



Original Article

Study on Emergency Contraception with Cu T 200 B and 0.75 mg Levonorgestrel (2 doses) Using Cafeteria Approach

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Abstract

Objectives: To study the need for emergency contraception (EC) and evaluate the efficacy and side effects of Cu T 200 B and Levonorgestrel (LNG). **Material and Methods:** A 2-years study was conducted at Kasturba Hospital, Delhi, India. **Results:** A total of 68 subjects were enrolled. Of them, 16 (23.53%) chose Cu T and 52 (76.47%) chose LNG as emergency contraceptives. LNG was given to subjects who came within 72 hours of unprotected intercourse and Cu T was given to those who came after 72 hours but within 120 hours of unprotected intercourse. Reasons for EC were: no contraception used (50%), problems with barrier method (42.65%), problems with IUD (7.35%). Side effects were minimal with LNG (5.77% subjects complained of nausea). Among Cu T users 12.5% subjects complained of irregular bleeding and 18.75% had low abdominal pain. **Conclusions:** Both LNG and Cu T 200 B are safe and effective methods of EC with low side effects.

Keywords: emergency contraception, levonorgestrel, copper T200B.

Introduction

Contraception is defined as a method which a woman can use after unprotected intercourse to prevent pregnancy. Emergency contraception (EC) refers to a particular type of contraception that is used as an emergency procedure to prevent pregnancy following unprotected intercourse. The purpose of this study was to evaluate the clinical effectiveness and side effects

associated with the use of levonorgestrel (LNG) and Cu T 200 B in EC, and to study the need and relative acceptability of the methods when offered through cafeteria approach.

Objectives

The objectives of this investigation were: (1) to study the need for EC; (2) to study the profile of women seeking EC and the reasons for seeking EC; (3) relative acceptance of the two methods (LNG and Cu T 200 B); and (4) to evaluate the efficacy and side effects of the two methods.

Material and Methods

The present study was carried out in the Department of Obstetrics and Gynecology, Kasturba Hospital, Delhi, for a period of 2 years. During this period, women of

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reproductive age group who visited the hospital within 120 hours of single unprotected intercourse wishing to avoid unwanted pregnancy were selected. The women were explained about the advantages and disadvantages of both methods, and emergency contraceptive of the patient's choice was administered after screening and ruling out exclusion criteria and contraindications. However, patients were offered both LNG and Cu T 200 B if they reported to the hospital within 72 hours of unprotected intercourse. If they reported after 72 hours, but within 120 hours, of unprotected intercourse only Cu T 200 B was offered.

The inclusion criteria were: (1) Regular menstrual cycle for last 3 months; (2) A single act of unprotected intercourse within 72-120 hours; (3) Willing not to have further acts of intercourse during the same cycle; and (4) Available for follow-up.

Women with known or suspected pregnancy, nulliparity, undiagnosed vaginal bleeding, previous ectopic pregnancy, thromboembolism, migraine, and evidence of reproductive tract infection were excluded.

The women who fulfilled the criteria for inclusion and were willing to participate were enrolled for the study. Written informed consent was obtained from each subject.

Observation and Results

During the study period of 2 years, a total of 68 subjects were enrolled. Emergency contraceptive was given to the subjects after excluding contraindications and exclusion criteria, and according to their own choice.

Total subjects who requested for EC during study period	346
EC given to	68
Not eligible for EC	278 (80.35%)
Reason for non eligibility:	
Intercourse >5 days	105 (30.26%)
Intercourse >3 days but wanted to use LNG	2 (0.57%)
Period overdue	91 (26.30%)
More than one unprotected intercourse	15 (4.33%)
H/O Irregular period	29 (8.38%)
Lactational amenorrhea	24 (6.93%)
Out of area of approach for follow up	12 (3.46%)

The subjects were divided into two groups, A and B.

Group A

Majority (n=52; 76.47%) of the women opted for LNG treatment. The first dose 0.75 mg tablet was given orally within 72 hours of single unprotected intercourse followed by the second dose after 12 hours.

Group B

A total of 16 (23.53%) women who opted for Cu T 200 B came after 72 hours, but within 120 hours, of single unprotected intercourse. Cu T 200 B was inserted under aseptic conditions.

Follow-up was done within 7 days of onset of vaginal spotting or bleeding. At follow-up visit presence of any side effects, time of onset, and duration and amount of menstrual bleeding were noted. If there were further acts of intercourse, the type of contraception used was noted.

Table 1 shows demographic profile of the study group. Majority of subjects were aged between 25 and 34 years (69.23% in LNG group and 50% in Cu T 200 B group). More than half (51.92%) of the subjects of LNG group and 50% subjects of Cu T group had one or two children. Majority (51.92%) of subjects in LNG group and 25% in Cu T group reached hospital within 24 hours of unprotected coitus. Less than half (37.5%) of subjects reached hospital after 72 hours, but within 120 hours, of unprotected coitus.

