

# A CLINICAL STUDY OF Cu-T I.U.C.D.

(A Review of 1400 Cases)

by

CHANDNI M. ALWANI,\*

AJITA V. MANDLEKAR,\*\*

USHA R. KRISHNA\*\*\*

and

V. N. PURANDARE\*\*\*\*

## Introduction

Several efforts have been made to overcome the drawbacks of IUD's. Now a second generation of IUCD's is being developed which are known as the bio-active IUCD's. Bio-active substances are released at the uterine level, with the hope of increasing contraceptive effectiveness and decreasing bleeding, pain and expulsion rate. Zipper demonstrated the antifertility effect of Cu in 1969. The advantages of adding Cu have been thoroughly explored. Now the Cu IUCD's are being tested in various shapes. The Cu-T of Tatum, Cu-7, Cu-Lippes Loop and Soonawalla's Cu-Y. A thin copper wire is entwined around the vertical arm of Cu-T and Cu-7. On Lippes Loop the Cu is added on the horizontal bars. Cu-200 represents a surface area of 200 sq. mms. of Cu.

The mode of action of Cu is probably due to the following factors:

1. Release of Cu ions into the uterine cavity influences various biochemical reactions. The changes are local and little or no Cu is found systemically.

2. The contraceptive effect is possibly due to the cationic antagonism specifically related to Zn. It may inhibit the Zn containing enzyme carbonic anhydrase and thus resist implantation.

3. Recent advances indicate that the Cu ions interfere with the cellular DNA in the endometrium with glycogen metabolism and with the normal oestrogen uptake by the uterine mucosa.

4. Parr (1973) has noted the induction of an inflammatory response in the endometrium similar to an inert IUCD.

## Material and Methods

One thousand and four hundred cases of Cu-T insertion have been studied and analysed for 7703 cycles over a 3½ year period in the Obstetrics and Gynaec. Department of K.E.M. Hospital, Bombay. In 647 women Cu-T insertion was done immediately after a M.T.P.; 591 Cu-T's were inserted in interval cases (i.e. those who were not recently pregnant). One hundred and twenty-three insertions were done within 5 days postpartum and in 39 patients Cu-T was inserted when

\*Prof. of Obst. & Gynaec.

\*\*Medical Officer.

\*\*\*Hon. Assoc. Prof. of Obst. & Gynec.

\*\*\*\*Head of the Dept. of Obst. & Gynec.

From: Department of Obstetrics & Gynaecology, K.E.M. Hospital & Seth G.S.M. College, Parel, Bombay 400 012.

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patients came for postnatal follow-up. Effort was made to follow up all the patients at 1 month, 3 months, 6 months, 9 months and 12 months after insertion and subsequently every 6 months.

#### Age and Parity

Tables I and II give the distribution of women according to the age and parity.

#### Previous use of contraception

It is interesting to note that majority of the patients had not used any form of contraception in the past. Only about 41% had used some method of contraception and were now willing to use Cu-T. Persistent motivation is required to convince the non-contraceptive users to accept any form of intrauterine device. The natural reluctance of the patients to accept an

TABLE I  
Age-wise Distribution

Age Group	Less than 20	21-25	26-30	31-35	36-40	41 & above	Total
No. of Cases	159	641	391	92	52	65	1400
Percentage	11.35	45.77	27.98	6.56	3.70	4.64	—

TABLE II  
Parity

No. of Children	0	1	2	3	4 and Above	Total
No. of Cases	23	275	509	372	221	1400
Percentage	1.6	19.6	36.3	26.5	16	—

Majority of the women were in the age group of 21-25 years and 2nd paras. 1.6% were nulliparous women and about 16% women had more than 4 children.

#### Education

Nearly 38% of the patients had secondary school education. About 14.2% were graduates and 24.7% were illiterate. Most of our hospital patients came from low socio-economic class.

IUCD is partly overcome by explaining to them that this is a new medicated device which is imported from abroad!

#### Expulsion According to Age, Parity and Case Selection

We found that the expulsions are maximum in the age group between 31-35 years, and minimum below the age of 25 years (Table III). Lewit (1973) has how-

TABLE III  
Expulsion According to Age

Age group	Less than 20	21-25	26-30	31-35	36 and above	Total
Complete Expulsion	3	12	13	12	5	45
Partial Expulsion	2	8	7	11	1	29
Percentage	3.13	3.2	5.1	25	5.2	74

ever reported that girls between 15-19 have expulsion rate of 15.0 per 100 Cu-T users, the rate falls to 8.5-8.7 for women between the ages of 20-24 years and 25-29 years. For the older women the rate is even lower—6% for women between 30-34 and 3% for women between 35-39 years.

