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Pitfalls and benefits of virtual reality hypnosis during transcatheter aortic valve implantation in high risk patients

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Abstract: *Background:* in high risk patients unfit for cardiopulmonary bypass and general anaesthesia (GA), Transcatheter Aortic Valve Implantation (TAVI) with local anaesthesia and conscious sedation (LACS) is an approved alternative. Further reduction of sedatives benefits complication rate, length of stay and patient satisfaction. Several non-pharmacological strategies were proposed in other domains, of which virtual reality hypnosis (VRH) is increasingly popular.
Our goal was to evaluate recent VRH implementation in our TAVI protocol for patients with high anxiety levels.
Methods: an ethical approved retrospective chart review of TAVI care at Antwerp University Hospital, Belgium was performed. All femoral TAVI procedures (N=81) between 2019 and 2021 were included and anonymized data was compared in three groups (GA, awake and VRH). Primary objectives were: 30-day mortality, postoperative valve function (regurgitation, mean and maximum LV-Ao gradient), vascular complications, conduction disorders, pacemaker implantation, procedural time and length of stay. Pitfalls compromising future prospective research were identified (secondary outcome).
Results & Discussion: an overview of our current care was established. Primary outcome parameters showed no differences except for reduced procedure time in awake and VRH groups. VRH implementation in our TAVI protocol showed no harm and can be seen as a save alternative for sedation. Periprocedural observations showed that by interrupting visual and auditory VR input, a hypnotic dissociative state was not reached or maintained. Painful TAVI sheath introduction and rapid pacing related nausea was suppressed insufficiently in some cases.
Conclusion: VRH implementation in our TAVI protocol is safe. This trial led to an updated approach for improved procedure time, patient satisfaction and procedural outcome. A prospective study is ready to be launched. This will not only benefit future standard care in high risk patients, but also in medium and low risk patients.

Keywords: Transcatheter aortic valve replacement; virtual reality; hypnosis.

Introduction

Transcatheter Aortic Valve Implantation (TAVI) has become the second most frequently performed cardiac procedure after CABG and surpassed the number of conventional aortic valve replacements, regarding to the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS-ACSD) (1). An important part of patients in need of aortic valve replacement is considered unfit for conventional surgical aortic valve replacement (SAVR), due to high age and comorbidities. TAVI under local anaesthesia and conscious sedation (LACS) is an approved alternative. To determine high risk or non-operable state, several scoring systems are developed, but The Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) stands out in terms of prediction perioperative and long-term mortality in comparison to EuroSCORE and Ambler Risk Score (ARS) (2). Growing operator experience and evolution in TAVI devices, delivery systems and preoperative work-up resulted in less major vascular complications and less paravalvular leakage. Based on the most important clinical trials (NOTION, PARTNER 2 and SURTAVI), early and midterm mortality after TAVI is non-inferior to SAVR in high risk patients (3). A shift is generated towards TAVI indications for medium and low risk patients too, which was anticipated by last year's FDA approval and adaptations to the ESC guidelines (2, 4-6).

TAVI procedure involves the implantation of a self-deployable nitinol stent, loaded with 3 biological leaflets and a skirt (porcine pericardium). If vascular anomalies impede transfemoral access, another approach (subclavian, carotid, truncal or transapical) is possible. Once a temporary pacing lead and a rigid guidewire are positioned, balloon

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aortic valvuloplasty (BAV) is performed (7). Major complications are associated with this manoeuvre like stroke, valve regurgitation, valve rupture, tamponade and life threatening AV conduction disturbances (8). To minimise risks BAV is performed during rapid pacing (180 bpm), to impair cardiac output with eliminated pulsatile balloon movement and only when the delivery system is loaded. This can provoke extreme nausea, sweating and discomfort in an awake patient. Recent studies suggest that BAV could be discarded in the newest Edwards SAPIEN 3 (Edwards Lifesciences Inc., Irvine, CA) and Medtronic CoreValve (Medtronic, Minneapolis, MN) devices (9). Next a bulky (18 Fr) delivery system is introduced. Valve deployment is a two stage process. Slow moderate valve opening and fine adjustments made by the operator leads to optimal positioning. During further deployment the skirt shortly compromises cardiac output with a significant drop of blood pressure and extreme syncopal feeling. Extrasystolic beats could have a displacing effect during this process, thus ventricular pacing (100-120 bpm) is applied. Also pressure on the left conducting system could cause conduction disturbances and need for rescue pacing or definitive pacemaker implantation.

