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To Evaluate the Diagnostic and Economic Impact of Additional Cardiac Magnetic Resonance Interrogation (CMR) To Routine Clinical Practice in Patients for Tissue Characterization and Cardiac Volume Evaluation in Pakistan.

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Abstract: ***Introduction***: Cardiac magnetic resonance imaging (CMR) plays a very important role in patients with congenital heart defects as well as cardiomyopathies in addition to usual myocardial perfusion and viability studies though its utilization is not widespread in Pakistan. ***Objective***: In this study, we aimed to assess diagnostic utility as well as economic impact of CMR in terms of avoiding unnecessary interventions and modifying treatment plan in resource constraint country setting. ***Material and Methods:*** This non-interventional descriptive cohort study was conducted at The Children's Hospital, Lahore, Pakistan. All consecutive patients referred for CMR from December 2015 to May 2018 were enrolled. Any difference in diagnosis or change in medical or surgical plan, estimated cost prevented or additional cost incurred was calculated using averaged institutional procedural cost as landmark. Patients were followed up for at least 3years. ***Results***: Out of 163patients, 97% (159/164) completed the test. Mean age was 22+13yrs. Male to female distribution was 2.6:1. Ninety-four patients (59%) required chamber volume assessment while 65 (41%) myocardial tissue characterization. Clinical management changed in 113 (71.1%) patients. Major economic benefit was noted in 19 patients as well as 14 patients with prohibitive surgical risk with median expense saved over 3 years was PKR 141,300/patient CMR. ***Conclusion***: CMR is even more pertinent in resource limited countries as it not only optimizes patient care but also helps in reducing cost by defining optimal timing for intervention.

Keywords Congenital heart defect, Cardiomyopathy, Cardiac magnetic resonance.

INTRODUCTION

Magnetic resonance imaging is a well-established, safety proven modality and is used across the world with important diagnostic, prognostic and therapeutic implication in various fields of medicine and surgery. Cardiac magnetic resonance imaging (CMR) is also gaining widespread importance mainly due to its radiation free technique1. Accurate tissue characterization and cardiac volume evaluation have been a hallmark of CMR in addition to cardiac perfusion and tissue viability assessment2,3. CMR has recently started to gain momentum in Pakistan as well, however it is not reaching its maximum potential.

The main reasons for the slow adoption and utilization of this modality remains lack of knowledge on part of practicing physicians being unaware of the

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impact of this investigation both in terms of diagnostic accuracy as well as future treatment plan4. Other reasons include paucity of facilities performing the test, time consuming data accusation and processing, requirement of being able to lie supine and hold breath up to 8 seconds, sometimes longer and difficulty in acquisition in presence of arrhythmias4.

CMR plays a very important role in children and adults with congenital heart defects, not only for improved dynamic images but also for ventricular volume assessment. Similarly, CMR has a pivotal role in diagnosis and long term management of both right and left heart cardiomyopathies. In this study, we aimed to assess the improvement in diagnosis in these patients and clinical as well as economic impact of this modality in terms of avoiding unnecessary interventions and directing a focused treatment plan. It will help to identify the conditions where CMR has profound impact on patient management, thus reinforcing the need for CMR and promote its due utilization[5].

MATERIALS AND METHOD:

The study was conducted at The Children's Hospital and Institute of Child Health, Lahore, Pakistan between 1st December, 2015 to 30th May, 2021 after obtaining written consent from the patients or their parents in case of minor children. It was a non-interventional descriptive cohort study. All consecutive patients referred for CMR were enrolled in the study after obtaining written consent. Biophysical profile was recorded each child or adult. Details about disease, reason for referral and anticipated plan was documented through patient history and referring physician/surgeon notes. Pre-procedure diagnostic reports were assessed and recorded. CMR was performed following routine hospital protocols including quality assurance and safety. Total duration for data acquisition and amount of contrast agent (if used) was documented. Post processing report was evaluated for diagnostic points including cardiac anatomy and ventricular volumes. Any difference in diagnosis from previous investigations was assessed. Any change in treatment plan was also recorded. In case of a change in medical or surgical plan, estimated cost prevented or additional cost incurred was calculated using averaged institutional procedural cost as landmark. Patients were followed up for 5years or next intervention through telephonic feedback. The data was entered in SPSS v. 20 and analyzed using its statistical software. Mean with standard deviation was calculated for normally distributed data. Median with range was used for non-normal distribution variables confirmed through Kolmogorov-Smirnov or Shapiro-Wilk test. Frequencies were calculated for nominal data. Student's T test was used to find statistically significant difference between variables if applicable considering $p<0.05$ as significant.

