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Long-term experience with Multiload intrauterine devices

H.E. VAN KETS (1), M. THIERY (1), H. VAN DER PAS (1) and T.O.M. DIEBEN (2)

(1) Department of Obstetrics, University Hospital, B-9000 Gent, Belgium
(2) Scientific Development Group, Organon, Oss, The Netherlands

Abstract

This paper reports the joint experience of three investigators who used three types of the Multiload (ML) IUD (MLCu250 Short, MLCu250 Standard, and MLCu375) in 1987 consecutive insertions during which an experience of 56 005 woman-months of use was accumulated. The material was analyzed using the life-table method and complemented with a case by case investigation, the main purpose of the study being the specific analysis of IUD-related complications. The authors also evaluated return of fertility whenever a device was removed because of wish of pregnancy.

Results indicate that serious IUD-related complications were rare, continuation rate high, and reversibility of fertility unaffected by the device.

Introduction

During the past decade an ever-increasing list of IUD-related side-effects and complications has been publicized [1,2]. Myths and facts, closely knit together, have found their way into the lay press. This prompted us to ascertain for ourselves the efficacy, the acceptability and more specifically the incidence of complications associated with this contraceptive method and in particular with the use of IUDs belonging to the Multiload (ML) family.

Our files contained a series of 1987 consecutive insertions of one of the following ML devices: the MLCu250 Standard, the MLCu250 Short and the MLCu375. This material was elaborated in two ways. First, a classical life-table was obtained according to the Tietze and Lewit method [3]. Second, each individual insertion and termination (removal of the IUD) was scrutinized for possible complications. A number of women requested the removal of their IUD wishing a new pregnancy and we took advantage of this opportunity to study the reversibility of the method, i.e. the return of fertility.

Patients and methods

Between November 3, 1974 and February 2, 1986, a total of 1987 women were fitted – upon their request – with an ML IUD, 1402 women receiving an MLCu250, 379 an MLCu375, and 206 an MLCu250 Short device. No distinction has been made in this study among these three models since the authors – who have published in detail about the individual types – could not demonstrate significant differences in performance [4–12]. The total experience amounted to 56 005 woman-months of use.

All the insertions were carried out by three gynecologists (H.E.V.K., M.T., H.V.D.P.) with long-standing experience in intrauterine contraception. The study was confined to private patients because experience had shown that the follow-up of these individuals is much better than is the case with an average out-patient clinic population. Every insertion of an ML IUD occurring during the study period was included, with no exception.