The earliest TAVI procedures required general anaesthesia (GA) because of these significant hemodynamic changes and painful sheath introduction. To avoid the risk of an increased cognitive impairment and respiratory failure related to GA, TAVI under LACS was introduced (10). Several studies showed no differences in complication rate. A shorter length of stay and a lower 30-day mortality was associated with LACS (11, 12, 13). Butala et al. (n=120,080) supported these findings (14). Today, vascular access possibility, annular size, coronaropathy and coplanar fluoroscopic angle prediction can be determined during preoperative work-up by 3D CT imaging (15, 16). As a result perioperative transoesophageal echocardiography (TOE) with semi-obligatory intubation is no longer required and almost all TAVI procedures are currently performed under LACS (14).

Sedatives may cause well-known side effects of which aspiration risk, postoperative nausea (PONV), respiratory problems (airway collapse, apnoea), hemodynamic instability and opioid related hyperalgesia or dependency are the most important (17). There often is a low threshold to escalate sedative load for improved analgesia and amnesia and its effect is not always predictable.

The presence of anxiety (73%) in the perioperative period cannot be underestimated (18, 19). Worrying starts with the news of unavoidable surgery and develops further during admission. Pure anaesthesia related anxiety (62%) takes a bigger part than fear of surgery (15%). In a recent (2016) Cochrane review Powell et al. confirmed the importance of psychological preparation prior to surgery, since it not only reduces pain, but shortens hospital admission time (poor quality of evidence) and has a low risk of harming patients (20). Few studies were included concerning the effects of hypnotherapy. In a narrative review Stamenkovic et al. pointed out some interesting insights concerning perioperative anxiety (21). Higher postoperative pain levels were seen and dose adjustments during induction with multimodal pain management are advised. Anxious patients are prone to somatization of pain. A correlation between anxiety and delirium in elderly was suggested. Accurate anxiety assessment, education and psychological referral results in a concomitant drop of distress and better outcome. The concept of multidisciplinary preoperative counselling has been implemented in Enhanced Recovery After Surgery (ERAS). Three well-known screening tools are: State-Trait Anxiety Inventory (STAI), Amsterdam Preoperative Anxiety and Information Scale (APAIS) and Modified Yale Preoperative Anxiety Scale (YPAS). For quick and easy self-assessment, the Visual Analogue Scale for anxiety (VAS-A) has been widely adopted (22).

Dexter et al. presented the Iowa Satisfaction with Anaesthesia Scale (ISAS) to assess satisfaction specific for anaesthesia in adult English speaking patients (23). The questionnaire is taken before discharge, but can be performed by telephone, which is more practical for multicentric investigations (24). It was validated for Arabic and French speaking patients, but not in Dutch (25, 26).

In 2014 the American Psychological Association (APA) published a renewed consensus of several definitions (27). Rousseaux et al. defined virtual reality as ”a computer-generated simulation of a lifelike environment that can be interacted with in a seemingly real or physical way by a person” (28). Patterson introduced the concept virtual reality hypnosis (VRH) as “a hypnotic induction and analgesic suggestion delivered by customized virtual reality (VR) hardware/software” (29). VRH has been adopted adjunctive to pharmacological and behavioural therapy in several medical fields (28, 30-32). Recently a promising protocol to evaluate perioperative VRH in CABG procedures was released by Rousseaux et al (33).

Takahashi et al. (34) presented the first study evaluating adjunctive hypnotherapy in TAVI under

LACS. Based on hypnotist availability in some cases (n=36; of a total of 143) preprocedural hypnotherapy was initiated moments before the start of LACS. The mental state reached by use of eye fixation and relaxation exercises was associated with reduced sedative requirements, a shorter length of stay but a longer procedure time (due to applying hypnotherapy upfront). Bruno et al performed a small pilot study of VR assisted sedation in TAVI procedures (35).

