

Noninvasive Ventilation during Left Atrial Appendage Closure under Sedation: Preliminary Experience with the Janus Mask

Abstract

Background: Percutaneous left atrial appendage occlusion (LAAO) is indicated in subjects with atrial fibrillation who cannot receive oral anticoagulants. This procedure requires transesophageal echocardiography guidance and is usually performed under general anesthesia. The Janus Mask is a new device designed to allow upper endoscopic procedures during noninvasive ventilation (NIV). **Aims:** This study aims to assess the possibility of performing LAAO under sedation and NIV. **Setting:** Cardiac electrophysiology laboratory. **Design:** Case-control study. **Materials and Methods:** Data from 11 subjects undergoing LAAO under sedation and NIV with the Janus Mask were retrospectively collected. Procedure duration, outcomes, and physicians' satisfaction were compared with those of 11 subjects who underwent LAAO under general anesthesia in the same period. **Statistical Analysis:** Univariate analysis and analysis of variance for between-groups comparison. **Results:** The 11 subjects treated with sedation experienced a good outcome, with a high degree of satisfaction from the medical team. An increase in arterial partial pressure of carbon dioxide in the Janus group (45 [43–62] mmHg vs. 33 [30–35] mmHg in the general anesthesia group, $P < 0.001$) led to a transient pH decrease 45 min after the beginning of the procedure (7.30 [7.18–7.36] vs. 7.40 [7.39–7.46], $P = 0.014$). No differences in arterial partial pressure of oxygen, FiO_2 , and hemodynamic parameters were observed. The subjects' conditions at discharge from the recovery room were comparable. No difference in procedure duration was registered. **Conclusions:** LAAO procedure under sedation and NIV through the Janus Mask is safe and feasible. This strategy might represent a valuable alternative to manage such a compromised and fragile population.

Keywords: Anesthesia, endoscopy, Janus mask, noninvasive ventilation, sedation

Introduction

Atrial fibrillation (AF) is among the most widespread cardiac arrhythmias, with a lifetime development risk of 26% in men and 23% in women, and is a well-known risk factor for embolic stroke.^[1,2] As most of the embolic thrombi in AF patients develop in the left atrial appendage (LAA), percutaneous LAA occlusion (LAAO) is a valuable strategy to prevent stroke in patients with contraindications to lifelong oral anticoagulant therapy.^[3,4]

During LAAO, intraprocedural transesophageal echocardiography (TEE) is performed in all patients on a routine basis to guide the transseptal puncture^[5] and to have a full view of the LAA, which is needed to obtain accurate measurements.^[3,6]

As TEE assessment and immobility of the patients are key factors to the success

and safety of the procedure, LAAO is usually performed under general anesthesia.^[6] Unfortunately, patients undergoing LAAO are frequently old, frail and with several comorbidities. All these factors increase the risks of complications of general anesthesia, including pulmonary complications and cognitive decline.^[7,8] Furthermore, LAAO is often performed in the cardiac catheterization laboratory, where the presence of anesthesiologists and other personnel qualified to perform general anesthesia is not always granted or possible.^[9,10] Therefore, the possibility of undergoing LAAO without performing general anesthesia is particularly attractive.

The Janus Mask (Biomedical Srl; Florence, Italy) [Figure 1] is a device designed to permit endoscopic procedures on airways or upper gastrointestinal tract during noninvasive ventilation (NIV).^[11–17]

The aim of this preliminary double-cohort study was to compare procedural and

Alberto Zangrillo^{1,2},
 Patrizio Mazzone³,
 Alessandro Oriani¹,
 Marina Pieri¹,
 Giovanna Frau¹,
 Giuseppe
 D'Angelo³,
 Chiara Sartini¹,
 Riccardo Capucci¹,
 Alessandro Belletti¹,
 Paolo Della Bella³,
 Fabrizio Monaco¹

¹Department of Anesthesia and Intensive Care, IRCCS San Raffaele Scientific Institute, ²Vita-Salute San Raffaele University, ³Department of Cardio-Thoracic-Vascular, Arrhythmology and Electrophysiology Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy

Address for correspondence:
 Dr. Fabrizio Monaco,
 Department of Anesthesia and Intensive Care, IRCCS San Raffaele Scientific Institute,
 Via Olgettina 60, Milan, Italy.
 E-mail: monaco.fabrizio@hsr.it

