Initial Experience of a TAVI Program: Analysis of the Anesthetic Decision and its Evolution

Experiência Inicial de um Programa de TAVI: Análise da Decisão Anestésica e sua Evolução

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ABSTRACT

Introduction: Transcatheter aortic valve implantation is a less invasive option for aortic valve replacement. The number of transcatheter aortic valve implantations under local anesthesia with sedation has been increasing as the team's experience increases and less invasive accesses are used. The aim of this study is to describe the evolution of the anesthetic technique in patients undergoing transcatheter aortic valve implantation at our center over the years, as which was compared.

Material and Methods: Retrospective study in 149 consecutive patients undergoing transcatheter aortic valve implantation in Hospital Santa Marta (January 2010 to December 2016). Data was collected from the periprocedural records of patients. Patients were stratified according to anesthetic technique.

Results: From our patients' sample, 57.0% were female, with median age 82 [58 - 95] years. Most patients underwent general anesthesia (68.5%). In the local anesthesia with sedation group there was a shorter duration of the procedure (120; [60 - 285] *vs* 155 [30 - 360]) and a lower number of patients requiring administration of vasopressors (61.8% *vs* 28.3%) – $p < 0.05$. There were no differences regarding length of hospital stay (9 [4 - 59] *vs* 10 [3 - 87]), periprocedural complications (66.0% *vs* 72.5%), readmission rate (4.3% *vs* 3.9%) or 30-days (2.1% *vs* 4.9%) and 1-year mortality (6.4% *vs* 7.8%) – $p > 0.05$. There was an increasing number of transcatheter aortic valve implantations performed under local anesthesia with sedation over the years.

Discussion: The choice of anesthetic technique depends on the patient's characteristics, experience and preference of the team.

Conclusion: Local anesthesia with sedation seems to be associated with similar results as general anesthesia. The increase in the number of transcatheter aortic valve implantations under local anesthesia with sedation seems to follow the trend of lower invasiveness of the procedure.

Keywords: Anesthesia, General; Anesthesia, Local; Heart Valve Prosthesis Implantation; Transcatheter Aortic Valve Replacement

RESUMO

Introdução: A implantação percutânea de válvula aórtica constitui uma opção menos invasiva de substituição valvular. O número de procedimentos sob anestesia local com sedação tem vindo a crescer com o aumento da experiência da equipa e os acessos cada vez menos invasivos. O trabalho tem como objetivo a descrição da evolução da técnica anestésica utilizada nos doentes submetidos a implantação percutânea de válvula aórtica no nosso centro ao longo dos anos, e sua comparação.

Material e Métodos: Estudo retrospetivo em 149 doentes consecutivos submetidos a implantação percutânea de válvula aórtica no Hospital de Santa Marta (janeiro de 2010 a dezembro de 2016). Os dados foram colhidos a partir dos registos peri-procedimento e estratificados de acordo com a técnica anestésica.

Resultados: Da amostra recolhida, 57,0% dos doentes eram do sexo feminino, com mediana idade 82 [58 - 95] anos. A maioria dos doentes foi submetida a anestesia geral (68,5%). Verificou-se menor duração do procedimento (120 [60 - 285] *vs* 155 [30 - 360]) e menor número de doentes com necessidade de administração de vasopressores na implantação percutânea de válvula aórtica (61,8% *vs* 28,3%) – $p < 0,05$. Não se registaram diferenças referentes à duração do internamento (9 [4 - 59] *vs* 10 [3 - 87]), complicações periprocedimento (66,0% *vs* 72,5%), reinternamento (4,3% *vs* 3,9%), mortalidade aos 30 dias (2,1% *vs* 4,9%) e 1 ano (6,4% *vs* 7,8%) – $p > 0,05$. O número de implantações percutâneas de válvula aórtica realizados sob anestesia local com sedação aumentou ao longo dos anos.

Discussão: A escolha da técnica anestésica tende a variar consoante as características do doente, a experiência e preferência da equipa.

