

Complications of Levonorgesterol Intrauterine System versus Multiload CU 375 as Contraceptive Method

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Objective: To compare the complications of levonorgesterol releasing intrauterine system with multiload as a contraceptive method in women of reproductive age.

Study Design: Randomized Control trial

Place and Duration of Study: Department of obstetrics and gynecology , Shifa Hospital, from January 2008 to June 2009.

Patients and Methods: 200 female patients of reproductive age group were included in this study selected by consecutive sampling and divided randomly (lottery method) in two groups (100 each). Informed written consent was obtained. A structural proforma was used to collect information regarding age of patients , type of intrauterine device used, continuation of use. Women were followed up to 1 year for complications. Outcome data included side effects (daysmenorrhoea , menorrhagia, vaginal discharge , intermenstrual bleeding episodes) and satisfaction rate.

Results: 30% patients experienced dysmenorrhoea in Group A (Multiload) as compared to 5% patients in Mirena (Group B). Menorrhagia was observed in 40% of the females using multiload (Group A) . Intermenstrual bleeding was observed in 2% of the females (multiload group) and 10% of females (Mirena group) in first 6 months of insertion. Pelvic inflammatory disease was observed in 3% of females using multiload which lead to discontinuation of it while none was observed in mirena group. 94% of the women were satisfied in multiload (Group A) while 100% satisfaction was observed in Mirena Group (Group B). Pregnancy was not observed in both groups during study period.

Conclusion: The levonorgesterol-releasing intrauterine system (LNG IUS) is a good choice for contraception.

Key Words: Contraception, Intrauterine device , Family planning , Mirena.

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Introduction

Unwanted pregnancies are a major public health problem for both developing and developed nations. Unplanned pregnancies generally result from ineffective use of contraceptives and result in induced abortion.¹ In the 1970s a new approach to the delivery of hormonal contraception was researched and hormones were incorporated into non-medicated contraceptive device to improve contraceptive action.² Intrauterine contraceptive devices are relatively maintenance free, with users having to consciously discontinue using them

to become pregnant rather than taking a proactive daily decision to avoid conception.^{1,2} Intrauterine Contraceptive Device is a long-term contraceptive method that is popular and widely used.³ Use of modern contraceptive methods has been shown to reduce unwanted pregnancy, high parity and maternal mortality. Intrauterine contraceptive devices which are among the safest and most effective reversible contraceptives available, are particularly suitable for women in developing countries as they are affordable, convenient to use, do not require re-supply visits and are very cost-effective.⁴ However, sociocultural and behavioral factors play an eminent role in continuation of use as well as discontinuation of a contraceptive.⁵ The levonorgesterol-

releasing intrauterine system (LNG-IUS) is a T-shaped IUD with a steroid reservoir containing 52 mg of levonorgestrel that is released at an initial rate of 20 µg daily. Most users experience a dramatic reduction in menstrual bleeding, and most of the women become amenorrheic 1 year after insertion.⁶ The 'unmet' need for reproductive health care in Asia requires a wide demand net. Besides the efforts being made to increase the availability of oral contraceptives, condoms and IUDs, an approach for increasing Health education is recommended through education about the variety of safe contraceptives and the use of traditional methods as well. While guidelines of the World Health Organization for quality care in family planning should be implemented in rural and urban sectors, concomitant efforts should also be made to create awareness regarding recent advances in contraceptive technology for improving women's reproductive health.⁷ For women planning long term contraception IUDs (Intrauterine contraceptive devices) offer an excellent contraception option including both hormonal and non hormonal one. IUD is a reversible ,highly effective , safe and long acting method of contraception whose widespread use decrease the high rate of unintended pregnancy.⁸ In developing countries it is used by 14.5% women of reproductive age while in developed world this percentage is 7.6% , with highest use in Asia. It is a good option for women who are breast feeding and cannot use estrogen based oral contraceptive methods.⁹ This randomized Control trial was designed to compare the complications and patient satisfaction between Group A (Multiload) and Group B (levonorgestrel releasing intrauterine system) in women of reproductive age. As there is an unmet need for safe and effective contraceptive methods, so this study was planned to determine a good IUCD (Intra uterine contraceptive device) for women desiring Family Planning.

Materials and Methods

This study was conducted in Gynaecology and obstetrics department of Shifa International Hospital, from January 2008 to June 2009. The ethical requirements for the study were fulfilled. Permission was obtained from the Hospital Ethical review committee before the commencement of study. There was no conflict of interest. Informed written consent was obtained prior to the start of the study. 200 patients were selected by consecutive (non-probability) sampling technique from the Gynecology Outpatient department. Those 200 patients were randomly divided into either group A (Multiload) or group B (Mirena) by lottery method. There were 100 patients each in group A or B. Single blind technique was used. Women were selected from the Gynecology OPD and were followed up later on, initially for six months for the development of any

