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**Performance of the Copper T-380A Intrauterine Device
in Breastfeeding Women**

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Abstract

The effect of breastfeeding on performance of the TCU-380A IUD was evaluated using data derived from multicenter clinical trials. Insertion events for breastfeeding women (N=559) and non-breastfeeding women (N=590) were compared as well as discontinuations of IUD use through six months following insertion. Results indicate that breastfeeding women inserted with a TCU-380A are more likely than non-breastfeeding women to have a smooth, pain-free insertion, few postinsertion bleeding and pain problems, and a high rate of continuation of IUD use. There were no uterine perforations reported from either group of women.

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Introduction

Modern methods of contraception have replaced breastfeeding's role in child spacing and added a new degree of control over human fertility. Unfortunately, most clinical analyses of contraception start with the non-breastfeeding, menstruating woman, whereas in reality, every modern method of contraception has a somewhat altered profile of advantages and disadvantages when used by lactational amenorrheic women. Biologically and clinically, there is a great need to analyze contraceptive performance, risks and benefits for breastfeeding women.

The intrauterine device (IUD) is usually recommended for contraceptive use in breastfeeding women because studies have repeatedly shown its lack of adverse effect on breastfeeding.^{1,2,3} Studies evaluating IUD performance in breastfeeding women, on the other hand, are few and often have conflicting results.^{4,5}

The Copper T-380A (TCu-380A) has been widely used in Canada and a number of European countries and is now being marketed in the U.S. It is also the only IUD currently being donated by the U.S. Agency for International Development (USAID) worldwide.⁶ No studies focusing exclusively on the performance of this relatively new device in breastfeeding women have ever been reported. Since May 1985 Family Health International (FHI) has sponsored randomized, multicenter clinical trials of the TCu-380A in women not recently pregnant (at least 42 days since her last delivery). Our data set offers a timely and unique opportunity to evaluate the performance of this new device in terms of termination events (i.e., pregnancy, expulsion and medical removal) and insertion-related events (e.g., severe insertional pain) for women who were breastfeeding at the time of insertion, as compared to their non-breastfeeding counterparts. The study results should be useful for service providers as well as breastfeeding women themselves.

Materials and Methods

The Device

The TCu-380A, developed by the Population Council, was approved by the U.S. Food and Drug Administration in 1984. The device consists of a small inert polyethylene "T" with copper wire wound around the stem and a copper sleeve fitted tightly on each half of the cross bar. It has a length of 36 mm, a width of 32 mm and an exposed surface area of copper of 380 square millimeters. The diameter of the inserter is 4.4 mm, and the insertion is performed by a withdrawal method. Two white threads are attached to the stem. The life span of this device is estimated to be at least six years, and some researchers estimate that it may be as long as ten to fifteen years.

The FHI data set

FHI's international clinical trials of the TCU-380A are designed for comparison with the device most widely used in each particular country. All participating sites use identical case record forms and protocols. Information on selected socio-demographic characteristics, reproductive and contraceptive histories and pre-existing medical conditions are obtained at the time of admission to the study. The woman's breastfeeding and menstrual status (i.e., whether she is still amenorrheic or has resumed menses) since her last delivery is determined at admission and at every follow-up visit. At all sites, follow-up examinations are scheduled at one, three, six and 12 months post-insertion. Insertion-related events are recorded on the admission form, and subsequent pertinent events in terms of accidental pregnancy, expulsion, removal, complications and complaints are ascertained at each follow-up. By the end of 1986, a total of 1362 women had been inserted with a TCU-380A in these trials. Among the women admitted, the numbers who were and were not breastfeeding at the time of insertion were approximately equal.

The Study Population

A woman was included in this analysis if she was inserted with a TCU-380A at least 42 days after her last delivery and her last delivery was a vaginally delivered term live birth. Center requirements included: 1) at least 50 or more such insertions were performed; 2) at the time of IUD insertion, the breastfeeding status of more than 74 percent of the women was known; 3) at least 10% of the women were breastfeeding at the time of IUD insertion; and 4) the 6-month follow-up rate was 75% or higher. The follow-up rate is defined as the percentage of women returning for follow-up among those who were not previously terminated.

A total of 1149 women from five sites were included as our study population. Among them, at the time of insertion 559 were breastfeeding (breastfeeding status includes both full lactation and partial lactation defined as providing supplementary food in addition to breastfeeding) and 590 were not breastfeeding. Three centers are located in Latin America, and two are located in Asia. These insertions were performed between May 1985 and December 1986. Analysis of data was performed in February 1988 to allow sufficient time for patient follow-up data to be processed at FHI.

