

3.0T iMRI Guided Resection in Cerebral Glioma Surgery: Interim Analysis of a Prospective, Randomized, Triple-blind, Parallel-controlled Trial

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Introduction

Intraoperative MRI (iMRI)-guided glioma surgery, has been assumed to enable reliable resection control to eliminate the effect of brain shift on extent of resection (EOR). Most of previous studies belong to retrospective ones so that at best level 2C evidence can be provided. We hypothesize that the use of high-field iMRI will increase EOR reduce the morbidity and achieve more improved progress free survival (PFS) and quality of life than conventional neuronavigation.

Methods

A single center prospective randomized triple-blind controlled clinical trial was designed to assess the effect of iMRI on surgical efficacy of malignant gliomas. The estimated sample size was larger than 300 subjects in the intent-to-treat analysis to give 80% complete power (ie, probability of rejecting all false null hypotheses) with an experiment-wise type I error of 0.05. Randomization was conducted when the blinded surgeons deemed that the surgical goal was met, to avoid potential treatment bias. The blinding people included the patients, surgeons, the assessment personnel, and the statisticians. The protocol has been registered at ClinicalTrials.gov (NCT1479686).

Results

The primary endpoints were EOR (volumetric analysis) and surgical morbidity. The secondary endpoints were PFS and overall survival (OS). The first 78 patients were analyzed here. 3 patients with glioma of WHO I were excluded. Finally, 38 patients in the iMRI group and 37 ones in the control group were analyzed. Patient characteristics were balanced between both groups. The results between the 1st iMRI and control group are similar as our expected. Complete resection rates in iMRI group and control group are 84% and 51% (p=0.0907), respectively. Specifically, for high grade glioma, the rates are 88.24% and 66.67% (p=0.1596); while for low grade glioma, they are 80.95% and 44% (p=0.0090).

Conclusions

We provided the first level 1 evidence for the application of 3.0T iMRI in glioma surgery, both in low-grade and high-grade glioma.

Learning Objectives

By the conclusion of this session, participants should be able to draw a conclusion that high field iMRI contributes to increase the complete resection rate according to our primary result.

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