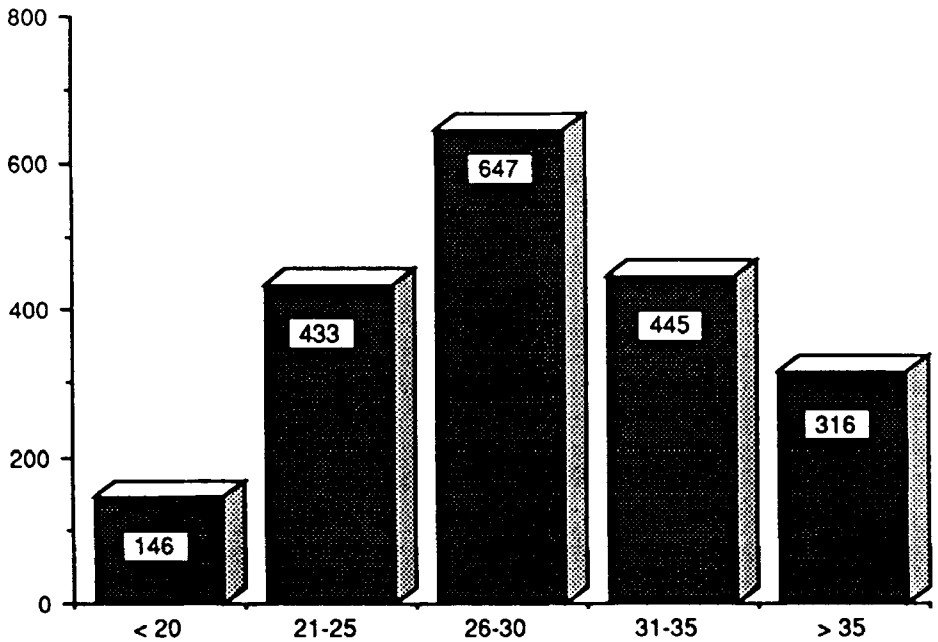

Figure 1 Distribution of patients (n = 1987) according to age group at admission

Recipients were scheduled for check-up one, three, and six months after insertion and at yearly intervals thereafter. At each visit they were thoroughly questioned and a pelvic examination was performed. Both at insertion and at each follow-up visit a specially designed data sheet (type: Population Council NY) was filled in and fed into a computer for life-table analysis. Every individual insertion, follow-up and

termination (removal of the IUD) was later reviewed by one of the authors (T.O.M.D.) for assessment of IUD-related complications. A search was made in every case of removal 'wanting pregnancy' to evaluate the reversibility of the method.

Most of the insertions were performed in the outpatient premises of each of the three gynecologists, during or after menstruation (interval insertion, n = 1544) using the push-in technique after disinfection of the vagina and cervix. Before insertion the depth of the uterus was measured with a sound while steadying the cervix with a vulsellum. Some of the insertions were completed within ten minutes after the expulsion of the placenta (immediate postplacental insertion or IPPI, n = 433). This procedure is well tolerated by our population [13,14].

The candidates for an IUD were selected according to the following criteria. Inclusion criteria: subjects of fertile age, sexually active and at risk for pregnancy, who gave voluntary informed consent and who agreed to supply follow-up data and return for a check-up visit at least once a year. Excluded were subjects with acute genital infection or a history of PID, subjects who were possibly pregnant, and subjects with anatomical abnormalities of the uterus or with a sound length of less than 6 or more than 9 cm.

Age and parity distribution of the recipients is shown in Figures 1 and 2. It should be noted that the percentage of nulliparous women amounted to 16.4 (n = 325) of the entire study population.

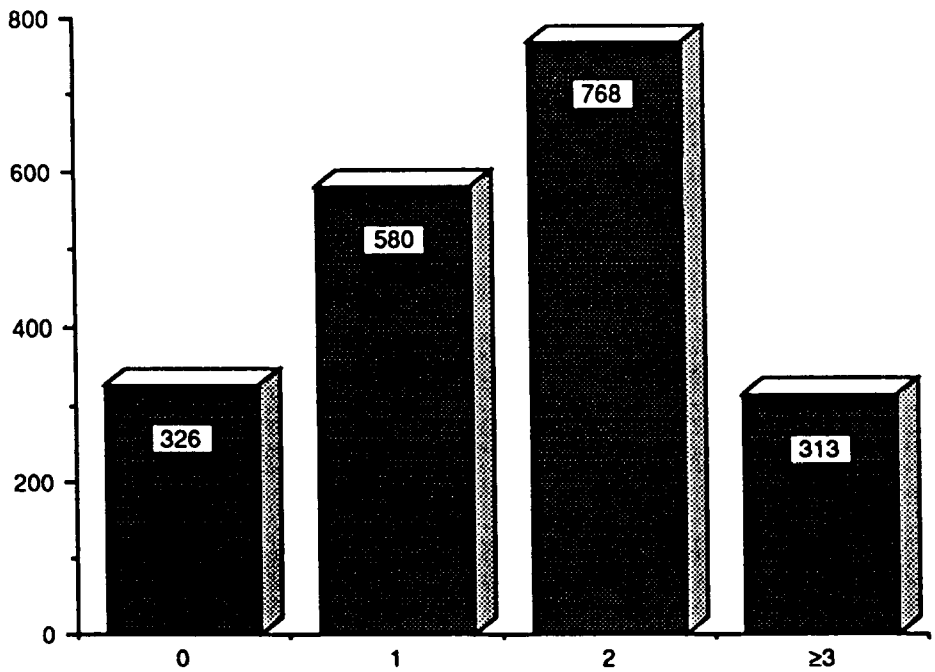

Figure 2 Distribution of patients (n = 1987) according to parity at admission

Results

Life-table

As already mentioned, no distinction has been made between the various Multiload models. Table 1 gives the gross cumulative event rates at twelve-month intervals during the first three years of use.