The expulsion rate in nulliparas was nil at the end of 3½ years. The expulsion rate increased with increased parity; it was 13.2% in patients having 4 or more children (Table IV). From the published

ed the incidence or severity of early complications nor lengthened the stay in hospital after abortions. The expulsion rate was only 7% in his post M.T.P. patients after one month.

#### *Post insertional bleeding and menstrual pattern*

Post insertional bleeding was present in 28% of the patients, of which heavy bleeding was experienced by 2.5%, moderate by 8.5% and spotting by 11%.

Menstrual data was compared in indivi-

TABLE IV  
*Expulsion According to Parity*

Parity	0	1	2	3	4 and above	Total
Complete Expulsion	0	4	12	11	18	45
Partial Expulsion	0	2	7	9	11	29
Percentage	0	2.18	3.8	5.33	13.2	—

data of 1960's it is seen that nulliparous women do not tolerate inert IUD's as well as multiparous do. High expulsion rate of the inert IUCD's in nulliparas upto 20 per 100 woman years, causes high rates of unwanted pregnancies. Moreover, the nulliparas also report more pain and bleeding. In an analysis by Lewit of Cu-T insertions which includes over 2000 nulliparas, expulsion rate of Cu-IUCD's ranged from 0.8-1.7 per 100 women months of use. Several other recently published studies of Cu-IUD's suggest that the expulsion and pregnancy rates in nulliparas are low as compared to the earlier experience of the inert IUD's.

The expulsion rate is highest as expected in post-partum group of patients and lowest in the interval group. Timonon *et al* (1972) has reported in his study of 154 women fitted with Cu-T after abortion that the insertion of IUD neither increas-

ed the incidence or severity of early complications nor lengthened the stay in hospital after abortions. The expulsion rate was only 7% in his post M.T.P. patients after one month.

Post insertional bleeding was present in 28% of the patients, of which heavy bleeding was experienced by 2.5%, moderate by 8.5% and spotting by 11%.

Menstrual data was compared in individual women with control menstrual cycles prior to insertion of the device. Cycle length was 25-35 days in 96% of the women prior to the insertion of the device or recent pregnancy. At the time of insertion 11.5 patients had lactational amenorrhoea. At the end of 4 months only 78% of the women continued to have same cycle length which subsequently returned to normal in 92% of the women at the end of 12-14 months, about 1% women continued to have lactational amenorrhoea, 7% continued to have menorrhagia necessitating removal of the device in 4.93% cases.

#### *Reasons for closure*

Eight and a half per cent were closed for medical reasons of which the most important was profuse bleeding or menorrhagia (Table V). In 4.93% of the patients Cu-T was removed and conser-

TABLE V  
Reasons for Closure

Medical		Non-Medical	
Menometrorrhagia	69 (4.93%)	Change to other method	32
Pain etc.	28 (2.00%)	Moving out of Bombay	88
Infection	6 (0.4%)	Lost to follow up	64
Failure	7 (0.5%)	Desired Pregnancy	39
Perforation	1 (.007%)	Removed after 3 years	18
Expulsion	9 (0.64%)		
	120 (8.6%)		241

vative treatment with hormones was given. None of them needed blood transfusion.

Removal was done in 2% of the cases due to pain in lower abdomen and weakness, and in 0.4% cases due to mild infection, i.e. tenderness in fornices and slight fever. There were no cases of severe infection in our series. 7 cases were closed due to failure. Of the 7 pregnancies, 1 was ectopic pregnancy. Exploratory laparotomy and left salpingectomy was done. Sterilisation could not be done as patient was 2nd para and she desired to have a son. Three patients came when they were 20-22 weeks pregnant. These 3 patients continued to term and delivered normally. Three patients had pregnancy of 6-8 weeks of which 1 desired to continue pregnancy as she had only 1 child. In 2 cases termination was done and they refused to accept any other method of contraception. In addition to these 7 cases closed for failure, we had 12 other cases of failure in whom termination was done and Cu-T was reinserted and hence they continue to be active cases. In 13 cases out of the total of 19 cases of failure, Cu-T was in situ. Only in 6 cases pregnancy had occurred after expulsion of the Cu-T. Our total failure rate is 1.36%.

