



# Does the Use of Local Anesthesia with Conscious Sedation Rather Than General Anesthesia Improve the Outcomes of Transfemoral Transcatheter Aortic Valve Replacement?

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## Mini Abstract

According to the results of this study, TF-TAVR under LACS seems to be as safe and effective as it is under GA. LACS could reduce infectious complications and median hospital stay after TF-TAVR.

## Abstract

**Background:** Transcatheter aortic valve replacement is a proven treatment for patients with aortic stenosis who are considered at high-risk or with contraindications for surgical aortic valve replacement. General anesthesia (GA) and local anesthesia with conscious sedation (LACS) have been described for this procedure. However, there is no randomized study that looked for the benefit of using LACS for this procedure. The anesthetic management during TAVR is still controversial, and some centers are still performing it mainly under GA. This study aimed to look for benefits of LACS over GA regarding the outcomes of transfemoral transcatheter aortic valve replacement (TF-TAVR).

**Methods:** We analyzed data of our patients' cohort, who underwent TF-TAVR between February 2010 and October 2011 at La Pitie-Salpetriere Hospital, those patients were part of the French Aortic National Core Valve and Edwards 2 (FRANCE2). The procedure was performed either under GA or LACS. Two TAVR systems were used. Device success, safety and efficacy endpoints, prosthetic valve performance, complications and hospital stay were compared between LACS and GA groups.

**Results:** From 78 consecutive patients who underwent TF-TAVR, 40 received LACS and 38 received GA. Device success rate was 90.0% in the LACS group and 92.1% in the GA group ( $p=1.00$ ). Thirty-day mortality rate was 14.1% overall, with no significant difference between groups ( $p=0.29$ ). There were no significant differences in safety and efficacy endpoints, the prosthetic valve performance, therapy-specific and prosthetic valve associated complications between the two groups. Infectious complications rate was significantly lower ( $p=0.04$ ) and the median hospital stay was significantly shorter ( $p=0.04$ ) in LACS group.

**Conclusion:** In our experience, TF-TAVR performed under LACS seems to be as safe and effective as it is under GA. LACS could reduce infectious complications and median hospital stay after the procedure.

**Keywords:** Aortic stenosis; TAVR; General anesthesia; Local anesthesia; SAVR

**Abbreviations:** AR: Aortic Regurgitation; AVA: Aortic Valve Area; AVB: Atrioventricular Block; AVR: Aortic Valve Replacement; CABG: Coronary Artery Bypass Graft; COPD: Chronic Obstructive Pulmonary Disease; Euro SCORE: European System for Cardiac Operative Risk Evaluation; GA: General Anesthesia; HF: Heart Failure; LACS: Local Anesthesia with Conscious Sedation; LV: Left Ventricular; LVEF: Left Ventricular Ejection Fraction; MI: Myocardial Infarction; MR: Mitral Regurgitation; SAVR: Surgical Aortic Valve Replacement; TAVR: Transcatheter Aortic Valve Replacement; TF-TAVR: Transfemoral Transcatheter Aortic Valve Replacement; VARC: Valve Academic Research Consortium

## Introduction

Transcatheter aortic valve replacement (TAVR) has emerged as a credible alternative therapy for patients with aortic stenosis who are considered at high-risk or with contraindications for surgical aortic valve replacement (SAVR) [1]. Centers still disagree about the preferred anesthetic technique for TF-TAVR [2]. Most teams perform the procedure under general anesthesia (GA), although local anesthesia with conscious sedation (LACS) may suffice for the transfemoral approach [1].

The subanalysis of the French Aortic National Core Valve and Edwards 2 Registry (FRANCE2) [3] compared clinical outcomes and safety of TAVR Under GA versus local anesthesia, and didn't demonstrated a clinical benefit of the local anesthesia over the GA. However, the lack of finding a benefit of performing the procedure under local anesthesia could be due to the nationwide nature of the registry and to the fact that many outcomes were self-reported and not independently adjudicated. The purpose of this study was to report the analysis of the clinical outcomes of transfemoral transcatheter aortic valve replacement (TF-TAVR) under LACS compared to GA performed in our Centre, the patients included here were also part of FRANCE 2 registry [3]. The collect of clinical endpoints was more extensive in the present study.