Access this article online

Website: www.annals.in

DOI: 10.4103/aca.ACA_145_18

Quick Response Code:



How to cite this article: Zangrillo A, Mazzone P, Oriani A, Pieri M, Frau G, D'Angelo G, *et al.* Noninvasive ventilation during left atrial appendage closure under sedation: Preliminary experience with the Janus Mask. *Ann Card Anaesth* 2019;22:400-6.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

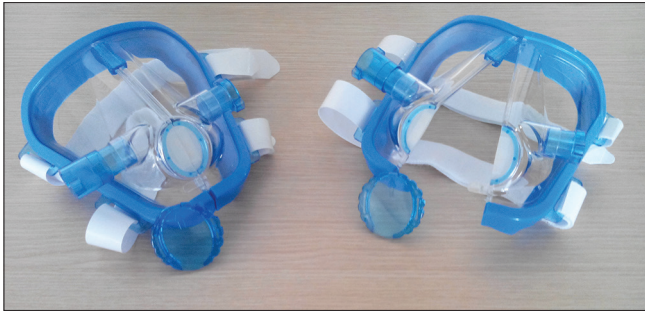


Figure 1: The Janus Mask device closed for use (left) and open for positioning (right)

clinical outcomes of patients undergoing LAAO with sedation and ventilatory support through the Janus Mask with a standard management including general anesthesia.

Materials and Methods

We performed a retrospective study of all subjects undergoing LAAO at a tertiary care university hospital from November 2015 to October 2016.

All subjects signed a consent allowing for scientific data management. Ethical Committee Approval was waived for this retrospective study according to the Italian law (Art. 20–21, DL 196/2003; <http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1115480>, published in *Giornale Ufficiale* no. 190 of August 14, 2004). The present study is in compliance with the Helsinki Declaration.

The inclusion criteria were scheduled procedure, written informed consent for anesthesia and procedure, and age ≥ 18 years. No exclusion criteria for the study were present. However, subjects with contraindications to NIV were obviously not selected for NIV.

Clinical records were reviewed, and demographic data, clinical parameters, medical history, and perioperative data were collected for all subjects.

Arterial cannulation for invasive blood pressure monitoring and blood sampling was performed before induction of anesthesia/sedation. Invasive blood pressure, electrocardiography, and pulse oximetry (SpO_2) were continuously monitored during the procedure. Arterial partial pressure of oxygen (PaO_2) and carbon dioxide ($PaCO_2$), pH, blood bicarbonate and lactate levels were measured at T_0 , after 15 and 45 min from induction of anesthesia (T_{15} , T_{45} respectively), and before discharge from the recovery room. Hemodynamic data were recorded from anesthesia charts at the same time points.

In the sedation plus Janus mask group (Janus group), induction was performed with fentanyl (0.5 $\mu\text{g}/\text{kg}$) and propofol (1 mg/kg); sedation was then maintained with continuous infusion of propofol (starting dose 3 mg/kg/h, titrated to maintain adequate operative conditions and

spontaneous ventilation) and remifentanyl (0.05 $\mu\text{g}/\text{kg}/\text{min}$). The Janus mask was positioned on patient's face after insertion of the TEE probe without the necessity of removing it. Spontaneous ventilation was maintained and assisted with a positive end-expiratory pressure of 5 mmHg with an initial oxygen inspiratory fraction of 0.5.

Subjects undergoing LAAO under general anesthesia (control group) were administered fentanyl (1–2 $\mu\text{g}/\text{kg}$), midazolam (0.1 mg/kg), propofol (1–2 mg/kg), and rocuronium (0.6 mg/kg) at induction; then anesthesia was maintained with sevoflurane (target minimum alveolar concentration above 0.7). All subjects in the control group underwent endotracheal intubation and received protective mechanical ventilation (target $PaO_2 > 80$ mmHg and $PaCO_2$ 35–45 mmHg).

The decision to use Janus mask or perform LAAO under general anesthesia with endotracheal intubation was at the discretion of attending physicians and based on clinical judgment and subjects' preference.

