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Cardiac CT: necessary for precise sizing for transcatheter aortic implantation

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KEYWORDS
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Abstract

Sizing for transcutaneous aortic valve replacement (TAVI) relies on non-invasive imaging. Incorrect sizing may result in adverse outcomes including paraprosthetic regurgitation, asymmetrical expansion which may impair prosthesis durability and, in the case of severe sizing errors, device embolisation or aortic root rupture. This review addresses the optimal approach for sizing. It is based on currently available data including the anatomical implications of using different imaging modalities, the steps of how to reproducibly measure the correct annulus diameter on MSCT, and current evidence for different sizing strategies.

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Background

Patients with severe aortic stenosis who are denied surgery due to perceived prohibitive risk have a poor prognosis with medical therapy[1-4]. Transcatheter aortic valve implantation (TAVI) was developed as an alternative treatment for patients in this high risk category and is increasingly being performed[5-8]. Two devices are currently commercially available in Europe namely the Medtronic CoreValve self-expandable prosthesis and the Edwards SAPIEN balloon expandable prosthesis[5,6]. Although the estimated number of TAVI procedures performed worldwide may already exceed 10,000 many questions remain to be answered, including the precise approach for sizing i.e., selecting the prosthesis size to optimally match patient anatomy[9]. Incorrect sizing may result in adverse outcomes including paraprosthetic regurgitation, asymmetrical expansion which may impair prosthesis durability and, in the case of severe sizing errors, device embolisation or aortic root rupture[10-11]. This review will address the optimal approach for sizing based on currently available data.

What is sizing? Matching prosthesis to anatomy

Sizing is the selection of one of a range of available prosthesis sizes to best fit into the native aortic root. The aortic root has a complex 3-dimensional structure and it is the diameter at the base of the aortic root, or aortic annulus, which is used for sizing[12]. The aortic annulus is not a true anatomical entity but is defined as a virtual ring with three anatomical anchor points at the nadir of each of the attachments of the three aortic leaflets. It is now recognised that the aortic annulus is non-circular, usually oval in shape[13-15] (Figure 1).

The differences in sizing for TAVI and surgical aortic valve replacement (SAVR)

During SAVR, sizing proceeds under direct vision and by selecting a sizing probe that best fits into the base of the aortic root after removal of the calcified native aortic leaflets. The sizing probes are not standard in the sense that every prosthesis type has a unique set of probes that are not interchangeable. The aortic annulus may also be measured non-invasively using transthoracic or transoesophageal echocardiography (TTE or TEE), but the measurements are not always directly translatable into a prosthesis size so that sizing probes remain widely used. However, differences in measurements of annulus diameter for the purpose of sizing may matter less with SAVR, where the prosthesis is sewn into place, than with TAVI were the positional stability and freedom from paravalvular regurgitation (PAR) relies on good apposition of the prosthesis to the adjacent tissue.

In contrast to SAVR sizing for TAVI relies completely on imaging. Multimodality imaging of the aortic root is generally recommended for patient selection and sizing including TTE, TEE, contrast aortography (CA) and multislice computer tomography (MSCT).

Which modality? MSCT for anatomy

As discussed above, the base of the aortic root or annulus is a complex crown-like 3D anatomical structure that cannot be reliably reproduced on a 2D echocardiographic tomogram or a 2D composite image such as CA (Figures 1A&B). Due to this 3D geometry and spatial orientation of the annulus, a 3D imaging modality such as MSCT, 3D TTE/TEE or cardiac magnetic

