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A Comparison of the Lippes Loop and Two Copper-Bearing Intrauterine Devices

Lynda P. Cole and David A. Edelman
International Fertility Research Program, Research Triangle Park, North Carolina, USA

ABSTRACT

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A review of published studies and studies conducted through the International Fertility Research Program on the Lippes Loop D, TCu and Cu-7 shows that none of the three devices evaluated is better with respect to continuation and all types of event rates. There is a trend toward lower expulsion rates for the copper-bearing IUDs, but other factors such as the cost of devices and the need for replacement must be considered in determining the merits of the devices for large-scale programs.

INTRODUCTION

For more than 10 years, the Lippes Loop has been the standard against which other IUDs have been evaluated, probably because the Loop has been the most widely used of all IUDs. Copper-bearing IUDs such as the Cu-7 and TCu have likewise met with widespread acceptance, especially for use in nulliparous women. For multiparous women, their advantage over the Lippes Loop for use in large-scale programs has not been clearly established. The accepted advantage of the Cu-7 and TCu IUDs compared to the Lippes Loop is a smaller menstrual blood loss associated with their use. However, the Cu-7 and TCu are more expensive than nonmedicated IUDs and should be replaced every two to three years.

Since 1972, the International Fertility Research Program (IFRP) has conducted numerous studies to evaluate the safety and efficacy of experimental and commercial IUDs, including the Lippes Loop, Cu-7 and TCu. This report reviews the results of published studies and studies conducted through the IFRP that have evaluated the relative performance of these IUDs.

The results of published evaluations of the Lippes Loop, Cu-7 and TCu do not indicate any distinct advantages in continuation rates for the copper-bearing IUDs in terms of events that lead to IUD discontinuation (3, 5–7, 9). Table I summarizes the results from some of these evaluations. The table does not show the rates of pregnancy, expulsion or removal for bleeding/pain to be consistently higher or lower for any one of the three types of IUDs.

Differences in the event rates shown in Table I may be influenced by differences in the characteristics of the women in the studies, in the intensity of the patient follow-up procedures and in the methods used for the analyses of the data. One additional difficulty of the data presented in Table I is that the statistical significance of the event rates cannot be assessed.

ANALYSES OF IFRP DATA

To further evaluate the relative performance of the Lippes Loop, Cu-7 and TCu IUDs, data collected through IFRP clinical trials were analyzed.

Only data from not recently pregnant (currently menstruating), multiparous women were included in the analysis. There were too few insertions of the Lippes Loop, Cu-7 or TCu in women who had recently been pregnant or in nulliparous women for reliable comparisons of specific event rates. The analysis is limited to comparisons of events (pregnancy, expulsion and removal) that lead to IUD discontinuation. Gross life-table event rates (per 100 women) were calculated according to the method of Potter (10). Life-table rates were not calculated if fewer than 50 women remained in any of the groups being compared. Life-table rates were compared using a χ^2 statistic suggested by Azen et al (1) that permits comparison of the cumulative event rates.

Pooled data

Comparisons of event rates for the Lippes Loop D, Cu-7 and TCu are presented in Table II. The

Table I. Comparison of one-year net pregnancy, expulsion, removal and continuation rates for selected IUDs in major studies, 1968–1977.

Type of Device	Country	Author and/or Date[a]	Number of Insertions	Net Event Rates per 100 Women: Pregnancy	Expulsion	Removals for Bleeding/Pain	Continuation Rate
Lippes Loop D	USA	Lippes, 1968[1]	NA[b]	1.8	7.3	9.1	80.1
	Many	Tietze, 1970[1]	7553	2.7	9.5	11.7	77.4
	USA/Canada	Tatum, 1972[2]	945	3.0	13.0	9.0	70.2
	Colombia	1975[3]	749	1.8	5.3	15.4[c]	78.0
	Iran	1975[3]	447	1.4	7.4	12.6[c]	78.2
	Korea	1975[3]	951	0.4	8.6	20.8[c]	65.5
	Thailand	1975[3]	610	1.7	10.0	4.0[c]	80.8
	United Kingdom	1977[4]	2082	1.4	5.2	10.1	64.0
TCu-200	Mainly USA	Lewit, 1973[1]	4127	2.2	8.3	6.4	76.4
	Sweden	Liedholm, 1974[1]	750	1.2	0.7	8.1	85.7
	USA/Canada	Tatum, 1972[2]	750	2.2	7.2	5.6	76.5
	Colombia	1975[3]	775	2.5	3.8	10.6[c]	78.8
	Iran	1975[3]	719	2.6	9.2	15.2[c]	71.5
	Korea	1975[3]	1050	1.0	6.0	22.3[c]	68.7
	Thailand	1975[3]	1996	1.0	6.7	5.2[c]	81.9
TCu-200	United Kingdom	1977[4]	1498	0.4	5.7	7.9	NA
Cu-7-200	Many	Gibor, 1972[1]	8065	1.4	5.9	8.9	75.3
	India	Tejuja, 1974[1]	854	2.4	6.4	10.9	70.6
Cu-7-200	United Kingdom	1977[4]	8098	2.1	11.7	9.4	NA

[a] *Sources for author and/or dates are as follows: [1]Huber SC et al (6), [2]Tatum HJ (12), [3]The Population Council (9), [4]Family Planning Research Unit (3).*
[b] *NA, not available.*
[c] *Includes all medical removals.*

Table II. Gross termination rates per 100 menstruating, multiparous women for Lippes Loop, Cu-7 and TCu users.

