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Impact of Stress Cardiac Magnetic Resonance Imaging on Clinical Care

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Abstract

Given the rising costs of imaging, there is increasing pressure to provide evidence for direct additive impact on clinical care. Appropriate use criteria (AUC) were developed to optimize test-patient selection, and are increasingly used by payers to assess reimbursement. However, these criteria were created by expert consensus with limited systematic validation. The aims of this study were therefore to determine: 1) rates of active clinical change resulting from stress cardiovascular magnetic resonance (CMR) imaging; and 2) whether the AUC can predict these changes. We prospectively enrolled 350 consecutive outpatients referred for stress CMR. Categories of "active changes in clinical care" due to stress CMR were pre-defined. Appropriateness was classified according to the 2013 AUC. Multivariable logistic regression analysis was used to identify factors independently associated with active change. Overall, stress CMR led to an active change in clinical care in about 70% of patients. Rates of change in clinical care did not vary significantly across AUC categories (p=0.767). In a multivariable model adjusting for clinical variables and AUC, only ischemia (OR 6.896, 95% CI 2.637–18.032, p<0.001), known CAD (OR 0.300, 95% CI 0.161–0.559, p<0.001), and age (OR 0.977, 95% CI 0.954–1.000, p=0.050) independently predicted significant clinical change. In conclusion, stress CMR made a significant impact on clinical management, resulting in active change in clinical care in about 70% of patients. AUC categories were not an independent predictor of clinical change. Clinical change was independently associated with presence of ischemia, absence of known CAD, and younger age.

Keywords

Cardiovascular magnetic resonance imaging; stress testing; appropriate use criteria

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INTRODUCTION

The appropriate use criteria (AUC) for stress cardiac-magnetic-resonance (CMR) have recently been published as part of a multimodality approach to detection and risk assessment of stable ischemic heart disease[1]. These criteria were created by expert consensus with limited systematic validation[2–10] – particularly for CMR. We recently reported downstream utilization rates of angiography and revascularization procedures after stress-CMR, based on the most recent AUC[11]. However, stress CMR routinely provides significant information beyond ischemia assessment[12, 13]. We therefore hypothesized that the overall clinical impact of stress-CMR may extend beyond just angiography and revascularization procedures to other aspects of patient management and care[14]. Moreover, given that the purpose of the AUC is to optimize test-patient selection, one might expect it to predict active change in clinical management resulting from the test[15]. The aims of this study were therefore: 1) to determine overall rates of active clinical change resulting from stress CMR in the outpatient setting; and 2) to determine whether the AUC can predict these rates of active change.

METHODS

350 consecutive outpatients referred for CMR stress testing were prospectively enrolled in a single academic medical center. Patients were excluded if they had metallic implants incompatible with CMR, glomerular filtration rate < 30 ml/min, high degree atrio-ventricular block, severe active wheezing from asthma or severe claustrophobia. Subjects were asked to abstain from caffeine-containing products for at least 12 h prior to the test. Information on baseline demographic variables and prior laboratory testing was obtained from patient interviews and the electronic medical record. Patients gave informed written consent for the protocol, which was approved by the local institutional review board.

Images were acquired on a 3 T scanner (Philips Achieva, Philips Medical Systems, Best, the Netherlands) using a six-element phased-array receiver coil as previously described[16]. Steady-state free-precession cine images were acquired in multiple short-axis and three long-axis views (repetition time, 3.0 ms; echo time, 1.5 ms; flip angle, 40°; slice thickness 6 mm).

The patient table was then partially pulled outside the scanner bore to allow direct observation of the patient and full access. A 0.4 mg bolus of regadenoson (Lexiscan, Astellas Pharma Inc) was infused under continuous electrocardiography and blood pressure monitoring. Approximately 1 min after regadenoson administration, the perfusion sequence was applied and Gadolinium contrast (0.075 mmol/kg gadoteridol, Bracco Diagnostics) followed by a saline flush (30 ml) was infused (4.5 ml/s) via an antecubital vein. On the console, the perfusion images were observed as they were acquired, with breath-holding starting from the appearance of contrast in the right ventricular cavity. Imaging was completed 10 to 15 s after the gadolinium bolus had transited the left ventricular myocardium. Perfusion images consisted of three to four short-axis slices obtained every heartbeat with a saturation-recovery, gradient-echo sequence (repetition time 2.8 ms; echo time 1.1 ms; flip angle 20°; voxel size, $2.5 \times 2.5 \times 8$ mm). Aminophylline (100 mg IV) was

administered immediately after stress perfusion imaging[16]. Rest perfusion images were acquired 15 min after stress imaging with an additional contrast bolus (0.075 mmol/kg gadoteridol) using identical sequence parameters. Five minutes after rest perfusion, late gadolinium enhancement (LGE) imaging was performed with a 2D segmented gradient echo phase-sensitive inversion-recovery sequence in the identical views as cine-CMR. Inversion delay times were typically 280 to 360 ms. Perfusion and LGE images were visually interpreted by standard methods[12].

