ORIGINAL ARTICLE

Efficacy and Safety of Transfemoral Transcatheter Aortic Valve Replacement under General Anesthesia versus Local Anesthesia with Conscious Sedation

Eficacia y seguridad del implante valvular aórtico percutáneo por vía transfemoral bajo anestesia general vs. anestesia local más sedación consciente

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ABSTRACT

Background: Currently, there is no consensus about the most adequate anesthetic management in transfemoral transcatheter aortic valve replacement. Although it has been shown that local anesthesia (LA) with or without conscious sedation is feasible, clinical results are controversial.
Objective: The aim of this study was to evaluate the safety and efficacy of transfemoral transcatheter aortic valve replacement performed under general anesthesia versus local anesthesia with conscious sedation.
Methods: This was a single-center, retrospective study of high risk patients with severe aortic stenosis undergoing transfemoral transcatheter aortic valve replacement between March 2009 and December 2016. The population was divided according to anesthetic management. Safety and efficacy outcomes were evaluated at 30-days and were classified according to definitions of the Valve Academic Research Consortium-2. In addition, key times during hospitalization were evaluated.
Results: A total of 121 patients undergoing transfemoral transcatheter aortic valve replacement under general anesthesia (n=55, 45.5%) or local anesthesia with conscious sedation (n=66, 54.5%). were included in this analysis. Mean age was 83.2±5.7 years and 48.8% were men. There were no differences in either the procedural result or in the 30-day efficacy and safety outcomes. The rate of death at 30-days was 7.3% in the group with general anesthesia and 3% in the local anesthesia with conscious sedation group (log-rank p 0.28). The need of conversion to general anesthesia was 3% (2 patients), in all cases due to major vascular complications during the procedure. In the local anesthesia with conscious sedation group shorter procedural time, intensive care unit and hospital length of stay were observed.
Conclusions: Transfemoral transcatheter aortic valve replacement performed under local anesthesia with conscious sedation seems to be a safe and effective alternative to the use of general anesthesia.

Key words: Aortic stenosis - Transcatheter aortic valve replacement - General anesthesia - Local anesthesia.

RESUMEN

Introducción: Actualmente no hay consenso sobre el manejo anestésico más adecuado en el implante valvular aórtico percutáneo por vía transfemoral. Aunque se ha demostrado la factibilidad de concretar el procedimiento bajo anestesia local con sedación consciente o sin esta, los resultados clínicos reportados son controvertidos.
Objetivos: Evaluar la seguridad y eficacia del implante valvular aórtico percutáneo por vía transfemoral realizado bajo anestesia general versus anestesia local con sedación consciente.
Material y métodos: Análisis unicéntrico y retrospectivo de los pacientes con estenosis aórtica grave sintomática con alto riesgo quirúrgico sometidos a un implante valvular aórtico percutáneo por vía transfemoral desde marzo de 2009 a diciembre de 2016, según el manejo anestésico. Los desenlaces de seguridad y eficacia fueron evaluados a 30 días según las definiciones del Valve Academic Research Consortium-2. Además, se evaluaron los principales tiempos durante la internación.
Resultados: Se incluyeron 121 pacientes (Edad 83,2 ± 5,7 años, hombres 48,8%), tratados con un implante valvular aórtico percutáneo por vía transfemoral bajo anestesia general (n = 55, 45,5%) o anestesia local con sedación consciente (n = 66, 54,5%). No se observaron diferencias significativas en los resultados intraprocedimiento ni en los desenlaces de seguridad y eficacia a 30 días. La mortalidad a 30 días fue del 7,3% en el grupo AG y del 3% en el grupo anestesia local con sedación consciente 3%, p log-rank 0,28 (mortalidad global 5%). La necesidad de conversión a anestesia general se presentó en 2 pacientes (3%), por complicaciones vasculares mayores durante el procedimiento. El grupo anestesia local con sedación consciente presentó menor tiempo total de procedimiento, internación en unidad de cuidados intensivos e internación total.
Conclusión: El implante valvular aórtico percutáneo por vía transfemoral realizado bajo anestesia local con sedación consciente, parece ser una alternativa segura y eficaz al uso de anestesia general.

