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A COMPARATIVE STUDY OF INTRAUTERINE DEVICES,  
TCu 380A VERSUS TCu 200  
IN OUAGADOUGOU, BURKINA FASO

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## **I. INTRODUCTION**

The intrauterine device (IUD) is a popular and highly tested method of contraception. About 85 million women worldwide use IUDs. The current generation of IUDs is safe for most women and about 99 percent effective over one year of use. However, not all women should use IUDs. The provider must carefully screen potential users, insert the IUD correctly and follow-up users to assess safety. This study was part of Family Health International's (FHI) Investigator Network Needs (INN) program to train doctors in conducting clinical trials. The study assessed the clinical performance and contraceptive effectiveness of the TCU 380A and TCU 200 IUDs in two family planning clinics in Burkina Faso.

## **II. MATERIALS AND METHODS**

### *Study Design*

This study was conducted at the family planning clinic, Association Burkinabée de Bien-Etre Familiale (ABBEF), in Ouagadougou, and at the MCH center at Samandin in Burkina Faso. The TCU 380A IUD and the TCU 200 IUD were randomly assigned to volunteer participants according to sealed random allocation envelopes pre-printed at FHI. At the time of each woman's admission to the study, the envelope was opened, indicating the IUD to be inserted. The factors evaluated were complications and complaints, participant's status after twelve months of use, and gross cumulative life-table discontinuation rates over a twelve-month follow-up period.

The protocol, as well as the fact sheet and volunteer agreement form to be used in the study, were approved by the FHI Protection of Human Subjects Committee before initiation.

### *Study Products*

The TCU 380A is a T-shaped IUD made of polyethylene with barium sulfate for x-ray detectability. It has two 33 mm<sup>2</sup> solid copper sleeves on each transverse arm and 314 mm of copper wire wound tightly around the vertical stem. The increased copper surface area has been shown to improve the efficacy of the TCU 380A over the TCU 200 IUD. The device is 32 mm wide and 36 mm long with a plastic ball at the bottom of the vertical stem to guard against cervical penetration. A polyethylene filament is tied through the ball and provides two marker threads.

The TCU 200 is also a T-shaped IUD made of polyethylene with barium sulfate added for x-ray detectability. It is wound with copper wire on the stem providing a total surface area of 200 mm<sup>2</sup>. The cross-arm is 32 mm in width and the vertical arm is 36 mm in length. The proximal end of the IUD is provided with two polyethylene marker threads.

### *Selection Criteria*

Women 18 to 40 years old who were healthy, sexually active, parity of one or more,  $\geq 42$  days postpartum, freely consenting to participate in the study, could conveniently return for follow-up, and were willing to rely solely on the IUD for contraception were admitted into the trial. Women were to be excluded if there was evidence of pregnancy, a history of ectopic pregnancy, current sexually transmitted disease (STD) or pelvic inflammatory disease (PID). In addition, women were excluded if they had undiagnosed vaginal bleeding, allergy to copper, or a history or evidence of clinically significant gastrointestinal or renal disease. Candidates were also to be excluded if they had an abnormal Pap smear three months or less prior to admission into the study, but no Pap smears were taken by the participating centers at admission.

### *Admission Procedures*

At the initial visit, women were screened for study eligibility using predetermined screening criteria. The screening process included taking a medical history and performing a pelvic examination. The risks and benefits of study participation were explained to each woman. All participants gave informed consent before admission and agreed to return to the clinic for follow-up visits. The Family Planning Association systematically required a four-day antibiotic prophylaxis treatment for all women receiving an IUD. The cost of this treatment was approximately \$10 (U.S.) per woman.

### *Follow-up Procedures*

The subjects were requested to return for follow-up visits at 1, 3, 6, and 12 months after IUD insertion or at any time complications occurred. At the follow-up visits, pelvic examinations were performed and appropriate treatment if necessary, was provided; the data collected were documented on the case record form (CRF) by clinic staff. A follow-up system was set up whereby a midwife would make a home visit to locate women who did not come in for their scheduled visit.

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 expelled or displaced after insertion were not reinserted. Depending upon the physician's judgment, a woman's IUD could be left in place at the end of the study period in accordance with approved FDA labeling on the IUDs, and the woman was to be followed-up according to standard medical practices.

### *Data Analysis*

Data were sent to FHI for processing and analysis. Differences in all complications and complaints rates between the two groups returning for follow-up were tested using Fisher's exact test. Comparison of important study events were made on the basis of pregnancy, expulsion, bleeding and/or pain, and other specific removal rates. Accidental pregnancies were diagnosed if a woman became pregnant with the IUD *in situ* during her 12-month study period.

