

Original Research Article

TO COMPARE QUALITY OF LIFE (QOL) OF COPPER-T 380 A AND LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE DEVICE USERS: A PROSPECTIVE COMPARATIVE STUDY

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Received : 05/01/2025
Received in revised form : 23/02/2025
Accepted : 10/03/2025

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DOI: 10.70034/ijmedph.2025.1.294

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (1); 1567-1571

ABSTRACT

Background: To utilize the WHO QOL questionnaire to evaluate and compare the quality of life (QOL) of users of Copper-T 380-A to those of levonorgestrel-releasing intrauterine contraceptive devices (LNG IUCD).

Materials and Methods: This was part of the prospective comparative study. Every woman seeking contraception at the Obstetrics & Gynecology OPD received counselling. A thorough examination was performed on people who agreed to have an IUCD inserted; those who chose copper-T were assigned to Group-A, while those who chose LNG IUCD were assigned to Group-B. At baseline and six months, these patients' quality of life was evaluated using the WHOQOL-BREF questionnaire. Women between 18 to 45 years those who are willing to choose an intrauterine device (Copper T 380 A or LNG IUCD) for contraception were included. Women with Pregnancy or suspicion of pregnancy, Current or recurrent pelvic inflammatory disease, 48 hours - 4 weeks since parturition or abortion, Undiagnosed genital tract bleeding, Genital tract malformations, genital tract malignancy, breast cancer, adnexal mass, history of hydatidiform mole in previous pregnancy were excluded. Using an online sample size calculator for trials (<https://clincalc.com/stats/samplesize.aspx>), a sample size of 98 (49 women in each group with an allocation ratio of 1:1) was determined.

Results: Quality of life (QOL) assessment was done by the WHO Quality of Life- BREF (WHO QOL-BREF) questionnaire, which is an abbreviated WHO QOL questionnaire. Assessment is done at baseline and 6 months. The questionnaire comprises 26 items that measure the four broad domains: Physical health, Psychological health, Social relationship and Environment. There was no significant difference in baseline physical, psychological, Social Relationships and Environment health score between Cu T and LNG IUCD users. A significant increase was seen in all four health scores at 6 months when compared to baseline in LNG IUCD users, p-value (<.0001).

Conclusion: Our study compared the quality of life among Cu T 380 A and LNG IUCD users at the time of insertion and at 6 months of insertion. There was no effect on the overall quality of life in Cu-T 380 users. However, the use of LNG IUCD significantly improved the quality of life parameters (physical, physiological and environmental domains). This improvement in quality of- life in LNG IUCD users may be attributed due to the reduction that was observed in menstrual blood loss and dysmenorrhea as observed after 6 months of use of the LNG IUCD.

Keywords: Levonorgestrel-releasing intrauterine contraceptive devices, Copper-T380-A, WHOQOL-BREF questionnaire

INTRODUCTION

The world's first family planning program and population policy was in India. The adoption of small family norms across India is still a dream.^[1] Contraceptive use is rising in India. In 1970s, 13% of married women used contemporary contraception; by 2009, 48% did and 56.5% by 2019.^[2] Even with increased contraceptive use, incorrect or inconsistent use may explain the high percentage of unplanned pregnancies.^[3] In India, female sterilization is the main contraception. Long-acting reversible contraception (LARC) is an option for women not ready for permanent. Long-acting reversible contraceptives are administered less than once every menstrual cycle or month.^[4] LARC approaches eliminate adherence and user dependence with a single motivational act, improving contraceptive effectiveness. LARCs are one of the Most effective contraception with low failure rates (less than 1/100 women-years), similar to female sterilization.^[5] LARC approaches are cost-effective and user-independent. This increases continuation rates, making them one of the finest tools for preventing unplanned births.^[6] LARC contains IUCDs, injectable, and implanted progestogens. IUCDs are the second-most-used contraceptive.^[7] IUCDs are classified by composition as inert or non-medicated or bioactive or medicated. Second- and third-generation IUCD contain copper or hormones.^[4] The free contraceptive delivery policy in India covers the CuT-380A IUCD. It has a polyethylene T-shaped framework with copper wire wrapped on the main limb and copper sleeves on the arms. About 380 mm sq. of copper wraps it. The device releases 50mcg copper daily. Copper T 380 A lasts 10 years. Potential mechanisms include chemical and biological alterations in the endometrium that make it unfriendly to implantation, impaired sperm ascent, increased tubal motility, and copper's local anti-fertility effect. After stopping this non-hormonal technique, fertility returns promptly. Levonorgestrel-releasing intra-uterine systems (LNG-IUS, Mirena) and LNG IUCD are improved LARCs.^[8] LNG-IUCD hormone-polyethylene T-shaped release device. It contains 52 mg LNG and releases 20mcg daily. LNG-IUS acts for 5 years by limiting implantation in the endometrium due to progesterone's local action and by making the cervical mucus thick, sparse, and unfriendly to spermatozoa. It also prevents ovulation. The non-contraceptive features of LNG IUS make it appealing to many people, including adolescents. LNG-IUS lowers dysmenorrhea and monthly blood loss by 90%. LNG is preferable to Cu T for this reason. Many women's symptoms worsen following copper IUCD treatment.^[9] Switching contraceptives may be due to dissatisfaction or inability to meet needs. Women must also weigh the pros and cons of a contraceptive method before continuing it.^[10] Quality of life and sexual function affect women's contentment with one

