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ORIGINAL ARTICLE

Long-acting reversible contraceptives - Implant vs. Intrauterine Device; Why go for either?

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ABSTRACT… Objective: To compare the clinical performance and side effects of Implant (jadelle) and intrauterine contraceptive device (Cu-T). **Study Design:** Prospective Analytic study. **Setting:** Department of Obstetrics & Gynaecology, PNS Shifa Hospital, Bahria University of Health Sciences, Karachi. **Period:** 1st January 2021 to 31st December 2021. **Material & Methods:** A total of 162 married females of childbearing age participated in our study, n=81 in each group. Group A consisted of those females who had subdermal implant jadelle inserted and Group B included those ladies who were using intrauterine devices (IUDs) for contraception. Patient with pre-existing medical disrorders and those using levonorgestrel Intrauterine system (Mirena) were excluded. They were interviewed using a structured questionnaire at 6-months post insertion. The outcome were success/ failure rate and side effects. Data was analysed using SPSS 22. **Results:** A total of 162 women were part of this study. Most, 30(37.03%) were between 26-30 years in age in Group A (Implant) vs. 36 (44.4%) in Group B Intrauterine devices. 56 (61.7%) in Group A vs. 68 (83.9%) in Group B had regular menstruation prior to use of LARC; p-value 0.05 which is statistically significant. 45 (55.5%) in Group A vs. 33 (40.7%) in Group B had at least secondary level of education. Among the two study groups, 12(14.8) of Group A vs. 24 (29.6%) of Group B reported mild increase in menstrual bleeding, p-value 0. 000. Other side effects noticed were headache, nausea, and weight gain. **Conclusion:** Progesterone only subdermal implant showed same efficacy as Copper T IUD (intrauterine devices) with significantly fewer side effects.

Key words: Implant, Intrauterine Devices, Long-acting Reversible Contraceptives, Menstrual Disturbance, Side Effects.

INTRODUCTION

Long-acting reversible contraceptive methods are effective, cheap and user friendly. They are safe and provide reversible contraception for longer duration of period. They include intrauterine devices (IUDs), injections and subdermal implants. Advanced countries like the USA are faced with unintended pregnancies of nearly 3 million per year, about 45% of all pregnancies[1] Unplanned pregnancies adversely affect the country's health system as the morbidity associated with induced miscarriages and legal abortions are many folds[2,3] Developing countries like Pakistan, where weak health system is unable to take care of basic health needs, increasing number of children per family is a load on the meagre resources of the country.

Women need to practise contraception for approximately 30 years as the average age of first intercourse in 16 years and age of menopause is 51 years. Despite the high use of contraceptives in the UK, the number of unintended pregnancies is high and so is the abortion rates i.e., 11.6-16 per 1000 women of reproductive age in 2016.[4,5] Ineffective methods used for contraception result in increase in abortion rates due to unintended pregnancies and 30% of pregnant women giving birth were unintended at conception[6]

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Population explosion has taken a toll on education, health, social life, and job opportunities. Many fertile couples are unable to use the contraceptive methods due to cultural and religious values. Low education status is another confounding factor as is the limited knowledge of the methods.

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Poor availability, long distances, and healthcare provider's skill, also affect the use of contraceptive methods. In this scenario, LARC provide an effective and long-term contraception. In recent years LARC use has increased[7,8]

LARC include levonorgestrel containing implant-Jadelle- inserted under the skin, lasting 5 years. It is one of the most effective birth control methods with one year failure rate of 0.05%.[9] It is 99% effective in preventing pregnancy. Progesterone only contraceptive is less used than combined hormonal contraception and so lesser data available on long term use. Implants inhibit ovulation, affect the cervical mucus, and reduce the sperm penetration. Twenty percent of implant users have amenorrhea. Rest have regular cyclical bleeding. Heavy bleeding is uncommon.