To reduce procedural time and postoperative pulmonary complications GA was abandoned in 2019 for TAVI procedures at the Antwerp University Hospital (UZA). Our main concern to withhold conscious sedation was the unpredictable effect and risk of patient agitation with hazardous movement where immobility is important at several procedural steps. In order to reduce anxiety and any discomfort VRH was added, by use of Digital Sedation™ (Oncomfort SA, Wavre, Belgium). Local anaesthesia infiltration varied; levobupivacaine 2.5 mg ml^{-1} was infiltrated by the anaesthetist prior to installation and VRH started afterwards or lidocaine 10 mg ml^{-1} was infiltrated prior to sheath introduction by the cardiologist.

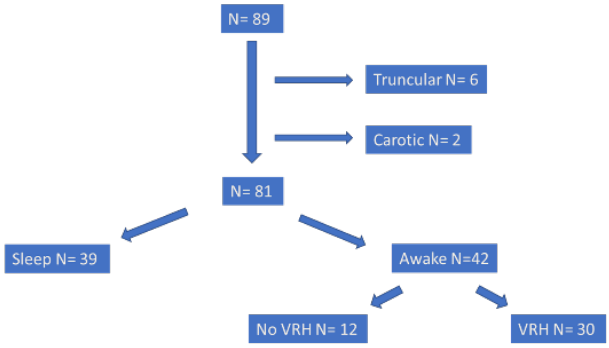

Fig. 1. — Flowchart study design.

Methodology

In this retrospective chart review all TAVI procedures between 2019 and 2021 were anonymized and listed, but femoral procedures only were included for comparison as shown in Figure 1. Demographic variables were sex (male 44.4%; female 55.6%), age (mean 82.6 yo; SD 5.5), length (mean 165.8 cm; SD 9.4), BMI (mean 26.2; SD 5.2), creatinine (1.01mg/dl; SD 0.4), eGFR (mean 63.4 ml/min; SD 18.2), diabetes mellitus, arterial hypertension (AHT), COPD, peripheral and coronary vascular disease. Valve descriptive variables were aortic regurgitation (0-4/4), aortic valve area (AVA; mean 0.62 cm^2; SD 0.18), mean Lv-Ao gradient (mean 49.8 mmHg; SD 21.1) and maximum Lv-Ao gradient (mean 78.1 mmHg; SD 31.2), next to preoperative conduction disorders and pre-existing pacemaker implantation. Inclusion and exclusion criteria are shown in Table 1.

Table 1

Inclusion/exclusion criteria

Inclusion/exclusion criteria
Inclusion overall
Randomised sample of TAVI between 1/1/2019 and 2/11/2020
Inclusion VRH
Significant anxiety with desire for distraction
Exclusion VRH
Not being able to cooperate
Deafness
Blindness
Allergy to local anaesthetics
Adversity to visual or auditory clues present in the operating room
Epilepsy
Psychiatric disorders
Use of psychoactive medication
Drug abuse
Claustrophobia
Relative contra-indications VRH (fear of water and motion sickness)
Exclusion awake procedure
Not being able to cooperate
Allergy for local anaesthetics
Adversity to visual or auditory clues
Truncular access via mini sternotomy
Expected complicated procedure

Primary objective parameters were: 30-day mortality, postoperative valve function (aortic regurgitation, mean and maximum LV-Ao gradients on day 0 and after 2 months), vascular complications, new conduction disorders, pacemaker implantation, procedural time and length of stay. Next to that, anxiety level and patient satisfaction were evaluated. Secondary outcome was to identify pitfalls compromising a prospective study design.

Data was compared in 3 groups: general anaesthesia (GA), awake with local anaesthetics (awake) and awake with local anaesthetics and VR glasses (VRH). Investigation of procedure times and LOS was also performed within 2 groups (GA vs awake/VRH).

Statistics was performed with SPSS software. Normality was tested by one sample Kolmogorov-Smirnov test. For normal distributed data comparative analysis was performed by one way ANOVA and post hoc Turkey-HSD test. Non normal distributed data were analysed by Kruskal-Wallis and post hoc Dunn's pairwise test with additional Bonferroni correction.

