.5 mg. A polyethylene monofilament is tied through the 3 mm ball on the stem, providing two white threads for detection and removal. The ball at the bottom of the stem helps reduce the risk of cervical perforation. The IUD frame contains barium sulfate, making it radio-opaque.

The TCu380A is referred to as a banded device because it has copper sleeves on the horizontal arms while the TCu380S has copper sleeves at the ends of the horizontal arms, embedded into the arms. The TCu380A (T-Safe380A®) is no longer available in the UK and has been replaced by the TCu380S (TT380 Slimline® and T-Safe 380A QuickLoad®). The T Cu 380 Slimline has the copper sleeves flush at the end of the horizontal arms to facilitate easier loading and insertion. The T Cu 380 Ag is identical to the T Cu 380 A, but the copper wire on the stem has a silver core to prevent fragmentation and extend the life span of the copper. The performance of the T Cu 380 Ag and the T Cu 380 Slimline is equal to that of the T Cu 380 A.

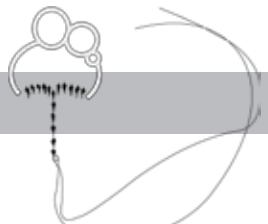
The Multiload 375 has 375 sq mm of copper wire, wound around its stem. The flexible arms were designed to minimize expulsions. This is a popular device in many parts of the world. The Multiload 375 and T Cu 380 A are similar in their efficacy and performance.

Two smaller versions of framed IUDs are available in the UK, the MiniTT380 Slimline® (a smaller version of the TT380 Slimline) and a shorter version of the Multiload Cu375. Neither has been adequately assessed.

The modern generation of IUDs in China includes a stainless steel ring with copper wire that also releases indomethacin (very effective with low expulsion rate and less blood loss), a V shaped copper IUD, and a copper IUD shaped like the uterine cavity. The Sof-T is a copper IUD used only in Switzerland.

Efforts still continue to develop IUDs that address the main problems of bleeding and cramping and this has resulted in development of the newer medicated and frameless IUDs.

The Cu SAFE 300 IUD has 300 sq mm of copper in its vertical arm and a transverse arm with sharply bent ends that are adapted to the uterine cavity and help hold this IUD



in the fundus. It is made from a more flexible plastic and is smaller than the worlds two most popular IUDs, the T Cu 380 A and the Multiload 375. Pregnancy rates with the Cu SAFE 300 are comparable to these two devices, but rates of removal for pain and bleeding are reported to be lower.

The Hormone Releasing IUD

Hormonal uterine devices contain progestogen and do not increase bleeding as inert and copper-containing IUDs do. Rather, they reduce menstrual bleeding or prevent menstruation altogether, and can be used as a treatment for menorrhagia (heavy periods).

Progestasert was the first hormonal uterine device, developed in 1976 and manufactured until 2001. It released progesterone, was replaced annually, and had a failure rate of 2% per year.

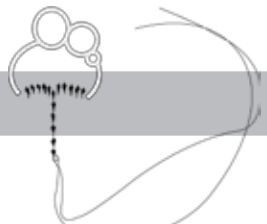
As of 2007, the LNG-20 IUS is the only IntraUterine System available. First introduced in 1990, it releases levonorgestrel (a progestogen) and may be used for five years. The LNG 20 (Mirena) , manufactured by Leiras Schering A.G of Finland, releases in vitro 20 mcg of levonorgestrel per day. This T shaped device has a collar attached to the vertical arm, which contains 52 mg of levonorgestrel dispersed in polydimethyl siloxane and released initially at a rate of 20 mcg per day in vivo, progressively declining (reaching half of the initial rate after 5 years). The levonorgestrel IUD lasts up to 10 years and reduces menstrual blood loss and pelvic infection rates. Indeed, the levonorgestrel IUD is about as effective as endometrial ablation for the treatment of menorrhagia. The local progestin effect directed to the endometrium can be utilized in patients on tamoxifen, patients with dysmenorrheal, and in post-menopausal women receiving estrogen therapy.

A lower-dose T-shaped Intra Uterine System named Femilis is being developed by Contrel, a Belgian company.

Figure 2: Modern IUDs available in India

Newer IUDs

The Ombrelle 250 and Ombrelle 380, designed to be more flexible to reduce expulsion and side effects have been marketed in France.



A frameless IUD , the Flexigard (also known as the Cu Fix or the Gyne Fix) invented by Dirk Wildemeersch in 1983 in Belgium, consists of 6 copper sleeves (330 sq mm of copper) strung on a surgical nylon (polypropylene) thread that is knotted at one end. The knot is pushed into the myometrium at the fundus of the uterus during insertion with a notched needle that works like a miniature harpoon. The GyneFix does not have a T-shape, but rather is a loop that holds several copper tubes. Because it is frameless, it has a low rate of removal for bleeding or pain, but a more difficult insertion may lead to a higher expulsion rate. However, when inserted by experienced clinicians, the expulsion rate is very low, and the device is especially suited for nulligravid and nulliparous women. This IUD is increasingly popular in Europe. A Cochrane review (including more than 23 180 years of use) identified comparable failure rates for a framed (TCu380A) and a frameless device (GyneFix®) but the efficacy of the frameless device may be compromised by an increase rate of expulsion. A retained GyneFix is particularly effective for up to 5 years of use

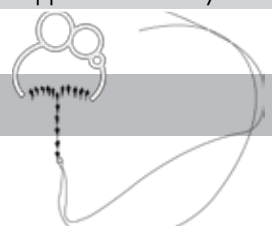
Figure 3: The Gynefix

A shorter intra-uterine system combined with a reservoir for the sustained release of levonorgestrel has been developed; a frameless version (Fibroplant) that releases 14 mcg of levonorgestrel per day .Contrel manufactures the FibroPlant-LNG, which is anchored to the fundus of the uterus like the GyneFix IUD . Although a number of trials have shown positive results, FibroPlant is not yet commercially available.

The UK National Institute for Clinical Effectiveness and new Finnish guidelines for heavy menstrual bleeding suggest that LNG-IUS should be positioned as first-line treatment prior to endometrial ablation or hysterectomy.

Table : Intrauterine Devices available in the U.K

Devices currently available in the UK	Copper Content (mm^2)	Recommended duration of use (years)
Levonorgestrel-releasing (Mirena®)	Not applicable	5 years (contraception and idiopathic menorrhagia) 4 years (endometrial protection
Copper devices framed		
Copper sleeves		
TCu380S[a]		
TT380Slimline®[b] TCu380A QuickLoad®[c]	380 380	10 10
Mini TT® 380 Slimline[d]	380	5
Flexi-T® 380[e]	380	5
Copper in stem only		



Multiload® 375	375	5
UT® 380	380	5
UT® 380 Short[d]	380	5
Nova-T® T380	380	5
Neo-Safe® T380	380	5
Multiload® Cu375[d]	375	5
MultiSafe® 375	375	5
MultiSafe® 375 Short Loop	375	5
Flexi-T® 300[d]	300	5
Copper devices (frameless)		
GyneFix®[d]	330	5

aRecommended device of first choice for all women opting for a Cu-IUD. These devices have copper sleeves on the horizontal arms.
bThe TT380 Slimline® is marketed as a replacement for the Ortho Gynae® T380 which is no longer available in the UK. Women already using Ortho Gynae T380 may continue to use it for its 10 year duration
cThe TCu380A (T-Safe®380A) is no longer available in the UK. The replacement is the T-Safe 380A Quickload®.
dThese devices can be used when the uterine cavity on sounding is less than 6.5 cm.
eData on the Flexi-T 380 are limited and it cannot be recommended for 10 years of use as for other banded devices

IUD Brands Available in India

Product Name	Contraceptive Coverage/Pack	Manufacturer	Shelf life
Pregna- TCu 380A	3 years	Famy Care	5 years
Multiload-Cu 250	3 years	Organon	5 years
Multiload-Cu 375	5 years	Organon	5 years
Mirena- Levonorgestrel releasing	5 years	Cadila Pharma	
U Care- Cu375	5 years	DKT	5 years
U Care- Cu 250	3 years	DKT	
Trust- Copper T 380 A	10 years	Hindustan Latex. Marketed by Janani	7 years
Khushi T- Cu 380A	10 years	PHSI	7 years
Khushi Load- Cu375	5 years	PHSI	5 years
Freedom 5-Cu 375	5 years	Famy Care. Marketed by PSI	5 Years

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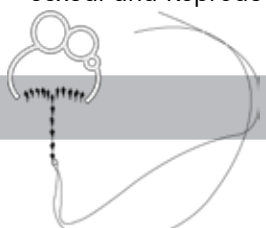


Selecting Women for IUD

Dr. Basab Mukherjee

Introduction

Proper selection of patients prior to IUD insertion increases compliance, decreases discontinuation rates and establishes confidence in the method. Counseling women for IUCD should essentially include ruling out contraindications for use, clearing misconceptions if any and providing evidence-based information about the device. Pros and cons of IUDs over presently used or more popularly used contraceptive methods may then be discussed.

Ruling Out Contraindications for IUD use

The WHO Medical Eligibility of Contraception provides clear guidelines on situations where the use of an IUD would be restricted. A detailed history and physical examination would in most cases be able to identify these conditions.

Irregular Bleeding

The date of the last menstrual period is helpful in suspecting an existing pregnancy. In case of doubtful LMP or irregularity of cycles it is prudent to have a urine pregnancy test performed. Ongoing pregnancy is an absolute contraindication for IUD insertion.

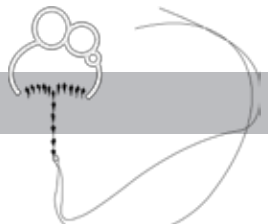
Intrauterine lesions may also result in irregular or heavy bleeding. This may be ruled out by a trans vaginal sonogram or sometimes by a hysteroscopy.

For women with regular cycles, insertion may occur on any of the first 12 days of the period. (Five day emergency contraceptive effect added to the traditional timing of first seven days of the cycle)

STIs

History of current pelvic infection may be suspected from lower abdominal pain, dysmenorrhoea, dyspareunia and a malodourous discharge. Lower abdomen tenderness and tender fornices on pelvic examination support the diagnosis. Acute PID is a contraindication for IUD insertion.

A history of high-risk behavior of the woman or her partner is pertinent as this increases the risk of pelvic inflammatory disease, independent of the presence of the IUCD. Barrier contraception should be advised in these cases, in addition to IUD, for preventing spread of infection.



Cancer of the genital tract

History of cancer of the genital tract – especially cervix and uterus are contraindications for IUCD insertion. Malignant

On speculum examination, the cervix should be inspected for discharge and observed for tenderness on movement. Any suspicious lesion on the cervix would need evaluation by Pap smear or biopsy. The size of the uterus should be ascertained for an unsuspected pregnancy or possibly fibroids, which may distort the endometrial cavity.

Medical Diseases

Women with bacterial endocarditis should have pre insertion antibiotic prophylaxis.

For women with the rare Wilson's disease, copper-containing IUDs would be contraindicated.

Clearing Misconceptions

Unfortunately the IUD is shrouded with misconceptions, which though may sound absurd, has over the ages deterred women from using the device. Migrating to different parts of the body, causing infertility and cancer and resulting in damage inside the body are some of commonly held beliefs.

Evidence based Counseling

Once contraindications are ruled out and the woman considers the option of an IUCD among other contraceptive methods, proper counseling is necessary for making an informed choice.

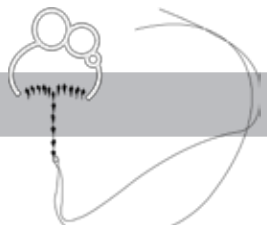
Counseling may be divided into pre-insertion and post-insertion segments.

Pre insertion Counseling

The insertion process needs to be explained in detail. This includes the temporary discomfort and minimal spotting which may follow insertion. Side effects of IUCD to be discussed should include short-term increased bleeding (15 – 20%) and small chances of coiling up or being expelled (<5%).

Post Insertion Counseling

After insertion of an IUCD, regular follow up should be impressed upon the woman. The first visit should be in the first three months of insertion, usually after her period, to check the IUD tail. At the same visit menstrual abnormalities if any are addressed. She is also reminded the time of effectiveness of the device i.e. 3/5/10 yrs after which an



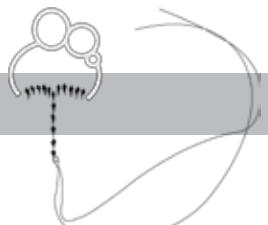
informed choice would be taken on She would need annual follow-ups. The removal takes even less time than insertion and may be done anytime. If the IUCD tail goes missing investigations may be necessary to find out if it has coiled up inside.

IUD and other Contraceptives

IUD use is coitus-independent as compared to the barrier contraceptives. The efficacy of the device is comparable to the Pearl Index of combined oral contraceptives. The long-term data of 10 yr IUDs show failure rates comparable to female sterilization. The one-time motivation helps IUDs score over oral pills, which have to be taken daily and compliance invariably falls with time. As IUD has no protection against STIs, women at high-risk of infections should be advised additional barrier contraception.

IUD for the 21st Century Woman

Effective, hassle-free, one-time, coitus-independent contraception is preferred by most women of the present generation. It is here where IUDs fits the bill perfectly and scores over other contraceptive methods. However as with other methods of contraception, proper selection of women backed with effective counseling and dispelling myths will help in the long-term acceptance of IUDs.



Counselling for Intrauterine Device

Dr Parag Biniwale & Dr Sneha Bhuyar

Intrauterine contraception has a unique advantage of providing long term effective contraception which requires only one time motivation. Informative counselling, which is focused on clients' needs, helps clients make good choices and can increase successful use of contraceptive methods. Women who receive good counselling are more satisfied with their methods and use them longer than women who receive poorer counselling. Thus, success for correct & efficacious use of Intrauterine device (IUD) and its continuation depends on good counselling.

How to approach a client?

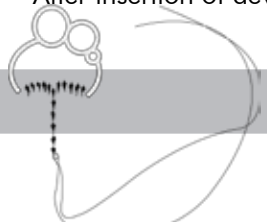
When a client walks in the clinic or family planning centre seeking contraception, GATHER approach must be followed.

1. G: greet the client. Introduce yourself & get information of the client. Make her & partner comfortable. Make sure that privacy & confidentiality is maintained.
2. A: Ask her what she wants. She wants temporary or permanent method. Ask her obstetric history, relevant medical history & relevant history of recent diseases. Ask her about prior use of contraception, her previous experiences with various contraceptives.
3. T: Tell her various options she has. Give relevant & evidence based information to her in a language she understands. Avoid using jargon of difficult medical terminology.
4. H: Help her to choose method by giving information & understand how a particular method is used. By asking specific & relevant questions help her understand what she wants.
5. E: Ensure supply of the contraceptive of the client's choice. Explain possible untoward & side effects of the method after she decides which method is to be used. Inform her that if she experiences any problems, she should get in touch with you.
6. R: Return for follow up. Explain her follow up schedule. Check if she is using the method correctly. Elicit her concerns & clarify them.

Role of Counselling in IUD users

Counselling for IUD has three dimensions before putting it to use for a client.

- Choosing suitable method of contraception
- Just before insertion of device
- After insertion of device



Choosing suitable method of contraception

Since many years, family planning programs have focussed primarily on 'Cafeteria approach' where providers gives clients a lot of information about all methods equally to help clients make informed choices. It was later concluded that this approach can overload the client with information about irrelevant methods confusing the client and can also leave little time for discussing how to use the chosen method. Today, programs encourage client-centered counselling, in which the clients' concerns, desires, and comfort are addressed to, on priority. The focus is on what client wants & what her concerns are. Providers tailor information based on the client's needs and preferences. Involving clients' partners in counselling, whenever possible and acceptable to the client, can help clients use contraception effectively.

Once a client expresses a preference for a specific method, the provider and client should discuss that method in more detail to confirm her decision and to help her learn how to use the method correctly.

While counselling the client on IUD following information should be provided.

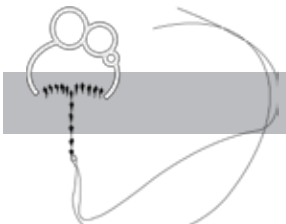
General information:

- IUD provides long-term protection against pregnancy for up to 3 -10 years depending on the intrauterine device chosen.
- IUD is a small, flexible, plastic and copper device placed in the uterus. Most IUDs have 1 or 2 thin strings that hang from the cervix into the vagina.
- A trained provider must insert and remove the IUD.
- IUD typically causes longer and heavier bleeding and more cramps or pain during menstruation during 3 – 6 cycles.
- It is safe for a woman with HIV or with AIDS who is clinically well on antiretroviral (ARV) therapy.
- IUD is not advised for a woman at very high risk of having a sexually transmitted infection (STI).
- Immediate return to fertility after IUD is removed.
- IUD does not interfere with sex.

IUD is not advised if a client:

- is pregnant or likely be pregnant.
- has unusual vaginal bleeding.
- has active genital or pelvic infection.
- is at very high risk of having an STI.

If the client chooses to have Intrauterine device inserted, following information should be provided



- How the IUD is inserted and removed (shown using a pelvic model if possible). This will enable the client to understand what exactly is done during insertion& where IUD is placed.
- Potential side effects (especially bleeding changes) and other possible problems, such as expulsion, perforation, and PID should be informed to client. This will improve follow up & increase reporting in case of complications.
- How the client can check that her IUD is in place by feeling for the IUD strings. This should be taught to the client so that she reports if she can't feel the thread.
- When and where the insertion will take place and who will perform the procedure. This makes the client better prepared for the insertion.

