ORIGINAL ARTICLE

COMPARISON OF CLINICAL EFFICACY AND SIDE EFFECTS OF LEVONORGESTREL IMPLANTS VERSUS COPPER T IUCD: A SIX-MONTH STUDY

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Background: This study investigates long-term contraceptive methods, specifically comparing levonorgestrel implants and copper IUCDs, with a focus on their effectiveness and associated side effects. The objective was to evaluate the performance and acceptability of levonorgestrel implants versus copper IUCDs, while documenting the side effects of each method. **Methods:** The study was conducted at the Obstetrics & Gynecology Departments of PAF Hospital Islamabad and PAF Hospital Kamra, from December 2023 to May 2024. Women opting for either levonorgestrel implants or copper IUCDs were enrolled. Out of a targeted sample of 166, 145 women aged 20–40 years participated. Women using other contraceptive methods or with medical contraindications were excluded. Follow-ups over six months were used to collect demographic and side effect data, which was analyzed using SPSS version 22, considering a *p*-value ≤0.05 as statistically significant. **Results:** Among the 145 participants most of whom were aged 26–30 those using IUCDs reported a higher incidence of pre-study menstrual irregularities (83.3%) compared to levonorgestrel implant users (61.7%). Levonorgestrel implants were associated with fewer side effects, including dysmenorrhea and headaches. **Conclusion:** Both levonorgestrel implants and copper IUCDs are effective in preventing pregnancy. However, levonorgestrel implants were linked to fewer side effects such as menstrual changes and weight gain, making them a favorable choice. After six months, both methods showed high levels of user satisfaction.

Keywords: Long-acting reversible contraception; Levonorgestrel implant; Copper intrauterine device; Contraceptive side effects; Menstrual irregularities; Contraceptive efficacy.

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INTRODUCTION

Long-acting reversible contraceptives (LARCs) are affordable, easy to use, and provide extended protection. They include devices placed in the uterus, injections, and implants under the skin. Unplanned pregnancies strain health systems, especially where resources are scarce, like in Pakistan. Women typically need contraception for about 30 years, starting from age 16 to menopause at 51. Ineffective contraception leads to more abortions due to unplanned pregnancies, with 30% of births being unintended.[1] Rapid population growth impacts education, health, social life, and employment. Cultural and religious beliefs, along with low education and awareness, hinder contraceptive use.

Access issues, distance, and healthcare provider skills also limit contraceptive use. LARCs offer a reliable, long-term solution, with increasing usage in recent years.[2,3] The implant Levonorgestrel implants, which releases levonorgestrel and lasts five years, is highly effective, with a one-year failure rate of 0.05%.[4] It's 99% effective at preventing pregnancy. Implants work by stopping ovulation, changing cervical mucus, and reducing sperm movement. Some users experience no periods, while others have regular cycles; heavy bleeding is rare. The IUD, a T-shaped plastic and copper device, lasts 5–10 years and is a highly effective non-hormonal option, with a failure rate of 0.1–0.4%.[4] Copper IUDs can also be used for emergency contraception and last up to 10 years, depending on the copper content. Any copper IUD inserted after age 40 can stay until contraception is no longer needed, up to a year after menopause. All devices must eventually be removed. Copper IUDs prevent pregnancy by creating a toxic environment for sperm and eggs and preventing implantation through an inflammatory response. They're not suitable for those with certain health conditions.[5] They can cause increased menstrual bleeding and pain due to their effect on the uterine lining. Pregnancy is an ideal time to discuss contraception options. LARCs, including injectables, intrauterine devices, and implants, are among the most effective methods. Their success depends on proper use and adherence. Injectable contraceptives last for 13 weeks and require commitment and skilled healthcare workers.

In Pakistan, data on implant use is limited. This study compares the effectiveness and acceptance of Levonorgestrel implants and copper IUDs among women visiting a Gynecology clinic.

MATERIAL AND METHODS

This multi-center study was conducted at the Obstetrics & Gynecology Department of PAF Hospital, Islamabad and PAF Hospital Kamra from December 1, 2023 to May 31, 2024. Women were advised on long-acting reversible contraceptives (LARCs), specifically Levonorgestrel implants and IUDs. With the hospital ethics committee's approval, women who chose to have a subdermal implant or IUD and gave informed consent completed a detailed questionnaire. The intended sample size was 166, with 83 in each group, as calculated using the WHO Sample Size Calculator.[6] However, only 145 married women aged 20–40 agreed to participate: 73 in the Levonorgestrel group and 72 in the Copper-T IUCD users. Exclusions were those using other contraceptives, needing emergency contraception, or with contraindications or medical illnesses. Participants were surveyed at insertion and followed up for six months. The questionnaire covered demographics, lactation status, and side effects. Groups were compared for symptoms like menstrual changes and pain. Data was analyzed with SPSS-22, using the T-test and Chi-square test to determine significance, with a *p*-value of s 0.05 indicating significance

