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Use of the Cu-7 Device In a Family Planning Clinic

SUMMARY

The experience of 707 women undergoing a first insertion of the Cu-7® at the Family Planning Clinic, Edmundston, has been assessed.

The majority (67.3%) of patients were parous, and 77.2% were 20-29 years of age. Insertion of the Cu-7 was considered easy in both nulliparous and parous patients.

Two years of use have been completed by 136 women (7,917 woman months of use). Relevant life-table discontinuation rates for the first two years of use, respectively, were: involuntary pregnancy 1.50%, 1.39%; expulsion 6.60%, 1.11%; removal of the Cu-7 for some medical reason 19.83%, 14.85%.

Removals for pain among nulliparous women were significantly more frequent than among parous patients ($p<.001$). (Can Fam Physician 1980; 26:1507-1514).

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SINCE ITS INTRODUCTION in 1974, the Cu-7 IUD has been routinely used at the Family Planning Clinic, Hôtel-Dieu Hospital, Edmundston. This clinic serves a community of approximately 13,000, predominantly French-Canadians. The staff consists of one physician and two nurses. In order to monitor the success of this device and any possible adverse effects, careful records were kept of all patients in whom a Cu-7 was inserted. To date, over 800 Cu-7 insertions have been performed. This report details the experience of the 707 women in whom a first insertion was performed prior to April 1, 1978.

Method

Patients wishing to use an intrauterine contraceptive device (IUD), or those in whom the physician considered this method desirable, were fitted with a Cu-7 after undergoing a thorough physical examination. Insertions were usually performed during menses.

Patients returned approximately two months post-insertion for a follow-up examination; any complaints were noted. Thereafter, annual checkups were performed unless problems were encountered. The clinic nurse provided support and encouragement at all times, and patients were able to contact the clinic concerning any con-

TABLE 1
Age and Parity Distribution of Study Population

	Parity						
Age	0	1-2	3-4	5-6	7-9	Total	% of Population
15-19	64	27	—	—	—	91	12.9
20-29	165	340	39	1	1	546	77.2
30-39	2	37	17	3	1	60	8.5
40-52	—	—	2	4	3	9	1.3
Not indicated	—	1	—	—	—	1	0.1
Total	**231**	**405**	**58**	**8**	**5**	**707**	
% of Population	**32.7**	**57.3**	**8.2**	**1.1**	**0.7**	**100.0**	

cerns or complaints while wearing the device.

Initially, devices were removed routinely after two years of use. However, on insertion of a replacement device, patients sometimes encountered problems of pain and bleeding. Thus, a decision was made to forego routine removals of the Cu-7 after two years of use. Some patients have successfully worn the Cu-7 for three years of uninterrupted use.

Data Analysis

The present report covers insertions during the period August 1, 1974 to April 1, 1978. Multiple decrement life-table analysis of the first two years of use was performed. First segment experience only has been considered. Although 25 women have successfully completed three years of uninterrupted use, these numbers are too small for life-table methods. Termination rates between nulliparous and parous patients were compared using the log-rank test, based on chi-square, described by Azen *et al.*[1]

TABLE 2

Contraceptive Method Employed Prior to Insertion of Cu-7

Method	Patients #	Patients %
None	86	12.2
Oral contraceptives	415	58.7
Intrauterine device	12	1.7
Diaphragm	1	0.1
Condom	43	6.1
Foam/Jelly/Vaginal Suppositories	7	1.0
Rhythm	32	4.5
Withdrawal	13	1.8
Recent pregnancy	9	1.3
	618	**87.4**
Not indicated	89	12.6
	707	**100.0**

Results

During the period between August 1, 1974 and April 1, 1978, 749 Cu-7 insertions were performed, of which 42 were reinsertions in previous users. Thus, 707 patients had a first insertion. Table 1 details the age and parity distribution of the study population. The majority (67.3%) of patients were parous, and 77.2% were aged 20-29. More than half (58.7%) of the patients had been using oral contraceptives prior to insertion of the Cu-7 and a further 12.2% had used no form of contraception. Only 12 patients (1.7%) had been wearing an intrauterine device (Table 2).

