

Effectiveness of virtual reality in reducing Pain During Intrauterine Device Insertion: A Systematic Review and Meta-analysis

Review
Article

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ABSTRACT

Background: The intrauterine device (IUD) is an effective form of contraception, but its utilization worldwide is low due to discomfort and anxiety during insertion. Virtual reality (VR) technology shows promise in reducing pain during IUD insertion.

Objective: To evaluate the efficacy of VR technology exposure in relieving pain associated with IUD insertions.

Search Strategy: PubMed, Scopus, Web of Science, and Cochrane Library from database inception to April 2024.

Selection Criteria: Randomized controlled trials (RCTs) assessing the efficacy of VR in reducing pain and anxiety during IUD insertion. Main outcomes were pain and anxiety levels during IUD insertion.

Data Collection And Analysis: Effect measures were expressed as standardized mean difference [SMD] with 95% confidence interval [CI]. Study quality was assessed using Cochrane risk of bias 2(ROB2) tool.

Main Results: Four RCTs (n= 315 patients) were included. The VR group had a significantly lower pain scores during IUD insertion compared to the standard practice group (SMD= -1.69, 95% CI: [-3.20, -0.18]; $P= 0.03$). However, the differences in anxiety levels during IUD insertion or post-procedural women satisfaction was not statistically significant between the two study groups ($P=0.51$ & $P= 0.30$, respectively). Most included studies had a low risk of bias.

Conclusion and Relevance: VR technology demonstrated a clinically significant reduction in pain during IUD insertion compared to standard practice, while no significant differences were observed in patients' anxiety or post-insertion satisfaction between the study groups.

Key Words: Intrauterine device, meta-analysis, pain, visual analog scale, virtual reality.

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INTRODUCTION

Intrauterine devices (IUDs) are among the most effective contraceptive methods available, and most women, regardless of age or parity, can use them^[1,2]. Due to its high safety and long-term contraceptive efficacy, the American College of Obstetrics and Gynecology recommends IUDs as a first-line option for contraception^[3]. Intrauterine device use varies by country, with an average of 15% among reproductive-age women in underdeveloped countries and 9% in developed countries^[4].

Although IUD is gaining popularity among patients and healthcare providers, pain or fear of pain remains a significant barrier to wide IUD utilization^[5]. IUD insertion can cause pain throughout different steps of the procedure, including speculum insertion, tenaculum placement, uterine sound insertion, and IUD inserter advancement through the cervical canal into the uterine cavity^[6]. A number of risk factors, including anxiety, history of dysmenorrhea, nulliparity, and high expected pain levels, might influence the intensity of perceived pain^[7,8].

Numerous analgesic pharmacological and non-pharmacological interventions, such as non-steroidal anti-inflammatory drugs, topical anesthetic gel or spray, paracervical block, nitrous oxide, misoprostol, and conscious sedation, have been studied to lessen pain during IUD insertion; however, the findings of these studies are conflicting and inconclusive^[9]. A Cochrane meta-analysis reported that misoprostol, lidocaine gel (2%), and most non-steroidal anti-inflammatory drugs are not effective in reducing pain during IUD insertion^[10]. The role of naproxen and tramadol in alleviating pain during IUD insertion varies in different studies^[11-14]. Additionally, pharmacological treatments might be associated with medication-related side effects such as fever, cramps, nausea, vomiting, shivering with misoprostol administration^[15], or pain during needle injection with paracervical lidocaine^[16].

Research on non-pharmacological interventions for the management of anxiety and pain during IUD insertion is still lacking. Nevertheless, non-pharmacological approaches demonstrated mixed results regarding their effectiveness in alleviating pain with IUD insertion. Slow

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vulsellum application and video-assisted information are associated with a statistically significant decrease in pain^[17,18], while aromatherapy with lavender inhalation, inhaled nitrous oxide, and cold compresses failed to alleviate IUD insertion pain^[19–21]. There is evidence that certain measures, like distraction and reassurance, may help reduce anxiety related to IUD placement^[22].