RESULTS

In our study, 145 women participated. Most were 26–30 years old, with 37.03% in Group A and 44.4% in Copper-T IUCD users. Homemakers made up 74% of Levonorgestrel Implant users and 65.4% of Copper-T IUCD users. In Levonorgestrel Implant group, 61.2% had an infant under one year, compared to 51.8% in the Copper-T IUCD group. We compared demographic and socio-economic characteristics between the groups. Differences in age, occupation, and breastfeeding status were not significant. In our study population, prior to the intervention, menstrual irregularities were present in 43.9% of Levonorgestrel implant users and 33.3% of in the Levonorgestrel group at 23.3%, compared to 20.3% in the Copper-T group, with a *p*-value of .03 (Table-2) Copper-T IUCD users, a difference that was not statistically significant (*p*-value =0.8) (Table-1). At the end of the study, 56.1 % of Levonorgestrel users and 66. 7% of Copper-T users reported no menstrual irregularities. Among those with initial menstrual irregularities, 16.4% of Levonorgestrel users and 5.5% of Copper-T users reported no change in menstrual bleeding, while an increase in bleeding was observed in 6.9% of Levonorgestrel users and 4.2% of Copper-T users. Notably, normal menstruation resumed in 76.7% of Levonorgestrel users and 90.3% of Copper-T users by the study's condusion (*p*-value = 0.03). Education levels differed significantly, with 55.5% in Levonorgestrel Implant users and 40.7% in Copper-T IUCD users having at least secondary education.

In assessing the side effects associated with Levonorgestrel implants and Copper-T IUCD, distinct differences emerged. Dysmenorrhea severity varied significantly between the groups, with 28.8% of Levonorgestrel users experiencing mild symptoms compared to 11.1% of Copper-T users. Moderate dysmenorrhea was reported by 16.4% of Levonorgestrel users and 6.9% of Copper-T users. Severe cases were less common, affecting 2.8% of Levonorgestrel users and 1.4% of Copper-T users, with these differences reaching statistical significance (*p*-value =.004).

Vaginal discharge was more frequent among Copper-T users, with 29.2% reporting this issue compared to only 8.3% of Levonorgestrel users, which was statistically significant (*p*-value = .0012). Weight gain showed a significant difference (*p*-value = .04), reported by 19.2% of Levonorgestrel users and 12.5% of Copper-T users.

Further, 26.0% of Levonorgestrel users experienced headaches, significantly more than the 9. 7% in the Copper-T group (*p*-value = .01). Nausea was also more frequent among Levonorgestrel users at 28.8%, compared to 6.9% among Copper-T users, with a notable *p*-value of .001.

Abdominal pain was reported by 9.6% of Levonorgestrel users and 25.0% of Copper-T users, showing a significant difference (*p*-value = .014). Lastly, backache was more common.

Table-1: Pre- and post-study menstrual irregularity in study population

Variable		Levonorgestrel implant users	Copper-T IUCD users	
Menstrual Irregularity before the study	Present	32 (43.9%)	24 (33.3%)	0.8
	Absent	41 (56.1%)	48 (66.7%)	
Change in menstrual bleeding at the end of study (in those with menstrual irregularity at the start of study)	No change	12 (16.4%1	4 (5.5%)	
	Increased	516.9%1	3 (4.2%)	0.03
	Normal			
	Menstruation	56 (76.7%)	65 (90.3%)	

Table-2: Frequency of side effects in both arouse of study population

Variable		Levonorgestrel implant users	Copper-T IUCD users	*p* value
Dysmenorrhea	Mild	21 (28.8%)	8 (11.1%)	**.004**
	Moderate	12 (16.4%)	5 (6.9%)	
	severe	2 (2.8%)	1 (1.4%)	
	No	38 (52.0%)	58 (80.6%)	
Vaginal discharge	Yes	6 (8.3%)	21 (29.2%)	.0012
	No	67 (91.7 %)	51 (70.8%)	
Weight gain	Yes	19 (26.0%)	9 (12.5%)	.04
	No	54 (74.0%)	63 (87.5%)	
Headache	Yes	19 (26.0%)	7 (9.7%}	.01
	No	54 (74.0%)	65 (90.3%)	
Nausea	Yes	21 (28.8%)	5 (6.9%)	.001
	No	52 (71.2%)	67 (93.1%)	
Abdominal pain	Yes	7 (9.6%)	18 (25.0%)	.014
	No	66 (90.4%)	54 (75.0%)	
Backache	Yes	17 (23.3%)	29 (40.3%)	.03
	No	56 (76.7%)	43 (59.7%)	

