Virtual Reality as an Adjunctive Nonpharmacological Sedative During Orthopedic Surgery Under Regional Anesthesia: A Pilot and Feasibility Study

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This pilot study assessed the feasibility and potential for any possible sedation sparing effect of immersive virtual reality (IVR) therapy on patients undergoing joint replacement surgery under regional anesthesia. Nine participants were given IVR, regional anesthetic, and sedation. Ten received conventional care. Mean propofol usage was 155 ± 45 mg/h in the conventional care group and 63 ± 21 mg/h in the IVR group (P = .088, mean difference -91.6 mg/h, 95% confidence interval, -200 to 16.87 mg/h). There was no significant difference in postoperative satisfaction between the 2 groups. This pilot study demonstrates that it is possible to safely provide IVR in an operating theater environment and may confer a sedation sparing effect. A larger, more powered, and randomized study is needed to assess this effect. (Anesth Analg 2017;125:1200-2)

mmersive virtual reality (IVR) therapy is a form of distraction therapy that has been described generally in the context of psychiatric disorders. It involves the use of computer-generated auditory and visual stimuli to create a so-called illusion of presence or the creation of the perception of a virtual object in a physical world.² The greater the illusion of presence and degree of immersiveness and distraction, the greater the postulated analgesic effect.3 Achieving proper "illusion of presence" has traditionally been limited by technical deficiencies, large bulky hardware, unsatisfying user experiences, and motion sickness. Recent advances in technology have paved the way for small, more portable headsets. Specifically, the Oculus Rift is an inexpensive (\$400) wide field-of-view 3-dimensional virtual reality headset that projects video and rendered graphics into 2 independent lenses. The current model is the size of a small pair of ski goggles, weighs 440 g, and is maintained on the head with elastic straps.

Other forms of distraction therapy, including music⁴ or viewing scenes on a television,⁵ have been used as a method of reducing pain as early as 1982.⁶ In the perioperative environment, distraction therapy has been successfully used, showing benefits in pain control but not anxiety.⁷ More recently, visual distraction was used during colonoscopy without sedation, decreasing pain and anxiety.⁸

It has been suggested that IVR, however, has the potential for increased effectiveness, largely due to its ability to create a more engaging and immersive level of distraction.³

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IVR has successfully been used in the perioperative setting in burn patients.⁹

This study aimed to (1) assess the feasibility of using virtual reality during joint replacement surgery, (2) obtain subjective data with regard to patient feedback and satisfaction, and (3) describe the patterns of sedative use in both IVR and routine surgery and potentially compare these patterns in a way that might guide future, well-powered, randomized studies.

METHODS

This study was conducted at St. Vincent's Hospital, Melbourne, Australia, and was approved by the St. Vincent's Hospital Research and Ethics Committee (HREC Approval LRR 039/15).

Patients receiving orthopedic surgery under regional anesthesia were recruited on the day of surgery between February and June 2015. Inclusion criteria were English-speaking patients with no significant cardiovascular or respiratory disease. Exclusion criteria were patients receiving a general anesthetic, cognitive impairment preventing the use of outcome surveys, visual or hearing impairment, and non-English speaking. Regional anesthesia was performed in all cases by the anesthesiologist and involved a spinal anesthetic for hip operations, a spinal anesthetic, femoral nerve catheter, and popliteal nerve block for total knee replacements and a femoral nerve catheter and sciatic block for ankle surgery.

A sample size of 10 in each group was attempted largely based on the sample sizes of previous IVR studies,^{3,9} the likelihood that this would give enough information to guide power calculations for future studies, and also what could be feasibly performed over a 6-week period without causing too much disruption to the flow of the orthopedic operating theater.

A modified version of the quality of recovery survey was used (see Supplemental Digital Content, Table, http://links.lww.com/AA/B780) to assess patient satisfaction. Patients were also asked if they would be willing to undergo future invasive surgeries with IVR.

Additional outcomes measured during the case were the amount and type of sedation used as a premedication, dose (mg) of propofol used throughout the case, the amount and type of sedation in addition to propofol, the duration of the surgery, and the time spent with the goggles attached.