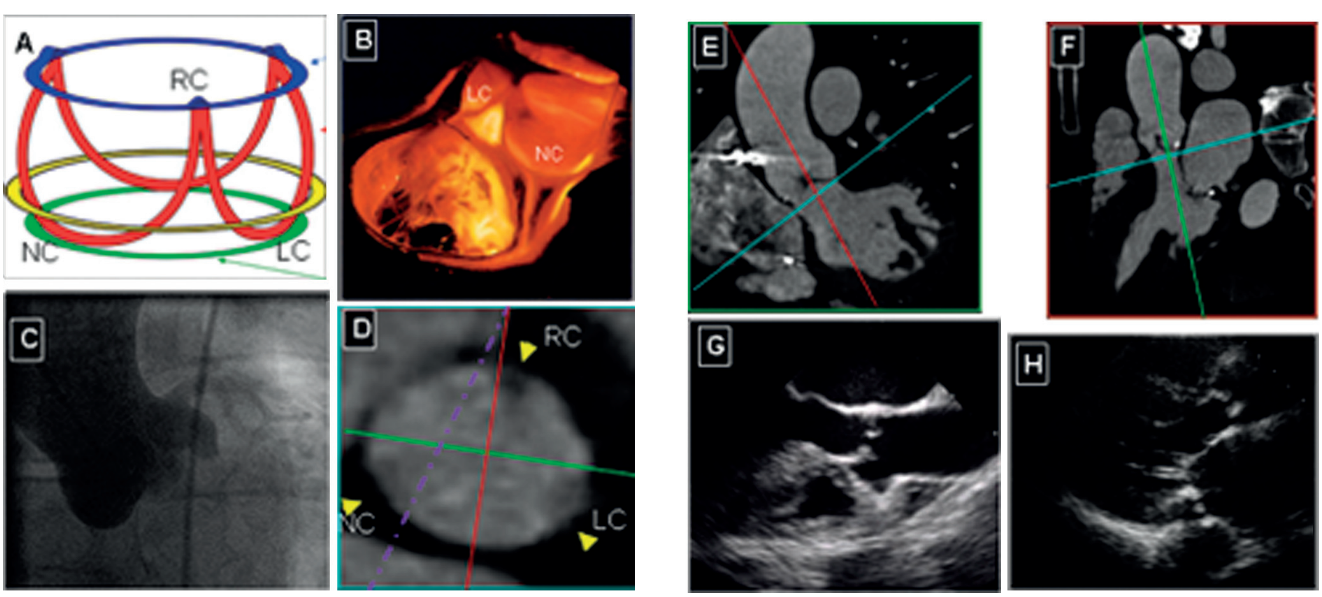

Figure 1. Definition of the aortic annulus on MSCT. The aortic leaflet attachment line is crown shaped (Panel B) so that the aortic annulus is not a true anatomical entity but is defined as a virtual ring with three anatomical anchor points at the nadir of each of the attachments of the three aortic leaflets (Panel A, green circle). This anatomical definition of the aortic annulus may be reliably reproduced using MSCT on an axial image (Panel D, arrow heads indicate the nadirs of the 3-leaflet attachments), but can not be reproduced on the 2D tomograms of transoesophageal (TEE) or transthoracic echocardiography (TTE) (Panels G&H, view approximated on MSCT sagittal view Panel F) or contrast aortography (Panel C, view reproduced on MSCT coronal view Panel E). The purple line on Panel D represents the plane through the annulus when measuring from the attachment of the right coronary leaflet to the attachment of the non-coronary leaflet on 2D TTE/TEE. It can be seen that a true diameter measurement running though the centre of the annulus can not be obtained using such an approach.

resonance imaging is required where an axial plane through the annulus may be reproduced that shows the basal attachments of all three aortic leaflets on one axial image. The 2D TTE/TEE definition of the aortic annulus diameter is used to measure from the basal attachment of the non-coronary leaflet to the basal attachment of the right coronary leaflet on the parasternal long axis view for TTE or the three chamber view for TEE. By reproducing this definition on an axial image from a 3D virtual heart dataset acquired by MSCT it can be seen that this definition does not allow a true diameter measurement, but rather an oblique cut through the annulus (Figure 1A). Furthermore, the parasternal long-axis view for TTE or the 3-chamber view for TEE correspond to an oblique sagittal plane, which measures the smallest diameter of the oval shaped annulus, whereas the largest diameter tends to be in the oblique coronal plane[16,17] (Figures 1A&B). Three-D TEE does not have the same limitations as 2D TTE/TEE, so that the same measurement principles for a 3D modality apply as for MSCT.

