Sizing the aortic annulus

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Abstract: Transcatheter aortic valve implantation (TAVI) is a valuable alternative for aortic valve replacement in selected high-risk candidates. Accurate preoperative assessment of the aortic annular dimensions is crucial for the success of TAVI, since choice of an incorrectly sized prosthesis may result in catastrophic complications. These complications include annular rupture and coronary arterial obstruction, if the prosthesis is too big, or prosthesis migration and severe paravalvular leakage, if the prosthesis is too small. According to current recommendations, the choice of prosthesis size is based on transoesophageal echocardiography (TEE) measurements. However, TEE results are dependent on operator experience. Moreover, recent research has shown that TEE can significantly underestimate annular dimensional measurements. Alternative sizing methods based on Multidetector Computed Tomography (MDCT) or manometry during balloon aortic valvuloplasty have therefore been developed. We present a brief overview of the imaging modalities available for preoperative assessment of annular size and discuss their potential advantages and limitations.

Key Words: Aortic valve replacement; transcatheter aortic valve implantation; balloon aortic valvuloplasty

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Introduction

Transcatheter aortic valve implantation (TAVI) is a valuable alternative for aortic valve replacement in selected candidates. To date, TAVI has been performed in more than 20,000 patients worldwide, and data concerning proper indications, optimal techniques and patient outcomes of this procedure continue to accumulate (1). Accurate preoperative assessment of the aortic annulus dimension is crucial for successful TAVI, as an incorrectly sized prosthesis may result in catastrophic complications, whether it is too big, causing annular rupture and coronary arteries obstruction, or too small, resulting in prosthesis migration and severe paravalvular leakage (2). According to the current recommendations, the choice of the prosthesis size is based on transoesophageal echocardiography (TEE) measurements (3). However, TEE results are largely operator dependent. Recent research demonstrates that TEE significantly underestimates the annulus as measured at surgery (4,5). For this reason, alternative sizing methods based on multidetector computed tomography (MDCT) (4,6,7) or manometry during balloon aortic valvuloplasty (BAV) (5,8) have been developed.

Here we present a quick overview of the imaging modalities available for the preoperative assessment of the annular size and discuss their potential advantages and limitations.

Echocardiography

Echocardiography is widely available, reproducible, non-invasive and plays a key role in a patient's evaluation before and during the TAVI procedure (7). The indications for transcatheter prosthesis size selection provided by the manufacturers are based on transthoracic echocardiography (TTE) and TEE measurements (2,3). Both these techniques may be used to accurately determine the size of the aortic annulus and the excellent results of transcatheter aortic valve replacement reported to date may be attributable to these complementary techniques (1,4,9).

The optimal methods for determining the size of the aortic annulus, the geometry of the left ventricular outflow tract and of the aortic root at echocardiography are well

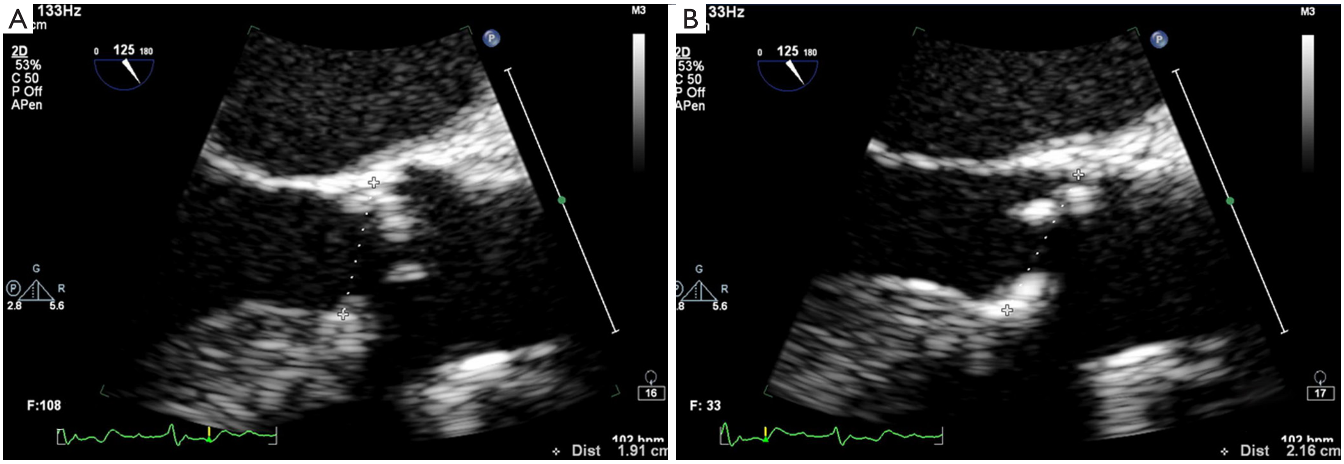


Figure 1 A. The annulus is measured as the distance between the hinge point of the cusps and calcifications are included in the measurement. In this picture, the correct section of the left ventricle outflow tract and of the aortic root is shown; B. A common mistake. The aortic valve cusps are not symmetrically cut. In this case the hinge point of the non-coronary cusp (upper one) is not at the nadir of the cusp, but on the ascending part of the insertion line in the aortic root. This error leads to a significant overestimation of the annulus (in this particular patient, 19 mm in A *vs.* 22 mm in B)

established and the indications for such techniques are widely accepted (2,3,10,11). According to the guidelines of the American Society of Echocardiography, the aortic annulus should be measured as the distance between the insertion of two adjacent leaflets on the parasternal long axis view (TTE) or on the midesophageal long-axis view of the ascending aorta and aortic valve (TEE) at end-systole (*Figure 1*) (10,11).

