International Journal of Cardiology Congenital Heart Disease 7 (2022) 100332

Contents lists available at ScienceDirect

International Journal of Cardiology Congenital Heart Disease

journal homepage: www.journals.elsevier.com/international-journal-of-cardiology-congenital-heart-disease

Pre-procedural virtual reality education reduces anxiety in patients undergoing atrial septal closure – Results from a randomized trial

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ARTICLE INFO

Keywords:
Virtual reality
Patent foramen ovale
Atrial septal defect
Patient education
Congenital heart disease

ABSTRACT

Background: Patients undergoing invasive cardiothoracic procedures are prone for pre-procedural anxiety and depression. Patient education is known to reduce anxiety. This study was performed to assess the effect of Virtual Reality (VR) as a means to educate patients to reduce pre-procedural anxiety in adult patients undergoing percutaneous closure of a patent foramen ovale (PFO) or atrial septal defect (ASD).

Methods and results: We randomly assigned 60 patients (48% male; age 44 ± 11 years) with an indication for percutaneous PFO or ASD closure to receive pre-procedural education by their cardiologist (control) or to receive additional education through a VR information film depicting the day of the procedure (intervention). The primary outcome was change in the pre-procedural anxiety as assessed using the State Trait Anxiety Inventory (STAI) and the Amsterdam Pre-operative Anxiety and Information Scale (APAIS) questionnaires, filled-in during the outpatient clinic visit (baseline) and one week prior to the procedure (follow-up). At baseline patients in both groups experienced equal levels of anxiety (STAI state anxiety: control 40 ± 10 vs. intervention 39 ± 9; p = 0.70). During follow-up, anxiety increased in the control group, but remained unchanged in the intervention group (45 ± 11 vs. 38 ± 7, p = 0.02). No differences were found for the APAIS anxiety scale.

Conclusion: Patient education using Virtual Reality is effective in reducing pre-procedural anxiety in patients undergoing percutaneous PFO or ASD closure. General introduction of VR for a large population of patients undergoing invasive cardiac procedures should be considered to reduce anxiety in this already fragile population.

1. Introduction

Up to 80% of patients awaiting cardiothoracic surgery or transcutaneous cardiac interventions experience preprocedural anxiety [1,2]. Preprocedural anxiety is associated with adverse psychological and somatic outcomes, such as decreased quality of life and patient satisfaction, prolonged postoperative recovery, increased re-hospitalization risk, and decreased adherence to medication and rehabilitation schemes [1–5]. Moreover, increased anxiety is associated with higher use of anesthetics during the procedure [1,3]. To reduce pre-procedural anxiety, pharmacological interventions, and patient education are used with mixed results [6].

In general, thorough patient education decreases preoperative anxiety and feelings of depression [7]. Media that most accurately present a precarious situation seem most effective in anxiety reduction, both in patients undergoing an invasive medical procedure and in patients with debilitating phobias [5,8–10]. Providing audio-visual information prior to the operation reduces anxiety for various types of surgery [11–14], with even higher efficacy if patients are familiarized with the surgical environment, and with the steps undertaken during hospitalization [15]. Taking video a step further, such as using 360-degree Virtual Reality (VR) film to provide patients with a more immersive, and interactive experience [10], could demonstrate to further help reduce anxiety [6,16–18].

Previous studies on VR as a means of patient education were

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https://doi.org/10.1016/j.ijcchd.2022.100332
Received 21 October 2021; Received in revised form 7 January 2022; Accepted 16 January 2022

performed in surgery, dentistry, paediatrics, and psychiatry [19–21]. Many cardiac patients require invasive interventions for diagnostic or treatment purposes, with subsequent risk of pre-procedural anxiety. Therefore, we hypothesize that patient education using a 360-degree VR film reduces preprocedural anxiety in patients undergoing elective transcutaneous patent foramen ovale (PFO) or atrial septal defect (ASD) closure.