Conclusão: Os resultados da anestesia local com sedação são similares aos da anestesia geral, tendo o aumento do número de procedimentos de implantação percutânea de válvula aórtica sob anestesia local com sedação acompanhado a tendência de menor invasibilidade do procedimento.

Palavras-chave: Anestesia Geral; Anestesia Local; Implante de Prótese de Válvula Cardíaca; Substituição Percutânea da Válvula Aórtica

INTRODUCTION

Severe aortic stenosis is associated with poor outcomes when left untreated. Approximately 4.4% of the population aged 65 and older are affected each year,[1,2] with an increasing prevalence expected with population ageing.

Transcatheter aortic valve replacement or implantation (TAVI) is a minimally invasive treatment option[1] in frail patients, with symptomatic, inoperable severe aortic stenosis (namely due to the presence of 'porcelain aorta') as well as in high-risk surgical patients.[1,3-7]

Therefore, constraints related to the procedure itself as well as to the approach to patients undergoing valve implantation should be taken into consideration.

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High success rates with transcatheter prosthetic heart valve implantation explain for the increasing number of procedures.[1] It is believed that it will become a treatment option in low-risk patients due to the simplification of the procedure, the technological development and an increasing experience.[1,8]

The approach to TAVI has become a less and less invasive procedure (when compared to open-heart surgical aortic valve replacement) and so it makes sense that anaesthesia follows the same trend.[6,7]

General anaesthesia (GA) has been most widely used during the period of implementation of these programs in different European centres, with an increasing number of procedures carried out under local anaesthesia plus sedation (LAPS) due to an increasing experience and minimally invasive approaches have increasingly been used.[7]

Wide differences regarding the preferred anaesthetic technique have been found between hospital centres and there is still no consensus on which is the best choice.[6]

Similar outcomes as regards success rate and patient's morbidity and mortality rate have been described with both anaesthetic techniques.[1,8] Differences regarding procedure length and the length of hospital stay have been found, while a significant decline in both has been found with the use of conscious sedation.[7,8]

This study was aimed at describing the different anaesthetic techniques used in our centre over the years in patients undergoing TAVI, in addition to compare the outcomes with both techniques (LAPS *vs.* GA).

MATERIAL AND METHODS

This was a retrospective study including 149 consecutive patients who underwent TAVI via transfemoral or transubclavian access at the *Hospital de Santa Marta* between Jan 2010 and Dec 2016; all the patients were considered for the procedure due to the presence of severe aortic stenosis and were considered as inoperable or at a high operative risk.

Data were collected from patient's medical records.

Patient's demographic and echocardiography characteristics, anaesthetic technique, perioperative complications and short and medium-term outcomes were considered for data analysis.

Patients were monitored according to the American Society of Anesthesiologists – ASA guidelines. All patients were also monitored with BIS® (bispectral index) score. Trans-oesophageal echocardiography (TOE) was used in GA patient monitoring, while fluoroscopy and trans-thoracic echocardiogram have been used in LAPS patient monitoring.

Cardiac pacing was used in all patients, through central venous catheter (CVC), radial arterial catheter (RAC) and electro-catheter placement.

Fentanyl (1 – 3 mg/kg), propofol (1 – 2 mg/kg) and rocuronium (0.6 mg/kg) were used in GA induction, through tracheal intubation and halogenated agents or propofol were used in maintenance under target-controlled infusion (TCI). Patients were extubated at the end of the procedure following anaesthesia recovery.

Propofol and remifentanil were used under TCI and spontaneous ventilation was maintained in LAPS patients.

Venous access was assessed by computed tomography (CT) scan and poor venous access was defined by the presence of diameter < 5 mm and extensive calcification.

Valve Academic Research Consortium-2 (VARC-2) criteria were used for the definition of perioperative complications.[9]

The mortality rate referred to patients who underwent TAVI in 2016 was assessed up to data collection.

SPSS 22.0 version (IBM Analytics, Armonk, USA) software was used in statistical analysis.

Patients were stratified according to the anaesthesia technique.

