Impact of aortic aneurysms in trans-catheter aortic valve replacement: A single center experience

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1. Introduction

Multi-detector computer tomography (MDCT) is the current gold-standard imaging modality for pre-procedural planning of trans-catheter aortic valve replacement (TAVR). It allows for determination of both the optimal approach as well as accurate valve size in each case [1,2]. In addition, MDCT may also identify undiagnosed pathology as may be present in some cases such as aortic aneurysms [1].

Although prior landmark TAVR clinical trials excluded patients with significant aortic aneurysms [3,4], in clinical practice, patients with aortic aneurysms may undergo TAVR. Ascending aortic dilatation has been reported in up to 25% of patients undergoing TAVR; however, it does not appear to affect mid-term survival [5].

In Rylski’s study [5], the impact of ascending aortic dilatation on the procedural outcomes such as vascular complications has not been addressed. It has been seen that vascular complications are associated with increased mortality after TAVR [6]. Prior studies have demonstrated that female gender [7], arterial calcification [7,8] and arterial puncture above the inferior epigastric artery [9] are associated with vascular complications. Thus, the presence of aortic aneurysms can be associated with increased rate of vascular complications.

In contrast to ascending aortic dilatation, little is known regarding the incidence of abdominal aortic aneurysm (AAA) and its impact on procedural and clinical outcomes among patients undergoing TAVR. The aim of this study is to clarify 1) the incidence of AAA and thoracic aortic aneurysm (TAA) on patients undergoing...
TAVR, and 2) the impact of TAA and AAA on procedural and clinical outcomes in patients undergoing TAVR.

2. Material and methods

2.1. Subjects

A retrospective analysis was performed on 232 consecutive patients with symptomatic severe aortic stenosis (AS) who had prohibitive or high surgical risk and underwent TAVR between January 2012 to June 2016 at Banner University Medical Center, Phoenix, Arizona. All patients underwent pre-TAVR contrast enhanced MDCT with retrospective electrocardiography gating on a 64-slice scanner using a standard TAVR protocol [10]. Computed tomography (CT) images were reviewed by an experienced radiologist who was blinded to clinical outcomes. Aortic aneurysm was defined as a presence of permanent localized dilatation of the aorta having at least a 50% increase in diameter compared to the expected normal diameter of the aorta in line with published clinical guidelines [11]. All TAVR procedures were performed by a dedicated team composed of an interventional cardiologist, cardiac surgeons, and anesthesiologists. All patients underwent TAVR under general anesthesia in a hybrid operating room suite.

Electronic medical records were reviewed and patients’ demographic data were extracted. Pre-TAVR trans-thoracic eco-cardiograms were reviewed and baseline echocardiographic parameters were collected. Procedural outcomes and incidence of vascular complications, bleeding complications, and acute kidney injury were recorded. All study endpoints were defined by the Valve Academic Research Consortium 2 (VARC 2) Consensus Statement [12]. Device success was defined as correct positioning of a single prosthetic heart valve into the proper anatomical location and adequate delivery system retrieval. Length of stay was calculated from TAVR procedure (day 0) to day of discharge.

Prior to discharge from our hospital, 30-day follow-up appointment with a treating interventional cardiologist was given to all patients, and the information regarding 30-day readmission was obtained through this outpatient follow-up. Six-month clinical outcomes such as all-cause mortality, cardiac arrest, myocardial infarction (MI), and stroke were obtained by reviewing inpatient, outpatient, and emergency room medical records, which are system wide electronic medical records shared in our hospital and its affiliated institutions. All procedures were performed by a single interventional cardiologist and the treating interventional cardiologist was contacted for long-term follow-up information. Present study complied with the Declaration of Helsinki and was approved by the institutional review board of the hospital.

2.2. Primary endpoint

The primary endpoint was 6-month major adverse cardiac events (MACE) defined as a composite of all-cause mortality, cardiac arrest, MI, and stroke. In addition, in-hospital MACE as well as 30-day readmission rates were recorded.