Virtual Reality (VR) is a computer-simulated approach that creates a visually immersive digital environment using a headset connected to a computer or smartphone. It is a non-pharmacological therapeutic and distraction intervention that delivers a pleasant experience with accompanying images and audio. This technology alleviates pain and anxiety by affecting non-painful neural signaling and enabling individuals to perceive, experience, and interact with stimuli in the virtual environment as if they were in the actual physical world^[23,24].

Virtual reality therapy is a simple, non-invasive, available technology that successfully reduces pain during different gynecological and obstetric procedures^[25–27]. Using VR technology as a distraction therapy can reduce pain perception by diverting attention from harmful stimuli and increasing attention to pleasurable stimuli.

The role of virtual reality in alleviating pain during IUD has been studied in previous RCTs, which yielded conflicting results. Some studies found it an effective pain-relieving strategy^[25,28,29], while Benazzouz *et al.* concluded that VR therapy during IUD insertion did not relieve procedure-related pain^[30]. Therefore, we aimed to evaluate the efficacy of VR technology in lowering pain and anxiety in women undergoing IUD insertion procedures.

MATERIALS AND METHODS

We conducted this review according to the guidelines of Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement^[31,32]. We prospectively registered the study protocol in Open Science Framework (OSF) registries for systematic reviews (<https://doi.org/10.17605/OSF.IO/YC7W6>). Due to the nature of the study, Institutional Review Board approval was not required.

Literature search

We systematically searched PubMed, Scopus, Web of Science, and Cochrane Library from database inception to April 2024 for all RCTs that evaluate the effect of VR on pain relief during IUD insertion. We used combinations of the following search terms for the search strategy: "intrauterine device", "IUD", "virtual reality", "VR", "pain", and "visual analog scale". There were no restrictions concerning race, country, or time of publication. We thoroughly screened

references of included studies to ensure no ones were missed and maintain high-quality screening.

Eligibility criteria and study selection

We selected studies that met the following PICO criteria: (i) Population: women undergoing copper (Cu-IUD) or levonorgestrel-releasing intrauterine devices (LNG-IUD) insertion for contraception purposes, (ii) Intervention: VR technology, (iii) Comparator: was the standard practice, (iv) Outcomes: Primary outcome was patient-reported pain during IUD insertion. Secondary outcomes include anxiety during IUD insertion and women's satisfaction.

(v) study design: Published randomized clinical trials (RCTs). We only considered RCTs as they provide the strongest evidence for causal associations. We excluded non-human studies, conference abstracts, quasi-randomized or observational study designs, retracted papers or those with expressions of concern, academic theses, the impossibility of isolating/extracting outcome data and articles without full texts, case series, and non-English articles.

After combining all references from different databases, we used EndNote X7 (Clarivate Analytics) to remove duplicates. Unique records were then imported into an Excel spreadsheet for screening. Two reviewers (AS&MR) independently screened all potentially eligible records in two stages: initially by title and abstract screening and then full-text screening. Moreover, reviewers manually screened references of included studies and those of previous related systematic reviews and meta-analyses for potentially relevant studies. A consensus and discussion settled disagreements in the study selection process.

Data extraction

Two authors independently collected data from the included studies using a standardized data extraction sheet. The following information was extracted: summary characteristics of included articles, baseline characteristics of study population, risk of bias domains, and study outcomes. Additionally, details on the VR technology device used and the content displayed during the IUD insertion were recorded. We recorded participants' baseline characteristics, including the total number of participants, age of participants, number of first IUD users, placement method (e.g., direct or standard), and professional responsible for insertion (e.g., physician, midwife). Study outcomes include pain and anxiety levels during IUD insertion and patient satisfaction post-insertion. Pain scores were measured using the 10-cm/100-mm visual analog scale (VAS), where zero indicates no pain at all and 10/100 corresponds to the worst pain ever. A senior author reviewed the entire data extraction process.

Risk of bias assessment

Two authors independently conducted a quality assessment for included studies using the Cochrane Risk of Bias assessment tool described in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0. This tool consists of the following domains: six domains, namely random sequence generation (selection bias), allocation sequence concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other potential sources of bias^[33]. The authors' judgments of included RCTs were categorized as "low risk," "high risk," or "unclear risk" of bias. Disagreements between the two authors were resolved by consensus and discussion with a senior reviewer.