In principle, IUDs were retrieved after 36 months of use, according to prescription rules. Some women, however, requested – after being informed – to keep their device for a longer period, usually because they were considering a sterilization in the near future or were approaching menopause. This practice appears safe, as the copper wire usually lasts longer than the anticipated three years [15].

Table 1 MLCu250, MLCu375 and MLCu250 Short: gross cumulative termination rates/100 users at 1, 2 and 3 years of use. Confidence limits at 95% level in parentheses

	One year	*Two years*	*Three years*
Number of subjects	1569	1245	953
Woman-months of use	20 834	37 186	50 226
Events			
Pregnancy	1.0 (0.5–1.5)	2.5 (1.7–3.4)	3.5 (2.5–4.5)
Expulsion	3.5 (2.7–4.4)	5.3 (4.2–6.4)	5.9 (4.7–7.0)
Removal for:			
– bleeding, pain or both	4.4 (3.4–5.4)	7.6 (6.3–8.9)	10.4 (8.8–11.9)
– other medical reasons	0.6 (0.2–1.0)	1.1 (0.5–1.6)	1.7 (1.0–2.4)
– planned pregnancy	5.6 (4.5–6.7)	12.5 (10.8–14.1)	17.3 (15.4–19.2)
– other personal reasons	1.7 (1.0–2.3)	4.1 (3.1–5.1)	7.0 (5.6–8.4)
– investigator's choice	0.8 (0.4–1.2)	1.4 (0.8–1.9)	16.5 (14.2–18.7)
Continuation rate	82.4	65.5	37.7
Lost to follow-up	6.7 (5.6 –7.9)	9.3 (7.9–10.6)	11.6 (10.0–13.1)
Released from study	0.1 (0.0–0.4)	1.0 (0.5–1.5)	1.7 (1.0–2.4)

Individual case studies

Since the life-table method gives only rates, it was decided to study the material in more detail, and every one of the 1987 insertions was reviewed individually.

Table 2 gives the reasons for IUD removal in 1887 terminations. One hundred women were still wearing the device at the cut-off date (June 30, 1987).

In Table 2 a distinction is made between non-use-related ($n = 1500$ or 79%) and use-related terminations ($n = 387$ or 21%).

Table 2 Reasons for removal of the IUD (1887 terminations)

	n	%
Non-IUD-related terminations		
Investigators choice	801	42.2
Wishing to become pregnant	290	15.3
Released from study	29	1.5
Lost to follow-up	204	10.8
Elective sterilization	119	6.3
Unintentional IUD retrieval	2	
Menopause	18	1
Surgery on genital tract	6	
No longer sexually active	2	
Patient died	2	
Other personal reasons	27	
Total	1500	79
IUD-related terminations		
Pregnancy – with IUD *in situ*	49	2.6
– after expulsion	6	
Expulsion	103	5.5
Bleeding	115	6
Pain	45	2.4
Bleeding and pain	42	2.2
PID	8	
Intrauterine translocation	6	
Uterine perforation	1	
Failed insertion	1	
Alleged allergy to copper	1	
Increased vaginal discharge	4	
Discomfort for husband	1	
Vague abdominal complaints	5	
Total	387	21

Non-IUD-related terminations

Removals at the investigator's choice were invariably removals after an uneventful *in situ* period of three years or more ($n=801$).

Removal for wish of pregnancy is the next important group ($n=290$) and the follow-up of these women demonstrates that they conceived after a lapse of time not different from that of women who never used an IUD. Table 3 shows the interval between the removal of the device and the onset of pregnancy. Remarkably, 39 women conceived immediately, i.e. during the very cycle the device was removed. These results are not different from those reported by other investigators [15–20].

