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Estimation of the Aortic Valve Annular Size Measured by Pre-Operative Echocardiogram Validated Against Intra Operative Measurement by Standard Valve Sizers in Patient Undergoing Aortic Valve Replacement Open Heart Surgery

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Abstract

Objective: This study was carried out to determine the diagnostic accuracy of transthoracic echocardiography (TTE) for preoperative sizing of the aortic annulus. It was done by comparing its measurements against the reference standard of direct intraoperative valve sizer measurement in patients who were undergoing surgical aortic valve replacement (SAVR).

Methodology: This cross-sectional was conducted at the Department of Cardiac Surgery, Hayatabad Medical Complex, Peshawar. from January 2023 to June 2023. Total 194 consecutive patients who were scheduled for SAVR were enrolled. Preoperative TTE measurements of the aortic annulus were performed in the parasternal long-axis view. The primary outcome was the agreement between TTE and sizer measurements. For this the concordance was defined as a difference of ±1 mm. After data collection the statistical analysis was performed using SPSS version 20.

Results: The mean age of our study population was found to be 66.8 ± 10.5 years, with 63.4% males. The TTE and sizer measurement showed a very strong positive correlation ($r = 0.978$, $p<0.001$). However, TTE systematically underestimated the annular diameter with a mean bias of -1.41 mm. The range of Bland-Altman limits of agreement was from -2.31 mm to -0.50 mm. The clinical concordance rate within ±1 mm was 81.4%. while analyzing the subgroups based on gender or valve morphology, they showed no significant differences in measurement discrepancy ($p>0.05$).

Conclusion: The TTE establishes a very strong correlation with direct intraoperative sizing, but it also exhibits a consistent underestimation bias.

Keywords: Aortic Valve, Aortic Valve Stenosis, Diagnostic Accuracy, Echocardiography, Heart Valve Prosthesis Implantation, Intraoperative Care

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INTRODUCTION

Aortic valve disease is a major and growing worldwide health burden, with calcific aortic stenosis being the most common valvular heart disease in industrialized nations.[1] Severe aortic stenosis prevalence increases steeply with age, affecting roughly 2-7% of the population over 65 years.[2] In Pakistan, the burden of valvular heart disease remains significant, with rheumatic heart disease still contributing notably to the pathology of aortic valve disease along with degenerative causes.[3]

The aortic annulus is a fibrous ring forming part of the heart's fibrous skeleton and represents the critical transition zone between the left ventricle and the aortic root.[4] It has a three-dimensional crown-like complex anatomy, which poses unique challenges for accurate measurement. The accurate sizing is important for successful aortic valve replacement. Because the proper annular assessment directly influences prosthesis selection, hemodynamic performance, and long-term outcomes.[5]

In the current times noninvasive imaging modalities are used for the preoperative assessment, among them transthoracic echocardiography (TTE) remains the most accessible and common initial investigation worldwide.[6] In countries like Pakistan where there are resource-limited settings, TTE often represents the first, and sometimes only, imaging modality for surgical planning. However, emerging evidence suggests that there may be potential limitations in its accuracy for precise annular measurement.[7]

Several studies have reported systematic inconsistencies between echocardiographic measurements and direct surgical assessment. Messika-Zeitoun et al. demonstrated that different imaging modalities yield close but not identical annular measurements, with TTE typically providing smaller dimensions compared to computed tomography.[8] Similarly, Choe et al. highlighted the superior accuracy of cross-sectional computed tomographic assessment for transcatheter aortic valve replacement sizing.[9]

The clinical implications of inaccurate sizing are immense. Undersizing may result in patient-prosthesis mismatch, high residual transvalvular gradients, and incomplete regression of left ventricular hypertrophy. On the other hand, oversizing might lead to annular injury, conduction abnormalities, or coronary ostial compromise.[10] Consequently, in the Pakistani context, where patients often present with advanced disease and limited resources for repeating investigations, the accuracy of the initial TTE assessment needs to be maximized.