## Methods

### Study participants

We analyzed data of our cohort of patients who underwent TF-TAVR with either the Medtronic Core valve System or the Edwards Sapien valve, who were part of the FRANCE 2 registry [4], from February 2010, to October 2011. From 102 consecutive patients with severe Aortic stenosis who underwent TAVR at La Pitie-Salpetriere University Hospital, 78 patients had TF-TAVR. All consecutive patients referred to our center for the management of symptomatic severe native aortic stenosis with high risk for open-heart surgery as expressed by a logistic European System for Cardiac Operative Risk Evaluation (Euro SCORE)  $\geq 20\%$  or with specific surgical contraindications as described previously [1,5] and who had a TF-TAVR were included. All these patients met the eligibility criteria defined for TAVR [1]. The decision to perform the procedure was made by a multidisciplinary team involving an interventional cardiologist, a cardiothoracic surgeon, a cardiologist, cardiac anesthesiologist, an echocardiographer and an imaging specialist. Written informed consent was obtained from each patient enrolled. The study protocol was approved by the local ethics committee.

### Pre-procedural evaluation

All patients had trans thoracic echocardiography or transesophageal echocardiography (TEE) when required, Doppler ultrasound of the supra-aortic arteries, coronary angiography, and multi slice computed tomography of the aortic root and aortoiliac system. Pulmonary function test was

performed if there was a history of respiratory disease. Assessing the feasibility of TF-TAVR was mainly based on the results of multi slice computed tomography. For all patients, aortic annulus measurement was performed by the multi slices scanner. Patients were excluded if this diameter was  $<18$  or  $>25$ mm, or if they had contraindications to the transfemoral approach [6]. A preanesthetic consultation was performed at least 48 hours before the procedure.

### Trans catheter aortic valve replacement procedure

All TF-TAVRs were performed in a hybrid operating room. Detailed technical aspects of the TAVR procedure have been previously described [1,7]. An interventional cardiologist and a cardiac surgeon actively took part in the procedure. Aortic annulus dimensions determined by the multi slice computer tomography guided the choice of the device. Four types of prosthesis were used (Edwards SAPIEN valve [ESV, Edwards Life sciences Inc. CA, USA] and Medtronic Core valve Revalving system [MCRSTM, Core Valve Inc. Irvine, CA, USA] were initially used, gradually replaced by subsequent generations SAPIENXT and Core valve Accutrack). The procedure was guided by fluoroscopy and angiography. Immediately after TAVR, autography, and TEE when ever available, were performed to assess the presence of aortic regurgitation, the patency of the coronary arteries and to rule out complications [1].

### Anesthesia

The procedure was performed either under GA or LACS. The choice of the type of anesthesia used for every patient was left to the discretion of the physician (s) involved. During the initial phase of the study, our practice of performing TF-TAVR was to operate mainly under GA then gradually we shifted to LACS. Anesthesia personnel involved in the procedure were a cardiac anesthetists and an experienced nurse anesthetist.

Detailed technical aspects of anesthetic and per operative management of patient under going the TAVR procedure have been previously reported [8,9]. GA was induced with an intravenous bolus of etomidate (0.25-0.4mg/kg) or propofol (1.2-2.5mg/kg) associated to either remifentanyl (1 $\mu$ g/Kg), alfentanil (50-100 $\mu$ g/Kg), sufentanil (0.5-2 $\mu$ g/Kg) or fentanyl (2-50 $\mu$ g/Kg). The choice of anesthetic drug was at the discretion of the anesthesiologist. It was facilitated by atracurium (0.3-0.6mg/Kg). Anesthesia was maintained with either a continuous infusion of propofol or in etomidate or an inhaled agent (desflurane, sevoflurane, or isoflurane) and the opioids used for induction. For LACS, ilioinguinal/Iliohypogastric blocks and infiltration with a mixture of lidocaine and ropivacaine were performed by the cardiac anesthesiologist approximately 30 minutes before the onset of the procedure. All patients under went sedation with remifentanyl (target-controlled infusion of 1-3ng/mL adjusted to obtain a Ramsay score of 2-3). If maximal dose of remifentanyl was insufficient, supplementation with a target-controlled infusion of propofol was performed.