IUD is a T shaped device made up of plastic and copper, placed in the uterus. It is effective for 5-10 years. It is a highly effective non-hormonal LARC method, with a failure rate of 0.1-0.4%.[9] In addition, Cu-T IUD (copper containing intrauterine device) can be used for the purpose of emergency contraception. Copper-T devices having 380 mm^3 copper can be used for 10 years and the one with 300 mm^3 for 5 years. Any Cu-IUD inserted at/after 40 years can be retained until no longer contraceptive is required, extending to one year after menopause. All devices have to be removed eventually. Cu IUD works by inhibiting fertilization attributable to toxic effects on ova and sperm. It also prevents implantation due to local inflammatory response. Few contraindications for these are current pelvic tuberculosis, cervical or endometrial cancer, pelvic inflammatory disease (PID) or symptomatic sexually transmitted infection.[10] Increased menstrual bleeding and dysmenorrhea are due to effects of Cu-IUD on endometrium. The antenatal period is the favourable time for discussing contraceptives so that the women are receptive and familiar with the methods after childbirth. LARC are the most effective methods including injectables, intrauterus contraception and implants.

The efficacy of the particular method, compliance, and adherence with the method, determine its effectiveness. The injectables containing progesterone last for 13 weeks, requiring perseverance and health care worker skill. Pakistan, limited data is available on the use of implants. This study aimed to find out comparative effectiveness of Jadelle and Copper containing IUD and its acceptability among females attending Gynaecology OPD of a Tertiary Care Hospital in Karachi.

MATERIAL & METHODS

This comparative study was carried out at Department of Obstetrics & Gynaecology, PNS Shifa Hospital, Bahria University of Health Sciences, Karachi from 1st January 2021 to 31st December 2021. Patients were counselled for LARC methods namely Jadelle and IUD insertion for contraception. After taking approval from the hospital's ethical committee (ERC/2021/Gynae./76), a predesigned questionnaire was filled out by females who got subdural implant or IUD inserted after informed consent. WHO Sample size calculator was used to calculate sample size as 166 (n=83) in each group.[11]

A total of 162 married females between the ages of 20-40 years were part of this study.; n=81 in each group. 4 women were lost to follow-up. Respondents of Group A had subdermal implant Jadelle inserted, and Group B were IUD users as LARC method.

Patients using Mirena (LNG IUS), contraceptive injections, pills, barriers, other methods of contraception or patient for emergency contraception or having any contraindication to respective methods were excluded from this study. Individuals having any medical illnesses were also excluded. They were interviewed and a structured questionnaire was filled out by them at time of insertion. All females were followed for 6 months after insertion, and they were interviewed after this period. The questionnaire included questions regarding demographic features, age, parity, education, occupation, lactational status and the LARC method used. It also included questions regarding any side effect associated with the particular method. The two groups were compared with respect to demographic details

and symptomology of menstrual disturbances, dysmenorrhea, backache, weight gain, vaginal discharge, abdominal pain, headache, and nausea.

Statistical analysis was done using SPSS-22. Quantitative data was presented as mean ±SD. Independent sample T test was used to calculate significance. Qualitative data presented as frequency and percentage. Chi square used to calculate significance. The p-value of ≤ 0.05 was significant in the study

RESULTS

A total of 162 females were included in our study, n=81 in each group. Most 30 (37.03%) were between 26-30 years in group A vs. 36 (44.4%) in group B. 60(74%) in group A and 53 (65.4%) in group B were homemakers. 52 (61.2%) had infant less than one year vs. 42 (51.8%) in group B. The demographic and socio-economic features were compared between the two 2 groups.

There were insignificant differences between the two groups regarding age, occupation and lactational status. Table-I

However, majority of females in Group B: 68 (83.9%) vs. Group A: 50 (61.7%) had regular menstruation prior to induction in this study, p-value 0.05, which is statistically important. Most 45 (55.5%) in Group A vs. 33 (40.7%) in Group B had least secondary level of education which is statistically significant.

The side effects associated with use of a particular LARC implant/ IUD were also compared. Only 6 (7.4%) in Group A reported no adverse effects vs. 5(6.2%) in Group B, p-value 1.00, which is not statistically significant.

Majority 75 (92.6%) in Group A and 76 (93.8%) in Group B reported variety of side effects associated with contraceptive. The p-value 1.00; which is not significant. The comparison of change in menstrual bleeding is given in Table-II.

Amongst the patients who reported increase in menstrual bleeding, most reported only mild increase 12 (14.8%) vs 24(29.6%) in Group A and B, respectively. The p-value was 0.00 which is statistically significant. The disturbance in menstrual bleeding in 2 groups is shown in Figure-1.