2. Methods

2.1. Trial design

This study was designed as a prospective, single-center, randomized controlled trial performed at the Amsterdam University Medical Center, the Netherlands. The study complied with the Declaration of Helsinki and the study protocol has been evaluated and approved by the local Ethics Committee. Every patient provided oral consent prior to randomization.

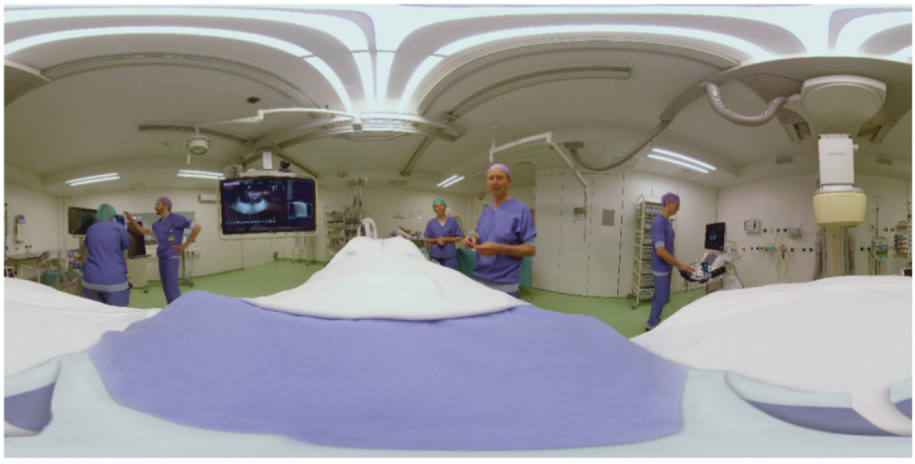
2.2. Patient selection

Eligible patients for inclusion were adult patients planned for transcutaneous PFO or ASD closure, irrespective of the closure indication. This patient population was specifically selected as they are young, and predominantly without prior interventions or surgery. All patients planned for informed consent visit with their cardiologist at the outpatient clinic were screened and, if found eligible, requested to participate in the study. Exclusion criteria were the inability to read, speak or understand the Dutch language, age younger than 18 years old, and mental or physical incapability to fill out the questionnaires.

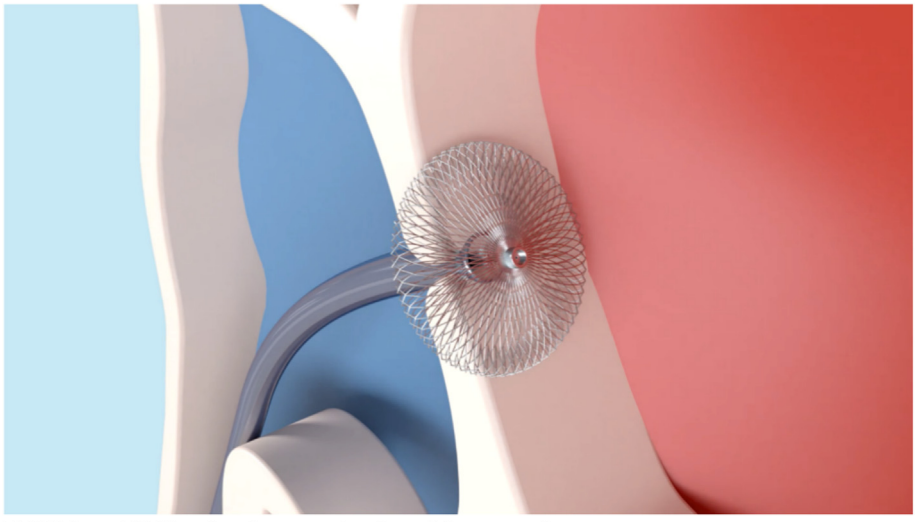
2.3. Randomization and intervention

At the outpatient clinic visit, patients were randomly assigned to either the intervention group or the control group, based on 1:1 randomization blocks of 4. Inclusion was performed from March 2019 to October 2020. The control group received routine oral information on the procedure from their treating cardiologist during the outpatient clinic visit, and received an informative flyer on the upcoming procedure. The intervention group received similar oral information on the procedure from their treating cardiologist, and the informative flyer, followed by an additional viewing of a 5-min educational VR video.

