Minimalist Approach for Percutaneous Aortic Valve Implantation

Implante percutáneo de la válvula aórtica con estrategia minimalista

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is becoming the standard procedure for high-risk patients requiring aortic valve replacement. This technique has evolved rapidly and the so-called minimalist strategy is gaining worldwide attention, while supporting evidence is still being assembled.

Objective: The aim of this study was to compare 30-day outcomes of the minimalist approach (MA) versus the standard approach (SA) for TAVI performed in a single center.

Methods: Between September 2009 and February 2018, 303 consecutive TAVI procedures were performed, 229 (75.6%) using the MA and 74 (24.4%) with the SA.

Results: Mean age was 79.5 years and both groups had similar characteristics. There were no differences in hypertension, diabetes, smoking habits, previous percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery, acute myocardial infarction (AMI), chronic obstructive pulmonary disease, atrial fibrillation and dialysis. PCI before TAVI (combined procedure) and kidney failure (eGFR <60 ml / min / 1.73 m2) were more common in the SA group. The STS score was similar in both groups. The total duration of the procedure and in-hospital stay were lower in the MA group (125±26 vs. 211±48 minutes; p <0.001, and 4.1 vs. 6.3 days; p=0.01, respectively). There were no differences in mortality (3.9% vs. 1.4%; p=ns), incidence of AMI, stroke, major bleeding requiring transfusion or vascular complications at 30 days. The closure device failed in four patients (one underwent surgical repair and three required a covered stent). Moderate paravalvular leaks (PVL) were more frequent in the SA group (11.8% vs. 23%; p=0.01) but the incidence of severe PVL was similar (1.3% vs. 2.7%).

Conclusion: The MA for TAVI proved to be feasible and safe, reducing the procedure duration and in-hospital stay, with 30-day outcomes similar to those of the SA but providing better comfort for the patient.

Key words: Transcatheter Aortic Valve Replacement – Cardiac Catheterization - Heart Valve Prosthesis Implantation - Vascular Closure Devices

RESUMEN

Introducción: El reemplazo de válvula aórtica transcatéter (TAVR) se está convirtiendo en un procedimiento estándar para pacientes con alto riesgo quirúrgico que necesitan el reemplazo de la válvula aórtica. Esta técnica ha evolucionado rápidamente y la llamada estrategia minimalista está ganando adeptos en todo el mundo, mientras la evidencia en su favor todavía se está acumulando.

Objetivo: Analizar los resultados a 30 días de la estrategia minimalista (MIN-A) en comparación con la técnica convencional (CON-A) en la experiencia de un solo centro.

Material y métodos: Entre septiembre de 2009 y febrero de 2018, se realizaron 303 procedimientos consecutivos de TAVR por acceso femoral, 229 (75,6%) de ellos con MIN-A y 74 (24,4%) con CON-A.

Resultados: La edad promedio de los pacientes fue de 79,5 años y ambos grupos tenían características similares. No hubo diferencias entre estos en lo referido a hipertensión, diabetes, tabaquismo, ICP o CRM previa, IAM, EPOC, fibrilación auricular y diálisis. La ATC por etapas antes del TAVR (procedimiento combinado) y la insuficiencia renal (eGFR <60 ml / min / 1,73 m2) fueron más frecuentes en los sometidos a CON-A. El score del STS fue similar en ambos grupos. El tiempo del procedimiento fue menor en el grupo MIN-A (125±26 vs. 211±48 minutos; p<0,001), al igual que el tiempo de hospitalización (4,1 vs. 6,3 días; p = 0,01). A los 30 días, no hubo diferencias en la mortalidad (3,9% frente a 1,4%; p = 0,29), IAM, accidente cerebrovascular, hemorragia, transfusión y complicaciones vasculares. Cuatro pacientes tuvieron falla del dispositivo de cierre (1 requirió reparación quirúrgica, 3 requirieron stent cubierto). Las fugas paravalvulares (PVL) moderadas fueron más frecuentes en el grupo CON-A (11,8% vs. 23%; p=0,01), pero las PVL graves tuvieron similar incidencia (1,3% vs. 2,7%).

Conclusión: La estrategia minimalista en el implante percutáneo de la válvula aórtica demostró ser factible y segura; dicha estrategia disminuyó el tiempo del procedimiento y la estadía en el hospital, con similares resultados clínicos que la estrategia convencional a 30 días, pero con mejor confort para el paciente.