The following definition was used for classifying discontinuation cases when both conception and expulsion were reported for the same woman. Accidental pregnancy includes:

- all conceptions occurring after insertion of the IUD and prior to removal or an expulsion noticed by the wearer, or
- all conceptions associated with an expulsion not noticed by the wearer, or
- all conceptions associated with a perforation of the uterus.

This does not include conceptions prior to insertion or after a noticed expulsion, or after the IUD was removed for whatever reason. In these instances discontinuation was due to the event leading to IUD removal [1]. The estimated date of discontinuation for noticed and unnoticed, complete or partial expulsions is calculated as the midpoint between the date of last follow-up and the visit at which the expulsion was reported.

The life-table method was used to calculate all termination rates. Single decrement gross life-table rates were compared using the log rank statistic which permits the overall comparison of cumulative life table event rates. Statistical significance was set at  $p \leq 0.05$  for comparing complications and complaints, and  $p \leq 0.05$  for comparing discontinuation rates. With the final sample size, the power to detect a statistically significant difference between the two study groups with pregnancy rates of 1.0 per 100 women in the TCu 380A IUD group and 0.0 per 100 women in the TCu 200 IUD group is about 19% ( $\alpha = .05$ ).

## **III. RESULTS**

### *Subject Population*

Two hundred women were enrolled over a 13-month period beginning in November 1989. By random allocation, 101 received the TCu 380A IUD and 99 received the TCu 200 IUD. However, due to a site coding error and late receipt of query information, one TCu 200 subject was excluded from analysis. There were three random allocation errors, one subject received the TCu 200 instead of the TCu 380A and two received the TCu 380A instead of the TCu 200. All subjects had the IUD inserted six weeks or more since their last pregnancy

termination. Two subjects were over the maximum age, at 45 and 46 years, and four subjects had current candidiasis and one subject had trichomoniasis at the time of insertion. These were considered to be minor protocol violations, and the subjects were permitted to continue in the study in the groups corresponding to the IUD they had actually received.

### *Baseline Measures*

The mean age  $\pm$  standard deviation (SD) of the women in the TCu 380A IUD group was  $30.3 \pm 5.2$  years and  $29.2 \pm 5.7$  years for the TCu 200 IUD group (Table I). The reproductive history for the women also is detailed in Table I. All the women had at least one live birth prior to study admission. The mean  $\pm$  SD for the total number of live births was  $4.4 \pm 1.9$  for the TCu 380A IUD group and  $4.3 \pm 2.1$  for the TCu 200 IUD group. About half of the women in both groups reported using no contraceptive method during the month prior to study enrollment. When a method was used, the most frequent choices were IUDs, oral contraceptives, or abstinence.

### *Insertion Status*

There were no complications or complaints reported at insertion (Table II), but a few pre-existing conditions were reported. In the TCu 380A IUD group, three subjects had dysmenorrhea, two had candidiasis and one had trichomoniasis. In the TCu 200 IUD group, one subject had a single episode of previous PID, two had dysmenorrhea, and two had candidiasis.

### *Follow-up Status*

Only one subject was lost to follow-up, and 174 out of the 199 subjects, or 87.4% completed the study through the 12-month follow-up visit. All complications and complaints reported during the study are listed in Table II. Intermenstrual pelvic pain was the most frequent problem reported: 12 (12.0%) women in the TCu 380A IUD group and 9 (9.2%) women in the TCu 200 IUD group. Dysmenorrhea was reported by 8 (8.0%) women in the TCu 380A IUD group and by 10 (10.2%) women in the TCu 200 IUD group. About 5% of women in both groups reported menorrhagia. There were few reports of intermenstrual spotting or bleeding in either group. The differences between the study groups were not statistically significant.

Table II also lists the occurrence of PID, STDs, and other inflammations or infections that occurred during follow-up. For all subjects from both clinics, 8 (8.1%) women in the TCu 380A IUD group and 1 (1.0%) woman in the TCu 200 IUD group were reported to have PID confined to the adnexa ( $p=.035$ ). Five (5.0%) women in the TCu 380A IUD group and 2 (2.0%) women in the TCu 200 IUD group had PID involving both the uterus and adnexa.

Three (3.0%) women in the TCu 380A IUD group and 2 (2.0%) women in the TCu 200 IUD group had PID confined to the uterus.