IVR Simulation Used

A passive simulation modeled after the University of Washington-designed Snow World,9 named Iceland, was used. This simulation consisted of a 30-minute "on rails" flight over a computer-generated Arctic tundra and was designed by Gert-Jan Werburg at VergeVr.com¹⁰ played on an Oculus Rift DK2 (Oculus VR, Menlo Park, CA) run via a laptop computer. This simulation was chosen specifically due to its similarity to Snow World and because it could be customized to function in the lateral and supine positions. Classical music from the Hush Collection¹¹ was provided with permission by Dr Catherine Crock of the Royal Children's Hospital, Melbourne. The simulation was initiated after spinal anesthetic, transfer to the operating table, and after patient positioning, but before the start of the operation.

Statistical Analysis

All statistical analyses were performed using IBM SPSS v20 (IBM, Armonk, NY). All categorical values, namely sex, and type of surgery were expressed as number (%) and quartiles, with IVR the exposure. Differences were compared using a χ^2 test. In the event of the expected values being <5 or a 2 \times 2 comparison being made, the Fisher exact test was used. Normally distributed continuous data, namely age, time of surgery, and sedation use, were analyzed using a 2-group Student t test with IVR being the exposure. A 2-sided *P* value of <.05 was used for statistical significance.

RESULTS

A total of 9 patients were consecutively recruited for IVR treatment and subsequently compared with 10 patients who underwent routine care in a nonrandomized fashion. Routine care consisted of a regional anesthetic, as well as pharmacological sedation. Hip surgery consisted of total hip joint replacements and dynamic hip screws. Knee surgery all consisted of total knee joint replacements. Other lower limb surgery included ankle and foot operations. The characteristics of the study population are listed in the Table.

There was no significant difference in the mean duration of the anesthesia between the 2 groups (P = .69, mean difference -7.3 minutes, confidence interval [CI], -45 to 30 minutes). In the IVR group, therapy was continued to the end of the procedure in 8 of 9 cases, with 1 simulation ending prematurely due to the goggles feeling uncomfortable on the face. All patients expressed interest in using IVR again for

Table. Summary of Demographic and Case Data From Routine Care and Intervention Groups

	Routine Care (n = 10)	IVR Therapy (n = 9)	P
Knee surgery	3 (15.8%)	3 (15.8%)	.711ª
Hip surgery	6 (31.6%)	4 (21.0%)	
Other	1 (5.3%)	2 (10.6%)	
Age (y)	65 (57-76)	50 (36-66)	.142b
Sex	2 Male (10.6%)	2 Male (10.6%)	>.99ª
	8 Female (42.1%)	7 Female (36.8%)	
Time of case (min)	120 (72–135)	125 (85–150)	.69b

Frequencies and percentages reported for categorical values. Median and quartiles reported for continuous variables.

Abbreviation: IVR, immersive virtual reality,

other awake, invasive procedures. There was no significant difference in the satisfaction scores between the 2 groups.

Adverse Outcomes

Nausea was reported in 1 patient in the IVR group. This nausea settled with a single dose of intravenous ondansetron (4 mg). No patients in the routine care group reported nausea.

During the procedure, a combination of propofol infusions and fentanyl and midazolam boluses was administered to patients by the anesthesiologist, titrated to patient comfort. A mean propofol dose of $155 \pm 45 \,\mathrm{mg/h}$ was used in the routine care group and 63 ± 21 mg/h in the IVR group (P = .088, mean difference -91.6 mg/h, 95% CI, -200 to 16.87 mg/h). The total fentanyl use in the IVR group and the routine care group was $38 \pm 45 \mu g$ and $15 \pm 21 \mu g$, respectively (P = .17, mean difference 22.5 $\mu g,\,95\%$ CI, -10 to 55.9 $\mu g). The total$ midazolam use in the IVR and the standard care group was 2 ± 1 and 3 ± 3 (P = .36, mean difference -0.97 mg, 95% CI, -3.2 to 1.21 mg; Figure).

