Contraceptive Effectiveness of Levonorgestrel Releasing Intrauterine System

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Abstract

Background: This study evaluated the contraceptive effectiveness of progesterone releasing intrauterine contraceptive devices (IUCD) and compared it with the Copper T device.

Methods: Seventy patients were selected in each group. Menstrual charts were maintained and data recorded at one, three, six months and one year after insertion of the device.

Result: One year follow up was completed by 66 patients in the Levonorgestrel Releasing Intrauterine System (LNG-IUS) group and 62 in the Cu T group. They were age, parity and education level matched. The mean duration of menstrual flow for the LNG-IUS group was 3.6 days and that for CuT group was 5.1 days ($p>0.05$). Insertion of LNG-IUS was found to be significantly difficult than the Cu T 380, with increased pain at insertion ($p<0.05$). There was no pregnancy in the LNG-IUS group and expulsion rates were low. The most significant difference was scanty periods and at times amenorrhoea in the LNG-IUS group. Termination rates for various reasons were almost equal in both groups.

Conclusion: Both devices were effective, safe, well accepted and tolerated. LNG-IUS scores high in patients with preexisting menorrhagia or dysmenorrhoea while Cu T 380 has advantages of lower cost, ease of insertion and comparable efficacy.

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Key Words: Copper T 380; Levonorgestrel intrauterine system; Contraception; Menorrhagia; Amenorrhea

Introduction

Contraception dates back as far as ancient Egypt and Greece. After World War II, the increase in world population was alarming and birth control pill was developed for contraception. Technology has allowed the contraception industry to develop different types of contraception for females, with varying degrees of acceptance and success [1].

Intrauterine devices (IUDs) are safe and effective method of reversible, long-term contraception for most women [2]. They are small flexible devices made of metal and/or plastic whose popularity stems from their efficacy and long duration of effectiveness. The most widely used IUDs are copper-bearing IUDs. They do not affect breastfeeding, interfere with intercourse, or have hormonal side effects. One drawback of IUDs is their tendency to cause heavy menstrual bleeding. With most devices the pregnancy rate ranges from 1 to 3 per 100 women per year. CuT 380 A has one of the lowest failure rate of less than 1 per 100 women/year [2].

Levonorgestrel Releasing Intrauterine System (LNG-IUS) is one of the newest forms of contraception. It is as effective as sterilisation in preventing pregnancy. It has been widely used in Europe for over 10 years [3]. It

is considered an ideal method of contraception for women who want to avoid oral contraceptive pills (OCPs) and are yet averse to sterilisation.

The aims and objectives of this study were to evaluate the contraceptive effectiveness and side effects of LNG-IUS as compared to Cu T 380. An effort was made to study the menstrual abnormalities and other systemic side effects of LNG-IUS.

Material and Methods

The study was conducted as a single blind randomised prospective study. Parous women in the age group of 20–40 years, desiring contraception, in good health without contraindications to copper, contraceptive steroids or IUD use were candidates for the study. History was taken with regards to persistent abnormal vaginal bleeding, pelvic inflammatory disease (PID) in the recent past and ectopic pregnancy and women with positive history were excluded from the study, as were women with history of current. Patients who would not be available for follow up were excluded. Informed consent was taken for use of either LNG IUS or the Cu T 380 and participants were randomly selected for each group. The device was inserted between Days 1 to 7 of periods. Alternatively the device was inserted three days after a 1st trimester medical termination of pregnancy (MTP). Mefenamic acid 500mg thrice daily was prescribed to

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the patients in both groups for pain relief. Patients were asked to keep a menstrual calendar recording the number of days of bleeding or spotting as well as the amount of bleeding expressed as the number of pads or part there of used. The menstrual chart was recorded onto the protocol form.

A total of 70 patients were selected for each group and followed up. Follow up was done at one, three, six months and one year post insertion.

Results

Four patients in the LNG-IUS group and eight patients in the CuT 380 group were lost to follow up after six months. These patients were removed from the data analysis.

Majority of the patients were para 2 or above in both groups in the age group of 26-35 years (Tables 1-3). The mean duration of menstrual flow for the LNG-IUS group was 3.6 days and that for CuT 380 group was 5.1 days. Using the unpaired T Test this difference was statistically not significant ($p=1.11$). A total of 78 (60.9%) were post menstrual insertions and 50 (39.06%) following 1st trimester MTP.

Physician's judgment was used to define insertions as either easy or difficult. None of the patients were given any pre-insertion preparation except in two cases where insertion was perceived as difficult and had to be given a paracervical block. Both these patients had previous caesarean deliveries and fell in the LNG-IUS group. Using the Fisher Exact Test it was found that a significantly higher percentage of the LNG-IUS group had 'difficult' insertions as compared to the CuT 380 group. Pain at insertion felt by the women was moderate to severe in a larger number of patients in the LNG-IUS group (Table 4).

There were no pregnancies in the LNG-IUS group as against one in the CuT 380 group. The expulsion rate was 1.5% (1/66) for LNG-IUS and 3.2% (2/62) for CuT 380 group. This is not statistically significant ($p=0.67$). The change in menstrual pattern varied from an increase in bleeding to amenorrhea depending on the device used. The findings at the end of one year are summated in Table 5.