Palabras clave: Reemplazo de la válvula aórtica transcatéter – Cateterismo cardíaco - Implantación de prótesis de válvulas cardíacas Dispositivos de cierre vascular

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Abbreviations

AMI	Acute myocardial infarction		**PVL**	Paravalvular leak
CABGS	Coronary artery bypass graft surgery		**SA**	Standard approach
Fr	French		**TAVI**	Transcatheter aortic valve implantation
IV	Intravenous		**TEE**	Transesophageal echocardiography
MA	Minimalist approach		**TTE**	Transthoracic echocardiography
PCI	Percutaneous coronary intervention			

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is currently the strategy of choice in high-risk or inoperable patients. (1, 2) It is also a valid option for intermediate-risk patients, (3, 4) particularly when the transfemoral access is feasible. The use of TAVI for low risk patients is currently under evaluation. (5)

This technique emerged as a complex procedure under general anesthesia, orotracheal intubation, with surgical venous access, invasive pulmonary and arterial pressure monitoring, routine transesophageal ecochardiography, urinary catheterization and temporary pacemaker for at least 24 hours. However, the technique has been simplified to be less aggressive in an elderly and frail population with comorbidities, in whom any invasive procedure, including prolonged hospitalization, can be risky or harmful.

Based on this concept, a minimalist approach (MA) for TAVI has emerged and is continuously evolving. For this analysis, MA was defined as the use of local anesthesia and conscious sedation (sedation/analgesia), use of transthoracic Doppler echocardiography and percutaneous closure of the vascular access. The aim of this study was to compare the MA with the standard approach (SA) for TAVI.

METHODS

Between September 2009 and February 2018, 311 consecutive TAVI procedures were performed; 8 of them (2.6%) were excluded from this analysis because a non-transfemoral access was used [3 subclavian, 3 transapical and 2 transaortic], which required general anesthesia. Of the remaining 303 procedures via the transfemoral access, 229 (75.6%) were performed with the MA, while the SA was used in the rest.

Severe aortic stenosis was defined as the presence of mean pressure gradient >40 mm Hg, peak systolic velocity >4 m/s, aortic valve area <1 cm^2, or indexed aortic valve area <0.6 cm^2/m^2, defined by Doppler echocardiography.

All the patients underwent coronary angiography and helical computed tomography angiography with 3D reconstruction using a 64-row scanner to evaluate the aortic valve, and the thoracic and abdominal aorta. All the patients were evaluated by the heart team, which decided to perform a percutaneous procedure (TAVI) considering the individual risk characteristics.

The procedures were performed in the catheterization laboratory prepared for a surgical procedure. Conscious sedation with dexmedetomidine (0.2 μg/kg/h), with or without propofol (2 μg/ml) was used for MA TAVI, and local anesthesia (2% lidocaine) was administered before vascular puncture.

Although transthoracic Doppler echocardiography (TTE) is not routinely performed in some centers, we used it to monitor valve positioning, evaluate the presence of paravalvular leak (PVL) and rule out complications in some patients. In those few cases in which TTE could not resolve an issue (in general, due to a poor ultrasound window), transesophageal echocardiography (TEE) was performed.

The femoral access site was chosen according to the presence of calcification, tortuosity, level of the femoral artery bifurcation and luminal size, in order to predict the correct insertion of the suture-mediated closure device which is placed before inserting the introducer sheath (Pre-close technique) and then, that of the introducer required to advance each specific device. Once the access site was identified, the contralateral femoral artery was punctured and a 7 Fr arterial introducer was inserted, through which, a 5 Fr pigtail catheter was advanced to perform crossover and progress it to the common femoral artery of the chosen access site. The common femoral artery was identified under angiographic guidance to avoid low puncture sites or punctures at the bifurcation, and was accessed through its anterior aspect. Subsequently, a 6 Fr introducer was inserted and a 0.018" x 300 cm guidewire was advanced through the contralateral pigtail catheter and was positioned distally in the superficial femoral artery ipsilateral to the valve access site; then, the catheter was removed. This guidewire was used at the end of the procedure to advance a balloon through the contralateral access and insufflate it to achieve hemostasis of the access site, together with manual compression, if necessary.

Then, a closure device (a 10 Fr Pre-close device, Abbott Vascular, Abbott Park IL, US) was inserted (the so called Pre-close technique). When this device is removed, it leaves a guidewire to allow the introduction of a larger introducer and close up to 24 Fr access sites. The size of the introducers used for TAVI range between 14 Fr and 18 Fr, according to the device.

In MA cases, urinary catheters were not used and the temporary pacemaker catheter was introduced through another femoral access.