The Analysis

Performance of the TCU-380A through six months post-insertion was compared between women who were breastfeeding (BF) and those who

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were not breastfeeding (NBF) at the time of insertion. Their 6-month follow-up rates were, respectively, 84.4% and 82.9%. Rare but medically serious insertion-related events were compared between the two groups by the Chi-square test of association or Fisher's Exact Test if the numbers were small. Gross cumulative life-table event rates were calculated by Potter's method⁷ and compared by the log-rank method.⁸ Herson's method was used to produce age-adjusted rates.⁹ All study subjects (Br and NBF) were used as the standard population for age-adjustment. The effect of breastfeeding at IUD insertion was also examined by stratification of the age-adjusted event rates by potentially confounding variables (e.g., previous use of oral contraceptives). $P < 0.05$ (two-tailed) was considered statistically significant.

Results

1. Characteristics of the women (Table I)

The BF and NBF women were on the average, similar in their educational level, number of live births and proportion desiring additional children. However, the BF women, as compared to the NBF women, were about two-and-a-half years younger, and as would be expected, much less likely to have used oral contraceptives in the month prior to this TCu-380A insertion. They were much more likely to be still amenorrheic at insertion and to have had their IUD inserted within six months after delivery. Overall, for the pooled data, most insertions were performed by obstetricians/gynecologists; the remainder of the insertions were done by other types of physicians or paramedics. More than half of our study subjects were from Center A.

2. Insertion-related events (Table II)

No incidences of uterine perforation, syncope or insertion failure occurred in either group. Other insertion-related events were rare, but the incidences of these rare events were generally lower in the BF than in the NBF women. Significantly more NBF women experienced moderate or severe insertional pain than did BF women ($p < 0.05$ by Fisher's Exact Test). The NBF women were also more likely than BF women to require cervical dilatation to facilitate IUD insertion ($p < 0.05$, Fisher's Exact Test).

3. Pertinent Termination events (Table III)

By three months postinsertion, no pregnancies had occurred in the BF group. One NBF woman was found to be pregnant, but it was suspected that she had been pregnant at the time of IUD insertion. At the six-month follow-up examination, one pregnancy was confirmed for a BF woman, thought to be due to an unnoticed expulsion of the IUD. One additional NBF

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Table I. Selected Characteristics of Breastfeeding and Non-breastfeeding Women at the Time of Insertion of the TCU-380A Device at Five Latin American and Asian Centers, 1985-1986

	BF* (N=559)		NBF* (N=590)	
	No.	%	No.	%
Age in years**				
<25	307	54.9	210	35.6
25-29	154	27.5	193	32.7
30+	98	17.6	187	31.6
Mean ± SD	25.2 ± 4.7		27.6 ± 5.5	
No. of live births				
1	299	53.5	291	49.3
2	154	27.5	193	32.7
3+	106	19.0	106	18.0
Mean ± SD	1.8 ± 1.1		1.8 ± 1.1	
Education in years				
0-6	208	42.7	209	40.7
7-12	205	42.1	202	39.4
13+	74	15.2	102	19.9
Mean ± SD	8.5 ± 4.1		9.0 ± 4.3	
Wanting additional children				
No	259	46.3	254	43.3
Yes	300	53.7	333	56.7
Contraceptive method used in previous month**				
IUD	17	3.0	74	12.5
OC	43	7.7	202	34.2
None or others	498	89.3	314	53.2
Menstrual status at insertion**				
Still amenorrheic	364	66.3	85	14.7
Resumed menses	185	33.7	494	85.3
Type of insertors**				
Obstetrician/gynecologist	458	81.9	409	69.3
Others	101	18.1	181	30.7
Open interval (months)**,**				
<6	465	83.2	155	26.3
6-11.9	51	9.1	76	12.9
12-23.9	26	4.7	94	15.9
24+	17	3.0	265	44.9
Center**				
A	332	59.4	285	48.3
B	69	12.3	77	13.1
C	33	5.9	74	12.5
D	35	6.3	112	19.0
E	90	16.1	42	7.1

*BF denotes women breastfeeding, full or partial, and NBF, not breastfeeding at IUD insertion. Numbers of cases do not necessarily add to total due to unknown values. Cases with unknown values were excluded from both the denominators and numerators when percentages were calculated.