The VR video was presented by the researchers (MOP, JH, AK) via the Oculus GO headsets (Oculus, Facebook Technologies, LLC, Menlo Park, CA, USA), pre-programmed with the Virtual Reality film. The VR video initiated with the introduction of the team of physicians involved in the procedure. During the video patients virtually visited, using 360-degree views, all locations the patient would visit the day of their procedure (i.e., the cardiology ward, the catheterisation laboratory, and the recovery room, Fig. 1a). In addition, a 3D visualization video of the procedure was projected within the VR environment to explain the



a) Still from VR film showing the cardiac catheterization laboratory



b) Still from VR film showing an animation of the procedure

Fig. 1. Stills from Virtual Reality (VR) film.

procedure in more detail (Fig. 1b). The video ended with a final shot of the treating physicians, wishing the patient luck with their procedure. To ensure better understanding of the procedure, the patient's partner simultaneously viewed the VR-film with a second pair of goggles. All patients in the intervention group received a Youtube-link for additional viewing of the film at home.

2.4. Outcome and data assessment

Both groups were requested to fill in two validated questionnaires to evaluate pre-procedural anxiety, the State-Trait Anxiety Inventory (STAI) and the Amsterdam Preoperative Anxiety and Information Scale (APAIS). Patients in the control group were asked to fill in the questionnaire immediately after their consent consultation with the cardiologist, and patients in the intervention group filled in the questionnaires after their consultation and the viewing of the VR-film. Patients received the same questionnaires digitally during follow-up, which was within one week prior to the procedure.

The STAI-questionnaire consists of two separate scales, the state anxiety score, which resembles a temporary condition/current state of anxiety, and the trait anxiety score, which resembles the more general, stable and long-standing occurrence of anxiety, with 20 questions per scale (in total 40 questions) [22]. For the STAI-questionnaire each item is given a weighted score of 1–4. A rating of 4 indicates the presence of a high level of anxiety for specific anxiety-related item. Half of the questions are anxiety-absent questions, for which the scoring is reversed. Scores can vary from a minimum of 20 to a maximum of 80. A score of 80 indicates the presence of a maximum level of anxiety [22]. A cut-off value of 40 is used to classify cases as anxious [23].

The APAIS-questionnaire consists of 6 items. Two separate scales derive from this questionnaire, an anxiety scale (based on 4 items) and a need-for-information scale (based on 2 items). For the APAIS-questionnaire each item is given a weighted score of 1–5. A rating of 5 indicates the presence of a high level of anxiety or a high need for information. Scores can vary from a minimum of 4 to a maximum of 20 for the anxiety scale, and a minimum of 2 to a maximum of 10 for the need-for-information scale. A maximum score indicates the presence of a maximum level of anxiety and/or need for information. A cut-off point of 11 has been suggested to classify cases as anxious [24]. For the APAIS need-for-information scale a score of 2–4 can be classified as having no or little information requirements, patients with a score of 5–7 can be classified as having an average information requirement, and those with a score of 8–10 as having a high information requirement [24]. Supplement 1.

The anxiety scores, deriving from the state anxiety scale of the STAI and the anxiety scale of the APAIS were used as primary outcome measures. The need-for-information scale and the STAI trait anxiety scale are secondary endpoints.

2.5. Statistical analysis

Descriptive data were summarized as number with percentage, mean ± standard deviation, or median with interquartile range (IQR). Baseline and follow-up data, compared between the two randomization groups, were tested with the independent student t-test (normally distributed data) or Chi-square test (non-normally distributed data). Data has been tested for normal distribution using the Shapiro-Wilk test. Statistical analysis of baseline and follow-up data within the randomization groups itself, were performed by paired Student t-tests (normally distributed data) or Wilcoxon signed-rank tests (non-normally distributed data). All statistical analyses were performed using SPSS 24.0 (SPSS, Inc., Chicago, IL, USA). A two-tailed p-value of 0.05 was considered statistically significant.