Just before insertion of IUD

When the client returns for insertion of IUD; the provider should once again discuss in detail the steps of the insertion procedure:

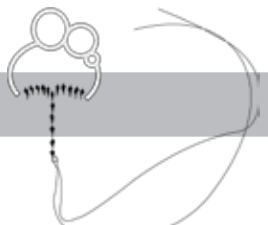
- The provider should explain to the client that she may experience some discomfort or cramping during insertion and that she may have cramps for several days following insertion.
- The provider should encourage the client to speak up any time during the procedure if she feels discomfort or pain.
- The provider can advise the client to take ibuprofen 30 minutes before insertion and in the days following insertion to reduce cramping and pain.
- While the IUD is being inserted, the steps should be explained to the client

Details of insertion explained to the client would improve acceptance of IUD.

After insertion of device

After the device is inserted, the client needs to be provided with following information

- The client may experience spotting/ bleeding/ pain which can continue off & on for 3 -6 months.
- She should be given information regarding name of the IUD, date of insertion, and date when it will need to be removed or replaced. It should preferably be written on an information card.
- If she has any questions or problems which could not be clarified in the same sitting, she should come back for discussion.



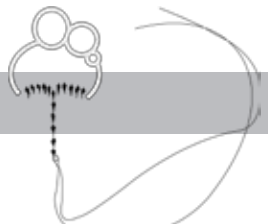
- If the client experiences following problems, she must see healthcare provider immediately
  * increasing or severe pain in the lower abdomen
  * pain during sex
  * unusual vaginal discharge
  * fever, chills, nausea, or vomiting
- The first follow up is scheduled a post-insertion visit 4 to 6 weeks after insertion of IUD / usually after first menses.
- If the clients feels that IUD may have slipped out of place (not feeling the strings or feeling the hard plastic of an IUD that has partially come out of the uterus), she must report to the facility.
- If the client misses menstrual period or wants to remove the IUD for any reason, she should meet the provider.

Our country contributes only 3% to IUD users in the world, there is a great potential in our country for increase in no. of users. Proper selection & appropriate counselling will certainly have positive impact. In turn, this will prevent unwanted pregnancies and problems arising due to terminations of such pregnancies.

The changes in the prescribing information for the copper IUD may have a profound effect on use. Clinicians should familiarize themselves with the new information in order to be able to offer this reliable, reversible method of contraception to a new generation of women.

Key points

- Assess client's knowledge, attitudes, expectations and any concerns about IUD.
- Discuss important advantages of the IUD High effectiveness, Long duration of effectiveness, Safety, Not related to sex, Rapid return to fertility
- Discuss important disadvantages of the IUD e.g. various common side effects (for example: pain, bleeding), Requires insertion by a trained health provider
- Assess with client her individual STI risk regarding choice of IUD.
- Address common myths.
- Provide a simple description of insertion procedure.
- Plan routine follow-up after the first menses or four to six weeks following insertion or if she has any problems.
- Discuss when and how to have IUD removed.



Timing of Intra Uterine Contraception Device Insertion

Dr Jaideep Malhotra, Dr Narendra Malhotra &
Dr Neharika Malhotra

Introduction:

Intrauterine contraceptive device is used by more than 100 million women in the world. The maximum users are in China and India. There is a growing need for a safe and well-tolerated reversible contraceptive world over. The discontinuation of IUCD is due to heavy periods and pain, even though the efficacy of today's modern IUCD's is almost same as oral pills. The discontinuation is due to improper insertion.

Counselling and Examination

Counselling for IUCD insertion timing is mandatory

Clinical history should be taken to assess the sex health risks for each woman,also examination and testing for STDs may be offered.

Pelvic examination and if possible Transvaginal ultrasound prior to inserting the device to assess the size,shape,depth and position of uterus should be performed.

No routine antibiotic prophylaxis required .

Timing:

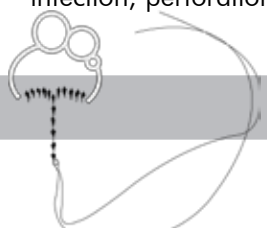
The common day gynaecologist is usually advising a post menstrual insertion of IUCD's to all patients, though this is the best time to insert an IUCD but in practice we can do the insertion at any time

A. After Delivery (Post Partum Insertion)
B. After Spontaneous or induced abortion
C. During menstrual cycle

A. Post Partum insertion

Various studies have shown that IUCD can be inserted between 4-8 weeks post partum without any increase in pregnancy rates, perforation or removals for bleeding and pain.

Insertion can also be done immediately after vaginal delivery (no extra risk of infection, perforation, PPH or sub involution, however expulsion is more frequent.)



.Immediate post placental insertion (IPPI) is an accepted form of IUD use ,but there is still discussion about the advantages of fitting the IUD 10 minutes later after placenta expulsion. IPPI is becoming very popular despite greater expulsion rate,has become a routine practice in some centres.

WHO medicall eligibility criteria state that risks outweigh benefits if postpartum insertion occurs between 48hrs to 4weeks.However after 4 weeks benefits outweigh the risks .

Insertion can be done during caesarian section. The long arm of IUCD can be fixed to posterior wall of uterine cavity by a catgut suture.

B. Post Abortal Insertion

After a first trimester spontaneous abortion or MTP ,the IUCD can be inserted at the same time without any added risks, however after a second trimester abortion it is advisable to wait for 4-6 weeks. Before a post abortal insertion it is advisable to check the uterine cavity by ultrasound and only if cavity is empty of all POC's, the IUCD may be inserted.

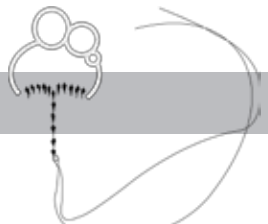
C. During Menstrual Cycle

The best time for insertion is during first seven days of the normal cycle. This timing of insertion must be planned to avoid an already unplanted pregnancy, since IUCD's do not act as very effective post coital contraceptives. After day seven of menstrual cycle IUCD's can still be inserted if there is a believable abstinence before and post insertion but a 7 days condom use is recommended. The insertion can be a little difficult in mid cycle due to the fact that cervix is closed.

D. Emergency contraception

Emergency contraception with the copper-bearing IUD is effective and provides long-lasting protection, unlike emergency hormonal contraception,provided the IUCD is inserted within 5 days of sexual contact,though there can be various issues like timing of ovulation is not fixed. As expected, the risk of pregnancy after IUD insertion was 10% of that in the watchful-waiting group.

For LNG – IUCD (Mirena) a more cautious timing of insertions is recommended. In a normal cycle LNG – IUCD's if inserted after day 7 of menses may harm the already implanted fetus due to the very high concentration of LNG in the cavity / endometrium. Also women who are on DMPA or COC's or only progesterone pills (POP) the IUCD's can be inserted at any time without any extra precautions.



Conclusions:

For a proper continuation rate and prevention of any IUCD induced complication, it is necessary to do the correct timing of insertion. There are no trials comparing various timings (immediate postpartum, delayed post partum and interval) of IUCD insertion. Eight trials that compared different IUCDs or modifications od IUCDs to aid retention in utero were included. the principle outcome measures included pregnancy,spontaneous expulsion and continuation rates.the twelve month pregnancy rates reported in these studies ranged from 0.0 to 12.1.The expulsion rates at 6-36 months ranged from 6.2 to 44.1 per 100 women and 6-36 months continuation rates varied from 39.1 to 93.3 per 100 women.

The modification of conventional IUCD by adding chromic catgut or additional appendages had no impact on clinical outcomes.

In terms of expulsion rates CuT 200 proved to be superior to progesterone –releasing IUCDs for postpartum insertion.

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Optimum Insertion of IUDs – Technical Nuances

Dr. Nozer Sheriar & Dr. Punit Bhojani

'What one does easily, one does well.' Andrew Carnegie

It is now an accepted fact that insertion is the factor in the causation of most IUD related problems with the infrequency of insertion being the major reason for enhanced efficacy and fewer side effects of the contemporary long acting IUDs.

Initiating IUD use requires a range of communication and technical skills needed for balanced counselling, appropriate selection and matching and safe insertion. While information about these is an inherent part of UG and PG medical curriculum, these skills can be honed, acquired or even taught to medical practitioners and mid level providers through structured training programmes. Presented here is a step by step approach to the major insertion techniques.

Suitability for IUD Use

The ideal IUD acceptors are parous women in a stable, mutually monogamous relationship, with no history of PID. Although not contraindicated in nulliparous women IUDs tend to have higher expulsion and failure rates with more challenging insertions because of a smaller uterine cavity.

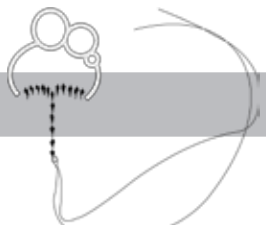
While women exposed to STDs have a greater chance of developing PID, a remote history of PID does not totally preclude IUD use. Women who have been pregnant after an occurrence of PID and are not currently at risk for infection are suitable candidates for IUD use.

The hormone releasing IUD has special benefits for women with anemia, menorrhagia or dysmenorrhea. An increased risk for spotting or irregular bleeding soon after LNG IUS insertion decreases significantly at 12 months post insertion.

Selection for IUD Insertion

The provider should discuss with the client the risks and benefits of various IUDs and if necessary alternative forms of contraception. This discussion should review the standardized patient information materials and address any client concerns.

Informed consent though not mandated, may be obtained particularly if the insertion is coupled with a surgical procedure such as an MVA/EVA, D&C and diagnostic or operative hysteroscopy.



Insertion is best performed during menstruation or early follicular phase to provide additional reassurance that the woman is not pregnant. While IUDs may be inserted anytime during the menstrual cycle, insertion should only be performed during the luteal phase if the likelihood of pregnancy is low with another non hormonal contraceptive being recommended for use after insertion until after the next menses.

IUD manufacturers have created practice kits that can help providers learn to insert an IUD many of which have subtle difference in insertion techniques.

Preparing for Insertion

An IUD should not be inserted in a woman with a high suspicion of RTI or STD. Pelvic examination done before insertion may include screen for Chlamydia and gonorrhea on a case specific basis. Obvious vaginal or cervical infection should be treated before insertion.

While evidence does not support routine prophylactic antibiotic administration at the time of IUD insertion, there may be value in using doxycycline, erythromycin or a suitable alternative antibiotic for prophylaxis.

Administration of a nonsteroidal anti-inflammatory drug such as ibuprofen 600 to 800 mg or mefenamic acid 500mg one hour before insertion may alleviate discomfort.

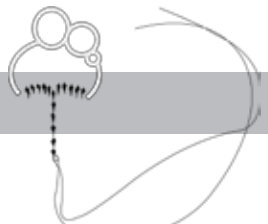
Setting Up the IUD Insertion

A standardized set of instruments as listed below should be available with appropriate sterilization. The set may vary according to the type of IUD and be individualized as per provider preference.

- Cervical vulsellum or tenaculum
- Cotton balls with antiseptic solution – Povidone iodine or Chlorhexidine
- Long suture scissors – Mayo's
- Sponge holding forceps
- Sterile and nonsterile examination gloves
- Sterile IUD package with IUD
- Sterile tray for the procedure
- Sterile vaginal speculum
- Uterine sound and slim dilators 4, 5 and 6 mms

The proper equipment should be assembled before the procedure. Then a bimanual examination with non sterile gloves should be performed to determine the position of the uterus.

Sterile technique including sterile gloves is necessary during the procedure to minimize



the risk of contamination or infection. The cervix and adjacent vaginal fornices should be cleansed liberally with an antiseptic solution.

The cervix should be stabilized during the insertion of the IUD with a vulsellum or tenaculum. Local anesthesia such as 5 percent lignocaine gel placed in the cervical canal, or a paracervical block may be used to minimize discomfort.

A sterile uterine sound should be used to determine the depth of the uterine cavity. Contact with the vagina or speculum blades should be avoided. An alternative to the uterine sound is a 4 mm MVA cannula which bears markings for assessing the UCL. An adequate uterine depth is between 6 and 9 cm and should be documented in client records. An IUD should not be inserted if the depth of the uterus is less than 6 cm.

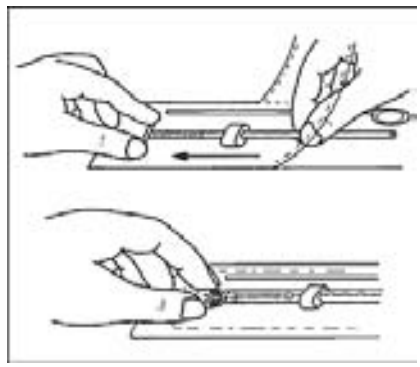
IUD Insertion Techniques – Technical Nuances

Copper Releasing IUDs

The copper-releasing IUD is a polyethylene device with exposed surface area of copper on its stem and sometimes on its arms. The released copper ions interfere with sperm mobility and incite a foreign-body reaction that results in a spermicidal environment. Barium sulfate has been added to the polyethylene substrate to make the device radiopaque. A 3-mm plastic ball is located at the base of the IUD, through which the monofilament thread passes. Once inserted, the IUD can remain in place for periods ranging from 3 to 10 years. Extended effectiveness has been well established with IUDs such as Cu T - Safe 380 A, Flexi - T 380 A, Nova T 380 and Multiload Cu 375.

It was the introduction of the withdrawal technique for Copper Releasing IUDs that made IUD insertion a safe procedure in contrast to the earlier push technique.

Insertion Technique for the T Shaped IUD

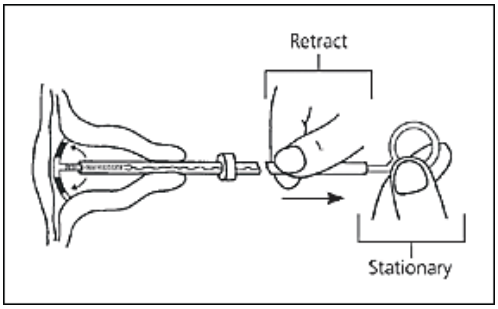


The arms of the IUD are to be folded into the insertion tube far enough to retain them by working through the sterile package or using a loading device devised for this purpose. This should be done immediately before the start of the procedure to avoid interfering with the inherent memory of the device.

Using sterile gloves the IUD is removed from the sterile package. The blue flange should be aligned with the IUD arms and set at the distance the uterus was sounded. The inserter rod should then be placed into the insertion tube at the end opposite the arms of the IUD and approximated against the ball at the base of

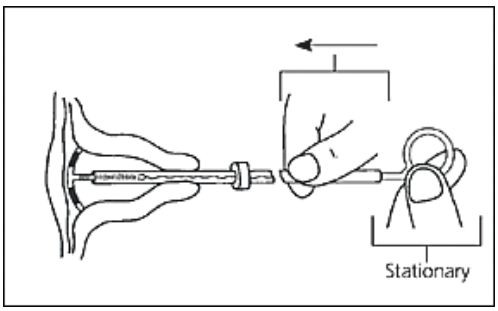
the IUD.

The IUD is then introduced into the uterus until the flange is against the cervical os. The clear inserter tube should be pulled back on the insertion rod approximately 2 cm releasing the horizontal arms so that they can spread to the "T" position.

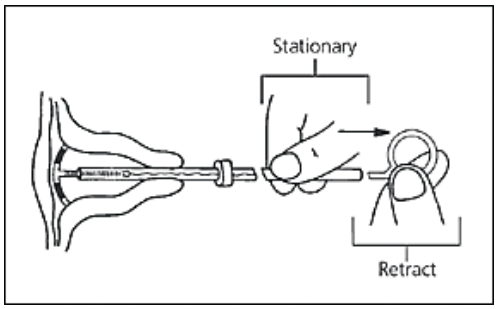


The tube should be advanced slowly to ensure a correct positioning of the IUD.

The insertion rod is then removed by holding the insertion tube in place, followed by removal of the insertion tube and then the vulsellum or tenaculum.



Finally, the threads emerging from the cervical os should be cut to a length of 3 cm. The length of the threads in the vagina should be noted for further reference.



Insertion Technique for the Multiload IUD

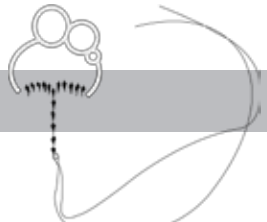
The IUDs in Multiload design have simplified the insertion technique of the T Shaped IUDs even further avoiding even the slightest pressure of an insertion rod on the IUD.

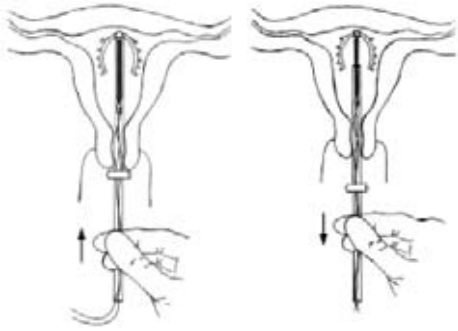
The IUD in the clear inserter without an inserter rod is introduced into the uterus until the flange of the inserter tube set at the UCL is at the cervical os.

Once in the cavity having made contact with the fundus the distinctive fundal seeking projections of the side arms retain the IUD in perfect intrauterine position as the inserter tube is withdrawn. The threads emerging from the cervical os should be cut to a length of 3 cm.

Hormone Releasing IUD

The LNG IUS is a radiopaque T-shaped device with 52 mg of levonorgestrel on its arms and stem. The progestin is released at a rate of 20 mcg a day. Levonorgestrel is thought to thicken cervical mucus, creating a barrier to sperm penetration through the cervix,





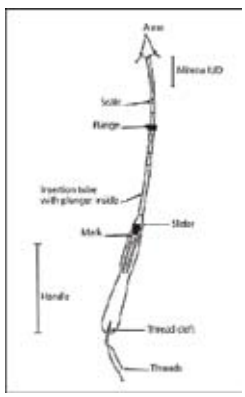
and it may stop ovulation and thin the uterus lining. Once inserted, the IUD can remain in place for up to five years.

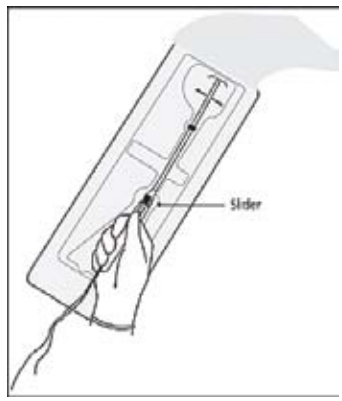
The LNG IUS has a unique insertion technique developed to address the challenge of safe fundal placement with a modified push technique made necessary by the thicker vertical limb with the LNG reservoir.

