Companion for Obstetrics & Gynecology Practical Examination

Haresh U Doshi

SIXTEENTH EDITION

Foreword
NT Vani

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Contents

CHAPTER

5

Contraception

METHODS OF CONTRACEPTION

Contraception method of two types:
A. Temporary, B. Permanent

Temporary Contraception

- **Natural family planning methods**:
  - Total abstinence
  - *Coitus interruptus*: During sexual intercourse (coitus) penis is withdrawn from vagina just before ejaculation.
  - *Lactational amenorrhea method (LAM):* Criteria for this method include
    - Exclusive breastfeeding
    - Menstruation has not started
    - Up to 6 months postpartum

    It is effective in preventing pregnancy by 98%.
  - Methods based on fertility awareness:
    - Calendar or rhythm method: Record the number of days for previous six menstrual cycles. Subtract 18 from the length of her shortest cycle. This is first day of her fertile period. Then subtract 11 days from the length of her longest cycle. This is the last day of her fertile period. Sexual intercourse is avoided during this period.
    - Basal body temperature method (BBT): Daily morning temperature is recorded before getting up from the bed. With ovulation temperature rises to 0.4°F or more due to progesterone effect. Fertile period ends three days after the temperature rise. In this method preovulatory safe period is not detected. Couple has to abstain from intercourse for a longer period, i.e. onset of menses to end of fertile period.
    - Cervical mucous (billings method): Here the fertile period starts from the first day of any cervical secretions or feeling of vaginal wetness until the 4th day after the peak day of slippery secretions. Its typical use failure rate is up to 22%.
    - Symptothermal method: At least 2 indicators are used to identify fertile period, i.e. BBT+ Cervical mucous or BBT + calendar rhythm for calculating fertile period.
    - High tech hormonal monitoring: Here small electronic devices detect urinary metabolites of LH and estrogen, estrone-3-glucuronide (E_3G). Threshold level of estrogen determines the beginning of the fertile period and 4 days past a threshold level of LH marks the end of fertile period. "Persona" is such personal device with test strips. The

strips are daily dipped into urine and then fed into the monitor. A green light displayed on the device means a woman is not fertile, a red light indicates that a woman is at or near ovulation and woman should then abstain from intercourse. It is 94% reliable.

- **Barrier contraceptives:**
  - *Mechanical*:
    - Male: Condom
    - Female: Female condom, diaphragm, Cervical cap, dumas cap, etc.
  - Chemical: Spermicidal substances in the form of foam tablets, creams, jellies, suppositories.
  - Combined: Mechanical + chemical.
- Intrauterine contraceptive devices (IUCD): TCu 380A, multiload 250/375, Mirena, etc.
- Steroidal contraceptives: Oral contraceptives (OCs), injectables, implants, vaginal rings, skin patch.
- Emergency contraception: Postcoital contraception.
- Uterotubal junction devices – Silastic or ceramic plugs, Essure coils.
- Miscellaneous: Male pill - gossypol immunological (under research).

Permanent Contraception

- Male: Vasectomy operation.
- Female: Different sterilization operations (See Chapter 9)

Commonly used temporary methods are discussed.

BARRIER CONTRACEPTIVES

They are especially suitable for the following couples:

- Those who have contraindications to OCs and IUCDs
- Those who cannot tolerate OCs and IUCDs
- Those who have intercourse infrequently
- Those who take a break, for a period of time from OCs and IUCDs
- Those who are sexually active with a number of partners
- Those who for personal reasons prefer not to use OCs or IUCDs.

CONDOM

It is male barrier contraceptive. The origin of word "Condom" is believed to have come from the latin word "Condom" meaning a receptacle. Its invention is also attributed to physician Dr Condom who recommended it to King Charles II to prevent illegal offsprings. It is made up of fine latex material and is disposable one. Thick rubber washable (reusable) condoms, used in past, are now outdated. The natural (animal) membrane (lambskin) condoms are also rarely used. They are costly and as they contain tiny pores transmission of HIV and other STIs is not prevented unlike other condoms.

Latex condoms are available in different sizes from 160–180 mm length, 49–52 mm in flat width and thickness varying from 0.04 to 0.07 mm. It may be plain or there is teat at the tip for collection of semen during ejaculation. It is available in different colors and also as flavored condoms, warming condoms, glow in the dark condoms, etc. It is always checked by manufacturer for tear or leaks, so there is no need for retesting by the user. It can be prelubricated type, e.g. Deluxe Nirodh, Durex, Kamasutra or spermicidal ones, e.g. Rakshak, Share. According to WHO spermicidally lubricated condoms should no longer be promoted.

Method of Use

- It should be applied on erect penis and prelubricated one is preferred.
- If there is no teat, some space pressed empty of air, is left at the end.
- During sexual act, after ejaculation is over one should be sure that condom does not get dislodged from the penis, i.e. penis should be withdrawn while still erect and

condom should be held firmly at the root of the penis by fingers.
- Chemical contraceptive (spermicidally jelly) used along with it gives extra protection and lubrication.
- Do not use oil based lubricants with condom, it might break the condom.
- Store condoms in a cool, dark place. Heat, light and humidity damage condoms.
- Handle condoms carefully. Fingernails and rings can tear them.
- Do not unroll condoms before use. This may weaken them. Also, an unrolled condom is difficult to put on.
- Check the condom for tear before throwing it away and if it has torn, use one of the emergency contraceptive methods.
- Do not reuse the condom. Do not use double condoms.