We included moderate-risk or high-risk patients with indication of TAVI according to the heart team. Patients with severe coronary artery stenoses of major epicardial vessels or of bypass grafts and with clinical indication of revascularization underwent percutaneous coronary intervention (PCI) between 1 and 120 days before TAVI.

The procedures were performed under anticoagulation with unfractionated heparin to reach an activated clotting time >250 seconds.

After the procedure, all the patients received dual antiplatelet therapy with aspirin and clopidogrel or ticagrelor for at least three months. Patients with indication of anticoagulation were treated with dual therapy with aspirin and oral anticoagulation or clopidogrel and oral anticoagulation in those who had undergone PCI within the past six months and with indication of oral anticoagulation for different reasons (generally, atrial fibrillation).

Once the valve was implanted and the delivery system was removed, a balloon was advanced through the contralateral access to the external iliac artery ipsilateral to the access site, while the introducer was removed and the vascular access site was closed with the percutaneous closure device. After suturing, the balloon was advanced to the common femoral artery and was carefully insufflated at low pressure for 3-5 minutes. If necessary, after balloon deflation, manual compression was used for hemostasis during 5-10 minutes. Finally, closure of the access site was confirmed by angiography.

Impaired kidney function before TAVI was defined as eGFR <60 ml/min/1.73 m^2, while the definitions of the Valvular Academic Research Consortium (VARC) were used to define acute kidney injury after TAVI. (6)

Procedural success was defined as the correct positioning of a prosthetic heart valve in the proper anatomical location in the absence of mortality, prothesis mismatch, with mean gradient <0 mm Hg or peak velocity <3 m/s and absence of moderate or severe aortic regurgitation.

Paralvvular leaks (PVL) were evaluated by Doppler echocardiography using the criteria of jet width (vena contracta), jet density and jet deceleration rate, and reverse flow in the descending aorta. Leak severity was assessed by the extent of regurgitant area with respect to the prosthetic valve circumference and was considered mild when it occupied <10%, moderate when it was between 10% and 20%, and severe when it was >20%. (7)

The total duration of the procedure was considered as the interval since the patient arrived at and left the catheterization laboratory.

Despite all the patients remain under continuous follow-up, for the purposes of this publication we shall only report the outcomes at 30 days.

Statistical analysis

Continuous variables were expressed as medians and percentages ± standard deviation. The chi-square test for categorical variables was used to compare patients' characteristics.

Ethical considerations

In all the cases, the procedure, the expected risks and benefits, and the potential complications were explained to the patients, who signed a specific informed consent approved by the Institutional Ethics Committee.

RESULTS

Mean age was 79.7±7.6 years in the MA group and 79.5±7.4 years in the SA group. There were no differences in hypertension, diabetes, smoking habits, PCI (combined procedure in stages), previous acute myocardial infarction (AMI) and coronary artery bypass graft surgery (CABGS), chronic obstructive pulmonary disease (COPD), atrial fibrillation and need for dialysis. However, the proportion of men, PCI before TAVI and impaired kidney function was greater in the SA group. Aortic valve area, aortic gradient, left ventricular systolic function on Doppler echocardiography, and STS risk score were similar in both groups (Table 1).

One patient in the MA group required TEE due to poor ultrasound window for TTE. The use of the MA increased over time and with the experience of the medical team (Figure 1).

CoreValve was the most frequently implanted prosthesis, followed by CoreValve Evolute R, Lotus, Sapiens XT, Accurate Neo and Portico.

The total duration of the procedure and in-hospital stay were lower in the MA group (125±26 vs. 211±48 minutes, p <0.001, and 4.1 vs. 6.3 days; p=0.01, respectively) (Table 2). The duration of the procedure in the cath lab became significantly shorter over time and with the learning curve of the team.

There were no differences in mortality (3.9% vs. 1.4%; p=ns), incidence of AMI, any type of stroke, major bleeding requiring transfusion or vascular complications at 30 days (Table 2). After percutaneous closure of the vascular access, three patients in the MA group presented bleeding unresponsive to external compression and inflation of the contralateral balloon, and required implantation of a covered stent. Three patients presented bleeding; one was a patient in the MA group (the same patient who required conversion due to poor ultrasound window for TTE), and bleeding was caused by the transesophageal probe. This complication was severe and required transfusions. The incidence of moderate PVL was greater in the SA, but there were no differences in severe PVL (Table 2).

