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## SCIENTIFIC ARTICLE

# Inhalational anesthesia maintenance with the Janus facial mask for transcatheter aortic-valve replacement: a case series



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### KEYWORDS

Transcatheter aortic valve replacement;  
Aortic stenosis;  
Transesophageal echocardiogram;  
Noninvasive ventilation;  
Tracheal intubation;  
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### Abstract

**Background and objectives:** Aortic stenosis is the most common type of heart valve disease. Percutaneous aortic valve replacement has become the alternative for patients considered at high risk for surgery. Controlled mechanical ventilation with tracheal intubation has been the choice for this type of procedure, however the use of noninvasive ventilation in cardiac patients has shown to be beneficial. Janus is a novel full-face mask that allows application of noninvasive ventilation support during anesthesia. Our main objective was to evaluate the feasibility of transcatheter aortic valve replacement with prolonged transesophageal echocardiographic monitoring under deep inhalational sedation delivered through a new mask for noninvasive ventilation.

**Methods:** A case series observational study that included five patients with critical aortic stenosis that underwent inhalational anesthesia with sevoflurane for transcatheter aortic valve replacement in a hybrid room of a teaching hospital. Standard monitors and bispectral index were used, followed by inhalational induction and placement of the Janus mask. Anesthesia was maintained with sevoflurane. Patients were transferred to intensive care unit after the procedure. Complications related to the mask use, transesophageal echocardiography accessibility and respiratory implications to the patients were recorded.

**Results:** All procedures were uneventful and no major complications were observed intraoperatively. One patient presented CO<sub>2</sub> retention (50 mmHg) and sevoflurane leak around the central opening of the mask, both without clinical significance.

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**PALAVRAS-CHAVE**

Substituição de válvula aórtica transcater; Estenose aórtica; Ecocardiograma transesofágico; Ventilação não invasiva; Intubação traqueal; Anestésicos voláteis

**Conclusions:** The use of inhalational anesthesia with the facial mask Janus is a safe and efficient alternative to general anesthesia with tracheal intubation for transcatheter aortic valve replacement and can easily accommodate the use of transesophageal echocardiography intraoperatively.

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## Manutenção da anestesia inalatória com a máscara facial Janus para substituição de válvula aórtica transcater: uma série de casos

**Resumo**

**Justificativa e objetivos:** A estenose aórtica é o tipo mais comum de doença valvular cardíaca. A substituição percutânea de válvula aórtica tornou-se a alternativa para pacientes cirúrgicos considerados de alto risco. A ventilação mecânica controlada com intubação traqueal tem sido a escolha para este tipo de procedimento; porém, o uso de ventilação não invasiva em pacientes cardíacos mostrou ser benéfico. Janus é uma nova máscara facial que permite a aplicação de suporte à VNI durante a anestesia. Nosso objetivo primário foi avaliar a viabilidade da substituição transcater de valva aórtica com monitoração ecocardiográfica transesofágica prolongada sob sedação inalatória profunda através de uma nova máscara para ventilação não invasiva.

**Métodos:** Estudo observacional de série de casos que incluiu cinco pacientes com estenose aórtica em fase crítica, submetidos à anestesia inalatória com sevoflurano para substituição transcater de valva aórtica em uma sala híbrida de um hospital universitário. Monitores padrão e índice bispectral foram utilizados, seguidos de indução inalatória e colocação da máscara Janus. A anestesia foi mantida com sevoflurano. Os pacientes foram transferidos para a unidade de terapia intensiva após o procedimento. As complicações relacionadas ao uso da máscara, a acessibilidade da ecocardiografia transesofágica e as implicações respiratórias para os pacientes foram registradas.

**Resultados:** Todos os procedimentos transcorreram sem incidentes e não foram observadas complicações maiores no intraoperatório. Um paciente apresentou retenção de CO<sub>2</sub> (50 mmHg) e vazamento de sevoflurano em torno da abertura central da máscara, ambos sem significância clínica.

**Conclusões:** O uso de anestesia inalatória com a máscara facial Janus é uma alternativa segura e eficiente à anestesia geral com intubação traqueal para substituição transcater de valva aórtica e pode facilmente acomodar o uso de ecocardiografia transesofágica no intraoperatório.

