A life table analysis technique for the evaluation of intrauterine contraceptive devices

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SUMMARY. Four hundred and seventeen patients in a single practice who were fitted with 562 intrauterine contraceptive devices (IUCDs) over a period of 13 years were surveyed prolictively. Three hundred and eighty-nine first time users of five principal types of IUCD were reviewed using a computer-derived life table analysis technique. In parous patients followed over a 10 year period, the Saf-T-Coil 33SX achieved significantly better overall results than any other type of device used. In nulliparous women using the Gravigard IUCD, no pregnancies occurred and removal for medical reasons such as infection appeared to be less frequent than in those using the Dalkon N Shield. Overall, this study did not show that device-related events, particularly infection, occurred significantly more frequently in nulliparous women. The relatively small cohort numbers and other undefined characteristics may account for this variance from other surveys.

Introduction

A major problem in achieving effective contraception is that of patient compliance. To ensure success, hormonal, barrier, chemical or rhythm methods of contraception all require a high degree of motivation and intelligent participation by the patient. Intrauterine contraception, on the other hand, is the only readily reversible method that is free of these constraints, and therein lies its appeal. The history and principles of action and design of intrauterine contraceptive devices have been well reviewed.[1]

Lippes Loops, Saf-T-Coils and Dalkon Shields (the latter two are no longer available in the United Kingdom) were the first generation of IUCDs, but these devices were inserted less often in the late 1970s with the introduction of medicated (copper-bearing) models (Gravigard, Gyne-T and Multiload Cu-250) which had the potential advantages of ease of insertion and lower incidence of side effects and which, theoretically, might be more appropriate for nulliparous women. The disadvantage of these new devices is that renewal is recommended after two to three years of use whereas the earlier inert plastic types could (in the absence of symptoms) be left in place for many years. Dalkon Shields were briefly in vogue in the early 1970s but were later withdrawn because of the risk of infection.

Traditionally, contraceptive method performance has been measured by the Pearl index,[2] which relates the number of events (method failures, specific complications, and so on) to the number of months per woman the method has been employed and is expressed in terms of 'events per hundred woman years'. Its main shortcoming, where IUCDs are concerned, is that the incidence of complications is not constant but declines exponentially with continuing usage. A more reliable method of evaluation[3] is the 'life table' approach applied originally by Potter,[4] developed subsequently for IUCDs, and described in detail by Tietze and Lewit.[5] Put simply,[6] this method, which is based on the collective experiences of various cohorts of women using particular devices, assesses the probability of defined events occurring at specific intervals after the fitting of the device. The results can be expressed either as nett cumulative event rates, when the calculated risk of a given event takes into account the risk of all other events, or as gross cumulative rates which look at the incidence of one particular factor irrespective of all other events. Nett rates are most useful for looking at the overall performance of one particular type of device; gross rates, on the other hand, will compare the occurrence of one particular event with different types of device in varying cohorts of patients ordered, for example, by age or parity. For this survey, the life table

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approach was used; the calculations used are, however, complex and laborious. It was fortunate, therefore, that a similar approach had been adopted in Oxford for the analysis of clinical trials requiring prolonged observation of patients[7,8] and translated into a survival analysis program available on Oxford University's ICL 2980 computer. This program not only enables analyses of percentage survival (Kaplan Meier) in either numerical or graphical form, but also the calculation of log-rank *P* values[9] to test the statistical significance of observed differences in performance and the validity of apparent trends. Moreover, retrospective stratification (for example, by age group, device type, parity, segment number, and so on) can be performed to evaluate the significance of events observed, taking into account the effect of other variables (nett cumulative event rates). The statistical basis of the system has been described by Peto and colleagues.[8]

In 1967 I sought training in the technique of inserting intrauterine contraceptive devices and thenceforth kept records of every IUCD insertion performed in my practice. This presentation is, therefore, a prolictive survey (a retrospective analysis of data collected prospectively) from that year until the end of 1980. The objectives of the survey were (1) to examine the outcome of IUCD usage in different user groups and (2) to compare the various types of device.

Method

Patients using an IUCD were included in the study on an *ad hoc* basis. Choice of this method of contraception was based on: failure of other methods of contraception; contraindications to, or side effects of, hormonal contraception; disaffection with barrier methods; or simply the patient's personal preference. Choice of device was determined by availability and prevailing fashion.

Details of patients and each IUCD episode were recorded on an edge-notched card.[10] Each patient was reviewed at least annually after IUCD insertion, until that particular segment (episode) of use had ended. The duration of use and reason for removal were then recorded. A new card was used for each successive segment.