Palabras claves: Estenosis aórtica - Implante valvular aórtico percutáneo - Anestesia general - Anestesia local

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Abbreviations

AoR	Aortic regurgitation	**TEE**	Transesophageal echocardiography
GA	General anesthesia	**(TF-TAVR).**	Transfemoral Transcatheter Aortic Valve Replacement
LA	Local anesthesia	**TTE**	Transthoracic echocardiography
LA+CS	Local anesthesia with conscious sedation		

INTRODUCTION

Since its origin, (1) percutaneous aortic valve replacement (TAVR) underwent numerous modifications until it became a safe and effective treatment with predictable results in high surgical risk patients with symptomatic severe aortic stenosis. (2-4) Currently, it presents universally accepted indications and is a new therapeutic tool in the usual cardiologic practice. (5) Transfemoral transcatheter aortic valve replacement (TF-TAVR) represents the approach of choice, due to the greater technical simplicity and the better results reported compared with other access routes. (6)

However, there are controversies regarding the most appropriate procedural method. Initially, percutaneous aortic valve replacement was performed under general anesthesia (GA), with surgical access and transesophageal echocardiography (TEE) control. (6) With cardiac valve device evolution and greater operator experience, many are leaning toward a minimalist approach characterized by the use of local anesthesia (LA) with or without conscious sedation, percutaneous access and no intraprocedure TEE. (7-9).

Recently, large center reports have demonstrated, in their experience, the feasibility of carrying out TF-TAVR using LA. (10-12) Although this is an attractive alternative for the management of high-risk patients, the reported clinical results are controversial. (13-16)

This work evaluates the safety and efficacy of TF-TAVR performed under LA with conscious sedation (LA+CS) versus GA.

METHODS

Population

In our institution, the TAVR program began in 2009. In this single center, retrospective analysis, patients admitted on a scheduled basis and treated by transfemoral access until December 2016 were included in the study. Aortic valve replacement devices used were CoreValve™ (Medtronic, Minneapolis, MN) and Lotus Valve System® (Boston Scientific Corporation, Marlborough, MA). The demographic, clinical, imaging and follow-up data were prospectively included in the database of the interventional cardiology division.

The cases were evaluated and selected by a multidisciplinary team (Heart Team), consisting of clinical and interventional cardiologists, cardiovascular surgeons and experts in imaging studies and valvulopathies, based on surgical risk, comorbidities, frailty indexes, life expectancy and transfemoral approach feasibility.

The evaluation of valve anatomy prior to the procedure has varied over the years. The current assessment includes transthoracic echocardiography (TTE) and multislice angiotomography for the evaluation of femoral access, measurement of the aortic annulus, (aortic annulus diameter, calcification pattern and distance to the coronary arteries) and a preliminary evaluation of the coronary arteries. If necessary, a selective coronary angiography, an aortogram or an iliofemoral angiography are performed.

The procedures were performed in the catheterization room involving interventional cardiologists, an anesthesiologist and an echocardiography specialist. Thirty-day and 1-year clinical follow-up was carried out after the intervention.

Anesthetic management

Anesthesia of the patient undergoing TF-TAVR can be performed by administering GA or LA. In both cases, we implemented advanced monitoring, due to the clinical characteristics of this population and for the early detection of possible complications associated with the procedure. This includes electrocardiogram, oxygen saturation, capnography (patient in mechanical ventilation), blood pressure (usually radial) and central venous catheter for transient pacemaker placement.

The drugs used to achieve adequate sedation without compromising spontaneous ventilation are midazolam at titratable doses between 0.01 to 0.05 mg/kg plus fentanyl at doses of 0.5 to 2 ug/kg. This is usually supplemented with inhaled sevoflurane through nasal cannula with oxygen flow at 4-6 l/min. The criterion was to go from lower to higher anesthetic levels, given that the conversion to GA is feasible if all the necessary elements are available. In this case, the anesthetic level is deepened, usually with propofol and neuromuscular relaxation with rocuronium, managing variables that ensure adequate hemodynamic stability (preload, heart rate, blood pressure), and avoiding arterial hypotension and tachycardia.

Definitions

All the information in our database has been reviewed to ensure the classification of safety and efficacy outcomes according to the definitions of the Valve Academic Research Consortium-2 (VARC-2). (17)

The main times during hospital stay were taken from the electronic medical records of the institution

- **Total hospitalization days:** Time in days from hospital. admission to discharge
- **Days in intensive care unit (ICU)**: Time in days from admission to the ICU after the procedure until transfer to an area of less complexity or hospital discharge.
- **Total time of the procedure**: Time in minutes from performance of the first vascular access tothe patient's exit from the catheterization room.