DISCUSSION

This analysis demonstrates that TAVI using MA is a feasible and safe procedure, with similar results to those of the SA, but has the advantage of being less invasive for the patients and reduces in-hospital stay. One of the greatest challenges of TAVI is to reduce vascular complications which were the most important causes of mortality reported by all the series at the beginning of the experience. (8-12)

The rate of vascular complications reported by the different series according to the definitions of the VARC-2 range between 9% and 50%, depending on the subgroup and the experience of the center. The presence of vascular complications has been associated with a 2 to 3-fold increase in 30-day mortality (13), especially with the use of first-generation valves, which had a higher profile. Professional experience, the reduction in the size of delivery systems and percutaneous closure devices have helped to reduce this fearsome complication, which has decreased in experienced centers to values of 7-15%, or even less, with figures close to 4% when last generation valves with low-profile delivery systems (14 Fr) are used. (14) The rate of failure with these valves is 0.8-2%, depending on the device.

Among the few studies comparing closure devices, one analysis demonstrated the better performance of the ProGlide system (usually two devices are inserted to create a figure in X closure) compared to Prostar. (15) Our rates of vascular complications were lower than those of the aforementioned study, possibly because we had considerable experience in the use of these systems for implanting endovascular stent

	MA n (%)	SA n (%)	p
n	229	74	
Age	79.7±7.6	79.5±7.4	
≥ 90 years	13 (4.7)	5 (6.7)	
Men	112 (48.9)	43 (58.1)	0.01
Hypertension	204 (89.1)	68 (91.9)	0.5
Diabetes	56 (24.5)	15 (20.3)	0.7
Smoking habits	78 (34.5)	33 (44.6)	0.16
Previous AMI	58 (25.3)	18 (24.3)	0.83
CABGS	50 (21.8)	18 (24.3)	0.53
PCI	71 (31)	30 (40.5)	0.19
PCI before TAVI	34 (14.9)	22 (29.7)	0.004
Atrial fibrillation	46 (20.1)	12 (16.2)	0.8
History of major stroke	10 (4.3)	6 (8.1)	0.45
History of minor stroke	2 (0.9)	-	1
COPD	42 (19.2)	14 (19.7)	0.51
Kidney failure	24 (13.3)	23 (31.1)	0.001
Dialysis	6 (2.6)	2 (2.7)	0.59
LV ejection fraction	52.3±10.4	53.7±11.9	0.9
Aortic valve area	0.64±0.18	0.65±0.19	0.8
Gradient (mm Hg)	60.8±25.3	63.5±0.19	0.9
STS score	6.8±1.9	6.9±1.6	0.7

Table 1. Population characteristics

MA: Minimalist approach. SA: Standard approach. AMI: Acute myocardial infarction. CABGS: Coronary artery bypass graft surgery. PCI: Percutaneous coronary intervention. TAVI: Transcatheter aortic valve implantation. COPD: Chronic obstructive pulmonary disease. LV: Left ventricular. STS: Society of Thoracic Surgeons.
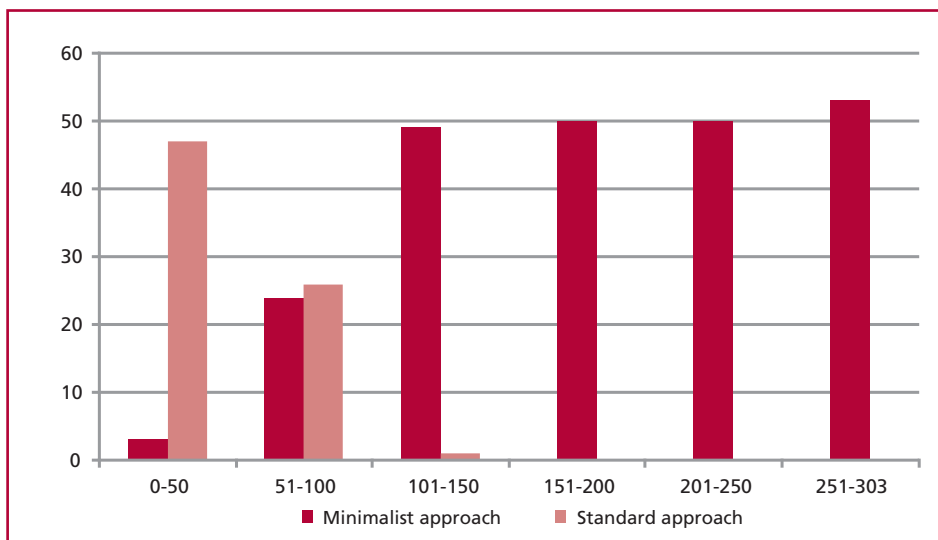

Fig. 1. Number of cases and strategy used during the learning curve

grafts in the aorta with this technique and the routine use of a contralateral balloon and adjuvant compression (which helped resolve some minor initial defects during closure). In addition, the final angiography was useful to verify the result or adopt the necessary corrective measures to avoid complications due to closure failure.