How to measure the annulus – definition of the virtual ring on MSCT

Any 2D tomogram through the aortic annulus may be reproduced on MSCT including for example the TTE parasternal long-axis view, the 3-chamber view on TEE or the coronal (postero-anterior) view of contrast aortography that are frequently used for annulus diameter measurements[16,17] (Figure 1). Reproducing these views on MSCT is useful for understanding how these tomograms cut through the aortic annulus and, therefore, what measurements can be obtained from them, but for reasons that are discussed elsewhere in this text, these views are not ideal for the measurement of aortic annulus diameter on MSCT. Three points are required to orientate an imaging plane in 3D space and the nadirs of the three leaflets provide the anatomical anchor points for the plane of the annulus. Therefore by reproducing the anatomical definition of the aortic annulus on MSCT, the plane of the annulus is automatically defined. This key step allows an axial view of the annulus that is required to ensure true diameter measurements that are both axial to and cut through the centre of the aortic annulus. Note that this can not be accurately done on a 2D tomogram. MSCT datasets may be analysed either on a standard MSCT workstation or on dedicated software for the analysis of the aortic root. The anatomical definition of the annulus may be reproduced on both types of software as described in the following section.

Standard MSCT workstation

A standard MSCT workstation (Siemens Circulation software, Siemens, Forcheim, Germany is used in the example images) has three orthogonal analysis windows respectively in the coronal, sagittal and axial orientation once the dataset is loaded into the software. Each window has a coloured border and its cut-plane through the virtual heart is represented in the other two windows by the line in the crosshairs that shares the same colour (Figure 2). We take the following steps with the important caveat that the cross-hairs are locked so that the cut-planes always remain orthogonal to one another. 1) The crosshairs are centred on the aortic root in any

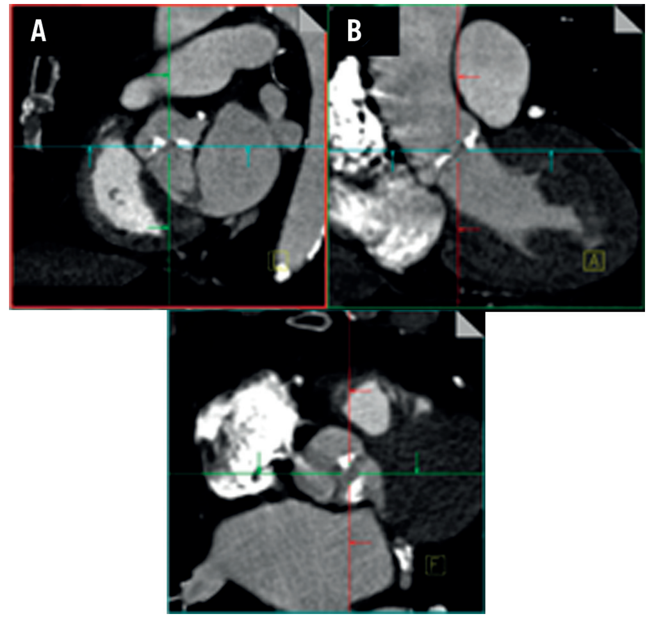

Figure 2. Definition of the annulus on a MSCT workstation: step 1. Once the crosshairs have been centred on the aortic root the workstation provides two orthogonal planes through the virtual heart dataset: sagittal (Panel A), coronal (Panel B) and axial (Panel C). Each plane has a coloured border and is represented in the other planes by the line in the crosshair that shares the same colour e.g. vertical red line in panels B and C represent panel A or the sagittal plane.

