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Enhancing Patient Experience in Office-Based Laryngology Procedures With Passive Virtual Reality

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Abstract

Objectives. Virtual reality (VR) has been used as nonpharmacologic anxiolysis benefiting patients undergoing office-based procedures. There is little research on VR use in laryngology. This study aims to determine the efficacy of VR as anxiolysis for patients undergoing in-office laryngotracheal procedures.

Study Design. Randomized controlled trial.

Setting. Tertiary care center.

Methods. Adult patients undergoing office-based larynx and trachea injections, biopsy, or laser ablation were recruited and randomized to receive standard care with local anesthesia only or local anesthesia with adjunctive VR. Primary end point was procedural anxiety measured by the Subjective Units of Distress Scale (SUDS). Subjective pain, measured using a visual analog scale, satisfaction scores, and procedure time, and baseline anxiety, measured using the Hospital Anxiety and Depression Scale (HADS), were also collected.

Results. Eight patients were randomized to the control group and 8 to the VR group. SUDS scores were lower in the VR group than in the control group with mean values of 26.25 and 53.13, respectively (P = .037). Baseline HADS scores did not differ between groups. There were no statistically significant differences in pain, satisfaction, or procedure time. Average satisfaction scores in VR and control groups were 6.44 and 6.25, respectively (P = .770). Average pain scores were 3.53 and 2.64, respectively (P = .434).

Conclusion. This pilot study suggests that VR distraction may be used as an adjunctive measure to decrease patient anxiety during office-based laryngology procedures. Procedures performed using standard local anesthesia resulted in low pain scores and high satisfaction scores even without adjunctive VR analgesia.

Level of Evidence. 1

Keywords

virtual reality, distraction analgesia, office-based procedures, injection laryngoplasty

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Over the past few decades within the field of laryngology, there has been a drive toward moving procedures traditionally performed under general anesthesia in the operating room into the office with local anesthesia only.[1,2] This drive toward office-based procedures has been attributed in part to advances in technology, including stronger light sources, distal chip endoscopes that allow higher definition imaging, and fiber-delivered lasers that allow transfer of laser energy through channeled endoscopes.[1]

Similarly, advances in virtual reality (VR) have opened new opportunities for improving patient experience. While active VR distraction has been shown to decrease pain perception in wound care,[3,4] physical therapy,[5] and phlebotomy,[6-8] passive VR distraction has been shown to increase pain.[9] On the other hand, both passive and active VR have also been shown to decrease patient anxiety.[10,11] Given overall low pain perception in office-based laryngology procedures and high preprocedural anxiety,[12] anxiolysis may be a higher yield target to improve patient experience.

This study aims to determine the efficacy of passive VR distraction as anxiolysis for patients undergoing office-based laryngotracheal procedures with the ultimate goal of improving patient experience. While active engagement in VR may further reduce pain, it seemed likely to also increase involuntary patient movement. Passive VR distraction was,

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therefore, determined to be a more ideal intervention for this pilot study on the use of VR in office-based laryngology procedures. The primary aim of our study was assessment of anxiety; secondary aims were to assess pain perception, patient satisfaction, and feasibility of using a head set system during office-based laryngology procedures.

Materials and Methods

Patient Selection and Preparation

The Institutional Review Board of Mount Sinai Hospital approved this study. Patients aged 18 to 85 years undergoing office-based laryngotracheal procedures by a single fellowship-trained laryngologist (M.C.) were recruited for the study. Procedures included injection laryngoplasty with Juvéderm (Allergan) or Prolaryn Gel (Merz North America, Inc.), transnasal endoscopic injection of vocal folds with Botox (Allergan), intralesional steroid injection for airway stenosis, endoscopic vocal fold biopsy, and potassium titanyl phosphate (KTP) laser ablation of vocal fold lesions. Exclusion criteria included patients with a history of chronic pain or neurologic or seizure disorders. Patients underwent computer-generated block randomization into the VR or control study arms. Baseline demographic data were recorded.

