Effect of an Immersive Preoperative Virtual Reality Experience on Patient Reported Outcomes

A Randomized Controlled Trial

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Objective: To investigate the effect of exposure to a virtual reality (VR) environment preoperatively on patient-reported outcomes for surgical operations.

Background: There is a scarcity of well-developed quality improvement initiatives targeting patient satisfaction.

Methods: We performed a randomized controlled trial of patients undergoing cranial and spinal operations in a tertiary referral center. Patients underwent a 1:1 randomization to an immersive preoperative VR experience or standard preoperative experience stratified on type of operation. The primary outcome measures were the Evaluation du Vecu de l'Anesthesie Generale (EVAN-G) score and the Amsterdam Preoperative Anxiety and Information (APAIS) score, as markers of the patient's experience during the surgical encounter.

Results: During the study period, a total of 127 patients (mean age 55.3 years, 41.9% females) underwent randomization. The average EVAN-G score was 84.3 (standard deviation, SD, 6.4) after VR, and 64.3 (SD, 11.7) after standard preoperative experience (difference, 20.0; 95% confidence interval, CI, 16.6–23.3). Exposure to an immersive VR experience also led to higher APAIS score (difference, 29.9; 95% CI, 24.5–35.2). In addition, VR led to lower preoperative VAS stress score (difference, −41.7; 95% CI, −33.1 to −50.2), and higher preoperative VAS preparedness (difference, 32.4; 95% CI, 24.9–39.8), and VAS satisfaction (difference, 33.2; 95% CI, 25.4–41.0) scores. No association was identified with VAS stress score (difference, −1.6; 95% CI, −13.4 to 10.2).

Conclusions: In a randomized controlled trial, we demonstrated that patients exposed to preoperative VR had increased satisfaction during the surgical encounter. Harnessing the power of this technology, hospitals can create an immersive environment that minimizes stress, and enhances the perioperative experience.

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As the practice of medicine is shifting from authority to accountability, the quality of surgical interventions is under continuous scrutiny by patients, peers, payers, and policy makers.[1] In this setting, there is increasing focus on patient satisfaction as a quality indicator.[1] An important part of surgical outcomes is the patients' perception of the result of the intervention and their overall experience.[2,3] Anxiety, a potent behavioral and psychological reaction, weighs heavily on this experience and is exacerbated by unfamiliar environments, multiple forms to be signed, and several short encounters with new personnel.[2,3] These create confusion, increase baseline stress, and can negatively affect the patient experience, and by extension surgical outcomes.[2,4] A qualitative systematic review noted a scarcity of well-development quality improvement initiatives targeting patient satisfaction.[5]

Prior trials examining the effectiveness of such initiatives have focused on pharmacologic interventions,[2] or preoperative education,[6–17] aimed at minimizing anxiety. However, these approaches have demonstrated varied patient engagement and conflicting results.[6–17] On the contrary, a more immersive intervention geared towards increasing familiarity with this environment can help patients feel informed about what matters most to them, and have accurate expectations of possible benefits and harms of their options.[18,19] This can potentially decrease overall anxiety, and improve patient satisfaction. Virtual reality (VR) addresses a lot of these issues,[20] and could allow the immersion of patients in the perioperative environment.[21] However, it has not been employed in patient satisfaction initiatives before.

To assess the efficacy of VR on improving patient satisfaction, we conducted a randomized clinical trial among patients undergoing cranial and spinal operations. We compared perioperative self-reported outcomes, among patients exposed with a preoperative immersive VR experience, and those undergoing a standard preoperative experience.

METHODS

Trial Design

This study was a single center randomized parallel controlled trial that was conducted in a tertiary referral center, where cranial and spinal procedures were routinely performed. The study was approved by the Dartmouth Committee for Protection of Human Subjects.

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accuracy and completeness of the data in all analyses, and for the fidelity of this report to the trial protocol, which is available online (Supplementary Methods, http://links.lww.com/SLA/B150).

Patients

Patients were eligible for inclusion if they were scheduled to undergo any elective craniotomy or spine surgery. All consecutive patients scheduled for surgery were screened for inclusion. Elective procedures were defined as those happening 48 hours after initial patient evaluation. Patients were excluded if they fulfilled one of the following criteria: pediatric patients, emergency procedures for which no preoperative visit had been scheduled, patients that have undergone any prior operations, or had any exposure to the preoperative experience, inability to complete a self-reported questionnaire preoperatively and postoperatively, or cognitive impairment. All patients provided written informed consent.

