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Transcatheter Aortic Valve Replacement in Patients With Symptomatic Severe Aortic Stenosis and Prior External Chest Radiation☆

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A B S T R A C T

Background/purpose: Surgical aortic valve replacement (SAVR) in patients with symptomatic severe aortic stenosis (AS) and prior chest radiation is associated with poor outcomes in comparison with patients without prior radiation. Our objective was to compare clinical outcomes of patients with and without prior chest radiation undergoing transcatheter aortic valve replacement (TAVR) for symptomatic severe AS.
Methods/materials: Between January 2003 and January 2017, 1150 patients underwent TAVR at our institution. Of these, 44 had prior chest radiation. Baseline demographic and clinical characteristics, procedural details, and clinical outcomes were prospectively collected.
Results: Patients with prior chest radiation were younger, 76 ± 13 years, compared with those without prior chest radiation, 82 ± 8 years ($p = 0.002$). Median Society of Thoracic Surgeons score for chest radiation patients was 7 ± 4, compared to 8 ± 5 in those without prior radiation. Despite higher prevalence of complete heart block, there was no significant difference between the 2 groups with regard to the need for permanent pacemaker implantation. There was a trend toward longer length of intensive care unit stay in chest radiation patients, but there was no significant difference in 30-day or 1-year mortality.
Conclusions: Thus, TAVR appears to be a safe treatment option in the short and medium term for patients with symptomatic severe AS and prior chest radiation.

1. Introduction

Chest radiation is integrated into thoracic malignancy treatment regimens for breast cancer and Hodgkin's lymphoma in up to 50% of patients [1]. With early diagnosis and better treatment regimens, the survival rate for cancer has increased [2]. Thus, cancer survivors may present later in life with radiation-induced cardiotoxicity. Commonly described cardiotoxicities related to chest radiation are constrictive pericarditis, restrictive cardiomyopathy, valvular disease, coronary artery disease, conduction disease, and thoracic aortic calcification [3,4]. In a study of 415 Hodgkin's lymphoma patients who underwent radiation therapy, the incidence of clinically significant valvular disease was 1% at 10 years, 4% at 15 years, and 6% at 20 years following initial radiation therapy, with the majority being significant aortic stenosis (AS) [5]. Mechanistically, accelerated fibrosis of the valvular apparatus is believed to lead to restricted valvular mobility and, eventually, stenosis [6].Chest radiation-induced cardiac pathology can add to the risks of cardiothoracic surgery. Indeed, patients with prior chest radiation undergoing surgical aortic valve replacement (SAVR) demonstrate greater short- and long-term mortality than patients without prior radiation do [7]. The treatment of symptomatic severe AS has evolved over the past decade, with transcatheter aortic valve replacement (TAVR) now being offered to patients deemed inoperable, high risk, and intermediate risk for SAVR [8,9]. The objective of this study was to describe the baseline characteristics of TAVR patients with prior chest radiation and to explore the impact of chest radiation on clinical outcomes.

2. Methods

We included consecutive patients undergoing TAVR between January 2003 and January 2017 at a single high-volume US center. All

Abbreviations: AS, aortic stenosis; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.
☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.
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patients were evaluated by the institutional multidisciplinary Heart Team, including interventional cardiologists, general cardiologists, imaging cardiologists, and cardiac surgeons. Two expert cardiac surgeons determined the surgical risk for each patient. Inoperability and high-surgical-risk determination were based on both technical factors (e.g., hostile chest, porcelain aorta) and clinical factors (e.g., Society of Thoracic Surgeons score, frailty, severe liver disease).

Pre-TAVR evaluation included coronary angiography to detect significant coronary artery disease. Contrast-enhanced computed tomography of the heart was performed to measure aortic annulus dimensions. Contrast-enhanced computed tomography of the iliofemoral arteries was performed to determine eligibility for transfemoral access. Two-dimensional transthoracic echocardiography was performed for detailed aortic valve peak velocity, mean gradient, aortic valve area, dimensionless index, left ventricular ejection fraction, and estimation of systolic pulmonary pressures.

Baseline demographic, clinical, imaging, and follow-up data were prospectively collected into an institutional database. Valve Academic Resource Consortium-2 definitions were used for all clinical end points (myocardial infarction, stroke, bleeding complications, vascular complications, in-hospital death, death from cardiovascular cause, death from any cause, and 30-day and 1-year all-cause mortality) [10]. Deaths were confirmed through the Social Security Death Index Database, careful inspection of death certificates, and contacting patients at defined time intervals. The study was approved by the institutional review board of MedStar Washington Hospital Center, Washington, DC.