of the windows where it is visible, Figure 2). In the coronal window the horizontal line or axial cut-plane is rotated in the anti-clockwise direction, so as to run from right-caudal to left cranial, in order to be orthogonal to the long-axis of the aortic annulus or aortic sinuses, Figure 3. When doing this step it is important that the cross-hairs are locked so that the cut-planes always remain orthogonal to one another 3) In the sagittal window the horizontal line or axial cut-plane usually has to be rotated either clockwise or anti-clockwise, in order to be orthogonal to the long axis of the aortic annulus or sinuses. Note that the plane of the annulus is often very different to that of the ascending aorta, which may seem confusing at first, and this can be variable between patients so that adjustments in the sagittal window are often done only after following step 4. 4) In either the coronal or sagittal window, the horizontal line or axial cut-plane is dragged up and down so that the axial window scrolls through the aortic root until the most caudal attachment points of the three aortic leaflets come into view. If the plane is unbalanced i.e., one of the three leaflet attachments comes into view at a more cranial or caudal level than the other two then small adjustments are made in either the coronal or sagittal window (see steps 2-3) (Figures 3, 4). For example: If the right coronary leaflet, which lies anterior to the other two leaflets, comes into view at a more cranial or caudal level than the left and non-coronary leaflets, then the rotation of the cut-planes has to be adjusted in the sagittal window (Figures 3, 4). On the other hand, if either the non-or left coronary leaflet attachments, which lay posterior respectively and to the left and right of the right coronary leaflet, appear out of plane, then the orientation of the cut-planes has to be adjusted in the coronal

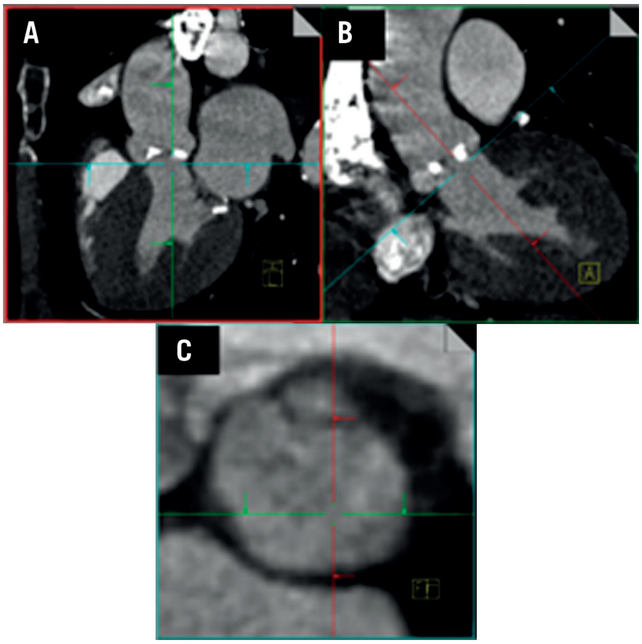

Figure 3. Definition of the annulus on a MSCT workstation: step 2. The crosshairs are locked so that they remain orthogonal. In the coronal window (Panel B) the horizontal line (blue) or axial cut-plane is rotated in the anti-clockwise direction, so as to run from (patient's) right-caudal to left cranial, in order to be orthogonal to the long-axis of the aortic annulus or aortic sinuses (end result in Panel B). In either the coronal or sagittal window the horizontal line or axial cut-plane is then dragged up and down so that the axial window (Panel C) scrolls through the aortic root until the most caudal attachment points of the three aortic leaflets come into view (Panel C). If the plane is unbalanced i.e., one of the 3-leaflet attachments comes into view at a more cranial or caudal level than the other two then small adjustments are made in either the coronal or sagittal window. In this example in the axial cut through the annulus (Panel C) the right coronary leaflet appears at a more cranial level to the non- or left coronary leaflets so that slight adjustment to the rotation of the cut-planes need to be made in the sagittal window (Panel B). The result after slight anti-clockwise rotation of the planes in Panel A is shown in Figure 4.

window. Once the nadir of all three leaflets can be seen simultaneously in one axial image, the correct plane through the aortic annulus has been obtained (Figures 4, 5).

