Can Abbreviated Cardiac Magnetic Resonance Imaging Adequately Support Clinical Decision Making After Repair of Tetralogy of Fallot?

Abstract

Quantification of pulmonary regurgitation (PR), pulmonary flow distribution, and ventricular function is important for clinical surveillance in repaired Tetralogy of Fallot (TOF). Cardiovascular magnetic resonance (CMR) is the established reference, but cost, test duration, and patient discomfort are potential limitations to its serial use. We investigated whether an Abbreviated CMR protocol would alter clinical decisions in TOF from those that would have been made using a full protocol. Patients > 7 years with repaired TOF were identified. CMR was performed according to standard complete imaging protocol. CMRs were prepared in two ways, Full and Abbreviated and submitted for review by two imaging specialists. In conjunction with clinical information and case-specific quantitative CMR data (PR fraction, ventricular volumes, ejection fraction, branch pulmonary artery flow), Full and Abbreviated image sets were anonymized and uploaded for review. For the first half, Imager 1 received Abbreviated, and Imager 2 Full and for the remaining, Imager 1 received Full and Imager 2 received Abbreviated. Blinded to the other's choices, Imagers provided clinical decisions. Inter-rater agreement for each decision was measured. In all, 124 studies from 80 patients (mean 17.8 years) were analyzed. For 'intervention versus no-intervention' decision, the inter-rater agreement was strong [κ 0.75, $p < 0.0001$, 95% CI (0.630, 0.869)]. Agreement for recommended timing of follow-up imaging was good (κ 0.64, $p < 0.0001$, 95% CI (0.474, 0.811)] in the 'no-intervention' group. When raters were asked whether or not further imaging was necessary, agreement was modest [κ 0.363 ($p < 0.0001$), 95% CI (0.038, 0.687)]. In conclusion, Abbreviated CMR yield decisions for clinical care similar to those made using the standard full protocol. These results suggest a potential enhancement of clinical practice in which efficiency and cost saving might be achieved using Abbreviated CMR for routine follow-up surveillance of TOF.

Introduction

Long-term survival and quality of life have consistently improved for individuals with repaired Tetralogy of Fallot (TOF), but several long-term

complications are well described [1,2,3]. Chronic pulmonary regurgitation (PR) [1, 3] as a result of right ventricular (RV) outflow tract reconstruction and subsequent remodeling can result in RV dilation and dysfunction, which in turn has been associated with exercise intolerance, arrhythmias, and sudden death [1]. When timely pulmonary valve replacement (PVR) is performed, there is often a reduction in RV size and an improvement in RV ejection fraction; however, if PVR is performed late, RV recovery is incomplete [4, 5]. Clinical and imaging surveillance for the adequacy of pulmonary valve and right heart function therefore assumes a critical role in care after TOF repair. Cardiac magnetic resonance (CMR) has well documented accuracy and reproducibility [6, 7] for quantitative assessment of biventricular size and function, flow measurements, and myocardial viability [8] and has emerged as an important tool for risk stratification in this patient population [9,10,11]. Notably, most investigations from which PVR criteria have been derived are based on CMR data [5, 12, 13], making CMR the current imaging modality of choice for surgical decision making in repaired TOF. Despite these advantages, lengthy standard CMR protocols render them inherently expensive and time consuming and increase cost and resource utilization. Concern over potential over-testing has led to the development of appropriate use criteria for echocardiography, cardiac CT, and CMR [14]. Published guidelines from the European Society of Cardiology, the Canadian Society of Cardiology, and the American Heart Association address recommended frequency of surveillance and imaging tests [15,16,17,18,19,20,21]. Despite guidelines, there is considerable variation in practice between providers and centers [22]. Best patient value is achieved by efforts to improve processes without compromising quality, which may be promoting the gradual shift within the cardiac imaging community from a broad diagnostic screening process to one of targeted testing. One approach to targeted testing is to develop imaging protocols for specific disease processes, eliminate the superfluous components of the examination, and thereby reduce cost, time, data redundancy, and need for anesthesia. This study is a retrospective comparison of clinical decision making in the management of repaired TOF with Abbreviated CMR versus standard complete CMR to test the hypothesis that complete and abbreviated protocols yield information of equivalent clinical relevance.