Insertion Technique for the LNG IUS

As with the copper-releasing IUD, the proper equipment for insertion of the hormone-releasing IUD should be assembled before the procedure.

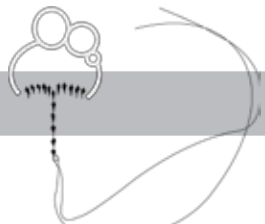
The sterile IUD package is opened, the inserter containing the IUD picked up wearing sterile gloves and the threads carefully released from behind the slider, allowing them to hang freely. The slider should be positioned at the top of the handle nearest the IUD. While looking at the insertion tube, the physician should check that the arms of the device are horizontal. If not, they must be aligned using sterile technique.



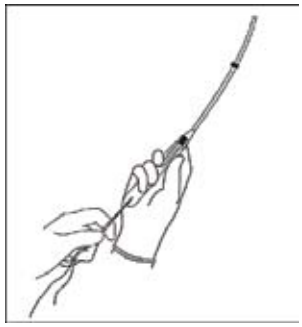


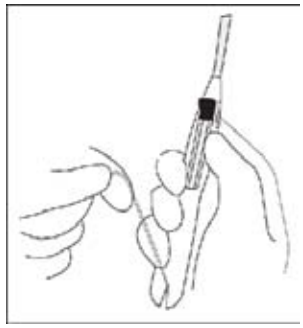
The threads should be pulled to draw the IUD into the insertion tube so that the knobs at the end of the arms cover the open end of the inserter. The threads should be fixed tightly in the cleft at the end of the handle.

The flange should be set to the depth measured by the sound. The IUD is inserted by holding the slider firmly at the top of the handle and gently placing the inserter into the cervical canal. The insertion tube should be advanced into the uterus until the flange is situated at a distance of about 1.5 to 2 cm from the external cervical os, allowing ample

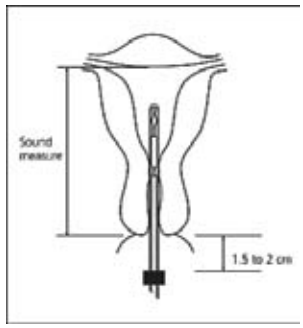


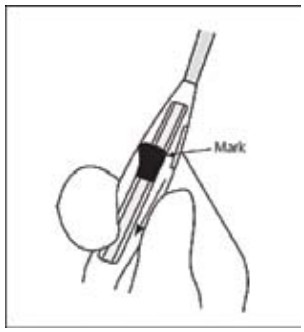
space for the IUD arms to open. While holding the inserter steady, the physician should release the arms of the IUD by pulling the slider back until the top of the slider reaches the raised horizontal line on the handle.



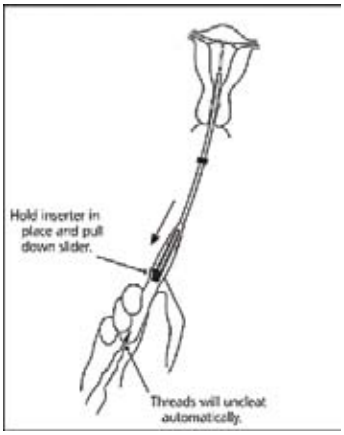


The inserter should be pushed gently into the uterine cavity until the flange touches the cervix.





The IUD should now be positioned at the top of the fundus. The physician then releases the IUD by pulling the slider all the way down while holding the inserter firmly in position. The threads will be released automatically. The inserter should be removed from the uterus. Finally, the threads emerging from the cervical os should be cut to a length of 2 to 3 cm. The length of the threads in the vagina should be noted in the patient's record for further reference.



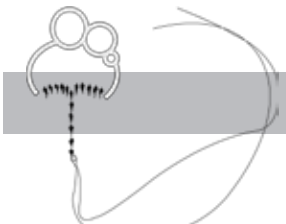
Post Insertion Advice and Follow Up

Following insertion of either device, a follow-up appointment should be planned after the next menses to address any concerns or adverse effects, ensure the absence of infection and check the presence of the strings.

The client must be handed and instructed to preserve a User Card documenting the Lot number, the date of insertion and the intended date of removal.

The most common short term adverse effects of IUDs are cramping, abnormal uterine bleeding, and expulsion for which a preemptive prescription of an anti-inflammatory analgesic and tranexamic acid may be beneficial.

On the face of it the insertion technique for IUDs may seem obvious and simple. However in practice we are faced by a variety of situations and indications, individual differences in uterine size, direction and consistency, unique demands of distinct IUD types and an



imperative need to broaden the provider base so as to make IUDs accessible to women who need and want them. These challenges make the perfection of IUD insertion technique through insight and training a prerequisite for any successful contraceptive delivery programme.

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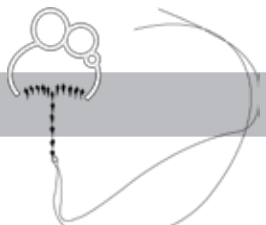


IUCD in Special Situations

Dr Sujata Misra, Dr Suchitra Pandit & Dr Prachi B Shitut

World population is projected to grow by a billion each decade and is estimated to touch 8.5 billions by 2025. In India, this population explosion has serious socio economic and medical implications. Family planning is essential for the welfare of the individual, her family and for the socioeconomic development of the nation. The need of the hour is distilled and formulated information essential for the intelligent use of contraception The intrauterine device is a safe, cheap, effective and convenient method of contraception. "Fit and forget" is the greatest advan¬tage of this method. However it is not without its own share of myths which need to be revisited and cleared.

Counseling

In providing family planning services, a good face to face interaction between the client and provider is of utmost importance and is the key of good quality services. Counseling often has six elements embodied in the word GATHER : Greet, Ask, Tell , Help, Explain and Return to address her ongoing queries as and when they arise.

Certain myths pertaining to IUD which need to be clarified are that: IUD

- Rarely lead to PID
- Do not increase the risk of STIs, including HIV
- Do not increase risk of miscarriage when a woman becomes pregnant after the IUD is removed
- Do not cause infertility
- Do not cause birth defects
- Do not cause cancer
- Do not move to heart or brain
- Do not cause discomfort to the woman during sex
- Substantially reduce the risk of ectopic pregnancy

Mentioned in the table 1 is a comprehensive overview of the benefits, limitations and client suitability profile for insertion of IUD.

WHO categories for IUD insertion:

IUD is safe and suitable for nearly all women, however, it is not recommended in some women due to the presence of certain medical conditions. Based on WHO Medical Eligibility Criteria (MEC 2004) for IUD, Ministry of Health & Family Welfare (MOHFW) ,

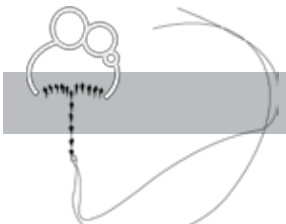


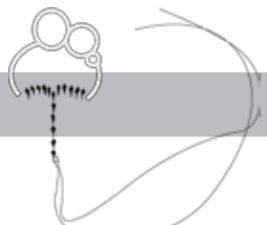
TABLE 1

METHOD MECHANISM OF ACTION	CONTRACEPTIVE EFFECTIVENESS	BENEFITS	LIMITATIONS	WHO CAN USE THE METHOD	WHO SHOULD NOT USE THE METHOD
Intrauterine Contraceptive Device (IUD) Copper-releasing IUDs (Multiload Cu 375 & Copper T 380A) slows sperm movement A long-acting and highly effective method.	Consistent and Correct Use: 0.6 Typical Use: 0.8	• Does not interfere with sexual intercourse. • No hormonal side effects with copper-bearing IUDs. • Immediately reversible with no delay in return to fertility. • Does not interfere with breastfeeding. • No interactions with any medicines. • Helps prevent ectopic pregnancies (but does not prevent all). • Long-term method. • After initial follow-up visit, the woman needs to return to the clinic only if there is a problem. • Women do not need to purchase any supplies. • Can act as emergency contraceptive method when inserted within 5 days of unprotected sex.	• Possibility of: – Longer and heavier menstrual periods; – Bleeding or spotting between periods; – More cramps or pain during periods. • Does not protect against STIs and HIV. • May increase risk of pelvic inflammatory disease (PID) and subsequent infertility in women at risk for STIs. • Requires a trained health care provider to insert and remove the IUD. • May be spontaneously expelled.	Women who: • Have just had an abortion or miscarriage (if no evidence of infection) • Are breastfeeding • Have benign breast disease • Have or had breast cancer • Have headaches • Have high blood pressure (> 140/90 mm hg) • Have heart disease • Have diabetes • Have liver or gallbladder disease • Have epilepsy • Have non-pelvic tuberculosis • Are HIV positive and/or AIDS who are clinically well.	Women with the following conditions: • Current PID, gonorrhea, or chlamydia • High risk for gonorrhea or Chlamydia • Women with AIDS who are not clinically well. • Immediate post-septic abortion • Pregnancy • Pelvic tuberculosis • Distorted uterine cavity • Unexplained abnormal vaginal bleeding • Genital tract cancer (awaiting treatment) • Puerperal sepsis • 48 hours to less than 6 weeks postpartum • Malignant trophoblastic disease

Government of India, has clearly defined four categories for eligibility depending upon the condition/s present:

CATEGORY 1

- Can use the IUD with no restriction. Women with conditions that fall into this category include, but are not limited, to the following:
- Women with lactational amenorrhea after reasonably excluding pregnancy.
- Post menstrual insertion any time in the cycle, after excluding pregnancy.
- Immediately following a first- trimester abortion (spontaneous and induced).
- More than 6 weeks post partum provided there is no evidence of infection.
- Benign ovarian tumours/ cysts or uterine fibroids that do not distort the uterine cavity.
- Genital infections with mild non purulent discharged to be treated and inserted simultaneously (e.g. bacterial vaginosis, candida albicans, trichomoniasis).
- History of PID with a subsequent pregnancy (assuming there are no known current risks of STI's).
- Women who have breast disease including breast cancer.
- Viral hepatitis or malaria.
- Controlled diabetes, hypertension or "uncomplicated valvular heart disease.
- Women who smoke or are obese.
- Women with a history of ectopic pregnancy.
- As emergency contraception within 5 days of unsafe sex.

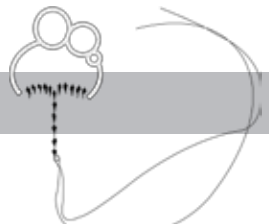


CATEGORY 2

- Can generally use the IUD (the advantages generally outweigh the risks, although additional care / follow up will be needed):
- <20 years of age (and nulliparous) or are nulliparous. As there is a slightly greater risk of expulsion due to the smaller size of the uterus.
- Immediately following a second trimester abortion(spontaneous/induced) in the absence of infection. To be inserted by a trained provider (as there is an increased risk of expulsion).
- <48 hrs postpartum, provided there is no evidence of infection.
- Having anatomical abnormalities of the reproductive tract that do not distort the uterine cavity in a way that might interfere with IUD insertion or placement (e.g. cervical stenosis).
- Are at risk of STIs other than Gonorrhoea or (e.g. HIV, Herpes.Syphilis,hepatitis) Chlamydia.
- Genital infection with severe nonpurulent discharge (e.g. herpes, syphilis, and trichomoniasis) should be treated, reviewed and then inserted.
- Have a history of PID without a subsequent pregnancy (assuming there are no known current risk factors for STIs).
- Women who are HIV-infected and clinically well.
- Women who have AIDS, are on ARV (antiretroviral therapy) therapy, and are clinically well.
- Have complicated valvular heart disease (e.g. artificial shunts, rheumatic heart disease), although prophylactic antibiotics are advised for IUD insertion to prevent endocarditis.
- With anemia (including thalassemia, sickle cell disease and iron deficiency anemia), although there is some concern about increased menstrual blood loss with copper bearing IUDs , and thus in these conditions iron supplements should be given.
- Those with first and second degree uterine prolapse.
- Those with rectovaginal fistulas.

CATEGORY 3

- Use of the IUCD is not recommended for women with the following (the risks generally outweigh the advantages); they should use a different method unless no other method is available or acceptable:
- Heavy/prolonged or painful menstruation, endometriosis, or severe dysmenorrhea, may wish to consider another family planning method, as heavier menstrual bleeding and cramping are common effects of the IUCD.
- 48 hours to less than 6 weeks postpartum
- Benign trophoblastic disease.
- Ovarian cancer (although they are Category 2 for continuation).



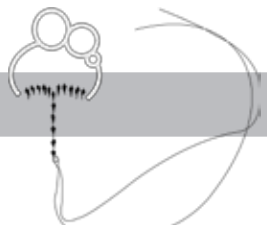
- Have a high individual risk for gonorrhoea or Chlamydia having purulent cervical discharge (although they are Category 2 for continuation).
- Have AIDS but are not on ARV therapy (although they are Category 2 for continuation)
- Those with 3rd degree uterine prolapse .
- Those with Vesicovaginal fistulas

CATEGORY 4:

- Should not use the IUD:
- Who are pregnant
- Have history of infection or signs/symptoms of infection within 6 weeks postpartum (puerperal sepsis), or immediately following an abortion (immediate post-septic abortion).
- With malignant trophoblastic disease.
- With cervical or endometrial / uterine cancer (although they are Category 2 for continuation while awaiting evaluation).
- Have anatomical abnormalities of the reproductive tract or uterine fibroids that distort the uterine cavity in a way that interfere with IUCD insertion or placement.
- Have pelvic tuberculosis
- Unexplained vaginal bleeding (although they are Category 2 for continuation while awaiting evaluation).
- Have current PID, purulent cervicitis, Chlamydia, or gonorrhea (although they are Category 2 for continuation while awaiting evaluation or undergoing treatment.)

Postpartum insertion of IUD

IUDs are an effective method in postpartum period . Postpartum insertion of IUD is in accordance to the rule of 3. It is inserted in the third postpartum month in women who are practicing full breast feeding (i.e. more than 6 day time feeds & at least once in the night).In woman who are not breast feeding regulary , IUD is inserted by the 3rd post partum week.. If IUDs are inserted within 48 hrs of delivery ,it is to be inserted by a specifically trained provider as it is associated with a slightly increased risk of expulsion .If inserted more than 48 hrs of delivery ,it can even be delayed up to 4 weeks. Between 4 – 8 weeks postpartum Cu IUD can be inserted without an increase in pregnancy rate /expulsion / uterine perforation/removal for bleeding and pain.(WHO guidelines for post partum IUCDs). There is no increased risk of infection with the post partum use of IUDs.



Post abortal IUD insertion

IUD can be inserted immediately postabortal or within 12 hours. This use is neither associated with increased infection rates, nor is any backup method necessary.If the insertion is delayed beyond 12 ,days a backup method of contraception is required.

In cases of septic abortions the use of IUCDs is to be avoided.

During early months of breast feeding when using the levonorgestrel-releasing IUS, very low serum levels are observed. This does not affect the quality and quantity of breast feeding and can be safely used

IUD and ectopic pregnancy

IUD users are 50% less likely to have an ectopic pregnancy when compared with women using no contraception.(WHO multinational study ;Clin reprod fertil 3;131,1985). However,IUDs are more protective against intrauterine pregnancies as compared to ectopic pregnancies. When an IUD user does become pregnant, the pregnancy is more likely to be ectopic than in a non-IUD user. Hence any woman who has an IUD fitted and complains of pain with vaginal bleeding or with amenorrhoea one must always exclude a possible ectopic pregnancy.

Ectopic Pregnancy Rates per 1000 Woman-Years : Table 2

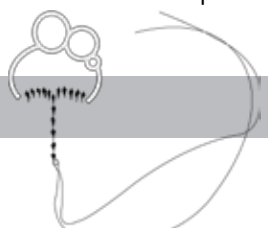
Noncontraceptive users, all ages	3.00-4.50
Levonorgestrel IUD	0.20
Tcu-380A IUD	0.20

IUD and Pelvic Infection

Pelvic infection associated with IUD use may occur when the insertion is performed under unsanitary conditions, or when the IUD is inserted in the presence of an undiagnosed STI. It may also develop later in women at risk of STIs.The usual symptoms are vaginal discharge, pelvic pain or tenderness, abnormal bleeding, chills & fever, but the infection can also be silent.

If PID is diagnosed, the appropriate antibiotic therapy is started and there is no need for removal of the IUD if the woman wishes to continue its use. If the women desires the removal of the IUD, it must be done after the antibiotic therapy has been started. In situations where the infection does not improve, it is better to remove the IUD and continue with the antibiotics. .Provide comprehensive management for STIs, including counseling about the use of condom.

There are a few studies supporting the protective effect of IUDs against STIs.LNG releasing IUD have been reported to exert a protective effect against STIs due to production of



thick mucous. Copper IUDs are associated with lower titers of chlamydial antibodies as copper inhibits chlamydial growth in the endometrial cells. Sexual behavior is the most important modifier of the risk of infection. The couple is counseled for using IUD + condom – if male partner is suspected STI carrier.

Important tips:

- *IUD related bacterial infection is due to contamination of the endometrial cavity at the time of insertion*
- *Infections occurring 3-4 months after insertion are due to acquired STIs & not the direct result of IUD*
- *PID is extremely rare beyond the first 20 days of insertion.*
- *Doxycycline (200 mg)/Azithromycin (500mg) administered orally 1 hr prior to insertion – protective against insertion related infections.*
- *There is no need for removal of the IUD if the woman wishes to continue its use.*

IUD and HIV

IUDs can generally be used in this situation, provided the woman is clinically well (e.g., has not been feeling ill, has not been diagnosed with AIDS) and has access to adequate care. Additional care/follow-up may be needed because the IUD provides no protection against HIV reinfection or other STIs.She should be counseled regarding the use of condoms

IUD and AIDS

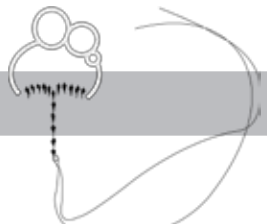
The IUCD often can generally be used in this situation, provided the woman is on antiretroviral therapy and is clinically well (e.g., has not been feeling ill, does not have opportunistic infections), with access to adequate care If she is not on ARV therapy (regardless of whether she is clinically well or has access to care),advise her that the IUCD is not recommended for women in this situation. Help her choose a different method.