Dedicated software

Software packages are now available that are dedicated to the analysis of the aortic root. As with all dedicated analysis systems there is less versatility, but improvements in time efficiency and ease of use especially for those unfamiliar with a conventional MSCT workstation. The 3mensio system (3mensio Medical Imaging, Bilthoven, The Netherlands) is demonstrated in the examples. Once the dataset is loaded and the aortic root analysis pack tab is selected, a centreline is drawn by clicking on appropriate points starting from the ascending aorta, through the aortic root and into the LVOT (Figure 6). The image positions are updated automatically as each anchor point is selected in order to facilitate the selection of subsequent anchor points (Figure 6). The aortic root is then extracted and displayed as two orthogonal multiplanar reformatted

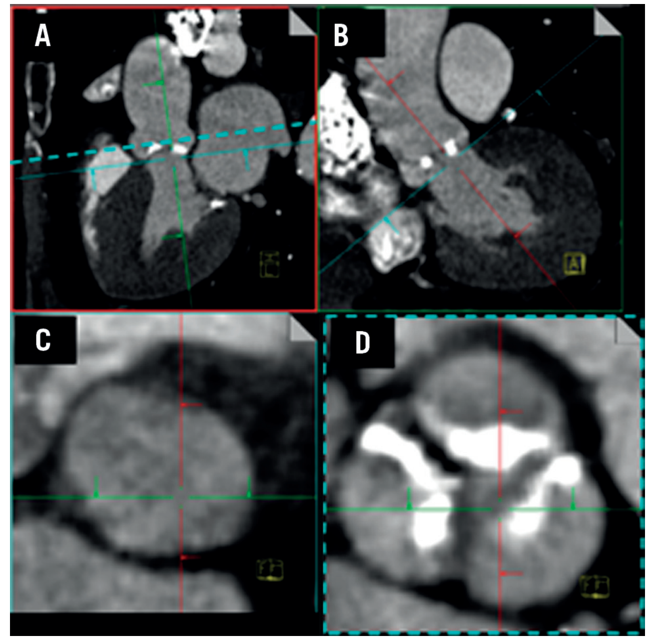

Figure 4. Definition of the annulus on a MSCT workstation: step 3. Shifting the axial cut plane (blue line, Panel A or Panel B) without rotation will scroll through the aortic root in the axial plane (Panel C). In this example to parallel axial images are shown one through the aortic annulus (Panel C) and one through the widest point of the aortic sinuses (Panel D).

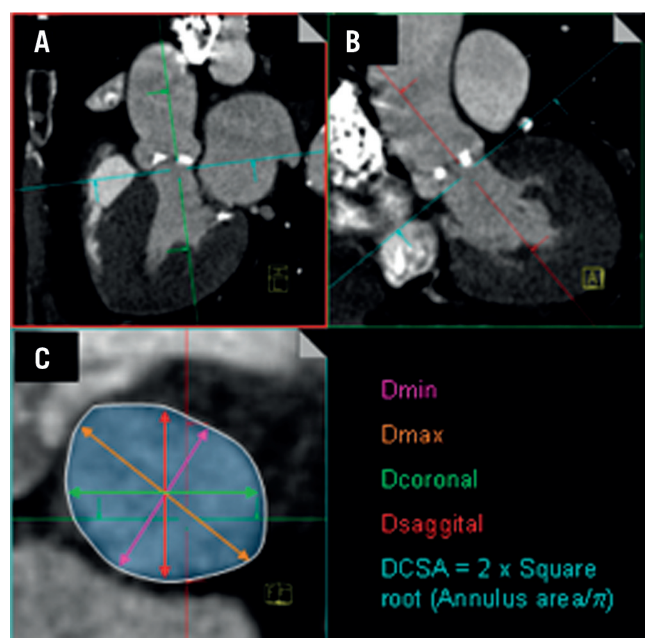

Figure 5. Definition of the annulus on a MSCT workstation: step 4. Once the nadir of all three leaflets can be seen simultaneously in one axial image the correct plane through the aortic annulus has been obtained. Annulus dimensions that can be measured include the minimum and maximum diameters (Dmin and Dmax) the coronal or sagittal diameters (Dcoronal, Dsagittal) and the surface area which can also be transposed into a mean diameter (DCSA) based on the formula for the area of a circle.