Methods

This was a single-institution study with retrospective data that were prospectively analyzed. Institutional Review Board approval was obtained and informed consent was waived for retrospective review of medical records. All patients > 7 years old with surgically repaired TOF followed in an academic children's hospital-based pediatric-adult congenital cardiology

group practice with complete CMR images on file from January 2008 to January 2015 were identified. Demographics, cardiac and surgical histories obtained from the institutional cardiology database included patient age, symptoms, most recent surgical or catheter-based intervention, QRS duration, echocardiogram results, and stress test results.

All CMR was performed according to Society for Cardiovascular Magnetic Resonance TOF imaging protocol on a 1.5-T scanner (Philips Medical Systems, Best, The Netherlands). Ventricular dimensions and function were assessed with an electrocardiographically gated steady-state free-precession cine magnetic resonance pulse sequence during brief periods of breath-holding in the following planes: ventricular two-chamber (vertical long-axis), four-chamber (horizontal long-axis), and short-axis planes (perpendicular to the ventricular long-axis plane on the basis of the previous four-chamber images), with 12 to 14 equidistant slices (slice thickness 8 mm, interslice space 0 mm) completely covering both ventricles [15]. Axial cine stacks and black blood sequences were acquired. Quantitative phase-contrast flow measurements were performed in the aorta, main and branch pulmonary arteries. Myocardial late enhancement (viability assessment) was performed 10–15 min after a magnetic resonance angiogram. The myocardial delayed enhancement protocol consisted of electrocardiogram-triggered, inversion-recovery prepared, fast-gradient echo pulse sequence acquisitions in the short- and long-axis planes.

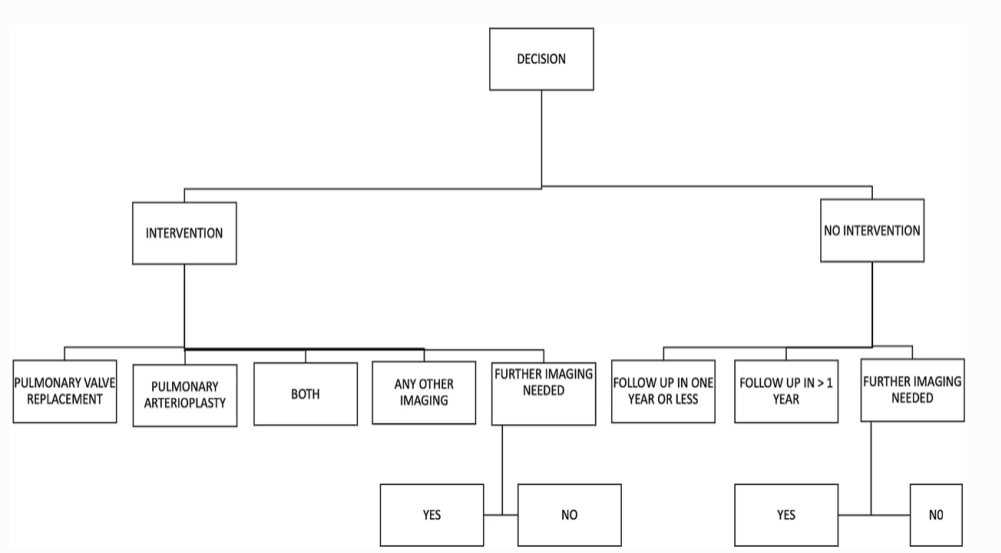
The CMR data were analyzed using commercially available software packages (Q-MASS; MEDIS Medical Imaging Systems, Leiden, The Netherlands). The end-diastolic and end-systolic volumes, stroke volumes, and EFs were measured. Ventricular end-diastolic volumes were adjusted to body surface area calculated using the Haycock formula [16]. CMRs were prepared in two ways (Full and Abbreviated) and submitted for review by two board-certified cardiac imaging specialists with advanced training in non-invasive imaging and over 5 years of experience (Imagers) who were knowledgeable in published guidelines for management of TOF [9, 13, 15, 17, 20, 21].

