Outcomes of Incidental Findings on Multi-Detector Computed Tomography for Transcatheter Aortic Valve Implantation Assessment: A Single-Centre Study and Review of the Literature

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ABSTRACT

Introduction

Patients with severe aortic stenosis (AS) require multi-detector computed tomography (MDCT) when considered for transcatheter aortic valve implantation (TAVI). Incidental findings on MDCT are common given the age group and region imaged. Our aim was to evaluate the frequency and outcome of incidental findings (IF) identified on MDCT and the impact on survival.

Methods

This single-centre analysis retrospectively reviewed severe AS patients who underwent MDCT during TAVI workup. MDCT reports were reviewed for any IF and defined into three categories: IF of no relevant clinical significance (IF-NoCS), IF of non-immediate clinical significance (IF-NICS) and IF of immediate clinical significance (IF-ICS). Demographics, follow-up of IF, and survival was calculated from MDCT date.

Results

265 patients underwent MDCT for TAVI suitability (mean age 83 ± 6 years, 52% male). The majority proceeded to TAVI (65%). Renal lesions (25%) and lung nodules (18%) were the most common IF. Fifty-nine patients (22%) had IF-NICS; 39% (23/59) were benign, 59% were not further investigated and one patient had suspected lung cancer. Six patients (2.3%) had IF-ICS and all were diagnosed with lung cancer. During a median follow-up of 272 days, there was

no survival difference between patients with IF-ICS or IF-NICS versus patients without IF or IF-NoCS overall (p=0.44) or in TAVI patients TAVI (p=0.88).

Conclusion

IF on MDCT are common with one-quarter having IF-ICS or IF-NCIS. Most patients with IF-NICS did not undergo further investigation. Standardised reporting of MDCT may assist in clarifying the need for further investigation which will in turn influence decision and timing to proceed with TAVI.

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) for severe aortic stenosis (AS) is increasingly performed in Australia(1). Current guidelines recommend Heart Team assessment and TAVI in patients with severe symptomatic AS who are inoperable or high risk for surgery(2). In the assessment of suitability for TAVI, patients undergo focused cardiac investigations including a TAVI protocol contrast multi-detector computed tomography (MDCT). The scan extends from the mandible to the femoral head and is required for identification and accurate sizing of the annulus, the assessment of calcification burden particularly within the left ventricular outflow tract, assessment of the potential risk of coronary occlusion and in order to determine the most appropriate vascular access route(3). As severe AS patients are often elderly and due to the number of non-cardiac organs captured in MDCT, incidental findings (IF) are common and are reported in up to 70% of cases(4).

The significance of IF found on MDCT is currently unclear. The definition of IF ranges between studies from simple colorectal diverticulosis or hernias to potentially malignant cancers(5). Such findings may reduce the likelihood of receiving TAVI and delay time from MDCT to the TAVI procedure(5). Previous studies have focused on the impact of MDCT-IF on survival, yielding conflicting results(4-9). Differences likely reflect variations in the definition of IF, the threshold of reporting findings, and malignant potential of individual findings. So far, there are limited

1 data assessing the follow-up of IF in patients with severe AS. Moreover, it is unclear how many
2 patients have MDCT findings correlated with previous imaging, undergo further diagnostic
3 imaging, and how many suspicious findings are discovered to be malignant. This study reviewed
4 consecutive cases of patients with severe AS from a tertiary centre who underwent MDCT in the
5 workup for TAVI to identify the types of IF, the outcome of IF on patient follow-up, and the
6 influence of IF on survival.

7 8 **METHODS**

9 We reviewed consecutive patients from a prospectively-maintained registry who underwent
10 MDCT as part of TAVI workup at a tertiary institution over 10 years (2009 to 2018). The
11 registry included all patients who had been referred for TAVI consideration and thus also
12 included patients who did not proceed to TAVI. Retrospective electrocardiogram-gated cardiac
13 and delayed Flash angiographic phases were performed for image acquisition using one of three
14 available systems (GE Revolution CT 256-slice scanner; GE Healthcare, Chicago, United States;
15 Siemens Somatom Sensation 64 and Siemens Definition Flash 128-slice scanner; Siemens AG,
16 Germany). The MDCT was assessed by a consultant radiologist with varying degrees of
17 experience and subspecialty exposure. There was no standardised template or protocol used for
18 reporting MDCT for TAVI workup at our centre. The patient's technical suitability for TAVI
19 was performed with the aid of the 3Mensio Structural HeartTM system (Pie Medical Imaging,
20 Maastricht, Netherlands). This study was approved by the institution's ethics review committee.