Statistical analyses were performed using SAS 9.2 (SAS Institute, Cary, NC). Continuous variables are expressed as mean ± SD for normally distributed variables. Categorical variables are expressed as percentages. Categorical variables were compared using the $\chi 2$ or Fisher exact test. Continuous variables were compared using a 2-sample *t*-test. A *p* value <0.05 was considered significant.

3. Results

From January 2003 to January 2017, 44 TAVR patients with prior chest radiation and 1150 TAVR patients with no history of prior chest radiation with symptomatic severe AS were included in this study. Demographics and baseline characteristics stratified by presence or absence of chest radiation are shown in Table 1. Compared with patients without prior chest radiation, those with prior chest radiation were predominantly female and younger. There were no major differences between the two groups with regard to racial distribution, diabetes mellitus, severe chronic obstructive pulmonary disease, prior stroke/transient ischemic attack, prior percutaneous coronary intervention or coronary artery bypass grafting, New York Heart Association class status, and prior peripheral artery disease. The median Society of Thoracic Surgeons score also did not show any significant difference between the two groups.

There was no difference between the two groups with regard to ejection fraction and mean aortic valve area. The mean gradient across the aortic valve was significantly higher in those without prior chest radiation. Prevalence of severe mitral annular calcification was higher in the prior-chest-radiation group. Porcelain aorta was present in 19% of those with prior chest radiation and 5% of those without prior chest radiation. Moderate to severe ascending aortic calcification was prevalent in 48% of those with prior chest radiation and 29% of those without prior chest radiation.

Table 1
Baseline characteristics of the patients.

Variables	Prior chest radiation ($n = 44$)	No prior chest radiation ($n = 1150$)	P value
Age – year (Median ± SD)	76 ± 13 (44/44)	82 ± 8 (1140/1150)	0.002
Male Gender – no. (%)	10/44(23%)	583/1150(51%)	<0.001
Race			
White race – no. (%)	37/44(85%)	963/1150(84%)	0.9
African American – no. (%)	5/44(11%)	145/1150 (13%)	0.7
Asian – no. (%)	2/44(4%)	17/1150 (1.5%)	0.2
BMI	29.1 ± 8.9(44/44)	28.2 ± 8.6 (44/44)	0.5
Weight – kg (Median ± SD)	79.1 ± 26 (44/44)	77.8 ± 21 (44/44)	0.7
Diabetes Mellitus– no. (%)	13/42 (31%)	392/1136 (34%)	0.6
Hypertension – no. (%)	37/43(86%)	1062/1141(93%)	0.12
Hyperlipidemia – no. (%)	37/43(86%)	940/1136 (83%)	0.7
Severe chronic obstructive pulmonary disease – no. (%)	8/38 (21%)	168/1061 (16%)	0.4
Prior stroke or transient ischemic attack – no. (%)	4/43 (9%)	125/1052(12%)	0.6
Prior myocardial infarction– no. (%)	3/42 (7%)	193/1111 (17%)	0.08
Prior PCI– no. (%)	15/43 (35%)	336/1125 (30%)	0.5
Prior CABG– no. (%)	9/42(21%)	338/1131(30%)	0.2
Symptomatic congestive heart failure– no. (%)	41/42(98%)	1094/1124(97%)	1.0
NYHA III or IV – no. (%)	32/44(82.1%)	835/1153(79%)	0.63
Peripheral artery disease– no. (%)	11/47 (27%)	316/1110(29%)	0.7
Renal insufficiency (GFR < 60 or hemodialysis dependent) – no. (%)	7/42 (18%)	448/1124 (40%)	0.002
Prior malignancy – no. (%)	39/40(97%)	203/974(21%)	<0.001
Median STS score with interquartile range, %	7 ± 4 (42/44)	8 ± 5(1127/1150)	0.2
Extreme risk cohort	17/24(71%)	291/613(47%)	0.02
Prior balloon aortic valvuloplasty (BAV) – no. (%)	7/41(17%)	283/1067(26%)	0.2
Chronic immunosuppressive therapy – no. (%)	8/39(21%)	79/987(8%)	0.013
Echocardiographic data			
LVEF, %	53 ± 11(42/44)	52 ± 13(1098/1150)	0.8
AVA, cm^2	0.68 ± 0.13(43/44)	0.68 ± 0.16(1041/1150)	0.7
Mean aortic valve mean gradient, mm Hg	41 ± 9(43/44)	45 ± 13(1044/1150)	0.03
Severe mitral annular calcification– no. (%)	18/36(50%)	309/888(35%)	0.06
Computerized tomographic data			
Mod-Sev ascending aortic calcification – no. (%)	16/33(48%)	215/728(29%)	0.01
Porcelain Aorta – no. (%)	8/43(19%)	61/1143(5%)	0.002

AVA — aortic valve area; CABG — coronary artery bypass graft; GFR — glomerular filtration rate; LVEF — left ventricle ejection fraction; PCI — percutaneous coronary intervention; STS — society of thoracic surgeons.

