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ORIGINAL ARTICLE

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Development of quality metrics for ambulatory pediatric cardiology: Transposition of the great arteries after arterial switch operation

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Abstract

Objective: To develop quality metrics (QMs) for the ambulatory care of patients with transposition of the great arteries following arterial switch operation (TGA/ASO).

Design: Under the auspices of the American College of Cardiology Adult Congenital and Pediatric Cardiology (ACPC) Steering committee, the TGA/ASO team generated candidate QMs related to TGA/ASO ambulatory care. Candidate QMs were submitted to the ACPC Steering Committee and were reviewed for validity and feasibility using individual expert panel member scoring according to the RAND-UCLA methodology. QMs were then made available for review by the entire ACC ACPC during an "open comment period." Final approval of each QM was provided by a vote of the ACC ACPC Council.

Patients: Patients with TGA who had undergone an ASO were included. Patients with complex transposition were excluded.

Results: Twelve candidate QMs were generated. Seven metrics passed the RAND-UCLA process. Four passed the "open comment period" and were ultimately approved by the Council. These included: (1) at least 1 echocardiogram performed during the first year of life reporting on the function, aortic dimension, degree of neoaortic valve insufficiency, the patency of the systemic and pulmonary outflows, the patency of the branch pulmonary arteries and coronary arteries, (2) neurodevelopmental (ND) assessment after ASO; (3) lipid profile by age 11 years; and (4) documentation of a transition of care plan to an adult congenital heart disease (CHD) provider by 18 years of age.

Conclusions: Application of the RAND-UCLA methodology and linkage of this methodology to the ACPC approval process led to successful generation of 4 QMs relevant to the care of TGA/ASO pediatric patients in the ambulatory setting. These metrics have now been incorporated into the ACPC Quality Network providing guidance for the care of TGA/ASO patients across 30 CHD centers.

KEYWORDS

arterial switch operation, pediatrics, quality, transposition

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1 | INTRODUCTION

The goal of quality metric (QM) development is to create self assessment measures that can be easily utilized by providers and healthcare systems. These metrics should address key issues related to patient management and allow for evidence based care, greater consistency in care and ultimately, when utilized, lead to improvements in clinical care and patient outcome.[1] Historically, the outpatient management of children with congenital heart disease (CHD) has varied according to center and provider preference.[2] Consistent and evidence based clinical practice has been limited by the paucity of established guidelines and the challenge of creating evidence based recommendations given heterogeneity within the CHD population, even for a single diagnosis and intervention.

While mortality rates associated with transposition of the great arteries (TGA) following arterial switch operation (ASO) have improved over time, patients with TGA/ASO remain at risk for significant midterm and long-term complications including myocardial ischemia, left ventricular dysfunction, arrhythmia and sudden cardiac death (SCD),[2–12] neoaortic valve regurgitation (NAR), aortic root dilation (ARD), supravalvar pulmonary stenosis (SPS), supravalvar aortic stenosis (SAS),[2,13–17] impaired neurodevelopmental (ND) outcome,[18–24] and the development of risk factors for premature atherosclerosis, including unhealthy weight, elevated blood pressure and high cholesterol.[25] Similar to many CHD patients, teenagers with TGA/ASO are vulnerable to delays in transition of care to an adult provider and lapses in care, as a result.[26,27]

To date there have been no established guidelines offering metrics for quality improvement in the ambulatory care setting for children with TGA/ASO.[2,24–30] Recognizing the need to develop valid and feasible QM in 5 key areas of pediatric and congenital disease care, including children with TGA/ASO, the American College of Cardiology (ACC) Adult Congenital and Pediatric Cardiology Council (ACPC) proposed use of a 2 step review process, incorporating the modified RAND-UCLA methodology, for the creation of QMs relevant to the ambulatory care of TGA/ASO pediatric patients.[31] This article outlines the process utilized to generate QMs, reviews the candidate QMs and describes the QMs that were ultimately selected for TGA/ASO patients.

2 | METHODS

Members of the TGA/ASO QM group were members of the ACC and were selected on a volunteer basis. There were 12 members of the TGA/ASO group. Members were expected to have content expertise and to participate in biweekly conference calls. Two to three person groups were created among the members to divide up the work of evaluating the existing literature and to create candidate QMs to be reviewed by the entire team. Each 2–3 person group generated candidate QMs. Given that the goal was to generate metrics for quality improvement in ambulatory practice, proposed candidate QMs included a description of the proposed metric, a numerator (e.g., what was to be measured from a patient's chart), a denominator (e.g., the target population), exclusions, and a summary of the key references (see Supporting Information Appendix 1). The QMs were designed for ease of ascertainment of data from a patient's electronic medical record (EMR). All resulting QMs were discussed over a series of conference calls involving the entire TGA/ASO team.

