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OPINION

Current state of intrauterine contraceptive devices

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ABSTRACT

Background: Intrauterine contraceptive device (IUCD) is the most commonly used method of contraception in many countries. Despite the availability of many generations of IUDs with variable shapes and configurations, side effects and complications are frequent. We hypothesize that a modified IUD design with a fundal seeking effect will nullify the side effects and the complications of the currently available IUDs. Such a design will be at least as effective as the traditional copper devices without their well-known disadvantages. This simple modification of the IUD shape will add to the acceptability of this method even in communities with known preferences to other alternatives.
Keywords: Intrauterine contraceptive device, contraception, family planning.

Background and significance

Contraceptive practices: Methods and Trends

Contraceptive prevalence is dependant on method availability or woman choice. However, what is called as a method mix is a documented biosocial phenomenon when one or two methods predominate in a given country. Contraceptive method skew is operationally defined as a single method constituting 50% or more of contraceptive use in a given country. Recently, the Center for Communication Programs, Johns Hopkins Bloomberg School of Public Health, USA examined this phenomenon in 96 countries (1). They found that 34 countries have this type of skewed method mix. These 34 countries were categorized in three groups: 1. sixteen countries in which traditional methods dominate, most of which are in sub-Saharan Africa; 2. four countries in which female sterilization predominates (India, Brazil, Dominican Republic and Panama); and 3. fourteen countries that rely on a single reversible method (the pill in Algeria, Kuwait, Liberia, Morocco, Sudan and Zimbabwe; the IUD in Cuba, Egypt, Kazakhstan, Kyrgyz Republic, Moldova, Turkmenistan and Uzbekistan; and the injectable in Malawi). Method skew in some countries reflects cultural preferences or social norms. Consequently, in 7 countries 50% or more of women using contraception opt to use the intrauterine devices (IUDs) (1).

Patterns of fertility in Egypt were found in 1995 survey to be 3.5 children per woman: 3.0 in urban areas, 4.2 in rural areas, 4.6 among uneducated women, and 3.0 among women with at least a secondary education. Fertility was 67/1000 women per year among women 15-19 years old in the 4 years preceding the survey, 213/1000 women 25-29 years old, and 211/1000 women 20-24 years old. Fertility declined in each age group over time and with increasing age. Modern contraceptive prevalence was 45.5%. Contraceptive prevalence ranged from a low of 39.1% among the uneducated

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to 52.9% among women with at least some secondary education. The highest contraceptive prevalence was among women living in urban areas. 62.7% of all methods were obtained from private sources. The most frequently used method was the IUD with 30% of women users. 10.4% of women used the pill (2).

Worldwide, IUDs are among the most commonly used reversible methods of contraception. Outside of the People's Republic of China, the most widely used IUDs are the Multiload and various T-shaped devices that release microgram amounts of copper over at least 5 years, including the TCu 380A and Nova T. Copper-releasing IUDs are highly effective in preventing pregnancy with pregnancy rates of less than 0.8 per 100 women per year. The two most frequently occurring events that lead to IUD discontinuation are expulsion of the device from the uterus (including partial expulsion that then requires removal of the IUD) and removal because of bleeding and/or pain. Expulsion rates and removal rates for bleeding and pain are highest during the first year of IUD use and decline over time.

Clinical aspects of IUDs

The intrauterine devices are composed of plastic or metal or a combination of both. They are to be inserted in the uterine cavity via the cervix. Since the introduction of the IUDs, a wide and extensive variety of shapes, sizes and combinations of materials have been used with a wide spectrum of indications, contraindications, acceptability, compliance, contraceptive effectiveness and worldwide extent of use. Currently, IUDs are used more frequently in the Middle and the Far East compared to Europe and the USA. Only 3 IUDs are available for use in the U.S.: the Progestasert, the Copper TCu380A (Paragard), and a levonorgestrel-releasing system (Mirena). The Progestasert is made of a special polymer that contains a reservoir of 38 mg of progesterone, which is released at a rate of 65 micrograms per day. Consequently, it is effective for 1 year only. The Paragard is wrapped with a copper wire that creates a surface area of copper of 300 mm2 on the vertical arms and 40 mm2 on each of the transverse arms. It is effective for up to 10 years.

