**Distraction therapies for office-based Otolaryngology procedures performed on the upper airway**

# Abstract

**Objective:**

To assess the effectiveness of auditory and visual distraction interventions on patient discomfort, pain and anxiety during office-based Otolaryngologic upper airway procedures.

**Data Sources:**

Literature searches were done through Cochrane Central Register of Controlled Trials, Lilacs, MEDLINE, Embase, PsycINFO, and Cumulative Index to Nursing and Allied Health Literature.

**Review Methods:**

The protocol was registered in PROSPERO on August 17th 2022, under Registration number CRD42020204354.

**Results:**

We identified 138 records; two randomized controlled trials using virtual reality as a distraction technique in adults and one in children were included. All studies had some concerns regarding risk of bias. In adults, anxiety was lower in the virtual reality group than in the standard of care, (mean difference -16.72, 95% CI -27.19 to -6.24, p=0.002, I2=0%). There was no difference in procedure related pain between groups, (mean difference -0.28, 95% CI -1.24 to 0.68, p=0.57, I2=10%). There was no difference in satisfaction between groups (Standardized mean difference 0.18, 95% CI -0.22 to 0.58, p = 0.37, I2=0%). Only one Pediatric study was included hence no meta-analysis was done. Anxiety and pain were lower and satisfaction was higher in the group using virtual reality.

**Conclusions:**

The use of virtual reality distraction in addition to standard analgesia during office-based Otolaryngology upper airway procedures reduced anxiety in adults. It did not decrease pain or increase the level of patient satisfaction. In the paediatric population, there is a reported benefit for procedural anxiety, pain and satisfaction.

**Key Points**: Upper airway procedures; audio-visual; virtual-reality, anxiety, pain reductio.

# INTRODUCTION

Distraction techniques have been used to manage pain and reduce the anxiety associated with medical procedures1. Distraction techniques can be active or passive.2 a  Passive distraction does not require interaction by the patient and includes activities such as listening to music or watching videos thus only using visual and auditory senses.3 Active distraction requires the patient to engage in and to participate in activities during the medical procedure. These can include such activities as breathing exercises, singing, or playing with electronic devices.2

In children, audio-visual distraction interventions have been utilized to reduce pain and anxiety during awake medical and dental procedures.1,4,5A recent systematic review showed that audio-visual aids assist in reducing pain and anxiety in children undergoing dental procedures.1 Virtual reality (VR) is a relatively new audio-visual distraction intervention used for this purpose. It has been shown to be safe and reduce pain and anxiety in children undergoing dental care, burn care, oncological care as well as venous access. 5,6

Distraction interventions have also been used in adults in order to manage pain and anxiety during awake medical procedures. Music and audio-visual distraction (music videos and tv shows) have been found to be safe, effective and low-cost interventions to reduce pain and anxiety during medical procedures such as extracorporeal shock wave lithotripsy, fiberoptic bronchoscopy and reduction of nasal bone fractures with local anesthesia.7,8 The use of virtual reality as a distraction technique in adults has shown inconsistent results. Goergen (2022) showed that virtual reality is associated with a reduction of pain and discomfort in patients undergoing rigid cystoscopy under local anesthesia.9 However, when used during outpatient operative hysteroscopy without anesthesia or unsedated gastrointestinal endoscopy, virtual reality has not been shown to have a significant effect on pain.10,11

Advances in technology have facilitated the development of non-sedated, office-based diagnostic and therapeutic otolaryngology procedures.12,13 These otolaryngology procedures range from diagnostic studies which include upper airway endoscopy to therapeutic interventions such as laryngeal injections.12,13 The adoption of office-base procedures presents advantages such as the elimination of the risks associated with the use of general anesthesia as well as lower cost.14 Ultimately, a patient’s tolerance determines which procedures can be performed without sedation or with formal anesthesia.15 Generally, office-based otolaryngology procedures are well tolerated by patients and are associated with low levels of pain and discomfort.12 However, anxiety before and during the procedure can affect the patient’s experience, periprocedural discomfort, level of satisfaction, and willingness to undergo further procedures.16,17 Some studies have reported the use of distraction techniques during office-based upper airway endoscopy, however, there have been no systematic reviews encompassing this topic. Therefore, it is important to better understand the potential efficacy of these distraction techniques to update physicians on methods of optimizing patient’s experience for procedures performed on the upper airway given their common place in clinical practice. This study aims to evaluate the evidence for office-based auditory and/or visual distraction therapies and their effect on procedural anxiety, pain and discomfort during upper airway Otolaryngologic procedures.