Publication Bias

We could assess for publication bias among pooled studies only if their number were at least ten. To assess the risk of bias across included studies, we used the test developed by Egger *et al.*, and its results were displayed as a funnel plot graph and considered the analysis to be free from publication bias if the p-value of the Egger's test was less than 0.05^[34]. Additionally, two authors (DL&AS) independently assessed the risk of bias, and any discrepancies were resolved through a consensus reached by the involved authors.

Data synthesis

Two authors independently performed the meta-analysis using Review Manager software version 5.4 (Nordic Cochrane Centre, Cochrane Collaboration, Denmark). A senior author compared the consistency of the results and resolved any discrepancies through discussion. Standards mean difference (SMD) with 95% confidence interval (CI) was used to pool continuous data. We used Mantel-Haenszel and Inverse-Variance methods for meta-analyses, respectively. Heterogeneity was assessed using chi-square and I-square tests, with low heterogeneity defined as $I^2 < 30\%$, moderate as $30\% - 50\%$, and high as $> 50\%$. Significant heterogeneity was indicated by chi-square test $p < 0.1$ and I^2 test > 50 . The homogeneous and heterogeneous results were analyzed using the fixed-effects and random-effects models, respectively. Statistical significance was defined as $p < .05$.

RESULTS

Results of the literature search and characteristics of included studies

Our database search strategy yielded 531 records. After removing duplicates, we screened the titles and abstracts of 142 studies. Following the 1st screening phase, six articles were deemed suitable for full-text screening. Four studies were included in the qualitative and quantitative analysis after excluding two studies for different designs and ineligible outcomes^[25,28-30]. Upon verifying the sources of the included studies, no additional publications were missing. (Figure 1) shows the PRISMA flow diagram of the included studies.

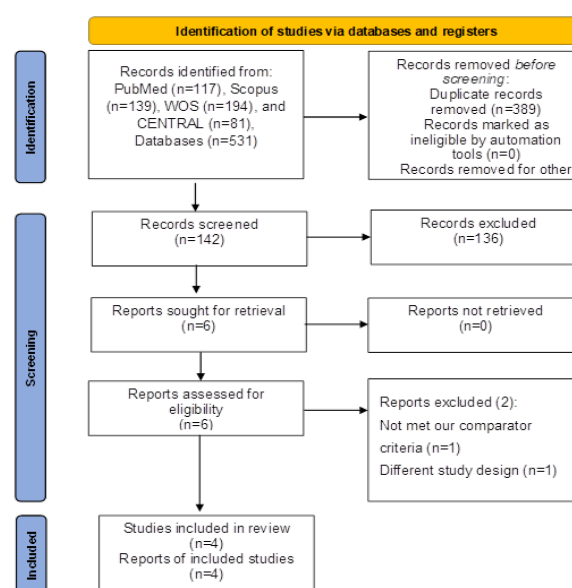


Fig. 1: PRISMA chart flow diagram for the included studies

Our meta-analysis included four RCTs with a total number of 315 patients, of whom 157 were allocated to VR group, while 158 were assigned to the standard practice group. The mean participants' age was 29.4 ± 6.8 years, with 149 women being first users of IUDs. Standard technique for IUD insertion was employed in all studies^[25,28-30] except Benazzouz *et al.*^[30] study, which utilized Both standard and direct methods to insert IUDs. Both copper and hormonal IUDs were used in Benazzouz *et al.*^[30] study while copper IUD was utilized in Seif *et al.* study^[29]. The IUD insertion was performed by physicians in three studies^[28-30] and by midwives in two studies^[25,30]. Various VR content was displayed to participants in the VR group in each study. (Table 1) summarizes the characteristics of the included studies.