In 1 case of perforation, the vertical

limb was partially visualised coming out of the cervix and the horizontal limb had penetrated the cervix at 9 o'clock position and was seen to protrude into the right fornix. Removal of Cu-T in this case did not present any difficulty.

Nine cases of expulsion discontinued the use of IUCD; 8 of them switched over to oral contraceptives.

Seventeen per cent of the cases were closed due to various non-medical reasons. Most of them changed over to other methods as they were unwilling to come for regular follow-up.

Papanicolaou smear was taken in 1130 patients. In 7% of the patients, the pap. smear changed from normal to inflammatory but there was no case of moderate or severe dysplasia or Ca.-in-situ in our series. Tatum (1972) has reported that among 6000 women with Cu-IUCD's who were checked annually with Papanicolaou smear over a period of 4 years there has been no evidence of either premalignant or malignant cervical or endometrial lesions.

#### Discussion

Table VI shows 3 series of Cu-T 200 cases. In all the 3 series, approximately 6-8% of removals are due to bleeding and pain. As with other IUD's, bleeding is the most frequent problem

TABLE VI  
Comparative Data

	Women months of use	Expulsion rate	REMOVALS			Continuation Rate
			Preg.	Bleeding	Pain	
Present Series (1400)	7703	5.3%	1.36%	4.93%	2.07%	74.3%
Tatum (945)	7740	7.2%	2.2%	—	5.6%	77%
Silvin (915)	6885	3.5%	1.8%	4.1%	2.7%	82%

associated with Cu-IUCD use. With the addition of Cu, the incidence of spotting or painful menstruation has been reduced but by no means eliminated. The expulsion rate is slightly higher in Tatum's series while continuation rate in all the 3 series is comparable.

Fortier (1973) has reported that 25% of Canadian women with Cu-200 experienced spotting in comparison to 38% with inert Lippes loop. Furthermore, using the Cu-device 11% of the women experienced increased menstrual bleeding compared with 27% using Lippes loop. In some cases spotting and painful or profuse menstruation were sufficiently severe to warrant removal of IUD. The removal rates for Cu-T were considerably lower than that for the inert Lippes loop—3.8% as compared to 12.4%. Similarly, a study of Cu-T by Lewit shows that the termination rate due to bleeding was lower for Cu-T's (6.4%) than for inert Lippes Loop (11.8%). Lewit also states that the excessive or painful flow does not seem to be influenced by the age of the woman. Landesman states that post abortion insertion of the device is not an influencing factor in post IUD bleeding pattern, while Mishell has indicated that bleeding and pain are more prevalent in nulliparous than in multiparous women.

Some interesting observations have been presented by various research workers on Cu-T. Unlike condom

which offer protection against venereal disease, an inert IUD offers no such protection. Recent studies however suggest that Cu-IUCD's may offer some indirect prophylaxis against gonococcal infection. Fiscilla *et al* (1973) have demonstrated that in vitro Cu ions kill or inhibit growth of *Nisseria gonorrhoea*; this effect has not been demonstrated in vivo as yet.

Hagenfeldt (1971) has demonstrated that during the first year the daily release of Cu was about 45 mc gms. After 1 year a Cu-200 device had lost a total of 10.3 mgms. Since Cu is constantly released from the device it is eventually exhausted and pharmacological action ceases. Hence replacement of old Cu devices with new ones may be necessary to maintain protection against pregnancy. Since the rate of release diminishes over time Cu-200 IUD is estimated to provide upto 4 years of effective Cu release. However, it is recommended that Cu devices should be changed every 2-3 years.

Cu-T has reduced the side effects to a substantial level compared to the inert IUCD's, but even so, bleeding still remains a major problem. Many sizes and shapes of Cu IUD's have evolved. Further evolution is in the direction of other medicated devices though the number of cases studied has been very few. So far at least progesterone loaded devices have not shown improved results. A very high percentage of removals are due to non-medical reasons which can be

reduced by proper motivation and education.

Summary

A clinical study of 1,400 cases of Cu-T insertions was done. In addition to other factors, effect of age, parity and case selection on the expulsion rate has been brought out. At the end of 3 1/2 years the overall expulsion rate is 5.3%. Seven per cent of the cases were closed due to bleeding and pain. The failure rate in our series was 1.36%; 74.3% of the patients are still active cases.

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