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BRIEF REPORT

Trend and Outcomes of Direct Transcatheter Aortic Valve Replacement from a Single-Center Experience

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ABSTRACT

Introduction: When transcatheter aortic valve replacement (TAVR) was introduced, pre-implantation balloon aortic valvuloplasty (BAV) was a routine part of the procedure. Smaller device profiles have resulted in selective use of BAV; however, there is a paucity of data about the trend in use of direct TAVR and the safety of this strategy.

Methods: All patients who underwent TAVR at a Veterans Affairs Medical Center from September 2013 to November 2016 were included in this retrospective analysis. We reviewed angiography films and verified with procedure reports to assess if direct TAVR was performed. Troponin T was assessed within 72 h after the TAVR. Multivariate analysis examined the association between direct TAVR and periprocedural myocardial infarction (MI) or 1-year mortality.

Results: Overall, 207 patients were available for analysis. The mean follow-up was 13.3 months. A balloon-expandable valve was used 93.2% of the time, and 35.3% of patients were treated with conscious sedation. Periprocedural MI or 1-year mortality occurred in 12.5% of the direct TAVR group versus 18.3% of the pre-implantation BAV group ($p = 0.30$). After controlling for potential confounding variables, direct TAVR was not associated with periprocedural MI or 1-year mortality.

Conclusions: Direct TAVR appears to be safe and is not associated with periprocedural MI or 1-year mortality. With current generation devices, this strategy can be considered for most patients undergoing TAVR.

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INTRODUCTION

Avoiding pre-implantation balloon aortic valvuloplasty (BAV) during transcatheter aortic valve replacement (TAVR) is termed direct TAVR and is a feasible strategy. The United Kingdom registry found no increase in adverse

events from this approach; however, direct TAVR was only used in the minority of patients [1]. Accordingly, we sought to examine the trend and association between direct TAVR and periprocedural myocardial infarction or 1-year mortality in a Veterans Affairs Hospital where this strategy is now common and periprocedural cardiac enzymes are routinely measured.

METHODS

This study was approved by our Institutional Review Board. This article is based on previously conducted studies and does not involve any new studies of human participants or animal subjects performed by any of the authors. TAVR procedures were performed between September 2013 and November 2016. Direct TAVR was performed according to operator discretion. Postoperative troponin T values and transthoracic echocardiography were obtained on all patients. Periprocedural myocardial infarction was defined according to the Valve Academic Research Consortium-2 (troponin T > 15 × upper limit of normal) [2]. Multivariate logistic regression examined independent predictors for perioperative myocardial infarction or 1-year mortality. Statistics were performed with SPSS software (Version 22, IBM Co., Armonk, NY, USA).

RESULTS

Overall, 207 patients were available for analysis. The median follow-up was 13.3 months (mean, 15.3 ± 11.6 months). The frequency of direct TAVR increased over time [14% in the first quarter of the study period, 30% in the second quarter of the study period, 80% in the third quarter of the study period, and 83% in fourth quarter of the study period ($p < 0.001$)]. Among the total cohort, the mean age was 77.6 ± 8.7 years; mean left-ventricular ejection fraction; 52.3 ± 10.4%; and mean stroke volume index, 38.2 ± 9.9 cc/m^2. Table 1 provides complete study characteristics. A balloon-expandable valve was used in 93.2% ($n = 193$) and conscious sedation in 35.3% ($n = 73$). In the direct TAVR group versus the pre-implantation BAV group, there was a higher frequency of conscious sedation, *trans*-femoral access, and second/third-generation valves ($p < 0.05$ for each).

The mean troponin *T* value was 0.093 ± 0.2 ng/ml in the direct TAVR group and 0.13 ± 0.18 ng/ml in the pre-implantation BAV group ($p = 0.16$). Periprocedural myocardial infarction or 1-year mortality occurred in 12.5% of the direct TAVR group versus 18.3% of the pre-implantation BAV group ($p = 0.30$) (Table 2). Heart rate-adjusted diastolic delta (HR-DD) < 25 after valve implantation occurred in 9.1% of the direct TAVR group (5/55) compared with 2.4% of the pre-implantation BAV group (3/125) ($p = 0.06$) [3]. Univariate predictors of periprocedural myocardial infarction or 1-year mortality included history of coronary artery bypass grafting, mean pulmonary pressure ≥ 45 mm Hg, general anesthesia, *trans*-apical access, TAVR in the first half of the program, and HR-DD < 25. Direct TAVR was not associated with periprocedural myocardial infarction or 1-year mortality with multivariate analysis after controlling for history of coronary artery bypass grafting, mean pulmonary pressure ≥ 45 mm Hg, and HR-DD < 25. The results were the same in a subgroup analysis that was restricted to transfemoral access ($n = 170$). Table 3 provides complete procedural outcomes.