Variable		Group A (Implant) n (%)	Group B (IUCD)	P-Value
Age (years)	20-25	19 (61.3%)	12 (38.7%)	0.091
	26-30	30 (58.8%)	21 (41.2%)	
	31-35	23 (39%)	36 (61%)	
	36-40	9 (42.9%)	12 (57.1%)	
Education	Illiterate	9 (26.5%)	25 (73.5%)	0.05
	Secondary level	45 (57.7%)	33 (42.3%)	
	Higher secondary level	11 (73.3%)	4 (26.5%)	
	Graduate	9 (37.5%)	15 (62.5%)	
	Post-graduate	7 (63.6%)	4 (36.4%)	
Occupation	Homemaker	60 (53.1%)	53 (46.9%)	0.305
	Workers	21 (42.9%)	28 (57.1%)	
Last born child (years)	≤1 year	52 (57.8%)	38 (42.2%)	0.062
	>1 year	29 (40.8%)	42 (59.2%)	
Pre-study Menstrual Regularity	Yes	50 (42.4%)	68 (57.6%)	0.005
	No	25 (73.5%)	9 (26.5%)	
Lactating mothers	Yes	6 (60%)	4 (40%)	0.746
	No	75 (49.3%)	77 (50.7%)	

Table-I. Comparison of demographic profiles of study groups.

Variable		Group A (Implant) n (%)	Group B (IUCD) n (%)	P-Value
Menstrual Bleeding	No Change	34 (42%)	29 (35.8%)	0.000
	Increased	19 (23.5%)	48 (59.3%)	
	Oligomenorrhea	8 (9.9%)	3 (3.7%)	
	Amenorrhea	20 (24.7%)	1 (1.2%)	

Table-II. Comparison of change in menstrual bleeding.

Variable		Group A (Implant) n (%)	Group B (IUCD) n (%)	P-Value
Dysmenorrhea	Mild	11 (13.6%)	24 (29.6%)	0.006
	Moderate	2 (2.5%)	7 (8.6%)	
	severe	-	-	
	No	68 (84%)	50 (61.7%)	
	Post-graduate	7 (63.6%)	4 (36.4%)	
Backache	Yes	64 (79%)	50 (61.7%)	0.025
	No	17 (21%)	31 (38.3%)	
Weight gain	Yes	12 (14.8%)	15 (18.5%)	0.674
	No	69 (85.2%)	66 (81.5%)	
Vaginal discharge	Yes	4 (4.9%)	33 (40.7%)	0.000
	No	77 (95.1%)	48 (59.3%)	
Abdominal pain	Yes	7 (8.6%)	8 (9.9%)	1.000
	No	74 (91.4%)	73 (90.1%)	
Headache	Yes	-	7 (8.6%)	0.014
	No	81 (100%)	74 (91.4%)	
Nausea	Yes	1 (1.2%)	5 (6.2%)	0.210
	No	80 (98.8%)	76 (93.8%)	

Table-III. Comparison of side effects in study groups.

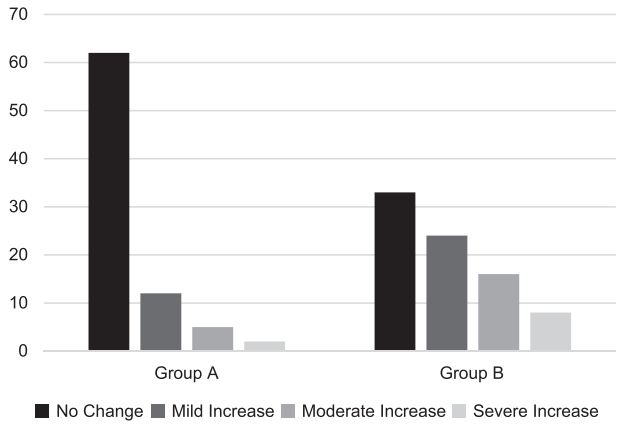

Figure-1. Comparison of change in menstrual bleeding.

Dysmenorrhea was more in IUD than implant users 31(38.2%) vs. 13 (16%) p-value 0.006.

Backache 64(79%) vs. 50 (61.7%) Group A and B respectively p-value 0.025. More women experienced backache in Group A.

Vaginal discharge more in IUD Group B: 33(40.7%) vs. Group A: 4(4.9%). P-value 0.00 Headache in 7(8.6%) of IUD users p-value 0.014.

There is 100% compliance with respective modes of LARC and no one requested change of method of contraception. No one conceived as well during this period of follow up.