**Differences between BF and NBF women are statistically significant at $p < 0.05$.

***Defined as the number of months between last delivery and time of IUD insertion.

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Table II. Incidences of Insertion Events in Breastfeeding and Non-breastfeeding Women Inserted with the TCU-380A Device at Five Latin American and Asian Centers, 1985-1986

	BF* (N=559)		NBF* (N=590)		p**
	No.	%	No.	%	
Dilatation required	1	0.2	8	1.4	0.039
Moderate/severe pain	5	0.9	16	2.7	0.026
Cervical laceration	5	0.9	8	1.4	0.581
Uterine perforation	0	0.0	0	0.0	--
Any of the above***	9	1.6	28	4.7	0.002

*BF denotes women breastfeeding, full or partial, and NBF, not breastfeeding at IUD insertion.

**By Fisher's Exact Test.

***More than one event may be reported for each woman.

pregnancy was detected, probably due to a method failure; the TCU-380A device was removed accordingly. All three pregnancies were intrauterine.

Gross cumulative expulsion rates were generally comparable for the two groups of women at three and six months postinsertion. The bleeding/pain removal rates were, however, significantly lower in BF than in NBF women ($p < 0.05$). Correspondingly, total method-related termination rates were also significantly lower for BF women than for NBF women ($p < 0.05$).

4. Age-adjustment and stratification (Tables IV-VI)

Further analyses of expulsion and bleeding/pain removal rates were conducted adjusting for the age of the women and stratifying by potentially confounding variables. These variables included: 1) contraceptive method used in the month before insertion (IUD or oral contraceptives vs. other methods or no method); 2) length of open interval, defined as number of months from delivery to insertion (< 6 months vs. 6 or more months); 3) menstrual status at insertion (still amenorrheic vs. resumed menses); and 4) center (Center A vs. other centers). All confounders were dichotomized to provide adequate sample sizes for the calculation of life-table rates.

Expulsion rates remained comparable for the BF and NBF women when adjusted for age or stratified by any of the potentially confounding variables. No consistent patterns in direction of differences between the two groups emerged (Table not shown).

Table III. Cumulative Number of Occurrences and Gross Cumulative Life-Table Rates per 100 Women of Pertinent Events at Three Months and Six Months of Use by Breastfeeding and Non-breastfeeding Women Inserted with the TCU-380A Device at Five Latin American and Asian Centers, 1985-1986

Pertinent Events	<u>At Three Months of Use</u>				<u>At Six Months of Use</u>			
	<u>No. of Occurrences</u>		<u>Rate \pm Standard Error</u>		<u>No. of Occurrences</u>		<u>Rate \pm Standard Error</u>	
	BF*	NBF*	BF*	NBF*	BF*	NBF*	BF*	NBF*
Pregnancy	0	1	0.0 \pm 0.0	0.2 \pm 0.2	1	2	0.2 \pm 0.2	0.4 \pm 0.3
Expulsion	11	12	2.0 \pm 0.6	2.2 \pm 0.6	13	15	2.5 \pm 0.7	2.8 \pm 0.7
Bleeding/pain removal**	0	12	0.0 \pm 0.0	2.2 \pm 0.6	4	17	0.9 \pm 0.4	3.2 \pm 0.8
Other medical removal	2	1	0.4 \pm 0.3	0.2 \pm 0.2	2	4	0.4 \pm 0.3	0.8 \pm 0.4
Total method-related terminations**	13	26	2.4 \pm 0.7	4.6 \pm 0.9	20	38	3.9 \pm 0.9	7.1 \pm 1.1
Total terminations***	16	28	3.4 \pm 0.8	5.0 \pm 0.9	27	41	6.3 \pm 1.1	8.4 \pm 1.2
No. of woman-months	1559.0	1641.5	-	-	2907.0	3026.5	-	-
Follow-up rate****	-	-	92.8	93.3	-	-	84.4	82.9

*BF denotes women breastfeeding, full or partial, and NBF, not breastfeeding at IUD insertion.

**Differences between the BF and NBF women are statistically significant at $p < 0.05$.

***Total terminations include total method-related terminations, removals for planned pregnancy and removals for other personal reasons.

****The follow-up rate is defined as the percentage of women returning for follow-up among those who were not previously terminated.

