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Postpartum Study of the TCu 380A IUD  
Hospital de Maternidad  
San Salvador, El Salvador

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## I. Introduction

The immediate postplacental period is an opportune time to insert an intrauterine device (IUD); the dilated cervix facilitates insertion, and it is a time when impoverished women are most likely to have access to appropriate medical attention. Immediate postpartum IUD insertion, however, has been associated with high expulsion rates, and some physicians continue to be reluctant to insert IUDs at this time. A clinical trial to assess the practicality of providing IUDs to postpartum women was conducted at the Hospital de Maternidad in San Salvador, El Salvador. The purpose of this twelve-month study was to evaluate the introduction of a postpartum IUD-insertion program in El Salvador; the IUD used in this study was the Copper T 380A (TCu 380A). Evaluation of study results will focus on pregnancy, expulsion, and continuation rates, and on the reports of complications and complaints.

## II. Materials and Methods

### *Study Products*

The TCu 380A is a T-shaped device 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<sup>2</sup> of copper wire wound tightly around the vertical stem. This increased copper surface area, the most found on any commercially available copper IUD, is expected to improve the efficacy of the TCu 380A over other available IUDs. 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 to provide two marker threads. An

expanded lifespan of six years for the IUD has been demonstrated by studies done by the World Health Organization, although at the time of this study, the US Food and Drug Administration approved lifespan was four years.

### *Selection Criteria*

Study subjects were recruited from women undergoing childbirth at the hospital. Subjects were between 18 to 40 years of age, had a normal vaginal delivery, and were willing to have an IUD inserted within ten minutes of spontaneous postplacental expulsion (immediate postplacental status). The attending physician should also have been able to feel the uterine fundus upon abdominal palpation. Subjects were to be sexually active and desired the IUD for contraceptive purposes.

Candidates for this study were excluded if they had abnormalities of the uterus or other reproductive organs, precluding accommodation of an IUD; a cesarean section delivery; manual removal of the placenta; postpartum or antepartum hemorrhage; chorioamnionitis or prolonged rupture of the membranes; uterine overdistension or uterine hypotonia; suspected uterine rupture; evidence of either pelvic infection (PID) or sexually transmitted disease (STD) or a history of repeated episodes of PID or STD; history of ectopic pregnancy; heavy menstrual flow; severe menstrual cramps or unexplained vaginal bleeding prior to pregnancy; history of impaired fertility with desire for future pregnancy; insulin-dependent diabetes; suspicious or abnormal Pap test (grade III or higher); or valvular heart disease

One hundred and sixty-one women were enrolled over a 17-month period beginning in July 1988. Admissions to the trial were halted in December 1989 because of the political unrest in the city and the proposed goal of 200 study participants not being met. All potential cases were identified in the "sala de partos" (delivery room) by a social worker. Data were recorded on standard case report forms by clinic staff and sent to Family Health International (FHI) for processing and analysis.

#### *Admission Procedures*

This was a noncomparative study with all study volunteers receiving a TCu 380A IUD within ten minutes of spontaneous placental expulsion. Primary recruitment of study patients occurred during visits to the hospital for antenatal care. All women gave their informed consent before admission. Insertion of the IUDs was performed by a group of residents at the Hospital de Maternidad. Of the 161 women, eight (4.9%) had IUDs inserted between ten minutes and two hours of placental expulsion, and one woman was admitted with a history of PID; these women were permitted to continue in the study and are included in both the safety and efficacy analyses. The efficacy analysis with the protocol violations excluded is displayed in Appendix A.

The women were to return for follow-up at 1, 3, 6, and 12 months after insertion of their IUD or at any time complications occurred. If no complications developed during IUD insertion and the patient wished to continue using the IUD as her sole method of contraception, she continued in the study for twelve months. 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. A study device that was partially or totally expelled after insertion was not to be reinserted. Depending upon the physician's judgment, the device was left in place at the end of the patient's twelfth month of participation in accordance with approved US FDA labeling for the TCu 380A. The woman then received medical care according to standard practice.

### III. Patient Characteristics

The mean age of the 161 women was 21.5 years (Table I) with the median number of total live births being 1.7. Over 75% of the women reported using no contraceptive method during the month prior to conception. When reported, the most frequently used methods were IUDs and oral contraceptives.