DISCUSSION

In this retrospective analysis, the proportion of veterans undergoing direct TAVR increased significantly over time, reaching 83% in the last quarter of the study period. While there was a numerical difference favoring a lower incidence of periprocedural myocardial infarction or 1-year mortality with direct TAVR, this relationship was not significant after controlling for multiple confounding variables (general anesthesia, stroke volume index < 35, mean pulmonary pressure ≥45 mm Hg, HR-DD < 25 [3], and aortic insufficiency ≥ moderate).

When TAVR was first introduced, pre-implantation BAV was considered a necessary part

Table 1 Study characteristics of the cohort

Baseline characteristic	Total (n = 207)	Direct TAVR (n = 136)	Pre-implantation BAV (n = 71)	P value
Age, mean years ± SD	77.6 ± 8.7	76.8 ± .5	78.9 ± 7.5	0.08
Body mass index, mean kg/m^2 ± SD	28.7 ± 5.7	29.1 ± 5.5	27.8 ± 6.2	0.12
Diabetes mellitus, *n*	103 (49.7%)	67 (49.3%)	36 (50.7%)	0.76
Peripheral vascular disease, *n*	93 (44.9%)	67 (49.3%)	26 (36.6%)	0.10
Coronary artery bypass grafting, *n*	77 (37.2%)	52 (37.4%)	25 (35.2%)	0.87
Percutaneous coronary intervention, *n*	58 (28.0%)	38 (27.9%)	20 (28.2%)	1.0
Stroke/transient ischemic attack, *n*	32 (15.4%)	20 (14.7%)	12 (16.9%)	0.70
Atrial fibrillation, *n*	65 (31.4%)	45 (33.1%)	20 (28.2%)	0.53
Chronic obstructive pulmonary disease, *n*	77 (37.2%)	50 (36.7%)	27 (38.0%)	0.88
Creatinine, mean mg/dl ± SD	1.29 ± 0.85	1.30 ± 0.8	1.28 ± 0.4	0.89
Pre-operative echo				
LVEF, mean mm Hg ± SD	52.3 ± 10.4	52.3 ± 10.9	52.4 ± 9.4	0.94
Mean aortic valve gradient, mean mm Hg ± SD	40.7 ± 12.2	39.1 ± 10.9	43.6 ± 14.0	0.01
Mean gradient < 40 mm Hg, *n*	95 (45.9%)	67 (51.6%)	28 (40.9%)	0.21
Pre-operative cath				
SVi*, mean cc/m^2 ± SD	36.9 ± 9.5	37.6 ± 9.8	35.8 ± 8.7	0.18
SVi < 35 cc/m^2, *n*	91/205 (44.9%)	58/135 (42.9%)	33/70 (47.1%)	0.65
Pulmonary pressure, mean mm Hg ± SD	27.9 ± 10.2	27.5 ± 9.8	28.8 ± 10.9	0.47
Pulmonary pressure (mean ≥ 45 mm Hg)**, *n*	10/153 (6.5%)	6/101 (5.9%)	4/52 (7.7%)	0.73
Pre-operative CT				
Valve area oversize ≥ 15%***, *n*	63/179 (35.2%)	38/114 (33.3%)	32/65 (49.2%)	0.001
Procedural details				
General anesthesia, *n*	134 (64.7%)	72 (52.9%)	62 (87.3%)	< 0.001
Conscious sedation, *n*	73 (35.3%)	64 (47.1%)	9 (12.7%)	< 0.001
Native implant, *n*	191 (92.3%)	124 (91.2%)	67 (80.3%)	0.58
Valve-in-valve implant, *n*	16 (7.7%)	12 (8.8%)	4 (6.6%)	0.58
Trans-apical access, *n*	21 (10.1%)	12 (8.8%)	9 (12.7%)	0.63
Trans-femoral access, *n*	170 (82.1%)	109 (77.9%)	61 (85.9%)	0.63
Balloon expandable valve, *n*	193 (93.2%)	125 (91.9%)	68 (95.8%)	0.55
Sapien, *n*	22 (10.6%)	6 (4.4%)	16 (22.5%)	< 0.001
Sapien XT, *n*	52 (25.1%)	11 (8.1%)	41 (57.7%)	< 0.001

Table 1 continued

Baseline characteristic	Total (n = 207)	Direct TAVR (n = 136)	Pre-implantation BAV (n = 71)	P value
Sapien S3, n	119 (57.5%)	108 (79.4%)	11 (15.5%)	< 0.001
Self expandable valve, n	14 (6.8%)	11 (8.1%)	3 (4.2%)	0.55
CoreValve, n	9 (4.3%)	8 (5.9%)	1 (1.4%)	0.2
Evolut R, n	5 (2.4%)	3 (2.2%)	2 (2.8%)	1.0
Evolut Pro	0 (0%)	0 (0%)	0 (0%)	1.00
Total pacing runs ≥ 2	130 (62.8%)	60 (44.1%)	70 (98.6%)	< 0.001
Contrast, mean cc ± SD	128.9 ± 51.4	128.9 ± 55.7	128.7 ± 42.4	0.53

