ORIGINAL ARTICLE

Transapical and Transfemoral Aortic Valve Implantation. Impact and General Considerations of both Approaches

Implante valvular aórtico percutáneo por vía transfemoral y apical. Impacto y consideraciones generales de ambos abordajes

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has emerged as a therapeutic option in inoperable or high surgical risk patients with severe symptomatic aortic stenosis. The transapical approach is an alternative access for patients with contraindications for the transfemoral access.
Objective: The aim of this study was to evaluate the feasibility and reproducibility of transapical TAVI and compare the short and mid-term outcome with that of transfemoral TAVI.
Methods: A cohort of 80 patients undergoing transapical (n=24) and transfemoral (n=56) TAVI was retrospectively evaluated. Procedure-related complications as defined by VARC-2 criteria, and short-term and mid-term mortality were analyzed and compared in both groups.
Results: Patients in the transapical group were older (83.6 ± 5 vs. 80.0 ± 8.3; p = 0.04) and had greater prevalence of coronary artery disease (75 vs. 44%; p = 0.04) and peripheral vascular disease (37% vs. 16%; p = 0.01). Patients in the transapical group had lower fluoroscopy time (14.9 minutes ± 5.8 vs. 22.9 minutes ± 8.7; p = 0.001) and presented a non-significant trend toward greater requirement of dialysis after the procedure (12.5% vs. 1.8%, p = 0.13). Hospital stay was longer in the transapical group (13.6 ± 23 days vs. 7-2 ± 6.9 days, p = 0.05). Mortality at 30 days and one year was greater in the transapical group (20.8% vs. 5.4%; p = 0.03 and 25% vs. 8.9%; p = 0.04), respectively.
Conclusions: In our experience, transapical TAVI is a feasible and reproducible procedure for patients with severe symptomatic aortic stenosis unsuitable for transfemoral approach. Transapical access was associated with increased risk of mortality at 30 days, in agreement with several publications.

Key words: Aortic Valve Stenosis - Transcatheter Aortic Valve Replacement - Endovascular Procedures

RESUMEN

Introducción: El implante valvular aórtico percutáneo (TAVI) ha surgido como una alternativa terapéutica en pacientes con estenosis aórtica grave sintomática inoperables o de elevado riesgo quirúrgico. El acceso transapical surge como alternativa para aquellos pacientes con contraindicación de implante valvular aórtico percutáneo transfemoral.
Objetivo: Valorar la factibilidad y la reproducibilidad del implante valvular aórtico percutáneo transapical en nuestro centro y comparar la evolución a corto y mediano plazo con los pacientes sometidos a implante valvular aórtico percutáneo transfemoral.
Material y métodos: Se evaluó una cohorte retrospectiva de 80 pacientes tratados con implante valvular aórtico percutáneo transapical (n=24) y transfemoral (n=56) en nuestro centro. Se compararon las complicaciones relacionadas con el procedimiento según las definiciones VARC-2, y se analizó la mortalidad a corto y mediano plazo entre ambos grupos.
Resultados: Los pacientes del grupo transapical eran más añosos (83,6 ± 5 versus 80,0 ± 8,3; p = 0,04); presentaron mayor prevalencia de coronariopatía (el 75% versus el 44%; p = 0,04) y mayor prevalencia de vasculopatía periférica (el 37% versus el 16%; p = 0,01). El grupo transapical tuvo menor exposición a rayos X, (tiempo de fluoroscopia de 14,9 minutos ± 5,8 versus 22,9 minutos ± 8,7; p = 0,001); y una mayor tendencia a requerir diálisis luego del procedimiento (el 12,5% versus 1,8%, p = 0,13). El grupo transapical permaneció más tiempo internado (13,6 ± 23 días versus 7,2 ± 6,9 días, p = 0,05). La mortalidad a 30 días fue mayor en el grupo transapical (el 20,8% versus el 5,4%; p = 0,03) y al año (el 25% versus el 8,9%; p = 0,04).
Conclusiones: En nuestra experiencia, el implante valvular aórtico percutáneo transapical es factible y puede ser realizado como un procedimiento reproducible para pacientes no aptos para el implante valvular aórtico percutáneo transfemoral. El acceso transapical se asoció con mayor mortalidad durante el seguimiento, particularmente en el período posoperatorio a 30 días, lo que coincide con varios reportes publicados.