New polyurethane condoms are nonlatex condoms available as "Avanti, on", etc. Polyurethane is resistant to deterioration. They are thinner, stronger and less elastic than latex. It is useful for those who are sensitive or allergic to latex. Tactylon is a new condom made up of synthetic material styrene ethylene butylene styrene (SEBS). Polyisoprene condoms (SKYN) are also new nonlatex condoms. As compared to polyurethane condoms they are softer, stretchier and more resistant to breakage.

The newer condoms are claimed to have less odor, fit more comfortably and are less constricting. However, they brake or slip more often during intercourse than latex condoms yet the failure rate is almost same.

Advantages

- Easy to use
- Relatively cheap
- Freely available without medical supervision prescription
- Failure rate is low as compared to physiological and chemical methods
- Protects against common vaginal infections, i.e. trichomoniasis and moniliasis as well as sexually transmitted diseases like syphilis, gonorrhea, nongonoccocal urethritis, chlamydia, herpes virus, human papilloma virus, hepatitis B virus and human immunodeficiency virus (HIV) infection.
- Protects against Ca cervix. Because Ca cervix is caused by highly oncogenic strains (e.g. 16, 18) of human papilloma virus which is sexually transmitted.
- Safe. No hormonal side effects.
- Can be used at any age.
- Often helps in preventing premature ejaculation.
- Can be used where pills and IUCD are contraindicated, i.e. follow-up of vesicular mole, diabetes, valvular heart disease.

Disadvantages

- Failure rate is high as compared to IUCD and pills.
- Because it prevents full genital contact, it may decrease sensation making sex less enjoyable for either partner.
- Couple require some time to put the condom on the erect penis before sex. It must be readily available.
- In male partner rarely it causes psychological disturbances and even impotence.
- Disposal is a social problem. It may embarrass some couples to buy condoms.
- Hypersensitivity reaction to either of the partners.

Failure rate: 3–18/100 women years observation (3–8/HWY if used with chemical contraceptive). It is known as **Pearl index.**

Pearl Index

The **Pearl index** is defined as the number of contraceptive failures per 100 women-years of exposure so the formula would be:

Pearl index

$$= \frac{\text{No. of Pregnancies} \times 12}{\text{No. of women} \times \text{No. of months}} \times 100$$

There are two types of failure rates described.

1. **Typical use failure rate:** Failure rate occurring with that contraceptive method used in real life scenario. It takes into account human error.
2. **Perfect use failure rate**: Failure rate occurring with correct and consistent use of that contraceptive method. It happens in clinical trial.

Usually the typical use failure rate for any contraceptive method is higher than perfect use failure rate except LARC (long acting reversible contraception) methods.

Causes of Failure

- Incorrect use
- Inconsistent use. Not used with each sexual act, e.g. patient under effect of alcohol
- Defect in condom
- Used without chemical contraceptive
- Tearing or bursting of condom during sexual act (4%).

Other Uses of Condom

- In **transvaginal sonography:** It is applied over the vaginal probe to prevent cross infection
- In obstetrics condom is used to create **condom balloon tamponade** in treatment of **atonic PPH.** It is done aseptically by tying condom to simple rubber catheter or Foley's catheter, passing it into the uterine cavity and inflating it by 250–500 mL normal saline as per need. It is kept for 12–24 hours and then gradually deflated at convenient hour.
- For preparation of **mould for vaginoplasty.**
- Immunological cervical factor in infertility. Husband should use it for 3 to 6 months so that antibody level against the sperms in cervical mucous decreases. Then chances of pregnancy might increase.
- Threatened abortion: After 4 to 6 weeks if couple resumes sexual relations, male partner should use condom, because semen contains prostaglandins which may cause abortion.

Female Condom (Fem Shield)

It is a female barrier contraceptive. It has combined features of diaphragm and condom. It consists of two flexible polyurethane rings located at the either end of a 15 cm soft loose fitting polyurethane sheath. The inner ring is placed high in vagina, while outer ring covers the labia and base of penis. It is prelubricated with silicone based lubricant. It is available with different names, e.g. Reality, Femidom, Femshield. New FC2 female condom is made from synthetic nitrile, which is softer than polyurethane (FC1) and less costly.

Figs. 5.1A to C: (A) Male condom; (B) Female condom; (C) Diaphragm.

Advantages

- Controlled by woman
- It prevents STDs more effectively than condom as it covers some perineal area also.
- No allergic reactions as it is made up of polyurethane.
- More convenient than male condom as it can be inserted precoitus.
- Less chances of breakage.

Disadvantages

- Expensive.
- Some women have difficulties in insertion.

It is meant for single time use however WHO recommends reuse for maximum 5 times with proper care for disinfection, washing and drying. Its perfect use failure rate is 5% while typical use failure rate is 21%.

VAGINAL DIAPHRAGM (DUTCH CAP)

It is female barrier contraceptive. It is saucer shaped device made up of latex or silicone with flexible metal spring in its rim. Spring can be of different types, i.e. arcing spring coil spring or flat spring. It is available in 5–10 cm diameters with 2.5–5 mm increments. Its rim fits firmly across the vagina from upper end in the posterior fornix to lower end at the back of symphysis pubis (at least one finger breadth above external urinary meatus). Its typical use failure rate is 12%.

