

Clinical Evaluation of Intrauterine Devices CuT 200 and CuT 380A - An Experience on 5 years use

Indian Council of Medical Research (ICMR) Task Force On IUD and Hormonal Contraceptives

I. Kambo • A. Nair • B S Dhillon • S L Chauhan • B. N. Saxena

Division of Reproductive Health and Nutrition, Indian Council of Medical Research, Ansari Nagar, New Delhi 110029.

Summary: The clinical performance of CuT 200 and CuT 380A was evaluated in a cohort of women till 5 years of use. There was no significant difference in demographic & obstetric profile of acceptors of both devices (CuT 200 & CuT 380 A). The overall continuation rates of both the devices were similar, the continuation rates of CuT 200 were 59.2, 38.5 and 18.7 per 100 users & that of CuT 380A were 58.9, 41.4, and 21.1 per 100 users at 3,4 and 5 years of use respectively. In both the groups, the continuation rates at one year were more than 89 per 100 users. Majority of women discontinued the use of IUDs after 2 years for planning pregnancy.

The pregnancy rates in CuT 200 and CuT 380A acceptors (1.5 and 0.3 per 100 users respectively) were quite low in comparison to global data at 5 years use. However, statistically significant difference was observed after 4 years of use in method failure rates of CuT 200 and CuT 380A.

The performance of both IUDs (CuT 200 & CuT 380A) was satisfactory in terms of efficacy and continuation rates. Recommendation may be made to increase the duration of use of CuT 200 up to 5 years in National Family Welfare Programme (NFWP) of India; at present recommended use of CuT 200 is for 3 years in the NFWP of India.

Introduction

Intrauterine devices (IUDs) are among the safest, most cost-effective and widely used contraceptive methods available worldwide. It is estimated that worldwide over 106 million women are using intrauterine devices (IUDs) (Population Reports IUDs- An update 1997). In India IUDs are being used by women as a method of contraception for more than 3 decades. It has gained popularity and in order of preference IUDs are the first choice of women amongst the spacing of methods.

Indian Council of Medical Research (ICMR) is involved in evaluation of various types of IUDs since mid 1970s (Tejuja s., et al 1974, ICMR Task Force on IUDs, 1989). Based on experience of these studies CuT 200 was

introduced and continued to be used in National Family Welfare Programme of India (NFWP).

In 1989, ICMR initiated a study in 61 Post-partum centres through its network of Human Reproduction Research Centres (HRRCs) with a objective to improve the utilization of spacing methods through training & counselling and to evaluate contraceptive efficacy & continuation rates of CuT 200 & CuT 380A upto 5 years of use. The report of 2 years of contraceptive use indicated high efficacy & continuation rates with both the devices ICMR Task Force on IUD and Hormonal Contraceptives, 1994).

In the present paper, observations on the women using CuT 200 and CuT 380A upto 5 years of use are being discussed.

Methodology

Those women who were willing to participate in evaluation of comparative trial of IUDs i.e. CuT 200 or CuT 380A as per randomisation procedure were enrolled in the study after screening for suitability of IUD use. The IUD was inserted within 10 days of last menstrual period (LMP) or concurrent with medical termination of pregnancy (MTP) / abortion. In those women who had lactational amenorrhoea, pregnancy was ruled out. Written consent was obtained from the women accepting CuT 380A as this device is not included in the NFWP of India.

The follow-up schedule for IUD acceptors was at one month after insertion and subsequently at six monthly intervals for a period of 5 years to record the complaints/ side effects and reason for discontinuations.

The information was collected on uniform proforma by Postpartum Centre (PPC) staff, which included screening, the demographic profile of acceptors, complaints during use and reasons for discontinuations of the method.

Statistical Method

Net cumulative probabilities for discontinuations were computed using daily life table method. For the comparison of rates between the two types of IUDs, Chi-square test with one degree of freedom using log rank method was used. (AZEN S.P. et al 1977).

Results

The enrollment was initiated in November 1989 and a total of 4,808 acceptors (2,446 of CuT 200 & 2,362 of CuT 380A) were enrolled and followed for 79385 and 78377 women months of use for CuT 200 & CuT 380A respectively upto 5 years of use. The cut off date for analysis was 31st January 1996.