The main limitation of echocardiography relates to its two-dimensional nature. The aortic root in fact has a complex three-dimensional geometry and the semi lunar attachments of the aortic cusps take the shape of a 3-pronged coronet. Working on a uni-planar view leads to the possibility of underestimating or overestimating the annular size, due to the fact that the actual plane of the section may lie out of the annulus center (4,6,12). Three-dimensional equipment and a multi-planar reconstruction of the aortic root and of the outflow tract can overcome this limitation but the capacity to visualize the entire annulus can be limited by the calcifications. With bi-dimensional equipment the section of the annulus can be maximized by choosing the largest measure of the annulus, taking care to obtain a symmetrical visualization of the cusps. In this case the section plane is supposed to pass through the nadir of two cusps close to the center of the outflow tract (*Figure 1*). However, irrespective of the imaging modality employed, "hinge to hinge" measurements on bi-planar images are often inaccurate. For instance, measuring the distance between the basal attachment of one leaflet to the depicted hinge point across the lumen will take a more diagonal path in relation to the aortic root's axis, while a measurement between the basal attachments of two adjacent leaflets would represent a secant across the aortic root, resulting in a overestimation or underestimation of the annular size respectively (*Figure 2*) (6,12). Moreover, recent research has shown that the hinge points of the three aortic valve cusps is the tissue that provides the first resistance and anchoring force to the transcatheter valve stent. These points lie on the so-called "Virtual basal ring" (12,13), which represents the transition between the left ventricular outflow tract and the aortic root. The virtual basal ring is elliptical and largely non-homogeneous, adding further complexity to any attempt to measure the aortic annulus diameter on two-dimensional images (6,7,9,14). These concepts have been illustrated well by Piazza and associates in a recent review (12).

Multidetector computed tomography

Beyond diameter measurements, a detailed understanding of the anatomy is essential in predicting the final shape of the prosthetic valve, displacement of the native calcified leaflets and sealing around the prosthesis (9). Multidetector computed tomography (MDCT) allows a detailed understanding of the complex three-dimensional aortic root anatomy, including the crown-shaped anatomic aortic annulus, the virtual basal ring, the sinuses of Valsalva with

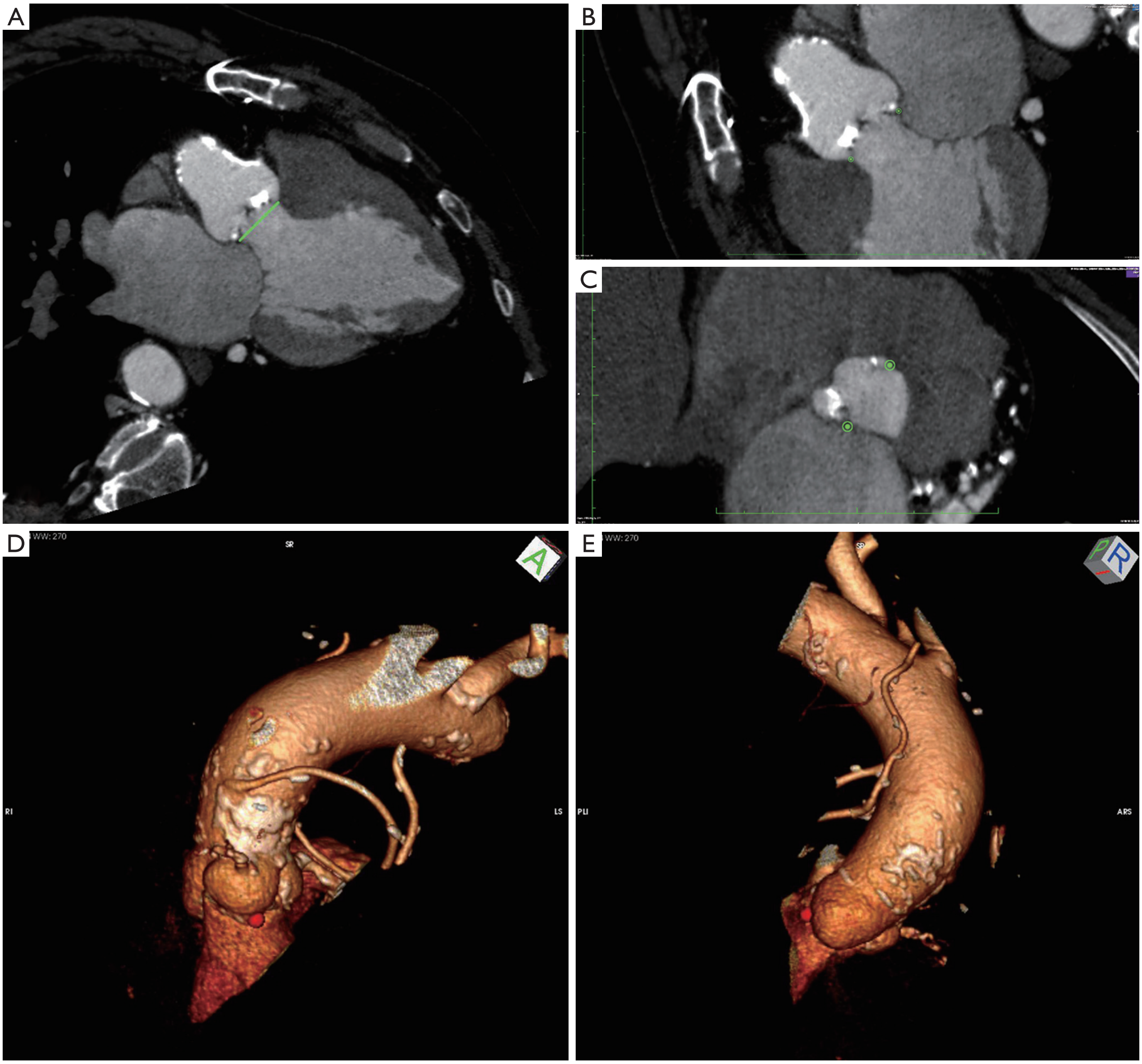


Figure 2 Bi-dimensional imaging is limited in its ability/capacity to measure the "true" annulus diameter. A. In this example, the annulus has been measured as the hinge-to-hinge distance between two cusps (non-coronary and right coronary) on the the 3-Chamber view at MDCT, a multiplanar reconstruction that closely approximates the mid-esophageal long axis view at the TEE (see *Figure 3*); B. The hinge point of the two cusps has been marked by selecting two regions of interest (ROI's, green mark) on the CT image; C. Axial oblique reconstruction showing the position of the two ROI's as they were set in the previous step. Note that while the ROI at the hinge point of the right coronary cusp its close to the correct position, the ROI on the non-coronary sinus is well away from the true hinge point of the corresponding aortic cusp. Also note that this plane does not correspond to the true virtual basal ring plane (see *Figure 4*) and measurements made on this image would probably be inaccurate. In this example, the measurement (24.1 mm) is close to the minimum diameter and 3 mm smaller than the average diameter calculated from the area of the true basal ring (see *Figures 4, 5*). D, E. three-dimensional reconstructions demonstrating again the near correct position of the ROI (red dot) at the hinge point of the right coronary cusp and the wrong position of the ROI on the insertion of the non-coronary cusp

