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Long-term Use Effectiveness of the CU-7-200 IUD

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ABSTRACT

Zipper, J., Medel, M., Osorio, A., Goldsmith, A. and Edelman, D. A. (Escuela de Medicina, Universidad de Chile, Santiago, Chile and International Fertility Research Program, Research Triangle Park, North Carolina, USA). *Long-term use effectiveness of the CU-7-200 IUD.*

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Copper-containing IUDs have been demonstrated to be as good, if not better, than other presently used inert devices. There is, however, no consensus on the duration of contraceptive effectiveness of copper-containing IUDs. The long-term contraceptive effectiveness of one copper-containing IUD, the CU-7-200 Gravigard[®], is evaluated in this report on 514 patients. IUDs were inserted in the intermenstrual period and patients were followed up for as long as 63 months. The probability of pregnancy, expulsion, or removal for medical reasons did not increase with increasing duration of IUD use, but instead appeared to slightly decrease with increasing duration of IUD use. The results of this study indicate that the CU-7-200 continues to be an effective contraceptive for at least five years after insertion.

INTRODUCTION

The increased contraceptive effectiveness resulting from the addition of small amounts of copper wire to otherwise inert plastic intra-uterine devices (IUDs) has been documented by a number of investigators (1). Although the exact mechanism through which copper exerts its contraceptive effectiveness is not known, it is currently hypothesized that the copper acts locally on the endometrium to inhibit implantation (4). The device should, according to this hypothesis, continue to be effective as long as it releases copper.

Initially, it was recommended that copper-

containing IUDs be removed after two years of use (5). This recommendation was based on hypothesized adverse effects of a sustained release of copper into the uterine cavity and a decrease in IUD effectiveness resulting from a depletion of the copper. Some studies indicated a daily copper-release rate of about 50 μgm per day after 21 months of continued use (1). These studies suggest that copper devices may be retained for longer than two years without adverse effects or diminished contraceptive efficacy (6).

The present study was undertaken to evaluate the long-term (up to 63 months of continued use) efficacy of the Cu-7-200 (Gravigard[®]) IUD based on 514 first insertions.

METHODS AND MATERIALS

From June to December 1976, 514 women had Cu-7-200 IUDs inserted. Insertions were performed in the proliferative phase of the menstrual cycle. Each patient was scheduled for a routine history and follow-up examinations at one, three, and six months after IUD insertion and every six months thereafter. As of September 1975, 53 women with 59 to 63 months of use were still using the IUDs. The net cumulative lost-to-follow-up rate at five years was 54.0. The annual lost-to-follow-up rates varied from 8.5 to 12.9. This relatively high follow-up rate reflects the source of the data (a family planning program) and probably results in an increase in rates of pregnancy, expulsion, and removals if it is assumed that the women who were lost to follow-up were continuing users.

This study evaluates the contraceptive efficacy of the Cu-7-200 IUD in a family planning program on the basis of net cumulative life table rates for pregnancy, expulsion, and removal. These rates are compared to the five-year net rates from another family planning program in which Lippes loops C and D were inserted among patients similar in age and parity to those in this study (2).

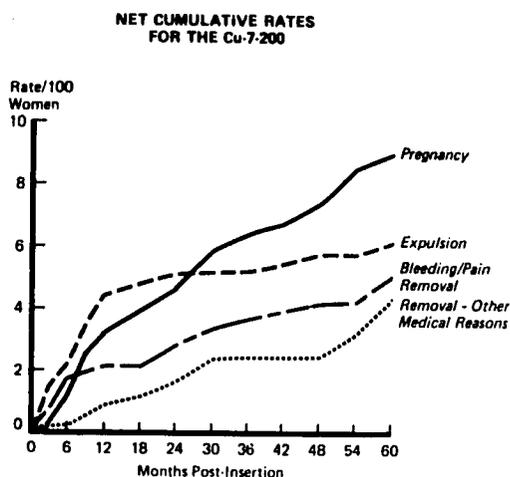


Fig. 1. Net cumulative rates for the Cu-7-200.

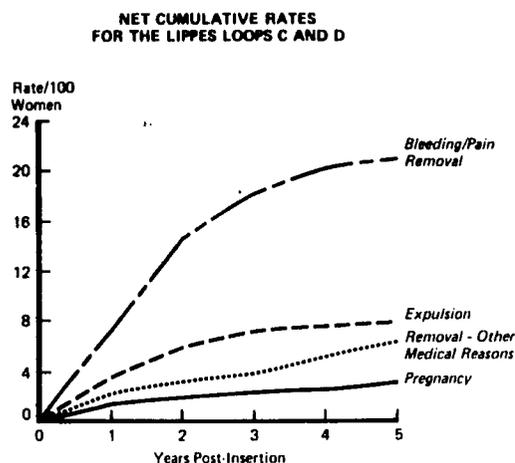


Fig. 2. Net cumulative rates for the Lippes loops C and D. (After Lippes, J., et al., reference 2.)

