

Contraception

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Definition

Contraception is the prevention of conception by methods other than abstinence from coitus.

Indications for conception

Limiting the population

Early marriage-defer pregnancy

Birth spacing

Previous obstetric complications

Family limitation

Chronic systemic disease in the women

Temporary ill health in either partner

Later years of marriage

On request

Emergency contraception .

Efficacy of contraception

It is generally assessed by measuring the number of unplanned pregnancies that occur during a specific period of exposure and use of a contraceptive method.

Two methods for measuring contraceptive efficacy

Pearl index

Life table analysis

Pearl index

The pearl index is defined as the number of failures per 100 women years (HWY) of exposure multiplied by 1200 if the denominator consist of months or by 1300 if the denominator consist of cycles.

$$\text{Pearl index} = \frac{\text{Number of pregnancies} \times 1,200}{\text{Total months or cycle of exposure from the onset of method}}$$

Life style analysis

**It calculate a failure rate per month of use.
Contraceptive failure do occur & for many reasons.
It is less confusing to simple compare the very best
performance (the lowest expected failure rate)
with usual experience (typical failure rate).
The lowest expected failure rates are determined in
clinical trial**

Contraceptive method

Various contraceptive methods available are

Reversible methods

Natural family planning

Barrier method

Intrauterine contraceptive device

Steroidal contraception

—a. Combined hormonal contraception &

—b. Progesterone only contraception

Non steroidal contraception

Postcoital or emergency contraception

Others

Cont.

Permanent method

Female —tubal ligation

Male — Vasectomy

Choice of Contraception

The choice of contraceptive method depends on the circumstances in which it is applied and on its acceptance by the patient. The acronym 'GATHER' is used to refer to the process of counselling for contraceptive use:

G—Greet the client

A—Ask the client about herself

T—Tell the client about choices available

H—Help the client to make an informed choice

E—Explain fully how to use the chosen method

R—Return visit should be encouraged

E —Eventually, the choice of contraceptive is a very personal one.

Natural Family planning method

Failure rate 18-25 pregnancy per HWY

Fertility awareness based method or traditional methods

Fertile phase or calendar method - calculated by rhythm, safe
Cervical mucus method or BILLING method change of odour,
amount & touch of cervical mucus discharge

Basal body temperature rises 0.5°C or 1°C

Symptothermal method-is combine method of identify fertile &
infertile days by combining BBT, cervical mucus changes & other S/
S of ovulation like abd pain, breasts tenderness etc.

Failure high because ovulation varies.

Natural

Lactational amenorrhoea method (LAM) is based on physiology of breastfeeding.

If a breastfeeding woman meet 3 criteria, her risk of pregnancy in 1st 6 months is 2% HWY

Lactational amenorrhoea

Exclusive breastfeeding or nearly full breastfeeding, day or night on demand of baby.

Less than 6 months postpartum

Rule of 3's for postpartum initiation of contraception, i.e. full breast feeding, begin in 3rd postpartum months & partial or no feeding , begin in 3rd postpartum week.

Cont

Elevated level of prolactin inhibit the pulsatile release of gonadotrophin-releasing hormone leading to erratic or anovulatory cycle, with short luteal phase & interference of implantation owing to suckling induced release of oxytocin.

**Coitus interruptus (Withdrawal Method) failure rate 18-20per HWY
It means withdraw before ejaculation, means discharge of semen outside the vagina**

Barriers method

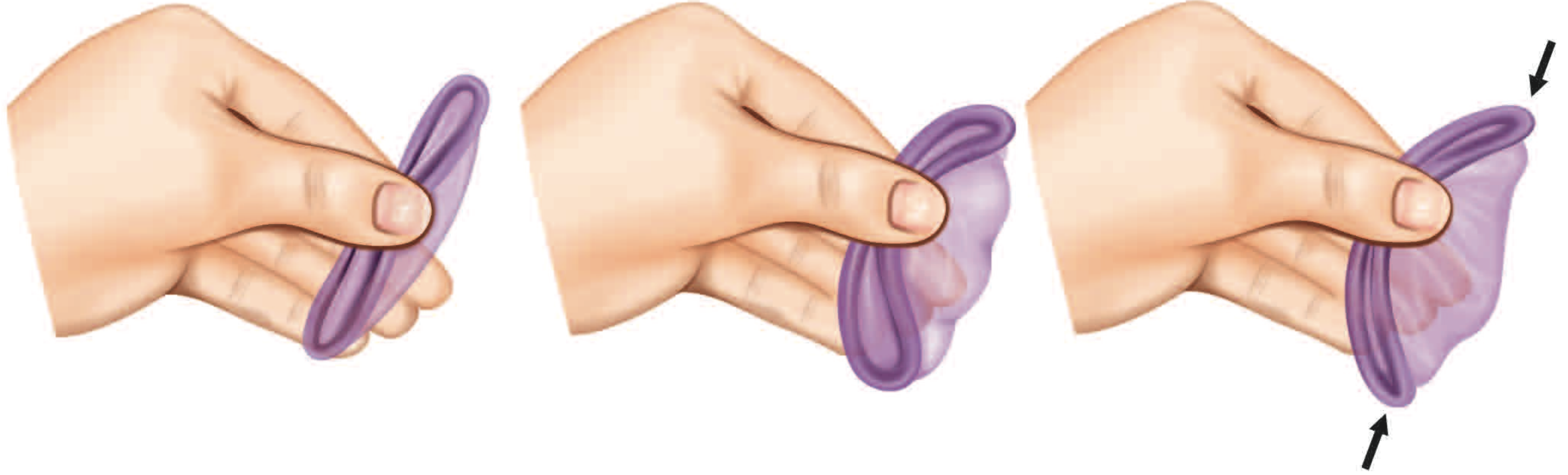
- Barrier contraceptives are family planning methods, which act as barriers and prevent the union of sperms and ovum necessary for pregnancy.
- Recently barrier methods of contraception have gained much more importance in view of the facts they prevent precancerous lesions, cancer of cervix and spread of AIDS. Only condoms have been proven to prevent HIV infection. STD protection has a beneficial impact on the risk of tubal infertility and ectopic pregnancy.
- The risk of toxic shock syndrome is increased with female barrier methods but the actual incidence is so rare that this is not a significant clinical consideration.
- Different kinds of barrier methods are available.

The following specific goals:

- Correct use
- Consistent use
- Affordable and easy availability

Various types of condoms are available.

- Most are made of latex. Polyurethane and silicon rubber condoms are also now manufactured.
- Latex condoms are 0.3–0.8 mm thick. Sperms that are 0.003 mm in diameter cannot penetrate latex condoms. They are circular, 15–20 cm in length, 3–3.5 cm diameter (Different sizes are also now available).
- Those individual, who are allergic to latex condoms, can use polyurethane condoms.
- Types
 - Dry type—Nirodh, Duropac, etc.



Acceptability and usage: Condom use is more common in the developed countries where 12% of MWRA are protected by condoms against 4% in the developing countries. Condom are used worldwide particularly as a preventive measure against HIV and STDs.

Effectiveness: Typical average failure rate of condom as commonly used is 12% (WHO 1994). When used correctly and consistently failure rate is only 3%.

Advantages:

Condoms need no prescription and no medical help for use.

Easily available and harmless method of contraception

It gives very good protection against STDs, HIV and hepatitis B virus.

They are suitable in any age group, during lactation and for those who cannot tolerate oral pills and IUCDs.

Barrier methods reduce the chance of developing severe cervical dysplasia and cervical cancer.

Disadvantages:

