

openheart Effectiveness of virtual reality on anxiety and pain management in patients undergoing cardiac procedures: a protocol for systematic review and meta-analysis

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ABSTRACT

Introduction Anxiety and pain associated with cardiac procedures can lead to worse outcomes and poor satisfaction. Virtual reality (VR) can offer an innovative approach to a more informative experience that may enhance procedural understanding and reduce anxiety. It may also provide a more enjoyable experience by controlling procedure-related pain and improving satisfaction. Previous studies have shown benefits of VR-related therapies in improving anxiety related to cardiac rehabilitation and different surgical procedures. We aim to evaluate the effectiveness of VR technology in comparison to the standard of care in reducing anxiety and pain related to cardiac procedures.

Methods and analysis This systematic review and meta-analysis protocol is structured according to the Preferred Reporting for Systematic Review and Meta-analysis-Protocol (PRISMA-P) guidelines. A comprehensive search strategy will be used to search the online databases for randomised controlled trials (RCTs) on VR, cardiac procedures, anxiety, and pain. Risk of bias will be analysed using revised Cochrane risk of bias tool for RCTs. Effect estimates will be reported as standardised mean differences with a 95% CI. Random effect model will be used to generate effect estimates if heterogeneity is significant ($I^2 > 60\%$), otherwise fixed effect model will be used. A p value of < 0.05 will be taken as statistically significant. Publication bias will be reported using Egger's regression test. Statistical analysis will be performed using Stata SE V.17.0 and RevMan5.

Ethics and dissemination There will be no direct involvement of the patient or the public in the conception, design, data collection, and analysis of this systematic review and meta-analysis. Results of this systematic review and meta-analysis will be disseminated via journal articles.

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INTRODUCTION

Anxiety related to cardiac procedures is a well-established phenomenon that is characterised by excessive fear with a sense of impending danger and can occur both preprocedurally

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The utilisation of virtual reality (VR) technology is increasing in medicine. It has the potential to provide a real experience through an abstract environment. Prior studies have shown great promise in improving anxiety related to cardiac rehabilitation and different surgical procedures. However, VR-assisted anxiety and pain management during cardiac procedures have shown mixed results.

WHAT THIS STUDY ADDS

⇒ We aim to synthesise evidence and report findings on the impact of VR technology on cardiac procedure-related anxiety and pain management. This will include all types of cardiac procedures and will involve a direct comparison of novel VR technology with the standard of care.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our review will provide evidence on the impact of utilising innovative VR technology on patient experience and satisfaction during cardiac procedures. The findings may underscore the importance of continued research and development of novel approaches in improving patient experience and reducing anxiety and pain during cardiac procedures.

and peri-procedurally.¹ Approximately one-third to one-half of patients, who are undergoing cardiac procedures, have been reported to experience significant anxiety.² Anxiety is associated with increased cardiovascular morbidity and mortality after cardiac procedure, and is an independent predictor for postoperative cardiovascular outcomes and 4-year mortality.³ There is ample data to demonstrate that high level of preoperative anxiety negatively impacts the intervention itself and the immediate subsequent recovery by triggering cardiac autonomic dysfunction,^{4 5} which, in turn, results in elevated

heart rate, blood pressure, and reduced heart rate variability.⁶ This can lead to discomfort during medical procedures,⁶ and the associated autonomic dysfunction can be worsened by anticipatory pain prior to and during the procedure.

The two leading causes of peri-procedural anxiety are poor knowledge of the procedure and poorly controlled pain during the procedure.² These psychosomatic factors have been identified as important risk factors for incident cardiovascular disease as well as mortality.⁷⁻⁹

Anxiety and pain often manifest with somatic symptoms, which can mimic symptoms related to cardiac pathology such as chest pain and shortness of breath.¹⁰ This poses diagnostic challenges for the physicians to identify these symptoms as non-cardiac in origin, potentially adding to the anxiety and distress of the patients. In addition, well-controlled pain is associated with higher patient satisfaction,¹¹ which is paramount in the overall patient well-being. Anxiety and poor pain management may limit patients' ability to understand and retain important information provided by healthcare professionals, underscoring the importance of improving patient experience and satisfaction.

Various strategies are used to manage anxiety and pain, including distraction as a simple, complementary and a non-pharmacological approach that has proven effective by diverting patients' attention to pleasant stimuli.¹²⁻¹³ Different modalities for distraction, including virtual reality (VR) technology, have been used in pain management,¹⁴⁻¹⁵ and visual distraction has been shown to be particularly effective.¹⁶ VR has the potential to provide a visually enjoyable and more interactive experience in the management of anxiety and pain.

Previous studies have shown efficacy of VR technology in reducing anxiety and pain in patients undergoing cardiopulmonary rehabilitation¹⁷⁻¹⁸ and different surgical procedures.¹⁹ However, the use of VR technology in managing anxiety and pain in patients undergoing cardiac procedures has yielded mixed results.²⁰⁻²² As a result, this systematic review and meta-analysis aims to provide a comprehensive summary of the available evidence on the effectiveness of VR in reducing anxiety

and pain in patients undergoing all types of cardiac procedures.

Review question

The objective of this study is to synthesise evidence and assess whether the use of VR is more effective than standard of care in reducing anxiety and pain levels in patients undergoing all types of cardiac procedures.

