

Long term use of inert intrauterine contraceptive devices in 94 women in Israel

LIORA DAFNI

ADA TAMIR

TOMAS SPENSER

SHEINE SPENSER

SUMMARY. A 22 year retrospective survey was undertaken in an Israeli family practice to determine how long inert (plastic only, unmedicated) intrauterine contraceptive devices could be safely left in place. Ninety four women were identified who had used 100 inert intrauterine contraceptive devices continuously for between five and 19 years. Fifty nine women complained of pain, increased uterine bleeding or increased vaginal discharge, but these were the reasons for removal of the device in only 32 women. There was only one case of pelvic inflammatory disease but this was treated without removal of the intrauterine contraceptive device. Of 14 women who requested to have their device removed after between five and nine years without having had any side effects, 11 women conceived within nine months. The results of the study indicate that inert intrauterine contraceptive devices can be safely left in place until the menopause. As it will take many years before the new type of copper devices can be shown to be as safe for long term use, it seems an appropriate time to reintroduce inert intrauterine contraceptive devices for women.

Keywords: intrauterine devices; long term use; long term outcome; contraceptive methods.

Introduction

THE inert (plastic only, unmedicated) intrauterine contraceptive device, among the first modern intrauterine contraceptive devices to be used, appeared on the market in the early 1960s. During the past decade its popularity has diminished following reported deaths from sepsis associated with the Dalkon shield® (Robins) intrauterine contraceptive device,¹ which was withdrawn from the market in 1975. Since then, all other inert devices have been gradually withdrawn in most countries because of fear of litigation, and have been largely replaced by devices containing copper wire, which are reported to result in a lower pregnancy rate.² Since 1975, papers have been published which have argued a convincing case for long term uninterrupted use of inert intrauterine contraceptive devices for between 10 and 15 years.³⁻⁶

In 1983 a 17 year retrospective survey of the use of intrauterine contraceptive devices was carried out in a defined rural population in Upper Galilee, Israel.⁷ The survey of 287 women

covered 1403 woman years of the use of 527 intrauterine contraceptive devices and showed the rates for accidental pregnancy, expulsion and removal for uterine bleeding and/or pain to be similar to those rates reported in the literature.⁸ Surprisingly, pelvic inflammatory disease was found to be considerably more frequent in women using copper devices (4.1% per 100 woman years of use) than in women using inert devices (0.9% per 100 woman years), independent of frequency of change. This finding differs from other findings reported in the literature.⁹ The survey included 58 women in whom inert intrauterine contraceptive devices had been in place continuously for between seven and 15 years, with no pregnancy or pelvic inflammatory disease.

The aim of this study was to follow up a group of women in the same practice as the earlier survey, whose inert intrauterine contraceptive devices had been in place continuously for five years or more, to establish the safety and efficacy of leaving inert devices in place for an unlimited period.

Method

The original practice covered patients from one Arab village, two moshavim (cooperative Jewish settlements) and three kibbutzim (communal settlements). The total population in 1983 was 3731 and included 942 women of childbearing age (18-55 years). A total of 287 women (30%) were identified who had ever used an intrauterine contraceptive device, using 527 devices. In the practice, family planning and follow up had been provided by the same two general practitioners since 1966 (T S and S S).

At the end of 1988 the files of all intrauterine contraceptive device users from three of the six original settlements (the Arab village and two kibbutzim) were reviewed (181 out of the original 287 women). Ten women had left the area and so were lost to follow up. Sixty four of the remaining 171 women (37%) were identified who had used an inert intrauterine contraceptive device continuously for five years or more prior to 1988 and data were extracted from their files. Of the remaining 106 women whose files were not reviewed in 1988, 30 (28%) had used an inert intrauterine contraceptive device for five years or more at the time of the 1983 survey and the data for these were added.

Data were collected on age, parity, type of intrauterine contraceptive device, length of use, side effects, reason for removal if removed, alternative contraceptive methods used and fertility after removal. Second devices used by women were excluded from parts of the analysis in order not to bias the outcomes.¹⁰ Life table analysis techniques were carried out using the statistical package for the social sciences (SPSSX) which is used in survival analysis. Here, it related to the survival of the intrauterine contraceptive device in the uterus. The percentage of women in whom the device survived at various points in time after insertion was calculated.