### IV. Results

#### *Complications/Complaints*

Complications and complaints reported during the study period are summarized in Table II. Six women reported mild pelvic pain during insertion. One woman had her IUD inserted on the doctor's fifth attempt; this was not considered a failed insertion, and the woman continued in the study without problems.

One hundred and forty-two women (88.2%) returned for at least one follow-up visit. One woman was hospitalized approximately two weeks after insertion for excessive vaginal bleeding; she had retained part

of the postpartum placenta and had a puerperal infection. The IUD was removed and a dilation and curettage was performed; the event was considered non-IUD related.

Table II also includes data on bleeding and/or pain complaints at follow-up. These included intermenstrual spotting reported by 19 women; intermenstrual pelvic pain experienced by 12 women; and intermenstrual bleeding reported by one woman. Other menstrual complaints included dysmenorrhea, menorrhagia, and polymenorrhea.

Five women were diagnosed with vaginal inflammation or infection; there were four cases of leukorrhea and one case of candidiasis (Table II). Five women were diagnosed with STD; these included two reports of trichomoniasis and one report each of condyloma, herpes virus, and human papilloma virus. Also, eight cases of PID were diagnosed that were confined to either the uterus or adnexa.

Other problems were also recorded at the follow-up visits. These problems included two cases of dyspareunia, an enlarged left ovary, a urinary tract infection, and an unspecified problem. None of these conditions were considered to be serious by the attending physician.

#### *Termination Events*

Table III summarizes the woman's status at the end of the twelve months of use, and Table IV presents the gross-cumulative lifetable rates for these termination events; 161 women were available for analysis. Rates of discontinuation for a specific reason were

calculated using the lifetable method [1]. Single decrement gross-cumulative lifetable rates were used to assess the efficacy of the TCu 380A as a postpartum IUD [2]. In Appendix A, the nine protocol violations were excluded from the efficacy analysis and data for 152 women were analyzed. There were no significant differences in the data when protocol violations were excluded.

Evaluations of efficacy were made on the basis of various termination rates and continuation rates, with a focus on the pregnancy and expulsion rates. Pertinent terminations include accidental pregnancy, expulsion, removal for bleeding and/or pain, and medical reasons such as uterine perforation and infection. Nonpertinent termination reasons include planning a pregnancy and removals for other personal reasons (e.g., husband's objections or no need for contraception).

One pregnancy occurred in the study, but it was determined that the patient's IUD was displaced before conception and she was terminated for expulsion/displacement rather than for pregnancy. IUDs were diagnosed as expelled or displaced in 47 women at the time of examination. The twelve-month gross-cumulative expulsion lifetable rate was 34.2 per 100 women.

Four women had their IUDs removed because of bleeding and/or pain complaints. One of these women had the IUD removed after the twelve-month trial period was completed and is not included in the twelve-month rate. The twelve-month lifetable rate for bleeding and/or pain was 3.6 per 100 women.

Two women had their IUDs removed for other medical reasons: one for endometritis and one for excessive bleeding due to the retention of the postpartum placenta. This yielded a twelve-month gross-cumulative lifetable rate of 1.5 per 100 women.

A total of eight women had their IUDs removed for personal reasons. These reasons included: husband's objection, dissatisfaction with the IUD, and desire to change to another contraceptive. These terminations yielded a twelve-month lifetable rate of 7.7 per 100 women.

Lifetable rates for continuation with the IUD and follow-up percentages were also calculated for the 161 postplacental women (Table V). Pooled continuation rates are defined as 100 minus the total termination rate and indicate that the user had not been terminated from the trial by the specified follow-up period. At twelve months the continuation rates were 57.6 per 100 women. Follow-up status (Table V) is defined as the percentage of women not previously terminated who returned for a follow-up visit. These percentages were above 60% over the duration of the study. Nineteen women did not return for follow-up after their admission into the study, but are included in the continuation rates until censored by the lifetable procedure.