Statistical analysis

Qualitative variables were expressed as percentages and analyzed with the chi-square test or Fisher's exact test, as appropriate. Quantitative variables were subjected to different tests of normality before deciding their treatment: Kolmogorov-Smirnov test or Shapiro-Wilk test and histogram analysis (asymmetry, kurtosis, z-value of the asymmetry and kurtosis). Those with normal distribution were described as

mean ± standard deviation (SD) and analyzed using Student's t test, while those that did not comply with this condition were expressed as median ± interquartile range (IQR) and analyzed using the Mann-Whitney U-test.

Clinical safety and efficacy outcomes at 30 days were compared by the Kaplan-Meier method. Two-tailed analysis was performed for all statistical variables, and a p value <0.05 was considered significant. Statistical analyses were performed with SPSS statistical package (version 22.0, IBM, Armonk, New York).

Ethical considerations

The work was evaluated and approved by the Institutional Ethics Committee.

RESULTS

Among the 121 patients included in the study, 55 received GA (45.5%) and 66 (54.5%) LA+CS. Table 1 describes the clinical and demographic characteristics of the population. Although there were no significant differences with the risk measured by the Society of Thoracic Surgeons (STS), the GA group presented greater symptomatic severity according to the classification of the New York Heart Association. Ventricular function was similar in both groups; however, in the GA group there was a greater mean gradient measured by TTE. On the other hand, the LA+CS group showed a tendency towards greater chronic obstructive pulmonary disease.

The overall rate of TEE use was high (87.6%) and significant differences were found between both groups (GA 96.4% vs. LA+CS 80.3%, p 0.008), as well as in the rate of percutaneous access (GA 63.6% vs. LA+CS 100%, p <0.0001) These differences reflect the progressive changes that have been occurring in our methodology. (Figure 1)

Intraprocedural and hospital results are detailed in Table 2. The cardiac valve device success rate was similar in both groups (GA 82.9% vs. LA+CS 83.5%, p 0.82). On the other hand, the rates of moderate aortic regurgitation (AoR) quantified by TTE (performed in the first 24 h after the end of the procedure) were similar in both groups (GA 10.9% vs. LA+CS 12.1%, p 0.83) .No patient had severe residual AoR and no differences were observed in the safety and efficacy outcomes at 30 days according to the VARC-2 classification (Table 2).

The main times measured during hospital stay are detailed in Table 3. In the LA+CS group, a reduction of 20.4% was observed in the total time of the procedure (GA 155.6 min vs. LA+CS 123.9 min, p 0.004). Likewise, the length of stay in ICU (GA 3 days vs. LA+CS 2 days, p 0.001) and the total hospital stay (GA 6 days vs. LA+CS 4 days, p 0.009) were significantly higher in the GA group (Figure 2).

Overall mortality at 30 days was 5%, without significant differences between the two groups (GA 7.3% vs. LA+CS 3% p 0.28).

The need for conversion to GA occurred in 2 patients (3.1%) due to major vascular complications requiring fast surgical resolution.

Table 1. Baseline characteristics of the population

	Global (n = 121)	General Anesthesia (n = 55)	Local Anesthesia (n = 66)	p
Baseline characteristics				
Age (± SD)	83.2 ± 5,7	82.9 ± 5,2	83.5 ± 6,1	0.54
Men, n (%)	59 (48.8%)	26 (47.3%)	33 (50%)	0.76
STS (± SD)	7 ± 4.1	6.44 ± 3.8	7.5 ± 4,3	0.13
NYHA 3-4, n (%)	70 (57.9%)	37 (67.3%)	33 (50%)	0.05
AMI, n (%)	15 (12.4%)	5 (9.1%)	10 (15.2%)	0.31
Stroke, n (%)	12 (9.9%)	3 (5.5%)	9 (13.6%)	0.13
Atrial fibrillation, n (%)	30 (24.8%)	13 (23.6%)	17 (25.8%)	0.78
Periferal vascular disease, n (%)	23 (19%)	10 (18.2%)	13 (19.7%)	0.83
Pacemaker, n (%)	20 (16.5%)	6 (10.9%)	14 (21.2%)	0.12
COPD*, n (%)	28 (23.1%)	9 (16.4%)	19 (28.8%)	0.10
Chronic renal failure, n (%)	20 (16.5%)	8 (14.5%)	12 (18.2%)	0.75
Percutaneous access, n (%)	101 (83.5%)	35 (63.6%)	66 (100%)	< 0.0001
Transesophageal echocardiogram, n (%)	106 (87.6%)	53 (96.4%)	53 (80.3%)	0.008
Echocardiographic parameters				
Ejection fraction, % (± SD)	55.9 ± 12	56.4 ± 12.1	55.8 ± 12.1	0.66
Valve area, cm2 (± SD)	0.62 ± 0.16	0.59 ± 0.13	0.63 ± 0.18	0.16
Mean gradient, mmHg (± SD)	46.5 ± 13.5	49.2 ± 12.8	44.2 ± 13.8	0.04
Peak systolic velocity, m/s (± SD)	4.2 ± 0.61	4.3 ± 0.63	4.1 ± 0.57	0.12

STS: Society of Thoracic Surgeons. NYHA: New York Heart Association. AMI: Acute myocardial infarction. COPD: Chronic obstructive pulmonary disease.