Only QMs relevant to the outpatient management of TGA/ASO recipients and that addressed risk factors for mid and long term morbidity and mortality following the ASO procedure were created. We excluded patients with complex TGA, including those with a hemodynamically significant ventricular septal defect (VSD), aortic arch obstruction, or congenitally corrected transposition, to analyze a more homogenous population. We also excluded TGA patients who had undergone Mustard or Senning operations.

Candidate QMs were then submitted to the ACC ACPC Steering Committee for expert panel review. Employing the RAND-UCLA process,[32] candidate QMs were first individually scored for validity and feasibility by a single member of the expert panel and then independently scored by each member of the expert panel during an in-person meeting of the Steering Committee and expert panel on October 3 and 4, 2013 at the ACC Heart House. Members discussed and refined the QMs before a final score was obtained from each member of the expert panel. Candidate metrics were scored for validity and feasibility on a scale to 1–9, where 9 represented the most valid or most feasible. To be recommended for "open comment," a candidate metric required a mean validity score of 7–9 and a mean feasibility score of 4–9. Consensus among expert panel members was not required for approval during either round of scoring.

QMs recommended following the RAND-UCLA two-step process were posted on the ACC website for "open comment" from existing ACC ACPC members. Comments received during this process were reviewed and discussed by the Steering Committee and were used to modify the language of the QM. Final approval of the QMs was determined by a vote of the ACC ACPC Council.[31]

3 | RESULTS

3.1 | Literature review

Morbidity and mortality related outcomes post ASO among "simple" TGA patients are generally quite good.[3,12,17] However, patients remain at risk for arrhythmia. They are also at risk for myocardial ischemia

secondary to problems that occur during coronary artery transfer and secondary to more complex coronary artery anatomy as well as to the translocation process itself.[12] Common mid and late-term complications following ASO include aortic root dilation,[15] neoaortic valve insufficiency, supravalvar stenosis (e.g., aortic and pulmonary), and branch pulmonary artery stenosis.[3] Children who undergo ASO are also at risk for abnormal ND[19] as well as acquired cardiovascular disease (CVD).[25] Finally, transition of care to an adult provider represents a particularly vulnerable time for the child post ASO, providing an avenue for poor outcome.[33]

A formal systematic review was beyond the scope of this project. However, a thorough review of the existing literature was carried out to generate candidate metrics. We also searched and reviewed existing guidelines.[2,30,34] Existing guidelines regarding the management of TGA patients following ASO include the ACC/AHA 2008 Guidelines for the Management of Adults with CHD[34] and a single center study providing general recommendations for outpatient management post ASO.[2]

3.2 | Metric #1–#3: Electrocardiogram, Holter monitoring and exercise stress testing post ASO

The ASO procedure and the translocation of the coronary arteries poses a potential for immediate as well as mid-term and long-term complications related to compromised coronary artery perfusion.[35] Children with complex coronary artery anatomy (e.g., intramural course) are at particularly high risk for coronary artery stenosis and subsequent myocardial ischemia.[36] Sudden cardiac death post surgery is rare and has been reported in 0.3%–0.5% of all TGA/ASO patients.[9,37] Children are also at risk for arrhythmia.[6,10,38] However, rates of arrhythmia are low and 98% of ASO/TGA patients have normal sinus rhythm by Holter monitoring with occasional premature beats reported in approximately 50%. Rarely reported are episodes of supraventricular tachycardia or ventricular tachycardia following ASO.[39]

Exercise capacity following ASO is typically normal. Exercise testing has been considered useful for detecting exercise induced ischemia or arrhythmia.[40]

3.3 | Metric #4–#5: Echocardiogram evaluation

Neoaortic regurgitation (NAR), aortic root dilation (ARD), supravalvar pulmonary stenosis (SPS), and supravalvar aortic stenosis (SAS) are commonly reported mid and long-term complications post the ASO procedure.[2,13,17,41,42] NAR occurs early post ASO, is most commonly mild, but can progress especially among individuals with a history of size discrepancy between the pulmonary artery and aorta.[43] Freedom from moderate (or more) NAR is 98% at 1 year and 93% at 10 years.[42]

Aortic root dilation has been reported to occur in at least two-thirds of TGA/ASO patients[42] with a freedom from ARD at 10 years of 51%.[42] Furthermore, 10%–15% of TGA/ASO patients develop supravalvar pulmonary stenosis by 20 years after ASO.[9] Branch pulmonary artery stenosis is the most frequent reason for reintervention.[44]

Typically ventricular function post ASO is normal, however, mild left ventricular dysfunction can develop (e.g., EF 30%–45%) and may occur secondary to coronary artery stenosis.[16] Given these findings, echocardiographic monitoring has been proposed as a reasonable method of screening for these complications.