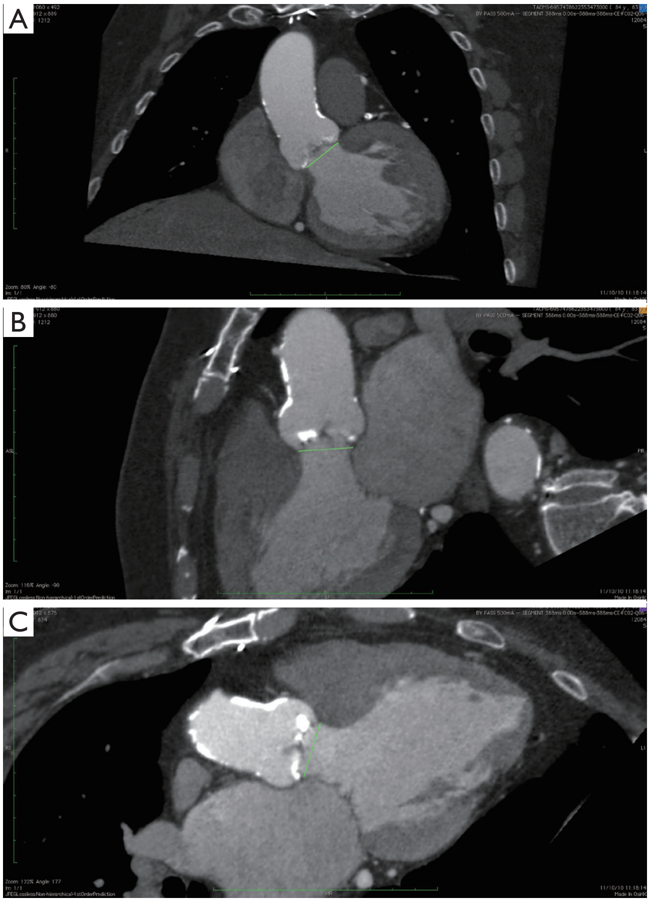


Figure 3 "Hinge-to-hinge" measurements of the aortic annulus diameter may be performed on coronal oblique (A) and sagittal oblique (B) reconstructions, or in the so-called "3-chamber reconstruction", that replicates the long axis echocardiographic images. This view may be easily obtained by generating a short axis view at the base of the left ventricle, diagonal to the line traced from the center of the mitral valve to the left ventricular apex, and then placing a cut-plane at the base of the short axis projection out to left ventricular outflow tract and aorta (C)

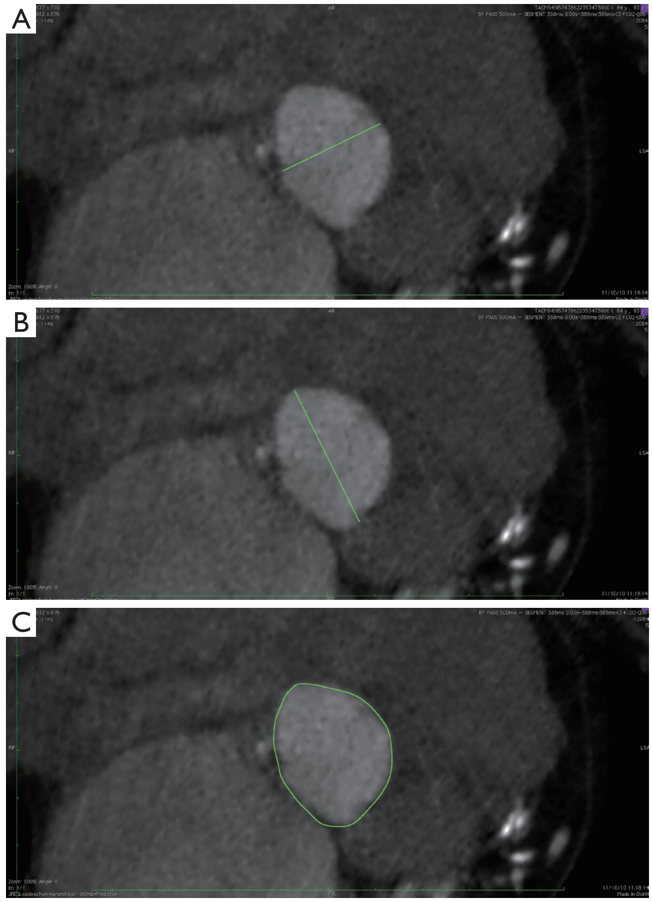


Figure 4 On a double oblique axial view, the elliptical virtual basal ring has been identified. On this plane it is possible to measure the minimum (A) and maximum (B) diameter, as well as the circumference and area of the virtual ring (in this example. 22.7 mm, 30.1 mm, 8.69 cm and 5.76 cm^2. The average diameter calculated from the circumference is 27.6 mm. The average diameter calculated from the area is 27.1. The patient underwent successful transapical implantation of a 29 mm Edwards Sapien valve)

the origin of the coronary arteries, the valve leaflets and the sinotubular junction. MDCT has become the "gold standard" for non-invasive preoperative evaluation of the aortic root and aortic annulus prior to TAVI (4,6,7,12,13,15-20).

Several scan protocols for TAVI assessment have been developed. The technical details on how to obtain a good scan are beyond the scope of this article, but a high quality acquisition without artifacts is a pre-requisite for all the post-processing and image analysis (20).

Many different techniques have been developed to measure the aortic annular diameter at MDCT (6,7,20). In general, they can be divided into two main categories: hinge-to-hinge measurements on a single oblique view (similar to what it is done at echocardiography) (*Figure 3*) (6,16,19); and measurements derived from the area or the circumference of the virtual basal ring (*Figure 4*) (4,6,18,20,21). In this second case, the virtual basal ring may be traced manually or automatically assessed by dedicated post-processing software (21).