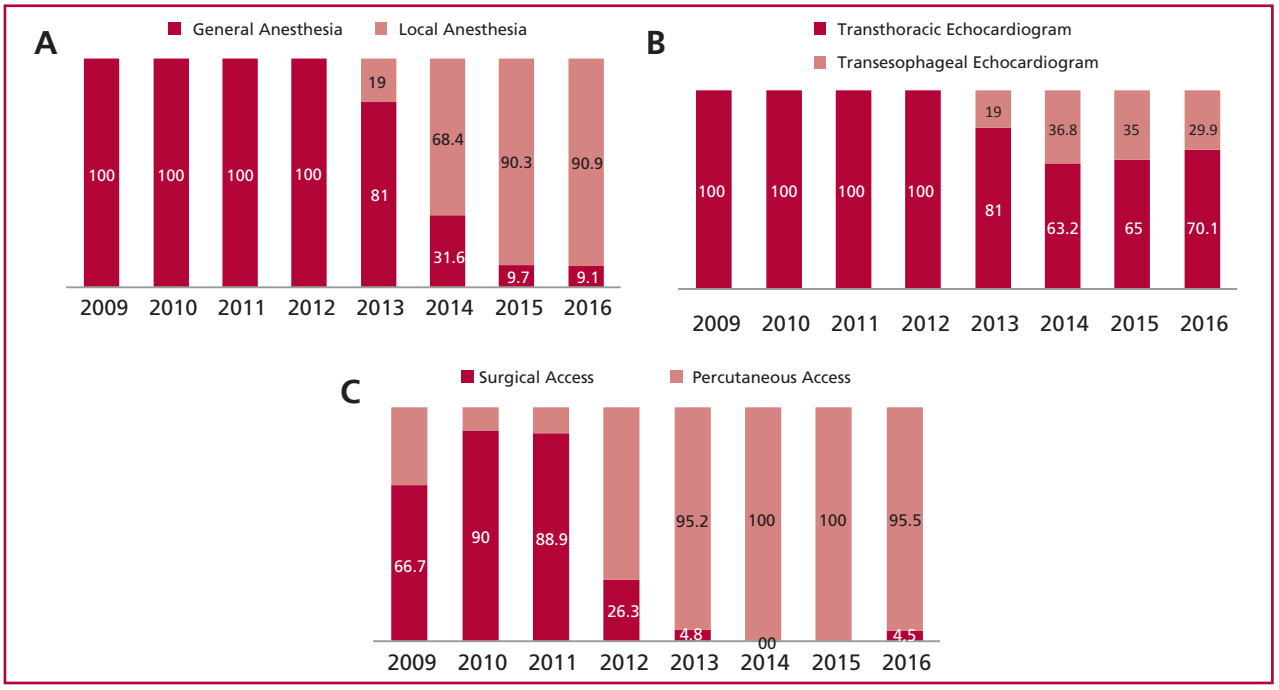

Fig. 1. Evolution of the working system in our institution. A. Modifications in the anesthetic method. B. Modifications in the use of TEE. C. Modifications in the access route.

Table 2. Procedural results and safety and efficacy outcomes according to the VARC-2 classification at 30 days.

