A COMPARATIVE STUDY OF THE TCu 380A IUD AND THE TCu 200 IUD IN EL SALVADOR

Prepared for

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I. INTRODUCTION

A comparative study using the Copper T 380A (TCu 380A) intrauterine device (IUD) and the Copper T 200 (TCu 200) IUD was conducted at the Associación Demográfica Salvadoreña in San Salvador, El Salvador. The purpose of this project was to discover differences in clinical acceptability and effectiveness of the TCu 380A and the TCu 200 IUDs. The factors evaluated were complications/complaints, participant's status at the end of the study and gross cumulative lifetable event and continuation rates over a 12-month follow-up period. Devices were randomly assigned to 300 women and insertions of IUDs were performed from February 1986 through March 1987. Data were recorded on standardized forms designed and processed by Family Health International (FHI).

I. STUDY PRODUCTS

The TCu 200 is a T-shaped IUD made of polyethylene with barium sulfate added for visibility on x-rays. It is wound with copper wire providing a surface area of 200mm^2. Its cross arm is 32mm in width and the vertical arm is 36mm in length. The proximal end of the IUD stem is provided with two threads of polyethylene to serve as a markers.

The TCu 380A, also a T-shaped IUD made of polyethylene, has two copper sleeves, one on each side of the crossarm of the T, and has 314mm^2 of copper wire wound tightly around the stem and crossarms, providing a larger copper surface area than most copper IUDs. This factor is expected to improve the

efficacy of the TCu 380A over the standard TCu 200 IUD. The additional copper increases the theoretical life-span of the TCu 380A up to ten years. The effective use of the TCu 380A for four years has been demonstrated by studies done by the Population Council (USA).

III. METHODOLOGY

Three hundred women were enrolled over a 13 month period beginning in February 1986. Women 18 to 40 years old who were healthy, sexually active, seeking intrauterine contraception, and willing to rely solely on the IUD for contraception were admitted to the trial. Other criteria for inclusion were that their general and pelvic examinations, including Pap smear, were normal and they had no active sexually transmitted diseases, undiagnosed vaginal bleeding or allergy to copper. Candidates for this study were excluded if they had a history of ectopic pregnancy, an abnormal pap smear (3 months or less prior to study), and history or evidence of clinically significant gastrointestinal or renal disease. All women gave informed consent before admission and agreed to return to the clinic for follow-up visits.

The two IUDs were randomly assigned to volunteers according to sealed random allocation envelopes preprinted at FHI and opened at the time of each woman's admission to the study. Insertions were performed no sooner than 42 days after the end of the most recent pregnancy. Patients were requested to return for follow-up at 1, 3, 6 and 12 months after insertion of their IUD or at any time complications occurred. Women were terminated 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

Of the 300 women enrolled into the study, 149 women received the TCu 380A IUD and 151 women the TCu 200 IUD. Selected sociodemographic characteristics of these women are presented in Table I. The mean age was 24.8 years for women in the TCu 380A group and 25.2 years in the TCu 200 group. The mean number of live births in both study groups was 1.7. The mean number of years of education was similar, 9.9 for the TCu 380A group and 9.5 for the TCu 200 group. Over 40 percent of the women in both groups reported using no contraceptive method during the month prior to their admission to the study. When a contraceptive method was noted, however, oral contraceptive use was reported most often in both groups.

V. COMPLICATIONS AND COMPLAINTS

Complications and complaints recorded at insertion and follow-up are presented in Table II. One failed insertion occurred with a woman scheduled to receive the TCU 200; she was not included in the follow-up analysis. Nine cervical lacerations were reported during insertion in the TCu 380A group and 12 in the TCu 200 group, none of which required treatment. In each of these cases the reported mechanism of laceration was by a tenaculum. During

insertion 30 women in the TCu 380A group and 43 in the TCu 200 group reported that they experienced mild pelvic pain, but this difference was not statistically significant. Another nine women in the TCu 380A group and 11 women in the TCu 200 group reported moderate pelvic pain; one woman in the TCu 380A group reported severe pelvic pain. When comparing the total insertion complications/complaints of both groups, the TCu 380A has a lower reported number of complication/complaints than the TCu 200 with a statistical significance at the 0.5 level (x^2=4.17)