**Data collection and definition of evaluation criteria**

Clinical and par clinical data have been collected partially prospectively taken from our center’s registry which is part of FRANCE 2 registry, and completed retrospectively from the health records for more extensive endpoints collect. We assessed base line patient characteristics, procedural characteristics and anesthesia-related information. Post-procedural outcomes, defined according to the Valve Academic Research Consortium criteria (VARC) [10], were collected over a follow-up of 30-days and were compared between the two groups: LACS versus GA.

**Statistical Analysis**

All statistical analyses were performed with the use of IBMSPSS Statistics version 20 (SPSS, Chicago, IL, USA). Continuous variables were presented as means ± standard deviations when normally distributed and as medians (25<sup>th</sup>-75<sup>th</sup>percentiles)

**Table1:** Baseline patient characteristics.

	Overall (N=78)	LACS (N=40)	GA (N=38)	p-value
Age: years	83.5±6.9	83.9±6.2	83.1±7.7	0.59
Male sex: no.(%)	46(59.0)	24(60.0)	22(57.9)	0.85
Body mass index(kg/m2)	26.4±5.0	26.0±4.1	26.8±5.9	0.49
Diabetes mellitus no.(%)	24(31.2)	13(33.3)	11(28.9)	0.68
Hypertension: no.(%)	63(81.8)	35(89.7)	28(73.7)	0.68
Dyslipidemia: no.(%)	46(59.7)	24(61.5)	22(57.9)	0.74
Coronar yartery disease: no.(%)	42(54.5)	22(56.4)	20(52.6)	0.74
Previous CABG: no.(%)	9(11.7)	6(15.4)	3(7.9)	0.31
Previous bioprosthesis AVR: no.(%)	2(2.6)	0(0.0)	2(5.3)	0.15
Peripheral or cerebral vascular disease, or history of stroke: no.(%)	44(57.1)	25(64.1)	19(50.0)	0.21
Abdominal aortic neurysm: no.(%)	4(5.2)	2(5.1)	2(5.3)	0.98
Previous HF: no.(%)	44(57.9)	21(53.8)	23(62.2)	0.46
Pacemaker: no.(%)	6(7.7)	5(12.5)	1(2.6)	0.10
COPD: no.(%)	21(27.3)	11(28.2)	10(26.3)	0.85
Renal failure: no.(%)	39(50.0)	23(57.5)	16(42.1)	0.17
Creatinine: μmol/L ,median	93.5	96.0	86.0	0.14
	[74.5-126.0]	[80.0-140.75]	[68.8-117.8]	
Creatinine clearance: mL/ m <sup>2</sup>	63.2±27.4	58.4±24.7	68.3±29.4	0.11

when not normally distributed. They were tested for differences with the Student’s t-test or non-parametric tests respectively. Categorical variables, were expressed as percentages, and were compared with the use of the Pearson’s chi-square or the Fisher’s exact test, as appropriate. All statistical tests were 2 sided and a p value<0.05 was considered significant.

**Results**

**Baseline Patient characteristics and Procedural characteristics**

At otal of 78 consecutive patients under went TF-TAVR, 38 under GA and 40 under LACS. There were no differences in base line patient characteristics between the 2 groups (Table1). The overall patient population was at high risk (mean logistic Euro SCORE22.7±11.3%).