METHODS AND ANALYSIS

This systematic review and meta-analysis protocol is reported according to the published PRISMA-P guidelines.²³

Search strategy and participants

A comprehensive search strategy developed by a health sciences librarian will be used to search the articles and these articles will be imported into Covidence for screening. The search strategy will include a mix of keywords and controlled vocabulary terms for the concepts of different types of cardiac procedures, pain, anxiety and VR, and will be conducted in the following academic research databases: MEDLINE (via Ovid), CINAHL (via EBSCO), Cochrane Central Register of Controlled Trials (CENTRAL), Web of Sciences and EMBASE (via Embase.com). The searches in MEDLINE, CINAHL and EMBASE will also include validated search filters for RCTs.²⁴⁻²⁷ All of these databases will be searched from inception until the time of final analysis to ensure all articles, which meet our inclusion criteria are included (online supplemental file 1).

Inclusion and exclusion criteria

Inclusion criteria will be based on the Participants, Intervention, Comparator, and Outcome framework (table 1) and will include adult patients (>18 years of age) undergoing all types of cardiac procedures. The procedural care programme for anxiety and pain management should include the addition of VR software. Only RCTs published in English language will be included. Exclusion criteria include all the clustered control trials, observational studies, case series, case reports, and RCTs published in non-English language.

Table 1 PICO framework for eligibility criteria

Study selection	This systematic review and meta-analysis will include only RCTs published in English language from inception till the end of study period. Clustered control trials, observational studies, case series and case reports will be excluded.
Participants	This includes adult population (18 years or older) undergoing all types of cardiac procedures. The procedural care programme for anxiety and pain management should include the addition of VR software.
Intervention	The VR group will use various immersive and non-immersive VR technologies to manage anxiety and pain in patients undergoing cardiac procedures.
Comparator	The standard of care group will follow the regular anxiety and pain management protocols used by the respective hospitals for patients undergoing cardiac procedures.
Outcomes	Anxiety and pain assessed using standardised and non-standardised commonly used questionnaires.
RCTs, randomised controlled trials; VR, virtual reality.	

Description of groups

The VR group will use various immersive and non-immersive VR technologies to manage anxiety and pain in patients undergoing cardiac procedures.

The standard of care group will follow the regular anxiety and pain management protocol used by the respective hospitals for patients undergoing cardiac procedures.

Study selection

The full text of all non-duplicate articles will be reviewed independently by two reviewers (ZB and SB) based on the inclusion and exclusion criteria. If there are any conflicts between the reviewers, they will be resolved through discussion (online supplemental file 2). The outcome measures assessed will include anxiety and pain, using both standardised and non-standardised questionnaires that are commonly used.

The data extraction strategy will be similar to our previous protocols.^{28 29} The data will be entered into a Microsoft Excel Spreadsheet under specific headings for the VR-based anxiety and pain management as well as the standard of care group. The data extracted will include the total population of the intervention and comparator groups as well as the peri-procedural differences in anxiety and pain scores between the intervention and standard of care groups. In order to maintain uniformity in the collected data, a higher SD of the outcome measures will be recorded in the spreadsheet as the SD of the mean difference.

Outcome measures

The outcome assessment methodology will be similar to our previous protocols.^{28 29} The outcomes will be assessed by measuring the peri-procedural differences in the anxiety and pain scores. Both standardised and non-standardised questionnaires that are commonly used will be considered for outcome assessment. All articles that assess the outcomes in non-quantitative manner or have significant heterogeneity in the methodology for assessing and reporting the results will be mentioned in the narrative description.

Quality and risk of bias assessment

Cochrane Risk of Bias tool will be used to assess the bias in the included studies. The tool assesses articles based on five components: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result. For each domain, we will report one of three levels of risks: low risk of bias, some concerns or high risk of bias. Additionally, we will report the overall risk of bias in all the studies.

Data synthesis

The results will be assessed on the basis of per protocol analysis. Mean and SD will be used for continuous

variables. The results will be pooled using standardised mean differences with a 95% CI for both anxiety and pain outcomes. A fixed effect model will be used to calculate effect estimates if heterogeneity is not significant. However, if there is significant heterogeneity between studies, a DerSimonian and Laird random effect model will be used. Heterogeneity between the studies will be assessed quantitatively using Q statistics,³⁰ and a value greater than 60% will be considered significant heterogeneity. Egger's regression test will be used to assess publication bias.³¹ A p value of <0.05 will indicate statistical significance. Subgroup and sensitivity analysis will be performed based on the types of outcome assessment questionnaire used, the degree of VR immersion, and the percentage of the total weight of the studies if applicable. The certainty of body of evidence will be assessed by GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) method if more than 10 studies are included in each of the outcomes. Data analysis will be conducted using Stata SE V.17.0 (College Station, Texas) and RevMan V.5.

CONCLUSION

To the best of our knowledge, this will be the first comprehensive systematic review and meta-analysis that will directly compare the use of VR technology for anxiety and pain management in patients undergoing cardiac procedures with the current standard of care in the peri-procedural period. This study will provide valuable insights into the potential benefits of incorporating this novel technology into cardiac procedure-related anxiety and pain management.

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Contributors ZB is involved in the conception, design, statistical analysis, writing and revising of the manuscript. CM is involved in devising the search strategy and writing the manuscript. PH will be involved in statistical analysis and has contributed to the analysis part of the protocol. SB is involved in writing and reviewing the manuscript.

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