

COPPER-BEARING INTRAUTERINE DEVICE (COPPER-T200) IN CLINICAL PRACTICE

by

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The logic of using an intrauterine device as a vehicle or carrier for an active antifertility agent was conceived independently in 1968 by Zipper *et al* who used metallic copper, and Doyle and Clewe, who used a synthetic progestin. A medicated IUD, using metallic copper, was first tested in the human female by Zipper and associates in 1969. Subsequently, clinical trials were conducted with several models of copper bearing devices, and among them copper T-200 (TCu-200) was the most extensively studied model (Tatum, 1972 and 1973). Representative data on the use-effectiveness of copper T-200 from India was published by Tejuja and co-workers in 1975. As a consequence of the pioneering position of the copper T-200 in the field of medicated IUDs, this device, at present, is serving as the standard for evaluation of other IUDs, medicated as well as nonmedicated.

Ever since copper T-200 was made available in our institution (October,

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Accepted for publication on 9-10-1977.

1975), this device has dominated over the Lippes loop. With the increased use of elective abortion for unplanned and unwanted pregnancies, there is a growing need and demand for a contraceptive method that can be recommended and initiated coincident with the termination of an early pregnancy. As a post-abort contraceptive, we have elected to apply copper-T-200 concomitantly with endometrial aspiration procedure for early abortions (Rajan and Kaimal, 1977). This meaningful procedure, which combines patient convenience with clinical effectiveness, does not increase the incidence of somatic complications of early abortions (Rajan and John, 1978). In our family planning clinic, 60% of the women who underwent endometrial aspiration accepted simultaneous insertion of copper T.

Over the last two years, post-abort contraception with copper T-200 was planned in 352 women which amounts to 3196 woman-months of use of the IUD. Evaluation of the clinical data of these copper T users form the basis of this presentation.

Materials and Methods

Following the post-abort insertion of copper T-200, the patients were routinely seen after 7 days, (first check-up). Any

complaints related to blood loss, abdominal pain or IUD displacements were recorded. Position of IUD was confirmed by a pelvic examination. Cases of incomplete abortion were subjected to a curettage after removal of the IUD. If no complications were detected, the patient was advised to report after 3 months (second follow-up). During the second visit, data related to duration of menstrual flow, regularity of cycle, back pain or IUD displacements were collected. The IUD was removed if the patient complained of menorrhagia or severe back pain, and sometimes for psychological reasons. If the device was acceptable for the patient she was advised to wear it for 2 years, with periodic check-up every 6 months.

Results

Copper T-200 was inserted for 352 women, in the age group between 18 to 48 years (mean 28.2 years), with majority in the 20 to 30 years range. Paras 1 and 2 constituted the majority of the IUD acceptors (71%), and there were no nulliparous women in this group (Table I). 26% were college educated,

TABLE I
Parity of the 352 Copper 'T' Users

Parity	No. of women	Percentage
Para 1	133	38.00
Para 2	114	33.00
Para 3	54	15.00
Para 4	22	6.00
Para 5 and above	29	8.00

and the rest had school education. The better educational status enabled proper motivation and regular follow-up.

Of the 352 insertions, the IUD was expelled or removed in 12 cases following incomplete abortion. When these 12 patients were excluded, there were no

immediate post-insertion complications in the remaining 340 women.

At the second follow-up, 21 patients got the IUD removed for bleeding, pain and other personal reasons. In another 10 patients the IUD was either spontaneously expelled, or displaced downwards into the cervical canal necessitating removal. Three women conceived with the copper T-200 in situ, within 3 to 6 months of insertion. The pregnancies were terminated by suction curettage, and the IUD was removed at the time of evacuation. There was 1 case of pelvic inflammatory disease, in the form of unilateral tubo-ovarian mass, which was operated 7 months after the IUD insertion. (Table II).

TABLE II
Clinical Experience with Copper 'T'-200—Event Rate/100 users 2 yrs. use)

Accidental Pregnancy	0.90
Displacement, complete & incomplete	3.00
Removal: (a) Bleeding/pain	5.00
(b) Personal	1.10
Pelvic Inflammatory disease	0.30
Total event rate	10.40
Continuation rate	89.60
Total insertions	352
Woman—months of use	3,196

Excluding the 47 IUD rejections, due to some type of complications, a continuation rate of 89.60/100 women users was recorded. Among these IUD users there was an alteration in the menstrual pattern, in the form of prolonged flow and irregular cycles, in 32% of the cases (Table III). Many patients complained

TABLE III
Menstrual Pattern of the First 3 Months on the Copper 'T' Users

Nature of menstrual cycle	Percentage
Regular cycles with normal flow	68.00
Prolonged flow	25.00
Irregular cycles	7.00

of mild back pain which was promptly relieved by analgesics. However, after the first three months of use there was a significant decline in the incidence of such complications, and the patients got well adapted to the copper device.

