International Journal of Cardiology 202 (2016) 631–635

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

One-year outcomes after direct transcatheter aortic valve implantation with a self-expanding bioprosthesis. A two-center international experience.

Konstantinos Toutouzas [a,*], George Latsios [a], Konstantinos Stathogiannis [a], Maria Drakopoulou [a], Andreas Synetos [a], Elias Sanidas [b], Antonios Mastrokostopoulos [a], George Trantalis [a], Odysseas Kaitozis [a], George Lazaros [a], Seyrani Yuecel [c], Ulrich Gerckens [c], Eberhard Grube [d], Dimitrios Tousoulis [a]

[a] First Department of Cardiology, Hippokration Hospital, Athens Medical School, Athens, Greece
[b] Cardiology Department, Laikon Hospital, Athens, Greece
[c] Gemeinschaftskrankenhaus Bonn, Germany
[d] University Hospital, Dept of Medicine II, Bonn, Germany

ARTICLE INFO

Article history:
Received 4 July 2015
Received in revised form 24 August 2015
Accepted 21 September 2015
Available online 25 September 2015

Keywords:
TAVI
CoreValve
Direct
Mortality
Balloon aortic valvuloplasty

ABSTRACT

Background: Balloon aortic valvuloplasty (BAV) is considered to be an essential part of the transcatheter aortic valve implantation (TAVI) procedure and is being performed routinely. At present there is insufficient long-term data as to the benefits of routine BAV prior to TAVI.
Aim: The aim of this study was to evaluate the safety of direct TAVI and the mortality rate at 1-year in patients undergoing TAVI with or without BAV with a self-expanding bioprosthesis.
Methods: Between January 2008 and September 2013 consecutive patients undergoing TAVI with the Medtronic CoreValve in two experienced centers in Athens, Greece and in Siegburg, Germany were studied. All data were prospectively collected and retrospectively analyzed. Primary endpoint was mortality at 1 year. Procedural data and clinical data (bleeding, vascular complications and echocardiographic parameters) were analyzed.
Results: A total of 210 patients undergoing TAVI were evaluated (non-direct = 120 patients, direct = 90 patients). All-cause mortality at 30 days and at 1 year was similar in both groups (4% in non-direct versus 2% in direct, p = 0.6 and 15% in non-direct versus 11% in direct, p = 0.5, respectively). Device success rate was similar in both groups (77% in non-direct versus 83% in direct, p = 0.2). Major vascular complications were comparable for both groups (5% in non-direct versus 3% in direct, p = 0.5). The direct group had less moderate/severe paravalvular leakage than the non-direct group after the device implantation (7% versus 33%, p<0.01).
Conclusions: Performing direct TAVI with the self-expanding bioprosthesis is safe and feasible showing similar mortality rates compared to patients undergoing non-direct TAVI at 30 days and at 1-year.

1. Introduction

Degenerative aortic valve stenosis is a burden to western societies, given the increasingly aging population [1–3].

Transcatheter aortic valve implantation (TAVI) has emerged as an alternative to surgical aortic valve replacement and has become the mainstay of treatment for high-risk inoperable patients with severe aortic stenosis [4]. Furthermore, the field of TAVI is rapidly evolving and intermediate-risk patients have already been treated with TAVI with similar results compared to patients undergoing surgery [5].

Frequently, balloon aortic valvuloplasty (BAV) is performed in order to improve the functional orifice area and offer a better landing spot for the bioprosthesis before placing it. Nonetheless, this practice carries several important procedural risks such as stroke, myocardial infarction, bleeding and death [6–8]. Currently, there are few reports on short-term clinical outcomes after direct TAVI with a self-expanding valve [9–11]. However, there is a lack of evidence in patients undergoing direct TAVI with a self-expanding valve in the long-term.

The aim of this study was to evaluate 1) the safety of direct TAVI and 2) the mortality rate at 1-year in patients undergoing TAVI with or without BAV with a self-expanding bioprosthesis.

