

Non-Valvular Findings before Trans-Catheter Aortic Valve Implantation and their Impact on the Procedure

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ABSTRACT: **Background:** Trans-catheter valve implantation (TAVI) is a non-surgical alternative for patients with severe aortic stenosis (AS). Pre-procedural computed tomography angiography (CTA) allows accurate “road mapping,” aortic annulus sizing and the detection of incidental findings.

Objectives: To document the prevalence of non-valvular extracardiac findings on CTA prior to TAVI and the impact of these findings on the procedure.

Methods: Ninety AS patients underwent CTA as part of pre-TAVI planning. Scans extended from the clavicles to the groin. Non-vascular non-valvular findings were documented and graded as follows: (A) significant findings causing TAVI cancellation or postponement, (B) significant findings leading to a change in the TAVI procedure approach, (C) non-significant findings not affecting the TAVI procedure.

Results: TAVI was planned for 90 patients; their average age was 80.2 ± 7.5 years, 53% were females. Overall, non-valvular cardiac, extracardiac and extravascular significant and non-significant incidental findings were documented in 97% of scans (87/90). Significant pathologies causing TAVI cancellation or postponement (category A) were documented in 8%. Significant findings affecting the TAVI procedure (category B) were found in 16% of patients.

Conclusions: Pre-TAVI CTA detected non-valvular extravascular pathologies leading to procedure cancellation/postponement or procedure modification in 8% and 16%, respectively. Comprehensive CTA evaluation that acknowledges the importance of such findings is of major importance since it might alter the TAVI procedure or even render it inappropriate.

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reaching 60% [1]. Surgical aortic valve replacement (AVR) has been shown to be the only effective treatment for alleviating symptoms and prolonging life [2]. However, up to 50% of patients are too frail due to significant co-morbidities excluding them from surgery [3,4]. Thus, in the last decade, trans-catheter aortic valve implantation (TAVI) was introduced and gained acceptance as an alternative treatment option for severe AS in this subgroup of patients [5-8]. Appropriate patient selection is crucial for the success of TAVI [6-9].

Computed tomography angiography (CTA) plays an important role in the evaluation prior to undertaking TAVI. It offers accurate sizing of the aortic annulus and the aortic root, enabling selection of the optimal implanted device (size and type) [10-14]. Moreover, CTA provides necessary information regarding the preferred access pathway (trans-femoral or subclavian vs. apical) [11,13]. Since the entire chest and abdomen are included in the CTA study performed for aortic annulus and access evaluation prior to TAVI, additional incidental information in these scans cannot be overlooked. The present study included sequential patients who were candidates for TAVI, and all underwent a pre-procedural TAVI CTA. The purpose of this study was to assess the prevalence of non-valvular cardiac, extracardiac and extravascular findings in this population and evaluate the additional clinical value of TAVI CTA in those patients. Our results stress the importance of a comprehensive assessment of these pathologic findings before TAVI.

PATIENTS AND METHODS

The study group included patients with consecutive scans performed between August 2010 and September 2012 as part of the evaluation prior to TAVI.

ACQUISITION PROTOCOL

All patients underwent TAVI CTA for evaluation of cardiac and non-valvular findings before TAVI using a 256-slice scanner (Brilliance iCT, Philips Healthcare, Cleveland, OH, USA). Data were acquired with the following parameters: collimation of 96×0.625 mm, gantry rotation time of 330 ms, pitch value 0.2, tube current 485 mA and 120 kV. Scans included the entire chest

Severe aortic valve stenosis (AS) is common in the elderly population, especially since life expectancy continues to increase in the 21st century. The natural history of patients with AS is grim and is associated with a 5 year mortality rate

and the abdomen, starting at the clavicles and continuing to the femoral area in a cranio-caudal direction. Non-ionic contrast media (Iomeron 350™, Bracco, Milan, Italy) was administered intravenously at a mean amount of 70 ml (range 60–90 ml) and flow rate of 4 ml/sec, followed by a 30 ml saline flush (4 ml/sec). Automated peak enhancement detection in the descending aorta was used for scan timing. Data acquisition was automatically initiated at a threshold level of 100 Hounsfield units. Images were reconstructed with a slice thickness of 0.67 for the cardiac region and 2 mm for the entire scan.