There were a large number of inflammations and infections reported; however, the differences between the two IUD groups were not statistically significant. In the TCu 380A IUD group, 16 (16.2%) women had candidiasis and 10 (10.1%) had trichomoniasis. In the TCu 200 IUD group 18 (18.4%) women had candidiasis and 18 (18.4%) had trichomoniasis. In the TCu 380A IUD group, 18 (18%) women were reported to have leukorrhea and 13 (13%) cervicitis. In the TCu 200 IUD group, 12 (12.2%) women were reported to have leukorrhea and 8 (8.2%) cervicitis. Eight women (8.2%) in the TCu 200 IUD group, and 3 women (3%) in the TCu 380A IUD group had pruritus vulvae of undetermined origin.

### *Subject Discontinuation*

Table III summarizes the women's status at the end of twelve months of use and Table IV presents the 12-month gross cumulative life-table rates for these termination events. Evaluations of efficacy were made on the basis of various termination rates and continuation rates, with a focus on the accidental pregnancy and expulsion rates. Non-pertinent termination reasons included planning a pregnancy and removals for other personal reasons. The differences in life-table rates between the two groups for the discontinuation reasons listed were not statistically significant, ( $p>.05$ ).

There was one accidental pregnancy (1.0%) in the TCu 380A IUD group yielding a 12-month life-table rate of 1.0 per 100 women. The woman was found to be pregnant approximately 6 weeks after insertion, with the IUD *in situ*. The gestational age was 4 weeks at the time of IUD removal; the pregnancy outcome was not reported. No pregnancies were reported in the TCu 200 group.

There were a total of seven IUD expulsions or displacements in the study: 3 (3.0%) in the TCu 380A IUD group and 4 (4.1%) in the TCu 200 IUD group. The 12-month gross life-table rates were 3.2 per 100 women for the TCu 380A IUD group and 4.1 per 100 women for the TCu 200 IUD group.

Removals for bleeding and/or pain included four women (4.0%) in the TCu 380A IUD group and one woman (1.0%) in the TCu 200 IUD group. The life-table removal rates for these TCu 380A and TCu 200 IUD users were 4.5 per 100 women and 1.1 per 100 women, respectively.

Two women (2.0%) in the TCu 380A IUD group and one woman (1.0%) in the TCu 200 IUD group were terminated from the study for a medical reason. All three subjects had their IUD removed for repeated infections (leukorrhea). The 12-month gross cumulative life-table rates were 2.1 per 100 women for the TCu 380A IUD group and 1.1 for the TCu 200 IUD group.

There were a small number of women who requested IUD removal in order to plan a pregnancy. One woman in each IUD group requested removal for this reason, with a 12-month gross cumulative life-table rate of 1.2 per 100 women for the TCU 380A group and 1.1 per 100 women for the TCU 200 IUD group.

A total of six women had their IUD removed because of personal reasons. Of the three women (3.0%) in the TCU 380A IUD group, two requested removal because of separation from their husbands (one went on a journey and the other was divorced), and the other woman requested removal because she had chronic leukorrhea and candidiasis and could not afford to fill the prescriptions. In the TCU 200 IUD group, three women (3.1%) requested removal, two because their husbands objected, and one requested removal at 25 months because her husband died. This event was not detected in the life-table rates as the removal occurred beyond the 12-month study cut-off period. The 12-month gross cumulative life-table rates were 3.3 per 100 women for the TCU 380A IUD group and 2.2 per 100 women for the TCU 200 IUD group.

#### **IV. SUMMARY**

From November 22, 1989 to December 7, 1990, IUDs were inserted in 200 women in a 12-month comparative clinical trial conducted at the family planning clinic, Association Burkinabée de Bien-Etre Familiale (ABBEF), in Ouagadougou, and at the MCH center at Samandin in Burkina Faso. This study was designed to assess the contraceptive safety and efficacy with two comparative IUDs and to provide the investigator experience in conducting a clinical trial. By random allocation, 101 women received the TCU 380A IUD and 98 received the TCU 200 IUD. Participants in the two groups were similar with respect to selected socio-demographic characteristics and reproductive history.

The most frequently reported menstrual complaints for both groups were intermenstrual pelvic pain and dysmenorrhea. The incidence of PID and other inflammations or infections was found to be higher in the TCU 380A group. Although this is statistically significant, this difference may have been due to chance. With 31 tests of complications at the .05 level, there is about an 80% chance of finding a statistically significant result when in fact there is no true difference. Other larger studies have not shown an increased risk of PID in TCU 380A users compared to TCU 200 users.

For this population of women, the TCU 200 IUD group had no accidental pregnancies while there was one accidental pregnancy in the TCU 380A IUD group. Of the women who returned for their twelve month visit, at least 85% decided to continue wearing the IUD after the study had ended. While no significant overall differences between the two study IUDs were observed in the incidence of terminations or complications, the power to detect a statistically significant difference was low in this study.