Literature also shows a distinct lack of region-specific validation of TTE for annular sizing against the reference standard of intraoperative valve sizers. While several international studies have compared different imaging modalities, few specifically assess the diagnostic performance of TTE in surgical aortic valve replacement populations using direct surgical measurement as the gold standard. In this regard, the current study will systematically determine the accuracy of TTE in our population to provide evidence-based guidance for surgical planning in resource-constrained settings[10].

Proper preoperative evaluation of the aortic annulus is the key to success of surgical aortic valve replacement (SAVR). Prosthesis size directly depends on the credible annular measurements, which determine postoperative hemodynamics, the survival of the implanted valve, and the prognosis of the patient in the long term. With the ever-improving technologies of surgery and prosthetic, the accuracy of preoperative imaging grew to be of importance to prevent such complications as paravalvular leak, patient-prosthesis mismatch, and structural deterioration of the valves. Even though different imaging modalities can be used nowadays, they have a significant difference in terms of applicability and reliability in different clinical settings[11].

TTE is the most commonly available imaging technology in most of the low-income and middle-income countries such as Pakistan and, hence, is used as the main tool of preoperative assessment. Although TTE is associated with many benefits, there have been concerns about the capability of TTE to accurately assess the three-dimensional geometry of the aortic annulus and particularly in patients with calcified or anatomically deformed valves. These constraints lead to critical clinical issues on whether TTE is a reliable indicator to make decisions on the choice of the prosthesis when direct measurements in the operating room are applied, which are still the gold standard[12].

Although it is the key element of everyday practice, it is clear that the diagnostic accuracy of TTE used in the annular sizing has not been thoroughly tested in local communities. The variations in the demographics of patients, the etiology of the disease, and the limited resources indicate the necessity of region-specific evidence [13]. Thus, to improve the work of the TTE concerning the intraoperative valve sizers, it is essential to assess it in the context of the decision-making process in surgery and guarantee the safe and evidence-based practice under the conditions of resource-limiting settings.

METHODOLOGY

This cross-sectional validation study was carried out at the Department of Cardiac Surgery, Hayatabad Medical Complex, Peshawar, from 10 January 2023 to 10-June 2023. The study was approved by the Institutional Review Committee of Hayatabad Medical Complex, Reference No: HMC/IRC/2022/45, and CPSP Ref No. CPSP/REU/CDS-2022-021-408, dated December 15, 2022, and was in accordance with the principles of the Declaration of Helsinki. Informed consent in writing was taken from all the participants or their guardians before enrollment.

Sample size of 194 was calculated using the sensitivity and specificity by Buderer's formula for diagnostic tests. Assuming from previous literature an expected sensitivity of 92%, expected specificity of 85%, expected prevalence of accurate sizing of 30%, desired precision of 7%, and 95% confidence level yields[14], A consecutive sampling technique was employed

The formulas used were: (nsens = Z2.Se(1-Se)/L2.Prev**)** where is Z the standard normal deviate for a 95% confidence level (1.96), is expected sensitivity, Sp expected specificity, Prev the prevalence of the condition of interest (here: prevalence of accurate sizing), and *L* he desired absolute precision (half-width of the confidence interval). Using values from prior literature and pilot assumptions (Se = 0.92, Prev = 0.30, L = 0.07, Z = 1.96) gives:

The larger value (for sensitivity) was taken as the required sample size: 193. Allowing a small contingency for incomplete data, the final sample size recruited was 194 participants.

All male and female patients of any age diagnosed with aortic valve insufficiency-both stenosis and regurgitation-who required surgical AVR either in isolation or in combination with other cardiac surgery were included. those patients who were to undergo aortic valve repair rather than replacement, and those undergoing redo aortic valve surgeries due to the fact that previous interventions may have caused anatomical distortions were excluded.

