Mine Sargut, Stefan Schorn, Alexander Novotny, Helmut Friess, Dirk Wilhelm, Maximilian Berlet, Michael Kranzfelder*

The effect of Virtual Reality (VR) on anxiety and pain in patients undergoing port implantation

Preliminary results of a feasibility study

https://doi.org/10.1515/cdbme-2022-0025

Abstract: A growing body of evidence supports Virtual Reality (VR) as an effective and safe strategy for management of pain and stress associated with medical procedures in both adults and children. We therefore initiated a feasibility study to investigate the effect of VR on pain, stress, and anxiety during elective surgery, e.g. implantation of a central-venous port catheter, hypothesizing that VR can reduce intraoperative pain, stress and anxiety of the patient.

In this manuscript, the preliminary results of the first 20 (out of 6o planned) patients are presented. Baseline pain characteristics did not differ between the two study groups (VR group (n=10) and standard (no VR device) group (n=10)). System usability ("easy to use", "easy to learn" and "safe") was rated "good – very good" by the study participants. Self-assessment of anxiety components (Y-6 item questionnaire) revealed a calming (3.3 ± 0.5 vs. 2.4 ± 0.5, P= 0.009) and relaxing (2.7 ± 1.2 vs. 1.8 ± 0.4; P=0.09) effect of the VR device. Evaluation of pain level (Short form McGill questionnaire) during the procedure revealed a lower pain intensity (VAS) level (17.5 ± 12.1 vs. 19.5 ± 10.6; P= 0.834) and present pain intensity (PPI) score (0.9 ± 0.6 vs. 1.0 ± 0.5; P= 0.841) in the VR group

Preliminary data of our feasibility study indicates a positive effect of VR towards reduction of pain and stress in patients undergoing minor surgery in local anaesthesia. However, further data is needed to substantiate these results.

Keywords: Virtual Reality (VR), port implantation, pain, anxiety, feasibility study

1 Introduction

Over 20 years ago, Virtual Reality (VR) was successfully introduced in the medical field as an adjunctive pain treatment for burn victims [1]. Since then, a growing body of evidence now supports VR as an effective and safe strategy for management of acute pain associated with different medical procedures in both adults and children [2, 3]. It is assumed that the perception of pain is related to the amount of attention that is given to pain stimuli in the brain [4]. VR acts as a distraction to limit the user's processing of nociceptive stimuli by stimulating the visual cortex in the brain [5]. In addition, VR has also proven to be a useful tool in reducing perioperative anxiety [6]. Whereas former VR devices tended to be expensive and non-portable, the emergence of more affordable devices such as head mounted displays (HMD) has made VR now more feasible for clinical use [7].

The purpose of this study is to investigate the effect of VR on pain, stress, and anxiety during elective surgery, e.g. implantation of a central-venous port catheter. We hypothesize that VR can reduce intraoperative pain, stress and anxiety of the patient.

2 Methods

This study is a monocentric feasibility study carried out in the Department of Surgery, Klinikum rechts der Isar, TU Munich. Patients aged 18 years and older with an indication for port implantation are included. The operation is performed according to house standard with local anaesthesia. Written

***Corresponding author: Michael Kranzfelder:** Department of Surgery, Klinikum rechts der Isar, TU Munich, Ismaningerstr. 22, 81675 Munich, Germany, e-mail: michael.kranzfelder@tum.de
Mine Sargut, Stefan Schorn, Alexander Novotny, Helmut Friess, Dirk Wilhelm, Maximilian Berlet: Department of Surgery, Klinikum rechts der Isar, TU Munich, Ismaningerstr. 22, 81675 Munich, Germany

informed consent is required for participation in the study. Exclusion criteria are patients with chronic pain. These are defined as "persistent or recurrent pain" or "pain lasting longer than 3 months", chronic use of analgesics (opioids), previous opioid use, (use within 8 to 90 days before the surgical procedure), alcohol or drug abuse, history of epileptic seizures, claustrophobia, and blindness.

Figure 1. VR headset (type Pico G2 4K Premium), SyncVR Medical GmbH, Utrecht, the Netherlands.

Primary endpoint

The primary endpoint is the reduction of the intraoperative pain sensation as well as the level of anxiety and stress. These are assessed by Short Form McGill Pain questionnaire [8] and Y-6 item questionnaire for self-assessment of anxiety components [9].