The descriptive data reported in this comparison trial suggest that the two T-shaped devices are generally similar in respect to reports of inflammations/infections, and termination events. At the time of this study the approved lifespan of the TCU 380A was four years, with a published four-year life-table pregnancy rate of 2.8 per 100 women based on 1,927 women-years of use. [2] However, studies conducted by the Population Council have demonstrated an extended lifespan of eight years. An extended lifespan would allow for longer contraceptive protection.

The data from the present trial also indicate the need for improved patient screening. As stated earlier, the health care provider should take a detailed medical history regarding IUD candidates. There were reports of a previous history of leukorrhea, candidiasis, trichomoniasis and a single episode of PID among study subjects. Over the duration of the study, there were numerous reports of leukorrhea, cervicitis and infections in each IUD group. The high frequency of these reports may reflect this population's risk of these infections. Previous studies have shown that women using IUDs are about twice as likely to develop pelvic inflammatory disease as women using no contraception, but this increased risk of PID is largely concentrated in the first few months after insertion and, thereafter, among women exposed to STDs. [3] Subjects at these clinics who are at risk for exposure for STDs and HIV are generally not appropriate candidates for IUDs. Additional research may be needed to test the use of various risk indicators during the screening process.

## **V. DATA QUALITY STATEMENT**

The clinic staff was very dedicated to the study and meticulous in their work. There was a slow recruitment at the beginning, but after starting recruitment at a second center (Samandin) in August 1990, recruitment was completed in four months. There were three random allocation errors and three protocol deviations, two from age requirements, and one from exclusion requirements (pre-existing STD). The forms were conscientiously completed and great attention was paid to answering queries and correcting data problems. Follow up was good; the social worker was able to contact almost all of the women who did not return for their scheduled visit.

Note: This statement is provided to the investigator to help him set the study's results in the proper context. The quality of the data collected may affect the validity of the stated results.

## **VI. ACKNOWLEDGEMENT**

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**Table I**  
**Subject Characteristics at Admission**

Characteristics	TCu 380A (N=101)		TCu 200 (N=98)	
	No.	% <sup>1</sup>	No.	% <sup>1</sup>
<u>Age in Years Completed</u>				
Less than 20	0	0.0	3	3.1
20-24	14	13.9	18	18.4
25-29	32	31.7	34	34.7
30-34	31	30.7	22	22.4
35-39	22	21.8	19	19.4
40+	2	2.0	2	2.0
Mean (S.D.)	30.3	(5.2)	29.2	(5.7)
<u>Total Number of Live Births</u>				
1	1	1.0	1	1.0
2	11	10.9	18	18.4
3	30	29.7	24	24.5
4	18	17.8	17	17.3
5	14	13.9	16	16.3
6	12	11.9	8	8.2
7	10	9.9	8	8.2
8+	5	4.9	6	6.1
Mean (S.D.)	4.4	(1.9)	4.3	(2.1)
<u>Contraceptive Used in the Past Month</u>				
None	54	53.5	50	51.0
Abstinence	7	6.9	7	7.1
IUD	20	19.8	17	17.3
Orals	18	17.8	21	21.4
Injectables	0	0.0	2	2.0
Condoms	1	1.0	0	0.0
Other Barrier Method	1	1.0	0	0.0
Withdrawal	0	0.0	1	1.0

<sup>1</sup>Percentages may not total 100 due to rounding.

**Table II**  
**Complications and Complaints Reported During the Study**

Complications/Complaints <sup>1</sup>	TCu 380A		TCu 200	
	No.	%	No.	%
<b>Total Women at Insertion</b>	<b>101</b>	<b>100.0</b>	<b>98</b>	<b>100.0</b>
<u>Admission</u>				
Single Episode of Prev. PID	0	0.0	1	1.0
Dysmenorrhea	3	3.0	2	2.0
Candidiasis	2	2.0	1	1.0
Trichomoniasis	1	1.0	0	0.0
Leukorrhea	0	0.0	1	1.0
Cervicitis	1	1.0	0	0.0
Pruritus Vulvae	0	0.0	1	1.0
Weight Gain	1	1.0	0	0.0
<b>Total Women ever Followed-up</b>	<b>100</b>	<b>99.0</b>	<b>98</b>	<b>100.0</b>
<u>Menstrual Problems:</u>				
<u>Intermenstrual</u>				
Pelvic Pain	12	12.0	9	9.2
Bleeding	1	1.0	3	3.1
Spotting	0	0.0	1	1.0
Dysmenorrhea	8	8.0	10	10.2
Menorrhagia	4	4.0	6	6.1
Amenorrhea	3	3.0	2	2.0
Polymenorrhea	0	0.0	1	1.0
Early Menstruation	0	0.0	1	1.0
<u>PID:</u>				
Confined to Uterus	3	3.0	2	2.0
Confined to Adnexa	8	8.1	1	1.0
Confined to Uterus & Adnexa	5	5.0	2	2.0
<u>Inflammations/Infections:</u>				
Candidiasis	16	16.2	18	18.4
Cervicitis	13	13.0	8	8.2
Trichomoniasis	10	10.1	18	18.4
Pruritus Vulvae	3	3.0	8	8.2
Vaginitis	1	1.0	0	0.0
<u>Other Problems:</u>				
Leukorrhea	18	18.0	12	12.2
Pelvic Pain	4	4.0	6	6.1
Erosion of Cervix	2	2.0	1	1.0
Nabothian Cysts	1	1.0	3	3.1
Ulcerated Cervix	1	1.0	1	1.0
Scab on Vulva	1	1.0	0	0.0
Strings Not Visible	1	1.0	0	0.0
Dysuria	0	0.0	1	1.0

