Implementing a Continuous Quality Improvement Program in a High-Volume Clinical Echocardiography Laboratory

Improving Care for Patients With Aortic Stenosis

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Background—The management of aortic stenosis rests on accurate echocardiographic diagnosis. Hence, it was chosen as a test case to examine the utility of continuous quality improvement (CQI) approaches to increase echocardiographic data accuracy and reliability. A novel, multistep CQI program was designed and prospectively used to investigate whether it could minimize the difference in aortic valve mean gradients reported by echocardiography when compared with cardiac catheterization.

Methods and Results—The Duke Echo Laboratory compiled a multidisciplinary CQI team including 4 senior sonographers and MD faculty to develop a mapped CQI process that incorporated Intersocietal Accreditation Commission standards. Quarterly, the CQI team reviewed all moderate- or greater-severity aortic stenosis echocardiography studies with concomitant catheterization data, and deidentified individual and group results were shared at meetings attended by cardiologists and sonographers. After review of 2011 data, the CQI team proposed specific amendments implemented over 2012: the use of nontraditional imaging and Doppler windows as well as evaluation of aortic gradients by a second sonographer. The primary outcome measure was agreement between catheterization- and echocardiography-derived mean gradients calculated by using the coverage probability index with a prespecified acceptable echocardiography–catheterization difference of <10 mm Hg in mean gradient. Between January 2011 and January 2014, 2093 echocardiograms reported moderate or greater aortic stenosis. Among cases with available catheterization data pre- and post-CQI, the coverage probability index increased from 54% to 70% (P=0.03; 98 cases, year 2011; 70 cases, year 2013). The proportion of patients referred for invasive valve hemodynamics decreased from 47% pre-CQI to 19% post-CQI (P<0.001).

Conclusions—A laboratory practice pattern that was amenable to reform was identified, and a multistep modification was designed and implemented that produced clinically valuable performance improvements. The new protocol improved aortic stenosis mean gradient agreement between echocardiography and catheterization and was associated with a measurable decrease in referrals of patients for invasive studies. (Circ Cardiovasc Imaging. 2016;9:e003708. DOI: 10.1161/CIRCIMAGING.115.003708.)

Key Words: aortic valve stenosis • catheterization • echocardiography • image acquisition • image quality • quality improvement
assessment and improvement, designed to ensure and maintain consistent quality across laboratories.6–8 However, the feasibility and effectiveness of the real world implementation of these guidelines in echocardiography laboratories, particularly high-volume clinical laboratories, remain to be tested.

Aortic stenosis (AS) is a burgeoning disease with increasing volumes seen in echocardiography laboratories and increasingly wider treatment options where appropriate treatment selection rests on careful patient evaluation and an accurate echocardiographic diagnosis.9–11 AS is currently the target for a nation-wide initiative by the American College of Cardiology to improve quality and achieve good outcomes.12 Accurate echocardiographic evaluation of AS is technically challenging and requires the integration of clinical, 2-dimensional echocardiographic and Doppler data.13 Therefore, we chose to study the echocardiographic evaluation of AS to test the hypothesis that implementation of a multi-step continuous quality improvement (CQI) protocol would be feasible in a high-volume echocardiography laboratory and result in a meaningful, measurable improvement in quality outcomes.

Methods
This program was specifically developed to complement existing CQI methods in the Duke University Cardiac Diagnostic Unit & Echocardiography Laboratories (Duke Echo Laboratory) and to comply with the Intersocietal Accreditation Commission (IAC) requirements. The Duke Echo Laboratory has been accredited since November 1999. Historically, investments included training, weekly cardiovascular imaging grand rounds, performance management, information technology, and acquisition of equipment which undergoes rigorous ultrasound machine-to-machine and manufacturer-to-manufacturer evaluations. Since 1995, 4 days per week, the laboratory has had a scheduled lunch hour for the entire staff during which mandatory training is held. Specifically, the reading attending provides clinical cases for team review, feedback, coaching, and mentoring. In 2011, the laboratory leadership established a dedicated multidisciplinary CQI team comprised of 4 senior sonographers and MD faculty. This team met regularly with the laboratory medical, technical, and administrative leadership and was charged with shaping and leading CQI efforts. The CQI team formulated and implemented a comprehensive framework to address the 4 principle domains of echocardiography quality: (1) patient selection, (2) image acquisition, (3) image interpretation, and (4) results communication. A comprehensive CQI schema was developed, implemented, and followed in the Duke Echo Laboratory and is shown in Figure 1A.