2. Methods

2.1. Study population

Two hundred ten consecutive patients, undergoing TAVI with the newer generation Medtronic CoreValve (utilizing a sheath ≤ 18Fr) in two experienced centers in Athens, Greece and in Siegburg, Germany, were studied between January 2008 and September

* Corresponding author at: 24, Karaoli Dimitriou Street, Holargos, 15562, Athens, Greece.
E-mail address: ktoutouz@gmail.com (K. Toutouzas).

http://dx.doi.org/10.1016/j.ijcard.2015.09.075
0167-5273/

2013. All data were prospectively collected and retrospectively analyzed. All patients gave their written consent for the procedure and data acquisition.

2.2. Screening

A heart team comprised of cardiologists, interventional cardiologists, heart surgeons and imaging specialists evaluated all patients. All patients underwent angiography to define coronary anatomy. Doppler echocardiography was performed for evaluating the aortic valve annulus diameter, left ventricular ejection fraction (LVEF), pulmonary artery systolic pressure [defined as moderate if pulmonary artery systolic pressure (PASP) ≥ 31 mmHg and ≤55 mmHg and severe if PASP > 55 mmHg] [12], transvalvular gradients and effective orifice area (EOA) measured by the continuity equation. In addition, multi-slice computed tomography was performed and measurement of the aortic valve calcium score was determined as previously described and a level of 750 and above was deemed significant [13]. Decision to perform TAVI was based on the severity of the symptoms of AS, risk evaluation and consideration of special contraindications to surgery. Severe aortic stenosis was defined as EOA < 1 cm^2 or EOAi [EOA indexed to the body surface area (BSA)] <0.6 cm^2/m^2. The surgical risk was calculated by the logistic European System for Cardiac Operative Risk Evaluation (log EuroSCORE) [14] and patients with log EuroSCORE ≥ 20% were considered high-risk. In addition, surgical contraindications not evaluated by the above score such as porcelain aorta, previous chest irradiation, liver cirrhosis or frailty, were also used to assess surgical risk. Left ventricular outflow tract was measured in the parasternal long-axis view in mid-systole parallel to the aortic valve plane and within 0.5–1.0 cm of the valve orifice, as previously described [15]. The aortic valve annulus was deemed appropriate for TAVI if the annulus diameter was measured >18 mm and <29 mm.

2.3. Procedural characteristics

The implantations were performed at the catheterization laboratories under strict sterile conditions. General anesthesia or monitored anesthesia care was used depending on the heart team's evaluation of the patient. The devices were implanted through the transfemoral [16], subclavian [17] and transaortic [18] routes. Closure of the femoral artery was performed using preloaded suture techniques (Prostar XL or ProGlide, Abbott Vascular, Abbott Park, IL, U.S.A.).

The device implanted was the Medtronic CoreValve. CoreValve is a porcine pericardial tissue valve within a self-expandable nitinol frame. The 23 mm valve was used for 18–20 mm annuli, the 26 mm valve was used for 20–23 mm aortic annuli, the 29 mm valve for 23–26 mm annuli and the 31 mm valve for 26–29 mm annuli. The valve was delivered through an 18 Fr sheath.

In the predilatation group consecutive patients since 2008 from both centers were included in the study. In one center (Athens, Greece) direct TAVI was performed in consecutive patients since 2010. Balloon size for predilatation and new pacemaker implantation was left to operator's discretion.

2.4. Definitions

The primary endpoint of the study was 1-year mortality for both groups. Further measured outcomes were in-hospital complications and mortality at 30 days as designated by the Valve Academic Research Consortium-2 [19] criteria. Device success rate was defined as absence of periprocedural mortality and 1) correct positioning of a single valve, 2) no prosthesis–patient mismatch, 3) mean aortic valve gradient < 20 mmHg or peak velocity < 3 m/s, and 4) no moderate or severe aortic regurgitation. Paravalvular aortic leakage (PVL) was evaluated according to the latest recommendations from the European Society of Cardiology (none, mild, moderate, severe) [20]. The EOA after TAVI was calculated with the continuity equation as for the pre TAVI EOA measurement. The EOA was indexed to BSA (EOAi) and prosthesis–patient mismatch (PPM) was defined as: non-significant if EOAi > 0.85 cm^2/m^2, moderate if EOAi ≤ 0.85 cm^2/m^2 and EOAi > 0.65 cm^2/m^2, and severe if EOAi ≤ 0.65 cm^2/m^2 [21].