IUD in Menorrhagia

LNG IUD is locally acting and is an effective measure for controlling of bleeding .It reduces the endometrial thickness and may ultimately lead to amenorrhea. It is also found to reduce the size of uterine fibroids which cause menorrhagia. Vaginal bleeding pattern is altered by use of LNG IUD. Over the period of time LNG IUD users are more likely than nonusers to have amenorrhea. Hence thorough counseling is needed before the use of LNG IUDs.

IUD and Anemia

In Anemic women (thalassemia, sickle cell disease & iron-deficiency anemia), there is



some concern about increased menstrual blood loss with copper-bearing IUCDs and hence in these conditions iron supplements should be given.

IUD and Endocarditis/ RHD/ Prosthetic valves

In patients with valvular heart disease (e.g.artificial shunts, rheumatic heart disease) prophylactic antibiotics are advised prior to IUCD insertion in order to prevent endocarditis. Bacteriologic contamination of the uterine cavity at insertion is short livedand injectable amoxicillin 2 g 1 hr prior to insertion or removal is advocated.

IUD and Diabetes Mellitus

IUDs are an appropriate contraceptive device for diabetic women with no contraindications for use, because of excellent efficacy, minimal metabolic effects, and cost-effectiveness. According to WHO, the copper IUD falls into category 1 (no restrictions on use) for women with type 1 and type2 DM, whereas the levonorgestrel IUD falls into category 2 (benefits generally outweigh risks) because of the potential effect of levonorgestrel [the hormone in Mirena] on carbohydrate metabolism.

Miscellaneous

The use of both Cu IUDs & LNG IUDs is safe in any of the thyroid diseases. It can be safely used in patients with Hypertension, DVT and hepatic disorders. In cases of pulmonary tuberculosis ,the IUDs may not affect the course of disease. But in known pelvic tuberculosis or active disease the IUD insertion may worsen condition

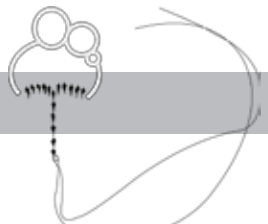
Some FAQs

Should women with irregular menstrual bleeding patterns use IUDs?

With proper counseling, menstrual irregularities should not affect IUD use. Menses are normally heavier with the IUD, and intermenstrual bleeding may occur; this decreases over time with IUD use. Oral iron supplements can improve hemoglobin levels if bleeding is heavy or the woman is anemic. A woman in pain in the first month after insertion can receive a short regimen of a nonsteroidal, anti-inflammatory agent other than aspirin. If a woman wants the IUD removed or if pelvic infection is diagnosed, remove the IUD.Hormonal IUDs too have a role in these cases with both, contraceptive and styptic benefits

Should a woman with a sexually transmitted disease (STD) use an IUD? Can she in the future?

A woman who has an STD, or has had one in the last three months, should not receive an IUD. Any STD, purulent cervicitis or PID should be treated. If a woman will be at low risk of STD infection in the future, and she gets careful counseling, an IUD may be



inserted after an STD infection is treated and resolved; for acute PID, wait three months after PID is resolved before inserting an IUD.

Should a woman at risk of STDs use an IUD?

Women using an IUD should be at low risk of STDs, especially young women. A woman at low risk of STDs does not need a lab test prior to IUD use. If other more appropriate methods are not available or acceptable, even women at high risk of STDs could use an IUD, according to the World Health Organization (WHO), as long as the woman is monitored closely for infection during the first six weeks after insertion.

If the cervix is red, can the IUD be inserted?

Yes, if the redness is due to cervical ectopy/ectropion, which is not an infection, or cervical erosion, if the woman is not at risk of STDs; and if the pelvic exam is normal (no cervicitis).

Should a woman with past PID but no current risk of STDs use an IUD?

WHO reports state that If she has had a subsequent pregnancy, previous PID does not affect IUD use,. If there has not been a subsequent pregnancy since PID, there may be some added risk of PID, but advantages generally outweigh risks.

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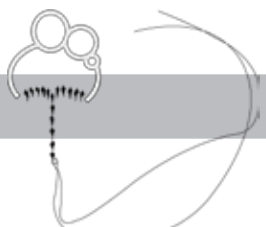


Use of IUCD in Non-Contraceptive Situations

Dr. Sasikala Kola

The intrauterine contraceptive device (IUD) is the most cost-effective temporary contraceptive method for long term use with high efficacy, safety and convenience.

Evolution of IUCD

1st generation	Grafenberg IU silver ring 1928
2nd generation	Barium impregnated plastic non medicated IUDs – 1960s
3rd generation	Copper bearing IUCDs – 1970s
4th generation	Hormone releasing IUCDs 1995 onwards
	Levonorgestrel intrauterine system LNG-IUS
5th generation	Intrauterine contraceptive implants
	Miniature, frameless, Flexible with no plastic body
	(Cu and hormone – releasing intrauterine implants)

Levonorgestrel intrauterine systems (LNG-IUS) acts by releasing about 20 micro gms of Levonorgestrel directly into the uterine cavity and the drug is mainly concentrated in the endometrium. It's concentration in the tubes and myometrium is in the same range as with oral administration of 30 mgms but the endometrial concentrations are 200-300 times higher with LNG-IUS use. (1, 2)

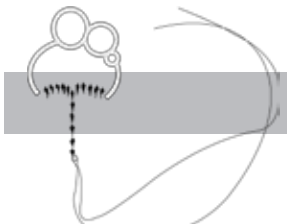
The non-contraceptive benefits of the system is mainly due to this local high endometrial levels of LNG and present unique opportunities for treatment of a variety of gynecologic problems in symptomatic patients, with or without contraceptive needs. The LNG-IUS offers most of the health benefits seen with systemic hormonal contraception – reduction in menstrual flow, dysmenorrhoea and pelvic pain symptoms, its main advantage being oestrogen free and local release without side effects of systemic progestin therapy. Hence, fewer hormone-related symptoms. (3)

Changes in bleeding patterns

Use of the LNG-IUS results in endometrial thinning, glandular atrophy, stromal decidualization. As a result, spotting occurs frequently during the initial 4 to 6 cycles followed by reduced amount and duration of menstrual bleeding in most women. Amenorrhoea occurs in 15-20% of LNG-IUS users in the 1st year of use and increases to 30-40% with longer durations of use. (4)

LNG-IUS in Menorrhagia

The LNG-IUS is approved in over 100 countries for the treatment of menorrhagia(5) It



has better outcome than other hormonal and non-hormonal medical treatment options. (6)

A study of 34 Chinese women who failed conventional therapy for menorrhagia showed a 98% reduction in average menstrual blood loss.

2 years after insertion of a LNG-IUS with 3/4 of them reporting amenorrhoea by 6 months. (7)

A number of studies support LNG-IUS use as an effective, conservative treatment option that preserves reproductive function and avoids surgical risks and costs. A 5 year RCT in Finland comparing women with menorrhagia randomized to LNG-IUS or hysterectomy found similar measures of satisfaction and quality of life between treatment groups at significantly lower costs in the LNG-IUS group. (8) A recent Cochrane review included 5 randomized trials directly comparing ablation to LNG-IUS for management of menorrhagia. Of these two showed better control of bleeding at 1 year with ablation and three showed no difference in bleeding control at 1 to 3 years between these two options. (9) Another RCT of 83 women from Newzealand showed better bleeding profile with LNG-IUS compared to balloon ablation after 2 years. (10)

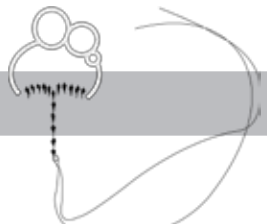
Correction of Anemia (secondary to reduced menstrual blood loss) Long term follow-up studies of LNG-IUS in healthy women have demonstrated favourable sustained increase from baseline in haemoglobin concentrations with a mean increase of 1.6 gm/dl after 5 years of use and 1.44 gm/dl after 7 years of use. (11) LNG-IUS also resulted in sustained increases in haemoglobin, haematocrit and serum ferritin levels. (12)

Treatment of endometrial hyperplasia in peri and post menopausal women.

There is evidence of complete histological regression of endometrial hyperplasia with LNG-IUS treatment. In a 2 year follow up study of 15 women bleeding decreased quantitatively by 3 to 6 months and resulted in amenorrhoea at 24 months. (13) Endometrial biopsis performed at 12 months revealed atrophy endometrium in 93.3% and secretory endometrium in 6.7% ($P<0.001$). At 24 months endometrial atrophy was documented in 100% of women. A recent, non-randomized Norwegian study compared LNG-IUS, oral progestins and observation among 370 women with simple and atypical hyperplasia. In this study, the LNG-IUS showed superior resolution over the other two and there were no cases that progressed to cancer when followed to a maximum of 106 months. (14)

LNG-IUS and Uterine myoma

The LNG-IUS has been shown to reduce blood loss associated with fibroids. (15) Data about its ability to reduce the size of fibroids or overall dimension of uterus is less consistant. In a Russian study 67 women with myomas, uterine size of 12 weeks and



a normal uterine cavity, the LNG-IUS substantially reduced blood loss at 12 months and decreased uterine and leomyomata size with 40% amenorrhoea by 12 months and 66/67 with >12 gm/dl Hb % by 12 months. (16) A Turkish study of 32 women with menorrhagia atleast one submucous fibroid <50% into the uterine cavity and uterine volume 380 ml received LNG-IUS. At 12 months followup, bleeding and Hb% levels showed similar improvement as compared to 32 controls who underwent thermal balloon ablation. There were no changes in uterine volume or fibroid sizes. (17) Size of the uterus >12 weeks and presence of submucous fibroids preclude use of LNG-IUS. Hysteroscopic myomectomy of submucous fibroids followed by LNG-IUS is another option.

Potential preventive effect on Fibroids?

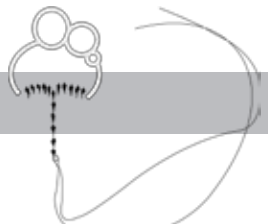
Among women randomized to treatment with either LNG-IUS or copper T 380A, the incidence over 7 years of a new diagnosis of uterine myoma or myoma-related surgery was significantly lower in the LNG-IUS group. (18)

Pain associated with Endometriosis and Adenomyosis.

Several small pilot studies suggest that the LNG-IUS can be useful in the treatment of pelvic pain associated with endometroisis and adenomyosis. (19, 20, 21) Two studies evaluated post-operative insertion of LNG-IUS resulting in a significant reduction in the symptoms of dysmenorrhoea in women treated with laparoscopy for endometriosis (19, 22). Another randomized study found that the improvement in pain and quality of life achieved in women with endometriosis with the LNG-IUS is comparable to that achieved with a GnRH agonist even with stage III/IV disease. (23)

It is not known precisely how progestins relieve symptoms of endometriosis, but they probably work by suppressing the growth of endometrial implants in some way, causing them to gradually waste away. They may also reduce endometriosis induced inflammation in the pelvic cavity.

Successful management of pain and abnormal bleeding associated with adenomyosis has also been reported. (24) Several mechanisms could explain the role of LNG-IUS in Adenomyosis. It decidualizes the endometrium, followed by atrophic changes resulting in marked reduction in menstrual blood loss. It also acts directly on the adenomyotic deposits due to high local LNG levels. Down regulation of oestrogen receptors which are present in both glandular and stromal endometrial tissues occurs shortly after placement of the device and persists for atleast the first year of use. The adenomyotic deposits then reduce in size, and as a result of these shrinking deposits, uterine contractility improves and the uterine size decreases. LNG-IUS also improves dysmenorrhoea which is thought to occur because of the reduction of prostaglandin production within the endometrium. Reduction in the size and activity of deposits of adenomyosis may also account for



the improvement in dysmenorrhoea. This reduction is also reported in women without adenomyosis.

LNG-IUS has also been used with good effect in women with rectovaginal endometriosis. In a study of 11 women with rectovaginal endometriosis who used the LNG-IUS for 12 months, dysmenorrhoea, pelvic pain and deep dysparunea greatly improved and the size of the endometriotic lesions was significantly reduced by treatment. (25) However, it is not clear whether some of these women had coexisting adenomyosis.

A Brazilian study of 29 women with adenomyosis showed a reduction in junctional zone thickness between endometrium and myometrium by MRI but no decrease in uterine volume. (20) Another recent Chinese study showed effectiveness in treating adenomyosis with 3 years of continuous use. (21)

IUCD in post operative management of Asherman's syndrome

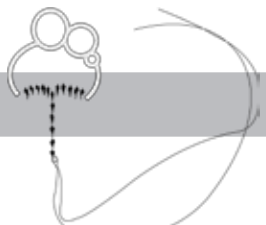
After lysis of endometrial adhesions a Cu IUCD without the copper wire is inserted to act as a barrier to prevent re-adhesion formation and the woman is put on oestrogen treatment to help regeneration of endometrium. The IU device is removed after improvement in endometrial thickness as shown in transvaginal ultrasound exam.

Endometrial protection during hormone replacement

Use of LNG-IUS provides endometrial protection in women receiving estrogen replacement therapy, and is an approved indication of LNG-IUS in over 90 countries. In a randomized study of 40 perimenopausal women who received oral estradiol 2 mg and either a LNG-IUS or levonorgestrel 250 gms orally for the last 10 days of the cycle, bleeding disturbances gradually diminished in LNG-IUS group and 83% of women were amenorrheic by 12 months. (26) No endometrial proliferation or atypia was apparent in the biopsy samples from either group. The favourable findings were corroborated by studies using LNG-IUS in conjunction with sustained release subdermal, transdermal and oral estrogen delivery systems with 1 to 3 years of follow-up. (27) Three further trials have reported the sustained endometrial protection effects of the LNG-IUS over 5 years. (28)

LNG-IUS and early endometrial cancer

Three case series have reported treatment with the LNG-IUS. These studies collectively include a total of 27 women with grade I endometrial carcinoma, have shown a regression rate of 25-75% after LNG-IUS exposure.(29, 30) Further studies are needed to determine the utility and safety of LNG-IUS for the treatment of endometrial cancer.



LNG-IUS as adjuvant therapy with tamoxifen

Tamoxifen stimulates with uterus and increases the risk of endometrial polyps, fibroids, hyperplasia and endometrial cancer. (31) Results from a randomized trial determined that the LNG-IUS prevented the development of endometrial polyps or hyperplasia in patients using tamoxifen over 1 year of use. (32) However these women experience more bleeding. Given the unproven safety of the LNG-IUS in breast cancer patients, longer-term randomized studies are needed to determine the benefit to risk balance in these patients. (33) It is reassuring to note that population based studies have not shown an increase in the risk of breast cancer among LNG-IUS users.

The wide range of benefits of the LNG-IUS in treatment of gynecological disorders make it an attractive option for women worldwide. It can offer women improvement in anemia menorrhagia, endometriosis, control of uterine fibroids & adenomyosis and protection against and treatment of endometrial hyperplasia and possibility early endometrial cancer. Because of its effectiveness, high patient acceptability and demonstrated safety, gynecologists should offer it as an important option wherever required as it continues to provide important benefits in women's reproductive health.

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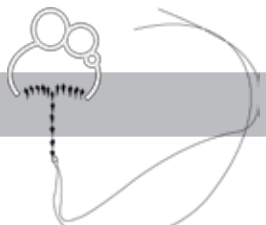

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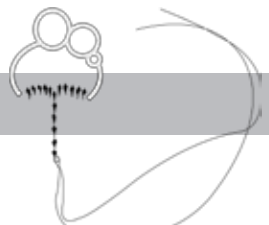

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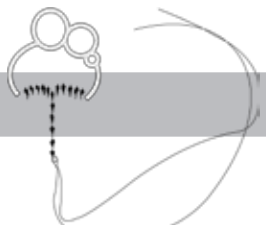


Complications of IUCD use: could it be prevented?

Prof Alka Kriplani & Dr. N. Deepa Maheswari

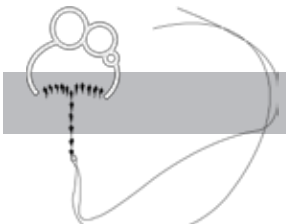
Introduction:

The use of intrauterine devices for contraception is one of the oldest methods of contraception known and the first such reported use was by Arabs who put pebbles into uterus of camels to prevent pregnancy during long journeys. In the nineteenth century, several types of pessaries (stem pessary, wishbone shaped pessary) made of various materials like wood, glass, silver, gold and ivory were tried to prevent pregnancy. These pessaries led to severe infection. The first widely used IUCD was introduced in Germany by Ernst Grafenberg in the late 1920's. It was made of silkworm gut and silver wire and was also associated with severe problems. This was followed by the use of plastic for making IUCD's and these fared better. In order to reduce the complications of IUCD and reduce efficacy, various innovations have been introduced like introduction of copper containing and hormone releasing devices and also frameless devices and we have come a long way in improvising on the IUCD. These developments have greatly improved the acceptance and continuation rates for IUCD as a contraceptive method.

IUCD is a safe and effective method of contraception and it is less costly when compared to OCP in the long run. It does not affect sex-play (unlike barrier methods) and has no systemic effects. It is a one-time procedure (unlike OCP/barrier) and does not need regular motivation for continued use, since the newer devices have long life spans. However, the low usage rates and high discontinuation rates of IUCD in India is a matter of concern. There are a few problems with IUCDs which result in discontinuation even with newer devices. These problems may be prevented to some extent and this would improve the acceptance and continuation rates for IUCD. The various problems and ways to prevent them are discussed further.