Two general cardiologists reviewed all clinical information dated before the CMR stress test. These reviewers were blinded to the results of the CMR and to the clinical course subsequent to the test. The CMR stress tests were classified as "appropriate', "maybe appropriate" or "rarely appropriate" as defined by the 2013 AUC[1]. A third blinded independent physician adjudicated any discrepancy between the interpreters.

Two general cardiologists blinded to AUC classification independently assessed the clinical impact of each stress CMR by review of the electronic medical records through to the next outpatient visit with the ordering provider. If referral for coronary angiography was made then occurrence of revascularization was noted. Clinical impact was defined a priori in one of the following two mutually exclusive categories: 1) active change in care and 2) no change in care. Categories of active change included referral to coronary angiography, revascularization, pre-operative clearance, medication change, subspecialty referral, ordering of additional diagnostic testing, and discharge from cardiology clinic. Categorization strictly required the presence of a statement by the referring physician in the follow-up clinical note - stating that the change (e.g. discharge from clinic or medication change) was initiated as a result of the stress CMR results. Patients could be included in more than one category of the active change group.

Normally distributed data were expressed as mean ± SD. Continuous variables were compared by the Student's t-test or Wilcoxon rank-sum (depending on data normality). Comparisons of discrete variables were made using the chi-square test; Fisher's exact test was used when the assumptions of the chi-square test were not met. To identify which clinical indices were associated with active clinical change, we performed univariable (unadjusted) logistic regression analysis to estimate the unadjusted odds ratios (OR) and the 95% confidence intervals (CIs) for baseline clinical variables and AUC categorization. For the multivariable model, covariates were chosen on the basis of established clinical risk factors as well as significant univariate predictors (at $p < 0.10$) from the list of baseline characteristics. A p value of < 0.05 was considered statistically significant.

RESULTS

Table 1 summarizes baseline patient characteristics. In the overall cohort, 243 (69.5%) of stress CMRs resulted in an active change in care, and 107 (30.5%) led to no change (Table 2 and Figure 1). The most common active changes were discharge from cardiology clinic (21.1%) or medication change (18.3%) (Table 2 and 3). The majority of active changes were non-invasive (65.5%) as opposed to invasive (8.6%) in nature (Figure 1). A significant minority (4.6%) underwent both a non-invasive and invasive change in management.

Based on the 2013 AUC, 52% of stress CMRs were classified as appropriate, 36% as maybe appropriate, and 12% as rarely appropriate. The most common rarely appropriate categories in this study are shown in table 4. The overall rates of active clinical change were similar between studies classified as appropriate (68%), may be appropriate (72%), and rarely appropriate (72%)(p=0.766) (Figure 2). However, there were significantly more invasive changes in the appropriate group compared with the rarely appropriate group (16.5% vs 2.3%, p=0.015%).

Presence of ischemia (OR 3.517, 95% CI 1.447–8.550, p=0.006), known coronary artery disease (OR 0.374, 95% CI 0.232–0.603, p<0.001), hyperlipidemia (OR 0.520, 95% CI 0.325–0.831, p=0.006), and age (OR 0.976, 95% CI 0.959–0.995, p=0.010) were significant univariable predictors of significant clinical impact (Table 5). In a multivariable model adjusting for clinical variables and AUC, only ischemia (OR 6.896, 95% CI 2.637–18.032, p<0.001), known coronary artery disease (OR 0.300, 95% CI 0.161–0.559, p<0.001), and age (OR 0.977, 95% CI 0.954–1.000, p=0.050) independently predicted significant clinical change (Table 5). AUC categories were not an independent predictor of clinical change (OR 0.936, 95% CI 0.637–1.376, p=0.736). AUC were still not an independent predictor of clinical change even if surgical clearance was excluded as a category of change (OR 0.891, 95% CI 0.689–1.153, p=0.380).

DISCUSSION

In this study we have shown that stress CMR made a significant impact on clinical management, resulting in active change in clinical care in about 70% of patients. However, overall rates of change were similar across AUC categories (p=0.766), highlighting the current limitations of the AUC. To the best of our knowledge this is the first study to systematically and prospectively assess the overall clinical impact of stress CMR based on the AUC.