One hundred and forty-seven women in the TCu 380A group and 149 women in the TCu 200 group returned for at least one follow-up visit. Several complications or complaints were reported throughout the follow-up period, but no significant differences between the two IUDs were noted (Table II). An ectopic pregnancy in the left Fallopian tube was diagnosed in one woman eight months after the insertion of a TCu 380A. A left salpingectomy was performed; this patient was discontinued from the trial. When reported, the primary post-insertion bleeding/pain complaints among both study groups included: intermenstrual bleeding experienced by 16 TCu 380A users (10.9%) and 28 TCu 200 users (18.8%); intermenstrual spotting experienced by 38 TCu 380A users (25.9%) and 33 TCu 200 users (22.1%); and intermenstrual pelvic pain, reported by 68 TCu 380A users (46.3%) and 67 TCu 200 users (45.0%). The most frequently reported complaint was dysmenorrhea reported by 114 women in the TCu 380A group (77.6%) and 103 women in the TCu 200 group (69.1%). Among the two groups, no statistically significant differences were noted.

According to the investigator, many women in both groups were diagnosed as developing either pelvic inflammatory disease (PID), a sexually transmitted

disease (STD) or other inflammations and infections which may or may not have been IUD related. A total of 32 women developed PID, 17 in the TCU 380A group and 15 in the TCu 200 group. These included reports of adnexitis and endometritis but none of these women required hospitalization. A total of 11 women in both groups had trichomonas: five TCu 380A users and 6 TCu 200 users. A total of 32 women were diagnosed with other inflammations and infections. These included eight cases of cervicitis in the TCu 380A group and nine cases in the TCu 200 group. Vaginitis was reported for three women in the TCu 380A group and for four women in the TCu 200 group. Lastly, four cases of leukorrhea were reported in each group.

VI. TERMINATION EVENTS

Tables III and IV present data on participant's status at the end of their 12-month follow-up period, including gross-cumulative life-table events and continuation rates. There were two method-related pregnancies among the TCu 380A users, yielding a twelve-month accidental pregnancy rate of 1.7 per 100 women. Three method-related pregnancies were reported among the TCu 200 users also yielding an accidental pregnancy rate of 1.7 per 100 women. IUDs were expelled or displaced in seven TCu 380A users and four TCu 200 users. Twelve-month expulsion/displacements rates were 5.1 per 100 women in the TCu 380A group and 2.9 per 100 women in the TCu 200 group.

Pain and bleeding were the cause of the greatest number of method-related terminations in this study. Ten removals for pain and bleeding occurred in the TCu 380A group and 14 in the TCu 200, yielding twelve-month lifetable rates of 7.7 per 100 women in the TCU 380A group and 8.7 per 100 women for

the TCu 200 group. Four women, one in the TCu 380A group and three in the TCu 200 group, had the device removed for other medical reasons; for example, endometritis and prolonged menses. The twelve-month termination rates for other medical reasons were 0.8 per 100 women in the TCu 380A group and 2.3 per 100 women in the TCu 200 group. One TCu 380A user and three TCu 200 users had their IUD removed for a planned pregnancy. These removals yielded a twelve-month lifetable rate of 0.8 per 100 women in the TCu 380A group and 1.8 per 100 women in the TCu 200 group. A total of 23 woman, 12 in the TCu 380A group and 11 in the TCu 200 group, requested removal of their IUD for personal reasons; for example, husband's choice, husband's absence, and change in method of contraceptive. The twelve-month lifetable termination rates for personal reasons were 7.1 per 100 women in the TCu 380A group and 9.3 per 100 women in the TCu 200 group. The total method-related terminations include pregnancy, expulsion/displacement, removal for bleeding/pain and removal for other medical reasons. At 12 months these rates were 14.6 per 100 women in the TCu 380A group and 14.9 per 100 women the TCu 200 group. When comparing the termination rates of these groups, no statistical significances were noted.

