AFRICAN JOURNAL OF MEDICINE and medical sciences

VOLUME 24, NUMBER 1, MARCH 1995

EDITOR: B.O. ONADEKO
ASSISTANT EDITORS:
B.O. OSOTIMEHIN and A.O. UWAIFO

SPECTRUM BOOKS LIMITED
Ibadan • Owerri • Kaduna • Lagos

ISSN 1116—4077

Afr. J. Med. med. Sci. (1995) 24, 59-65

Performances of copper T 380A and multiload copper 375/250 intrauterine contraceptive devices in a comparative clinical trial

A.O. AROWOJOLU,* E.O. OTOLORIN and O.A. LADIPO
Fertiligy Research Unit, Department of Obstetrics & Gynaecology, University College Hospital, Ibadan, Nigeria.

Summary

An evaluation of the performances of copper T 380A (TCU 380A) and multiload copper 375/250 (MLCU 375/250) intrauterine contraceptive devices (IUCDS) was carried out at University College Hospital, Ibadan, Nigeria (UCH) in a clinical comparative trial.

The IUCDS showed similar low vent rates at one year of continuous use. The difference in cumulative net probabilities for termination due to pelvic inflammatory disease was weakly significant at the sixth month of follow up with MLCU 250 having the highest rate. (TCU 380A-0%; MLCU 375-0%; MLCU 250-3.1%; X^2=6.0; P < 0.05). This significant difference disappeared by the twelfth month of continuous use. Likewise, the difference in cumulative net probabilities for overall termination was significant at six months and insignificant at twelve months of follow up. The continuation rate after one year were 86%, 92% and 87% respectively for TCU 380A, MLCU 375 and MLCU 250. These rates were higher than 80% and 51% quoted for the previously available Lippes loop in the same environment[1,2].

It was therefore concluded that the three IUCDS are comparable in performances in the first year of use and could be used at our family planning clinic or any other clinic in a similar setting.

Résumé

Une évaluation clinique, comparée des performances des contraceptifs intra-utérines (IUCDS) à Cuivre T380A) et à Cuivre multi-chargé 375/250 (MLCU 375/250) a été faite à l'University College Hospital (UCH) Ibadan.

Les IUCDS ont demontré les mêmes taux d'incidence après un an d'emploi continu. Après 6 mois d'emploi le desir de terminer l'emploi des IUCDS s'est faiblement manifesté, le MLCU 250 étant plus refusé à savoir (TCU 380A-0%; MLCU 375-0%; MLCU 250-3.1%; X^2=6.0; P < 0,05). Cette différence significative a disparu après 12 mois d'emploi continu. De même la différence des pobabilités cumulatives pour la terminaison généralisée etait significative après 6 mois mais négligeable après un an. Les taux de continuation après 12 mois étaient de 86%, 92% et 87% pour le TCU 380A, MLCU 375 et MLCU 250 respectivement. Cex taux sont plus elevés que les 80% et les 51% cités pour la loupe de Lippes dans la même région (1.2).

En conclusion les performances des trois contraceptifs intra-utérines sont comparables ou similaires pendant la prmière année d'usage et sont utilisables dans nos cliniques de planning familial ou toute autre clinique dans les environs similaires.

Introduction

One of the popularly accepted contraceptive methods available in Nigeria is the IUCD. It was the choice of 82% of new family planning ushers in U.C.H., Ibadan, Nigeria[3]. It is the second most popular method used among overall acceptors in the country, coming after oral contraceptives (Planned Parenthood of Nigeria; Personal communication). At the University of Ilorin Teaching Hospital, Ilorin, Nigeria, apart from its acceptance by two thirds of the new acceptors in 1985, it had the highest continuation rate of 51% compared to other methods of contraception[2].

Until recently, the commonly used IUCD at U.C.H. Ibadan was the Lippes loop. Copper T 380A and Multiload 375/250 have just been introduced in replacement of the Lippes loop which is no longer available in the country. These new devices have performed better than the Lippes loop in several trials in developing countries[4,5]. However, prior to 1987,

* To whom all correspondence should be addressed.

there was no reported study evaluating the performances of these new IUCDS among Nigerians whose sociocultural background differ significantly from those of acceptors in developed countries. The need for a clinical evaluation of these new devices therefore arose.