“Full” included all cines, two, three, and four chamber, outflow tracts, axial and short-axis stacks, black bloods, MR angiogram, three-dimensional isotropic whole heart, multiple phase-contrast flow acquisitions, and viability; “Abbreviated” protocol was designed to include all the images that would potentially yield the necessary data for clinical decisions in repaired TOF. It consisted of four chamber, outflow tracts and short-axis stack cine, and phase-contrast flow data of the main and branch pulmonary arteries. Both image sets were de-identified and uploaded to http://www.precessionsaas.com, a secure cloud-based SAAS (software as a service) system (Heart Imaging Technologies, Inc., Durham, North Carolina). Using the web-based system

allowed blinded and convenient access to the image groups assigned to each reader [23].

For half the cases, Imager 1 received Full and Imager 2 received Abbreviated sets along with identical case-specific quantitative CMR data. The CMR data included measured PR fraction, indexed biventricular volumes, ejection fraction, and branch pulmonary artery flow; clinical information included age, surgical and interventional history, current symptoms, QRS duration, and results of echocardiogram, stress test, and any cardiac catheterization hemodynamic data. For the other half of the sample, Imager 1 received Abbreviated sets, and Imager 2 Full sets. Both Imagers received the full complement of clinical information. Blinded to the other's choices, Imagers provided clinical decisions as outlined in the flow chart (Fig. 1). We then studied agreement in clinical decisions between the Abbreviated group and the Full group. For the studies with discordant decisions, the reader who received the Abbreviated set of images was given the Full set for a blinded review and decision making. The discordant decisions were then re-analyzed.

Fig. 1



Clinical decision chart

Variables were expressed as mean ± standard deviation and ranges. Threshold for statistical significance was $p < 0.05$. Inter-rater agreement for each decision was measured using the κ statistic. κ Statistics and their corresponding 95% confidence intervals were calculated to measure agreement. PC SAS version 9.4 (SAS Institute, Inc., Cary, NC) was used for all analyses.

Results

The study population consisted of 80 patients with 124 CMR examinations. There were 53 males and 27 females. Patient characteristics including age, height, weight, and CMR data are summarized in Table 1.

Table 1 Demographic characteristics and CMR data of the 124 studies

Variables	Values
Patient demographics	
Age (years)	18.5 (8.8–54.1)
Height (cm)	165 (124–193)
Weight (kg)	64 (25–137.4)
Body surface area (m^2)	1.7 (0.9–2.7)
CMR data	
Right ventricle end-diastolic volume index (ml/m^2)	124.2 ± 32.6 (56.5–219)
RV EF (%)	42.5 ± 8.8 (12–60)
LV EF (%)	55.1 ± 7.3 (32–77)
PR (%)	31.3 ± 19.8 (0–82)
Stress test $V_{O_2}max$	34.4 (16–54)

Data expressed as mean ± standard deviation

There were 124 CMR studies, each of which had a Full and an Abbreviated form, and upon these 228 decisions were based. Eighty-five percent of clinical decisions were concordant between the Imager using the Abbreviated image set and the Imager using the Full image set. There were a total of 35 disagreements, 9 of which were in the intervention versus no-intervention decision, 14 regarding the time recommended until next follow-up, and 12 with respect to the need for further imaging now. Only in a minority (9) of these 35 ambiguous cases could disagreement be resolved by providing the Abbreviated reader, the Full image sets.

For intervention versus no intervention, the inter-rater agreement was strong [κ0.75, $p < 0.0001$, 95% CI (0.630, 0.869)]. There were nine disagreements, only two which were resolved by review of Full image sets by the Imager who originally received the Abbreviated format. In the no-intervention group, agreement regarding recommended follow-up was good [κ 0.64, $p < 0.0001$, 95% CI (0.474, 0.811)]. There were 14 disagreements, of which 4 were resolved based on Full image sets by both Imagers. Inter-rater agreement was modest for whether further imaging was necessary [κ 0.363, $p < 0.0001$), 95% CI (0.038, 0.687)]. There were 12 disagreements in this category, 3 of which were resolved when Full data were supplied to both Imagers (Table 2).