Method of Use

Patient should be able to feel her cervix by self-examination. Spermicidal jelly is smeared on both sides of diaphragm and some jelly is taken in hollow. It also lubricates the instrument. It is inserted before the sexual act in a squatting position or sitting at the edge of the table. Before use check for its intactness by filling it with clean water. Diaphragm is compressed between fingers and thumb, introduced in A-P diameter and upper end is pushed by index finger high up in posterior fornix. It should be kept for minimum 6 hours after sexual act. It remains in position by tension of the spring and elasticity of vaginal wall.

- Douching is unnecessary but if it is done it should be done before the diaphragm is removed.
- Refitting is advisable after pelvic surgery, delivery, annually or after rapid and large alterations in weight (10 kg or more).
- Changed yearly as wear and tear process may occur.

Contraindications

These include uterine or vaginal wall prolapse. Severe retroversion, local infection and allergy to rubber.

Failure rate: 4–12/100 women years.

Failure can be due to wrong size, improper insertion, lack of spermicidal jelly, defect in the diaphragm or displacement during coitus.

Advantages

- Relatively cheap.
- Effective as compared to physiological and chemical methods.
- Used by female so cooperation of male partner is not required.
- It does not interfere with natural coitus or orgasm of either of the partners.
- It also gives some protection against PID.

Disadvantages

- In sensitive patients it may cause embarrassment and some women may consider diaphragm unesthetic. Use of spermicide is messy.
- Failure rate is high as compared to IUCD and pills.
- High degree of motivation of the patient is required for its use.
- Allergic reactions to rubber may occur.
- Vaginitis, UTI and rarely toxic shock syndrome are reported.

Preservation: After use wash it with mild soap and warm water, then it is kept in its container or wrapped in clean cloth.

Other female barrier contraceptives are cervical cap, dumas cap (Vault cap), vimule cap. Contra cap is cervical cap with one way valve, which is said to permit the passage of cervical secretions and menstrual fluid down in the vagina but not sperms upwards.

Today

Today is vaginal contraceptive sponge containing 100 mg of Nonoxynol-9. It is effective for 24 hours. It is made wet with clean water before insertion. One should wait for 6 hours after last intercourse before removing the sponge. Sponge should not be kept in vagina for > 30 hours. One should not reuse

the sponge. Today is also available as small pessary form containing Nonxynol-9.

Nonoxynol has bactericidal and virucidal activity, however it does not effectively prevent HIV infection or other STIs. Usually, there are no major side effects. It may produce allergic type reactions and vaginal or penile irritation. Patient may have vaginal discomfort like soreness, itching, stinging. Rarely toxic shock syndrome can occur.

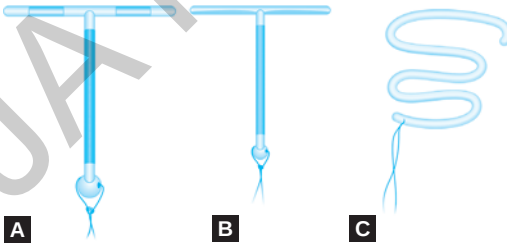
INTRAUTERINE CONTRACEPTIVE DEVICES (IUCD)

Grafenberg's ring, a silver coiled wire ring was the first popular IUCD widely used in the past. It was introduced by Grafenberg of Germany in 1929. Since then many different types of devices are invented. They are divided into two groups: **first generation** or inert or unmedicated devices, e.g. Lippes loop, Saf-T-coil, **second generation** or bioactive or medicated devices containing metals like copper (Cu-T, Cu-7,) zinc, silver or containing hormones, e.g. Mirena, Progestasert.

Hormone containing IUCDs are also called as **third generation** IUCDs.

Various IUCDs were used in past, e.g. Grafenberg's ring, Chinese ring, Ota ring, Birnberg bow, Margulies coil, soonawala loop, Saf-t-coil, Dalkon shield, Hall-stone ring, Antigon-F, Dana super.

Copper- T was invented by Howard Tatum (USA) and Jaime Zipper (Chile).



Figs. 5.2A to C: (A) T Cu 380 A; (B) Cu-T 200; (C) Lippes loop.

TCu 380A

TCu 380A is a T-shaped IUCD made from low density polyethylene with barium sulfate added for X-ray opacity. The device is 32 mm wide and 36 mm long with plastic ball at the bottom of vertical stem to prevent cervical penetration. Copper wire (surface area 310 mm^2) is wound tightly around the vertical stem. There are 2 solid copper sleeves on transverse arms. (each has surface area 35 mm^2). Thus total surface area is 380 mm^2. It has 2 monofilament polyethylene white threads tied through a hole in the ball at lower end. The diameter of vertical stem is 1.5 mm and that of horizontal arm is 1.6 mm. Its applicator, made up of synthetic plastic consists of cannula with guard and a plunger rod. Guard is blue and mobile. Cu-T along with its applicator is supplied in a plastic pack presterilized by gamma radiation.

Specifications:

- Length - 36 mm
- Width - 32 mm
- Weight - 310 mg
- Surface area of copper - 380 sq mm
- Diameter - 0.25 mm

The Cu-T 380S (slim line) has the copper wire on vertical stem as usual but copper sleeves are the ends of horizontal arms (as against middle of each arm in 380A) embedded into the arms. In TCu-380 Ag (silver line) copper wire on the vertical stem has a silver core. The silver core prevents fragmentation of copper and lengthens the effective life of the device.

Copper T (Cu-T 200)

Previously Cu-T 200 was used. Its dimensions are same as Cu-T 380, but it has only copper wire on vertical stem (surface area 200 mm^2) and no copper sleeves on transverse arms. Cu-T 200 B has a small ball at its lower end.