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Table IV. Age-adjusted* Three-month and Six-month Gross Cumulative Bleeding/Pain Removal Rates, Stratified by Potentially Confounding Variables for Breastfeeding and Non-breastfeeding Women Inserted with the TCu-380A Device at Five Latin American and Asian Centers, 1985-1986

	Bleeding/Pain Removal Rate \pm Standard Error					
	No. of Women at Insertion		At Three Months		At Six Months	
	BF**	NBF**	BF**	NBF**	BF**	NBF**
Total Women	559	590	0.0 \pm 0.0***	2.4 \pm 0.7	0.9 \pm 0.4***	3.2 \pm 0.8
By contraceptive method used previously						
OC or IUD	60	276	0.0 \pm 0.0	1.7 \pm 0.9	4.1 \pm 2.9	2.2 \pm 1.1
None or other methods	499	314	0.0 \pm 0.0***	2.9 \pm 1.0	0.5 \pm 0.4***	4.4 \pm 1.3
By length of open interval						
<6 months	465	155	0.0 \pm 0.0***	2.6 \pm 1.3	0.5 \pm 0.4***	4.4 \pm 1.3
6+ months	94	435	0.0 \pm 0.0	2.2 \pm 0.8	2.7 \pm 1.8	2.2 \pm 1.1
By menstrual status at insertion:						
Still amenorrheic	364	85	0.0 \pm 0.0	1.1 \pm 1.1	0.3 \pm 0.3***	4.4 \pm 1.3
Resumed menses	185	494	0.0 \pm 0.0***	2.7 \pm 0.8	2.2 \pm 1.3	3.2 \pm 0.8
By center						
Center A	332	285	0.0 \pm 0.0	1.4 \pm 0.7	0.7 \pm 0.5	2.2 \pm 1.1
Other centers	227	305	0.0 \pm 0.0***	3.1 \pm 1.1	2.7 \pm 1.2***	4.4 \pm 1.3

*Age-adjustment (<25, 25+) was performed using the total study subject standard population; Herson's method⁹ was used.

**BF denotes women breastfeeding, full or partial, and NBF, not breast IUD insertion.

***Comparison between breastfeeding and non-breastfeeding women is statistically significant at $p < 0.05$.

****Comparison between breastfeeding and non-breastfeeding women is borderline significant at $p = 0.056$.

Table V. Age-adjusted* Three-month and Six-month Gross Cumulative Bleeding/Pain Removal Rates by Extent of Breastfeeding at the Time of Insertion of the TCU-380A Device at Five Latin American and Asian Centers, 1985-1986

<u>Breastfeeding Status</u>	<u>Number of Women at Admission</u>	<u>Bleeding/Pain Removal Rate ± Standard Error</u>	
		<u>At Three Months***</u>	<u>At Six Months***</u>
Full	300	0.0 ± 0.0	0.4 ± 0.4
Partial**	259	0.0 ± 0.0	1.4 ± 0.8
None	590	2.4 ± 0.6	3.2 ± 0.8

*Age-adjustment (<25, 25+) was performed using the total study subjects as the standard population; Herson's method⁷ was used.

**Defined as breastfeeding with supplementary food given.

***p<0.05 by log-rank method comparing the three groups.

The differences in removal rates for bleeding/pain between the BF and NBF women became somewhat more marked with age-adjustment and remained statistically significant (p<0.05). Also, the direction of differences showed a remarkable consistency when the rates were further stratified by any of the potentially confounding variables. In comparisons where the sample sizes in each group were sufficiently large, the differences were usually statistically significant at p<0.05 (Table IV).

The "dose-response" relationship between breastfeeding status at insertion and the risk of IUD removal for bleeding/pain was examined in Table V. A gradient is apparent over the six-month rates with the full-breastfeeding women having the lowest bleeding/pain removal rates, non-breastfeeding women with highest rates, and partially breastfeeding women experiencing rates in-between (p<0.05). Three-month rates followed a similar pattern, and the difference was also statistically significant (p<0.05).

We further examined the effect of breastfeeding status during follow-up on bleeding/pain removal rates because theoretically, this status should be more relevant to the event than breastfeeding status at insertion. Table VI reveals that for women who had resumed menses by three and six months after insertion, the age-adjusted cumulative rates for

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those who were breastfeeding were lower than for those who did not breastfeed or had stopped breastfeeding ($p < 0.05$). The number of women who were no longer breastfeeding and were still amenorrheic at the three- and six-month follow-ups was too small for meaningful comparisons.