Table 2
Procedural characteristics.

Variables	Prior chest radiation ($n = 44$)	No prior chest radiation ($n = 1150$)	P value
Type of TAVR valve			
Self-expandable – no. (%)	10/44(23%)	318/1150(29%)	0.4
Balloon expandable – no. (%)	31/44 (71%)	756/1150(68%)	0.7
Access			
Transfemoral, %	37/44(84%)	949/1150(83%)	0.8
Transapical, %	5/44(11%)	150/1153(13%)	0.7
Others, %	2/44(5%)	39/1153(4%)	0.6
Procedure length, mins	68 ± 30(21/44)	78 ± 82(542/1150)	0.1
Fluoro Time, mins	22 ± 17(44/44)	21 ± 17(1110/1150)	0.7
Contrast volume, cc	114 ± 58 (44/44)	120 ± 64(1098/1150)	0.5
Access site complication			
Percutaneous intervention – no. (%)	2/25(8%)	70/729(9.6%)	1
Surgical intervention – no. (%)			0.6

TAVR — transcatheter aortic valve replacement.

Procedural details and in-hospital outcomes stratified by presence or absence of chest radiation are shown in Tables 2 and 3, respectively. The 2 groups did not differ with respect to the choice of valve or choice of access. Procedure duration, fluoroscopy time, and iodinated contrast volume were similar between the 2 groups. The rate of access site complications requiring percutaneous intervention was 8% in the prior-chest-radiation group and 9.6% in those without prior chest radiation. Post-valve deployment, 2D echo showed a similar decrease in mean gradient between the two groups.

Post-procedure, there was no significant difference in permanent pacemaker implantation rate between the 2 groups (9% vs. 9.2%, $p = 1.0$). Recurrent heart failure symptoms after TAVR was significantly higher in patients with prior chest radiation (23% vs. 12%, $p = 0.02$). There was no significant difference between the 2 groups with regard to the occurrence of life-threatening bleeding, need for transfusion, or major stroke. Overall, the length of stay was longer in those with prior chest radiation than in those without prior chest radiation. Unadjusted in-hospital death was 6.8% in the prior chest radiation group and 4.8% in those without prior chest radiation. At 30 days, all-cause mortality was 6.8% in the prior-chest-radiation group and 5.6% in those without prior chest radiation (Fig. 1). At 1-year follow up, all-cause mortality was 25% in the prior-chest-radiation group and 17.5% in those without prior chest radiation (Fig. 2).

4. Discussion

The main findings of our study are: 1) compared to the general TAVR population, patients with prior chest radiation undergoing TAVR were younger and predominantly female; 2) following TAVR, there was an increased incidence of left bundle branch block or complete atrioventricular block without any significant increase in permanent pacemaker implantation compared to the general TAVR population; and 3) there was significant increase in worsening of heart failure symptoms in patients with prior chest radiation, which might explain their longer length of intensive care unit and in-hospital stay. Despite these complications, there were no significant differences in in-hospital and 30-day survival between TAVR patients with prior chest radiation and the general TAVR population. There was a trend toward higher 1-year mortality in the patients with prior chest radiation, but this was not statistically significant.

The treatment of symptomatic severe AS has evolved over the past decade. A subset of patients with high surgical risk consists of patients with previous chest radiation. Other than valvular fibrosis or calcification, chest radiation might be associated with premature atherosclerosis, myocardial fibrosis, pericardial thickening, and conduction abnormalities. Fibrosis of the myocardium can lead to restrictive cardiomyopathy and diastolic heart failure. Similarly, collagen deposition in the parietal pericardium can lead to a rigid pericardial sac, resulting in increased thickness and cardiac constriction. This might lead to poor cardiac reserve and increased susceptibility for perioperative hemodynamic instability in these patients.

Chest radiation causes mediastinal fibrosis and pulmonary fibrosis. Extensive mediastinal fibrosis or lack of a safety margin between the sternum and adjacent structures might preclude use of median sternotomy approach. Radiation also induces accelerated calcification

Table 3
In-hospital outcomes and long term outcomes.