After identifying the target pathology of AS, the CQI team performed a baseline assessment of reporting quality and correlation of echocardiographic findings with cardiac catheterization in patients with AS documented on echocardiography during 2011. This was followed by an intensive case review that resulted in protocol changes and multiple teaching interventions over a 12-month period. In 2013, the CQI team reassessed agreement between echocardiography and cardiac catheterization in patients with AS.

Figure 1. A, Mapped quality assurance process implemented at the Duke Echocardiography Laboratory. B, General schema of continuous quality improvement (QI) process. AS indicates aortic stenosis. CMR indicates cardiac magnetic resonance imaging; NP, nurse practitioner; PA, physician assistant; QA, quality assurance; TEE, transesophageal echocardiography; and TTE, transthoracic echocardiography.
Baseline Assessments
The Duke Echocardiography Laboratory database was queried for echocardiograms completed in 2011 that reported moderate or greater AS (ie, significant AS). From this group, patients who also underwent aortic valve (AV) gradient assessment by catheterization within 3 months of echocardiography were identified. AV mean gradients and calculated AV areas were compared between echocardiography and cardiac catheterization among these patients. We prospectively set the maximum acceptable difference between echocardiography and catheterization at <10 mm Hg for mean AV gradients. The differences in mean AV gradient between cardiac catheterization and echocardiography were presented during the Duke Echo Laboratory’s quarterly meetings for faculty and sonographers. Feedback from colleagues in the interventional cardiology teams was also sought. After a review of 2011 data, the CQI team devised and implemented a multistep process to improve correlation between echocardiography and catheterization in assessing AS. The approach included a revised laboratory imaging protocol, peer review, group measurement exercises, and implementation of a sonographer buddy system. This served as the process model for the actual evaluation of the efforts to identify and correct problems.

Peer Review
A single reviewer with over 15 years of cardiac sonography experience was selected to perform peer reviews. Two significant cases per sonographer were evaluated. Reviews focused on adherence to the revised laboratory imaging protocol and the accuracy and completeness of AS reporting. Review results were presented to the sonographers in a quality meeting with adherence rates blinded for individuals and the group overall. The revised imaging protocol (Figure 2) was presented and reviewed in this meeting with an emphasis placed on the need to use multiple windows with imaging and nonimaging probes to ensure accurate Doppler assessment. Each sonographer was provided with confidential feedback from the peer review.

Teaching Sessions and Group Measurement Exercises
Several teaching interventions were designed and conducted. The first intervention was a group measurement exercise. Sonographers were each given a deidentified study of a patient with significant AS. They were asked to individually perform measurements on the images, capture and store screenshots of measurements, and record measurements on spreadsheets. Measurements and calculations included left ventricular outflow tract (LVOT) diameter, LVOT peak velocity, LVOT velocity time integral (VTI), aortic VTI, aortic peak velocity, aortic peak gradient, aortic mean gradient, and the AV areas using the continuity equation by VTI. Results were compiled and presented to the group in a subsequent meeting. The group discussed each measurement parameter and reviewed screenshots of outlier measurements. Discussion included how to measure the diameter of a calcified LVOT, the significant impact of LVOT diameter on calculated AV areas, how to reproducibly measure LVOT and aortic VTI, and image optimization on both the echocardiography machine and study-viewing station before measurement. Examples of cases showing how measurement technique altered AV areas and aortic VTI were shared with the group (Figure 3). Sonographers received individual results along with blinded group results so they could see comparisons with their peers. This process was repeated the following quarter with a different study using the same measurements. Results were compiled and presented to the group again with detailed discussion on image optimization.