**METHODS**

The methods for the review were established a priori. This systematic review has been reported according to guidance from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).18 The protocol was registered in PROSPERO on August 17th 2022, under Registration number CRD42020204354.

**Eligibility Criteria**

Inclusion criteria consisted of randomized controlled trials (RCTs), including cross-over trials comparing the use of auditory and/or visual distraction interventions to no distraction or to other distraction intervention in the management of discomfort, pain and/or anxiety experienced by patients during office-based upper airway otolaryngologic procedures. Studies in adults and children were included. Studies including office-based upper airway procedures such as nasopharyngolaryngoscopy, nasal endoscopy, flexible laryngoscopy, in clinic sinus surgery or polypectomy, post-operative debridement with nasal endoscopy, laryngeal injections, nasal/paranasal sinus/pharyngeal biopsy, and laryngeal biopsy were included. Interventions included but were not limited to music, virtual reality, television, reading and manual activities. Review articles, non-interventional studies, abstracts, case reports and letters to the editor were excluded. Studies published in a language other than English, French or Spanish were also excluded.

**Search Strategy**

A literature search was performed by an experienced librarian to locate relevant studies. We searched Medline, Embase PsycINFO and CENTRAL to Sept 29, 2022. CINAHL and LILACS to Oct 4, 2022. Clinicaltrials.gov and the World Health Organization International Clinical Trials Registry were searched on Oct 4, 2022. See Appendix 1 for details about the search strategy.

**Selection process**

Screening of titles and abstracts was done independently by two reviewers (TC/AL) based on the previously mentioned inclusion and exclusion criteria. Next, full text manuscripts were retrieved and independently reviewed by the same reviewers. Disagreements were resolved by consensus, and if a disagreement persisted, a third reviewer (SK), was consulted. Covidence systematic review software19 was used for this process.

**Data extraction**

Two independent review authors (TK/AL) completed the data extraction using a pre-defined Covidence19 form. The following were extracted from each study: study design, study population demographics (age, sex), type of office-based procedure, type of distraction therapy used, outcome measures for pain/discomfort, anxiety, satisfaction, adverse events, time needed for the procedures and cost of the intervention if available. Disagreements were resolved by consensus.

**Risk Of Bias in Individual Studies**

The Risk of Bias 2 (RoB 2) 20 tool for individually-randomized, parallel-group trials was used to assess the risk of bias of all studies including a cross-over randomized controlled trial given that only data from the first period of this study was used. Studies were evaluated by two study reviewers (TC and AL) and disagreements were resolved by consensus.

**Approach to data synthesis**

Studies were grouped by population (adults and children) for analysis. The I² test was used to evaluate heterogeneity; an I² higher than 50% was considered substantial. A descriptive summary of the results of the studies is presented. A fixed effects model was used to analyze the studies that were pooled. Treatment effect for continuous data is presented as standardized mean differences (SMD) when different scales were used for the same outcome and as mean differences (MD) when studies used the same scales.

Following the recommendations of Elbourne et al 21 only the data from the first study period was used for the single cross-over trial included in this review19 as there was evidence of longitudinal effect. Analysis was done using RevMan version 5.4.

**RESULTS**

**Study selection**

Our search identified a total of 138 citations for review following removal of duplicates. Amongst them, 118 were found to be irrelevant, and the remaining 20 were assessed for eligibility in full text. Three unique studies were deemed eligible for inclusion, and 17 were excluded. Details of the selection process are shown in the PRISMA-Flowchart (2020) (See Figure1.)