3.4 | Metric #6: Advanced imaging

It was the opinion of the TGA/ASO team that there are times when echocardiogram images are limited and additional imaging modalities are necessary to evaluate for the presence of common mid and long term complications post ASO. Computed tomography (CT),[45] magnetic resonance imaging (MRI) and cardiac catheterization with angiography[46] were proposed. Studies have shown that CT is a safe and feasible imaging modality for evaluating the coronary arteries in children 5–6 years of age.[45] Unfortunately, advanced imaging is costly and invasive (e.g., coronary angiography) and it remains unclear what percentage of TGA/ASO patients will ultimately require such testing for such a recommendation to be considered a QM.

3.5 | Metric #7: ND assessment

The ASO procedure and the circulatory arrest required to carry out the ASO procedure, places patients at a greater risk of neurocognitive delay with 27% and 40% greater prevalence of neurologic and speech impairments among TGA/ASO, respectively.[20] Heart surgery performed with circulatory arrest as the predominant support strategy is associated with a higher risk of delayed motor development and neurologic abnormalities at the age of one year.[19] Transient postoperative seizures following the ASO procedure also place children at greater risk for worse ND outcomes at ages 1–2½ years.[47] Among children status post TGA/ASO, weaknesses have been noted in expressive language, visual-motor integration, motor planning and organization, and oromotor control.[21–23] Given the prevalence of these complications, neurocognitive testing was proposed as a QM.

3.6 | Metric #8–#10: Screening for acquired CVD risk factors

It is well known that children with CHD are at risk for acquired heart disease, deconditioning and metabolic disease.[48] Studies suggest that children with TGA/ASO do not meet the recommended guidelines for physical activity[49] and many children with CHD have modifiable risk factors for premature CVD, including diets rich in high fat and sugar and poor in the recommended intake of fresh fruit, vegetables and lean meat.[50] Furthermore, children who have undergone surgical manipulation of the coronary arteries, such as TGA/ASO patients, have been shown to have abnormalities in coronary function in later childhood and may be at increased risk for atherosclerosis as adults.[2,25,48] Measurement of body mass index (BMI), blood pressure, and lipid screening are important and recommended according to existing guidelines.[30]

3.7 | Metric #11–#12: Transition plan

The AHA currently recommends that all adolescents have a written transition of care from the pediatric to the adult provider.[34] The AAP

TABLE 1 Candidate QM for TGA after ASO submitted to Steering Committee

Candidate measure	Numerator	Denominator
At least one echo in the first year of life, after ASO that reports on LV function, aortic root dimension, degree of aortic insufficiency (AI), patency of systemic and pulmonary outflows, branch pulmonary artery stenosis and coronary arteries.	Number of ASO patients reaching their first birthday for whom at least 1 echocardiogram has been performed and which documents left ventricular function, aortic root dimensions, degree of aortic regurgitation, nature of systemic and pulmonary outflow tracts and the branch pulmonary arteries	Number of ASO patients reaching their first birthday
ND assessment after ASO	Number of ASO patients age 24 months or more who have undergone formal, age-appropriate ND assessment within the previous 12 months and the number of patients ages 5–12 years who have undergone assessment within the previous 24 months	Number of ASO patients reaching the age of 24 months and the number of patients between 5 and 12 years
Assessment of lipid profile by age 11 years	Number of ASO patients age 11 years who have undergone assessment of lipid profile within previous 2 years	Number of ASO patients reaching their 11th birthday
Transition of care: patients with ASO (at age 18 or greater) with documented transition of care in the past 2 years	Patients following ASO, age 18 years with a transition plan documented in the medical record within the previous 2 years	Number of ASO patients age 18 years

recommends that this transition of care take place between 18 and 21 years of age.[29] The TGA/ASO team also recognized the importance of transition of case as well as reproductive health counselling.[28,29,39,51,52]

3.8 | Quality metrics

Final recommendations from the TGA/ASO group submitted to the Steering Committee are shown in Table 1. Twelve QMS were proposed by the TGA/ASO group (See Supporting Information Appendix 1). Of the 12 candidate QMs, 7 passed the RAND process and were recommended for review by ACC members during the "open comment period." Four QMs passed the "open comment period."[31] Selected QMs included: (1) the performance of at least 1 echocardiogram during the first year of life, after ASO, that reports the left ventricular function, aortic root dimension, the degree of neoaortic valve insufficiency, and the patency of systemic and pulmonary outflow tracts, the branch pulmonary arteries and the coronary arteries; (2) ND assessment after ASO; (3) assessment of lipid profile by age 11 years; and (4) documentation of a transition of care plan to an adult congenital heart disease (ACHD) provider within the prior 2 years for ASO recipients 18 years of age or older.