Table 2 κ Analysis of decisions between the complete and abbreviated imaging sets

Decision	κ values, p values (95% CI)
Intervention versus no intervention	0.75, $p<0.0001$ (0.630, 0.869)
Recommended follow-up in no-intervention group	0.64, $p<0.0001$ (0.474, 0.811)
Necessity of further imaging	0.363, $p<0.0001$ (0.038, 0.687)

Discussion

The main finding of this investigation is that Abbreviated CMR protocols and standard Full CMR protocols result in similar clinical decisions in the repaired TOF population. The strongest agreement between Abbreviated CMR-based and Full CMR-based decision making was on the critical question of whether to recommend intervention or not. Even when recommendations differed, revelation of the Full CMR to the Imager who had previously worked from the Abbreviated CMR did not often result in a change of recommendation, suggesting that the divergence in decision making likely reflects a difference in physician practice pattern rather than an influence of the use of Abbreviated versus Full CMR.

Current guidelines propose an integrated multimodality imaging approach for repaired TOF patients involving echocardiography, CMR, CT, diagnostic catheterization [24]. In pre-adolescents, CMR is recommended when the clinical and echocardiographic data are inconsistent or suggestive of disease progression [24]. In late adolescents and adults however, CMR is recommended as a routine surveillance test, since the hemodynamic burden of residual lesions is likely to have become more significant and echocardiographic windows are often more restricted. Despite these practice guidelines and consensus-based appropriate use criteria, there is wide variation in practice patterns [22]. This is especially noteworthy in the context of burgeoning utilization of CMR globally for congenital heart disease. A 40% increase in CMR for the primary indication of CHD has been reported in the UK over only a 2-year period [25]. Within the US, similar trends of increasing CMR utilization for CHD are well documented [26,27,28]. Our own institutional series revealed 0.14 CMR or CT examinations per patient year of observation in repaired TOF patients [22].

Because we did not find major differences in clinical decision making based on Abbreviated and Full CMR, it is appropriate to explore potential benefits of using an abbreviated protocol for routine surveillance. The Abbreviated CMR protocol outlined in our study would accomplish the key goals of routine surveillance for repaired TOF [24], which includes accurate quantitative assessment of biventricular volumes, ventricular mass, stroke volumes, and

ejection fractions. It would also evaluate regional wall motion abnormalities and define the anatomy of the RV outflow tract, main and branch pulmonary arteries, aorta, and allow quantification of PR, cardiac output, and intra-cardiac shunts. Additionally, the abbreviated protocol does not include gadolinium administration eliminating the need for intravenous access and limiting exposure to the potential adverse effects of gadolinium [29, 30].

An abbreviated protocol would decrease acquisition and interpretation times. Although we did not acquire these data in the present study, based on our experience, a Full CMR protocol for TOF takes approximately twice the scanning time compared to the proposed abbreviated protocol. This could increase CMR operational throughput and more efficient utilization of the CMR equipment. This increased throughput in appropriate circumstances is likely to result in decreased wait times for patients, and resultant improved patient satisfaction [31]. Decreased acquisition and interpretation time would also potentially increase physician time-efficiency, a key resource driver in calculating internal costs and a powerful measure in the value equation [32].

While there are limited data in the congenital heart disease population about the utility of abbreviated imaging protocols, this is well studied in other radiology protocols such as cancer radiology. Abbreviated breast MRI protocols have successfully been used to shorten acquisition and interpretation times while maintaining diagnostic accuracy, and have allowed increased access to MRIs for screening in a high-risk population [33,34,35]. In a similar way, Abbreviated CMR could find particularly valuable application for select patients who have unsatisfactory prior echocardiographic tests. Instead of attempting repeat echocardiography, which would likely result in unrecoverable cost and lost time, an Abbreviated CMR may find application in this circumstance as a first-line imaging tool.