Studies classified as appropriate resulted in significantly greater invasive changes than studies classified as rarely appropriate. Despite this, the overall rates of active change in clinical care were similar across AUC categories. This finding does not appear to be driven by surgical clearance of rarely appropriate cases. Since there are 43 rarely appropriate studies and surgical clearance accounted for just 4. Our study suggests that outpatient stress CMR testing can be useful in patient management even when it does not lead to angiography or revascularization and that the current AUC may be too narrowly focused on invasive outcomes [17].

In this study, AUC categories were not an independent predictor of clinical change following stress-CMR. In contrast, clinical change was independently associated with presence of ischemia, absence of known CAD, and younger age. Ischemia as a predictor of clinical change is not surprising. However, it is not clear why absence of known CAD and younger age should be independently associated with clinical change. It is interesting to speculate that perhaps a normal study in these individuals tended to result in exclusion of CAD as a cause for their symptoms and consequent discharge from clinic. However, overall 302 studies were negative for ischemia, and 76.2% of these negative studies for ischemia

continued to be followed up in clinic. Thus not all negative studies automatically resulted in clinic discharge.

Although LGE and ejection fraction are well known predictors of adverse cardiovascular outcomes[18, 19], our endpoint of "clinical change" is significantly different and not associated with these variables. For example, a patient with known left ventricular dysfunction will likely not have a clinical change on the basis of a depressed CMR derived ejection fraction. Similarly LGE was present most commonly in the setting of patients with known CAD, thus finding LGE typically did not lead the physician to change management.

Future validation of the AUC requires prospective randomized outcome trials, ideally integrating multiple different imaging modalities and strategies. However, such studies are challenging to fund, and are unlikely to be performed. One approach is to compare the prognostic ability of stress CMR across AUC categories. This was undertaken by Doukky et al in a large nuclear study, which suggested that inappropriate use of SPECT was associated with reduced prognostic value[20]. In those patients whose scans were appropriate or uncertain, abnormal scans were of significant value in predicting major adverse cardiac events. However, in those with inappropriate scans, abnormal studies did not achieve significance in predicting adverse cardiac events.

In this study, the great majority (88%) of tests ordered were classified as appropriate or maybe appropriate. It is possible that growing pre-certification demands by third-party payers may have affected physicians test orderings patterns. The upcoming changes in Medicare reimbursement which have been legislated by the US Congress are likely to significantly increase pressure on physicians in this regard[9, 10]. Interestingly, a recent meta-analysis systematically reviewed published evidence to identify whether the promulgation of AUC over the last 10 years has led to improvements in the proportion of appropriate cardiac imaging requests[21]. They found that rates of reported appropriate use in imaging showed improvements for transthoracic echocardiography and coronary CT but not for stress echocardiography, SPECT imaging or transesophageal echocardiography. The authors provided no data for CMR.

The performance of this study at a single US academic medical center limits its generalizability to other practice settings. Differences may exist in adherence to AUC by region, practice type, practice size, clinician experience, and payer mix that cannot be captured by this single-center study. In this study, active change was assigned if an action was taken because of the stress CMR, with no consideration of whether the change was clinically indicated. Therefore, active change in care in our study may not necessarily indicate better care. This study was limited by not providing data regarding clinical outcomes such as hospitalization, heart failure, myocardial infarction or mortality. The inclusion of surgical clearance as a category of change may be criticized, but these patients constitute an important portion of cases referred to most general cardiology clinics. Even if surgical clearance is excluded, 60% (n=209) of patients still had an active clinical change. Similarly discharge from clinic is a major change in patient management and needs to be accounted for. Of note, the AUC were not independent predictors of clinical change even if these two categories were excluded from the analysis[OR=0.814 (0.617–1.072), p=0.143].

Cost-effectiveness was not assessed in this study and needs to be the subject of future studies. Finally, assessment of active change relied on review of the electronic medical records, which may have led to misclassification of impact owing to incomplete documentation.

