CLINICAL STUDY OF ML CU 250

by

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Introduction

Among the newer techniques available for population control, the IUCD offers a unique combination of effectiveness, reversibility, long action and one shot method. Moreover, it does not require continuous motivation.

In 1969, Zipper *et al* demonstrated the antifertility effect of copper. Subsequently many workers have designed various models of copper bearing IUCDs with variable amount of copper. Copper incorporated IUCDs have an edge over the rigid plain ones due to their efficiency, lower incidence of bleeding problems and better continuation rate.

The combined multiload (MLCu 250) is supposed to be a hybrid of Dalkon shield and the 'T' shaped device (Fig. 1). It has the advantage of easy insertion, it offers resistance to expulsion and the size of the device is compatible with the average uterine cavity. Moreover, effective endometrial response is produced inspite of small surface in contact with the endometrium thus minimising the rate of medical removals.

This paper presents the clinical evaluation of ML Cu-250 conducted at our Family Planning Centre of K.E.M. Hospital.

Material and Methods

Nine hundred and forty-eight patients were fitted with ML Cu-250. The insertions were done in post MTP, interval and post partum period.

The IUCD is inserted by pushing the device through the internal os without a plunger (Fig. 2). On withdrawing the insertor the device opens and remains in the uterine cavity (Figs. 3 and 4). There was no difficulty in insertion in any patient, either in MTP group or interval group. However, it should be mentioned that there were no nulliparous in the interval group in this series.

Seven hundred and forty-eight cases out of 948 (78.90%) were between 21-30 years. Six hundred and sixty-three cases out of 948 (70%) had family income upto Rs. 600.

55% of the acceptors were illiterate, 30% were educated only upto the primary level. Thus indicating its acceptability in low socio-economic and educational group.

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Patients in post MTP group received Caps. Terramycin—four times a day (6 hourly) for 5 days (20 caps) as prophylaxis. Patients in other two groups did not receive any antibiotics. The follow-up visits were planned on the 8th post-insertional day and once every 3 months subsequently to note the menstrual pattern, clinical findings, side effects and complications. The study was conducted for a period of 2 years.

Results

In 76.16% cases the insertion was post MTP. In 1.69% the insertion was post partum. The rest were interval cases.

Seven hundred and twenty-eight out of 948 cases (76.80%) were 1st and 2nd para. Eighty-nine cases (9.6%) were after first pregnancy termination. The rest of the cases were having 3 or more children.

The expulsion rate was highest in post MTP cases. Fifteen patients out of 722 cases in post MTP group (2.07%) had expelled the device. One patient out of 210 interval cases (0.48%) and 1 patient out of 16 post partum cases (6.25%) expelled the IUCD.

The continuation rate in the post MTP, interval and post partum group is 88.47%, 89.52% and 87.50% respectively. Thus the continuation rate in the post MTP group is as good as interval group (Table I).

TABLE I
Cases Closed According to Case Selection

Case selection	No. of Cases closed	Continuing Cases
MTP	84 (11.63%)	638 (88.37%)
Interval	22 (10.48%)	188 (89.52%)
PP	2 (12.50%)	14 (87.50%)
Total	108 (11.39%)	840 (88.61%)

Table II indicates the reasons for closure. The closure for unrelated reasons is more as compared to related reasons.

1.27% of the total cases discontinued due to bleeding, whereas 6.12% discontinued to plan their pregnancy. The IUCD therefore has been found acceptable in lower socio-economic, educational group, to young first and second paras, to post MTP and post partum patients.

The discontinuation rate due to medical

TABLE II
Reasons for Closure

Reasons	MTP	Interval	PP	Total	%
Bleeding	8	4	—	12	1.27
Spotting	1	1	—	2	0.21
Menorrhagia	2	1	—	3	0.32
Expulsion	5	—	—	5	0.52
Failure	—	1	—	1	0.11
Planned Pregnancy	45	11	2	58	6.12
Other medical	8	2	—	10	1.05
Change of Method	4	1	—	5	0.52
Out of Bombay	4	1	—	5	0.52
Personal Reasons	7	—	—	7	0.74
Total	84	22	2	108	11.39
Per cent	10.25	10.48	12.50	—	—

reasons and expulsion is very low and the side effects in the post MTP group is not more frequent than the interval group.