**Study Characteristics**

Details of the included studies are summarized in Table 1. All included studies were randomized controlled trials; two were parallel RCTs 22,23 while one was a cross-over RCT.24 Two studies were done in adults22,24while one was done in children.23 The otolaryngology procedures performed on the study patients included laryngeal biopsies, injections and laser ablation,22 nasal endoscopy and debridement following surgery 24 and nasal endoscopy.23 All studies used VR as distraction therapy. Two studies used active VR in addition to standard of care 23,24 while one study used passive VR in addition to standard of care.22 The control intervention for all studies was standard of care alone. All studies used the Subjective Units of Distress Scale (SUDS) to evaluate anxiety. Two studies used a Visual Analogue Scale (VAS)22,24 to evaluate procedural pain while one study used the Wong-Baker Faces Pain Score.23 All studies used a Likert scale to evaluate satisfaction.

**Findings from Risk of Bias Appraisals**

## All studies had low risk of bias with regards to the randomization process and deviations from the intended interventions. For missing outcome data, the study by Chang (2021)22 had some concerns. For all the studies there were some concerns for measurement of the outcome and selection of the reported results. This was primarily due to the fact that the intervention could not be masked, and the outcomes of pain, anxiety and satisfaction were measured using patient reported outcomes. Overall, all studies had concerns with regards to risk of bias. The results of the assessment are presented in Figure 2.

**Study Outcomes**

**Meta-Analysis**

**Anxiety**

Two studies in the adult population evaluated the efficacy of VR distraction as a nonpharmacologic anxiolytic during office-based upper endoscopy procedures.22,24 A total of 51 patients were evaluated for this outcome. Anxiety was assessed using the Subjective Units of Distress Scale (SUDS) in both studies. The analysis showed no heterogeneity among the studies (I2= 0%,). Anxiety was significantly lower in the those who were assigned to the VR group (MD = -16.72 (95% CI -27.19 to -6.24), p=0.002). See Figure 3.

**Pain**

Two studies assessed procedural pain using a Visual Analog Scale (VAS) in adults.22,24 The analysis showed low heterogeneity (I2= 10%). There was no difference in the VAS between the group that used virtual reality during their procedure and the group that received standard of care (MD= -0.28 95% CI -1.24 to 0.68). See Figure 4.

**Satisfaction**

Two studies22,24 evaluated satisfaction with the procedure as measured by a 7-point Likert scale ranging from extremely satisfied to extremely dissatisfied. There was no statistically significant difference between the satisfaction of patients in the VR group vs the control during upper airway procedures (95% CI 0.18 (-0.22, to 0.58), p = 0.37). This analysis showed no heterogeneity (I2 = 0%). See Figure 5.

Chang 202122 reported data on adverse events and time required for the procedure. Time required for the procedures was not different between groups. No adverse events in relation to the intervention were reported.

A descriptive summary is provided for the pediatric population as there was only one study in this subgroup.23 Anxiety was measured using the SUDS scale. Patient in the VR group reported decreased anxiety compared to the patients in the control group (9.50 ±12.48 vs. 38.48 ± 29.83, respectively p=0.0002). Pain was evaluated using the Wong-Baker FACES rating scale; patient’s in the VR group reported significantly less pain during the procedure than the patients in the control group (0.80 ±1.06 vs. 2.26 ± 2.38, respectively, p=0.018). Satisfaction with the procedure was higher on the Likert scale for patients in the VR group that those in the control group (6.40 ± 0.77 vs. 4.74 ± 1.74, p= 0.0002).

**DISCUSSION**

This is the first systematic review and meta-analysis to evaluate the evidence for auditory and visual distraction therapies and their patient benefits for procedural pain, discomfort and anxiety during office-based upper airway otolaryngologic procedures when compared to the standard of care.