The use of TEE makes the procedure not only more complex, but also adds potential complications in a very frail population, especially in elderly women with very small body surface area. (16) In our series, three patients presented non-fatal bleeding; possibly frailty (a condition present in the three individuals) played an important role in this complication and bleeding could have been avoided with the use of TTE, in the presence of adequate ultrasound windows.

Table 2. 30-day outcomes

	MA n (%)	SA n (%)	p
Mortality	9 (3.9)	1 (1.4)	0.29
AMI	2 (0.9)	-	1
Major stroke	2 (0.9)	-	1
Minor stroke	2 (0.9)	-	1
Severe PVL	3 (1.3)	2 (2.7)	0.6
Moderate PVL	21 (11.8)	17 (23)	0.01
Permanent pacemaker	72 (35.8)	25 (33.8)	0.58
Major bleeding	14 (6.1)	3 (4)	0.41
Bleeding due to TEE	1 (0.4)	2 (2.8)	0.48
Pseudoaneurysm	1 (0.4)	-	1
Pseudoaneurysm requiring surgical repair	2 (0.9)	-	1
Access site bleeding (need for covered stenting)	3 (1.3)	-	1
Thrombosis requiring Fogarty catheter thrombectomy	1 (0.4)	-	1
Procedure duration	125±26	211±48	<0.001
Days of hospitalization	4.1±1.8	6.1±5.2	0.01

MA: Minimalist approach. SA: Standard approach. AMI: Acute myocardial infarction. PVL: Paravalvular leak. TEE: Transesophageal echocardiography.

Conversion to the SA is about 3% according to different series, (17, 18) and is associated with obesity, severe pulmonary disease, complex vascular accesses, chronic back pain and mental disorders, among others.

In a sub-analysis of the OBSERVANT study, (19) in which after a propensity score was applied, 310 pairs were matched (SA/MA), there were no differences in mortality at 30 days and 3 years, with similar risk of PVL ≥ mild. There were no differences in the need for permanent pacemaker, with a trend toward shorter intensive care unit stay in the MA group. Nowadays, advances in the MA have reduced the need for conversion.

The incidence of severe PVL was low and similar in both groups, but moderate PVL was more common in the SA group, probably associated to our learning curve.

Hemodynamic monitoring with a Swan Ganz catheter, which was performed in our initial experience, is no longer used to further simplify the approach. A temporary pacemaker was initially inserted into a vein of the neck, but was afterwards changed to the femoral vein. Although rapid pacing can be performed with the wire used for valve implantation, we still insert a temporary pacemaker catheter because we use self-expanding valves which generally require definite pacemaker according to different publications and our own experience. In addition, right ventricular perforations are uncommon with balloon-tipped floating catheters currently used for temporary pacing.

The avoidance of urinary catheters provided greater comfort to the patients, favored early ambulation and reduced the possibility of infections. In this sense, in the study published by Lauck et al. (20), (20) which included 408 patients undergoing TAVI, the incidence of urinary tract infections requiring antibiotics and documented hematuria was significantly lower (1.4% vs. 6.1%; p=0.001 and 3.7% vs. 17.6%; p=0.001, respectively). In addition, frail patients with urinary catheters had poor outcome.

In different analyses, the MA has demonstrated to reduce hospital costs due to shorter intensive care unit stay, shorter stay in the general ward and to the possibility of performing the procedure in an adapted catheterization laboratory or hybrid room and not in the operating room. In addition, avoidance of Swan Ganz catheters and urinary catheterization, together with the use of conscious sedation, allow a faster recovery and favor premature ambulation, reducing the rate of complications related to the lack of mobilization and longer in-hospital stay. (21, 22)

Study limitations

The retrospective nature of this single-center study is a limitation of this analysis. In addition, the devices have evolved over time and the strategies have changed according to the experience of the operators and heart team.

The lack of randomization could have contributed to produce a selection bias during the early stage of the experience, where patients with better anatomy (not reflected by the scores) were selected. The difference in mortality of 3.9% vs. 1.4% implies a 1.8-fold increased risk, which could indicate the type 2 error caused by the small sample size.

CONCLUSIONS

A MA during TAVI in suitable patients proved to be feasible and safe. Compared to the SA, the MA reduced the duration of the procedure and in-hospital stay, with similar outcomes at 30 days.

Conflicts of interest
None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

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