

# openheart Incidental abnormal CT scan findings during transcatheter aortic valve implantation assessment: incidence and implications

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## ABSTRACT

**Objectives** The aim of this retrospective series is to describe the prevalence and clinical significance of the incidental findings found during pre-transcatheter aortic valve implantation (TAVI) work-up and to ascertain the clinical course of such patients.

**Methods** Consecutive patients undergoing TAVI from 2013 to 2015 where a TAVI CT assessment was performed (n=138) were included in the study. All incidental findings that were not expected from the patient's history were discussed at the TAVI multidisciplinary meeting in order to ascertain the clinical significance of said findings and whether they would alter the proposed course of treatment. Mortality data were determined by careful retrospective case note and follow-up appointment analysis.

**Results** Seventy-eight patients (57%) were found to have incidental findings on pre-TAVI CT scan. The majority of patients had benign pathology with high incidence in particular of diverticular disease, pleural effusions, gallstones, hiatus hernia and degenerative spinal disease. Vascular pathology such as superior mesenteric, renal and iliac artery stenoses and abdominal aortic aneurysm was detected in seven patients. In terms of long-term mortality data, we found no significant difference between those with incidental findings and those without (p=0.48). Survival as assessed by Kaplan-Meier analysis showed no significant difference between those with and without incidental abnormal CT scan findings (p=0.98).

**Conclusions** Incidental findings with potential for malignancy are common in an elderly, comorbid population. Ultimately, clinical correlation and prognosis must be swiftly ascertained in order to streamline the patients down the appropriate management pathway while avoiding unnecessary delay for treatment of their aortic stenosis.

## INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is an established treatment modality in high-risk aortic valve stenosis. CT provides a detailed anatomical assessment of the LVOT, aortic root, arch, descending aorta and distal arterial tree; this enables patient

## Key messages

### What is already known about this subject?

► Transcatheter aortic valve implantation (TAVI) is an established treatment modality in high-risk aortic valve stenosis. Patient selection is crucial for TAVI success and anatomical criteria must be met in order to facilitate valve delivery and optimal placement.<sup>1</sup> As a consequence of the extensive imaging, incidental pathological findings involving non-cardiovascular structures are often picked up. The discovery of said findings can pose a dilemma in terms of determining the next step in management, and it can raise questions about the patient's life expectancy following TAVI and thus about the futility of this intervention.

### What does this study add?

► This study adds a thorough assessment of incidental findings in a cohort of pre-TAVI patients with further dichotomisation according to significance of said findings. There is correlation made with outcome and while there are studies that have already reported on this relationship, most have not delved into outcome correlation nor have they provided information on how to approach this potentially difficult area in terms of clinical decision-making.

### How might this impact on clinical practice?

► We believe that this study can assist the local MDT or heart team in making key decisions that will influence patient pathway and potential outcome when faced with incidental findings both of significance and non-significance. Furthermore, carrying out robust clinical assessment post imaging will help to inform on whether proceeding with TAVI is in the patient's best interests, which ultimately is the aim; this paper should help to inform clinical practice such that patient interest is kept at the forefront of all decision-making.

selection, pre-procedural planning and intra-operative decision-making. Patient selection is crucial for TAVI success and anatomical criteria must be met in order to facilitate

valve delivery and optimal placement.<sup>1</sup> As a consequence of the extensive imaging, incidental pathological findings involving non-cardiovascular structures are often picked up. The discovery of said findings can pose a dilemma in terms of determining the next step in management, and it can raise questions about the patient's life expectancy following TAVI and thus about the futility of this intervention.<sup>2</sup> The earlier detection of non-cardiovascular disease can expedite potentially life-saving therapy faster; however, the contrary to this is overinvestigation, over-treatment and ultimately delaying definitive treatment of the aortic stenosis.<sup>2</sup> The aim of this retrospective series is to describe the prevalence and clinical significance of the incidental findings found during pre-TAVI work-up and to ascertain the clinical course of such patients.