Twenty-nine women were released from the study, mainly because they have moved away. Inevitably in a large city, 204 other women were lost to follow-up.

Two devices were unintentionally retrieved by a physician who – unaware of the presence of the IUD – eagerly exerted traction on the strings protruding from the cervix.

Table 3 Return of fertility after removal of the IUD for planned pregnancy ($n=290$)

Months after IUD removal	*Number of conceptions*
0	39
1	58
2	42
3	26
Subtotal	165
4	16
5	6
6	9
7	9
8	8
9	3
10	1
11	4
12	4
13 – 30	10
>30	2
Pregnancies, interval known	237
Pregnancies, interval unknown	4
Total pregnancies	241
	Number of women
No pregnancy:	
follow-up until 9 months after removal; LFU	1
follow-up until 29 months after removal; LFU	1
follow-up until 24 months after removal	1
follow-up until 36 months after removal	1
no pregnancy, azoospermia	1
no pregnancy, change of mind	8
lost to follow-up	36

LFU = lost to follow-up

Eighteen were removed after menopause and six others were retrieved during surgery on the genital tract: hysterectomy for carcinoma *in situ* of the cervix ($n=1$), oophorectomy for breast cancer ($n=1$), tubal ligation during ovarian cystectomy ($n=1$), and conization for abnormal cytological findings ($n=3$). Elective tubal ligation accounted for 119 removals. Two women lost their partner and requested the IUD to be taken out, one woman died in a traffic accident, and one was killed criminally. Indications of removals for other personal reasons ($n=27$) ranged from philosophical

considerations (the woman or her partner considered the IUD to be an abortifacient) to objections to the idea of having to wear a foreign body.

IUD-related terminations

Pregnancy and/or expulsion. In this series totalling 1987 insertions, 49 pregnancies occurred with the device *in situ* and six others after expulsion unnoticed by the wearer. Most expulsions ($n = 103$) were not followed by conception.

None of the six pregnancies associated with expulsion was ectopic. In women conceiving with the IUD *in situ*, devices were removed as early as possible by gentle traction on the strings or by hysteroscopy. In one case the device could be removed only at delivery, following an uneventful course of gestation. The evolution of 49 pregnancies with IUD *in situ* is given in Table 4.

It should be noted that 44 of the 109 expulsions (40%) occurred after immediate postplacental insertion, a timing of insertions which represents but 22.3% of the total of insertions. In 12 women expulsion was a recurrent phenomenon.

Table 4 Follow-up of pregnancies with Multiload MLCu IUD *in situ* at conception ($n = 49$)

Ectopic pregnancy	8
Normal pregnancy	17
Spontaneous abortion	11
Interruption of pregnancy	12
Lost to follow-up	1
Total	49

Bleeding and/or pain. As in other large-scale studies [20] bleeding was the main indication for discontinuation of the method and 115 terminations were based upon bleeding alone and 42 on combined bleeding and pain. Pain accounted for 45 removals of the IUD (Table 2).

Pelvic inflammatory disease (PID)

Eight cases of PID were observed in this series and this rate of 0.4% does not differ significantly from the incidence of PID in the population at large [21,22]. It should be mentioned here that the incidence of genital and/or sexually transmitted diseases is low in our population [23,24].

All patients who developed PID were parous: three had one child and five had two. In six of the eight cases the diagnosis of PID was made on clinical (fever, pain) or biological (sedimentation rate, white cell count, C-reactive protein) data and did

respond so well to conservative treatment with antibiotics and rest in Fowler position that neither surgery nor laparoscopy was justified. Four of these patients later underwent a laparoscopic sterilization and no sequelae of a pelvic infection could be visualized at the time of operation.

The remaining two cases of PID required laparotomy and in both bilateral tubo-ovarian abscesses were found, 12 and 32 months after insertion of the IUD, respectively. After hysterectomy and bilateral salpingectomy both patients made an uneventful recovery.

