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MENSTRUAL AND FERTILITY DATA AFTER TCu 200 mm²
REMOVAL OR EXPULSION

by

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Intra Uterine Contraceptive Device is accepted as one of the reversible effective economical methods of contraception that require only the decision to have the device inserted rather than sustained motivation. Because of these advantages IUCD forms one of the most important methods of mass fertility control among indigent masses in the developing countries, who demonstrate very little concern about Fertility Control.

In spite of many elegantly designed animal experimental studies, the exact mode of anti-fertility action of copper remains largely unproven. It was suggested that copper prevents cellular proliferation and in vitro experiments copper was found to be lethal to the embryo. But pregnancies do occur with Copper devices in utero and such infants when delivered were normal (Tatum).

Elstein *et al* reported that sperm penetration decreased when Copper T was incubated for a long time with midcycle cervical mucus. But level of copper released in vivo is much less than the level in the in vitro studies. One of the widely accepted suggestions about mode of action is that the contraceptive effect

is due to endometrial changes, resulting in alteration of intra-uterine milieu which is rendered hostile to the embryo.

Endometrial studies cannot provide an answer to these questions because even among patients who complain of menorrhagia, endometrial histology does not reveal any consistent pathological alteration in the majority of cases and the trauma of biopsy cannot be repeatedly inflicted on patients in order to study the endometrial changes after removal of the device. A systematic follow up of all women who had the device removed or expelled will provide the menstrual and fertility data that will answer these two pertinent questions.

Material and Methods

Thousand women had copper T 200mm² device inserted prior to October 1973. Of these 284 had the device removed; 61 expelled the device and 5 women conceived with the device in utero prior to July 1974 and these were taken for menstrual and fertility study (Table I).

TABLE I
Cases taken for Menstrual and Fertility Study

	Number	Percentage
Removals	284	81.14
Expulsions	61	17.43
Pregnancy with TCu 200 mm ² in situ	5	1.43
	350	100.00

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The reason for removal of the device is listed in Table II—28% because they

TABLE II
Reasons for Removal

	Number	Percentage
Wants to conceive	81	28.52
Bleeding	44	15.49
Pain abdomen	7	2.46
Adopted other temporary method of contraception	15	5.28
Adopted permanent method of contraception	22	7.76
Not requiring contraception	16	5.63
Non medical reasons	99	34.86
	284	100.00

wanted to conceive, 19% because they adopted some other methods of contraception or did not require contraception; 15% of removals were due to menstrual disorders and 35% for non-medical reasons. A survey of all these women at 1 month, after removal or expulsion, and later once in every 3 months until the cut-off date for data collection—i.e., October, 1974 was done and the collected data was analysed.

Observations

Menstrual Data: (Table III)

TABLE III

Menstrual History at the Time of TCu 200 mm² Removal Expulsion

	Number	Percentage
Normal	296	74.71
Menorrhagia	44	12.43
Menopause	1	0.29
Conceived with TCu in situ	5	1.43
Conceived with partially expelled device	4	1.14
	350	100.00

Of the 350 women who had the device removed prior to July 1974, 5 had conceived with the device in utero; 4 conceived with partially expelled device; 12 conceived in the same cycle after removal or expulsion and 6 women were lost for follow up. Thus only 323 women were available for study of menstrual data and 279 (86.4%) had no menstrual disorders prior to or after removal. One patient had the device removed, because she had attained menopause. Forty-four women had the device removed because of menorrhagia, whose post-removal menstrual pattern was the focal point of interest. One conceived in the same cycle after Tcu removal. Seven opted for combined pill or injection for contraception and had normal menstrual cycle restored in the same cycle. Of the remaining 36, 23 (66.4%) had normal menstrual cycle restored in the next cycle and 11 (20.6%) within 3 months. Menstrual disorders persisted in 2 women. Endometrium showed cystoglandular hyperplasia; patient conceived after the cut off date 1 year 6 months after Tcu removal. Second patient developed dysfunctional uterine bleeding for the first time while she had Tcu in situ, which persisted for 9 months. Endometrium showed cystoglandular hyperplasia and patient was put on combined pill for cyclical hormonal therapy for 3 months. Normal cycles were restored after 3 months therapy and patient conceived 3 months after stopping combined pills.

Fertility Data

At the time of cut off date 167 (47.71%) had conceived. Of these 5 had conceived with the device in situ giving a crude pregnancy rate of 5%; Pearl pregnancy rate with device in utero was .4/100 woman years. Four women conceived with partially expelled device giving a

crude pregnancy rate of 8.3% and a Pearl pregnancy rate of 18.2 per hundred woman years.

One hundred and fifty eight women (45.14%) conceived after variable period after TCU removal or expulsion; 110 adopted other methods of Fertility Control, 15 were lost for follow-up leaving only 58 (16.57%) women who were yet to conceive in spite of not using any contraception at the time of the cut off date.