Logistic Euro SCORE: %	22.7±11.3	21.5±9.3	23.9±13.1	0.37
Indexed AVA: cm <sup>2</sup> /m <sup>2</sup>	0.37±0.1	0.38±0.1	0.36±0.1	0.56
Mean gradient: mmHg	48.3±14.5	46.3±14.4	49.9±14.7	0.35
Mean gradient<40mmHg: no.(%)	16(27.6)	8(29.6)	8(25.8)	0.74
LVEF: %	52.2±14.8	52.0±14.4	52.5±15.4	0.87
LVEF<40%: no.(%)	12(16.0)	6(15.4)	6(16.7)	0.88
MR grade≥2: no.(%)	9(17.3)	5(18.5)	4(16.0)	0.81
Pulmonary hypertension: no.(%)	18(46.2)	11(28.2)	7(17.9)	0.40

AV: Aortic Valve Area; AVR: Aortic Valve Replacement; CABG: Coronary Artery Bypass Graft; COPD: Chronic Obstructive Pulmonary Disease; Euro SCORE: European System for Cardiac Operative Risk Evaluation; GA: General Anesthesia; HF: Heart Failure; LACS: Local Anesthesia with Conscious Sedation; LVEF: Left Ventricular Ejection Fraction; MR: Mitral Regurgitation  
All P values are for between group comparisons.

**Table 2:** Procedural characteristics and device success.

	Overall (N=78)	LACS (N=40)	GA (N=38)	p value
Bioprosthesis				
SAPIEN valve : no. (%)	29 (37.2)	14 (48.3)	15 (51.7)	0.11
a) Size 23 mm : no. (%)	9 (31.0)	2 (22.2)	7 (77.8)	
b) Size 26 mm : no. (%)	20 (69.0)	12 (60.0)	8 (40.0)	
Core Valve : no. (%)	49 (62.8)	26 (53.1)	23 (46.9)	0.51
c) Size 26 mm : no. (%)	12 (24.5)	5 (41.7)	7 (58.3)	
d) Size 29 mm : no. (%)	37 (75.5)	21 (56.8)	16 (43.2)	
Device success: no. (%)	71 (91.0)	36 (90.0)	35 (92.1)	1.00

GA: General Anesthesia; LACS: Local Anesthesia with Conscious Sedation.

All P value sare for between-group comparisons.

The procedural characteristics and device success rate are shown in (Table2). Overall, device success was achieved in 91.0% of patients, and was similar in the two groups (p=1.00). Three cases had device failures in GA group, they were due to a prosthetic aortic regurgitation grade ≥ 3 in 2 patients who had asymmetric aortic annulus and to an incomplete opening of the prosthesis secondary to calcareous fragments at the

native valve in another patient. In LACS group, four cases didn't meet device success criteria, two of them had prosthetic aortic regurgitation grade ≥ 3 due to prosthesis malposition, one case had left ventricular wall perforation and unfortunately had a peril-procedural death, and in one case the iliac artery was impassable and required conversion to on-pump SAVR.

### Safety and efficacy endpoint sand Prosthetic valve performance

**Table 3:** Efficacy and safety endpoints and prosthetic valve performance.

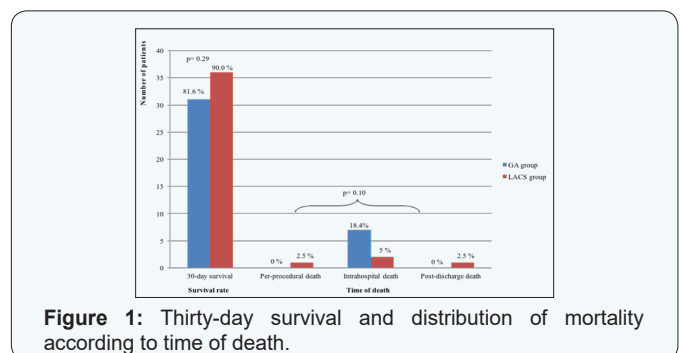
	Overall(N=78)	LACS(N=40)	GA (N=38)	p value
VARC combined safety endpoint: no.(%)	12(15.4)	4(10.0)	8(21.1)	0.22
Death: no.(%)	11(14.1)	4(10.0)	7(18.4)	0.29
Death from cardio vascular cause: no.(%)	8(10.3)	3(7.5)	5(13.2)	0.21