Patients with impaired renal function (creatinine > 1.4 mg/dl) or at increased risk of acute kidney injury received balanced intravenous volume expansion with isotonic sodium chloride [15]. Based on creatinine level no patients were excluded from CT study.

Scans were prospectively reviewed by an experienced radiologist (O.G., a dedicated cardiac imaging radiologist with 9 years experience), and assessed for cardiac, extracardiac and extravascular incidental findings apart from the aortic stenosis itself. These findings were graded according to previously published criteria: (A) significant findings causing TAVI cancellation or postponement, (B) significant findings that required changing the TAVI procedure approach, and (C) non-significant incidental findings not affecting the decision to perform TAVI [16].

The study was approved by the Institutional Review Board and the patients signed a dedicated informed consent form.

RESULTS

Ninety patients comprised the study cohort. Average patient age was 80.2 ± 7.5 years, 53% of the patients were females. Patients' characteristics are presented in Table 1.

Table 1. Baseline characteristics

	N=90
Gender	
Male	42 (47%)
Ischemic heart disease	
S/P myocardial infarct	10 (11%)
S/P coronary artery bypass grafting	13 (14%)
S/P percutaneous coronary intervention	15 (16.7%)
Coronary artery disease	29 (32.2%)
Smoking	
Past	19 (21%)
Present	16 (18%)
Hypertension	63 (70%)
Hyperlipidemia	55 (61%)
Diabetes mellitus	22 (24%)
Chronic obstructive pulmonary disease	12 (13%)
Paroxysmal atrial fibrillation	21 (23%)
Renal failure	Creatinine > 1.4: 38 (42%)

Overall, non-valvular cardiac, extracardiac and extravascular significant and non-significant incidental findings (categories A,B,C) were documented in 97% of scans (87/90). Significant pathologies – categories A and B – were found in 23.3% of the patients (21/90) [Table 2]. Category A included findings necessitating TAVI cancellation or postponement: adenocarcinoma of lung (N=2), malignant pancreatic tumor (N=1), renal cell carcinoma (N=1) [Figure 1A] and renal artery stenosis (N=3). Category B included findings requiring a change in the TAVI procedure approach: left ventricular thrombi (N=2) [Figure 1B], moderate pericardial effusions (N=3), calcified left ventricular aneurysm (N=1), pulmonary embolism (N=1) [Figure 1C], large hiatal hernia (N=6) [Figure 1D], and esophageal varices (N=1) [Table 2]. The presence of these significant findings led to specific clinical decisions [Table 2]. TAVI was canceled in all four cases of proven malignancy. Renal artery stenosis documentation led to hypertension evaluation and workup, which postponed the procedure. The procedure was performed using a trans-femoral approach (not trans-apical) in cases where left ventricular thrombi [Figure 1B] or calcified left ventricular aneurysms were documented. Pericardiocentesis was undertaken in the presence of large pericardial effusion. The presence of a large hiatal hernia [Figure 1D] and esophageal varices prevented the use of trans-esophageal (TEE) monitoring during the TAVI procedure. The patient with the pulmonic embolus [Figure 1C] was treated with anticoagulation.