## METHODS

Patients with severe symptomatic aortic stenosis with a high risk of operative mortality as assessed by the TAVI Heart-Team MDT (interventional cardiologist, non-interventional cardiologist and cardiac surgeon) were worked up for TAVI. Consecutive patients undergoing TAVI from 2013 to 2015 where a TAVI CT assessment was performed (n=138) were included in the study. Of these, 138 patients underwent TAVI with a pre-TAVI CT assessment. The CT method included contrast and ECG gating in order to assess the aortic valve annulus size as well as subclavian artery to iliofemoral angiography in order to delineate the optimal access route.

The CT scans were carried out on a Philips Brilliance ICT 64-slice scanner (0.625 mm slices) (Philips Healthcare, Guildford, Surrey, UK). A thoracic phase scan was performed using 75 mL of Omnipaque 300 arterial contrast followed by 25 mL of saline injected at 5 mL/s using a power injector in order to assess the aortic arch. The abdominal phase was carried out in a similar manner using 75 mL of Omnipaque 300 (Philips Healthcare) arterial contrast (bolus-trapped technique) with slices from the liver to the superficial femoral arteries.

All the CT scan images were prospectively reviewed and reported by an experienced team of radiologists. All incidental findings that were not expected from the patient's history were discussed at the TAVI multidisciplinary meeting where cardiologists, cardiothoracic surgeons and radiologists convened in order to ascertain the clinical significance of said findings and whether they would alter the proposed course of management.

Mortality data were determined by careful retrospective analysis of the case notes from the patient's last follow-up appointment and subsequently 1-year survival data were ascertained. The data were tabulated according to the overall population and then further stratified according to those with incidental findings (both significant and non-significant) and then individually in terms of clinical significance. Our definition of significance largely comes from work done by Horton's group,<sup>3</sup> where findings that required further clinical or radiological follow-up prior to

**Table 1** Baseline patient characteristics

Variable	Patients N=138
Age (years)	80.2±7.3
Female	46% (64)
Logistic EUROscore	18.96±10.7
Diabetes	23% (31)
Smoking history	42% (58)
Pulmonary disease	25% (34)
Chronic renal failure on dialysis	0.7% (1)
Cerebrovascular disease	13% (18)
Extracardiac arteriopathy	15% (20)
Previous cardiac surgery	13% (18)
Previous PCI	8% (11)
Poor ejection fraction (<30%)	8% (11)
Aortic valve area (cm <sup>2</sup> )	0.71±0.18

cardiac intervention were deemed significant. Moreover, those that were significant were also correlated on a clinical basis, which was assessed in the outpatient clinic and deemed significant in that they were life limiting as well as severe enough to functionally limiting. Similarly, those that were deemed non-significant were assessed clinically in the same manner and carried a largely normal survival prognosis based on individual patient case and were not life-limiting.

Continuous variables are expressed as mean (SD) or median (minimum, maximum) for Gaussian and skewed distributed data, respectively. Group comparison was carried out using the t-test or non-parametric test accordingly. Categorical data are expressed as percentage and differences between the two groups assessed using the  $\chi^2$  test of independence. The tests were considered significant at  $p < 0.05$ . SPSS V.16.0 was used for statistical analysis. Survival was assessed using the Kaplan-Meier method.

## RESULTS

The group analysed consisted of 138 patients (46% being female). The average age within this cohort was 80.2±7.3 years (table 1).

Median follow-up was 17.6 months (0.7, 41.2 months). Within the study group, 78 patients (57%) were found to have incidental findings on pre-TAVI CT scan. A summary of all the significant and non-significant incidental findings can be found in tables 2 and 3, respectively. Baseline characteristic differences between these two study groups were not significant.