DISCUSSION

Our study has shown that Jadelle implant was as effective as Cu-T IUD in preventing pregnancy. It also showed statistically lower incidents of side effects including increased menstrual bleeding, weight gain, vaginal discharge, headache, and dysmenorrhea. However, women from both the groups were satisfied with their method of contraception at 6 months, with no request to change the method. The overall risk of ectopic pregnancy is reduced in females using IUD i.e., 0.07/100-woman years.[12] Increased menstrual bleeding and dysmenorrhea are due to effects

of Cu-IUD on endometrium. The short inter-pregnancy interval is less than 12 months, then it results in increase in preterm birth and neonatal death.[13] The data from the USA shows 80% of females continue the LARC method namely IUD and implant at 12 months[14] There has been an increase in use of LARC methods, particularly implants in young women.[15] The implants and IUD are independent of user compliance and can be relied upon for extended periods. Access to IUD is relatively easier than implant placement[16,17]

According to authors' knowledge, limited data is available comparing hormonal implant and non-hormonal IUD. The study showed that majority of implant (Jadelle) users were in younger age group as compared to IUD users. The majority of participants in both the groups had secondary level of education. Group A individuals reported lesser side effects, however, 61.75% in group A vs 83.9% in group B had regular menstruation prior to induction in the study. Among the individuals experiencing increase in menstrual bleeding, most reported only mild increase 12 (14.8%) vs. 24(29.6%) in A and B, respectively.

These results are similar to a study by VC Pam and colleagues, who found that three quarters (73.5%) of females had at least secondary school education, 90% of these ladies had regular periods before the use of LARC and major reason for removal was menstrual irregularity.[18] Other minor symptoms, statistically significant, were dysmenorrhoea, backache, vaginal discharge, and headaches. LARC methods including implant (Jadelle) are highly effective and safe having a protracted duration of action. These offer immediate reversal to fertility on removal and there is no interference with coitus as well.[9,19] However, skill of health care provider is required for proper insertion and removal.

Morena Luigia Rocca found that abnormal menstrual bleeding is a common side effect for those using etonorgestrel (ENG) single rod as LARC.[20] It is a highly safe and effective contraceptive device used for 3 years. This ENG implant could be an alternative to IUD in young females such as post-partum/ post abortion.

In another study, authors found that majority (72.6%) of females were willing to switch to LARC method, if readily available to them- 58% of women in this study- would be underserved by not being provided equal access to implant. This decreased availability may elevate unintended pregnancies in United States by 8% of all pregnancies per year.[21,22]

The contraceptive CHOICE project studied contraceptive method choice, continuation and outcome of repeat abortion and teen pregnancy.[23,24] LARC users reported greater continuation than non-LARC users (87% vs. 57%), LARC methods were 20 times more effective and there was decrease in repeat abortions. In a study in Karachi Pakistan[25], authors found 93.4% of participants had knowledge of contraception while 49.7% were using contraception. The frequently used methods were condoms (65.5%), withdrawal (28.5%) and pill (24.9%). This usage was more prevalent among the educated class.

In a research study by N Shamim et al, the main finding was continuation with the contraceptive implant (Norplant) after 2 years (91.2%). Other findings were increased in mean weight ($p<0.001$), decrease in mean duration of menstrual cycle ($p<0.001$). Around 67.6% individuals had menstrual disturbances.[26]

In a study by Gao, Ji et al, comparing Levonorgestrel-IUD (LNG-IUD) and Norplant in China, findings were menstrual disturbance as the side effect especially in the LNG-IUD group. The discontinuation rates were 9.0 and 3.0, respectively[11] Implants use had increased in a study by Roy Jacobstein- who found rapid increase in its use in sub-Saharan African states.[27]

Our study had certain limitations. Firstly, we followed our patients uptil six months and hence we cannot comment on long term comparison pf Cu-T IUD and Jadelle implant. Secondly, the results of Jadelle implant cannot be predictive of performance of other brands of implants.

Strengths: this study compared the efficacy of hormonal vs. non- hormonal LARC method and

has effectively shown the benefit Jadelle with lesser side-effects when compared to Cu-T

CONCLUSION

Progesterone only subdermal implant showed same efficacy as Copper T IUD with significantly fewer side effects.

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3	Samina Rehan Khan	Organization + Data convention.	
4	Noureen Jawad	Facilitation.	
5	Tariq Mahmood Malik	Final review + Critique.	
6	Manahil Tariq Malik	Data analysis.	