Secondary endpoints

The secondary endpoints are the recording of preoperative pain and anxiety levels (baseline assessment) using the Pain Catastrophizing Scale (PCS) questionnaire [10]. The VR device was additionally assessed by system usability questionnaire.

In this study, the VR headset (type Pico G2 4K Premium) from SyncVR Medical GmbH, Utrecht, Netherlands with HypnoVR and SyncVR Relax & Distract software is used [11]. The patients can choose from different film scenarios (underwater world, beach, winter landscape, forest walk, space) and background music (jazz, lounge, classical), which are projected in the VR headset. This is a passive, audio-visual VR immersion and not a form of medical hypnosis (Figure 1).

Patients were randomized to either intervention or standard procedure group. Patients randomized to the intervention, i.e. VR group, receive the VR device during the procedure, which simulates a relaxing virtual environment. In the standard procedure group, the procedure is performed without VR glasses. This group will have access to a music program of their choice if desired.

In both groups, the operation is performed under local anaesthesia. After the operation, the pain sensation during the operation and the level of anxiety and stress are assessed using Short Form McGill Pain questionnaire and Y-6 item questionnaire for self-assessment of anxiety components.

Statistics

The feasibility study is planned with independent cases and controls with one control per case. Our hypothesis is that virtual reality (VR= intervention) will show a positive effect on pain perception, anxiety and stress during surgery.

Statistical analysis in this manuscript was performed by using Microsoft© Excel 2016 XLSTAT (Microsoft Corporation). Descriptive analyses were obtained where applicable. Mann-Whitney U tests were calculated for nonparametric distribution. Statistical significance was determined by $P < 0.05$.

3 Results

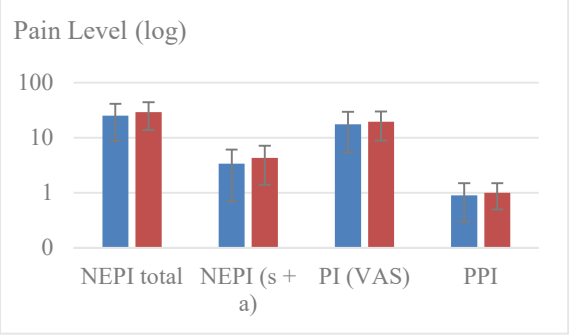
Female:male ratio was 7:3 in the VR group (n=10) and 5:5 in the standard (no VR device) group (n=10)). Mean age was 66.8 ± 7.2 vs 67.2 ± 5,4 years (n.s.). Baseline pain characteristics did not differ between the two study groups. Table 1 gives an overview of the study participants pain type and -experience evaluation using the Pain Catastrophizing Scale (PCS) questionnaire that quantifies individuals´ pain experience (helplessness (Q1-5, Q12), magnification (Q6,7,13), rumination (Q8-12)).

Table 1. Baseline characteristics of pain type and -experience evaluation (Pain Catastrophizing Scale (PCS) questionnaire). 0=not at all, 1=to a slight degree, 2=to a moderate degree, 3=to a great degree, 4=all the time.

Q	VR		Non-VR		P
	Mean ± SD	∑	Mean ± SD	∑	
1	0.9 ± 1.2	9	0.9 ± 1.2	9	0.798
2	0.8 ± 0.9	12	0.7 ± 0.9	16	0.793
3	0.8 ± 0.9	9	0.9 ± 0.9	9	0.793
4	0.5 ± 1.0	5	0.5 ± 1.0	5	0.772
5	0.5 ± 1.3	5	0.5 ± 1.3	5	0.718
6	0.7 ± 0.9	7	0.7 ± 0.9	7	0.798
7	0.7 ± 0.9	7	0.7 ± 0.9	7	0.798
8	0.5 ± 1.0	5	0.7 ± 0.9	7	0.585
9	0.5 ± 1.3	5	0.5 ± 1.3	5	0.718
10	0.7 ± 1.3	7	0.8 ± 1.3	8	0.867
11	0.4 ± 1.0	4	0.6 ± 1.0	6	0.587
12	0.5 ± 1.3	5	0.6 ± 1.3	6	0.929
13	0.6 ± 1.1	6	0.7 ± 1.1	7	0.929

Primary endpoint of the study is to prove whether VR is able to reduce intraoperative pain sensations as well as anxiety and stress levels or not. Figure 2 gives an overview of reported pain levels (Short form McGill questionnaire) during surgery. Both total normative estimated pain intensity (25.2 ± 16.4 vs. 29.1 ± 15.3) as well as present pain intensity (0.9 ± 0.6 vs. 1.0 ± 0.5) were slightly higher in the Non-VR group.

