

A COMPARATIVE STUDY OF THE  
TCu 380A IUD AND THE MULTILOAD Cu 250 IUD  
IN SRI LANKA

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## I. INTRODUCTION

A study comparing the safety and effectiveness of the Copper T 380A (TCu 380A) intrauterine device (IUD) and the Multiload Cu 250 (MLCu 250) IUD was conducted at the University of Ruhuna Teaching Hospital in Galle, Sri Lanka. The project was intended to establish the acceptability and effectiveness of the TCu 380A compared to the MLCu 250 when measured by continuation and gross cumulative lifetable rates at the end of 12 months of follow-up. Devices were randomly assigned to 300 women from April 1986 through December 1986.

## II. STUDY PRODUCTS

The TCu 380A is a plastic T-shaped IUD that has copper collars, one on each side of the crossarm of the T, and has a total copper surface of 380 mm<sup>2</sup> of copper wire wound tightly around the stem. This IUD has a larger copper surface area than most copper IUDs, and the copper sleeves place the copper higher into the fundus than earlier copper IUDs. These factors are expected to improve the efficacy of this device over other IUDs. Theoretically the addition of more copper could increase the life-span of the device to up to ten years. The effective use of the TCu 380A for four years has been demonstrated by the Population Council (USA).

The Multiload Cu 250 (MLCu 250) is a horseshoe-shaped device with 250 mm<sup>2</sup> of exposed copper wound around the stem. The arms are flexible plastic serrated fins intended to help hold the device in place. The approved life-span of the MLCu 250 in Europe is three years.

### III. METHODOLOGY

three hundred sexually active women were enrolled over an 8-month period beginning in April 1986. Volunteers were to be generally healthy women from 18 to 40 years of age who were at risk of pregnancy (at least 42 days since the outcome of their last pregnancy) at the time of study enrollment. They were not to have clinical evidence of pelvic inflammatory disease (PID) or a sexually transmitted disease. In addition, they could not be allergic to copper, have an abnormal PAP smear (Class III or IV) within the past three months prior to study admission, or have evidence or history of clinically significant gastrointestinal or renal disease. Subjects were to rely on the IUD as their sole means of contraception while participating in the study. Informed consent was to be given before admission into the trial.

The IUDs were randomly assigned to participants according to sealed random allocation envelopes preprinted at FHI and opened at the time of each woman's admission into the study. Patients were requested to return for follow-up at 1, 3, 6 and 12 months after insertion of their assigned IUD or at any time complications or complaints occurred. Women were discontinued from the study if pregnancy occurred, if their IUD was partially or totally expelled, or if their IUD was removed for any reason. Study devices that were partially or totally expelled were not to be reinserted.

### IV. USER CHARACTERISTICS

A total of 300 women were enrolled into the study, with 149 women receiving the TCu 380A IUD and 151 women the MLCu 250 IUD. Selected sociodemographic characteristics of these women are shown in Table I. The mean age was 27.1

years for women in the TCU 380A group and 27.4 years in the MLCu 250 group. The mean number of live births in both study groups was similar, as was the mean number of additional children desired. Over 70 percent of the women in both groups reported using no contraceptive method during the month previous to their admission into the study. When a contraceptive method was noted, however, IUD use was most often reported in both groups.

#### V. COMPLICATIONS AND COMPLAINTS

Complications and complaints at insertion and follow-up are shown in Table II. During insertion 48 women in the TCU 380A group and 46 women in the MLCu 250 group reported that they experienced mild pelvic pain, but these occurrences were not considered serious or unexpected by the study physician. No other insertion complications or complaints were noted.

All of the patients enrolled into the trial returned for at least one follow-up visit during the 12-month follow-up interval. Few complications or complaints were reported throughout the trial (Table II). Primary postinsertion bleeding/pain complaints among both study groups, when reported, included: intermenstrual spotting experienced by three TCU 380A users (2.0%) and one MLCu 250 user (0.7%); intermenstrual bleeding reported by five TCU 380A users (3.4%) and three MLCu 250 users (2.0%); and intermenstrual pelvic pain, reported by 26 TCU 380A users (18.4%) and 18 MLCu 250 users (11.9%). Thirty-six women in the TCU 380A group (24.2%) experienced dysmenorrhea, compared to 22 women in the MLCu 250 group (14.6%), statistically significant at the .05 level ( $X^2 = 4.4$ ). Two cases of cervicitis were reported in the TCU 380A group, while one case of trichomonas, two cases of cervicitis, and one case of vaginitis were reported in

the MLCu 250 group. One intrauterine pregnancy was reported during the trial at the 6-month follow-up period and it was in the MLCu 250 group.

## VI. TERMINATION EVENTS

Gross cumulative lifetable termination and event rates are shown in Table III. One pregnancy occurred among MLCu 250 users, yielding a 12-month pregnancy rate of 0.7 per 100 women for this group. IUDs were expelled or displaced in five TCu 380A users and three MLCu 250 users, with most expulsions or displacements occurring within the first six months of use. The twelve-month expulsion/displacement rates were 3.5 per 100 women in the TCu 380A group and 2.1 per 100 women in the MLCu 250 group. There was one removal in the TCu 380A group and two in the MLCu 250 group for bleeding/pain, yielding a 12-month lifetable rate of 0.7 and 1.4 per 100 women for the two groups, respectively. A total of five women, one in the TCu 380A group and four in the MLCu 250 group, requested to have their devices removed for personal reasons (husband's objection to the method, husband died, and husband went abroad). The twelve-month lifetable termination rates for personal reasons were 0.7 per 100 women in the TCu 380A group and 2.8 per 100 women in the MLCu 250 group. Twelve-month total termination rates were 4.8 and 6.8 per 100 women in both study groups, respectively.