The decrease in bleeding amount was progressive from

the 4th -5th month of use of LNG-IUS. The pattern of menstrual flow in LNG-IUS users, in decreasing frequency were scanty bleeding, spotting, amenorrhea and menorrhagia. The reasons for termination of IUCD use are summated in Table 6. No distinct trend was seen in termination rates suggesting that the counselling of the patient is more important more than the basic educational background ($p=0.5$). At the end of one year 86.4% of LNG-IUS users and 79.1% of Cu T 380 users were willing to continue with the contraceptive.

Discussion

The insertion of LNG-IUS is different from the conventional pull back technique used for copper devices. Luukkainen et al [3], recommended that 15-20 seconds should be allowed for the device arms to open in the uterine cavity before it is gently pushed into the fundus of the uterus for correct placement of the device.

The tip of LNG-IUS is larger than the copper devices, which could account for the increase in the difficulty and pain at insertion. Our study showed higher incidence of difficult insertions and more patients with moderate to severe pain at insertion which was statistically significant. Luukkainen et al [3], have recommended use of paracervical block and cervical dilatation or use of Misoprostol prior to insertion. It was felt that smooth insertion of LNG-IUS is a learnt technique and is very different from the pull back technique used to the copper IUDs.

Both IUDs proved to be effective and safe with no pregnancies in the LNG-IUS group and one in the Cu T group. This is probably because of limited number of cases in both groups and a shorter study period of one year. Various studies have documented the failure rate of LNG-IUS to be approximately 0.18 pregnancies per hundred women years and that of Cu T 380 to be less than 0.2 per 100 women years of use [4]. Shamaash et al [5], did not report a single pregnancy in 320 lactating women who used LNG-IUS and Cu T 380 A over a

Table 1
Patient distribution by parity

Parity	LNG-IUS group (n=66)	CuT 380 group(n=62)	Remarks
Para 1	12	14	$p=0.776$
Para 2	30	25	Not significant
Para 3 and +	24	23	

Table 2
Patient distribution by age

Age (years)	LNG-IUS group (n=66)	CuT 380 group (n=62)	Remarks
20-25	14	17	$p=0.365$
26-30	22	23	Not significant
31-35	23	20	
36-40	07	02	

Table 3
Patient distribution by educational status

Level of education	LNG-IUS group (n=66)	CuT 380 group(n=62)
Class X and below	10	12
Class XI – XII	15	17
Beyond Class XII	41	33

Table 4
Comparison of pain at insertion of device

Pain at insertion	LNG-IUS group	CuT 380 group	Remarks
None	26 (39.4%)	23 (37.1%)	$p=0.026$
Mild	29 (43.9%)	37 (59.6%)	Significant
Moderate	09 (13.6%)	01 (1.6%)	
Severe	02 (3.03%)	01 (1.6%)	

Table 5**Comparison of change in menstrual pattern for both devices**

Menstrual pattern	Device	Increase	No change	Decrease	Remarks
Menstrual flow	LNG-IUS	03	18	45 *	p<0.00000001
	CuT 380	47	14	01	Significant
Days of bleeding	LNG-IUS	09	22	35	p<0.00000001
	CuT 380	36	26	00	Significant
Length of cycle	LNG-IUS	19	44	03	p<0.001
	CuT 380	02	60	00	Significant
Intermenstrual bleed/ spotting	LNG-IUS	09	29	28	p<0.000003
	CuT 380	19	40	03	Significant
Dysmenorrhoea	LNG-IUS	04	20	42	p<0.0000001
	CuT 380	42	18	02	Significant

* 14 of these 45 women using LNG-IUS had amenorrhea at the end of one year.

Table 6**Reasons for termination of IUCD use**

Reason for termination	LNG-IUS	Cu T 380
Pregnancy	Nil	01
Expulsion	01	02
Menorrhagia/ persistent spotting	02	05
Amenorrhea	03	Nil
Dysmenorrhoea	01	02
PID	Nil	02
Other medical	02	01
Total terminations	09/66 (13.6%)	13/62 (20.9%)

period of one year.

LNG-IUS significantly reduced menstrual blood loss as compared to the copper IUD. Bleeding days were reduced after insertion accompanied by an increase in spotting. After the first few months of insertion, LNG-IUS significantly reduced the bleeding as well as spotting days in comparison to Cu T 380, with normal menstrual patterns. It lengthened the cycle length with a trend towards amenorrhea in 21.2% of the cases. Similar findings have been documented by others in a large multicentric studies [4,6].

Continuation rates were influenced by counselling at the initial and subsequent visits. The side effects were more acceptable if they were known to the women. The older and multiparous patients found the amenorrhea caused by LNG-IUS more acceptable than the younger ones. Continuation rates at the end of one year were similar to those reported by others [4,5].

Amongst the non-menstrual effects, the lower incidence of PID in LNG-IUS users, though statistically not significant due to small number of cases, may find an explanation in the fact that progesterone causes the cervical mucous to thicken, thus preventing ascending infection.

We concluded that both devices were effective, safe, well accepted and tolerated. LNG-IUS scores higher in patients with preexisting menorrhagia or dysmenorrhoea. Cu T 380 has advantages of lower cost, ease of insertion and equal efficacy. Proper counseling helps in the acceptance and continuation with both devices.

Conflicts of Interest

None identified

Intellectual Contribution of Authors

Study Concept : Surg Cdr A Kapur, Surg Cmde S Kumar

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