All subjects were monitored in a recovery room following procedure. Modified Aldrete's Score was calculated before discharge from the recovery room.^[18]

Anesthesiologist and surgeon's satisfaction was assessed with a 5-point score (from 0 to 5), where 0 indicates the lowest satisfaction degree and 5 the best-operating conditions.

Statistical analysis

All data were stored in an electronic database. Categorical data were univariately analyzed with a Chi-square test when the minimum number of observations in a category was > 5 ; otherwise, the Fisher's exact test was used. Student's *t*-test was used to analyze continuous variables that had normal distribution, while the Mann–Whitney U-test was used for variables that had nonnormal distribution. Dichotomous and categorical variables were expressed as numbers and percentages, while continuous variables were expressed as means \pm standard deviations in case of normal distribution, or median and interquartile range in case of nonnormal distribution. $P < 0.05$ was considered statistically significant. Analysis of variance (ANOVA) was also performed to assess differences between groups.

Results

A total of 22 subjects underwent LAAO during the study and are included in the analysis. Eleven subjects underwent the procedure under NIV and sedation (Janus group), while the other 11 received general anesthesia (control group). Baseline parameters [Table 1] and preoperative medical therapy [Table 2] were comparable between the two groups. Preoperative echocardiographic data are shown in Table 3, together with the most relevant comorbidities. All subjects were > 65 years old and were predominantly

Table 1: Patients characteristics at baseline

	Control group (n=11)	Janus group (n=11)	P
Age (years)	75±6.4	79±5.1	0.20
Sex (male)	8 (73)	6 (55)	0.70
Height (cm)	165±9.9	165±7.3	0.90
Weight (kg)	79±16.9	74±13.4	0.50
Systolic blood pressure (mmHg)	147±22.9	170±36.7	0.09
Diastolic blood pressure (mmHg)	73±10.6	79±14.9	0.30
Heart rate (beats/min)	73±16.3	77±17.1	0.60
SpO ₂ in room air (%)	97±2.1	98±2.5	0.80
Hemoglobin (g/dL)	12±1.5	13±2.1	0.08
Hematocrit (%)	39±3.2	42±5.4	0.10
Platelet count (×10 ³ /μL)	204±63.1	239±74.1	0.20
International normalized ratio	1.15 (1.08-2.18)	1.10 (1.03-1.61)	0.30
Activated partial thromboplastin time (ratio)	1.08 (1.01-1.17)	1.04 (0.99-1.16)	0.60
Alanine aminotransferase (UI/L)	22 (20-22)	23 (14-45)	0.90
Aspartate aminotransferase (UI/L)	25 (22-30)	25 (18-31)	0.70
Sodium (mEq/L)	149±31.0	141±2.5	0.40
Potassium (mEq/L)	4.5±0.47	4.3±0.49	0.20
pH	7.44 (7.42-7.48)	7.42 (7.41-7.43)	0.20
PaO ₂ (mmHg)	77 (72-113)	72 (68-87)	0.50
PaCO ₂ (mmHg)	35.6 (31.8-37.0)	37.8 (33.8-42.0)	0.40
HCO ₃ (mmol/L)	23.7 (20.9-24.5)	23.7 (21.6-26.0)	0.60
Lactate (mmol/L)	1.16 (0.72-1.18)	1.13 (1.04-1.34)	0.50

Data reported as: mean±SD, n (%), median (IQR). HCO₃: Arterial bicarbonate, PaO₂: Arterial partial oxygen tension, PaCO₂: Arterial partial carbon dioxide tension, SpO₂: Peripheral arterial oxygen saturation, SD: Standard deviation, IQR: Interquartile range

Table 2: Patients' chronic medical therapy

	Control group (n=11)	Janus group (n=11)	P
Beta-blockers	7 (64)	8 (73)	0.90
Angiotensin converting enzyme inhibitors	4 (36)	6 (55)	0.70
Loop diuretics	7 (64)	7 (64)	0.90
Antiarrhythmics	4 (36)	3 (27)	0.90
Digoxin	1 (9.1)	2 (18)	0.90
Statins	4 (36)	2 (18)	0.60
Acetylsalicylic acid	6 (55)	3 (27)	0.40
Other antiplatelet agents	5 (45)	2 (18)	0.40
Vitamin K antagonists	2 (18)	3 (27)	0.90
New oral anticoagulants	2 (18)	5 (45)	0.40
Low molecular weight heparin	4 (36)	4 (36)	0.90
Other cardiovascular agents	6 (55)	3 (27)	0.40

Data reported as: n (%)

men with mild or moderate mitral regurgitation and on beta-blocker therapy. Two patients had secondary moderate mitral regurgitation, while all other patients had primary mitral regurgitation.