To manually trace the virtual basal ring, the three multiplanar reformation planes are used. The orientation of the horizontal line representing the axial cut-plane across the aortic root is adjusted on the sagittal and coronal planes to obtain a double oblique transverse view at the level of the aortic root. The line is then moved from the aorta to the ventricle until the most caudal attachment of the three aortic cusps is identified. Ideally, when the orientation of the cut-plane is appropriate, all the three leaflets should disappear and appear at the same time while scrolling the horizontal line caudally or cephalad across the virtual basal ring respectively (*Figure 4*, *Figure 5A*, *B*, *C*). It should be observed, however, that the exact identification of the plane on which the basal ring lays is not always straightforward in clinical practice. In fact, the nadir of any particular cusp is located at the point where that cusp is "seen to disappear," and the operator judges that the plane is correctly oriented when the three cusps disappear all together, an occurrence that may be hard to reproduce in some patients, such as those with heavy or asymmetrical annular calcifications or an extremely elliptical annulus. While it is easy to identify the "height" of the nadir of a cusp in the aortic root on the sagittal and coronal oblique views, its angular position on the annular circumference may be hard to locate in some patients. An easy, step-by-step method to overcome this issue is described in *Figure 5*.

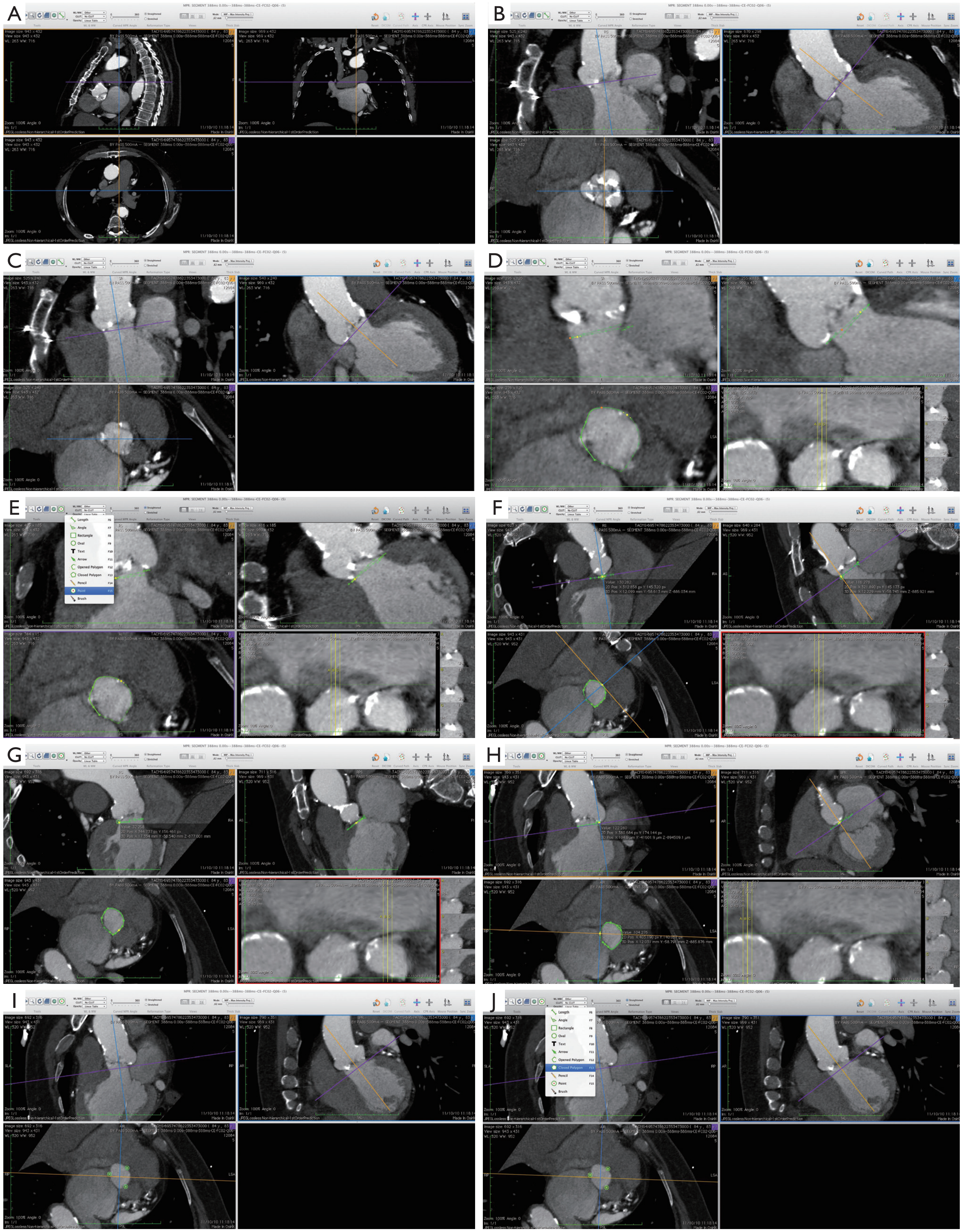
A large amount of evidence has accumulated demonstrating that the MDCT measurements based on the calculation of the average diameter of the virtual basal ring from the virtual basal ring area or circumference are much more accurate and reproducible than echocardiography, and that the use of the MDCT derived measures would result in a strategy change in a substantial number of patients (4,6,15-18,22). Furthermore, it has recently been demonstrated that transcatheter valve implantation alters the geometry of the aortic annulus to a more circular configuration. Interestingly, there is a close and significant correlation between the pre-implant area of the elliptical virtual basal ring and the area of the circularized, post-implant aortic annulus, meaning that MDCT could help to predict the final shape and dimension of the aortic annulus-prosthesis complex after the valve implantation (6). Finally, recent evidence suggests that the use of MDCT for annulus sizing and prosthesis size selection could result in a significant reduction in the risk of post-procedural paravalvular aortic regurgitation, a complication that is known to negatively affect the short- and mid- term results of TAVI (6,15,17,18,22).

Assessment of the annulus diameter by calibrated balloon aortic valvuloplasty:more than just a number

As suggested, MDCT may become the gold standard for non-invasive assessment of the aortic annulus, since it allows a detailed evaluation of aortic root anatomy, and can predict the final shape and orientation of the transcatheter valve and of the aortic root after valve deployment. Despite these advances, complications of TAVI are still reported in the MDCT era, even with experienced TAVI operators. (*Figure 6*) (15-20,22).