Randomization and Interventions

Eligible patients were randomly assigned in a 1:1 ratio to VR or standard preoperative experience. Randomization was stratified according to type of procedure (craniotomy, spinal surgery). A block-randomization design was used with randomly permuted block sizes of 4 on the basis of a computerized random-number generator with sequentially numbered opaque, sealed envelopes for each stratum. Randomization happened during the clinic visit, after the patient had agreed to undergo a surgical procedure and had signed consent for it. Because of the nature of the interventions, patients and treating physicians were aware of the study-group assignments. However, the physicians conducting the interviews to collect the primary and secondary outcome data, and the data analysts were blinded to the group assignments.

Patients in the VR group watched a 5-minute VR video through VR goggles (Oculus VR, Irvine, CA) describing the preoperative and postoperative experience for the day of the surgery. Concurrent audio was provided through earplugs to compete the patients' immersion. The video was written and directed by George Kakoulides, neurosurgeon and filmmaker. Filming was performed using a rig of 6 appropriately adapted GoPro Hero VR cameras (GoPro, San Mateo, CA), using the professional services of Surround Vision (London, UK). We utilized actors and real physicians and nurses re-enacting a typical day for a mock patient undergoing an uncomplicated operation. Patients were allowed to watch the video as many time as they desired and were encouraged to ask questions at the end. They were allowed to move freely so that they could experience all aspects of the virtual space.

Patients in the standard preoperative experience were provided with routine audiovisual descriptions of the preoperative experience. In addition, a physician explained to them what the preoperative experience would entail. Patients were encouraged to ask questions.

Outcome Variables

The primary outcomes (Supplementary Methods, http://links.lww.com/SLA/B150) were the Evaluation du Vecu de l'Anesthesie Generale (EVAN-G) score and the Amsterdam Preoperative Anxiety and Information (APAIS) score.[22] EVAN-G was obtained immediately postoperatively within 24 hours of the procedure. EVAN-G is a validated self-reported instrument that assesses patient experience and satisfaction during the perioperative period.[5,22] Prior studies have demonstrated high reliability and validity.[22] It consists of 26 patient-generated items, structured in 6 domains, and a global index [range 0 (worst) to 100 (best)]. A score was obtained for each domain by computing the mean of the items corresponding to this domain. Global index calculation was based on prior literature.[22] EVAN-G was considered the most appropriate tool to capture the entire perioperative experience.[23]

The APAIS score [range 4 (worst) to 20 (best)] is a standardized self-reported questionnaire to evaluated preoperative patient anxiety (Supplementary Methods, http://links.lww.com/SLA/B150).[24] It consists of 6 items, which cover 3 separate anxiety domains, and was obtained preoperatively on the day of the surgery.[24] The final score was transformed to a 100 point scale to be comparable with the rest of the outcomes.

Secondary outcomes included visual analog scales [range 0 (worst) to 100 (best)] measuring patient pain and satisfaction, which were obtained preoperatively on the day of the surgery and postoperatively within 24 hours of the procedure. Visual analog scales [range 0 (worst) to 100 (best)] measuring patient preparedness, and stress were obtained preoperatively on the day of the surgery. Visual analog scales [range 0 (worst) to 100 (best)] measuring patient pain 30-days postoperatively were only obtained for spine patients. (Supplementary Methods, http://links.lww.com/SLA/B150).

Statistical Analysis

Given a 1:1 randomization a sample size of 134 would yield an 80% power at the usual 5% type 1 error rate to detect a difference between the two arms of one half (0.5) standard deviations in the primary outcome. We anticipated not being able to obtain the primary outcome on up to 10% of patients, and therefore the intended study population was 150 patients.

Baseline characteristics in each arm were reported as frequencies and percentages for categorical variables, and as means and standard deviations or medians and interquartile ranges for continuous variables, as appropriate. Categorical variables were compared with the use of the χ^2 test and continuous variables were compared with the use of Student t test, as appropriate.

Our primary analyses were modeled using our primary and secondary outcomes as dependent variables and the exposure variable of interest (VR) as an independent variable, stratified on the type of operation.