Candidate QMs that did not pass the RAND process included QMs related to reproductive health counseling, arrhythmia screening, stress testing and use of additional, more expensive imaging modalities; these candidate QMs did not pass due to low validity scores (i.e., mean validity score of 6 during round 1 and mean validity score of 4–5 during round 2) and a lack of sufficient evidence. In particular, the following QMs did not pass the RAND process: (1) patients after ASO should be provided with age appropriate reproductive health counseling on sexual health, contraception, and pregnancy beginning early adolescence; (2) a patient after ASO should undergo periodic electrocardiogram (ECGs); (3) a patient after ASO should undergo periodic Holter monitoring after the ASO; (4) a patient after ASO should have at least 1 stress test by age 11 years; and (5) advanced imaging (MRI, CT, cath) after ASO between 7 and 11 years of age.

Candidate QMs that passed the RAND process but that were not ultimately selected by the ACC ACPC Council following the "open comment period" included: (1) periodic echocardiogram monitoring beyond infancy following the ASO; (2) a patient after ASO should undergo regular surveillance of BMI and arterial pressure after ASO; and (3) provision of information outlining exercise recommendations after ASO. Although some single center studies suggested echocardiograms be performed every 1–2 years following ASO,[2] comments received during the "open comment period" stated that the proposed frequency of echocardiography after infancy among ASO recipients was too aggressive. Several comments were received with suggestions to include additional imaging modalities, beyond echocardiography alone and a recommendation to decrease the frequency of echocardiograms to every 3–5 years. A recommendation for annual visits with the pediatric cardiologist was also found to be excessive. Although it is recommended that BMI and BP be assessed yearly among all children,[30] not all children following ASO require annual visits with a pediatric cardiologist. Lipid levels, conversely, can typically be checked much less frequently and often with a single measurement between 9 and 11 years of age.[30] Finally, a recommendation for providing information outlining exercise recommendations was considered too difficult to measure as data would be difficult to collect from the EMR.[31]

4 | DISCUSSION

Since the first ASO procedure in 1975, associated mortality rates have declined and efforts now focus on ensuring appropriate and data driven mid-term and long-term follow-up. The current study is timely and unique in that it identifies methods for improving the care of children with TGA/ASO. To date, existing guidelines regarding the management of individuals with TGA/ASO have focused on adult

populations or single center studies.[2,34] The QMs created are now being utilized as a tool for data collection and quality improvement by 30 centers, participating in the Adult Congenital and Pediatric Quality Network—a national network of CHD centers dedicated to collecting and sharing data with the goal of providing best practice for CHD patients.[53]

Twelve candidate QMs were proposed and 4 were approved. The approved QMs provide valid and feasible methods for assessing quality and improving the care of "simple" TGA/ASO patients. The metrics are not intended to address the highest risk TGA patients, including those with complex TGA who are more likely to require reintervention or individuals with variant coronary artery anatomy who are at greatest risk for arrhythmia and sudden death.[54–56]

The selected QMs address, however, the most common complications and risks for poor outcome in the simple TGA/ASO patient population. The selected metrics include use of echocardiograms to identify anatomic problems, followed by identifying risk factors associated with acquired heart disease (i.e., lipid screening), ND screening and transition of care. Metrics addressing less common complications, such as arrhythmia and coronary artery stenosis, were not selected due to lack of evidence and significantly lower reported rates of such complications in the non-high risk TGA/ASO population.[20] More costly imaging modalities such as MRI, CT, and angiography were not selected as these tests may be of low yield in the majority of TGA/ASO patients.[57]

While not selected, screening BMI and arterial blood pressure should be performed at all ambulatory care visits regardless of the presence of TGA/ASO. Furthermore, even though a formal discussion of reproductive issues was not selected as a metric, it is quite possible that these discussions take place during the transition process.

Potential challenges with implementation of these metrics include variations in practice style, preference and limited resource availability. While echocardiograms are routinely performed and while lipid panels can be performed in the majority of children, ND and adult congenital resources may be limited. Future challenges will include not only making ND and adult congenital resources more readily available, but identifying appropriate QM for complex cases of TGA. The current metrics do not take into consideration special circumstances, such as variant coronary artery anatomy, the presence of a large VSD or the presence of risk factors for early mortality including left ventricular outflow tract obstruction, arrhythmia, weight less than 2.5 kg at time of ASO, or the need for extracorporeal membrane oxygenation.[38]

Standardized practices for addressing less critical complications following the ASO are also needed. For example, metrics that address how best to manage supravalvar stenosis, branch pulmonary artery stenosis and ARD are needed. Future efforts may include a potential role for biomarkers and the inclusion of studies that address risk stratification processes for those at greatest risk of SCD following ASO.

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CONFLICT OF INTEREST

None

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

Appendix 1

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