AVR, TAVI, VR, VRH, Outcome, VAS-A, ISAS and LACS were terms used in Pubmed and

Cochrane databases for literature review. This study was approved by the hospital ethical committee. Written informed consent was obtained at admission.

Results

A total of 81 cases were included and compared in 3 groups: GA (N=39), awake (N=12) and VRH (N=30). Except for age (GA (80.6 yr.) vs awake (85.6 yr.); p=0.015 and GA vs VRH (83.9 yr.); p=0.035)) and BMI (GA: 27.1 vs awake 23.0; p=0.025) no demographic differences were found between these groups. Postoperative outcome showed no significant differences, except for a 20 minutes longer procedure time in GA cases vs the awake group (p=0.023). GA vs VRH showed no significant difference. Also LOS was not significantly shorter when GA was avoided. Both variables were then compared in two groups (GA, N=39 vs awake/VRH, N=42). No differences in LOS were seen, but there was an 18 minutes longer procedure time in the GA group (p=0.018). Plot diagrams are shown for procedure times and length of hospital stay (LOS) in Figure 2. Aortic valve regurgitation evolved from a score of 0-1/4 direct postoperative to 1-2/4 after 2 months. Almost all GA (89%) cases needed vasopressors whereas no GA cases needed antihypertensives. In the awake/VRH group antihypertensives were added in 45.2% and only 11.9% needed vasopressor support. Overall, 4 strokes and TIA appeared in 81 femoral cases (3 in awake group, 1 in GA group). No deaths were found during data registration (30-day mortality = 0).

Discussion

Except for shorter procedure times, no significant differences were found between GA and awake groups (awake/VRH). No 30-day mortality was encountered. As described before, awake TAVI procedure is indeed a safe alternative to GA and VRH implementation showed no harm. More (prospective) data is needed to confirm these results. No conclusions can be drawn about preoperative anxiety and patient satisfaction, due to absent data registration.