Acknowledgments

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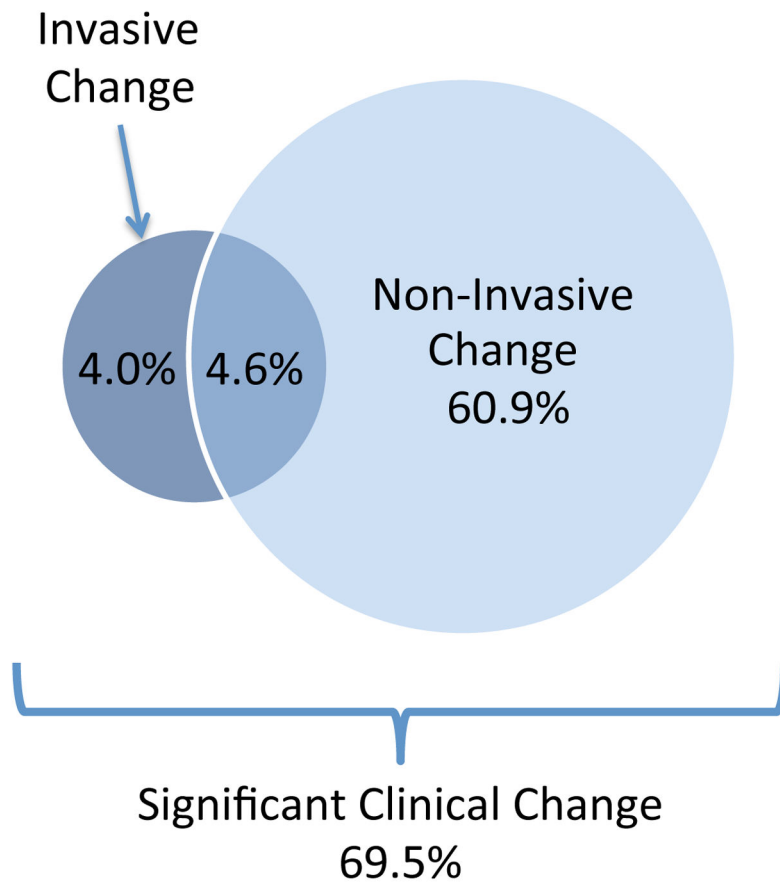
Figure 1. Clinical Impact of CMR

On the basis of CMR findings, 65.5% of patients had a non-invasive change in management and 8.6% of patients had an invasive change. In 4.6% of patients CMR resulted in both a non-invasive and invasive change in management. In total, CMR had a significant clinical impact on 69.5% of patients.
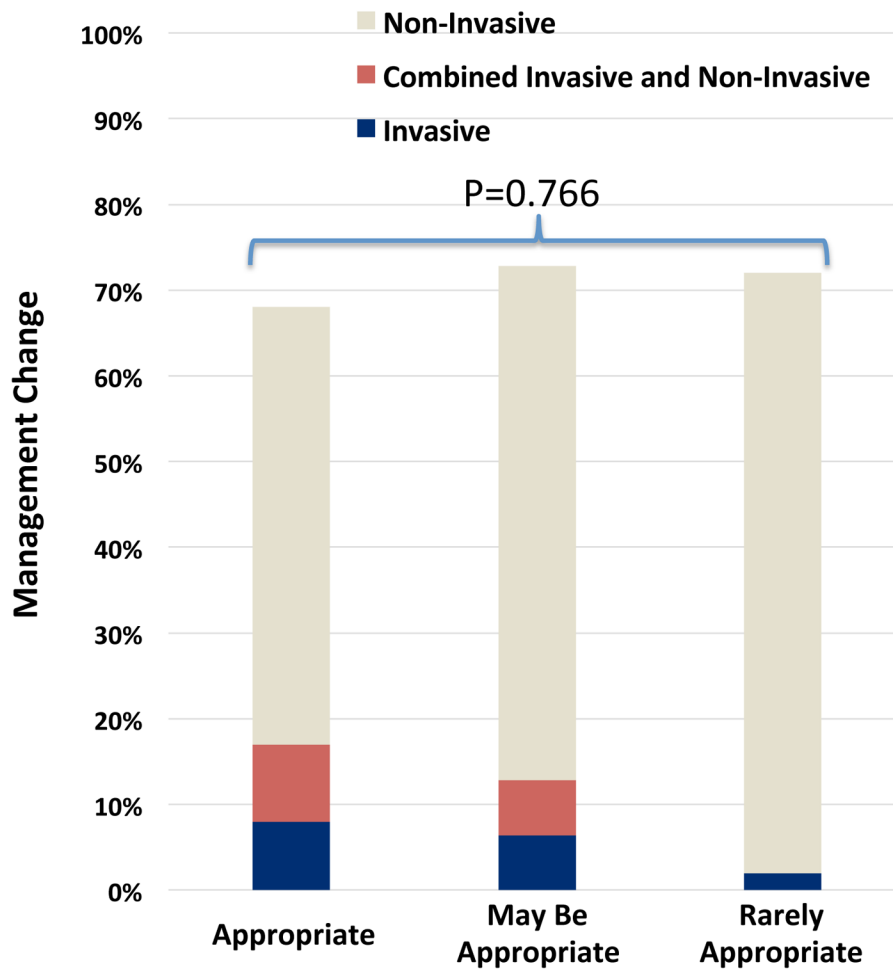
Figure 2. Clinical change categorized by AUC