Variables with non-normal distribution are presented as frequency and mean + standard deviation or median and interquartile range (25^{th} – 75^{th} percentiles, IQR). Normality of quantitative variables was assessed with the Shapiro-Wilk test; categorical variables are presented as absolute values and percentage. Chi-square test was used in bivariate analysis.

Quantitative variables were compared with t-test or Mann-Whitney's test.

The results were considered as statistically significant when $p < 0.05$.

RESULTS

A group of 149 patients was included in the study (64 male – 43.0%; median age 82 [IQR 78 – 85]). All patients were classified as ASA III (n = 54; 36.2%) or IV (n = 95; 63.8%).

All patients were primarily diagnosed with severe aortic stenosis and underwent TAVI, mostly via transfemoral access (n = 145; 97.3%), while the remaining were approached via subclavian access due to the presence of poor quality femoral access.

A 150 minute median procedure length (IQR 120 – 180) has been found, in addition to a median 3-day length of stay at the ICU (IQR 2 – 5) and 10-day total hospital stay (8 – 17).

Patient's demographic and ultrasound characteristics, as well as perioperative data are shown in Table 1, 2 and 3.

Most patients underwent TAVI under GA (n = 102; 68.5%).

Lower ASA severity score, in addition to lower incidence of hypertension (HTN), peripheral vascular disease (PVD), poor tolerance of dorsal decubitus position and poor venous access have been found in LAPS patients. However, the presence of previous acute myocardial infarction (AMI) has been mostly found in these patients.

Lower procedure length ($p < 0.05$) in addition to lower vasopressor use ($p < 0.05$) were found in LAPS patients, when compared to GA patients, as shown in Table 3. More patients in need for vasopressor support were found in the group of GA patients, while no differences were found

between both techniques regarding other variables, namely age, gender, EuroScore II, TAVI approach, total and ICU length of stay, type of perioperative complications, readmission rate and 30-day and 1-year mortality ($p > 0.05$).

An increasing number of TAVI procedures under LAPS has been found throughout the study period, when compared to GA (all procedures were carried out under GA in 2010, while 50.0% of these were carried out under LAPS in 2015) – Fig. 1.

Intraoperative bleeding complications (9.3%) and acute kidney injury (AKI) (3.1%), new-onset arrhythmias including atrial fibrillation (8.6%), vascular complications (namely

Table 1 – Characteristics of the group of patients (preoperative)

	Total (n = 149)	Anaesthesia technique		p
		GA (n = 102)	LAPS (n = 47)	
Age				
Median [IQR]	82 [78 - 85]	82 [78 - 85]	81 [77 - 85]	0.953
Gender				0.37
Male	64 (43.0%)	41 (40.2%)	23 (48.9%)	
Female	85 (57.0%)	61 (59.8%)	24 (51.1%)	
ASA score				**0.04***
ASA 3	54 (36.2%)	31 (30.4%)	23 (48.9%)	
ASA 4	95 (63.8%)	71 (69.6%)	24 (51.1%)	
EuroScore II				0.77
Low: 0 - 2	15 (10.1%)	9 (8.9%)	6 (12.8%)	
Moderate: 3 - 5	49 (32.9%)	34 (33.3%)	15 (31.9%)	
High: > 5	85 (57.0%)	59 (57.8%)	26 (53.3%)	
HTN	121 (81.2%)	78 (76.5%)	43 (91.5%)	**0.04***
DM	43 (28.9%)	29 (28.4%)	14 (29.8%)	0.84
Dyslipidaemia	87 (58.4%)	57 (55.9%)	30 (63.8%)	0.38
Obesity	28 (18.8%)	16 (15.7%)	12 (25.5%)	0.18
Smoking	12 (8.1%)	8 (7.8%)	4 (8.5%)	1.00
COPD	27 (18.1%)	22 (21.6%)	5 (10.6%)	0.17
PVA criteria	33 (22.15%)	23 (22.5%)	10 (21.3%)	1.00
NYHA classification of CHF				0.20
Class I-II	53 (35.6%)	40 (39.2%)	13 (27.7%)	
Class III-IV	96 (64.4%)	62 (60.8%)	34 (72.3%)	
Previous CKD (GFR < 60 mL/min)	63 (42.0%)	38 (37.3%)	21 (47.7%)	0.27
PVD	39 (26.2%)	32 (31.4%)	7 (14.9%)	**0.04***
CAD	61 (40.9%)	40 (39.2%)	21 (44.7%)	0.59
Previous AMI	23 (15.4%)	11 (10.8%)	12 (25.5%)	**0.03***
PCI	28 (18.8%)	20 (19.6%)	8 (17.0%)	0.82
Previous heart surgery	14 (26.8%)	23 (22.5%)	17 (36.2%)	0.11
Previous CABG	31 (20.8%)	17 (16.7%)	14 (29.8%)	0.08
Arrhythmia	13 (8.7%)	10 (9.8%)	3 (6.4%)	0.76
AF	43 (28.9%)	31 (30.4%)	12 (25.5%)	0.70
Previous neurological impairment/stroke/TIA	21 (14.1%)	16 (15.7%)	5 (10.6%)	0.46
Previous sensory impairment	6 (4.03%)	6 (5.9%)	0 (0.0%)	0.18
Poor tolerance of dorsal decubitus position	28 (18.8%)	28 (27.5%)	0 (0.0%)	**< 0.01***
Preoperative haematocrit				
Mean	37.03 ± 5.41	36.65 ± 5.49	37.84 ± 5.18	0.22
Poor venous access as per CT-scan	39 (26.2%)	36 (35.3%)	3 (6.4%)	**< 0.01***

