

ENHANCING HYSTEROSALPINGOGRAPHY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS ON THE USE OF VIRTUAL REALITY OR MUSIC FOR REDUCING PAIN AND ANXIETY

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Keywords	ABSTRACT
Hysterosalpingography, Virtual Reality, Auditory Stimuli, Pain, Anxiety	Background Hysterosalpingography (HSG) is a diagnostic procedure used to assess the uterus and fallopian tubes, often associated with pain and anxiety. This systematic review and meta-analysis evaluate the effectiveness of virtual reality (VR) and auditory stimuli in reducing pain and anxiety during HSG, exploring non-pharmacological strategies to enhance patient comfort and outcomes. Materials & Methods We conducted a systematic search in November 2024 using PubMed, Ovid Medline, and Ovid Cochrane databases. The Revised Cochrane Risk of Bias (RoB2) assessment tool was utilized to assess the risk of bias of the included randomized controlled trials (RCTs). The data were analyzed using RevMan software. Results This systematic review and meta-analysis included five RCTs with a total of 513 women undergoing hysterosalpingography (HSG). Pain levels, measured using the Visual Analog Scale (VAS), were significantly lower in the VR group compared to the control group, with a mean difference (MD) of -2.35 (95% CI [-3.90, -0.80], P = 0.003) during HSG. Additionally, pain 15 minutes after the procedure was significantly reduced in the VR group (MD = -3.19, 95% CI [-5.71, -0.68], P = 0.01). Regarding anxiety, no significant difference was found between the VR group and the control group (MD = -2.40, 95% CI [-7.56, 2.76], P = 0.36), but auditory stimuli significantly reduced post-HSG anxiety (MD = -8.93, 95% CI [-17.28, -0.59], P = 0.04). The risk of bias assessment revealed "some concerns" in most included studies.

	Conclusion While virtual reality significantly reduces pain during hysterosalpingography, its effect on anxiety is minimal, whereas auditory stimuli effectively reduce post-procedural anxiety, highlighting the need for further research to optimize these non-pharmacological interventions.
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INTRODUCTION

Hysterosalpingography (HSG) is a diagnostic procedure used to visualize the internal structure of the uterus and assess the patency of the fallopian tubes. It is primarily performed to investigate infertility or to identify space-occupying lesions within the uterine cavity [1]. During the procedure, a radiopaque dye is injected through the cervix, traveling through the cervical canal into the uterine cavity and fallopian tubes. Fluoroscopy and X-ray images are captured at various stages to evaluate the structure of the endometrial cavity and the surrounding pelvic peritoneum [2]. HSG is typically performed within 3 to 7 days after menstruation has ended to minimize the risk of pregnancy and ensure optimal visualization. However, it is contraindicated during pregnancy, active uterine bleeding, or if there is an existing pelvic infection [3].

During the procedure, patients may experience mild discomfort, anxiety, and a transient sensation of heaviness or fullness in the lower abdomen as the contrast dye enters the uterine cavity [4, 5]. As the dye progresses deeper, it can induce spasms and irritation of the fallopian tubes [5]. The most intense pain is typically felt when the uterus distends with the dye, triggering the release of local prostaglandins and causing uterine cramps [4]. Approximately 72% of patients report experiencing pain during the procedure [6].

This invasive diagnostic and therapeutic procedure is also associated with significant stress. Preprocedural anxiety can heighten pain perception and exacerbate stress levels during the examination [7]. Infertile women are particularly vulnerable, facing an increased risk of distress, anxiety, and depression [8]. Moreover, patients who independently seek information about the HSG procedure often experience greater anxiety levels after the examination [9]. These stressors can lead to physiological changes such as elevated heart rate and blood pressure and may also cause tubal spasms, resulting in false diagnoses of tubal occlusions and necessitating repeat procedures [10, 11]. Therefore, implementing effective stress management strategies is essential to regulate vital signs, enhance diagnostic accuracy, and improve overall patient outcomes [10].

To measure the level of pain, the Visual Analogue Scale (VAS) has been used since the 1920s [3, 12, 13]. VAS consists of a 100mm line in length; one end represents 'no pain' and the other end represents 'worst pain imaginable'. The patient marks the line to reflect their perception of pain intensity, and the distance from their mark to the endpoint is measured [12, 13]. On the other hand, the State Trait Anxiety Inventory (STAI) is a commonly used measure of anxiety. The trait scale consists of 20 statements, requiring individuals to rate how they generally feel on a four-point Likert-type scale [10].

