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Magnetocardiography Using a Novel Analysis System (Cardioflux) in ED Observation Unit Chest Pain Patients – A Feasibility Study

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ABSTRACT

Background: Cardiovascular disease is currently the leading cause of death in the United States and is the second most common chief complaint among Emergency Department (ED) patients. Magnetocardiography (MCG) has emerged as a viable, non-invasive option for the evaluation of coronary artery stenosis. Cardioflux (CF) is a novel MCG imaging and analysis system. This study aims to evaluate the feasibility of using MCG using CF (MCG-CF) in our Emergency Department Observation Unit (EDOU).

Methods: This is a single-center, retrospective, observational study of ED patients placed in the EDOU with symptoms of possible cardiac ischemia from July 1, 2017 to October 31, 2017 with a non-invasive stress test ordered, to evaluate if they would have been eligible for MCG-CF scanning.

Results: Of the 225 patients that met inclusion criteria, 69% were eligible for an MCG-CF scan (n = 156). The average patient was 55 years, 54% were women and 59% were Black. The most common exclusion was having a BMI of greater than or equal to 35kg/m2 making up 86% of exclusions.

Conclusions: This feasibility study demonstrates that most patients in our EDOU are eligible for a MCG-CF scan. Slight revisions to the device would allow more patients with larger BMI to be included.

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Introduction

Cardiovascular disease is the leading cause of death for both males and females in the United States, representing greater than 25% of all-cause mortality above the age of 65 in 2017 [1]. Chest pain is the second most common chief complaint in patients presenting to the Emergency Department (ED) [2-4]. Most low to intermediate risk chest pain patients are not diagnosed with acute coronary syndrome (ACS) in the ED and have nonspecific ECGs and negative cardiac biomarkers [5, 6]. Patients with low-intermediate risk of ACS, who are not discharged, can be placed in an observation unit (OU) for additional monitoring, diagnostic testing, and/or cardiology consultation [5, 7]. ED observation units (EDOU) provide a protocol-based and cost-effective management of undifferentiated chest pain [5, 8, 9]. Magnetocardiography (MCG) is a non-invasive method of measuring the magnetic field produced from the electrical activity of the heart during the cardiac cycle. The first published results of MCG for cardiac analysis were 50 years ago, and MCG use is increasing [10, 11]. MCG scans share similar features to an electrocardiogram (ECG), including QRS complexes, P and T waves. In contrast to other cardiac testing methods, MCG produces no radiation, requires no additional medications or intravenous contrast agents, and is performed quickly while the patient is resting comfortably. In addition, compared to ECG, MCG is much less affected by the conductivity variations of different tissues.

For forty years, single-channel MCG was utilized, which required repositioning patients several times to create a complete magnetic field map. MCGs with numerous channels were developed that simultaneously collected data and created a complete map [12]. Multichannel MCG allowed for accurate determination of cardiac arrhythmias and arrhythmogenic risk assessment; thus, its first implementation. Previous MCG studies have found that in patients with coronary artery disease (CAD), MCG was capable of identifying patients with stenosis.[13, 14] Other studies found MCG detects ischemia in patients with myocardial infarctions better than ECG with good interrater reliability [15, 16]. MCG may detect abnormalities consistent with ischemia in patients with normal ECGs and negative troponins [17]. Cardioflux (CF) is a novel MCG imaging and analysis system (developed by Genetesis, Inc. Mason, Ohio) that uses a series of diagnostic algorithms to convert and interpret magnetic field data into dynamic images with a total imaging time of 90 seconds. Preliminary results from a pilot study using MCG with CF (MCG-CF) shows promise in MCG detection of abnormal myocardial flow in non-high-risk chest pain patients [18].

While many studies have examined the potential benefits of using MCG, few have examined the feasibility of using MCG in the ED setting. The purpose of this study is to evaluate the feasibility of using MCG-CF in our EDOU. We predicted that at least half of all patients placed in the EDOU for evaluation of symptoms concerning for cardiac ischemia would be eligible for an MCG-CF scan.

