SyMRI Statistical Analysis Plan

Reducing scan times and improving care through quantitative imaging:
Evaluating SyMRI in pediatric populations
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Analysis

SyMRI will be primarily evaluated on its ability to generate clinically useful images, and if it can be used to reduce total scan times in all, or some, of the target age groups. A secondary output of this project will be to evaluate the usability of SyMRI software and determine if it could be reasonably integrated into a radiologist's existing workflow.

Clinical Utility – SyMRI's average rating as 'Better', ' Equal', or 'Worse' than conventional imaging will be tabulated from all reviewer responses. Assigning a value of 3, 2, and 1 respectively to these ratings – SyMRI is expected to average no lower than a 2.0 – at least equal to conventional imaging. Paired parametric (t-test) and non-parametric (wilcoxon signed-rank) statistical tests will be used to compare time spent using SyMRI vs Conventional MRI to determine if one approach is significantly faster than the other.

Quantitative Image Quality – Image SNR in WM/GM will be calculated and compared between conventional MRI and SyMRI (used to generate fixed / comparable contrasts). Paired parametric (t-test) and non-parametric (wilcoxon signed-rank) statistical tests will be used to evaluate if one approach is significantly better than the other.

Scan Time Reduction – Average scan time of SyMRI vs. Conventional MRI will be computed based on timing data stored in the MR images. A minimum of 5 minutes of scan time is expected be saved using SyMRI.

Evaluation:

1) Evaluate product performance relative to conventional T1, T2, FLAIR, qT1 and qT2
   a) Preliminary evaluation – 6 adult volunteers (>18 years of age)
   b) Clinical Evaluation
      i) **25 neonates (<1 month of age)**
      ii) **25 infants (1mth – 2 years of age)**
      iii) **25 adolescents (2 – 12 years of age)**
      iv) **25 teenagers (13-18 years of age)**
2) Evaluation
   a) Scan Time Impact - Scan report forms, documenting time spent scanning SyMRI, vs conventional MRI.
   b) Quantitative – Comparison of conventional and synthetic MR images using Matlab.
      i) SNR, CNR. Repeatability of images.

    c)   Qualitative – Train radiologists / fellows to use SyMRI software. Complete questionnaire with respect to experience working with software. Diagnostic quality of SyMRI image

3) Data to be provided by Sickkids to SyMRI
    a)   4 in-vivo clinical imaging datasets including conventional clinical and product protocol
        i)   De-identified DICOM images including clinical interpretation and commentary
        ii)   2 neonatal/infant and 2 adolescent/teenager