Middle Articles

Insertion of Lippes Loop by Nurse-Midwives and Doctors

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Summary: Follow-up studies of 7 to 19 months of two groups of 500 women each in Barbados, in one of which a Lippes loop had been inserted by a doctor and in the other by a nurse-midwife, showed a slightly higher incidence of pregnancy and expulsion of the loop in the second group, though the difference was not statistically significant. The insertion of loops by paramedical personnel when this is an economic necessity is thought not to be contraindicated, but adequate training is essential.

Introduction

Several national family planning programmes offer the intra-uterine contraceptive device (I.U.D.) as a contraceptive method. Usually the doctor is responsible for inserting the I.U.D., yet there are few data to show that this could not be done equally well by paramedical personnel. We have conducted a study in Barbados, West Indies, in which Lippes loops C and D were inserted either by specially trained nurse-midwives or by volunteer doctors in the same clinic. Two groups of 500 consecutive cases in one of which insertions were made by a doctor and in the other by a nurse-midwife are compared with respect to pregnancy, expulsion, removal, and the incidence of pelvic inflammation.

Methods

Barbados is a Caribbean island of 166 square miles (430 sq. km.) with an average population density of 1,500 per square mile (580 per sq. km.). There is a ratio of one doctor for each 3,000 inhabitants. Three Barbadian nurse-midwives were selected to work full time taking Papanicolaou smears and inserting I.U.D.s (Lippes loops C and D) in association with an island-wide uterine cancer eradication campaign (Cummins and Vaillant, 1966). The first nurse-midwife insertions were made in May 1965 in a clinic in which 10 volunteer doctors had been inserting the loops since September 1964.

Clinic Routine

Loops were inserted in one clinic where similar technique, instrumentation, and sterilization were used. Whether a loop was inserted by a volunteer doctor or nurse-midwife depended on the personnel available during a particular day. Few patients objected to being treated by the nurse-midwives, who perform most deliveries in Barbados. There was no difference in fee or

follow-up procedure for the patients in either group. These methods are believed to have resulted in treatment groups that are similar with respect to age, parity, motivation, and socio-economic status.

A few patients whose insertions were technically difficult were referred by the nurse to a doctor. In a separate study (H. W. Vaillant, unpublished) of these cases there was no greater incidence of complications among these referrals than among the routine insertions by nurses. In December 1965 a double-blind comparison of Lippes loop D and Lippes loop C was instituted. All previous insertions were of Lippes loop D. The protocol did not favour either nurse-midwives or doctors inserting a particular type.

The clinical routine at the time of loop insertion consisted of a social, reproductive, and medical history, obtained by a social worker; a Papanicolaou smear; a pelvic examination to exclude leiomyomata, infection, neoplasia, and pregnancy; and a gentle sounding of the uterus with a stainless steel probe. The loop was then inserted in the usual manner. The loops and loop-inserters were sterilized in cold iodine or cetrimide solution. Candidates for loop insertion were limited to parous women more than six weeks postpartum. Loops were inserted at any time in the menstrual cycle unless the previous menses were overdue. Women with postpartum amenorrhoea had loops inserted if there was no clinical evidence of pregnancy.

Follow-up Examination

A follow-up examination was planned for two months and for 12 months after insertion, and annually thereafter. Because the I.U.D. programme was associated with a uterine cancer prevention programme, patients received a written reminder to return for their annual Papanicolaou smear one year after loop insertion. Otherwise no reminders were sent.

The clinic was open six days a week and each patient was given a card containing information about the loop, the clinic schedule, and a telephone number to call if she experienced any complications. She was also asked to show the card to any private doctor treating her outside the clinic. Only one general hospital was serving the majority of indigent patients, and gynaecological admissions were monitored during the study. These methods are believed to have led to the reporting of most complications.

Follow-up examinations were conducted by both nurse-midwives and doctors, but all complaints or complications were referred to a doctor for evaluation. Most patients who expelled loops had a loop reinserted, but they were no longer followed up in this study, the population of which consists entirely of those having first Lippes loop insertions.

Analysis of Cases

The case analyses were made as follows: September 1966 was used as cut-off date, and the case records of 500 consecutive nurse-midwife first insertions performed between 1 June 1965

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and 25 February 1966, and 500 consecutive doctor first insertions between 4 March 1965 and 28 February 1966 were reviewed. Follow-up records throughout October and November 1966 were available in most cases to confirm the questionable findings at 30 September. Thus the minimum follow-up was seven months for both groups and the maximum 19 months for the doctors' patients and 16 months for those of the nurse-midwives.

Results

The results of this comparative study are summarized in Table I. The causes of patient-attrition have been grouped into five classes on the basis of Tietze's (1967) criteria with one exception. Women recalled for treatment of abnormal Papanicolaou smears taken at the time of loop insertion whose treatment required loop removal were classified as non-medical removals.