The profile of acceptors of both the devices (CuT 200

and CuT 380A) were comparable in terms of age, parity, obstetric status of women (Postpartum/MTP/Interval) and educational status.

Table 1
Characteristic of IUD Users

	CuT 200 Mean \pm SD	CuT 380 A Mean \pm SD
Age (years)	25.3 \pm 4.4	25.5 \pm 4.5
Living children	1.9 \pm 1.0	1.9 \pm 1.0
Literate (%)	76.7	79.1
Post MTP / Postpartum %	16.9	13.7
N	2,446	2,362

Continuation Rates

Continuation rates were comparable of both the devices. The continuation rates of CuT 200 were 59.2, 38.5 and 18.7 per 100 users and those of CuT 380A were 58.9, 41.4 and 21.1 per 100 users at 3,4 and 5 years of use respectively. One year continuation rates with both the devices were 89 per 100 users.

Table II
Number of Acceptors, Women-Month of use and continuation rates of IUD users

	Months	CuT 200	CuT 380 A
No. of acceptors		2446	2362
No. completing	12	2053	1972
	24	1659	1614
	36	1171	1149
	48	631	679
	60	165	214
Women month of use	12	26329	25455
	24	48477	46913
	36	65169	66219
	48	75359	73577
	60	79385	78377
Continuation rates per 100 users	12	89.6	89.2
	24	76.4	76.2
	36	59.2	58.9
	48	38.5	41.4
	60	18.7	21.1
Lost to Follow-up (%)	12	6.5	6.1
	24	9.7	8.6
	36	13.5	11.6
	48	18.8	16.1
	60	23.1	21.2

Reasons for Discontinuation

The cumulative discontinuation rates by reasons are given in Table III.

The cumulative method failure rates of CuT 200 were 0.7, 0.9 and 1.5 per 100 users at 3, 4 and 5 years of use respectively. The method failure rates of CuT 380A were 0.3 per 100 users at 3, 4 and 5 years of use respectively. Statistically significant difference was observed only after 4 years of use.

In the present study, no case of perforation was reported in the acceptors of either of the devices during 5 years of use.

The cumulative discontinuation rates due to pelvic infection of the CuT 200 acceptors were less than 1 per 100 users upto 3 years and less than 2 per 100 users upto five years of use.

The discontinuation rates due to expulsions, bleeding/pain and other medical reasons did not show statistically significant differences.

Discontinuations due to desire for pregnancy were quite high particularly after two to three years of use. Out of the total IUD users 47 per 100 users for CuT 200 and 43 per 100 users for CuT 380A discontinued due to desire for pregnancy by 5 years of use.

The other reasons for discontinuation included 'adopted permanent method', 'objection from husband', change of residence' etc.

Discussion

Data from present study indicates that the pregnancy rates were less than 1 per 100 users for CuT 200 and CuT 380A and were comparable till 4 years of use (Pregnancy rate 0.9 and 0.3 per 100 users of CuT 200 and CuT 380A respectively at 5 years of use). These rates are lower as

compared to global data (Population Reports IUDs - An update, 1997 and Diaz J et al 1992)

The continuation rates observed in the present study which was carried out under programme conditions were comparable with those observed in earlier clinical trials carried out by ICMR in teaching hospitals. This could be due to the efforts of medical & paramedical staff of postpartum centres who were re-trained in counselling, screening, IUD insertion & Follow-up care by HRRC staff.

There was no case of perforation observed in the acceptors of either of the devices during 5 years of use. In similar studies conducted elsewhere, discontinuation of the method due to perforation had been rare, not more than 1.3 per 1000 insertions (Population Reports IUDs- An update, 1997)

Discontinuations due to Pelvic infection were low for both the devices (less than 1 per 100 users upto 3 year of IUD use). Global data also indicates that although IUD users are more likely to develop Pelvic Inflammatory diseases than non-users, it is still an uncommon complication (Population Reports, IUDs- An update 1997).

It was observed that discontinuation rates due to planning pregnancy increased after 2-3 year of use in acceptors of both the devices (CuT 200 & CuT 380A), which is suggestive that the Indian women need spacing for 2-3 years. At 5 years of use majority of the cases discontinued due to this reason (47 & 43 per 100 users for CuT 200 and CuT 380A respectively).

