Three-dimensional transesophageal echocardiography is comparable to multi-slice computed tomography for aortic annulus sizing pre transcatheter aortic valve replacement

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Abstract

Background In transcatheter aortic valve replacement (TAVR), accurate aortic annulus measurements are essential for prosthesis sizing to ensure procedural success. Although multi-slice computed tomography (MSCT) is considered the gold standard for aortic annulus measurement pre TAVR, MSCT might be contraindicated in some patients. Aim In patients undergoing TAVR, we sought to correlate manual and newer semi-automated three-dimensional (3D) transesophageal echocardiography (TEE) aortic annular measurements to MSCT measurements. In addition, we assessed the reproducibility of these 3D TEE methods. Methods Retrospective, single centre trial involving 39 patients with severe symptomatic aortic stenosis (AS) planned for TAVR, who underwent both pre-procedural MSCT and pre/peri- procedural manual and semi-automated 3D TEE. Results Mean age was 85.3 $\pm$ 4.7 years. Both 3D TEE methods highly correlated with MSCT for annular diameters (semi-automated r =0.96, p<0.0001 and manual r=0.84, p<0.0001) and for annular areas (semi-automated r=0.96, p<0.0001 and manual r=0.82, p<0.0001). Inter-observer reproducibility was high for both 3D TEE methods for annular diameters (semi-automated r=0.96, p<0.001 and manual r=0.91, p<0.001) and annular area (semi-automated r=0.96, p<0.0001 and manual was 0.95 p<0.0001). Conclusion Both semi-automated and manual 3D TEE for sizing of the aortic annulus for TAVR is comparable to MSCT. 3D TEE methods are easily reproducible. Newer semi-automated 3D TEE has the best correlation to MSCT. 3D TEE is an excellent alternative imaging modality for TAVR planning in patients whom MSCT is contraindicated.

1. Introduction

Severe symptomatic aortic stenosis (AS) is associated with a poor prognosis when managed with medical therapy alone [1]. Until recently, severe symptomatic AS has been traditionally treated with surgical aortic valve replacement (SAVR) with better outcomes than medical therapy alone [2-4]. Trans-catheter aortic valve replacement (TAVR) is superior to best medical therapy alone in severe symptomatic AS patients who are deemed inoperable [5,6]. Indeed TAVR has revolutionised the treatment of patients with severe symptomatic AS, offering a less invasive alternative to surgery. TAVR is now a well-established alternative to SAVR for the management of patients with severe symptomatic AS who are at high or moderate surgical risk [7-12]. Recent evidence demonstrates similar efficacy with TAVR comparable to surgery in low surgical risk patients as well [13,14]. There's also an ongoing trial for TAVR in severe asymptomatic AS patients, which if positive will increase the already growing population of patients eligible for TAVR [15]. This cumulative evidence has resulted in the exponential rise of TAVR procedures. In 2015 TAVR procedures were estimated to be around 300 000 per year worldwide by the year 2025 [16]. This estimate is likely to increase further with the emergence of recent TAVR data from randomised controlled trials.

Correct sizing of the TAVR device which is determined by aortic annulus size is imperative for procedural success. This is pivotal for avoiding paravalvular aortic regurgitation (PVAR) post TAVR, coronary obstruction and aortic root trauma. Under sizing in particular is associated with PVAR [17-19]. All grades of PVAR are associated with worse outcomes whether it is at least moderate PVAR, [20-22] or even mild PVAR [23]. Multi-slice computed tomography (MSCT) is now considered the gold standard for the measurement of the aortic annulus to determine TAVR device sizing [24-29]. Two dimensional (2D) and three-dimensional (3D) transesophageal echocardiography (TEE) has previously been shown to generally underestimate the annulus size and hence TEE is not as widely accepted as MSCT for the aortic annular sizing for TAVR device [30-34].

