Treatment Efficacy of Virtual Reality Distraction in the Reduction of Pain and Anxiety During Cystoscopy

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ABSTRACT Objective: Assessment of virtual reality (VR) distraction for alleviating pain and anxiety during flexible cystoscopy. Cystoscopy is a common ambulatory procedure performed in Urology and can be associated with moderate pain and anxiety. Sophisticated distraction techniques are not used with cystoscopy and VR has not been studied for this procedure. We designed a prospective, randomized, controlled trial assessing the efficacy of VR for alleviating pain and anxiety during flexible cystoscopy. Methods: Adult men referred for cystoscopy were randomized into a control or VR group. Subjects were given preprocedure and postprocedure questionnaires addressing anxiety, pain, and time spent thinking about pain. Vitals signs and galvanic skin monitors were used as objective measures. The control group underwent routine cystoscopy and the VR group underwent cystoscopy with VR. Physicians answered a postprocedure questionnaire assessing the difficulty of the exam. All questionnaires used a visual analog score for assessment. Results: 23 patients enrolled in the control group and 22 in the VR group. Mean scores and Student's *t*-test were employed to analyze the data. No data endpoints showed a statistically significant difference between the 2 groups. Conclusions: We concluded no benefit to VR distraction mitigating pain in male patients during cystoscopy.

INTRODUCTION

The experience of pain is a complex phenomenon, which simultaneously occurs on cognitive, emotional, and behavioral levels. Within the field of medicine, pharmacologic treatments for pain predominate; however, they have variable efficacy, deleterious side effects, and can display tachyphylaxis. Nonpharmacologic interventions, including distraction techniques, guided imagery, and cognitive therapy, have made an impact in the experience of pain, with far fewer side effects.[1] In the last decade, virtual reality (VR) distraction has emerged as a potent tool to diminish the experience of pain and has been studied in several settings. Distraction therapy works on the premise that a person has a finite attention and that reallocating a patient's attention from a painful stimulus to a nonpainful stimulus will diminish the perception of pain.[2] Conversation, blowing a pinwheel, and watching television are examples of simple distraction techniques. VR distraction allows for much higher level, interactive distraction and delivers multimodal sensory immersion. A recent plethora of literature on VR has shown a benefit of VR distraction during medical procedures. Success has been demonstrated in IV placement, dressing changes for burn patients, and chemotherapy administration, among others.[3,4] In a controlled study, Hoffman et al reported that adult burn patients undergoing physical therapy reported less pain with VR distraction.[4,5] In separate studies, Hoffman also found a significant benefit during dental procedures and wound care.[6,7] In the realm of pediatrics, Gold et al assessed 100 children undergoing venipuncture in a randomized controlled trial and found decreased frequency of moderate-to-severe pain in subjects with VR distraction.[8] In a similar study, Gold et al also found that children undergoing intravenous line placement had less pain with VR distraction.[9] Despite the emergence of VR distraction in both adult and pediatric settings, there is only a single VR distraction case report in Urology. This case report reveals decreased pain scores during cycles of transurethral microwave thermotherapy with VR distraction compared to cycles without VR distraction in a single patient.[10]

In Urology, office-based flexible cystoscopy is a necessary and commonly performed procedure. Nevertheless, it is invasive and can be associated with moderate pain and anxiety, especially in men, who have a longer urethra and surrounding prostate. There have been numerous studies assessing pain during cystoscopy. In a recent meta-analysis, Patel et al found 46 clinical trials assessing cystoscopy and pain. They specifically looked at lidocaine gel and concluded that lidocaine gel has no significant benefit in pain reduction over plain gel.[11] In a separate study, Patel et al found that patients who viewed their cystoscopy on the monitor had less pain, thus suggesting a benefit for distraction therapy during cystoscopy.[12] Since simple distraction therapy has shown some potential for reducing pain during cystoscopy, we postulate that VR distraction can furnish a significant reduction in pain during this procedure. Based on this hypothesis, we designed a prospective, randomized, controlled trial to assess the efficacy of VR distraction for alleviating pain and anxiety during flexible cystoscopy.

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SUBJECTS AND METHODS

After Institutional Review Board approval, we enrolled men aged 18 to 70 years, who were referred for flexible cystoscopy. Only English-speaking men who had not undergone prior cystoscopy were eligible for the study. Women were excluded as only rigid cystoscopy is used for women in our clinic. In addition, patients with motion sickness or uncorrected visual impairment (legal blindness) were excluded as they likely would not benefit from VR distraction. Finally, patients taking psychotropic medications or analgesics were also deemed ineligible due to their potential confounding influence on pain or the perception of pain.