Table 1: Characteristics of included studies

| Study ID | Location | Sample size | Age (years) | First IUD (n) | IUD type | Placement method | Placement professional | Type of VR device | VR display show | Assessed outcomes |
|----------------|-----------|-------------|----------------------|---------------|----------------------------|----------------------------|---|------------------------|---|--|
| Benazzouz 2024 | France | 94 | 23.6±6.7 | 81 | Copper (65), hormonal (29) | Standard (73), direct (21) | Physician, Intern, Midwife, Midwife student | NR | One of four virtual universes: the forest, the meadow, the ocean floor, or outer space. | Pain during and after IUD insertion measured by VAS score. Anxiety during IUD insertion. Patient satisfaction after IUD insertion. |
| Riska 2024 | Indonesia | 60 | <35: n=26, >35: n=34 | NR | NR | NR | Midwife | NR | Underwater scenery, roller coaster rides, museums, and overseas trips. | Pain (VAS score) perceived by the patient during IUD insertion. |
| Seif 2024 | Egypt | 80 | 27.7±5.8 | 68 | Copper | NR | Physician | NR | Imagery of a blossoming tree and ocean waves accompanied by meditative auditory guidance specific for divert attention. | Pain (VAS score), anxiety, and satisfaction during IUD insertion. |
| Öz 2024 | Turkey | 80 | 34.3±7.7 | NR | NR | NR | Physician | Everest VR0022 VR BOX® | Nature walk accompanied by soft music. | Patient levels of pain (NRS), anxiety, and satisfaction during IUD insertion. |

Abbreviations: IUD: Intrauterine device, VAS: Visual Analogue Scale, VR: Visual Reality, NRS: Numerical Rating Scale, NR: Not reported

Quality and Risk of Bias Assessment

(Figures 2,3) illustrate the risk of bias summary and graph for the included studies. All the included studies are evaluated as having a "low" risk of bias except for Seif et al., who assessed a high risk of bias due to several concerns^[29]. The authors did not provide details about participant randomization or group allocation. Due to the nature of VR technology, all included studies had a high risk of bias in participants and study personnel blinding. Attrition bias, reporting bias, and other sources of bias are considered "low" risk of bias in all trials.

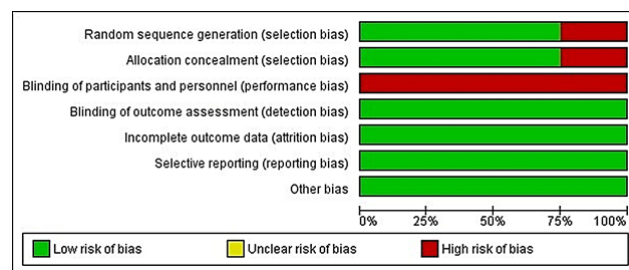


Fig. 2: Risk of bias summary for the included studies

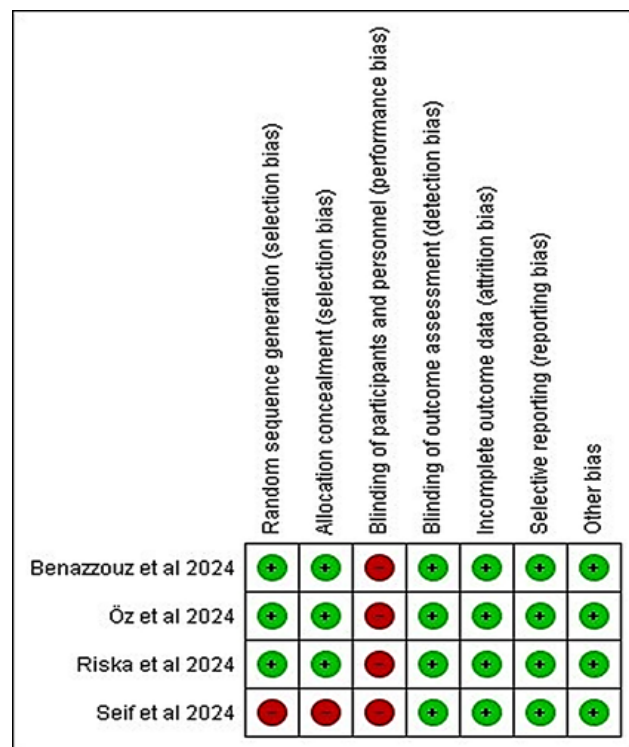


Fig. 3: Risk of bias graph for the included studies

Study Outcomes

pain during IUD insertion

Pain during IUD insertion was reported in all 4 RCTs (N= 315 participants). Three studies assessed the pain using the VAS score^[25,28,30], and one trial used the Numeric Rating Scale (NRS)^[29]. Pain during insertion was significantly lower in the VR group compared to the standard practice group (SMD= -1.69, 95% CI: [-3.20, -0.18]; P= 0.03). Significant heterogeneity (I²= 97%) was found, which could not be resolved by sensitivity or subgroup analysis (Figure 4).