Palabras clave: Estenosis de la Válvula Aórtica - Reemplazo de la Válvula Aórtica Transcatéter -Procedimientos Endovasculares

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Abbreviations

MI	Myocardial infarction	**TAVI**	Transcatheter aortic valve implantation
CABGS	Coronary artery bypass graft surgery	**TA-TAVI**	Transapical TAVI
MRI	Magnetic resonance imaging	**TF-TAVI**	Transfemoral TAVI

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has demonstrated similar results to surgical valve replacement in inoperable or high surgical risk patients. (1, 2) Transfemoral (TF) TAVI is preferred over transapical (TA) TAVI and other accesses for being less invasive and owing to its ability to be performed with local anesthesia. (3) On the other hand, patients undergoing TF-TAVI could be at increased risk for stroke and vascular complications secondary to friction of the delivery system with the iliofemoral axis, ascending aorta, and aortic arch. (4) There is a population of patients unsuitable for TF access simply because they have small peripheral arteries or significant peripheral vascular disease not allowing the introduction of large introducers and valve delivery systems. The TA approach has been accepted as an alternative access in patients with inadequate peripheral access. The positive results reported in patients undergoing TA-TAVI have been inferior to those of the TF access, and whether this depends on the access and access-related complications, or on prior clinical conditions of the population, still remains unclear. (5-7) The aim of this study is to evaluate the feasibility and reproducibility of TA-TAVI and compare the short and mid-term outcome of TA-TAVI with that of TF-TAVI in terms of mortality and procedure-related complications as defined by the Valve Academic Research Consortium (VARC-2). (8)

METHODS

The clinical records of 89 patients with symptomatic severe aortic stenosis treated with TAVI at Hospital Italiano de Buenos Aires, Argentina, between March 2009 and April 2016, were retrospectively reviewed. Patients who underwent TA-TAVI (n=24) and TF-TAVI (n=56) were selected for the analysis, while those who were accessed through the aorta, the iliac arteries or the suclavian arteries were excluded from the study (n=9). The bioprostheses used for the TA approach were Acurate TA™ (Symeris) while those used for TF access were Corevalve™ (Medtronic), Accurate Neo™ (Symetis) and Lotus™ (Boston Scientific) according to the preferences of the treating team (Figure 1).

Baseline population characteristics, echocardiographic and computed tomography angiography scan results, and the variables related with the procedure and the short-term (30 days) and long-term (one year) outcome were retrieved from the electronic medical records. Complications were reported according to VARC-2 criteria. (8)

All the patients selected for TAVI were previously evaluated and rejected for surgery by a multidisciplinary team (the Heart Team) consisting of clinical cardiologists, interventional cardiologists, specialists in diagnostic imaging, cardiovascular surgeons and gerontologists according to the recommendations. (9) Frailty and physical functioning of old patients were evaluated through different scores (ADL scale, clock drawing test, Mini-Mental State Examination, Edmonton score and gait speed test). Coronary anatomy was assessed by coronary angiography. All the patients underwent transthoracic or transesophageal Doppler echocardiography according to echocardiography practice guideline recommendations for assessment of percutaneous interventions in valvular heart disease. (10) The aortoiliac anatomy (minimal luminal diameter, calcification and tortuosity) was evaluated with 64 or 320-detector row computed tomography angiography or conventional angiography to decide the vascular access. All the patients signed an informed consent form approved by the Ethics Committee, based on Joint Commission International (JCI) standards.