*: $p < 0.05$; IQR: interquartile range [25th - 75th]; HTN: hypertension; DM: diabetes mellitus; COPD: chronic obstructive pulmonary disease; PVA: poor venous access; NYHA: New York Heart Association; CHF: congestive heart failure; CKD: chronic kidney disease; PVD: peripheral vascular disease; CAD: coronary artery disease; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; AF: atrial fibrillation; TIA: transient ischaemic attack; GFR: glomerular filtration rate; CT: computed tomography

Table 2 – Echocardiography data

	Total (n = 149)	Anaesthesia technique		p
		GA (n = 102)	LAPS (n = 47)	
Ejection fraction				0.80
Normal (≥ 50%)	115 (78.2%)	78 (77.2%)	37 (80.4%)	
Below normal (40 - 49%)	19 (12.9%)	13 (12.9%)	6 (13.0%)	
Low (< 40%)	13 (8.8%)	10 (9.9%)	3 (6.5%)	
Mitral regurgitation (moderate/severe)	59 (39.60%)	47 (46.1%)	12 (25.5%)	**0.02***
Pre-TAVI AVA (cm²) Median [IQR][1]	0.63 [0.50 - 0.80]	0.61 [0.50 - 0.80]	0.63 [0.50 - 0.81]	0.87
Pre-TAVI PASP (mmHg) Median [IQR][1]	40.00 [31.75 - 51.00]	40.00 [30.00 - 51.00]	40.00 [33.50 - 53.25]	0.29
Pre-TAVI Ao Peak Gradient (mmHg) Median [IQR][1]	81.00 [68.75 - 97.50]	81.00 [69.50 - 96.50]	83.00 [66.00 - 103.00]	0.72
Pre-TAVI Ao Mean Gradient (mmHg) Median [IQR][1]	50.50 [42.25 - 61.75]	51.50 [42.25 - 60.75]	49.50 [41.50 - 63.50]	0.89
Post-TAVI AVA (cm²) Median [IQR][1]	1.30 [1.10 - 1.90]	1.20 [1.00 - 1.45]	1.60 [1.20 - 2.00]	0.09
Post-TAVI PASP (mmHg) Median [IQR][1]	38.00 [31.00 - 45.00]	38.00 [31.00 - 44.00]	40.00 [31.75 - 47.00]	0.41
Post-TAVI Ao Peak Gradient (mmHg) Median [IQR][1]	17.50 [13.25 - 24.75]	19.50 [14.00 - 26.00]	15.00 [13.00 - 19.75]	0.06
Post-TAVI Ao Mean Gradient (mmHg) Median [IQR][1]	10.00 [7.00 - 13.00]	10.00 [8.00 - 14.50]	8.50 [7.00 - 12.25]	0.23

*: $p < 0.05$; AVA: aortic valve area; PASP: pulmonary artery systolic pressure; Ao: aortic valve

affecting the lower limb with the use of transfemoral route – 11.0%) and thromboembolic events (3.8%) were among the most frequent complications found, all affecting postoperative outcomes of each patient.