This systematic review and meta-analysis included a total of three studies with 151 patients. Our meta-analysis found that in adults, virtual reality is effective at reducing anxiety experienced during a range of upper airway otolaryngologic procedures. Virtual reality had no effect on pain or satisfaction with the procedure. A likely explanation for this finding is that all participants received the same analgesia as part of their standard of care, therefore pain was well controlled already and VR could not offer any additional benefit. Limited data in the pediatric population showed that the use of virtual reality decreased patient reported pain and anxiety and improved patient satisfaction with the procedure. This evidence seems consistent with what has been observed in other areas where similar studies were done. A recent systematic review found that the use of audio-visual distraction in children undergoing dental treatment reduces pain and anxiety.1 Similarly, virtual reality was found to be effective at reducing pain, fear and anxiety in children during venous access, burn and oncological care.4,6

The implication of anxiety reduction is important for office-based procedures. Anxiety in this context can lead to persistent stress after interventions which can result in behaviour change and poor compliance with future procedures.16,17 Given the results of this study, VR is an interventional option that can decrease procedural anxiety which could possibly lead to improved patient experience. It is also a simple and relatively affordable distraction method. Incidentally all the studies that met our inclusion criteria used VR. There are other interventions such as music that may require even less equipment and may potentially be even more affordable to use in an outpatient office-based setting. Opartpunyasarn et al. 25 showed favorable results with binaural beat music among patients undergoing fiberoptic bronchoscopy in terms of reducing anxiety. From the work of Schimberg et al. (2019)14 there is evidence that office-based laryngopharyngeal procedures under topical anesthesia lowers cost of treatment compared to similar procedures performed under general anesthesia. An area yet to be explored, is whether there exists a cost benefit between different audio-visual techniques such as VR and music alone.

In our study we had different types of upper airway ENT procedures; from simple endoscopy to vocal fold injections, biopsies and nasal debridement. As these are different upper airway procedures, the baseline levels of anxiety and pain experienced by patients may differ. Further, anxiety, discomfort and pain were mainly reported using patient reported outcomes, however, future objective outcome measures such as blood pressure, heart rate and oxygen saturation levels, in addition to patient reported outcomes.

Importantly, no complications were reported in any of the studies, from the use of VR during in-office otolaryngology procedures. Procedural time in seconds was not different between the two groups, when measured. However, cost of the intervention and use of VR versus standard of care was not reported.

Our study had some limitations which should be taken into account when interpreting the results. Our sample size was small, only three studies met the inclusion criteria. Due to the presence of carry-over effect we only analyzed the data from the first period of the included cross-over trial24. As mentioned previously, there was only one study in the pediatric population and hence we are unable to fully assess effectiveness even though we ascertained that there was benefit in procedural pain, anxiety and satisfaction. There were concerns with all studies in terms of risk of bias. This is due to patients being aware of the treatment assignment and the use only of patient reported outcomes. Furthermore, our study had only virtual reality as an audio/visual distraction technique. As such there is scope to do future research in this area to study other distraction interventions such as music.

**CONCLUSION**

The use of virtual reality distraction in addition to standard analgesia during office-based otolaryngologic upper airway procedures reduces anxiety in adults. The use of virtual reality did not decrease pain or increase the level of patient satisfaction with the procedure in adults. In the pediatric population a single study showed benefit for procedural anxiety, pain and satisfaction. This VR technique was safe with no reported adverse outcomes. Based on these results, VR could be incorporated into clinical practice for upper airway procedures and be widely applied to patients in an ambulatory setting.

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**Titles/Captions**

Figure 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only

Figure 2. Risk of Bias Summary

Figure 3. Meta-analysis of the effect of virtual reality as a distraction intervention for anxiety during in-office otolaryngology procedures.

Figure 4. Meta-analysis of the effect of virtual reality as a distraction intervention for pain during in-office otolaryngology procedures.

Figure 5. Meta-analysis of the effect of virtual reality as a distraction intervention on satisfaction with in-office otolaryngology procedures.