	Global (n = 121)	General Anesthesia (n = 55)	Local Anesthesia (n = 66)	p
Procedural results				
Device sucess, n (%)	100 (82.6%)	45 (81.8%)	55 (83.3%)	0.82
Fluoroscopy time, min (IQR)	32 (24.6-40)	30.7 (IQR 22.1-43.7)	32 (IQR 25.2-38.1)	0.64
Contrast (ml)	100 (52.5-192.5)	125 (IQR 60-200)	100 (IQR 50-150)	0.83
Radiation dosis, Kerma, Gy (IQR)	1,092 (658-2,336)	1,291 (IQR 715-1,738)	1,058 (IQR 618,5-1,357)	0.24
Conversion to GA, n (%)	-	-	2 (3%)	NA
Moderate aortic regurgitation, n (%)	14 (11.6%)	6 (10.9%)	8 (12.1%)	0.83
Clinical results at 30 days				
In-hospital mortality, n (%)	5 (4.1%)	3 (5.5%)	2 (3%)	0.49
All cause mortality, n (%)	6 (5%)	4 (7.3%)	2 (3%)	0.28
AMI, n (%)	1 (0.8%)	1 (1.8%)	0	0.27
Stroke, n (%)	5 (4.1%)	3 (5.5%)	2 (3%)	0.50
PM implant, n (%)	36 (29.8%)	17 (30.9%)	19 (28.8%)	0.79
Readmission, n (%)	10 (8.7%)	3 (5.9%)	7 (10.9%)	0.33

AMI: Acute myocardial infarction; PM: Pacemaker.

Table 3. Key times during hospital stay

	Global (n = 121)	General Anesthesia (n = 55)	Local Anesthesia (n = 66)	p
Procedural time, min (± SD)	136.7 ± 46.7	155.6 ± 56.6	123.9 ± 32.8	0.001
Length of stay in ICU, days	3 (IQR 1-3.5)	3 (IQR 2-4)	2 (IQR 1-3)	0.004
(IQR)	5 (IQR 3-8)	6 (IQR 4-8)	4 (IQR 3-6.5)	0.004
Total hospital length of stay, days (IQR)				

ICU: Intensive care unit.

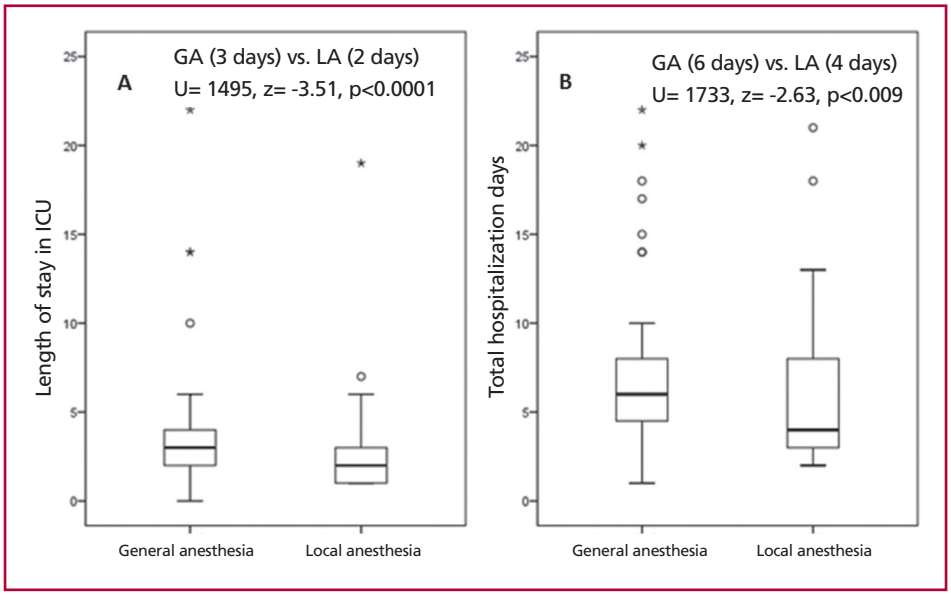

Fig. 2. Comparison of ICU (A) and total hospital (B) length of stay between both groups.

DISCUSSION

Based on our results, the use of LA+CS administered by an experienced anesthesiologist seems to be a safe and effective alternative to the use of GA in TF-TAVR. We have observed that LA confers less total procedural time, as well as fewer days of ICU and total hospital stay. In addition, there were no significant differences in safety and efficacy outcomes at 30 days.

In our institution, we started the TAVR program using GA with orotracheal intubation, surgical access and TTE used in 100% of cases to control the intervention. This system prevailed until 2012, when we had performed 28.1% of the procedures. Since then, motivated by the greater experience of the institution, the progress of cardiac valve devices and the implementation of percutaneous closure devices, our working methodology has been progressively modified towards a minimalist strategy (Figure 2). Although the feasibility of carrying out TAVR under LA has been previously demonstrated, (10, 11, 12) there are no data from randomized studies evaluating the safety and efficacy of the procedure by comparing both anesthetic methods. (18) Furthermore, the information derives from observational studies with very heterogeneous intraprocedural and clinical outcomes. (19)