IUCD for contraception: Usage and discontinuation rates.

NFHS3 (2005-6) reported the rate of contraceptive use (all methods) at 56.3%. Female sterilization is the most common method used accounting for 37.3% of women. 1.7 % of women were using IUCD for contraception. This survey also found that the use of IUCD is more in urban women (3.2%) compared to rural women (1.1%), and more in educated women (5.2%) compared to illiterate women (0.6%). (1)



The continuation rate for IUCD depends on various factors like

1. Experience and attitude of IUCD provider- Pre-insertion counseling and support is very important and influences continuation rates.
2. Motivation of the woman
3. Cultural make up towards vaginal bleeding (excess/unscheduled)
4. Age and parity of the woman- Removal is less common in older women, multipara and long term users.
5. Socioeconomic condition
6. Availability of alternate methods of contraception
7. Type of IUCD used

The Continuation rates for IUCD have been quoted as 70-90 per 100 women at the end of 1 year worldwide (WHO 1987). In India, several authors have found discontinuation rate for the IUCD in the range of 20–40% at the end of one year. (2, 3, 4) The ICMR task force (1994) found continuation rates of 76-89 per 100 users at the end of 1 year for Copper containing IUCD.

In a study done in rural north India, the authors found an overall continuation rate of 79•6% for IUCD use. Cumulative probabilities of discontinuation for IUCD use tend to be higher among women with a more than usual amount of menstrual flow before insertion, inter-menstrual bleeding after insertion, those who experienced dysmenorrhoea before insertion or pain during insertion. (5)

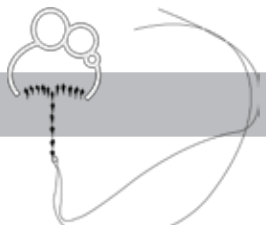
Complications of IUCD

Even with the newer IUCDs, there are problems which lead to these high discontinuation rates. It is essential to develop strategies to prevent or overcome this problem and improve the acceptance of IUCD as a contraceptive method. Some of the problems and the strategies to overcome them are discussed below:

Increased bleeding and inter-menstrual bleeding

It is one of the greatest disadvantages of IUCD use and along with pain, account for their removal in 2-10 per 100 users in the first year (Population reports, 1988). Increase of 20-30% of mean menstrual loss is reported in most studies. It was more common with older IUCDs which were inert (lippe's loop) compared to copper containing devices but menorrhagia is still a significant problem of copper containing devices.

The cause of menorrhagia associated with IUCD use is not precisely known. It has been attributed to various factors like increased production of plasminogen activating enzymes leading to lysis of fibrin, increased vascularity of endometrium and hormonal asynchronization. Inter-menstrual bleeding is due to mechanical damage to endometrium which heals in time, so it passes off in a few months.



This problem can be prevented to some extent by proper screening of women and excluding those who have menstrual disturbances or uterine fibroids before insertion. If only those women who report normal menstrual cycles had IUCDs inserted, it is very likely that the high discontinuation rate due to menstrual disturbance could be reduced. Use of LNG impregnated IUCD (Mirena), reduces menstrual blood loss but is costlier.

If menorrhagia does occur, mild cases may be managed with NSAIDs and iron supplement. For severe cases, the IUCD needs to be removed and an alternate method of contraception is to be chosen. Intermenstrual bleeding usually passes off in a few months and patient needs counseling. If persistent and associated with pain and discharge, it may be associated with endometritis and needs appropriate treatment. Irregular inter-menstrual spotting is a known problem of the Mirena in the first 3 months and improves after that, so counseling is very important.

Pain:

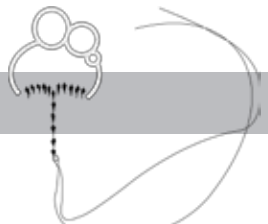
Pain after insertion is usually due to uterine cramps and subsides within a week. It is managed by symptomatic treatment with NSAIDS and analgesics. Persistent pain may be due to abnormal position, uterine perforation, the beginning of expulsion, disparity between size of IUCD and uterus, associated PID/ectopic. A per speculum examination and bimanual pelvic examination must be done to rule out these possibilities. Patient must also be evaluated to rule out PID and ectopic.

This can be prevented by careful technique of insertion, the IUCD must be aligned properly so that the arms are in the horizontal plane and fit comfortably at the cornua, care is taken not to enter the myometrium during insertion and cause a perforation. The utero-cervical length is to be measured before insertion to look for any gross deviation from normal as it would lead to abnormal position and pain. Assessment of utero-cervical length and adjusting the flange accordingly also prevents perforation.

IUCD use is discouraged in women with significant dysmenorrhea before insertion as the pain may increase necessitating removal. LNG IUCD improves dysmenorrhea associated with endometriosis.

IUCD expulsion:

This may be Partial or complete and occurs in 2-8% of women in first year. It is more common in younger women and nullipara. It is more common with lippes loop than with Copper containing devices, and with postpartum insertion and faulty technique of insertion. Highest incidence of expulsion is in the first 3 months of use, mostly during menstruation, especially in the first period after insertion. To notice expulsion, every woman must look for the tail of the device by inserting a finger in the vagina following menstruation and also check her pad for expelled device in the first 3 months. The woman



is advised that if she cannot feel the tail, she must abstain or use barrier contraception till she is able to meet a doctor.

In order to prevention of expulsion, adequately trained personnel should insert the device, device must be left high in uterine cavity, should not be introduced into the inserter for more than 2-5 minutes before insertion as it tends to lose its memory, i.e, shape.

If a patient expels a Cu-T, and there is no evidence of PID, another one can be reinserted, which is retained in two-third of cases. If expulsion is incomplete, it should be removed and may be replaced with another one or a alternate method can be chosen.

Perforation:

Perforation is rare, and occurs at the rate of 1.2 per 1000 insertions as found in large clinical trials by WHO. More recent studies involving newer devices have shown rates less than 1 per 3000. As a result of perforation, the device may become embedded in uterine musculature or migrate outside the uterus (commonly into the peritoneal cavity, rarely into the bladder or rectum). Most perforations occur at the time of insertion due to faulty technique. It is more common with push out technique than the withdrawal technique. Sometimes the perforation is initiated at the time of insertion and is completed by uterine contractions. The occurrence of sharp pain at time of insertion, post insertion bleeding and disappearance of the tail and are all signs of perforation.

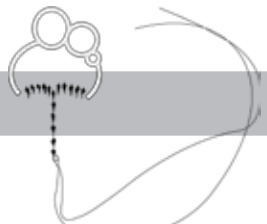
Perforation risk can be reduced by careful technique at time of insertion, use of withdrawal technique, and use of certain devices like the Mirena and frameless devices.

Pelvic inflammatory disease:

Vaginal discharge may be increased up to the first menstrual period owing to foreign body reaction. Persistent discharge is due to infection. Earlier reports overestimated the incidence of PID related to IUCD use. The prevalence of PID in IUCD users is 1.6 per 100 woman years of use (WHO 1997). The risk of infection is highest in the first 20 days after insertion for women in a monogamous relationship. After 20 days, risk is low and usually due to freshly acquired infection. PID associated with IUCD is more common in young nulliparous women

Association of PID with IUCD may be due to:

- Infection introduced at the time of insertion
- Flare up of old or undiagnosed genital infection
- Freshly acquired infection from partner
- Increased volume and duration of menstrual flow and foreign body reaction associated with IUCD help in the growth of organisms



In order to prevent IUCD associated infection, the following steps can be taken:

- Proper patient selection: exclude active infection/ high risk behavior for acquiring infection.
- Levonorgestrel releasing IUCD have a protective effect by causing thickening of cervical mucus and preventing ascent of organisms
- Use of prophylactic antibiotic at the time of insertion: Doxycycline 200mg or azithromycin 500 mg may be used 1 hr before insertion. However, this is not recommended by WHO.
- Proper asepsis to be followed at time of insertion.

If infection occurs with an IUCD in situ, broad spectrum antibiotics are started (metronidazole and ampicillin or cephalosporin) for 7-14 days. IUCD is removed 24-48 hrs after initiation of antibiotic.

Colonization with actinomycosis increases with duration of IUCD use. Routine removal and reinsertion in an asymptomatic patient is not recommended by the international Planned Parenthood Federation (IPPF). A course of penicillin or tetracycline may be given to such patients.

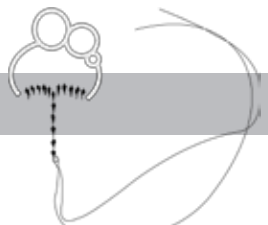
Failure of IUCD, accidental pregnancy and ectopic pregnancy:

No contraceptive method is fool-proof and failure may occur even after surgical sterilization. Failure rates are more with barrier method (failure rate when used correctly is 5% and 21% with typical use). Most of the modern OCP have pearl index less than 1, however, the typical failure rates are higher due to missed pills. The failure rate of IUCD have been improving and the pearl index is less than 1 for the newer devices

Failure rate of various IUCDs:

Group 1:	Lippes loop, Cu-7, Cu-T200: Pearl index › 2
Group2:	Nova T, Multiload Cu-250, Cu-T 220: Pearl index beween 1 & 2
Group3:	Cu-T 380A, Cu-T 380S, Multiload Cu-375, LNG-IUCD: Pearl index ‹1, mostly ‹0.5

If a patient conceives with a Copper T in situ and it is an intrauterine pregnancy, the IUCD must be removed if the thread is seen. There is a slight risk of bleeding and abortion at time of removal. If the thread is not seen, it is left in situ. There is a slightly higher chance of second trimester abortion but Copper is not teratogenic. At the time of delivery, the IUCD is usually expelled along with the placenta.



Ectopic pregnancy: IUCD users are 50% less likely to have an ectopic compared to women using no contraception. However, when pregnancy occurs in an IUCD user, it is more likely to be ectopic (30%) than intrauterine. This is prevented by avoiding IUCD use in women with previous PID, ectopic pregnancy, multiple sex partners, etc.

IUCD use does not significantly affect fertility in low risk women, 70% conceive in 1 year (population report 1982).it may increase chance of tubal factor infertility in high risk women. It does not promote cervical/ endometrial malignancy.

Case report:

A 27 year old patient, P2L2 came to the Gynae OPD after 3 months of Cu-T insertion with the complaint of inability to feel the thread and pain abdomen. On speculum examination, the thread was not seen. An ultrasound was done and the IUCD was not found in the uterus. A sound was introduced into the uterus and an X-ray of the abdomen was taken, both AP and lateral view. The copper T was found in the abdomen outside the uterus. A decision was taken to perform laparoscopic removal. At the time of lararoscopy, the IUCD was not visualized in the abdomen. A C-arm was then brought to the OT and intraoperative fluoroscopy was done and the IUCD was visualized on it. It was then located in the abdomen, totally engulfed by omentum as a result of which it was not seen initially. It was then removed along with a part of the omentum to which it was adherent.

Discussion:

Missing thread of an IUCD is a common problem. The possibilities with a missing IUCD are that it has been

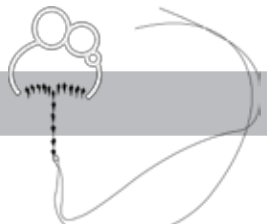
- Expelled
- Thread coiled up in cervical canal and IUCD in uterus
- Perforation- IUCD embedded in myometrium/ migration into peritoneal cavity, bladder or rectum.

The evaluation involves the following in a stepwise manner:

- Speculum examination to look for thread, probe the endocervical canal to see if thread is coiled up there
- USG pelvis to look for device in uterus
- X-ray abdomen – AP and lateral view with a sound in uterus (distance of displaced IUCD from sound helps to identify the location of the lost IUCD- intrauterine or extrauterine)
- In rare cases, intra-operative fluoroscopy is needed to locate it, as in our case

The management will depend on where the IUCD is:

- Expelled IUCD: another IUCD is inserted or another method of contraception



- Found in uterus: hysteroscopy guided removal
- Perforated into peritoneal cavity: removal by laparoscopy or laparotomy.

Conclusion

Thus the problems of menorrhagia and pain have largely been overcome by use of hormone containing devices, careful patient selection, use of careful technique and certain other simple measures. Use of smaller/ frameless devices is likely to reduce complications further. Good counseling by the provider is the key to continued use of the IUCD. Implication of these strategies to prevent the complications of IUCD use will be to reduce the discontinuation rates and improve the acceptance rates among the general population for the use of IUCD for contraception. The IUCD is a simple, cost-effective method which health workers may be trained to insert and does not require continuous patient motivation or partner support. Hence high continuation rates may be expected if these problems are overcome and it will provide a good method to be promoted by the national birth control program.

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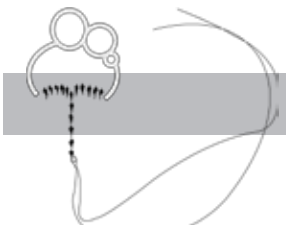


Imaging in IUCD

Dr Atul Ganatra

Nothing is permanent but change

Heraclitus

Ultrasound & Laparoscopy have revolutionized the practice of obstetrics & gynecology in the last decade

It would not be wrong to say that it is difficult to practice today without the knowledge of ultrasound & every gynecologist must have adequate knowledge of Ultrasound

Intrauterine contraceptive devices (IUDs) are the most widely used reversible contraceptive methods worldwide.(1) The history of IUDs dates back more than 3000 years, when smooth pebbles were inserted into the uterus of camels to prevent pregnancy during long trips in the desert.(2)

Imaging has an important role in the evaluation of IUDs, not only to check that an IUD is in the correct position to be effective but also to assess for associated complications. Sonography (Figure 1) is the commonly used method to evaluate IUDs because it is easy to perform, is cost-effective, and lacks a risk of radiation. When an IUD is not found on a sonogram, a plain radiograph of the abdomen is helpful to determine its location (Figure 2). Computed tomography (CT) and magnetic resonance imaging (MRI) are not commonly used for assessment of an IUD

When complications such as abscesses arise from an IUD, CT can be helpful in further management. (3, 4) On CT, IUDs appear dense (Figure 3), and on MRI, they appear as signal voids (Figure 4). It is safe to perform MRI at 1.5 T and lower magnet strengths in patients with IUDs. At 3 T, metal-free IUDs appear to be safe. However, the safety of metal-containing IUDs at 3 T has not yet been proven, with theoretic risks of heating or motion. (5)

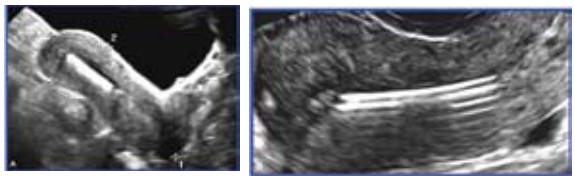


Figure 1. Copper IUD. Sagittal transabdominal (A) and transvaginal (B) sonograms show the echogenic shaft of the copper IUD, with shadowing best seen on the transvaginal image.

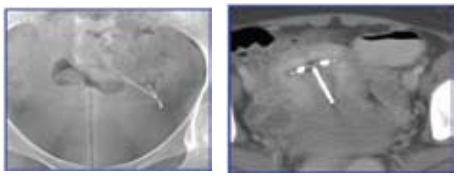


Figure 2. Intrauterine contraceptive device in the peritoneal cavity of a patient with a nonvisualized IUD on sonography. Plain radiograph shows a Mirena IUD in the left hemipelvis. This was confirmed to have perforated into the cul-de-sac at laparoscopy.

Figure 3. Axial CT image shows a dense copper IUD located in the endometrial cavity.

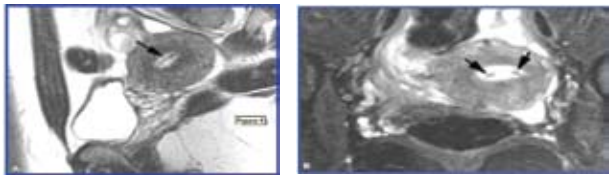


Figure 4. MRI appearance of an IUD. Sagittal T2-weighted (A) and coronal short tau inversion recovery (B) views show linear signal voids arrows) in the endometrium from the IUD.

Intrauterine contraceptive devices can be divided into 3 basic types: (1) inert, (2) copper containing (first and second generation), and (3) hormone containing. It is helpful to know the type of IUD inserted for accurate assessment. In a T-shaped IUD, the stem and the arms of the T should be identified, with the proximal end in the internal os and the distal end in the fundal region within the endometrium. If an IUD is difficult to visualize, assessing its shadow may be helpful (Figure 5). Some advocate 3-dimensional (3D) sonography to ensure that the entire IUD is within the endometrial cavity (Figure 6). Volume contrast imaging with a 2- to 4-mm slice thickness, showing the acoustic shadows, can also be helpful, especially in the presence of uterine anomalies, scarring, and other technically difficult situations. (6)

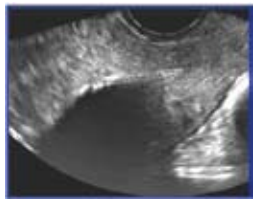


Figure 5. Intrauterine contraceptive device shadow. Sagittal transvaginal sonogram shows strong shadowing from a Mirena IUD, which can help in identification of an otherwise difficult-to-visualize IUD.

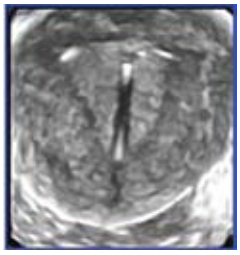
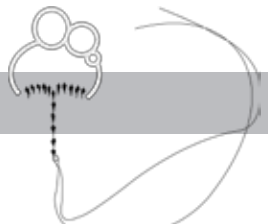


Figure 6. Coronal 3D reconstructed sonogram of a Mirena IUD shows the expected location of the shaft and crossbars simultaneously

Types of IUCD

Inert IUDs

The first IUD used in humans was a ring-shaped device, developed in the early 1900s by Ernst Grafenberg. (7) However, this was not widely used because of fear of infection and difficulty of removal. The first American IUD was the Margulies spiral (Gynecoil; Ortho Pharmaceutical, Raritan, NJ), which frequently caused bleeding and cramping and had a hard, uncomfortable tail. It was modified by Jack Lippes, who created the Lippes Loop IUD (Ortho Pharmaceutical), changed the ring to a loop for easy removal, and also attached a softer string for checking its position. This IUD is curved back and forth on itself and thus on a sagittal image has an appearance of 5 echogenic foci aligned in the endometrial cavity with shadowing (Figure 7).