contraception.^[11] Contraceptives can impair physical, mental, and sexual health. Contraceptive methods' safety, efficacy, subjective experience, and health impacts affect women's happiness.^[12] The WHO QOL questionnaire measures life quality broadly. The gold standard for global quality of life comparison is WHO QOL-BREF.^[13]

Aims and Objectives

1. To utilize the WHO QOL questionnaire to evaluate and compare the quality of life (QOL) of users of Copper-T 380-A to those of levonorgestrel-releasing intrauterine contraceptive devices (LNG IUCD).

MATERIALS AND METHODS

Eighteen months after receiving ethical permission, the prospective comparative study was carried out in the Department of Obstetrics & Gynecology. Every woman seeking contraception at the Obstetrics & Gynecology OPD received counselling. A thorough examination was performed on people who agreed to have an IUCD inserted; those who chose copper-T were assigned to Group-A, while those who chose LNG IUCD were assigned to Group-B. At baseline and six months, these patients' quality of life were evaluated using the WHOQOL-BREF questionnaire. Women between 18 to 45 years those who are willing to choose an intrauterine device (Copper T 380 A or LNG IUCD) for contraception were included. Women with Pregnancy or suspicion of pregnancy, current or recurrent pelvic inflammatory disease, 48 hours - 4 weeks since parturition or abortion, undiagnosed genital tract bleeding, genital tract malformations, genital tract malignancy, breast cancer, adnexal mass, history of hydatidiform mole in previous pregnancy were excluded.

Sample size calculation

Using an online sample size calculator for trials (<https://clincalc.com/stats/samplesize.aspx>), a sample size of 98 (49 women in each group with an allocation ratio of 1:1) was determined to achieve 80% power, taking into account the mean difference of 6.5 in quality-of-life scores between users of levonorgestrel-releasing intrauterine contraceptive devices and those who used copper-intrauterine contraceptive devices (64.5 ±10.9 vs. 71.0 ±10.3). Ferreira et al.'s study on sexual function and quality of life served as the source for these values (14). The test aims for a significance level of 0.05. The sample size was determined to be 98 (49 in each group) after accounting for a 10% attrition during follow-up.

Statistical Analysis

Categorical variables are represented by numbers and percentages. Quantitative and non-normally distributed variables were compared using the Mann-Whitney test (for two groups), and follow-up variables were compared using the Wilcoxon signed-rank test. When comparing qualitative variables, the Chi-Square test was employed. The Statistical Package for Social Sciences (SPSS) software,

manufactured by IBM in Chicago, USA, version 21.0, was used for the final analysis after data entry was completed in a Microsoft Excel spreadsheet. A p-value of less than 0.05 was deemed statistically significant for statistical significance.

RESULTS

WHO QOL BREF SCORE (WHO quality of life BREF questionnaire)

Quality of life (QOL) assessment was done by the WHO Quality of Life- BREF (WHO QOL-BREF) questionnaire, which is an abbreviated WHO QOL questionnaire. Assessment is done at baseline and 6 months. The questionnaire comprises 26 items that measure the four broad domains:

1. Physical health
2. Psychological health
3. Social relationship
4. Environment

Each item used a 5-point Likert scale.

5=very satisfied, 4=satisfied, 3=neither satisfied nor dissatisfied, 2=dissatisfied, and 1=very dissatisfied. The higher scores indicate a better QOL. The participants were asked to complete the WHO QOL-BREF questionnaire before insertion and at six months of follow-up.

Physical Health

As shown in Table No.1, there was no significant difference was seen in physical health scores at baseline between Cu T and LNG IUCD users (p value=0.43). The median score (25th-75th percentile) of physical health in LNG IUS users at 6 months was 70(65-82) which was significantly higher as compared to Cu T users 65(63-69) (p value=0.007). No significant difference in health score was seen in Cu T users after 6 months (p value=0.426). Also, the change in health score at 6 months in LNG IUCD users is 2(1- 4) which is significantly higher when compared to Cu T users 1(-10-2) (p value=0.0001).

