Study Title: Single Breath Hold MRI

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1) Protocol Title: Single Breath Hold Abdominal MRI

Short Title: Single BH Abdominal MRI

2) Purpose of the Study: To develop a single breath hold abdominal MRI protocol, and compare the image quality of respiratory triggered 3D T_1-weighted images against conventional breath hold images.

3) Background and Significance: T_1-weighted imaging is a mainstay of abdominal MRI, providing information about both intrinsic tissue properties and lesional vascular properties (when an intravenous contrast agent is administered).

However, T_1-weighted imaging is highly motion-sensitive and typically performed in a breath hold. Particularly in ill patients, such as inpatients and those presenting to the Emergency Department, breath holding capacity may be diminished, and high-quality T_1-weighted imaging may be difficult to obtain. Many motion compensation methods have been developed, including respiratory triggered and radial imaging. However, these methods are, in general, too time-consuming for routine use in dynamic liver MRI, which requires the acquisition of arterial, portal venous, and equilibrium phase images in relatively rapid succession.

Recently, high temporal acceleration factors for T_1-weighted imaging have been combined with respiratory triggering in order to produce respiratory triggered sequences that are more suitable for dynamic imaging; these are based on combining conventional respiratory triggering with optimized versions of the conventional LAVA (Liver Acquisition with Volume Acquisition) pulse sequence. Such a sequence is rapid enough for portal venous and equilibrium phase imaging during free breathing, though not necessarily for arterial phase imaging. This sequence could allow for an optimized liver MRI protocol that could be performed with only one breath hold in the arterial phase, and no additional breath holds, in contrast to the typical examination which typically requires four or more breath holds.

The purpose of this study is to evaluate a single breath hold abdominal MRI protocol, to and compare the image quality of respiratory triggered 3D T_1-weighted images against conventional breath hold images.

4) Design and Procedures: This will be a prospective study with written informed consent obtained. Patients presenting to DUHS for clinical abdominal MRI at the Duke Medical Pavilion (inpatients and emergency department patients) as part of their routine care will be included. In addition to their typical contrast-enhanced abdominal MRI protocol, we will acquire three extra image sets:

1) Respiratory-triggered T_1w DISCO LAVA precontrast
2) Respiratory-triggered T_1w DISCO LAVA in the portal venous phase

3) Respiratory-triggered T_1w DISCO LAVA in the equilibrium phase

The only modification to the patients' clinical scan protocol will be to add these three image sets. This is expected to add about 5 minutes to their scan time, and will not significantly affect clinical workflow/throughput. All patients presenting for imaging on the appropriate MRI scanner while a CRC is available to obtain written informed consent, who are able to give consent, will be offered the opportunity to participate in this study. The clinical image data which are routinely sent to PACS will be deidentified and exported for offline analysis, and raw data may be collected in some cases for reprocessing.

Only subjects presenting for clinical MRI will be included. Up to 100 subjects will be included. On data collection, an investigator will assign a serial code number and document pertinent demographic information such as patient age and gender. The code number assigned will not be derived from any personal identifier for the subject. The investigator will also access Maestro records to confirm the indication for the examination and to obtain laboratory values near the time of the examination. The imaging examinations and clinical information will have all patient identifiers removed, including the name, medical record number, and date of birth. Subsequently, the individual MRI examinations and clinical information will be labeled with a unique assigned code number. After all relevant information is recorded and the exams/reports coded, the investigator will destroy the key linking any subject's personal history information to the assigned code numbers.

Rationale for prospective design: This project would not be possible to perform in a retrospective setting, because clinical rationale for performing the additional T_1-weighted acquisitions above is lacking.

5) Selection of Subjects: The study population will include up to 100 consecutive subjects undergoing abdominal MRI, age 18 years and older. All subjects regardless of gender or race who had the appropriate imaging will be included. Information will be obtained from electronic records and PACS.

6) Subject Recruitment and Compensation: There will be no financial compensation to subjects as part of this study. Subject recruitment will consist of discussion of the study with potential subjects by the clinical research coordinator or other study team members just prior to the beginning of the examination. The study will be briefly discussed prior to the examination, and if the patient indicates their interest in participating, there will be a more thorough discussion of the study, and a consent form will be provided to the potential subject. Subjects will be provided adequate time to review the consent form and decide whether to participate in the study. If a patient does not wish to participate, they will have their MRI examination per clinical routine.

7) Consent Process: Informed written consent will be obtained from the subjects by the study staff at the time of examination. It will be made clear that if the subject does not wish to

participate in the study, the typical MRI of the liver which had been previously ordered will be performed with no change in care as a result of nonparticipation.

8) Subject Capacity to Give Legally Effective Consent: Only subjects with the capacity to provide written, informed consent, as determined by the study staff.

9) Study Interventions: No interventions will be performed as part of this study.

10) Risk/Benefit Assessment: The only risk of performing this study is the loss of confidentiality in the use of patient data. This is minimized by immediate de-identification of all patient and image data using linking data and destruction of the linking data as soon as possible in the data collection process. The remaining data will only be retained in a password-protected folder on a research shared drive supported by DHTS. The benefits of performing this study include improving our understanding of liver nodule characteristics.

Please note that the pulse sequences used in this study (standard LAVA and respiratory-triggered DISCO LAVA) are FDA/510k cleared and are to be used within the FDA-cleared parameters. Thus, we believe that no IDE or IDE exemption is needed.

11) Costs to the Subject: There will be no costs to any subjects.

12) Data Analysis and Statistical Considerations: Up to 100 subjects will be included in the study population.

Two investigators will independently evaluate MRI examinations. They will assign motion scores and other measures of image quality between respiratory triggered and corresponding breath hold acquisitions. Comparisons between motion scores as well as other image quality scores will be made using the Wilcoxon rank sum test. Inter-reader agreement will be assessed using the Interclass Correlation Coefficient.

The motion scoring scale has been used in prior studies and is described as follows: 1 = no motion artifact; 2 = minimal motion artifact, no effect on diagnostic quality; 3 = moderate motion artifact with some, but not severe, effect on diagnostic quality; 4 = severe motion artifact, images degraded but interpretable; and 5 = extensive motion artifact, images nondiagnostic.

13) Data and Safety Monitoring: An investigator will assign a serial code number and document pertinent clinical information. The code number assigned will not be derived from any personal identifier for the subject. The imaging exams and clinical data will have all patient identifiers removed, including the name, medical record number, and date of birth. Subsequently, the imaging exams and clinical data will be labeled with a unique assigned code number. After all relevant information is recorded and the exams/data coded, the study coordinator will destroy the key linking any subject's personal history information to the assigned code number. Available coded clinical data will be reviewed following the completion of imaging exam evaluation. All data will be retained in a password-protected folder on a

research shared drive supported by DHTS. A formal data safety and monitoring board will not be used.

14) Privacy, Data Storage & Confidentiality: Every effort will be made to ensure subjects' confidentiality. All study files containing subject information will be kept on secure password protected computers with only study staff having access to the files. No identifying patient information will be included on any images or reported in any subsequent publications. Study data will be kept only for a period of six years after the study is completed, at which time all relevant study documents will be destroyed.

No identifiable PHI will be released outside of DUHS.