Lippes Loop

It was serpentine device made up of polyethylene or polypropylene. It was barium

sulfate impregnated device. It was available in 4 sizes: A, B, C, and D with difference in length, width, and color of 2 nylon threads. Its guard was white and fixed. With Cu-T available since decades lippes loop is not used or available now.

Time of Insertion

- During menstrual period from 2nd day onwards or within 10 days of menstruation. (During menses it is easy to insert and bleeding related to insertion is masked). It can be inserted even after 10 days if patient is sure of not pregnant.
- Immediately after first trimester MTP or spontaneous abortion or within 7 days.
- Postpartum
  - Postplacental
  - Within 48 hours
  - After 4 weeks

  Postplacental insertion is done within 10 minutes of placental delivery vaginally (If required by using long sponge holding forceps). At cesarean section it is inserted manually before the uterus is closed. Long nylon threads are passed down the cervical canal in the vagina and cut short in follow-up.
- Postcoital - within 5 days of unprotected intercourse in a fertile period, i.e. as emergency contraception.

Life Span

- Cu-T 380A is for 10 years. Its effectively decreases afterwards.
- There is no time limit for non-medicated device, i.e. loop. It can remain for several years without causing any harm.

Contraindications

Absolute

As per WHO Medical Eligibility Criteria (discussed under steroidal contraceptives) 2015 following conditions are **category 4** for copper IUDS:

- Suspected pregnancy.
- Postabortal or puerperal sepsis.
- Unexplained abnormal vaginal bleeding.
- Cervical or uterine cancer
- STI
- Pelvic tuberculosis.
- Uterine abnormalities
- H/O pelvic infection in past 3 months.

Category 3

- Postpartum between 48 hours and 4 weeks.
- Benign gestational trophoblastic disease
- Ovarian cancer.
- AIDS.

Method of Insertion

- Patient is explained about the type, principles, side effects and failure rate, etc. of the device.
- Informed consent is taken.
- Detailed history is elicited and complete pelvic examination is done to rule out contraindications.
- Full aseptic and antiseptic precautions are observed.
- Sounding is done to know the direction and the length of utero-cervical canal.

For TCu380A Withdrawal Technique

Loaded applicator is introduced with guard adjusted at the total utero-cervical length of that patient, so that when the guard is at external OS, tip of the applicator with Cu-T is at fundus. Now plunger is fixed by one hand and cannula is withdrawn over it, so Cu-T is released high up at fundus without being pushed. Then plunger is withdrawn, cannula is withdrawn and threads are cut for 2–3 cm from external so that patient can easily feel it by self-examination.

Method of Removal

Per-speculum examination is done, threads are visualized, caught by any simple instrument, i.e. artery forceps and the device is pulled out. It should be checked for its intactness.

Advice to the patient

- Patient is taught to feel the thread by self-examination and should regularly check the thread and particularly after the first menstrual period.
- She is informed about possible initial reactions increased bleeding, pain for first 2–3 months, etc. They are treated symptomatically. They gradually disappear with time.
- She should come for follow-up after first menstrual period and then yearly.
- She should consult the doctor immediately if she misses a period, it she develops any complications, or if she does not feel the thread.
- The device should be replaced, when time limit is over.

Mechanism of Action

Exact mechanism of action for Cu-T is not yet established. It works primarily by preventing fertilization.

- Presence of device with its nylon thread causes mechanical obstruction to ascent of sperms.
- Nylon threads cause changes in the cervical mucous and make it hostile to sperms.
- IgM levels in serum is increased so antifertility action is in part to their ability to produce antibodies.
- Actions of copper:
  - Directly damages sperms and fertilized ovum.
  - Biochemical changes in cervical mucous and renders it hostile. Sperm motility and capacitation are affected.
  - Changes in the endometrium: (1) enzymatic inhibition, i.e. carbonic anhydrase (copper replaces zinc), alkaline phosphatase, glycogen synthase, etc., (2) intense leukocytic infiltration, (3) changes in DNA constituent of endometrial cells, (4) decrease in glycogen content of cells, (5) increase in fibrinolytic activity of endometrium, and (6) endometrial vasoconstriction and ischemic damage.
- Increase in tubal motility so fertilized ovum, before it is mature enough for implantation, reaches the uterus which is also unprepared.
- Increase in uterine contractions which result in expulsion of newly implanted ovum.
- Device causes low-grade tissue reaction (i.e. inflammatory) in the endometrium making it unreceptable for implantation. It attracts macrophages which engulf the sperms as well as fertilized ovum by phagocytosis.

Indications for Removal of Cu-T

- If patient develops complications
- Time is over
- Patient has entered in menopause
- Displaced device
- Patient wants to become pregnant
- Failure - pregnancy
- Sterilization operation of patient or her husband

Failure rate: Both typical use failure rate and perfect use failure rate is < 1%.

Side-effects and Complications

- Menstrual problems: Spotting, heavy periods and prolonged periods frequently occur in first 2–3 months
- Cramps like pain in lower abdomen. Removal due to excessive bleeding and pain occurs in 5–15/100 users
- Dysmenorrhea: Spasmodic type, with infection there can be congestive type also
- Leukorrhea
- Pelvic infection: Risk is more in first month of insertion. It occurs if IUD is inserted without proper aseptic precautions or it is inserted in presence of an undiagnosed pelvic infections. If may also develop later in women at risk of STIs. If infection is diagnosed treat it with proper antibiotics.

There is no need to remove IUD if woman wishes to continue its use.