For obvious reasons, calibrated aortic angiography has been among the first techniques used to measure the aortic annulus. Balloon inflation with simultaneous contrast injection to check the "stop flow" diameter was originally described by Alain Cribier (23), and it is still an excellent method to determine the size of the transcatheter prosthesis to be implanted (14). In fact, the behavior of the aortic root and aortic annulus during the deployment of transcatheter valves is not always predictable based only on the preoperative non-invasive imaging (9). This is partly due to intrinsic anatomic properties of the aortic root - the "virtual ring" is largely non-homogeneous, coursing through the muscular septum, the membranous septum and the mitral-aortic curtain. Moreover, leaflet and annular calcifications are often asymmetrical, adding further complexity to any attempt to predict the final shape of the prosthetic valve, the displacement of the native calcified leaflets and the sealing of the annulus around the prosthesis. Appropriate device sizing may therefore be dependent on the observation of anatomy–device interaction and aortic angiography during calibrated balloon valvuloplasty represents a very simple and safe method to test this interaction prior to valve deployment (5,8,14,23).

At our institution, the indications for invasive assessment of the aortic annulus size by calibrated balloon aortic valvuloplasty are as follows: (I) major discrepancy between the results of the non-invasive measures; (II) borderline annulus (21-22 and 24-25 mm); (III) massive and/or eccentric calcifications of the aortic annulus/leaflets; (IV) bicuspid aortic valve. The procedure is performed in the catheterization laboratory, as part of the implant procedure (for percutaneous procedures) or during preoperative cardiac catheterization (for transapical procedures). An appropriately sized valvuloplasty balloon (Cristal Balloon, Balt, Montmorency, France) is inflated on the bench with a known volume of diluted contrast agent (15% iomeprol),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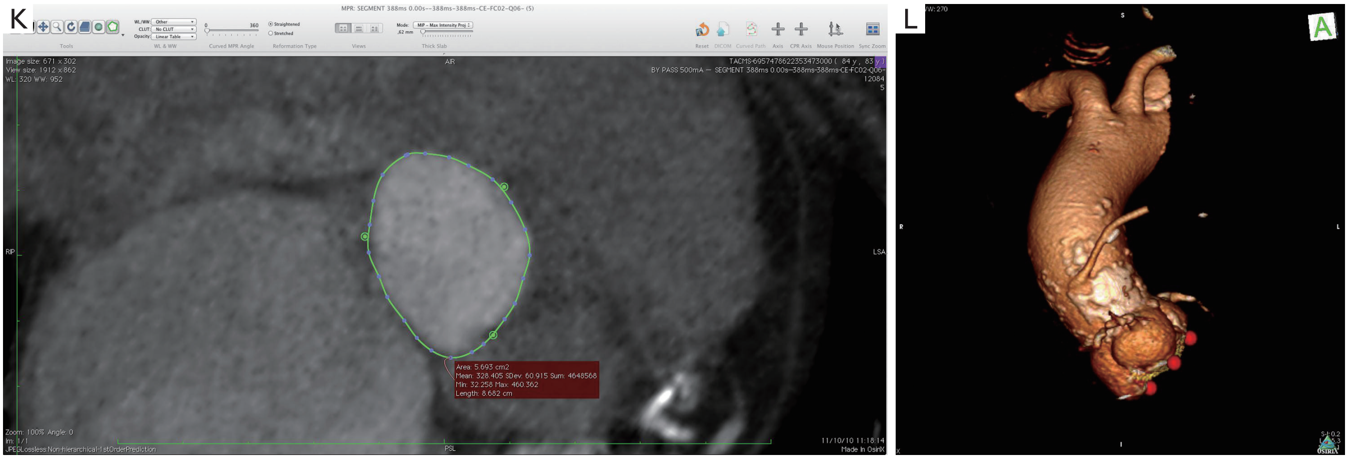

Figure 5 A simple technique to determine the "angular coordinate" of the nadir of the three aortic valve cusps. The CT-derived measurements of the aortic annulus rely on the identification of the so-called virtual basal ring, the ideal, more or less circular transition between the left ventricle and the aorta which lies on the plane passing through the nadir of the three aortic cusps. To obtain an accurate measurement, it is essential that the virtual basal ring is traced on the correct plane, and since according to the third Euclid axiom a plane is defined by three points, it is of paramount importance to exactly determine all three spatial coordinates of the nadir of any single aortic cusp. This task may look simple, but in some instances (markedly elliptical shape of the annulus, heavy asymmetrical calcifications), it can be cumbersome. Here is a simple technique to determine the exact position of these three points by selecting three punctiform ROI's on the OsiriX Imaging Software. (A) From the "2D/3D Reconstruction Tools" menu, the "3D Curved-MPR" tool has been selected. The axess are shown in all the three diagonal planes and the "Sync Zoom function" is active. At this stage, it is useful to set the "Window level" and the "Zoom" to a comfortable value; (B) In the sagittal and coronal planes, the axes are centered on the aortic valve by dragging them with the "Move" tool selected, and then rotating them to obtain a double oblique axial, short axis view of the valve in the low left panel; (C) By slowly dragging the horizontal line (purple axis) up and down across the annulus and gently adjusting its orientation on the upper panels, it is usually possible to obtain a figure like the one shown here in the axial oblique image (lower left panel), in which the three cusps are disappearing at once. This is a very good approximation of the virtual basal ring plane and may be used for tracing it in most instances. However it has to be noted that while two of the three coordinates of the nadir of any of the three cusps may be precisely set on the coronal oblique and sagittal oblique projections (upper panels), the third one, the angular coordinate around the ring, is only approximated as the point where the cusp disappears; (D) By selecting the "Curved MPR" tool and approximately tracing the virtual basal ring as obtained in the previous step, it is possible to obtain a development of the inner surface of the ventriculo-aortic junction, in which the scalloped insertion line of the aortic cusps on the aortic root wall is clearly visible (lower right panel). The angular coordinate of the cusps' nadir may be easily determined on this reformatted image; (E) The central yellow marker "B" in the lower right panel, which corresponds to the yellow dot in the other three panels, has been positioned at the level of the nadir of the right coronary cusp. The "Point" tool is selected; (F) On the axial oblique plane (lower left panel), the axes have been placed on the yellow dot, which is now in the correct angular position. One of the axes is brought to the center of the basal ring, and the other two coordinates of the point corresponding to the first cusp's nadir are now easily set in the oblique sagittal plane (upper right panel). An as-small-as-possible ROI is set at this point. The ROI dimension can be reduced using the command "ALT-" while holding the ROI selected. The yellow "B" marker can now be moved at the nadir of the left coronary cusp (G) and of the non coronary cusp (H), and the exact position of the nadir of the remaining aortic cusps can be determined and marked with a ROI with a similar procedure. The exact position of the three points corresponding to the nadir of the three aortic cusps is now known; (I) The axes are centered again on the valve, as in b. By slowly dragging the purple axis up and down across the annulus and gently adjusting its orientation on the upper panels, the axial oblique plane on which all the three ROI's lay is identified. This is the virtual basal ring plane. The "Closed Polygon" tool may now be selected (J), and used to trace the virtual basal ring (K). The system will automatically return to the operator the circumference and the area of the virtual basal ring. Both may be used to easily determine the average diameter of the aortic annulus. In the example here (same patient as in Figures 2-4) the circumference was 8.69 cm and the area 5.693, two values that were closely approximated by the empirical method (see Figure 4); (L) The correct positioning of the three ROI's may be confirmed on a "Volume rendering" reconstruction

