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Extended Use of a Copper Intrauterine Device Beyond Theoretical Effectiveness

A ten-year study on the Multiload Cu-250 in a gynecologic private practice in Indonesia with specific reference to its use in the national family planning and population program

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ABSTRAK

Pemakaian IUD Bertembaga dalam waktu lama melewati masa efektip teoretis tidak menggganggu efektifitasnya untuk mencegah terjadinya kehamilan. Hal ini disimpulkan dari penelitian selama sepuluh tahun meliputi 52 pasien praktek spesialis pribadi yang setuju untuk terus menggunakan Multiload Cu-250 tanpa ganti setelah pemakaian selama tiga tahun yang merupakan batasan masa pakai efektip teoretis bagi jenis IUD ini. Lama pemakaian tercatat berkisar antara 36,08 sampai 100,51 bulan, sedangkan rata-rata pemakaian adalah 52,10 bulan. Sebanyak 25 (48,07%) wanita memakainya selama 3—4 tahun, 19 (36,53%) selama 4—5 tahun dan 9 (17,30%) selama 6—7 tahun. Pemakaian terlama tercatat pada 4 wanita selama 77,60; 72,48; 92,72 dan 100,51 bulan. Tidak terjadi satu pun kegagalan kehamilan dalam kelompok penelitian ini. Kelompok pembanding terdiri atas 63 wanita pemakai jenis IUD yang sama selama waktu kurang dari tiga tahun dan berasal dari praktek pribadi yang sama. Gangguan subyektip, perdarahan, kelainan haid dan ekspulsi tidak menunjukkan peningkatan frekuensi yang berarti. Sebaliknya, infeksi panggul dan sekresi vaginal yang berlebihan bertambah sering secara bermakna, meski masih dalam derajat yang ringan dan mudah teratasi. Bisa pula dipahami bahwa terjadi lebih banyak permintaan untuk melepas IUD karena ingin hamil lagi. Karena Multiload Cu-250 sudah terpilih sebagai IUD Bertembaga utama yang digunakan dalam program keluarga berencana nasional di Indonesia, hasil penelitian ini dapat bermanfaat dalam kaitannya dengan masalah kontinuasi pemakaian, keamanan, efektifitas, penghematan biaya dan penyediaan peralatan, baik dari segi kepentingan pemakai maupun dari segi kepentingan program. Dalam penelitian lain yang sedang berjalan hasil-hasil ini akan dibandingkan dengan kelompok pemakai lain yang berganti IUD setelah usai masa efektip teoretis tiga tahun. Dianggap perlu diadakannya penelitian-penelitian lain dalam lingkup epidemiologik lapangan yang lebih luas dengan kondisi klinis medis yang mungkin tidak selalu optimal.

Key Words: copper intrauterine device — family planning — Multiload Cu-250 — demography — gynecology

INTRODUCTION

Family planning services in Indonesia have made enormous strides since the introduction in the mid-sixties of oral contraceptives and the first generation of modern-day intrauterine devices (IUD, IUCD; *Alat Kontrasepsi Dalam Rahim,* AKDR). Sponsored initially by a private organization (*Perkumpulan Keluarga Berencana Indonesia,* PKBI, founded in 1957), these contraceptive technologies

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have gained popular acceptance with their adoption into its official program by the National Family Planning Coordinating Board (*Badan Koordinasi Keluarga Berencana Nasional,* BKKBN, established in 1970). Further widespread endorsement and services by the medical profession working in clinic and private practice have enhanced the IUD use. By 1985, 27 per cent of contraceptive users in Indonesia chose to use the IUD compared with only 11 per cent ten years before. This shift to IUD preference resulted in a corresponding drop in pill use from 70 per cent to 55 per cent (Marsidi Judono, 1985). With certain groups of women and doctors the IUD has even attained top selection.

The importance of IUD role in the national family planning and population program is becoming more obvious, considering the magnitude of existing constraints relative to the big population size of the country (165 million, of which 83 per cent is rural, 20—25 per cent illiterate, and around 30 per cent living below poverty line), and the extensive area to be covered (13 000 islands, 1.9 million km^2), with inadequate numbers of medical and paramedical personnel and logistical supplies compounding problems.