2.3. Statistical analysis

Patients were separated by the presence or absence of aneurysm. The clinical variables identified above were compared between the two groups. In addition, sub-group analysis was performed to compare clinical variables between those with TAA and control patients (sub-group analysis 1) and those with AAA and control patients (sub-group analysis 2). Data were expressed as either a number (percentage) or median (interquartile range). Continuous variables were compared using Wilcoxon rank sum test. Dichotomous variables were compared using the chi-squared test or Fisher’s exact test. Two-sided p values <0.05 were considered statistically significant. All statistical analyses were performed with R software (version 3.0.1).

3. Results

A total 232 patients were included in the final analysis, of which 22 patients (9.5%) had aortic aneurysms (11 patients had AAA, 8 patients had TAA, and 3 patients had both AAA and TAA). Two of 22 patients (9.1%) with aortic aneurysms had a known history of aortic aneurysms. One patient had an AAA greater than 5 cm. Among 11 patients with TAA, 6 patients had aortic aneurysms at ascending aorta, 1 patient at aortic arch, and 4 patients at descending thoracic aorta. Among the 6 patients with ascending aortic aneurysms, 3 patients had aneurysm >4.5 cm. In contrast, none of patient with aortic arch aneurysm had aneurysm >5.5 cm, and none of 4 patients with descending thoracic aneurysms had aneurysm >6.0 cm. The average AAA diameter was 3.6 cm and the average TAA diameter was 3.8 cm. In patients without aortic aneurysms on pre-TAVR MDCT, 2 patients (1.0%) had a prior history of aortic aneurysm repair.

Baseline demographic and clinical characteristics were summarized in Table 1. There was a trend for a higher rate of smoking history in patients with aortic aneurysms (63.6% vs. 42.9%, p = 0.062). The Society of Thoracic Surgeons Risk Score was comparable between the two groups (7.9 [6.2 – 12.2] vs. 6.6 [4.6 – 10.1], p = 0.32).

Baseline pre-TAVR echocardiographic and MDCT findings were summarized in Table 2. Left ventricular ejection fraction was similar between the two groups (55% [50–60] vs. 55% [45–60], p = 0.87). Patients with aortic aneurysms had a trend towards higher, albeit statistically insignificant, rate of bicuspid aortic valve morphology (13.6% vs. 4.3%, p = 0.093). This difference was mainly driven by a higher rate of bicuspid aortic valve morphology in patients with TAA (27.3% vs. 4.3%, p = 0.016).

Procedural outcomes are summarized and presented in Table 3. There was a trend for a longer fluoroscopy time in patients with aortic aneurysms (14 min [12–22] vs. 12 min [9–18], p = 0.087). Patients with aortic aneurysms received a higher dose of contrast during the index procedure (144 ml [83–246] vs. 100 ml [70–151], p = 0.037). The majority of patients with and without aortic aneurysms underwent trans-femoral TAVR (72.7% vs. 71.4%, p = 0.90). The same trend was seen in both sub-group analysis 1 in patients with TAA (63.6% vs. 71.4%, p = 0.73) and sub-group analysis 2 in patients with AAA (71.4% vs. 71.4%, p = 1.0). None of patients required emergent change of access sites. Patients with aortic aneurysms had a similar rate of successful device implantation (100% vs. 97.1%, p = 1.0) compared to those without.

In-hospital outcomes and 6-month outcomes are summarized and presented in Table 4. There was a trend for a higher rate of minor bleeding complications in patients with aortic aneurysms (13.6% vs. 3.3%, p = 0.057). The rate of vascular complication was similar between the two groups (9.1% vs. 10.5%, p = 1.0). Among patients with aortic aneurysms, one patient required right popliteal artery thrombectomy and another patient had percutaneous closure device failure. One patient in control group developed an aortic root injury. Patients with aortic aneurysms had a similar in-hospital MACE (4.5% vs. 6.2%, p = 1.0) and 6-month MACE (9.1% vs. 9.0%, p = 1.0) compared to those without. Among patients with aortic aneurysms, one patient had cardiac arrest due to cardiac tamponade during the index admission and another patient passed away from heart failure 2 months after TAVR. None of patients with aortic aneurysms had death related to aneurysm or required aortic aneurysm repair at 6-month follow-up.
Table 1  
Baseline clinical characteristics of patients with aneurysm and those without aneurysm.

