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# **Routine use of procedural sedation and analgesia for transcatheter edge-to-edge mitral valve repair**

**Short title:** Procedural sedation for percutaneous mitral valve repair

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## **INTRODUCTION**

Transcatheter edge-to-edge repair (TEER) of the mitral valve has become a well-established treatment for moderate-to-severe secondary mitral valve regurgitation in patients not eligible for classical surgery [1]. It is the most widely used technique of transcatheter mitral valve repair in Poland [2]. It effectively reduces the rate of heart failure (HF)-related hospitalizations and improves symptoms and quality of life [3]. The TEER procedure is associated with a similar safety in patients with multiple comorbidities compared to less frail patients qualified for surgical procedures [4]. Therefore, it appears reasonable to assume that minimally invasive mitral valve repair should involve minimally invasive anesthetic management.

TEER is typically performed under general anesthesia (GA). There are, however, reports of this procedure performed under procedural sedation and analgesia (PSA) [6].

In the current study, we evaluated the safety and feasibility of the PSA protocol in twenty-six patients undergoing mitral TEER.

## **METHODS**

### **Preoperative care**

The choice of anesthesia management for TEER depends on several factors and should be chosen by the Heart Team individually for the patient. The base of therapeutic success is excellent communication between the cardiologist, cardiac surgeon, and anesthesiologist.

The patient's medical history, anatomy, and the procedure's course can affect the choice of anesthesia method. Following the "less is more" principle, all patients in our center are qualified for PSA unless indications for GA are present. Among the most GA indications are neurological disorders, possible difficulties in maintaining an open airway, trouble maintaining a still supine position. Also, the expected length of the procedure and any foreseeable technical difficulties related to mitral valve anatomy should be considered.

A contraindication to PSA is the patient's lack of consent, which may result from fear and poor understanding of the procedure. Usually, a conversation and a detailed explanation of the upcoming procedure results in consent for PSA. In addition, proper education reduces anxiety, and premedication is typically not needed.

### **Intraoperative care**

The surgical procedure is performed in a hybrid operating theater. The surgical team includes cardiologists, cardiac surgeons, anesthesiologists, radiology technicians, and nurses. Also, a cardiac surgery team remains on-call if a sternotomy is required. The interventional echocardiographer is responsible for intraoperative transesophageal echocardiography (TOE). The hybrid room setup for TEER under PSA is shown in [Figure 1](#). Anesthetic management includes monitoring of ECG, SpO<sub>2</sub>, invasive blood pressure (IBP), diuresis, and temperature. A heating mattress placed under the patient is used to prevent intraoperative hypothermia without affecting the quality of X-ray imaging. The high flow nasal oxygen therapy (HFNOT) provides respiratory support with a fresh gas flow of 40–60 l/min and the inspiratory fraction of oxygen (FiO<sub>2</sub>) 40%–50% adjusted according to SpO<sub>2</sub>. In addition to precisely titrating the FiO<sub>2</sub>, HFNOT allows high flow rates. Such excess provides an adequate volume of fresh gas mix and produces continuous positive airway pressure, potentially reducing the size of pulmonary atelectasis. Next, a peripheral venous 18G cannula is placed, and an intravenous infusion of dexmedetomidine 0.2–0.7 µg/kg/h is started and maintained during the procedure

with the target Richmond Agitation Sedation Scale (RASS) 0/–1 pt. Because of the need for invasive blood pressure monitoring, radial artery cannulation is performed in every patient. Central venous cannulation through the right internal jugular vein under ultrasound guidance is done routinely for the same reason. A Foley catheter is inserted during sedation.

For local access site anesthesia, 0.5% ropivacaine is administered under ultrasound guidance. If not contraindicated, preemptive 1.0 g paracetamol and 1.0 g metamizole are administered intravenously as part of multimodal analgesia.