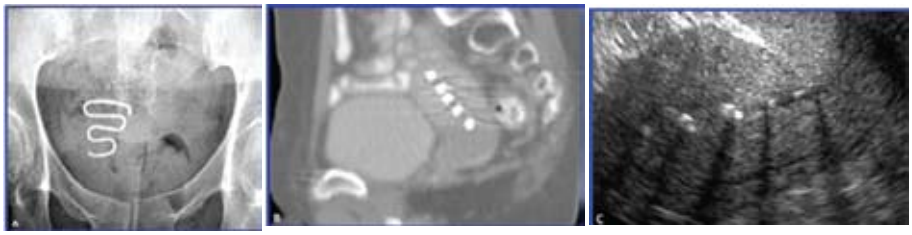


Figure 7. Lippes Loop on multiple modalities. A, Pelvic radiograph shows the curved appearance. B and C, Sagittal CT reconstruction (B) and transvaginal sonogram (C) show 5 intermittent echogenic shadowing foci.

In the late 1960s, the Lippes Loop was followed by another inert IUD, the Saf-T-coil (Julius Schmid Laboratories, Little Falls, NJ), which has a seagull-shaped appearance in the crossbars. These IUDs were made of plastic polyethylene with some barium sulfate added so that they could be visualized on radiographs.

These inert IUDs were in wide use before the introduction of copper-containing IUDs. Several other IUDs were available in the late 1960s and 1970s, some of which were associated with complications, controversies, and lawsuits which made IUDs less popular as contraceptive methods. The most controversial IUD was the Dalkon Shield (A. H. Robins Company, Richmond, VA), which looked like a bug with 1 large eye and 5 legs on each side. It had a braided tail consisting of multiple filaments enclosed in a sheath (Figure 8). (7) This multifilament tail acted as a source of infection, leading to pelvic inflammatory disease and septic abortions.

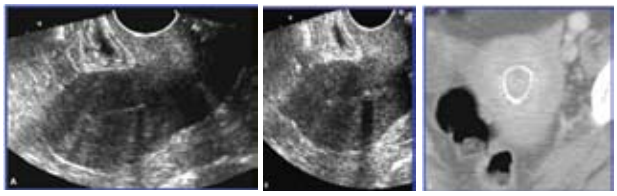


Figure 8. Dalkon shield. A and B, Sagittal (A) and transverse (B) sonograms of the uterus with a Dalkon shield IUD. C, Abdominal CT image of the patient shows the characteristic appearance of a bug with 5 legs on each side. Note the difficult sonographic visualization of the entire IUD

An inert IUD that is still in use today is the ring-shaped IUD, widely used in China (Figure 9). These are typically inserted in patients postpartum. They have a higher failure rate than the T-shaped IUDs and are also difficult to remove. (8)

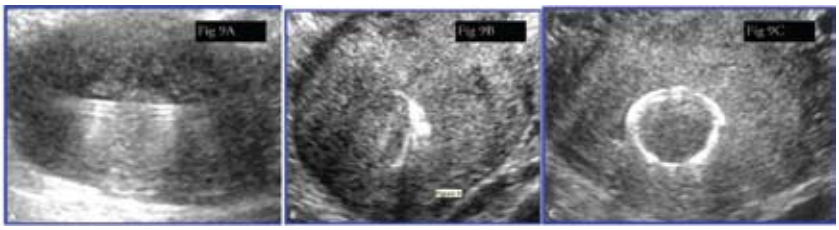
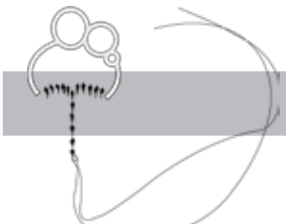


Figure 9. Stainless steel ring IUD. Sagittal (A), oblique sagittal (B), and transverse (C) sonograms of the uterus show the ring appearance of the IUD.



Copper-Containing IUDs

Copper-containing IUDs are of several different types and consist of first generation-models developed in early 1970s, such as the Copper 7, second-generation types such as the Nova T and third-generation types such as the T Cu380A. These IUDs typically have a straight shaft and crossbars that form the shape of a 7 or a T (Figures 1 and 10). The copper IUD available in the United States is the ParaGard IUD, which is effective for 10 years. (9)

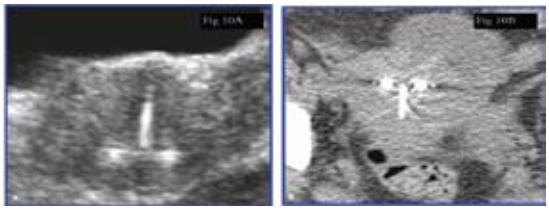


Figure 10. ParaGard IUD. A, Coronal sonogram of a retroflexed uterus shows a ParaGard IUD in the expected location in the endometrial cavity. B, In a different patient, axial CT image shows the radiopaque metallic IUD in the expected location in the mid uterus.

Hormone-Containing IUDs

Hormone-containing IUDs have either natural progesterone hormone (Progestasert; Alza Corporation, Palo Alto, CA), with 38 mg of naturally occurring progesterone in the reservoir, effective for 1 year (Figure 11), or levonorgestrel, which is a synthetic progestogen. These became available for clinical use in 2001 in the United States as Mirena (Leiras Oy) and earlier elsewhere as Levo Nova (Leiras Oy). Levonorgestrel-containing IUDs are highly effective, with a very low failure rate. (10) The levonorgestrel-containing IUDs have the additional advantage of reducing menorrhagia, dysmenorrheal and anemia. (11-15)

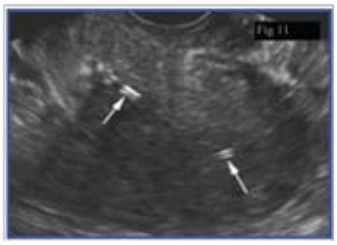
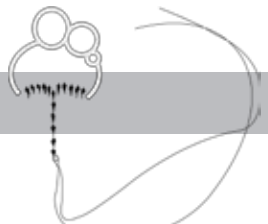


Figure 11. Progestasert IUD. Sagittal sonographic image of the uterus shows the echogenic proximal and distal ends (arrows) and shadowing in between

The Mirena IUD has a T-shaped polyethylene frame, with a 32-mm vertical stem and a 32-mm horizontal portion with arms containing barium sulfate. The stem has a reservoir containing a mixture of levonorgestrel and silicone covered by a silicone membrane.(16) The Mirena IUD has a characteristic appearance, with acoustic shadowing between the echogenic proximal and distal ends, unlike copper IUDs, which are more completely echogenic (Figure 12).(17) Early versions of the Mirena IUD were very difficult to visualize sonographically (Figure 13). The string can have a very echogenic appearance. (17) In our anecdotal experience, more recent versions have a more easily identifiable IUD shaft appearance and a slightly less echogenic but still readily identifiable string (Figure 12)



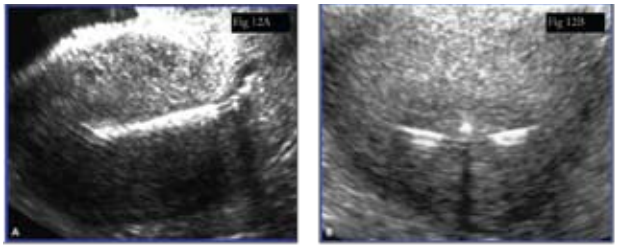


Figure 12. Mirena IUD. Sagittal (A) and coronal (B) transvaginal sonograms show the echogenic T-shaped Mirena IUD with the crossbars in the expected location in the endometrium, just below the fundus.

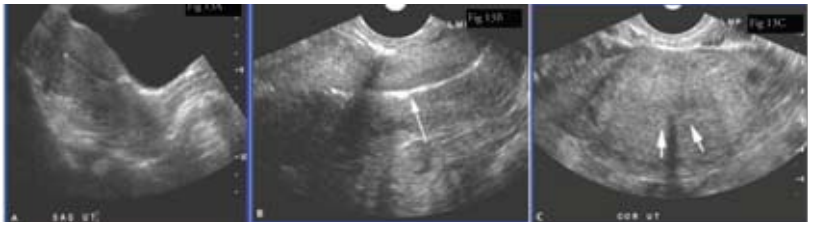


Figure 13. Mirena IUD. A, Transabdominal sagittal image shows the difficult-to-visualize shaft of the IUD. B, Transvaginal sagittal image shows the echogenic string in the cervix (arrow). C, Transvaginal coronal image shows the difficult-to-visualize crossbars (arrows).

Essure Device

A recent contraceptive device is the Essure device (Conceptus, San Carlos, CA). This is a permanent sterilization device consisting of 2 microinsert coils that are hysteroscopically placed in each fallopian tube. The Essure microinsert consists of a stainless steel inner coil, a nickel-titanium superelastic outer coil, and polyethylene fibers that are wound in and around the inner coil. The fibers stimulate tissue ingrowth. Along with the microinsert coil, these fibers act as scaffolding into which the tissue grows, further anchoring the microinsert within the fallopian tube and occluding the tubal lumen, resulting in sterilization.(18) Hysterosalpingography is performed about 3 months after the procedure to document tubal occlusion. On sonography, the Essure device appears as a curvilinear, dense, uniformly echogenic structure with shadowing in the region of the fallopian tube, with the proximal tip at the uterine cornu (Figure 14).

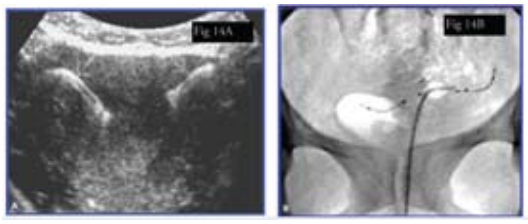
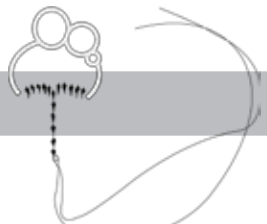


Figure 14. Essure device. A, Transverse transabdominal sonogram shows the curvilinear, uniformly echogenic Essure device (arrows) extending from the uterine fundus to the fallopian tubes bilaterally. B, In a different patient, scout radiograph with the HSG catheter in place shows the radiopaque Essure device bilaterally.

Complications of IUDs

The radiologically relevant complications of IUDs include malposition, uterine perforation, pelvic inflammatory disease, and pregnancy. These issues are discussed in the following sections.



Malposition of the IUD

A low position of an IUD is a commonly encountered complication, with the patient usually having a long string. The malpositioned IUD can be visualized with the tip in the mid or lower uterus or in the cervix (Figure 15). Malpositioned IUDs can be a cause of pain, especially during intercourse. Intrauterine contraceptive devices in a slightly low position may spontaneously migrate into a normal position in 2 to 3 months. (19) 3D transvaginal sonography has been shown to be more accurate in identifying the type and location of the IUD than 2-dimensional transvaginal sonography. (20) Because structures that are not located in the same plane can be imaged simultaneously with this technique, 3D sonography is especially useful in accurate evaluation of misplaced IUDs. (21)

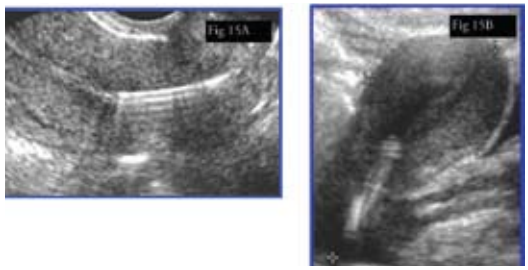


Figure 15. Low position of an IUD. Sagittal transabdominal (A) and transvaginal (B) sonograms show a ParaGard IUD low in the uterus, extending into the cervix.

In patients with prior uterine surgery, it is possible that the IUD will migrate into the scar and be a cause of pain. In our anecdotal experience, patients with prior cesarean deliveries may have extension of the lower end of the IUD into the scar (Figure 16).

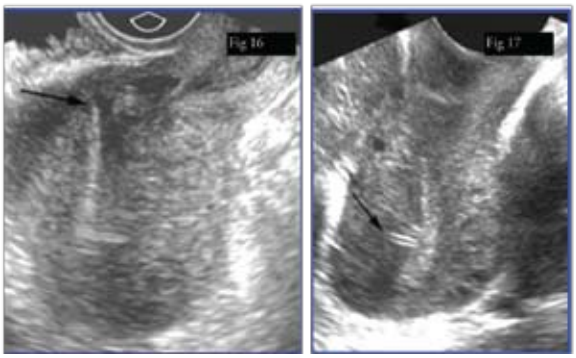
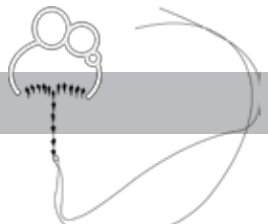


Figure 16. Intrauterine contraceptive device in a cesarean delivery scar in a patient with pelvic pain. Sagittal transvaginal sonogram shows the lower portion of a Mirena IUD (arrow) extending into the defect of the cesarean delivery scar.

Figure 17. Intrauterine contraceptive device perforation. Sagittal transvaginal sonogram shows one of the crossbars (arrow) of the IUD extending out of the endometrial cavity into the myometrium

Malposition can also occur when the shaft or crossbar of an IUD extends into the myometrium. The patient may have pain. Clues to this diagnosis are when the crossbars are low in the uterus or when they extend in an anteroposterior direction rather than the typical transverse position in the uterine fundus (Figure 17). Extension into the myometrium typically occurs at the time of insertion. When scanning women with IUDs in place, it is important to assess for extension of the echogenic portion of the IUD outside the endometrium into the myometrium.



Uterine Expulsion

The expulsion rate is highest when the IUD is placed in the immediate postpartum period after a vaginal delivery. (22)

Uterine Perforation

The perforation rate for IUDs is quoted as 1 to 2 per 1000 and is increased in the following instances: (1) with placement by inexperienced operators; (2) when the IUD is placed less than 6 months postpartum; (3) in women with fewer prior pregnancies; and (4) in women with an increased number of miscarriages. (23) When the IUD migrates outside the uterus, it can lead to additional complications, such as bowel or bladder perforation. (24) In addition, in a hormone-containing IUD, the serum hormone levels can be up to 10 times higher when the IUD is in a peritoneal location than when it is intrauterine. When an IUD cannot be visualized sonographically, a plain radiograph of the abdomen can help in localizing the IUD (Figure 2). A CT scan of the abdomen can help in more accurate localization of an IUD for appropriate management.

Pregnancy in Patients With IUDs in Place

When pregnancy occurs with an IUD in the uterus, the pregnancy is usually ectopic because implantation is unlikely to occur in the endometrial cavity (Figure 18). Therefore, patients with IUDs in place and positive pregnancy test results should be expected to have ectopic pregnancy until proven otherwise. However, intrauterine pregnancy can also occur (Figure 19). In patients with IUDs and intrauterine pregnancy, the IUD typically is removed under sonographic guidance to lessen the risks of infection, miscarriage, and premature delivery, which can occur if the IUD is left in place. (25)

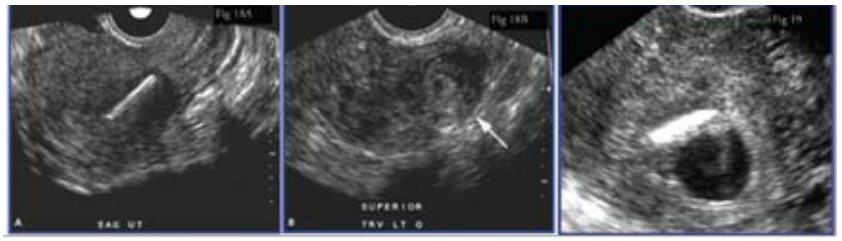
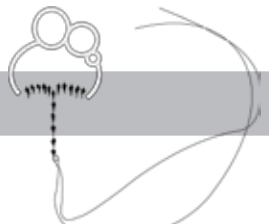


Figure 18. Ectopic pregnancy in a patient with an IUD in the uterus and a human chorionic gonadotropin value of 1300 mIU/mL 5 weeks 5 days after her last menstrual period. A, Sagittal transvaginal sonogram shows the IUD in the uterus. There was also free fluid in the pelvis (not shown). B, Transvaginal transverse sonogram shows a left adnexal mass (arrow) superior to and separate from the ovary on real-time imaging. This was confirmed to be an ectopic pregnancy at surgery

Figure 19. Intrauterine contraceptive device and intrauterine gestation. Sagittal transvaginal sonogram shows an intrauterine gestational sac adjacent to the IUD.



Pelvic Inflammatory Disease

Patients with IUDs are at increased risk of pelvic inflammatory disease, although this risk is less common than in the past. The presence of cervical chlamydial or gonorrheal infection at the time of insertion of an IUD increases the risk of infection. (26) Pelvic inflammatory disease can manifest as endometritis, pyosalpinx, or a tuboovarian abscess (Figures 20 and 21). A CT scan of the pelvis is useful in evaluating the extent of inflammatory disease. (27)

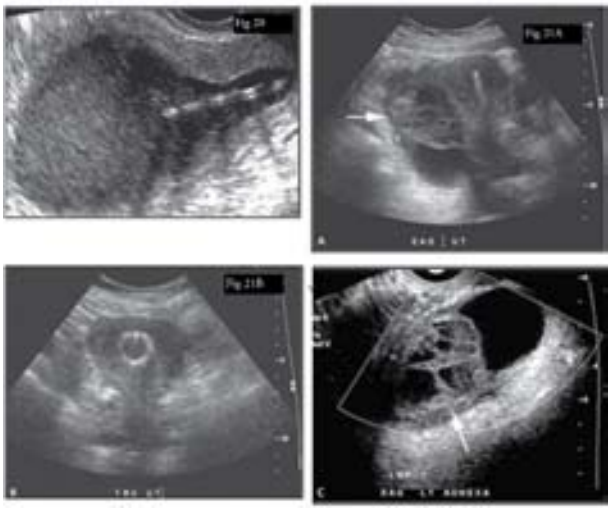


Figure 20. Pyohematometra in association with an IUD. Sagittal transvaginal sonogram shows a distended uterus with complex echogenic fluid and a Lippes Loop IUD in a low position. At surgery, pyohematometra was confirmed.