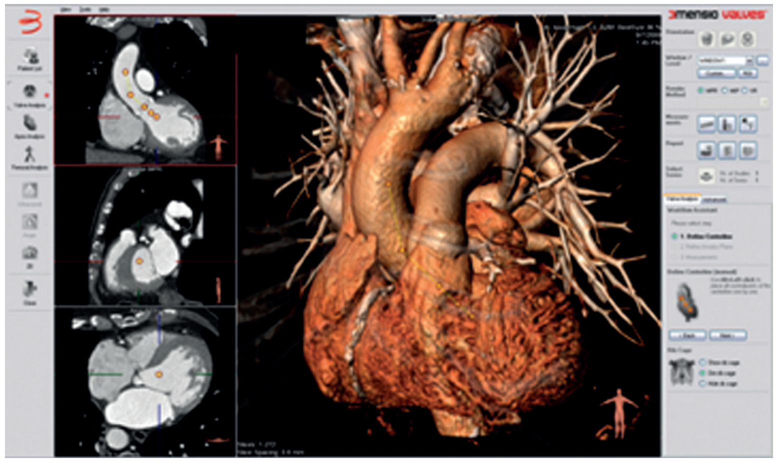

Figure 6. Definition of the annulus on dedicated MSCT analysis software for evaluation of the aortic root: step 1. Once the dataset is loaded and the aortic root analysis tab is selected a centreline is drawn by clicking on appropriate points starting from the ascending aorta, through the aortic root and into the LVOT. A starting point an be selected in the ascending aorta on any of the images because the image positions are updated automatically as points are selected in order to facilitate the selection of subsequent anchor points.

images showing longitudinal cuts through the root and with a third window showing an axial view (Figure 7A). The centreline may be easily manually adjusted if necessary. Thereafter, by parallel shifting the level of the axial cut to the level of the nadir of the leaflets the orientation of the plane through the annulus can be verified. If the nadir of all three of the leaflets are not in the same plane (Figure 7A) small adjustments of the tilt of the planes at the level of the nadir of the leaflets in the two longitudinal windows may be required before true axial measurements are obtained (Figure 7B). The centreline and position of the annulus are then confirmed to allow measurements of annulus diameter (Figure 8).

Measurements

To ensure true diameter measurements that are both axial to and through the centre of the aortic annulus, it is recommended that annulus dimensions are measured on the axial image[17]. The minimum and maximum diameters can be measured as well as the cross-sectional area of the annulus, which may be transposed into a diameter measurement (Figure 5).

Limitations in manufacturers' guidelines for sizing for TAVI

The Medtronic CoreValve prosthesis (MCRS) comes in two sizes. The 26 mm inflow device is recommended for an annulus with diameter of 20-23 mm whereas the 29 mm inflow device is recommended for an annulus of 23-27 mm in diameter. The Edwards SAPIEN prosthesis also comes in two sizes. The 23 mm prosthesis is recommended for an annulus of >18 and ≤21 mm and the 26 mm prosthesis is recommended for an annulus of >21 and ≤25 mm. There are differences in the manufacturers' recommen-