Outcome data are presented in Table 4. A transient increase in PaCO₂ in Janus group observed 15 and 45 min ($P = 0.01$ and <0.001 , respectively) after the start of sedation and led to a respiratory acidosis [Table 4]. No difference in lactate

levels or bicarbonate between groups was noted and PaCO₂ and pH were comparable after the end of the procedure. The difference in pH and PaCO₂ level between the two groups was further confirmed with ANOVA ($P = 0.006$ and $P = 0.003$, respectively).

There was no difference in SpO₂ and PaO₂ between groups at the time of discharge from the recovery room.

The modified Aldrete's score before discharge from the recovery room was similar in the Janus and control group. All subjects were transferred to the general cardiology ward after discharge from the recovery room.

Three subjects of the Janus group had an episode of transient apnea during the procedure, which quickly resolved after reduction of the level of sedation. No other complication was recorded.

A comparable satisfaction degree was recorded in the two groups both from anesthesiologists' and operators' perspective [Table 4].

Discussion

In this retrospective study, we described the feasibility of LAAO procedure without performing general anesthesia, based on intravenous sedation and a special mask (Janus mask) designed for NIV during continuous transesophageal echocardiography. No difference in heart rate, systolic/diastolic blood pressure, respiratory, and metabolic

Table 3: Patients' comorbidities and baseline echocardiographic data

	Control group (n=11)	Janus group (n=11)	P
Comorbidities			
Dementia	1 (9.1)	2 (18)	0.90
Connective tissue disease	1 (9.1)	0 (0.0)	0.90
Diabetes	5 (45)	4 (36)	0.90
With organ damage	2 (18)	1 (9.1)	0.90
Mild liver dysfunction	0 (0.0)	1 (9.1)	0.90
Moderate-severe liver dysfunction	0 (0.0)	1 (10)	0.50
Cerebrovascular disease	3 (27)	5 (45)	0.70
Chronic obstructive pulmonary disease	2 (18)	2 (18)	0.90
Peptic ulcer	1 (9.1)	0 (0.0)	0.90
Cancer	2 (18)	2 (20)	0.90
Echocardiographic parameters			
Ejection fraction (%)	46 (30-55)	56 (50-60)	0.20
Mitral regurgitation			
Absent	3 (27)	4 (36)	0.90
Mild	5 (45)	4 (36)	
Moderate	3 (27)	3 (27)	
Severe	0 (0)	0 (0)	
Aortic stenosis			
Absent	10 (91)	11 (100)	0.30
Mild	1 (9.1)	0 (0.0)	
Moderate	0 (0)	0 (0)	
Severe	0 (0)	0 (0)	
Aortic regurgitation			
Absent	9 (82)	9 (82)	0.50
Mild	1 (9.1)	2 (18)	
Moderate	1 (9.1)	0 (0.0)	
Severe	0 (0)	0 (0)	
Tricuspid regurgitation			
Absent	7 (64)	8 (73)	0.60
Mild	1 (9.1)	2 (18)	
Moderate	2 (18)	1 (9.1)	
Severe	1 (9.1)	0 (0.0)	

Data reported as: *n* (%) or median (IQR). IQR: Interquartile range

parameters was found at the end of the procedure, while a transient respiratory acidosis was observed in the Janus group. The same grade of physicians' satisfaction was obtained in the two groups.

