LONG-TERM USE OF Cu T 200

by

K. PREMA,* M.D., D.G.O., M.A.M.S.

T. L. GAYATHRI,** M.B., B.S., D.G.O.

and

F. S. PHILIPS,*** M.B.,B.S., D.G.O. M.R.C.O.G.

Intrauterine contraceptive devices have become an important modern method of mass fertility control in several developing countries. Ample evidence exists today to indicate that no single inert IUD has any definite advantage over the others. World wide clinical trials (Jain, 1975, Mishell 1973, Sivin 1973, Tejuja *et al* 1974, Tatum 1972, Tietze and Lewit 1972) have demonstrated that Copper IUDs are safe and effective. In India more than 50% of IUD insertions are done in women who have 2 or more children at the time of insertion, who use IUD for family limitation rather than for spacing. Because of the preponderance of this group it becomes essential to determine possible long term deleterious effects of the copper T. device. Unlike inert IUD's Copper T has to be changed when the Copper coil gets exhausted. It is therefore essential to find out how long Cu T retains its contraceptive efficacy.

Material and Methods

During the 50 months from August 1971 to September 1975, 1531 women had Cu T 200 mm^2 device insertion done in the peripheral contraceptive testing unit of Indian Council of Medical Research at Madurai. The majority of these women were urban residents between 20-30 years of age with 2 or more children. They belonged to the low income group, and had very little formal education. About 25% had used Lippes loop for contraception prior to Cu T insertion. In about 1/3 of the women, IUD insertion was done in the immediate postabortal or postpartum period. All these women were instructed to attend the follow up clinic at 1 month, 3 months, 6 months, 9 months, 12 months and subsequently once in 6 months. Endometrial biopsy was attempted in majority of the women coming for interval insertion. At the time of removal, endometrial biopsy was done in majority of cases.

Observations

Table I shows the net cumulative termination rate for all segments upto a period of 54 months. Continuation rate was 76.3% at 12 months, 52.9% at 24 months, 34.1% at 36 months, 25.9% at 48 months and 22.1 at 54 months. Termination rates due to pregnancies, expulsions and removals decreased with increasing duration of use upto a period of 54 months.

Table II shows the event rates during various time intervals. Here also the progressive decrease in menstrual and

* *Senior Research Officer, I.C.M.R.*

** *Asst. Research Officer, Contraceptive Testing Unit, Madurai.*

*** *Officer-in-charge, Contraceptive Testing Unit, Madurai Medical College, Madurai.*

Accepted for publication on 1-10-1977.

TABLE I

Copper T200 mm² Device

Net Cumulative Termination Rates at 54 Months in 1531 Women

	12 months	24 Months	36 Months	48 Months	54 Months
PREGNANCY	0.3	0.9	1.4	1.4	1.4
EXPULSION	4.4	8.5	9.0	9.0	9.0
REMOVALS					
1. Menstrual Disorder	4.3	5.8	6.0	6.0	6.0
2. Pain	0.2	0.4	0.6	0.6	0.6
3. Wanted pregnancy	3.4	12.6	22.4	25.1	25.1
. Opted for other contraception	1.4	3.1	4.3	5.5	5.5
5. Personal	9.7	14.9	17.6	18.2	18.2
6. Investigators choice	0.0	0.9	4.6	8.3	12.1
(1-6) Overall removal rate	10.0	37.7	55.5	63.7	67.5
Closure rate	23.7	47.1	65.9	74.1	77.9
Continuation rate	76.3	52.9	34.1	25.9	22.1
Months of use	16038	27139	32881	35773	37949
Numbers	1142	708	249	98	26
Lost for follow up	5.3	8.6	9.6	9.6	9.6

TABLE II

Event Rate

	12 Months	24 Months	36 Months	48 Months	54 Months
Post insertional bleeding	5.1	5.1	5.1	5.1	5.1
Menstrual disorders	12.6	19.8	24.9	29.1	29.1
Leucorrhea	3.6	5.2	8.7	10.2	12.6
Pain	4.6	7.8	11.3	11.3	11.3
Pregnancy	0.3	0.9	1.4	1.4	1.4
Expulsion	7.6	11.7	12.5	12.5	12.5

other side effects, expulsions and pregnancy rates with increasing duration of use is obvious. Apparently copper T 200 is safe and retains its contraceptive efficacy upto the period of 54 months.