MI: no.(%)	1(1.3)	1(2.5)	0(0.0)	1.00
Stroke: no.(%)	1(1.3)	1(2.5)	0(0.0)	1.00
Bleeding				
Life threatening or disabling bleeding: no.(%)	3(3.8)	1(2.5)	2(5.3)	0.63
Major bleeding: no.(%)	5(6.4)	4(10.0)	1(2.6)	
Minor bleeding: no.(%)	15(19.2)	8(20.0)	7(18.4)	
Acute kidney injury				
Stage1: no.(%)	7(9.1)	3(7.7)	4(10.5)	0.47
Stage2: no.(%)	3(3.9)	1(2.6)	2(5.3)	
Stage3: no.(%)	2(2.6)	0(0.0)	2(5.3)	
Vascular complications				
Major: no.(%)	4(5.1)	3(7.5)	1(2.6)	0.72
Minor: no.(%)	17(21.8)	8(20.0)	9(23.7)	
Prosthetic valve regurgitation	54(73.0)	26(70.3)	28(75.7)	
Paravalvular: no.(%)	46(62.2)	24(64.9)	22(59.5)	0.40
Central: no.(%)	8(10.8)	2(5.4)	6(16.2)	
Gradesofre gurgitation				
Grade1: no.(%)	39(53.4)	20(54.1)	19(52.8)	0.78
Grade≥2: no.(%)	14(19.2)	6(16.2)	8(22.2)	
Mean aortic gradient: mmHg	10.2±4.4	9.2±3.7	11.3±5.0	0.10

GA: General Anesthesia; LACS: Local Anesthesia with Conscious Sedation; MI: Myocardial Infarction; VARC: Valve Academic Research Consortium.

All P values are for between-group comparisons.

There were no significant differences in terms of efficacy and safety endpoints between the two groups (Table 3). The Valve Academic Research Consortium combined safety endpoint (all-cause mortality, major stroke, peril-procedural myocardial infarction, life-threatening bleeding, and kidney injury RIFLE stage3) was comparable for the two groups (10.0% [n=4] in LACS group vs. 21.1% [n=8] in GA group, p=0.22). All-cause 30-day mortality rate (including intra-hospital mortality) was 14.1% (n=11) for the whole of the series, 10.0% (n=4) in LACS group vs. 18.4% (n=7) in GA group, (p=0.29). Overall 10.3% (n=8) were due to cardiovascular causes. The distribution of the 30-day mortality according to its timing related to the procedure is illustrated in (Figure 1).



GA: General Anesthesia; LACS: Local Anesthesia with Conscious Sedation

**Table 4:** Causes of all 30-day mortality.

Time of death	Anesthesia type	Days to death	Causes of deaths
Peri-procedural	LACS	0	Hemo pericardium (LV perforation)
Intra-hospital	GA	5	Septic shock
	GA	7	HF and Septic shock
	GA	7	HF, acute kidney injury and multiorgan failure
	GA	10	HF
	GA	13	Septic shock
	GA	15	HF, acute kidney injury and multiorgan failure
	GA	38	HF(moderate to severe AR), Septic shock and multiorgan failure
	LACS	4	HF, stroke and multiorgan failure
	LACS	10	HF, acute kidney injury and multiorgan failure(conversion to SAVR)
After hospital discharge			
	LACS	29	Unknown cause

AR: Aortic Regurgitation; GA: General Anesthesia; HF: Heart Failure; LACS: Local Anesthesia with Conscious Sedation; LV: Left Ventricular; SAVR: Surgical Aortic Valve Replacement.

The details of all-cause 30-day mortality are shown in (Table 4). One death occurred on the day 38 post-procedure in GA group and was included in the 30-day mortality, as it occurred during the index hospitalization. A single peri-procedural death occurred in LACS group, due to a perforation of the left ventricular wall. In GA group, all 30-day deaths were intra-hospital, but none was peri-procedural. One peri-procedural myocardial infarction occurred in LACS group, diagnosed after the procedure. This case had conversion to on-pump SAVR. One stroke occurred in LACS group. The prevalence of bleeding, vascular complications and acute kidney injury was the same between the 2 groups (Table 3). No deaths were directly related to a vascular access site complication.