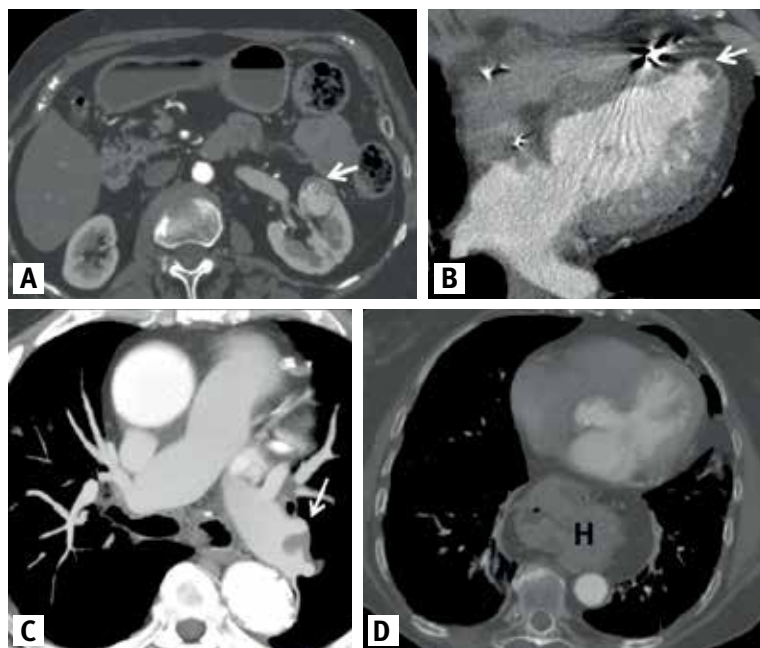
Non-significant incidental findings (category C) included 210 pathologies documented in 80/90 patients (88% of scans). These included cardiac, chest and abdominal pathologies and skeletal findings. These findings did not lead to any further clinical evaluation, nor did they have any impact on the TAVI procedure.

Table 2. Significant pathologies causing procedure cancellation or postponement (A) or procedure approach modification (B)

Category	Pathology	N	Effect on the procedure
A	Adenocarcinoma of lung	2	TAVI cancelled
A	Pancreatic malignant tumor	1	TAVI cancelled
A	Renal cell carcinoma	1	TAVI cancelled
A	Renal artery stenosis	3	TAVI postponed
B	Large hiatal hernia	6	No TEE during procedure
B	Esophageal varices	1	No TEE during procedure
B	Moderate pericardial effusion	3	Pericardiocentesis
B	Pulmonary emboli	1	Anticoagulation therapy
B	LV thrombus	2	TAVI trans-femoral
B	Calcified LV aneurysm	1	TAVI trans-femoral
	Total	21	

TAVI = trans-catheter valve implantation, LV = left ventricle, TEE = trans-esophageal echocardiography

Figure 1. [A] Axial CTA section demonstrating a heterogeneous left renal mass, proving as a renal cell carcinoma (arrow). [B] Four-chamber CTA view showing an apical thrombus (arrow). [C] Axial CTA section showing filling defect in the left pulmonary artery (arrow). [D] Axial CTA section depicting a large hiatal hernia (H). Most of the stomach is with the chest cavity



DISCUSSION

In the last decade TAVI was established as a safe and effective alternative to surgical AVR for high risk surgical patients with severe symptomatic aortic stenosis [5,7,8,17]. CTA had been accepted as an important non-invasive modality prior to TAVI, offering, per patient, accurate aortic root anatomic evaluation, and tailoring the appropriate access route. The present CTA study documented a significantly high incidence of non-valvular cardiac, extracardiac and extravascular incidental findings. The overall prevalence of these findings was 97%. Significant findings necessitating TAVI cancellation or postponement were demonstrated in 8% of the patients (7/90); significant findings requiring a change in the procedure approach were seen in 16% (14/90). Previous studies have addressed the issue of non-cardiac findings in CTA scans performed for various cardiac conditions including evaluation of coronary arteries, pulmonary veins and coronary grafts [18,19]. A recent systematic review summarized 13 relevant studies [20]. The average prevalence of overall extracardiac findings was 41%; clinically significant and life-threatening or malignant findings were found on average in 16% and 2.2%, respectively [20]. The lower incidence of non-cardiac findings in these studies compared to our series can be explained by various factors. First, the mean age was 58–65

Table 3. Literature review of studies addressing non-cardiac findings in pre-TAVI scan

Authors, year [ref]	Mean age	Study size (N)	Significant findings	Malignant findings	Study population
Guffler et al., 2014 [24]	81.6	131	23.7%	3.8%	TAVI
Ben Dor et al., 2010 [23]	82.3	259	34.3%	4.2%	TAVI
Present study	80.2	90	22.1%	4.4%	TAVI

years in these studies as compared to 81.6 years in our cohort. Secondly, as mentioned, pre-TAVI studies utilized a large field of view including the entire chest and abdomen. Karius et al. [20] and Aglan et al. [21] believed the large field of view influenced the detection of extracardiac findings. Earl and colleagues [22] indeed concluded that such cardiac studies should be reconstructed in the maximum field of view and adequately reviewed to detect extracardiac pathologic findings.