RESULTS:

One hundred and sixty three consecutive referred patients for cardiac tissue characterization or chamber volume assessment were included in the study. Three patients could not complete the test due to claustrophobia and one patient due to extremely variable rhythm with frequent multifocal ectopic beats. A total 159 patients successfully completed the test. Success rate to test completion was 97% (159/164). Mean age was 22±13yrs (Median 17yr, range 4-76yrs). Mean height was 1.55m (Median 1.6m, range0.71-2.0m). Mean weight was 51kg (Median 51kg, range 13-102kg) and mean surface area 1.46m^2 (Median 1.52m^2, range 0.6-2.2m^2). Male to female distribution was 2.6:1. Mean time required was 66min (Median 65min, range 35-95min). Intravenous bolus contrast was used in 116 patients (73%).

In a broader distribution, 94 patients (59%) required chamber volume assessment while 65 (41%) required myocardial tissue characterization.

Mean age for patients requiring chamber volume assessment was 19±9yrs (Median 17yr, range 4-47yrs). Mean height was 1.56m (Median 1.6m, range0.99-2.0m). Mean weight was 49kg (Median 48kg, range 14-102kg) and mean surface area 1.44m^2 (Median 1.45m^2, range 0.6-2.2m^2). Male to female distribution was 3.3:1. Mean time required was 64min (Median 65min, range 40-90min). Contrast agent was used in 58 patients (61.7%) where additional information about tissue characteristics was required. Mean age for patients requiring tissue characterization was 26±17yrs (Median 21yr, range 5-76yrs). Mean height was 1.54m (Median 1.6m, range0.71-1.93m). Mean weight was 54kg (Median 56kg, range 13-95kg) and mean surface area 1.51m^2 (Median 1.58m^2, range 0.6-2.1m^2). Male to female distribution was 1.95:1. Mean time required was 71min (Median 75min, range 35-95min). Contrast was injected in 58 patients (89%) patients while 7 (11%) undergoing iron load assessment required no contrast.

Most commonly confirmed conditions were pre or post-operative ventricular volume status in congenital heart defects (n=92, 57.8%), (Table 1). In preoperative assessment cases, 13 patients had no prior surgery, 5 required planning for second stage surgery (Table 2). In 74 postoperative patients, complications were assessed including ventricular volumes and conduit interrogation, (Table 3). Out of the total, nearly a quarter (n=44, 27.7%) reaffirmed the original echocardiographic, ECG or clinical assessment. Nearly half of the patients (n=80, 50.4%) had more advanced disease or significant additional finding leading to increased medication or even change in

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management. On the other hand, around 22% (n=35) had significantly better cardiac status deferring imminent change in medication or even surgery.

Impact on clinical management:
Clinical management changed in 113 (71.1%) patients. Out of these, 62% had a major change in treatment strategy (Figure 1). CMR was helpful in advising earlier surgery or cardiac catheterization including radiofrequency ablation than anticipated in 46 patients, deferred immediate surgery in 19 patients and advised against surgery due to prohibitive risk in 14 patients. The rest of patients had reassurance about efficacy of previously prescribed medications.

Changes in dose of previously prescribed medication or addition of new drugs did improve patient condition without any significant increase in cost. Early surgical referral also helped in optimizing patient condition. The major economic benefit was noted where immediate surgery was averted in 19 patients (median PKR 475,000, range PKR 385,000-675,000), a cumulative amount of PKR 8,075,000 (USD 48,065). A further expense was averted in 14 patients where surgical risk was prohibitive (median PKR 415,000, range PKR 225,000-635,000), cumulative amount of PKR 5,392,000 (USD 32,095). Hence, immediate gross economic benefit was found to be over PKR 13,467,000 (USD 80,160) or PKR 115,100/patient CMR (USD 677/patient CMR) for patients already planned for surgery before CMR result changed management plan. Figure 2 demonstrates median expected and actual expenditure per patient over 3 years post CMR test showing an average PKR 141300/patient CMR saved. Thus, the modality not only improves clinical outcome but also is cost effective preventing undue expenditure.