The first generation Lippes Loop is the IUD which is mainly being used in the national program, approximately 10 million so far. In 1978 the second generation copperized types of IUDs came into use in an effort to overcome some of the problems experienced with the Lippes Loop such as high expulsion and low continuation rates, their numbers amounting now to around 1½ million Copper T and 2½ million Multiload. The ML Cu-250 has now became the first choice copper IUD as issued by the BKKBN (Marsidi Judono, 1985). Other types of active IUDs are also available commercially enabling wider choice with acceptors and service providers in private practice.

The copper IUDs are expected to be more effective compared to the inert types in preventing pregnancy, ascribing this to their increased chemotactic and gametotoxic properties. With the passage of time, however, decreasing amounts of released ionized copper may lead to decreasing efficacy, inducing the widely recommended practice of removing and replacing the IUD with a fresh one at the end of its theoretical effective lifetime of 2—3 years (Davis, 1971). Ease of removal and insertion with the usualy smaller sized copper IUDs seems to contribute to acceptance of this practice. However, it should be noted that such procedure might cause in not too seldom a case renewed anxiety, cost and possible complications on the part of the woman, aside from the additional time and expense on the part of the service provider. Furthermore, as reported by many researchers (Zipper, 1977; Edelman *et al.*, 1979; Sivin & Stern, 1979; Thiery *et al.*, 1980; Gobeaux-Castadot *et al.*, 1981; Larson *et al.*, 1981), continuing efficacy for a minimal of four years has been proven, when in variance to the replacement routine the copper IUD is being retained in utero.

The Multiload. The ML Cu-250 is claimed to be a third generation intrauterine contraceptive device with specific morphologic design resulting in augmented fundal-seeking effect and therefore improved retentional characteristics. Made from polyethylen with 27 mm length of 0.3 mm diameter copper wire wound for 3.6 cm on its stem, it provides 250 mm^2 copper surface area. It has a recommended theoretical effectiveness of three years (Manufacturer's product

leaflet[1]). Another type, the ML Cu-375 with 375 mm² copper surface area is recommended for five years usage.

PURPOSE OF STUDY

The present study was meant to look into the clinical or use effectiveness of the ML Cu-250 when used beyond its declared theoretical effectiveness of three years. The underlying thought was that if the ML Cu-250 could be retained for a longer period of time beyond this three-year limit with sustained efficacy, such regimen would present distinct advantages in terms of comfort, continuation of use, financial commitment and valuable time for both the patient and the busy doctor. Furthermore, it would lessen possibilities of inducing infection, trauma and other kinds of complications, which clearly tend to increase with each removal and reinsertion of IUDs, the more so when performed in one session. Findings are expected to be of relevance to the national program.

MATERIALS AND METHODS

Records of patients from the author's gynecologic private practice seen during a ten-year period from 1 January 1977 to 31 December 1986 provided the materials for this study. Users of ML Cu-250 for three years or longer (the study group) were scrutinized for age, parity, date of insertion, length of usage, complications and other sequelae. Data obtained are clinically and statistically compared with data from another group of ML Cu-250 users from the same practice with less than three years usage, seen between 1 January 1984 and 31 December 1986 (the control group).

Except for two cases all women from both the study and the control groups were fitted with their ML Cu-250 IUDs by the author himself, either in their late postpartum or early interval periods using the same criteria for indications and contraindications. A standard regimen of pre-insertion history taking and pelvic examination, aseptic and antiseptic insertion technique, and post-insertion antimicrobial and antispasmodic preventive medication was used throughout. Patients were seen one week after insertion, one month thereafter, and with varying degrees of compliance at three-month intervals when an overall check-up was performed. All were first time IUD users, had good fertility status and uneventful obstetric and gynecologic histories.

For purposes of this study users who nominally came up for renewal of IUD after three years of use, were advised to retain their devices, and consenting continued with their normal schedule of follow-up. In this way the study carried also a prospective feature.

Excluded from the study were those cases who did not manage to show up sufficiently frequent for post-insertion follow-up to provide satisfactory assessment of performance.