Results

The 94 women who were identified had used 100 inert intrauterine contraceptive devices continuously for between five and 19 years. The mean age of the 94 women at insertion of the intrauterine contraceptive device was 34 years (range 22-47 years). Twenty three women were aged between 22 and 29 years, 55 women were between 30 and 39 years, and 16 women were between 40 and 47 years. The mean parity of the 40 Arab women

L Dafni, MD and S Spenser, MB, general practitioners, Health Insurance Institution of the General Federation of Labour, Upper Galilee. A Tamir, PhD, statistician, Technion, Haifa. T Spenser, MB, FRCGP, senior lecturer in family medicine, Faculty of Medicine, Technion, Haifa, Israel. Submitted: 25 July 1991; accepted: 28 January 1992.

was six pregnancies (range two to 12 pregnancies); the mean parity of the eight Jewish women in the moshavim was six pregnancies (range three to 10); and the mean parity of the 46 Jewish women in the kibbutzim was three pregnancies (range 0 to five).

The percentage of the 94 first intrauterine contraceptive devices which had not been removed as a result of an 'event' associated with the device after between 60 and 180 months is shown in Figure 1. Removal for a non-intrauterine contraceptive device related reason, for example at the woman's request, usually for a further pregnancy, postmenopause, and routine exchange, was not considered as an 'event'. There was a steep fall in the percentage of devices remaining in place after between 60 and 108 months. The fall became less steep until 168 months, when it reached 37%. After that, only one device was removed for a medical event, at 226 months. Six women had used two separate intrauterine contraceptive devices for periods longer than five years but none of the second devices for longer than nine years. Seventy four of the devices were Lippes Loops® (Ortho) and 26 were Saf-T-Coils® (Schmid). The median time of use per device was 86 months, with an accumulated total of 805 woman years of use at the time of the survey.

Table 1 shows the outcome of the 94 first intrauterine contraceptive devices. Of the 27 devices still in place, 17 had been in place for between five and nine years, seven had been in place for between 10 and 14 years and three for between 15 and 19 years. Five of the devices removed after the menopause had been in place for between five and nine years, two for between 10 and 14 years and two for between 15 and 19 years. Bleeding and/or pain experienced between five and nine years resulted in 20 intrauterine contraceptive devices being removed, three were removed for bleeding and/or pain after between 10 and 14 years and one was removed after between 15 and 19 years. Where the other intrauterine contraceptive devices were removed, these were all removed after between five and nine years. Most of the intrauterine contraceptive device-related events (33) occurred between the fifth and ninth year of use, four events occurred between 10 and 19 years' use.

Eighteen women had had their intrauterine contraceptive

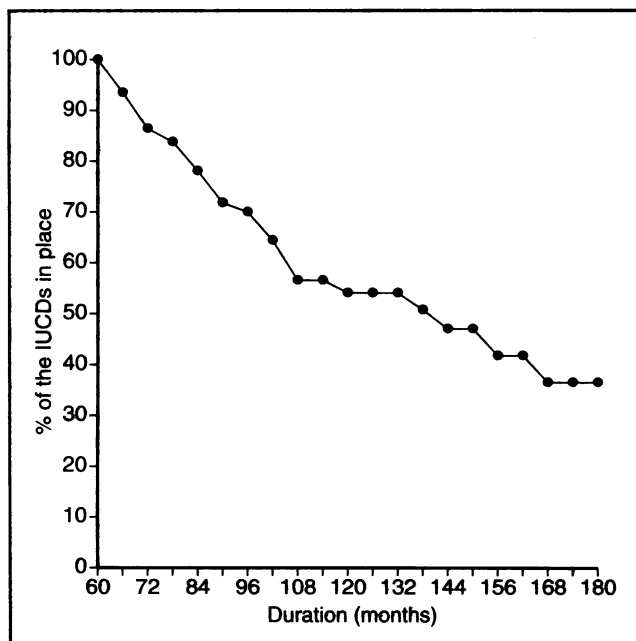


Figure 1. Percentage of the 94 first intrauterine contraceptive devices (IUCDs) which had not been removed as a result of an IUCD-related event between 60 months and 180 months after insertion.