|                          | Aneurysm (n = 22) | Control (n = 210) | p value |
|--------------------------|-------------------|-------------------|---------|
| Demographics             |                   |                   |         |
| Age (years)              | 83 [71–88]        | 83 [75–86]        | 0.85    |
| Male (%)                 | 10 (45.5)         | 115 (54.8)        | 0.4     |
| Body mass index (kg/m²)  | 26 [24–27]        | 27 [24–30]        | 0.24    |
| Caucasian ethnicity (%)  | 18 (81.8)         | 189 (90.0)        | 0.13    |
| Hypertension (%)         | 21 (95.4)         | 200 (95.2)        | 1       |
| Diabetes (%)             | 4 (18.2)          | 80 (38.1)         | 0.064   |
| Hyperlipidemia (%)       | 14 (63.6)         | 163 (77.6)        | 0.14    |
| Chronic kidney disease (eGFR<60mL/min/1.73m²) (%) | 5 (22.7) | 86 (41.0) | 0.096 |
| Hemodialysis (%)         | 1 (4.5)           | 7 (3.3)           | 0.56    |
| Smoking history (%)      | 14 (63.6)         | 90 (42.9)         | 0.062   |
| Chronic obstructive pulmonary disease (%) | 7 (31.8) | 58 (27.6) | 0.68   |
| Coronary artery disease (%) | 14 (63.6) | 140 (66.7) | 0.77   |
| History of aortic aneurysm (%) | 2 (9.1) | 2 (1.0) | 0.046  |
| History of aortic aneurysm repair (%) | 0 (0.0) | 2 (1.0) | 1      |
| Previous percutaneous coronary intervention (%) | 11 (50.0) | 94 (44.8) | 0.64    |
| Previous coronary artery bypass grafting (%) | 4 (18.2) | 50 (23.8) | 0.55    |
| Previous stroke or transient ischemic attack (%) | 6 (27.3) | 35 (16.7) | 0.24   |
| Society of Thoracic Surgeons Risk Score | 7.9 [6.2–12.3] | 6.6 [4.6–10.1] | 0.32    |

eGFR: estimated glomerular filtration rate.
Data are expressed as a number (percent) or median (interquartile range).

4. Discussion

TAVR is a treatment of choice in high risk and inoperable patients with symptomatic severe AS [3,4]. Recently, TAVR was also approved for intermediate risk patients [13]. However, the prior landmark clinical trials excluded patients with aortic aneurysms of more than 5.0 cm [3,4], and the incidence of aortic aneurysms and their clinical significance was not addressed [13]. Although the impact of concomitant aortic aneurysms in patients undergoing TAVR has not been fully addressed, previous studies have examined the impact of aortic aneurysms in patients undergoing coronary angiogram [14–16]. Ueda et al evaluated the safety of pre-operative coronary angiogram in patients with TAA.

Table 2  
Electrocardiographic and computed tomographic characteristics of patients with aneurysm and those without aneurysm.

|                          | Aneurysm (n = 22) | Control (n = 210) | p value |
|--------------------------|-------------------|-------------------|---------|
| Pre-procedural echocardiographic findings |                   |                   |         |
| Left ventricular ejection fraction (%) | 55 [50–60] | 55 [45–60] | 0.87    |
| Aortic valve area (cm²) | 0.64 [0.49–0.82] | 0.67 [0.52–0.82] | 0.78   |
| Mean aortic valve pressure gradient (mmHg) | 40 [37–45] | 41 [34–51] | 0.89    |
| Max velocity across aortic valve (m/second) | 4.1 [4.0–4.3] | 4.2 [3.9–4.6] | 0.36    |
| Concomitant aortic regurgitation |                   |                   |         |
| Moderate aortic regurgitation (%) | 5 (22.7) | 57 (27.1) | 0.82    |
| Severe aortic regurgitation (%) | 1 (4.5) | 4 (1.9) | 0.37    |
| Pulmonary artery systolic pressure (mmHg) | 35 [29–49] | 34 [25–48] | 0.62    |
| Pre-procedural computer tomographic findings |                   |                   |         |
| Bicuspid aortic valve (%) | 3 (13.6) | 9 (4.3) | 0.093   |
| Abdominal aortic aneurysm (%) | 14 (63.6) | 0 (0.0) | <0.001 |
| Thoracic aortic aneurysm (%) | 11 (50.0) | 0 (0.0) | <0.001 |
| Major anulus diameter (mm) | 26 [23–27] | 26 [24–29] | 0.37    |
| Minor anulus diameter (mm) | 21 [19–22] | 22 [20–23] | 0.19    |
| Left common iliac artery diameter (mm) | 7.8 [7.0–8.8] | 8.0 [6.4–9.1] | 0.93    |
| Right common iliac artery diameter (mm) | 8.0 [6.1–9.0] | 8.0 [6.0–9.0] | 0.9      |
| Angulation of ascending aorta (degree) | 47 [42–54] | 49 [43–56] | 0.88    |