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1) The Multiload ML Cu-250 was (at one time) manufactured in sterile individual packing for the BKKBN by J. Van Brunschot B. V., Amsterdam, Holland.

In another study results relative to the study group are matched against a series of cases who got their ML Cu-250s replaced after three years.

RESULTS

Dropped from the study due to insufficient follow-up data were 10 cases in the more than three years usage group, and another 17 cases in the less than three years usage group.

The study group comprised thus 52 cases. Values for mean ± SD were: For age 26, 67 ± 4.25 years, for parity 2.00 ± 0.90. Duration of use totalled 2709.46 womanmonths, ranged between 36.08 and 100.51 months, with means ± SD values of 52.10 ± 15.43 months.

The control group covered 63 women, with mean ± SD values for age 27, 77 ± 4.42 years, and for parity 1.79 ± 0.93. Length of usage totalled 1237.75 womanmonths, ranged between 5.87 and 35.75 months, with mean ± SD values of 19.64 ± 8.26 months.

In terms of age and parity the two groups showed more or less identical characteristics clinically, while the average length of use in the study group was nearly three times that in the control group. As recorded four cases in the study group stood out for their exceptional above average length of usage, amounting to 77.60, 92.48, 92.72 and 100.51 months respectively, with more months to be added due to their continuation of IUD use. Their histories are presented below in more detail:

1. *Rec 6849:* Mrs. RS, age 28, para-2. ML Cu-250 insertion 2-2-1978. Mildly increased vaginal discharge in second year, and mild pelvic infection in third year of use. Both complications responded well to treatment. Last seen 19-6-1986 with everything in order. Recorded length of use 100.51 months (8 years 4½ months).
2. *Rec 6573:* Mrs. SS, age 30, para-3. Insertion 11-6-1977. Seen on 27-2-1985 with 92.48 months of use recorded for data tabulation. On a subsequent visit she asked for removal of her IUD due to anxiety for a recurrent mild infection that first occurred in her third year of use. Removal performed 11-9-1986 and infection duely treated. Usage thus reached 9 years 3 months, the longest recorded ML Cu-250 use in the series.
3. *Rec 7184:* Mrs. ES, age 27, para-2. Insertion 31-5-1978. Mild infection in fifth year responded well to treatment. All was well when seen last on 25-2-1986, when usage amounted to 92.72 months (7 years 9 months).
4. *Rec 8292:* Mrs. MS, age 24, para-1, ML Cu-250 inserted 28-9-1979. Mild infection in fifth year successfully treated and uneventful use continued until 18-3-1986, when removal took place out of desire of another pregnancy. Length of use was thus 77.60 months (6 years 6 months).

From the case histories presented it was evident that infection, although of mild nature usually, was the most frequent complication to be reckoned with, especially in cases of extended use of intrauterine devices. Futher detailed data on age, parity and length of use are grouped and presented in TABLE 1 and TABLE 2.

TABLE 1.— Age parity and duration of ML Cu-250 use

Group	Total		Range	Mean	S.D.	Median	Mode(s)
Study group (n = 52)							
Age (years)	1387	18	(20-80)	26.67	4.25	26	24
Parity	104	3	(1-4)	2.00	0.90	2	2
Use (months)	2709.46	64.47	(36.08-100.51)	52.10	15.43	48.43	48
Control group (n = 62)							
Age (years)	1750	19	(20-39)	27.77	4.42	28	28
Parity	113	4	(1-5)	1.79	0.93	2	28
Use (months)	1237.75	29.88	(5.87-35.75)	19.64	8.26	20.69	11 18 22