Variables	Prior chest radiation (n = 44)	No prior chest radiation (n = 1150)	P value
Post procedure LBBB – no. (%)	13/44(32%)	186/1017(18%)	0.02
Complete atrio-ventricular block – no. (%)	6/40(15%)	78/1017(7%)	0.1
Need for permanent pacemaker – no. (%)	4/44(9%)	105/1141(9.2%)	1.0
Cardiac tamponade/pleural effusion – no. (%)	3/44(7%)	57/1128(5.1%)	0.5
Post procedure life threatening bleeding – no. (%)	2/44(4.8%)	67/1127(6%)	1
Any post procedure transfusion – no. (%)	15/44(34%)	350/1148(31%)	0.6
Post procedure major stroke– no. (%)	2/44(4.8%)	20/1138(1.8%)	0.1
Worsening congestive heart failure – no. (%)	10/44(23%)	134/1134(12%)	0.03
Post procedure echo findings			
LVEF, %	56.9 ± 10(38/44)	54.3 ± 13(1050/1150)	0.25
Difference in aortic valve mean gradient, mmHg	32 ± 9.7(32/44)	33 ± 13 (731/1150)	0.7
Length of ICU stay in days – no. (%)	5.3 ± 9(44/44)	3.8 ± 6.7(1112/1150)	0.2
Length of stay in days	8.1 ± 8.9 (44/44)	6.4 ± 5.9 (1153/1153)	0.2
Death from cardiovascular causes — no. (%)	1/44(2.3%)	31/1147(2.7%)	1.0
Death from any cause — no. (%)	3/44(6.8%)	55/1148(4.8%)	0.5
30-day mortality – no. (%)	3/44(6.8%)	64/1150(5.5%)	0.73
1-year mortality – no. (%)	11/44(25%)	201/1150(17.5%)	0.19

LBBB — left bundle branch block; LVEF — left ventricular ejection fraction; MI- myocardial infarction; ICU — intensive care unit.

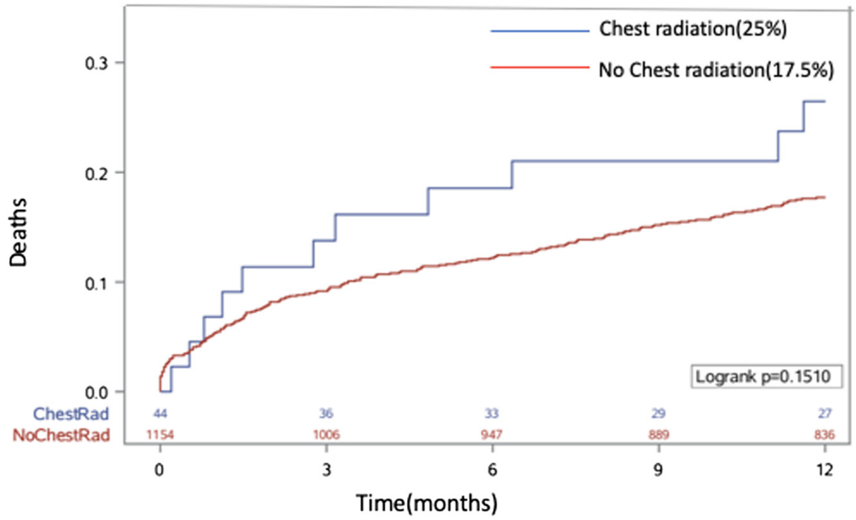

Fig. 1. Kaplan-Meier survival curve for all-cause mortality at 30 days – At 30 days, all-cause mortality was 6.8% ($n = 3$) in prior chest radiation group and 5.5% ($n = 64$) in those without prior chest radiation.

of the thoracic aorta and is frequently associated with porcelain aorta, wherein there is near or completely circumferential calcification of the ascending aorta and the arch of the aorta [11]. This condition prevents manipulation and cross-clamping of the ascending aorta, precluding cardiopulmonary bypass, and significantly increases periprocedural stroke and mortality [12]. Patients with pulmonary fibrosis following SAVR are at increased risk of mortality due to cardiorespiratory illness. Post-procedure, these patients are at increased risk of prolonged intubation, need for prolonged chest tube drainage, and possible need for tracheostomy or pleurodesis/pleural decortication. Thus, the combination of a hostile surgical environment and increased post-surgical morbidity and mortality would make SAVR a less favorable procedure for symptomatic severe AS.