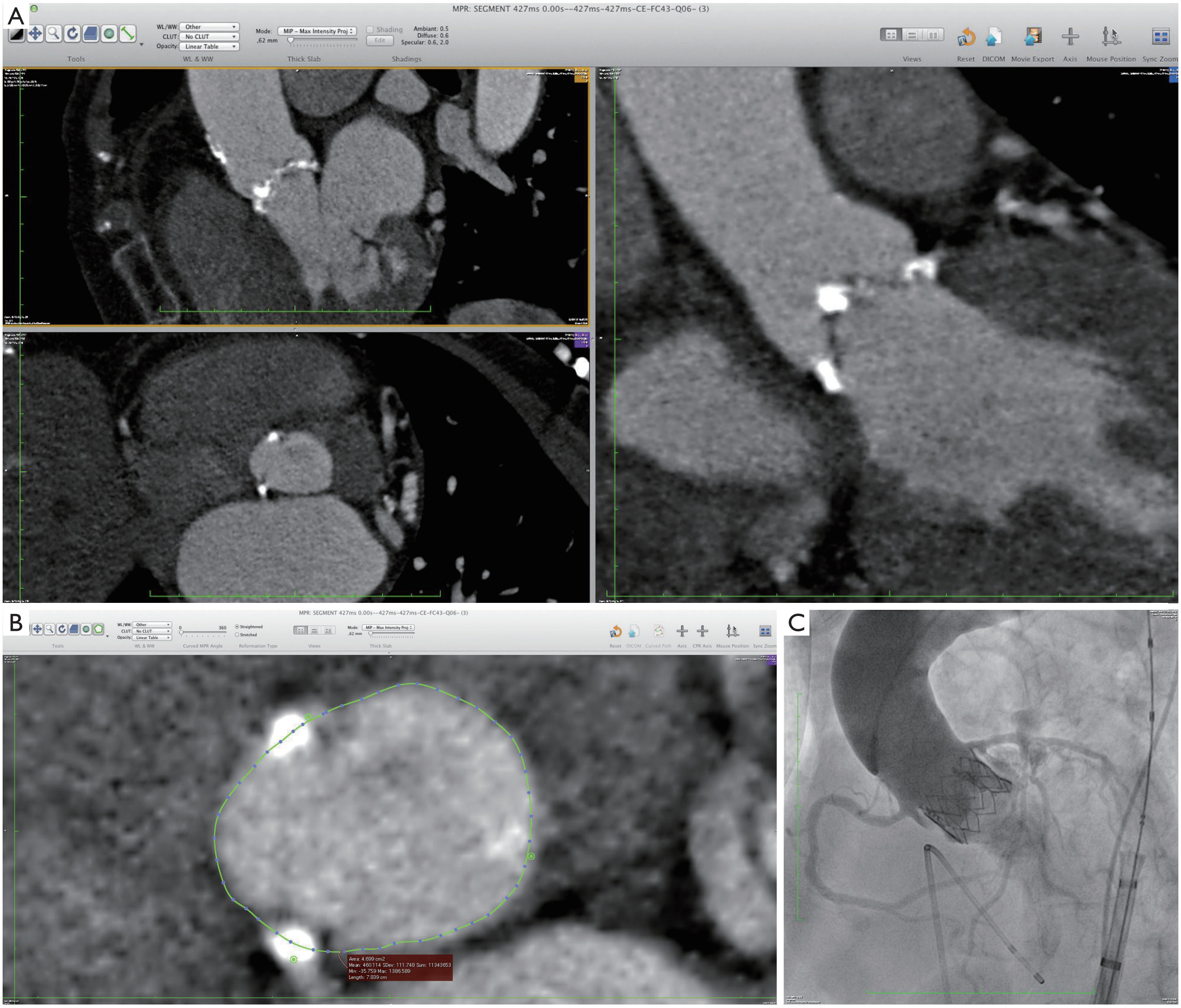

Figure 6 A. An 86 years old lady with multiple comorbidities was addressed? To our TAVI program. At echocardiography, the annulus was 23 mm. MDCT demonstrated the presence of a heavily calcified, markedly elliptical annulus (29.5×21.1 mm at the level of the virtual basal ring); B. The area of the virtual ring was 4.7 cm^2 and the circumference was 7.84 cm. The resulting average diameter was 24.4/24.9 mm, respectively. The decision was taken to implant a 26 mm Edwards Sapien valve percutaneously; C. After the valve deployment, the patient developed refractory hypotension. The aortography demonstrated leakage of contrast medium into the pericardium and echocardiography showed cardiac tamponade. At the emergency surgical exploration the diagnosis of annular rupture was made

and is then sized with a sterile plastic mask for technical drawing (*Figure 7A, B*). The initial volume of inflation is set to obtain a balloon size of 1 mm less than the TEE measurement. The balloon is positioned across the aortic valve through a 10 gauge femoral sheath and inflated with the same volume during rapid ventricular pacing, using a manometric deflator device connected to a 30 cc inflation syringe. At full inflation, an aortography is performed. The following parameters are recorded: (I) presence of a waist on the balloon at the level of the annulus, (II) intra-balloon pressure, (III) patency of the coronary artery ostia and their relations with the displaced aortic valve cusps, (IV) presence