Four patients were found to have malignancy in the lungs, kidneys, bladder and large bowel. These patients were deemed operable from their respective cancers and thus underwent appropriate resection after the TAVI procedure. The majority of patients had benign pathology with high incidence in particular of diverticular disease,

**Table 2** Significant non-cardiac findings on pre-assessment CT scan

Abnormality	n (%)
Overall no of significant findings	23 (17)
Lung malignancy	1 (0.72)
Renal malignancy	1 (0.72)
Bladder malignancy	1 (0.72)
Sigmoid colon/rectal malignancy	1 (0.72)
Mediastinal lymphadenopathy	1 (0.72)
Non-calcified pulmonary nodules (0–10 mm)	4 (2.90)
Non-calcified pulmonary nodules (>10 mm)	1 (0.72)
Pleural plaques	3 (2.17)
Sclerotic spinal lesions	1 (0.72)
Adrenal mass (<5 cm)	1 (0.72)
Splenic infarct	1 (0.72)
Renal mass (<5 cm)	1 (0.72)
Abdominal aortic aneurysm	4 (2.90)
Inferior mesenteric artery occlusion	1 (0.72)
Large abdominal hernia	1 (0.72)

pleural effusions, gallstones, hiatus hernia and degenerative spinal disease. Vascular pathology such as superior mesenteric, renal and iliac artery stenoses and abdominal aortic aneurysm was detected in seven patients; suboptimal lower abdominal or lower limb arterial tree anatomy altered the access strategy for the route of TAVI delivery: four direct aortic, four subclavian and four via transapical route.

In terms of long-term mortality data (table 4), we found no significant difference between those with incidental findings and those without ( $p=0.48$ ). This was also the case when the data were further stratified for clinically significant and non-significant findings ( $p=0.43$ ).

Survival as assessed by Kaplan-Meier analysis (figure 1) showed no significant difference between those with and without incidental abnormal CT scan findings ( $p=0.98$ ).

An additional cohort of patients within our institution were also screened for potential TAVI with a preoperative CT scan but did not undergo TAVI for various reasons (table 5); interestingly, this was not due to incidental findings.

## DISCUSSION

From this observational series, rates of 17% and 53% for significant and non-significant incidental CT scan findings, respectively, were found. The majority of significant findings were malignant tumours and the majority of non-significant findings were diverticulosis, pleural effusion and hiatus hernia. These tend to associate with advanced age and risk factors such as smoking. Previous study groups have reported incidental non-cardiovascular findings in up to 70% of patients screened with pre-TAVI CT scanning.<sup>2 4 5</sup> While this figure seems rather high, it

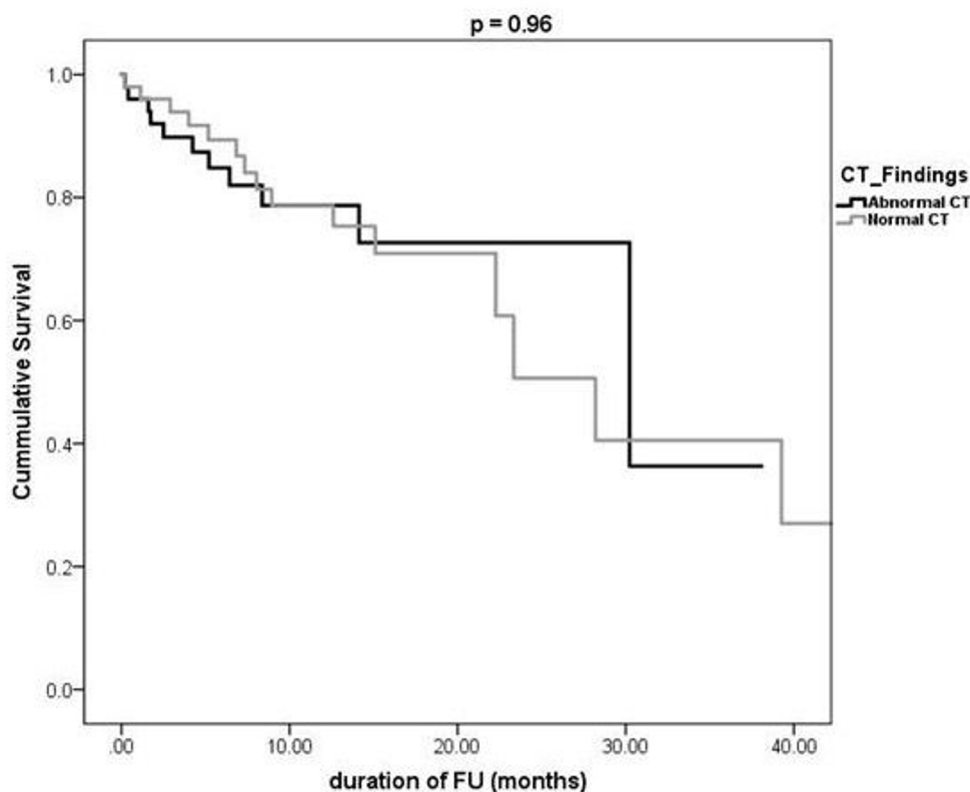
**Table 3** Non-significant non-cardiac findings on pre-assessment CT scan