Sedation with lower doses of intravenous anesthetics and/or opioid analgesics may provide adequate operative conditions without requiring endotracheal intubation and mechanical ventilation.^[19] We believe that the maintenance of spontaneous breathing has several advantages over general anesthesia. Indeed, sedation avoids first the hemodynamic derangements following administration of general anesthetics and opioids; second, the need of endotracheal intubation which is an invasive maneuver with potential risks and complications; third, the administration

of neuromuscular blocking agents which may impair the respiratory function and lead to postoperative residual curarization. In addition, compared to general anesthesia, sedation allows for a reduction in the total dose of anesthetics administered with potential advantages on the incidence of postoperative delirium and cognitive dysfunction.^[20] However, this anesthetic management strategy carries the risk of respiratory depression and hypoxia. Unfortunately, this risk is higher in these patients due to the same conditions which increases the risk associated with general anesthesia. Furthermore, hypoxic events may themselves be particularly detrimental in these patients who frequently have cardiovascular and cerebral comorbidities. The combination of sedation with NIV is an interesting alternative.^[21-25] However, the current NIV masks do not allow for insertion of a TEE probe (which is usually required for LAO procedures) unless hand-made modifications of the mask are performed (e.g., by creating a hole with a surgical cutter) or complex adjustments with equipment are made.^[26] For this reason, we used the innovative Janus Mask device specifically designed to allow upper endoscopies during NIV support to overcome this issue.^[11]

To the best of our knowledge, only one case-series describing LAO under conscious sedation has been published so far.^[27] Chan *et al.* describe their experience in 11 subjects undergoing LAO under sedation with fentanyl and midazolam, and report no major complications following the procedure. In contrast to our study, they did not provide a comparison with subjects undergoing LAO under general anesthesia. In addition, subjects described in their study are younger, with a lower prevalence of comorbidities and better cardiac function (as reflected by the higher mean ejection fraction) as compared with those enrolled in our study.^[27]

Our group recently published a case-series of three subjects undergoing LAO under sedation and NIV with Janus mask, reporting for the first time feasibility of this approach.^[13] In the current manuscript, we report for the first time a case-control study including a comparison with a group receiving general anesthesia (which is standard of care), and we expanded our case-series to a total of 11 subjects. Our preliminary experience suggests that sedation and ventilator support with the Janus mask may be an interesting alternative strategy to general anesthesia for LAO procedures. Therefore, this less invasive management strategy is extremely promising in such a fragile population. However, in our case-series, respiratory acidosis and one case of transient apnea occurred. Although this did not result in a worse outcome in our population, it highlights that close monitoring is required when performing sedation in high-risk patients, as the occurrence of these complications might jeopardize advantages of sedation over general anesthesia. In addition, the risk of aspiration of gastric content should always be considered before proceeding with

Table 4: Hemodynamic and outcome data

	Control group (n=11)	Janus group (n=11)	P
Length of procedure (min)	60 (55-60)	70 (59-72)	0.08
Time spent by patients in the operating room (min)	112 (100-120)	112 (75-133)	0.90
Systolic blood pressure			
After 15 min (mmHg)	100 (90-110)	110 (90-142)	0.21
After 45 min (mmHg)	110 (90-114)	130 (100-136)	0.08
Before RR discharge (mmHg)	130 (120-140)	134 (115-151)	0.60
Diastolic blood pressure			
After 15 min (mmHg)	60 (50-60)	60 (50-73)	0.60
After 45 min (mmHg)	60 (60-65)	60 (60-70)	0.50
Before RR discharge (mmHg)	70 (65-75)	65 (57-75)	0.50
Heart rate			
After 15 min (bpm)	69 (59-80)	69 (61-80)	0.90
After 45 min (bpm)	65 (61-80)	75 (60-82)	0.80
Before RR discharge (bpm)	64 (60-80)	78 (64-92)	0.50
PaO ₂ /FiO ₂ ratio			
After 15 min	198 (194-200)	196 (100-283)	0.90
After 45 min	196 (162-200)	100 (100-252)	0.60
Before RR discharge	448 (249-464)	460 (199-470)	0.50
pH			
After 15 min	7.42 (7.40-7.45)	7.34 (7.26-7.37)	0.02
After 45 min	7.40 (7.39-7.46)	7.30 (7.18-7.36)	0.001
Before RR discharge	7.37 (7.35-7.41)	7.39 (7.35-7.40)	0.90
PaCO ₂			
After 15 min (mmHg)	35 (33-38)	47 (39-59)	0.01
After 45 min (mmHg)	33 (30-35)	45 (43-62)	<0.001
Before RR discharge (mmHg)	36 (35-41)	39 (35-45)	0.80
Blood bicarbonate			
After 15 min (mmol/L)	24.0 (21.0-24.0)	25.0 (22.0-26.0)	0.30
After 45 min (mmol/L)	21.4 (21.1-22.2)	23.1 (21.7-25.0)	0.10
Before RR discharge (mmol/L)	22.4 (19.5-22.7)	23.0 (20.6-26.4)	0.20
Blood lactate			
After 15 min (mmol/L)	1.04 (0.75-1.09)	1.08 (0.77-1.26)	0.50
After 45 min (mmol/L)	0.98 (0.91-1.21)	0.95 (0.85-0.96)	0.20
Before RR discharge (mmol/L)	0.91 (0.89-1.07)	1.05 (0.99-1.05)	0.40
Modified Aldrete's score before RR discharge	10 (9-10)	10 (8-10)	0.60
Surgeon satisfaction			
0 - not sufficient	0 (0.0)	0 (0.0)	0.70
1 - poor	0 (0.0)	0 (0.0)	
2 - sufficient	0 (0.0)	1 (9.1)	
3 - intermediate	1 (9.1)	1 (9.1)	
4 - very good	1 (9.1)	2 (18)	
5 - excellent	9 (82)	7 (64)	
Anaesthetist satisfaction (0 - poor; 5 - excellent)			
0 - not sufficient	0 (0.0)	0 (0.0)	0.10
1 - poor	0 (0.0)	0 (0.0)	
2 - sufficient	1 (9.1)	0 (0.0)	
3 - intermediate	0 (0.0)	3 (27)	
4 - very good	1 (9.1)	3 (27)	
5 - excellent	9 (82)	5 (45)	
Postprocedural hospital LOS (days)	3 (2-5.5)	2 (2-3)	0.10