Breakage is greater problem for couples at risk of STD

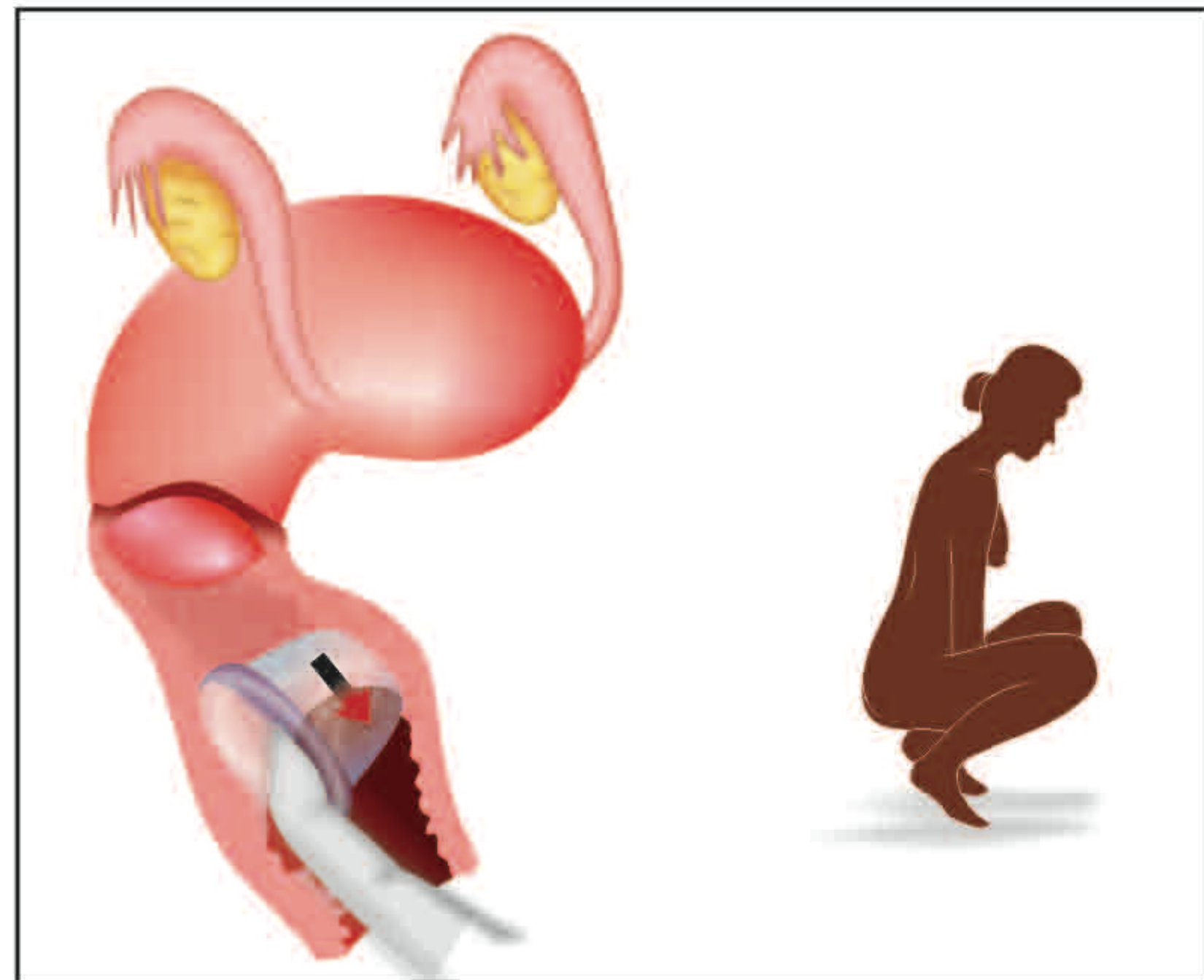
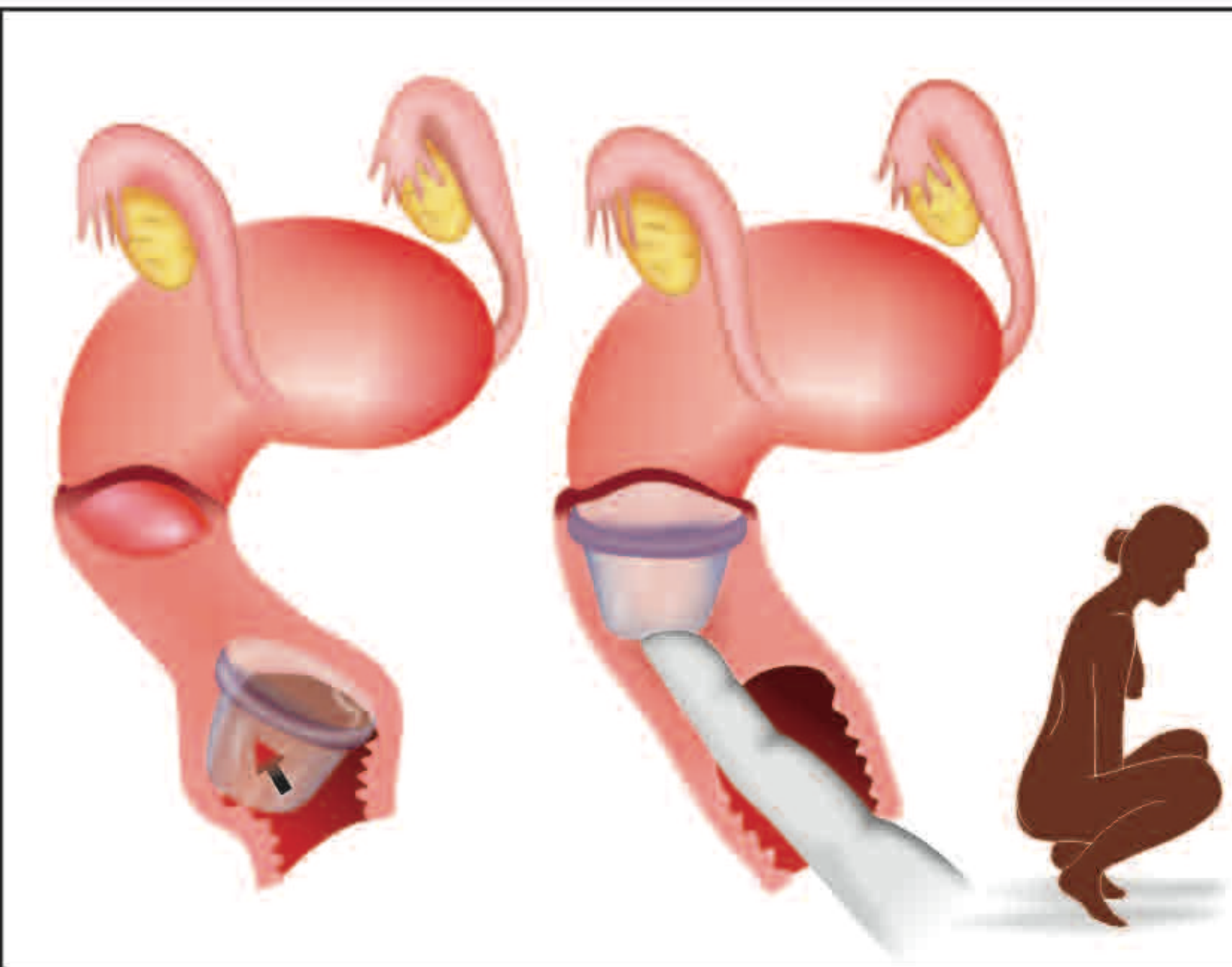
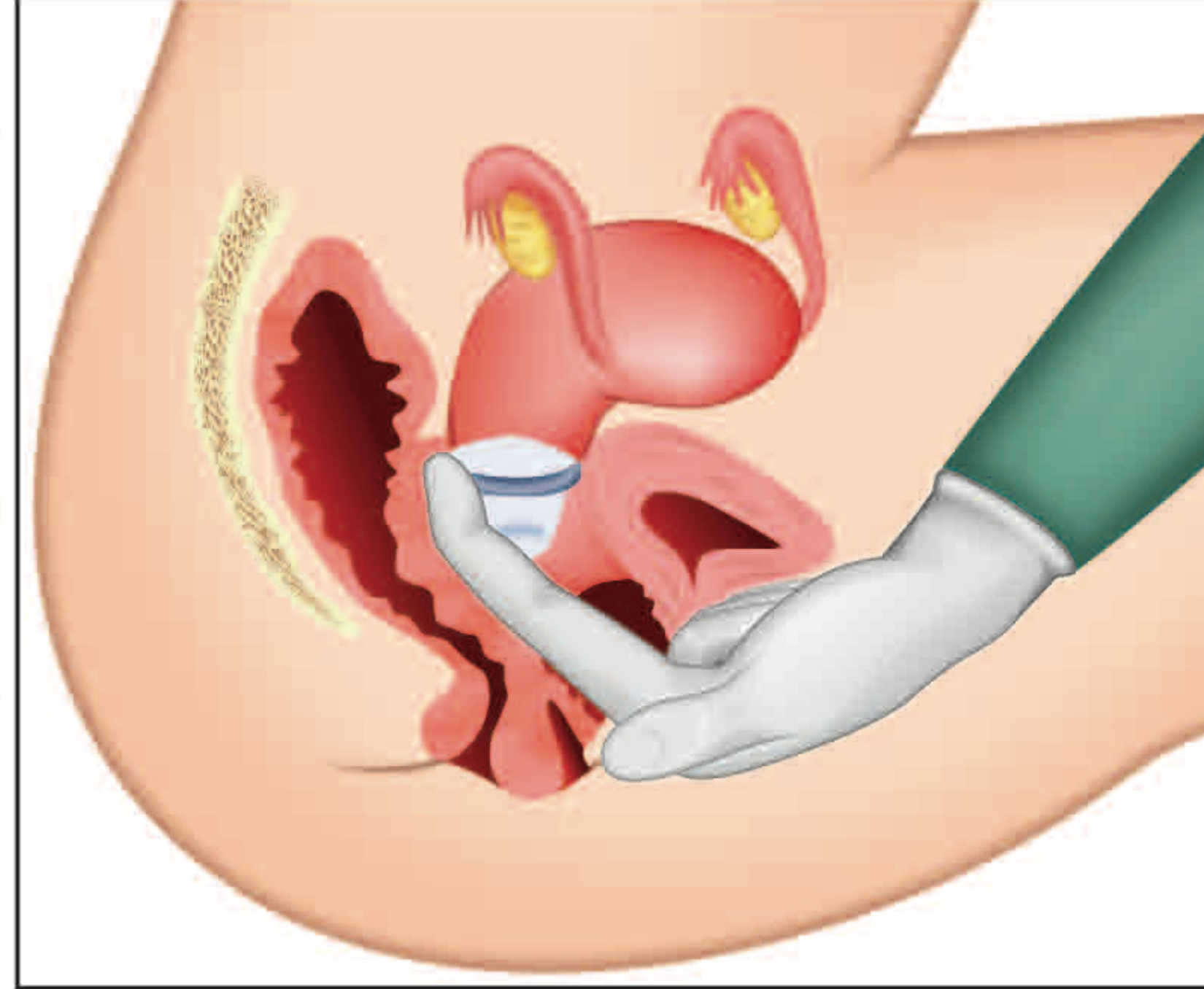
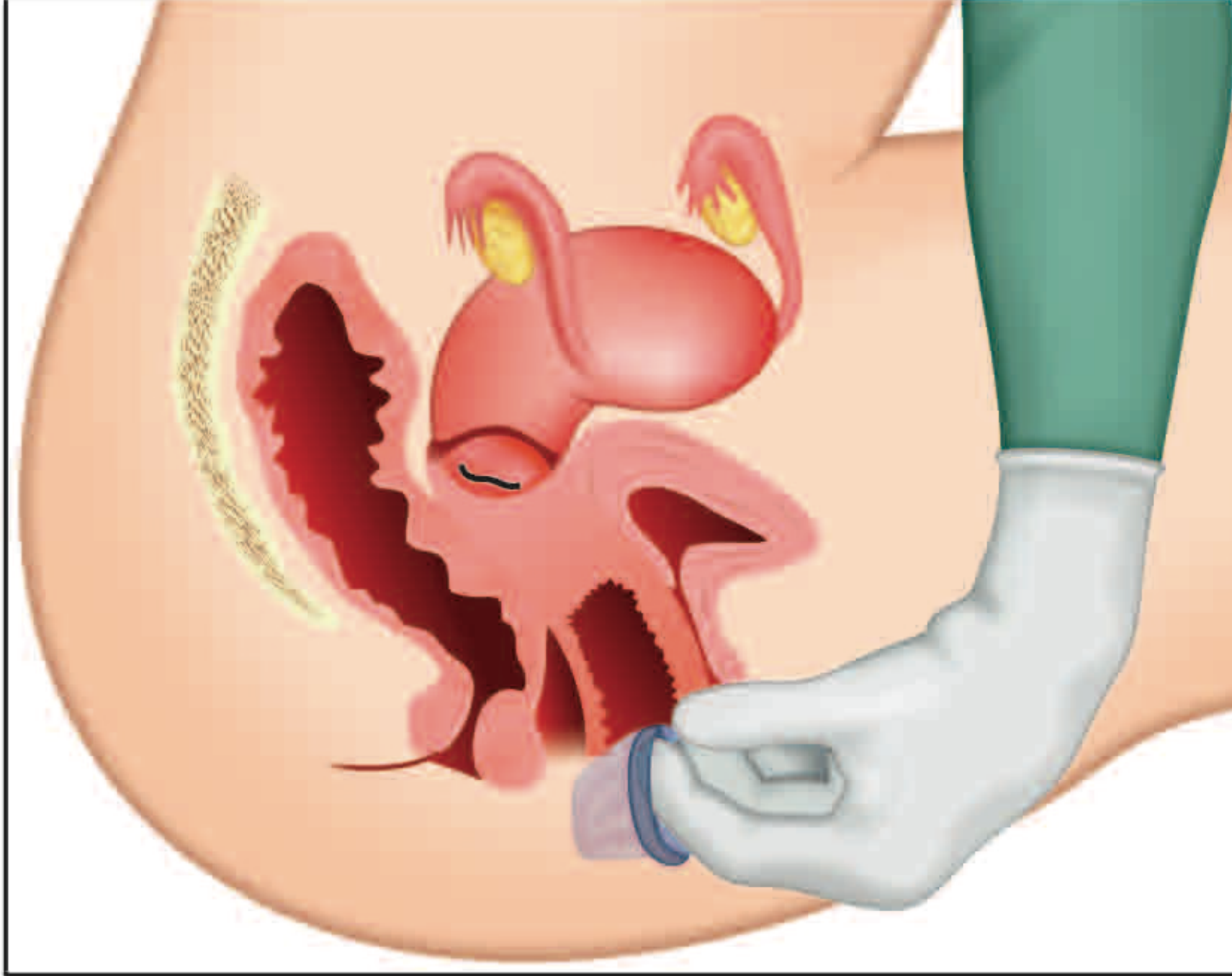
Rarely they produce hypersensitisation