The continuation rates for both study groups remained high throughout the trial (Table IV). The 12-month continuation rate was 95.2 for the TCu 380A group and 93.2 for the MLCu 250 group. The follow-up rates, defined as the percentage of women not previously terminated from the study who returned for follow-up, were high at 12 months, being 91.3 and 93.6 for both groups of users, respectively.

## VII. SUMMARY

From April through December 1986 intrauterine devices were inserted in 300 interval women who participated in a study at the University of Ruhuna in Galle, Sri Lanka. One hundred and forty-nine women received the TCu 380A IUD and 151 women to Multiload Cu 250 IUD by random assignment. Patients in the two study groups were similar with respect to a variety of sociodemographic characteristics.

The only insertion-related complaint reported was mild pelvic pain, experienced by roughly one-third of the women in both of the device groups. Intermenstrual pelvic pain and dysmenorrhea were the method-related complaints reported most often during the study. The incidence of infection/inflammation was low. The majority of terminations in both study groups were due to expulsion/displacement of the device, bleeding/pain, and for personal reasons. These terminations, however, were not common and most of the 300 patients completed the 12-month follow-up interval. The rate of continuation was very high at the 12-month follow-up period, with over 90 percent of the women in both groups electing to continue using their devices as their method of contraception. Overall, both the TCu 380A and the Multiload 250 were found to be safe, effective and acceptable methods of intrauterine contraception for this population of users.

### VIII. DATA QUALITY

Overall data quality was excellent. The center enrolled the requisite 300 patients and were able to follow-up over 90 percent throughout the study. Case record forms were in good order and data queries were answered in a timely fashion.

Table I Patient characteristics at admission: comparative study of IUDs in Sri Lanka, 1986-1988.

	Percent of women	
	TCu 380A (N=149)	MLCu 250 (N=151)
<b>Patient's age (years)</b>		
<20	6.7	4.6
20-24	30.9	33.8
25-29	36.2	35.1
30-34	20.1	14.6
35+	6.1	11.9
mean age	27.1	27.4
<b>Number of live births</b>		
1	30.9	19.2
2	33.6	44.4
3	23.5	30.5
4+	12.0	5.9
mean live births	2.1	2.2
<b>Contraceptive method used in month preceding study</b>		
None	72.5	71.5
IUD	20.1	19.9
Orals	4.7	6.6
Others	2.7	2.4
<b>Number of additional children desired</b>		
None	47.0	43.0
1	36.2	42.4
2-3	16.8	14.6
mean	0.6	0.7

Table II. Events at insertion and follow-up<sup>1</sup>: comparative study of IUDs in Sri Lanka, 1986-1988.

	Number of Women Reporting Event	
	TCu 380A (N=149)	MLCu 250 (N=151)
<u>At Insertion</u>		
Mild pelvic pain	48	46
<u>At Follow-up</u>		
Primary bleeding/pain complaints		
Intermenstrual		
Spotting	3	1
Bleeding	5	3
Pelvic pain	26	18
Dysmenorrhea	36	22
Infection/inflammation		
Trichomonas	0	1
Cervicitis*	2	2
Vaginitis**	0	1
Pregnancy	0	1

<sup>1</sup>More than one event may be reported for the same woman.

\*Includes cervical erosion and ectropion.

\*\*Includes monilia and colpitis.

Table III. Gross cumulative lifetable rates per 100 users: comparative study of IUDs in Sri Lanka, 1986-1988.

Termination Type and Period	TCu 380A (N=149)		MLCu 250 (N=151)	
	Rate	S.E.	Rate	S.E.
<b>Pregnancy</b>				
3 months	0.0	+ 0.0	0.0	+ 0.0
6 months	0.0	+ 0.0	0.7	+ 0.7
12 months	0.0	+ 0.0	0.7	+ 0.7
<b>Expulsion/displacement</b>				
3 months	2.0	+ 1.2	1.4	+ 1.0
6 months	2.7	+ 1.3	1.4	+ 1.0
12 months	3.5	+ 1.5	2.1	+ 1.2
<b>Removal for bleeding/pain</b>				
3 months	0.7	+ 0.7	1.4	+ 1.0
6 months	0.7	+ 0.7	1.4	+ 1.0
12 months	0.7	+ 0.7	1.4	+ 1.0
<b>Removal for other personal reasons</b>				
3 months	0.0	+ 0.0	1.4	+ 1.0
6 months	0.0	+ 0.0	2.1	+ 1.2
12 months	0.7	+ 0.7	2.8	+ 1.4
<b>Total terminations</b>				
3 months	2.7	+ 1.3	4.0	+ 1.6
6 months	3.4	+ 1.5	5.4	+ 1.9
12 months	4.8	+ 1.8	6.8	+ 2.1

Table IV. Continuation and Follow-up rates: comparative study of IUDs in Sri Lanka, 1986-1988.

Rate and Period	TCu 380A (N=149) Rate	MLCu 250 (N=151) Rate
<b>Rate of continuation</b>		
1 month	98.0	98.7
3 months	97.3	96.0
6 months	96.6	94.6
12 months	95.2	93.2
<b>Follow-up rate*</b>		
1 month	100.0	100.0
3 months	100.0	98.0
6 months	98.6	95.8
12 months	91.3	93.6

\*Follow-up rate is defined as the percentage of women not previously terminated who return for follow-up.