Pelvic inflammatory diseases. Patients with menorrhagia, dysmenorrhoea and who already had pelvic inflammatory disease due to some pathology were not offered IUDs and were not included in this study. Data was collected on pre structured proforma which included age of the patients, type of the IUD used and its duration. Women were followed up for a year. Outcome data included dysmenorrhoea , menorrhagia, vaginal discharge and intermenstrual bleeding. Participant satisfaction with treatment results was collected regarding the respondent's experience with the study and the patient satisfaction regarding the particular method of contraception. Satisfaction rate was recorded using visual analogue scale that included score 1 to 5 rating not satisfied (0), satisfied (1-3), highly satisfied (4-5). The study included currently married women in the child bearing age i.e. 18-45 years. The women selected were residents of Islamabad/Rawalpindi and had access to the hospital for the visits. These women belonged to different socioeconomic groups. These women had normal 28-35 day menstrual cycles with no history of menorrhagia. It was ensured that these women had normal cervical cytology and Mammograms (if >35 years). Also they had no history of uncontrolled Hypertension, Diabetes, thrombotic event, Dysfunctional Uterine Bleeding and abnormal Liver Function Tests.

Results

The mean age of patients was 28 years, SD +0.81. Regarding the complication rate in two groups (**Table I**), it was found that 30% of the patients in multiload group (Group A) developed dysmenorrhea vs 5% in mirena group (Group B) with $p < 0.02$. However, 40% of the patients in Group A developed menorrhagia and none in Group B, thus giving p value < 0.05 which is significant.

Intermenstrual bleeding was observed in 2% of Group A (multiload) while in Group B (Mirena), 10% of the females developed this complaint but only for initial six months, which settled later on ($p < 0.02$). Vaginal discharge was seen in 3% of women of Group A

Table I: Complications associated with intrauterine contraceptive devices

S no	Complications Associated with intrauterine devices	Multiload (Group A)	Mirena (Group B)	p value
1	Dysmenorrhoea	30%	5%	$p < 0.02$
2	Menorrhagia	40%	0%	$p < 0.05$
3	Intermenstrual bleeding	2%	10%	$p < 0.02$
4	Pelvic inflamatory disease	3%	0%	$p < 0.08$

(multiload) and none in Group B (mirena) with $p < 0.08$ which is not statistically significant. Regarding the satisfaction rate, 94% of the patients were found to be satisfied in Group A (multiload) and 100% satisfaction was observed in Group B (Mirena). Discontinuation rate was observed in 3% of the females with multiload due to pelvic inflammatory disease.

Discussion

It was found that 30% of the females complained of dysmenorrhoea in Group A (multiload group) as compared to 5% in Group B (mirena group). A study carried out to determine the socio-demographic characteristics of intrauterine contraceptive device acceptors, at the University of Uyo Teaching hospital revealed dysmenorrhea and lower abdominal pain as the most frequently encountered complications associated with IUCD.¹⁰

Menorrhagia was observed in 40% of the patients in Group A, while in mirena group no one developed this complaint (p value < 0.05). The LNG-IUS is a new contraceptive method having the beneficial effects of both hormonal and intrauterine contraception, rather it can be considered an alternative method in the treatment of menorrhagia and dysfunctional uterine bleeding.¹¹ In another study it was observed that most of the LNG-IUS users experienced a dramatic reduction in menstrual bleeding, and most of the women became amenorrheic after one year of insertion.¹² In another study irregular vaginal spotting was observed in 25% of mirena users at six months.¹³ Yet another study showed that spotting was observed in 25% of the mirena users at 6 months, decreasing to 8% and 11% at 18 and 24 months, respectively. Oligomenorrhea was described by one-quarter of women.¹⁴ Same trend was observed in our study that 10% of mirena users developed irregular bleeding in initial six months of its use which later on settled, while in multiload group 2% of the females developed this complaint.

The issue of increased risk of greater severity of infection among IUCD users has been a prominent concern. However the rate of pelvic inflammatory disease in IUCD is lower, with cases observed in first 20 days after insertion.¹⁵ In our study 3% of the females in multiload group developed pelvic inflammatory disease. Another study showed that one of the main reasons for discontinuation of multiload usage in the first 3 months of insertion was pelvic inflammatory disease.¹⁶

High satisfaction rate are observed after one year of use of mirena,¹⁷ however in our study comparison of satisfaction rate is giving p value < 0.10 , which is not statistically significant.

IUCD's are found to be highly effective contraceptive method with global cumulative pregnancy rate of $< 2\%$ at five year however levonorgestrel releasing device has

been found out to be more effective with pregnancy cumulative rate at five years of $< 0.5\%$.¹⁸ LNG IUS is approved for 5 years of contraceptive use, and there is evidence that it can be effective for up to 7 years of continuous use.¹⁹ In our study period none of the females were found to be pregnant. On the contrary LNG-20 IUS has been proved to be more effective in preventing either intrauterine or ectopic pregnancies than multiload.²⁰ Counseling before use should be done so that women can deal with the effects of menstrual changes which are commonly encountered.²¹

The quality of life of women suffering from menorrhagia is impaired in many respects. Excessive bleeding or pain, or both, may impose severe constraints on their professional, social, and family activities.²² LNG-IUS was originally developed for contraception, It has been shown to decrease the amount and duration of normal menstrual flow. LNG-IUS has been found out to be as equally effective in improving quality of life and psychological wellbeing as hysterectomy.²³

Conclusion

Levonorgestrol containing IUCD is a better option for women desiring contraception and has good acceptance level.

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