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Balloon dilatation and outcome among patients undergoing trans-femoral aortic valve replacement

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ABSTRACT

Background: Balloon pre-dilatation before transcatheter aortic valve replacement (TAVR) is performed at the discretion of the treating physician. Clinical data assessing the implications of this step on procedural outcomes are limited.

Methods: We conducted a retrospective analysis of 1164 consecutive TAVR patients in the Israeli multicenter TAVR registry (Sheba, Rabin, and Tel Aviv Medical Centers) between the years 2008 and 2014. Patients were divided to those who underwent balloon pre-dilation ($n = 1026$) versus those who did not ($n = 138$).

Results: Rates of balloon pre-dilation decreased from 95% in 2008–2011 to 59% in 2014 (p for trend $= 0.002$). Baseline characteristics between groups were similar except for more smoking (22% vs. 8%, $p = 0.008$), less past CABG (18% vs. 26%, $p = 0.016$), less diabetes mellitus (35% vs. 45%, $p = 0.01$), and lower STS mortality scores (5.2 ± 3.7 vs. 6.1 ± 3.5, $p = 0.006$) in the pre-dilatation group. The pre-dilation group included less patients with moderate to severely depressed LVEF (7% vs. 16%, $p < 0.001$) and higher aortic peak gradients (76.9 ± 22.7 mmHg vs. 71.4 ± 24.3 mmHg, $p = 0.01$). Stroke rates were comparable in both groups (2.5% vs. 3%, $p = 0.8$), but pre-dilation was associated with lower rates of balloon post-dilatation (9% vs. 26%, $p < 0.001$). On multivariate analysis, balloon pre-dilatation was not a predictor of device success or any post-procedural complications ($p = 0.07$).

Conclusions: Balloon pre-dilatation was not associated with procedural adverse events and may decrease the need for balloon post-dilatation. The results of the present study support the current practice to perform liberally balloon pre-dilatation prior to valve implantation.

1. Introduction

Transcatheter aortic valve replacement (TAVR) is now a valid treatment option for patients with severe aortic stenosis at intermediate or higher surgical risk [1–5]. During the initial clinical experience with TAVR, balloon pre-dilatation of the aortic valve prior to transcatheter heart valve implantation was considered mandatory. However, as clinical experience accumulated and delivery systems improved, balloon pre-dilatation of the aortic valve has become an elective part of the procedure [6]. While there is a theoretical rationale for "preparing" the aortic valve with balloon dilatation to facilitate transcatheter heart valve crossing [7], and perhaps to decrease the need for balloon post-dilatation, there are potential drawbacks for pre-dilatation which would argue against routine balloon pre-dilatation during TAVR, including the potentially increased risk for cerebral emboli [8] and the need for an additional pacing period.

There are limited data to assess potential benefits and consequences of performing aortic valve pre-dilatation prior to valve delivery. Thus, the aim of the present study was to assess the effect of aortic valve pre-dilatation on procedural success and the need for balloon post-dilatation and clinical outcome in a large cohort of consecutive TAVR patients.

Abbreviations: CABG, Coronary artery bypass graft; LVEF, Left ventricular ejection fraction; NYHA, New York Heart Association; PCI, Percutaneous coronary intervention; STS score, Society of thoracic surgery score; TAVR, Transcatheter aortic valve replacement; VARC 2, Valve Academic Research Consortium 2.

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2. Methods

2.1. Patient population

All consecutive patients with severe symptomatic aortic stenosis and high or prohibitive operative risk undergoing TAVR at three major medical centers in Israel (Sheba, Rabin, and Tel Aviv Medical Centers) from September 2008 to December 2014 were included in this retrospective analysis. The study was approved by the institutional review board of each of the participating centers. Patients undergoing valve in bioprosthetic valve procedures or procedures performed for predominantly aortic insufficiency were excluded from the present analysis. Transcatheter aortic valve implantation was performed using self-expandable or balloon-expandable valves. A trans-femoral approach was the default strategy for all patients. Balloon pre-dilatation and post-dilatation were performed according to operator discretion during rapid ventricular pacing via the TAVR sheaths, and patients were grouped according to whether aortic valve pre-dilatation was performed or not. For cases in which the pre-dilatation balloon was provided as part of the transcatheter valve kit (e.g. balloon-expandable valve)—the provided balloon was used for pre-dilatation. For cases in which pre-dilatation balloon was not provided, such as cases of self-expandable valves, Nucleus™ (NuMed, Hopkinton, NY, USA) or VACS II™ (OSYPKA AG, Germany) were utilized.