Sonographer Buddy System
After the initial review of AS correlation data, the CQI team amended the AS imaging protocol to include a sonographer buddy system for all patients with AS. This protocol was implemented in all cases where any degree of AS (mean gradient >10 mm Hg) was found. The buddy system required an additional AS assessment by a second sonographer, the buddy, to help ensure peak Doppler information was
obtained and reported. The study by the initial sonographer included the techniques and measurements listed in the revised imaging protocol (Figure 2). After the initial sonographer completed the study, a second sonographer, the buddy, scanned the patient and re-evaluated aortic gradients using the new protocol. If a second sonographer was unavailable, this was documented on the preliminary report. Sonographers were also coached on routinely gathering additional Doppler information on all patients with known or suspected AS using the nonimaging Pedof probe from nontraditional acoustic windows, including the right parasternal, subxiphoid, suprasternal notch, and supraclavicular window in addition to apical windows.

Cardiac Catheterization Data
During measurement of invasive hemodynamics, simultaneous LV and ascending aortic pressure measurements were obtained using a double lumen pigtail catheter. Oxygen consumption was calculated from the patient’s body surface area, and pulmonary and systemic arterial blood oxygen content were measured to estimate the cardiac output using the Fick principle. Mean gradients obtained on catheterization were recorded.

Study Outcome
The primary outcome measure was the agreement between catheterization and echocardiography on mean gradients using the coverage probability index. Secondary outcomes included the rate of invasive pressure gradient estimation use in follow-up and the change in range of gradients obtained in a given scan before and after CQI implementation. We also examined image acquisition times before and after CQI implementation.

Statistical Analysis
Continuous data were presented as mean and medians and categorical data as percentages. Consecutive patients who underwent both catheterization and echocardiography in 2013 (post-CQI implementation cohort) were included in the analysis. Agreements between echocardiography and catheterization done on the same subject in either the pre- or post-CQI implementation cohorts were described using the coverage probability index. Coverage probability is an unscaled agreement index that measures the proportion of cases within a prespecified boundary of allowed differences. We prospectively set the predetermined boundary for an acceptable difference between catheterization and echocardiography for each individual patient [δ (≠0)], that is, <10 mm Hg mean gradient difference.14–17 The coverage probability thus is defined as the probability, π, that the absolute difference between the 2 measurements, that is, $Y_{\text{catheterization}} - Y_{\text{echocardiography}}$, made on the same subject is < δ, that is, $\pi = \Pr\left(\left|Y_{\text{catheterization}} - Y_{\text{echocardiography}}\right| \leq \delta\right)$.18 The proportion of cases falling within the acceptable difference of mean gradients obtained by catheterization and echocardiography was calculated both in the pre-CQI and post-CQI samples and compared using Z test.

To examine the effect of additional views and use of the buddy system on maximum Doppler information obtained and average scan time, we chose a random subset of 50 patients with AS examined pre-CQI implementation and a random subset of 50 patients with AS examined post-CQI implementation. The lowest and highest AV mean gradient information were noted from each scan. The time stamps on the first image and last image were noted to calculate total scan times. The ranges of mean gradients obtained pre- to post-CQI implementation were compared using a Mann–Whitney test. To examine whether the time taken to conduct a single AS echocardiography examination had increased pre- to post-CQI implementation were compared using a Mann–Whitney test. To examine whether the time taken to conduct a single AS echocardiography examination had increased pre- to post-CQI implementation, the mean scan times were compared pre- and post-CQI implementation in the sample sets described above using an independent 2 sample t test. All statistical calculations were done using Statgraphics Centurion XVI.I (Statpoint Technologies, Warrenton VA) and JMP Pro Version 11.0 (SAS Institute Inc, Cary, NC). This study was performed under the approval of the Duke IRB.

