



Research paper

Virtual reality for pain management in patients with heart failure: Study rationale and design

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ABSTRACT

Background: Patients with advanced heart failure commonly experience acute and/or chronic moderate to severe pain related to disease, treatment, or both. While pain management strategies typically focus on drug therapies, non-pharmacological interventions may prove beneficial without risk of significant clinical side effects or contraindications. One novel strategy, virtual reality, has been shown to improve pain control in addition to usual pharmacological interventions.

Methods: This is a prospective, two-armed, single center randomized controlled pilot study of a virtual reality intervention in 128 hospitalized subjects with ACC/AHA stage C or stage D heart failure who self-report pain rated 4/10 or greater compared to an active control, two-dimensional guided imagery. The primary outcome is change in self-reported pain score measured by the Brief Pain Inventory (Short Form). Secondary end points include changes in self-reported distress, quality of life, and satisfaction with pain management.

Conclusion: This randomized controlled study aims to provide empiric data to support application and expansion of novel technologies such as virtual reality to augment usual pharmacological pain management strategies in hospitalized patients with heart failure.

1. Background

Patients with advanced heart failure commonly experience acute and/or chronic moderate to severe pain related to disease, treatment, or both [1–3]. By definition, patients with American College of Cardiology/American Heart Association (ACC/AHA) Stage C or Stage D heart failure are significantly limited in function and quality of life due to disease progression [4]. Compared to patients with cancer, patients with advanced heart failure may experience similar or more pronounced acute or chronic pain syndromes [5]. While other common symptoms such as shortness of breath or fatigue may readily improve with heart failure disease management, pain usually does not, making pain management compelling to study in this heart failure population.

Palliative care is a medical subspecialty that aims to relieve pain and suffering of such patients through pharmacologic and non-pharmacologic therapies. Those receiving inpatient palliative care consultation for pain management typically only receive drug therapies for analgesia. Many of these drug therapies, such as opioids, non-

steroidal anti-inflammatory drugs (NSAIDs), or acetaminophen carry risk of significant side effects. Additionally, the current nationwide opioid epidemic highlights serious risks associated with prolonged opioid use in non-cancer populations. Many non-pharmacologic pain management strategies are not reimbursed by insurance, limiting use to those with disposable financial resources [6]. However, clinical literature and expert opinion underline the importance of utilizing such non-pharmacologic therapies to maximize relief without additional side effects [7].

One such non-pharmacologic intervention, virtual reality, continues to demonstrate effectiveness in pain management [8,9]. Virtual reality (VR) is a rapidly developing technology that temporarily immerses the subject in a calm, pleasant environment, providing distraction from pain and lowering pain sensation. To experience VR, subjects use a specially-designed headset (similar in size/structure to ski goggles) and equipment that introduces computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way by the user. Early clinical research in

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patients undergoing painful procedures such as burn wound care or dental procedures shows that brief VR sessions (e.g. 3–30 min) can lower self-reported pain scores, lower opioid drug use, and improve satisfaction with pain management [8,9]. While the pathophysiology of pain is complex, such non-pharmacologic interventions seem to modulate pain by reducing the level of attention paid to noxious stimuli, thereby suppressing transmission of painful sensations to the cerebral cortex [10, 11]. When used in addition to usual care (opioid analgesics, with or without non-interactive distraction therapies), VR has been shown to provide clinically and statistically significant reduction in subjective pain score ratings [12,13]. The immersive nature of VR makes it a more engaging form of distraction therapy compared to playing a video game or listening to music (e.g. rather than watching a video of a beach, one visually and acoustically experiences being at the beach). Additionally, VR sessions can serve to pleasantly block out potentially bothersome stimuli such as excessive noise and artificial light from the healthcare environment, improving overall hospital experience.

While existing studies evaluating VR therapy for pain management consider hospitalized patient populations [14,15] or outpatients with chronic stable illnesses [16,17], no investigation has extended this important, rapidly evolving technology to patients with advanced heart failure, whose progressive disease and its complications such as secondary kidney or liver impairment usually limit available pharmacological analgesia to opioids. In the face of the rising national opioid epidemic, clinicians and investigators must develop and implement new strategies to address pain and suffering without increasing risk to patient and community.