Materials and Methods

This was a single-center, retrospective observational study of ED patients placed in the EDOU for evaluation of symptoms of ACS from July 1st, 2017, to October 31, 2017. The Electronic Medical Record (EMR) of these patients was reviewed to determine eligibility for MCG-CF scanning. Eligibility criteria included patients ≥18 years of age who underwent stress testing while placed in the EDOU with symptoms concerning for ACS that were of low-intermediate risk defined as having a negative first troponin result and a non-diagnostic ECG. Data collected included ED reports, radiology reports, cardiology, and other consultant or progress notes. Data collection forms were stored in a locked file cabinet when not in use, and all electronic data was stored on a password-protected, encrypted computer. This study was conducted in accordance with the ethical standards of human subject's research. It was approved by the hospital Institutional Review Board and did not require patient consent.

Exclusion criteria included patients younger than 18 years of age, inability to fit into the device (defined as BMI ≥ 35kg/m^2), non-ambulatory, having metal present in the chest area (e.g., metal fragments), atrial fibrillation with rapid ventricular response (RVR), pregnancy, homelessness, prisoner patients, and previously enrolled patients.

Data analysis

The mean for continuous variables and frequency distributions for categorical variables were analyzed using SPSS v. 25.0. The percentage of eligible patients and the primary exclusion criteria were reported.

Results

There were 403 patients placed in the EDOU with symptoms concerning for ACS; 178 were excluded as they did not have a stress test (Figure 1). There were 225 patients who underwent stress testing and met the inclusion criteria. Demographic data shows the average age was 55 years old, with 41% being male, 60% Black, 34% White, and 5% Other. The most common concerning symptom was chest pain (87%), followed by dyspnea (5%). (Table 1 and 2).

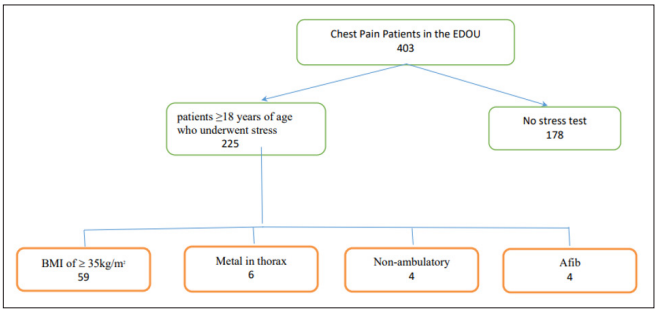

Figure 1: Study flow diagram

Table 1: Patient Age, Gender and Race

	All N = 225	Eligible N = 156
Age mean	55 years	55 years
Male	92 (41%)	71 (46%)
Race:		
Black	136 (60%)	92 (59%)
White	77 (34%)	56 (36%)
Other	12 (5%)	8 (5%)

Table 2: Patient Eligibility and Concerning Symptom Count

	All	Eligible
Total Eligible	225	156 (69%)
Concerning Symptoms:		
Chest Pain	201 (89%)	138 (61%)
Dyspnea	11 (5%)	6 (3%)
Anginal Equivalent	4 (2%)	4 (2%)
Other	9 (4.0%)	8 (4%)

Of the 225 patients evaluated for exclusion through review of EMR, 156 patients (69%) would have been able to undergo MCG-CF scanning, and 69 (31%) patients met exclusion criteria and therefore would be unable to undergo MCG-CF scanning. Tables 1 and 2 include demographic and concerning symptoms data of the eligible group. The most common exclusion was having a BMI of ≥ 35kg/m^2 making up 86% of exclusions (n = 59). High BMI made fitting into the bore of the MCG difficult (Figure 2). This is followed by having metal in the thoracic area (n = 6) or being non-ambulatory (n=4). Four patients also had atrial fibrillation with RVR. No patients met exclusion criteria of pregnancy, prisoners, homelessness, or repeat EDOU visits.