Several methods have been explored to alleviate pain and anxiety during HSG, aiming to make the procedure more tolerable for patients. These approaches include the topical, intravenous, and local injection of analgesics or anesthetics, which are often associated with various side effects [14]. As a result, non-pharmacological and less invasive strategies have been recommended [6]. Virtual reality (VR) is one such approach, which works by diverting the patient's attention from the medical environment, refocusing it on more pleasant stimuli. This distraction reduces the patient's ability to process pain signals, thereby minimizing discomfort [15]. Additionally, auditory stimuli, such as music or natural sounds, have shown promise in reducing anxiety [16, 17]. These effects are thought to be mediated through neurochemical changes, such as increased dopamine and opioid release, as well as the reduction of cortisol levels in both natural and stressful environments [17]. Given the promising results of these non-pharmacological interventions, our systematic review and meta-analysis aim to evaluate the effectiveness of VR and auditory stimuli in reducing pain and anxiety with HSG.

MATERIALS & METHODS

Literature review

This review follows the Cochrane review methodology and adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [18, 19]. Registered in the International Prospective Register of Systematic Reviews (PROSPERO) (ID: CRD42024611855), the research was conducted in November 2024. Data was collected from three databases: PubMed, Ovid Medline, and Ovid Cochrane, with no restrictions on the time frame. The search strategy employed the following keywords: (hysterosalpingography OR HSG) AND (virtual reality OR VR OR music OR natural sounds OR video OR informative video) AND (pain OR pain score OR VAS OR Visual Analog Scale).

Study selection

The selection and assessment of studies were managed using Rayyan software (<https://new.rayyan.ai/>) [20]. Four authors independently reviewed the titles and abstracts of studies found in the database searches to evaluate their eligibility to potentially meet the qualification requirement for a full review based on defined inclusion and exclusion criteria. In case of any discrepancies, the article is proceeded to a full-text review. The inclusion criteria for the systematic review are as follows: (1) Studies published up to November 2024, without any time restrictions, (2) Studies that included the number of patients assessed, (3) Studies published in English, (4) Studies comparing the use of virtual reality, music, or informative videos with a control group in female patients undergoing HSG, (5) Studies reporting relevant outcomes related to the clinical question, (6) Original research articles, including cross-sectional, prospective cohort, retrospective studies, case-control studies, case series, or randomized controlled trials. Consequently, the exclusion criteria for the study are outlined as follows: (1) Studies published in languages other than English, (2) Studies not comparing virtual reality, music, or informative videos to a control group in female patients undergoing HSG, (3) Studies lacking relevant outcome reporting for the clinical question, (4) Case reports, systematic reviews, meta-analyses, narrative reviews, and scoping reviews.

Screening and data extraction

After identifying potentially eligible studies, the full texts of those meeting the inclusion criteria were obtained for further evaluation by two authors independently to confirm their eligibility. Any discrepancies were resolved with input from the lead author. The entire screening process, along with reasons for exclusions, was meticulously documented using a PRISMA flowchart. Additionally, two authors were tasked with collecting data from the studies included in the review. The data collected from the included studies encompassed several key variables: patient age, total sample size, follow-up duration, the number of cases using each intervention (such as virtual reality, music, or informative video), and the pain scores recorded during and after the HSG procedure for both the intervention and control groups. A third researcher was involved to verify the accuracy of the extracted data. If any critical data was missing, efforts were made to contact the corresponding author for clarification. If contact could not be made or if the missing information remained unavailable, the study was excluded from the analysis.

Bias assessment

The Revised Cochrane Risk of Bias (RoB2) assessment tool was utilized by two reviewers independently to assess the risk of bias in all included RCTs. A third reviewer subsequently conducts a further evaluation of the assessments. RoB2 tool consists of five predefined domains emphasizing aspects related to the design, implementation, and presentation of the trial [21]. Specific inquiries, known as “signaling questions”, were employed within these domains to elicit details relevant to the risk of bias. Subsequently, an algorithm was used to assess these responses, resulting in categorizations of ‘low’ (indicating a low risk of bias across all domains), ‘some concerns’ (suggesting some concern in at least one domain), or ‘high’ (indicating either a high risk in at least one domain or some concerns in multiple domains).