BAV indicates balloon aortic valvuloplasty, *CT* indicates computed tomography, *LVEF* indicates left ventricular ejection fraction, *SD* indicates standard deviation, *SVi* indicates stroke volume index

*Preferentially obtained from pre-operative catheterization (n = 146); however, echocardiogram-derived SVi used if the former not available (n = 59)

**Obtained from pre-operative catheterization (n = 153)

***Applies to balloon expandable valve implanted in a native aortic valve

Table 2 Frequencies of troponin T elevation after transcatheter aortic valve replacement (TAVR)

	Total cohort (n = 189)	Direct TAVR (n = 128)	Pre-implantation BAV (n = 61)	P value
Troponin T mean ng/ml ± SD	0.10 ± 0.2	0.093 ± 0.20	0.13 ± 0.18	0.16
≥ 0.45 (> 15× ULN), n (%)	5 (2.6%)	2 (1.6%)	3 (4.9%)	0.33
≥ 0.3 (> 10× ULN), n (%)	9 (4.8%)	4 (3.1%)	5 (8.2%)	0.15
≥ 0.15 (> 5× ULN), n (%)	41 (21.7%)	23 (18.0%)	18 (29.5%)	0.09
≥ 0.09 (> 3× ULN), n (%)	71 (37.6)	42 (32.8%)	29 (47.5%)	0.06
≥ 0.03 (> ULN), n (%)	138 (73.0%) (n = 207)	87 (68.0%) (n = 136)	51 (83.6%) (n = 71)	0.02
30-day mortality, n (%)	6 (2.9%)	5 (3.7%)	1 (1.4)	0.66
1-year mortality, n (%)	27 (13.0%)	16 (11.8%)	11 (15.5%)	0.52
Periprocedural MI or 1-year mortality, n (%)	30 (14.5%)	17 (12.5%)	13 (18.3%)	0.30

BAV indicates balloon aortic valvuloplasty, *MI* indicates myocardial infarction, *ULN* indicates upper limit of normal

of the procedure. This was done to avoid crossing failures or hypotension that could potentially result from the bulky TAVR valve occupying a tight orifice [4]. With the introduction of the self-expandable valve and later-generation balloon-expandable valves, experience accumulated that avoiding BAV is feasible and can streamline the procedure [1]. Accordingly, this strategy appears to be increasing in popularity worldwide.

Table 3 Frequencies of post transcatheter aortic valve replacement (TAVR) complications

	Total cohort (n = 207)	Direct TAVR (n = 136)	Pre-implantation BAV (n = 71)	P value
Immediate procedure success, n (%)	202 (97.6%)	132 (97.1%)	70 (98.6%)	0.66
30-day mortality, n (%)	6 (2.9%)	5 (3.7%)	1 (1.4%)	0.66
Cardiac mortality, n (%)	3 (1.4%)	3 (2.2%)	0 (0%)	0.55
Stroke, n (%)	2 (1%)	2 (1.5%)	0 (0%)	0.54
Major bleeding, n (%)	2 (1.0%)	1 (0.7%)	1 (1.4%)	1.0
Major vascular complication, n (%)	4 (1.9%)	1 (0.7%)	3 (4.2%)	0.12
Coronary artery obstruction, n (%)	0 (0%)	0 (0%)	0 (0%)	1.0
$\geq$ Moderate paravalvular AI, n (%)	3 (1.4%)	0 (0%)	3 (4.2%)	0.04
Mild paravalvular AI, n (%)	24 (11.6%)	13 (9.6%)	11 (15.5%)	0.25

AI aortic insufficiency, *BAV* balloon aortic valvuloplasty

It is interesting that approximately three-fourths of patients had detectable cardiac enzyme elevation (> upper limit of normal); however, this does not appear to be clinically relevant [2]. Another study found that the median troponin value was lower in the direct TAVR group compared with the pre-implantation BAV group; however, that study did not assess for VARC-2 periprocedural myocardial infarction [5]. While direct TAVR is likely preferential with current-generation devices, selective BAV still has a role in certain cases. In our own institution, we perform selective BAV with aortic valve area $\leq 0.6\ cm^2$ or mean *trans*-aortic gradient ≥ 60 mm Hg, bicuspid aortic valve, horizontal aorta, and during simultaneous aortography when there is concern about coronary artery occlusion. A limitation of the present study was single-center design conducted almost exclusively in men. A strength of the study is incorporation of important hemodynamic variables such as stroke volume index, which are frequently lacking in other studies, especially large registries. Additional information on this topic will come from the randomized DIRECTAVI trial, which is designed to evaluate the non-inferiority of direct TAVR compared with pre-implantation BAV [6].

CONCLUSIONS

In summary, in a single-center experience, direct TAVR increased significantly over time and was not associated with periprocedural myocardial infarction or 1-year mortality. With current generation devices, this strategy can be considered for most patients undergoing TAVR.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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