

## **Project Title:**

# **A pilot study of virtual reality technology as an alternative to pharmacological sedation during colonoscopy (VR Tech)**

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## I. Background and Significance

In the United States today only a small fraction of colonoscopies is performed without sedation.<sup>1</sup> However, sedation is not routine across the globe, even among other developed countries. A recent study of colonoscopy practice in Italy reported that 45% of patients go without sedation.<sup>1</sup> This number soars to 75% in Portugal and 82% in China.<sup>1</sup> The use or lack of sedation does not alter the risks associated with the procedure; medication is only a matter of preference and comfort. Further research shows that time to reach the cecum is comparable in sedated and un-sedated patients, and discharge time is significantly shorter for un-sedated patients.<sup>2</sup> Subjects in both groups were similarly willing to return to the same physician if a repeat colonoscopy was indicated.<sup>2</sup> While the U.S. is a leader in sedated colonoscopies, there are increasing reasons for moving away from pharmacological analgesia.

In the midst of an opioid shortage projected to last into 2019, hospitals around the U.S. are searching for ways to conserve their dwindling drug supply for the patients most in need. As a significant percentage of colonoscopies worldwide are done without sedatives, and the use of sedation does not alter the associated risks, colonoscopy is an ideal procedure on which to try out alternative analgesics. Nearly 15 million colonoscopies are performed in the U.S. every year, and providing non-opioid pain-management options during these procedures has the potential to save huge quantities of medications, and help healthcare professionals effectively treat their patients during times of shortage.

While completely un-sedated colonoscopies are reported to be safe and well-tolerated among patients, there exist non-pharmacological methods of pain management that would confer the benefits of an un-sedated procedure, and possibly reduce patient pain perception and discomfort. One such method is the use of virtual reality (VR). This technology immerses the user in a virtual environment, and has been shown to have analgesic effects on patients undergoing procedures such as dental work and surgery done under local anesthesia.<sup>3</sup> Burn wound care is a procedure that has been widely studied with patients using virtual reality. A within-subject study of both pediatric and adult burn patients found that the use of virtual reality during burn wound care significantly reduced perception of pain among participants.<sup>4</sup> This decrease in pain perception was also seen in a recent Korean study, wherein virtual reality was used on patients during adductor canal catheter insertion. Subjects who received virtual reality during the procedure needed significantly lower doses of fentanyl and midazolam than the non-VR group, and reported overall lower levels of procedural pain.<sup>5</sup>

Virtual reality may reduce perception of pain through distraction. Research has shown that in order to fully process nociceptor signals, the brain must focus attention on the pain itself.<sup>6</sup> This claim is backed up with a large body of evidence showing that both adult and pediatric patients have a reduced perception of pain when using a variety of distraction methods.<sup>7-9</sup> Subsequently, results reveal that the amount of attention directed towards pain is positively correlated with the level of pain experienced.<sup>10</sup> Virtual reality technology provides users with an immersive experience on which to focus attention, leaving less available attention to direct towards pain.

## **II. Specific Aims**

The goal of this pilot study is to assess whether a virtual reality strategy is an acceptable alternative to pharmacological sedation during colonoscopy. We will collect data on patient willingness, tolerability, experience, and desire to use virtual reality during subsequent colonoscopy to draw a conclusion and make decisions about future research in this field.

## **III. Subject Selection**

Inclusion criteria: Participants will be routine colonoscopy patients ages 18 years and over who have had a prior colonoscopy. Subjects of any race and gender will be recruited.

Exclusion criteria: Patients who are scheduled for monitored anesthesia care or general anesthesia will be excluded. Children (under 18 years) will be excluded because pediatric endoscopy patients receive general anesthesia at Massachusetts General Hospital.

First-time colonoscopy patients are excluded from the population to avoid the additional anxiety often experienced by patients undergoing this procedure for the first time. Virtual reality distraction depends largely upon the user allowing him/herself to turn attention to the virtual experiences and away from real experiences. Stressful situations, such as being in an unfamiliar medical environment awaiting an invasive procedure, activate the sympathetic nervous system. Sympathetic activation leads to hypervigilance – an active opponent of any distraction method. This pilot study will allow us to assess the effectiveness of this virtual reality pain management strategy in subjects who may not be as anxious, and allow us to determine whether the distraction method may be strong enough to reasonably offer it to first-time colonoscopy patients in future research.

All participants must be willing and able to provide written informed consent.

## **IV. Subject Enrollment**

Adult patients (over the age of 18) who have a scheduled screening or surveillance colonoscopy and have undergone at least one prior colonoscopy will be eligible for recruitment. The electronic medical record of the potential subject may be reviewed prior to contacting the patient to confirm eligibility status. Once a potential subject is identified, the patient will be sent a mailing which will outline the study, and request the opportunity for the research coordinator to contact them by phone regarding the study. This letter will provide the phone number of the research coordinator, and patients will be asked to contact the coordinator if they wish to participate. If the patient has not contacted the research coordinator two weeks after the letter has been sent, the coordinator will contact potential subjects by phone. A disclaimer on the letter will be included stating this. If the subject declines to take part in the

study, his/her name will be removed from the mailing list and they will not be contacted again regarding this research.