Figure 21. Ring IUD and pelvic inflammatory disease in a woman with vaginal bleeding, left lower quadrant pain, and fever. A, Sagittal transabdominal sonogram shows the IUD and a complex fluid collection in the left adnexa (arrow). The IUD was removed, and patient improved with antibiotics. B, Transverse transabdominal sonogram shows the ring-shaped IUD in the uterus. C, Sagittal transvaginal sonogram shows the internal architecture of the left adnexal complex fluid collection more clearly (arrow).

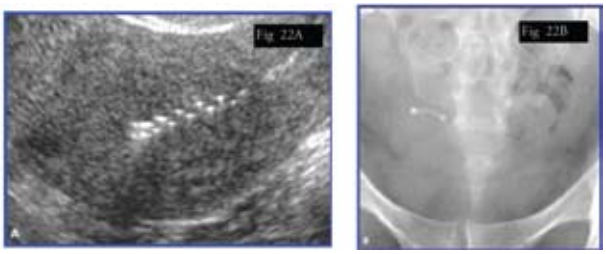


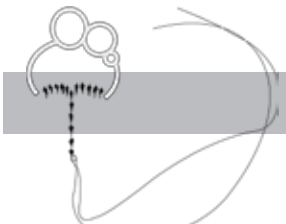
Figure 22. Fragmented ring IUD in a patient who had pelvic pain and bleeding. A, Sagittal sonogram shows a discontinuous echogenic foreign body in the uterus. B, Frontal pelvic radiograph shows a fragmented IUD.

Retention and Fragmentation

An IUD left in the uterus for a prolonged period can become encrusted with a fibrous reaction and can be difficult to remove. At times, there can be fragmentation and retention of all or portions of the IUD (Figure 22).

Conclusions

Imaging, especially sonography, has a crucial role in evaluation IUD locations as well as management of associated complications. Knowledge of the various types of IUDs and their appearances will aid the imager in accurate assessment of the various types of IUDs.



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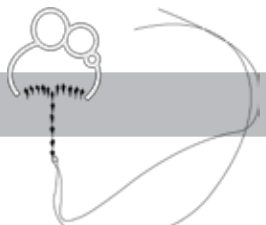

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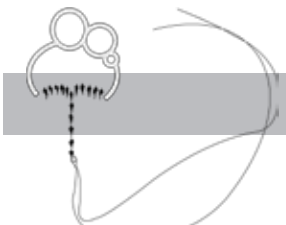


Myths and Misconceptions

Dr. Rishma Dhillon Pai & Dr. Hrishikesh D. Pai

Rumours are unconfirmed stories that are passed on from one person to another by word of mouth and these usually happen when an issue has not been clearly explained and there is no one to clarify the information.

A misconception is a mistaken interpretation of information.

Though IUCD's have been used for many years now and are backed up by a lot of scientific evidence, rumours and misconceptions about them, still persist. A negative opinion among potential users and providers based upon misconceptions or a lack of current scientific information is a major obstacle to IUD use.

How to deal with rumours and misconceptions.

- Always listen with attention to the patients ideas, even if they are wrong.
- Explain the facts.
- Use scientific facts – including the positive and negative effects of the method.
- Give examples of satisfied users.
- Reassure and let the patient know that you are available to solve any doubts or problems that she may have.

Rumour or misconceptions and the facts.

- The thread of the IIUD can harm or hurt the penis during intercourse:

  The stings of the IUD are soft, flexible and cling to the cervix or vaginal wall and are rarely felt during the intercourse. It can be cut very short in case it can be felt.• *A women with an IUD cannot do heavy work.*

  A IUD does not interfere in a women's life in anyway, in most cases she does not even realize that she has an IUD inside.

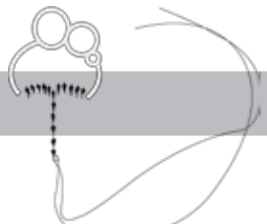
- A women becomes infertile after using an IUD

  A women's fertility comes back to normal soon after the IUD is removed.

- A IUD can migrate through the uterus to other parts of the body.

  There is not connection from the uterus to the other organs of the of the body. It can only get expelled and come out through the vagina or rarely can perforate through the uterus, usually during a wrong insertion technique.

- If a women with an IUD becomes pregnant, the IUD can hurt the baby.



If a woman gets pregnant with an IUD in the uterus, the IUD is usually removed to prevent infection. However if it is left inside it is usually expelled with the placenta and is never found inside the sac so as to hurt the baby.

- The IUD can rot inside the uterus if it remains there for long.

  The IUD is made of material that cannot get spoilt. However, its effectiveness becomes less and it may become more brittle with time.• You cannot insert an IUD till three months after delivery.

  The expulsion rates are higher if the IUD is inserted upto 48 hours after delivery. After 4 weeks postpartum, an IUD can be safely inserted. IUD does not affect breast milk and can be used safely during breastfeeding.

- IUD causes ectopic pregnancy.

  In fact, IUD's are so effective in preventing pregnancy, they protect well against ectopic pregnancy also. Infact, studies have shown that women who use copper or hormone IUD's have a such lower chance of an ectopic pregnancy than do women s using no contraception. However, if there is a pregnancy in a women with a Copper T, than it is more likely to be an ectopic than in a pregnancy in a non IUD user.

- An IUD can't be inserted after an abortion.

  After first trimester MTP or miscarriage and IUD can be inserted immediately provided the abortion is complete and there is no infection. After late second trimester abortions the IUD insertion should be delayed for six weeks.

- Nullipara's cannot use an IUD

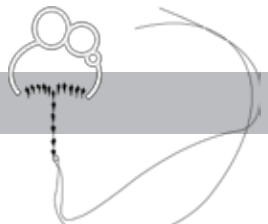
  According to the WHO, nulliparas fall into category II, where the benefits of IUD outweigh potential or known risks. These women have a slightly higher risk of IUD expulsions.

- Women with HIV cannot use an IUD.

  IUD is safe in HIV positive woman who are on antiretroviral treatment and no increased risk of infection.

- IUD's make a woman more prone to Pelvic Inflammatory disease.

  Many studies have shown that the IUD insertion process and not the IUD pose a risk of infection. If inserted with sterile precautions the risk of infection is low. PID in an IUD user is usually caused by an STD, such as Chlamydia or gonorrhoea and not by the IUD. The uterus is sterile while the vagina may have harmful bacteria with are then transferred into the uterus during IUD insertion. Therefore if the vaginal



or pelvicinfection is treated before inserting the IUD, there is no increased risk of infection.

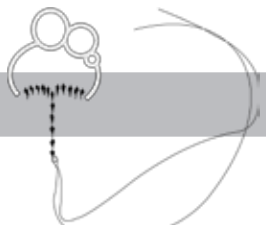
- IUD's act by preventing implantation, not fertilization hence are an interruption of pregnancy.

  The primary mechanism of action of copper IUD's is prevention of fertilization, hence even the population which is against abortions, can use this method as it does not work by preventing implantation of a fertilized egg (or early abortion).

- IUD's cause excessive menstrual bleeding.

  Excessive menstrual bleeding can occur due to increased fibronolytic activity in the endometrium following IUD use. This can be easily controlled by fibrinolytic inhibitors such as epsilon amino caproc acid. Also use of the hormone IUD significantly reduces menorrhagia and causes amenorrhoea in a majority of women.

Women deserve accurate information about all methods to make a well informed choice about their contraceptive use. IUD's are safe, effective, affordable and convenient to use, provided that are offered by high quality service delivery units.



Medicolegal issues in Intrauterine devices

Dr. Dilip Walke

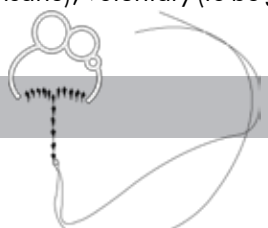
Intrauterine device is the commonest outdoor procedure carried out on in the OPD of an Obstetrician and Gynaecologist. The procedure though simple, is not entirely devoid of complications. Since it is a simple outdoor procedure, complications are not accepted to patients and there is very high chance that remedy is sought in courts. This short article aims at an overview of possible reasons for litigations and will attempt to draw message to avert such litigations.

The possible areas of litigation in IUD's are as follows

- Alleged negligence in technique of insertion
- Insertion by unqualified service provider
- Lack of proper counseling
- Complications like
    - Perforation
    - Infection
    - Failure leading to continuation of pregnancy

Negligence in insertion: The procedure while deciding a case of alleged negligence while performing any medical procedure has been described in details by the Supreme Court in the famous Jacob Mathews Vs State of Punjab case on 5th August 2005. Firstly it is decided whether the service provider possess the skill he claims to possess. Secondly it is decided whether a reasonable care was exercised while professing the skill. Here the Bolam test requires that he possess an average and ordinary skill in the field and not of highest standard. In case of IUD insertion there are no acts or law to govern the qualification of the provider. Several GOI schemes encourage training to paramedical staff to insert IUD. Hence any Gynaecologist by virtue of his/her degree is automatically qualified to insert an IUD. What remains to be proved (by way of notes on the OPD papers) is what steps were followed for insertion and whether they were correct. Ideal notes for IUD insertion are mentioned in "Stepping ahead" a booklet published during the 2nd national Medicolegal Conference held in Pune in 2007. OPD case paper should be complete with these notes. They are the documentary proof for correct technique of insertion.

Pre-procedure counseling: While alleging that there was lack of proper pre-procedure counseling the patient tries to prove that proper "informed consent" was not taken before inserting the IUD. The topic of consent has been dealt by the Supreme Court in the Sameera Kohli Vs Prabha Manchanda case of 16th Jan 2008. The three basic requirements of an ideal and legal consent are Capacity (should not be a minor or insane), Voluntary (to be given by the patient herself) and Knowledge (should be explained



the nature, benefits, side effects, alternatives and consequences of refusal of treatment). While further detailing about knowledge Court says that we are not expected to explain the remote or theoretical consequences of the treatment or those of refusal that the patient gets frightened or confused. A balance is expected of us. In case of procedure like IUD insertion, traditionally a written consent is not expected to be taken and the fact that patient has come for spacing, it is considered to be an implied consent. However if IUD is being inserted along with a surgical procedure like MTP, it is prudent to obtain a written consent. It still remains to be proved that patient was counseled about the procedure and its possible complications. The best way to prove that informed consent (albeit oral) was taken is to provide information booklets to the patient for reading and discussing before the procedure. Such booklets have been published during the 2nd National Medicolegal Conference held in Pune in 2007.

Post-insertion infection: For defending a case of post-insertion infection one has to provide documentary proof that all aseptic precautions were taken and the infection hence was not due to negligence on part of the provider. Following documents would help

- Autoclave register
- Fumigation registers of the OT
- Documentary proof of post insertion antibiotics (if prescribed)

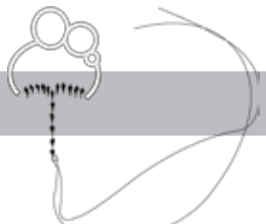
If follow up instructions are not followed by the patient, keep a proof of it to defend it as a case of contributory negligence.

Perforation: To defend a case of perforation one has to prove that patient was fully informed about this possible complication. The best way to prove this is to provide the patient with information booklets before the procedure as already described. Secondly one has to prove that proper care was taken to diagnose the complication and then to treat it. The follow-up case notes are of importance in this situation.

IUD failure: To defend a case of IUD failure and pregnancy with IUD, one has to prove that proper counseling about this complication was done (information booklets) and that she was asked to follow-up regularly. If patient had failed to follow-up it can be used in the court to prove contributory negligence.

Professional fees: One aspect of IUD especially in private practice deals with its charges. There are no restrictions on the professional charges of a private practitioner for insertion of an IUD since it is being used for commercial purpose alone. However it is unethical (as per the code of conducts of MCI) to sell an IUD to the patient at a rate higher than the market rate because that amounts to commercial activity which is unethical

Thus with proper counseling and documentation one can be sure of medicolegal safety in case of IUD. We need to be clinically alert, medicolegally aware and ethically acceptable.



Knowledge, Attitude, and Practice of Clinicians in India

Dr. Ritu Joshi & Dr. Girija Wagh

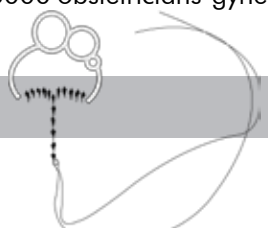
For the past decade, preventing unintended pregnancies has been an important issue for women's health. Against this background, the intrauterine device has been established either as the most cost effective method of contraception or the second most cost-effective reversible method. Despite the proven safety and cost effectiveness of today's IUDs, women who have unintended pregnancies are relying on less effective methods of contraception, many obstetric/gynecology professionals in India remain reluctant to recommend use of IUD, and around 1.6% of women in India report using IUD. This statistics contrasts sharply with the nearly 12% mean rate of IUD use world wide – a rate which has been measured as high as 33% in China and 18% in Scandinavia. In India, at least 37.3% of couples rely on permanent sterilization for contraception, although permanent contraception is not as cost effective as the IUD and is associated with higher morbidity rates and lower patient satisfaction rates.

The intrauterine device (IUD) provides safe and effective contraception. Before the debacle involving the Dalkon shield there was higher percentage of women using IUD. After the Dalkon shield, manufacturers withdrew most devices from the US market, and the IUD use decreased. Health care providers and public developed a persistent fear that all IUDs cause pelvic inflammatory disease (PID) despite evidence that modern Copper IUD insertion it rarely occurs, at a rate of 1.6 per 1000 woman-years of use. Reanalysis of earlier studies linking IUDs & PID question their methodology and generalizablility. The relative under use of the IUD in United States reflects these public and professional concerns. The reluctance of physicians to recommend IUDs except in narrowly selected patients contributes to this under use. There are many factors contributing to this reluctance, including a lack of training in use of IUDs during residency, a fear of litigation and a belief that the IUD creates a high risk of PID.

Little is known about how obstetricians-gynecologists use IUD in clinical practice, what their attitudes towards IUDs are, or how they select IUD candidates in their practice.

An electronic survey on knowledge, attitude and practice was started as a joint research venture by FOGSI-PSI in October 2009.

To understand the knowledge, attitudes and practices of obstetricians-gynecologists, a questionnaire was prepared and web enabled. The survey link was emailed to about 6000 obstetricians-gynecologists all over the country. The responses are directly fed into

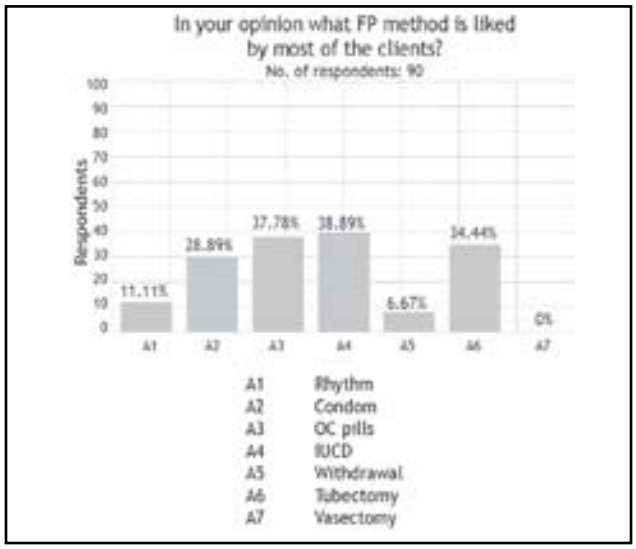


an online analytics engine that displays graphs and charts on various parameters of the survey dynamically. It continues to be available on the website where doctors interested in the survey can register and an email invite will be sent.

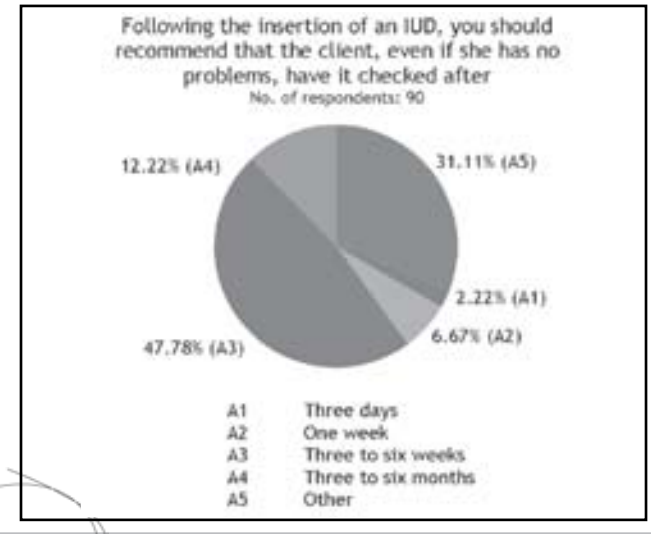
The questionnaire was divided into three areas – Knowledge and Attitude, Providing Services and the clients' profile.