Abnormality	n (%)
Overall no of non-significant findings	73 (53)
Pleural effusion	5 (3.62)
Pulmonary fibrosis	3 (2.17)
Bronchiectasis	10 (7.25)
Interstitial pulmonary oedema	2 (1.45)
Emphysema	6 (4.35)
Pulmonary granuloma	2 (1.45)
Pleural thickening	2 (1.45)
Goitre	1 (0.72)
Hiatus hernia	4 (2.90)
Renal cysts	3 (2.17)
Hepatic cysts	2 (1.45)
Adnexal cysts	1 (0.72)
Renal artery stenosis	1 (0.72)
Polycystic kidney disease	2 (1.45)
Diverticular disease	11 (7.97)
Gallstones	2 (1.45)
Renal calculi	3 (2.17)
Kyphosis	1 (0.72)
Degenerative spinal osteoarthritis	4 (2.90)
Paget's disease	1 (0.72)
Superior mesenteric artery stenosis	1 (0.72)
Common iliac artery stenosis	1 (0.72)
Dilated oesophagus	1 (0.72)
Small abdominal hernias	2 (1.45)
Extrarenal pelvis of kidney	1 (0.72)
Atrophic kidney	1 (0.72)

would be in keeping with the demographic nature of the population screened. TAVI patients tend to be of advanced age and comorbid status. Ben-Dor's group<sup>1</sup> further commented that the extensiveness of pre-TAVI

**Table 4** Mortality data at last follow-up

	Alive at 1-year follow-up	Mortality at 1-year follow-up	P values
Patients with incidental findings	57	17	0.48
Patients with no incidental findings	46	18	
Patients with significant findings	14	6	0.43
Patients with non-significant findings	46	12	



**Figure 1** Kaplan-Meier survival analysis.

<b>Table 5</b> Patients who did not progress for TAVI	
<b>Reason for not progressing to TAVI (n=26)</b>	<b>Number of patients</b>
UK TAVI Trial patient—randomised to surgery	3
Not suitable for TAVI—severe COPD (unable to lie flat), worsening dementia	4
Annulus too big for TAVI as seen on CT	2
Surgical treatment preferred by Heart MDT—(AVR+CABG, AVR+ascending aorta replacement, AVR+MVR)	4
Patient declined TAVI	3
Poor left ventricular function, underwent balloon valvuloplasty only, there was no improvement therefore TAVI not performed	2
Condition deteriorated while on waiting list, to a point where TAVI became unsuitable	2
TAVI performed at another unit after assessment and work-up in our unit	3
Patient did not attend for TAVI after CT scan	3

AVR, aortic valve replacement; CABG, Coronary Artery Bypass Graft; COPD, Chronic Obstructive Pulmonary Disease; MDT, Multi-disciplinary meeting; MVR, Mitral Valve Replacement; PCI, Percutaneous Coronary Intervention; TAVI, transcatheter aortic valve implantation.

CT imaging plays a role in the increased yield of incidental findings.

