Scientific Research Publishing

World Journal of Cardiovascular Diseases, 2019, 9, 772-780
https://www.scirp.org/journal/wjcd
ISSN Online: 2164-5337
ISSN Print: 2164-5329

Transcatheter Aortic Valve Implantation: Experience of Sainte Clotilde Hospital in Reunion Island

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How to cite this paper: Ali, A.A., Pouillot, C. and Rambaud, G. (2019) Transcatheter Aortic Valve Implantation: Experience of Sainte Clotilde Hospital in Reunion Island. *World Journal of Cardiovascular Diseases*, **9**, 772-780.
https://doi.org/10.4236/wjcd.2019.910069

Received: August 29, 2019
Accepted: October 28, 2019
Published: October 31, 2019

Abstract

Introduction: Degenerative aortic stenosis is the most common valvulopathy in developed countries. The implantation of a percutaneous aortic valve (TAVI) has taken an important place in the management of this valvulopathy. The objective of this work is to report the results of patients treated by TAVI by the team of Sainte Clotilde Hospital (Reunion Island). **Patients and Methods:** This was a descriptive retrospective study conducted from 01/10/2014 to 01/10/ 2017 in the Sainte Clotilde Hospital, Reunion Island. All patients who received TAVI for degenerative aortic stenosis were included in the study. Follow-up was completed until 31/08/19. **Results:** Forty-six (46) patients were included (sex ratio 0.53). The age was 82 (±7.5). Respectively, 56.5%, 21.7% and 6.5% of patients were diabetic [n = 26 (56.5%)], severe renal impairment [n = 10 (21.7%)] and hemodialysis [n = 3 (6.5%)]. All procedures were performed by femoral route under consious sedation. Edwards' prostheses were used more often (93%), 100% Sapien 3, 6% of which were size 23. The primary success rate was 97.8% and the failure rate was 2% (deaths per procedure). The TAVI range of 0.66 ± 0.14 and 46.8 ± 15.5 against 1.48 ± 4.3 and 13.8 ± 5 in post TAVI. Severe pulmonary arterial hypertension (>60 mmHg) was observed in 21.7% of pre-TAVI patients compared to 4% in post TAVI patients. The overall rate of complications was 17% (n = 8). They were related to conductive disorders [6.5% (n = 3)], paraprosthetic leakage [2% (n = 1)], tamponade [2% (n = 1)], and hemorrhagic complications [6.5% (n = 3)]. Mean follow-up was 946 days (median = 1007.5 days), mean follow-up death rate was 30.4% (n = 14). The causes of death were non-cardiac in 57% (n = 8) of the cases. **Conclusion:** The TAVI results of the Sainte Clotilde Hospital Clinic are comparable to those observed in the literature.

Keywords

Calcified Aortic Stenosis, Percutaneous Valve Replacement, Sainte Clotilde Hospital, Reunion Island

1. Introduction

Aortic stenosis (AS) is the most common primary valvulopathy leading to surgical or percutaneous surgery in Europe and North America. Its prevalence increases with the aging of the population [1]. It is a degenerative disease characterized by progressive calcification of the aortic valve (Mönckeberg's disease). In the calcified AS of the elderly, the aortic valve becomes restrictive, the area of the aortic ejection tract decreases and the diastolic pressure of the left ventricle increases [2]. The TAVI was developed in the early 2000s, following the work of Alain Cribier's team, a Cardiology department in Rouen, France. As a result, this technique has progressed rapidly to become the treatment of choice for severe aortic stenosis in high-risk or inoperable patients [3]. In recent years, we have seen an increase in the number of TAVI and the broadening of the spectrum of their medical indications [4]. The implantation of TAVI in patients at low to intermediate risk is one of the major transitions observed in recent years [5]. The first TAVI was performed in Reunion in October 2014 by the team of Dr. Christophe Pouillot of the Sainte Clotilde Hospital (SCH). The objective of this work is to report the results and the follow up of the patients who received TAVI by the SCH team (50th center in France TAVI).

2. Patients and Method

This is a retrospective, descriptive study carried out from 01/10/2014 to 01/10/2017 at SCH. Every patient who got a TAVI during this period was included in the study. The selection of our patients was based on the European Society of Cardiology recommendations [1]. They were recruited through the consultation or were sent to us by our correspondent cardiologists city.

The pre-TAVI assessment included: echocardiography, coronary angiography, supra-aortic trunk ultrasonography, thoracoabdominopelvicangioscan, respiratory function test, and dental care. The TAVI indications were validated by a multidisciplinary staff (heart team).

The interventions took place in the hybrid room of the Reunion University Hospital in presence of anesthesiologists and cardiac surgeons.

The TAVI was performed according to the following technique: after puncturing the femoral artery under local anesthesia (xylocaine) and sedation (by neuroleptic), the biological valve mounted on a stent was introduced and then moved foward to the aortic valve. The stent was then deployed in the aortic valve using a balloon (expendable balloon) or dropped to self-deploy. Once the procedure was completed, a cardiac ultrasound was performed to check the functionality of the bioprosthesis and to look for any complications. Then the patient

was placed in intensive care for 24 hours.