Sub-group 1

|                          | TAA (n = 11) | Control (n = 210) | p value |
|--------------------------|-------------|-------------------|---------|
| Concomitant aortic regurgitation |                   |                   |         |
| Moderate aortic regurgitation (%) | 3 (27.3) | 57 (27.1) | 1       |
| Severe aortic regurgitation (%) | 1 (9.1) | 4 (1.9) | 0.22    |
| Bicuspid aortic valve (%) | 3 (27.3) | 9 (4.3) | 0.016   |
| Angulation of ascending aorta (degree) | 45 [42–52] | 49 [43–56] | 0.7     |

Sub-group 2

|                          | AAA (n = 14) | Control (n = 210) | p value |
|--------------------------|-------------|-------------------|---------|
| Concomitant aortic regurgitation |                   |                   |         |
| Moderate aortic regurgitation (%) | 3 (21.4) | 57 (27.1) | 1       |
| Severe aortic regurgitation (%) | 3 (21.4) | 57 (27.1) | 1       |
| Bicuspid aortic valve (%) | 0 (0.0) | 4 (1.9) | 1       |
| Angulation of ascending aorta (degree) | 48 [42–52] | 49 [43–56] | 0.83    |

Data are expressed as a number (percent) or median (interquartile range).
TAA: thoracic aortic aneurysm, AAA: abdominal aortic aneurysm.
who were scheduled for TAA surgery and reported that 5.1% (3 out of 59 patients) of patients had angiogram related complications such as major stroke and severe MI [14]. Gertz et al retrospectively reviewed patients with ascending aortic aneurysms who were referred to coronary angiogram prior to elective surgery for ascending aortic aneurysms [15]. The author reported that none of their studied patients experienced adverse events. Furthermore, Israel et al evaluated the safety and feasibility of coronary angiogram in patients with ascending aortic aneurysms or dissection [16]. The author reported that the only major complication was one brachial artery occlusion and concluded that coronary angiogram can be safely performed in patients with ascending aortic aneurysms or dissection. Although the results of those prior studies were mixed and did not demonstrate the definitive association between the presence of aortic aneurysms and adverse procedural and clinical outcomes, Israel et al reported a high failure rate of selective coronary engagement [16]. In addition, Gertz et al also revealed that patients with ascending aortic aneurysms required longer fluoroscopy time and higher contrast volume [15]. In our study, patients with aortic aneurysms trended towards longer, albeit statistically insignificant, fluoroscopy time and larger amounts of contrast, implying the higher complexity of procedures and more challenging procedural imaging among patients with aortic aneurysms. However, patients with aortic aneurysms had a similar rate of successful device implantation compared to those without.

It has been reported that ascending aortic dilatation was commonly seen in patients with AS [17]. Ryłski et al evaluated the safety and feasibility of TAVR in patients with ascending aortic dilatation (defined as diameter more than 4.0 cm) [5]. The author reported that concomitant ascending aortic dilatation was common (25%) and concluded that ascending aortic dilatation was not associated with increased adverse aortic events, nor did it affect mid-term survival. In our study, the incidence of TAA, which was defined in line with the current clinical guidelines [11], was 4.7%. Patients with TAA had a similar rate of vascular complications as well as short- and long-term MACE compared to those without. In our present study, none of 3 patients with ascending aortic aneurysms greater than 4.5 cm developed any symptoms or signs of aortic route injury. In addition, none of patients with TAA required aortic aneurysm repair or had aneurysm related death at 6-month follow-up. However, in both our study and Ryłski’s study, the number of patients with large TAA were too small to derive definitive conclusions.