- Displacement - Device may penetrate the uterine wall or cause perforation of uterus and migrate into pelvis or upper abdomen. Perforation commonly occurs at the time of insertion. Common sites of perforation are fundal and isthmic region. Incidence of perforations is 1 to 3 per 1000 insertions.
- Spontaneous expulsion - During first menstrual period or within the first year of insertion. Women who had dysmenorrhea or heavy menstrual flows are more likely to expel IUDS. The rate is 5–15/1000 insertions.
- Failure, i.e. pregnancy (discussed later).
- Ectopic pregnancy: 3–4% of pregnancies with IUCDs are ectopic, but as the failure rate is very low, overall there is protection against ectopic pregnancy as compared to no contraception used.
- Fracture or breaking of IUCD and embedding in the endometrium resulting in decreased efficacy and difficulty in removal.
- Rarely fainting and collapse at the time of insertion if patient is not properly motivated.

Advantages of IUCD over Other Methods

- Simplicity in insertion
- No loss of time
- Return of fertility is immediate on removal of device
- Cheap (supplied free by Government)
- Does not interfere with sexual act
- No systemic side effects
- Less failure rate (except pills)
- Long-term - TCu 380 A lasts for 10 years
- No effect on breast milk, can be inserted immediately after child birth.

Disadvantages

- Side effects: As mentioned before
- Does not prevent HIV/STDs
- Patient cannot use on her own or stop on her own. Some medical help required for insertion and removal
- May get expelled out without woman's knowledge
- Male partner may feel the strings during sexual act.

Other Uses of Cu-T

- After breaking of adhesions in a case of uterine synechia (Asherman syndrome) to prevent refusion of walls. Cu-T after removal of copper wire is kept.
- After strassman operation - to prevent fusion of anterior and posterior walls.

Management of a Patient who does not feel the Threads

Possibilities Mistake of the Patient

- Indrawing of threads inside the uterine cavity or cervix, or it is torn and expelled out.
- Perforation of uterus and migration in the peritoneal cavity.
- Spontaneous expulsion.
  - Do per speculum examination, if the thread is seen everything is alright and make the patient to palpate it.
  - If thread is not seen, USG (TVS) is done, if the device is inside the uterus it is easily seen on USG. But, if it has migrated in the peritoneal cavity it is **not seen on USG. Take simple X-ray abdomen,** if device is not seen anywhere in the X-ray, it is expelled out.
  - But, if it is seen in the X-ray it is displaced device.
  - IUCD whether it is intra-uterine or extra-uterine was in past checked by one of the following:
    1. A-P and lateral X-ray,
    2. A-P X-ray and X-ray with sounding after moving the uterus
    3. HSG.

Treatment

Any displaced IUCD requires removal either by laparoscopy or laparotomy. Medical devices cause adhesions and intestinal obstruction. In such situations patients is also psychologically disturbed.

If it is intrauterine it can be removed by different instruments like simple curette, long artery forceps, uterine dressing forceps, Shirodkar hook or with the help of hysteroscope. It may be badly embedded.

Management of Patient having Pregnancy with Cu-T in situ

Advice should be termination with removal of Cu-T because of following risks:

Increased risk of abortion, septic abortion, premature rupture of membranes, premature labor, IUGR, accidental hemorrhage, puerperal sepsis and ectopic pregnancy. However, it does not produce any congenital malformation.

With all risks explained, if patient is keen to continue her pregnancy at least Cu-T should be removed- if uterus is less than 12 weeks, if threads are seen and if device can be removed easily without disturbing the pregnancy. Otherwise leave it. Cu-T may be retrieved at the time of delivery.

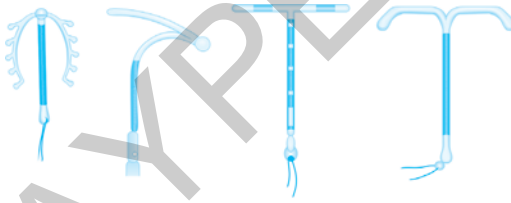


Fig. 5.3: From left to right multiload, Cu-7, TCu-220, and Nova T.

Other IUCDs

Multiload-Cu 250 (or Multiload-Cu 375)

It is made up of mixture of high density polypropylene and ethylene vinyl acetate copolymer impregnated with barium sulfate. Its shape is different from Cu-T, i.e. side arms of T are bent with small outer projections (Serrated fins) which help to hold the device in place without stretching the uterine cavity. Copper wire with 250 sq mm (or 375 sq mm) surface area is wrapped around vertical arm. Both are 36 mm long and 21 mm wide, but multiload Cu-375 has copper wire of 0.4 mm diameter effective life for Cu-250 is 3 years while that of Cu-375 is 5 years. Its inserter has **no plunger** and it is introduced by **withdrawal technique.** It has 2 nylon threads at its lower end, perforation and expulsion is less with multiload as compared to Cu-T.

Cu-7 (Gravigard)

It is "7" shaped device made up of polypropylene impregnated with barium sulfate. Copper wire is wrapped around vertical arm. Surface area of copper wire is 200 sq mm. It is 36 mm long and 26 mm wide. It has only one (instead of usual two) polypropylene thread blue in colour. Its life span is 3 years. It is inserted by withdrawal technique.

T Cu-220

It is T shaped device with 7 solid copper sleeves, 2 on transverse arm and 5 on vertical stem. Total exposed surface area of copper is 220 sq mm. It is developed by Population Council and its effective life is estimated to be 15–20 years. It has 2 threads and it is introduced by withdrawal technique.