The follow-up rates, defined as the percentage of women not previously terminated from the study who returned for follow-up, decreased slightly over the twelve month period. The twelve-month rates were 86.6 for the TCu 380A group and 84.7 for the TCu 200 group. Continuation rates are defined as 100 minus the total termination rate. The continuation rates for this study were not significantly different between the two groups. One hundred and fourteen women continued with the TCu 380A and 111 with the TCu 200 after the 12-month study period had ended. These continuations yielded a twelve-month rate of

78.7 for the TCu 380A group and 75.8 for the TCu 200.

VII. SUMMARY

From February 1986 through March 1987, intrauterine devices were inserted in 300 interval women who participated in a comparative clinical trial at the Asociación Demográfica Salvadoreña in San Salvador, El Salvador. One hundred and forty-nine women had the TCu 380A IUD inserted and 151 women the TCu 200 IUD, by random assignment. Participants in the two groups were similar with respect to a variety of sociodemographic characteristics.

Insertion-related complaints reported for both groups were primarily for pelvic pain, experienced by almost one-third of all the women. Cervical lacerations occurred during insertion in 21 women. These lacerations, caused by a tenaculum, required no treatment. There was one failed insertion. Menstrual complaints reported at follow-up were numerous in both study groups. They included dysmenorrhea, intermenstrual bleeding, and spotting and pelvic pain. However, neither IUD group was found to have a significantly higher incidence of menstrual complaints than the other. The incidence of PID, STDs, and inflammation/infections were similar in both groups. The most frequent termination event in both study groups were removals due to bleeding and pain.

The two IUDs appear to be acceptable methods of contraception for this population of users. Over two-thirds of the women in both groups elected to continue using their assigned IUD as their method of contraception after completing the trial. The data indicate that the TCu 380A is as acceptable

to users as the TCu 200. The TCu 380A has been shown to be as effective as the TCu 200 and offers the additional benefit of a longer lifespan.

TABLE I

Selected Sociodemographic Characteristics
Comparative Study of the TCu 380A vs. the TCu 200 IUDs
San Salvador, El Salvador

Characteristics	TCU 380A (N=149) No.	%	TCU 200 (N=151) No.	%[1]
Age (years)				
<20	24	16.1	22	14.6
20-24	66	44.3	58	38.4
25-29	38	25.5	46	30.5
30-34	13	8.7	19	12.6
35+	8	5.4	6	4.0
Mean	24.8		25.2	
Total Number of Live Births				
None	1	0.7	0	0.0
1	77	51.7	81	53.6
2	43	28.9	50	33.1
3	24	16.1	13	8.6
4+	4	2.7	7	4.6
Mean	1.7		1.7	
Use of a Contraceptive in the Past Month				
No	67	45.0	61	40.4
Yes	82	55.0	90	59.7
Education (years)				
None	1	0.7	4	2.6
1-3	9	6.0	11	7.3
4-6	27	18.1	23	15.2
7-9	41	27.5	48	31.8
10-12	49	32.9	45	29.8
13+	22	14.8	20	13.2
Mean	9.9		9.5	

[1] Percentages may not total 100% due to rounding.

TABLE II

Complications/Complaints Reported at Insertion and Follow-up[1]
Comparative Study of the TCu380A vs. TCu 200 IUDs
San Salvador, El Salvador

Complication/Complaint	TCU 380A (N=149) No.	TCU 200 (N=151) No.
Insertion		
Failed Insertion	0	1
Cervical Laceration	9	12
Pelvic Pain		
Mild	30	43
Moderate	9	11
Severe	1	0
Follow-up[2]		
Total Women ever followed-up	147	149
Major Events		
Ectopic Pregnancy	1	0
Menstrual Complaints		
Dysmenorrhea	114	103
Intermenstrual:		
Bleeding	16	28
Spotting	38	33
Pelvic Pain	68	67
Pelvic Inflammatory Disease (PID)		
Adnexitis	5	3
Endometritis	9	7
Anatomically Unspecified[3]	3	5
Sexually Transmitted Disease (STD)		
Trichomonas	5	6
Other Inflammation/Infection		
Cervicitis[4]	8	9
Vaginitis[5]	3	4
Leukorrhea (symptom)	4	4

[1] More than one event may be recorded for a woman.
[2] Excludes failed insertion.
[3] Patients with acute PID.
[4] Includes cervical erosion.
[5] Includes moniliasis (candidiasis) and colpitis.