No major disadvantage

Storage and disposal problems.

How to use: A condom must be placed on the penis before it touches a partner. Uncircumscised man should pull the foreskin back. Prior to unrolling the condom to the base of the penis, air should be squeezed out of the reservoir tip with a thumb and forefinger. The tip of condom should extend beyond the end of the penis to provide a reservoir to collect the ejaculate. If lubricants are used, they must be water based. Oil based lubricants will weaken the latex. After intercourse, the condom should be held at the base as the still erect penis is withdrawn. Semen must not be allowed to spill or leak. It should be handled very gently. If there is evidence of any spillage or leakage or when a condom breaks:

- Spermicidal agents should be quickly inserted into the vagina.
- Woman should contact a clinician within 72 hours. Emergency contraception should be provided.



Insertion and removal of cervical cap

Spermicides

- Various chemicals and wide variety of vehicles have been used vaginally as contraceptives for centuries.
- Modern spermicidal agents introduced in 1950s, contain surface active agents that damage the sperm cell membranes, this same action occurs with bacteria and viruses explaining the protection against STDs.
- The agents currently used are :
 - Non-oxynol-9
 - Octoxynol-9
 - Benzalkonium choride
 - Menfegol

Most preparations contain 60–100 mg of these agents in each vaginal application, with concentration ranging from 2% to 12.5%.

Available in the form of foam, jellies, creams, vaginal contraceptive film and suppositories.

“Advantage 24” is a contraceptive gel that adheres to the vaginal mucosa and provide longer availability of non- oxynol-9 effective for 24 hrs.

Efficacy: Failure rate of approximately 20–25/HWY during a year of use are most typical.

The principal minor problem is allergy that occurs in 1–5% of users.

Spermicide users who have an altered vaginal flora, providing the colonisation of *Escherichia coli*, leads to greater susceptibility of urinary tract infections.

Spermicides should not be used without condoms if a primary objective is to prevent infection with HIV, gonorrhoea and *Chlamydia*.

• INTRAUTERINE CONTRACEPTIVE DEVICES

Intrauterine contraceptive devices are made of plastic or metal or combination of these materials, meant for insertion into the uterine cavity for contraception.

The IUCD is the second most commonly used family planning method, after voluntary female sterilisation (WHO 1997).

Intrauterine contraceptive devices are an effective, safe and convenient contraceptive method. They are particularly suitable for a woman who:

- Want to delay pregnancy for some years

- Are breastfeeding

- Prefer method that does not require supervision or action before sexual intercourse.

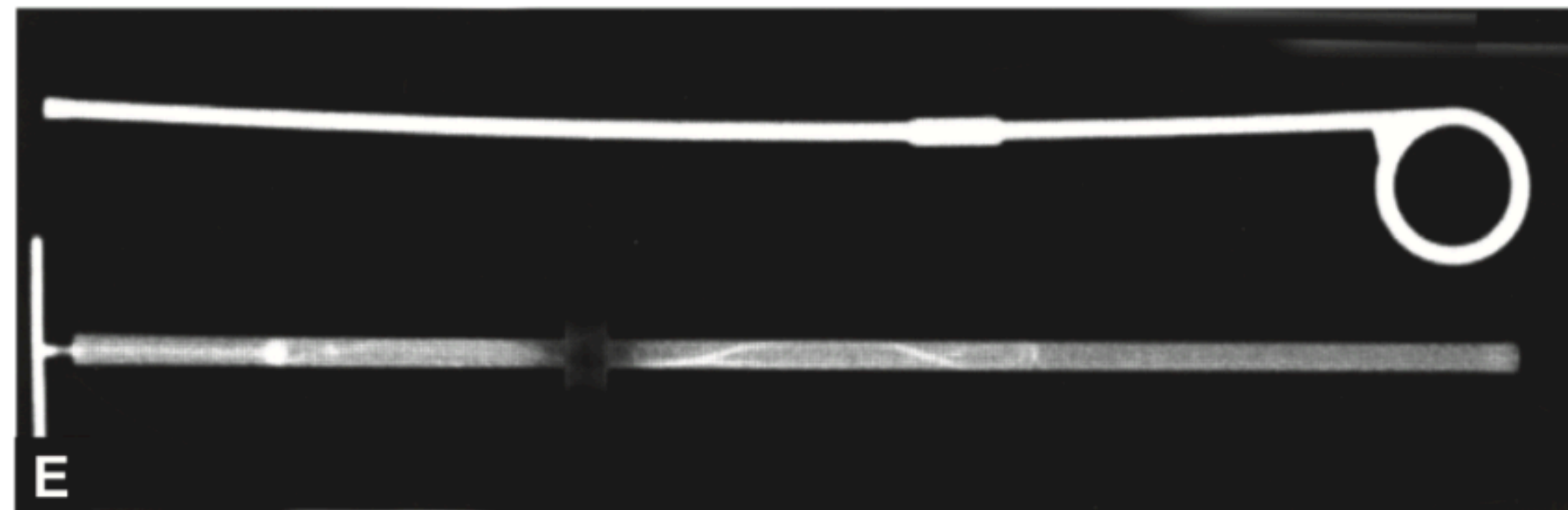
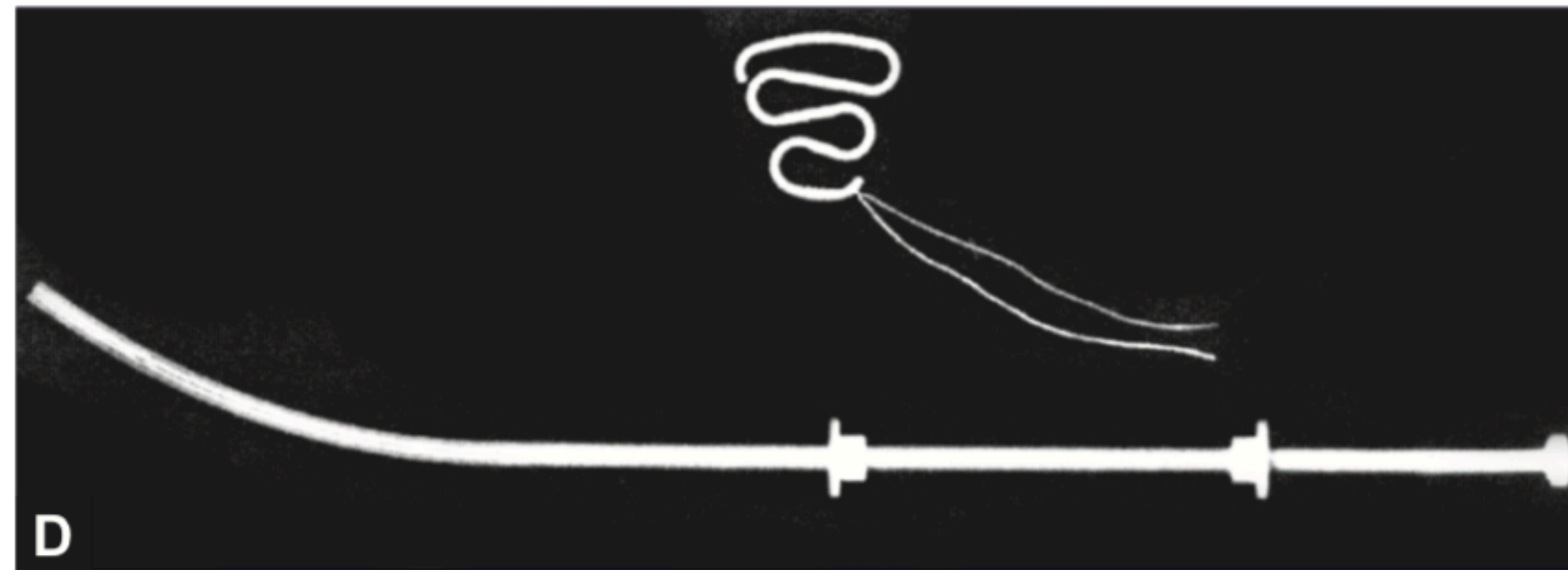
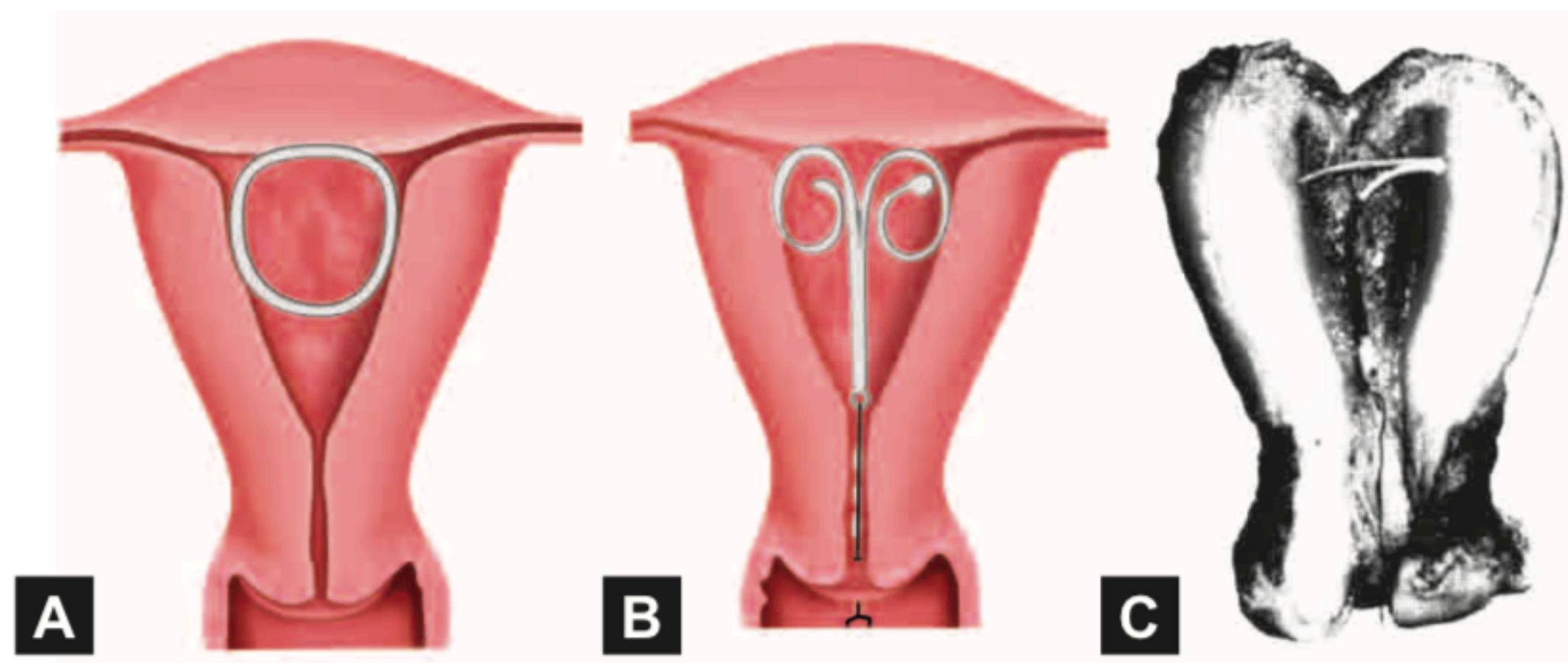
History