Subjects

Most subjects (53.1%) were less than 25 years of age, married (90.1%), and of parity two or less (52.3%). The age and parity means were 23.8 years and 3.0 children. Fifty-six percent of the women were not using contraceptives prior to the IUD insertion; 20.8% were previous IUD users; 15.4% were using orals; and the remainder were using conventional contraceptives.

RESULTS

Cu-7-200 event rates

The net cumulative event rates (pregnancy, expulsion, bleeding/pain removal, and removal for other medical reasons) did not appear to increase more rapidly with increasing duration of IUD use (Table I, Fig. 1). The net pregnancy and ex-

pulsion rates increased more rapidly during the first year of use than during the subsequent four years. The net cumulative pregnancy and expulsion rates per 100 users were 3.2 and 4.4 at the end of one year and 9.0 and 6.1 at the end of five years.

Event rates: Cu-7-200 vs. Lippes Loops C and D

Compared with 440 women (mean age, 27.2 years; mean parity, 3.5) who had Lippes loops C or D inserted (2), the net cumulative expulsion rates over five years were similar for Cu-7-200 and Lippes loop users (Figs. 1 and 2). Pregnancy rates were significantly higher for the Cu-7-200 users, but removals for bleeding and/or pain were significantly higher for the Lippes loop

Table I. Net cumulative rates per 100 users by type of termination Cu-7-200

Initial insertion: 514 Standard error of rates are in the parentheses.

Type of termination	Months post-IUD insertion				
	12	24	36	48	60
Pregnancy	3.2 (0.9)	4.6 (1.0)	6.4 (1.2)	6.7 (1.3)	9.0 (1.5)
Expulsion	4.4 (1.0)	5.1 (1.1)	5.1 (1.1)	5.7 (1.1)	6.1 (1.2)
Removals					
Bleeding/pain	2.1 (0.7)	2.8 (0.8)	3.6 (0.9)	4.2 (1.0)	5.1 (1.2)
Other medical	0.9 (0.5)	1.6 (0.6)	2.4 (0.8)	2.4 (0.8)	4.4 (1.3)
Personal reasons	0.5 (0.3)	1.9 (0.7)	2.1 (0.7)	3.6 (1.0)	4.7 (1.3)
Planning pregnancy	2.2 (0.7)	8.4 (1.4)	13.6 (1.7)	18.5 (2.0)	25.0 (2.6)
Total termination	13.0 (1.6)	24.0 (2.1)	36.9 (2.4)	41.3 (2.5)	54.0 (3.1)
Continuation rates	87.0	76.0	67.1	58.8	46.0
Woman-months of use	5 448	9 743	12 991.5	15 500	16 930.5

users (Figs. 1 and 2). After the first year, the net annual pregnancy rate for the Cu-7-200 and Lippes loops C and D were nearly constant. The net continuation rates were similar for the two groups of women: at one year 87.1 for the Cu-7-200 and 84.4 for the Lippes loop users, and at five years 46.1 for the Cu-7-200 and 53.1 for the Lippes loop users.

COMMENT

The results of this study support the contention that there is no need to remove the Cu-7-200 IUD after two years of use. In this study the pregnancy rate was higher during the first year of use than in each of the four subsequent years. Other event rates—expulsion and removal for pain, bleeding, and other medical reasons—did not increase more rapidly with increasing duration of IUD use.

The five-year continuation rates for women using either the Cu-7-200 or Lippes loops C or D appear to be similar based on the results of this study and those reported by Lippes (2). The differences in removal rates for the Cu-7-200 and Lippes loops C and D might be in part attributed to different clinic policies for IUD removal. However, other studies have indicated lower removal rates for the Cu-7-200 device than for the Lippes loops (1). This study appears to be consistent with studies (1) that have indicated a significantly smaller increase in the amount of menstrual blood loss after insertion of a Cu-7-200 IUD than after insertion of either a Lippes loop or a Dalkon shield.

Further studies will be required to evaluate possible adverse effects of prolonged use of copper-containing IUDs. However, to date, studies have indicated no adverse local or systemic effects resulting from the prolonged use of IUDs containing small amounts of copper.

ACKNOWLEDGEMENT

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