At present in NFWP of India, the use of CuT 200 is recommended for 3 years. Based on experience of present study the Deptt. of Family Welfare may consider to recommend use of CuT 200 for 5 years. CuT 380A being effective for longer period should be offered to those women who want to use contraception for longer duration or as an alternative to sterilization procedure to the women

Table III
Net Cumulative Discontinuation Rates per 100
users by Reasons for Discontinuations

Reason for discontinuation	Months	CuT 200 Rate \pm SE	CuT 380 A Rate \pm SE
Pregnancy	12	0.4 \pm 0.1	0.2 \pm 0.1
	24	0.7 \pm 0.2	0.3 \pm 0.1
	36	0.7 \pm 0.2	0.3 \pm 0.1
	48	0.9 \pm 0.2	0.3 \pm 0.1
	60*	1.5 \pm 0.4 (19)	0.3 \pm 0.1 (7)
Partial expulsion	12	0.8 \pm 0.2	0.8 \pm 0.2
	24	1.2 \pm 0.2	1.1 \pm 0.2
	36	1.4 \pm 0.3	1.3 \pm 0.2
	48	1.9 \pm 0.3	1.4 \pm 0.3
	60	2.7 \pm 0.4	3.0 \pm 0.5
Complete expulsion	12	0.9 \pm 0.2	0.8 \pm 0.2
	24	1.4 \pm 0.3	1.3 \pm 0.2
	36	1.7 \pm 0.3	1.5 \pm 0.3
	48	2.0 \pm 0.3	1.6 \pm 0.3
	60	2.0 \pm 0.3	1.8 \pm 0.3
Excessive / Irregular bleeding	12	4.2 \pm 0.4	5.3 \pm 0.5
	24	8.8 \pm 0.6	9.4 \pm 0.6
	36	12.5 \pm 0.7	13.6 \pm 0.8
	48	16.7 \pm 0.9	17.2 \pm 0.9
	60	21.9 \pm 1.1	23.6 \pm 1.1
Pelvic Infections	12	0.1 \pm 0.1	0.2 \pm 0.1
	24	0.2 \pm 0.1	0.5 \pm 0.2
	36*	0.3 \pm 0.1	1.0 \pm 0.2
	48*	0.7 \pm 0.2	1.9 \pm 0.4
	60	1.4 \pm 0.4	2.0 \pm 0.4
Other medical reasons	12	0.6 \pm 0.2	0.8 \pm 0.2
	24	2.0 \pm 0.3	1.9 \pm 0.3
	36	3.4 \pm 0.4	3.7 \pm 0.5
	48	6.5 \pm 0.7	5.9 \pm 0.6
	60	10.3 \pm 0.9	10.0 \pm 0.9
Desire for pregnancy	12	1.2 \pm 0.2	1.1 \pm 0.2
	24	5.7 \pm 0.5	5.6 \pm 0.5
	36	15.9 \pm 0.9	14.9 \pm 0.9
	48	29.4 \pm 1.2	26.2 \pm 1.2
	60	47.0 \pm 1.5	42.9 \pm 1.5
No need for further contraception	12	1.3 \pm 0.2	0.9 \pm 0.2
	24	3.8 \pm 0.4	2.7 \pm 0.4
	36	8.2 \pm 0.7	6.4 \pm 0.6
	48	16.5 \pm 1.0	13.5 \pm 0.9
	60	31.6 \pm 1.5	29.5 \pm 1.6
Other personal reasons	12	1.1 \pm 0.3	1.1 \pm 0.2
	24	2.3 \pm 0.3	3.5 \pm 0.4
	36	5.2 \pm 0.5	7.3 \pm 0.6
	48	11.2 \pm 0.9	12.1 \pm 0.9
	60	19.7 \pm 1.3	17.6 \pm 1.1

who had completed the family but not ready to accept permanent method, as according to USFDA the efficacy of CuT 380A is said to be 10 years.

Acknowledgement

The authors are grateful to the Population Council, New York, for the gift of the CuT 380A devices. The authors are also grateful to the State Health Authorities and Medical and Paramedical Staff of the PPCs for their co-operation in the implementation of the study.