Fig. 5.4: From left to right Zicoid, Flexigard, LNG-20 (Mirena).

Nova-TCu-200 and 200 Ag

It is T-shaped device made up of polyethylene with barium sulfate impregnated. The fine copper wire is wrapped around the vertical stem. The surface area of copper is 200 sq mm. In 200 Ag variety a silver core has been added to the copper wire to reduce its fragmentation. It has 2 white threads and it is inserted by withdrawal technique. As compared to other copper devices, it is slightly short (32 mm long instead of 36 mm).

Zicoid

It is T shaped device with flexible and resilient side arms with small projection on the inside of the side arms. This prevents irritation of the cervical canal during insertion. It's surface area is 350 sq mm and copper wire is placed in the upper part of the stem. Diameter of wire is 0.5 mm. Plunger with special stop at proximal end ensures high fundal placement of the device. It is effective for 5 years.

Gynefix

It is a frameless IUD. Originally developed frameless IUDs like flexiguard and Cu-Fix are now discarded due to complexity in insertion technique Gynefix consists of six 5 mm long copper sleeves on a polypropylene thread. It is inserted through vaginal route with a special applicator that sutures the thread to the fundus of the uterus. If is effective for 5 years.

Progesterone Containing Devices

a. **LNG 20 (Mirena, LNG – Intra-uterine system):** T-shaped device with flexible arms. The shape is that of Nova -T, but it has capsule on the stem. The core of the capsule contains a mixture of silicone rubber and 52 mg levonorgestrel, which is released at 20 µg/day. It is 32 mm long and 32 mm wide. It has a different type of inserter and it is inserted by special withdrawal technique. It is effective for 5 to 7 years. As contraceptive it has dual mechanism of action, i.e. that of IUCD as well as hormonal contraceptive. Apart from **contraception** it helps in treatment of **AUB, fibroids, adenomyosis** and **endometriosis**. It is also useful for protection from **endometrial hyperplasia** during estrogen replacement therapy. Failure rate is 0.1 to 0.2 per 100 women in the first year of use. Side effects due to hormone can occur, e.g. nausea, vomiting, headache, acne, dizziness, breast tenderness, weight gain, ovarian cysts and bleeding disturbances in first 3 months.
Progestasert was the first hormone containing IUD developed in 1976. But due to its short life span of 1 year, it did not become popular and replaced by Mirena containing levonorgestrel instead of progesterone.
Skyla and Liletta are other LNG releasing IUDs effective for up to three years available in western countries.

b. **Fibroplant:** It is derived from Gynefix, so it is frameless. It is levonorgestrel releasing IUD. LNG is released frame fibrous delivery system which is attached to the anchoring thread by means of a stainless steel clip. It is effective for 5 years**.**

STEROIDAL CONTRACEPTIVES

They contain synthetic female hormones (estrogen and progesterone) which are steroid in nature.

Types:
1. Oral: Commonly known as **Pills - OC pills.**
2. Injectable: Intramuscular.
3. Newer sustained release systems.

Oral Pills (OCs)

Types

1. Combined
2. Phasic
3. Minipill
4. Newer pills

Combined Oral Pill

- Combination of estrogen and progesterone-21 such tablets. As the dose of estrogen and progesterone remain constant they are called monophasic pills.
- Supplied as 21 tablets or in a pack of 28 tablets, where last 7 tablets are placebo containing iron and vitamins, to complete the menstrual cycle.
- Commonly used estrogen is ethinyl estradiol (EE) 30 µg or 20 µg.
- Commonly used progesterone are norethisterone, DL norgestrel, levonorgestrel, desogestrel etc.
- It is started from any of the first 5 days of the cycle (usually 5th day). It is taken daily one preferably at bedtime for 21 days. Second pack is started after 7 day irrespective of onset or stoppage of menstruation.
- In a family planning program it is supplied free of charge by Government: Mala D, Mala N.
- Composition of few OC pills preparations mentioned below:

Preparation	Estrogen (EE)	Progestogens
Mala D	30 µg	Norgestrel 0.3 mg
Mala N	30 µg	Norethisterone 1.0 mg
Ovral	50 µg	Norgestrel 0.5 mg
Ovral L	30 µg	Levonorgestrel 0.15 mg
Duoluton-L	30 µg	Levonorgestrel 0.25 mg
Novelon Intimacy Plus 3	30 µg	Desogestrel 0.15 mg
Femilon Intimacy Plus 2	20 µg	Desogestrel 0.15 mg

PHASIC PILLS

Biphasic, Triphasic or Quadriphasic

- Biphasic: All 21 tablets contain E + P, but dose of progesterone is doubled after first 10 days, dose of estrogen remaining constant (ethinyl estradiol 35 µg, Norethindrone 50 µg and 100 µg). It has slightly high failure rate and not available in India.

Fig. 5.5: Combined oral pills.

- Triphasic: All 21 tablets contain E + P, but dose vary in 3 phases, e.g.
  a. **Triquilar:**

EE	Levonorgestrel	Days
30 µg	50 µg	1–6
40 µg	75 µg	7–11
30 µg	125 µg	12–21

  Triquilar is started from the 5th day of cycle while second pack is started after 7 days of pack free interval.
  b. **"Cyclessa"** contains ethinyl estradiol 25 µg and triphasic desogestrel and **"Ortho-tricyclen"** contains EE 25 µg and triphasic norgestimate. They are not yet available in India.
- Quadriphasic pills provide 4 different doses of estrogen and progestogen both, estradiol valerate and dienogest. It is considered more physiological as it simulates natural cycle, so side effects are reduced. However there are more chances of pill taking errors and high cost. It is available in foreign countries as **Natazia** and **Qlaria.**

Mini Pill

- As they contain only synthetic progestogen (not estrogen) they are called mini pill or progestogen only pill (POP).
- Two are currently available **Cerazette** containing Desogestrel 75 µg and Micronor or Noriday containing Norethisterone 350 µg. Only cerazette is available in India.
- It is available as 28 tablets pack, all active tablets (No placebo).
- It is to be started from the first day of period for first 7 days backup method (condom) should be used.