Statistical analysis

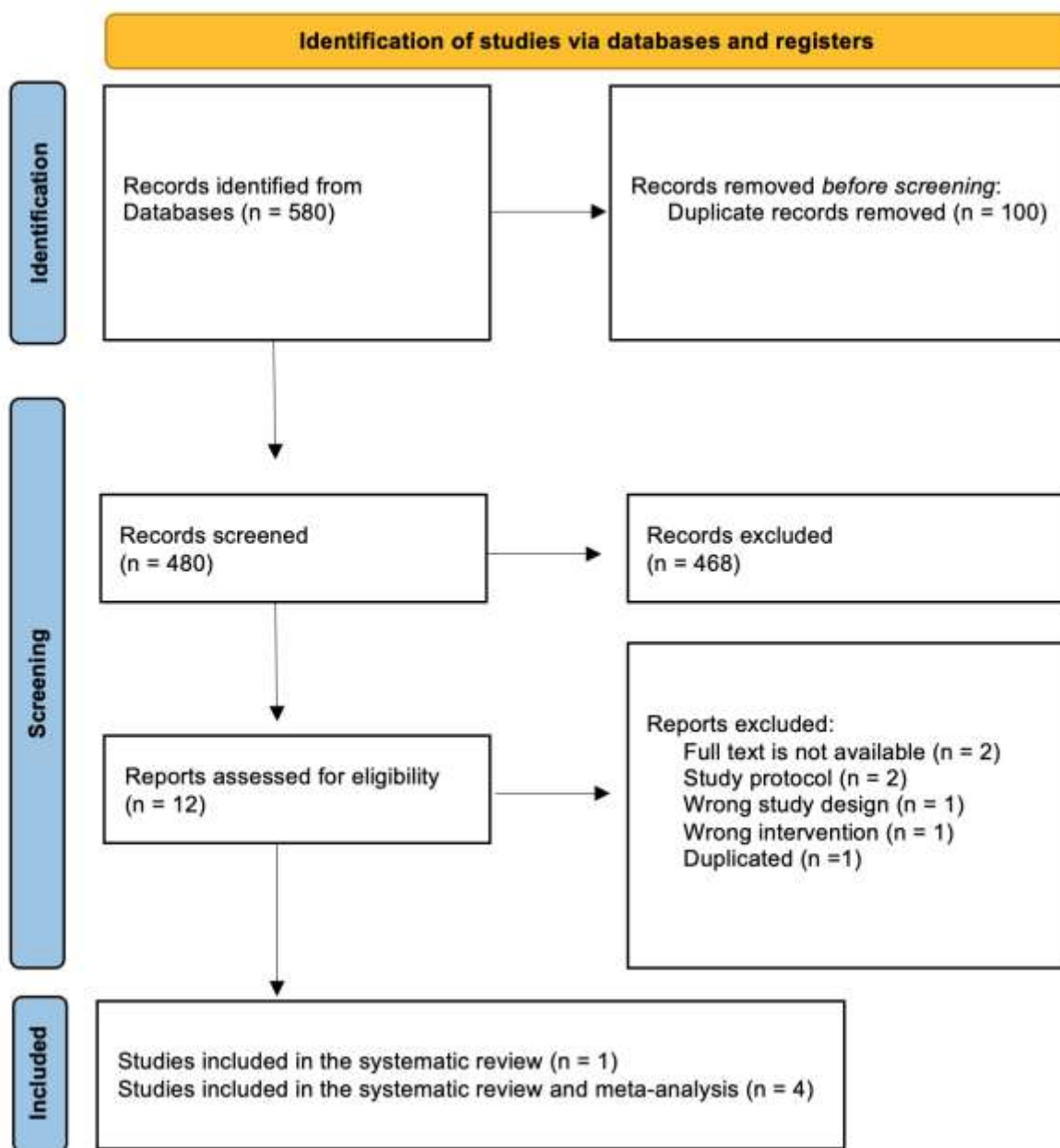
The meta-analysis will be managed by a statistically qualified author using RevMan. This analysis will compute standard mean differences or odds ratios, along with 95% confidence intervals as appropriate, with a significance level set at a P-value ≤ 0.05 . The heterogeneity among studies will be assessed via Chi^2 and I^2 tests within RevMan. A random-effects model will be applied for substantial heterogeneity ($I^2 > 50\%$); otherwise, a fixed-effects model will be implemented.