Using the life table approach, the data held on the edge-notched cards were entered, via a coding sheet, onto 80-column machine-punched cards acceptable for computer input. Patients lost to follow-up and those using devices in small numbers (Lippes C, Gyne-T and Multiload Cu-250) were excluded. Moreover, since outcome variables could be influenced, and results thus biased by previous experiences with IUCDs, it was decided to run the main analysis on first segment users only. An exception to this rule was made in the case of the Gravigard device, where consecutive segments of use were linked when no device-related events (see below) had been experienced by users and devices had been changed routinely at two-year intervals. The main analyses therefore relate to a total of 389 first segments: 140 Saf-T-Coil 33S, 30 Saf-T-Coil 32SX, 35 Dalkon N, 95 Dalkon M, and 89 Gravigard devices.

In this survey, the outcomes were examined not only in relation to device types but also with reference to age group and parity of the users and the reasons for removal, categorized[5] into events that were device-related and events that were not related to the device. The device-related events were:

1. Accidental pregnancy (whether or not the device was *in situ*).
2. Expulsion of device (complete or partial; noticed or not).
3. Removal of device on account of pain or bleeding.
4. Removal for other medical reasons, for example, infection.

Events not related to the device were:

5. Removal to achieve wanted pregnancy.
6. Removal for personal reasons (for example, contraception no longer required because of divorce, menopause, vasectomy of consort, and so on).
7. Removal on doctor's decision (for example, policy removal of Dalkon Shields, routine changing of copper-bearing devices, and so on).
8. Release from study (for example, patient leaving the practice with the device *in situ*).

Table 1. Segment number by parity.

Parity	Segment					Total	Percentage
	I	II	III	IV	V		
0	115	20	3	1	—	139	*24.9*
1	112	19	5	1	—	137	*24.3*
2	114	46	11	4	2	177	*31.4*
3	52	18	5	1	1	77	*13.7*
4	12	5	1	—	—	18	*3.2*
5	12	2	—	—	—	14	*2.5*
Total	417	110	25	7	3	562	

Table 2. Segment number by device type.

Device type	Segment					Total
	I	II	III	IV	V	
Lippes C	1	2	—	—	—	3
Saf-T-Coil 33S	145	15	3	—	—	163
Saf-T-Coil 32SX	31	15	8	1	—	55
Dalkon N	38	2	—	—	—	40
Dalkon M	97	27	4	—	—	128
Gravigard	95	31	4	1	1	132
Gyne-T	4	13	4	5	1	27
Multiload Cu-250	6	5	2	—	1	14
Total	417	110	25	7	3	562

Results

Four hundred and seventeen women were fitted with IUCDs on 562 occasions. Patients' parity and number of device experiences (referred to as segments) are shown in Table 1. The types of IUCDs are shown in Table 2, again categorized by segment number. Parity of patients by device type is shown in Table 3.

Overall, 92 patients (43 first segment) were still using their devices at the end of the study (31 December 1980) and 10 patients had used the same device for more than 10 years.

Figure 1 shows device experience (nett cumulative continuation rates) over a 10-year period by event category. The remainder of this paper concerns only the examination of device-related events in the study.

1. *Accidental pregnancy.* Accidental pregnancy was the least common reason for termination of device usage. It did not appear to be related to age although no pregnancies occurred in the over 40 years age group. Neither parity nor device type revealed statistically significant differences, although no pregnancies had occurred in Gravigard users in up to five years of observation.

2. *Expulsion of the device.* Expulsion was the next least common device-related event. Only in this group was it possible to perceive significant trends both in relation to age group and parity of users. Continuation rates in respect of expulsion improved both with increasing age and with parity ($P=0.05$). No expulsions occurred after two years of use—a point of some practical importance when considering follow-up routine. Gravigard users appeared to be at greater risk of expulsion of the device; Dalkon users did not fare better than those fitted with Saf-T-Coils.

3. *Removal of device on account of pain or bleeding.* Pain and bleeding was the major reason for terminating device usage. No trend could be ascertained with relation to age, parity or device type. The Gravigard users fared as badly as any of the others.

4. *Removal for other medical reasons.* Broadly, this category represents episodes of infection related to device use. There was wide, and apparently random, variation with parity and between the different age groups and, surprisingly, nulliparous patients seemed to do no worse than those in the highest parity group.