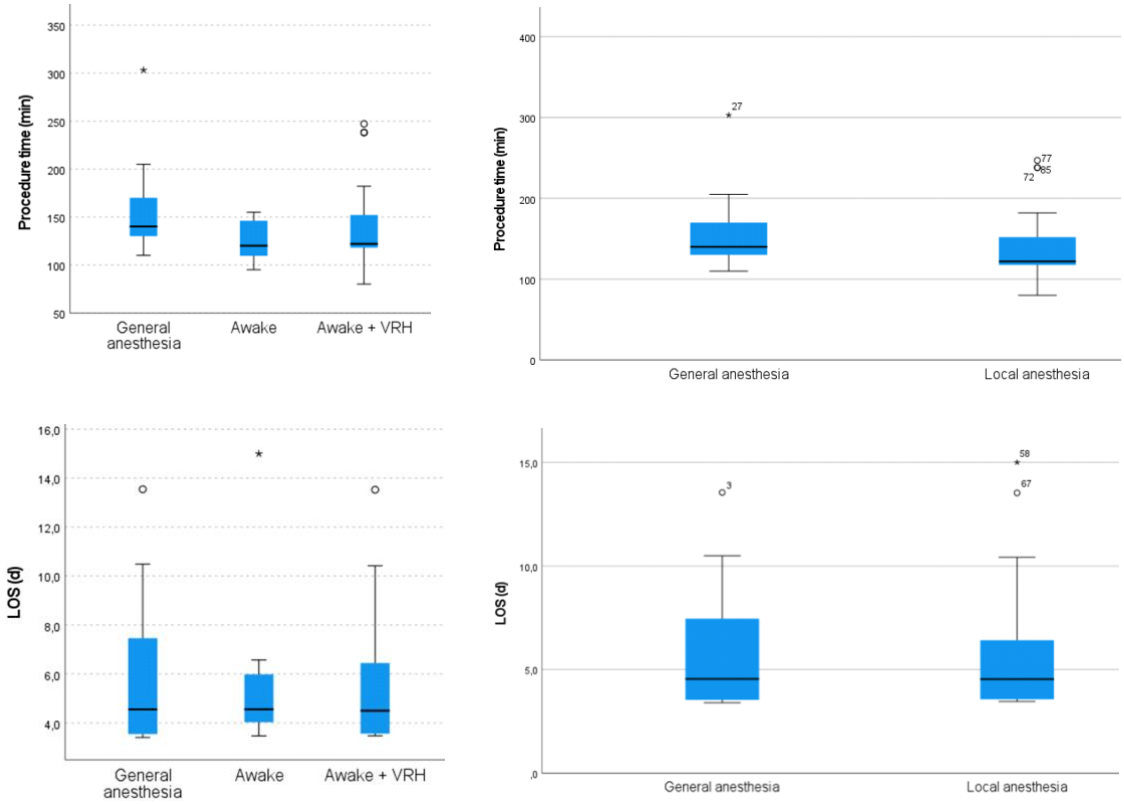

Fig. 2. — Plot diagrams for procedure time and length of stay. Comparison between 3 (GA vs Awake vs VRH) and 2 (GA vs Local Anaesthesia groups. Procedure times of GA (median 140 minutes; IQR 128-172) vs awake procedure without VRH (120 minutes; IQR 105-152) vs VRH (median 122 minutes; IQR 118-152). LOS of GA (median 4.6 days; IQR 3.5-7.5) vs awake procedure without VRH (median 4.6 days, IQR 3.8-6.2) vs VRH (median 4.5; IQR 3.6-6.5). Procedure times of GA (median 140 minutes; IQR 128-172) vs local anaesthesia (median 122 minutes; IQR 117-152. LOS in GA (median 4.6 days; IQR 3.5-7.5) vs local anaesthesia (median 4.5 days; IQR 3.6-6.4).

However, much was learned during chart review and detailed observation of our current practice of the TAVI procedures.

First, as stated before, preoperative anxiety can influence postoperative outcome. Unfortunately, to asses preoperative anxiety little attention was paid during work-up, nor was there any scoring system available. Secondly, by detailed study of our current routine practice, the use of the VR hypnosis seemed not standardized, nor in giving preoperative information, neither in perioperative use. Third, although VR hypnosis can provide a benefit for perioperative distress, negative suggestions or incorrect expectations can importantly influence its outcome. Last, despite providing VRH for increased comfort and patient satisfaction, with a subjective positive evaluation of its effect by the team, no objective scoring of patient comfort was done.

Improper data mining was expected, as it is the secondary outcome of our investigation. The setup of this retrospective review gave insight in what is needed to launch a prospective trial. Preoperative anxiety levels have to be taken into account in our future research by means of a validated scoring system, such as described above. Until now assigned anaesthetists were free to deviate at their own discretion. During the procedure, attention should be paid to minimize patient disturbances, because many verbal interactions with the patient were noted. Most patients reported being satisfied when VRH was applied, but disapproved the cessation of vocal and video input after 45 minutes, which had a disturbing effect. Guidelines to avoid unnecessary interruption of visual or auditory VR input with failure of hypnotic dissociation are needed. As the painful femoral sheath introduction and nausea related to rapid pacing and stent deployment also varied, a more extensive standardize method and timing of the instillation of local anaesthetics or even a proper locoregional block should be implemented. Double blind trials are of value. To eliminate bias a sham version without any hypnotic features of VRH software (available for research purposes) should be implemented in future prospective research. This way virtual reality hypnosis can be compared with VR distraction.

In summary, main contributions of this study are a clear overview of our current TAVI care leading to an updated TAVI protocol at our centre and the set-up of a prospective designed trial. Consistent with current evolution in the literature also medium and low risk patients could benefit.

Conclusions

This small cohort retrospective chart review makes it difficult to draw any hard conclusions. Primary outcome parameters showed no significant differences except for procedure time. VRH implementation to our existing TAVI protocol showed no harm and can be seen as a save alternative for anxious patients.

The value of this trial is the insight in our current TAVI care, which led to an updated TAVI approach at our centre. Shorter procedure time, improved patient satisfaction and better procedural outcome are expected. A prospective study is ready to be launched. This will not only benefit future standard care in high risk patients, but also in medium and low risk patients.

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