Data reported as n (%) or median (IQR). IQR: Interquartile range, FiO₂: Inspired oxygen fraction, PaO₂: Arterial partial oxygen tension, PaCO₂: Arterial partial carbon dioxide tension, RR: Recovery room, SpO₂: Peripheral arterial oxygen saturation, LOS: Length of stay

sedation, and adherence to recommended preprocedural fasting periods should be closely checked.

Specific equipment is required whenever a general anesthesia is performed. On the contrary, the management

of the patient with sedation and periprocedural NIV with the Janus Mask may be more suitable even in the absence of these conditions and in a hybrid operating room settings.

Moreover, sedation has been associated with increased efficiency and reduced hospital length of stay compared with general anesthesia in patients undergoing transcatheter aortic valve implantation^[28-30] and MitraClip implantation.^[19] Furthermore, the Janus mask may be useful in other clinical setting where another kind of endoscopic procedure is required for a long period or in fragile patients, such as certain gastrointestinal endoscopic procedures.^[23]

Notably, need to urgently convert sedation to general anesthesia may always occur. Therefore, we believe that trained personnel and equipment to administer general anesthesia should always be readily available. Luckily, no need for emergency induction of general anesthesia occurred in our case-series. However, the sample size might have been too small to adequately assess this issue. Furthermore, nonanesthesiologists are not allowed to perform sedation at our institution, and this may have limited the possibility to develop this complication. However, we acknowledge that this might not be worldwide standard of care.^[9,31]

Accordingly, an appropriately designed randomized controlled trial with clinically relevant endpoints is necessary to confirm our findings concerning both safety and efficacy.^[32] A strength of the study is that no specific safety issues arose with the use of the Janus mask, confirming preliminary data on the feasibility of such approach even in fragile patients.^[11]

This study has several limitations. First, the sample size is small, and the study was not powered; however, it should be noticed that our manuscript reports data of the largest case series available on this topic. We cannot exclude that enrolling a larger sample size of more compromised patients could lead to significant differences between groups. Second, the allocation of the subject to a specific treatment was not randomized; however, the two populations were comparable at baseline. We acknowledge that selection bias may nevertheless be present. However, we believe that an individualized management strategy tailored to the patient's characteristics is critical when managing severely compromised patients, and our results support this view. Third, no reduction in the time spent by the subjects in the Janus group in the operating room was found when compared to the general anesthesia group; nonetheless, we speculate that the routine use of the Janus mask can reduce the duration and the costs of LAAO procedures since the equipment and costs related to general anesthesia are avoided, while procedural time tends to become shorter with growing experience.^[33] We did not record length of stay in the postanesthesia care unit as in our institution this period is frequently prolonged for a logistical reason and might be misleading for the meaning of this study. Finally, we used a very simple scale to grade

operators' satisfaction. We acknowledge that using a more complex scale (e.g., a Likert scale) could have yielded results that are more precise.