2.5. Statistical analysis

Continuous variables are presented as mean ± standard deviation and compared with the Student's t-test. Categorical variables are presented as frequencies and percentages and were tested by the chi-square test. Kaplan Meier mortality curves were built from the time of the procedure up until one year. The analysis was performed with SPSS 21 statistical software (SPSS, Inc., Chicago, Illinois).

3. Results

3.1. Patients' characteristics

Table 1 depicts the baseline clinical characteristics of the study population. A total of 210 consecutive patients were included in this study from both TAVI centers: 120 patients were treated with BAV (non-direct group) and 90 patients underwent direct TAVI. Patients in the non-direct group were older and had a higher percentage of pacemaker implantation. The body mass index (BMI) was comparable for both groups, as were the creatinine levels. Calcium mass score was similar for both groups.

Table 1
Baseline clinical characteristics.

	Non-direct (n = 120)	Direct (n = 90)	P value
Age, years	82 ± 6	79 ± 17	0.04
Female sex	66 (55%)	51 (56%)	0.6
BMI, kg/m^2	26 ± 3	26 ± 4	0.4
Diabetes mellitus	53 (44%)	44 (48%)	0.5
Hypertension	42 (35%)	38 (42%)	0.3
Coronary artery disease	38 (32%)	27 (30%)	0.8
Creatinine, mg/dl	1.2 ± 0.5	1.1 ± 0.8	0.5
Calcium mass score	545 ± 394	518 ± 326	0.6
Log EuroSCORE, %	19 ± 15	21 ± 16	0.7
Pacemaker	14 (12%)	2 (2%)	0.01

BMI = body mass index. Data presented as n (%) unless otherwise noted.

3.2. Procedural data

Procedural data are depicted in Table 2. The majority of the patients in both groups underwent transfemoral TAVI. Nine patients underwent subclavian TAVI in the non-direct group and 6 from the direct group. Also, there was one patient receiving a transaortic TAVI in the direct group due to severely calcified and tortuous vessels. As the 31 mm CoreValve was not available until 2011 and the 23 mm CoreValve was made available in 2012, the majority of patients in both groups received the 26 mm or 29 mm bioprosthesis. Post-TAVI balloon dilatation was performed in 11 patients in the non-direct group and 8 patients in the direct group (9% each, p = 0.9). Device success was calculated based on the VARC-2 criteria and it was similar for both groups (77% in non-direct versus 83% in direct, p = 0.2). New pacemaker implantation was similar between the two groups.

3.3. Echocardiographic measurements

In Table 3 the echocardiographic parameters as measured by transthoracic echocardiography before TAVI as well as prior to discharge are demonstrated.

Before the procedure the echocardiographic examination demonstrated that patients in the non-direct group had lower mean pressure gradient and lower PASP. Aortic valve area was similar for both groups, as was the aortic annulus.

After the procedure the non-direct population still had lower mean gradient but did not differ significantly with the direct group. The direct group had less moderate/severe PVL than the non-direct group after the device implantation (7% versus 33%, p < 0.01). Leakage through the valve was not observed.

Table 2
Procedural data.

	Non-direct (n = 120)	Direct (n = 90)	P value
Vascular access			0.8
Transfemoral	111 (92%)	83 (92%)	
Subclavian	9 (8%)	6 (7%)	
Transaortic	0 (0%)	1 (1%)	
Valve size			0.08
23 mm	2 (2%)	3 (3%)	
26 mm	56 (47%)	37 (41%)	
29 mm	58 (48%)	44 (49%)	
31 mm	4 (3%)	6 (7%)	
Post dilatation	11 (9%)	8 (9%)	0.9
Device success, %	77	83	0.2
New pacemaker	44 (36%)	32 (35%)	0.8

Data presented as n (%), unless otherwise noted.