Regarding the prosthetic valve performance, results were similar between the 2 groups (Table 3). Overall significant prosthetic aortic valve regurgitations (grade≥2), occurred in 14 of 73 patients (19.2%), without significant difference between the two groups (p=0.78).

**Other Complications**

**Table 5:** Therapy-specific and prosthetic valve associated complications, and other outcomes.

	Overall (N=78)	LACS (N=40)	GA (N=38)	P-value
AVB requiring pacemaker: no.(%)	13(16.7)	9(22.5)	4(10.5)	0.23
New or worsening MR : no.(%)	14(20.6)	6(16.7)	8(25.0)	0.40
Unplanned cardio pulmonary bypass: no.(%)	2(2.6)	2(5.0)	0(0.0)	0.49
Conversion to surgical AVR: no.(%)	1(1.3)	1(2.5)	0(0.0)	1.00
Ventricular perforation: no.(%)	1(1.3)	1(2.5)	0(0.0)	1.00
Tamponade: no.(%)	4(5.1)	1(2.5)	3(7.9)	0.35
Prosthetic valve migration: no.(%)	4(5.1)	3(7.5)	1(2.6)	0.62
Post TAVR balloon redilatation: no.(%)	4(5.1)	3(7.5)	1(2.6)	0.62
TAVR 'valve-in-valve': no.(%)	1(1.3)	1(2.5)	0(0.0)	1.00
Device recapture or retrieval: no.(%)	4(5.1)	1(2.5)	3(7.9)	0.35
Re-intervention: no.(%)	22(28.2)	14(35.0)	8(21.1)	0.17
Transfusion: no.(%)	22(28.2)	12(30.0)	10(26.3)	0.72
Administration of catechol amines: no.(%)	17(21.8)	8(20.0)	9(23.7)	0.69
Confusion: no.(%)	6(7.7)	2(5.0)	4(10.5)	0.43
HF: no.(%)	24(30.8)	11(27.5)	13(34.2)	0.52
Infectious complications: no.(%)	17(21.8)	5(12.5)	12(31.6)	0.04
Median hospital stay: days	9.0[7.0-14.5]	8.0[6.0-13.5]	10.0[7.0-16.0]	0.04

AVB: Atrioventricular Block; AVR: Aortic Valve Replacement; GA: General Anesthesia; HF: Heart Failure; LACS: Local Anesthesia with Conscious Sedation; MR: Mitral Regurgitation; TAVR: Transcatheter Aortic Valve Replacement.

All P values are for between-group comparisons.

Prosthetic valve 'associated' complications and therapy-specific complications were similar between LACS and GA groups (Table 5). The occurrence of Atrioventricular bloc requiring a permanent pacemaker implantation didn't differ significantly between the two groups. Conversion to an 'open' SAVR was performed in 1 case in LACS group. Requirement of any cardiac or vascular surgery after the index procedure was similar between

the 2 groups, in 14 (35.0%) patients in LACS group and 8 patients (21.1%) in GA group,  $p=0.17$ . Reasons for those subsequent surgeries were in LACS group: pacemaker in 9 patients, migration of the bio prosthesis in 1 case, trans apical TAVR after failure of the femoral access in 1 case, surgical repair of left ventricular wall ruptures in 1 case, insertion of extracorporeal membrane oxygenation in 1 case and wound infection of the scarp in 1 case. In GA group indications of re-interventions were: pacemaker implantation in 4 cases, pseudoaneurysm in 1 case, surgical drainage of pericardial effusion in 2 cases and wound infection of the scarp in 1 case.

Some anesthesia and intensive care related aspects are also presented in (Table 5). Infectious complications rate was significantly lower in patients receiving LACS compared to those receiving GA (5 patients [12.5%] vs. 12 patients [31.6%],  $p=0.04$ ). Bronchopulmonary infections were the predominant infectious complications in GA group (8 cases of 12). In univariate analysis, we found that a history of chronic obstructive pulmonary disease was associated with the occurrence of bronchopulmonary infection ( $p=0.019$ ) in GA group, where as this association was not found in the LACS group ( $p=1.00$ ). The median of hospital stays was shorter in the LACS group ( $p=0.04$ ).