Conclusions

We have shown that sedation and NIV through the Janus mask is a feasible anesthesiological strategy for patients undergoing LAAO procedure, as it was not inferior to standard general anesthesia management in a preliminary case-control study. Further large randomized studies are needed to confirm this preliminary evidence.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

- Morin DP, Bernard ML, Madias C, Rogers PA, Tihanolipavan S, Estes NA 3rd, *et al.* The state of the art: Atrial fibrillation epidemiology, prevention, and treatment. *Mayo Clin Proc* 2016;91:1778-810.
- Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, *et al.* 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur Heart J* 2016;37:2893-962.
- Regazzoli D, Ancona F, Trevisi N, Guarracini F, Radinovic A, Oppizzi M, *et al.* Left atrial appendage: Physiology, pathology, and role as a therapeutic target. *Biomed Res Int* 2015;2015:205013.
- Figini F, Mazzone P, Regazzoli D, Porata G, Ruparella N, Giannini F, *et al.* Left atrial appendage closure: A single center experience and comparison of two contemporary devices. *Catheter Cardiovasc Interv* 2017;89:763-72.
- Radinovic A, Mazzone P, Landoni G, Agricola E, Regazzoli D, Bella PD, *et al.* Different transseptal puncture for different procedures: Optimization of left atrial catheterization guided by transesophageal echocardiography. *Ann Card Anaesth* 2016;19:589-93.
- Mitreva L, Trautman N, Vadlamudi R, Desai N, Sabir SA. Anesthesia and transesophageal echocardiography for WATCHMAN device implantation. *J Cardiothorac Vasc Anesth* 2016;30:1685-92.
- Miskovic A, Lumb AB. Postoperative pulmonary complications. *Br J Anaesth* 2017;118:317-34.
- Qiao Y, Feng H, Zhao T, Yan H, Zhang H, Zhao X, *et al.* Postoperative cognitive dysfunction after inhalational anesthesia in elderly patients undergoing major surgery: The influence of anesthetic technique, cerebral injury and systemic inflammation. *BMC Anesthesiol* 2015;15:154.
- Gaitan BD, Trentman TL, Fassett SL, Mueller JT, Altemose GT. Sedation and analgesia in the cardiac electrophysiology laboratory: A national survey of electrophysiologists investigating the who, how, and why? *J Cardiothorac Vasc Anesth* 2011;25:647-59.
- Hamid A. Anesthesia for cardiac catheterization procedures. *Heart Lung Vessel* 2014;6:225-31.
- Cabrini L, Landoni G. A novel non-invasive ventilation mask to prevent and manage respiratory failure during fiberoptic bronchoscopy, gastroscopy and transesophageal echocardiography. *Heart Lung Vessel* 2015;7:297-303.
- Cabrini L, Savia MD, Bevilacqua MD, Votta C, Filippini MD, Landoni MD, *et al.* Continuous positive airway pressure during upper endoscopies: A bench study on a novel device. *J Cardiothorac Vasc Anesth* 2016;30:e43-5.
- Zangrillo A, Mazzone P, Votta CD, Villari N, Della Bella P, Monaco F,