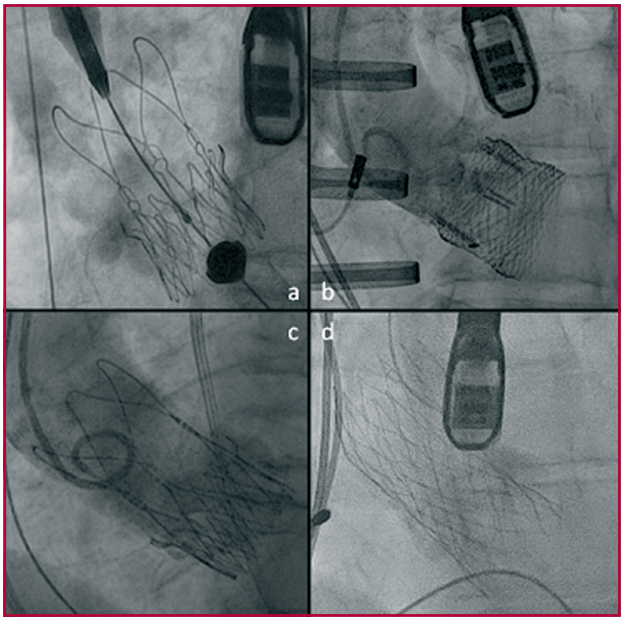

Fig. 1. Bioprostheses used (a) Acurate-TA™, (b) Lotus™, (c) Acurate Neo™, (d) CoreValve™.

All the procedures were performed under general anesthesia, and the TA or TF approach was accessed by a cardiovascular surgeon. During each procedure, transesophageal echocardiography was performed, except in case of contraindications when transthoracic echocardiography was chosen.

Statistical analysis

Categorical variables were expressed as frequencies or percentage and continuous variables as mean and standard deviation. Categorical variables were analyzed with the chi-square test or Fisher's exact test, as applicable. The Mann-Whitney test was used to compare continuous variables. Survival curves were estimated using the Kaplan-Meier

method and were compared with the log rank test. All the statistical calculations were performed using SSPSS 23.0 software package.

Ethics considerations

The study was approved by the institutional Ethics Committee and Directory, as it complies with normal treatment standards at our institution. '

RESULTS

Compared with the TF approach, patients undergoing TA-TAVI were older (83.6 ± 5 vs. 80.0 ± 8.3; p = 0.04) and had greater prevalence of coronary artery disease (75 vs. 44%; p = 0.04) and of peripheral vascular disease (37% vs. 16%; p = 0.01). There were no significant differences in EuroSCORE II and STS Score estimated risk of mortality between both groups (6.2 ± 4.0 vs. 6.6 ± 5.1; p = 0.73) and (6.1 ± 2.7 vs. 6.0 ± 4.0; p = 0.87), respectively. Baseline characteristics of the population are shown in Table 1.

The analysis of procedural data demonstrated that fluoroscopy time was significantly lower in the TA group compared with the TF group (14.9 minutes ± 5.8 vs. 22.9 minutes ± 8.7; p = 0.001). There was no difference in the need for postprocedural interventions, as balloon dilation (37% in the TA group vs. 34% in the TF group; p = 0.64).

Procedure-related complications are described in Table 2. There were no differences in TA-TAVI compared with TF-TAVI in the rate of major bleeding (8.3% vs. 7.1%, p = 0.06), stroke (8.3% vs. 3.5%, p = 0.53) and requirement of definite pacemaker after the procedure (12.5% vs. 12.5%, p = 0.7). There was a non-significant trend toward greater requirement of dialysis after the procedure in the TA group compared with the TF group (12.5% vs. 1.8%, p = 0.13), myocardial infarction within 72 hours (8.3% vs. 0%, p = 0.07) and cardiac tamponade (4.1% vs.1.8%, p = 0.06). Again, a non-significant trend was observed in the incidence of moderate or severe periprosthetic regurgitation in the TA group compared with the TF group (16% vs. 28%, p = 0.30). Hospital stay was longer in the TA group than in the TF group (13.6 ± 23 days vs. 7.2 ± 6.9 days, p = 0.05).

Considering both approaches, all-cause mortality was 10% at 30 days and 13.7% at 12 months. Mortality at 30 days and at 12 months was greater in the TA group compared with the TF group (20.8% vs. 5.4%; p = 0.03 and 25% vs. 8.9%; p = 0.04, respectively). There were no significant differences in cardiovascular mortality (TA group 12.5% vs. TF group 8.9%; p = 0.61).