The placement of the TOE probe is done after superficial anesthesia of the pharyngeal wall with 10% lidocaine. Suctioning excess saliva from the oral cavity is done with a dental suction device.

To enhance the patient's experience and comfort even further, in several cases, we have successfully used virtual reality (VR) goggles with a video previously selected by the patient displayed. Such an approach was well received by the patients.

### **Postoperative care**

After the procedure, the patient is transferred to the Cardiac Intensive Care Unit for 24 hours and subsequent step-down transfer to the cardiology ward according to clinical status.

The following aspects were considered in the analysis of the rationale for performing TEER procedures under PSA: (1) early complications, including hemodynamic and respiratory stability during the procedure; (2) postoperative complications; (3) surgical complications; (4) hospitalization time; and (5) in-hospital mortality.

### **Statistical analysis**

Descriptive Statistics was performed with StatsDirect 3.1 software (StatsDirect LDT, Birkenhead, UK). Quantitative variables are presented as median and interquartile range (IQR). Qualitative variables are presented as absolute values and percentages.

## **RESULTS AND DISCUSSION**

Between March 2021 and July 2022, twenty-seven TEER procedures were performed in our hospital. Of the operated patients, only one (3.7%) had elective general anesthesia, and the remaining (26/27, 96.3%) underwent TEER under PSA. Procedural success—was achieved in all patients.

The median age of the patients was 74 (67–81) years old, and the median EuroSCORE was 7.1 (4.8–11.4). The median procedure time was 105 (80–120) minutes.

We did not observe any serious adverse events during the anesthesia procedure.

To ensure hemodynamic stability, intraoperative catecholamine infusion was administered in only one case (3.8%). Most patients, including those with respiratory diseases, underwent the procedure without respiratory complications (25/26, 96.2%). Only in one case (3.8%) a transient face mask ventilation was necessary due to hypoventilation without subsequent complications. No case required conversion to GA.

In the postoperative period, the total time of HFNOT support was <24 hours. Respiratory complications requiring passive oxygen therapy with nasal cannula >48 hours occurred in four cases (15.4%). The most prolonged oxygen support lasted eight days in a patient with respiratory failure caused by pneumonia.

The most incident surgical complication was minor bleeding and access site hematoma, which occurred in seven cases (26.9%). Major bleeding requiring transfusion of red blood cells and/or blood products in the postoperative period was reported in two patients (7.7%). One patient (3.8%) required surgical management of access site bleeding.

The median length of hospital stay was 7 (5–8) days, and the time from procedure to discharge was 5 (4–6) days. There were no in-hospital deaths.

The main advantage of general anesthesia during the TEER is the fully controlled intraoperative conditions. However, general anesthesia has known disadvantages.

The use of general anesthesia in patients can lead to prolonged mechanical ventilation, increased risk of ventilation-associated pneumonia (VAP), and potentially increased costs of the procedure. As shown for transcatheter aortic valve implantation (TAVI), performing the procedure without G. can significantly reduce the length of hospital stay and costs [5]. TEER in most centers is done under GA because of the prolonged procedural time, implantation of multiple clips, use of stop-breath maneuver during grasping and widespread perception that only GA provides adequate patients comfort during the procedure. However, the progress in the technology and growing operators' experience lead to a significant shortening of the procedural times. Therefore PSA became a valid alternative. Moreover, a trend was shown towards clinically shorter procedure time overall for patients undergoing TEER with sedation compared with GA [6].

The meta-analysis [6] did not show statistically significant differences between sedation and G.A. in terms of the effectiveness of the procedure, mortality, and the most common periprocedural complications. One study showed decreased need for vasopressors in patients

undergoing TEER under sedation comparing to GA [7]. The patients undergoing TEER under PSA had a comparable total length of hospital stay, with shorter ICU stay. Previous studies comparing the use of GA vs. PSA for TEER procedures have shown comparable safety and effectiveness of the procedure in patients undergoing such anesthesia [6].