21
22 Baseline demographic data included age (from MDCT date), gender, New York Heart
23 Association (NYHA) class, relevant comorbidities, previous percutaneous coronary intervention
24 (PCI) or coronary artery bypass grafting (CABG), and previously diagnosed malignancy.
25 Chronic kidney disease was defined as an estimated glomerular filtration rate less than or equal
26 to 60 mL/min/1.73m². Further collected data included the date of MDCT, date of TAVI
27 procedure
28 (if performed), date of last follow-up, and patient survival.

Regarding IF on MDCT, reported pathologies across any internal organ were recorded and considered an IF. For lung, liver, kidney and pancreatic abnormalities (cyst or nodule or lesion), we also collected data on largest diameter where specified. Incidental findings were defined into three categories: IF with no relevant clinical significance (IF-NoCS) where the MDCT report did not suggest further investigation; IF with non-immediate clinical significance (IF-NICS) where the MDCT report suggested that it may warrant further investigation (correlation with previous imaging, further imaging or long term follow-up); and IF with immediate clinical significance (IF-ICS), where it required immediate investigation and was verbally communicated to the treating team. In patients with an IF-NICS and IF-ICS, we reviewed patient medical records to determine if any previous imaging was subsequently used for correlation, if patients underwent further investigation with an alternative imaging modality, or if patients underwent a follow-up scan to assess malignancy. For patients diagnosed with a malignant cancer from further investigation, we reviewed their subsequent follow-up and services involved in ongoing patient care.

Statistical analyses

Continuous data are presented as median with interquartile range (IQR) or if not normally distributed when visualised on histogram plot, presented as mean with standard deviation (SD). Between-group comparisons were performed using chi-square test for categorical variables and t-test or analysis of variance for continuous data. We characterised overall survival (death from any cause) from MDCT date using Kaplan-Meier method with log-rank test used for between-group comparisons. A p-value less than 0.05 was considered statistically significant. Statistical analyses were performed using STATA MP 14.0 (Stata Corp LP, College Station, TX).

RESULTS

Baseline characteristics

Between 2009 and 2018, 265 patients with severe AS were identified with MDCT for assessment of TAVI suitability. In this cohort, 171 patients (65%) underwent TAVI. Reasons for not

proceeding with TAVI are detailed in **Table S1** (Data Supplement). The most common reasons for not proceeding included surgical aortic valve replacement candidate as per Heart Team assessment (37/94), frailty (28/94), unsuitable anatomy (11/94) and declining the procedure (10/94). The mean age in the entire cohort was 83 ± 6 years and most patients were NYHA class II (62%) or III (25%). Cardiovascular comorbidities included diabetes mellitus (32%), hypercholesterolemia (66%) and ischaemic heart disease (IHD; 49%). About one-fifth of patients had undergone previous PCI (21%) or previous CABG (21%). Patients who did not proceed with TAVI were those with more frequent diabetes mellitus ($p=0.04$), but more absence of IHD ($p<0.001$) and correspondingly less likely to have had previous PCI ($p=0.03$). Baseline characteristics are shown in **Table 1**.

Incidental findings on MDCT

Any IF was reported in 191 patients (72%). The most common IF reported in MDCT included renal lesions (67/265; 25%), lung nodules (48/265; 18%) and colonic diverticulosis (49/265; 18%). Most renal lesions were unilateral (53/67; 79%) and uncomplicated (59/67; 88%) with a mean largest diameter of 38mm (range, 3-90mm). The renal lesion size however was not specified in most patients (46/67; 69%). For lung nodules, most patients only had a single nodule identified (33/48; 69%) with a mean largest diameter of 11mm (range, 2-38mm). Lung nodule size was not reported in 29% of patients (14/48). Mediastinal or hilar lymphadenopathy was identified in 27 patients (10%), with 7 of these patients having a concomitant lung nodule. Thyroid enlargement or nodules were identified in 20 patients (8%), pancreatic lesions identified in 10 patients (3%) and adrenal lesions identified in 12 patients (5%). There was no significant difference in the rate of IF-ICS or IF-NICS between patients who underwent TAVI and those who did not undergo TAVI (27% and 18%, respectively). **Table 2** demonstrates IF on MDCT.