After informed consent was obtained, subjects were randomized using a random number generator into a control group or a VR distraction group. All subjects were given preprocedure (Fig. 1) and postprocedure (Fig. 2) questionnaires addressing anxiety, pain, and time spent thinking about pain. All questionnaires used a 100 mm visual analog scale (VAS) for assessment. Vital signs to include pulse, temperature, blood pressure, and respirations were taken before and after cystoscopy. Galvanic skin monitors were measured before, during, and after the cystoscopy as objective measures of pain. The control group underwent routine cystoscopy, including intraurethral administration of 2% lidocaine jelly, the ability to watch their cystoscopy on the monitor, and routine interaction with the physician. Subjects in the VR group donned a VR helmet and track ball hand controller (Fig. 3) and underwent cystoscopy with VR distraction. These patients were immersed in a VR environment called SnowWorld where they were tasked to shoot snowballs at penguins, robots, and igloos (Fig. 4). Two percent lidocaine jelly was used for these subjects as well, however, the ability to see the monitor and converse with the Urologist were limited, as subjects were engaged in the VR distraction. All cystoscopies were performed by a single Urologist (JYC). The Urologist answered a postprocedure questionnaire about the difficulty of the exam and perception of the subject's pain (Fig. 5). Mean vital signs and VAS scores were calculated for each group. Patients in the VR group had an additional three questions addressing any nausea during the procedure, how much they felt immersed in the VR environment, and how entertaining they found the SnowWorld game. The study was powered to detect a 20% difference between the two groups by using the G* Power statistical analysis tool. A Student's *t*-test was used to compare the groups with a *p*-value of <0.05 indicating a significant result.

RESULTS

A total of 45 patients were enrolled in the study (23 in the control group and 22 in the VR group). Men in the VR group were younger (38 vs. 47 years old), however, this was not statistically significant. For data analysis, 2 subjects were excluded from the study, both from the control group. One patient did not have galvanic skin response recorded and the second could not complete the cystoscopy due to severe urethral stricture disease. Data from 43 subjects were available for analysis.

PATIENT QUESTIONNAIRE (PRE-PROCEDURE)

Subject ID #_____
Group #_____
Date: _____

Please answer the questions to the best of your ability with regards to the cystoscopic procedure you just underwent.

1. How much ANXIETY are you experiencing at this time?

0 1 2 3 4 5 6 7 8 9 10
None at all — Extreme Anxiety

2. In the past 24 hours, how much TIME did you spend thinking about the examination today?

0 1 2 3 4 5 6 7 8 9 10
None at all — All the time

FIGURE 1. Subject study preprocedure questionnaire with VAS.

PATIENT QUESTIONNAIRE (POST-PROCEDURE)

Subject ID #_____
Group #_____
Date: _____

Please answer the questions to the best of your ability with regards to the cystoscopic procedure you just underwent.

1. How much TIME did you spend thinking about your pain during the examination?

0	1	2	3	4	5	6	7	8	9	10
None of the time		Some of the time			Half of the time			Most of the time		All of the time

2. How UNPLEASANT was your pain during the examination (emotional component)?

0	1	2	3	4	5	6	7	8	9	10
not unpleasant at all		mildly unpleasant			moderately unpleasant			severely unpleasant		excruciatingly unpleasant

3. Rate your WORST PAIN during the examination (pain intensity)?

0	1	2	3	4	5	6	7	8	9	10
no pain at all		mild pain			moderate pain			severe pain		excruciating pain

4. Rate your AVERAGE PAIN during the examination (pain intensity).

0	1	2	3	4	5	6	7	8	9	10
No pain at all		Mild pain			Moderate pain			Severe pain		Excruciating pain

5. Rate your ANXIETY during the procedure.

0	1	2	3	4	5	6	7	8	9	10
no anxiety at all		mild anxiety			moderate anxiety			severe anxiety		highest anxiety

If you had the Virtual Reality Distraction during the cystoscopy, please answer the questions on the back of this form.