2.2. Data collection

Data were retrospectively collected and pooled into a dedicated dataset (the Israeli multicenter TAVR registry). Patients were grouped according to whether balloon pre-dilatation was performed prior to transcatheter valve implantation. Subgroup analysis was performed according to whether balloon post-dilatation was done. All centers used standardized definitions to collect all data including demographic parameters, medical history, chronic and peri-procedural medical treatment, echocardiographic measurements, procedural information, and outcome measures according to VARC-2 criteria [9]. Device success was defined according to VARC-2 as absence of procedural mortality, correct positioning of a single valve, mean aortic valve gradient post-procedure <20 mmHg, and no moderate–severe para-valvular leak. Mortality rates were ascertained with the Israeli Ministry of Interior death registry.

2.3. Statistical analysis

Data are presented as mean ± standard deviation if normally distributed or as median if not normally distributed. Continuous variables were tested with the Kolmogorov–Smirnov test for normal distribution. Categorical variables are given as frequencies and percentages. A chi-square test was used for analysis of categorical variables and a Student *t* test was performed for comparison between two groups of continuous variables. Models were constructed for multivariate analysis of the primary outcome using logistic regression analysis. In the multivariate analysis, we have entered those parameters with a p value below 0.05 in univariate analysis. Statistical significance was assumed when the null hypothesis could be rejected at $p < 0.05$. All p values are results of two-sided tests. A stepwise method was used to determine independent predictors of the outcome variables. Statistical analyses were conducted using IBM® SPSS® statistics software (version 20).

3. Results

A total of 1164 consecutive TAVR patients were included in the present analysis. Mean age was 82 ± 6.5 years, 43% were males, mean EuroSCORE 2 was 5.8 ± 5, and the mean Society of Thoracic Surgery (STS) score was 5.3 ± 3.7. The majority of patients ($n = 787$, 68%) underwent implantation with the CoreValve prosthesis, while 362 (31%) patients underwent implantation with the Edwards Sapien valve, and 1% with other valve types. Throughout the study period, a total of 1026 patients (88%) underwent balloon pre-dilatation. There was a significant trend for decrease in the use of balloon pre-dilatation over the study period, which was performed in 95% of TAVR procedures during the years 2008–2011, began to decline in 2012, and was performed in 59% of procedures in 2014 (p for trend = 0.002) (Fig. 1). Balloon sizes utilized for pre-dilatation varied between 18 and 26 mm, with two thirds of cases using smaller-sized balloons of up to 22 mm (449 cases with size 20 mm, 293 cases with size 22 mm, 110 cases with size 23 mm).

Table 1 presents the baseline clinical characteristics of TAVR patients according to balloon pre-dilatation performance. Patients selected for balloon pre-dilatation prior to valve implantation had higher rates of prior percutaneous coronary intervention (35% vs. 26%, $p = 0.03$) and peripheral vascular disease (52% vs. 42%, $p = 0.03$) and were more likely to be smokers (22% vs. 8%, $p = 0.008$); however, they had lower rates of diabetes mellitus (35% vs. 45%, $p = 0.01$) and prior bypass surgery (18% vs. 26%, $p = 0.016$). The balloon pre-dilatation group had lower EuroSCORE 2 (5.6 ± 4.8 vs. 6.9 ± 6.5, $p = 0.037$), lower STS scores (5.2 ± 3.7 vs. 6.1 ± 3.5, $p = 0.006$), and lower New York Heart Association (NYHA) class (3.02 ± 0.69 vs. 3.23 ± 0.66, $p = 0.001$) as compared with patients who did not undergo pre-dilatation.