## Discussion

The choice of anesthesia type for TF-TAVR is still controversial. In FRANCE 2 registry TAVR were performed with the use of local anesthesia for 40.8% of TAVR with femoral approach [11]. In the subanalysis of the French aortic national Core valve and Edwards 2 registry that compared clinical outcomes and safety of TAVR under GA versus local anesthesia, no benefit of LACS over GA was demonstrated. But the lack of finding any benefit could be due to the nationwide nature of the registry, some bias could be due to the self-report of results individually by each participating center. The aim of this study was to analyze and compare early outcomes of F-TAVR between patients consecutively undergoing LACS versus GA groups. This study has the advantage of being well balanced in terms of the size of each group (LACS and GA groups), in contrast to other similar studies [12,13].

Our results suggest that TF-TAVR is feasible under LACS as well as it is under GA. The 2 groups were equivalent in terms of device success rate and prosthetic valve performance, without any increase in prosthetic valve associated complications or therapy-specific complications in LACS group at 30-day follow up (Tables 2,3,5). The distribution of all-cause 30-day mortality depend in go the time of death (Figure 1) did not differ significantly between the 2 groups ( $p=0.10$ ).

The previously reported studies considered that the TEE was useful for the correct positioning of the prosthesis [12]. In our study, in principle the patients in the LACS group didn't have TEE and it was used in all the patients in the GA group. Thus, some of the expected disadvantages of the LACS were related to the lack of the use of TEE and its potential consequences on

the accuracy of the bio prosthesis positioning. But nevertheless prosthetic valve performance in LACS group was not less good than in the GA group (Table 3).

TAVR under LACS seems to be as safe and effective as TAVR under GA. GA certainly allows more comfortable working for the interventional team compared to the LACS by facilitating the procedure as the patient is completely relaxed and motionless. In our experience the use of LACS wasn't associated to any increase of vascular complications or peril-procedural bleeding complications (Table 3).

Were ported also in this study severe surgical complications of TF-TAVR, and their rate seemed to be below.

## Conclusion

In the present study, the 2 groups were equivalent in terms of the use of catecholamine's (Table 5); unlike others studies where the use of catecholamine's was higher in the GA group compared to the LACS group [12]. Our result could be explained by our method of induction of GA, which was slowly and carefully titrated to achieve the targeted effect. Post-procedural confusion was not less frequent as expected in LACS patients (Table 5). This similarity between the two groups might be due to the use of sedative agents and opioids even at low doses in LACS group.

Some authors believe that LACS has the advantage of simplified monitoring that shortens anesthesia preparation and could avoid nosocomial infections [12]. In this analysis, infectious complications rate was significantly lower in LACS group. Finally, LACS was associated with a shorter median hospital stay compared with GA (Table 5). This is comparable with reported data [12,14].

## Study limitations

This study reflects single-center experience, with limited number of patients. The study was observation a land non-randomized, so we can't conclude that the differences observed between TF-TAVR under LACS versus GA were due only to the type of anesthesia used. GA was used mainly during the initial phase of the study and was shifted progressively to LACS, so we can't exclude that an increasing experience with time bias could have an effect on the results.

## Conclusion

This study showed that TF-TAVR is feasible under LACS as well as it is under GA, with similar device success rate and prosthetic valve performance between the two groups. TAVR under LACS seems to be as safe and effective as the TAVR under GA. Thirty-day mortality didn't differ between the groups. TAVR under LACS seems to be associated with a lower rate of infectious complications and a shorter median hospital stay compared to GA group. The LACS was considered by the heart center's team as the preferred type of anesthesia for patients undergoing TF-TAVR.

## Conflicts of Interest Statement

Dr. Pascal Leprince is a proctor for Medtronic Core Valve and a consultant for Edwards Life sciences.

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