In our population, we did not observe significant differences in 30-day mortality and similar results were reported in publications with longer follow-up periods. (14, 20) However, some authors found higher short-term mortality in the GA group. (16, 21) It could be expected that, due to the design of these studies, the baseline dissimilarities between both groups and the marked tendency to GA in countries such as the United States, (22) these differences could be the expression of a selection bias. In our series, the GA group presented greater symptomatic severity. Although the surgical risk quantified by STS has been similar, we continue using GA in selected patients who present respiratory distress and cannot tolerate decubitus position during the procedure. For all these reasons, and until we have higher quality information, we consider it imprudent to state that GA leads, on its own, to an increase in mortality in TAVR. Even a recently published systematic review found no difference in this outcome at 30 days. (19)

One of the advantages attributable to GA in TAVR is the use of TEE to guide the procedure. (23) It would be logical to expect this to favor greater precision of implantation and the prevention of valve dysfunction. In this sense, it has been reported that LA is associated with more than mild AoR rate. (14, 16, 19) Although the reasons are not completely elucidated, some authors have attributed this to the lower use of TEE. (14) In our series, the use of TEE was greater in patients with GA. However, we did not observe significant differences in the more than mild AoR rate. Regarding our methodology, 87.6% of the procedures were guided by TEE and the use of this method has been very frequent in the LA group (80.3%), as in other publications with similar results. (20) Conversely, in the FRANCE-2 registry, the LA group presented a higher rate of AoR and the use of TEE in this group was only 16%. (13) It is important to emphasize that, although the use of TEE has been a protective variable on the manifestation of AoR, (24) there are other factors that might condition the results. (25, 26) In this sense, some authors found significant differences with respect to the need for permanent pacemaker implantation in favor of patients treated with GA, although in our experience we have not seen any difference. (19)

A fact of fundamental importance is the decrease of procedural time in the LA group, in agreement with other reports. (15, 23, 27, 28) This has a substantial

impact on the operative planning of the catheterization room, optimizing human, material and time resources.

Moreover, we observed a significant decrease in ICU and total hospital length of stay in patients of the LA group. It is well known that prolonged hospitalization brings with it numerous complications, many of which are not related to the admission problem. (29, 30) Bed rest, in elderly patients, causes an accelerated loss of muscle mass, decrease in plasma volume and ventilation, all favoring an increase in the prevalence of complications, such as falls, delirium, pressure ulcers and nosocomial infections. (31-33) In TAVR, the estimated delirium rate ranges between 21% and 56% and those who develop it present longer hospitalization, greater mortality and a high rate of referral to rehabilitation centers (61%). (34, 35) As a result, we consider that early mobilization of patients is very important, if possible within the first 12 h, with early discharge and close ambulatory follow-up.

Finally, the conversion rate to GA was 3.1%, in all cases due to major vascular complications during the procedure. The rate reported in the literature ranges from 2.2% to 16.7% (19) and the main reasons have been cardiac arrhythmias/hypotension/cardiac arrest (37.5%), major vascular complications (16.1%), conversion of percutaneous to surgical (16.1%), respiratory complications (16.1%), patient agitation (7.1%), and laryngeal trauma due to TEE (7.1%). (16)

In the light of these results, we consider it is extremely important to adequately plan the procedure and select the working method adapted to each patient and the experience of each center. Some authors suggest that, as part of a minimalist approach, the procedure should be carried out without the presence of an anesthesiologist in the room. (36) In our view, even though it is less and less frequent, TAVR has potential complications that could be catastrophic. (37, 38) From the point of view of the patient´s safety, we consider that team work is invaluable in order to be able to face complications quickly and effectively.

Our study has important limitations worth mentioning. First of all, due to its observational nature, the results could be subject to biases and confounders with respect to variables not measured in our database. Another aspect of fundamental importance is that there is a chronological division between both strategies (GA at the beginning of the learning curve) and we cannot rule out that some of the observed differences, particularly in the times evaluated, could be affected by the greater operational maturity of our institution. Finally, it should be noted that in our working system GA continues to be the method of preference in patients who cannot adequately tolerate decubitus position during the procedure, which inevitably generates a selection bias that could justify the trend reported in the combined outcome favoring the use of LA+CS.

CONCLUSIONS

Based on the results of this single-center study, TF-TAVR with LA+CS is a feasible alternative to the use of GA. Specifically, (a) there were no differences in the rate of clinical events at 30 days, (b) the total time of the procedure and the recovery time were lower in the LA group, (c) the LA group had shorter ICU and total hospital stay and (d) the conversion rate to AG was 3.1%.

Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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