In the TA group, 5 patients died within 30 days after the procedure: 2 due to nosocomial pneumonia (one patient at day 11 and the other at day 29 after TA-TAVI). Among non-infectious deaths, one patient who was discharged after one week but was readmitted 20 days after the procedure died of cardiogenic shock secondary to cardiac tamponade. This patient was receiving acenocumarol due to chronic atrial fibrillation and clopidogrel. Another patient underwent TA-TAVI plus coronary artery bypass graft surgery (CABGS) with placement of a left internal thoracic artery graft to the left anterior descending coronary artery using minimally invasive sternotomy. Transapical TAVI was successful, but grafting was technically impossible. The patient presented periprocedural acute myocardial infarction (AMI) and major bleeding, required dialysis due to acute renal failure and died at day 10 due to multiple organ failure. In the last patient, the procedure was not successful due to prosthesis malpositioning below the aortic valve annulus with severe paravalvular regurgitation, resulting in heart failure

Table 1. Baseline characteristics

	Global N = 80	Transapical N=24	Transfemoral N=56	p value
Age, years	81.6 ± 7.5	83.6 ± 5	80.0 ± 8.3	0.04
Male sex	38 (46%)	13 (54%)	25 (44%)	0.34
Diabetes mellitus	21 (25%)	8 (33%)	13 (23%)	0.47
Atrial fibrillation	17 (20%)	6 (25%)	11 (19%)	0.29
Coronary artery disease	43 (52%)	18 (75%)	25 (44%)	0.04
Previous CABGS	17 (20%)	7 (29%)	10 (18%)	0.49
Peripheral vascular disease	18 (22%)	9 (37%)	9 (16%)	0.01
Chronic obstructive pulmonary disease.	9 (11%)	2 (8%)	7 (12%)	0.81
Chronic kidney failure	29 (35%)	8 (33%)	21 (37 %)	0.41
STS estimated risk (18)	6.1 ±3.5	6.1 ± 2.7	6.0 ± 4.0	0.87
EuroSCORE II estimated risk (19)	6.8 ± 5.1	6.2 ± 4.0	6.6 ± 5.1	0.73
Aortic valve area (cm2)	0.71 ± 0.17	0.74 ± 0.16	0.70 ± 0.18	0.30
Mean aortic gradient (mm Hg)	43.2 ±14.3	41 ± 11.7	44.1 ± 15.8	0.38
Peak aortic gradient (mm Hg)	69.4 ±19.5	66.9 ± 16	70.1 ± 21.7	0.50
Mean annular diameter estimated by CT (mm)	26 ± 2.7	26.4 ± 3.3	26.2 ± 2.9	0.80
Mean annular area estimated by CT (mm2)	406.1 ±84.9	413 ± 89	427 ± 91.2	0.63

CABGS: Coronary artery bypass graft surgery. CT: Computed tomography.

	Global N = 80	Transapical N=24	Transfemoral N=56	p value
Post-TAVI 30-day mortality	8 (10%)	5 (20.8%)	3 (5.4%)	0.03
1-year mortality	11 (13.7%)	6 (25%)	5 (8.9%)	0.04
Cardiovascular mortality	8 (10%)	3 (12.5%)	5 (8.9%)	0.62
Stroke	4 (5%)	2 (8.3%)	2 (3.5%)	0.53
Immediate AMI (< 72 h)	2 (2.5%)	2 (8.3%)	0 (0%)	0.07
Cardiac tamponade	2 (2.5%)	1 (4.1%)	1(1.8%)	0.06
Moderate/severe paravalvular regurgitation	20 (25%)	4 (16%)	16 (28%)	0.30
Balloon redilation	28 (25%)	9 (37%)	19 (34%)	0.64
Major bleeding	6 (7.5%)	2 (8.3%)	4 (7.1%)	0.06
Major vascular complications	3 (3.7%)	2 (8.3%)	1 (1.8%)	0.08
Minor vascular complications	4 (5%)	0 (0%)	2(3.5%)	0.08
Post-TAVI permanent pacemaker implantation	10 (12.5%)	3 (12.5%)	7 (12.5%)	0.70
Post-TAVI dialysis requirement	4 (5%)	3 (12.5%)	1 (1.8%)	0.13
Fluoroscopy time (min)	21.1 ± 8.8	14.9 ± 5.8	22.9 ± 8.7	0.001
Days of hospitalization	9.4 ± 14.8	13.6 ± 23	6.9 ± 8.5	0.05

Table 2. Complications according to VARC-2 criteria

that required urgent surgical aortic valve replacement. The patient died on day three due to refractory cardiogenic shock.