We believe this study is important for several reasons: a) the presence of heart failure significantly limits available pharmacological interventions for acute or chronic pain management; b) patients continue to request inclusion of non-pharmacological strategies for pain management; c) hospitals (including the study site) lack adequate staffing to provide such non-pharmacological approaches; d) health insurance plans rarely provide adequate reimbursement for non-pharmacologic pain management interventions, leaving patients to provide their own resources; e) VR technology is rapidly evolving to deeper levels of immersive experience and affordable technology hardware including smartphones.

With funding from the Charles and Mary Latham Fund (<http://lathamfund.org/>), we will compare the impact of a virtual reality distraction therapy intervention on self-reported pain scores in hospitalized patients with heart failure compared to an active control, two-dimensional guided imagery. Our Specific Aims are 1) To collect and compare pilot data on the impact of a VR intervention and an active control intervention on pain management measures for hospitalized patients with heart failure; 2) To evaluate patient acceptance of and satisfaction with a VR intervention in hospitalized patients with heart failure.

2. Method

2.1. Overall design

Our study is a prospective, two-armed, single center pilot study of 128 hospitalized subjects with ACC/AHA stage C or stage D heart failure who self-report pain rated 4/10 or greater randomized 1:1 to receive either a single 10-min VR session or a single 10-min 2-dimensional guided-imagery session (active control). Following consent, subjects are randomized using a computer-generated randomization scheme [18]. The trial is unblinded since patients and the study coordinator cannot be blinded to the assigned distraction therapy. The primary outcome is change in pre-versus post-intervention self-reported pain measurement (Likert scale 0–10, where zero is no pain and 10 is the worst pain imaginable). The duration of participation in the study is two consecutive days to allow for pre- and post-intervention surveys immediately before and after the one-time intervention as well as a follow up survey

the next day. Given estimated hospital volumes, we anticipate the study will take 1 year for complete enrollment. We received Institutional Review Board approval for this study.

2.2. Study setting and population

MedStar Washington Hospital Center (MWHC) is a 912-bed tertiary referral academic hospital located in Washington, D.C. that serves a predominately socioeconomically underserved African-American patient population. MWHC is also home to the MedStar Heart and Vascular Institute's Advanced Heart Failure Program, the largest of its kind in the Washington, D.C. metro area. Last year, the MWHC Palliative Care served over 600 hospitalized patients with advanced cardiac disease.

This study enrolls patients age 18 or older, hospitalized at MWHC, living with ACC/AHA stage C or stage D heart failure, who report pain 4/10 or greater within the last 24 h. Subjects will be excluded if they already use VR for personal use, have intractable nausea/vomiting, history of motion sickness, history of seizures or epilepsy, have cranial structure abnormalities that prevent use of VR headset, are on contact isolation, and/or are participating in another pain management study. These criteria were chosen to assist in the efficiency of enrollment by excluding any patients with medical conditions that may not allow for informed consent, may increase risk of harm or injury, or may interfere with or confound data collection.

2.3. Study intervention

VR sessions will be administered using the Facebook (Facebook Inc., Menlo Park, CA) Oculus Go VR. This equipment was selected because it is portable and can be set up at the bedside in private or semi-private patient rooms. The hand controllers facilitate immersive, interactive VR experiences for patients who may be bedbound or have limited mobility in the inpatient setting. The VR software that will be used is the Forest of Serenity (Holosphere VR®, Birmingham, UK) application. This is a free VR application featuring a forest environment with voice narration that can be played in a seated or fixed position. Of note, we considered using smartphone-based VR technology for this study; however, we believe that smartphone-based VR technology has not yet evolved enough to provide an adequately immersive VR experience to assure accurate results. We anticipate that high-quality, immersive smartphone-based VR will be available in the future as technology is developed and refined. Subjects will use over-the-ear headphones for sound.

2.4. Active control

The guided-imagery session depicts a peaceful walk through a forest with instrumental background music and 2-dimensional imagery. Patients will watch the guided imagery video on a portable tablet for 10 min, the same duration as the VR intervention, also using over-the-ear headphones. In distraction therapy research, there is currently no predetermined time threshold for effect on pain experience; we chose 10 min for the intervention because it is a reasonably practical timeframe in a hospital setting and because it falls within the range of time frames (2 min–15 min) that have demonstrated benefit using VR for pain management. We chose guided imagery as an active control to mimic other forms of distraction therapy that are readily available and could be viewed as more cost favorable. Relaxation channels feature nature scenes and instrumental music and are increasingly available in healthcare settings (<https://www.healinghealth.com/care-channel-relaxation-programming/info/>). Tablet-based guided-imagery also approximates distraction therapy that patients could access from personal smartphones if they were in a setting that did not have access to a relaxation channel.