Incidental findings with non-immediate clinical significance

Fifty-nine patients (22%) had IF-NICS (**Figure 1**). Amongst these patients, lung nodules were the most common pathology (20/59; 34%) followed by renal pathology (17%) and adrenal pathology (15%). Twenty-three patients (23/59; 39%) who underwent further investigation were demonstrated to have benign pathology. A suspicious lung malignancy was identified in one patient (patient no 1, **Table 3**) with IF-NICS. Due to extensive comorbidities, he was managed conservatively regarding possible lung cancer with 6-monthly CT and respiratory team follow-up. Upon discussion with the Heart Team, he underwent TAVI in the interim in view of the likely symptomatic benefit and reasonable life expectancy (>12 months). Most patients with IF-NICS did not undergo further investigation (59%). Forty-four (75%) patients with IF-NICS proceeded with TAVI.

Incidental findings with immediate clinical significance

Six patients (2.3%) were identified to have IF-ICS verbally communicated to the treating team (**Figure 1** and **Table 3**). Five patients were found to have a primary lung malignancy following further investigation and referred to the respiratory team for multidisciplinary follow-up. One patient was found to have lung metastases on MDCT on a background of previous known colorectal malignancy which had been untreated (patient no. 4). After discussion with the Heart Team, one patient (patient no. 6) proceeded with TAVI prior to commencing oncology treatment in view of the likely symptomatic benefit and reasonable life expectancy for early-stage lung cancer (time from MDCT to TAVI, 97 days). A further patient underwent oncology treatment for lung cancer and after a stable remission was achieved, underwent TAVI about 1.65 years after his initial MDCT (patient no. 7). **Figure 2** depicts the lung malignancy initially identified on MDCT in this patient. In four patients who did not undergo TAVI, three died from cancer-related complications. There were no differences in baseline characteristics between patients with either IF-NICS or IF-ICS compared with no IF or IF-NoCS (**Table S2**, Data Supplement).

Survival from MDCT

There was no difference in time from date of MDCT to TAVI procedure between patients with IF-NICS compared with patients without IF or IF-NoCS (median 93 days [IQR 43-161 days]

versus 85 days [43-147 days]; $p=0.10$). During a median follow-up of 272 days (IQR, 131-632 days), there was no difference in overall survival from MDCT date between patients with IF-ICS or IF-NICS versus patients without IF or IF-NoCS in the overall cohort ($p=0.44$) or in patients who received TAVI ($p=0.88$; **Figure 3**).

DISCUSSION

The aim of this study was to evaluate the frequency and outcome of IF reported from MDCT as part of TAVI assessment. The main findings can be summarised as follows.

- (1) A total of 22% of patients had IF-NICS and 6 patients (2.3%) had IF-ICS
- (2) The most common pathologies reported were renal lesions (25%) and lung nodules (18%)
- (3) In six patients with IF-ICS, all were discovered to have a lung-related malignancy
- (4) 59% of patients did not undergo further investigation for IF-NICS
- (5) There was no difference in survival in patients with IF-NICS or IF-ICS compared with no IF or IF-NoCS in this cohort.

Incidental findings on MDCT for TAVI workup are common. As the field imaged extends from the mandible to the femoral heads, the scan has one of the highest rates of incidental non-cardiovascular findings, especially due to the elderly age demographic (10). The incidence of IF ranges from 20% to 100% due to different definitions of an IF and varying thresholds for reporting by individual radiologists(6, 11-14). Renal and lung pathologies were the most commonly reported findings in our study and this is consistent with previous data(9). Of note, no dimensions or size were reported for most kidney nodules or cysts identified (69%) and similarly for 29% of lung lesions. While reporting dimensions are presumably omitted due to either relatively small or benign nature of the pathology, this nevertheless has important implications for non-radiological clinicians who may be uncertain of the clinical significance of such findings. Our institution does not currently use a pre-specified template for reporting non-cardiac findings on MDCT in TAVI assessment. This likely influences the frequency of reported IF, and may

1 reduce heterogeneity of reporting between radiologists, as has been demonstrated on other
2 imaging techniques (15).