In prespecified sensitivity analyses, we employed a multivariable linear regression model, with treating physician used as a random effects variable to control for clustering at the provider level. All regressions were controlled for age, gender, type of operation (craniotomy, spine surgery) insurance coverage (Medicare, Medicaid, private, self-pay, other), and the following comorbidities present on admission: hypertension, myocardial infarction, cardiac arrhythmia, congestive heart failure, hyperlipidemia, coagulopathy, ischemic stroke, peripheral vascular disease, chronic obstructive pulmonary disease, other pulmonary disease, diabetes, alcohol abuse, malignancy, and psychiatric history. In posthoc sensitivity analyses, we repeated the analysis of our primary outcomes separately for cranial and spinal operations. The direction of the observed associations did not change and therefore these results are not presented any further.

The primary and secondary outcomes were obtained in all patients. All analyses were based on the intention-to-treat principle, and were performed at the two-sided alpha level of 0.05. STATA version 13 (StataCorp, College Station, TX), and the 64-bit version of R.2.12.2 (R Foundation for Statistical Computing) were used for statistical analysis.

RESULTS

Patient Characteristics

A total of 127 patients (mean age 55.3 years, 41.9% females) were randomized into this study from November 2015 to April 2016 (Fig. 1). Table 1 demonstrates the distribution of patient characteristics between patients exposed to a preoperative immersive VR experience, and those undergoing a standard preoperative experience.

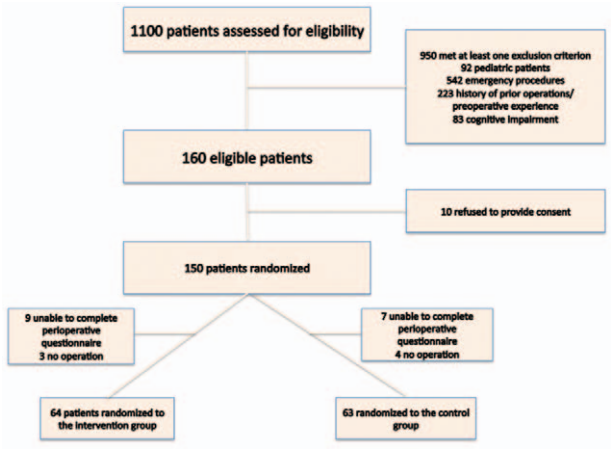

FIGURE 1. Cohort creation for the study.

TABLE 1. Patient Characteristics

	Total	Virtual Reality	No Virtual Reality
N	127	64	63
Age, mean (SD)	55.3 (14.0)	57.3 (13.2)	53.4 (14.6)
Female sex	53 (41.9%)	28 (44.3%)	25 (39.7%)
Insurance			
Medicaid	16 (12.9%)	7 (11.5%)	9 (14.2%)
Medicare	47 (37.1%)	25 (39.3%)	22 (34.9%)
Private	57 (45.2%)	28 (44.3%)	29 (46.0%)
Uninsured	1 (0.8%)	1 (1.6%)	0 (0%)
Other	5 (4.0%)	2 (3.3%)	3 (4.8%)
Cranial procedures	52 (41.1%)	29 (45.9%)	23 (36.5%)
Comorbidities¶			
Hypertension	58 (46.0%)	34 (52.6%)	24 (49.2%)
Hyperlipidemia	37 (29.0%)	13 (20.6%)	24 (33.3%)
Smoking	28 (21.8%)	14 (21.3%)	14 (22.2%)
Renal insufficiency	4 (3.2%)	2 (2.6%)	2 (3.2%)
Coronary heart disease	13 (10.5%)	2 (2.6%)	11 (6.3%)
Pulmonary disease§	25 (19.4%)	8 (13.1%)	17 (25.4%)
Malignancy	36 (28.2%)	18 (27.9%)	18 (28.6%)
Psychiatric disease	44 (34.7%)	11 (24.6%)	33 (44.4%)

SD indicates standard deviation.
Output represents crude numbers and percentages in parentheses.
¶Identified on admission for the surgical procedure.
§Non-smoking related.