First widely used IUCD was introduced in Germany by Grafenberg in late 1920s known as Grafenberg ring. OTA rings developed in Japan. These are composed of relatively non-irritant metal such as silver, gold and alloy of copper (Cu). The addition of copper was suggested by Zipper. The progestasert was developed by Alza Corporation. The progesterone diminishes the account of cramping and the amount of blood loss. The short life span has been solved by using a more potent progesterone such as levonorgestrel. The IUCDs of the future will possibly be medicated and frameless.

Types

Unmedicated or inert IUCDs, e.g. Lippes loop, Saf-t-coil, OTA ring, Mahua ring

Medicated IUCDs, e.g. copper releasing IUCDs—Cu 7, CuT 200, Multiload Cu 250, Multiload Cu 375, Novat, CuT 380Ag, CuT 380A; hormone releasing IUCDs—progestasert, levonorgestrel IUD



Figs 50.9A to E: (A to C) Intrauterine contraceptive device in uterus, (D) Lippes loop, (E) Copper T

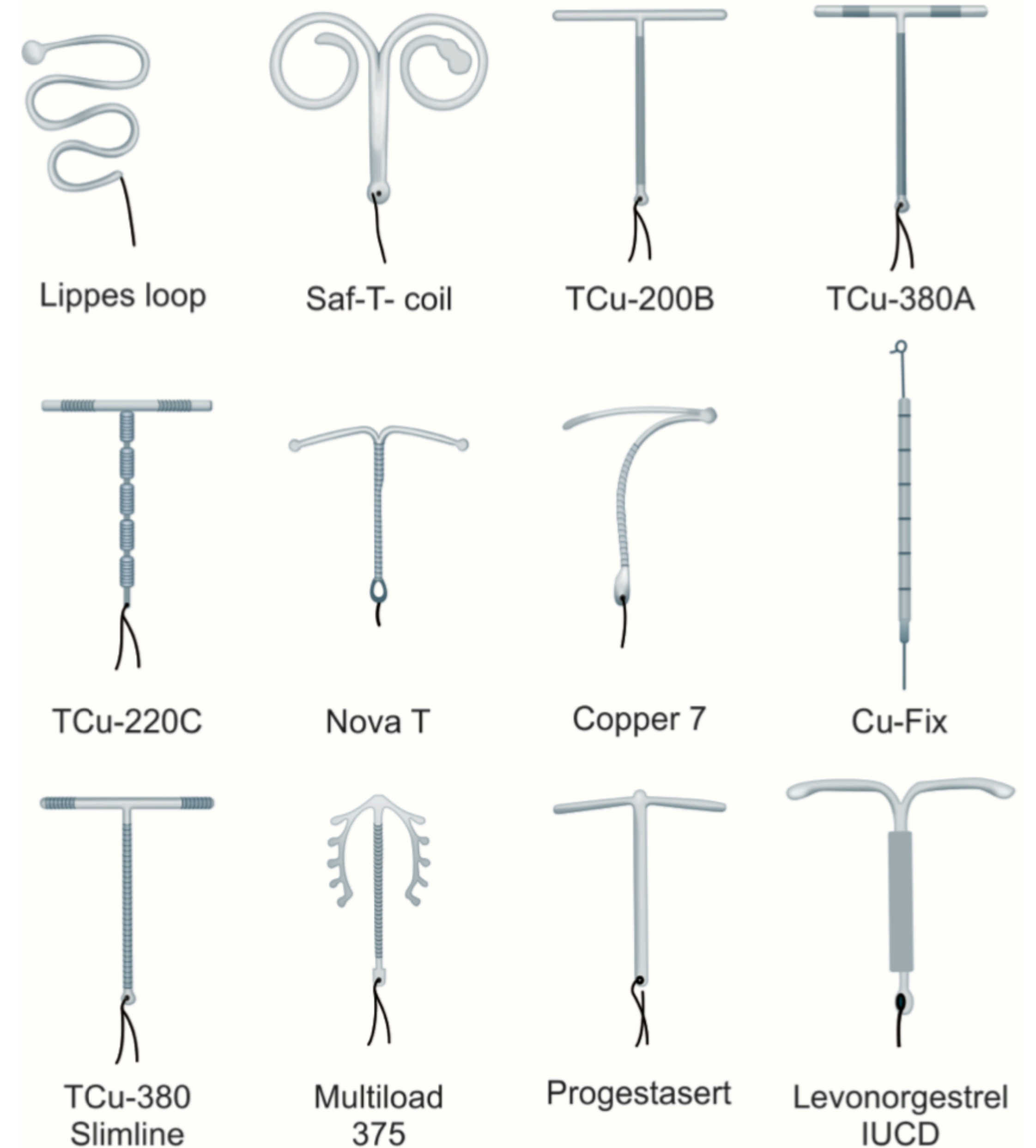


Fig. 50.10: Types of intrauterine contraceptive devices



Fig. 50.24: IUCD for postpartum insertion



Fig. 50.25: Fourth generation IUCD

Mechanism of Action

- The contraceptive action of all IUCDs is mainly in the uterine cavity.
- *Nonmedicated IUCDs: It depends for contraception on the general reaction of the uterus to a foreign body, a sterile inflammatory response sufficient enough to be spermicidal. So very few, if any, sperm reach to the ovum in the fallopian tube. Inflammatory response would also prevent implantation.*
- *Copper IUCDs: The copper IUCDs release free copper and copper salts that have both a biochemical and morphological impact on the endometrium and also produce alteration in cervical mucus and endometrial secretions. The copper IUCD is associated with an enhanced inflammatory response, marked by production in the endometrium of cytokine peptides breakdown and enhanced prostaglandin production.*
- *The progestrone releasing IUCDs: It adds the endometrial action of progesterone to the foreign body reaction. The endometrium becomes decidualised with atrophy of glands. It causes inhibition of implantation and inhibition of sperm capacitation and survival. Progesterone IUCD thicken the cervical mucus, creating a barrier to sperm penetration. They decrease menstrual blood loss (by about 40–50%) and dysmenorrhoea.*
- *LNG IUCD: Produces serum concentration of the progestin about half that of Norplant so that ovarian follicular development and ovulation are also partially inhibited. Bleeding can be reduced by 90%, 1 year after insertion.*

Time of Insertion

- During menstruation or on the last day of menstruation. Advantages of insertion during menses or shortly after are: (1) cervical canal more open so insertion is easier, (2) masking insertion related bleeding, (3) knowledge that the patient is not pregnant.
- After childbirth, it can be inserted anytime within 48 hours or as early as within 4–6 weeks of delivery. The disadvantages of immediate postpartum insertion are higher expulsion rate and uterine perforation.
- Postcoital insertion should be done within 5 days of an unprotected intercourse.
- Postabortal insertion of IUCD can be done safely immediately after evacuation of uterus. Postabortion insertion has a high acceptance rate.
- Insertion in lactating woman is safe, as it does not affect the quantity and quality of breast milk.