RESULTS

Study Selection

From an initial pool of 580 records identified through primary databases, including PubMed, Ovid Medline, and Ovid Cochrane, 12 studies were selected for eligibility assessment. Of these, five RCTs met our inclusion criteria [7, 11, 16, 22, 23], as shown in Figure 1.

Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) flow chart of the reviewed studies.



Study characteristics

Our systematic review included a total of 513 women undergoing HSG. Among them, 187 (36.5%) were in the VR group, with a mean age of 31.2 ± 6 years; 95 (18.5%) were in the auditory stimuli (music/natural sounds) group, with a mean age of 30.11 ± 5.99 years (mean age was not reported in one study); and 231 (45%) were in the control group, with a mean age of 31.34 ± 5.32 years (mean age was not reported in one study). Of note, four of the included studies utilized VR as the intervention, while only two studies employed an auditory intervention, as seen in Table 1.

Table 1 Overview of the included studies characteristics. VR: virtual reality; RCT: randomized controlled trial, HSG: hysterosalpingography; NA: not applicable.

Article	Country	Total Participants (n)	Study Design	Number of Patients (n)			Age (years), Mean $\pm$ SD (range)			Type of Intervention
				VR	Mus ic or Nat ural Sou nds	Con trol	VR	Music/N atural Sounds	Contr ol	
Roselle, 2024 [7]	Netherlands	134	RCT	69	NA	65	35 $\pm$ 5.00	NA	35 $\pm$ 4.00	VR (Relaxing Movies): VR headset allowing patients to choose from ~20 relaxing movies and breathing exercises during HSG.
Agwu, 2006 [11]	Nigeria	100	RCT	NA	50	50	NA	(20-44)		Music (Patient's Choice): Patient's favorite music played through an audio cassette player until the end of the procedure.
Baltaci, 2024 [16]	Turkey	135	RCT	45	45	45	29.55 $\pm$ 6.09	30.11 $\pm$ 5.99	28.60 $\pm$ 4.15	VR + Natural Sounds: 360° VR with relaxing nature video and sounds (water, waves, rain, wind, dolphins, birds, forests) for 30 min before and 15 min during HSG. Natural Sounds Only:

										30 min before and 15 min during HSG.
Bal, 2023 [22]	Turkey	82	RC T	42	NA	40	27.4±3.14	NA	28.33±4.55	VR (Nature Scenes): 360° VR video with nature scenes during HSG.
Yılmaz Sezer, 2023 [23]	Turkey	62	RC T	31	NA	31	30.41±6.41	NA	31.52±5.58	VR (Sea, Underwater, Forest, and Relaxing Music): 360° VR video with scenes of the sea, underwater, and forest, paired with relaxing music during HSG.

Assessment of Pain Levels Using the Visual Analog Scale (VAS)