Primary Outcomes

EVAN-G

The average EVAN-G score was 84.3 (standard deviation, SD, 6.4) after an immersive VR experience, and 64.3 (SD, 11.7) after standard preoperative experience. Exposure to an immersive VR experience led to higher EVAN-G score (difference, 20.0; 95% confidence interval, CI, 16.6–23.3) in the unadjusted analysis. Adjusting for confounders with a mixed effects multivariable linear regression model (Table 2) demonstrated a similar effect (adjusted difference, 20.5; 95% CI, 11.9–21.0).

TABLE 2. Correlation of Immersive Virtual Reality Preoperative Experience With Outcome Measures

Models	Primary Outcomes			
	EVAN-G¶		APAIS¶	
	Difference (95% CI)	*P*	Difference (95% CI)	*P*
Stratified on type of operation	20.0 (16.6 to 23.3)	<0.01	29.9 (24.5 to 35.2)	<0.01
Mixed effects linear regression model*	20.5 (11.9 to 21.0)	<0.01	31.1 (22.2 to 39.9)	<0.01

	Secondary Outcomes					
	Preoperative VAS Stress Score¶		Preoperative VAS Preparedness Score¶		Preoperative VAS Satisfaction Score¶	
	Difference (95% CI)	*P*	Difference (95% CI)	*P*	Difference (95% CI)	*P*
Stratified on type of operation	−41.7 (−33.1 to −50.2)	<0.01	32.4 (24.9 to 39.8)	<0.01	33.2 (25.4 to 41.0)	<0.01

	Preoperative VAS Pain Score¶		Postoperative VAS Pain Score¶		30-day Postoperative VAS Pain Score¶	
	Difference (95% CI)	*P*	Difference (95% CI)	*P*	Difference (95% CI)	*P*
Stratified on type of operation	−1.6 (−13.4 to 10.2)	0.18	−1.3 (−4.2 to 6.8)	0.99	−1.3 (−4.2 to 6.8)	0.92

	Postoperative VAS Satisfaction Score¶	
	Difference (95% CI)	*P*
Stratified on type of operation	26.4 (20.1 to 32.6)	0.18

APAIS indicates Amsterdam Preoperative Anxiety and Information; CI confidence interval; EVAN-G, Evaluation du Vecu de l'Anesthesie Generale; HR, hazards ratio; VAS, visual analog scale.
*Mixed effects: Includes treating physician as a random effect variable.
Adjusted for age, sex, insurance, hypertension, hyperlipidemia, smoking, diabetes mellitus, coronary artery disease, kidney disease, lung disease, cancer, and psychiatric history.
¶Analyses based on linear regression.