However in some patients, MSCT might not be feasible such as those with well documented anaphylaxis to iodinated contrast or those with chronic kidney disease (CKD). Moreover, TAVR is commonly considered in elderly patients who often have CKD and are at a higher risk of contrast induced nephropathy (CIN). In these instances where MSCT might not be ideal, 3D TEE is a reasonable imaging modality for aortic annulus sizing to determine TAVR device sizing, especially with recent improvements in 3D TEE technology that address previous pitfalls. The off-label use of newer commercially available software (Q-lab MVQ software version 8.1; Philips Medical Imaging, Andover, MA) normally designed to track the mitral annulus has been described in this setting for 3D TEE semi-automated aortic annulus sizing with good success [35-36].

The aim of our study was to determine the accuracy of aortic annulus sizing using (i) manual 3D TEE and (ii) more recent 3D semi-automated TEE annular detection software in patients undergoing TAVR procedures who had already undergone pre-planning MSCT in measuring annular measurements. In addition we sought to assess the reproducibility of these 3D TEE methods.

2. Methods

2.1 Patient population

Patients with severe symptomatic AS scheduled to undergo TAVR at Flinders Medical Centre between March 2013 and June 2015, who had both 3D TEE and MSCT images available were included in this study. During this period all patients who underwent TAVR had general anaesthesia and peri-procedural TEE performed. However, our current default protocol particularly for transfemoral TAVR is conscious sedation with the use of periprocedural transthoracic echocardiogram (TTE). Peri-procedural TEE is now only performed in a few select cases especially those of alternate vascular access. A balloon expandable Edwards SAPIEN XT transcatheter heart valve was implanted in all cases. TAVR sizes were predicted using standard measurements for Edwards Lifesciences SAPIEN transcatheter heart valves. The final sizing of the prosthesis was determined by the implanting physician using all available data. MSCT was performed 17.0 $\pm$ 11.0 weeks prior to TAVR. TEE was performed peri-procedurally. 3D TEE images were analysed offline. 3D TEE and MSCT measurements were performed separately in a blinded fashion. 3D TEE measurements were performed by cardiologists with expertise in echocardiography. The cardiologists were blinded from the MSCT measurements to eliminate measurement bias thereby ensuring validity of the comparisons between these imaging modalities. MSCT measurements were performed by an experienced radiologist. Informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the Southern Adelaide Clinical Human Research Ethics Committee.

2.2 Image acquisition

2.2.1 Echocardiography

Patients underwent procedural TEE using a commercially available machine (iE33, Philips Medical Imaging, Andover MA) with the X7-2 3D TEE probe. 3D data sets that included the left ventricular outflow tract using a single beat 3D zoom function were obtained from the aortic long axis view.

2.2.2 MSCT

All examinations were performed on a Philips Brilliance iCT 256 scanner using standard technical parameters.

2.3 Image analysis

2.3.1 3D manual TEE aortic annulus measurement

Multiple 3D zoom datasets were acquired and the dataset with the maximal aortic diameter was used for analysis. We routinely used biplane imaging from the aortic short axis view to ensure correct alignment of the orthogonal long axis plane through the maximal diameter. This has been previously shown to be a robust method of aortic annular measurement [37]. From our experience we find this easily reproducible. For 3D manual TEE aortic annulus measurement commercially available 3D software (Qlab 3DQ V10.1) was used. A multi-planar reconstructive mode was used to ensure accurate alignment of the aortic annulus. The data set was scrolled to maximal aortic valve opening in mid-systole and the 2 orthogonal long axis images (**Figure 1** , frame B and C) aligned to open up the left ventricular outflow tract. The transverse plane**(Figure 1** , frame A) was then aligned to transect through the aortic annulus at the insertion point of the aortic valve in both long axis views. The transverse plane was then used to measure both annulus area and minimum and maximum diameters.