Answer questions 6-8 only if you had the Virtual Reality Distraction during the cystoscopy:

6. To what extent (if at all) did you feel NAUSEA as a result of experiencing the virtual world?

0	1	2	3	4	5	6	7	8	9	10
no nausea at all		mild nausea			moderate nausea			severe nausea		vomited

7. While experiencing the virtual world, to what extent did you feel like you went into the virtual world?

0	1	2	3	4	5	6	7	8	9	10
Not at all		Mild sense of entering into it			Moderate sense of entering into it			Strong sense of entering into it		Completely went into it

8. How ENTERTAINING was the virtual world during the examination?

0	1	2	3	4	5	6	7	8	9	10
not at all		mildly			moderately			very		extremely

FIGURE 2. Subject study postprocedure questionnaire with VAS.

FIGURE 3. Subject engaged in VR distraction with VR helmet and trackball mouse.

Preprocedural anxiety (49 mm vs. 52 mm) and time spent thinking about pain (38 mm vs. 42 mm) were similar between the VR group and the control group, respectively. Intraprocedural anxiety (61 mm vs. 56 mm), average pain (44 mm vs. 43 mm), worst pain (66 mm vs. 59 mm), and time spent thinking about pain (58 mm vs. 54 mm) were higher in the VR group, however, without statistical significance (Fig. 6). None of the vital signs or galvanic skin sensors showed a statistically significant difference. Postprocedure physician questionnaires showed overall more difficulty with subjects in the VR group, however, without statistical significance (Fig. 7). VR distraction was well tolerated in our study. There were no adverse events reported to include nausea or dizziness. Subjects in the VR group found the SnowWorld moderately entertaining (39 mm), but did not feel entirely immersed in the VR environment (22 mm).

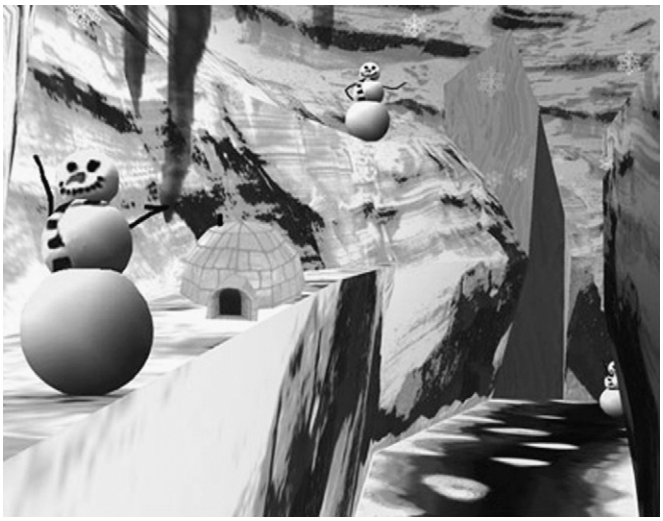

FIGURE 4. Subjects target snowmen and igloos in SnowWorld (image by Stephan Dagadakis, UW, copyright Hunter Hoffman, UW, www.vpain.com).

DISCUSSION

In our study, we assessed the utility of VR distraction for improving pain and anxiety in men undergoing flexible cystoscopy. None of the measures for pain or anxiety showed improvement in the VR distraction group. The study was powered to detect a difference of 20% between the two groups and it was felt that a 20% difference in the responses likely indicated a clinically significant difference between the two groups. Overall pain scores were lower than anticipated with means near 50 mm in both groups. Hoffman et al performed a controlled study on patients undergoing burn wound debridement. In their study, average pain scores were severe (>75 mm) in the control group. With VR distraction subjects were able to achieve pain scores in the moderate range (51 mm).[13] The authors postulate that patients with severe-to-excruciating pain will respond best to VR distraction. Based on this hypothesis, we performed a subset analysis of patients who had high preprocedural pain and anxiety (pain levels 80–100 mm) to see if we could find a subset of patients who would benefit from VR distraction, however, the data, again, showed no significant differences with 9 patients meeting this criteria.

We designed our control group to emulate our current practice as closely as possible. Subjects in the control group underwent usual cystoscopy with 2% lidocaine jelly lubrication, the ability to see their cystoscopy on a display monitor, and routine interaction with the Urologist. One strong possibility is that these measures likely diminished the experience of pain in the control group to a level comparable with VR distraction. Furthermore, if this is shown to be true, we can surmise that distraction techniques have a limited and finite ability to lessen the experience of pain, and perhaps routine distraction (conversation and watching the monitor) reaches that threshold sufficiently.