3. Results

3.1. Patient characteristics

In total 60 patients undergoing transcutaneous PFO or ASD closure were enrolled and randomly assigned to either the control or intervention group, using a 1:1 randomization ratio. The mean age was 43.4 years ±10.7; 29 (48.3%) patients were male; and mean duration between the baseline visit and follow-up (i.e. within one week prior to the procedure) was 40.2 days ±32.8. Baseline characteristics were equal for both groups (Table 1). Ten patients did not complete follow-up (n = 3 intervention group, n = 7 control group). The primary reasons for lost to follow-up were: (i) patient did not complete the second set of questionnaires (n = 9) and (ii) the cardiac intervention was not performed within the follow-up duration of this study (n = 1). Baseline characteristics of the patients lost to follow-up did not differ from those who completed follow-up. Further analysis has been performed with the 50 patients who completed follow-up. Fig. 2.

3.2. Anxiety scores

At baseline the control and intervention group scored equally on the STAI state anxiety scale (control group 38.0 ± 9.0 vs intervention group 39.1 ± 9.6; p = 0.70), and indicate low to intermediate levels of anxiety after receiving the information related to the planned procedure. Similar scores were observed in the APAIS anxiety scale, as no difference was found for baseline scores between the two randomization groups (10.3 ± 4.2 vs 11.0 ± 3.0; p = 0.83, Tables 2–3).

During follow-up a significant increase in anxiety levels in the control group was observed (Δ +5.2 ± 10.3; p = 0.02), whereas no change in anxiety levels in the intervention group was observed (Δ −0.2 ± 7.3; p = 0.87). At follow-up a significant difference in anxiety levels between both groups was found (control 45.3 ± 10.6 vs intervention 38.8 ± 7.3; p = 0.02) (Fig. 3). During baseline 23 patients (46%, 11 intervention vs 12 control patients) scored above the threshold of 40 for the state anxiety score, during follow-up this was increased to 26 patients (52%, 9 intervention vs 17 control patients).

For the APAIS anxiety scale, no changes in anxiety during baseline were observed within groups (10.3 ± 4.2 vs 10.2 ± 3.1; p = 0.94). Subsequently, there was no difference between the control and intervention groups at follow-up (10.8 ± 3.3 vs 10.6 ± 3.0; p = 0.83). During baseline 25 patients (50%, 15 intervention vs 10 control patients) scored above the threshold of 11 points on the anxiety scale, while during follow-up 27 patients (54%, 15 intervention vs 12 control patients) scored above the threshold of 11 points on the anxiety scale.

3.3. Secondary outcome measures

The STAI trait anxiety scale demonstrated different scores between groups at baseline (control 39.1 ± 8.8 vs intervention 30.0 ± 11.0; p =

Table 1
Baseline characteristics.

	VR group (n = 25)	Control group (n = 25)	p-value*
Age (years)	44.5 ± 9.9	43.1 ± 12.0	0.66
Sex, male	11 (44%)	13 (52%)	0.57
CHD Diagnosis			0.19
Atrium Septum Defect	4 (16%)	8 (32%)	
Patent Foramen Ovale	21 (84%)	17 (68%)	
FU duration (days)	44.0 (43.0)	31.6 ± 17.7	0.07

Data are mean ± standard deviation, median with interquartile range (IQR), n (%). *Group differences were tested with the independent student t-test or with the Chi-square test. CHD = Congenital Heart Disease, FU = Follow up.