**Recruitment group:** Patient contacts research coordinator regarding study via phone

If the patient calls the research coordinator after receiving the letter in the mail, the coordinator will explain the study using a call script.

**Recruitment group:** Patient does not contact research coordinator after letter has been sent

If the patient does not contact the research coordinator following the mailing, the coordinator will contact him/her by telephone to explain the study using the call script and answer any questions. One phone call attempt will be made; if there is no response, the patient will not be contacted further.

All participants will be required to sign the written informed consent form on the day of the procedure.

The consent form will be pre-mailed to participants at their request.

**Patient recruitment targets:** This is a pilot study meant to assess effectiveness of a virtual reality approach to pain management. We aim to recruit 25 participants that are coming for routine screening or surveillance colonoscopies at MGH.

## V. Study Procedures

Researchers will collect data from the electronic medical records of patients on relevant medical history that might affect the colonoscopy, such as history of prior abdominal surgery, infection, or peritonitis.

If the patient agrees to participate prior to the procedure, the research coordinator will meet the subject at his/her colonoscopy appointment. The research coordinator will review the study procedures, answer any remaining questions, and obtain written informed consent using the written informed consent form. The subject will then be prepped for his/her colonoscopy by a registered nurse, and standard colonoscopy consent including consent to pharmacological sedation will be obtained by the endoscopist.

Once inside the procedure room, the research coordinator will fit the consented participant with a virtual reality head-mounted display (HMD), and set up virtual experiences for the patient to go through during their procedure through a control tablet. The HMD will completely obscure the patient's sight of the real room. The virtual environment will be enhanced with sound effects from the HMD, but the participant will still be able to hear the sounds of the procedure room so that they may respond to the verbal requests of their clinicians. The colonoscopy will proceed according to standard practice using virtual reality instead of chemical analgesics for as long as the participant chooses.

Should a participant who consented to drug administration prior to the procedure request pain medication, the research coordinator will remove the HMD and a registered nurse will administer the appropriate medications, following the standard of care at MGH.

All subjects will be asked to complete a questionnaire about their experience regardless of whether pain medication was requested. The questionnaire will collect subjective data on patient experience. The research coordinator will complete a case report form with objective data about the procedure, including duration of colonoscopy, total time spent without sedation, and events and complications during the procedure as noted by the physician. Finally, the endoscopist will also complete a brief questionnaire about his/her experience working with the patient using virtual reality distraction.

The HMD will be cleaned in between each use. A Hyperkin sanitary mask will cover all parts of the HMD that contact the user. This mask will be removed, discarded, and replaced with a new one in between each use. The entire HMD will also be wiped with a sanitary wipe before and after every use.

**Remuneration:** Participants will receive a free 4-hour parking pass at Massachusetts General Hospital for participating in this study. Otherwise, expenses will be incurred by the study subject and/or his/her insurance carrier as usual for the scheduled screening or surveillance colonoscopy.

**Costs:** Subjects will not be charged for any examination or procedure done solely for the purposes of this study. Subjects and/or their insurers will be responsible for procedures and tests performed as a part of routine clinical care.

All virtual reality hardware and software will be provided by Rendeever, Inc. They are donating their equipment to us free-of-charge for the purposes of this study. A zero-dollar purchase order and gift agreement are attached to the IRB application with details of this donation.

## **VI. Risks and Discomforts**

It is unknown the extent to which virtual reality may ease pain and discomfort during colonoscopy. It is possible that the virtual reality technology used in this study will not sufficiently reduce pain and discomfort. If a subject experiences a level of pain or discomfort s/he would like pain medication for, s/he has only to verbalize the request for pain medication and it will be administered. This could result in the first part of the colonoscopy being more uncomfortable than it might have been, had the subject not participated in the study.

## **VII. Potential Benefits**

Subjects may or may not benefit from participating in this study. Should a subject complete his/her colonoscopy without pain medication, possible benefits may include shorter recovery time and lack of impairment for the rest of the day.

The results of this research will help us understand alternative methods of managing pain without the use of opioids.

## VIII. Monitoring and Quality Assurance

Questionnaires will be entered into a password-protected RedCap database – an online data capture system approved by the Partners Human Research Committee. Hard copies of the questionnaires will be held at MGH in a designated locked cabinet to which only study staff will have access. All data will be reviewed and updated weekly by the research coordinator, and any issues will be reported to the principal investigator and dealt with accordingly. The PI will supervise data and safety monitoring at all levels, and determine when the research must be altered or stopped.

Adverse events will be reported to the IRB as outlined in Partners Adverse Event Reporting Guidelines. Adverse events will also be reported to the HRC and comply with the Partners investigator guidelines for adverse events reporting. Adverse events will be reviewed on an ongoing basis by the principal investigator. In addition to being reported to the IRB as previously noted, adverse events occurring during any colonoscopy, whether done for clinical or study purposes, will continue to be reported to the MGH GI Unit adverse event reporting system.

## IX. References

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