DISCUSSION:

CMR is an advanced imaging technique using magnetic resonance instead of the usual radiation based imaging modalities in cardiac assessment. The radiation free imaging makes CMR a very attractive modality in line with echocardiography but with much better spatial resolution[2]. Thus, it equals echocardiography for structural analysis and well surpasses in ventricular and atrial chamber volume assessment with more precise and reproducible functional status in terms of ejection fraction, cardiac output and indirectly measuring Qp to Qs ratio[1].

Right ventricular (RV) volume is one aspect in which CMR surpasses all other imaging modalities including computerized tomographic angiography, conventional angiography and echocardiography[6]. Though 3D echocardiography is showing some promising advancements, CMR is still considered gold standard for RV volume and function assessment[7]. In our study, this was the most frequent indication for conducting CMR. As documented, echocardiographic assessment frequently did not provide correct volume and function assessment. Difference in measurement frequently led to change in management plan showing the benefit of CMR in this subgroup[2].

Left ventricular (LV) assessment is extensively tested through computerized tomography angiography (CTA), conventional cardiac catheterization and 2D/3D echocardiography reporting comparable results with CMR. Despite these reports, CMR is still gold standard for LV volume and function assessment[1]. Non interventional radiation free analysis puts this modality ahead of CTA and angiography. 3D echocardiography is still unable to assess LV if it has a modified dimension or in congenital heart with variable interventricular septation[2]. This makes CMR essential in labeling any cardiac chamber hypoplastic, critical information leading to surgical plan. In our study, such investigation helped at least 3 individuals to be managed as with biventricular rather than univentricular heart, significantly improving long term prognosis.

A feature unique to CMR is the ability to characterize normal and abnormal myocardium[8]. Tissue characterization in terms of myocardial perfusion and viability equals if not exceeds accuracy to nuclear scans without radiation[9]. Myocardial perfusion studies can precisely identify the culprit coronary vessels responsible for ischemia through their area of distribution[10]. The ability to differentiate ischemia from necrosis has been compared with actual tissue biopsy and found to accurately detect viable tissue. It has significant prognostic value to patients undergoing coronary bypass surgeries. This aspect is well studied and established and therefore not included in our cohort. Our focus remained on non-ischemic abnormalities that can be identified through CMR[3]. We were not only able to identify a significant number of patients with Arryhthmogenic RV cardiomyopathy (ARVC) but also directed electrophysiological intervention towards healthy myocardium, excluding regions with fibrosis improving interventional success rate. Various myocardial diseases ranging from acute myocarditis to chronic ailments like sarcoidosis and amyloidosis produce typical contrast distribution leading to accurate diagnosis and focused treatment in otherwise "idiopathic" cardiomyopathy[3]. Identifying subclinical persistent myocarditis in our data helped modification in treatment stopping progression of myocardial inflammation and leading to earlier normalization. Chagas disease, Anderson Fabry disease can be identified and turn a potentially lethal condition to completely normal status with accurate management[11,12].

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Cardiac tumors and clots can be accurately identified through CMR, otherwise impossible without an open biopsy[13]. In our cohort, primary and metastatic tumors were identified otherwise considered as clots on echocardiography helping in modifying anticancer therapy and avoiding undue anticoagulation in patients with already thrombocytopenia or bleeding diathesis. It avoided possible risk of hemorrhage associated morbidity.

Myocardial iron load detection is another extremely crucial investigation that is only possible through CMR and does not even require contrast injection[14]. In our data, patients with thalassemia had complete change in their chelation regimen based on CMR results preventing and even reversing cardiac impaired functions.

A negative study also helps to prognosticate and adjustment in medical management. Idiopathic dilated or hypertrophied cardiomyopathies were more accurately followed through serial CMR delivering more consistent and standardized cardiac output and myocardial mass[15]. It helped in discontinuing various medications safely that were no longer necessary with greater confidence.