Three deaths occurred at 30 days in the TF group. Two deaths were due to intraprocedural major bleeding. The other patient died on day 3 due to ventricular tachycardia associated with heart failure (the patient presented moderate left ventricular systolic dysfunction before the procedure).

Mean one-year survival was 10.5 months ± 0.4 (95% CI 9.7-11.3) for all the procedures. Survival was lower in the TA group (9.0 ± 1.1, 95% CI: 7.1-11.0) compared with the TF group (11.2 ± 0.3, 95% CI: 10.5-11.9). Figure 2 shows the survival curves estimated by the Kaplan-Meier method, with evidence of significant differences between both curves (log-rank test, p = 0.04).

DISCUSSION

The present registry represents our early experience in a cohort of patients from a single center -a community hospital of the city of Buenos Aires, Argentina- treated with TA-TAVI. A few conclusions can be drawn related with TA access in TAVI candidates with contraindication for TF access. Firstly, TA-TAVI is feasible in our center and can be consistently performed as a reproducible procedure, considering the 96% rate of success achieved (except for the previously described patient requiring surgical aortic valve replacement due to low implant of the prosthesis). In addition, since September 2012 24 procedures have been performed, four (4) above the 20 cases necessary to be considered an experienced center.

Secondly, TA-TAVI was associated with increased risk of mortality during follow-up compared with the TF access, particularly within 30 days after the procedure, a finding that is similar to that of previous publications (11, 12). The difference remained linear one year after the procedure (Figure 2), which means that the comparative risk of mortality is leveled after 30 days. The difference in 30-day mortality can be due to a selection bias. Despite the population had similar baseline characteristics (established by the EuroSCORE II and the STS score-estimated risk before the procedure), patients were older, frailer and with higher prevalence of established peripheral vascular disease and coronary artery disease, so that this population might be considered more vulnerable. In addition, the TA access in old and frail patients is not always tolerated. A study comparing left ventricular ejection fraction after TA-TAVI and transaortic TAVI in patients unsuitable for TF access, (12) showed that TA-TAVI was associated with a significantly lower improvement in the ejection fraction at 6 and 12 months compared with the transaortic group. (13) Another group reported apical dysfunction after TA-TAVI in 28% of the patients, (14) and although 50% of the patients recovered ventricular function, they were still associated with worse ejection fraction.

Several imaging tests have evaluated the apex in the context of the TA approach. A recent study evaluated the presence, site and extent of myocardial injury in patients undergoing TA and non-TA TAVI using cardiac magnetic resonance imaging (MRI) together with myocardial necrosis biomarkers, before and 30 days after the procedure. The TA approach not only presented greater levels of myocardial injury but also had new late gadolinium enhancement involving a median 5% of the apical myocardium. (15)

Several reports on TA-TAVI were associated with increased risk of acute renal failure despite using less amount of contrast agent during the procedure. (12) This could be due to greater systemic inflammatory response and hence greater tissue injury to the surgical trauma generated by the TA approach.