	12-Month Rates: Lippes Loop D (N = 2386)	Cu-7-200 (N = 1402)	TCu-200/220 (N = 2995)
Pregnancy	2.9 ± 0.5	1.9 ± 0.4	1.6 ± 0.3[a]
Expulsion	11.5 ± 0.8	5.3 ± 0.6[a]	5.2 ± 0.5[a]
Removal			
Bleeding/pain	10.2 ± 0.8	2.9 ± 0.5[a]	4.0 ± 0.4[a]
Other medical	2.6 ± 0.4	1.1 ± 0.3[a]	2.8 ± 0.4[a]
Planned pregnancy	1.7 ± 0.4	1.8 ± 0.4	3.1 ± 0.4[a]
Other personal	2.5 ± 0.4	1.6 ± 0.4	3.0 ± 0.4[a]
Percent of women not terminated who were followed up	55.8	91.4	71.5
Woman-months	17 760	14 901	26 401
Continuation rate	72.0	86.1[a]	81.8[a]

[a] *$p \leq 0.5$, in comparison with Lippes Loop D.*

cumulative rates for pregnancy, expulsion, removal for bleeding/pain or other medical reasons, and continuation for the Lippes Loop D were generally significantly different ($p \leq 0.05$) from those of the Cu-7 or TCu.

Since there were differences in the age and parity distributions of users of the three types of IUDs, the data were reanalyzed to adjust the life-table event rates for differences in the age and parity distributions of the women. The results of this analysis

showed that the copper IUDs continued to have significantly lower ($p < 0.05$) expulsion and bleeding/pain removal rates than the Loop. The adjusted pregnancy rates among the devices were not significantly different except in the 30+ age group of parity 1 or 2 where the TCu had a significantly lower pregnancy rate.

The data used for the analyses of pooled data came from 35 clinics in 14 countries serving populations that had dissimilar sociodemographic characteristics. Not all clinics reported data on both Lippes Loops and copper-bearing IUDs. The data were further analyzed to control for interinvestigator differences.

General studies

Table III presents IUD event rates from studies conducted in clinics in Latin America, Europe and Asia that have evaluated the Lippes Loop D, Cu-7 and/or TCu. Cumulative event rates for the Loop D were compared to those for the copper-bearing IUDs. In all three clinics, the cumulative expulsion rates for the Loop D were significantly higher ($p < 0.05$) than those for the TCu or Cu-7. These differences also reflected significantly higher ($p < 0.05$) continuation rates for the copper-bearing IUDs compared to the Lippes Loop D. There were no significant differences with respect to pregnancy rates.

Comparative studies

Dissimilarities among the groups of subjects are fewer in studies in which different types of IUDs are randomly assigned because potential biases in the study results due to selection biases are avoided. Such comparative studies have been conducted by the IFRP to evaluate the relative effectiveness of the Lippes Loop, Cu-7 and TCu. The results from two such studies, one conducted in Europe and the other in Latin America, are presented in Table IV. Within each of the comparative studies, women were similar in age, parity and gravidity. The only statistically significant differences occurred in the European study. The expulsion rate for the Loop D was significantly higher ($p < 0.05$) than that for the Cu-7, and the continuation rate for the Loop was significantly lower ($p < 0.05$).

COMMENTS

Continuation and event rates for any IUD vary widely from clinic to clinic and among groups of women within the same clinic. Based on the data presented in other reports, no one of the three IUDs

Table III. Twelve-month gross event and continuation rates per 100 users from IUD insertions in menstruating, multiparous women.