Incorporating new technology and questionnaires in a study often add multiple variables, which may be difficult to analyze. The specific questionnaire used, the specific times the questionnaires were administered, and the wording are all potential confounding variables. More importantly, the technology involved (VR helmet, track ball, VR software) is critically important in delivering the distraction and is a potential source of unpredictability. Since this study was performed higher quality graphics, improved sound, and more user-friendly interfaces have evolved and increased the potential for improving the distraction experience. In fact, Hoffman et al found that patients had significantly improved analgesia (34% decrease in worst pain scores) with a high-tech VR helmet vs. a low-tech helmet.[14] In our study, subjects did not feel fully immersed in the VR environment, leaving significant room for improvement in our technology.

Although there are many reports of VR improving the experience of patients in various clinical settings, this study did not show a benefit to VR distraction in mitigating the experience of pain in adult men undergoing flexible cystoscopy. More investigation is needed to see whether improved

PHYSICIAN QUESTIONNAIRE (POST-PROCEDURE)

Subject ID #_____
Group #_____
Date: _____

Please answer the questions to the best of your ability with regards to the cystoscopic procedure that was just completed.

1. Rate the difficulty of this procedure.

0	1	2	3	4	5	6	7	8	9	10
Not difficult at all			Mildly difficult		Moderately difficult		Very difficult			Extremely difficult

2. Rate your perception of the subject's discomfort during the procedure.

0	1	2	3	4	5	6	7	8	9	10
No pain at all			Mild pain		Moderate pain		Severe pain			Excruciating pain

3. Rate how frequently the subject moved during the procedure

0	1	2	3	4	5	6	7	8	9	10
None of the time			Some of the time		Half of the time		Most of the time			All of the time

4. Rate the intensity of the subject's movement during the procedure.

0	1	2	3	4	5	6	7	8	9	10
None			Mild		Moderate		Severe			Extreme

FIGURE 5. Physician study postprocedure questionnaire.

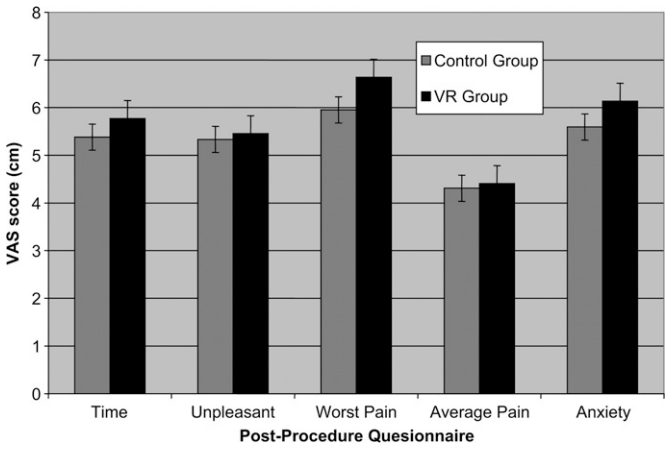

FIGURE 6. Subject postprocedural questionnaire. Individual questions showed no significant difference between the control (black) and VR (gray) groups.

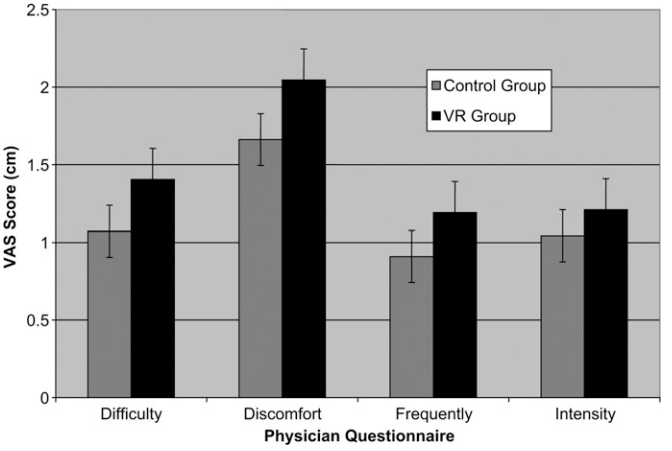

FIGURE 7. Physican postprocedural questionnaire. Overall, subjects in the VR group (gray) when compared with the control group (black) were rated to have higher pain scores, although not statistically significant.

technological factors can enhance the degree of VR distraction in order to decrease pain in this setting.

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