Figure 2: Results of pain type and -experience evaluation (Short-Form McGill questionnaire). Normative estimated pain intensity (NEPI), sensory (s) and affective (a) dimension, Pain intensity (PI/VAS) and Present pain intensity (PPI). 0= none, 1= mild, 2= moderate, 3= severe; VAS: 0 – 100; PPI: 0= no pain, 1= mild, 2= discomforting, 3= distressing, 4= horrible, 5= excruciating.



Although not reaching significance levels, pain intensity (PI/VAS) during the procedure was less in the VR group as compared to the standard group (17.5 ± 12.1 vs. 19.5 ± 10.6; P= 0.834).

Table 2: Results of the pain type and -experience evaluation (Short-Form McGill questionnaire). NEPI: 0= none, 1= mild, 2= moderate, 3= severe; VAS: 0 – 100; PPI: 0= no pain, 1= mild, 2= discomforting, 3= distressing, 4= horrible, 5= excruciating.

Normative estimated pain intensity (NEPI)		VR		Non-VR	
Sensory dimension	score	n	%	n	%
Throbbing	0	3	30	2	20
	1	7	70	8	80
	2 – 3	0			
Shooting	0	4	40	4	40
	1	6	60	5	50
	2	0		1	10
	3	0			
Stabbing	0	5	50	5	50
	1	4	40	3	30
	2	1	10	2	20
	3	0			
Sharp	0	6	60	5	50
	1	4	40	5	50
	2 – 3	0			
Cramping	0	10	100	9	90
	1	0		1	10
	2 – 3	0			
Gnawing	0	10	100	10	100
Hot/burning	0	8	80	7	70
	1	2	20	3	30
	2 – 3	0			
Aching	0	9	90	9	90
	1	1	10	1	10
	2 – 3	0			
Heavy	0	10	100	10	100
Tender	0	5	50	5	50
	1	5	50	3	30
	2	0		2	20
	3	0			
Splitting	0	9	90	9	90
	1	0		0	
	2	1	10	1	10
	3	0		0	
Affective dimension					
Tiring/exhausting	0	10	100	10	100
sickening	0	10	100	10	100
Fearful	0	9	90	8	80
	1	1	10	2	20
	2 – 3	0			
Punishing/cruel	0	10	100	10	100
Present Pain Intensity (PPI)	0	2	20	1	10
	1	7	70	8	80
	2	1	10	1	10
	3 - 5	0			
Pain intensity (VAS)	Mean ± SD			Mean ± SD	
	17.5 ± 12.1			19.5 ± 10.6	

Usability of the VR-device was rated “good – very good” by the study participants (Table 3). 8/10 patients stated that they would like to use the VR-device more often.

Table 3: Usability evaluation of the VR-device; 1= do not agree at all, 2= agree little, 3= neutral, 4= agree somewhat, 5= fully agree.

	Mean	SD
The system		
… is too complex	1.5	0.5
… is easy to use	4.4	0.5
… is easy to learn	4.4	0.5
… is safe	4.3	1.3
… is cumbersome	1.6	0.5
I would		
… need technical help	3.4	1.3
… like to use the system more often	4.3	0.5

Self-assessment of anxiety components (Y-6 item questionnaire) revealed a calming (3.3 ± 0.5 vs. 2.4 ± 0.5, P= 0.009) and relaxing (2.7 ± 1.2 vs. 1.8 ± 0.4; P=0.09) effect of the VR device (Table 4).

Table 4: Self-assessment of anxiety components (Y-6 item questionnaire). 1= not at all, 2= barely, 3= somewhat, 4= very much.

	VR		Non-VR		P
I feel	Mean	SD	Mean	SD	
… calm	3.3	0.5	2.4	0.5	0.009
… tense	2.0	1.0	2.8	0.7	0.05
… relaxed	2.7	1.2	1.8	0.4	0.09

4 Discussion

Most acute pain studies revealed VR to be an effective tool in reducing acute pain that is experienced during various medical procedures, e.g. urological or dental procedures [7]. In addition, VR can also be used as a safe and non-invasive analgesic method, without risks of e.g. drug addiction [4].

