ACRIN 6701

Test-retest Assessment of Repeatability of Quantitative DWI and DCE-MRI in Human Subjects
Study Goals:

- To assess the repeatability of quantitative MRI imaging metrics in human oncologic imaging

Methodology

- Target population: Prostate cancer patients
- Repeat assessment x2 (2-14 days apart)
- Unified quantitative DWI and DCE-MRI protocols
  - 4 B value DWI
  - Rapid 3D DCE-MRI
Study Aims:

**Primary Aims**
- \( DCE\)-MRI test-retest performance for whole prostate
- \( DWI\) test-retest performance for whole prostate.

**Secondary Aims**
- \( DCE\)-MRI and \( DWI\) test-retest performance for dominant tumor nodule.
- Reader effects on \( DCE\)-MRI and \( DWI\) test-retest performance.
- Compare test-retest of T1-dependent and T1-independent \( DCE\)-MRI models.

**Exploratory Aims**
- Correlation of \( DCE\)-MRI and \( DWI\) metrics in prostate and tumor nodule.
- Compare coffee-break and multi-day \( DWI\) test-retest performances.
Study Schema:

Recruitment:
• Referral for staging of newly diagnosed prostate cancer

Eligibility Check:
• Minimal pathologic tumor burden and/or Gleason grade
• No contraindication to MRI or gadolinium
• No major pelvic surgery

MRI #1 (Day 1):
• Anatomic Imaging
• DWI
• DCE-MRI

MRI #2 (Day 3-14):
• DWI x2 (pre- and post- “coffee-break”)
• DCE-MRI

Accrual Targets:
• 6 sites
  (2 sites per vendor)
• 5 subjects per site

30 Subjects Total
Site Eligibility:

- Access to 3T MRI scanner for study
- Adequate referral base for prostate MRI
- Body MRI radiologist experienced in prostate MRI
- Ability to comply with imaging protocol
- DWI and DCE-MRI phantom imaging within specifications via central image submission
Phantom Imaging: DWI

- Ice-water DWI Phantom
  - T Chenevert, UMich

- Central Compartment
  - ADC = 1.1 mm/sec\(^2\)

Phantom placement in array coil

Resulting T1W image and ADC map
Phantom Imaging: DCE-MRI

- 2nd gen. QIBA Phantom
  - E Jackson, MDACC
- NiCl₂ Dilutions
  - Mimics tissue and art [Gd]

Inner 14-cm diameter ring of spheres: Mimics vascular input function (VIF) relaxation rates.

Outer 29-cm ring: Mimics tissue relaxation rates, 3 groups of 8, each rotated ~90o from the others.
Subject Eligibility:

- Males 18 years of age or greater
- Recent TRUS diagnosis of prostate cancer
  - 28-90 days prior to study enrollment
- Minimum tumor burden (one of the following):
  - One core $\geq 50\%$ cancer burden & $\geq 5$ mm tumor length
  - 2+ cores in the same region with $\geq 30\%$ cancer burden
  - 3+ cores positive for prostate cancer (of any magnitude of cancer burden) in the same prostate region
  - Gleason score of 7 or higher
  - PSA $\geq 10$ ng/mL
Exclusion Criteria:

- Contraindication to MRI or gadolinium
- Prior major pelvic surgery (incl. hip prosthesis)
- Androgen deprivation tx <30 days from enrollment
- Prior XRT or brachytherapy to prostate
Imaging Protocol: DWI

- Non eCoil exam
- SE-EPI (single shot)
  - Axial (or oblique axial) FOV
  - Fat suppression (STIR recommended)
  - Four B values: 0, 100, 600, 800 sec²/mm
- Optimize acquisition parameters to minimize TE
- Repeat x2 during MRI #2
  - “coffee-break” protocol
Imaging Protocol: DCE-MRI

- Non eCoil exam
- 3D volume prescription
  - Axial (or oblique axial) slab
  - 32 partitions, 5 mm slice thickness
  - 2x parallel imaging
  - FOV to include femoral arteries
  - Eccentric slab positioning (see next slide)
    - Minimize arterial in-flow
Axial Slab Placement:

Scout View
Circle= Prostate
C= eCoil

Correct

Incorrect
(Slab too thin)

Incorrect
(Slab set too low)

*Use if T2 imaging and DWI imaging is performed with true axial imaging*
Oblique Axial Slab Placement:

Scout View
Circle = Prostate
C = eCoil

Correct
Incorrect
(Slab too thin)
Incorrect
(Slab set too low)

*Use if T2 imaging and DWI imaging is performed with oblique axial imaging*
Imaging Protocol: **DCE-MRI**

- **T1 mapping**
  - *Variable flip angle method (VFA)*
  - *Flip angles 2, 5, 10, 15, 20, 25, 30*

- **Coil mapping**
  - *Alternate body coil and torso receive coils*

- **DCE-MRI**
  - *~6 minute scan*
  - *5-8 second temporal resolution*
Imaging Strategy: Human Subjects

• Merge MRI visit #1 with clinical staging study

• Requires site decision on use of eCoil
  ▪ MRI #1 - eCoil optional to start
    • Based on local practice patterns for anatomic imaging
    • No eCoil for DWI and DCE-MRI (if anatomic imaging is done with eCoil, must remove before DWI & DCE-MRI)
  ▪ No eCoil use for MRI #2
MRI #1 (no eCoil)

Position/landmark

Anatomic imaging:
- Axial T1
- Axial T2
- Coronal T2

Other pre-gadolinium imaging (e.g. sagittal T2, large FOV for LN and bone staging)

DCE-MRI:
- T1 mapping
- Coil ratio map
- Dynamic enhanced imaging

Other post-gadolinium imaging

Gray Box

Required maneuvers or imaging

Green Box

Optional maneuvers or imaging
MRI #1 (with eCoil)

**Place eCoil**
- Position patient
- Localizer
  - Anatomic imaging:
    - Axial T1
    - Axial T2
    - Coronal T2

**eCoil DWI** (per institutional standards)
- DCE-MRI:
  - T1 mapping
  - Coil ratio map
  - Dynamic enhanced imaging

**Other pre-gadolinium imaging**
- (e.g. sagittal T2, large FOV for LN and bone staging)

**Remove eCoil**
- Re-position patient
- Redo localizer
- Rapid Axial T2 (e.g. HASTE, SS-FSE)
- DWI

**Other post-gadolinium imaging**

**Gray Box** Required maneuvers or imaging

**Green Box** Optional maneuvers or imaging
## MRI #2 (no eCoil)

| Position/landmark | Localizer | Rapid T2 (HASTE, SS-FSE) | Additional imaging if required for clinical care | DWI (pre-“coffee break”) | “Coffee break” |
|-------------------|-----------|--------------------------|-----------------------------------------------|--------------------------|----------------
|                   |           |                          |                                               |                          | Remove coils   |
|                   |           |                          |                                               |                          | Pt off/on table|
|                   |           |                          |                                               |                          | Replace coils  |
|                   |           |                          |                                               |                          | Re-landmark    |
|                   |           |                          |                                               |                          | Redo Axial T2  |

**“Coffee break”**
- Remove coils
- Pt off/on table
- Replace coils
- Re-landmark
- Redo Axial T2

**DCE-MRI:**
- T1 mapping
- Coil ratio map
- Dynamic enhanced imaging

### Gray Box
- Required maneuvers or imaging

### Green Box
- Optional maneuvers or imaging
Important Notes:

- The same MRI unit and configuration must be used for each subject’s MRI SCAN 1 and MRI SCAN 2
- The gadolinium agent MultiHance, Eovist, and Vasovist are **not** permitted to be used as a contrast agent for this trial
  - Allowed agents: Ominsca, ProHance, Magnevist, Optimark, and Gadovist
- The same brand, dose, and rate of contrast administration should be maintained for the subject’s MRI SCAN 1 and MRI SCAN 2
Site QC Tasks:

• Assess compliance with imaging protocol
  ▪ Assess for clinical reporting
    • Can repeat anatomic imaging during MRI #2
      – Alert ACRIN re additional MRI visit #2 imaging
    • Report DWI and DCE-MRI deviations to ACRIN
      – Option to re-do imaging session (if subject agrees)
  • Complete MR technical forms and ITW
Imaging Forms:

- The following imaging forms must be completed by the designated personnel for every submitted exam:
  1. **RT or RA**: Imaging Procedure Form
  2. **RT**: MRI Scan Administration Form*
  3. **M.D**: MRI Imaging Assessment Form (Anatomic)
  4. **M.D**: MRI Imaging Assessment Form (DWI/DCE)
  5. **RA**: Image Transmittal Worksheet (ITW)

*We recommend that a hard copy of this form be available for the MR Technologist to complete during image acquisition.