Results
The Duke Echo Laboratory performed 58,608 transthoracic echocardiograms between January 1, 2011, and January 1,
2014. Of these, 2093 reported moderate or greater severity AS. Between January 1, 2011, and December 31, 2013, 33 sonographers with a median scanning experience of 6 (interquartile range 2.75, 11.25) years were trained and participated in the CQI process.

Protocol Adherence
Before CQI implementation, a review of random sample of 50 cases with moderate or greater AS demonstrated that 2% used an AS buddy, 48% cases used nonstandard acoustic windows, and 72% used a Pedof probe to evaluate for the highest AV Doppler information. After CQI implementation, a sample of 50 independent, randomly selected cases with moderate or greater AS demonstrated that 78% were performed with a sonographer buddy, 96% used additional nonstandard acoustic windows to obtain peak Doppler information, and 100% used the Pedof probe. These metrics significantly increased after the multistep CQI implementation (Figure 4).

Correlation Between Cardiac Catheterization and Echocardiography
For this study, the CQI team reviewed consecutive cases with echocardiograms and available catheterization data: A total of 53/98 (54%) cases had <10 mm Hg difference in mean gradients between catheterization and echocardiography before CQI implementation, whereas post-CQI implementation, 49/70 (70%) had mean gradients falling in the acceptable 10 mm Hg difference range ($P=0.03$). Based on the mean gradient cut offs for AS categories defined by guidelines, the proportion of cases where agreement existed between catheterization and echocardiography increased from 56% in 2011 to 67% in 2013. Figure 4 shows the changes in mapped performance measures in AS.

Figure 5 shows the subset of our AS population who were evaluated for transcatheter AV implantation and, therefore, underwent both cardiac catheterization and echocardiography. Although echocardiographies and cardiac catheterization were consistently obtained on all patients, a marked drop in the frequency of invasive valve hemodynamics was observed after CQI implementation and remained low over the subsequent quarters. The proportion of patients referred for valve hemodynamics decreased from 47% pre-CQI to 19% post-CQI ($P<0.001$).

Laboratory Efficiency
The mean image acquisition time increased significantly from pre- to post-CQI implementation. The pre-CQI mean scan time of 31.8 minutes (95% confidence interval 28.6, 35.2) increased to 48.1 minutes (95% confidence interval 43.6, 52.6) post CQI implementation ($P<0.001$). The buddy system when used accounted for 5.5 minutes (median) of the increase in examination time (Figure 6).

Range of AV Gradients Obtained Pre- and Post-CQI Implementation
The spread of gradients obtained in a given patient with AS was examined by noting the lowest and highest AV mean gradients obtained in a single TTE examination. Post CQI
Acoustic Windows Providing Maximal Doppler Information

Before CQI implementation, the Pedof probe was used in 36/50 (72%) cases. Where used, the Pedof probe provided maximal Doppler information in 15/36 (42%). Overall, the imaging probe provided maximal Doppler information in 35/50 (70%). The apical acoustic window provided the maximal Doppler information in 42/50 (84%). Of the cases where nontraditional windows were used, the right parasternal window yielded maximal information in 7 and subcostal window in 1 case.

Post CQI implementation, when Pedof probe use climbed to 100%, the highest velocity Doppler information was obtained using the Pedof probe in 33/50 (66%) and imaging probe in 17/50 (34%) cases. The apical acoustic window yielded maximal Doppler information in 27/50 (54%). Of the cases where nontraditional windows were attempted, maximal Doppler information was obtained from the right parasternal window in 17, high left parasternal window in 1, suprasternal notch in 2, and supraclavicular window in 2 cases. The buddy system was used in 39/50, 78% of cases. In 44% of these cases (17/39), the buddy obtained mean gradient Doppler information that was higher than the initial scanner by a median of 7 mm Hg (interquartile range 2, 13 mm Hg).