2.3.2 3D semi-automated TEE aortic annulus measurement

Semi-automated aortic annulus measurements were made using the MVN program, normally designed for detecting the mitral valve annulus. This was achieved by scrolling the image in a multi-planar reconstruction mode to maximal aortic valve opening, aligning the aorta in an upright direction in the 2 orthogonal planes (figure 3, frame A and B) and defining the 4 annular points of aortic valve insertion. The software then automatically placed the remaining annular points with the operator able to manually override this placement if there was disagreement in 8 long axis frames of the aorta (giving 16 points of annular placement) Manual override of the automated placement of the annulus points did occur in at least 2 or more places for the majority of patients and tended to occur most often in the setting of acoustic shadowing by valvular calcium. However any adjustment made was minor in nature and did not add significantly to analysis time. The software then gave the circumference and area of the aortic annulus and the area was converted to a diameter by the equation

D= $\sqrt{\left(\frac{A}{\pi}\right)} \times 2$ where D=diameter and A=area.

2.3.3 MSCT

Measurements of the aortic annulus were obtained manually on a dedicated viewing station (Philips Extended Brilliance Workspace) using multi-planar reconstruction. A dataset of images produced by a scan throughout the cardiac cycle was reviewed for quality and artefact. A suitable subset was then selected in the diastolic phase (commonly at the 30 to 35% point in the cardiac cycle). Using multi-planar reconstruction of the selected dataset, the plane of the annulus was determined by selecting the basal attachments (hinge points) of the 3 aortic valve cusps. The 3 hinge points were then connected by a smooth curved line to create an ellipse along the periphery of the intra-aortic x-ray contrast density, the ellipse defining the perimeter of the virtual annulus. Three measurements were then obtained in that plane viz. maximal and minimal diameters, perimeter and cross sectional area.

2.4 Statistical analysis

Continuous variables are reported as mean $\pm$ standard deviation (SD) and discrete variables as number and percentage. Correlation between imaging methods was performed using Pearson's correlation and displayed using Bland-Altman plots. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 19.0 with statistical significance defined as $p < 0.05$.

3. Results

3.1 Patient characteristics

39 patients with severe symptomatic AS had annular measurements performed by 3D TEE and MSCT analysis. Mean age was 85.3 $\pm$ 4.7 years. 67% were male. Prior to intervention aortic mean gradient was

44.5 ± 15.2mmHg and mean aortic valve area was $0.83 \pm 0.20\text{cm}^2$. All patients received an Edwards-Sapien XT TAVR prosthesis. There were 8 (21%) 23mm, 23 (58%) 26mm and 8 (21%) 29mm valve sizes implanted. Patient and echocardiographic characteristics are shown in **Table 1.**

3.2 Annular measurements and reproducibility

A comparison of the aortic annular measurements between MSCT and both 3D TEE methods are shown in **Table 2** . Both 3D TEE methods highly correlated with MSCT for annular diameters (semi-automated r =0.96, p<0.0001 and manual r=0.84, p<0.0001) **Figure 3** and for annular areas (semi-automated r=0.96, p<0.0001 and manual r=0.82, p<0.0001) **Figure 4** . MSCT and semi-automated 3D TEE annular area measurements predicted similar TAVR prosthesis size except in only 1 patient where the semi-automated 3D TEE annular area size actually suggested a bigger TAVR prosthesis size, compared to MSCT annular area size. On the other hand, MSCT and manual 3D were discordant in 5 patients in predicting TAVR annular size. Of these, manual 3D TEE predicted a smaller TAVR prosthesis in 3 patients, compared to MSCT annular area measurements. Inter-observer reproducibility was high for both 3D TEE methods for annular diameters (semi-automated r=0.96, p<0.001 and manual r=0.91, p<0.001) **Figure 5** and annular areas (semi-automated r=0.96, p<0.0001) and manual was 0.95 p<0.0001)

Figure 6.

