

VISIUS Surgical Theatre

———— seeing is better

Summary of Prospective, Randomized, Triple Blind, Parallel- Controlled Trial Using High-Field iMRI – Interim Published Results

IMRIS Clinical Bulletin

Recently, the team at Huashan Hospital, Shanghai Medical College, Fudan University in Shanghai, China published interim results that provide the first Level One evidence for the clinical utility and benefits of 3.0T (high-field) iMRI image-guided maximal safe resection in glioma surgery. The following summary includes important highlights.



Huashan Hospital, Shanghai Medical College, Fudan University

Hospital Profile

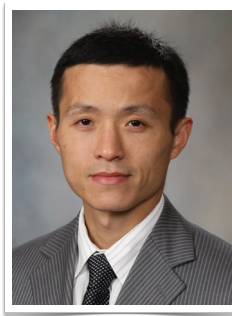
- » One of China's highest-level medical teaching and research centers
- » 15 dedicated neurosurgery operating rooms and 29-bed neuro-intensive care unit (NICU)
- » More than 10,000 neurosurgical procedures performed annually
- » Prof. Liang-Fu Zhou, Academician of Chinese Academy of Engineering, Chairman of the Department of Neurological Surgery at Huashan Hospital, Shanghai Medical College, Fudan University, Shanghai, China.
- » VISIUS Surgical Theatre opened September 2010. Two-room suite consisting of an operating room and diagnostic room with 3T MR. More than 1000 patients treated in suite as of June 2014.
- » Based on these early study results, the neurosurgical team, led by Dr. Jin-song Wu, was honored with the Journal of Neuro-Oncology Award at the Congress of Neurosurgical Surgeons (CNS) annual meeting in October 2013.
- » Website: <http://www.huashan-neurosurgery.com.cn/english/#3>

Published Paper

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

Neurosurgery, August 2014, Volume 61, p. 145-154.

Wu, Jin-Song MD, PhD; Gong, Xiu MD; Song, Yan-Yan PhD; Zhuang, Dong-Xiao MD, PhD; Yao, Cheng-Jun MD, PhD; Qiu, Tian-Ming MD; Lu, Jun-Feng MD, PhD; Zhang, Jie MD; Zhu, Wei MD, PhD; Mao, Ying MD, PhD; Zhou, Liang-Fu MD



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Highlights of Paper

This is the first article that provides level one evidence for the use of high-field iMRI for the surgical efficiency, morbidity, overall survival (OS) and progressive-free survival (PFS) in glioma resections.

Study Overview:

- » Prospective, randomized parallel controlled clinical trial
- » Estimated sample size of 320 participants
 - Interim report with 114 participants (58 iMRI /56 non-iMRI)
- » Triple-blind study
 - Participants
 - Neurosurgeons
 - Assessment personnel and statisticians
- » Single center, with participation of 6 Neurosurgeons (4 professors, 2 associated professors)
- » Newly-diagnosed, untreated malignant cerebral gliomas (WHO II, III & IV)
- » A dynamic allocation algorithm was use for the randomization

Endpoints:

- » Primary endpoint: Extent of Resection (EOR)
 - Quantitatively volumetric analyses

Gross Total Resection
100% Resection

Subtotal Resection
≥ 90% Resection

Partial Resection
≥ 70% Resection

- » Secondary Endpoints
 - Progression-free survival
 - Overall survival (OS)
 - Surgery related morbidity

Primary Endpoint Results:

Interim report on 87 participants (44 iMRI / 43 control group)

- » Patient demographics, molecular biomarkers and the adjuvant treatment initiated after surgery are all very well balanced between the iMRI and Control Group.
 - Median preoperative tumor volume were 52.39 cm³ for the iMRI group and 41.6 cm³ for the control group (p=0.07)
- » Gross Total Resection (100%):
 - Final Result of iMRI group vs. Control group **p=0.0008**
 - Result after the 1st iMRI vs. Control group p=0.59
 - Result after the 1st iMRI vs. final result of iMRI group **p=0.0001**

	iMRI (n=44)	Control (n=43)
Complete resection (100%)	1st iMRI: 21 (47.73%) Final: 38 (86.36%)	23 (53.49%)

- » Gross Total Resection – Volumetric Analysis:
 - iMRI Group (n=44)
 - 1st iMRI: median 98.91% (70.87%-100%)
 - Final: median 100% (70.87%-100%)
 - Control group (n=43)
 - 100% (51.81%-100%)
 - Final result iMRI vs. Control Group **p=0.001**
- » Gross Total Resection – High-Grade Glioma (HGG) vs. Low-Grade Glioma (LGG):
 - Final result of iMRI group vs. Control group
 - HGG p=0.20
 - LGG **p=0.01**
 - Result after the 1st iMRI vs. final result of iMRI group
 - HGG **p=0.01**
 - LGG **p=0.01**

	iMRI (n=44)	Control (n=43)	p value
High grade glioma (n=37) Complete resection (100%)	22 1 st iMRI: 12 (54.55%); Final: 20 (90.91%)	15 11 (73.33%)	p=0.20
Low grade glioma (n=50) Completer resection (100%)	22 1 st iMRI: 9 (40.91%); Final: 18 (81.82%)	28 12 (42.86%)	p=0.01

Comments:

Due to interim results, re-estimated sample size was reduced to 75 LGG and 228 HGG