Some of the questions in the knowledge and attitude area covered -

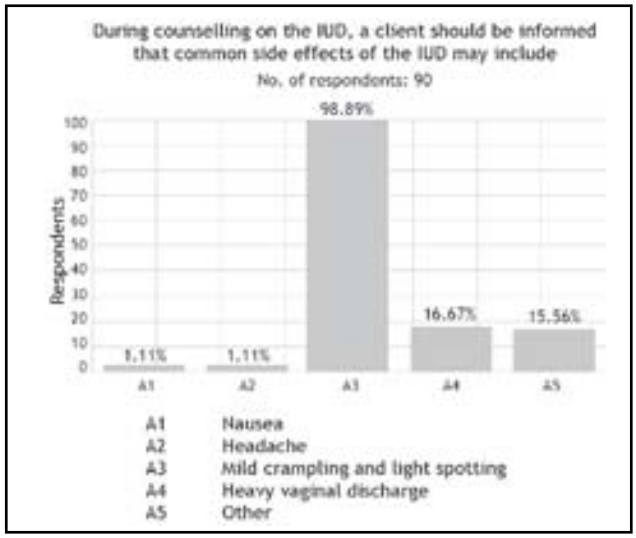
- Methods of family planning offered by the doctors to their clients (Cafeteria approach is offered mostly)
- Method most liked by the clients (OC Pills, IUD and Tubectomy)



- Following the insertion of the IUD, when should the client get it checked (50% of doctors say it is within 3 – 6 weeks)



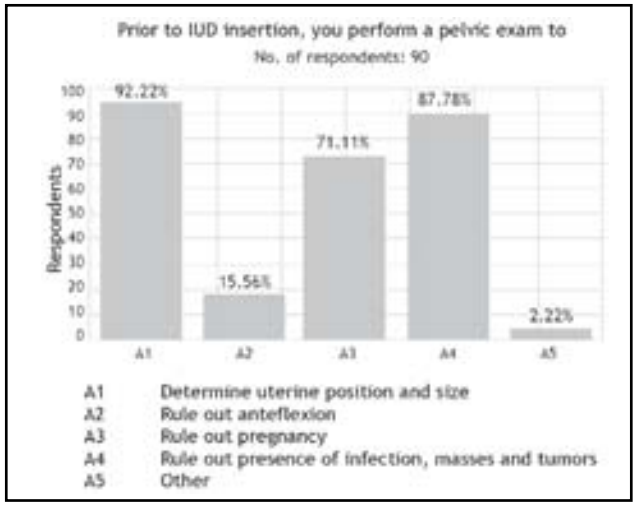
- IUD is not an appropriate contraceptive for women who have some conditions (98% say that she should not be recommended IUD when she has unexplained vaginal bleeding)
- The common side effects (98% of doctors say it is mild cramping and a little spotting)



- The effectiveness of the IUD (About 48% say it is greater than 99% while the rest say it is about 90- 95%)

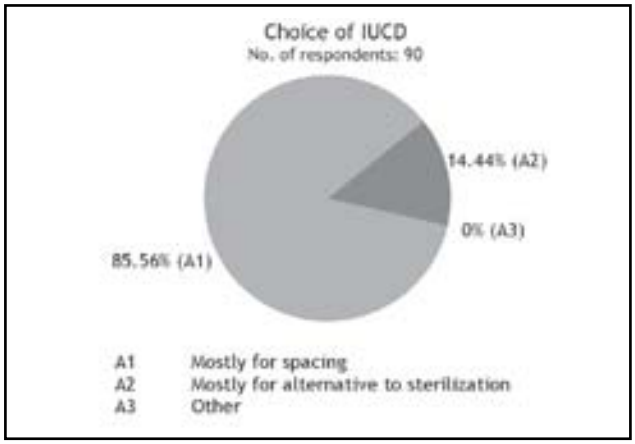
Some of the questions that the practices section covered were –

- The advantages of IUD (91% of the doctors say that it has no side effects for most women)
- Over 90% of doctors test for presence of infection, masses and tumors before recommending IUD
- Over 92% of the doctors determine Uterine Position and Size before inserting IUD



Some of the questions covered under clients' profile were –

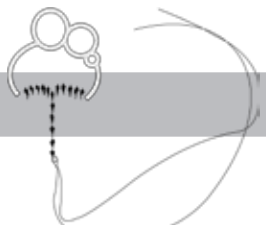
- The percentage of clients that ask for contraception(50% of the doctors say that 1 in 10 patients ask for contraception advice)
- After counseling, how many clients choose IUD over other methods (53% of the doctors say that most patients accept IUD)
- Time spent in counseling clients who want contraception (50% of the doctors spend about 10 minutes per patient, while 34% spend 20 minutes)
- Choice of IUD is mostly for spacing (85% of the doctors say that their clients choose it mostly for spacing)



- Percentage of clients that have some problems with IUD (About 70% of the doctors say that less than 10% of their patients have a problem)
- Main reason for women to discontinue IUD (Excess bleed – 60%)
- Average age of women who have IUD inserted (about 29 years)

Many women can safely use IUD to prevent unintended pregnancy. Educating physicians about the safety of IUD many expand their use of IUDs. More women would then be offered a method of convenient, safe, and highly effective long-term contraception.

(The web enabled survey and the associated analytics was constructed and deployed online by learn2turn consulting pvt ltd, Bangalore, a healthcare knowledge management company headed by Ravishankar Vishwanath. Dr Hema Divakar, working in conjunction with the Family Welfare Committee of FOGSI has provided her expert inputs on the questionnaire and the analytics.)



Recent Research - How Much & How Much More?

Dr. Hema Divakar & Dr. Bharti Dhorepatil

Population explosion is indeed a challenge to developing countries , including India and will continue to remain so for the next couple of decades. Safer contraceptives with additional health benefits are the demand for the future.

Changing behaviours,disease patterns,aging population and unmet needs of men and women are the driving factors for future research .

Exsisting contraceptive methods do not fit all and induce side effects.This article gives a brief overveiw of

- New contraceptive steroids
- Vaginal gels and dual protection methods
- Transdermal systems
- New long acting systems (one year rings,CDB 2914 - IUS)
- Progesterone receptor modulators
- Male contraception
- Non-hormonal methods on the horizon

(1) New contraceptive steroids

Newer selective non-androgenic progestins with estradiol -

Oral dienogest + E2V

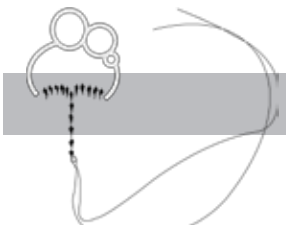
Oral nomegestrol Ac +E2

Non-oral (Nestorone +E2) in gels or rings

These have the benifits of no weight gain, no acne, no adverse effects on lipids.

Minimal impact on glucose and insulin is a great advantage to high risk Indian ethnic population for type II diabetes.

Cardiovascular risks are likely to be minimised since these preparations have less impact on blood vessels (ref 1)



(2) Vaginal gels and dual protection methods

Using a vaginal gel as a vehicle to deliver a progestin, levonorgestrel (LNG) to be used before intercourse.

When dosages of 0.75 mg /4ml gel was compared to equivalent dose by oral, the percentage of anoulation with follicular size stopping short at 12-14 mm was 100% with vaginal gel compared to 83% with oral. (Ref 2)

(3) Transdermal systems (TDS)

Using transdermal natural estrogen E2 should in theory be safer than EE

Drugs should pass through the skin more rapidly and form an invisible reservoir within the skin and the drug delivery applicators should be simple to use and accurate and flexible in dosing

New TDS of promise is Gestodene with low dose EE in phase III trials

(4) New long acting systems (one year rings,CDB 2914 - IUS)

The 1 year vaginal ring delivers NES/EE 150 /15 microgm per day for 13 cycles with 3 weeks on followed by one week off . This has been developed by Population Council

Dual protection ring has incorporated anti retroviral agents

(5) Progesterone Receptor (PR)modulator ring

Acts by blocking PR in the ovary

Inhibiting LH surge

Induces endometrial changes leading to ammenorrhea

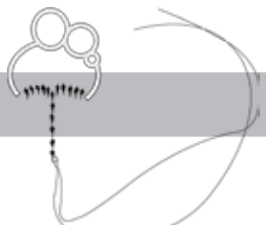
This offers estrogen free and bleed free contraception

This indeed has a high potential in fibroma, endometriosis and contraception. These are well tolerated molecules , but longterm safety on endometrium needs to be confirmed.

(6) Male contraception - is there a future?

It has taken long to develope, no advocay and support groups and not many industries coming forth with research!

A survey was conducted across Europe, USA, Latin America,Indonesia for determining willingness to use. Acceptance was only 28% in Indonesia representing developing



countries where the need is the most . As against this, the in advanced countries, acceptance was close to 50% (ref 3)

Same study showed that 64% of men desired the use of daily pill as against 46% who opted for monthly injection (ref 3)

The combination of oral testesterone formulations with anti gonadotropic agents are as follows-

* oral testesterone with Oral progestins.
* oral testesterone with dutasteride (inhibitor of 5 alpha reductase to prevent effects on prostrate
* oral testesterone with oral Acylin to decrease sperm production by blocking FSH, LH and Testesterone

IMPLANTS for use as male contraceptives - MENT

7 alpha -MEthyl - Nor - Testesterone

Is a tissue selective androgen with no effect on prostate.

And meant for one year of contraception causing azoospermia.

It maintains libido, muscle mass, and bone.

and this is a distinct advantage (ref 4)

Some targets for male contraceptive research revolve around preventing sperm entry into the ovum,produce immature sperm cells,and immotile spermatozoids

FUTURE HORIZONS

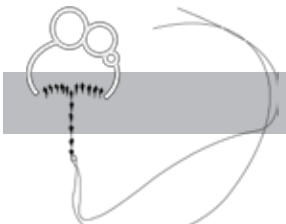
Novel methods of contraception with health benefits which are likely to be available soon are second generation pills with selective progestins and estradiol, Progesterone receptor modulators,smaller LNG - IUS for nulliparous women and male methods protecting the prostrate.

Genomics and Proteomics would proabaly identify genes regulating specific reproductive targets and also the enzymes, proteins, receptors and co-factors

Longterm safety remains an issue for contraceptive vaccines.

Anti-Sperm,anti-ZP,anti GnRH and anti- HCG contraceptive vaccines are currently under investigations.

Sperms constitute the most promising target for contraceptive vaccines.



Several sperm specific antigens are being explored.

Vaccines also target molecules involved in gamate function such as sperm antigens and zona pellucida proteins

HCG vaccine in phase 1 and phase II clinical trials with HCG tumors are promising

(Ref5)

CONCLUSIONS

Attitudes and roles have changed for the modern women with advancing education and career goals, relationship status and access to information.

Empowerment drives active involvement in individualised contraceptive choices.

In line with individualised contraceptive expectations of modern women leading modern lives, the quest in research continues.

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- Ref (2) Brache V et al , Contraception 2007 : 76; 111- 116
- Ref (3) Heineman K et al Hum Reprod 2005;20; 549 -556
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CONTRACEPTION QUIZ

Drs. Sheela Mane and Jyotika Desai

1. Previous history of Ectopic pregnancy is not a contraindication for
   a. COC
   b. POP
   c. IUCD
   d. LNGS

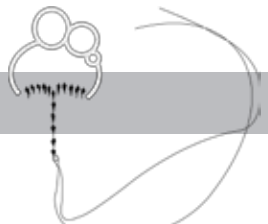
2. Which of the following sterilization procedures has the highest 10 year cumulative failure rates?
   a. Unipolar Coagulation
   b. Post partum Tubal Excision
   c. Falope Ring
   d. Hulka Clemens clip

3. Patients on Rifampicin should receive
   a. High dose OC pills only
   b. Non Hormonal methods of Contraception
   c. Very low dose OC pills only
   d. Any kind of OC pill

4. Which of the following is called "Billing"'s Method ?
   a. Coitus Interruptus
   b. Safe period method
   c. Cervical Mucus method
   d. Symptothermic method

5. Incidence of post pill amenorrhea is
   a. 0.07 % - 0.08 %
   b. 0.7 % - 0.8 %
   c. 7 % - 8 %
   d. 17 % - 18 %

6. The Unipath personal contraceptive system has dipsticks for
   a. Estrone 3 glucuronide & LH
   b. Pregnandiol glucuronide & LH
   c. FSH & LH
   d. Estradiol and pregnandiol



7. The following statement about female sterilization is not true
   a. Sterilisation at the time of Cesarean section has a higher failure rate than laparoscopic sterilization in nonpregnant.
   b. It is more likely to be regretted if performed at the time of termination of pregnancy
   c. It advances the age of menopause by an average of 3years.
   d. It does not eliminate the risk of ectopic pregnancy

8. Use of Copper to increase the contraceptive effectiveness of IUCDs was introduced by
   a. Dr. Jaime Zipper
   b. Dr. Tatum
   c. Dr. Jack Lippes
   d. Dr. William Van Os

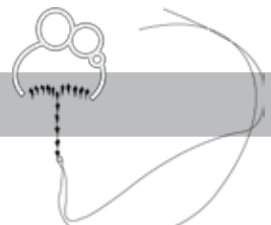
9. Condom was first introduced to
   a. Increase pleasure during intercourse
   b. To prevent STD
   c. To prevent unwanted pregnancy
   d. As a fancy item by the royals

10. Coitus saxonicus refers to
   a. Coitus interruptus
   b. Abstinence
   c. Oral sex
   d. Retrograde ejaculation

11. When to change from oral contraceptive to post menopausal hormone therapy in PM women
   a. At the age of 50
   b. When SH level is greater than 20 IU / L
   c. At the age of 55
   d. When the FSH level is greater than 50 IU / l

12. Break through bleeding in OC pill users may be due to all but
   a. Smoking
   b. Chlamydial infection
   c. Inconsistent use of the pill
   d. High progestin concentration in the pill

13. If a loop of the fallopian tube is crushed at the base and ligated with silk in the middle third portion, the method is called as
   a. Parkland's
   b. Kroener's



c. Madlener's
d. Pomeroy's

14. The Ogino – Knaus theory relates to

a. Rhythm method
b. Lactational amenorhoea method
c. Withdrawal method
d. BBT method

15. With a POP ovulation occurs in

a. 15% of pts
b. 30% of pts
c. 5% of pts
d. 40 % of pts

16. The only barrier contraceptive which needs a prescription is

a. Female Condom
b. Cervical cap
c. Diaphragm
d. Sponge

17. Dorairaj's triple method is a modification of

a. Lactation amenorrhoea method
b. BBT method
c. Billing's method
d. Coitus interruptus

18. All of the following are interceptive agents except

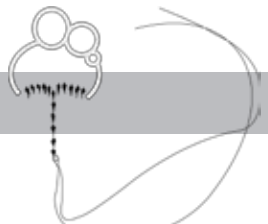
a. Oral stilbesterol
b. RU 486
c. IUCD
d. Intramuscular Injection of DMPA

19. ORTHO, MILER and PRENTIF…these are the names of

a. Diaphragms
b. Cervical Caps
c. Vault Caps
d. Vinule Caps

20. Who invented Laparoscopic sterilization?

a. Anderson
b. Kurt Semm



c. Bermheim
d. Jacobius

21. Drawbacks of Withdrawal method does not include
    a. High failure rate
    b. Hypothalamic amenorrhoea
    c. Sexual dissatisfaction and neurosis
    d. Pelvic inflammatory disease

22. The mechanism of action of anti HCG vaccine is referred to as
    a. Contraception
    b. Interception
    c. Chemical abortion
    d. None of the above

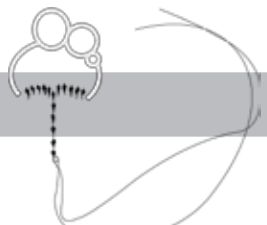
23. Pick the wrong statement about the Diaphragm
    a. It is as effective as a condom
    b. It should be used with a spermicide
    c. It does not protect against HIV
    d. It can safely be removed immediately after intercourse

24. The Unsafe period in a 28 day cycle is from
    a. Day 10 to 18
    b. Day 12 to 16
    c. Day 7 to 21
    d. Day14 to 22

25. Gynefix IUCD is:
    a. T shaped
    b. Ring shaped
    c. A string of cylinders
    d. None of the above

26. Which of the following adverse effect of the COC pill cannot be attributed to estrogen?
    a. Increase in fibrinogen
    b. Increase in other clotting factors
    c. Increase in Insulin resistance
    d. Increase in blood pressure.

27. The Distribution of Cu in Cu T380 is
    a. 314 Sqmm in the vertical stem and 33sqmm in each arm
    b. 320 Sqmm in the vertical stem and 30sqmm in each arm



c. 380 Sqmm in the vertical stem
d. 380 Sqmm in the arms

28. The Rovu meter measures

a. Cervico vaginal fluid volume
b. Urinary LH levels
c. Urinary Pregnanediol
d. Serum progesterone

29. Shelf life of a condom is

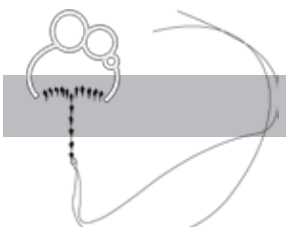
a. 2years
b. 3 years
c. 5 years
d. 7 years

30. Which of the following causes an increase in the SHBG?

a. Levonorgestrel
b. Medroxy Progesterone Acetate
c. Desogestrel
d. Norethindrone

KEY TO SCORE CARD - CONTRACEPTION QUIZ

Qn No	Ans	Qn No	Ans	Qn No	Ans
1	A	11	B	21	D
2	D	12	D	22	B
3	B	13	C	23	D
4	C	14	A	24	C
5	B	15	D	25	C
6	A	16	C	26	C
7	C	17	C	27	B
8	A	18	D	28	A
9	B	19	B	29	C
10	D	20	A	30	C



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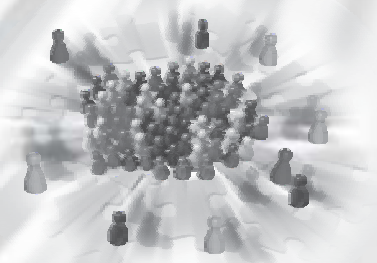

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Ashish Bhardwaj at ashish@psi.org.in