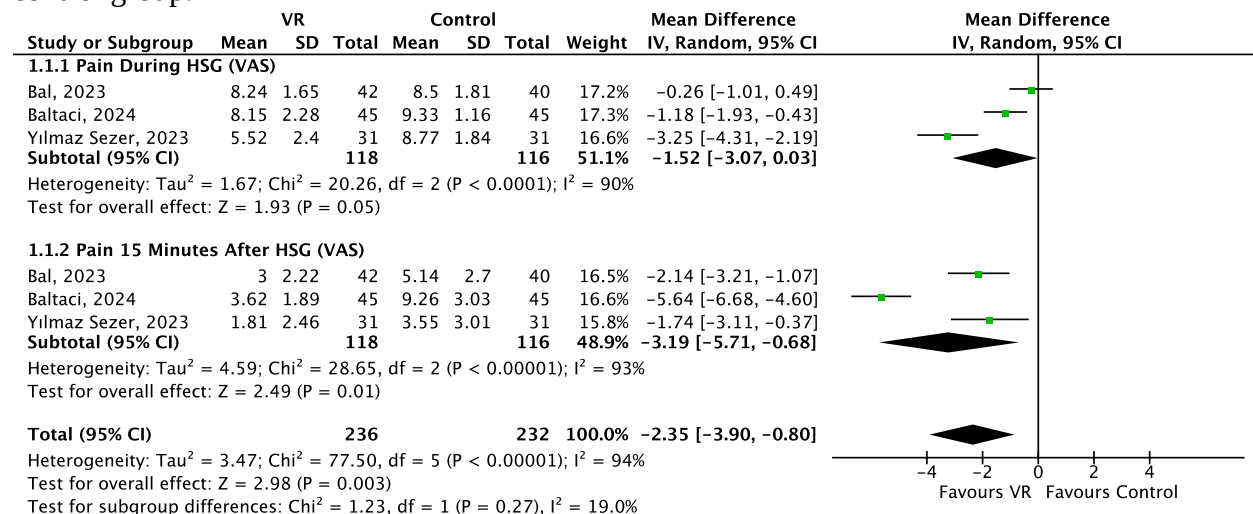
Four of the included studies evaluated pain levels using the VAS in association with HSG, as shown in Table 2. Among these, three studies assessed pain during HSG and 15 minutes post-procedure. Regarding VR, analysis of these three studies demonstrated a significant reduction in pain during HSG among participants using VR compared to those without, with a mean MD of -1.52 (95% CI [-3.07, 0.03], $P = 0.05$). However, high heterogeneity ($I^2 = 90\%$) necessitated the use of a random-effects model. Similarly, the pain score 15 minutes after HSG was significantly lower in the VR group compared to the control group, with an MD of -3.19 (95% CI [-5.71, -0.68], $P = 0.01$), and high heterogeneity was again observed ($I^2 = 90\%$). The overall pooled analysis for pain reduction during and 15 minutes after HSG favored VR over the control group, with an MD of -2.35 (95% CI [-3.90, -0.80], $P = 0.003$) and low heterogeneity across subgroups ($I^2 = 19\%$), as illustrated in Figure 2. Additionally, one study reported pain scores as peak pain and overall pain during HSG in both the VR and control groups [7], which precluded meta-analysis. However, the findings indicated no significant association between VR use and peak pain ($P = 0.519$) or overall pain ($P = 0.519$) during HSG.

Table 2 Pain levels by Visual Analog Scale (VAS) score in association with hysterosalpingography (HSG). VR: virtual reality; HSG: hysterosalpingography; NA: not applicable.

Article	During HSG	15 Minutes After HSG	Overall Pain	Peak Pain
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	VR	Music/ Natural Sounds	Control	VR	Music/ Natural Sounds	Control	VR	Music/ Natural Sounds	Control	VR	Music/ Natural Sounds	Control
Rosiele, 2024 [7]	NA	NA	NA	NA	NA	NA	5.0±2.10	NA	4.9±2.13	6.8±2.25	NA	6.6±2.40
Baltaci, 2024 [16]	8.15±2.28	8.71±1.96	9.33±1.16	3.62±1.89	3.46±2.71	9.26±3.03	NA	NA	NA	NA	NA	NA
Bal, 2023 [22]	8.24±1.65	NA	8.50±1.81	3.00±2.22	NA	5.14±2.70	NA	NA	NA	NA	NA	NA
Yılmaz Sezer, 2023 [23]	5.52±2.40	NA	8.77±1.84	1.81±2.46	NA	3.55±3.01	NA	NA	NA	NA	NA	NA

Figure 2. Forests plots assessing the pain levels using the Visual Analog Scale (VAS) during and 15 minutes after hysterosalpingography (HSG), comparing virtual reality (VR) group with a control group.



Regarding auditory stimuli, only one study compared natural sounds alone to the control group [16], also precluding meta-analysis. This study, however, also compared the VR + natural sound group with the natural sounds alone group and with a control group. Nevertheless, this study found no difference in pain levels between the VR with natural sounds group and the natural sounds alone group during the procedure ($P > 0.05$). However, pain levels in the VR with natural sounds

group were significantly lower than those in the control group ($P = 0.009$). Post-procedure, both the VR with natural sounds and the natural sounds alone groups experienced significantly lower pain levels compared to the control group ($P = 0.000$ for both comparisons).