Insertion of the Cu-7 posed no problems in either nulliparous or parous patients. No sedatives or local anesthetics were employed at the time of insertion. Approximately one in 22 (4.4%) insertions in parous women were associated with some pain, while approximately one in six (17.3%) nulliparae complained of some pain.

At the two month follow-up visit (Table 3), approximately half of the patients seen reported abdominal

cramps, and 28.4% considered their menses heavy. Intermenstrual spotting was present in 34.9% of women. Often, patients specified that these symptoms were present during the first one or two cycles only, and resolved with continuing use of the device. Twenty-six percent of patients reported a vaginal discharge.

TABLE 3
Observations at Two Months* Post-Insertion of Cu-7

Number of patients seen: 557

Complaint	Total Reports #	%
Abdominal cramps	281	50.4
Pain		
Leg	8	1.4
Back	16	2.9
Side	10	1.8
Breast	5	0.9
Other	65	11.7
Menstrual flow		
Heavy	158	28.4
Lightly increased	226	40.6
No change	103	18.5
Intermenstrual spotting		
Occasional	124	22.3
Frequent	70	12.6
Vaginal discharge	145	26.0
Difficulty in finding Cu-7 string	23	4.1
Awareness of Cu-7 string:		
Partner	13	2.3
Patient	14	2.5
Headache	6	1.1
Dyspareunia	12	2.2

* Actual time of visit within six months of insertion

Table 4 details multiple decrement life-table rates for terminations in the total study population, for the first two years of use.

Nine involuntary pregnancies were reported during the first year of use, and four during the second year of use, giving a two-year cumulative rate of 2.24%. All involuntary pregnancies were followed up. In one case, the pregnancy was ectopic, and the Cu-7 was removed at salpingectomy; three patients elected to terminate the pregnancy. Nine patients continued the pregnancy and all delivered normal, healthy babies; seven by vaginal deliv-

ery, and two by cesarean section. In five cases, the device remained *in situ* throughout the pregnancy.

As expected, expulsions were more frequent during the first months after insertion. The expulsion rate at three months was 3.96%—compared to 6.60% for the entire first year of use, and 1.11% for the second year of use.

The majority of removals during the first year were for pain and/or bleeding (17.54%). The rate declined during the second year of use (11.49%). Removals for pain were more frequent, with rates of 9.30% and 7.06% for the first and second years of use.

Removals for 'other medical reason' include 15 removals for suspected pelvic inflammatory disease, of which three were diagnosed as cases of salpingitis and two as cases of endometritis. If infections are considered separately, the annual rates were 1.61% and 1.87% for the first two years, respectively, with a two-year cumulative rate of 2.61%.

One uterine perforation was reported which was detected during laparotomy for an ovarian cyst. One patient requested removal of the Cu-7 because of dyspareunia.

During the study, 80 patients had the device removed in order to become pregnant. Follow-up information was available on 71 of these women, eight of whom later changed their mind and no longer desired pregnancy. Half of the women had conceived within three months of removal of the device, and 74.2% were pregnant within one year of removal. Of the 55 women who became pregnant, 40 delivered normal, healthy infants; seven miscarried within four months of conception; one baby was stillborn at full term; one premature infant died, and one infant had a congenital cardiac condition. The outcome of the pregnancy in five cases is not known.

Termination rates for nulliparous and parous patients are presented in Table 5. Only the first year of use has been considered, since an insufficient number of patients in each group have completed two years of use to permit a meaningful life-table analysis. Rates of involuntary pregnancy, expulsion and removals for medical reasons other than pain were very similar in the two groups. However, removals for pain among nulliparous women were significantly more frequent than among parous patients ($p<0.001$).