## V. Summary

From July 1988 through December 1989, the TCU 380A was inserted in 161 postpartum women participating in a clinical trial at the Hospital de Maternidad in San Salvador, El Salvador. This was a noncomparative twelve-month study; the women received a TCU 380A within ten minutes of spontaneous placental expulsion. Protocol violations included eight women who had IUDs inserted between ten minutes and two hours of placental expulsion and one woman with a history of multiple episodes of PID; these women were permitted to continue in the study. When these violations were excluded from the efficacy analysis, no differences were noted. The woman with a history of PID was not diagnosed with PID during the study, but her IUD was expelled one month after insertion. Insertion-related complaints were few, those being for mild pelvic pain.

One hundred and forty-two women returned for at least one follow-up visit. The most frequently reported menstrual complaints were intermenstrual spotting and intermenstrual pelvic pain. Eighteen women were diagnosed with an infection or disease, whether it was leukorrhea, an STD, or a PID. The most frequent termination event was for expulsion or displacement: 47 women were found to have their IUD either absent, expelled in the vagina, displaced in the cervical canal, or displaced in the uterus. Continuation rates were low as a result of the high number of terminations. Although follow-up procedures by the clinic were minimal, follow-up percentages were at or above 62% over the duration of the study.

The twelve-month expulsion rate detected during this study is not similar to rates reported in the medical literature for insertions occurring within ten minutes of spontaneous placenta expulsion [2]. In most of those studies, expulsion rates were between 9.0 and 15.0 per 100 women. However, the twelve-month expulsion rate in this trial is similar to those reported for IUD insertions occurring between 24 hours and 42 days postpartum. Why this occurred may be explained by the extenuating circumstances surrounding this study. For example, insertions were performed by rotating residents who were not associated with the study for more than a few months. Previous research indicates that expulsion rates decrease over a period of time as the inserter becomes more skilled with the procedure [3]. It is likely that residents inserting IUDs in this trial could have achieved lower expulsion rates if they had had more time to gain experience with the insertion techniques and by having inserted more IUDs during the study. In addition, acceptance of the program by participating residents was occasionally a problem and may have affected attentiveness to training and to performing the procedure properly. Although this cannot be evaluated quantitatively, comments received from permanent study staff indicate that cooperation among rotating residents assigned to the program could have been better.

The incompleteness of recruitment because of political turmoil and the limiting of enrollment to only patients delivering infants during business hours severely limits the generalizability of these data.

The higher-than-expected expulsion rate reported for this study in addition to the frequent rotation of participating residents suggests that the training procedures employed in this program may need reevaluation.

## References

1. Potter R. Use-effectiveness of intrauterine contraception as a problem in competing risks. In Freeman R, Takeshita J (eds.), *Family Planning in Taiwan*. Princeton, New Jersey: Princeton University Press, 1969.
2. Azen S, Roy S, Pike M, Casagrande. Some suggested improvements to the current statistical methods of analyzing contraceptive efficacy. *Journal of Chronic Diseases* 29, 1976.
3. Chi, I-Cheng, Farr G. Postpartum IUD contraception--a review of an international experience. *Advances in Contraception* 5, 1989.

**Table I**

Selected Sociodemographic Characteristics  
Postpartum Study of the TCU 380A IUD  
Hospital de Maternidad  
San Salvador, El Salvador

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Characteristics	TCu 380A (N=161)	
	No.	%
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<b>Age (years)</b>		
<20	58	36.0
20-24	75	46.6
25-29	23	14.3
30-34	4	2.5
35+	1	0.6
<b>Mean ± SD</b>	<b>21.5 ± 3.5</b>	
<b>Total Number of Live Births<sup>1</sup></b>		
1	72	44.7
2	56	34.8
3	23	14.3
4+	10	6.2
<b>Median</b>	<b>1.7</b>	
<b>Use of a Contraceptive in the Past Month</b>		
None	122	75.8
Orals	22	13.7
IUDs	10	6.2
Injectables	3	1.9
Withdrawal/rhythm	2	1.2
Other barrier methods	1	0.6
Sterilization	1	0.6

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<sup>1</sup> These include the live births just delivered at the hospital.