4. Discussion

The key finding of this study is that both manual and newer semi-automated 3DTEE measurements of the aortic annulus correlate well with MSCT. It had been previously reported that 3D TEE sizing of the aortic annulus was unable to accurately predict the implant size of the TAVR device when compared with MSCT [30-34]. Thus, MSCT has become the gold standard imaging modality for TAVR planning [29]. However, our findings plus other recent studies suggest that newer and improved 3D TEE technology is comparable to MSCT [35,36,38]. In the era of significant improvements in both imaging modalities (MSCT and 3D TEE), a recent systematic review and meta-analysis suggested that in pre-TAVR planning, 3D TEE is comparable to MSCT [39]. Indeed with rapidly increasing indications for TAVR, there's a crucial role for 3D TEE in those patients that cannot undergo MSCT. As such, we wish to emphasise that the 3D TEE should not be forgotten as it is an excellent alternative for annular sizing pre-TAVR. The main concern for TEE was annulus under sizing (compared to MSCT) resulting in PVAR. This was not the case in our cohort, particularly for semi-automated 3D TEE measurements. Indeed, when using the semi-automated technique for annulus area (the most robust measurement for sizing), the prosthesis sizing was different in only one patient which suggests that there is no real clinical difference between the two modalities. Moreover, in this single case the difference in measurements was only marginal and the 3D TEE actually predicted a larger prosthesis size. The inter-observer variability was very low when using the semi-automated 3D TEE method indicating that automating some of the measurement reduced the difference between readers. Our study provides great confidence in not only choosing 3D TEE when MSCT is contra-indicated but suggests that it is an excellent alternative regardless. Therefore, with better 3D TEE analysis packages specifically designed for the aortic annulus now available on the market which often use identical techniques to MSCT measurement methods, the mantra that MSCT is the gold standard needs to be revisited by further comparative studies [32,34]. Whether using 3D TEE alone in these cases will result in similar procedural outcomes such as PVAR compared to MSCT is not well known at this stage, but the fact that these two different imaging modalities chose the same prosthesis size in nearly all cases in our cohort suggests that the clinical outcomes would likely be comparable.

4.1 Limitations

This study has several limitations. The most important limitation is that it had a small sample size. It was a single centre trial and we chose to only use data from the same 3D TEE system. We did not compare clinical outcomes such as MACE and mortality or measurable echocardiography parameters such as the presence/severity of PVAR, as 3D TEE was not solely used as the imaging modality for deciding which TAVR prosthesis would be implanted. Our findings are not generalisable to other manual or semi-automated

3D TEE techniques/software other than the methods that we used.

5. Conclusion

Both semi-automated and manual 3D TEE for sizing of the aortic annulus for TAVR is comparable to MSCT. 3D TEE methods are easily reproducible and feasible. Newer semi-automated 3D TEE offers the best correlation to MSCT. Hence 3D TEE is an excellent imaging modality for TAVR planning in patients whom MSCT is either contraindicated or suboptimal.

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Conflict of interest

All authors declare no conflict of interest.

Author contributions

Augustine Mugwagwa: Visualisation, Conceptualisation, Writing - Original draft

preparation, Writing - Reviewing and Editing, Methodology and Investigation.

Rebecca Perry: Conceptualisation, Methodology, Formal analysis, Writing - Original draft preparation, Writing - Reviewing and Editing and Investigation.

Carl Gillebert: Conceptualisation, Resources, Writing - Reviewing and Editing and Investigation.

Tracy Hecker: Conceptualisation, Investigation, Resources and Writing - Reviewing and Editing.

Ajay Sinhal: Conceptualisation, Investigation, Resources and Writing - Reviewing and Editing.

Jean Engela: Conceptualisation, Investigation, Resources and Writing - Reviewing and Editing Validation.

Majo Joseph: Conceptualisation, Resources, Writing - Reviewing and Editing, Investigation and Supervision.

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Figure legend

Figure 1

A manual 3D TEE image in multi-planar reconstruction mode demonstrating alignment of the image. The transverse plane is aligned to transect through the aortic annulus at the insertion point of the aortic valve in both long axis views (frame B and C). The transverse plane was then used to measure both annulus area and minimum and maximum diameters (frame A).