This study was designed to compare the clinical performances of the three IUCDS (MLCU375, MLCU250 and CU T380A) in a double blind trial in terms of effectiveness and side effects in Nigerian acceptors.

Materials and methods

A) Intrauterine contraceptive devices

The TCU 380A (Finishing Enterprises Inc. North Tonowada, New York 14120) consists of a plastic T with copper sleves on its horizontal arms and tightly wound copper wire on the vertical stem. The total surface area of copper is 380mm^2. The T is 36mm in vertical dimension and 32mm in horizontal dimension. The vertical stem has a plastic ball at its lower end which prevents cervical perforation and to which a white plastic tail is attached.

The multiload copper 250 (Organon Ltd., Cambridge Science Park, Cambridge, UK) has 250mm^2 of copper wire wound around its stem. The arms are flexible plastic serrated fins which help to hold the device in place. It consists of three types to optimise uterine fitting. The standard type is for uteri with sound length 6-9cm, the short for uteri of 5-7cm length and the mini for uteri with sound length less than 5cm. Only the standard and the short types were used in this study.

The multiload copper 375 (Multian AC Port Fach 129, 88088 Pfarffikan 52 Switzerland) is like the standard MLCU 250 in size and shape but it carries a 375mm^2 copper wire around its stem.

B) Patients

Each of the three groups consisted of 100 sexually active non-contracepting healthy Nigerian women who had given informed consent for participation and desired contraception for more than twelve months. They met the insertion criteria of the manufacturers of each device. In allocating the devices, each woman randomly picked an envelope labelled against a particular device blindly and this was inserted into her uterus by the attending trained family planning nurse. To ensure that the study remained double blind, the admission cards of the patients were kept separately and not seen by the assessors until the end of the study.

C) Insertion of device

The insertions were carried out in the interval period (last pregnancy having terminated at least six weeks before insertion) during menstruation by only two experienced family planning nurses between 1st February 1987 and 30th March 1987. All patients were informed that the IUCD would provide adequate contraception and that no other form of contraception should be used throughout the course of the study. Compliance from each woman was assumed and not ensured in this respect. Follow up visits were arranged at one, six and twelve months following insertion. Those with complications were seen as they presented at the clinic by the first author.

D) Analysis of results

All analyses were performed on a microcomputer using Sistat and Datastat in July 1991. The cut off date was 1st April 1988 but follow up was continued until 30th June 1991. Therefore, no accidental pregnancy was overlooked and those lost to follow up had up to 38 months of nonreporting. Clients were terminated from the study when their IUCD was expelled or removed for any reason or when pregnancy occurred.

Differences between means were compared with Chi square test. The level of significance was set at P=0.05. The log rank method of life analysis[6] was employed to generate events rates and test for differences among the devices at six and twelve months of use according to the categories recommended by Tietze and Lewits[7].

Results

A) Sociodemographic characteristics — (Table 1)

The women in the three groups were similar in respect of age, total live births and interval between their last pregnancies and the times of insertion of the devices (Table 1). Majority of them (75.7%) had used no form of effective contraception since their last pregnancies and prior to admission to the study. This trend was also shown when each device was considered.

Table 1: Selected sociodemographic characteristics of women at insertion

Characteristics	TCU 380A (n=100)	MLCU 375 (n=100)	MLCU 250 (n=100)
a) Age: Range	20 - 40	20 - 39	23 - 40
mean ± SD (years)	30.5 ± 5.2	30.8 ± 4.7	31.9 ± 4.7
b) Total live births: Range	1 - 9	1 - 9	1 - 9
mean ± SD (children)	4.5 ± 1.6	4.4 ± 1.7	4.5 ± 1.8
c) Last pregnancy/insertion interval (years): Range	0 - 7	0 - 8	0 - 6
mean ± SD	1.3 ± 0.4	1.1 ± 0.6	1.6 ± 0.6
Previous contraceptive history (type of contraception)			
Oral contraceptive pills	16	11	12
Barrier and Jellies	2	3	6
Rhythm	1	0	2
IUCDS	4	7	9
None	77	79	71

B) Menstrual characteristics

All women were menstruating at the time of insertion. The mean duration of menstrual flow was 4.6 ± 0.8 days (range = 3-7). Sixteen women from each of the MLCU 375 and TCU 380A and 12 from MLCU 250 group were suffering from mild dysmenorrhoea before insertion. None of the women suffered from severe or moderate dysmenorrhoea, intermenstrual bleeding or spotting before insertion in keeping with the criteria for participation.