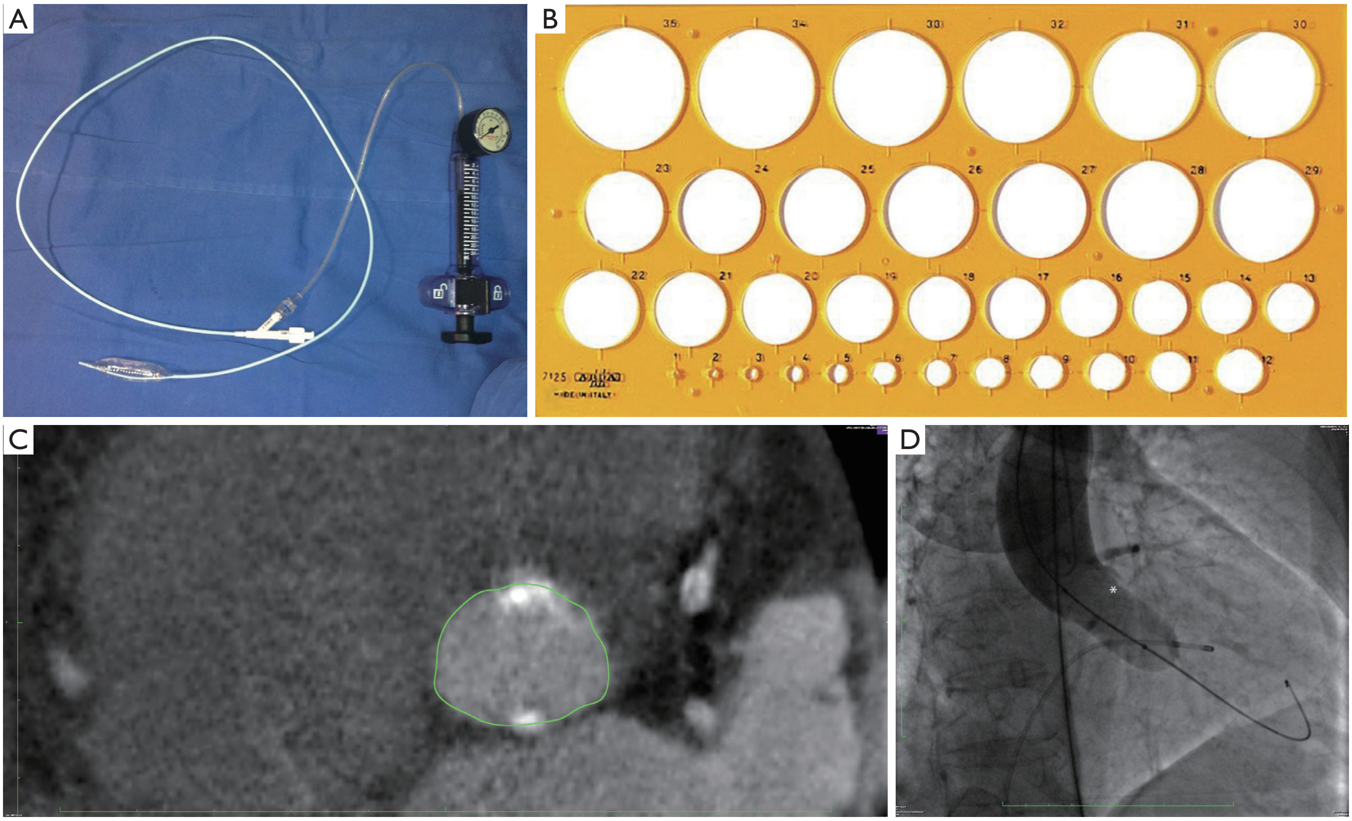

Figure 7 Calibrated balloon aortic valvuloplasty is performed with a cristal balloon? -balloon inflated with a manometric in-deflator? Or inflator? (A) The balloon is pre-inflated on the bench using a sterile plastic mask for technical drawing (B) to determine the amount of diluted contrast media needed to obtain the desired balloon diameter (usually 1 mm less than the TEE measurement); (C) In this particular patient, the annulus was sized 19.5 mm at the TEE. At MDCT, the annulus derived from the area of the virtual basal ring was 20.3 mm. Note the important eccentric calcifications of the annulus extending down in the left ventricular outflow tract; (D) A 20 mm cristal balloon? -balloon was inflated on the bench to obtain an initial diameter of 18 mm. During the balloon valvuloplasty, the intra-balloon pressure rose significantly above the pressure measured on the bench before reaching the target diameter (3 *vs.* 2 atm). At this stage, a waist on the balloon was already evident (*). The inflation was stopped, the annulus size was estimated to be less than 18mm and the patient was switched to conventional surgery. At the operation, the annulus was sized 18 mm with Hegar dilators after the removal of the native aortic valve leaflets and an extensive annular decalcification. The patient received a 19 mm supra-annular bioprosthesis

and entity of aortic regurgitation on aortography at full balloon inflation ("para-balloon leak") (*Figure 7*). In the absence of a waist on the balloon and/or in case of major para-balloon leak, the procedure is repeated with a larger diameter balloon (larger balloon or same balloon inflated with a larger volume of contrast media) (*Figure 8*).

From January 2009 to December 2011, 31 patients at our institution underwent balloon aortic valvuloplasty for annulus size determination as part of the evaluation process prior to TAVI. The procedure was motivated primarily by an incomplete or dubious characterization of aortic root anatomy by non-invasive techniques. Interestingly, this approach led to a strategy change (selection of a different size prosthesis or switch to conventional surgery) in 7 patients (22.6%). Of note, there were no cases of annulus or aortic rupture, aortic dissection, coronary ostia occlusion, prosthesis migration or more than mild paraprosthetic leak in this series.

Babaliaros and coworkers described a similar pressure-based technique to size the aortic annulus during balloon aortic valvuloplasty (5,8). A balloon of known diameter was inflated on the bench and its internal pressure was recorded. The balloon was then positioned across the aortic valve and inflated. The development of additional intra-