The presence of factors associated with the learning curve of TA-TAVI could have influence in the results. Our center started with the TAVI program

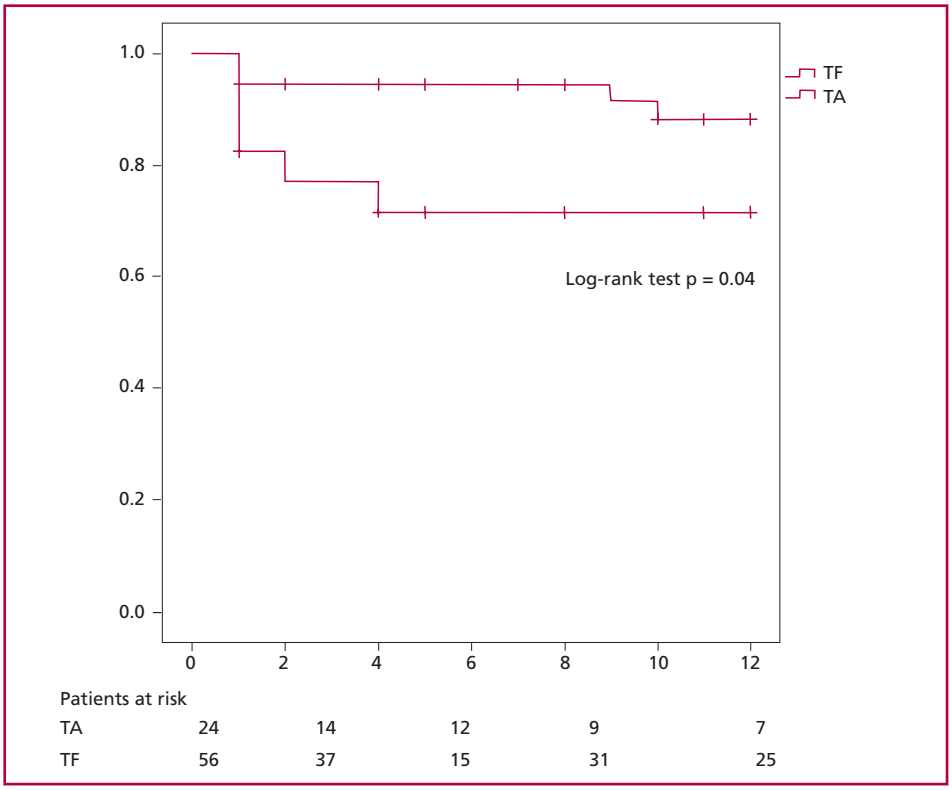

Fig. 2. Survival curves for TA-TAVI and TF-TAVI

in March 2009 only by the TF approach. The TA approach started in 2012 and, up to now, accounts for 27% of all the procedures. This means that the learning curves were different, not only due to the number of cases but because the TA approach started three years later. The learning curve of TA-TAVI was evaluated in a center which is pioneer in this approach, comparing the clinical outcomes between the first 150 (early experience) and the last 149 (recent experience) patients treated. (16) This comparison demonstrated that the amount of contrast agent used and the need to perform balloon redilation were significantly reduced in the recent experience group. Thirty-day mortality decreased from 11.3% to 6%, and 1-year mortality improved from 30.7% to 21.7% (p = 0.047). (16) This means that the experience of the center is critical in the short and long-term results when the TA approach is considered. We consider that due to the number of cases intervened we are going through the early experience with TA-TAVI.

Our study has some limitations. Our results should be cautiously interpreted due to the retrospective nature of this study which could have included a selection bias. In addition, this is the experience of a single center in Argentina. We think that the number of patients is relatively low for a comparative study, considering that the TAVI experience reported by single centers included high volume of procedures with greater number of patients (11, 17); therefore, it would be inappropriate to generalize the results. Nevertheless, we understand that this is the first registry comparing TA-TAVI versus TF-TAVI in Argentina. Another limitation is associated with the types of devices implanted. Nowadays, new-generation devices are used. These valve prostheses require smaller diameter introducers than those used in our center when these procedures were performed. We believe that these technological advances will improve the feasibility and safety of TAVI, particularly for the TF access.

In conclusion, TA-TAVI is a feasible and reproducible procedure in our center for patients with severe symptomatic aortic stenosis unsuitable for surgery and with contraindications for the TF approach. One-year survival was lower in the TA group, probably because this access is more aggressive, the characteristics of the population differed in some aspects and we are in the early stage of the learning curve.

Conflicts of interest

Dr. María R. Agatiello is a proctor for Symetis. The other authors declare to have no conflicts of interest. (See authors' conflicts of interest forms on the website/Supplementary material).

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