DISCUSSION

This pilot study demonstrates that IVR can be feasibly applied during joint replacement surgery and is subjectively well tolerated and enjoyed by patients. Next, there appears to be a potential for a sedation sparing effect that might be more properly elucidated in a better powered and properly designed study.

Nine patients used IVR, with all but one using it to for the duration of their procedures. Nausea was the only side effect demonstrated, and this occurred in a single patient. There was no significant difference in satisfaction scores in the IVR group compared to the routine care group. This lack of difference may be attributed to the IVR not causing the patients any undue distress, to there being appropriate sedation in both groups, or to the small sample size. All patients expressed a willingness to use the goggles again during awake, invasive procedures. Together, this suggests that the IVR intervention did not cause harm to patients.

While there was no statistically significant reduction in propofol use between IVR and routine care groups, there was a trend suggesting less use. The magnitude of the difference appears to be large; however, these results must be interpreted with major caution given the small sample size, the large variance of the amount of propofol administered, and the lack of randomization in the study. To achieve a power of 80% with a mean difference of 91 mg/h, a sample size of 22 in each group would be required. It must be emphasized, however, that this study was performed to assess the feasibility of providing IVR in a busy operating theater and to assess the potential for any signal that might lead to a statistically significant outcome benefit and not as a definitive answer to the benefits of IVR. While comparing the quantity of sedation in the IVR group to a nonrandomized, non-IVR cohort is fraught with statistical risk, it nonetheless suggests the potential for a sedation sparing effect and the justification to pursue a larger, well-designed study.

There are a number of other pitfalls that were exposed by this study that would need to be rectified for any future

bMann-Whitney U test.

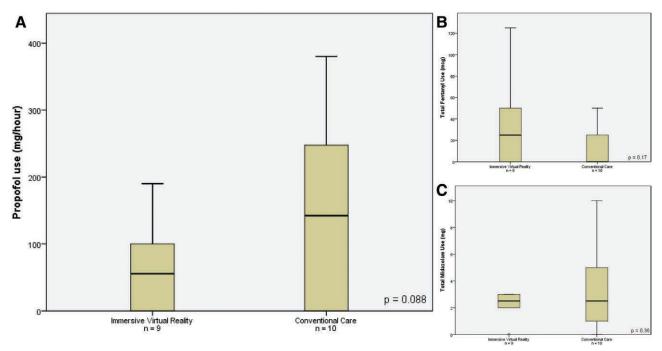


Figure. Average use of sedating medication in immersive virtual reality therapy and routine care groups. A, Propofol use per hour (mg/h), (B) total fentanyl use during case, (C) total midazolam use during case. P values given for results of the Student t test.

study. Given the fact that IVR administration was not blinded, there is the possibility that anesthesiologists unintentionally used less sedation than normal, expecting a treatment effect from the IVR. Next, the large variance in propofol use may be the result of different anesthesiologist practices and would need to be standardized. Additionally, there was no way of assessing if the patients were engaging with the IVR or were asleep, there was no way of knowing if the computer simulation in the goggles itself accounted for the apparent reduction in sedation, or if the effect was achieved simply through the removal of auditory and visual stimuli and could have been achieved with a blindfold and earplugs.

Any subsequent protocol would therefore necessitate not only an increase in sample size in both groups but also proper randomization, a method of assessing patient engagement with IVR, and a method of reducing anesthesiologist bias in the administration of propofol.

Despite problems in study methodology, this feasibility and pilot study comparing 2 nonrandomized groups has nonetheless provided a small signal that suggests a therapeutic benefit to IVR may indeed exist and provides the justification for pursuing a larger study. By comparing 2 groups instead of simply reporting the sedation use in a pilot IVR group, we are also able to calculate power for future studies. As a result of these results and difficulties encountered with our original pilot protocol in addition to no evidence that IVR causes any apparent harm, a larger, randomized study has been planned.

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DISCLOSURES

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Contribution: This author helped edit and finish the manuscript and analyze the data.

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