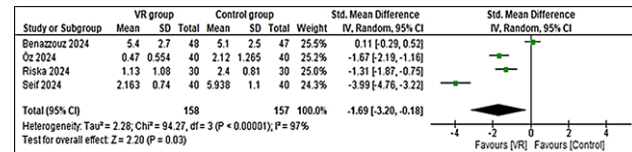


Fig. 4: Meta-analysis of pain during IUD insertion

Anxiety during IUD insertion

Two studies (N= 175 women) reported patient anxiety during IUD insertion^[29,30]. Anxiety during IUD insertion showed no statistically significant difference between the two study groups (SMD= -0.50, 95% CI: [-1.97, -0.97]; P= 0.51) (Figure 5). The studies were heterogenous (I²= 99%).

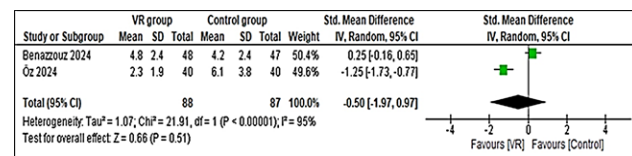


Fig. 5: Meta-analysis of anxiety during IUD insertion

Patient satisfaction with IUD insertion

Two studies (N= 175 women) reported women's satisfaction after IUD insertion, respectively^[29,30]. VR application did not result in significantly higher women satisfaction compared to the standard IUD insertion practice (SMD= 1.98, 95% CI: [-1.75, 5.70]; P= 0.30) (Figure 6). The meta-analysis results were significantly heterogeneous among the included studies (I²= 99%).

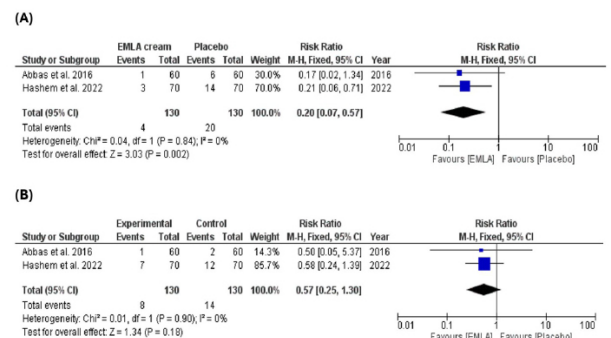


Fig. 6: Meta-analysis of patient satisfaction after IUD insertion

DISCUSSION

Findings Summary

We conducted a systematic review and meta-analysis to investigate the effect of using VR technology during the IUD insertion on patients' levels of pain, anxiety, and satisfaction. We found that virtual reality therapy significantly reduced pain during IUD placement. However, no statistically significant difference was found between the two study groups regarding patients' anxiety during IUD placement and post-insertion women's satisfaction.

Todd *et al.*^[35] found that a 13-mm VAS difference (95% CI 10 to 17 mm) was the smallest clinically significant change in acute pain severity. The minimum clinically significant difference (MCSD) for pain reduction in other studies was 15 mm mean difference in the 100-mm VAS^[36,37]. Based on these figures, our study's reduction in pain scores with VR therapy was clinically significant (MD=1.69).

Although our results were statistically and clinically significant, heterogeneity in reported outcomes was also significant. This high heterogeneity could be attributed to variations in virtual reality equipment throughout trials and the lack of a single, standard video shown to participants. Hence, it is plausible that various settings may potentially result in various perceptions of pain and anxiety.

Our results in the context of the literature

Despite the increasing focus of clinical medical professionals on patients' pain, their ability to manage pain remains inadequate. Distraction techniques vary from activities like communicating, watching videos with VR goggles, painting, and listening to music to more complex physical and mental exercises^[28]. These distraction strategies do not totally eliminate pain, but they lower its severity by enhancing control and pain tolerance^[28]. The VR therapy is one of the most promising distraction techniques that successfully alleviates pain and anxiety during different procedures such as episiotomy^[27], dressing change^[38], and first stage of labor^[39].