The presence of new-onset arrhythmias (39.2%) and major bleeding complications (34.3%), vascular complications (24.5%) and the need for permanent pacemaker implantation (22.5%) were included, by decreasing order, as the most frequent complications in the group of GA patients, while major bleeding complications (31.9%) and vascular complications (23.4%) were mostly found in LAPS patients.

The need for conversion to GA (three patients) is worth mentioning (due to cefazolin hypersensitivity - one patient and to vascular complications with haemodynamic repercussion - two patients).

No anaesthesia-related complications have been found.

DISCUSSION

Different anaesthesia techniques according to the centre, to patient's characteristics and team preferences are used in patients undergoing TAVI.

As no consensus was ever reached on which technique is preferred for this procedure, the selection of the most adequate alternative should be the responsibility of the anaesthetist, taking into account the technique with which the whole team feels more comfortable, always considering the patient's comorbidities, preoperative characteristics and echocardiographic evaluation, aimed at the patient's safety and comfort.

This study has shown the increasing number of TAVIs carried out under LAPS in our centre.

Lower procedure length and lower need for vasopressor use was found in LAPS patients (when compared to GA).

Differences in procedure lengths have been associated with longer time spent in induction and recovery from anaesthesia in GA patients, while the lower need for vasopressor use found in LAPS patients was probably due to the fact that sedation allowed for a reduction in cardiopressor and vasopressor effects which are usually associated with anaesthetic drugs in patients with severe aortic stenosis.

According to other studies, LAPS is also associated with other benefits including lower hospital stay as well as lower perioperative complication rate and lower short and long-term mortality rate, even though these were not found in this group of patients.[7]

Other postoperative benefits are associated with LAPS, including shorter recovery time and subsequently earlier ambulation, reducing the length of stay and associated costs.[8] An increasing experience of the cardiology and anaesthesia team with TAVI procedure is also associated with the increasing number of procedures carried out under LAPS, anticipating an even greater number of procedures in the future, under minimally invasive anaesthesia techniques. Conclusions from previous studies suggest the preference for the use of GA during the learning curve of operators as it helps keeping the patient steady, allowing for the control of the respiratory movements and the use of TOE monitoring.[8,11] The type of approach (transfemoral