Discussion

The introduction of copper-bearing IUDs (Zipper *et al* 1969, Tatum, 1973 and 1974) constitutes the most important recent development in the field of contraceptive technology. When devising the plain T-shaped IUD, Tatum (1973, 1974) accordingly attempted to combine a smaller IUD surface area with a better propensity to accommodate the shape of the uterine cavity, which indeed becomes T-shaped when the uterus is contracting. While reducing the uterine trauma and hence the complication rate, the T device recorded a very high pregnancy rate of 18/100 woman years. Adding copper to the T-shaped polyethylene skeleton permitted the use of a smaller device with a greater contraceptive propensity. Tatum also demonstrated that by increasing the surface area of the copper wire, the efficiency of his device was improved. Anti-fertility effect of copper coupled with the fundal-seeking and lateral extension properties of the slender T has substantially enhanced the contraceptive effectiveness of copper T device.

Being a post-abortual insertion, in our study, there was a 3% incidence of IUD removal for incomplete abortion. When these cases were excluded, there was an event rate of 10.40/100 women users and a continuation rate of 89.60/100 women users. These figures favour comparably with the documented reports of other authors (Table V). The copper T was well tolerated by those who continued to use the IUD. Even the minor menstrual complaints gradually disappeared follow-

TABLE IV
Copper T' (TCu-200): Net Rates of Events/100 Women

Events	Tatum (1972) USA & Canada	Tatum (1973) USA	Mishell (1973) USA	Zipper (1973) Chile	Timonen & Luukkainen (1974) Finland	Tejua (1975) India	Jain (1975) USA	Present series (1978) India
Pregnancy	0.80	1.50	1.70	1.70	1.60	0.90	2.60	0.90
Expulsion	6.00	8.40	5.40	3.40	2.20	7.40	7.30	3.00
Removal:								
Bleeding/pain	5.40	10.00	10.70	2.60	7.10	10.80	8.70	5.00
No. of Insertions	785	2,678	471	847	2,689	4,357	16,345	352
Women—months of use	6,727	13,117	6,044	7,697	29,143	37,429	116,155	3,196
Total event rate	21.00	25.90	25.80	10.90	—	—	—	10.40
Continuation rate	79.00	74.10	74.20	89.10	—	—	—	89.60

ing the first 3 months of the IUD use. However, it is illogical to assume that metallic copper wound round the polyethylene T will prove to be a panacea for the side effects and complications of the IUDs.

Blood loss: The most frequent side effect of IUD is a change in the uterine bleeding pattern. This symptom tremendously influences the continuation rate and use-effectiveness of any device. While the specific aetiology of IUD-related bleeding is not yet completely understood, reduction of physical trauma caused by the IUD is of fundamental importance in its prevention. Copper T, being a small and slender device, minimises the endometrial trauma and hence reduces the incidence of menorrhagia. In our series, the copper T removal rate for excessive bleeding was only 3.70/100 women users. Minor menstrual complaints, not requiring IUD removal was observed in 32% of the IUD users, and these complaints promptly disappeared after 3 months of IUD use. While endometrial fibrinolytic activity in women using copper IUDs is reportedly increased (Larsson *et al*), there is no conclusive data to indicate metallic copper per se influences uterine bleeding.

Pain: The severity of the uterine pain is a measure of the degree of distention of the endometrial cavity and the coincident stretching of the myometrium. Thus, the uterine reaction is minimised by using copper T which causes the least degree of uterine distention. Incidence of IUD removal for pain was as low as 1.10/100 women users, and in many instances the discomfort was very mild and responded satisfactorily to analgesics. The mild type of pain was not complained by the IUD users after three months of use.

Expulsion: Of the 352 copper T insertions there were 10 IUD expulsions, partial or complete (3/100 women users). In some instances the IUD is displaced downwards so that a portion is within the cervical canal. This incomplete expulsion results in a significant reduction in contraceptive effectiveness while at the same time increases the possibility of transcervical bacterial invasion of the uterine cavity. For these reasons the IUD found displaced in the cervical canal was removed, and if required was replaced by a properly located device.