• **Insertion Technique**

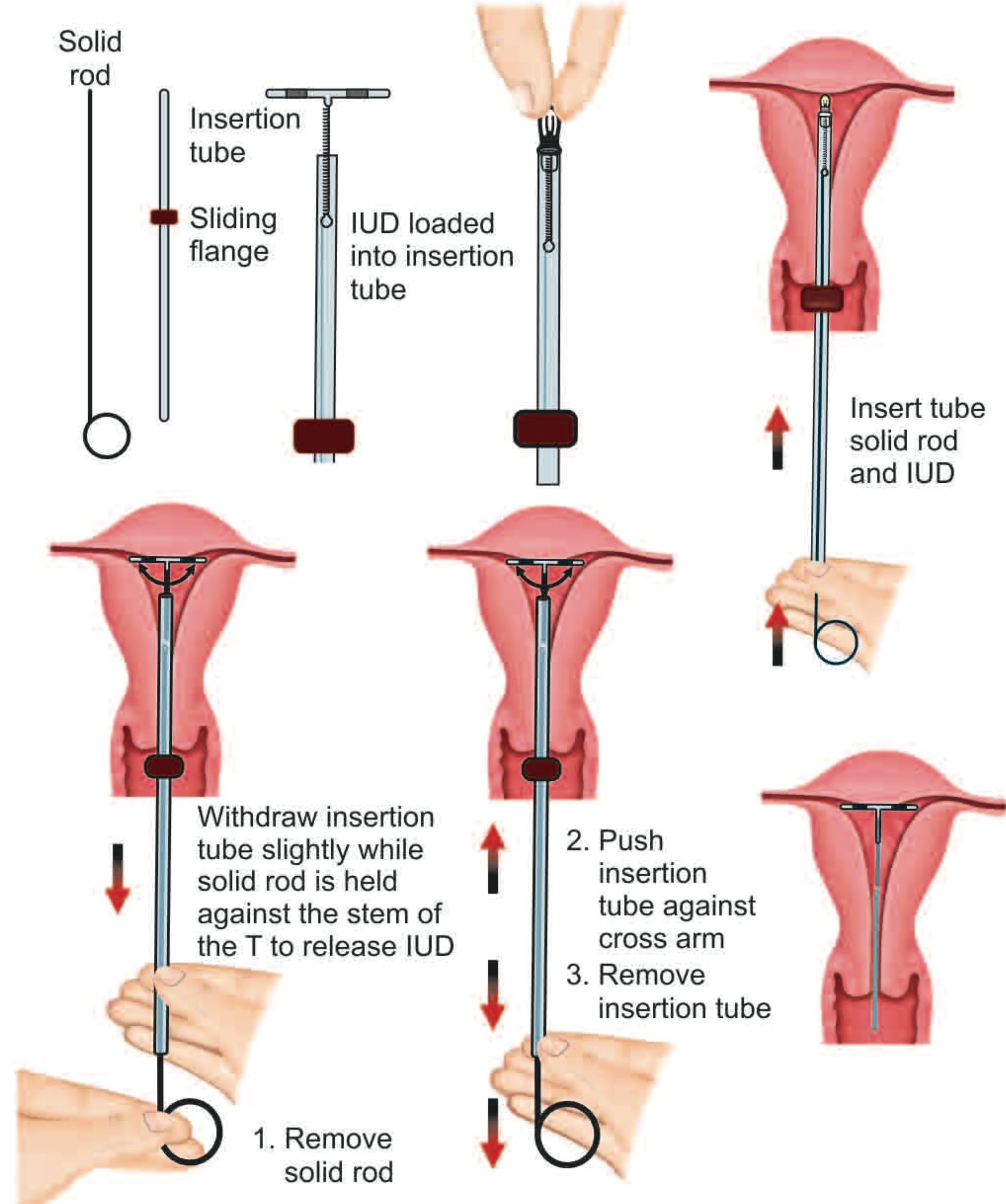
- Before any IUCD is inserted the patient should be informed, preferably in writing, of the principals involved in the method, its possible side effects, management and failure rate. She should give written consent for the insertion.
- Prior to the operation, complete history and a complete pelvic examination should be carried out to exclude any abnormality and cervical smear taken for cytology.
- All the plastic IUCDs have their own introducer as well as attached nylon tails, which hang through the cervix into the vagina. These permit the woman and her medical attendant a means of confirming that the device is in place and also of removing it by simple traction.
- The plastic material is impregnated with barium sulphate so the presence and position of device can be confirmed radiologically.

- After the application of an antiseptic the length of the uterine cavity is measured by a uterine sound and its direction confirmed.
- An appropriate device is then chosen and loaded into its introducer, which is passed into the uterus upto its flange or another marker. The method of insertion now depends on the device used. When the Lippes loop plunger is pressed to release the device, it resumes its inherent shape to lie in the uterus. With CuT, the loaded applicator is passed upto the fundus and the sheath is withdrawn to release the device.
- The plunger is then withdrawn together with the introducer, leaving the nylon threads in the vagina, these are shortened to a reasonable length.
- After the insertion the patient should rest for 10–15 minutes and remain under observation as she may feel faint.

Cont

The woman should be taught to feel for and recognise the threads. She should also be fully aware of the shape of the IUCD inserted.

If at any time during the procedure, the woman experiences significant pain or she collapses, the procedure should be abandoned. Difficulty in inserting the sound or introducer through the cervix calls for greatest caution because it is easy to make a false track and perforate the tissues



Further Supervision and Management

- Before or at the time the IUCD is introduced, the patient should be warned of possible initial reactions such as uterine bleeding and colic, and be told to report any significant reactions immediately.
- In any case, she should have routine follow-up visit immediately after her next menstrual period so that the retention of the device can be checked and any adverse side effects discussed.
- Next follow-up after 3–6 months is desirable; thereafter the woman is seen at yearly intervals, if necessary, the device can be removed and a new one inserted.
- There is no time limit for leaving inert devices in place and one can remain for several years without any harmful result. Sometimes after a year or two, they do get embedded in the endometrium and cause bleeding and discharge. This is an indication for taking out device and inserting a new one after next menses.
- Copper devices need to be replaced at intervals specified by the manufacturers. CuT 200 is recommended for 3 years, multiload 250 for 3 years, multiload 375 for 5 years and CuT 380 lasts for 10 years.
- Intrauterine contraceptive device is removed permanently once the menopause is established or if, at any time it causes unacceptable symptoms.

Prospective IUCD users should be aware of the following important possibilities:

- – Protection against unwanted pregnancy begins immediately after insertion.
- – Menses can be longer and heavier except hormonal IUCD.
- – Slightly increased risk of pelvic infection in the first few months after insertion.
- – Protection against STDs requires the use of condoms.
- – Ectopic pregnancies can still occur.
- – The IUCD can be spontaneously expelled, monthly palpation of the IUCD strings is important to avoid unwanted pregnancies.
- If the strings are not felt, a clinician should be notified immediately.

• **Indications**

- Those who want that one time insertion last for many years.
- The method required is the one which is independent of the act of coitus.
- The IUCDs are especially valuable in irresponsible woman or for the mentally challenged.
- In whom oral contraceptive pills are contraindicated and do not want to use other methods.
- As an emergency contraception.

• **Contraindications**

- Woman with irregular and heavy periods, uterine leiomyoma or other pelvic disease.
- When there is evidence of present or past pelvic infection of any kind.
- If the uterus is bicornuate. In this, pregnancy in one horn may be protected and a conceptus can implant in the other.
- Nulliparous woman
- Diabetes and heart disease
- A history of previous ectopic pregnancy (doubtful).

- **Efficacy of IUCDs**

- Considering all IUCDs together, the actual failure rate in the first year of use is approximately 3%, with a 10% expulsion rate and 15% rate of removal mainly for bleeding and pain .
- With increasing duration of use, failure rate decreases. The performance of CuT 380A in recent years has proved to be superior.
Failure rates with CuT 380A and other new copper IUCDs is less than 1/100 women per year.

- Expulsion**

Approximately 5% of patients spontaneously expel the CuT 380A within first year. This event can be associated with cramping, vaginal discharge or uterine bleeding or sometimes lengthening or absence of IUCD string. Patient should be cautioned to request immediate attention if expulsion is suspected.

Adverse Effects and Complications of IUCDs

- Fainting or collapse of the patient at the time of insertion of the IUCD.
- Intermenstrual spotting or menorrhagia occurs in about 55% of women. They are mostly seen during the first few days and months and tend to disappear later. Nevertheless, a tendency of anaemia can result.
- *Dysmenorrhoea or intermenstrual pain due to uterine colic:* These subside as the patient becomes tolerant or patient can be treated with nonsteroidal anti-inflammatory agents during the first few cycles for 3–5 days.
- Amenorrhoea can develop sometimes with progestasert and LNG IUCDs due to decidualising atrophic impact on the endometrium with LNG IUCD; 70% of patients are oligomenorrhoeic and 30% amenorrhoeic within 2 years.

Endometritis: IUCD always cause local foreign body reactions in the endometrium; aseptic endometritis, pressure atrophy, glandular hyperplasia, oedema, leucocytic infiltration. Such reactions disappear quickly, once the device is removed, probably because of the natural monthly shedding of the endometrium.

- *Cervical injury:* Sometimes devices can cause ulceration of the cervical tissues. Abnormal cervical smears are found but it is very rare.
- Acute and chronic salpingo-oophoritis occurs in 1% of women per year. This happens mostly when infection has been present already and has passed unrecognised or when it is inserted too soon after delivery or abortion. The presence of the IUCD may also encourage exposure to a new STD and if the infection is contracted, it is more likely to spread to the tubes if an IUCD is in place. If infection does occur, antibiotic therapy should be given and the device removed. The previous presence of infection with IUCD does not alter the treatment of PID. IUCD associated pelvic infection is more likely to be caused by non-STD organisms. HIV infected women who utilise IUCDs for contraception do not have a greater incidence of complication including PID.
- *Actinomyces:* The significance of actinomycosis infection in IUCD users is unclear. There has been some evidence of actinomycosis in cervical smears from IUCD users (around 30%).

Perforation of uterus: Sometimes the IUCD penetrates the uterine wall and escapes into the peritoneal cavity and causes adhesions and intestinal obstruction. It is nearly always the result of the uterine wall being perforated or deeply injured at the time of the insertion. Once in the peritoneal cavity IUCD travels to any site. Without X-ray screening it can sometimes be very difficult to find the device at laparoscopy or laparotomy. If it is an inert device, there is often no need to remove it. In case of copper IUCD, removal is always indicated as there is risk of pelvic adhesions due to continuous release of copper. Removal is often possible by laparoscopy rather than by laparotomy.

Embedded IUCDs: If removal of IUCD is not easily accomplished, direct visualisation of the IUCD with sonography or hysteroscopy can be helpful. Sonography is safer and less expensive. Under abdominal ultrasound guidance, we can remove it by forceps. If this method fails then hysteroscopy is indicated.

