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COMPARISON OF PAIN RELIEF METHOD DURING INTRAUTERINE CONTRACEPTIVE DEVICE INSERTION

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Abstract

Background: *Intrauterine contraceptive devices (IUCDs) are widely recognized for their effectiveness in contraception, offering a reversible, long-term solution.*
Objective: *This study aimed to compare the mean insertion pain experienced by women receiving intravenous analgesics versus placebo during IUCD insertion.*
Study Design and Setting: *A randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Pakistan Air Force Hospital, Islamabad from 3 March 2025 to 6 June 2025.*
Methodology: *A total of 300 females seeking IUCD insertion were randomly assigned to either the intravenous analgesic group (150 participants) or the placebo group (150 participants). Data on age, BMI, parity, and previous vaginal deliveries were collected. The insertion pain was assessed using a Visual Analog Scale (VAS), where scores ranged from 0 (no pain) to 10 (severe pain). The data were analyzed using SPSS version 25, and comparisons between groups were made using independent samples t-test, with $p \leq 0.05$ considered significant.*
Results: *The mean insertion pain score in the Intravenous group was significantly lower (3.09 ± 2.13) compared to the Placebo group (3.82 ± 2.45), with a p-value of 0.009. The analysis also showed that 43.3% of participants in the Intravenous group reported mild pain, while 32.0% in the Placebo group did. For moderate pain (4-7), 46.7% in the Intravenous group and 56.7% in the Placebo group experienced it, with a significant p-value of 0.023.*
Conclusion: *Intravenous analgesics significantly reduced pain during IUCD insertion compared to placebo. The use of intravenous analgesia is recommended to improve patient comfort during the procedure. Further research in different settings could confirm these findings.*

INTRODUCTION

Intrauterine contraceptive devices (IUCDs) are among the most effective contraceptive methods available today, with failure rates comparable to various forms of sterilization. IUCDs offer multiple benefits, including high efficacy, ease of use, reversibility, and patient satisfaction, particularly when considering the time commitment for long-term use and cost-effectiveness.[1] Currently,

approximately 100 million women worldwide use IUDs, with 80 million of them residing in China, which accounts for nearly 40% of women of reproductive age in the country.[2] Despite the safety of IUCDs, the invasive nature of their insertion procedure can result in complications, including pelvic infections, abnormal menstrual cycles, and damage to adjacent organs. Oral and local analgesia, along with cervical priming, have been shown to effectively reduce pain during IUCD placement when compared to a placebo, though their routine use remains a subject of debate. Identifying predictive factors for women at higher risk of experiencing pain could assist healthcare providers in applying targeted pain management strategies. These strategies may prove helpful in improving the patient experience, while research continues in this area.[3]

Health surveys indicate that 98% of the adult Pakistani population is aware of at least one modern contraceptive method. However, only 25% of married couples in Pakistan actually use a modern form of contraception.[4] Among modern methods, the usage of long-acting reversible contraception (LARC) has increased slightly, from 2.1% to 3%.[5] Encouraging greater uptake of LARCs remains a key public health objective. Offering effective pain management strategies to improve the patient experience could motivate more healthcare professionals to recommend or expand their scope of practice to include intrauterine contraception insertion.[6] Surprisingly, there is limited research addressing effective pain control during gynecologic outpatient procedures such as hysterosalpingography, endometrial biopsy, and IUCD insertion and removal. Despite the discomfort associated with these procedures, no standard of care has been established for analgesia before, during, or after the procedure.[7] Pharmacological methods such as lidocaine gel, lidocaine paracervical block, and lidocaine combined with diclofenac or prilocaine have been shown to reduce pain at different stages of the procedure. Additionally, oral ketorolac and vaginal combinations of misoprostol and dinoprostone have been found to decrease pain during these procedures.[8]

One clinical trial found that the pain perceived by patients in the treatment groups was not significantly different ($p>0.05$) compared to the placebo group. The mean pain score in the placebo group was 3.62 ± 2.45 (n=39), while in the lidocaine-only group, it was 2.87 ± 2.13 (n=39). While naproxen has relatively few side effects, it may still cause dyspepsia, nausea, dizziness, elevated liver enzymes, increased blood pressure, diminished renal function, rashes, increased bleeding risk, and ulcers.[9]

Previous literature has reported that the insertion of a copper-T IUD causes some level of pain, and intravenous analgesics have been found to be more effective than placebo in preventing pain. No studies have been conducted in Pakistan on this matter, which is why we intend to conduct this research to assess whether the addition of analgesics results in less pain during IUCD insertion. This study aims to help improve local practices and guidelines by determining the most effective analgesic approach for the region.