TABLE I.—Summary of Follow-up

Ordinal Month	Woman-Months of Use	Active Patients in Study Starting Ordinal Months	Losses Due to				Loss to Follow-up
			Preg-nancy	Expul-sions	Medical Removals	Non-medical Removals	
500 Patients with I.U.D.s Inserted by Doctors							
1	459	0	0	5	5	1	71
2	413.5	0	1	4	3	1	0
3	400	0	0	7	3	2	6
4	386	0	0	4	4	2	0
5	379.5	0	0	0	3	0	0
6	372.5	0	0	5	3	3	0
7	353	0	2	2	3	3	18
8	335	1	0	2	3	2	0
9	323	4	0	2	8	2	0
10	308	4	2	5	1	2	0
11	292	11	1	0	3	3	0
12	278	5	2	1	2	0	0
13	261.5	18	0	2	1	1	0
14	241.5	15	0	1	2	0	0
15	220	22	0	1	2	1	0
16	189.5	33	0	0	0	0	0
17	153	37	0	0	0	1	0
18	101	65	1	0	0	0	0
19	34	68	0	0	0	0	0
Total	5,500	283	9	41	48	24	95
500 Patients with I.U.D.s Inserted by Nurse-Midwives							
1	433.5	0	0	7	6	1	119
2	362	0	0	4	4	2	0
3	350	0	3	7	0	1	3
4	337.5	0	3	5	1	2	0
5	326	0	2	6	3	1	0
6	316.5	0	1	3	3	0	0
7	311.5	0	0	1	2	0	0
8	299.5	18	0	0	2	1	0
9	279	16	0	2	1	1	0
10	254.5	25	1	1	1	1	0
11	221.5	33	0	1	0	2	0
12	181.5	31	0	0	0	0	0
13	138	64	0	1	3	0	0
14	73.5	58	0	1	2	0	0
15	30.5	25	0	0	0	0	0
16	9	18	0	0	0	0	0
Total	3,924	288	10	39	29	12	122

The incidence of pregnancy and expulsion of the I.U.D. was little different in the two treatment groups. The overall loss due to both medical and non-medical removal was greater among patients whose loops were inserted by doctors. More of the patients whose loops were inserted by nurse-midwives were lost to follow-up. The pattern of loss occurring chiefly in months one and three was the result of scheduling follow-up visits at 2 and 12 months after insertion.

Each entry in the column headed "active patients in study starting ordinal month" represents the number of active patients for whom the respective months of follow-up have been obtained. All active patients have had at least seven months of follow-up. The differences between the two treatment groups with respect to the number of active patients starting different ordinal months is due, in part, to the earlier starting dates for doctor insertions—March 1965—whereas the first patients treated by the nurse-midwives were seen in June 1965. Similarly there are differences in the total of

cumulative experiences for each group—namely, 5,500 women-months of use in the doctor insertion group and 3,924 women-months of use among the group treated by nurse-midwives. This difference places the estimates of the causes of attrition on different bases for each group.

The cumulative rates of continuation to the end of each successive ordinal month after the insertion of the I.U.D. per woman entering the first month for each treatment group are shown in Fig. 1. These rates correspond to the 1_x variable in standard life table notation. The shapes of the curves representing the experience in the two groups are similar. The overall attrition among the group treated by nurse-midwives is apparently greater during the first eight months of follow-up.

Fig. 2 shows that the incidence of pregnancy in the two groups was somewhat different. Although these observed differences were not large at the end of the follow-up period, there was a consistently greater incidence of pregnancy among women whose loops were inserted by nurse-midwives than among those treated by doctors. One doctor insertion and two nurse-midwife insertions were performed in women who were felt in retrospect to have been pregnant at the time of insertion (classified as medical removals). In one of the pregnancies after insertion by a doctor and three of the pregnancies after insertion by a nurse-midwife there had been expulsion of the loop, which was not noticed by the patient (classified as pregnancies).

Fig. 3 shows that there was a slightly but consistently greater cumulative rate of expulsion among women whose loops were inserted by nurse-midwives than among those treated by doctors. The greatest differences between the cumulative experience of the two groups occurred in the fifth, sixth, and seventh months of follow-up. There is a suggestion that a plateau of expulsions appeared in both treatment groups at the fourteenth month. The difference in the level of this plateau between groups was apparently small—of the order of 1%. Removal of the I.U.D. for both medical and non-medical reasons (Figs. 4 and 5) occurred with greater frequency among patients treated by doctors than among women whose loops were inserted by nurse-midwives. The experience in the two groups with respect to these variables seems to have been similar during the first six months of follow-up. From the seventh to the twelfth month, however, the two treatment groups diverged increasingly with respect to the incidence of medical and non-medical removals. There were apparent plateaux for each cause of removal in each group.