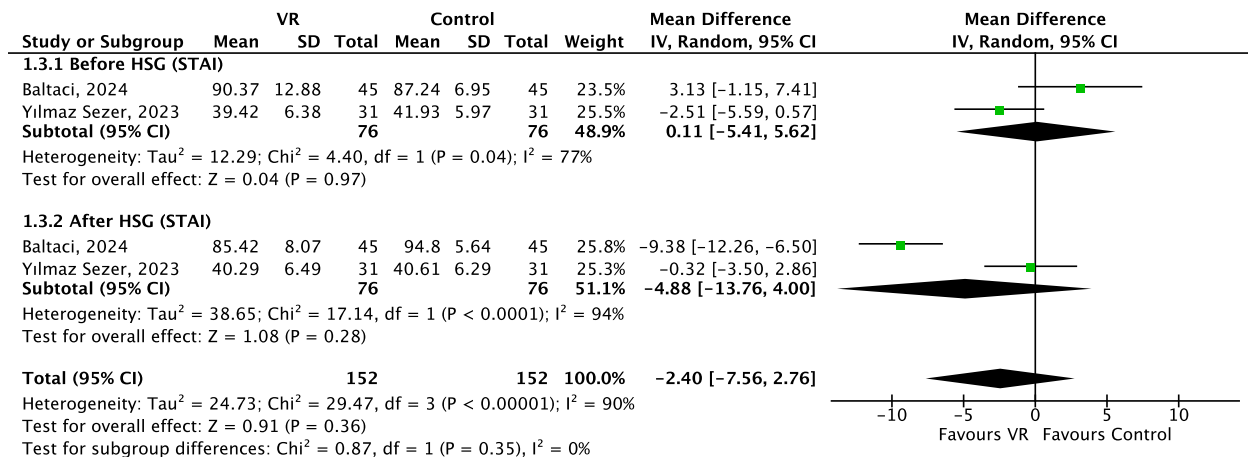
Assessment of Anxiety Levels Using the State–Trait Anxiety Inventory (STAI)

Three of the included studies assessed anxiety levels before and after HSG using the STAI score, as seen in Table 3. Two of these studies compared anxiety between a VR group and a control group. Before HSG, there was no statistically significant difference in anxiety levels between the two groups (MD 0.11, 95% CI [-5.41, 5.62], $P = 0.97$), although high heterogeneity was observed ($I^2 = 77\%$). Similarly, post-HSG anxiety levels showed no significant difference between groups (MD -4.88, 95% CI [-13.76, 4.00], $P = 0.28$), with high heterogeneity ($I^2 = 94\%$). The overall pooled analysis showed no statistically significant association between VR use and anxiety reduction (MD -2.40, 95% CI [-7.56, 2.76], $P = 0.36$) and low heterogeneity across subgroups ($I^2 = 0\%$), as shown in Figure 3.

Table 3 Anxiety levels by State–Trait Anxiety Inventory (STAI) score in association with hysterosalpingography (HSG). VR: virtual reality; HSG: hysterosalpingography; NA: not applicable.

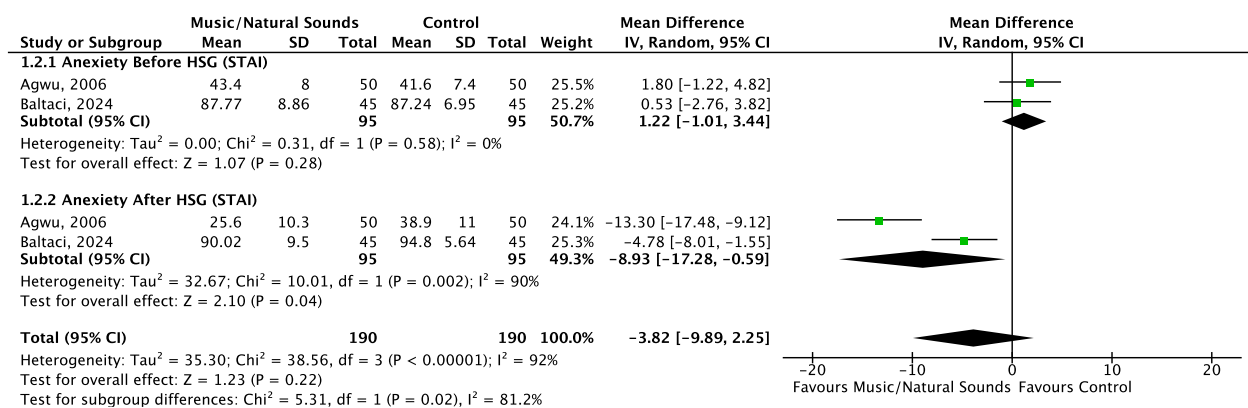
Article	Before HSG			After HSG		
	VR	Music/Natural Sounds	Control	VR	Music/Natural Sounds	Control
Agwu, 2006 [11]	NA	43.4±8.0	41.6±7.4	NA	25.6±10.3	38.9±11.0
Baltaci, 2024 [16]	90.37±12.88	87.77±8.86	87.24±6.95	85.42±8.07	90.02±9.51	94.80±5.64
Yilmaz Sezer, 2023 [23]	39.42±6.38	NA	41.93±5.97	40.29±6.49	NA	40.61±6.29

Figure 3. Forests plots assessing the anxiety levels using the State–Trait Anxiety Inventory (STAI) score before and after hysterosalpingography (HSG), comparing virtual reality (VR) group with a control group.