All patients in both the VR and control groups received topical laryngotracheal analgesia. In total, 4 mL of 4% lidocaine was applied directly onto the vocal folds through a channeled laryngoscope in the KTP ablation, vocal fold biopsy, and endoscopic Botox procedures; through a needle inserted via a transthyrohyoid approach in the injection laryngoplasty procedures; and through a needle inserted via a cricothyroid approach in the intralesional steroid injection procedures. Topical nasal lidocaine was applied for all procedures.

Figure 1. Office-based laryngology procedure using adjunctive virtual reality goggles.

Intervention

In the VR intervention group, subjects were provided with Samsung Gear VR goggles (207.1 × 120.7 × 98.6 mm dimensions; 101° field of view; 62 mm interpupillary distance) with a Galaxy S9 smartphone connected via micro USB port to provide audiovisual content (**Figure 1**). These subjects were placed in a VR program provided by the Coresights platform, where they were immersed in a relaxing virtual environment on a beach with the sound of waves crashing onto a shore playing during the experience. Subjects underwent the entirety of the procedure while immersed in the VR environment. Patients were monitored for VR side effects, including nausea, headache, and dizziness.[13-15] A research assistant recorded the procedure length as well as the number of times the procedure needed to be stopped due to patient discomfort.

Measures

Prior to the procedure, patients completed a Hospital Anxiety and Depression Scale (HADS)[16,17] questionnaire to assess their baseline anxiety levels. Following the procedure, patients completed a questionnaire including a visual analog scale (VAS) pain score,[18,19] Subjective Units of Distress (SUDS) anxiety score,[20] and procedure satisfaction score[21,22] (see Suppl. Figure S1 in the online version of the article). The VAS consists of a 10-cm line, with one end designated as ''no pain'' and the other end as ''pain as bad as it could be'' on which patients mark the level of pain they experienced during the procedure. Similarly, the SUDS consists of a rating scale ranging from 0 (totally relaxed) to 100 (highest distress/fear/anxiety/discomfort that you have ever felt). Patients circle a number on the scale that corresponds to the anxiety they experienced during the procedure.[20,23] Procedural satisfaction was assessed on a 7-point Likert scale, ranging from 1 (extremely dissatisfied) to 7 (extremely satisfied).[21,22] Patients in the VR group were also asked, ''How did the virtual reality experience compare to the standard-of-care experience?'' with answer choices ''worse,'' ''better,'' or ''same'' and ''Would you prefer to use the virtual reality experience for future procedures of this type?'' with answer choices ''yes,'' ''no,'' and ''unsure.''