The elderly TAVI population would be expected to have a higher prevalence of incidental pathological findings and while this study has not shown a significant association between said findings and mortality, Orme's group from the Mayo clinic have demonstrated that increasing numbers of potentially pathological incidental findings may be predictive of poorer survival.<sup>6</sup> The higher powered nature of this study enabled for a more robust survival analysis.<sup>6</sup> Stachon *et al*<sup>7</sup> showed that 2-year survival in patients treated with either TAVI or surgical AVR was independent from the presence of non-severe or severe potentially malignant incidental findings;  $p=0.92$  and  $p=0.82$ , respectively. Severe findings may be expected to limit life expectancy and as such patients were less likely to be scheduled for invasive treatment. This may seem counterintuitive based on the statistically insignificant association with 2-year survival, but the study concluded that it treated according to the American Heart Association recommendations, which state that patients with a greater than 1 year life expectancy should be recommended for TAVI.<sup>8</sup>

Ultimately, patients with severe symptomatic aortic stenosis carry a high mortality and thus mandate the need for prompt treatment.<sup>9</sup> Despite this, incidental findings found radiologically need to be appropriately investigated in order to exclude potential malignancy.<sup>7</sup> Studies have shown that incidental findings are not independent predictors of mortality in patients undergoing TAVI and moreover the need for additional tests to clarify the nature of a likely benign pathology that will have little impact on the patient's survival will delay the time to TAVI.<sup>10</sup> This is corroborated by one of the largest series to date in this patient group; Trenkwalder's group reported on a series of 1050 patients and in those who underwent TAVI; 30-day and 1-year mortality did not differ between those with and without clinically significant findings on pre-assessment CT scanning,  $p=0.339$  and  $p=0.226$ , respectively, and moreover there was no impact of said findings on overall mortality.<sup>11</sup>

Incidental findings that significantly alter the management course include malignancy; however, in general, TAVI will improve patient fitness and survivability, which will enable for further procedures at a lower operative risk of mortality for different pathologies that may have been identified at pre-TAVI work-up.

When faced with potentially malignant incidental findings, the decision to treat should be made following multidisciplinary discussion involving radiologists and oncologists. The decision to intervene regardless of the severity of the incidental finding is likely to bear no real difference on patient outcome.<sup>12</sup> In our own practice, when faced with clinically significant incidental findings, TAVI is only offered if the patient's prognosis is at least 2 years of survival from the non-aortic stenosis pathology.

### Limitations

This study's limitations are as follows: first, with it being an observational, retrospective series, it was prone to selection bias. Second, patients who were not captured within our time frame of follow-up may have led to unreliable mortality rates. Third, our definition of significant and non-significant incidental findings was broad and in particular within the significant group, many benign lesions were included. The stratification that we used was consistent however with previously conducted studies<sup>1 6 13 14</sup> and ultimately clinical correlation was the best guide for inclusion in the 'significant' group. Last, the small sample size of this study is a limiting factor; ideally, this study should serve as a pilot study to inform one in terms of a sample size calculation in order to conduct an adequately powered prospective study looking at the impact of incidental findings on patients undergoing TAVI.

### CONCLUSION

Incidental findings with potential for malignancy are common in an elderly, comorbid population. Ultimately, clinical correlation and prognosis must be swiftly ascertained in order to streamline the patients down the

appropriate management pathway while avoiding unnecessary delay for treatment of their aortic stenosis. Treating the aortic stenosis promptly may help to increase surgical fitness for further procedures for pathologies that require less urgent expedition. When faced with an incidental finding that is deemed significant from 'imaging' alone such as malignancy, the Heart Team should arrange for prompt clinical assessment to assess factors such as functional severity, survival prognosis and life limitation. If there is a good prognosis that requires urgent surgical treatment, further MDT discussion should be arranged to discuss addressing the aortic stenosis via TAVI to optimise surgical fitness for their definitive cancer operation. If prognosis and outcome is likely to be poor from the malignancy or treating said finding takes precedence on a clinical basis, treating the aortic stenosis via TAVI should be abandoned or deferred respectively in view of the patient's best interests.

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**Data sharing statement** There are additional unpublished data on the data storage systems with the audit manager at the Heart and Lung Centre, at New Cross Hospital Wolverhampton. These data are only available to clinicians, nurses or researchers wishing to use the data for research purposes provided they have applied for registration for a project with adequate clinical equipoise and have been accepted.

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