- et al.* Prolonged transesophageal echocardiography during percutaneous closure of the left atrial appendage without general anesthesia: The utility of the Janus mask. *Can J Anaesth* 2016;63:962-5.
14. Pieri M, Sardo S, Votta CD, Frau G, Oriani A, Zangrillo A, *et al.* Improving fiberoptic intubation in the conscious patient using the new Janus mask. *Med Intensiva* 2018;42:196-8.
 15. Bove T, Votta CD, Ciriaco P, Pappalardo F, Oriani A, Frau G, *et al.* Bronchoscopy during non-invasive ventilation in a patient with acute respiratory distress syndrome. *Signa Vitae* 2017;13:103-4.
 16. Monaco F, Vitiello C, Guarracino F. Beyond high-flow oxygen therapy to manage the hazards of intubation and prevent desaturation. *Minerva Anesthesiol* 2017;83:998-9.
 17. Neto CN, Costa ED, Bezerra FJ, Ruy MS, Saurith JL, Viesi JH, *et al.* Inhalational anesthesia maintenance with the Janus facial mask for transcatheter aortic-valve replacement: A case series. *Rev Bras Anesthesiol* 2018;68:437-41.
 18. Aldrete JA. The post-anesthesia recovery score revisited. *J Clin Anesth* 1995;7:89-91.
 19. de Waha S, Seeburger J, Ender J, Desch S, Eitel I, Reinhardt A, *et al.* Deep sedation versus general anesthesia in percutaneous edge-to-edge mitral valve reconstruction using the mitraclip system. *Clin Res Cardiol* 2016;105:535-43.
 20. Aldecoa C, Bettelli G, Bilotta F, Sanders RD, Audisio R, Borozdina A, *et al.* European society of anaesthesiology evidence-based and consensus-based guideline on postoperative delirium. *Eur J Anaesthesiol* 2017;34:192-214.
 21. Guarracino F, Cabrini L, Baldassarri R, Cariello C, Covello RD, Landoni G, *et al.* Non-invasive ventilation-aided transoesophageal echocardiography in high-risk patients: A pilot study. *Eur J Echocardiogr* 2010;11:554-6.
 22. Guarracino F, Cabrini L, Baldassarri R, Petronio S, De Carlo M, Covello RD, *et al.* Noninvasive ventilation for awake percutaneous aortic valve implantation in high-risk respiratory patients: A case series. *J Cardiothorac Vasc Anesth* 2011;25:1109-12.
 23. Beccaria P, Votta CD, Lucchetta L, Silvetti S, Agostoni M, Zangrillo A, *et al.* Two different endoscopic procedures made feasible by the Janus mask in a high-risk patient. *Indian J Crit Care Med* 2017;21:613-5.
 24. Pieri M, Landoni G, Cabrini L. Noninvasive ventilation during endoscopic procedures: Rationale, clinical use, and devices. *J Cardiothorac Vasc Anesth* 2018;32:928-34.
 25. Pieri M, Cabrini L, Landoni G. Preventing intubation-related cardiac arrest in ICU: A promising new ventilation mask. *Crit Care Med* 2018;46:e715.
 26. Cabrini L, Nobile L, Cama E, Borghi G, Pieri M, Bocchino S, *et al.* Non-invasive ventilation during upper endoscopies in adult patients. A systematic review. *Minerva Anesthesiol* 2013;79:683-94.
 27. Chan NY, Lau CL, Tsui PT, Lo YK, Mok NS. Experience of left atrial appendage closure performed under conscious sedation. *Asian Cardiovasc Thorac Ann* 2015;23:394-8.
 28. Miles LF, Joshi KR, Ogilvie EH, Densem CG, Klein AA, O'Sullivan M, *et al.* General anaesthesia vs. conscious sedation for transfemoral aortic valve implantation: A single UK centre before-and-after study. *Anaesthesia* 2016;71:892-900.
 29. Maas EH, Pieters BM, Van de Velde M, Rex S. General or local anesthesia for TAVI? A systematic review of the literature and meta-analysis. *Curr Pharm Des* 2016;22:1868-78.
 30. Toppen W, Johansen D, Sareh S, Fernandez J, Satou N, Patel KD, *et al.* Improved costs and outcomes with conscious sedation vs. general anesthesia in TAVR patients: Time to wake up? *PLoS One* 2017;12:e0173777.
 31. Dumonceau JM, Riphaut A, Schreiber F, Vilmann P, Beilenhoff U, Aparicio JR, *et al.* Non-anesthesiologist administration of propofol for gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy nurses and associates guideline—updated June 2015. *Endoscopy* 2015;47:1175-89.
 32. Greene CJ, Morland LA, Durkalski VL, Frueh BC. Noninferiority and equivalence designs: Issues and implications for mental health research. *J Trauma Stress* 2008;21:433-9.
 33. D'Ancona G, Pasic M, Unbehaun A, Dreysse S, Drews T, Buz S, *et al.* Transapical aortic valve implantation: Learning curve with reduced operating time and radiation exposure. *Ann Thorac Surg* 2014;97:43-7.