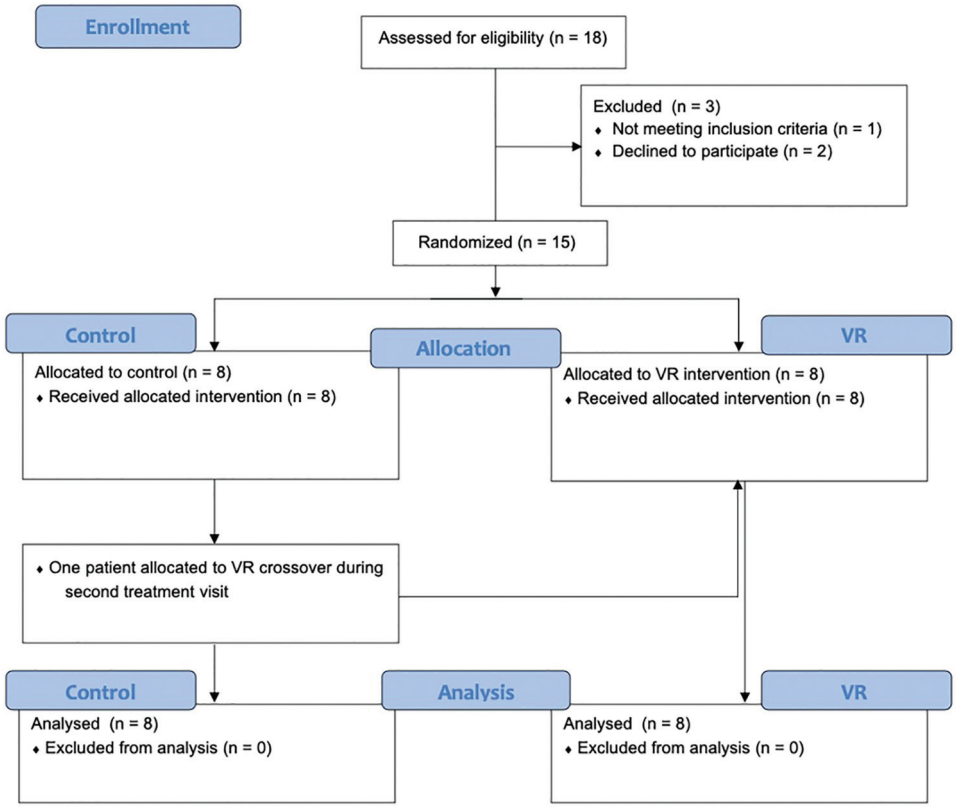

Figure 2. CONSORT flowchart.

Data Analysis

Statistical analysis was performed using SPSS version 26.0.0.1 statistical software (SPSS, Inc). This study was powered to detect a difference in procedural anxiety as measured by the SUDS score. Data from patients undergoing office-based laryngology procedures at Mount Sinai with and without VR prior to this study were used to estimate effect sizes and standard deviations. Power analysis using these estimates determined that a study size of 8 subjects in each arm would find a difference in SUDS score assuming a type I error of .05 and type II error of .2. A study size of 19 and 69 subjects per arm would be required to detect a difference in VAS and satisfaction scores, respectively.

Study results were considered statistically significant when associated with P values less than .05. Independent 2-tailed t tests and Mann-Whitney U tests were used to compare SUDS scores, HADS scores, VAS pain scores, satisfaction scores, and procedure times. Fisher exact tests, χ^2 tests, and 2-tailed t tests were used to compare baseline demographics.

Results

Patient Characteristics

A total of 8 procedures were performed in the control group and 8 procedures in the VR group. One patient had 1 procedure in the control group and a second procedure in the VR group (**Figure 2**). There were no statistically significant differences in age, sex, procedure type, prior procedures, and HADS scores between the control and VR groups (**Table 1**). Age ranged from 30 to 84 years, with a mean age of 59.4 years. Composition of procedure types was similar in both groups with 37.5% of patients undergoing injection laryngoplasty and 37.5% of patients undergoing KTP ablation in each group. Of the 6 total injection laryngoplasty patients, 5 received treatment for vocal fold paralysis, and 1, in the control group, was treated for vocal fold atrophy. Endoscopic Botox injection was performed for treatment of bilateral vocal fold paralysis.

Study Outcomes

Patients in the VR group reported significantly decreased procedural anxiety on the SUDS scale compared to patients in the control group (26.25 ± 16.64 in VR group vs 53.13 ± 28.40 in control group, P = .037). This corresponded to responses of moderate to strong anxiety or distress in the control group vs responses of minimal to mild anxiety or distress in the VR group. In the patient who crossed over from the control group during her first visit to the VR group during her second visit, her SUDS score dropped from 100 (highest distress/fear/anxiety/discomfort that you have ever felt) to 50 (moderate anxiety/distress). There was no statistically significant difference in patient-reported pain on the VAS scale between groups (3.53 ± 2.20 in VR group vs 2.64 ± 2.21 in control group, P = .434). Procedural satisfaction scores, reported by patients on a 7-point Likert scale, did not significantly differ between groups (6.44 ± 0.82 in

Table 1. Baseline Demographics and Patient Characteristics.