	Latin America				Europe		Asia		
	Lippes Loop D (N = 165)	TCu-200 (N = 722)	TCu-220 (N = 223)	Cu-7-200 (N = 447)	Lippes Loop D (N = 389)	TCu-200 (N = 89)	Lippes Loop D (N = 159)	TCu-200 (N = 88)	Cu-7-200 (N = 89)
Pregnancy	6.7 ± 2.2	2.5 ± 0.6	1.2 ± 0.8	3.1 ± 0.9	2.9 ± 1.0	1.2 ± 1.2	0.0	2.5 ± 1.8	0.0
Expulsion	12.2 ± 2.7	3.6 ± 0.7[a]	5.5 ± 1.6[a]	4.2 ± 1.0[a]	7.9 ± 1.5	0.0[a]	19.6 ± 4.0	2.4 ± 1.7[a]	5.9 ± 2.6[a]
Removal									
Bleeding/pain	2.1 ± 1.2	3.5 ± 0.7	1.7 ± 1.0	2.2 ± 0.7	6.5 ± 1.4	3.6 ± 2.0	3.2 ± 1.6	1.2 ± 1.2	1.2 ± 1.2
Other medical	1.4 ± 1.0	2.4 ± 0.6	0.6 ± 0.6	1.0 ± 0.5	3.8 ± 1.1	0.0	0.0	2.3 ± 1.6	1.4 ± 1.4
Planned pregnancy	0.9 ± 0.9	2.7 ± 0.6	2.2 ± 1.1	1.6 ± 0.6	0.7 ± 0.5	3.6 ± 2.0	0.0	0.0	2.5 ± 1.8
Other pregnancy	1.6 ± 1.1	1.2 ± 0.4	0.5 ± 0.5	0.5 ± 0.4	0.7 ± 0.5	2.3 ± 1.6	6.5 ± 2.6	0.0	2.3 ± 1.6
Percent of women not terminated who were followed up	86.2	93.5	81.1	88.3	85.8	97.5	49.2	92.6	91.0
Continuation rate	77.1	85.1	88.8[a]	88.0	79.5	89.8	72.3	91.8[a]	87.4[a]

[a] *$p \leq 0.05$, in comparison with Lippes Loop D.*

Table IV. Twelve-month gross termination rates per 100 users from comparative studies of IUD insertions in menstruating, multiparous women.

	Europe		Latin America	
	Lippes Loop D (N = 423)	Cu-7 (N = 427)	Lippes Loop D (N = 196)	TCu-200 (N = 191)
Pregnancy	3.0 ± 0.9	2.6 ± 0.8	2.6 ± 1.3	2.5 ± 1.2
Expulsion	7.6 ± 1.4	4.0 ± 1.0[a]	11.4 ± 2.3	9.7 ± 2.3
Removal				
Bleeding/pain	7.4 ± 1.4	3.2 ± 0.9	1.8 ± 1.1	4.2 ± 1.7
Other medical	3.3 ± 1.0	0.8 ± 0.5	7.0 ± 2.1	5.3 ± 1.8
Planned pregnancy	1.0 ± 0.6	0.9 ± 0.5	1.3 ± 0.9	5.1 ± 1.9
Other personal	0.6 ± 0.4	1.1 ± 0.6	2.0 ± 1.2	4.3 ± 1.7
Percent of women not terminated who were followed up	83.8	85.7	86.4	76.6
Continuation rate	79.0	88.0[a]	76.1	72.5

[a] $p \leq 0.05$.

evaluated (Lippes Loop D, TCu or Cu-7) can be identified as best with respect to continuation and all types of event rates.

Based on the IFRP pooled data analysis, it appears that there are advantages to use of the copper-bearing IUDs. The data suggest that there is a slight difference in the pregnancy rates of the Loop, TCu and Cu-7. There is, however, a definite trend toward lower expulsions and medical removal rates for the copper-bearing IUDs. When center variation is taken into account, however, the copper-bearing IUDs are better only with respect to expulsion rates.

Two other factors need to be considered when comparing the Loop with the Cu-7 and TCu. First, the Loop costs less than either of the others. Second, there is no need to replace the Loop after three years as is recommended for the Cu-7 and TCu. These two factors are important considerations for the developing world where there are limited economic and medical resources. In some family planning programs, the Lippes Loop would prove to be the device of choice for the populations served, and, for others, a copper-bearing IUD may be more successful.

Pregnancy, expulsion and medical removal rates provide a means for evaluating the relative effectiveness of different IUDs. However, IUD use is associated with other adverse events that may or may not lead to IUD discontinuation.

Pelvic inflammatory disease (PID) is a rare but potentially serious complication that can occur in association with IUD use. Available data from developed countries suggest that the use of any IUD is associated with an increased risk of PID (2, 8). To date, there is no evidence from clinical studies to indicate that the addition of copper to an IUD is in any way protective against PID, even though some studies have shown that copper has gonococcidal properties (4, 11). Among IUD users who become pregnant, there is a significantly higher proportion of ectopic pregnancies than among non-IUD users who become pregnant. However, there is yet no evidence to indicate that IUDs *cause* ectopic pregnancy (2). Other known adverse reactions of IUDs include higher rates of spontaneous abortion among women who become pregnant with the IUD in situ, and of uterine perforation. There is yet no evidence to indicate that the rates of these events are significantly different for different types of IUDs.

Results of studies do indicate that for women using either the Cu-7 or TCu the total menstrual blood loss is less than that for women using the Lippes Loop D. However, it has not yet been established whether the higher menstrual blood loss associated with the Loop increases the risks of iron-deficiency anemia among women with lowered hemoglobin levels or leads to higher rates of IUD discontinuation for any reason.

Further studies and research are required to evaluate the relative merits of different types of IUDs for use in different populations. Factors other than event rates influence the best IUD choice for a given subject and a given program. It is doubtful that any one type of IUD is best for all women.

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Information Coordinator
International Fertility Research Program
Research Triangle Park, NC 27709
USA