Our preliminary study results are consistent with previously published data, which have found VR to be effective in reducing pain sensations during medical interventions carried out in local anaesthesia [3]. Self-assessment of anxiety components revealed a calming (3.3 ± 0.5, P= 0.009) effect of the VR device. Usability of the deployed system was rated satisfactory (good – very good) by the majority of study participants. Mean age of the first 20 enrolled study participants as well as gender did not differ significantly between both groups (female:male ratio 7:3 in the VR group vs. 5:5 in the standard (no VR device) group; mean age 66.8 ± 7.2 vs 67.2 ± 5,4 years).

Based on our preliminary data, no correlation of patient age and VR acceptance can be shown at this time. Known VR side effects such as motion sickness and headache did not occur within the first 20 participants. A limitation of our study is the fact, that the study participants in the VR group cannot switch the virtual environment or music during the procedure, as these features are randomly played by the software. Another limitation could be, that there is still a lack of standardized measurement tools for evaluation of how immersed participants feel when undergoing a VR intervention. In our study, common pain and anxiety questionnaires were used [8-10]. However, a more comprehensive evaluation tool would be beneficial due to the complexity of immersion.

5 Conclusion

Preliminary data of our feasibility study indicates a positive effect of VR towards reduction of pain and stress in patients undergoing minor surgery in local anaesthesia. However, further data and research is needed to substantiate these results and to assess the extent to which one needs to be immersed in a VR environment in order to reduce pain and anxiety.

Author Statement

Research funding: The virtual reality (VR) device used in the study was financed by funds from the Stiftung Chirurgie, Klinikum rechts der Isar, TU Munich.

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board.

References

[1] Hoffman HG, Patterson DR, Carrougher GJ (2000) Use of virtual reality for adjunctive treatment of adult burn pain during physical therapy: a controlled study. The Clinical journal of pain 16**:**244-250

[2] Hoffman HG, Chambers GT, Meyer WJ, 3rd, Arceneaux LL, Russell WJ, Seibel EJ, Richards TL, Sharar SR, Patterson DR (2011) Virtual reality as an adjunctive non-pharmacologic analgesic for acute burn pain during medical procedures. Ann Behav Med 41:183-191

[3] Chan E, Foster S, Sambell R, Leong P (2018) Clinical efficacy of virtual reality for acute procedural pain management: A systematic review and meta-analysis. PLoS One 13:e0200987

[4] Dings SJM, van Stralen KJ, Struben VMD, Noordzij MA (2021) Pain and anxiety during vasectomies while distracting patients with video glasses or virtual reality glasses. BJU Int 128**:**561-567

[5] Spiegel B, Fuller G, Lopez M, Dupuy T, Noah B, Howard A, Albert M, Tashjian V, Lam R, Ahn J, Dailey F, Rosen BT, Vrahas M, Little M, Garlich J, Dzubur E, IsHak W, Danovitch I (2019) Virtual reality for management of pain in hospitalized patients: A randomized comparative effectiveness trial. PLoS One 14**:**e0219115

[6] Robertson A, Khan R, Fick D, Robertson WB, Gunaratne DGR, Yapa S, Bowden V, Hoffman HG, Rajan R (2017) The effect of Virtual Reality in reducing preoperative anxiety in patients prior to arthroscopic knee surgery: A randomised controlled trial. 2017 IEEE 5th International Conference on Serious Games and Applications for Health (SeGAH)**:**1-7

[7] Mallari B, Spaeth EK, Goh H, Boyd BS (2019) Virtual reality as an analgesic for acute and chronic pain in adults: a systematic review and meta-analysis. Journal of Pain Research 12**:**2053 – 208

[8] Spielberger C, Gorsuch R, Lushene R (1980) STAI Questionnaire for state and trait anxiety self-assessment. Organizzazioni Speciali, Firenze (IT)

[9] Melzack R (1987) The short-form McGill pain questionnaire. PAIN 30**:**191

[10] Sullivan MJ, Bishop SR, Pivik J (1995) The pain catastrophizing scale: development and validation. Psychological assessment 7**:**524.

[11] SyncVR (2022) SyncVR Relax & Distract. https://dashboard.syncvr.tech/platform/apps/tech.syncvr.painreduction