Table 1. Outcome for the 94 first intrauterine contraceptive devices in place continuously for between five and 19 years.

	No. of intrauterine contraceptive devices
In place	27
Removed at woman's request	13
Removed after menopause	9
Removed for exchange for new device	8
Removed owing to intrauterine pregnancy	2
Expelled	1
Removed for bleeding/pain	24
Removed for vaginal discharge	8
Removed for other reasons ^a	2

^a One device found to be broken on x-ray and one woman found to have a pathological cervical smear (later found to be normal).

device in place for more than 10 years; of these, six had had it for 15 years or more. Of the six women, three still had their device at the end of the study, two had it removed after reaching the menopause and one woman had it removed owing to menorrhagia.

Fifty nine women complained of side effects associated with the use of the intrauterine contraceptive device — pain, increased uterine bleeding or increased vaginal discharge — but these were the reasons for the removal of the device in only 32 women, the other complaints usually being mild or temporary.

The one spontaneous expulsion occurred after eight years' use. The two pregnancies occurred after 60 and 82 months of use and were intrauterine. There was only one case of pelvic inflammatory disease and this was treated without removal of the intrauterine contraceptive device. In addition to the device which was removed after being found on x-ray to be broken, two other devices removed for other reasons were found to be broken.

In three cases, removal was difficult, suggesting embedding. In one of these cases the intrauterine contraceptive device, which had been in place for 15 years, had to be removed by curettage. There was no difference in the rate of complications between the two types of device used.

Of all the 100 devices used, on 70 occasions 66 women had their intrauterine contraceptive device removed. Of these, 27 women went on to use a different method of contraception. Ten women were postmenopausal. Of the 14 women who requested to have the device removed after between five and nine years without having had any side effects, 11 women conceived within nine months (no information was available on the remaining three women).

Discussion

An extensive literature search revealed few reports on long term follow up of intrauterine contraceptive device use, the most recent reports being by Senanayake¹¹ and Edelman and colleagues.¹² Kaye and colleagues were among the first to report that leaving an intrauterine contraceptive device in place continuously for 10 years or more did not appear to be associated with increased morbidity or mortality.³ Pollock supports this view and reported inert devices having been safely left in place for 15 years.⁴ Edelman and colleagues agreed that there appeared to be no need to remove unmedicated devices routinely from asymptomatic women.¹²

The literature is unanimous in reporting that adverse device related events are commonest in the first two years of use.⁹ Our previous findings confirm this view.⁷ Indeed, this fact is a

major problem in comparing intrauterine contraceptive device performance in long term and short term studies. Bull stated that the traditional method of expressing performance in terms of events per 100 woman years was misleading in long term studies, as the incidence of complications declined exponentially with continuing usage.⁵ The 'life table' approach was therefore more reliable, expressed as a cumulative event rate and this is now standard practice.⁶ Figure 1 shows a survival diagram for the 94 first intrauterine contraceptive devices.

Eleven out of 14 women who requested to have their intrauterine contraceptive device removed in order to have a baby were known to have conceived within nine months. This finding confirms Randic and colleagues' view that fertility after removal of the intrauterine contraceptive device is not impaired, even after long term use, and that the only variable which seemed to affect conception rates was age.¹³ Side effects, including pain, uterine bleeding and vaginal discharge, from the 100 intrauterine contraceptive devices which had been in place for five years or more were relatively more commonly reported than side effects from the 527 devices, irrespective of length of use, in our 1983 study (59% compared with 23%).⁷ However, of the women reporting side effects after five years or more of use, 54% had the intrauterine contraceptive device removed for those reasons, compared with 78% in the 1983 study. This suggests that those women who wish to keep their device are motivated to put up with more discomfort, encouraged by being told that serious complications, such as pregnancy and pelvic inflammatory disease, are more rare the longer the device is in place.

Because of the virtual absence of pelvic inflammatory disease (only one case) in this study women were not investigated for actinomyces-like organisms. Cervical smears were not performed routinely in the practice because of the relative rarity of cervical cancer in Israel, its annual age adjusted incidence being less than four per 100 000 women during the years 1977-81 and its death rate being less than 2 per 100 000 women during the years 1981-87 (Central Bureau of Statistics, Jerusalem, Israel, 1990).