Accidental Pregnancy: Compared to the Lippes loop, copper-bearing IUDs have lower pregnancy rates (Van Os *et al* 1976). The incidence of accidental pregnancy for copper T is variously reported as 0.80 to 2.60 per 100 women users. Antifertility effect of copper coupled with the fundal-seeking and lateral extension properties of the T skeleton is responsible for the minimal failure rate of copper T. Contraceptive efficacy will be hampered by the improper placement of the IUD or cervical displacement. Since the spontaneous abortion rate is as high as 50% (Lewit, 1970) in the accidental pregnancies with the IUD insitu, and the possibility of intrauterine sepsis cannot be ruled out, we preferred to terminate all these accidental pregnancies.

Pelvic Inflammatory Disease: In his personal clinical experience Ledger (1974) has pointed out the possibility of development of unilateral pelvic infection in women wearing an IUD. Whether this unilateral response is related to the IUD or not, in our series there was one case of unilateral tubo-ovarian mass detected 7 months after copper T insertion. In vitro studies have confirmed that the gonococci are susceptible to the

bactericidal action of copper salts (Fiscina *et al* 1973, Spence *et al* 1975). If this could be clinically proved, it will have a remarkable impact upon the choice of contraception, especially in population at risk of such infection.

In this small series we have not encountered other complications such as fundal or cervical perforations, embedding and ectopic gestation.

Conclusion

Over a two year period, 352 copper T insertions were performed as a post-abortion contraceptive. (3,196 woman-months of use). An event rate of 10.40 and continuation rate of 89.60 per 100 women users is documented. Antifertility effect of copper and the fundal-seeking and lateral extension properties of the polyethylene T are the two factors responsible for the improved contraceptive effectiveness of the device. Since the small slender device conforms most readily to the uterine cavity and minimises the endometrial trauma and myometrial distension, there is a significant decrease in the removal rate for bleeding and pain. These qualities of copper T signifies a trend towards better patient acceptance.

Acknowledgement

Valuable help rendered by Dr. S. Venkitakrishnan, Family Planning Medical Officer, is gratefully acknowledged. The enthusiastic assistance of Dr. Rosamma John is appreciated. The authors also wish to thank Dr. J. Sathyadas, Medical Superintendent for his kind permission to make use of hospital records.

References

1. Doyle, L. L. and Clewe, T.: *Am. J. Obstet. & Gynec.* 101: 564, 1968.
2. Fiscina, B., Oster, G. K. and Oster, G.: *Am. J. Obstet. & Gynec.* 116: 86, 1973.
3. Jain, A. K.: *Analysis of Intrauterine Contraception*, Amsterdam, North Holland Publishing Co., 1975, p. 3.
4. Larsson, B., Leidholm, P., Sjoberg, N. O. and Astedt, B.: *Contraception*, 9: 531, 1974.
5. Lewit, S.: *Contraception*, 2: 47, 1970.
6. Ledger, W. J.: *Clin. Obstet. & Gynec.* 17: 79, 1974.
7. Mishell, D. R., Israel, R. and Freid, N.: *Am. J. Obst. & Gynec.* 116: 1092, 1973.
8. Rajan, R. and Kaimal, G.: *J. Obstet. & Gynec. India*, 27: 649, 1977.
9. Rajan, R. and John, R.: *J. Obstet. & Gynec. India*, 28: 35, 1978.
10. Spence, M. R., Stutz, D. R. and Paniom, W.: *Am. J. Obstet. & Gynec.* 122: 783, 1975.
11. Tatum, H. J.: *Am. J. Obstet. & Gynec.* 112: 1000, 1972.
12. Tatum, H. J.: *Am. J. Obstet. & Gynec.* 117: 609, 1973.
13. Tatum, H. J.: *Clin. Obstet. & Gynec.* 17: 93, 1974.
14. Tejuja, S., Saxena, N. C., Malhotra, U. and Choudhury, S. D.: *Analysis of intra-uterine contraception*, Amsterdam, North Holland Publishing Co., 1975, p. 165.
15. Timonen, H. and Luukkainen, T.: *Contraception*, 9: 1, 1974.
16. Van Os, W. A. A., H, Van Der Pas, Rhemrev, P. E. R., Kosasih, F, Van Kets, H., Amy, J. J. and Dombrowitz, N.: Paper presented at the 1st inter-congress of the Asian Federation of Obstetrics & Gynaecology, Singapore, April, 17-30, 1976.
17. Zipper, J. A., Medelm, M. and Prager, R.: *Sixth World Congress on Fertility and Sterility*, Tel Aviv, Israel, May 20-27, 1968, p. 154.
18. Zipper, J. A., Tatum, H. J., Pastene, L., Meded, M. and Rivera, M.: *Am. J. Obstet. & Gynec.* 105: 1274, 1969.
19. Zipper, J. A. and Medel, M.: Quoted by Tatum, H. J., *Clin. Obstet. & Gynec.* 17: 93, 1974.