Displaced IUCD: When an IUCD cannot be found on expulsion, one has to consider perforation in abdominal cavity or embedment into the myometrium. A quick, real time sonography is the best method to locate a lost IUCD whether or not removal is desired. If the IUCD cannot be visualised by ultrasound, abdominal X-rays are necessary because the IUCDs are radio-opaque and can be high and hidden. If the IUCD is identified perforating the myometrium or in abdominal cavity, it should be removed using operative laparoscopy under general anaesthesia. If it is located in the uterine cavity, first try to remove it under ultrasound guidance otherwise hysteroscopy is the best approach.

Pregnancy with an IUCD in situ: The incidence of pregnancy with IUCD in place is 2% during the first year after insertion, thereafter the rate increases to 3%. Associated complications are:

- Spontaneous miscarriage:

- Septic abortion: There is no evidence that there is an increased risk of septic abortion if pregnancy occurs with IUCD in situ except the Dalkon shield. If a patient plans to terminate a pregnancy, IUCD should be removed in a clinic if there is no evidence of infection. If an IUCD is in infected pregnant uterus, removal of the device should be undertaken only after antibiotic therapy has been initiated and equipment for cardiovascular support and resuscitation is immediately available as removal in infected uterus can lead to a septic shock.

- Preterm labour and births: The incidence is increased approximately four fold when IUCD is left in place during pregnancy.

- Congenital anomalies: There is no evidence that exposure of the foetus to medicated IUCD is harmful. The risk of congenital malformation is increased among infants born to woman with IUCD in place during pregnancy.

- Other complications: Obstetrical complications at delivery (e.g. haemorrhage, stillbirth and difficulties with place of removal) have been reported only with the Dalkon shield in situ.

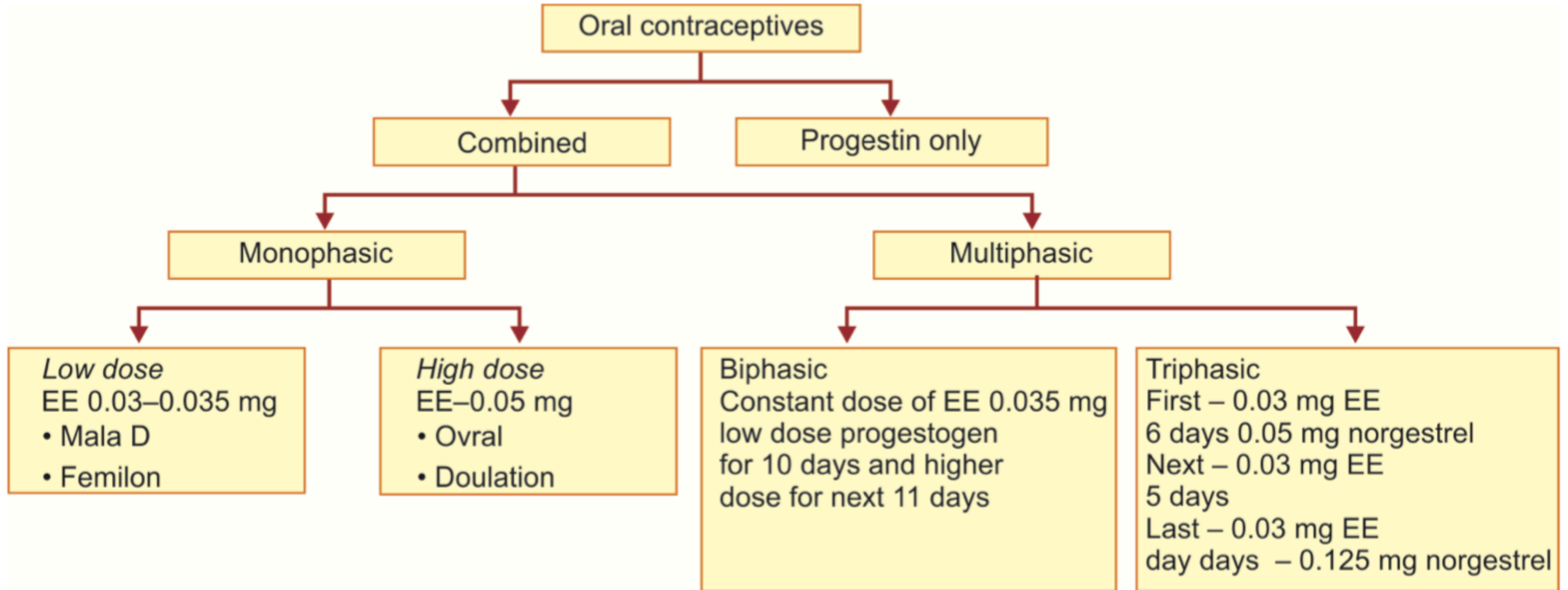
- **Advantages**

- They offer a cheap and practical means of considerably lowering fertility for a reasonably long period without the woman needing to pay any heed.
- No serious side effects, if any, they disappear immediately after the device is removed.
- This method does not require privacy or toilet facilities, as does the use of diaphragm.
- It does not lower fertility.
- It can be used as emergency contraception within 5 days of unprotected intercourse.
- No interaction with any medicine.
- No hormonal side effects.
- No effect on amount or quality of breast milk.

• **Postpartum Intrauterine Contraceptive Device**

- Copper IUCDs can be inserted between 4 weeks and 8 weeks postpartum without an increase in pregnancy rates, expulsion, uterine perforation or removal for bleeding and/ or pain. Expulsion rate is less with new IUCDs.
- Insertion can even occur immediately after a vaginal delivery if no intrauterine infection is present or suspected. A slightly higher rate of expulsion is to be expected, compared to insertion 4–8 weeks postpartum.
- Insertion of an IUCD in breastfeeding women is relatively easier and is associated with a lower removal rate for bleeding or pains, perforation rate is not more.
- An IUCD can be inserted immediately after a first trimester abortion but after a second trimester abortion, it is recommended to wait until uterine involution occurs.

Flow chart 50.1: Oral contraceptives and its doses



Estrogens used—ethinyl estradiol, mestranol; Progestrones—(1) norethindrone, (2) norgestel, (3) gestodene, desogestel, (4) drospiridone

• **Combined Oral Contraceptive Pills**

Combined hormonal oral contraceptive pills contain both oestrogen (usually ethinyl oestradiol) and a progestogen.

Oestrogen: Ethinyl oestradiol is a very potent oral oestrogen used in oral contraceptives. The dose of oestrogen used in the combined pill ranges from 15 µg to 50 µg. Low dose oral pills containing 20–35 µg of oestrogen are also available. Low dose pills are safer because cardiovascular risk and risk of thrombosis are mainly from oestrogen content of pill and are dose related. Therefore, the dose of oestrogen is a critical issue in selecting an oral contraceptive.

Progesterone: The progestational derivatives of testosterone were designated as 19-nortestosterones (denoting the missing 19-carbon). The androgenic properties of these compounds were not totally eliminated and minimal anabolic and androgenic potential remains within the structure.

Progestogens used in currently available pills are divided into four groups:

1. First generation progestogens = Norethindrone group.
2. Second generation progestogens = Norgestrel group. 0.05 – 0.25 µg of levonorgestrel which is an active isomer of norgestrel
3. Third generation progestogens = gestodene 0.075 µg, desogestrel 0.15 µg, norgestimate 0.25 µg
4. Newest progestogens—drospirenone has antiandrogenic and antimineralocorticoid activity.

Definitions used in epidemiologic studies:

Low dose oral contraceptives—products containing less than 50 µg ethinyl oestradiol.

- First generation oral contraceptives—products containing 50 µg or more of the ethinyl oestradiol.

- Second generation oral contraceptives—products containing levonorgestrel,

- Norgestimate and the other members of the norethindrone family and 30 or 35 µg ethinyl oestradiol.

Third generation oral contraceptives—products containing desogestrel or gestodene with 20 or 30 µg ethinyl oestradiol.

Missing Pills

- Pill missed
 - Missed pill taken as soon as remembered or 2 HS next day
 - No backup
- Pills missed
 - Week 1 → 2 pills daily 2 days then resume schedule
 - Week 3 → start new pack with backup for 7 days
- Pills missed
 - Start new pack with backup for 7 days.

Mode of Action

Inhibition of ovulation

Alteration of endometrium

Changes in cervical mucus that interfere with sperms transport

Tubal motility may be altered

Atrophy of endometrium

Uterine receptivity essential for successful implantation may be impaired.

Action of Oestrogen

Decreased follicle-stimulating hormone (FSH) release

Prevent emergence and selection of dominant follicle

Provide stability to endometrium

Prevent irregular shedding and unwanted breakthrough bleeding

Potentiates the action of progestational agents.

Action of Progestogens

- Prevent luteinizing hormone (LH) surge necessary for ovulation
- Cervical mucus becomes thick and impervious to sperm transport
- Produces an endometrium not receptive for implantation (decidualised bed with exhausted and atrophic glands)
- Influences secretion and peristalsis of fallopian tube
- Counteracts undesirable side effects of oestrogen like endometrial hyperplasia and heavy withdrawal bleeding.

- *If pills are missed in week 1 (day 1–7):* (Since the pill free interval has been extended) emergency contraception should be considered if she had unprotected sex in the pill free interval or in week 1.
- *If pills are missed in week 3 (day 15–21):* In order to avoid extending the pill free interval, she should finish her current pack and start a new pack the next day, thus omitting the pill free interval.
- *If pills are missed in week 3 (day 15–21):* In order to avoid extending the pill free interval, she should finish her current pack and start a new pack the next day, thus omitting the pill free interval.

Contraindications

Absolute contraindications (WHO medical eligibility criteria category 4 conditions) to the combined pill are listed.

Relative contraindications (WHOMEC category 3 or 3/4 conditions) include the presence of serious or multiple risks for arterial disease including hypertension, diabetes, smoking, age greater than 35 years, obesity and migraine.

Women with hyperprolactinaemia should be advised to use progestogen only contraception because oestrogen stimulates lactotrophes, thus increasing the prolactin concentration.