After leaving the hospital, all patients were regularly monitored by their attending physicians and by Dr. Pouillot's team (every 6 months). The monitoring was carried out until 31/08/19.

The following variables were studied:

- Characteristics of the population: sex, age, size, comorbiditties (diabetes, chronic renal failure and hemodialysis).
- Risk score: logistic Euro Score.
- Indications for TAVI: Surgery against Indicated, high operative risk, fragility, surgery refusal.
- Echocardiographic features: Left Ventricle Ejection Fraction (LVEF), Aortic Valve Area (AVA), Mean Trans aortic Gradient (MTAG), and severe Pulmonary Arterial Hypertension (PAH) before and after TAVI.
- Valve type: Edwards Sapien 3, Medtronic Core Valve.
- Success rate.
- During follow up:

Complications.

Death rate.

Causes of death.

Definitions:

Severe aortic stenosis was defined by: an AVA < 1 cm^2 (or 0.6 cm^2/m^2), MTAG ≥ 40 mmHg or maximum transaortic flow velocity ≥ 4.0 m/s (1). LVEF was considered normal if 70% ± 10%.

Severe PAH was defined by systolic pulmonary arterial pressure > 60 mmHg.

Statistical analysis

Quantitative variables were presented by their mean and standard deviation, and qualitative variables by their percentage. The analysis of the efficacy of TAVI was done by comparing pre- and post-test ultrasound data with a student test for continuous variables and a chi-square test for qualitative variables.

3. Results

During the period of our study, forty-six (46) patients were included: 16 men (35%) and 30 women (65%). The mean age was 82 ± 7.5 years, the sex ratio was 0.53 and the average EuroScore logistic risk score was 28.9 ± 18.7. The most common indication for TAVI was high-risk surgery (69.5%). Table 1 presents the epidemiological and clinical characteristics of the 46 patients. In pre-TAVI, the average ultrasound LVEF was 56.5%, the mean AVA was 0.66 ± 0.14 cm^2, the MTAG was 46.8 ± 15.5 mmHg, there was a severe PAH was in 21.7% of cases.

Technical caracteristic of the TAVI procedure:

All procedures were performed by femoral route under local anesthesia and neuroleptic sedation. The Edwards Sapien 3 bio prosthesis was more often used (93%), with 63 % Sapien 3 No. 23. The primary success rate was 97.8%. The average hospital stay was nine (9) days. Table 2 shows the technical characteristics of the TAVI procedure.

Table 1. Demographic, anamnestic and ultrasound characteristics of the 46 patients studied.

Characteristics	Frequency	Percentage (%)
Sex		
Men	16	34.7
Women	30	65
Age (year)		
Minimum	54	-
Medium	82 ± 7.5	-
Maximum	94	-
Average size (cm)		
Men	157.9 ± 6.6	-
Women	153.6 ± 6.8	-
Comorbidity		
Diabetes	26	56.5
Severe renal insuffisancy	10	21.7
Dialysis	3	6.5
Logistic Euro Score	28.9 ± 18.7	-
Main indication		
Surgery Against Indicated	6	13
High operative risk	32	69.5
Fragility	3	6.5
Refusal of surgery	5	10.8
Echocardiography		
LVEF (%) average	56.5 ± 11.3	-
Mean AVA (cm^2) average	0.66 ± 0.14	-
MTAG (mmHg)	46.8 ± 15.5	-
Severe PAH	10	21.7
Aortic in sufficiency ≥ 2 grade	-	-

Table 2. Technical characteristics of the TAVI procedure.

Characteristics	Fréquency	Pourcentage (%)
Look first		
Ilio-fémoral	46	100
Other	-	-
Type of anesthesia		
Local anesthesia and/or sédation	46	100
General anesthesia	-	-
Type of the valve		
Edwards-Sapien	43	93
Medtronic Core Valve	3	6.5
Diameter of the valve		
23	29	63
26	14	34
29	3	6.5
Successful procedure	45	97.8

On post-TAVI ultrasonography, LVEF averaged 57%, Mean AVA was 1.48 ± 4.3 cm^2, MTAG was 13.8 ± 5 mmHg, and severe PAH (>60 mmHg) was found in 4% of cases. Table 3 compares the pre- and post-TAVI echocardiographic data.

The complication rate was 17% (n = 8), mainly atrioventricular blocks 6.5% (n = 3) and local bleeding at the puncture site 6.5% (n = 3).

The mean follow-up was 946 days (median = 1007.5 days), mean follow-up death rate was 30.4% (n = 14), of which 11% (n = 5) died in the first year after TAVI. The causes of death were non-cardiac in 57% (n = 8) of cases, cardiac in 29% (n = 4) of cases and not known in 14% (n = 2) of cases. The different types of complications related to TAVI and causes of death outside the hospital period are summarized in Table 4.

4. Discussion

The AS evolves slowly until the first symptoms appear. The functional surface of

Table 3. Comparison of Echocardiographic Data Pre and Post TAVI.