Project Investigators: M. Bhattacharya (KEM Hospital, Bombay), Bukshee K (All India Institute of Medical Sciences, New Delhi), Bhargava H (Medical College, Jaipur), Baveja R (Moti Lal Nehru Medical College, Allahabad), Chaddha B (Kasturba Hospital, Delhi), Coyajee KJ (King Edward Memorial Hospital, Pune), Chatterjee P (R.G.Kar Medical College, Calcutta), Dhall K (Postgraduate Institute of Medical Education and Research, Chandigarh), Das K (King George Medical College, Lucknow), Das R K (Medical College, Guwahati), Ghosh A (S.S.K.M., Calcutta), Hazra MN (Medical College, Baroda), Kodkany BS (Jawaharlal Nehru Medical College, Belgaum), Kanthamani PN (Institute of Obstetrics and Gynaecology, Madras), Krishna U (King Edward Memorial Hospital, Bombay), Lalitha K (S.A.T. Medical College, Trivandrum), Mishra J (Medical College, Patna) Mishra P (S.P. Medical College, Bikaner), Madan R (Medical College, Jammu), Nanda UK (S.C.B. Medical College, Cuttack), Pal M.N. (Medical College, Goa), Premila S (K.G.H., Madras), Rohatgi P (G.S.V.M. Medical College, Kanpur), Rajaram P (Jawaharlal Postgraduate Institute of Medical Education and Research, Pondicherry), Sengupta A (Eden Hospital, Calcutta), Shrotri AN (B.J. Medical College, Pune), Sakhtivel G (Medical Collge, Madurai), Singh K (Safdarjung Hospital, Delhi), Seethamani P (Kilpauk Medical College, Madras), Sengupta PC (Rama Krishna Mission Seva Prathisthan, Calcutta), Sharma U (L.L.R.M. Medical College, Meerut), Vimla CM (Govt. R.S.R.M.

Hospital, Madras), Zaveri K (J.J. Group of Hospitals, Bombay)

Coordinating Unit : Datey S, Gaur LN, Gupta NK, Kumar S, Yadav BS ((Indian Council of Medical Research, New Delhi)

Project Co-Investigators: M Bhattacharya, KEM Bombay; K Buckshee, AIIMS New Delhi; I Chakraborty, IPGMR Calcutta; K Coyaji, KEM Pune; K Das, KGMC Lucknow; SK Das, SJ Hospital New Delhi; KC De, Eden Hospital Calcutta; D Gahlot, SPMC Bikaner; S Gopalan, PGI Chandigarh; A Goswami, Gauhati Medical College; S Gulati, Kasturba Hospital New Delhi; MN Hazra, Baroda Medical College; S Khajuria, Jammu Medical College; BS Kodkany, JNMC Belgaum; R Lakshmi, KMC Madras; T Mathur, SMSMC Jaipur; GG Mukherjee, RG Kar Calcutta; K Mukherjee, MLNMC Allahabad; VI Nalini, SAT hospital Trivendrum; A Oumachigui, Jipmer Pondicherry; MN Pal, Goa Medical college; V Rajappa, Madurai Medical College; Uma Rani, RSRM Madras; S Roy, Patna Medical College; A Senthamil Selvi, KG Hospital Madras; A Shanmugapriya,

IOG Madras; A Shrotri, BJMC Pune; VK Singh, GSVMMC Kanpur; HL Swain, Medical College Cuttack and K Zaveri, JJ Hospital Bombay.

Project Coordinator: Saxena BN (Indian Council of Medical Research, New Delhi).

References

1. Azen SP, Roy S, Pike MC, Casagrande J, Mishell DR, Jr. *Am J Obstet Gynaecol* 128:329, 1977.
2. Diaz J. Pinto Neto A., Diaz M., Marchi N.M., Bahamondes L. *Advances in contraception* 867-72, 1992.
3. Indian Council of Medical Research, Task Force on IUDs. *Contraception* 39:37-52, 1989.
4. Indian Council of Medical Research, Task Force on IUD and Hormonal Contraceptives. *Contraception* 50:, 215-228, 1994.
5. Population Reports, IUDs-An update (Series B No. 6 Jan 1997).
6. Tejuja, S., Saxena, N.C., Malhotra, U. Choudhary, S.D. and Bhinder, G. *Contraception* 1974s, 10: 337-350, 1974.