TABLE 2.— Distribution according to age, parity and length of ML Cu-250 use

	Study Group (n = 52) Length of IUD Use				Control Group (n = 63) Length of IUD Use			
	f	Total	Range	Mean ± SD	f	Total	Range	Mean ± SD
Age (Y)								
20—24	22	1086.68	36.31— 65.33	49.39 ± 11.40	16	328.57	5.87—34.00	20.53 ± 8.47
25—29	18	946.11	36.21—100.51	52.56 ± 18.91	29	551.22	6.24—37.75	19.00 ± 8.83
30—34	9	578.71	36.87— 92.48	58.96 ± 17.84	13	255.29	9.15—32.36	19.63 ± 8.28
35—39	3	145.96	43.00— 59.12	48.65 ± 9.07	5	102.67	10.72—28.12	20.53 ± 6.88
Parity								
1	18	887.41	36.39— 77.60	49.30 ± 11.33	30	584.46	5.87—32.03	19.48 ± 7.06
2	19	951.49	36.03— 92.72	50.07 ± 14.58	20	365.04	6.24—33.48	18.25 ± 10.68
3	12	718.73	36.21—100.51	59.47 ± 21.69	10	218.47	11.06—32.03	21.84 ± 7.54
4	3	156.83	47.78— 59.78	52.27 ± 6.54	2	43.90	17.36—26.54	21.95 ± 6.49
5					1	25.78		
Use(m)								
> 1— 12					17	157.68	5.87—11.75	9.27 ± 2.09
13— 24					24	446.21	12.45—22.54	18.59 ± 3.15
25— 36					22	633.85	24.09—35.75	28.81 ± 3.80
>36— 48	25	1008.57	36.03— 47.33	40.34 ± 3.88				
49— 60	14	744.34	48.42— 59.78	53.16 ± 4.27				
61— 72	9	593.24	61.03— 71.45	65.91 ± 3.25				
73— 84	1	77.60						
85— 96	2	185.20	92.48— 92.72	92.60 ± 0.16				
97—108	1	100.51						

Complications and sequelae. Discomfort, bleeding and menstrual disturbance showed no significant differences in frequency in both groups. There was no accidental pregnancy in the study group, denoting maintained efficacy in preventing conception. However, infection and heavier flow of vaginal discharge did show significantly increased incidences, albeit still of mild and amenable nature. There were no cases of translocation and fragmentation in both groups. Understandably removals for pregnancy wish in the study group did happen more frequently. Further detail on complications and sequelae are presented in TABLE 3.

Of the 15 cases of removals for pregnancy wish after 49.20 ± 12.80 months of their ML Cu-250 usage, 12 women were known to become pregnant subsequently: 4 within one month, 5 betwen two and seven months, and the other 3 eleven, twelve and thirteen months after removal (5.08 ± 4.42 months). Of the total of 18 removals in the study group, all were easily performed; there was not a single case of embeddiment or fragmentation of the device.

TABLE 3. – Complications and other sequelae

Complications and Other Sequelae	Study Group n = 52		Control Group n = 63		Significance of Difference[1]
No complaints ever	24	(46.15%)	33	(52.38%)	NS z = -2.103
Discomfort	0		3	(4.75%)	NS z = -1.597
Bleeding	0		1	(1.58%)	NS
Menstrual disturbance	0		1	(1.58%)	NS
Increased vaginal discharge	9	(17.30%)	6	(9.52%)	S z = 6.389
mild	9		2		
heavy	0		5		
Infection	9	(17.30%)	3	(4.76%)	S z = 6.426
mild	9		2		
severe	0		1		
Expulsion	3	(5.76%)	6	(9.52%)	NS z = -2.362
partial	2		6		
total	1		0		
Removal	18	(34.61%)	17	(26.98%)	S z = 2.798
medical	1		2		
partial expulsion	2		6		
pregnancy wish	15	(28.84%)	9	(14.285%)	S z = 6.048
Translocation/migration	0		0		
Fragmentation	0		0		
Accidental pregnancy	0		3	(4.76%)	NS z = -1.597

1) Level of significance = 0.01 Critical values (z) = ± 2.575
NS = not significant S = significant
Significancy computed for two proportions using the formula for critical ratio (Mason, 1974):

$$z = \frac{P_1 - P_2}{\sqrt{\frac{\hat{P}(1-\hat{P})}{n_1} + \frac{\hat{P}(1-\hat{P})}{n_2}}} \quad \text{and } \hat{P} \text{ (the weighted proportion)} = \frac{X_1 + X_2}{n_1 + n_2}$$

DISCUSSION

In spite of the fact that intrauterine devices have been widely used for more than two decades, their exact mechanisms in preventing pregnancy are still unknown. Several different mechanisms of action are apparently at work. Inflammatory and foreign body response in the uterus, presumably augmented by the ionized copper in the copperized types, causing cellular and biochemical changes in the endometrial lining and uterine fluids, are believed to be responsible for the contraceptive effect, by way of increased phagocytic, chemotactic and gametotoxic processes acting on spermatozoa or by way of creating a more inhospitable environment for implantation of the fertilized ovum (Corfman & Segal, 1968; Davis, 1971; Morese *et al.*, 1966; Morgenstern *et al.*, 1966; Sahwi & Moyer, 1970; Zipper *et al.*, 1969).