An abbreviated study with shorter acquisition times would be better tolerated from a patient comfort standpoint as well. Anxiety-related issues ranging from complaints about the duration of the test to psychological distress, panic, and claustrophobia are not infrequent in MRI suites. These may even result in aborted studies or images of poor diagnostic value, which would result in non-recoverable staff and equipment time [36]. Furthermore, CMR in young children is usually performed under general anesthesia, as the patient must essentially remain immobile within a cardiac coil for several minutes. Sedation or general anesthesia carries risks and can have adverse consequences—published data suggest significant rates of sedation-related adverse events (3.8% with conscious sedation, 9.2% with deep sedation) [37, 38]. While the majority of patients in our study were older and did not require anesthesia, the other disadvantages of a long CMR scan remain [39,40,41].

Concerns regarding missed findings present the major barrier to implementing an abbreviated protocol. While it is inevitable that an abbreviated study will not reveal all the information that a Full CMR does, a thorough pre-scan checklist including review of prior echocardiogram, prior CMR, and the clinical question at hand should ensure that information is not missed as a result of an abbreviated study. There certainly will be cases in which a Full CMR at follow-up would be the optimal test. While there is value in performing a Full CMR as a baseline study in adolescence, once it has been established that the patient does not have any additional anatomic or physiologic considerations that warrant a Full CMR at follow-up, an Abbreviated CMR would be a potentially efficient follow-up surveillance imaging strategy.

Widespread implementation of such an abbreviated protocol would require investment in the training of CMR technologists to consistently follow the intended imaging protocol. Real-time quality control is mandatory to confirm adequacy of images prior to patient leaving the scanner and is expected to minimize the need for additional studies. In actual clinical situations, decisions are usually consensus driven with input from the cardiologist, the surgeon, and the patient. It is therefore inevitable that CMR data alone, while critically important, will not be the sole determinant of patient care. Guidelines notwithstanding, a more aggressive team may choose to respond to a given CMR result with intervention, while a more conservative one might not, regardless of whether the CMR was abbreviated or full. We conclude from this investigation that Abbreviated and Full CMR provide similar decision support in the setting of repaired TOF, so cost effectiveness analysis would be a logical next step to evaluate the financial implications of abbreviated imaging protocols in congenital heart disease.

Limitations

This was a retrospective study of clinical decision making and carries limitations inherent in a retrospective design. The only outcome studied was whether the decisions made were based on Abbreviated and Full CMR, whereas we could not evaluate whether the decisions made using the Abbreviated CMR were in fact clinically appropriate. Our study design also did not allow for capture of acquisition and interpretation times of both groups or for cost analysis of the abbreviated study versus complete study. The patient population was heterogeneous, and included many potential confounders, including diverse ages at intra-cardiac repair and at entry into the study, and the patients were heterogeneous with regard to prior palliative shunts and subsequent surgical and catheter-mediated cardiac procedures. While this is an advantage in that it reflects the clinical realities of surgically modified TOF, the influences of the many clinical factors on the use of Abbreviated versus

Full CMR for decision making could not be effectively addressed. Additionally, the abbreviated protocol did not involve evaluation of myocardial scar burden by delayed myocardial enhancement, which may be important in select patients.

Conclusions

In our study, Abbreviated CMR data yielded decisions for clinical care similar to those made using standard CMR. These results suggest a potential enhancement of clinical practice in which efficiency and cost saving might be achieved using Abbreviated CMR for routine surveillance of repaired TOF.

Abbreviations

CMR:

Cardiac magnetic resonance

TOF:

Tetralogy of Fallot

PVR:

Pulmonary valve replacement

PR:

Pulmonary regurgitation

RV:

Right ventricular

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Ethics declarations

Conflict of interest

There is no disclosure of potential conflicts of interest.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the Ethical Standards of the Institutional and/or National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent

Our study is retrospective study, that the study formal consent is not required.

- **Adult congenital heart disease,**
- **Cardiovascular magnetic resonance**