Discussion

The modern concepts of CQI can be traced back to the 1920s when Bell Laboratories was searching for ways to improve the quality of telephone transmission systems. Walter Shewhart, a physicist and statistician at Bell Laboratories, originated the first methods for reducing variation in manufacturing, judging the processes, and understanding that continual process adjustment is necessary for improving products.\(^\text{19}\) In the early 1940s, Dodge and Romig, also at Bell laboratories, further advanced statistical modeling for judging quality improvement but World War II interrupted the development of quality processes.\(^\text{20}\) It was not until after the war, however, that W. Edwards Deming developed the contemporary processes of the involvement of people into a constant cycle of finding problems, fixing the problems, and then repeating the process all over again.\(^\text{21}\) Deming’s concepts were implemented, and proven, in post-war Japan and Europe allowing the automotive products from these countries to now be considered the international standards of high quality.\(^\text{3}\)

The current study is modeled after these evolutionary principles of identifying and fixing problems. The main findings of this study were (1) the development and implementation of a CQI program focusing on image acquisition, and measurement was feasible in a high-volume echocardiography laboratory. (2) A marked improvement was noted in a priori defined measures of laboratory quality including acquisition protocol compliance and correlation of echocardiography and cardiac catheterization on severity of AS. (3) Improved echocardiographic data accuracy was associated with reduced downstream utilization of catheterization-based assessment of valve hemodynamics. (4) There was a measurable increase in resource expenditure as defined by scan time.

The interpretation of an echocardiography can only be as good as the imaging data acquired. Our CQI interventions targeted an important domain in the imaging quality assurance process, namely imaging data acquisition. Other proposed domains\(^\text{5}\) in the imaging quality assurance model, including patient selection, image interpretation, and results communication, were also addressed in the mapped QA process formalized in the Duke Echo Laboratory and briefly outlined in Figure 1A and 1B. Although the targeting of multiple quality-related domains has not been previously reported, other investigators have successfully implemented teaching interventions aimed at quality improvement in the image interpretation domain and addressed commonly evaluated disease states across core laboratories\(^\text{15}\) and academic, university, and community echocardiographic laboratories.\(^\text{22,23}\) Johri et al successfully reduced interobserver variability in visual assessment of left ventricular ejection fraction through a simple teaching intervention at a large volume academic center.\(^\text{23}\) Similarly, Johnson et al reported on CQI steps to improve the characterization of diastolic function.\(^\text{21}\) They used a quality improvement protocol involving staff education with enhanced infrastructure and peer review that proved to be effective in improving the clinical performance of a community academic program echocardiography laboratory.\(^\text{22}\)

In light of data backing the accuracy of echocardiographic estimation of AS severity and known risk of silent or apparent cerebral embolism associated with retrograde catheterization of the AV, cardiac catheterization is often reserved for situations where an intervention is considered or a discrepancy exists between clinical assessment and echocardiographic information.\(^\text{14,24,25}\) We found a large difference between the reported mean gradients by echocardiography and
catheterization in most cases on our initial survey. Although the pressure recovery phenomenon could lead to a discrepancy between echocardiography and catheterization findings, it would be expected to give rise to higher gradients obtained on echocardiography compared with catheterization. In our cohort with correlative data, echocardiography predominantly underestimated gradients compared with catheterization. Case reviews revealed an opportunity for improving the comprehensive attainment of peak Doppler information. The Duke Echo Laboratory was able to reduce this difference by complementing existing CQI practices with a multi-pronged approach: a dedicated AS protocol emphasizing use of the Pedof probe, nonstandard acoustic windows, and a sonographer buddy system. As a marker of greater confidence in AS measures obtained by echocardiography, we noted a decline in the number of patients who had their valves crossed during catheterization for evaluation of transcatheter AV replacement. Thus, improved echocardiographic data accuracy was associated with reduced downstream utilization of catheterization-based assessment of valve hemodynamics. Although we demonstrated reduced down stream utilization of catheterization-based assessment of valve hemodynamics, there are other measurable outcomes, such as altered therapeutic decision making and clinical outcomes, that are likely affected by laboratory quality and data accuracy. Future research needs to address whether CQI strategies in the echocardiography laboratory can alter these clinically relevant outcomes.