Characteristic	All	Control (n = 8)	VR (n = 8)	*P* value
Age, mean ± SD, y	59.4 ± 16.7	56.6 ± 16.4	62.9 ± 16.5	.45
Sex, No. (%)				
Male	9 (60)	4 (50)	5 (62.5)	.61
Female	6 (40)	4 (50)	3 (37.5)	
Procedure type, No. (%)				
Injection laryngoplasty	6 (37.5)	3 (37.5)	3 (37.5)	1.00
Intralesional steroid injection	2 (12.5)	1 (12.5)	1 (12.5)	
Endoscopic Botox injection	1 (6.25)	1 (12.5)	0 (0)	
KTP laser ablation	6 (37.5)	3 (37.5)	3 (37.5)	
Vocal cord biopsy	1 (6.25)	0 (0)	1 (12.5)	
History of prior procedure of this type, No. (%)				
Yes	6 (37.5)	3 (37.5)	3 (37.5)	1.00
No	10 (62.5)	5 (62.5)	5 (62.5)	
HADS (score), mean ± SD		9.88 ± 7.34	9.88 ± 5.08	1.00

Abbreviations: HADS, Hospital Anxiety and Depression Scale; KTP, potassium titanyl phosphate; VR, virtual reality.

Table 2. Control vs VR Treatment Outcomes.

Characteristic	Control, mean ± SD	VR, mean ± SD	*P* value
VAS pain score	2.64 ± 2.21	3.53 ± 2.20	.434
SUDS	53.13 ± 28.40	26.25 ± 16.64	.037[a]
Satisfaction[b]	6.25 ± 1.04	6.44 ± 0.82	.770
Procedure time, min	9.32 ± 4.08	12.00 ± 3.64	.188

Abbreviations: SUDS, Subjective Units of Distress Scale (range 0 to 100, with 0 = totally relaxed to 100 = highest anxiety you have ever felt); VAS, visual analog scale pain score (range 0 to 10, with 0 = no pain to 10 = pain as bad as it could be); VR, virtual reality.
[a]Statistically significant difference, $P \leq .05$.
[b]Satisfaction: range 1 to 7 (1 = extremely dissatisfied to 7 = extremely satisfied).

VR group vs 6.25 ± 1.04 in control group, $P = .770$) (**Table 2**).

When asked, ''Would you prefer to use the virtual reality experience for future procedures of this type?'' 100% of the patients in the VR group answered ''yes.'' Three patients who had previously undergone the same type of office-based procedure were asked if their experience with VR was worse, better than, or the same compared to standard treatment, and 100% of these patients responded ''better.''

The VR intervention did not result in any significant differences in procedure time between groups (12.00 ± 3.64 minutes in VR group vs 9.32 ± 4.08 minutes in control group, $P = .188$). In addition, no patients requested that the procedure be stopped and there were no reported side effects from the VR intervention.

Discussion

Passive VR distraction was successful in decreasing the anxiety of patients undergoing office-based laryngology procedures in this study as measured by the SUDS score. Average SUDS for the control group was nearly twice as high as the experimental VR group, 53.13 vs 28.40, respectively ($P = .037$). While this did not translate into significant differences in satisfaction score ($P = .770$), all patients in the VR group preferred to use the VR goggles again if they were to undergo procedures in the future, and all reported the VR experience to be better than standard treatment. Moreover, the satisfaction score in both groups was high and approached the upper limit of the satisfaction scale, 6.25 and 6.44 in the control and VR groups, respectively, out of a 7-point Likert scale. As this study was powered to find a difference in the primary end point of SUDS, a larger study or a more sensitive measure would be needed to verify our suspicions that VR distraction leads to higher satisfaction with office-based procedures.

As expected, use of passive VR distraction in this study of office-based laryngeal procedures did not result in a significant improvement in pain. However, pain reported in this study was mild overall. This is no doubt related to the requirement that patients undergoing office-based laryngeal procedures have dense local anesthesia to prevent respiratory and laryngeal reflexes from preventing successful completion of the procedure. This may mean there is little room to observe additional anesthetic effect from distraction.