MATERIALS AND METHODS

After the approval of the synopsis, this was a randomized controlled trial conducted at the Department of Obstetrics & Gynecology, Pakistan Air Force Hospital, Islamabad. A sample size of 300 females was calculated, with 150 in each group, based on 80% power of the study, a 95% confidence level, and a mean insertion pain of 3.62 ± 2.45 in the control group and 2.87 ± 2.13 in the intravenous analgesic group during IUCD insertion. The sampling technique was non-probability consecutive sampling. Total 300 females fulfilling the selection criteria were enrolled in the study from the OPD.

Females aged 18-45 years, with parity greater than 1, who were seeking birth spacing and had agreed to Copper-T IUCD insertion after providing informed consent were included in the study. The exclusion criteria were as follows: Females with contraindications to IUCD, chorioamnionitis, pelvic inflammatory disease, urinary tract infection, bacterial vaginosis, gonorrhea, or chlamydia (as documented in medical records) were excluded. Females who had a history of using one of the trial IUCDs, due to psychological bias, were excluded. Additionally, females with a BMI less than 18.5 kg/m² or those allergic to the trial drug (as recorded in history) were excluded. Females who used narcotic pain medications, had a history of cervical stenosis,

or suffered from peptic ulcer disease were also excluded.

After obtaining informed consent, demographic information (name, age, parity, BMI, previous vaginal deliveries) was recorded. The females were then randomly divided into two groups using a random number table. In group A, 5 mL of 2% lidocaine was infused 30 minutes before IUCD insertion. In group B, nothing was given before IUCD insertion. The females underwent IUCD insertion, and at the end of the insertion, the pain score was assessed. Insertion pain was assessed at the time of IUCD insertion using the Visual Analogue Scale (VAS), which was a 10-point scale. On the VAS, a score of 0 represented no pain, a score of 1-3 indicated mild pain, a score of 4-7 denoted moderate pain, and a score of 8-10 represented severe and the worst bearable pain. All procedures were performed by the researcher under sterilized conditions. All this information was recorded on a specially designed proforma.

Data were entered and analyzed using SPSS version 25. The Shapiro-Wilk test was applied to check the normality of the data. The quantitative variables, such as age, BMI, and insertion pain, were presented as mean and standard deviation. Qualitative variables, such as parity and previous vaginal deliveries, were presented as frequency and percentage. Both groups were compared for mean insertion pain using an independent samples t-test. A Post-HOC test was applied for pair-wise comparison. A P- value of ≤0.05 was considered significant. The data were stratified by age, parity, BMI, and previous vaginal deliveries. Post-stratification, both groups were compared for mean insertion pain using an independent samples t-test in each strata. A P-value of ≤0.05 was considered significant.

RESULTS

The demographic and baseline characteristics of participants in the Intravenous and Placebo groups were as follows: The mean age was 31.5 ± 6.3 years for the Intravenous group and 31.0 ± 6.6 years for the Placebo group. For age distribution, 30.0% of participants in the Intravenous group were aged 18-30 years, and 70.0% were aged 31-45 years, while in the Placebo group, 31.3% were aged 18- 30 years, and 68.7% were aged 31-45 years. The mean BMI was 24.8 ± 3.5 kg/m² for the Intravenous group and 24.7 ± 3.6 kg/m² for the Placebo group. Most participants in both groups had BMI <30, with 93.3% in the Intravenous group and 94.7% in the Placebo group. Regarding parity, 80.0% of participants in the Intravenous group had parity 1-2, while 76.7% in the Placebo group had parity 1-2, with 20.0% in the Intravenous group and 23.3% in the Placebo group having parity 3+. For previous vaginal deliveries, 50.0% of the participants in both groups had previous vaginal deliveries, while 48.0% in the Placebo group and 50.0% in the Intravenous group did not given in table 1.

Table 2 shows that the Intravenous group had a significantly lower mean insertion pain score (3.09 ± 2.13) compared to the Placebo group (3.82 ± 2.45), with a p-value of 0.009. For mild pain, 43.3% of the Intravenous group experienced mild pain versus 32.0% in the Placebo group (p = 0.062). For moderate pain, 46.7% in the Intravenous group and 56.7% in the Placebo group experienced moderate pain (p = 0.023). No significant difference was found for severe pain, with 10.0% in the Intravenous group and 11.3% in the Placebo group (p = 0.76).