A comparative study was undertaken for 300 cases each of CuT, CuY and ML Cu at our centre. Evaluation of the termination rates for 100 women years at the end of 1 year was studied (Table III).

TABLE III

Termination Rates for 100 Women—Years at the End of 1 Year

Type of termination	Cu T	Cu Y	ML Cu
Removal for expulsion	2.56	4.11	1.04
Removal for bleeding	3.30	3.75	2.60
Removal for infection	0.36	0.74	Nil
Bachache and pain in abdomen	1.10	0.37	2.08
Failure	1.46	Nil	0.52
Non-medical	3.30	5.60	1.04
Des'red pregnancy	9.17	6.72	3.65
Continuation	78.75	78.75	89.07

The continuation rate with ML Cu-250 was 89.07 when compared to 78.75 and 78.73 of CuT and CuY respectively. The discontinuation rate was more due to unrelated reasons in all the 3 groups. The closure for expulsions, bleeding and other side effects was less with ML Cu-250 when compared to CuT and (SCOY) CuY.

Discussion

This intrauterine device is incorporated with copper and is small in size. There are no problems encountered during insertion. It easily adapts itself to the uterine cavity during relaxation or contraction of uterus. It has a small surface area in contact with the endometrium, does not stretch the uterine cavity and therefore the discontinuation rate for bleeding and other medical reasons is only 1.27 and 1.05 respectively.

The device (MLCu-250) combines an easy insertion with high resistance to expulsion, due to small external diameter of the inserter and great flexibility of the spurred side arms which provides continuous fundal seeking effect. The broad upper portion flexes and increases in resistance to expulsion, when expulsive uterine contractions are directed towards it. The negative pressure required to expel ML Cu-250 was twice as high as that required to expel Cu 7 or CuT (Van Os *et al*, 1976). With this advantage the surface area of copper on this device could be increased so that it could be kept in situ for 5 or more years (Van Os *et al*, 1976).

The expulsion rate was 1.79%. Majority of the expulsions were in post MTP group and post-partum group.

The continuation rate was 88.16% at the end of 2 years. This compares well with the continuation rate of 90.12% in the study of Van Os *et al*, 1976.

Intrauterine device would be even more acceptable if the bleeding is minimised. Some of the studies indicate that anti-prostaglandin drugs such as N-Phenyl ethyl Anthranilic acid, phenyl butazone, oxyphenbutazone, Salicylates, Ibrufen decrease the bleeding. Raote *et al* have shown decrease in bleeding from an average of 8.67 $\pm$ 2.15 days to 4.39 $\pm$ 0.86

days in 29 cases after using N Phenylethyl Anthranilic acid.

Proprietory compounds containing citrus bioflavonoid, ascorbic acid, calcium and vitamin K are supposed to increase the cementing substance in the endometrium and decrease the bleeding. Antihistaminics decrease the mast cells in the endometrium and reduce the blood loss (Choudary and Malhotra, 1980).

Drugs like epsilon amino caproic acid, transxamic acid acting against fibrinolysins decrease the menstrual blood loss.

These drugs are at present being studied at our centre in post MTP IUCD users. We observe that antihistaminics and anti PG drugs seem to be effective in reducing menstrual blood loss.

Infection after post MTP IUCD insertion is always a conncern. This could be due to aerobic as well as non-spore bearing anaerobic organisms like B Melaninogenicus, B Proteus, Peptostreptococci, Peptococci and Gram positive bacilli. Aerobic organisms are usually covered by antibiotics, but it is also important to cover the non-spore bearing anaerobic organisms by Metronidazole.

Kohli *et al* (1981) carried out a comparative study in 2 groups of patients using post MTP IUCD. The first group of 25 patients received oxytetracycline 250 mgm 4 times a day for 5 days. The second group of 29 patients received Metronidazole 200 mgm 3 times a day for 10 days in addition to oxytetracycline. Culture was taken 8 days after initiation of therapy. Seven cases out of 25 (28%) in the former group had a positive culture for anaerobic organism. These 7 cases were subsequently treated with Metronidazole 200 mgm 3 times a day for 10 days. Culture taken 8 days later showed no growth of anaerobic organism. The latter of second group did not show any anaerobic growth when culture was taken on 8th post operative day. This pilot study indicates the need for further work on the subject.

Thus the problem of expulsion, bleeding and infection could be minimised by a suitable IUCD inserted with good aseptic precautions and followed up meticulously.

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See Figs. on Art Paper II