Patient recruitment occurred through the cardiac surgery outpatient department and inpatient referrals. All patients received extensive preoperative assessment, including a detailed history, physical examination, and standard transthoracic echocardiography using commercially available ultrasound systems[25] (IE33, Philips Medical Systems, Cleveland, Ohio). The two consultant cardiologists who conducted the echocardiographic tests had over five years of echocardiography experience and were blinded to the measurements of the same during the operation. All of the measurements were taken per the common echocardiographic criteria and the annulus of the aorta was measured in the parasternal long-axis view during midsystole. To minimize variability in measurements, an average of three to five cardiac cycles was made per value. The diameter of the aortic annulus was determined in the parasternal long-axis view at midsystole using the zoom mode at the insertion points of the aortic valve leaflets. The measurements were performed by experienced echocardiographers who were blinded to the eventual surgical measurements and averaged over three to five cardiac cycles to take physiological variation into account.[26]

We standardized the intraoperative protocol across all cases. Cardiopulmonary bypass was established and the ascending aorta cross-clamped after the median sternotomy. For myocardial protection we administered cold blood cardioplegia. The native aortic valve leaflets were completely excised, along with thorough debridement of any calcifications on the aortic annulus. We then measured the annular diameter by using the largest fitting manufacturer's prosthesis sizing instrument (Edwards Lifesciences, Irvine, California) by the operating consultant cardiac surgeon. In order to reduce the operator-dependent variability, all the cases were undertaken by surgeons with at least five years of independent practice experience[27].

Demographic data collected on participants in the study included age, sex, body mass index; clinical characteristics of the participants such as valve pathology, valve morphology, left ventricular ejection fraction, and concomitant procedures; preoperative TTE measurements; intraoperative sizer measurements; and the size of the prosthesis implanted.

The primary outcome measure was the agreement between the TTE-derived annular diameter and the direct intraoperative sizer measurement. concordance was defined as an agreement within ±1 mm between the TTE and sizer measurements, a threshold consistent with established clinical practice.[15,16]

For all statistical analyses, SPSS version 20 was used (IBM Corporation, Armonk, New York). We presented continuous variables as mean ± standard deviation for normally distributed data, while categorical variables were summarized as frequencies and percentages. The Shapiro-Wilk test was used to assess the normality of the distribution of data. In order to investigate the agreement between the measurements obtained by TTE and sizer we performed the Bland-Altman analysis, including limits of agreement.[17] We used Pearson's correlation coefficient to calculate the correlation between the two measuring approaches. In comparisons of subgroups, Student's t-test was used for continuous variables and the Chi-square test for categorical variables; $p<0.05$ was considered statistically significant. All analyses were performed on an intention-to-diagnose basis.

written informed consent was obtained from all patients or their guardians before including them to the study, with proper explanation regarding the comparative imaging assessments. The research was in accordance with ethical standards, in which we ensured that all information about the patients remained confidential during the entire duration of the study.

RESULTS

A total of 194 patients who underwent aortic valve replacement were enrolled. **Table I** summarized study participant's baseline demographic and clinical characteristics. The mean age of the participants was 66.8 ± 10.5 years, in current study there was a male predominance (63.4%). Isolated aortic valve replacement was the most common procedure (57.2%), and stenosis was the predominant valve pathology (56.2%).There were 194 patients who were having the surgical aortic valve replacement that participated in the study. Table I shows the demographic and clinical background of the study population. The average age of the sample was 66.8 10.5 years, and of the patients male patients (63.4) prevailed, and female patients (36.4) were in minority. In the valve pathology, the most common was aortic stenosis (56.2%), then aortic regurgitation (24.2) and mixed valves disease (19.6). Regarding valve morphology, most of the patients were found to have tricuspid aortic valve morphology (86.6%), with few cases having bicuspid valve morphology (13.4%). In regard to surgical operations, 57.2 percent of patients have isolated aortic valve replacement (AVR) whereas 32.5 percent have AVR and cardiac artery bypass grafting (CABG) and other combination procedures constitute 10.3 percent. The average left ventricular ejection fraction (LVEF) of the study population was 54.2 including 12.8 and the average body mass index (BMI) was 28.4 including 4.5 kg/m 2 (Table I).