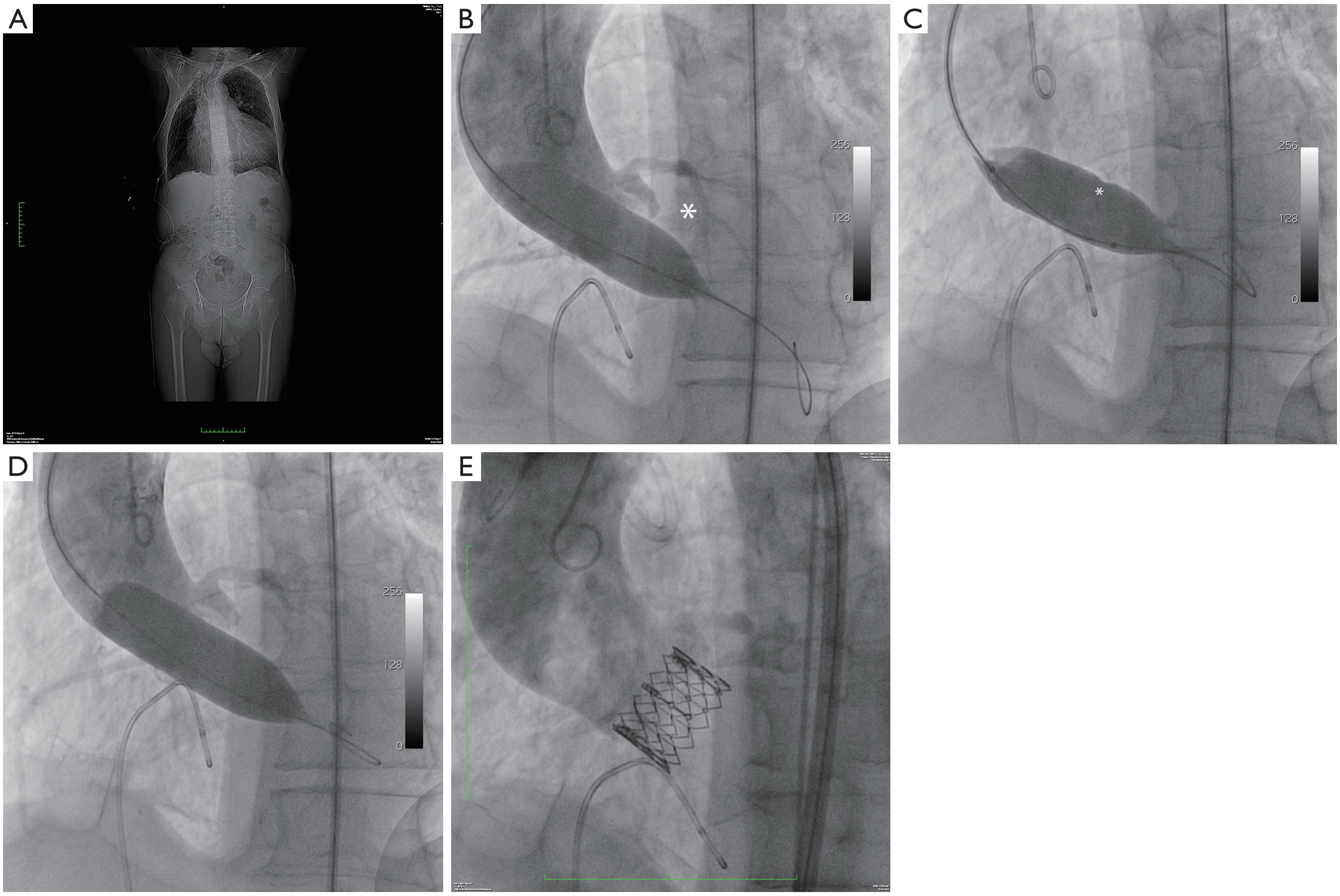

Figure 8 (A) A 72 year-old patient with right fibrothorax was evaluated at our TAVI-dedicated outpatients clinic. He was on domiciliary oxygen therapy and had severe left ventricular dysfunction. Echocardiography showed the presence of a bicuspid aortic valve. The annulus size was 23.5 mm at echo and 22 mm × 24 mm at chest CT. However the measurement was doubtful due to the presence of massive calcifications and to the anomalous anatomy. The patient was addressed to percutaneous TAVI with a 26 mm Edwards Sapien valve; (B) Calibrated balloon valvuloplasty with a 23 mm balloon was performed. At full inflation, the aortography demonstrated a significant para-balloon leakage (*). Moreover, no waist was generated on the balloon, and the intra-balloon pressure did not rise. The procedure was repeated with a 25 mm balloon. At this time, a waist was evident on the balloon (*, C), and the aortography at full balloon inflation showed no leak (D). The patient was addressed to TAVI with a larger device. Since we felt that opening the left pleural cavity for a transapical implant could have added a significant burden on the respiratory function of this particular patient, he was discharged home and closely monitored while waiting for the commercialization of the 29 mm percutaneous device, which was successfully implanted in May, 2012 (E)

balloon pressure was considered proof of the fact that the aortic annulus had been stretched and the nominal diameter of the balloon was used to size the annulus and choice the appropriate size prosthesis (8). In our experience, the development of additional intra-balloon pressure was not always associated with a complete circularization of the annulus and sealing of the balloon to the ventriculo-aortic junction. Indeed we used the intra-balloon pressure as a safety measure, taking care not to exceed the 4 atmospheres limit indicated by the manufacturer of the balloon during the inflation. Instead, we considered the absence of para-balloon leakage during aortography as the true end point of the procedure. In some patients, the additional intra-balloon pressure was developed along with a waist on the balloon profile when the aortography still showed and important para-balloon leakage and inflating the balloon with a slightly larger volume resulted in disappearance of the waist and of the leakage. Interestingly, however, the results of Babaliaros were similar to ours and in 25% of their patients balloon sizing resulted in selection of a transcatheter valve size that could not be achieved by TEE alone (8). This would confirm the idea that the preoperative non-invasive assessment of the aortic annulus may be not sufficiently accurate for some patients (9,14).

Conclusions

All the available imaging modalities provide important information on the anatomy of the aortic root and should be used in a complementary fashion to achieve optimal results. Due to its ability to generate three-dimensional isotropic images, MDCT should be considered the gold standard for the assessment of the average aortic annulus diameter on the virtual basal ring and for the evaluation of the relationship between the annulus, the aortic leaflets and the coronary ostia. Alternatively, echocardiography is readily available, does not require the use of contrast media and may be used during the valve implantation to monitor the procedure. Balloon aortic valvuloplasty is a safe and effective means of obtaining a direct measurement of the aortic annulus prior to TAVI and the information that it provides may significantly alter the prosthesis size selection process, helping to optimize the therapeutic strategy in selected patients. Furthermore, this technique may provide additional information that is crucial for the success of TAVI, simulating the behavior of the aortic annulus, of the valve leaflets and of the coronary artery ostia during the deployment of balloon expandable transcatheter valves, and allowing to "feel" the aortic annulus while measuring it.

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