Table 3 – Perioperative data

	Total (n = 149)	Anaesthesia technique		p
		GA (n = 102)	LAPS (n = 47)	
TAVI access route				0.31
Transfemoral	145 (97.3%)	98 (96.1%)	47 (100%)	
Trans-subclavian	4 (2.7%)	4 (3.9%)	0 (0.0%)	
Procedure length (minutes) Median [IQR][1]	150.00 [120.00 - 180.00]	155.00 [135.00 - 195.00]	120.00 [105.00 - 150.00]	**< 0.01***
Stay at ICU (days) Median [IQR][1]	3.00 [2.00 - 5.00]	3.00 [2.00 - 5.00]	3.00 [2.00 - 4.00]	0.26
Total length of stay (days) Median [IQR][1]	10.00 [8.00 - 17.00]	10.00 [8.00 - 18.50]	9.00 [7.00 - 14.00]	0.49
Need for vasopressor support	76 (51.4%)	63 (61.8%)	13 (28.3%)	**< 0.01***
Perioperative complications*	105 (70.5%)	74 (72.5%)	31 (66.0%)	0.44
Major bleeding complications	50 (33.56%)	35 (34.3%)	15 (31.9%)	0.85
Arrhythmia	53 (35.57%)	40 (39.2%)	13 (27.7%)	0.20
Permanent pacemaker implantation	30 (20.13%)	23 (22.5%)	7 (14.9%)	0.38
Vascular complications	36 (24.2%)	25 (24.5%)	11 (23.4%)	1.00
Infectious complications	28 (18.8%)	21 (20.6%)	7 (14.9%)	0.50
AKIN classification	22 (14.77%)	17 (16.7%)	5 (10.6%)	0.10
1	12 (8.1%)	11 (10.8%)	1 (2.1%)	
2	5 (3.36%)	3 (2.9%)	2 (4.3%)	
3	5 (3.36%)	3 (2.9%)	2 (4.3%)	
Respiratory failure	4 (2.7%)	4 (3.9%)	0 (0.0%)	0.31
Stroke/TIA	3 (2.0%)	2 (2.0%)	1 (2.1%)	1.00
ACS	7 (4.7%)	5 (4.9%)	2 (4.3%)	1.00
Complications – Other	16 (10.7%)	9 (8.8%)	7 (14.9%)	0.27
CRA	5 (3.4%)	4 (3.9%)	1 (2.1%)	1.00
Transfusion	46 (30.9%)	32 (31.4%)	14 (29.8%)	1.00
Readmission	6 (4.0%)	4 (3.9%)	2 (4.3%)	1.00
30-day mortality	6 (4.0%)	5 (4.9%)	1 (2.1%)	0.67
One-year mortality	11 (7.4%)	8 (7.8%)	3 (6.4%)	1.00

ICU: Intensive care unit; AKI: acute kidney injury; ACS: acute coronary syndrome; CRA: cardiorespiratory arrest.
*: $p < 0.05$

route being the most widely used) should always be taken into consideration in the selection of the anaesthesia technique.

In line with what has been found in the *Hospital de Santa Marta*, Ruggeri *et al.* have given their support to the use of GA in specific conditions due to the clinical assessment by both the anaesthetist and the operator, while TOE monitoring is recommended in high-risk patients or in patients at higher risk for complications.[11]

The need for anaesthetists to be prepared for GA induction at any moment, whenever required, has been recommended by every author supporting the use of LA.[11]

A low rate of the need for conversion to GA is another finding in support of this anaesthesia technique in TAVIs procedures, while no case of conversion was ever due to anaesthesia-related causes.

The good outcome rates found with TAVI in our centre when compared to open-heart surgical aortic valve replacement (SAVR) are worth mentioning, as well as the rate of complications, including intraoperative bleeding complications (9.3% *vs.* 19.5% with SAVR), AKI (3.1% *vs.* 3.2% in SAVR) and new-onset arrhythmias including atrial fibrillation (8.6% *vs.* 16.0% with SAVR). A higher number of vascular complications (particularly affecting the lower limb with the use of transfemoral route) (11.0% *vs.* 3.2% with SAVR) and thromboembolic events (3.8% *vs.* 2.1% with SAVR) have been found with TAVI under LAPS.[6,10]

The fact that this was a retrospective study, in addition to the fact that these results reflect the experience and results of a single centre are limitations of the study. Considering that the experience of the cardiologists is crucial in the selection of the anaesthesia technique, the development of multicentric studies in centres with different volumes of TAVIs is therefore crucial for the assessment of the applicability of the different anaesthesia alternatives.