DISCUSSION

Our findings indicate that both the Levonorgestrel implant and the Copper-T IUCD are similarly effective in preventing pregnancy. However, the Levonorgestrel implant exhibited a higher incidence of certain side effects, including weight gain and headaches, compared to the Copper-T IUCD. Despite these differences, both contraceptive methods maintained high levels of satisfaction among users over a six-month period. IUDs also showed a reduced risk of ectopic pregnancy, at 0.07 per 100 woman-years.[7] Short intervals between pregnancies, less than a year, may increase the risk of preterm births and neonatal mortality.[8] In the US, 80% of women continue with LARCs after one year[9], and their use, particularly implants, is growing among younger women[10]. LARCs are dependable for extended periods and do not rely on daily user action. IUDs are more accessible than implants.[11,12] Comparative data on hormonal implants versus non-hormonal IUDs is limited. Our findings show a preference for implants among younger women, with most having at least secondary education. The implant group reported fewer side effects, although more women in the IUD group had regular cycles before the study. Mild increases in menstrual flow were noted by 5 (6.9%) implant users compared to 3 (4.2%) IUD users. These findings are in contrast to a study by Tariq and colleagues from Karachi, who reported no statistically significant difference in occurrence of side effects in both the implant users as well as the IUD users.[13]

These results are consistent with VC Pam's research, which found that discontinuation of LARC was mainly due to menstrual irregularities.[14] Other symptoms, though less frequent, included menstrual pain, backaches, vaginal discharge, and headaches. LARCs, like the Levonorgestrel implants implant, are highly effective, safe, and long-lasting. They allow for immediate fertility return upon removal and do not affect sexual activity.[4,5] Proper insertion and removal require skilled healthcare providers.

Rocca identified irregular menstruation as a common side effect of the ENG implant, a reliable three-year contraceptive.[16] This could be an alternative to IUDs for young women postpartum or post-abortion. Another study suggested that 72.6% of women would opt for a LARC if it were readily available, noting that restricted access could increase unintended pregnancies in the US by 8% annually.[17,18] The CHOICE project reported higher continuation rates for LARC users (87%) compared to non-LARC users (57%), with a significant reduction in repeat abortions.[9,20] In Karachi, while 93.4% were aware of contraception, only 49.7% used it, predominantly condoms, withdrawal, and pills, more so among the educated.[21] Shamim *et al*. reported that 91.2% continued with the Norplant implant over two years, some experiencing weight gain and shorter cycles; 67.6% had menstrual disturbances.[22] Gao, Ji *et al*. found menstrual issues were especially prevalent with LNG-IUDs, leading to different discontinuation rates.[23] Jacobstein also noted a surge in implant usage in sub-Saharan Africa.[23]

CONCLUSION

Our study concludes that both Levonorgestrel implants and Cu-T IUDs are highly effective contraceptive methods with low pregnancy rates. Levonorgestrel implants have the advantage of causing fewer side effects such as menstrual irregularities, weight gain, and pain during menstruation. Both methods are well-received by users, with high satisfaction and continuation rates after six months. The strengths of our study are notable. Firstly, there is a high continuation rate among users, which suggests a high level of satisfaction with the contraceptive method. Secondly, our research contributes valuable comparative data on hormonal and nonhormonal long-acting reversible contraceptives (LARCs), filling a gap in the existing literature. Lastly, the study underscores the critical role that the accessibility of LARCs plays in preventing unintended pregnancies. On the other hand, the study has certain

limitations. The sample size is relatively small, which may not accurately represent the broader population's experiences with LARCs. Additionally, the follow-up period of six months is quite brief, potentially overlooking the long-term satisfaction and side effects of the contraceptive methods. Finally, the focus on a specific demographic might limit the ability to generalize the study's findings to a wider population. In view of conflicting results from Karachi, it is pertinent to note that these results need to be validated in a larger sample size to determine true nature of these associations.

For future research, we recommend expanding the scope of the study to encompass a broader and more varied demographic. This would help in making the findings more universally applicable. It's also advisable to prolong the duration of the follow-up period. Doing so would allow for a more comprehensive evaluation of the long-term effectiveness, user satisfaction, and potential side effects associated with LARC methods.

Additionally, it is crucial to identify and address the obstacles that limit access to LARCs. Developing targeted strategies could significantly enhance their availability, particularly for populations that are currently underserved. Another important step is to undertake qualitative studies to gain deeper insights into the personal experiences and preferences of individuals using LARCs.

Lastly, assessing the effectiveness of educational programs on the adoption and sustained use of LARCs could provide valuable information for improving continuation rates and overall satisfaction with these contraceptive methods.

AUTHORS' CONTRIBUTION

AA, AA, ST, GS: Conceptualization of the study design, literature search, write-up, proof reading. SF, SS: Data collection, analysis, interpretation.

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