Intrauterine translocation of IUD

In six women (0.3%) the device had somersaulted or was found in transverse position within the uterine cavity at the time of retrieval. Although numerically unimportant, this phenomenon, which occurs more after IPPI than after interval insertion, apparently does not affect contraceptive efficacy nor does it lead to erosion (and perforation) of the uterine wall.

Uterine perforation. Perforation through the dorsal aspect of the isthmus at insertion occurred once (0.05%) and was diagnosed immediately. Removal of the IUD posed no problem and an ML IUD was inserted successfully one month later.

Failed insertion (0.05%). In one other case, the operator could not pass the loaded inserter tube through the uterine isthmus and further attempts at insertion were abandoned.

Removal for other medical reasons included one case of unproven allergy for copper, four women complaining of increased vaginal discharge and one subject whose husband complained of feeling the strings during coitus. The remaining five removals were based on vague complaints.

Discussion

In the present analysis no distinction has been made according to timing of the insertion, i.e. interval insertion *vs* IPPI, a fact which by necessity must have influenced our expulsion rates.

Based on a randomized selection of several studies, Tatum and Connell [25] made a comparison of reasons for discontinuing the use of various IUD models. The annual discontinuation rates calculated by these authors are presented in Table 5, together with the results from our study. Since the rates of the other devices were derived from a variety of sources and different populations, they should be considered as relative values. Even so, the use-related event rates for the Multiload IUDs rank among the lowest for copper-containing devices.

In our uninterrupted series of 1987 insertions (56 005 women-months of use) of three ML IUD models by three trained gynecologists, serious complications were limited to eight cases of PID and a single eventless perforation diagnosed at the time of insertion.

The main medical indications for termination of IUD use were pregnancy, expulsion and bleeding with or without pain. In women who had their IUD removed for wish of pregnancy, reversibility of fertility was no different from that in non-users.

Table 5 Annual discontinuation rates for various types of IUD per 100 women per year in studies lasting two years [25]

IUD	*Pregnancy*	*Bleeding/pain*	*Expulsion*	*Continuations*	*Number of women*
TCu200	1.9	6.8	3.3	62.1	5669
Cu7 200	3.1	6.7	8.7	54.1	2330
TCu380Ag	0.6	9.1	4.1	56.9	1051
NovaT200Ag	0.7	7.8	2.9	65.0	961
Multiload (present study)	1.3	3.8	2.7	65.5	1245

Conclusions

A correctly inserted IUD is at this stage of our knowledge a valuable asset in the range of available contraceptive methods offering efficacy, safety and reversibility with acceptable risks to health.

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Resumé

Cet article rapporte l'expérience de trois investigateurs avec trois types de DIU Multiload (MLCu250 court, standard et MLCu375) dans une série consécutive de 1987 insertions et un total de 56.005 cycles. Le matériel a été analysé en faisant usage des tables-vie, complété par une investigation de chaque cas, le but principal étant cependant l'évaluation de complications relatives au port du DIU. Les auteurs ont également analysé la réversibilité de la fertilité après retraît pour désir d'une nouvelle grossesse. Les résultats indiquent que les complications sérieuses dues au DIU étaient rares et le taux de continuation élevé. Apparemment le retour de la fertilité n'était pas influencé par le port d'un DIU.

Resumen

En este trabajo se informa sobre la experiencia conjunta de tres investigadores que emplearon tres tipos de dispositivo intrauterino Multiload (ML) (MLCu250 Short, MLCu250 Standard y MLCu375) en 1.987 inserciones consecutivas, durante las cuales se registró una experiencia de 56.005 meses-mujer de uso. El material se analizó utilizando el método de tabla de vida y se complementó con un estudio de cada caso individual; el objetivo principal del estudio fue el análisis específico de complicaciones relacionadas con el empleo del DIU. Los autores evaluaron asimismo el retorno de la fecundidad cuandoquiera que se retirase un dispositivo debido al deseo de la mujer de quedar ambarazada.

Los resultados indican que rara vez hubo complicaciones graves relacionadas con el empleo del dispositivo, que la tasa de continuación fue alta y que la reversibilidad de la fecundidad no se vio afectada por el dispositivo.