C) Medical problems encountered at the time of insertion

Failure of insertion occurred in only one woman allocated to the TCU 380A group. This was due to cervical stenosis which could not be dilated by the attending nurse. She was therefore withdawn from the study.

Pelvic pain was reported by nine women; (6 with TCU 380A, 1 with MLCU 375 and 2 with MLCU 250). Among those wih TCU 380A one had severe pelvic pain while the rest had mild pain at insertion. Those with the other two devices had only mild pain at insertion. The same woman presenting with severe pelvic pain presented three days later with complaints of missing IUCD which was found to have been extruded into the peritoneal cavity. It is noteworthy that all these women were of low parity (i.e. para 1-2). There was no incidence of cervical trauma or syncope at insertion.

D) The complaints and complications occurring during follow up visits (Table 2)

1) *Infections:* Pelvic inflammatory disease (PID) occurred in 11 women, most of whom were women using MLCU 250. Two of the women diagnosed with PID were hospitalised. All eleven women were successfully treated with antibiotics. On the whole seven women had their devices removed due to poor response to treatment within 24 hours.

Table 2: Number of women with complaints and complications at follow up after twelve months

Events (Complications/complaints)	TCU 380A (n = 99)	MLCU 375 (n = 100)	MLCU 250 (n = 100)
1) Pelvic Inflammatory Disease: (PID)	2	2	7
Hospitalisation for PID	1	0	1
2) Menstrual Disturbance:			
a) Menorrhagia	4	5	2
b) Amenorrhoea	2	2	1
c) Intermenstrual Bleeding/ Spotting	6	4	4
d) Dysmenorrhoea	27	24	21
3) Pelvic Pain/Cramps:	3	1	2
4) Displacement of IUCD:			
a) Uterine perforation	1	0	0
b) Total expulsion	2	0	2
c) Partial expulsion	2	0	1

2) *Mestrual Problems:* Menorrhagia which occurred mostly in women using MLCU 375 accounted for withdrawal from the study in only two women. Amenorrhoea without positive pregnancy tests led to discontinuation in one woman from each of the TCU 380A and MLCU 375 groups. There was increased incidence of intermenstrual bleeding at follow up but no woman had her device removed on account of this. All reports on menstrual disorders were verbatim reports by users. No attempts were made to assess each by way of experimental analysis.

3) *Displacement of IUCD:* Uterine perforation occurred in only one woman who had complained of severe pelvic pain at insertion. The device was detected in the peritoneal cavity by ultrasound scan with a tracer IUCD in the uterine cavity and was later removed at laparoscopy.
The incidence of total expulsion was as shown on the table. Those with partial expulsion had their devices replaced but were withdrawn from the study.

4) *Pelvic pain and low abdominal cramps:* These occurred in six women on the whole but did not lead to withdrawal.

E) The cumulative net probabilities for various terminating events (Table 3):

The three devices were similar in performance in respect of each event rate. There was a weak significant difference in the cumulative net probability for termination as a result of PID (X^2 = 6.0, $P < 0.05$) at six months with users of MLCU 250 having the largest number of this terminating event. However when overall terminating events were considered at six months, TCU 380A contributed most to withdrawals (X^2 = 6.6; $P < 0.05$). These significant differences disappeared with follow up by the twelfth month (X^2 = 4.6 and 2.2 respectively at six months and twelve months). The total women months at risk was calculated by dividing the days at risk by 30.44 days and found to be 3,1191 months.

Table 3: Cumulative net probability (P%) for IUCDS with testing for difference among devices (X^2 value) for various terminating events