- Daily one tablet is taken at the same time (3 hours window) throughout the cycle.
- One should started the second pack immediately after the first pack is completed.
- It acts by inhibiting ovulation and also acts locally by making endometrium unreceptable for implantation and renders cervical mucous hostile to sperms.
- Its typical use failure rate is 9% while perfect use failure rate is only 0.3%.
- It avoids undesirable side effects of estrogen found with combined pills and sickle cell patients or lactating mothers can take it.
- Menstrual irregularities and amenorrhea are common with its use.
- Side effects contributed to progesterone content can occur, i.e. alopecia, loss of libido, weight gain, breast tenderness, bloating, nervous irritability. Androgenic side effects are less with cerazette.

Newer Pills

- **Intimacy plus 2, Femilon:** They contain only 20 µg ethinyl estradiol (as compared 30 µg in intimacy plus 3, Novelon) and 150 µg Desogestrel. Due to lowest dose of estrogen, estrogen related side effects like nausea, breast tenderness and headache are quite less.

Fig. 5.6: Anti-androgenic pills.

Desogestrel a newer progestogen which has minimal androgenic side effects: reduces the risk of cardiovascular disease and cures acne and hirsutism.

- **Post-coital pill:** Discussed in detail under emergency contraception.
- **Once a month pill:** Each pill contains 3 mg of Quinestrol (long acting estrogen) and 12 mg megestrol acetate (Progesterone). It is not available in India.
- **Pill with antiandrogenic effects:** It contains ethinyl estradiol (35 µg) + cyproterone acetate (2 mg) e.g. **MY Pill, Diane 35, Krimson 35.**

  Dronis, Rasmin and Yasmin contains EE (30 µg) + Drospirenone (3 mg) (aldosterone derivative).

  Freedase is recently introduced pill. Here 21 tablets contain ethinly estradiol 30 µg and dienogest (newer progestogen) 2 mg.

  Due to antiandrogenic effects they are useful in patients with PCOS, acne and hirsutism and androgenic alopecia. Cyproterone is considered most potent anti-androgen progestin. Drospirenone due to its antimineralocorticoid activity also decreases BP and weight in the users. It has favorable effect on lipid metabolism also. Dienogest has minimal effect in thyroid and glucose metabolism. Due to high selectivity as a progestogen it has favorable safety profile and tolerability as compared to other progestins.
- **Pills with extended cycle length (continuous use OC):** Seasonale contains 150 µg of the progestin LNG and 30 µg of estrogen EE. This monophasic pill is taken continuously for 84 days and then hormone free pill for 7 days. It leads to only 4 periods in a year and also reduces the side effects associated with monthly hormone withdrawal, e.g. migraine, headache, mood changes. However breakthrough bleeding is more than conventional OCs which diminishes after 3 courses, i.e. 9 months.

  Lybrel was another continuous OC pill approved by FDA. It contains 365 tables of 90 µg LNG and 20 µg EE. The Pill completely stops a women's period for full one year. Lybrel is discontinued by the manufacturer due to license issue and now it is available as generic under brand names **Amethyst, Lutera** and others.

Mechanism of Action

Pills containing estrogen and progesterone work in following ways:

- Their main action is inhibition of ovulation. They act at hypothalamic level inhibiting release of gonadotropin releasing hormone (GnRH). Secretion of FSH and LH from pituitary are thus suppressed, so there is no follicular growth. As there is no LH surge, ovulation is suppressed. It is also suggested that they directly inhibit pituitary as there is no response to exogenous GnRH administration in Pill users.
- They alter the maturation of endometrium making it unsuitable for implantation. Under the effect of progesterone there is stromal edema with glandular exhaustion and atrophy.
- Progesterone makes cervical mucous thick viscid, scanty and impermeable to sperms.
- Effect on tubal motility by progesterone is also suggested.

Patient Selection

- Before prescribing the pills to any patient complete clinical history and thorough examination is carried out to rule out contraindications (WHO-MEC).
- Weight and blood pressure are recorded and Pap smear is taken.
- Diabetes should be ruled out and liver function tests are carried out if necessary.
- Patients are informed about initial side effects and assured that they usually disappear spontaneously in course of time or with treatment.

Follow-up

- First at the end of 3 months and then annually. History regarding symptoms of thromboembolic disease is elicited.
- Pelvic examination, breasts examination, cervical smear, BP and weight recording are done and urine is tested for glycosuria.
- It is advisable to stop the pills after 50 years (35 years in smokers) and to keep breaks for 3–6 months every 3–5 years.
- Recent evidence shows that modern pill can be taken for 10 or even more years in a row without increased risk.