The mean annular diameter measured by transthoracic echocardiography (TTE) was 22.72 ± 2.21 mm. It was significantly lower than the mean diameter obtained via intraoperative sizer (24.13 ± 2.19 mm). There was a mean systematic underestimation of -1.41 ± 0.46 mm ($p<0.001$). A very strong positive correlation was observed between the two methods (r = 0.978, p<0.001). The comparative measurements are given in detail in Table 2. The Bland-Altman analysis confirmed this systematic bias, with limits of agreement ranging from -2.31 mm to -0.50 mm, indicating that 95% of the differences between TTE and sizer measurements fell within this range.

Using the pre-defined clinical concordance threshold of ±1 mm, the overall agreement between TTE and the intraoperative sizer was 81.4% (158/194). Upon analyses the subgroups revealed no statistically significant differences in the measurement discrepancy when stratified by gender (p=0.653) or valve morphology (p=0.399). Furthermore, the rate of valve size concordance was not significantly associated with the operating surgeon (p=0.402). The subgroup analysis proves that underestimation TTE degree is gender-neutral, valve morphology-neutral, and valve pathology-neutral. Despite the fact that the females recorded a slight difference in mean than the males, it was not statistically significant (p=0.653). Likewise, the discrepancies between the bicuspid and tricuspid valves were also similar, which shows that the anatomical variance was not a major determinant of the measurement (p=0.399). There were no significant differences in the mean in the case of stenosis, regurgitation and mixed pathology (p=0.271). All in all, TTE showed a consistent distribution of underestimation bias across all subgroups, which indicated its reliability but necessitated learning to interpret the results with caution in surgical planning. Analysis of the concordance reveals that transthoracic echocardiography has a high agreement with intraoperative sizing in the study population with the general concordance rate being 81.4%. Male (82.1) and female (80.3) concordance was similar, and it did not show any significant gender difference. Similar results were also obtained with valve morphology in which tricuspid and bicuspid valves exhibited almost equal concordance rates. There was greatest agreement with isolated AVR (83.8%), and AVR with CABG (77.8%), which is probably due to the increased complexity of the anatomy. In general, these results reveal that TTE has a stable diagnostic agreement among demographic and clinical subgroups.

When valve-size prediction was assessed against the implanted prosthesis size, TTE demonstrated a sensitivity of 79.9%, specificity of 100.0%, positive predictive value of 100.0%, negative predictive value of 29.4%, and an overall accuracy of 81.4%.

Table 1: Baseline Characteristics of the Study Population (N=194)

Characteristic	Value
Age (years), Mean ± SD	66.8 ± 10.5
Gender, n (%)	
Male	123 (63.4)
Female	71 (36.6)
Valve Pathology, n (%)	
Stenosis	109 (56.2)
Regurgitation	47 (24.2)
Mixed	38 (19.6)
Valve Morphology, n (%)	
Tricuspid	168 (86.6)
Bicuspid	26 (13.4)
Concomitant Procedure, n (%)	
Isolated AVR	111 (57.2)
AVR + CABG	63 (32.5)
Other	20 (10.3)
Left Ventricular Ejection Fraction (%), Mean ± SD	54.2 ± 12.8
Body Mass Index (kg/m²), Mean ± SD	28.4 ± 4.5

Figure 1: Bland-Altman plot: Aortic Annular Diameter

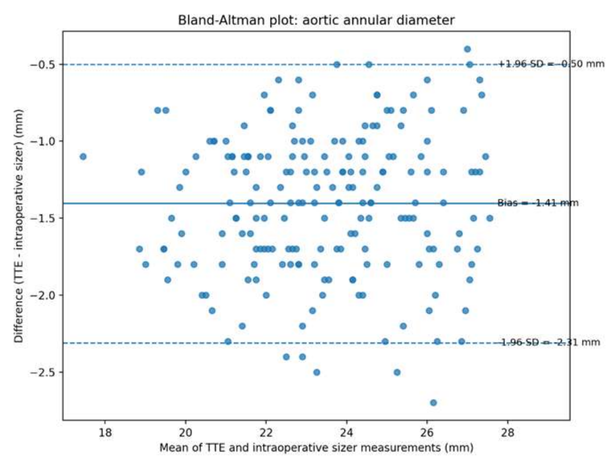

Table 2: Aortic Annular Diameter Measurements by TTE and Intraoperative Sizer

	TTE (mm)	Intraoperative Sizer (mm)	Mean Difference	Mean Difference
Mean ± SD	22.72 ± 2.21	24.13 ± 2.19	-1.41 ± 0.46	<0.001
Minimum	16.9	18.0		
Maximum	27.0	28.3		