In a recent study by Donnellan et al. [7], clinical outcomes of patients with severe AS with or without prior mediastinal radiation who underwent SAVR were compared. The 2 groups were age- and sex-matched and were similar in most of their demographics, co-morbidities, and echocardiographic findings. Interestingly, prior radiation was associated with longer length of hospital and intensive-care-unit stay, higher stroke rate, higher in-hospital mortality, more postoperative complications and transfusions, and higher readmission rate. However, our study comparing patients with or without prior radiation undergoing TAVR did not demonstrate such a difference. We observed overall good results in both groups after TAVR, even though patients in both groups were predominantly at high and extreme surgical risk.

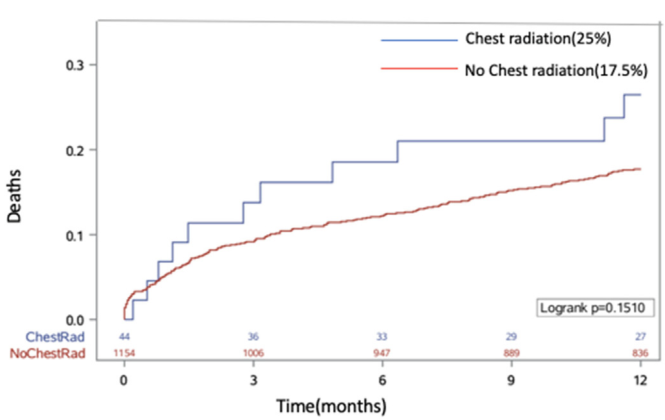

Fig. 2. Kaplan-Meier survival curve for all-cause mortality at 1 year – At 1-year follow-up, all-cause mortality was 25% ($n = 11$) in the prior chest radiation group and 17.5% ($n = 201$) in those without prior chest radiation.

Except for the development of left bundle branch block and worsening of cardiac failure symptoms after TAVR, all of the other post-procedural complications did not show any significant differences between the 2 groups.

There have been prior case series of TAVR in patients with prior chest radiation [13–16] . In one such series, of 10 patients with prior chest radiation undergoing TAVR [17], the cohort was relatively younger, with a mean age of 60 years. Given the low Society of Thoracic Surgeons and low EuroSCORE, in principle, these patients would be candidates for SAVR. However, prior mediastinal radiation and consequential porcelain aorta prohibited SAVR, and all underwent TAVR instead. Post-procedure, 2 out of 10 required permanent pacemaker implantation. The average intensive-care-unit length of stay was 1 day, and the total hospital stay was 5 days. There was no mortality at 30 days. The study lacked long-term follow-up. In another study of 98 patients with prior mediastinal radiation undergoing TAVR for severe symptomatic AS [18], at a mean follow-up of 2.3 ± 1.6 years, there were 20 deaths with an annualized mortality of 8% per year. The post-procedure pacemaker rate was 15%, and in-hospital survival was 96%. Our patients with prior chest radiation were relatively older and with higher prevalence of co-morbidities. Following TAVR, our study had comparable in-hospital mortality rate, with lesser need for permanent pacemaker implantation (9%). At 1-year follow-up, in our study, all-cause mortality was 25% in patients with prior chest radiation. This is likely related to the relatively older patient population and their associated comorbidities.

Our study compares outcomes after TAVR for symptomatic severe AS among those with prior chest radiation to those without prior chest radiation. Our results demonstrated that TAVR is safe in the short term in these patients and has acceptable results compared with the general TAVR population without prior radiation. We also demonstrated no difference in 30-day mortality between the groups, although there was a trend toward higher mortality in patients with radiation at 1 year. Although follow-up beyond 1 year was not available for these patients, it is reasonable to consider TAVR in patients with symptomatic severe AS and prior chest radiation. Given that prior chest radiotherapy is an independent risk factor for increased long-term mortality in patients undergoing SAVR [19], TAVR may be a safer and perhaps superior therapeutic strategy for these patients.

5. Limitations

The details of characteristics, dosage and duration of chest radiation were not available for all patients. We do acknowledge some missing variables given retrospective nature of the study. The sample size is also small, thus limiting the statistical power. This is also a single-center study, limiting generalizability.

6. Conclusions

Patients with prior chest radiation undergoing TAVR have few post-procedural complications, with rates similar to those of the general TAVR population. Thirty-day survival was also similar between the 2 groups, although there was a trend toward higher 1-year mortality in patients with prior radiation. Larger, multicenter studies are needed to assess long-term outcomes of TAVR patients with prior chest radiation.

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Declarations of interest

Toby Rogers – Consultant & Proctor: Medtronic; Proctor: Edwards Lifesciences.

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