Mirena is releasing levonorgestrel at 20 ug/day. It is effective for up to 5 years. It is as effective as copper TCu380A and Norplant but also more likely to cause amenorrhea. This function could actually be beneficial in some patients particularly those with menorrahgia. However, side effects of progesterone as depression, acne, headache, and weight change may also occur (3).

The exact mechanism of IUDs action is not well understood. The most accepted explanation for IUDs contraceptive effect is the initiation of a hostile environment to the fertilized ovum. The most widely observed phenomenon is the mobilization of leukocytes in response to the presence of the IUD. Supporting this hypothesis is the widely observed leukocytes aggregate around the IUD in the endometrial fluids and mucosa and, to a lesser extent, in the stroma and underlying myometrium. Alteration of the endometrial maturation with the progesterone-releasing device, tubal cilial action, and possible disruption of normal oocyte maturation are all proposed mechanisms for the copper devices. In additional a possible spermicidal activity is postulated (4).

The TCu380A is probably the most effective currently available IUD with a failure rate of less than 1% per year while the Progestasert failure rate is 1-1.5% (5). However, 25% of the pregnancies are ectopic. Consequently the latter device does not protect against ectopic pregnancy (6).

In a recent meta-analysis, 34 trials were included to compare different copper IUDs for their effectiveness and side effects. They found that TCu380A was more effective than MLCu375, MLCu250, TCu220 and TCu200. Changing the position of the copper on the arm of the IUD for TCu380S did not improve the efficacy of TCu380A. MLCu375 was no more effective than TCu220, at 1 year, MLCu250 to 3 years or Nova-T to 3 years Compared to TCu380A, none of the IUDs showed any benefits in terms of bleeding or pain, or any of the other reasons for early discontinuation. This meta-analysis showed that TCu380A is more effective compared to other IUDs. There is no data available comparing different IUDs in special subgroups, such as nulliparous women (7).

Indications an IUD

Ideally, IUDs are to be used in parous women in a mutually monogamous relationship who do not have a current or prior history of STDs or PID. Women desiring a method of high efficacy that is free of daily or sex related activity and women who cannot use hormonal contraception due to side effects or medical conditions are suitable candidates. Several surveys demonstrated that IUD users are highly satisfied with their method.

Contraindications to the Use of IUDs

Current pregnancy; undiagnosed abnormal vaginal bleeding; acute cervical, uterine, or salpingeal infection; past salpingitis; and suspected gynecologic malignancy are all absolute contraindications for IUDs. Relative contraindications include nulliparity or high priority attached to future childbearing; prior ectopic pregnancy; history of STDs; multiple sexual partners; moderate or severe dysmenorrhea; congenital anomalies of the uterus or other abnormalities such as leiomyomas; iron deficiency anemia; valvular heart disease; frequent expulsions or problems with prior IUD use; age younger than 25 years (due to higher prevalence of Chlamydia infections); and Wilson's disease (if a copper IUD is to be used). If the client is in a monogamous relationship, age younger than 25 years is not a contraindication.

Complications of Insertion

Mild to moderate discomfort or pain is often encountered at sounding or insertion. The degree of discomfort and pain is proportional to the size of the IUD. This also could be related to the dilatation of the cervical canal and distention of the endometrial cavity which may lead to syncopal attacks as well. It was suggested that paracervical anesthesia could reduce pain and syncope. It is also possible that analgesics may be helpful for several hours following IUD insertion. Partial or complete perforation of the uterus is a rare avoidable complication of IUD insertion. Accurate determination of the position and size of the uterus and strict adherence to the recommended insertion procedure could prevent perforation.

Disadvantages and Side Effects

A. Pregnancy

The management of intrauterine pregnancy with an IUD is mainly dependant on the patient wishes. If the patient wishes it to continue, the IUD may be removed by traction on the plastic tail. However, if this attempt is failed, it is advisable to leave the device in place. Should the pregnancy continue, the incidence of spontaneous miscarriage is around 50%, compared to only 12% in the general population. Such a high incidence of spontaneous miscarriage could be reduced to only 20-25% if the IUD is removed. In addition it nullifies the risk of septic abortion. Concerning ectopic pregnancy, copper IUDs, reduces the risk twofold or more relative to patients using no contraception.