Table 1: Comparison of physical health score (WHO QOL-BREF) between Cu T and LNG IUCD users

Physical health score	Group A(n=49) Copper-T 380A users	Group B (n=49) LNG IUCD users	p value
At baseline			
Median (25th-75th percentile)	69(63-75)	69(63-81)	0.43 [‡]
At 6 months			
Median (25th-75th percentile)	65(63-69)	70(65-82)	0.007 [‡]
Intra-group p value	0.426 [§]	<0.0001 [§]	-
Change at 6 months			
Median (25th-75th percentile)	1(-10-2)	2(1-4)	0.0001 [‡]

[‡] Mann Whitney test, [§] Wilcoxon Signed Ranks Test

PSYCHOLOGICAL HEALTH

Table No. 2, compares the psychological health of the two groups. There was no significant difference in baseline psychological health score between Cu T and LNG IUCD users. A significant increase was seen in psychological health scores at 6 months 70(60-81) when compared to baseline 69(56-75) in LNG IUCD users, p value (<.0001). No significant

change was seen in psychological health score at 6 months when compared to baseline in Cu T users (p value=0.203). The Median (25th-75th percentile) psychological score change at 6 months in LNG IUCD users was 2(1-4) which was significantly higher as compared to Cu T users 1 (-11-3) (p value=0.003).

Table 2: Comparison of Psychological health score (WHO QOL-BREF) between Cu T and LNG IUCD users

Psychological Health score	Group A(n=49) Copper-T380A users	Group B (n=49) LNG IUCD users	p value
At baseline			
Median (25th-75th percentile)	63(56-69)	69(56-75)	0.438 [‡]
At 6 months			
Median (25th-75th percentile)	60(55-66)	70(60-81)	0.003 [‡]
Intra-group p value	0.203 [§]	<0.0001 [§]	-
Change at 6 months			
Median (25th-75th percentile)	1(-11-3)	2(1-4)	0.003 [‡]

[‡] Mann Whitney test, [§] Wilcoxon Signed Ranks Test

SOCIAL RELATIONSHIP SCORE

As shown in Table No.3, no significant difference was seen in social relationship scores at baseline (p=0.193) and 6 months (p=0.063) between Cu T and

LNG IUCD users. A significant increase was seen in social relationship score at 6 months when compared to baseline in Cu T users (p value =0.001) and LNG IUCD (p value =0.0001) users. Change in social

relationship score at 6 months in Cu T users was 1(0-4) and in LNG IUCD users were 1(1-2) with no significant difference between them (p value=0.477).

Table 3: Comparison of social relationship score (WHO QOL-BREF) between Cu T and LNG IUCD users

Social relationship score	Group A(n=49) Copper-T 380A users	Group B (n=49) LNG IUCD users	p-value
At baseline			
Median (25th-75th percentile)	69(61-81)	69(69-75)	0.193 [‡]
At 6 months			
Median (25th-75th percentile)	75(62-82)	75(70-95)	0.063 [‡]
Intragroup p value	0.001 [§]	<0.0001 [§]	-
Change at 6 months			
Median (25th-75th percentile)	1(0-4)	1(1-2)	0.477 [‡]

[‡] Mann Whitney test, [§] Wilcoxon Signed Ranks Test

ENVIRONMENT SCORE

Table No.4, shows that there was no significant difference in environment score at baseline between Cu T and LNG IUCD users (median 75 in both groups) (p value=0.679). A significant increase was seen in environment {WHO QOL-BREF} at 6 months when compared to baseline (p value=0.008) in LNG IUCD users, whereas there was no significant

difference in Cu T users (p value=0.104). The Median (25th-75th percentile) environment score in LNG IUCD users at 6 months was 75(70-78) which was significantly higher as compared to Cu T users (70(60-76) (p value=0.003). Change at 6 months in LNG IUCD users was significantly lower as compared to Cu T users (p value=0.04).

Table 4: Comparison of Environment score (WHO QOL-BREF) between Cu T and LNG IUCD users

Environment score	Group A(n=49) Copper-T380A users	Group B (n=49) LNG IUCD users	p value
At baseline			
Median (25th-75th percentile)	75(69-75)	75(69-75)	0.679 [‡]
At 6 months			
Median (25th-75th percentile)	70(60-76)	75(70-78)	0.003 [‡]
Intragroup p-value	0.104 [§]	0.008 [§]	-
Change at 6 months			
Median (25th-75th percentile)	1(-15-1)	1(0-2)	0.04 [‡]

[‡] Mann Whitney test, [§] Wilcoxon Signed Ranks Test

DISCUSSIONS

Long-Acting Reversible Methods of Contraception (LARC) (IUCDS – Cu- T and LNG IUS, as well as subdermal implants) are extremely safe and effective contraception options for women of all ages. However, they may have some side effects that have a negative impact on one's quality of life, including sexual function. Cu T may lead to dysmenorrhea and increased flow during menstruation along with pelvic pain and abdominal cramps. The LNG IUS on one hand may reduce the menstrual blood loss but on the other hand side effects like irregular spotting and even amenorrhoea may alter the quality of life of some women as they may not like alteration in their menstrual pattern. Very few studies till date (Ferreira J14 et al and Enzli P10 et al) have compared the quality of life and sexual dysfunction in users of these two different methods of contraception.