Fig. 6 shows that there was no consistent difference in the incidence of pelvic inflammation between the two groups until the thirteenth month, when they appeared to plateau at different levels—3.8% for the group treated by nurse-midwives and 4.7% for the group treated by doctors. In four women treated by nurse-midwives and six treated by doctors these inflammations necessitated loop removal (classified as medical removals).

The only other complications of loop insertion brought to our notice were two uterine perforations by the uterine sound occurring during insertion by nurse-midwives. In both cases the complication was recognized by the nurse-midwife herself and confirmed by a doctor before a loop was inserted. Neither patient developed clinical symptoms or required admission to hospital.

Discussion

The most notable deficiency in a field study such as this is the large number of patients lost to follow-up. We attribute the larger loss among women treated by nurse-midwives than among those treated by doctors to the fact that as a whole the group treated by nurse-midwives had a somewhat later starting date. This resulted in fewer women having received a written reminder to return for their annual check-up and Papanicolaou smear. There is no way of knowing whether those in the two treatment groups who were lost to follow-up differed from each other with respect to complication rates.

The differences noted between the two followed-up groups have not been subjected to statistical tests of significance. A test of significance would be relatively insensitive owing to the small sample size, and in addition there are no criteria to establish, *a priori*, the magnitude of difference that would be con-

TABLE II.—Comparison of Results of Tietze's Co-operative Study with those in Barbados. Net Rate per 100 First Insertions at End of One Year

	Tietze*	Barbados	
		Doctors	Nurse-Midwives
No. of women	7,814	500	500
Pregnancies (rate per 100)	2.4	2.0	2.0
Expulsions	8.7	8.9	9.7
Medical removals	13.2	9.9	6.4
Non-medical removals	2.8	5.1	3.4
Pelvic inflammation	1.7	3.8	3.5

* Based on Lippes loop D only (Tietze, 1966). The figures on pelvic inflammation are taken from another paper (Tietze, 1965).

FIG. 1.—Cumulative net I.U.D. retention rate by ordinal month after I.U.D. insertion. (Note that the follow-up period for physicians extends to the 19th month whereas that for nurse-midwives extends to the 16th month only.) FIG. 2.—Cumulative net pregnancy rate by ordinal month after I.U.D. insertion. FIG. 3.—Cumulative net expulsion rate by ordinal month after I.U.D. insertion. FIG. 4.—Cumulative net medical removal rate by ordinal month after I.U.D. insertion. FIG. 5.—Cumulative net non-medical removal rate by ordinal month after I.U.D. insertion. FIG. 6.—Cumulative net pelvic inflammation rate by ordinal month after I.U.D. insertion.

sidered clinically important in this setting. The differences which have been noted between the two groups, however, imply, firstly, that there was a higher incidence of pregnancy and a lower incidence of medical removal and non-medical removal of the I.U.D. among women treated by nurse-midwives than among those treated by doctors; and, secondly, that there were no striking differences between the two treatment groups with respect to the rate of expulsion of the loop or the rate of pelvic inflammation.

We are aware of only one previously published report of a similar use of paramedical personnel. Beasley (1967) compared 150 women who had I.U.D.s inserted by a nurse-midwife with 60 treated by doctors, and found that the group treated by nurse-midwives had a higher pregnancy rate but lower

removal and expulsion rates than the group treated by doctors. Various types of devices were used, however, and the follow-up period was short.

Table II compares the Barbados cumulative net rates at the end of one year of pregnancy, expulsion, medical removal, non-medical removal, and pelvic inflammation with similar rates recently published by Tietze (1966) from his large co-operative study. His treatment group consisted primarily of women attending University Hospital and Planned Parenthood Clinics in the United States and only 3% of its population were lost to follow-up. He reports a higher rate of medical removals, a lower rate of non-medical removals, and a lower rate of pelvic inflammation than the Barbados rates. There is little difference with respect to pregnancy and expulsion. The difference in removal rates may be attributable to our classification as non-medical the temporary removal of a loop for treatment of cervical neoplasia (a disease of high prevalence in Barbados).

The increased incidence of pelvic inflammation in Barbados is consistent with the high incidence of gonorrhoea in the West Indies. The relative similarity of our results to those of Tietze suggests that, although some complications undoubtedly occurred in Barbados among the women lost to follow-up, they have not been grossly underreported.

Though our findings indicate that the incidence of certain complications of loop use may differ between groups of women according to who inserts the loops, there are no discrepancies so wide as to contraindicate the insertion of the Lippes loop by paramedical personnel. Because many preindustrial nations which are inaugurating family planning programmes suffer from a relative shortage of doctors, a trial of paramedical personnel to insert the Lippes loop in other clinical and cultural settings appears to be justified.

It must be emphasized, however, that certain requirements must be met before the responsibility of I.U.D. insertion is given to

non-physicians. An adequate training course is essential. Doctor supervision must always be available; and follow-up visits, particularly, require the presence of a doctor at every clinic to evaluate the significance of complaints relating to the I.U.D. Regular and critical analysis of complication rates, as always, must be carried out.

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