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**Introduction**

Aortic Stenosis (AS) is the most common valvular heart disease, occurring in up to 10% of all adults over 80 years old with a mortality rate of about 50% within 2 years.<sup>1</sup> The surgical aortic valve replacement still remains the standard approach for patients with low to intermediate surgical risk. Transcatheter Aortic Valve Replacement (TAVR) is the alternative for high-risk patients.<sup>2,3</sup>

Currently, TAVR is mainly performed under general anesthesia with tracheal intubation and mechanical ventilation. This technique is justified by the uncertainty linked to a new procedure, to the operator's learning curve, the possible complications and hemodynamic challenges, the necessity of a temporary cardiac immobility during the procedure, and the necessity for intraoperative Transesophageal Echocardiographic (TEE) imaging.<sup>4</sup>

Postoperative pulmonary complications in the elderly population are common after general anesthesia and they are associated with a prolonged hospital stay and an increased mortality rate.<sup>5</sup> Furthermore, avoiding general anesthesia in TAVR has been proved to reduce the overall procedure time and costs and to facilitate patients' mobilization and thus discharge.<sup>6</sup> Noninvasive Ventilation (NIV) has been evaluated in post-cardiac-surgery patients to prevent or treat postoperative acute respiratory failure. It has been increasingly used both in and outside the ICU setting, because it seems to be beneficial for respiratory and cardiovascular function, mainly in the elderly.<sup>7</sup> The Janus mask (Biomedical, Florence, Italy) is a full face mask that provides NIV and is also used for oxygen supplementation during sedation without tracheal intubation with an airtight port that allows TEE examination.



**Figure 1** Side view of the insertion of transesophageal echocardiography probe.

Our main objective in this case series was to evaluate the feasibility of deep inhalational sedation delivered through Janus mask for TAVR with prolonged transesophageal echocardiographic monitoring.

## Methods

After approval by the local research ethics committee and written informed consent was obtained, 5 patients scheduled for TAVR underwent deep sedation with sevoflurane remaining in spontaneous ventilation. All patients received 1.5 mg of midazolam intravenously after placement of venous access in the operating room. Monitoring included electrocardiography, noninvasive arterial blood pressure measurement, pulse oximetry, capnography, and the Bispectral Index (BIS).

All patients underwent inhalational induction with the use of a standard facial mask with a dialed concentration of 2% sevoflurane in 100% oxygen and fresh gas flow of  $6 \text{ L} \cdot \text{min}^{-1}$  for 30 s. The delivered concentration of sevoflurane was then increased to 7% until loss of consciousness, and then reduced to 2% after BIS values dropped below 65. A Guedel cannula was then inserted to keep the airway free with patients always maintained in spontaneous ventilation.

The standard facial mask was then removed and a Janus mask placed. The TEE probe was inserted thereafter through the mask central port (Fig. 1). Deep sedation with spontaneous ventilation was maintained with sevoflurane 0.5% to 2% end-tidal to maintain the BIS values between 40 and 60.

TAVR was performed in the hybrid operating room at Dante Pazzanese Institute of Cardiology, San Paolo, Brazil and high-resolution fluoroscopy, contrast aortography and continuous TEE were used as imaging methods to guide the implantation of the new prosthesis.

After the procedure, all patients were admitted in the ICU. If necessary, noninvasive ventilation was indicated until

**Table 1** Demographic data.

	Sevoflurane/Janus mask ( $n = 5$ )
Age, years	$80 \pm 3.7$
Gender (female), $n$ (%)	3 (60%)
American Society of Anesthesiology physical status (ASA) III, $n$ (%)	5 (100%)
Smoking, $n$ (%)	2 (40%)
Obesity, $n$ (%)	1 (20%)
Diabetes mellitus, $n$ (%)	2 (40%)
Hypertension, $n$ (%)	3 (60%)
Ejection fraction (EF), (%)	$62 \pm 4.6$
Aortic valve area, $\text{cm}^2$	$0.83 \pm 0.15$

Continuous data are expressed as mean and standard deviation ( $m \pm \text{SD}$ ). Count data are shown as number and percentage,  $n$  (%).

complete recovery from anesthesia, with the same mask used during the surgical procedure.

Complications related to the mask use, transesophageal echocardiography accessibility and respiratory perioperative implications to the patients were evaluated.

Data are expressed as mean  $\pm$  standard deviation, or as number and percentage as appropriate.

## Results

In this case series, 5 patients undergoing TAVR were maintained with inhalational deep sedation instead of general anesthesia with tracheal intubation or intravenous sedation.

The patients remained in spontaneous breathing all time and were supported with the new Janus mask, which also allowed performing continuous TEE during the procedure. The administration of sevoflurane through this mask was feasible, effective and with no complication.

Patients' characteristics are presented in Table 1.

All procedures were completed uneventfully, and no major complications were observed intraoperatively or in the ICU unit.