**Table II**

Complications/Complaints Reported at Admission and Follow-up  
 Postpartum Study of the TCU 380A IUD  
 Hospital de Maternidad  
 San Salvador, El Salvador

Complications/Complaints	No.	TCu 380A %
<b>Women at Admission</b>		<b>N=161</b>
Multiple episodes of previous PID	1	0.6
Mild pelvic pain	6	3.7
Insertion successful after fifth attempt	1	0.6
<b>Women Follow-up<sup>1</sup></b>		<b>N=142</b>
Hospitalization due to retention of placenta	1	0.7
Menstrual complaints		
Intermenstrual:		
Spotting	19	13.4
Pelvic pain	12	8.5
Bleeding	1	0.7
Dysmenorrhea	2	1.4
Menorrhagia	2	1.4
Polymenorrhea	1	0.7
Combination <sup>2</sup>	1	0.7
Inflammations/Infections		
Leukorrhea	4	2.8
Candidiasis	1	0.7
Sexually Transmitted Disease		
Trichomoniasis	2	1.4
Condyloma	1	0.7
Herpes virus	1	0.7
Human papilloma virus	1	0.7
Pelvic Inflammatory Disease <sup>3</sup>		
Confined to uterus	6	4.2
Confined to adnexa	2	1.4
Other Problems		
Dyspareunia	2	1.4
Enlarged left ovary	1	0.7
Urinary tract infection	1	0.7
Unspecified problem	1	0.7

<sup>1</sup> Number of women with at least one follow-up.

<sup>2</sup> A combination of polymenorrhea and dysmenorrhea.

<sup>3</sup> Includes endometritis and anatomically unspecified PID.

**Table III**

Participant Status After Twelve Months of Use  
Postpartum Study of the TCU 380A IUD  
Hospital de Maternidad  
San Salvador, El Salvador

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Status	TCu 380A (N=161)	
	No.	%
Continuing after twelve months	82	51.0
Expulsion/Displacement	47	29.2
Removal <sup>1</sup> :		
Bleeding and/or Pain	3	1.9
Other Medical Reasons:		
Endometritis	1	0.6
Bleeding due to retention of placenta	1	0.6
Personal Reasons:		
Women requested removal	3	1.9
Husband objected	2	1.2
Afraid to use IUD	1	0.6
No longer wanted to use IUD	1	0.6
Changed to orals	1	0.6
Not Followed-up	19	11.8

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<sup>1</sup> After the twelve-month period had ended, one woman had her IUD removed for bleeding and/or pain and one for planning a pregnancy. These women are not included in the analysis.

**Table IV**

Gross-Cumulative Lifetable Event Rates Per 100 Women  
Postpartum Study of the TCU 380A IUD  
Hospital de Maternidad  
San Salvador, El Salvador

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Termination Type and Period	TCu 380A (N=161)	
	Rate	S.E. <sup>1</sup>
<b>Expulsion/Displacement</b>		
3 months	28.8	+ 3.8
6 months	34.2	+ 4.1
12 months	34.2	+ 4.1
<b>Bleeding/Pain</b>		
3 months	1.0	+ 1.0
6 months	3.6	+ 2.1
12 months	3.6	+ 2.1
<b>Other Medical Reasons</b>		
3 months	1.5	+ 1.1
6 months	1.5	+ 1.1
12 months	1.5	+ 1.1
<b>Other Personal Reasons</b>		
3 months	5.1	+ 2.0
6 months	6.2	+ 2.3
12 months	7.7	+ 2.7
<b>Total Terminations</b>		
3 months	34.2	+ 4.0
6 months	41.5	+ 4.2
12 months	42.4	+ 4.2

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<sup>1</sup> Standard error; lost to follow-up cases censored by the lifetable procedure.

**Table V**

**Rate of Continuation and Follow-up Percentages  
Postpartum Study of the TCU 380A IUD  
Hospital de Maternidad  
San Salvador, El Salvador**

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Type and Period	TCu 380A (N=161)
<b>Continuation Lifetable Rate<sup>1</sup></b>	
3 months	65.8
6 months	58.5
12 months	57.6
<b>Follow-up Percentages<sup>2</sup></b>	
3 months	78.6
6 months	70.5
12 months	62.4

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<sup>1</sup> The continuation rate is defined as 100 minus the total termination lifetable rate (refer to Table IV). Lost to follow-up cases are censored by the life-table procedure.

<sup>2</sup> The percentage of women returning for follow-up who have not been previously terminated.