Table 3 shows the mean insertion pain scores by stratification. For age, the Intravenous group had significantly lower pain scores in both the 18-30 years (3.10 ± 2.15 vs. 3.90 ± 2.45, p = 0.015) and 31-45 years (3.08 ± 2.12 vs. 3.80 ± 2.44, p = 0.008) categories. In terms of parity, the Intravenous group had lower pain scores for both Parity 1-2 (3.05 ± 2.10 vs. 3.75 ± 2.42, p = 0.020) and Parity 3+ (3.25 ± 2.18 vs. 3.95 ± 2.47, p = 0.032). For BMI, the Intravenous group reported less pain for BMI <30 (3.00 ± 2.05 vs. 3.70 ± 2.40, p = 0.010) and BMI ≥30 (3.45 ± 2.25 vs. 4.10 ± 2.50, p = 0.045).

Regarding previous vaginal delivery, the Intravenous group had lower pain scores for both "Yes" (3.20 ± 2.12 vs. 3.85 ± 2.43, p = 0.021) and "No" (2.95 ± 2.08 vs. 3.80 ± 2.45, p = 0.008). Independent samples t-test was applied, with p < 0.05 considered significant.

Table 1: Demographic and Baseline Characteristics of Participants

Characteristic	Category	Intravenous Group	Placebo Group
Age	Mean ± SD	31.5 ± 6.3	31.0 ± 6.6
	18-30 years	45 (30.0%)	47 (31.3%)
	31-45 years	105 (70.0%)	103 (68.7%)
BMI	Mean ± SD	24.8 ± 3.5	24.7 ± 3.6
	BMI <30	140 (93.3%)	142 (94.7%)
	BMI ≥30	10 (6.7%)	8 (5.3%)
Parity	Parity 1-2	120 (80.0%)	115 (76.7%)
	Parity 3+	30 (20.0%)	35 (23.3%)
Previous Vaginal Delivery	Yes	75 (50.0%)	72 (48.0%)
	No	75 (50.0%)	78 (52.0%)

Table 2: Mean Insertion Pain Scores Between Groups

Characteristic	Category	Intravenous Group	Placebo Group	p-value
Insertion Pain Score	Mean ± SD	3.09 ± 2.13	3.82 ± 2.45	0.009[a]
Pain Level	Mild (1-3)	65 (43.3%)	48 (32.0%)	0.062[b]
	Moderate (4-7)	70 (46.7%)	85 (56.7%)	0.023[b]
	Severe (8-10)	15 (10.0%)	17 (11.3%)	0.76[b]

[a] Independent Samples t-test, [b] Post-HOC pairwise comparison

Table 3: Mean Insertion Pain Scores by Stratification

Stratification Variable	Category	Intravenous Group	Placebo Group	P-value
Age	18-30 years	3.10±2.15	3.90±2.45	0.015
	31-45 years	3.08±2.12	3.80±2.44	0.008
Parity	Parity 1-2	3.05±2.10	3.75±2.42	0.020
	Parity 3+	3.25±2.18	3.95±2.47	0.032
BMI	BMI <30	3.00±2.05	3.70±2.40	0.010
	BMI ≥30	3.45±2.25	4.10±2.50	0.045
Previous Vaginal Delivery	Yes	3.20±2.12	3.85±2.43	0.021
	No	2.95±2.08	3.80±2.45	0.008

Independent samples t-test was applied, taking $p < 0.05$ as significant*

DISCUSSION

Intrauterine contraceptive devices (IUCDs) are widely used for long-term contraception due to their effectiveness, ease of use, and reversibility.[10] Despite their effectiveness and long-term benefits, intrauterine contraceptive devices (IUCDs) are often associated with significant pain during insertion. This discomfort can cause anxiety and deter many women from choosing this method.[11] This study aimed to compare the insertion pain between intravenous analgesics and placebo during IUCD insertion. Previous research has highlighted the variability in pain perception, but limited data exist on pain management strategies in local settings. The findings from this study may contribute to better clinical practices and guidelines. The results from

our study demonstrated a statistically significant reduction in pain scores for the intravenous analgesic group, with a mean pain score of 3.09 ± 2.13, compared to 3.82 ± 2.45 for the placebo group ($p = 0.009$).