2.5. Standard pain management

Note that subjects in both arms will continue to receive standard pharmacologic pain management. Subjects may continue scheduled long-acting opioids and non-opioid analgesics throughout study participation. We chose to administer the intervention irrespective of timing of current pharmacologic management to assess how VR fits into real-world management of pain. We would not expect to demonstrate a reduction in opioid use in a patient population with chronic pain with a one-time pilot study intervention but see this as a future area of study. Demonstrating that patients are accepting of and respond well to VR for pain management is the first step in making non-pharmacologic modalities readily available as alternatives or additions to current pharmacologic treatments.

2.6. Measurements

Our primary outcome will measure pre- and post-intervention self-reported pain score using the Brief Pain Inventory-Short Form (BPI-SF, modified to assess symptoms in the last 24 h) [19]. We chose this outcome because self-reported pain scores remain the standard for clinical pain research. The BPI-SF includes a 0–10 Likert scale for self-reported pain as well as information about pain location, quality, and interference of pain on daily living.

Secondary outcomes will measure general distress, general quality of life, and satisfaction with pain management. General distress will be measured using the National Comprehensive Cancer Network Distress Thermometer (a Likert scale measuring from “No Distress” to “Extreme Distress,” where “distress” is defined by the patient); to limit survey burden we are not including the associated NCCN Distress Thermometer Problem List [20]. General quality of life will be measured using the Functional Assessment in Chronic Illness-Therapy in Palliative Care 14-item scale (FACIT-Pal 14) [21]. Patients will also be surveyed regarding comfort with technology and self-directed use of passive and active distraction therapies. Patients who are randomized to VR will be asked to rate on a Likert scale the level of immersion of the VR experience (“To what extent did you feel present or like you ‘went into’ the virtual environment?”).

In order to evaluate any potential residual effects of the distraction therapy, enrollees will be re-surveyed with BPI-SF, FACIT-Pal 14, NCCN Distress Thermometer, and pain management satisfaction questions on the following day.

2.7. Data collection

Participants will directly input survey responses using the Tonic Health platform on electronic tablets. All data will be password protected and de-identified prior to analysis. Results will be reported in aggregate by study groups. Participants will complete surveys immediately prior to the assigned distraction therapy experience and immediately after the distraction therapy experience, as well as the following day.

2.8. Sample size and statistical analysis

Our study will reach 80% power to detect a difference of 1 unit in the change in the pain score measure between the 2 groups using a two-sample *t*-test with equal variance at a two-sided $\alpha = 0.05$ and assuming a within-group standard deviation of 2 for each group (effect size = 0.5). Sample size calculations were conducted in PASS.

Baseline and outcomes data will be summarized using descriptive statistics such as means, medians and standard deviations for continuous variables and frequencies and percentages for categorical variables. Between groups comparisons will be tested using two-sample *t*-tests for continuous variables and chi-square or proportions test for categorical outcomes (Aim 1). Within-group changes will be tested using paired *t*-

tests (Aim 2). Multiple linear regression analyses will be conducted to test the differences in the change of pain scores adjusting for potential confounders such as age, gender, severity of illness and baseline pain scores. We will also compare frequency of completion between both arms. Descriptive data will be used to report qualitative data related to feasibility and satisfaction. Data analyses will be conducted by the statisticians in the Department of Biostatistics and Biomedical Informatics at MedStar Health Research Institute.

3. Conclusion

Patients who are hospitalized with heart failure commonly report untreated physical pain. Limitations offered by usual pharmacological therapies warrant exploration of non-pharmacological methods to augment relief, particularly those methods that can be developed to be patient-centered, portable, and easily scalable. This randomized controlled trial aims to provide empiric data to support application and expansion of novel technologies such as virtual reality to augment usual pharmacological pain management strategies in hospitalized patients with heart failure.

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