Table VI. Age-adjusted* Three-month and Six-month Gross Cumulative Bleeding/Pain Removal Rates for Women Inserted with the TCu-380A Device by Breastfeeding and Menstrual Status at Follow-up at Five Latin American and Asian Centers, 1985-1986

<u>Breastfeeding Status and Menstrual Status at Follow-up</u>	<u>No. of Women</u>	<u>Rate \pm Standard Error</u>
A. At Three Months Postinsertion		
Breastfeeding	511**	0.0 \pm 0.0
Still amenorrheic	217	0.0 \pm 0.0
Menses resumed	293	0.0 \pm 0.0***
Non-breastfeeding	638	2.1 \pm 0.6
Still amenorrheic	43	(0.0 \pm 0.0)****
Menses resumed	595	2.2 \pm 0.6***
B. At Six Months Postinsertion		
Breastfeeding	430**	0.0 \pm 0.0
Still amenorrheic	153	0.0 \pm 0.0
Menses resumed	276	0.0 \pm 0.0***
Non-breastfeeding	719	3.3 \pm 0.7
Still amenorrheic	17	(8.8 \pm 7.9)****
Menses resumed	702	3.2 \pm 0.7***

*Age-adjustment (<25, 25+) was performed using the total study subjects as the standard population; Herson's method³ was used.

**Numbers of cases do not necessarily add up due to unknown values.

*** $p < 0.05$ comparing breastfeeding and non-breastfeeding groups in women who have resumed menses by three- or six-month follow-ups.

****Rates were based on very small sample sizes.

5. Subsequent hospitalizations

Four women were hospitalized during the six months following insertion. One woman from the BF group was hospitalized due to a urinary tract infection (15 days after insertion). Three women from the NBF group were hospitalized. They were admitted, respectively, for urinary tract infection (35 days after insertion), metrorrhagia (23 days after insertion), and schizophrenia (6 months after insertion).

Discussion

Although Heartwell and Schlesselman reported an increased risk of uterine perforation with IUD insertion in breastfeeding women than in non-breastfeeding women,¹⁰ no uterine perforations were reported for either BF or NBF women in our study. We found significantly lower incidences for BF women as compared to NBF women of moderate/severe insertional pain and cervical dilatation required to facilitate insertion of the TCU-380A (Table II). These events were not found to be clustered in any one of the five study centers. Our present findings are in general agreement with our previous findings (using other device types) from case-control analyses where the center effect was controlled for by matching.^{11,12}

The focus of our analysis was performance of the TCU-380A in breastfeeding women in terms of pertinent event rates. Although the follow-up period used for evaluation in our study was too short for adequate comparison of pregnancy rates between BF and NBF women, the rates were low for both groups. Previous studies of the TCU-380A or the TCU-380Ag have consistently found a remarkably low accidental pregnancy rate.^{13,14,15,16,17,18,19,20}

Expulsion is an event that needs to be carefully examined for breastfeeding women using IUDs. On the one hand, physiologically, suckling stimulates uterine contraction and may thus increase the risk of IUD expulsion, while on the other, breastfeeding may reduce the risk of IUD expulsion by prolonging postpartum amenorrhea. Most postpartum IUD studies revealed high expulsion rates at the early stage of IUD use.^{21,22,23} However, the possible role of breastfeeding is rarely examined. Our study has sufficient power for examination of expulsion, since expulsion rates are usually highest during the first few months of IUD use.^{24,25} We did not detect an increased expulsion risk for BF women by comparing crude or age-adjusted cumulative rates. Also, no consistent differences were detected when the age-adjusted expulsion rates were stratified by other potentially confounding variables.

Previous studies have repeatedly shown that the majority of IUD discontinuations are due to removals, and the majority of

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removals are due to bleeding and/or pain. Like expulsion, removal rates of IUDs are highest during the first several months of use.^{24,25} Comparative studies in developed countries have generally found a higher cumulative bleeding/pain removal rate for users of the TCU-380A as compared to users of other devices.^{13,14,18} Studies from developing countries, however, have not detected such a difference.^{15,16,17,19,20} The discrepancy between these results may reflect the different proportions of insertions in nulliparous women included in their respective studies.