Table 3: Subgroup Comparison of TTE–Sizer Measurement Differences

Subgroup	n	Mean TTE Annulus (mm)	Mean Sizer Annulus (mm)	Mean Difference (mm)	p-value
Gender					
Male	123	22.81 ± 2.24	24.18 ± 2.17	-1.37 ± 0.45	0.653
Female	71	22.56 ± 2.18	24.07 ± 2.21	-1.51 ± 0.47	
Valve Morphology					
Tricuspid	168	22.70 ± 2.20	24.11 ± 2.20	-1.41 ± 0.46	0.399
Bicuspid	26	22.84 ± 2.27	24.21 ± 2.16	-1.37 ± 0.47	
Valve Pathology					
Stenosis	109	22.41 ± 2.16	23.84 ± 2.11	-1.43 ± 0.44	0.271
Regurgitation	47	23.04 ± 2.33	24.46 ± 2.25	-1.42 ± 0.49	
Mixed	38	22.93 ± 2.18	24.39 ± 2.30	-1.46 ± 0.48	

Table 4: Concordance between TTE and Intraoperative Sizer Measurements

Category	n (%)	Concordant (±1 mm)	Discordant (>1 mm)	Concordance Rate (%)
Total Cohort	194	158	36	81.4%
Gender				
Male	123 (63.4)	101	22	82.1%
Female	71 (36.6)	57	14	80.3%
Valve Morphology				
Tricuspid	168 (86.6)	137	31	81.5%
Bicuspid	26 (13.4)	21	5	80.8%
Procedure Type				
Isolated AVR	111 (57.2)	93	18	83.8%
AVR + CABG	63 (32.5)	49	14	77.8%
Other Combined	20 (10.3)	16	4	80.0%

Table 5 Diagnostic performance of TTE for prediction of implanted valve size

Parameter	Value
Sensitivity	79.9%
Specificity	100.0%
Positive predictive value	100.0%
Negative predictive value	29.4%
Overall accuracy	81.4%

DISCUSSION

Our current study provides a systematic, intraoperatively-validated assessment of transthoracic echocardiography for aortic annular sizing in a Pakistani surgical aortic valve replacement population. Our principal finding is that TTE demonstrates a very strong positive correlation (r = 0.978, p<0.001) with direct surgical measurement. In addition, it also exhibits a consistent and statistically significant underestimation of the annular diameter, with a mean systematic bias of -1.41 mm. However, when applying a clinically relevant ±1 mm agreement threshold, the concordance rate between TTE and the intraoperative sizer was substantially high at 81.4%. These findings underscore both the utility and the limitations of TTE as a primary sizing modality in resource-constrained environments, providing a clear, quantified measure of its performance for surgical planning.

This consistent underestimation of the aortic annulus by TTE that we have found in our cohort is reflective of the international literature. Wang et al., in a larger cohort of 227 patients, reported that TEE underestimation of the aortic annulus diameter occurred in 51.1%, with 16.7% being underestimations of more than one valve size.[8] Our study, using TTE, demonstrated a similar directional bias, which could be related to the intrinsic limitations of two-dimensional echocardiography to assess this complex, three-dimensional, and often elliptical structure.[18,19] The parasternal long-axis view tends to capture the annulus in its minor-axis dimension without accounting for the larger coronal diameter that would inevitably lead to undersizing.[20] Furthermore, Bland-Altman analysis revealed limits of agreement from -2.31 to -0.50 mm, indicating that while there is a consistent bias, the actual discrepancy in individual patients may be as large as 2.3 mm. This is clinically relevant and may represent a full-size difference. Heavy annular calcifications may also hide the anatomical markers, thereby further compromising measurement accuracy in a scenario not infrequently encountered in our population, who often present with advanced, calcific valve disease.