Additionally, two studies evaluated anxiety levels between an auditory stimuli group (using music or natural sounds) and a control group, as seen in Figure 4. No significant difference in anxiety levels was found between these groups before HSG (MD 1.22, 95% CI [-1.01, 3.44], $P = 0.28$). However, post-HSG anxiety was significantly lower in the auditory group compared to the control group (MD -8.93, 95% CI [-17.28, -0.59], $P = 0.04$), despite high heterogeneity ($I^2 = 90\%$). The overall pooled analysis indicated no significant association between auditory stimuli (music or natural sounds) and anxiety reduction during HSG (MD -3.82, 95% CI [-9.89, 2.25], $P = 0.22$). One study compared VR with natural sounds, natural sounds alone, and a control group, precluding meta-analysis. However, this study found that post-HSG anxiety levels were significantly lower in the VR with natural sounds group compared to both the natural sounds alone group ($P = 0.018$) and the control group ($P = 0.000$). Likewise, post-HSG anxiety levels were significantly lower in the natural sounds alone group compared to the control group ($P = 0.013$).

Figure 4. Forests plots assessing the anxiety levels using the State-Trait Anxiety Inventory (STAI) score before and after hysterosalpingography (HSG), comparing auditory (music/natural sounds) group with a control group.



Risk of Bias Assessment

The application of the RoB 2 tool guidelines revealed that the majority of the included RCTs had an overall risk categorized as having “some concerns”, with one study having an overall “low risk” and another study categorized with an overall “high risk”, as illustrated in Table 4. This is due to the studies having “high risk” in at least one of the domains or “some concerns” in more than one domain included in the RoB 2 tool, such as selection bias, attrition bias, detection bias, and performance bias. This is attributed to the fact that some studies lacked blinding, while others lacked concealment of allocation, leaving room for bias. The only domain that was considered “low risk” for almost all the included studies was reporting bias.

Table 4 Review authors' judgments about each risk of bias item for each of the included study article.

Included Study Articles	Bias arising from the randomization process	Bias due to deviations from intended intervention	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall RoB
Rosielle, 2024 [7]	High	Some concerns	Low	High	Low	High
Agwu, 2006 [11]	Low	Low	Some concerns	Low	Low	Some concerns
Baltaci, 2024 [16]	Low	Low	Low	Low	Low	Low
Bal, 2023 [22]	Low	Low	Some concerns	Low	Low	Some concerns
Yilmaz Sezer, 2023 [23]	Low	Some concerns	Low	Low	Low	Some concerns

DISCUSSION

This study aimed to assess the effectiveness of VR and auditory stimuli in reducing pain and anxiety with HSG, an invasive procedure often associated with significant discomfort and anxiety. A comprehensive systematic review of the literature was conducted, reporting data from five RCTs that involved 513 women, whose primary objective was to evaluate the efficacy of VR and music/natural sounds on minimizing pain or anxiety levels in women undergoing HSG. Previous studies have suggested that non-pharmacological interventions such as VR or auditory stimuli have

been shown to offer relief during invasive procedures in various patient groups, but their effectiveness has remained inconclusive [24-28].

In our paper, we found that VR interventions overall significantly reduced pain levels during and after the HSG procedure. The pooled analysis of three RCTs assessing pain levels using the VAS showed that VR led to a decline in pain both during the procedure and 15 minutes after the procedure ($P = 0.003$). The low heterogeneity ($I^2 = 19\%$) observed across the subgroups further supports the robustness of these findings. Similar to our result, a study conducted by Baradwan et al. found VR to be an effective intervention in reducing pain and anxiety during outpatient hysteroscopic procedures [29]. This stems from the notion that VR-based interventions function as a form of distraction therapy, attenuating pain perception by decreasing activity within the central pain-processing regions. It facilitates an immersive and comprehensive distraction by engaging diffuse attention, which interacts with emotional states positively in providing enhanced comfort and relaxation during invasive interventions. Moreover, it was demonstrated that VR applications in cardiac surgery patients can mitigate postoperative pain and even improve physiological parameters such as heart rate and blood pressure, thereby substantiating its interventional impact during surgical procedures [30].