3
4 The impact that suspicious IF on MDCT have on overall survival remains unclear with several
5 studies showing conflicting results (**Table 4**). In a single-center retrospective analysis of 553
6 patients who underwent TAVI with a follow-up of 5 years, a potentially malignant IF
7 independently predicted all-cause mortality (adjusted HR 1.46, 95% CI 1.07-1.99) (9).
8 Conversely, a large single-centre retrospective study of 1050 patients who underwent MDCT for
9 TAVI workup described no difference in survival in TAVI patients with versus without clinically
10 relevant IF at 30 days or 1 year(7). We similarly found no survival difference in our overall
11 cohort however, three out of four patients with IF-ICS who did not undergo TAVI died. A key
12 difference to explain the disparate findings is the inconsistent risk stratification of IF where
13 clearly not all IF are equivalent in impacting prognosis. Thus such findings, their likelihood of
14 malignancy and urgency of correlation or follow-up should be communicated to the Heart Team.
15 A subsequent holistic decision can be made regarding appropriateness and timing of TAVI or
16 other treatments.

17
18 Although previous studies have primarily focused on the impact of IF on survival, we aimed to
19 also evaluate the outcome of reported suspicious IF during follow-up. In six patients with
20 IF-ICS, all were subsequently discovered to have malignant lung cancer. While certainly other
21 primary organ tumours cannot be overlooked, clinicians should maintain a high index of
22 suspicion regarding lung pathology, particularly because dyspnoea and exercise intolerance are
23 complaints in both lung cancer and severe AS. Such findings alter treatment decisions as lung
24 cancer portends a poor prognosis in an elderly age group and TAVI may not be a feasible option
25 in those with a life expectancy of less than 12 months. Despite this, three patients with lung
26 cancer eventually underwent TAVI, with one patient proceeding after successful remission post
27 lung cancer treatment. Nevertheless, the presence of large pulmonary nodules (5 to 8mm or
28 more) still has a relatively low malignant potential with only 2 out of 87 patients diagnosed with
29 lung cancer during a median follow-up of 1.25 years in another single-centre retrospective
30 study(8). It could be argued that such a finding should not necessarily delay treatment for severe

AS as it may not impact survival(16). Cohesive judgment from both the multidisciplinary Heart Team and Thoracic team is vital to direct appropriate treatment.

In patients with IF-NICS, about 40% of potentially malignant findings were further investigated in this study and all found to be benign. While such findings may be detailed in the MDCT report, explicit recommendations regarding correlation, further investigation or follow-up may not be outlined in the reporting conclusion. Also, findings of unclear significance may not be verbally communicated to the treating team due to the likely benign natural history. This is not unusual with data on incidental pulmonary nodules noted on CT pulmonary angiographic studies demonstrating follow-up of nodules was generally poor (<30%) and reduced to 0% when nodules were only reported in the findings section alone(17). Importantly, the addition of the Fleischner Society guidelines for incidental pulmonary nodules on chest CT reports significantly increased the likelihood of patients receiving the recommended follow-up care(18). Evidently, standardised templates for reporting MDCT in TAVI workup, while potentially cumbersome, provides clinicians with a clear understanding of relevant follow-up and improved holistic care of patients. The perceived total cost of further investigations accrued from MDCT findings has been reported as relatively low and should not be prohibitive(19). However, the lack of follow-up regarding IF may also represent individual discussion with patients regarding such findings that may have led to a collaborative decision not to investigate further. While this is not captured in our data, it is not unreasonable in IF which may have malignant potential but are unlikely to drastically affect prognosis in the elderly. It therefore should not necessarily delay the decision to perform TAVI provided the life expectancy of the patient is greater than 12 months.