Abbreviations:

Ao – ascending aorta; Av – aortic valve; Ava – aortic valve annulus; LVot – left ventricular outflow tract

Figure 2

Semi-automated aortic annulus measurement. This image is achieved by scrolling the image in a multi-planar reconstruction mode to maximal aortic valve opening, aligning the aorta in an upright direction in the 2 orthogonal planes (frame A and B) and defining the annular points of aortic valve insertion. Frame C demonstrates the 2D plane of the annulus and frame D is the 3D reconstruction of the annulus.

Abbreviations:

A – anterior; AL – anterolateral; Ao – ascending aorta; Av – aortic valve; Ava – aortic valve annulus; LVot – left ventricular outflow tract; P – posterior; PM - posteromedial

Figure 3

Bland-Altman graphs demonstrating the correlation in aortic annulus diameters between MSCT and manual 3D TEE (frame A) and semi-automated 3D TEE (frame B).

Figure 4

Bland-Altman graphs demonstrating the correlation in aortic annulus areas between MSCT and manual 3D TEE (frame A) and semi-automated 3D TEE (frame B).

Figure 5

Bland-Altman graphs demonstrating the inter-operator variability of aortic annulus diameter using manual 3D TEE (frame A) and semi-automated 3D TEE (frame B).

Figure 6

Bland-Altman graphs demonstrating the inter-operator variability of aortic annulus area using manual 3D TEE (frame A) and semi-automated 3D TEE (frame B).

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Fig. 1

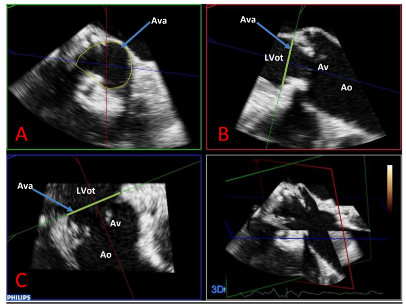
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Fig. 2

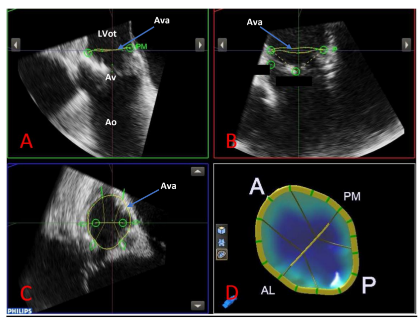
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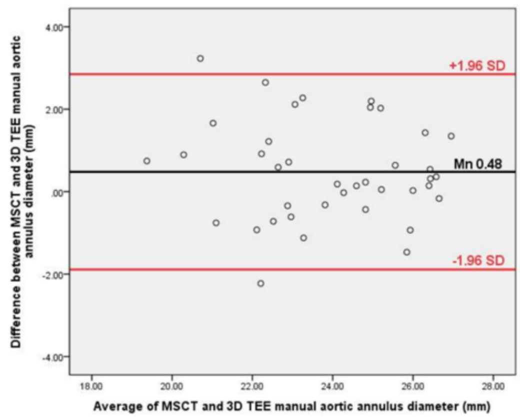
Figure 3A.



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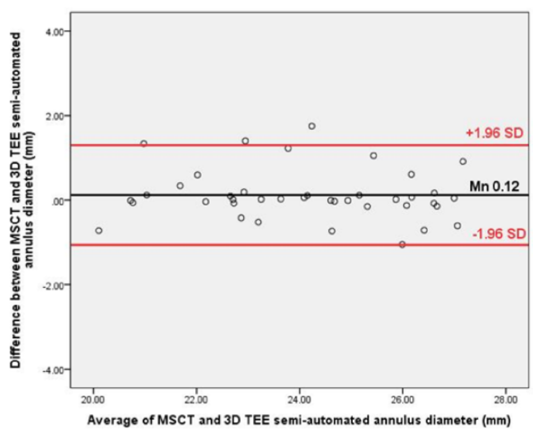

