PILOT STUDY OF THE USE OF I.U.C.D. IN 200 WOMEN

by

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Today most areas are populated to the limits of their resources, and almost every habitable area of the world is occupied. In India, the rate of growth of population is over two per cent per year; therefore, if the standards of living have to be improved, the birth rate must be brought down. In order to achieve this objective, an effective, safe, inexpensive and acceptable contraceptive method which is applicable on a large scale is desirable.

For many centuries insertion of a small round stone into the uterus of the camel has been used as a method of contraception by Arabic and Turkish camel owners.

Intrauterine contraception has been known to humans since ancient times. Stem and spring intrauterine pessaries were inserted to prevent pregnancy in the nineteenth and early twentieth centuries. Some of these were completely intrauterine and others with cervical extensions for easy removal. Gräfenberg's completely intrauterine ring was introduced in 1929. Experienced gynaecologists who knew how to insert the devices and who recognised the contra-indications to their use obtained good results. However, in inexperienced hands, sepsis, uterine perforation, pelvic abscess, abnormal bleeding, pain and ectopic pregnancy were reported and the Gräfenberg ring was mostly given up.

An upsurge for revival of interest in intrauterine devices throughout the world followed the publications of Oppenheimer (1959) from Israel and Ishihama (1959) from Japan who have successfully used them in a large number of women over a period of many years.

Numerous designs, some completely intrauterine and some with cervical extensions, have been described and many materials have been utilised. Margulies (1959) devised a polyethylene tube which required cervical dilatation to Hegar size 6. This being a painful procedure was not accepted by the patients. Lately, intrauterine devices have been designed in the form of a spiral and a loop of various sizes which can be straightened out and introduced with an applicator without prior cervical dilatation (Margulies 1962, Lippes 1962). Both of these consist of linear polyethylene with twenty per cent barium sulphate to permit x-ray visualisation.

Different workers have given variable reports regarding the efficacy,

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acceptability and side-effects of the intrauterine devices in use (Excerpta Medica Foundation, 1962). The aim of the present study is to compare and evaluate the possible side-effects and efficacy of Margulies spiral and Lippes loop.

Material and Methods

The present study was undertaken in the Department of Obstetrics and Gynaecology, Institute of Post-graduate Medical Education and Research, Chandigarh, and this preliminary report covers a series of 211 women observed from September 1964 to August 1965, with a total exposure of 1100 women-months. These cases were collected from the post-natal and family planning clinics of the Institute, the local Red Cross and Health Centres. The devices used were Margulies spiral and Lippes loop.

Prior to the insertion of the intrauterine device, a proper history was taken and a careful pelvic examination made in every case to rule out any abnormality in the menstrual cycle, any evidence of pelvic inflammation and other pelvic abnormality. Cases with large cervical erosions and unhealthy vaginal discharges were treated before introducing the device.

Of the 211 cases who attended, 11 were thought to be unsuitable due to the following reasons:

Pelvic inflammation 2, marked cervical erosion with unhealthy discharge 2, perforation of the uterus following previous dilatation and curettage 1, gross menstrual disorder 3, unhealthy vaginal discharge 2, second degree utero-vaginal prolpse 1. These were referred to the gynaecological departmet for appropriate treatment.

All these women were multiparous, of proved fertility. The average age of the patients was 28.5 years with a range of 19 to 40 years, and parity ranged from 1 to 7 living children. Majority of the patients belonged to middle-class families. The monthly income ranged between Rs. 30 to Rs. 2,500.

Time of Insertion

The patients were asked to come one or two days after the cessation of the menstrual flow. Post-partum and post-abortal cases were taken after six weeks had elapsed. Four patients were fitted with Lippes loop during lactational amenorrhoea where a pelvic examination revealed normal-sized uterus.

There was no difficulty in inserting the spiral or the loop. None of these cases required cervical dilatation or anaesthesia.

Instructions to the patients

Each patient was shown the device and after insertion was made to feel the cervical extension per vaginam in a squatting position. The patients were explained about the possible side-effects, like bleeding and cramps, and were reassured. In addition, the possibility of expulsion of the device was brought to their notice, especially at the time of the periods. They were instructed to report to the clinic, if any mishap occurred. For the first three months, they were routinely seen at monthly intervals and thereafter every six months.

Results

This report deals with results obtained in a total of 200 cases followed up for 1100 woman-months. Margulies spiral was introduced in 62 women, spiral of the large size in 38 and the small size in 24; 138 women were fitted with Lippes loop, size 31 mm in 110 size 30 mm in 26 and size 25 mm in 2.

Acceptability

These devices have been found acceptable to a very high percentage of users at the time of presentation of this report. The number of women still using this method of contraception is 194 out of 200 (97 per cent).

Contraceptive effectiveness

In the present series, none of the patients, equipped with the continued use of either of the two devices, has so far shown any evidence of pregnancy, after a careful followup study for 1100 woman-months of exposure. However, no conclusion can be reached in this regard as the follow-up period has been rather short; nevertheless, the initial success does show promise.

Spontaneous expulsions

There were a total of 10 (5 per cent) expulsions in 200 first insertions of both the devices. Seven of 62 cases ejected the spiral i.e., 11.29 per cent; small size spiral was more often expelled. The expulsion rate for the loop was 2.17 per cent (3 of 138). Majority of the expulsions occurred within the first three months after the insertion of the devices.

Each of these patients realised that the device had been extruded and promptly returned to the clinic for reinsertion. New devices of the same type but of a suitable size were reintroduced and were subsequently retained. No pregnancy has resulted in these cases. Partial expulsion was discovered in one case wearing Margulies large spiral at the sixth month follow up. A fresh small spiral was re-inserted and this has since been retained.