Removal or expulsion to conception interval varied between same cycle to 1-2 years. Nearly 90% of conceptions occurred within 6 months. Among the 18 women who conceived after 6 months, 5 had the device removed during lactational amenorrhoea and 9 adopted some form of contraception for varying periods of time. Taking only the women who were fully exposed to pregnancy risk, we find that 79% conceived within 6 months (Table IV).

Among the women who were yet to conceive, over 60% have been under observation for less than 6 months at the time of cut off date. Among the 21 women (35%) who failed to conceive even after 6 months, 3 were too ill to do so and 6 had the device removed during lactational amenorrhoea. Thus only 23% of the women who were under observation failed to conceive when fully exposed to pregnancy risk.

The duration the device has been in utero does not in any way adversely affect conception or time taken for conception to occur. All the patients who had the device in utero for less than 6 months and over 18 months have conceived in less than 6 months time. Only 4 among 80 who had the device for 16-18 months conceived after 6 months (Table V).

TABLE IV
Expulsion Removal—Conception Interval

	Same cycle	Next cycle	Less than 3 months	3-6 months	6-12 months	1-2 yrs.	Total
No contraception	12	46	43	38	3	1	143
Lactational amenorrhoea	0	0	0	0	3	2	5
Some contraception used for a while	0	0	1	0	8	1	10
	12	46	44	38	14	4	158
Percentage	7.59	29.11	27.85	24.06	8.86	2.53	100.00

TABLE V
Relation between Duration Device was in Utero and Subsequent Conceptions

Duration device was in situ	Removal/Expulsion			Conceptional interval	
	Within 3 months	3-6 months	6-12 months	Over one year	Total
Less than 3 months	22	9	0	0	31
3-6 months	18	7	0	0	25
6-12 months	30	6	2	1	39
12-18 months	19	11	1	0	31
18-24 months	9	5	0	0	14
Over 24 months	3	0	0	0	3
Total	101	38	3	1	143

Endometrial changes induced by the device are thought to be the reason behind menstrual disorders in IUCD wearers. Menstrual pattern returns to normal within 3 months in the majority

who had menorrhagia. But the total number of women in the menorrhagia group were only 9; so the exact statistical significance of this observation could not be assessed (Table VI).

TABLE VI
Relation Between Indication for Removal and Subsequent Conception Removal-Conception Interval

Reasons for removal	Within 3 months	3-6 months	6-12 months	1-2 years	Total
Wants pregnancy	41	15	0	0	56
Bleeding	4	3	2	0	9
Others	43	12	4	0	59
Total	88	30	6	0	124
Percentage	70.97	24.19	4.84	0	100.00

of cases and within 6 months in almost all cases.

We wanted to find out whether fertility was adversely affected in women with menstrual disorders. One patient with severe menorrhagia conceived in the same cycle, 4 within 3 months, 3 in 6 months and 2 within 1 year. Comparing this data with conception rate among women who had the device removed because they desired conception and those who had it removed due to non-medical reasons, we found that time taken for conception to occur was longer in those

The ideal persons on whom fertility study can be done are the women who had the device removed because they desired conception; 70% conceived, 10% changed their mind and adopted some other form of contraception and 20% were yet to conceive at the time of cut off date.

Summary and Conclusion

1. 350 women who had TCu 200 mm² device inserted prior to October 1973 and had it removed or expelled it prior to July 1974 were followed up till October

1974 with a view to find out post-removal/expulsion menstrual and fertility pattern.

2. Among the 44 women who had menorrhagia at the time of removal, only about 25% had menstrual disorders at the end of one month and only 2 who were both having cystoglandular hyperplasia continued to have menstrual disorders at the end of 3 months.

3. Among women who were available for fertility data study only 16% failed to conceive at the time of the cut off date.

4. Majority of conceptions occurred within 6 months.

5. Among those who failed to conceive, over 60% have been under observation for less than 6 months.

6. There was no relation between the

duration the device was in utero and subsequent conception.

7. It seemed as if women with menstrual disorders take a longer time to conceive than others, but the exact statistical significance of this finding cannot be assessed as the number of patients involved were only 9.

8. Among those who had the device removed because they wanted to conceive, only 20% failed to do so before cut off date. Majority of conceptions occurred within 3 months and all have occurred within 6 months.

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TABLE I

Group	No. of patients	Menstrual disorders at 1 month	Menstrual disorders at 3 months	Conception within 3 months	Conception within 6 months
Group 1	44	11	2	16	20
Group 2	10	2	0	5	6
Group 3	10	1	0	4	5
Group 4	10	1	0	4	5
Group 5	10	1	0	4	5
Group 6	10	1	0	4	5
Group 7	10	1	0	4	5
Group 8	10	1	0	4	5
Group 9	10	1	0	4	5
Group 10	10	1	0	4	5