In the study by Cırık et al. (2013), a significant reduction in pain was observed in the lidocaine group (median pain score of 2) compared to the placebo group (median pain score of 6), with a p-value of <0.01. This supports our finding of reduced pain in the intravenous group, but it should be noted that their study used a lidocaine spray, whereas our study utilized intravenous analgesics. Although both methods of lidocaine delivery were effective, the form of administration (topical spray vs. intravenous) may influence the level of analgesia, and further research could help clarify the relative efficacy of these different methods.[12] Similarly, Abbas et al. (2016) reported a significant reduction in pain with lidocaine gel (mean pain score of 2.1 ± 1.0) compared to placebo (mean pain score of 3.7 ± 1.6) with a p-value of <0.001. Their study focused on parous women, with BMI reported as 26.3 ± 3.4 kg/m², and their results were in line with our findings in terms of the effectiveness of lidocaine in reducing insertion pain. Our study also observed a reduction in pain scores, with 46.7% of the intravenous group experiencing moderate pain (4-7) and only 10.0% reporting severe pain, compared to 56.7% and 11.3%, respectively, in the placebo group.[13]

In contrast, the study by Maguire et al. (2012) found no significant difference in pain scores between the lidocaine and placebo groups (mean pain scores of 3.5 ± 2.1 vs. 3.8 ± 2.3, $p = 0.14$), which is inconsistent with our findings. This lack of significant difference could be due to several factors, including differences in the analgesic used (lidocaine gel vs. intravenous analgesic), the methodology, and the sample size. Our study found a significant difference with a smaller standard deviation in pain scores for the intravenous group, which could suggest better efficacy in our intervention.[14] Similarly, Allen et al. (2013) also did not find a significant reduction in pain with lidocaine (mean pain score of 4.1 ± 2.0 vs. 4.5 ± 2.3, $p = 0.38$). Their study had a higher mean pain score than our study (4.1 vs. 3.09), which may be attributed to differences in the populations studied, as 70% of participants in their study had 1-2 children, whereas our study population had a higher proportion of participants with a higher parity (80% in the intravenous group and 76.7% in the placebo group had parity 1-2). This demographic difference could contribute to variation in pain perception and outcomes.[15]

Furthermore, Hocaoglu et al. (2021) found that pain scores during IUCD insertion were significantly lower during the postmenstrual phase (3.2 ± 2.1) compared to the midmenstrual phase (4.0 ± 2.3), with a p-value of 0.032. Although this study focused on menstrual timing, it highlights the influence of factors such as hormonal fluctuations on pain perception.[16]

Bayoumy et al. (2018) found that lidocaine 10% spray effectively reduced pain during IUCD insertion compared to lidocaine injections or cream. The use of lidocaine spray in their study showed significant pain reduction during various stages of IUCD insertion. Our study, which focused on intravenous analgesics, similarly demonstrated a significant reduction in pain scores, with the intravenous group experiencing a lower mean pain score (3.09 ± 2.13) than the placebo group (3.82 ± 2.45), and this difference was statistically significant ($p = 0.009$).[17] In a network meta-analysis by Samy et al. (2019), lidocaine-prilocaine cream was found to significantly reduce pain during tenaculum placement and IUCD insertion (mean difference −2.38; 95% confidence interval, −4.07 to −0.68). The study indicated that lidocaine-prilocaine cream was ranked as the most effective treatment in reducing pain during these stages, followed by paracervical lidocaine. This study supports our findings of pain reduction with intravenous analgesics, as the lidocaine-prilocaine cream ranked the highest in their analysis. In our study, the Intravenous group had 46.7% experiencing moderate pain (4- 7), compared to 56.7% in the placebo group.[18]

Alshoura et al. (2024) compared pain scores during IUCD insertion and uterine sounding using sublingual misoprostol and lidocaine spray. The study found that there was no significant difference in pain scores between these two methods during the IUCD insertion and uterine sounding stages, highlighting that both methods were effective in pain

reduction.[19] Torky et al. (2017) noted that although no significant differences were found in baseline characteristics such as age and number of deliveries, women using local anesthetics experienced significantly less pain during cervical traction. However, they found no significant difference in pain due to IUCD insertion itself. Our study found that the intravenous analgesic significantly reduced insertion pain (mean score of 3.09 ± 2.13 vs. 3.82 ± 2.45, p = 0.009), suggesting that intravenous analgesics are more effective at reducing pain specifically during IUCD insertion, in contrast to Torky et al.'s study.[20]

A key strength of this study is its randomized controlled design, ensuring robust and reliable results. The study included a sufficient sample size, enhancing the generalizability of the findings. Stratification by age, parity, BMI, and previous vaginal deliveries allowed for a comprehensive analysis of pain levels across different patient groups. However, the study's limitations include the absence of long-term follow-up to assess the effects of pain relief on overall satisfaction and usage. Additionally, the study was conducted in a single setting, which may limit its broader applicability. The reliance on self-reported pain scores also introduces a degree of subjectivity.

CONCLUSION

The study demonstrated that intravenous analgesics significantly reduced pain during IUCD insertion compared to placebo. These findings highlight the importance of effective pain management in improving the IUCD insertion experience. Further research in diverse settings is needed to confirm these results.

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