On the other hand, there is reason to suspect that our strategy of passive VR distraction truly may not improve

pain. The VR program selected for use in this study was focused on relaxation and passive distraction; it intentionally did not involve active engagement from the patients in an attempt to minimize vocal fold and upper body movement that would have impaired the ability of the physicians to successfully complete the procedures. In a randomized trial comparing standard of care, passive distraction, and active distraction during burn wound care, passive distraction was found to be less effective than active distraction in reducing pain with little difference in pain perception between passive distraction and standard of care.[24] Furthermore, a randomized trial comparing morphine patient-controlled analgesia (PCA) with PCA in conjunction with VR relaxation in burn dressing changes found that the addition of VR relaxation significantly increased pain.[9] Future study into the effects of different VR programs on pain and patient satisfaction may be warranted.

Given the high patient satisfaction and known high completion rate of office-based laryngology procedures with standard techniques,[12] one might conclude that there is little quantifiable improvement to be gained by the addition of VR. On the other hand, all the VR patients, including 3 who had previously had office-based procedures without VR, indicated that they would prefer to use VR for any future procedures. This suggests that passive VR distraction may truly improve the patient experience in a way that was not detected with the satisfaction score in this study.

Moreover, a number of factors make this intervention easy to implement into the clinical workflow. VR is a low-cost intervention, approximately $130 per VR set at this time, that can be easily decontaminated between uses, requires little training to use, and resulted in no side effects in this study. Anecdotally, use of the VR goggles did not interfere with control of the endoscope.

The effects of VR on office-based laryngology procedures have not been fully evaluated by this study as it focuses only on the patient; a strong argument for adoption of this technology could be made if it significantly improves the procedure from a surgeon's perspective. Future directions may include the study of effects of passive VR distraction on ease of performing the procedure and the degree to which procedure goals are met, and it may also include recording objective signs related to anxiety such as heart rate and comparison with similar distraction techniques such as music played through earphones.

Limitations of this study include the heterogeneity of the procedures performed because, although discomfort between these procedures has been shown to be similar,[12] the patient distress and duration of each of these procedures are variable. Although the general composition of procedures is similar in the VR and control groups, the variety of procedures may inhibit accurate measurement of our study outcomes. In addition, as our study was initially powered to find a difference in SUDS, it may have had too few patients to find differences in the other measures, and future studies with larger cohorts of patients are warranted. Moreover, although there was a statistically significant difference in SUDS, we are not aware of any published minimal clinically important difference (MCID) for SUDS that would show the practical clinical benefit provided by VR.

Finally, the inclusion of 1 crossover patient in this study may present methodological issues. It is possible that a second exposure to office-based procedures is less distressing purely due to having prior experience with the procedure rather than any improvement due to VR. We therefore recalculated the SUDS, VAS, and procedural satisfaction scores excluding the data from the crossover patient's second procedure, which involved use of VR. Recalculated values again showed no statistically significant differences in VAS and satisfaction scores (P = .57 and .56) and again showed a significant difference in SUDS (P = .025). The SUDS value in the VR group decreased from 26.25 $\pm$ 16.64 to 22.86 $\pm$ 14.68 when excluding the crossover patient.

Conclusion

This pilot study suggests that passive VR distraction may be used as an adjunctive tool to decrease patient anxiety during office-based laryngology procedures. Standard of care using only local anesthesia resulted in low pain scores and high satisfaction scores with no additional statistically significant benefit from VR use, similar to existing studies in the literature. Further study is required to determine the full utility of VR distraction in improving the patient experience during office-based laryngology procedures.

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Author Contributions

Joseph Chang, contributed to study design, data collection, data analysis and the writing of the manuscript; **Sen Ninan**, contributed to study design, data collection, and data analysis; **Katherine Liu**, contributed to study design, data collection, data analysis, and the writing of the manuscript; **Alfred Marc Iloreta**, contributed to study conceptualization and design, and supervising the project; **Diana Kirke**, contributed to study design, data collection, supervising the project and editing the manuscript; **Mark Courey**, contributed to study conceptualization and design, overseeing all aspects of data collection and data analysis and supervising the project, and providing critical feedback on the manuscript.

Disclosures

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Supplemental Material

Additional supporting information is available at http://journals.sagepub.com/doi/suppl/10.1177/2473974X20975020

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