Although about 5% of the pregnancies that occur with a copper IUD in situ are ectopic, the overall contraceptive action of copper IUDs reduces the risk of all pregnancies and the absolute risk of an ectopic pregnancy. On the other side, Progestasert does not over any protection against ectopic pregnancy. It has been demonstrated that the risk may be 50% or greater in comparison with that of no contraception. Lastly with Mirena use, half of all pregnancies were ectopic. However the of ectopic with Mirena was not significantly different than the rate for sexually active women not using contraception. There is no increased incidence of congenital abnormalities in babies who are conceived with the IUD in utero.

B. Expulsion

Expulsions of IUDs are mostly spontaneous and occur in the immediate post-insertion period during menses. The quality and the configuration of the device is probably the most important detrimental factor controlling the incidence of expulsion. In addition the stiffness, size, and shape of the device are contributing factors. In general, the expulsion rate is roughly proportional to the degree of distortion of the endometrial cavity brought about by the presence of the IUD. Consequently, devices that fit the uterine cavity configuration the best are probably associated with the least incidence of expulsion.

Confirming that the device is in place is ascertained by periodic self examination to be assured that the tail of the device is still present. Expulsion of the IUD may not be noticeable. Common reasons for missed threads of the IUD may be due to that fact that the filament may have been drawn back into the cervix or endometrial cavity. Less commonly, the device may have perforated the uterine wall at insertion and passed into the peritoneal cavity which occurs in < 1 out of 1000 insertions. Sometimes the tail may have separated from the device and been expelled unnoticed. Ascertainment of the location of the IUD could be performed by careful inspection or exploration of the endometrial cavity with an ultrasound examination or, if necessary, by an x-ray examination that includes an anteroposterior as well as a lateral film and use of a sound to localize the uterine cavity.

C. Bleeding or Pain

Bleeding or pain or both are common reasons for removal of an IUD and discontinuation of this method of contraception. The incidence of these symptoms is more or less related to the degree of endometrial compression and myometrial distention brought about by the IUD configuration. Thus, an IUD that conforms to the natural size and shape of the endometrial cavity is likely to cause less pain or bleeding than one that distorts the cavity and the uterine wall. The adaptability and the conformational yielding of the device are of paramount importance for the success of the device.

D. Pelvic Infection

The association between IUD use and pelvic inflammatory disease or salpingitis has been demonstrated by several studies. However, on controlling for other risk factors associated with PID, the extent of the infection risk was reduced (8). The infection risk is the highest around the time of insertion with 3- to 4-fold increase suggesting that contamination is of essence. This was confirmed by the lack of evidence of an increased risk of PID after 3-4 months after insertion or thereafter after controlling for the known risks of PID as those with multiple sexual partners or prior STDs. The anaerobic, gram-positive bacteria, Actinomyces Israeli, the main pathogen associated with association with IUD induced infection (9). Ampicillin, 250 mg four times a day for 14 days is the recommended treatment upon diagnosis. If the repeat PAP smear is positive for A Israeli, the IUD should be removed (10).

Discontinuation of IUD

Desire for pregnancy is the primary reason for discontinuation. Partial expulsion, persistent cramping, bleeding, or anemia, accounting for about 20% of IUD discontinuation in the first 3 months; acute PID or Antinomies infection on Pap smear; pregnancy; perforation; and significant post-insertion pain, which may indicate improper placement or partial perforation are all indications for the removal of the device.

In a study cohort of 371 women who had an IUD, the cause of discontinuation was evaluated. The incidence of IUD discontinuation in the first year following insertion was 17.5%. Approximately 32% of the study sample continued using their devices after 5 years. The average duration of IUD use was 36 months. Of the 371 women, 39.6% discontinued IUD use because of a desire to conceive, 18.6% because of side effects, 4.9% because they were sexually inactive and 1.6% because of opposition from the woman's family. The most common side effects reported as reasons for discontinuation were bleeding, infection and pain. They found that discontinuation was inversely related to current age, marital age and number of living children. They suggested a strategy to minimize discontinuation through effective educational strategies on the process of fertility and contraception. They also suggested that improved counseling and good selection of candidates before IUD insertion is required (11). Similar results were reported in other countries as well (12).

Device Design

Research on developing new IUD devices was mainly focused to improve IUD performance by

developing better insertion mechanisms that permit better retention of the IUD in the uterus and the use of smaller and more flexible IUDs to minimize the insertion related complications. It is generally agreed that smaller and more flexible IUDs cause less pain and bleeding.

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