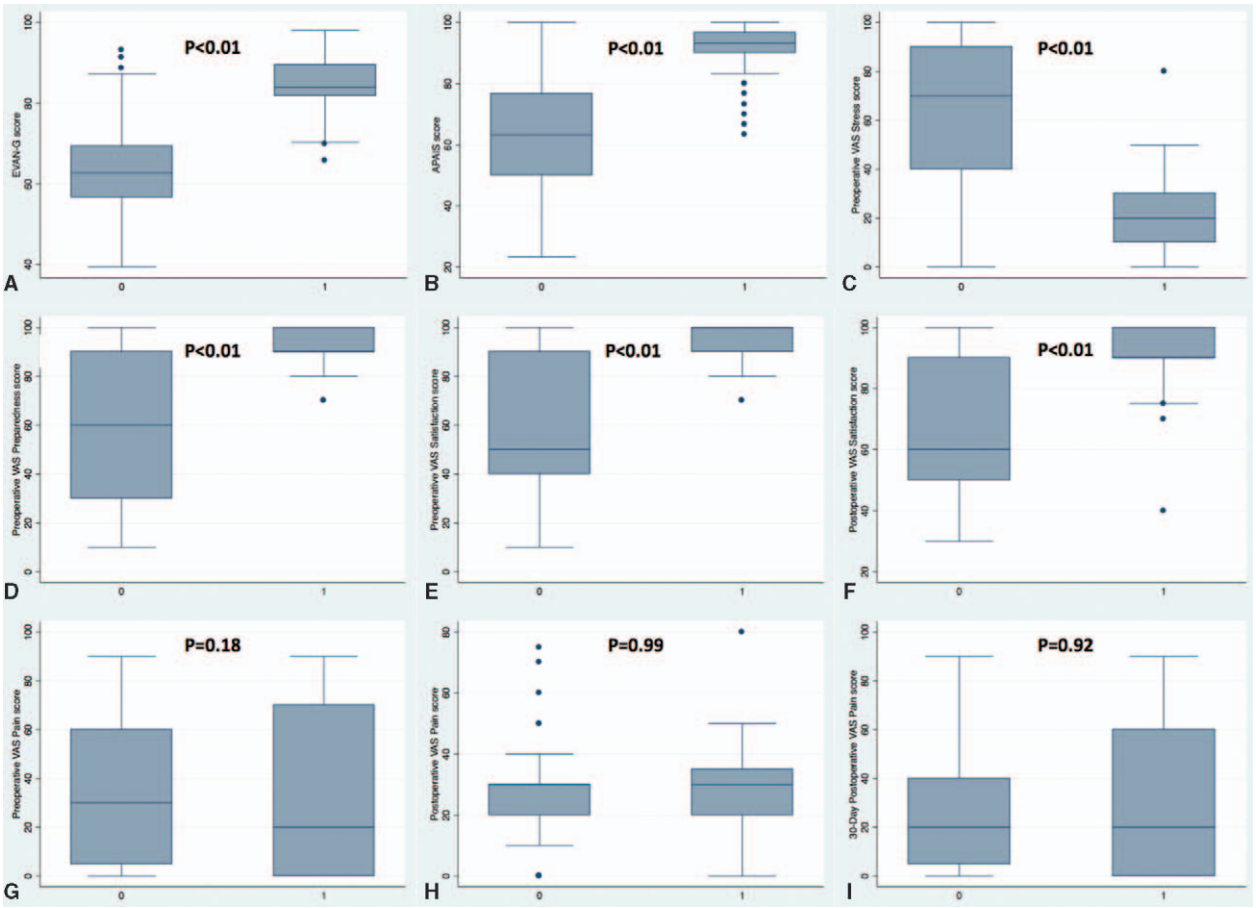

FIGURE 2. Box plots of (A) EVAN-G, (B) APAIS, (C) preoperative VAS stress, (D) preoperative VAS preparedness, (E) preoperative VAS satisfaction, (F) postoperative VAS satisfaction, (G) preoperative VAS pain, (H) postoperative VAS pain, (I) 30-day postoperative VAS pain scores between patients exposed to VR (1) preoperatively and those who underwent a standard experience (0). Bold lines represent median values. Horizontal lines represent the 1st and the 3rd quartile of the distribution. Whiskers represent the lowest datum still within 1.5 Interquartile range (IQR) of the lower quartile, and the highest datum still within 1.5 IQR of the upper quartile. Dots represent outliers.

APAIS

The average APAIS score was 90.7 after an immersive VR experience and 60.8 after standard preoperative experience. Exposure to an immersive VR experience led to higher APAIS score (difference, 29.9; 95% CI, 24.5–35.2) in the unadjusted analysis. Adjusting for confounders with a mixed effects multivariable linear regression model (Table 2) demonstrated a similar effect (adjusted difference, 31.1; 95% CI, 22.2–39.9).

Secondary Outcomes

Immersive VR experience led to (Table 2) lower average preoperative VAS stress score (difference, −41.7; 95% CI, −33.1 to −50.2).

On the contrary VR experience led to (Table 2) higher preoperative VAS preparedness (difference, 32.4; 95% CI, 24.9–39.8), and VAS satisfaction scores (difference, 33.2; 95% CI, 25.4–41.0). The same was true for the postoperative VAS satisfaction score (difference, 26.4; 95% CI, 20.1–32.6).

Lastly, we did not identify an effect (Table 2) of exposure to an immersive VR experience on average preoperative VAS pain score (difference, −1.6; 95% CI, −13.4 to 10.2), postoperative VAS pain score (difference, −1.3; 95% CI, −4.2 to 6.8), or 30-day postoperative (for spinal surgery patients only) VAS pain score (difference, −1.3; 95% CI, −4.2 to 6.8).

DISCUSSION

In a randomized controlled trial, assessing a new application of VR on the perioperative setting, we demonstrated that patients exposed to a preoperative immersive VR experience had increased satisfaction for the surgical encounter. The VR group was more prepared, and had less stress during the perioperative period. Perioperative pain was not affected by VR exposure. These results were consistent across techniques to control for confounders.