A post-CQI implementation evaluation of echocardiographies on 50 randomly selected patients revealed that, in any given patient, the range of obtainable Doppler information was wide. This difference was greater among patients scanned post-CQI compared with pre-CQI implementation. This highlights the critical need for sonographers to invest time to hunt for the maximal velocity Doppler data. The median difference between the lowest and highest peak Doppler data was 13 mm Hg, suggesting that the correct AS severity can be easily missed if sonographers do not search for the best Doppler information with the Pedof and imaging probes and multiple, nonstandard acoustic windows. The follow-up and therapeutic strategy implications of a misclassification of AS may lead to important lost therapeutic opportunities, especially in the present era of wider treatment options for patients.

Although data accuracy improved, the total image acquisition times increased, suggesting an expense of decreased laboratory efficiency. This is an area that needs further investigation. Although comprehensive examinations take time, they add value by providing increasingly accurate information. Yet this additional value may come at a cost that is not currently considered by third-party payers. Our data suggest that high-quality exams take longer times to complete, and as such, this conclusion is in keeping with the recommended IAC standards for scan times. Payment metrics that reward high-volume status can vary significantly over time and could affect gradients obtained by catheterization and echocardiography. In our study, we evaluated all patients who underwent cardiac catheterization within 3 months of their echocardiography.

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To more accurately correlate with catheterization, we would have needed to scan patients simultaneously at the time of their catheterization, which was impractical and unnecessary from a quality assessment perspective. In addition, the patient position and angles needed for accurate AV echocardiographic Doppler measurements are not achievable with the patient required to be supine on the catheterization laboratory table. However, this time difference introduces the potential for disparities based only on the patient’s clinical status and not because of a true difference or disagreement between the 2 modalities. It is important to note that testing the echocardiographic information accuracy against cardiac catheterization-based hemodynamics sets up for an inherent referral bias working against echocardiography because it is only in cases where the treating clinician suspects that the echocardiographic information provided is underestimating severity when valve crossing is sought during catheterization. Finally, the CQI process described herewith needs to be tested in other environments (eg, smaller laboratories, community practice laboratories) to evaluate the generalizability of this approach.

Conclusions

Implementation of a CQI plan in a high-volume laboratory is feasible, and it can result in measureable effects in the daily work of an echocardiography laboratory. Identifying an echocardiography laboratory practice pattern amenable to modification and designing a targeted, multistep CQI program can provide subsequent clinically valuable performance improvement. By demonstrating feasibility and meaningful improvements to reporting accuracy and quality, our study not only provides validation for the use of an IAC/American Society of Echocardiography-based CQI approach to improving quality in the echocardiography laboratory but also provides a framework that can be emulated in other laboratories seeking to meet IAC requirements. Using multiple echocardiographic windows with both imaging and nonimaging transducers along with a sonographer buddy system led to more accurate and reproducible AS mean gradients relative to catheterization with clinical important decrease in potentially higher-risk invasive assessments. Concomitant increase in scan times suggests an initial expense in clinical efficiency that may have downstream cost implications requiring further study. Whether CQI strategies in the echocardiography laboratory can alter therapeutic decision making and improve clinical outcomes requires further study.

Disclosures

None.

References

This study shows the potential benefits of implementing a continuous quality improvement (CQI) program in a high-volume echocardiography laboratory. The quality improvement initiative focused on the assessment of aortic stenosis and involved implementation of a peer review process, teaching sessions, and a sonographer buddy system whereby aortic valve gradients were reassessed by a second sonographer on each study. Echo-based measurements of aortic valve gradients were compared with invasive gradients by catheterization. Significant improvement in the concordance between echocardiography and catheterization assessments of aortic stenosis severity and reduction in downstream invasive testing utilization were noted after CQI implementation. Although the average time to complete an echocardiogram increased by 50% during CQI implementation, the decrease in downstream testing likely provided a net improvement in the efficiency of care delivery. This successful CQI effort required substantial planning and time investment by physician leadership, as well as nurses and sonographers. Whether CQI strategies in the echocardiography laboratory are feasible long term and can alter therapeutic decision-making and improve clinical outcomes require further study.
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