Patients who underwent balloon pre-dilatation had distinct echocardiographic characteristics with lower rates of depressed left ventricular ejection fraction (7% vs. 16%, $p < 0.001$) and higher peak aortic gradients (76.9 ± 22.7 vs. 71.4 ± 24.3, $p = 0.01$) as compared with patients who did not undergo pre-dilatation. (Table 2). There was no difference in mean aortic valve areas (0.7 ± 0.18 cm vs. 0.68 ± 0.18 cm, $p = 0.42$).

TAVR was performed using a trans-femoral access in over 90% of cases in both groups, and conscious sedation was used in 78–80% of patients in both groups. However, among the pre-dilatation group, the implantation rates of the Edwards valve were higher (33% vs. 14%, $p < 0.001$) and the CoreValve prosthesis were lower (66% vs. 85%, $p < 0.001$) as compared to the group in whom pre-dilatation was not performed (Table 3). When stratified by valve type, a clear association between the type of valve implanted and balloon pre-dilatation was identified; 95% of patients implanted with the Edwards valve underwent balloon pre-dilatation compared to 85% of patients implanted with the CoreValve prosthesis ($p < 0.001$) (Table 4).

Device success was significantly higher in the pre-dilatation group (94% vs. 85%, $p = 0.01$) mainly driven by lower rates of increased post-procedural mean aortic gradients (>20 mmHg) (0.6% vs. 6.5%, $p = 0.001$). It is plausible that balloon pre-dilatation may better disrupt adhesions at the aortic valve cusps between aortic valve leaflets and further dilate the aortic annulus, thus allowing better expansion of the deployed valve achieving lower post-procedural gradients across the aortic valve. However, a multivariate model to assess predictors for device success was performed using age, sex, pre-dilatation, and all parameters that were significantly different between groups at baseline. Pre-dilatation was not a predictor of device success ($p = 0.07$, 95% CI 0.04–1.13), as was the case for the other parameters included in the model (Fig. 2).

Valve malposition or migration occurred less frequently among the pre-dilatation groups (4% vs. 9%, $p = 0.015$). Other procedural complications did not differ whether balloon pre-dilatation was performed or not. Of note, stroke rates did not differ between groups (2.5% vs. 3%, $p = 0.8$) (Table 3).

Overall, among patients who underwent balloon pre-dilatation, the rates of balloon post-dilatation were lower compared to patients who underwent direct valve implantation (9% vs 26%, $p < 0.001$) (Table 3). Subgroup analysis according to valve type showed that balloon post-dilatation was performed more frequently among CoreValve patients as compared to Edwards Sapien valve (14% vs. 4%, $p < 0.001$). This finding, of higher post-dilatation rates in the CoreValve group, was irrespective of whether balloon pre-dilatation was performed or not (Table 4).

Balloon post-dilatation after valve implantation was associated with higher rates of valve malposition or migration (14% vs. 3%, $p = 0.002$), peri-procedural myocardial infarction (4% vs. 1%, $p = 0.02$), the need

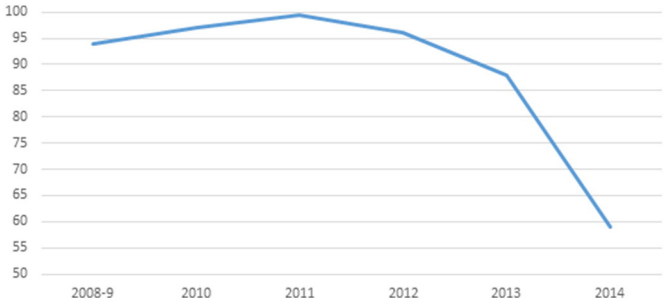

Fig. 1. Percent of balloon pre-dilatation per year.

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