This preliminary analysis provides a rationale for the use of PSA as an alternative to GA during TEER procedures. Specific PSA protocols for TEER procedures are lacking. This publication presents validated procedural management and sedation protocol that can be adopted on other centers performing TEER. Prospective comparisons to other PSA GA protocols are needed.

### **Article information**

**Conflict of interest:** None declared.

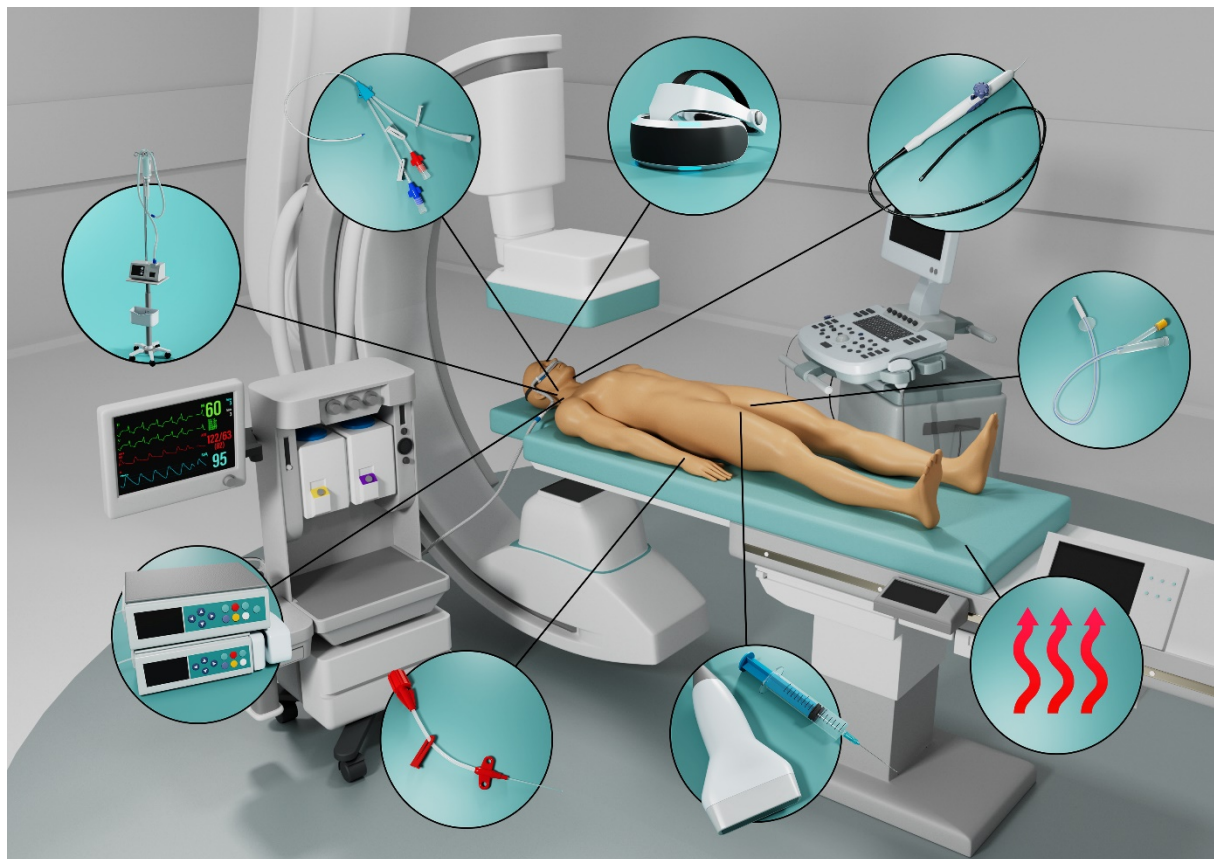
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**Figure 1.** Hybrid room setup for transcatheter edge-to-edge repair