TABLE 50.3

Category 4 condition (Absolute contraindications)

- Breastfeeding > 6 weeks postpartum
- Smoking > 15 cigarettes/day and aged > 35 years
- Blood pressure > 160/100 mmHg
- Hypertension with vascular disease
- History of or current deep venous thrombosis
- Major surgery with prolonged immobilisation
- Focal migraine
- Severe cirrhosis
- Liver tumour
- Current breast cancer
- Complicated valvular heart disease
- History of stroke
- History of or current myocardial infarction

TABLE 50.4

Category 3 and 3/4 conditions
(Relative contraindication)

- Breastfeeding 6 weeks to 6 months postpartum
- Before 3 weeks after childbirth
- Smoking < 15 cigarettes/day and aged > 35 years
- Adequate controlled hypertension
- Blood pressure > 140/90 mmHg
- Severe hyperlipidaemia
- Non focal migraine and age > 35 years
- Past breast cancer—5 years without recurrence
- Past COC related cholestatic
- Mild cirrhosis
- Current or medically treated gall bladder disease

Category 3/4 Conditions

- Multiple risk factors for cardiovascular disease
- Diabetes with retinopathy, nephropathy, neuropathy other vascular disease or of > 20 years duration

The Benefits of Low Dose Oral Contraceptive Pills

- Effective contraception
 - Less need for induced abortion
 - Less need for surgical sterilisation
- Less endometrial cancer
- Less ovarian cancer
- Fewer ectopic pregnancy
- More regular menstrual flow
 - Less dysmenorrhoea
 - Less anaemia
 - Less flow
- Less salpingitis
- Less anaemia
- Probably less endometriosis
 - Less benign breast disease
 - Less rheumatoid arthritis
 - Fewer fibroid
 - Fewer ovarian cyst
 - Protection against atherosclerosis.

- *Other Uses*

Oral contraceptives are frequently utilised to manage the following problems and disorders:

- Dysfunctional uterine bleeding
- Dysmenorrhoea
- Mittelschmerz
- Endometriosis prophylaxis
- Acne and hirsutism
- Hypothalamic amenorrhoea
- Prevention of menstrual porphyria
- Control of bleeding (dyscrasias, anovulation)
- Sometimes used for:
 - – Functional ovarian cyst
 - – Premenstrual syndrome

Progestogen Only Contraception

Progestogen only contraceptive is now available, with the active hormone administered as oral preparations, injectables, implants or intrauterine systems.

Indications

- Women with medical illness contraindicating the use of combined pills, e.g. hypertension, migraine with focal aura, diabetes or personal history of venous thromboembolism.
- Breastfeeding women
- Women who are at increased risk of venous or arterial disease with COC (obese and heavy smokers)
- Women who have oestrogenic side effects with COCs, e.g. headache, breast tenderness.
- Women who specifically choose for this method.

• **Mode of Action**

- It mainly acts by altering the cervical mucus to reduce the sperm penetration (thick and impermeable).
- It induces changes in the endometrium to prevent sperm survival and becomes hostile to implantation.
- Ovulation may be suppressed in 15–40% of cycles and only partly contributes to the mechanism of action.
- Ectopic pregnancy is not prevented as effectively as intrauterine pregnancy, although the overall incidence of ectopic pregnancy is not increased. However, when pregnancy occurs, we must suspect that it may be an ectopic.

Efficacy—Failure rates of the progestogen only pill (POP) vary from 1.1 to 9.6 per 100 women in the first year of use.

Failure rate is higher in younger women (3.1/HWY) compared with women around 40 years of age (0.3/HWY).

A POP containing 0.75 µg desogestrel, however, inhibits ovulation in 97–99% of the cycles, resulting in efficacy similar to combined oral pills.

Progesterone Only Injectables

- Depoprovera (depo medroxyprogesterone acetate) is the most commonly used injectable progesterone only contraceptive, which has been used extensively worldwide.
- Depoprovera comes as microcrystals, suspended in an aqueous solution. The correct dose for contraceptive purpose is 150 mg intramuscularly (gluteal or deltoid) every 3 months. Contraceptive level is maintained for at least 14 weeks. Women may occasionally attend late for their injection and no action needs to be taken until 14 weeks have elapsed.

The other progestogen only injectable is Noristerat. This contains 200 mg norethisterone enantate (NET-EN), given intramuscularly at every 8 weeks interval (2 months). NET- EN is used mainly for a woman whose husband is undergoing vasectomy, until the vasectomy is effective and in women immunised against rubella, to prevent pregnancy during the activity of virus. NET-EN can be used for long-term contraception in selected patients after counselling.

Progestogen Only Implants (Norplant)

Norplant is a sustained release system using silastic tubing permeable to steroid molecules to provide stable circulating levels of synthetic progestin over years of use. Norplant was first introduced into clinical trials in Chile in 1972.

Norplant was the first contraceptive implant system launched worldwide and is highly effective reversible contraceptive lasting for 5 years. It is a subdermal implant system (**Fig. 50.58**), which is low dose progestogen only method of contraception. It consists of six small, flexible sealed silastic capsules, each measuring 34 mm in length with a 2.4 mm outer diameter and containing 36 mg crystalline levonorgestrel. The cavity of the capsule has an inner diameter of 1.57 mm, with an inner length of 30 mm. The six capsules contain a total of 216 mg levonorgestrel, which is very stable and has remained unchanged in capsules examined after a year of use. It comes in heat sealed pouches that have a shelf life of 5 years from the date of manufacturing. It should be stored in a cool dry area away from direct sunlight. It releases 85 µg of hormone per day initially, then decreasing to 50 µg/ day by 6 months and 35 µg/day by 18 months.

Mechanisms of Action

The levonorgestrel diffuses through the wall of the tubing into the surrounding tissues where it is absorbed by the circulating system and distributed systemically, avoiding an initial high level in circulation as with oral or injectable steroids. Within 24 hrs of insertion, plasma concentration of levonorgestrel ranges from 0.4 µg/mL to 0.5 µg/mL, high enough to prevent conception.

Body weight affects the circulating levels of LNG. The greater the weight of the user, the lower the LNG concentrations at any time during Norplant use. But even for heavy women, the release rate is high enough to prevent pregnancy at least as reliably as oral contraceptives.

Progestogen Intrauterine System (Mirena)

Mirena is a new intrauterine hormonal contraceptive system releasing levonorgestrel. It has been available worldwide since 1995 and more than 6 million women worldwide have used it for contraception. Nowadays, in addition to contraception, it is used for idiopathic menorrhagia, for therapeutic benefits in fibroid, adenomyosis, endometriosis and more recently as the progestogen component of hormone replacement therapy.

Structure

Mirena consists of a plain plastic T-shaped frame with a steroid reservoir around the vertical stem. This reservoir consists of a cylinder, made of LNG and polydimethylsiloxane mixture, containing a total of 52 mg LNG. The total length of the system is 32 mm. The reservoir forms a 19 mm long sleeve around the vertical arm of the plastic body and is covered by a polydimethylsiloxane membrane, which regulates the minimal intrauterine release of LNG. The T-shaped frame is impregnated with barium sulphate to make it radio-opaque. With mirena, only 20 µg/day of LNG is released.

The recommended duration of use for mirena is 5 years. Thereafter it should be removed and replaced by a new system, if needed.

- *Time of Insertion*

It should be inserted within the first 7 days of the menstrual cycle when bleeding is not heavy.

Efficacy

With mirena, 1 year and 5 years pregnancy rates are 0.1% and 0.5% respectively and has very high continuation rate with around 82% of women using it after 3 years.

Indications

- *Contraception: Mirena is highly effective contraceptive. It provides fertility control comparable to female sterilisation.*
- *Idiopathic menorrhagia: It also markedly reduces menstrual blood flow and alleviates dysmenorrhoea.*
- For regression of endometrial hyperplasia.
- It can prevent endometrial proliferation and reduce the uterine bleeding associated with oral or transdermal oestradiol.
- Mirena may be effective for long term prevention of fibroids and also regulates the growth of fibroids. Studies are going on.

Adverse Effects

- During the first few months after insertion of mirena, recipient may experience transient hormonal side effects including oedema, headache, breast tenderness, acne or other skin problems.
- Sometimes lower abdominal or back pain, vaginal discharge and nausea.

EMERGENCY POSTCOITAL CONTRACEPTION (MORNING AFTER PILLS)

Emergency contraception is a method of contraception used before menstruation is missed as an emergency procedure, to prevent pregnancy following unprotected intercourse or expected failure of contraception. This method can be used only as an emergency measure following a single act of intercourse before the menses are missed. It cannot be used as an ongoing method of contraception because of relatively high failure rates and high incidence of irregular bleeding.

Indication

- For aged couple who meet very infrequently.
- Following a single act of sexual exposure in young girls.
- When pregnancy is apprehended owing to rupture of condoms, detection of defect in diaphragm after its use or premature ejaculation in couples practising coitus interruptus regularly.
- When unprotected isolated intercourse happens at some odd moments among couples otherwise using conventional contraceptives.
- In cases of rape and incest.

- **Advantages**

- Saves the couples from unwanted pregnancies
- From unnecessary operative interferences for fear of pregnancy
- From the agony of waiting for the next menstrual cycle
- Prevents adolescent pregnancies
- Helps to reduce unsafe abortion

Two methods of emergency contraception are available now—hormonal and mechanical.

- **Hormonal Emergency Contraception**

High doses of oestrogen were used most widely for 5 days upto the early 1970s, but most women experienced side effects particularly nausea and vomiting. This oestrogen only method has been abandoned completely.

Two types of hormonal contraceptive method used now are: (1) combined oestrogen and progestogen pills, (2) levonorgestrel only pill.

Combined Oestrogen and Progestogen Pills

Yuzpe developed a method utilizing a COC, resulting in an important reduction in dosage. The following treatment regimens have been documented to be effective.

- Ovral—2 tablets followed by 2 tablets 12 hours later
- Alesse—5 tablets followed by 5 tablets 12 hours later
- Loovral, Nordette, Levlen, Triphasil, Trilevlen—4 tablets followed by 4 tablets 12 hours later
- Pills should be taken within 72 hours of unprotected intercourse.

Mode of action:

It may act through:

- Inhibition or delay of ovulation
- Prevention of implantation in the altered endometrium.

Exact mechanism of action is not known, studies are going on.

Effectiveness: The Yuzpe regimen prevents about 75% of pregnancies that otherwise were expected to occur. Approximately 8% of women can be expected to become pregnant after a single act of unprotected intercourse on a random day of menstrual cycle but only 2% become pregnant if they use the Yuzpe regimen.