We found a significantly lower ($p < 0.05$) gross cumulative bleeding/pain removal rate for BF women than for NBF women. This difference generally persisted when the rates were age-adjusted and stratified by confounding variables. The dose-response relationship detected between breastfeeding status at IUD insertion and bleeding/pain removal rates further supports the assertion that breastfeeding women inserted with a TCU-380A device are associated with a decreased bleeding/pain removal rate, at least in short-term use. Comparing bleeding/pain removal rates by breastfeeding status and menstrual status at follow-up essentially showed similar findings for women who had resumed menses. For these women, those who were still breastfeeding exhibited lower rates.

Our findings here should be evaluated together with the two afore-mentioned studies^{4,5} that showed discrepancies in findings of IUD performance in breastfeeding women. Both studies used earlier FHI data on interval insertions of IUD types other than the TCU-380A. Cole et al.'s study,⁵ based on three months of observation after insertion of the Lippes Loop D or the Copper T-200 showed findings very similar to ours: a comparable expulsion rate and a remarkably lower bleeding/pain removal rate for BF women as compared to NBF women. Chi et al.'s study,⁴ on the other hand, based on one year of observation after insertion of the Copper T-200 or the Copper 7 disclosed a higher expulsion rate and a higher bleeding/pain removal rate in the BF women.*

It appears that our finding of a lower bleeding/pain removal rate for BF women using a TCU-380A compared with NBF women using this device may apply to other IUDs as well. However, it should be noticed that in this study, the greater difference in the bleeding/pain removal rates between the BF and NBF women was in

* The two studies used different data sets. Data in Cole et al.'s study⁵ were collected between May 1976 and May 1981. Data in Chi et al.'s⁴ study were collected between 1967 and 1976. In the latter study, the 12-month parity-adjusted expulsion rate of the Copper T-200 was significantly higher ($p < 0.05$) in the BF than in the NBF women. The bleeding/pain removal rate was also consistently higher (but not significantly higher) for both IUDs in the BF women.

their first three months (0.0 vs 2.2) rather than in the latter three months (0.9 vs 1.0) of use of the TCU-380A (Table III). The more programmatically important concern is whether, with longer use of the IUD, women who are breastfeeding at insertion will be able to maintain a low bleeding/pain removal rate and hence a low long-term cumulative discontinuation rate or if they will suffer bleeding/pain problems leading to IUD removal once they stop breastfeeding, resulting in a long-term cumulative discontinuation rate commensurate to or even higher than that of their NBF counterparts. The same concern is applicable to long-term expulsion rates as well.

In this data set, among women who returned for one-year follow-up examinations, the BF women exhibited a somewhat higher cumulative one-year expulsion rate (3.4 per 100 women) than the NBF women (2.8). The difference between group bleeding/pain removal rates narrowed at one year (3.9 vs 4.7) as compared to the difference found at six months (0.9 vs 3.2). However, the one-year follow-up rate for this data set was low at the cut-off date. (At this point in these on-going studies, the one-year follow-up rate for the BF group is 47.0 per 100 and for the NBF group, 49.3 per 100.) Therefore, these one-year findings are far from conclusive.

In conclusion, we found no increased risk of adverse effects for breastfeeding women using the TCU-380A as compared to their non-breastfeeding counterparts, whether in terms of insertion-related problems, pertinent termination events, or serious medical complications requiring hospitalization. In fact, the breastfeeding women fared significantly better than the non-breastfeeding women with regard to ease of insertion, bleeding/pain problems and overall continuation of IUD use through six months postinsertion. One important strength of the TCU-380A device is its long life span; therefore an assessment of whether our findings will persist with long-term use of the TCU-380A is especially needed.

The marketing of the TCU-380A in the U.S. is not only welcome news to U.S. women who prefer IUD contraception, but will dispel the doubt and confusion surrounding IUD use in developing countries, caused by the recent withdrawal from the U.S. market of all previously available IUDs except the Progestasert.²⁶ U.S. marketing of the TCU-380A, together with donation from USAID to assure availability abroad, should ensure a worldwide increase in the use of this highly effective IUD. The improvement of IUD efficacy will have programmatic impact in countries where IUD use is prevalent. This is illustrated by Sivin's estimate²⁷ that if the risk of accidental pregnancy can be reduced from five to two per 100 women, at two years of IUD use in the People's Republic of China, it could mean a reduction of about 600,000 unwanted pregnancies per year. Reduction of other IUD termination events

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such as expulsions and medical removals would also help to increase the IUD program's efficiency, especially pertinent in developing countries where medical resources are limited.

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