Clinical application

Requests for MDCT as part of TAVI assessment will increase as TAVI uptake expands into potentially intermediate and low-risk AS patients. In Australia, TAVI numbers are projected to increase up to 4-10 times, particularly if low-risk populations are offered TAVI in the future (20). Members of the Heart Team may not be aware of IF on MDCT unless reasonably communicated or recognise the clinical significance of such findings. This is particularly challenging given the

sheer frequency of IF that emerge from MDCT given the large body regions imaged. Standardised reporting templates for MDCT are valuable not only for consistent vascular assessment for TAVI but potentially for clear specification of incidental findings, their clinical significance, and relevant follow-up. However, the presence of IF must be correlated with the patient's clinical history and examination which may not be accessible to the reporting radiologist. Thus a multidisciplinary approach with clear communication is crucial to determining and reporting the clinical significance of IF on MDCT for TAVI assessment. Furthermore, while renal, adrenal and thyroid pathologies were common in this study, particular suspicion should be raised for lung pathologies in view of their frequency, malignant potential and overlapping clinical presentation with severe AS(21). Finally, it is currently unclear whether potentially malignant findings on MDCT impact survival. While clearly each IF should be considered on an individual basis, the decision to proceed with TAVI should not necessarily be delayed if the incidentaloma is unlikely to significantly alter prognosis and can be investigated at a later stage.

Limitations

We acknowledge several limitations to this study. First, these data arise from a retrospective review of MDCT reports amongst potential TAVI candidates from a prospectively-maintained registry. There have been no prospective studies in this area thus far and this could influence the frequency of IF noted. Second, this study involved a single centre and it is unclear whether the rate of IF and their follow-up can be extrapolated to other institutions. Third, our median follow-up was relatively limited and thus conclusions regarding survival must be interpreted with caution, especially since IF may only affect intermediate to long term survival. Fourth, the MDCT was reported by radiologists at our centre and their threshold for reporting IF will differ. These data reflect real-world experience and we opted not to further review MDCT reports to potentially detect more IF a priori. Finally, it is possible that patients may have had their IF investigated at an external institution or imaging centre. While these were not accessible in these data, we reviewed medical record notes to determine if any further external correspondence including imaging conducted elsewhere were performed.

CONCLUSION

Incidental findings on MDCT are common with 22% of patients having an IF-NICS and 2% of patients having IF-ICS. Common pathologies involve the lung and kidney, with all malignant findings related to the lung. Most patients (60%) with IF-NICS did not undergo further investigation. Standardised reporting of MDCT may assist with consistent reporting of IF and recommended follow-up strategy which will in turn influence the decision to proceed with TAVI and its appropriate timing.

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FIGURE LEGEND

Figure 1. Outcome of incidental findings of immediate and non-immediate clinical significance.

Figure 2. Example of incidental lung cancer found on MDCT.

Primary bronchogenic carcinoma identified in patient no. 7 in (A) coronal view and (B) axial view. At the left hilum, there is a soft tissue mass which compresses the left upper lobe pulmonary artery and narrows the left upper lobe bronchus. The mass measures approximately 30 x 28 x 30 mm and invades the adjacent mediastinal fat.

Figure 3. Survival from MDCT

(A) Overall survival in entire cohort from MDCT date. (B) Overall survival in TAVI patients from MDCT date.

IF, Incidental finding; IF-ICS, Incidental finding of immediate clinical significance; IF-NICS, Incidental finding of non-immediate clinical significance; IF-NoCS, Incidental finding of no relevant clinical significance; MDCT, Multi-detector computed tomography; TAVI, Transcatheter aortic valve implantation

Table 1. Baseline characteristics

	Total, n=265	TAVI, n=171	No TAVI, n=94	p-value for difference
Age, mean years $\pm$ SD	83 $\pm$ 6	83 $\pm$ 5	82 $\pm$ 6	0.90
Male (%)	137 (52)	82 (48)	55 (59)	0.12
NYHA class (%)				
I	16 (6)	5 (3)	11 (13)	0.01
II	164 (62)	106 (62)	58 (62)	
III	66 (25)	46 (27)	20 (21)	
IV	14 (5)	11 (6)	3 (3)	
Not recorded	5 (2)			
Comorbidities				
Diabetes mellitus (%)	85 (32)	48 (28)	37 (39)	0.04
Hypercholesterolemia (%)	174 (66)	120 (70)	54 (57)	0.09
Hypertension (%)	223 (84)	148 (87)	75 (80)	0.46
IHD (%)	131 (49)	100 (59)	31 (33)	<0.001
CKD (%)	76 (29)	48 (28)	28 (30)	0.67

COPD (%)	33 (12)	20 (12)	13 (14)	0.56
History of smoking (%)	102 (38)	67 (39)	35 (37)	0.93
Previous CVA (%)	28 (11)	17 (11)	11 (13)	0.68
Previous PCI (%)	56 (21)	44 (26)	12 (13)	0.03
Previous CABG (%)	55 (21)	42 (25)	13 (14)	0.08

CABG, Coronary artery bypass grafts; CKD, Chronic kidney disease; COPD, Chronic obstructive pulmonary disease; CVA; Cerebrovascular event; IHD, Ischaemic heart disease; NYHA, New York Heart Association; PCI, Percutaneous coronary intervention; TAVI, Transcatheter aortic valve implantation

Table 2. Incidental findings on MDCT.