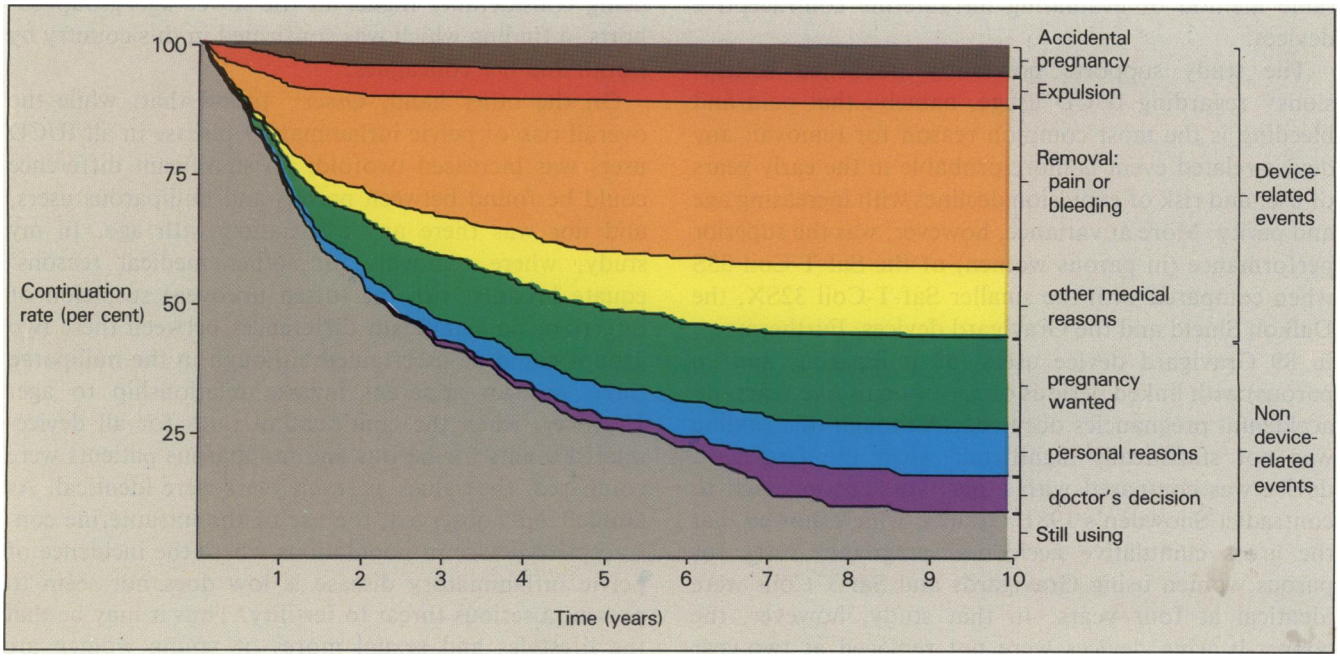
When all device-related events were aggregated, no statistically significant trends appeared with relation to age group or parity. However, when device types were compared (Figure 2), the less acutely sloping continuation plot for the original Saf-T-Coil 33S indicated a superior performance compared with the other four types (conditional χ^2 test for trend $=4.99$; $0.01<P<0.05$). The relatively poor performance of the Saf-T-Coil modification, 32SX, is difficult to explain.

The experiences of 102 nulliparous women in the study group were compared with those of 287 parous women. Accidental pregnancy occurred slightly less frequently and expulsion slightly more often in nulliparae, but these events were not statistically significant. Removal for pain and bleeding occurred more often in the nulliparous women in the first year of use but over a longer period the continuation rate was not affected. Similarly, continuation rates for all parous and all nulliparous patients of removal for 'other medical rea-

Table 3. All segments: device type by parity.

Device type	Parity						Total
	0	1	2	3	4	5	
Lippes C	—	2	—	—	1	—	3
Saf-T-Coil 33S	2	37	67	39	10	8	163
Saf-T-Coil 32SX	1	21	21	10	1	1	55
Dalkon N	39	—	1	—	—	—	40
Dalkon M	4	44	53	18	5	4	128
Gravigard	86	22	22	2	—	—	132
Gyne-T	5	7	10	3	1	1	27
Multiload Cu-250	2	4	3	5	—	—	14
Total	139	137	177	77	18	14	562