Terminating Events and Devices	Net cumulative at 6 months	Probabilities (P%) at 12 months
a) Pelvic inflammatory disease:		
TCU 380A	0	1.2
MLCU 375	0	1.0
MLCU 250	3.1	5.2
X^2	6.0*	4.6
b) Expulsion of device:		
TCU 380A	3.0	4.1
MLCU 375	0	0
MLCU 250	2.0	3.1
X^2	2.9	3.9
c) Pregnancy:		
TCU 380A	1.1	1.1
MLCU 375	0	0
MLCU 250	0	0
X^2	2.1	2.1
d) Amenorrhoea:		
TCU 380A	1.1	1.1
MLCU 375	0	1.1
MLCU 250	0	0
X^2	2.1	2.1
e) Planning pregnancy:		
TCU 380A	4.2	5.2
MLCU 375	2.0	4.0
MLCU 250	2.0	5.2
X^2	2.0	0.7
f) Other personal reasons:		
TCU 380A	2.1	2.1
MLCU 375	0	1.0
MLCU 250	0	1.0
X^2	4.1	2.2
g) Cumulative termination rate:		
TCU 380A	11.1	14.2
MLCU 375	3.0	8.0
MLCU 250	7.0	13.0
X^2	6.6*	2.2
h) Cumulative continuation rate:		
TCU 380A	88.9	85.8
MLCU 375	97.0	92.0
MLCU 250	93.0	87.0

Total woman's month of risk evaluated by dividing the days by 30.44 days = 3,119.1
*Slightly significant value ($P < 0.05$)

Discussion

Majority of women receiving IUCDS for contraception at University College Hospital, Ibadan, Nigeria now rely on TCU 380A, MLCU 375 and MLCU 250 IUCDS. In this clinical evaluation of these three devices, the event rates and termination rates were low and did not differ significantly with respect to each device. The women were from the same environment and similar in terms of the selected sociodemographic characteristics (Table 1), so differences in environmental factors were not expected to play a significant role in this study. The simple insertion technique of multiload copper IUCDS which requires less manipulation than TCU 380A (Manufacturer's guide to insertion of the MLCU and TCU 380A IUCDS) may be a distinct advantage in IUCD programmes where relatively inexperienced personnel may be performing the insertions. Pain which is the most frequent reason for insertion failures[8] did not play a role in this study as there were no insertion failurs due to pain. This is possibly because all the women recruited were parous and had insertions during menses, a period when the cervix is soft and has a slightly open os, thus allowing easy insertions. The advantage of carrying out insertions during menstruation and in parous women has been realised by several workers[8]. However, menstruation could be a hindrance where women object to pelvic examinations in the presence of vaginal bleeding.

The occurrence of very few complaints and complications in this study was comparable to reported observations with the same devices elsewhere[9,10]. Menstrual disturbances still remain a major problem as once reported by Akinla[11] and Oyediran[12] respectively in this environment although the incidence was lower in the present study. These finding were based on verbal reports by the patients and no attempts were made to assess such menstrual disturbances by laboratory investigations. This raises a question of the objectivity of such report which may not reflect the actual pattern of menstrual disturbances occurring among the groups. However from the user's point of view, continued use of a device depends on how she tolerates the use- related complications and not their scientific quantifications.

No definite inference could be drawn from the net probability rate for pregnancy in this study but studies elsewhere have shown that the pregnancy rates in women on TCU 380A and MLCU 375 were comparable but lower than those of women on MLCU 250 during the first year of use[4,10,13-15]. The larger copper load carried by the TCU 380A and MLCU 375 devices may be responsible for this, although such assumption has not been completely validated by other workers[16]. It is possible that a study involving a larger sample size may corroborate previous reports on copper T and multiload copper IUCD trials. While ectopic pregnancy did not occur in this study, several studies have shown a high rate of ectopic pregnancies where the devices have failed[4,17]. The risk of an ectopic pregnancy increases with duration of IUCD use, and persists for a year after the device has been removed[17,18] due to nonbacterial inflammatory changes that develop in the fallopian tubes when IUCDS are in use. A longer follow up of the women continuing with their devices *in situ* in this study will be essential to enable an evaluation of the probability rate of subsequent ectopic pregnancies.

The low incidence of use-related hospitalisation shows that the complications associated with these new devices may be milder than with old ones where higher hospitalisation rates have been reported[19]. From the point of view of family planning programmes, the success of a device is measured in terms of overall continuation rate, which is similar for the three devices tested in this study over twelve months of follow up. As most terminating events occurred in the first six months of use and were not very serious, counselling on the various use-related events may further improve the acceptance of IUCDS. From the women's point of view, accidental pregnancy is far more important than the inconveniences of other use-related events as she is forced to make a decision based on recognised risks if she conceives with a device *in situ*. Therefore these new devices with proven lower pregnancy rates will be better replacements for the Lippes loop in this environment and could be used at our family planning clinic or any others of similar setting. Their performances on a long term basis is currently being investigated.