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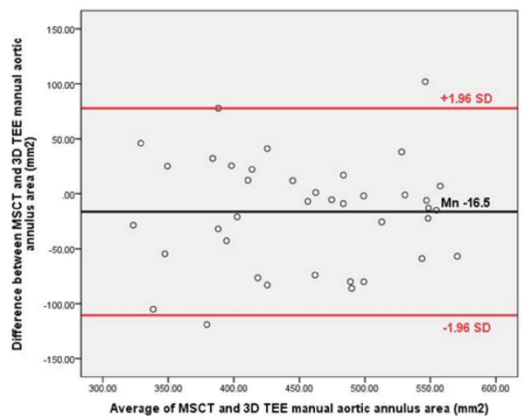

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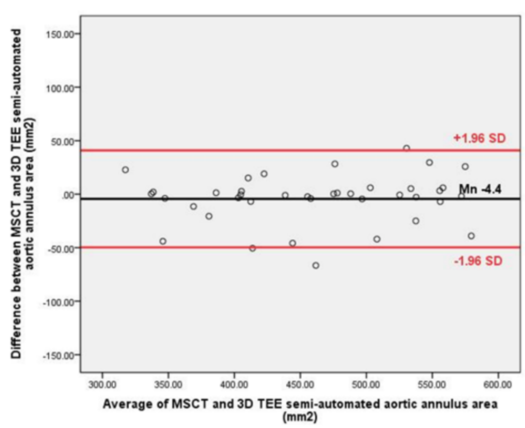

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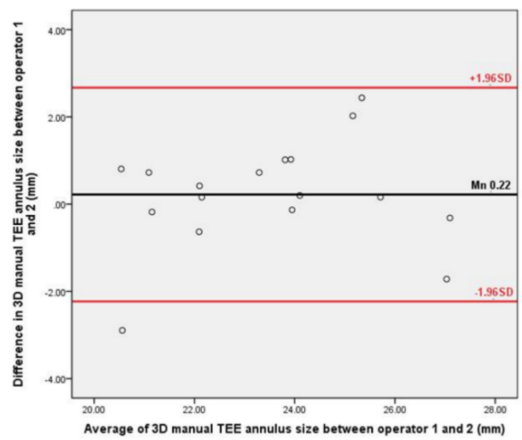

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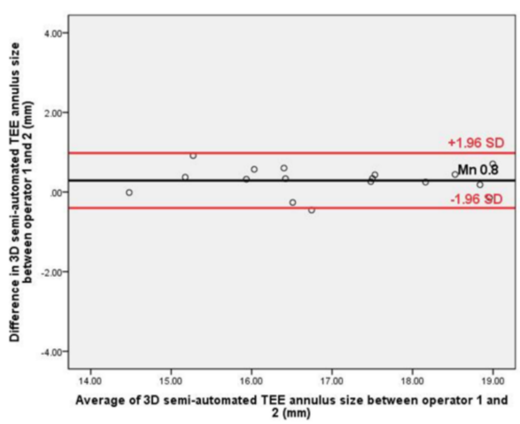

Figure 6A.

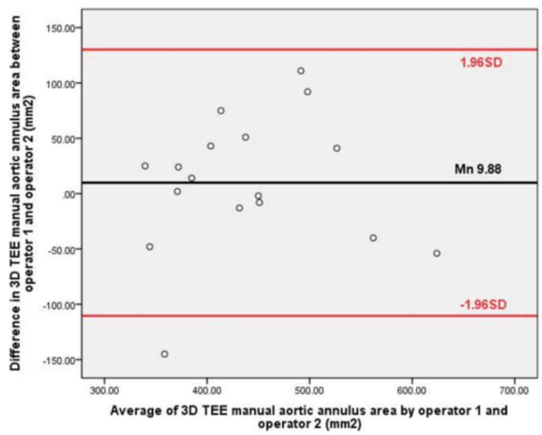

Figure 6B.