Contraindications

WHO published **medical eligibility criteria** (WHOMEC, 2004) for initiating and continuing use of contraceptives on the basis of latest clinical and epidemiological information taking into account health risks and benefits. The criteria are revised and updated in 2015. There are four categories for use of any contraceptive method as follows:

- **Category I:** No restriction for the use of the contraceptive method.
- **Category II:** Advantages generally outweigh the theoretical or proven risks (The method is used with precautions).
- **Category III:** Theoretical or proven risks usually outweigh the advantages (The contraceptive method generally should not be used. An alternative method is preferred. However health personnel may make an exception in individual case with her informed consent).
- **Category IV:** A method that represents an unacceptable health risk (It should not be used).

WHO (2015) has come out with **WHOMEC wheel** for starting use of contraceptive methods. The wheel includes recommendations on initiating use of nine common type of contraceptive methods, i.e. COC pills, progesterone only pills, patch, vaginal ring, combined injectables, progesterone only injectables, progesterone only implants, copper bearing IUDS and LNG-IUD.

WHO has recently launched an App for contraceptive use. This digital tool will help healthcare workers in recommending safe, effective and acceptable contraceptive

methods for women with different medical conditions.

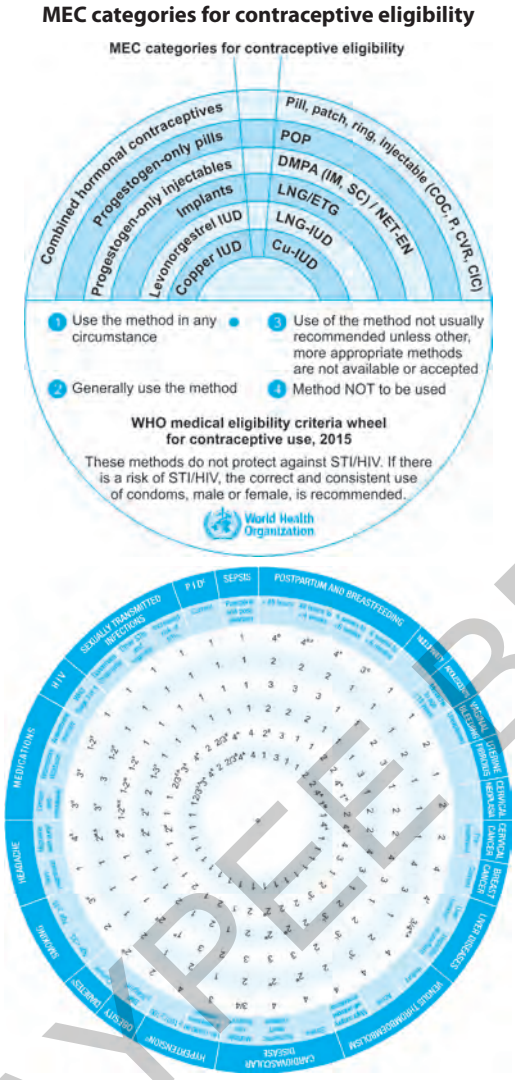


Fig. 5.7: WHOMEC wheel.

Side Effects and Complications

1. **Nausea and vomiting:** It is very common side effect. It is related to the estrogen content of the pill. It is managed by (a) reassurance that it subsides as therapy continues, (b) taking the pill after food or with cup of milk, (c) taking the pill at bedtime so that the individual is sleeping during peak concentrations of drug in the blood, (d) changing over to another compound with lower dose of estrogen.
2. **Break through bleeding:** It occurs in almost half of all patients at some time. It may be due to failure to take the pill at the same time each day. It is more common with low dose pill. However with newer pills cycle control is good. It diminishes after first 3–4 pill cycles.
   Management: (a) Switching to another low dose compound or (b) increase in the estrogen dose of the pill temporarily or taking short course of additional estrogen temporarily, (c) a search for pathological causes of bleeding must be made.
3. **Absence of withdrawal bleeding (Pill amenorrhea):**
   Management: After ruling out the pregnancy either of the following options is given to the patient (a) reassuring the patient the likelihood of regular menstruation when the pills are discontinued and second pack is started from the seventh day of last pill, (b) if withdrawal bleeding is desired switching to a pill with higher estrogen activity or adding tablet of estrogen, i.e. EE 0.02 mg last 7 days for few cycles is advised. Amenorrhea and oligomenorrhea are less common with triphasic pills.
4. **Hypertension:** It is 3 times more common in pill users. Both systolic and diastolic BP rises. It is minimal with triphasic pills.
5. **Cardiovascular diseases:** Venous thromboembolism—deep vein thrombosis is 5–6 times more common in users, while superficial vein thrombosis is 2–3 times more common in users. It is due to estrogen and it is dose dependent. OC pills containing drospirenone has increased chances of venous thrombo-embolism.
   Myocardial infarction—It is 2–3 times more common in pill users. It is due to

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Haresh U Doshi is an eminent teacher with more than 35 years of teaching experience. Currently he is a Professor and Head, Department of Obstetrics and Gynecology at Gujarat Cancer Society Medical College, Ahmedabad, Gujarat, India. He passed his MD (Gynec) and PhD from BJ Medical College, Ahmedabad. Over the years, he has been involved in many UG and PG teaching courses across the country. He was Chairperson of Practical Obstetric Committee, FOGSI 2004-2008; President, Ahmedabad Obstetrics and Gynaecological Society 2003; President, State Organization of Obstetrics and Gynecology 2004 and Vice President, FOGSI 2019. He is a Teacher of Teachers and Doctor of Doctors. He has authored 3 books, 3 booklets, 18 book chapters and published 28 scientific papers in national and international journals. This book is the essence of his vast experience, wisdom and strong academics.

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ISBN 978-93-89776-74-4