A small group of patients was included in our study and

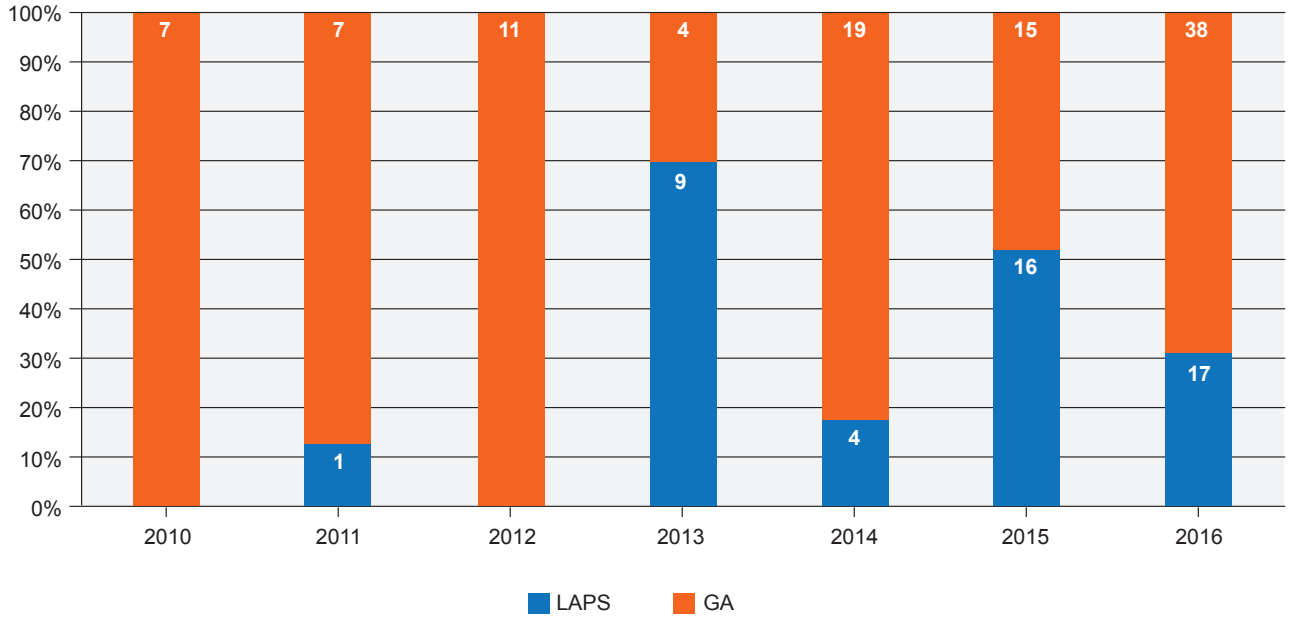

Figure 1 – Number of TAVI procedures performed per year and anaesthesia technique

further studies involving greater groups of patients and throughout longer follow-up periods are also crucial in the identification of the impact of the anaesthesia technique on long-term outcomes.

Considering that a wide range of interventions are included in LAPS techniques, the specification of the different drugs that were used is also necessary to assess and study the interference of each drug with the outcomes.

A comparison of the immediate postoperative outcomes between GA and LAPS patients aimed at studying any differences in the levels of sedation and confusional states would also be very important.[12]

All these aspects are now very topical, as short-acting agents currently used in GA do have pharmacokinetic properties that allow for increasingly faster induction and recovery times, associated with an increasingly safer profile and immediate postoperative extubation.[12]

CONCLUSION

TAVI procedures have progressively been performed and increasingly selected in patients with severe aortic stenosis.

Different benefits regarding a decline in procedure length and in the need for vasopressor agents have been found in our study with patients undergoing TAVI under LAPS.

The selection of the anaesthesia technique does not seem to affect the outcomes.

Considering the increasing experience of cardiologists and anaesthetists in the approach to patients undergoing TAVI and with the benefits that were found, the use of LAPS as minimally invasive technique in patients undergoing TAVI has increased in our centre.

Further multicentric studies are required, taking into account the level of experience of each centre, allowing for the identification of any preoperative characteristics as well as the evaluation of medium and long-term outcomes that could be crucial for the selection of the most adequate anaesthesia technique.

Anaesthetists should have a relevant role in the approach to high-risk patients throughout the whole perioperative period, from anaesthesia assessment – including frailty assessment – up to follow-up and the evaluation of the specific impact of anaesthesia. It is also very important that the trend towards minimally invasive techniques that has been followed by endovascular valve replacement procedures would also be followed by anaesthesia.

HUMAN AND ANIMAL PROTECTION

The authors declare that the followed procedures were according to regulations established by the Ethics and Clinical Research Committee and according to the Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data**.** Informed consents were obtained.

CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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