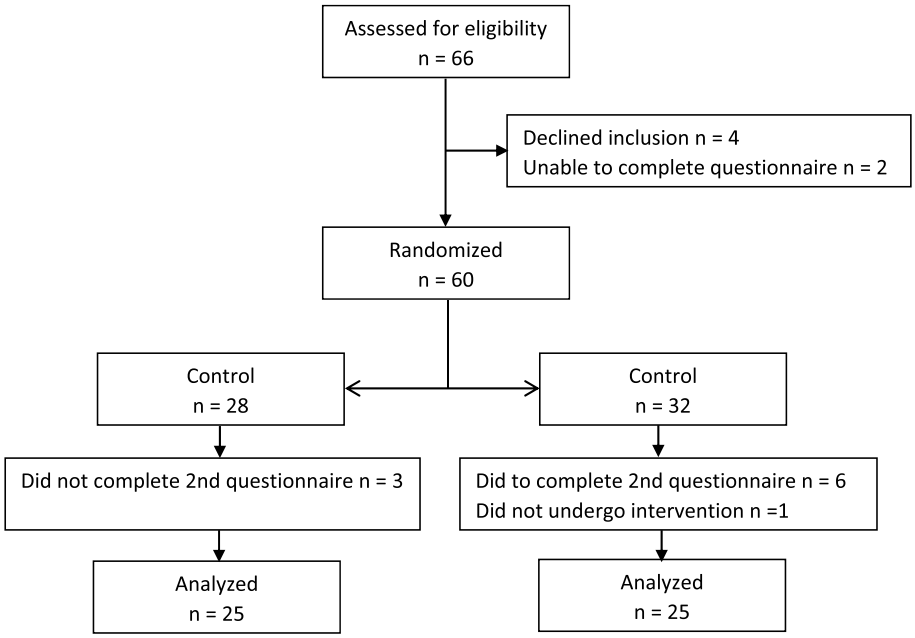


Fig. 2. Consort diagram of the RCT. Sixty-six patients were assessed for eligibility, of whom 60 were randomized. Fifty patients were included in the final analyis.

Table 2
Results within groups.

Questionnaires	VR group (n = 25)				Control group (n = 25)			
	Baseline	Follow-up	Δ intervention group	Within group p-value	Baseline	Follow-up	Δ control group	Within group p-value
STAI (State Trait Anxiety Inventory)								
State Anxiety score (20–80)	39.1 ± 9.6	38.8 ± 7.3	−0.2 ± 7.3	0.87	38.0 ± 9.0	45.3 ± 10.6	5.2 ± 10.3	0.02
Trait Anxiety score (20–80)	30.0 ± 11.0	32.5 ± 9.0	−0.7 ± 5.9	0.56	39.1 ± 8.8	39.2 ± 10.3	0.1 ± 4.7	0.90
APAIS (Amsterdam Pre-operative Anxiety and Information Scale)								
Anxiety score (4–20)	11.0 ± 3.0	10.6 ± 3.0	0.4 ± 3.1	0.54	10.3 ± 4.2	10.8 ± 3.3	0.5 ± 2.2	0.25
Need for information score (2–10)	6.3 ± 1.6	6.5 ± 1.5	0.2 ± 1.9	0.69	6.9 ± 2.0	6.9 ± 1.8	1.0 ± 1.9	1.0

Data are mean ± standard deviation, or median with interquartile range (IQR). Δ = mean change in scores during follow-up (FU - BL).

Table 3
Results between groups.

Questionnaires	Baseline		Follow-up	
	Δ between groups	Between group p-value	Δ between groups	Between group p-value
STAI (State Trait Anxiety Inventory)				
State Anxiety score (20–80)	−1.0 ± 13.1	0.70	−6.5 ± 10.3	0.02
Trait Anxiety score (20–80)	−5.9 ± 12.3	0.04	−6.7 ± 13.3	0.02
APAIS (Amsterdam Pre-operative Anxiety and Information Scale)				
Anxiety score (4–20)	−0.1 ± 5.6	0.94	−0.2 ± 4.2	0.83
Need for information score (2–10)	−0.6 ± 2.5	0.28	−0.4 ± 1.9	0.40

Data are mean ± standard deviation. Δ = mean change in scores (intervention - control).