There has recently been a trend among authorities, as yet unsupported by firm data, suggesting that copper bearing intrauterine contraceptive devices may also be left in place as long as they are needed, despite the manufacturers' recommendations that they should be removed after not more than five years. This trend is based on the solid body of opinion that the risks of reinsertion outweigh by far the risks of leaving the intrauterine contraceptive device in place.¹⁴

The findings from this study show that inert intrauterine contraceptive devices can safely be left in place until the menopause if there are no problems, or if the woman so wishes despite any side effects. Whether or not any of the latest type of copper devices will be as safe for long term use will only be known in 20 years' time. This, together with the previous finding that pelvic inflammatory disease is considerably less common in inert than in copper devices, may suggest that this is an appropriate time to reintroduce inert unmedicated intrauterine contraceptive devices for women.

References

1. Cates W, Ory HW, Rochat RW, Tyler CW. The intrauterine device and deaths from spontaneous abortion. *N Engl J Med* 1976; **295**: 1155-1159.
2. Sivin I, Schmidt F. Effectiveness of IUDs: a review. *Contraception* 1987; **36**: 55-85.
3. Kaye BM, Reaney BV, Kaye DL, Edelman DA. Long-term safety and use-effectiveness of intrauterine devices. *Fertil Steril* 1977; **28**: 937-942.
4. Pollock M. Letting intrauterine devices lie. *BMJ* 1982; **285**: 395-396.
5. Bull MJV. A life-table analysis technique for the evaluation of intrauterine contraceptive devices. *J R Coll Gen Pract* 1983; **33**: 403-407.
6. Edelman DA. IUD complications in perspective. *Contraception* 1987; **36**: 159-167.
7. Dafni L. *A long term follow-up of women using intrauterine devices in a defined rural community* [MD thesis]. Israel: Tel Aviv University, 1984.
8. Presley AP. An audit of intrauterine device use and outcome in general practice. *Practitioner* 1980; **224**: 1089-1091.
9. Anonymous. *Population reports. Intrauterine devices (series B, number 5)*. Baltimore, MD: John Hopkins University, 1988.
10. Tietze C, Lewit S. Recommended procedures for the statistical evaluation of intra-uterine contraception. *Stud Fam Plan* 1973; **4**: 35-42.
11. Senanayake P. IUDs: a global review. *Br J Family Planning* 1990; **15**: 8-12.
12. Edelman DA, Porter CW, van Oss WAA. When should intrauterine devices be removed and replaced? *Br J Family Planning* 1991; **16**: 132-138.
13. Randic L, Vlastic S, Matrljan I, Waszak CS. Return to fertility after IUD removal for planned pregnancy. *Contraception* 1985; **32**: 253-259.
14. Guillebaud J. Intrauterine devices. In: *Contraception — your questions answered*. Edinburgh: Churchill Livingstone, 1989.

Acknowledgements

We are grateful to Leon Epstein and to John Guillebaud for their advice.

Address for correspondence

Dr T Spenser, Kibbutz Sasa, Galilee 13870, Israel.

RCGP

Courses
and
conferences



JOINT CONFERENCE BETWEEN THE
FACULTY OF PUBLIC HEALTH
MEDICINE AND THE
ROYAL COLLEGE OF GENERAL
PRACTITIONERS

**WHOSE HEALTH?
— THE INDIVIDUAL'S
OR THE
POPULATION'S?**

Wednesday 10 February 1993

The changes brought about by the NHS and Community Care Act 1990 present enormous challenges and opportunities for general practitioners and public health physicians to improve the population's health. The aim of this conference is to advance understanding between public health physicians and general practitioners of their respective roles in the promotion of health.

The conference will focus on four main themes of common concern and interest: purchasing for quality, health promotion, care in the community, and the use of annual reports to assess population health and health care needs. A space in the programme will be maintained for issues which may emerge prior to the date.

The themes will be discussed by a pair of speakers representing each specialty's perspective. In the case of care in the community, the dialogue will be enhanced by an expert adviser to the government.

The fee for the day is £85.00 including lunch and papers.

For further details please contact the Corporate Development Unit, Royal College of General Practitioners, 14 Princes Gate, Hyde Park, London SW7 1PU. Tel: 071-823 9703. Fax: 071-225 3047.