Economic impact was two fold in our setting. In a resource constrained setting, the above mentioned assessments using CMR lead to optimize treatment strategy. The most important impact was on delaying surgery safely in congenital heart defects (CHD). A typical subgroup in this scenario was patients with congenital heart defects having undergone RV outflow tract (RVOT) resection. Younger patients with Tetralogy of Fallot and other CHDs requiring RVOT resection during surgical repair tend to develop marked pulmonary regurgitation. Prosthetic pulmonary valve is not available for younger patients hence it is done at a relatively older age. The optimal timing of valve replacement is medically and to some extant economically important in our setting. If valve replacement is done too early in a small child, the valve becomes small for the growing patients in a relatively short period, requiring a repeat open heart surgery and a new larger prosthetic valve, This incurs additional risk of complications from a second open heart surgery as well as additional cost for reoperation as well as a new prosthetic valve. Delaying too much on the other hand, leads to RV dilation and irreversible impaired RV systolic functions. Furthermore, underlying RV fibrosis leads to increased risk of ventricular arrhythmias, a potential cause of sudden death. The optimal time in such scenario is best dictated by CMR analysis balancing the pros and cons guiding the best management timeline[16,17].

CMR has certain constraints[4,18]. One of the main limiting factors is requirement of holding breath for artifact free imaging. Younger age or unstable patients cannot undergo CMR. Such individuals need general anesthesia from conducting CMR requiring additional MR compatible equipment and trained work force. Long acquisition time is also a major setback. Normal acquisition time range between 45 min to 90min as also documented in our data. Though, it significantly decreases to lower limits as institution gains experience. Claustrophobia can be challenging, though can usually be overcome by mock practice. Frequent arrhythmias limit assessment and make the results inaccurate. In such circumstances, alternate modalities have to be employed.

Limitations:
This data does not include younger children due to unavailability of anesthesia. It is a single center experience but there is hardly any other center in Pakistan performing CMR for conditions highlighted here and multicenter data was not possible.

Conflict of interest: None.
***Financial disclosure*:** None.

CONCLUSION:

CMR plays an important role in management of patients with congenital heart defect and cardiomyopathies. This modality is even more pertinent in resource limited countries as it not only optimizes patient care by improving diagnosis but also helps in reducing cost by defining optimal timing for intervention.

Table 1: Frequency of various conditions confirmed on CMR.

Condition	Frequency	Percentage
Pre or Post-operative Congenital heart defect for ventricular volume assessment	92	57.8%
Dilated/Hypertrophied/Restrictive cardiomyopathy	21	13.2%
RV cardiomyopathies including arrhythmogenic right ventricular cardiomyopathy (ARVC)	14	8.8%
Cardiac hemosiderosis (Iron overload in Thalassemia)	8	5%
Valvulopathies/ vasculopathies including tricuspid valve anomalies, idiopathic pulmonary artery or aortic root dilatation	8	5%
Acute myocarditis	5	3.1%

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Cardiac tumors	5	3.1%
Constrictive pericarditis	1	0.6%
Normal	5	3.1%

Table 2: Pre-operative assessment in congenital heart defects and impact:

Assessment for 1st stage /corrective surgery (n=13)		Major change in surgical strategy (univentricular vs. biventricular /palliative vs. corrective repair)	Minor change in surgical strategy (Approach /Technique)	No change in course of management
	Assessment of right ventricular volume (n=5)	4 (80%)		1 (20%)
	Assessment of left ventricular volume (n=2)	2 (100%)		
	Pulmonary vein anomaly(abnormal connection/stenosis) (n=3)		2 (67%)	1(33%)
	Coarctation of the aorta (n=1)		1 (100%)	
	VSD committability in double outlet right ventricle (n=2)	2 (100%)		
Assessment for 2nd stage /corrective surgery (n=5)		Major change in surgical strategy (univentricular vs. biventricular /palliative vs. corrective repair)	Minor change in surgical strategy (Approach /Technique)	No change in course of management
	Assessment of LV mass/volume (Congenitally corrected transposition of great arteries post PA banding, n=3)	2 (67%)		1 (33%)
	Assessment of RV volume (Complete atrioventricular septal defect post PA banding, n=2)	2 (100%)		

Table 3: Post-operative assessment in congenital heart defects and impact:

	Major change in surgical strategy (valve replacement/ repair)	Minor intervention (balloon valvuloplasty /angioplasty /stenting)	No change in course of management

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Assessment of conduit complication (n=7)	3 (43%)	3 (43%)	1 (14%)
Assessment of associated complications including RV volume (n=67)	45 (67%)	1 (1.5%)	21 (31.5%)

Figure 1: Distribution of type of change in treatment or clinical management following cardiac MRI.

Figure 2: Expenditure in patients with planned surgery prior and after CMR over 3yr follow up.

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