**Appendix A**  
**Table A1**

**Participant Status After Twelve Months of Use**  
**Excluding Protocol Violations**

Status	TCu 380A (N=152)	
	No.	%
<b>Continuing after twelve months</b>	79	51.9
<b>Expulsion/Displacement</b>	44	28.9
<b>Removal<sup>1</sup>:</b>		
Bleeding/Pain	2	1.3
Other Medical:		
Endometritis	1	0.7
Bleeding to due retention of placenta	1	0.7
Personal Reasons:		
Women requested removal	3	1.9
Husband Objected	1	0.7
Afraid to use IUD	1	0.7
No longer wanted to use IUD	1	0.7
Changed to Orals	1	0.7
<b>Not Followed-up</b>	18	11.8

<sup>1</sup> After the twelve-month period had ended, one woman had her IUD removed for bleeding and/or pain and one for planning a pregnancy. These women are not included in the analysis.

**Appendix A  
Table 2A**

**Gross-Cumulative Lifetable Event Rates Per 100 Women  
Protocol Violations Excluded**

Termination Type and Period	TCu 380A (N=152)		
	Rate		S.E. <sup>1</sup>
<b>Expulsion/Displacement</b>			
3 months	28.4	+	3.9
6 months	34.0	+	4.2
12 months	34.0	+	4.2
<b>Bleeding/Pain</b>			
3 months	1.1	+	1.0
6 months	2.5	+	1.8
12 months	2.5	+	1.8
<b>Other Medical Reasons</b>			
3 months	1.6	+	1.1
6 months	1.6	+	1.1
12 months	1.6	+	1.1
<b>Other Personal Reasons</b>			
3 months	4.2	+	1.9
6 months	5.4	+	2.2
12 months	6.9	+	2.6
<b>Total Terminations</b>			
3 months	33.3	+	4.0
6 months	40.2	+	4.3
12 months	41.1	+	4.3

<sup>1</sup> Standard error; lost to follow-up cases censored by the lifetable procedure.

**Appendix A  
Table A3**

**Rate of Continuation and Follow-up Percentages Excluding  
Protocol Violations**

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Type and Period	TCu 380A (N=152)
<b>Continuation Lifetable Rate<sup>1</sup></b>	
3 months	66.7
6 months	59.8
12 months	58.9
<b>Follow-up Percentages<sup>2</sup></b>	
3 months	78.4
6 months	71.3
12 months	62.9

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<sup>1</sup> The continuation rate is defined as 100 minus the total termination lifetable rate (refer to Table IV). Lost to follow-up cases are censored by the lifetable procedure.

<sup>2</sup> The percentage of women returning for follow-up who have not been previously terminated.

## Data Quality Statement

Medical training and information dissemination meeting was held before the study began and seven insertions were performed during medical training. The admission process and filling out of forms was to be performed by residents and IUD insertions by physician; however, residents performed the insertions. Voluntary consent was obtained in all cases and the documentation was available in the records. All potential cases were identified in the delivery room by the social worker.

Protocol violations included eight women who had IUDs inserted between ten minutes and two hours of spontaneous postplacental expulsion and one woman with a history of multiple episodes of PID. These women were permitted to continue in the study but were excluded from the efficacy analysis in Appendix A as major protocol violations.

The project was managed by the social workers; they were very well organized and acted as the "motor" driving the program. They exercised control over all aspects of the project, except the actual insertion of the device. The IUDs and forms were maintained in the social worker's office. They were distributed according to the demands of the project. Since the social workers only worked 9 to 5, Monday through Friday, women giving birth on the weekends or in the evenings were generally not given the option to participate in the program. Along with unstable political situations in the city, this restriction hindered the recruitment process and the proposed number of study subjects was not met.

This study was also affected by the lack of cooperation with "rotating" residents and with the concern of a high expulsion rate in first 68 cases. The expulsion rates may have been lower if the residents had gained more experience with IUD insertion. As a result, the principal investigator needed to exert some pressure on residents to be more willing to cooperate with the social worker. There was a need for a Spanish version of the protocol to be developed for this project and a need for a written explanation of the suggested interpretations of the data collection items on the admission and follow-up forms. With the rotating residents and the potential for changes in project personnel, complete documentation of all aspects of the project was necessary.

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 state results.