The incidence of non-cardiac findings on CTA scans performed in preparation for TAVI was reported in only three previous studies [Table 3] [16,23,24]. Ben Dor and co-researchers [23] screened 259 patients performing non-contrast chest CT and a contrast CT to evaluate ilio-femoral anatomy. Similar to our results, significant cardiovascular findings and non-significant findings were identified in 34% and 85%, respectively [23]. As compared to the study by Ben Dor et al. [23], the present study utilized contrast CT for chest anatomy evaluation. Contrast administration allowed accurate depiction of relevant non-valvular cardiac findings. This is important since additional cardiac pathologies, apart from the stenotic aortic valve, might coexist in these patients and influence their management. In the current series these pathologies included left ventricular thrombi, aneurysm and moderate pericardial effusion [Figure 1B, Table 2]. Acknowledging the presence of a left ventricular thrombus and an apical aneurysm is crucial when considering a trans-apical TAVI approach. In these three patients, the TAVI procedure was performed using a trans-vascular approach. Other important prevalent pathologies detected in the current series included hiatal hernias demonstrated in 31% (28/90), of which 7% (6/90) were large enough [Figure 1D] to prevent the option of TEE probe insertion during the procedure (either trans-femoral or trans-apical) [Figure 2]. TEE is not a mandatory tool during TAVI and is used according to site preference. When TEE is not used the presence of a large hiatal hernia is of less concern. Thus, changes in the TAVI procedure itself due to these significant additional findings occurred in 10% of the patients in our series. Malignancies causing procedure cancellation were documented in 4.4% (4/90). Ben Dor and colleagues [23] reported a similar incidence of malignancy.

Guffler and team [24] reported a series of 131 pre-TAVI patients using thoraco-abdominal CTA to evaluate the presence of clinically significant and potentially malignant incidental

findings. Similar to our findings and those of Ben Dor et al. [24], significant extravascular incidental findings were found in 23.7% and potentially malignant lesions in 3.8%. As in our series, this series also reported non-valvular additional cardiac findings.

Currently, patients referred for TAVI are those at high surgical risk because of advanced age and/or significant co-morbidities. A recently published expert consensus document on CT imaging before TAVI recommended that TAVI CTA evaluation include a complete assessment of both extracardiac and extravascular pathologies [11]. This expert recommendation, however, was based on current practice but not on actually published data. The present study together with the above quoted studies provide objective data supporting these recommendations, highlighting the high prevalence of non-valvular cardiac and extracardiac findings and their importance for appropriate patient management [16,23,24]. The occasional discovery of malignancy in the pre-TAVI workup presents the physician with a significant challenge: to weigh the survival advantage of the procedure against the life expectancy of the associated pathology. According to current expert recommendations, TAVI should not be performed in patients with co-morbidity leading to a life expectancy of less than 12 months [25]. The findings of the current study support the need to evaluate these patients by a Heart Team comprising a cardiac surgeon, an invasive cardiologist, and a physician expert in the specific additional pathologies.

With regard to limitations, the cohort was relatively small; however, it was prospective in nature.

In conclusion, the current study, together with previously reported series [16,23,24], demonstrates that non-valvular cardiac, extracardiac and extravascular findings detected on CTA should not be overlooked. A structured report addressing such findings as well as their evaluation by a comprehensive dedicated team is of major clinical importance. These findings might affect how the TAVI procedure is carried out – determining the access route and even the entire procedure.

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