Table 2 shows reasons for EC. There were no contraceptive used (50%), problems with barrier methods (42.65%), and problems with Cu T (7.35%). Majority (48.08%) in LNG group and 25% in Cu T group used EC due to problems with barrier methods in the form of slippage, breakage, or failure to use condom during intercourse.

There was no failure of EC in any group in the present study.

Table 3 shows resumption of menses after EC use. Menses resumed on time, i.e., within ± 7 days of expected date of next menses in 78.85% cases of LNG group and 81.25% cases of Cu T group. Menses started before 7 days of next expected date in 11.54% cases of LNG group and 18.75% cases of Cu T group. Delay for >7 days occurred in 9.62% cases of LNG group, while in Cu T group there was no delay in onset of period.

Table 1
Demographic characteristics

Characteristic		LNG (n=52)		Cu T 200 B (n=16)		Total (n=68)	
		No.	(%)	No.	(%)	No.	(%)
Age (years)	<25	7	(13.46)	3	(18.75)	10	(14.71)
	25-34	36	(69.23)	8	(50.00)	44	(64.71)
	>35	9	(17.30)	5	(31.25)	14	(20.58)
Partiy	1-2	27	(51.92)	8	(50.00)	35	(51.47)
	3-4	23	(44.23)	5	(31.25)	28	(41.18)
	>4	2	(3.85)	3	(18.75)	5	(7.35)
Coitus EC interval (hours)	<24	27	(51.92)	4	(25.00)	31	(45.59)
	24-48	22	(42.30)	5	(31.25)	27	(39.70)
	49-72	3	(5.77)	1	(6.25)	4	(5.88)
	>72	0	(0)	6	(37.50)	6	(8.82)

Table 2
Reasons for using EC

Reason	LNG (n=52)		Cu T 200 B (n=16)		Total (n=68)	
	No.	(%)	No.	(%)	No.	(%)
No use of contraception	26	(50)	8	(50)	34	(50)
Slippage of condom	2	(3.85)	1	(6.25)	3	(4.41)
Breakage of condom	13	(25)	1	(6.25)	14	(20.59)
Forgot to use condom	10	(19.23)	2	(12.5)	12	(17.65)
Displaced/expelled IUD	1	(1.92)	4	(25)	5	(7.35)

Table 3
Resumption of menses

Time from expected menses (days)	LNG (n=52)		Cu T 200 B (n=16)		Total (n=68)	
	No.	(%)	No.	(%)	No.	(%)
Early (<7)	6	(11.54)	3	(18.75)	9	(13.21)
On time (+7)	41	(78.85)	13	(81.25)	54	(79.41)
Delay (>7)	5	(9.62)	0	(0)	5	(7.35)

In LNG group, the incidence of nausea, giddiness, and menstrual disturbances was very low, (Table 4); 5.77% subjects developed nausea, only 9.62% subjects experienced more bleeding than previous menses, and 5.77% subjects had irregular bleeding or spotting after LNG use. In Cu T group there was low abdominal pain in 18.75% cases, heavy bleeding in 25%, and irregular bleeding in 12.5%.

Discussion

EC is the woman's only reliable option for preventing pregnancy after an unintended or unprotected sexual intercourse or failure of contraception. EC can save millions of women from unplanned and unwanted pregnancies and complications and deaths from illegal or unsafe abortions. It is thus obvious that a wider knowledge and more extensive use of effective EC would be life saving for many women. Therefore, there is an increasing demand for EC, and search for effective methods to prevent unwanted pregnancy is continuing incessantly worldwide.

Postcoital hormonal contraception with high-dose estrogen was first reported in 1960s for rape victims¹. Emergency contraceptive pills were also known as "morning after pills". Use of Cu T as a method of EC was introduced in late 1976 by Lippes. The combined regimen of estrogen and progestogen was introduced in the early 1970s and became popular as Yuzpe method. The Yuzpe

regime consists of the administration of two doses of 100 ug of ethinyl estradiol plus 500 ug of levonorgestrel each, with a 12-hr interval between doses. However, there was high incidence of side effects in the form of nausea and vomiting. To decrease the side effects of estrogen-progestogen combination, new generation progestogen LNG was introduced as postcoital pill by Latin American team in 1980². Johansson et al. (2002) conducted pharmacokinetic study of different dose regimens of LNG³. Joint analysis of effectiveness of LNG as EC was studied by Mikolajczyk and Stanford (2007) who concluded that LNG acted as EC by disruption of ovulation as well as its postfertilization effects⁴.