The prevalent preference for the IUD is based on its increasingly valid recognition as a clinically effective and medically safe contraceptive, providing reversible long acting and eventually permanent protection against unplanned and unwanted pregnancy. It does so without any systemic side effects unlike the pill. Aesthetically and technically it does not interfere with the preparation and the spontaneity of sexual intercourse unlike the condom. It needs only one-time motivation, is easy to insert (especially with the new usually smaller copper IUDs) and to remove, and is suitable for self-checking by the woman herself, requiring no high educational level to that end, contrasting favourably with the daily intake of the pill. Although for optimal performance individualization and skill are a must, basically there is no need for specialized staff to administer and to follow-up. Moreover, with the new generation of active IUDs, improved design and better selection of materials have resulted in even more increased structural, functional and retentional characteristics, making the IUD as nearly effective as the latest developed oral pills. Unlike the hormonal contraceptives it does not cause or promote cervical or endometrial malignancy, an issue of paramount importance with extended use over a long period (Population Reports Series B 3, 1979, p. B-56). From a statistical point of view the IUD is 15 times safer than the pill (Inman and Vessey, cited in Davis, 1971:54).

The present study showed a maintained efficacy in preventing with extended use of the copper ML Cu-250 IUD. The longest duration of use was 9 years, with most of the users carrying the device between 3 and 6 years in 48 out of 52 cases (92.30%). As most of the women are still continuing to use their IUDs, the length of use in this series will certainly increase with time. A tighter follow-up schedule is planned for these particular users. However, as also reported by others (Eschenbach *et al.*, 1977) the study also showed that one of the basic problems of IUDs that remained unresolved is the significantly increased frequency of pelvic infection, specifically with more extended duration of use, even when the strictest adherence to aseptic technique and pre-insertion selection of users is practiced. Under less than optimal clinical conditions this potential to developing infection with extended use deserves even more careful consideration. As reported by Wahab *et al.* (1985) cultures of vaginal and cervical secretions showed a statistically significant increase in some of the aerobic microorganisms, e. g. the Gram negative bacilli, resulting in pelvic infection and heavier vaginal discharge. These two most frequent kinds of complications matter of fact require ample attention to prevent and to treat at insertion time and at follow-up visits, the more at extended usage of the intrauterine device.

Demographic considerations. To be effective in the demographic sense a contraceptive technique must be suitable for limiting family size as well as useful in spacing the interval between pregnancies. It should also be medically safe, easily and economically available, adaptable to mass use without too much individual supervision, fit for the less educated segment of the population. From this point of view, oral contraceptives have proven useful as a child spacing technique, but do not constitute a practical answer to population pressures, particularly in developing countries with insufficient resources and prevalent problems of compliance. The demographically growing importance of the IUD is based on its unique combination of reversibility and permanence which the method presents.

Experience in the decade from 1960 to 1970 in meeting population pressures clearly indicated that the most successful programs have stressed the use of IUDs, medical abortion and surgical contraception. A shift to the IUD as the priority method to be used in population control programs in the eighties, specifically in developing countries with more urgent populations pressures, is understandably in the making.

In Indonesia, where abortion on socioeconomic indications is not legalized, and surgical contraception despite growing popular acceptance has not yet been officially adopted in the national family planning and population program, the shift to the IUD has been clearly evident as reported by Marsidi Judono (1985). Speaking at the FIGO Congress 21—25 September in Berlin on behalf of the Vice-Chairman of the BKKBN, he reported that the IUD is now the leading method of choice in contraception in Indonesia, being the choice in over 5 million women because of its recognized effectiveness in spacing pregnancies. The numbers in millions of the devices used up to now has been mentioned in previous lines. The ML Cu-250 was introduced in the national program since 1978 to overcome some of the problems relative to the Lippes Loop such as higher expulsion rates and lower continuation rates as compared to other IUDs tested. The specific advantages of the Multiload include its ease of insertion, particulary when sterile gloves may not be available, its lower rate of expulsion, and its ability to remain in the uterus for years without the necessity of replacement.