Side effects:

- Nausea occurs in 50% of users but does not last for more than 24 hours.
- Vomiting occurs in 20% of users; if vomiting occurs within 2 hours of taking the pills, the dose should be repeated.
- *Irregular uterine bleeding:* Some women may experience some spotting after taking the pills. The majority of women will have an early onset and in some, menstruation is delayed by 7 days. If there is a delay of more than 7 days, a pregnancy test should be performed.
- Others are like headache, dizziness, fatigue and breast tenderness.

- **Levonorgestrel Only Pills**

Levonorgestrel in a dose of 0.75 mg given twice, 12 hours apart, is more successful and better tolerated than the COC method. This dose of LNG is equivalent to 20 pills of the norgestrel progestin only minipills.

In many countries, special packages of 0.75 mg levo- norgestrel are available for emergency contraception.

Efficacy: Efficacy with levonorgestrel only method will be even better. In the worldwide WHO study, the risk of pregnancy was 60% lower with LNG only method compared with the oral contraceptive method. Failure rate was only 1.1% for LNG only group while it was 3.2% for the Yuzpe group.

Side effects are less with this method.

Mechanism of action is not known with certainty but it is believed with justification that this treatment is mainly a delay of ovulation combined with a local effect on the endometrium.

Treatment method:

- Treatment should be initiated as soon after exposure as possible and the standard recommendation is that it should be no later than 72 hours.
- Because of the possible but unlikely, harmful effects of these high doses to a foetus, an already existing pregnancy should be ruled out prior to the use of postcoital method.
- The patient should be offered induced abortion if method fail.

Newer Emergency Contraceptives

- *EllaOne* (30 mg) → Preg prevention upto 120 hours of unprotected sex Contains *ulipristal* → selective progesterone receptor modulator. Inhibits ovulation and also prevents fertilisation. Also known as **Morning after pill**.

Mechanical Emergency Contraception : IUD

Intrauterine devices introduced postcoitally can prevent pregnancy very successfully. This method is being tried since the mid-1970s. Indication

- Intrauterine contraceptive devices are preferable if the woman desires IUCD as an ongoing method of contraception.
- If there is contraindication to the use of oestrogen (LNG pills can also be used in these cases).

Advantages

- Intrauterine contraceptive device can be used postcoitally upto 5 days following sexual exposure.
- Intrauterine contraceptive device is effective as soon as it is inserted and therefore gives immediate protection for subsequent acts of intercourse in the same cycle.
- It can be used as an ongoing method of contraception upto 3–10 years depending upon type of IUCD used.

Disadvantages

- Apart from the usual side effects of IUCDs like bleeding, pain and expulsion, there is a chance of severe pelvic infection if the woman has vaginal infection including STD or asymptomatic PID at the time of insertion.
- Intrauterine contraceptive devices do not prevent against HIV/AIDS.

Others

Mifepristone (RU486) in a single dose of 600 mg is associated with markedly less nausea and vomiting and an efficacy rate of nearly 100%. In a worldwide randomised trial 10 mg of mifepristone was as effective as 50 mg or 600 mg of mifepristone, achieving a pregnancy rate of only 0.9% and efficacy was not diminished by delaying treatment as long as 5 days after intercourse. It is still under trial. It can make an effective contribution to preventing unwanted pregnancies and induced abortions.

The use of **danazol (400 mg)** for emergency contraception is not effective.

OTHER METHODS OF CONTRACEPTION

- *Hormone agonist and antagonist*: There is an ongoing search for methods of suppressing ovulation without using oestrogens. One possible development in this field is the synthesis of GnRH agonist and antagonists. GnRH agonists prevent FSH and LH surges. However, suppression of ovarian activity has undesirable side effects on the bone, CVS, etc., and incomplete suppression lead to the consequences of unopposed oestrogen action. At the present time they may have a place in short term contraception, e.g. in the breastfeeding mother.
- *Mifepristone (Progesterone antagonist)*: Progesterone antagonist have a greater potential for fertility regulation, mifepristone blocks the action of progesterone on the endometrium and is used in emergency contra- ception. Daily doses of 2 mg and weekly doses of 100 mg are effective in inhibiting ovulation. Development of once a month pill given in luteal phase is also under consideration (WHO 1994).
- *Centchroman*: To avoid bad effects of OCs, centchroman has been produced by the researchers of Central Drug Research Institute, Lucknow, India. It is a non-hormonal chemical synthetic once a week oral contraceptive. It is available freely in the Indian market at a relatively low cost. Each tablet contains 30 mg of centchroman. The recommended dose is one tablet twice a week starting from the first day of menses for the first 3 months and then once a week irrespective of menstruation. It was a weak oestrogen and potent antioestrogenic effect, acting mostly on the endometrial target organ to suppress proliferation of endometrium.

Immunological Method

- Efforts to make a woman infertile by vaccinating her with semen to produce antibodies have so far failed. A vaccine against part of the β -subunit of LNG has been developed which can be effective for 6–12 months but has significant local reaction. In India, a vaccine against the whole β -subunit has been developed. It cross reacts with LH, but there is no significant menstrual disturbance. However, the duration of effectiveness and long term safety has not yet been established.
- Vaccines against the zona pellucida are effective in animal studies but in animals they lead to permanent ovarian dysfunction, sterility and premature menopause.

•Male Contraceptive Pill

A reversible method of contraception for men has been sought for years. Hormonal contraception for men is inherently a difficult physiologic problem because, unlike cyclic ovulation in women, spermatogenesis is continuous, dependent upon gonadotrophin and high levels of intratesticular testosterone.

The *sex steroids* reduce testosterone synthesis, which leads to loss of libido and development of female secondary sexual characteristics. Furthermore, despite the use of large doses, sperm counts are not adequately reduced in all subjects.

-Levonorgestrel, cyproterone acetate and medroxyprogesterone acetate all have been studied, combined with testosterone, given intramuscularly to provide the desired systemic androgen effects.

-Gonadotrophin releasing hormone *analogues* also decrease the endogenous synthesis of testosterone and supplemental testosterone must be provided. The overall metabolic and health consequences of these approaches have not been assessed and frequent injections are required.

-Gossypol, a derivative of cotton seed oil, sex steroids and the use of GnRH analogues.
effectively decreases sperm counts to contraceptive levels, apparently by incapacitating the sperm producing cells. Gossypol pills are taken daily for 2 months until sperms are no longer observed in the ejaculate and then the pills are taken weekly. Fertility returns to normal 3 months after discontinuation.

- **Adolescent's Choice of Contraception**

Providing contraception or information about contraception for young people under age 20 is an important factor. Teenage girls carry the burdens of unprotected sexual activity like unwanted pregnancy, undetected STDs and pelvic inflammatory disease. Rates of HIV infection are rising faster in young women than in any other group. Premature parenthood and the STDs are the risks of sexual experimentation.

Contraceptive education must be combined with an emphasis on overall life issues and interventions including decision to become sexually active, no single message or approach by itself will be broadly effective for all adolescents.

- Our goals are to promote abstinence among teenagers who are not yet ready to cope with sex and its consequences and to promote behaviour that will prevent pregnancy and STDs in sexually active adolescents.
- Building trust and good communication are requirements for a successful interaction between clinician and adolescents.

Choice of Methods

- *Oral contraception*: The COC is the most popular and most requested method of contraception by teenagers. OCs are almost never medically contraindicated in healthy adolescents. Thus, the high efficacy of COC is an excellent choice for teenagers.
 - Because younger women change partners more frequently than older ones, a dual approach is recommended, COCs combined with the use of barrier methods so that they can prevent PID, STDs and HIV.
- *Barrier methods*: After oral contraception, the condom use with a spermicide is the next best choice for young women obviously this is the only choice for male adolescents. The diaphragm and cervical caps should be reserved for very motivated and young people.
- *Intrauterine device*: IUCDs have not been recommended for nulligravid women and those who have a high risk of STDs. It can be considered for young parous woman who is in stable monogamous relationship. It is also a good choice for patients with chronic illness such as diabetes mellitus or SLE.
 - – The creams, foams, suppositories and jellies are not ideal for adolescents. They require proper timing, careful placement and consistent use to achieve good efficacy.
 - – There are special candidates to consider for long- acting contraception (depoprovera or Norplant), teens who have failed oral contraception and who are mentally retarded or have chronic illnesses.
 - – Because adolescents often have unplanned sexual intercourse, access to emergency postcoital contraception is very important. The failure rate is approximately 2% using OCPs and 1% using LNG pills.

- POST PARTUM CONTRACEPTION: role of three:
- In the presence of full breastfeeding, a contraceptive method should be used beginning in the 3rd postpartum month.
- With partial and no breastfeeding, a contraceptive method should begin during the 3rd postpartum week.
- After the termination of pregnancy of less than 12 weeks, oral contraception can be started immediately.
- After a pregnancy of 12 or more weeks, the 3rd postpartum week rule should be followed. This delay has been based on a theoretical concern over an increased risk of thrombosis early in postpartum period.

Contraception Choice for Older Women

Oral contraception: Oral contraceptive benefits to be emphasised with older women.

Less endometrial cancer

Less ovarian cancer

More regular menses

Increase in bone density and others mentioned before

In all women greater than 35 years of age, non-smoker, lowest dose oestrogen (20 µg) combined pills should be used.

The progestin only minipill is a good choice for older woman especially in whom combined pills are contraindicated.

The oral contraceptives that contain 20 µg oestrogen provides effective contraception, improves cycle regularity, diminishes bleeding and relieves menopausal symptoms.

- ***Transition from oral contraception to postmenopausal hormone therapy:*** It is very important to change because even with lowest oestrogen dose oral contraceptive available, the oestrogen dose is four-fold greater than the standard postmenopausal dose. With increasing age, dose related risks with oestrogen become significant. To establish the onset of postmenopausal years, FSH levels are measured yearly beginning at age 50, sample is taken on day 6 or 7 of pill free week. When FSH is greater than 20 IU/L, it is time to change to a postmenopausal hormonal therapy.
- Long-acting methods are especially advantageous for smokers and for women with a history of thromboembolic disease.
- Intrauterine contraceptive devices (Cu and LNG IUCDs) are amongst the most effective contraception for older women, as they are more likely to be mutually monogamous and less likely to develop PID as they have already had their children.

Thank you all