Pregnancies

There were 12 pregnancies among the 1531 device wearers. Of these 4 occured in the first year, 6 in the second year and 2 in the third year. There were no pregnancies among the small group of women who had worn the device for longer than 36 months. Even after taking into account the fact that there were fewer users of Cu T after 24 months and that the more fertile women might have been eliminated by earlier occurence of pregnancies, the pregnancy rate after 24 months must be considered to be very low. Thus clinical experience seems to indicate that contrary to earlier estimates Copper T 200 retains its contraceptive efficacy upto a period of 54 months. (Table I).

Expulsions

There were 138 expulsions. Ninety-nine expulsions occured within the first year of use and 37 in the second year. Only 2 expulsions were noted among the women who had worn the device for

longer than 24 months. Out of the 138 expulsions, 52 were partial and 86 were total. Partial expulsions were more often detected during the first year. (41 out of 52 partial expulsions were seen in the first year). Total expulsions were seen both during the first and second year (54 in the first and 30 in the second). Partial expulsions were more frequently detected during the first year probably because the follow up check was done once in 3 months and so expulsions were detected before the process was complete. The majority of partial expulsions were detected during routine check up and the device could often be reinserted without the patient's knowledge. This accounts for the low termination rate due to expulsion in the first year. (Event rate 7.6 termination rate 4.4). Expulsions occuring after the second year were rare. (Tables I and II).

Side Effects

Side effects, especially menstrual disorders decreased with increasing duration the device was left in utero. When questioned about the amount of blood loss during periods, over 80% of device wearers—irrespective of duration of use —reported an increase as compared to the periods prior to insertion. Studies on the actual estimation of the amount of blood lost during periods in various IUD wearers have shown that this is a universal phenomenon in all IUD wearers irrespective of the duration of use. In view of this, patients should be reassured repeatedly that this an expected 'effect' of IUD rather than an alarming side effect.

Evaluation of the incidence of menorrhagia in IUD wearers poses many problems. Women who want to retain the IUD tend to minimise and women who are afraid of IUD tend to exaggerate the blood loss. So we depended on the clinical assessment of amount of bleeding during periods which is therefore necessary to get a true estimate for assessment of menorrhagia. Incidence of menorrhagia was maximum (12.6%) at 12 months and progressively decreased with increasing duration the device was in utero (Table I). Removal rate because of menstrual disorders also progressively decreased with increasing duration of use. (Table II). The event rate for menstrual disorders was higher at all intervals as compared with termination rate. The question why some women tolerate menstrual disorders while others do not remains unanswered. In addition to the cultural, religious and social norms and the individual's determination to avoid pregnancy, the removal rate for bleeding is strongly influenced by the attitude of the physician providing the follow up care.

Guttorm (1971) reported that iron deficiency anaemia was 4-5 times more common among IUD users as compared to a control population because of the excessive blood loss during periods. None of our women became anaemic during the period of observation, but this might have been so because they were routinely given iron and folic acid tablets sufficient to last for one month during each follow up visit.

Pain in the back, abdominal pain and leucorrhoea were the other side effects of IUD use but these were minor problems as compared with the menstrual side effects.

Removal

Removal rate remained more or less similar during the first 3 years and then decreased during the fourth and fifth year of use. The reasons for removal showed distinct trends during different years of use. Removal rate for

menstrual disorders progressively decreased with increasing duration of use. Younger women who had used the device for spacing opt for removal in the second and third years so that removal rate for planning pregnancy is maximal in the second and third years. Removal for personal reasons mainly due to poor motivation and lack of confidence show a marked decrease after the first year of use. Removal rate for personal reasons was high 9.7 in the first year. In our past experience with Lippes loop we found that the poorly motivated, dissatisfied women often spread mythical tales of "sufferings" during IUD use. Follow up of such patients was difficult and they usually went to other doctors and had the device removed. To obviate the problem it has been our policy to remove the device in dissatisfied device wearers who could not be persuaded to continue. Removal rate for personal reasons decreased with increasing duration of use because of the better patient doctor rapport. Removal rate because of investigators choice increased with increasing duration of use.