<sup>1</sup>More than one item can be diagnosed for each woman.

**Table III**  
**Subject Status at Twelve Months**

Status	TCu 380A (N=101)		TCu 200 (N=98)	
	No.	% <sup>1</sup>	No.	%
Continuing <sup>2</sup>	86	85.1	88	89.8
Accidental Pregnancy	1	1.0	0	0.0
Expulsion/ Displacement	3	3.0	4	4.1
<u>Removals for:</u>				
Bleeding/Pain	4	4.0	1	1.0
Other Medical Reasons	2	2.0	1	1.0
Planning Pregnancy	1	1.0	1	1.0
Other Personal Reasons <sup>3</sup>	3	3.0	3	3.1
Lost to Follow-up	1	1.0	0	0.0

<sup>1</sup> Percentages may not total 100 due to rounding.

<sup>2</sup> Includes women followed for at least 12 months who were continuing to wear the IUD at their last visit.

<sup>3</sup> One removal from TCu 200 group at 25 months after admission.

**Table IV**  
**Gross Cumulative Life-table Discontinuation Rates Per 100 Women**

Discontinuation Type and Period	TCu 380A			TCu 200		
	At Risk (N)	Rate	(S.E.)	At Risk (N)	Rate	(S.E.)
<b>Accidental Pregnancy</b>						
3 months	96.0	1.0	(1.0)	95.5	0.0	(0.0)
6 months	91.5	1.0	(1.0)	91.5	0.0	(0.0)
12 months	71.0	1.0	(1.0)	78.5	0.0	(0.0)
<b>Expulsion/Displacement</b>						
3 months	96.5	2.0	(1.4)	96.0	3.1	(1.7)
6 months	91.5	2.0	(1.4)	91.5	4.1	(2.0)
12 months	71.0	3.2	(1.8)	78.5	4.1	(2.0)
<b>Planning Pregnancy</b>						
3 months	96.0	0.0	(0.0)	95.5	0.0	(0.0)
6 months	91.5	0.0	(0.0)	91.5	0.0	(0.0)
12 months	71.0	1.2	(1.2)	78.5	1.1	(1.1)
<b>Other Medical Reasons</b>						
3 months	96.0	0.0	(0.0)	95.5	0.0	(0.0)
6 months	91.5	2.1	(1.5)	91.5	1.1	(1.1)
12 months	71.0	2.1	(1.5)	78.5	1.1	(1.1)
<b>Personal Reasons<sup>1</sup></b>						
3 months	97.0	2.1	(1.4)	95.5	0.0	(0.0)
6 months	91.5	2.1	(1.4)	91.5	1.1	(1.0)
12 months	71.0	3.3	(1.9)	78.5	2.2	(1.5)
<b>Bleeding/Pain</b>						
3 months	96.0	0.0	(0.0)	95.5	0.0	(0.0)
6 months	92.0	1.1	(1.1)	91.5	0.0	(0.0)
12 months	71.0	4.5	(2.2)	78.5	1.1	(1.1)
<b>Total Discontinuation Rate</b>						
3 months	97.5	5.0	(2.2)	96.0	3.1	(1.7)
6 months	92.5	8.0	(2.7)	91.5	6.1	(2.4)
12 months	71.0	14.4	(3.6)	78.5	9.3	(3.0)
<b>Continuation Rate</b>						
3 months		95.0			96.9	
6 months		92.0			93.9	
12 months		85.6			90.7	

<sup>1</sup> One subject whose TCu 200 was removed at 25 months is not included in the life-table rates.