Although the use of the IUCD has dramatically fallen in developed countries, it still plays a great role in the developing countries in terms of cost effectiveness and acceptability, where many women detest regular oral tablets or surgery and will accept a form of contraception remote from their partners' influence.

Acknowledgements

We wish to acknowledge the contributions of our Family Planning Research Nurses, especially Mrs. Olowe and Mrs. Akinso, who inserted the IUCDS and collected the follow-up data. This study was partly supported by Organon (Nigeria) Ltd., Lagos.

References

1. Ololorin EO, Ladipo OA. Comparison of intramenstrual IUD insertion with insertion following menstrual regulation. Adv. Contracept. 1985; 1: 45-49.
2. Fakeye OO, Okwerekuru FO. The follow up characteristics of acceptors of the pill and intrauterine device at Ilorin. Planners' Forum Magazine. 1988; 2 (2): 10-13.
3. Ololorin EO, Falase EAO, Delano GE, Akande E, Ladipo OA. Contraceptive choice of new acceptors at the University College Hospital, Ibadan, Nigeria; a 16 year review. Advances in Fertil. Steril, 1987; 6: 113-118.
4. Population Reports: IUCD: An appropriate contraceptive for many women. Population reports of IUCDS series B. 1985; 4: 101-135.
5. World Health Organisation (WHO). Special Programme of Research Development and Research Training in Human Reproduction. 9th Annual Report, Geneva. WHO 1980 pg 162.
6. Asen SP, Roy S, Pike MC, Casagrande J, Mishell Jr. A new procedure for the statistical evaluation of intrauterine contraception. Am. J. Obstet. Gynaecol 1977; 128: 329-335.
7. Tietz C, Lewits S. Recommended procedures for the statistical evaluation of intrauterine contraception. Studies in Family Planning. 1973; 3: 35-40.
8. Chi K, Wilkens LR, Siemens AJ, Potta M. Rare events occurring at insertion of an intrauterine device — A review of an international experience. Adv. Contracept. 1987; 3: 49-61.
9. Cole LP, Potts DM, Aranda C, Benilovic B, Etman E, Moreno J, Randic L. An evaluation of the TCU 380Ag and MLCU 375. Fertil. Steril. 1985; 45 (2) 214-216.
10. Ogedengbe OK, Giwa-Osagie OF, Oye-Adeniran BA. A comparison of multiload with Copper T IUDS in a Family Planning Clinic in Lagos. Br. J. Family Planning. 1991; 17(3): 67-71.
11. Akinla O. Bleeding and the use of effectiveness of the copper T 200 IUD; a brief review. Nig. Med. Jr. 1977; 7(1) 71-76.
12. Oyediran MA. Comparative study of the effectiveness of the Lippes Loop, copper T 200 and Nova T IUDS in Lagos, Nigeria. Int. Jr. Fertil. 1982; 27(2): 109-112.
13. Van Os WAA, De Mooyer CCA, Bakker S, Bomert L, Rhemen PFR, Loendershoot EW. Evaluation of combined multiload copper IUD (MLCU 250 and MLCU 375) Int. Jr. Fertil. 1978; 23 (2): 152-155.
14. Snowden R. Evaluation of the multiload CU 250 IUD Devon England University of Exeter, Institute of population studies. 1980. (Report 2/80).
15. Sivin I, Tatum J. Four years' experience with TCU 380A intrauterine contraceptive device. Fertil. Steril. 1981; 36(2): 159-163.
16. Rhemrev PE, Van Os WA, Keinhout J, De Nooyer. Comparison of three multiload IUDS: MLCU 250, MLCU 375 and MLAgCU 250. Adv. Contracept. 1985; 1 (1): 31-36.
17. Sivin I. Copper IUD use and ectopic pregnancy rate in the United States. Contraception. 1979; 19 (2): 151-173.
18. Ory WW, Women's Health Study group. Ectopic pregnancy and intrauterine contraceptive devices. New Perspectives. Obstet. Gynaecol. 1981; 57 (2): 137-144.
19. Tatum HJ, Connell EB. Managing patients with intrauterine devices. 1st Ed. Durant informatics Inc. 1985.

(Accepted 20 July, 1992)