Figure 2: MCG Machine

Discussion

Of 225 records examined, 156 or 69% of patients could have been assessed for their symptoms concerning for ACS with an MCG-CF scan. It has been suggested that MCG and in particular, MCG-CF may be a non-invasive alternative to cardiac stress testing in patients with suspected cardiac ischemia. In a low-intermediate risk group, Pena et al found the specificity of MCG-CF compared to stress testing was 77.8% [67.5%, 85.6%] and NPV 89.7% [80.3%, 95.2%] in non-high-risk EDOU chest pain patients, suggesting that MCG-CF may offer a rapid (less than 5 minutes), non-invasive alternative diagnostic modality that does not produce radiation or require contrast of any type [18].

In our study, the most significant factor limiting MCG-CF scanning was the bore size of the scanner, as it was difficult to accommodate patients with BMIs over 35. A high BMI was the most common exclusion for MCG-CF scanning, excluding 59 (86%) of all patients. Similar to other diagnostic scans using chambers such as a magnetic resonance imaging (MRI) scanner, claustrophobia is an important consideration. Studies have shown that claustrophobia negatively affects 1-15% of MRI results and 30% of patients report being uncomfortable during an MRI scan due to claustrophobia [19, 20]. In this study, information about whether a patient suffered from claustrophobia was unable to be extracted from the EMR. However, it can be hypothesized that because the MCG-CF scan time is only 90 seconds and therefore significantly less time is spent in a chamber compared to MRI scanning, some patients with claustrophobia may be able to tolerate MCG-CF.

Standard diagnostic tests used to evaluate possible ACS also have exclusion criteria. For example, patients cannot complete an exercise stress test if they are unable to exercise, had a myocardial infarction in the previous 2-3 days, have untreated unstable angina, or are hemodynamically unstable, to list a few. Coronary CTA is also limited by a BMI greater than 40 kg/m^2, atrial fibrillation, focal arrhythmias, tachycardia, inability to take beta-blockers, renal insufficiency and contrast allergies. In addition, cardiac MRIs cannot be done on patients with MRI incompatible metal implants, arrhythmias, patients weighing more than 440 lbs., renal failure, or claustrophobia. Non-invasive diagnostic tests provide many benefits for the patient, such as circumventing vascular complications seen in invasive procedures, reduced pain, and essentially no recovery period. Since MCG-CF scanning is a non-invasive test, it not only has these benefits, but presents as a novel approach to possibly reducing the need for stress testing and invasive catheterization in patients with suspected ACS.

Limitations

Reviewing limitations, if a patient did not have a CT or X-ray from the initial ED encounter, previous CTs or X-rays were used possibly reducing the count of patients with metal in the chest region. Also, patient data were taken only from July 2017 - October 2017. Therefore, a larger sample of patients could provide more accurate data on MCG-CF eligibility. Patient ambulation data was often taken through triage notes or nursing ambulation scores; however, these scores do not always reflect if a patient can ambulate onto the MGC-CF scanner.

After completing this study, a second-generation device was built with a larger bore size and a higher number of sensors. In a subsequent study using this device, 104 patients were enrolled and included subjects with a BMI of up to 57. Therefore, all patients in this feasibility study that were excluded for body size would have theoretically qualified for an MCG-CF scan.

Conclusion

This feasibility study found that 69% of patients that underwent stress testing in our EDOU would have been eligible for an MCG-CF scan. The most common exclusion for MCG-CF scanning was a high BMI, accounting for 86% of excluded patients. The proposed approach would allow the majority of cardiac patients to be screened. Contrary to other advanced cardiac testing, MCG testing does not involve radiation and takes less than 5 minutes. Since this study Genetesis has made a second and third generation MCG machine with a larger bore to accommodate a large body habitus. As a precursor to other MCG studies, this feasibility study was prudent to show some of the limitations and rate limiting steps for MCG evaluation.

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