Anxiety Reduction in TAVI using Virtual Reality Trial

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To evaluate the effect of an immersive VR environment on procedural anxiety in patients undergoing TAVI under local anaesthesia in a randomized controlled setting.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON50951

Source
ToetsingOnline

Brief title
ART-VR

Condition

- Cardiac valve disorders

Synonym
Anxiety during TAVI, Anxiety during transcatheter aortic valve replacement procedure under local anesthesia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Patient satisfaction, TAVI, Virtual Reality

Outcome measures

Primary outcome

Primary endpoint: Procedural anxiety assessed on a visual analogue scale (VAS)

directly post-procedure.

Secondary outcome

Patient procedural satisfaction

Change in anxiety pre- vs. postprocedure

Procedural pain assessed on a VAS directly post-procedure

Procedural sedative use and dosage

Procedural analgesic use and dosage

Procedural nausea

Procedural vomiting

Admission time

Study description

Background summary

In the last decade, transcatheter aortic valve implantation (TAVI) has matured into a minimally invasive procedure under local anaesthesia. Although local anaesthesia may reduce complication rates (particularly delirium and hospital acquired infections), patients might experience procedural discomfort. Pain and anxiety may lead to administration of additional sedation or conversion to general anaesthesia. Although not extensively researched in TAVI, procedural anxiety is associated with worse outcome in cardiovascular procedures under local anaesthesia. Pharmacological treatment can reduce anxiety, but may introduce additional hazards and prolong in-hospital and intensive care unit stay.

Virtual reality (VR) allows patients to be fully immerged in an engaging, interactive 3-D environment. Its applications are broad and include treatment of phobias, stress-disorders, pain reduction. Recently, VR has been adopted in various medical procedures to reduce pre- and per-procedural anxiety. In TAVI, per-procedural VR immersion could potentially reduce patient anxiety leading to increased overall patient satisfaction. However, contemporary large scale, randomized evidence on VR application in TAVI is lacking

Study objective

To evaluate the effect of an immersive VR environment on procedural anxiety in patients undergoing TAVI under local anaesthesia in a randomized controlled setting.

Study design

International multi-center randomized controlled trial

Intervention

VR-immersion using a head mounted VR-device during TAVI procedure

Study burden and risks

The current application of VR is as a non-invasive modality associated with no significant risks. Previous studies have reported nausea, vomiting and headaches as a result of VR-use (i.e. cybersickness). However, these rates are low in elderly patients and are easily treated (by removing the device). In this study, we will not use concomitant headphones or earplugs as direct contact and the option to instruct the patient need to be preserved during the procedure. Additionally, to limit excessive movement by the patient, the VR-immersion does not involve a user-held controller. The level of interaction thereby is limited to subtle head movements which will not influence the TAVI procedure, which is executed according to standard of care. Use of this VR application will not affect the standard procedure flow of a TAVI procedure. Potential benefits of VR-immersion in TAVI are reduction in procedural anxiety, reduction in subjective pain and possible reduction in analgesics. It may enhance the overall patient experience and increase patient satisfaction scores.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Age * 18 years
o Symptomatic severe aortic stenosis
o Indication for transfemoral TAVI under local anaesthesia per local heart team consensus
o Patient is able to understand and sign written informed consent
o Patient speaks Dutch, German or English

Exclusion criteria

o Need for emergent TAVI
o Need for planned concomitant cardiac intervention during index procedure
o History of TAVI under local anesthesia/conscious sedation
o Chronic use of benzodiapines, opioids, pregabalin or antidepressants
o History of opioid use (within 8-30 days prior to randomization)
o Claustrophobia
o Any psychiatric illness diagnosed by a psychiatrist or psychologist
o Blindness or severe visual impairment despite visual aid (glasses, contact

lenses)
o Epilepsy
o Extensive cognitive impairment (MMSE <21 or as diagnosed by geriatrician)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2021
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	SyncVR Relax & Distract
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-08-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77298.078.21