The critical implication of our findings lies in the 18.6% of patients where TTE and surgical sizing disagreed by more than 1 mm. Inaccurate sizing, particularly undersizing, carries substantial clinical risks, including patient-prosthesis mismatch, elevated transvalvular gradients, and impaired left ventricular mass regression.10 Our data supports a pragmatic approach: surgeons should be aware of the consistent -1.4 mm bias. If a TTE measurement is at the very upper limit of a valve size (e.g., 22.1 mm for a 23 mm valve), they should have a high index of suspicion that the patient may actually accommodate the next larger size (e.g., a 25 mm valve). Our subgroup analyses reassuringly found no significant differences in measurement discrepancy based on gender or valve morphology, indicating that TTE's performance is consistently biased but not disproportionately affected by these common variables. This consistency allows for the potential application of a general correction factor in clinical judgment.

Our findings invite comparison with studies advocating for more advanced imaging. Multidetector computed tomography is increasingly seen as the gold standard for pre-procedural annular assessment, particularly for transcatheter aortic valve replacement. George et al. showed that preoperative MDCT measurements commonly indicated larger valve sizes than did direct surgical sizing and that theoretical TAVR valve implantation based on MDCT would have resulted in significantly larger geometric orifice areas.[21] This reveals a basic difference in sizing philosophy and anatomic assessment between modern cross-sectional imaging and traditional surgical sizing. Similarly, innovative approaches like 3D printing of the aortic root from CT data showed excellent agreement with both CT and intraoperative measurements, providing a tactile, patient-specific model for pre-procedural planning.[22]

However, the universal adoption of MDCT or 3D printing in resource-limited settings remains a distant prospect due to constraints of cost, availability, and expertise. Therefore, the pragmatic approach is not to discard TTE but to optimize its use and define its place in a tiered diagnostic algorithm. For the 18.6% of patients where TTE may be misleading, or for those with complex root anatomy, borderline measurements, or a high risk of patient-prosthesis mismatch, every effort should be made to secure advanced imaging with CT or CMR, if feasible, to refine the surgical plan.[23]

Limitations of the study. Our study has several limitations. Firstly, it was conducted at a single tertiary care center, which may limit the generalizability of the findings to all practice settings within the country. Secondly, the TTE measurements were performed by experienced echocardiographers, and the results may not be fully replicable in centers with less specialized expertise. Thirdly, we did not compare TTE with other advanced imaging modalities like CT or CMR in the same cohort, which would have provided a more comprehensive multi-modality analysis. Finally, we focused on the agreement of annular sizing and did not correlate the degree of discrepancy with long-term clinical outcomes such as patient-prosthesis mismatch or hemodynamic performance, which should be the focus of future prospective studies.

CONCLUSION

To sum it up our study demonstrates that the TTE maintains a strong correlation and a high rate of clinical concordance (81.4%) with direct intraoperative annular sizing in a resource-limited population. Although it shows a consistent underestimation bias of approximately 1.4 mm. It proves to be a fundamentally useful tool for preoperative planning in SAVR. For surgeons, knowledge of its systematic bias is essential in order to moderate the risk of prosthesis undersizing. In an ideal scenario, a heart team approach incorporating advanced imaging for complex cases would be optimal; however, in realities defined by resource constraints, a thorough understanding of TTE's validated performance and limitations allows for its continued safe and effective application.

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Authors Contribution:
Muhammad Aftab Alam Khan: Main conception of study, manuscript writing, data collection, results and conclusion, final approval
Muhammad Aasim: Data analysis data collection, manuscript writing
Ata Ul Mohsin: Data collection, data interpretation, final approval, manuscript writing
Sajid Khan: Revision, data collection, final approval, manuscript writing
Muhammad Sadeeq: Data analysis, data collection, final approval, manuscript writing
Abdul Aziz Ahmad: Main conception of study, overall supervision critical revisions, final approval

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