For patients with severe AS, when the ascending aortic diameter exceeds 4.5 cm, the clinical guidelines recommend simultaneous root replacement [11]. In contrast to ascending aortic aneurysms, operative treatment is recommended when the diameter of arch exceeds >5.5 cm and the diameter of descending thoracic aorta exceeds >6.0 cm in patients with isolated aortic arch aneurysms and descending thoracic aortic aneurysms [11]. Although the guidelines do not specifically address the management of aortic aneurysms at the time of TAVR, Allen et al reported a patient with TAA (8.0 cm) and critical AS who was successfully treated with simultaneous trans-apical TAVR and thoracic endovascular aortic repair (TEVAR) [18]. Similar case was also reported by Zhu et al who described a patient with a saccular aortic arch aneurysm (4.2 cm) and critical AS who was successfully treated with simultaneous trans-apical TAVR and TEVAR [19]. TAA size had profound impact on rupture, dissection, and death [20]. Davies et al reported that for TAA greater than 6.0 cm in diameter, rupture or dissection occurred at 6.9% per year and death occurred at 11.8% per year. Inoperable and high-risk severe AS patients have post TAVR 1-year mortality 30.7% and 24.2%, respectively [3, 4]. Given their baseline high-risk profiles, maintaining a conservative approach to concomitant TAA seems to be a reasonable strategy. In fact, it was reported that there was no increase in the diameter of proximal ascending aorta after TAVR in high-risk severe AS
patients complicated with ascending aortic dilatation.\(^5\) Patients with a bicuspid aortic valve, on the other hand, have progressive dilatation of the ascending aorta after surgical aortic valve replacement [21]. Given the potential longer life expectancy in patients with bicuspid aortic valve [22], patients with bicuspid aortic valve and concomitant TAA should not undergo TAVR. In addition, low and intermediate risk patients with concomitant TAA should not undergo TAVR at this time as the unknown related to what happens with aortic root after TAVR and long life expectancy of those patients make TAVR less attractive without additional data.

In contrast to TAA, the incidence of AAA and its impact on procedural and clinical outcomes in patients undergoing TAVR have not been previously addressed. In our study, the incidence of AAA was 6.0%, similar to data previously reported [1]. Patients with AAA had a similar rate of vascular complications as well as short- and long-term MACE compared to those without. However, the safety and feasibility of TAVR in patients with large AAA remained unclear as only one patient had AAA greater than 5.0 cm.

A series of case reports described simultaneous TAVR and endovascular aortic repair in patients with large AAA and confirmed its feasibility [23–27]. The annual risk of rupture in patients with AAA between 5.0 to 6.9 cm is 3.0–20.0 % [28]. Considering post TAVR 1-year mortality is higher than 20.0% in inoperable and high-risk patients [3,4], conservative management seems reasonable in patients with AAA between 5.0–6.9 cm. In contrast, patients with a AAA greater than 7.0 cm carry a high risk of rupture at 20.0% per year [28]. This rate is similar to post TAVR 1-year mortality in high-risk patients [4], thus a case for simultaneous treatment can be made in high-risk patients to prevent death from concomitant AAA.

All the limitations applicable to a single center retrospective observational cohort study are applicable to this study. Our study included relatively a small number of patients and small number of clinical events, limiting the statistical power to detect differences in clinical outcomes. In addition, the average diameter of aortic aneurysms in our study was relatively small, which may have masked the true differences in the procedural and clinical outcomes between those with and without aortic aneurysms. Follow-up MDCT was available in a small number of patients, thus we do not know if there was any increase in the diameter of aortic aneurysms after TAVR. Finally, longer-term clinical follow-up with MDCT to assess 1-year and 3-year clinical outcomes and aortic remodeling after TAVR would have been ideal and is the focus of future study.

In summary, this study identified the incidence of concomitant aortic aneurysms was 9.5% (AAA was 6.0% and TAA was 4.7%) of patients who underwent TAVR. The presence of aortic aneurysms either in the thoracic or abdominal aorta did not confer any incremental risk to TAVR procedures with respect to vascular complications or short- and long-term outcomes. Longer-term follow-up in a larger study will be necessary to draw a definitive conclusion.

5. Conclusions

We conclude that in our cohort of patients who underwent TAVR, 9.5% of patients had aortic aneurysms. Patients with aortic
aneurysm had similar incidences of vascular complication as well as in-hospital and 6-month MACE compared with those without.

Declaration of interest
None.

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