As mentioned previously, the ML Cu-250 was selected as the standard copper IUD as issued by the BKKBN. The reliance on this specific type of copper IUD may become more distinct in years to come, in view of its proven performance and acceptability. Moreover, as a result of the announced withdrawal from the United States market and cessation of production of the Lippes Loop, Copper 7 and the Tatum 7 by their respective manufacturers, this dependence may become more pronounced. As reported (in Pathways, 1986, as cited in the August 1986 issue of the ESCAP Population Headliners) those three IUDs are being removed from the United States' market, not for medical reasons but for business reasons, including "unwarranted product litigation" and the difficulty of obtaining product liability insurance.

The maintained efficacy of the ML Cu-250 when used over an extended period beyond its stated theoretical lifespan of three years as proven in this present study, may be of decisive relevance for both the acceptors, the providers and the service program. However, it is felt that further studies in a broader epidemiological field setting under less than optimal conditions medically are warranted.

From a demographic point of view the data presented in TABLES 1 and 2 in matters of age and parity revealed a very heartening trend towards the popular acceptance of the small-family-idea within the format of the two-child-family as is now officially and widely being advocated troughout the country. In the study group 77 per cent of the women were in the 20—29 age group with 71 per cent in the 1—2 parity group. Matching figures in the control group were 73 per cent and 81 per cent respectively. This represents a very different picture from that of 10—15 years before when parity 5 and above and pregnant women aged 35 or more constituted a far bigger segment among the active reproductive groups.

This clearly denotes change and points to a promise of long-time success for the family planning movement in Indonesia and the two-child or the four-member family *(keluarga caturwarga)* ideal (Soeprono, 1983).

CONCLUSION AND RECOMMENDATION

1. The Multiload Cu-250 can be used with assured efficacy and with reasonable safety over a much longer period beyond its theoretical effective lifespan of three years without replacement.

2. Adoption as such an extended usage regimen would mean considerable savings in precious time and scarce monies, assures continuation of use, reduces anxiety and incidence of complications.

3. Futher studies in a broader epidemiological setting under less than optimal field conditions are recommended to justify adoption of such extended usage regimen in the national service programs.

4. The use of the Multiload Cu-250 merits consideration in cases where a more permanent protection against accidental pregnancy is wanted and when surgical contraception is not available or is not desired.

ABSTRACT

The extended use of a copper intrauterine device beyond its stated period of theoretical effectiveness seems not to adversely affect its efficacy in preventing pregnancy. This was the conclusion of a ten-year study covering 52 cases of prolonged use of the Multiload Cu-250 among patients in a gynecologic private practice. Length of use ranged between 36.08 and 100.51 months with an average of 52.10 months. In 25 (48.07%) women the recorded use was 3—4 years, in 19 (36,53%) 4—5 years, and in 9 (17.30%) 6—7 years. In the four cases with the longest recorded duration of use, the length of usage amounted to 77.60, 90.48, 92.72 and 100.51 months respectively. There was not a single case of accidental pregnancy in this study group. Sixty three users of the same type of device from the same private practice with less than three years length of use served as control. Discomfort, bleeding, menstrual disturbance and expulsion presented no augmented problems. However, significantly increased incidences of heavier flow of vaginal discharge and pelvic infection, though still of mild and amenable nature, merited special consideration, aside from the understandably more frequent removals desiring another pregnancy. As the Multiload Cu-250 has become the primary choice of copper intrauterine device in the Indonesian national family planning and population program, these findings could be of particular relevance in terms of continuation of use, safety, efficacy and economics for both the acceptors and the service program. In another study these results are compared with another series of cases who got their devices replaced at the end of their theoretical lifespan of three years. Further studies in a broader epidemiological setting under possibly less than optimal conditions clinically are recommended.

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