0.04) and follow-up (control 39.2 ± 10.3 vs intervention 32.5 ± 9.0; p = 0.02). No significant change was found for the mean difference in STAI Trait scores between baseline and follow-up within the individual groups (control 0.1 ± 5.2; p = 0.90, vs intervention −0.7 ± 5.9; p = 0.56).

At baseline, patients in the control and intervention group had the same average need for information requirement based on the APAIS need-for-information scale scores (Table 2) (control 6.9 ± 2.0 vs intervention 6.3 ± 1.6; p = 0.28), which remained unchanged during follow-up (6.9 ± 1.8 vs 6.5 ± 1.5; p = 0.40). No significant change between baseline and follow-up could be found within the individual groups (control 0.0 ± 1.8; p = 1.0 vs intervention 0.2 ± 1.9; p = 0.69). At baseline 30 patients (60%, 17 intervention vs 13 control patients) had an average need for information, while 15 patients (30%, 5 intervention vs 10 control patients) had a high need for information. During follow-up 29 patients (58%, 15 intervention vs 14 control patients had an average need for information, while 17 patients (34%, 8 intervention vs 9 control patients) had a high need for information.

4. Discussion

Our randomized controlled trial is the first to demonstrate that in adult patients undergoing percutaneous PFO or ASD closure pre-procedural education with a 360-degree VR-film contributes in preventing increasing pre-procedural anxiety. Current progress in VR-possibilities enables the use this innovative technique to educate our patients on upcoming procedures at low-cost. Therefore, we recommend

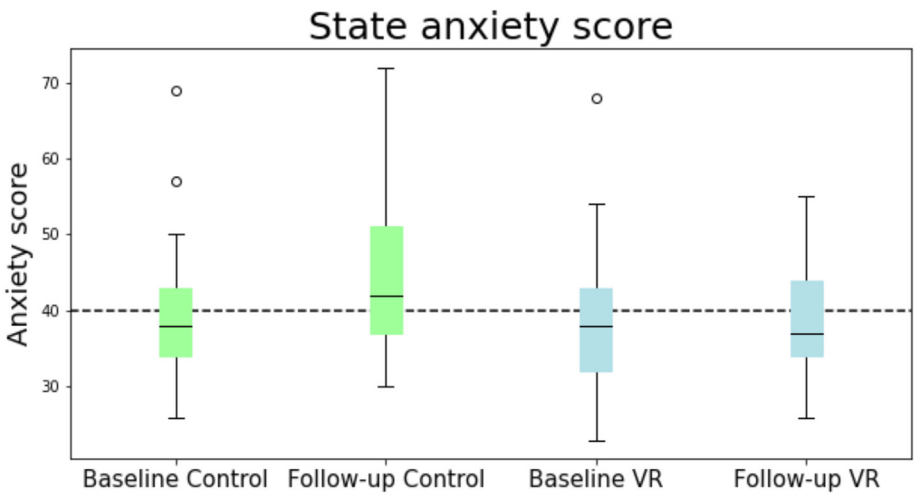


Fig. 3. Boxplot showing State anxiety score in patients in the control and intervention group. A value $\geq$ 40 is classified as anxious.

the implementation of VR in the pre-procedural setting to diminish pre-procedural anxiety, to increase patient satisfaction, and quality of life, and to decrease the number of adverse events [25,26].

VR allows for an immersive, realistic exposure to the team of physicians, the environment, the procedure, and enhances the comprehension of the upcoming intervention. The concept that more realistic patient education diminishes anxiety was already established by Spalding et al. [15], who lowered anxiety by providing patients an understanding of the experience during and after surgery, giving the patient an opportunity to physically meet the staff, and familiarizing the patient with the clinical and surgical environment. This has paved the way for other means for realistic patient education, such as 360-degree virtual reality films. Although this is the first study to evaluate the use of VR-based patient education to reduce anxiety in patients undergoing a transcutaneous cardiac intervention, VR has been found effective in several disciplines of medicine, particularly in the context of anxiety-related psychiatric disorders, such as phobias and posttraumatic stress disorders. In these settings too VR enables realistic exposure therapy by controlled sensory stimuli, with proven anxiety relieve [19]. In a clinical setting, the effects of VR seem to be very promising as well. After viewing of a VR-film patients undergoing elective craniotomy or spine surgery, felt better prepared for the surgery and had less stress during the preoperative period [5,7,27]. In the study of Yang et al. [28] patients undergoing arthroscopic knee surgery experienced less anxiety if they were educated on their procedure using VR, and Ryu et al. [27] found that the use of VR to educate children significantly reduced anxiety and improved compliance during the introduction of anesthesia.