Figure 1. *Nett continuation rates by event category.*



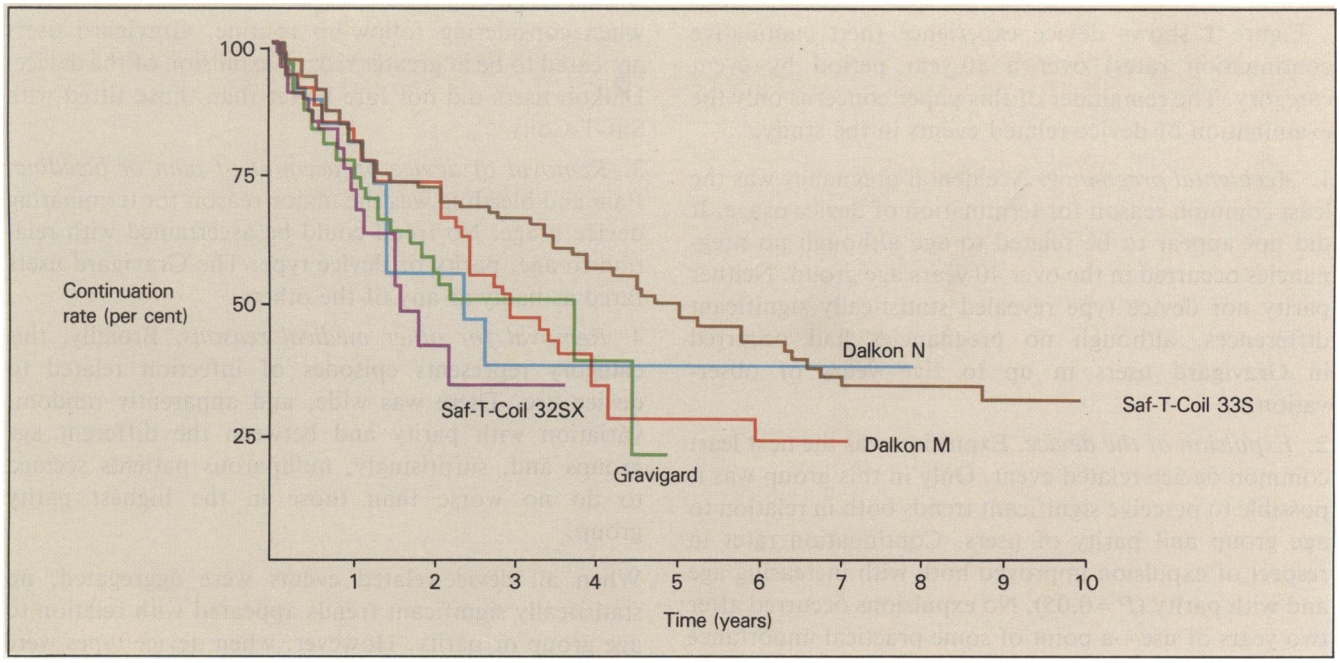


Figure 2. *All device-related events: by device type.*

sons' were not significantly different; however, when nulliparae were analysed by age group, the older cohorts fared considerably better than the younger. Finally, when nulliparous patients were surveyed by device type (35 Dalkon N and 63 Gravigard users), no statistically significant differences were found.

Discussion

The chief limitation of this type of survey in a single practice is the relatively small number of patients involved. This disadvantage is offset by the long period of observation of some of the contraceptive users, and it has been possible to illustrate the advantages of the life table method of evaluating intrauterine contraceptive devices.

The study supports previously published conclusions[11] regarding IUCD usage, namely: that pain and bleeding is the most common reason for removal; any device-related event is more probable in the early years of use; and risk of expulsion declines with increasing age and parity. More at variance, however, was the superior performance (in parous women) of the Saf-T-Coil 33S when compared with the smaller Saf-T-Coil 32SX, the Dalkon Shield and the Gravigard devices. Furthermore, in 89 Gravigard device users (63 nulliparous and 26 parous) with linked periods of use of up to five years, no accidental pregnancies occurred. Although this finding was not statistically significant when the Gravigard device was compared with other types, it appeared to contradict Snowden's 1981[12] results, which showed that the gross cumulative accidental pregnancy rates for parous women using Gravigards and Saf-T-Coils were identical at four years. In that study, however, the copper-bearing devices were not replaced at two-year intervals as they were in this survey. The results reported here seem to confirm those of Newton,[13] that regular replacement of this type of device lowers the incidence of accidental pregnancy.

A further contemporary problem with intrauterine contraception concerns the risk of pelvic inflammatory disease especially in the case of nulliparous women, for whom there might be a potential hazard to subsequent fertility. The literature abounds with conflicting opinions. In Weström's[14] series the increased risk of pelvic inflammatory disease in IUCD users was found to be three times that in parous non-users, and seven times as great in nulliparae. Gray,[15] using Weström's figures, showed that the risk in nulliparae was also age-related, being considerably higher in the lower age group cohorts, a finding which was confirmed in this country by Booth and her colleagues.[16]

On the other hand, Osser[17] found that, while the overall risk of pelvic inflammatory disease in all IUCD users was increased twofold, no significant difference could be found between parous and nulliparous users, and nor was there any association with age. In my study, where removals for 'other medical reasons' equate broadly with the (often uproven) suspicion of infection, no significant differences between these two groups could be ascertained although in the nulliparae there was an apparent inverse relationship to age. However, when the continuation rates for all device-related events for parous and nulliparous patients were compared, the values at seven years were identical. As Guillebaud[18] observed, the use of the intrauterine contraceptive device in populations where the incidence of pelvic inflammatory disease is low does not seem to present a serious threat to fertility. Thus it may be that the lifestyles and sexual mores of young women are

more important in this respect than the method of contraception employed.

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