Title: Refinement and Assessment of New MRI Technologies for Cardiovascular Exams Using the Phillips Cardiac Magnetic Resonance (CMR) Patch

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Study Protocol: Refinement and Assessment of New MRI Technologies for Thoracic/ Cardiovascular Exams using the Phillips CMR Patch

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Background:

Magnetic resonance imaging is an extremely flexible modality capable of generating high quality images of patient anatomy as well as biophysical measures related to tissue composition, function and physiology. An MRI scanner produces these images by the interplay of its two components: hardware and software. MRI hardware and software technologies are still in a state of rapid evolution. Some evolutional steps only involve changes to hardware components of the MRI system. Many enhancements are “software only” and involve alteration of the MRI data acquisition software, or post-processing software applicable after completion of the MRI exam. Lastly, some developments involve a combination hardware, acquisition software, and post-processing software all used in concert. Regardless of its makeup, the new technology is designed to improve quality or add content to the MRI data, or improve scan speed and patient comfort.

Sophistication and high cost of MRI software/hardware requires that technical advancements in MRI will continue to be heavily dependent on engineering provided MRI system vendors. Certainly a key motivation of MRI vendors is commercial success of their products. Nevertheless, MRI vendors realize they do not fully understand the medical issues for which their technology is designed, thus they are equally dependent on leading medical academic centers for guidance in the technology development

process. Indeed, both parties (medical and commercial) fully understand the co-dependence where clinical application drives new products, and new technology is required to
solve clinical problems. The proven path to achieve these coupled objectives is via a partnership between MRI industry and academic medical centers which have the additional scientific and technical infrastructure, as we have within UM Department of Radiology.

- The CMR patch is a Philips tested patch that supports multiple cardiac MR imaging enhancements compiled from several individual patches generated by multiple Philips MR research collaborators. Using both 1.5 and 3T Philips scanners.
- The current revision of the patch has been tested to verify functionality on both 1.5 and 3T Philips scanners.
- Michigan Philips scanners that will run the patch have the same scanner software release that the Philips used for tesing the CMR patch.
- The patch does NOT change the non-significant risk classification of the Philips MR scanners but is classified as investigational because FDA regulatory approval has not been submitted.

Goals of the Study:

To establish an IRB-approved mechanism to recruit patients to participate in the assessment of new MRI technologies designed to improve MRI examinations of the chest region that will result in an improvement in patient care.

To allow involved UM faculty to provide de-identified MRI data of these patient scans to MRI vendors as descriptive examples of the performance of the new technology.

To allow involved UM faculty to present and publish de-identified MRI data of these patient scans in reports regarding the performance of the new technology at scientific meetings in radiology/MRI journals.

Objectives :

Philips MR is releasing a cardiac imaging patch (CMR) that is a compilation of functionality supported by multiple patches produced by multiple Philips cardiac MR researchers. Philips is providing the patch to the PI to improve support of ongoing cardiac MR studies under IRB protocol. The patch will also support pending grant submissions by the PI. The PI will also submit conference submissions, manuscripts and provide Philips feedback on the clinical utility of the various techniques and workflow enhancements supported by the CMR patch.

The cardiac patch is the improved version of sequences that we use in our routine clinical practice that will improve the quality of our images and yield improved diagnosis for our patients. The scientists at Philips have worked to improve our service and answer our need. For example,

we have used one patch in the past to minimize the artifact of ICD to allow us to identify myocardial scar that would have been otherwise obscured by the artifact.

These are all software updates that we will continue using them. These patches are for cardiac imaging

The patch is specific to improve current cardiac imaging sequences. Cardiac imaging is very tricky and the images are degraded by respiratory and cardiac motion. The scanning is lengthy and we are trying to improve sequences and make them easy on the patients with after scanning.

These cardiac applications are designed for cardiac imaging of cardiac vascular diseases. These particular sequences are not going to be used for different body parts.

If we identify a clinical need to investigate other sequences that are not currently part of this patch we will amend the protocol.

Once we identify that particular sequences are providing improved imaging compared to older version of the sequence we have, then we will modify our clinical imaging protocol accordingly to better answer clinical care..

Significance:

Increasing the quality and content of chest MRI examinations will aid diagnosis. Scan speed enhancements will improve patient throughput, comfort and compliance. Any and all of these technical enhancements can improve management of our current patients, as well as have a positive impact on future clinical MRI procedures.

Risks:

The patch does not change the non-significant risk classification of the Philips MR scanners but is classified as investigational because FDA regulatory approval has not been submitted.

This new technology to be studied will be operated within established safety guidelines for MRI scanning. Risks associated with the new technologies will be limited to be no greater than risk associated with standard clinical MRI scanning. Inherent within the operating system and hardware of the MRI scanner are built-in safety constraints

Benefits:

Using this new technology is designed to improve quality of images looking for heart muscle damage.

Statistical analysis of results:

Assessment of the new technologies will be quantified by a variety of performance and image quality/content measures. The appropriate set of measures will selected based on specific features offered by each assessed technology, but will drawn from the following quantities:

1) Scan speed: Scan speed is time required to set-up and run the new technique relative to the standard method.
2) industry and academic medical centers which have the additional scientific and technical infrastructure, as we have within UM Department of Radiology.

Goals of the study:

To establish an IRB-approved mechanism to recruit patients to participate in the assessment of new MRI technologies the (Phillips CMR Patch) which is post processing software designed to improve MRI examinations of the chest region that will result in an improvement in patient care.

To allow involved UM faculty to provide de-identified MRI data of these patient scans to MRI vendors as descriptive examples of the performance of the new technology.

To allow involved UM faculty to present and publish de-identified MRI data of these patient scans in reports regarding the performance of the new technology at scientific meetings in radiology/MRI journal

Confidentiality:

All patient data (i.e. MR images) will be electronically de-identified prior to their inclusion in reports, charts, and slide presentations sent to the MRI vendor. Any clinical information provided with the images will be limited to: patient age, sex, weight, and disease diagnosis (eg. myocardial infarct). Additionally, these data will be compiled and evaluated by UM Faculty for quality control and trends. In any case, all study logs and databases will be kept in a locked and secure area within the Department of Radiology by the PI.

Experimental Design:

500 patients who will have a clinically ordered MRI will be recruited for this study. Male and non-pregnant female patients, age 18 years or older, of all ethnic backgrounds presenting for a clinically-ordered cardiac MRI exams will be eligible.

When a patient presents for a clinically indicated cardiac MRI examination a member of the study team will approach the patient prior to their exam. Pre-screening of MRI schedules by a study team member will identify potential subjects. If a patient is interested in participating, a member of the study team will provide the patient with a copy of the informed consent. Sufficient time will be allowed to each individual to read the

consent, and have all questions answered prior to the signing of the document. Clinical patients complete a safety questionnaire as part of their clinically ordered MRI.
Women interested in participating in this study as patients will be screened for pregnancy following standard clinical practices for all MRI studies at University of Michigan, these include screening for pregnancy by questionnaire.

Inclusion Criteria

Adult patients undergoing clinical MRI

Exclusion Criteria

Patients with contraindication to MRI