New evidence suggests that unless the woman experiences pain or syncope in the first day after insertion, and must have it removed, devices can be used with equal success in the nulliparous.

All patients should receive a complete pelvic examination, including visual inspection of the cervix, and a Papanicolaou smear prior to insertion of an intrauterine device. Where pelvic disease is suspected or diagnosed, patients should be referred for definitive diagnosis and treatment. Early examination following the first or second menstrual flow after insertion offers the best chance of detecting an expulsion not noticed by the patient before pregnancy has occurred. Good medical practice requires that all women be seen annually for a complete pelvic examination and Pap smear.

Side Effects

Chief among the minor side effects of intrauterine devices are irregular bleeding and uterine cramps or pelvic pain. They occur commonly during the first two or three months after insertion and tend to disappear with continued use.

More serious is the occurrence or recrudescence of pelvic inflammatory disease (PID). The incidence of PID in women using IUDs has been reported to be about 2.5 per cent during the first year, falling to about 1.5 per cent during the second. The rates are highest during the first month after insertion. An advisory committee of the Food and Drug Administration believes that even this low rate of infection can be reduced by use of sterile pre-packaged devices with disposable inserters. The use of pre-packaged, sterile devices is recommended. If these are not used, it is recommended that a 1:2500 solution of aqueous iodine be used. (2 cc tincture of iodine, USP. In 100 cc water, soak for 5-10 minutes; if Betadine is used, 1.5 cc in 100 cc water.) There are also indications that antiseptic cleansing of the vagina and cervix reduces infection. Acute or subacute pelvic inflammatory disease, however, is considered a contraindication, as are large fibroids, especially those causing distortion of the uterine cavity.

Perforation of the uterus following insertion is extremely uncommon and often unnoticed by the physician. Its incidence, from 1 to 4 per 10,000 insertions, is probably the result of trauma caused by the introducer during insertion. The FDA believes that the incidence of perforation can be reduced by careful sounding of the uterus before insertion to ascertain the depth and direction of the uterine cavity, and by routine use of a tenaculum to maintain the uterus relatively straight. With the closed devices there have been reports of intestinal obstruction following perforation. Perforation of the uterus with intestinal obstruction has not been reported, however, with open devices. In general, therefore, the closed devices can no longer be recommended. If perforation is known to have occurred with a closed device, the device should be surgically removed without delay. If perforation occurs with an open device, removal will depend on the judgement of the attending physician, after consultation with the patient.

In no instance has the IUD been shown to produce a neoplasm in either the cervix or the endometrium of women, and available reports indicate no effect of the device on the course of preexisting dysplasia.

If pregnancy occurs with the intrauterine device in situ, and proceeds to full term, the device is found to be outside the membranes or occasionally beneath the placenta. The limited numbers of infants so far available for study do not have a greater than expected incidence of prematurity or malformations.

On the few occasions when pregnancy does occur with the device in place, ectopic gestation occurs about once in 20 pregnancies. Although this ratio is 10 times the normal rate, it is attributed to the relatively greater reduction in the number of intrauterine pregnancies. In other words, IUDs prevent intrauterine pregnancies more effectively than they prevent ectopic pregnancies.

Mechanism of Action

The exact mechanism of action of the intrauterine devices in humans is yet to be determined. IUDs have an anti-fertility effect in every animal that has been tested, but the mechanism is different in different species. It is thought that the action takes place sometime between ovulation and implantation. The suggestion that the device acts in humans by increasing tubal motility has not been proven, according to the FDA, but needs further study and confirmation.

Effectiveness

In terms of use effectiveness in clinic patients the IUDs have proved far more reliable than the traditional methods of contraception and slightly less reliable than the oral compounds. Theoretically, however, the IUDs are less reliable than oral contraceptives given according to the combined or the sequential regimen, and are probably not more effective than the diaphragm or condom, if the conventional forms of contraception are used correctly by highly motivated patients. Unlike other forms of contraception, however, the IUDs use-effectiveness approaches theoretical effectiveness, since the method requires neither daily nor periodic medication nor any manipulation before, during or after intercourse. The FDA points out that the careful woman can, however, increase her chances of protection by inspecting her menstrual pads or tampons to see whether the device has