In line with previous studies, our results demonstrate the necessity of addressing pre-procedural anxiety, as both patients in the intervention and control group experienced moderate levels of anxiety prior to their procedure [7]. However, awaiting their procedure, anxiety scores in the intervention group remained unchanged, while anxiety significantly increased in the control group. We found that general, stable and long-standing presence of anxiety (STAI trait score) remained unchanged in both groups. The fact that the APAIS anxiety score did not show any difference between the intervention and control groups, is likely due to the general nature of the questions. The scores of both groups were just below the cut-off value for anxiety, which could be expected since almost all patients experience some degree of anxiety before their surgery or procedure [7]. Although both groups stated to have been adequately informed, as there were no differences in the APAIS need-for-information scores, additional information using the 360-degree VR-film did relieve anxiety in the intervention group. This demonstrates that the value of good patient education is underestimated, both by physicians, and patients alike.

Besides the mental burden of anxiety, there is ample evidence that preprocedural anxiety has negative physical effects, and leads to reduced treatment compliance, an increase in readmission rates, and a higher risk of morbidity and mortality [25,26]. It is known that preprocedural anxiety is negatively associated with anesthetic outcome measures, such as medication demand, or duration of anesthesia. Kil et al. [3] found that patients with increased anxiety scores (both state and trait STAI anxiety scores) required more propofol during the procedure, thus increasing the anesthesia duration. The current study was not powered to demonstrate positive physical effect of VR-based patient education.

4.1. Limitations

Our study had several limitations. The study was conducted at a single tertiary referral center, and with relatively low sample size. Nonetheless, we found significant differences between the control and intervention group in term of change of anxiety. However, the investigators were not blinded and a possible bias towards the intervention group is possible. We remain uninformed on the impact of the patient education done by the patient's physician, as questionnaire were only conducted after personal consultation had taken place. Due to technical issues related to the VR goggles at study initiation, followed by the COVID-19 pandemic, inclusion of patients in the intervention group was delayed. One would expect longer follow-up duration to result in increased anxiety. The fact that we find the opposite strengthens our conclusions. We observed a relatively large number of patients who did not complete the follow-up. The follow-up questionnaires were sent via email, and the response rate was 83.3%, and lower in the control group, despite active contact. Lastly, the scope of this study is limited to patients undergoing PFO or ASD closure, specifically selected to obtain a young and homogenous population with irrelevant clinical histories. However, as anxiety is a general finding prior to (cardiothoracic) intervention and surgery, we believe that anxiety levels of our patient population are representative for cardiac intervention patients at large. These patients had no prior cardiac intervention, patients who do have prior cardiac experiences in the hospital could be less anxious as they know what to expect, or may be more anxious because of prior, negative experiences. Research has to be conducted in which patients with cardiac history is included to know how VR can influence their anxiety levels prior to the cardiac intervention.

5. Conclusion

Patient education using a 360-degree Virtual Reality experience depicting every aspect of an invasive cardiovascular procedure prevents

pre-procedural progression of anxiety in patient undergoing percutaneous PFO- or ASD-closure. Our data illustrate the great potential of this innovative tool to improve education of every cardiac patient undergoing (surgical) intervention, as anxiety is common and negatively influences patient outcome. The rapid progression of Virtual reality possibilities enables swift introduction into clinical practice.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

This work was supported by the Dutch Heart Foundation under [grant number 2018T068] to [M.D. Oudkerk Pool and M.M. Winter].

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcchd.2022.100332.

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