Janus mask was well tolerated by all patients and all TEE examinations were performed successfully. Urgent access to the patient's airway or respiratory management was never required.

One patient had hypercapnia (maximum 50 mmHg) during the procedure but  $\text{CO}_2$  levels were well tolerated with no need for further intervention or clinical repercussions. There were no unplanned conversions to general anesthesia or any need for airway management.

Sevoflurane leakage through the central opening of the mask during the TEE's probe manipulation was noted.

All patients recovered in the ICU unit with noninvasive ventilation for at least one hour with no respiratory complications.

## Discussion

In this report we presented a case series of 5 patients undergoing TAVR under deep sedation with sevoflurane using

prolonged intraoperative TEE through the opening of the full face Janus mask.

General anesthesia with tracheal intubation is associated with significant potential complications, particularly respiratory complications, and high-risk cardiac patients poorly tolerate it. Such patients benefit from minimally invasive anesthetic techniques.<sup>8</sup> Volatile anesthetic agents have been suggested to contribute to myocardial protection through a preconditioning effect on the myocardium and reducing mortality when used in cardiac procedures.<sup>9–11</sup> Sevoflurane is one of the most widely used halogen fluoride volatile anesthetics and it has advantages such as, rapid induction, less airway irritation, quicker recovery and no significant side effects. In this case series the use of sevoflurane was well tolerated with no significant adverse events during induction, maintenance or awakening.<sup>12,13</sup>

Several studies reported the use of intraoperative NIV in patients that are considered high risk for respiratory complications during mechanical ventilation and general anesthesia.<sup>14–17</sup> NIV restores lung volumes by treating atelectasis, increases alveolar ventilation and reduces the work of breathing. NIV can also offer beneficial effects on the cardiovascular function, lowering left ventricle afterload and improving cardiac output.<sup>18</sup> In our study, all patients observed in the ICU unit with NIV with the same mask used intraoperatively, recovered with no respiratory complications.

One problem observed with the use of the Janus mask in these procedures was the gas leakage around the central opening that allows for the TEE's probe insertion and manipulation. This can be a source of room pollution and risk of occupational hazard for the operating room staff due to exposure to volatile agents. The mask allows delivering only 4–5 cm of PEEP (because of leakage around the inserted probe) and should be used as CPAP in spontaneous breathing patients (and not as a full mechanical ventilation).<sup>19</sup> However, in spite of these limitations, it was efficient in keeping all patients unconscious and in spontaneous ventilation during the entire procedure.

Transesophageal echocardiography examination is associated with temporary arterial oxygen tension worsening during and after uncomplicated echo examination, and patients with severe cardiac disease are at risk of developing respiratory failure or serious cardiac arrhythmias under these circumstances. The patient's tolerance to the TEE probe is also a concern in awake patients. Our patients were unconscious and the use of the TEE probe with the Janus mask showed to be easy to combine with no trouble for insertion thought the mask, or for manipulation during the exam. We did not observe any interference with the patient's airway, nor arrhythmias while using the TEE with the Janus mask. Furthermore, the Janus mask may also be placed when the TEE is already ongoing and the probe inserted, to support the patient's ventilation.

In the EuroSTAR registry patients who underwent endovascular aortic aneurysm repair under local or regional anesthesia had significantly lower indices of mortality, morbidity, length of hospital stay, and length of ICU.<sup>18</sup> The use of sedation versus general anesthesia with tracheal intubation has been discussed before and the conclusion was that the decision to perform TAVR under sedation or general anesthesia may ultimately be dictated by the experience of the

Heart Team and local hospital policy since that are no data available from randomized trials comparing the technics.<sup>20</sup>

TAVR procedures are occurring with increasing frequency. Some authors believe that in the near future a shift will be seen from surgical valve replacement to transcatheter valve replacement when intervention for AS is required.<sup>21</sup> Anesthesiologists are ready to offer all the available monitoring while maintaining patients' comfort.

## Conclusion

The benefits of sedation should be weighed against the risk of an uncontrolled airway and hemodynamic compromise or procedural complications when choosing between that technique and general anesthesia with tracheal intubation for TAVR. Inhalational anesthesia maintenance with the Janus mask seems to have efficient profile that has the potential to avoid the complications of general anesthesia with tracheal intubation while allowing continuous and comfortable TEE examination. Preventing respiratory complications and improving cardiovascular function during and after the procedure might be another benefit from this alternative technique. Randomized controlled clinical trials data in the future might shed a light whether sedation or general anesthesia is the best anesthetic approach to TAVR procedures.

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## Conflicts of interest

The authors declare no conflicts of interest.

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