In recent years, patient satisfaction has been at the center of healthcare reform. The creation of public reporting platforms, such as the Hospital Compare[25] and Physician Compare[26] websites by the Centers of Medicare and Medicaid Services (CMS), has put significant weight on patient experience. Most recently Medicare has released its 5-star ratings for hospitals and a new array of patient satisfaction metrics.[25] Prior studies have demonstrated that better performance in these measures correlates with improved objective

surgical outcomes, such as mortality and readmissions.[27,28] Although, these initiatives started in 2007 as purely informative, they have assumed center stage in the efforts of CMS to bring quality to the forefront of care delivery.[1] Hospital reimbursement is now tied to some degree to surveys filled out by patients after their discharge from these institutions.[1] However, hundreds of hospitals still struggle to improve patient satisfaction, and there are a limited number of comprehensive initiatives targeting the patient experience.[29]

Prior investigations have demonstrated conflicting results for efforts to improve perioperative patient satisfaction. Maurice-Szamburski et al,[2] in a randomized trial of surgical patients in France, failed to demonstrate a benefit of sedative premedication on surgical patient satisfaction as measured by the EVAN-G score. Pharmacologic intervention does not address the root of the anxiety experienced by a lot of patients around the time of their surgery. Other initiatives have focused on minimizing waiting times, improving the physician-patient interactions, and creating new healthcare delivery systems.[30] However, little effect has been seen in terms of measurable improvement in patient experience.[30] Other groups have employed preoperative patient education as a means of improving satisfaction, albeit with conflicting results.[6–17] The degree of patient engagement with this approach is varied, justifying the inconsistent efficacy observed.[6–17]

Previous studies have demonstrated that surgical patients feel uncertain, vulnerable, and exposed.[31] Although the extent to which they contribute to patient dissatisfaction remains uncertain, the use of virtual reality attempts to address these feelings. Preoperative use of VR in our study allowed patients to be immersed in the entire perioperative encounter from the safety of the physician's office, without the stress of the impending operation. They can place themselves in the hospital space and experience various interactions with healthcare personnel, transitions of care, different spaces (including the operating room), and postoperative care. Patients can ask questions and move around in space, focusing on elements that are more important to them. We hypothesized that this individualized experience can facilitate patient participation in their care and minimize anxiety. Our study demonstrates that, harnessing the power of this technology, hospitals can create an immersive environment that improves patient satisfaction and enhances the perioperative experience.

These effects are in accordance with prior literature utilizing VR as a mechanism for exposure therapy in patients with psychiatric disorders.[20] In several randomized trials, VR has demonstrated superior outcomes to standard behavioral therapies for a series of anxiety disorders.[21,32] In fact, Garcia-Palacios et al[33] have demonstrated that 80% of their patients preferred virtual exposure to in vivo exposure. The hypothesized mechanism behind the effectiveness of this approach lies with the processes of habituation and extinction.[20] Patients are not mere observers; instead they are given control of complex, immersive, and dynamic 3-dimensional presentations in the virtual environment they are sensorially inserted.[34,35] This approach diminishes the gap between imagination and the real world allowing the patients to align their expectations with reality.[20] The sense of security it offers can permit the expression of thoughts and feelings that in real situations would be difficult to be materialize.[34,35] This can further strengthen the physician-patient relationship.

Our study has several limitations. First, although this is a randomized controlled trial, it was performed in a single tertiary referral center. The extrapolation of these results in general community settings should be done with caution. Second, patients and providers could not be blinded in regards to the group assignment. However, research personnel conducting interviews and analyzing the data were blinded to the study group allocation, limiting this bias.

CONCLUSIONS

There is a scarcity of well-development quality improvement initiatives targeting patient satisfaction. We investigated the effect of exposure to a VR environment preoperatively on patient-reported outcomes for surgical operations. In a randomized controlled trial, we demonstrated that patients exposed to a preoperative immersive VR experience had increased satisfaction during the surgical encounter. The VR group was more prepared, and had less stress in the perioperative period. Perioperative pain was not affected by VR exposure. Harnessing the power of this technology, hospitals can create an immersive environment that minimizes stress, and enhances the perioperative experience (Fig. 2).

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