Echocardiographic Features	Pre-TAVI	Post-TAVI	P
LVEF (%) average	56.5	57	0.99
AVA (cm^2) ± standard deviation	0.66 ± 0.14	1.48 ± 4.3	0.44
MTAG (mmHg) ± standard deviation	46.8 ± 15.5	13.8 ± 5	0.03
severe PAH	21.7%	4%	0.05
Aortic in sufficiency ≥ 2 grade	-	1/46 (2%)	-

Table 4. Complications related to TAVI and causes of death outside the hospital period.

	Frequency	Pourcentage (%)
Type of complication		
Conductive disorders with implantation of a Pace maker	3	6.5
Tamponed	1	2
Cardiac surgery under extra corporeal circulation	-	-
First vascular complication leading to surgery or stent	1	2
Hemorrhagic complication requiring transfusion and/or surgery	3	6.5
Stroke	-	-
Cause of mortalityoutside the hospitalperiod		
Fracture of the femoral neck	2	4
Septicshock	1	2
Liver cancer	1	2
Kidney cancer	1	2
Malnutrition	1	2
Heart failure	3	6.5
Pace Maker Infection	1	2
Not known	2	4

the valve decreases progressively causing the increase in left ventricular filling pressures. The mortality is 50% at 2 years in untreated patients from the onset of the first symptoms [6]. Survival declines when AS becomes very tight [7] [8]. Mean survival is less than 12 months after the first episode of cardiac decompensation. The combination of stage III or IV dyspnea, left ventricular dysfunction and mitral insufficiency further aggravates mortality with a 3-year survival of less than 20% [9]. Echocardiography is a key examination, it can confirm the diagnosis and search for associated valvulopathies.

TAVI has taken an important place in the management of calcified AS of the elderly in France and worldwide [10] thanks to the improvement of the technique (decrease of the device size (14F), improvement of the prostheses), improved operator experience (lack of systematic predilatation, better sizing of prostheses by measuring aortic CT diameter), and excellent results in patients contraindicated for surgery, at high risk, or at intermediate risk [11] [12] [13]. The European Society of Cardiology recommends TAVI [1] in symptomatic patients contraindicated for aortic valve replacement surgery or in patients over 75 years at high or intermediate risk (STS or EuroSCORE II > 4% or Logistic EuroSCORE I > 10%) or with comorbidities not taken into account by the risk scores (frail patients or having undergone a first thoracotomy, or with reduced mobility) and for whom the femoral approach is possible (Grade IB) [14] [15] [16] [17].

In this study we found that our patients were at high surgical risk with a high Logistic EuroScore, a high prevalence of diabetes (nearly 10% of Reunion Islanders are diabetic according to French National Institute of Statistics and Economic Studies 2012), and renal failure. The femoral route was used in 100% of our patients. The femoral route is the most used and gives the best results [18] [19] [20]. The results were at least as good as those of France TAVI [20] with a primary success rate of 97.8%. There was almost immediate clinical improvement in post TAVI with a significant decrease in MTAG ($P = 0.03$), and severe PAH ($P = 0.05$). Mean AVA and MTAG were relatively high in post TAVI compared to France TAVI data [20]. This may reflect to the use of smaller valves tailored to our patients who have smaller aortic rings in relation to their smaller size. The complication rate was low; only one case of significant aortic leakage (2%), the rate of atrioventricular block requiring the implantation of a pacemaker was 6.5% in our series and 17.5% in France TAVI [20], one of the major complications of many studies [21] [22] [23].

Only one case of femoral artery dissection and three cases of localized hemorrhages at the puncture site were observed. The widespread adoption of scanner for the selection of vascular pathways and the increasing experience of operators in the management of vascular access have reduced the incidence of complications. The incidence of major vascular complications in current TAVI practice is now <5% [24]. There were no cases of stroke in our study. In France TAVI stroke rate was 1.6% and 3.4% to 4.8% in the literature [25] [26]. Mean

hospital stay was relatively short in our study and comparable to France-TAVI [20]. The mortality rate was 30.4% for an average follow-up of 946 days, and the causes of mortality were non-cardiac in more than half of the cases. The results of our study are encouraging and consistent with recent literature data and with the France TAVI registry [27] [28].

Limitations of Our Study

The main limitation of this study is the small sample size.

5. Conclusion

The TAVI experience of SCH is positive with a high success rate, a low complication rate, and acceptable mid-term mortality.

Conflicts of Interest

The authors do not declare any conflict of interest.

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Abbreviations

AS: Aortic Stenosis;

TAVI: Transcatheter Aortic Valve Implantation;

SCH: Sainte Clotilde Hospital;

AVA: Aortic Valve Area;

LVEF: Systolic Ejection Fraction of the Left Ventricle;

MTAG: Mean Trans Aortic Gradient;

PAH: Pulmonary Arterial Hypertension;

Euro SCORE: European System for Cardiac Operative Risk Evaluation;

STS: Society of Thoracic Surgeons.