The overall rates of active clinical change were similar between studies classified as appropriate (68%), may be appropriate (72%), and rarely appropriate (72%)(p=0.766). However, there were significantly more invasive changes in the appropriate group compared with the rarely appropriate group (16.5% vs 2.3%, p=0.015%).

Table 1

Clinical Baseline Characteristics of Enrolled Patients. Values are expressed as mean (±SD) or number (percentage).

CHARACTERISTICS	Total (N=350)
Age (years)	59 (±13.7)
Body Mass Index (kg/m2)	30.6 (±5.9)
Male	46.3%
Diabetes Mellitus	34.9%
Hyperlipidemia	53.4%
Smoker	18.9%
Hypertension	74.9%
Known Coronary Artery Disease	31.4%
Left Ventricular Ejection Fraction	59 (±11.5)
Late Gadolinium Enhancement present	20.3%
Ischemia present	13.7%

Table 2

Breakdown of categories of clinical change

Please note that patients could have more than one category of clinical change.

CATEGORY	DEFINITION	N=350 (%)
Active Change in Clinical Care	Angiography with Revascularization	19 (5.4%)
	Angiography without Revascularization	27 (7.7%)
	Preoperative Clearance	39 (11.1%)
	Medication Changes	64 (18.3%)
	Subspecialty Consultation	33 (9.4%)
	Additional Diagnostic Test Ordered	32 (9.1%)
	Discharge from Cardiology Clinic	74 (21.1%)
No Active Change in Clinical Care	Continuation of pre-CMR Care	107 (30.5%)

Table 3

Medication changes occurring as a result of stress CMR results.

DRUG CLASS	INITIATION or INCREASE	DISCONTINUATION or DECREASE
Beta-Blocker	17	3
ACE inhibitor/Angiotensin Receptor Blocker	14	3
Cholesterol Lowering	13	0
Antiplatelet	12	5
Diuretic	8	2
Nitrate	6	1
Calcium Channel Blocker	3	1
Hydralazine	2	0

Table 4

Most common rarely appropriate classifications.

AUC DESCRIPTION	N
Symptomatic with low pre-test probability of CAD and interpretable ECG and able to exercise	23
Follow up testing (> 90 Days) with asymptomatic or stable symptoms with an abnormal prior stress imaging study < 2 years ago	3
Follow up testing (> 90 Days) with asymptomatic or stable symptoms with a normal prior stress imaging study or non-obstructive CAD on angiogram and low global CAD risk	3

Table 5

Univariable and multivariable predictors of clinical change.

VARIABLES	Univariable		Multivariable	
	Odds Ratio (95% CI)	**P Value**	**Odds Ratio (95% CI)**	**P Value**
Age	0.976 (0.959–0.994)	0.010	**0.977 (0.954–1.000)**	**0.050**
Body Mass Index	1.019 (0.980–1.060)	0.348	1.004 (0.959–1.051)	0.858
Male	1.016 (0.932–1.109)	0.713	1.004 (0.863–1.170)	0.950
Diabetes Mellitus	1.147 (0.709–1.857)	0.576	1.667 (0.923–3.011)	0.090
Hyperlipidemia	0.520 (0.325–0.831)	0.006	0.600 (0.338–1.067)	0.082
Smoking	0.854 (0.482–1.513)	0.589	0.901 (0.482–1.681)	0.742
Hypertension	0.937 (0.553–1.588)	0.809	1.562 (0.794–3.070)	0.196
Known Coronary Artery Disease	0.374 (0.232–0.603)	<0.001	**0.300 (0.161–0.559)**	**<0.001**
Appropriate Use Criteria	1.168 (0.838–1.629)	0.360	0.936 (0.637–1.376)	0.736
Left Ventricular Ejection Fraction	0.993 (0.973–1.013)	0.512	0.996 (0.973–1.019)	0.742
Late Gadolinium Enhancement	1.661 (0.965–2.860)	0.067	1.268 (0.653–2.465)	0.483
Ischemia	3.517 (1.447–8.550)	0.006	**6.896 (2.637–18.032)**	**<0.001**