	Total, n=265	TAVI, n=171	No TAVI, n=94
Lung nodule (%)	48 (18)	27 (16)	21 (22)
Single	33	17	16
Multiple	15	10	5
Largest size, mean (range) in mm	11 (2-38)	(3-30)	(2-38)
Size not specified	14	4	10
Pleural effusion	25 (9)	9 (5)	16 (17)
Mediastinal/hilar lymphadenopathy (%)	27 (10)	12 (7)	15 (16)
Liver nodule/cyst (%)	21 (8)	15 (9)	6 (6)
Single	8	5	3
Multiple	13	10	3
Largest size, mean (range) in mm	12 (2-28)	(2-10)	(2-28)
Size not specified	14	10	4
Renal lesion (%)	67 (25)	43 (25)	24 (26)
Unilateral	53	33	20
Bilateral	14	10	4
Simple/uncomplicated	59	40	19
Complex	3	2	1
Largest size, mean (range) in mm	38 (3-90)	(7-90)	(3-90)
Size not specified	46	28	18
Pancreatic lesion (%)	10 (3)	7 (4)	3 (3)

Largest size, mean (range) in mm	12 (6-20)	(6-8)	(6-20)
Adrenal lesion (%)	12 (5)	9 (5)	3 (3)
Thyroid goiter / nodule (%)	20 (8)	12 (7)	8 (9)
Breast lesion (%)	2 (1)	2 (1)	0
Splenic lesion (%)	3 (1)	2 (1)	1 (1)
Ovarian cyst/nodule (%)	3 (1)	3 (2)	0
Colonic diverticulosis (%)	49 (18)	32 (19)	17 (18)
Hernia (%)	29 (11)	19 (11)	10 (11)
Gall stones (%)	12 (5)	8 (5)	4 (4)

1 **Table 3. Patients with suspected or confirmed malignant cancer diagnosis.**

Patient no.	Age	Sex	Related organ	Largest diameter	Primary cancer diagnosis	Histopathology	TAVI	Follow-up post MDCT, days	Outcome
1	81	M	Lung	NS	Stage IA lung	Suspected NSCLC	Yes	511	Alive
2	78	M	Lung	17mm	Stage IA lung	Squamous cell carcinoma	No	431	Dead
3	87	F	Lung	27mm	Stage IV lung	NSCLC	No	220	Dead
4	82	M	Lung	NS	Stage IV colorectal primary	Sigmoid adenocarcinoma	No	373	Dead
5	79	M	Lung	38mm	Stage IIA lung	Adenocarcinoma	No	22	Alive
6	71	M	Lung	27	Stage IA lung primary	Pleomorphic carcinoma	Yes	168	Alive
7	80	M	Lung	30	Stage IIIA lung	NSCLC	Yes	604	Alive

Table 4. Studies of suspicious incidental findings on MDCT and association with mortality.

Author (year)	No. of patients	Age, years	Incidence of suspicious IF	Follow-up, months	Association between suspicious IF and mortality
Orme et al. (2014)	424	82±8	67%	9.5	Adjusted HR 1.45, 95% CI 1.19-1.76, p<0.01
Lindsay et al. (2015)	279	79	19%	24	No association (p=0.56)
Showkathali et al. (2015)	295	83±7	30%	21	Adjusted HR 1.5, 95% CI 1-2.2, p=0.04
Stachon et al. (2015)	414	80±9	19%	24	No association (p=0.82)
Kesteren et al. (2018)	553	82	25%	60	Adjusted HR 1.84, 95% CI 1.06-3.20, p=0.03
Patel et al. (2018)	138	80	57%	18	No association (p=0.48)
Trenkwalder et al. (2018)	1050	80±7	25%	20	No association (p=0.79)

HR, Hazard ratio; IF, Incidental finding

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