Complications

Luckily, in our series, we did not encounter any case of perforation or pelvic inflammatory diseases. The absence of serious pelvic inflammatory disease might be partly due to the use of sterile prepacked device, careful screening for infection and strict adherence to aseptic precautions during insertion.

Endometrial study

Endometrial biopsy was available in 447 women at the time of removal of the device. There were no cases of atypical hyperplasia or dysplasia. Ovulation as shown by the presence of secretory endometrium was undisturbed by IUD use. An inflammatory cellular exudate was seen in about 30% of cases. The proportion of biopsies showing inflammatory change and the type and degree of inflammatory response was similar to those seen in Lippes loop wearers.

Discussion

Based on the release rate of copper worked out by Hagenfeldt (1972), it was recommended that Cu T 200 should be removed and replaced once in 2 years. Need for removal every 2 years imposes practical limitations on the use of Cu T in national IUD programmes. Further experiments with release rates have yielded contradictory reports. Gibor (1973) found that release rate of copper decreased from 55 μgrm/day at 6 months to 8.9 μgrm at 21 months and that Cu T provided effective release of copper upto 4 years. This solves the problem of repeated need to change the device but raises another question. Is Copper release rate really related to contraceptive efficacy and if so how is it that after 18 months 1/4th of the initial release rate suffices to maintain contraceptive efficacy? In this context it is interesting to note that in contrast to earlier findings of Zipper (1969), Marongoni *et al* (1976) found that there was no difference in pregnancy rate among women wearing Cu T 30, Cu T 120 Cu T 200 and Cu T 340 when copper coil was evently spread all over the vertical limb, indicating that the presence throughout the length of uterine cavity and not the amount of copper released is related to contraceptive efficacy. Whatever may be the answers to these theoretical considerations, our clinical experience suggests that Cu T 200 mm^2 device retains its contraceptive efficacy as long as 54 months and is safe with minimal long term side effects.

Acknowledgement

The above work has been carried out in the Peripheral Contraceptive Testing Unit of Indian Council of Medical Research at Madurai Medical College, Madurai. Our thanks are due to Director-General, Indian Council of Medical Research and Dean Madurai Medical College.

References

1. Copper IUD's performance upto date Population reports. Series B. No. 1, 1973.
2. Gibor: quoted in Population reports series B. No. 1, 1973.
3. Guttorm, E.: Acta. Obstet. & Gynec. Scandinavia. 50: 9, 1971.
4. Hagenfeldt, K.: Acta endocrinol4 Suppl. 71: 169, 1972.
5. Hefnawi, F., Askalani, H. and Zaki, K.: Contraction, 9(2): 133, 1974.
6. Jain, A.: Contraception, 11: 243, 1975.
7. Marangoni, P., Rodrigez, G. and Faundes, A.: Contraception, 13: 715, 1976.
8. Mishell, D. R., Israel, R. and Fried, N.: Am. J. Obstet. & Gynec. 116: 1092, 1973.
9. Sivin, I.: Studies in family planning. 4: 162, 1973.
10. Tejuja, S., Saxena, N. C., Malhotra, U., Choudhury, S. D. and Bhinder, G.: Contraception. 10: 337, 1974.
11. Tatum, H. J.: Clinical Obstet. & Gynec. 17: 93, 1974.
12. Tietze, C. and Lewit, S.: Studies in Family Planning, 3: 277, 1972.
13. Zipper, T. A., Tatum, H. J., Paslene, L., Medel, M. and Rivera, M.: Am. J. Obstet. & Gynec. 105: 1274, 1969.