The effect of VR therapy on anxiety is not consistent in different studies. While Dutucu *et al.* agreed with our findings and concluded that VR decreased only pain, not anxiety, during mammography^[40], Karaman *et al.* reported significant positive results in both pain and anxiety during breast biopsy^[41]. Additionally, Almedhesh *et al.*^[42] stated that women having CS under regional anesthetic had significantly lower stress and anxiety when using virtual reality. Contrarily, Hecken *et al.*^[43] found that women

having colposcopies report no differences in satisfaction or anxiety when using a VR headset that plays a 360-degree surround vision film.

Our study found that VR does not increase women's satisfaction with IUD insertion procedure, which contradicts other studies reporting significantly higher patient satisfaction levels using VR technology in burn care and during labor & episiotomy^[27,39,44]. These discrepancies could be attributed to the small number of included studies in our review and the small sample size. Additionally, anticipated pain and pre-procedural anxiety, lack of knowledge and negative perceptions, erroneous information, and methods of IUD insertion could all affect the anxiety and satisfaction results^[24,25,30,45].

Our results were in agreement with previous studies, which confirmed the analgesic and anti-anxiety role of VR therapy during different obstetric and gynecologic procedures. Baradwan *et al.*^[46] examined how virtual reality affects normal labor pain management. The study revealed that virtual reality is highly beneficial in reducing anxiety, enhancing satisfaction, and improving pain management in normal labor.

Vitagliano *et al.*^[47] meta-analysis assessed the benefits of virtual reality technology (VRT) for lowering pain during outpatient hysteroscopy. Five RCTs were included, concluding that active VRT potentially reduced pain perception, whereas passive VRT failed to lower pain scores. The MD = -1.42, which is considered clinically insignificant. The meta-analysis by Cohen *et al.* meta-analysis^[48], shown that while VR approaches do not lessen patients' perception of pain during OH, they do help lower their anxiety levels.

Baradwan *et al.*^[26] investigated the role of VR in lowering pain and anxiety levels during outpatient hysteroscopy(OH). Six RCTs were included (N=patients). Virtual reality significantly reduced VAS pain scores during OH and post-procedure compared to control (MD - 1.43& MD - 1.52, respectively). procedural anxiety was significantly lower among VR group than control group ($P = 0.01$).

Although VR is a safe, harmless procedure, it might lead to a visual-vestibular mismatch causing headache, eye strain, and motion sickness like symptoms (nausea, vomiting, disorientation, sweating, and pallor) that lessens with a seated position^[49].

Study strengths

We had several strength points. We comprehensively searched different electronic databases with a comprehensive search strategy validated by an experienced

librarian. We strictly adhered to Cochrane guidelines and included only RCTs. Based on a literature search, our meta-analysis is the first to address the value of VR therapy during IUD insertion.

Study limitations

Several limitations were noted in the study, including the limited number of included trials (4 studies only were meta-analyzed), small sample sizes, and lack of blinding due to the nature of the intervention. Different types of IUDs (copper and hormonal) and variations in VR equipment and software, exposure time, and content-restricted findings between studies. Prolonged VR exposure and the lack of vital sign monitoring during IUD insertion may have caused recall bias. Our findings showed significant heterogeneity due to varied patient and VR characteristics. Exclusion of grey literature and related studies in other Languages rather than English.

Future studies with larger sample sizes and rigorous design are needed. Future studies should optimize VR technology, examine economic consequences, prescribe VR treatment parameters during IUD insertion, and use VR for patient education.

CONCLUSION

Virtual reality technology resulted in a clinically significant pain reduction during IUD insertion. However, patients' anxiety and post-insertion women's satisfaction were comparable between VR and standard care groups. During IUD insertion, VR could be used alone or as an auxiliary analgesic intervention. More trials are required to confirm and strengthen our findings.

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CONFLICT OF INTERESTS

There are no conflicts of interest.

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