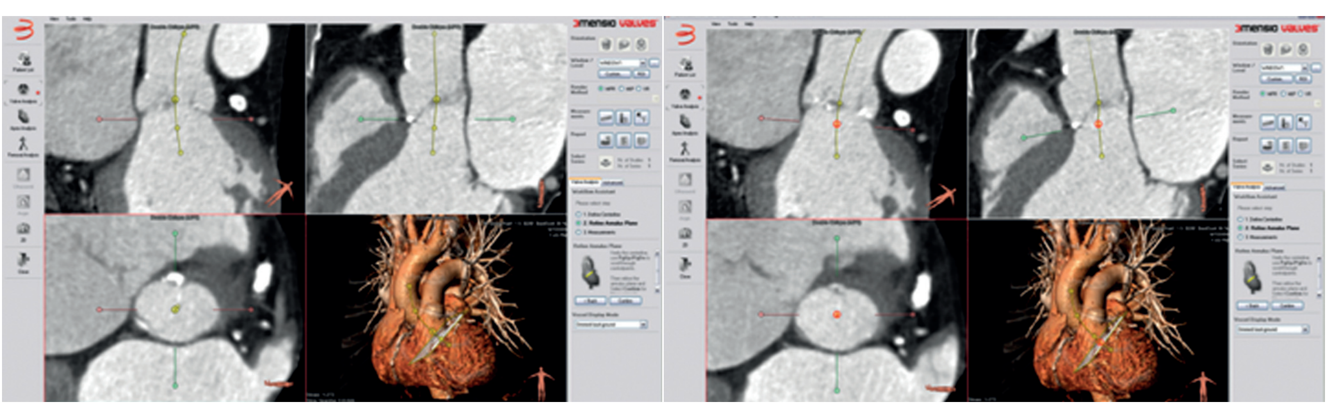

Figure 7. Definition of the annulus on dedicated MSCT analysis software for evaluation of the aortic root: step 2. A) The aortic root is extracted and displayed as two orthogonal multiplanar reformatted images showing longitudinal cuts through the root (upper panels) and with a third window showing an axial view (left lower panel). The centreline should be verified and may be easily manually adjusted if necessary. Thereafter by shifting the level of the axial cut (horizontal line on one of the upper panels) to the level of the nadir of the leaflets the orientation of the plane through the annulus can be verified on the axial image (left lower panel). If the nadir of all three of the leaflets are not in the same plane, small adjustments of the tilt of the planes at the level of the nadir of the leaflets in the two longitudinal windows may be required before true axial measurements are obtained. In the example shown here the left coronary cusp attachment is not in view so that adjustment is necessary to the tilt of the axial plane (horizontal lines) in the two upper windows. The results of such an adjustment are shown in Figure 7B.

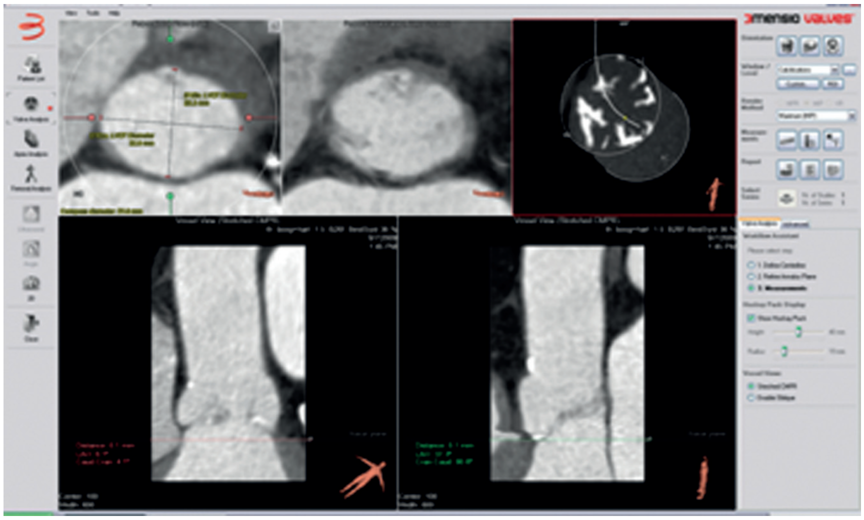

Figure 8. Definition of the annulus on dedicated MSCT analysis software for evaluation of the aortic root: step 3. Once the centreline and position of the annulus are confirmed measurements of annulus diameter are easily obtained and saved to a report.

dations for sizing in so far as for sizing for the MCRS the use of at least three imaging modalities is recommend including TTE, TEE, CA or MSCT, whereas for the Edwards SAPIEN valve, TEE is most frequently used for the annulus diameter measurement.

3D imaging modalities, including MSCT, 3D TTE and CMRI have demonstrated that the aortic annulus is oval in shape and the mean difference between the minimum and maximum diameter of the annulus, as measured on MSCT, is 6.5 mm with a 95% confidence interval of 5.7 to 7.2 mm[17]. These differences may have substantial effects on which prosthesis size is chosen, depending on which diameter is measured and which imaging modality is used. It may seem surprising therefore that neither of the manufacturers' guidelines currently recognises the oval shape of the annulus. Furthermore, although TTE and or TEE are mostly used for sizing both of these are 2D imaging modalities and consequently have potentially significant limitations as discussed elsewhere.