In regards to the efficacy of auditory stimuli (music or natural sounds), a study conducted by Baltaci et al. employed the use of natural sounds alongside VR and found notable results in reducing pain levels both during and after the injection ($P = 0.000$) of a contrast agent into the uterus—considered to be the most painful step in HSG [16]. This could be due to multiple factors pertaining to distraction, emotional modulation, and neurophysiological responses. One of the ways of pain management is distraction. Auditory distractions, such as music, can decrease pain levels by diverting the patient's attention away from the stimulus [31, 32]. Another crucial factor is the emotional reaction induced and generation of positive emotions, which influences the perception of pain [33, 34]. Lastly, neurophysiological processes play a role in the analgesic effects of auditory stimuli. For instance, interactions between the auditory cortex and pain-related brain networks suggest that auditory stimuli can affect the neural handling of pain [35]. Additionally, pleasant sounds or music can stimulate the release of neurotransmitters like dopamine, which are associated with pain relief, thereby enhancing its analgesic effect [34]. Overall, the integration of both VR and auditory stimuli showed promising results in diminishing pain levels, owing to their concurrent application and synergistic effect. Thus fostering an empathetic environment for patients undergoing HSG, as well as an alternative strategy for pain reduction, potentially providing a more affordable approach without the adverse effects typically associated with pharmacological agents [11, 16].

When assessing for anxiety reduction in our study, no significant association was found between the use of VR and anxiety levels ($P = 0.36$; $I^2 = 0\%$). However, the association between auditory stimuli (natural sounds or music) and anxiety reduction after HSG ($P = 0.04$; $I^2 = 90\%$) was statistically significant. In contrast to our findings, a study by Cohen et al. reported a favorable contribution of VR towards reduction in the anxiety levels experienced by patients who underwent hysteroscopy [35]. This disparity may be attributed to the nature of the procedures, as hysteroscopy is often perceived as more invasive and potentially painful compared to HSG.

Our study is the first systematic review and meta-analysis to synthesize the effects of both VR and auditory stimuli on pain and anxiety during HSG. In addition, the rigorous study selection and inclusion criteria, with the inclusion of RCTs only, ensure that the evidence gathered is of high methodological quality. However, several limitations should also be acknowledged. Firstly, the small number of studies (five RCTs) included in our meta-analysis may attenuate the statistical power and precision and thereby limit the generalizability of our findings. Secondly, due to the varied quality in included studies, some lacking blinding, this may have contributed towards reporting bias. The use of random-effects models accounts for the substantial heterogeneity found across the included RCT studies. Moreover, amongst the included studies that utilized VR, two studies used sounds in conjunction with VR while 2 studies did not; this inconsistency in intervention design further introduces bias and makes it difficult to isolate the specific effects of VR alone.

The findings of this review have important implications that suggest both VR and auditory stimuli to be promising, cost-efficient, and non-invasive tools for pain alleviation during HSG. Given the potential benefits observed, healthcare providers should consider incorporating VR as a non-pharmacological option for pain relief, especially for women with a low threshold for procedural pain or anxiety. While the evidence for anxiety reduction with VR is less conclusive, the potential benefits of auditory interventions post-procedure warrant its consideration in clinical practice. There is an imperative need for more comprehensive/robust RCTs to confirm the effects of VR and auditory stimuli on both pain and anxiety levels during HSG, especially studies catered towards larger sample sizes and standardized intervention protocols. Moreover, investigating the combination of VR with auditory stimuli could yield insights into their synergistic effects. Additionally, further research should consider comparing the cost-effectiveness of VR and auditory interventions with conventional pharmacological approaches; such an approach would be beneficial in guiding healthcare practice and informing policy decisions.

CONCLUSION

This meta-analysis, in conclusion, provides evidence supporting the use of VR for pain reduction during HSG; while auditory stimuli shows potential for anxiety management. The overall trend across studies reinforces the use of non-pharmacological interventions to improve patient comfort during diagnostic procedures. Ultimately, these non-invasive interventions significantly improve patient experience during HSG procedures, warranting further investigation and their potential integration into clinical practice.

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