Quality of life (QOL) assessment was done by the WHO Quality of Life- BREF (WHOQOL-BREF) questionnaire, which is an abbreviated form of the WHO QOL questionnaire. The assessment was done

at baseline and 6-month after the use of IUCDs. In our study, there was a significant increase in the physical health score after 6 months in LNG IUCD users whereas there was no significant change in Cu T users after 6 months. The median physical health score at 6 months was 70(65-82) which was significantly higher as compared to Cu T users 65(63-69) (p value=0.007). Change in physical health score in LNG IUCD users after 6 months is also statistically significant, in LNG IUCD users 2(1-4) which is significantly higher when compared to Cu T users 1(-10-2) (p value=0.0001). In a cross-sectional study of a cohort of Brazilian women to compare the quality of life and sexual function among Cu-T and LNG IUCD users, it was discovered that the mean score in the physical domain in Cu T users was 59.9±12.6 and in LNG IUCD users was 78.0±14.3, indicating a better health score with LNG IUCD use (p 0.001).^[14] However, in a research done by Skrzypulec et al., there was no significant difference in the physical health score as determined by the 'Short Form 36' health survey questionnaire (SF -36) between LNG IUS (Mirena) users and other IUCD users.^[15]

In the present study, psychological health scores were also better in the LNG IUCD group after 6 months of use (p value $<.0001$) as compared to the Cu T group. No increase in score was noted in Cu-T Users. Similarly, the median psychological score change at 6 months in LNG IUCD users was 2(1-4) which was significantly higher as compared to Cu T users 1(-11-3) (p value=0.003). In contrast to the results in our study, there was no significant difference in psychological scores among Cu-T (64.7 ± 11.4) and LNG IUCD (65.4 ± 10.0) users ($p=0.511$) in a cross sectional study conducted among 645 Brazilian women.^[14] Similarly, in a study conducted in 2004 by Enzil P,^[10] et al, there was no significant difference found with regards to psychological variables such as depressive symptoms assessed by Beck Depression Inventory Score (BDI score) 4.7 in LNG IUCD users as compared to 3.9 in Cu T users ($p = 0.328$), general well-being assessed by WHO-5 score: 16.8 in LNG IUCD users and 17.7 in Cu T users with (p value =0.17).^[10] In a cross sectional study conducted by Ferreira et al., the mean social relationship score in Cu T users was 74.5 ± 18.1 and in LNG IUCD users were 74.9 ± 15.3 with no significant difference between the two groups ($p=0.779$).^[14] Interestingly a study showed significantly higher disorders of the emotional-psychological sphere in other IUCD users (60.8 ± 33.2) as compared to the Mirena (LNG IUS) group (70.0 ± 8.4).^[50] In this study, the median social score was 69 at the start and 75 after 6 months in both groups, with no significant difference between them. In all groups, however, there was a substantial rise in the social relationship score after 6 months when compared to the baseline score. In another study conducted by Caruso et al social functioning score, as assessed by SF 36 questionnaire in the Mirena group was 91.5 ± 16.7 as compared to the other IUCDs 89.3 ± 7.4 ; this was found statistically non-significant.^[16] This study observed a significantly better environment score at 6 months when compared to baseline (p value=0.008) in LNG IUCD users, whereas there was no significant difference in Cu T users (p value=0.104). The environment score at 6 months was also significantly higher in LNG group as compared to Cu T users at 6 months (p value=0.003). Our results were similar to what was observed in a cross-sectional study by Ferreira J,^[14] et.al. Where mean score environment score in LNG IUCD users was significantly higher than Cu-T IUCD users ($p < 0.001$).

Limitations of the study

There aren't many studies that compare the quality of life of LNG IUCD with copper T IUCD users. We only followed up with participants for six months; longer-term follow-up is necessary to further understand both negative and positive impacts.

CONCLUSION

Cu T 380 A and LNG IUCD users' quality of life were compared in the study both at the time of insertion

and six months later. The general quality of life of Cu-T 380 consumers remained unaffected. Nonetheless, the physical, physiological, and environmental aspects of quality of life were greatly enhanced by the use of LNG IUCD. After six months of using the LNG IUCD, there was a decrease in menstrual blood loss and dysmenorrhea, which may be the cause of this improvement in quality of life among users.

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