TABLE 4
Termination Rates (Multiple Decrement Life-Table) During The First Two Years of Cu-7 Use, In The Total Study Population

Reason For Termination	Year-Specific % Termination Rates 1st Year	2nd Year	% Cumulative Rate 24 Months
Involuntary pregnancy	1.50	1.39	2.24
Explusion	6.60	1.11	7.19
Removal For:			
Pain	9.30	7.06	13.05
Bleeding	6.29	3.71	8.26
Both pain and bleeding	1.95	0.72	2.33
Other medical reason	2.29	3.36	4.08
Voluntary pregnancy	6.09	16.14	14.67
Other non-medical reason	2.65	5.10	5.36
All terminations	36.67	38.59	57.18
Lost to follow-up	10.18	9.03	14.98
Woman months of use	**5,425.5**	**2,491.5**	**7,917.0**

TABLE 5
Termination Rates (Multiple Decrement Life-Table) In Nulliparous and Parous Women, During The First Year of Cu-7 Use

Reason For Termination	Nulliparae	Parae
Involuntary pregnancy	1.62	1.44
Expulsion	6.72	6.56
Removal for:		
Pain	17.30	5.98
Bleeding	7.89	5.31
Both pain and bleeding	2.61	1.67
Other medical reason	2.64	2.15
Voluntary pregnancy	8.09	5.21
Other non-medical reason	0.52	3.62
All terminations	47.39	31.94
Lost to follow-up	11.00	9.91
Woman months of use	**1,539**	**3,870**

Discussion

Patient experience with an IUD varies from one clinic to another, since not only is accurate placement of the device important, but supportive counselling influences patient attitude and acceptance of the device.[2]

The advent of smaller, efficacious IUDs, coupled with adverse publicity about the use of oral contraceptives, appears, at least in our experience, to have resulted in more women accepting intrauterine contraception. This is borne out in that only 1.7% of all patients requesting Cu-7 insertion had previously employed an IUD, while 58.7% had used oral contraceptives. Since 89.7% of Cu-7 acceptors were under 30, there seems to be a growing interest in intrauterine contraception among younger women in our patient population.

Rates for involuntary pregnancy during the first and second year of use were virtually identical (1.50%; 1.39%), and the two-year cumulative pregnancy rate of 2.24% compares with the 2.7% reported by Stewart *et al*,[3] based on 16,402 insertions. Although insufficient numbers of patients have completed a third year of

use to permit statistical analysis, our impression, like several reports in the literature, [3-5] is that satisfactory contraceptive protection may be afforded beyond two years of use.

As has been noted by others,[6] the expulsion rate declined with time. The majority of expulsions occurred during the first three months post insertion and became very infrequent thereafter. This is reflected in the expulsion rate of 1.11% during the second year of use. Although for purposes of this analysis, a first expulsion was considered a closure, more than half of these patients requested a re-insertion of the device; three of the 23 re-insertions resulted in a second expulsion. All insertions were performed by one physician; of the first 100 insertions, 12 devices were eventually expelled; of the second 100 devices inserted, six resulted in expulsion; of the third 100 devices inserted, six devices were expelled. All of these insertions were performed before the cut-off date for inclusion in this analysis so that length of time in the study is not a factor. Therefore, these data support a physician "learning effect" in the technique of correct placement of the device, which subsequently affects the patient's experience with the device.[2]

The majority of removals were related to pain and/or bleeding. Although removal rates for this reason reported in the literature show considerable variation,[7] the rate reported here (17.54%) is somewhat high. The rate of removal for pain among nulliparous women (17.30%) was significantly higher than that in parous women (5.98%), although termination rates for all other reasons, including removal for bleeding, were very similar. Distortion of the uterine cavity by the plastic vector, rather than any property of copper, is thought responsible for cramping symptoms.[7, 8] The Cu-7 has a small horizontal dimension (28 mm); however, fundal width in normal women has been estimated to be 21-50 mm.[9] Thus, there will be women whose uterine cavity is simply too small to accommodate the IUD properly. Since nulliparae tend to have smaller uterine dimensions than parous women,[11] they could experience pain more frequently.

The Cu-7 did not appear to interfere with fecundity subsequent to removal of the device. Within 12 months after removal of the device for a planned pregnancy, 74.0% of patients had conceived. These data agree well with Southam's[11] estimate of a 73% suc-

cess rate during the first year of attempted conception in the general population.

The Cu-7 has met with a high degree of acceptance among our patient population, and seems a particularly suitable contraceptive method for couples who wish to plan their family. ◉

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