Which diameter measurement? Finding the shoe that fits

In order to better understand the potential effects on sizing for MCRS of using different aortic annulus diameter measurements we measured the minimum (Dmin) and maximum (Dmax) diameters and the cross-sectional area (CSA) of the annulus[17]. Mean diameters were calculated from the minimum and maximum (Dmean) and from the CSA (DCSA). Substantial differences were noted in prosthesis size eligibility depending on which diameter measurement was used. Interestingly using Dmean or DCSA gave similar outcomes and resulted in the most patients (90%) being eligible for either a size 26 or size 29 MCRS[17]. Sizing based on the different annulus diameters was also retrospectively compared to what the operators selected in patients who had already had TAVI. Sizing based on Dmean and DCSA compared best to operator choice, with a modification to the operator decision in approximately 24% of cases when compared to DCSA[17].

A study that investigated the potential effect of using different diameter measurements from TTE, TEE or MSCT on sizing for the Edwards SAPIEN prosthesis did not compare the different selection strategies with operator choice of device, but reported that TEE modified the strategy defined by TTE in 17% of cases, whereas MSCT Dmean modified the sizing strategy defined by TEE in 38% of cases[18]. Furthermore, based on MSCT Dmean 38% of patients would not be eligible for an Edwards SAPIEN device[18]. The higher rate of non-eligibility in that study when compared with the study of the MCRS is explained by the eligibility criteria for the Edwards SAPIEN valve which has an annulus diameter upper limit of 25 mm compared to 27 mm for the MCRS. Population differences between the two studies may also have played a role[17,18]. In our study on sizing for MCRS sizing on Dmin or Dmax resulted in approximately 40% of patients not being eligible for TAVI due to an annulus that was deemed respectively too small or too large and these figures are similar to those reported by another study of the Edwards SAPIEN valve[17,18].

In a separate study we investigated the geometry of the MCRS frame using MSCT after implantation[19]. In patients where the annulus was oval in shape, the minimum and maximum dimensions of the MCRS inflow after implantation closely corresponded to the minimum and maximum dimensions of the annulus as measured on MSCT pre-implantation[18]. Similar data were observed in patients with MSCT before and one month after TAVI with the Edwards SAPIEN prosthesis[20], although the implanted Edwards SAPIEN prosthesis may slightly reduce the degree of non-circularity of the annulus[20]. Given that the area of an ellipse is a function of the minimum and maximum diameters, the best single estimate of the minimum and maximum annulus diameter would be Dmean or DCSA (Figure 5)[17,19]. Taken together these data suggest that DCSA or Dmean might better predict the size of the inflow of the MCRS after implantation than either the coronal or sagittal diameter. Furthermore, at least for the MCRS sizing on DCSA or Dmean would result in the largest possible proportion of patients being eligible for TAVI in the population studied, whereas this may only apply to the Edwards SAPIEN prosthesis once larger size prostheses become available.

Sizing and outcome

Only one study so far attempted to investigate the potential effect of different sizing strategies on outcome[17]. The data were compatible with the hypothesis that sizing on Dmean or DCSA might reduce adverse outcomes, but the number of patients studied was too small to reach clinically or statistically significant conclusions. Two small single centre studies have reported that a smaller ratio of nominal prosthesis size to annulus is associated with paraprosthetic aortic regurgitation (PAR). One study reported that in a patient who received an Edwards SAPIEN prosthesis that prosthesis coverage was negatively associated with an increased risk of PAR[21]. The other study reported that for the MCRS the ratio of nominal prosthesis inflow to native annulus area was negatively associated with PAR. Both of these studies indicate that sizing is likely to be an important determinant of PAR, although other determinants such as volume of aortic root calcification were also identified[21,22]. However, further studies are needed on the effect of different sizing strategies on outcome.

Conclusions

The anatomical definition of the aortic annulus may be reproduced on a MSCT dataset by obtaining an axial image of the annulus with the three anatomical anchor points at the nadirs of the three leaflets. Measurement of annulus dimensions in an axial image allows verification that true diameter measurements are obtained that pass through the centre of the annulus. Sizing based on the mean annulus diameter calculated either from the minimum and maximum annulus diameter or from the annulus area may best predict the dimensions obtained by the prosthesis inflow after implantation and may result in the largest proportion of patients being eligible for TAVI.

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