Side-effects

The majority of women have no complaints or side-effects after insertion of the device.

Vaginal bleeding

The commonest side-effect was vaginal bleeding after insertion.

Sixty-eight out of 200 (34 per cent) cases had vaginal bleeding of a variable degree as shown in Table I. Profuse bleeding appeared to be more common with the large spiral as compared to the loop. In a great majority of the cases abnormal vaginal bleeding occurred during the first three months of insertion. Such cases were treated with Vitamin C and Methergin orally or parenterally depending upon the severity of the condition. Most of the patients recovered within 2-3 months. Five patients (2.5 per cent) got their device removed because of profuse bleeding.

Polymenorrhoea and polymenorrhagia

These menstrual disturbances occurred mostly within the first three months; there were 20 such cases

TABLE I

Vaginal Bleeding (by type and size of device)

Type of device & size	No. of cases (total)	Spotting to mild bleeding	Moderate bleeding	Profuse bleeding	Total No. of bleeding cases	Total percentage
SPIRAL						
Large ..	38	6 (15.8%)	2 (5.3%)	9 (23.6%)	17 (44.7%)	48.4%
Small ..	22	2 (8.3%)	6 (25%)	5 (20.8%)	13 (54.1%)	
LOOP						
31 mm. ..	110	12 (10.9%)	5 (3.4%)	6 (5.4%)	23 (20.9%)	27.5%
30 mm. ..	26	10 (38.4%)	3 (11.6%)	—	13 50%)	
25 mm. ..	2	2 (100%)	—	—	2 (100%)	

(10%). In 13.5 per cent of cases (27) the duration of flow was prolonged from 7 to 15 days. Delayed periods were recorded in 3 cases (1.5%). Pelvic examination did not reveal any abnormality. Injection Disecron was given to these patients and withdrawal bleeding followed in all.

Pelvic inflammation

No case of apparent pelvic inflammation was seen following the insertion of the intrauterine device. Endocervical smears were cultured in 55 cases before insertion of the device, and were repeated in 35 cases at the second month follow-up examination. The discharge was sterile in 25 cases before and after the insertion of the device and in the other 10 there was no change in the organisms grown.

Pain

Pain of variable intensity was complained of by 35 women, 17.5% of 200 first insertions. This was in the nature of painful cramps in the lower abdomen and backache. It was found that this side-effect was more common with spirals than with loops; 19 of 62 women (30.6 per cent) wearing the spiral complained of pain, being severe in only two cases, who were fitted with the large size, while only 16 of 138 with loops (11.6%) complained of pain. The pain was severe in three cases with 31 mm. loop and in one case with 30 mm. loop. In only one case the device (large spiral) had to be removed because of severe pain. The rest responded to explanation and reassurance, in addition to analgesics like aspirin and novalgin.

Removals

Withdrawal of the device was necessitated because of patient's intolerance in spite of explanation and reassurance and medication for side-effects.

Margulies spiral of the large size had to be removed in 4 cases (6.4%). In three cases (7.8%) it had to be removed because of annoying and persistent bleeding per vaginam, and in one case as a result of severe painful cramps in the lower abdomen.

Lippes loop, size 31 mm, had to be removed in only 2 cases (1.4 per cent) again because of annoying bleeding per vaginam.

Discussion

The actual mode of action by which intrauterine contraceptive devices prevent pregnancy in humans is not known so far. The device appears to interfere with conception at some place between ovulation and implantation. Vaginal and endometrial smears indicate that ovulation occurs in most cases in presence of the device. (Vorys N. *et al.* 1964). Sperm migration to the fallopian tube is not interfered with. Histopathological studies of the endometrium do not reveal any inflammatory reaction because of its presence. (Malkani, P. K. 1964). Tubal spasm has not been found (Siegler, 1964). Margulies has suggested that the device in place brings about changes in uterine and tubal motility but as yet there is no definite evidence to support this.

The intrauterine contraceptive device is known to cause few untoward side-effects in the nature of vaginal bleeding, painful cramps and occasionally pelvic inflammation. Chances of spontaneous expulsion of the device are also there. Our cases were specially studied from this point of view. To achieve satisfactory results, it appears important to properly select the cases for intrauterine contraception, and explain and reassure them regarding the possibility of minor initial discomforts in some cases. The results indicate that these side-effects mainly occur in the first few months of use of the device and that the incidence of complications is not very high. The patient should be specially warned against the possibility of spontaneous expulsion of the device.

The main advantage of the intrauterine method of contraception appears to be that it eliminates the need for continuous motivation and preparation on the part of the couple. The device once introduced can be left in situ for an indefinite period of time. It can be used for prevention of any further pregnancies and for spacing of children. The devices are easy to introduce and involve very little time for insertion. The cost of the device is negligible. The device is effective soon after insertion and the cervical appendage does not interfere with coitus.

The data presented show that the results with Lippes loop are better than with Margulies spiral. Lippes loop is the only device being used in our clinic since January 1965.

Summary

Of a total of 211 women seen in the family planning clinic, intrauterine devices could be used in 200.

The side-effects with the use of Margulies spiral and Lippes loop have been studied in 200 cases, the spiral being used in 62 and the loop in 138 women.

In 1.4 per cent of cases with the loop and 6.4 per cent with the spiral, the symptoms were of such severity as to need removal of the device.

Spontaneous expulsion rate was 11.2 per cent with the spiral and 2.1 per cent with the loop. However, these were all re-introduced and subsequently retained; 194 (97 per cent) of 200 women have continued to use the device, for 1100 women-months.

No pregnancy has been reported so far with the device in place.

The incidence of spontaneous expulsion and side-effects appears to be less amongst the loop-wearers than the spiral-wearers.

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