Table III.
Participant Status at the End of the Study
Comparative Study of the TCu 380A vs. TCu 200 IUDs
San Salvador, El Salvador

Participant Status	TCU 380A (N=149) No.	%	TCU 200 (N=150)[1] No.	%
Continuing	114	76.5	111	74.0
Pregnancy	2	1.3	3	2.0
Expulsion	7	4.7	4	2.7
Removal:				
Pain/Bleeding	10	6.8	14	9.3
Medical reasons				
End metritis	1	0.7	1	0.7
Other	0	0.0	2	1.3
Planned pregnancy	1	0.7	3	2.0
Personal reasons				
Husband's choice	2	1.3	2	1.3
Husband's absence	4	2.7	2	1.3
Changed contraceptive method	3	2.0	3	2.0
Other	3	2.0	4	2.7
Not followed-up	2	1.3	1	0.7

[1] Excludes failed insertion.

Table IV.
Gross-Cumulative Life-Table Event and Continuation Rates Per 100 Women
Comparative Study of the TCu 380A vs. TCu 200 IUDs
San Salvador, El Salvador

Termination Type and Period	TCU 380A Rate	TCU 380A S.E.[1]	TCU 200 Rate	TCU 200 S.E.
Accidental Pregnancy				
3 months	0.0	± 0.0	0.0	± 0.0
6 months	0.8	± 0.8	0.8	± 0.8
12 months	1.7	± 1.2	1.7	± 1.2
Expulsion/Displacement				
3 months	4.2	± 1.7	2.1	± 1.2
6 months	4.2	± 1.7	2.9	± 1.4
12 months	5.1	± 1.9	2.9	± 1.4
Removal for bleeding/pain				
3 months	3.5	± 1.5	6.9	± 2.1
6 months	5.1	± 1.9	6.9	± 2.1
12 months	7.7	± 2.4	8.7	± 2.4
Removal for other medical reasons				
3 months	0.0	± 0.0	0.8	± 0.8
6 months	0.8	± 0.8	2.3	± 1.3
12 months	0.8	± 0.8	2.3	± 1.3
Removal for planned pregnancy				
3 months	0.0	± 0.0	0.0	± 0.0
6 months	0.8	± 0.8	0.8	± 0.8
12 months	0.8	± 0.8	1.8	± 1.3
Removal for other personal reasons				
3 months	2.2	± 1.2	1.5	± 1.0
6 months	4.5	± 1.8	3.9	± 1.7
12 months	7.1	± 2.3	9.3	± 2.7
Total method-related terminations[2]				
3 months	7.6	± 2.2	9.5	± 2.4
6 months	10.6	± 2.6	12.4	± 2.7
12 months	14.6	± 3.0	14.9	± 3.0

[1] Standard Error
[2] Includes accidental pregnancy, expulsion/displacement and removal for bleeding and/or pain.

TABLE IV. Continued
Gross-Cumulative Life-Table Event and Continuation Rates Per 100 Women
Comparaive Study of the TCu 380A vs. TCu 200 IUDs
San Salvador, El Salvador

Termination Type and Period	TCU 380A Rate	TCU 200 Rate
Continuation Rate		
3 months	90.4	89.1
6 months	84.7	83.5
12 months	78.7	75.8
Follow-up Rate[3]		
3 months	97.1	97.1
6 months	93.0	93.0
12 months	86.6	84.7

[3] The percentage of women returning for follow-up who have not been previously terminated.