Present study was conducted to determine the need for EC and evaluate the efficacy and the side effects of Cu T and LNG as emergency contraceptive agents. Women who reported to hospital within 72 hours of unprotected intercourse had to make informed decision to receive either levonorgestrel or Cu T 200 B, after briefing them on the advantages and disadvantages of both methods. However, if they reported after 72 hours of unprotected intercourse, but before 120 hours, they were offered only Cu T 200 B.

Need for EC

During the 2-year study period, 346 subjects requested for EC, indicating its need. However, 278 (80.35%) women were not eligible for EC as 91 (26.30%) were

Table 4
Side effects

Side effect	LNG (n=52)		Cu T 200 B (n=16)	
	No.	(%)	No.	(%)
Nausea	3	(5.77)	0	(0)
Giddiness	1	(1.92)	0	(0)
Abdominal pain	0	(0)	3	(18.75)
Heavy bleeding	5	(9.62)	4	(25)
Irregular bleeding	3	(5.77)	2	(12.5)
Scanty period	1	(1.92)	0	(0)

already overdue, 105 (30.26%) had their intercourse >5 days earlier, and 15 (4.33%) had more than one unprotected intercourse. This shows that there is a great need for public awareness regarding proper use of EC.

Relative Acceptance of LNG and Cu T 200 B

When both LNG and Cu T were offered as emergency contraceptive agents using cafeteria approach, majority (76.47%) opted for LNG and only 23.53% who had come after 72 hours but within 120 hours of intercourse opted for Cu T. Two subjects (0.57%) who had inter-course between 72 and 120 hours refused Cu T, but were willing for LNG as EC which could not be provided to them as per the study. This indicates that majority of women do not like Cu T as EC though it will provide them continued contraception.

Profile of Woman Seeking EC

On study of demographic characteristics (Table 1), 64.71% women belonged to age group of 25-34 years. It was observed that 7.35% women were para ≥ 4 ; 31 women (45.59%) reported within 24 hours and 6 (8.82%) after 72 hours of intercourse. These six women were eligible for only Cu T 200 B.

Reasons for Seeking EC

EC was needed by 50% of women because they had not used any contraceptive methods, by 20.59% women due to breakage of condom and by 7.35% due to displaced/expelled IUD. Few (17.65%) women needed EC as they had forgot to use condom (Table 2). This indicates the need to educate the women regarding regular contraceptive use and also regarding correct and consistent use of condom.

Efficacy of EC

No failure of EC was observed in the present study with the use of either LNG or Cu T 200 B. In 1997-1998, a study was carried out under World Health Organization in which women from 14 countries had EC using YUZPE regime or LNG, and the reported failure rate was 3.2 and 1.1%, respectively⁵. Fasoli et al (1989)⁶ summarized nine studies and reported that out of 879 women who accepted Copper containing IUD as the sole method of postcoital contraception only 1 pregnancy was reported⁶. Trussel

and Stewart (1998) reported 1% failure rate of IUD insertion ≤ 5 days after unprotected coitus⁷.

Resumption of Menses After EC

Resumption of menses after EC was studied in both groups (Table 3). In 78.85% cases of LNG group and 81.25% cases of Cu T group, menses were resumed on time, i.e., within ± 7 days of expected date of next menses. Delay of >7 days beyond expected date of next menses was observed in 9.62% cases who had used LNG, but in none of the cases who had used Cu T. Delay of menses may cause anxiety to women and pregnancy has to be ruled out and women reassured.

Side Effects

In the present study, minimal side effects were observed with use of LNG (Table 4). Nausea was reported in 5.77% cases and no vomiting was reported. Herten and Von Look (1998)⁵ reported nausea and vomiting in 23.1 and 5.6%, respectively, with use of LNG, and 50.5 and 18.8%, respectively, with use of Yuzpe regime.

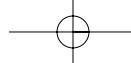
Abdominal pain was complained by 18.75% cases after Cu T use. Heavy bleeding was reported by 25% cases after use of Cu T as compared to 9.62% cases after use of LNG, while irregular bleeding was reported by 12.5% cases after Cu T insertion as compared to 5.77% cases after LNG use. This indicates that Cu T had more side effects in form of pain abdomen (not seen with LNG) and heavy and irregular bleeding (less with LNG).

Conclusion

EC has a definite place in preventing unwanted pregnancies in present day society as an emergency measure in cases of rape, incest, failure of barrier or natural contraceptive methods, and unprotected or unplanned coitus. In community, LNG is preferred over Cu T. LNG has high acceptability with low side effects, while Cu T can be inserted at long interception period and provides contraception for longer period but may produce pelvic pain and menorrhagia.

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