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Opinion paper

Randomized trial for superiority of high field strength intra-operative magnetic resonance imaging guided resection in pituitary surgery

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ABSTRACT

Till date there are no randomized trials to suggest the superiority of intra-operative magnetic resonance imaging (IOMRI) guided trans-sphenoidal pituitary resection over two dimensional fluoroscopic (2D-F) guided resections. We conducted this trial to establish the superiority of IOMRI in pituitary surgery. Primary objective was to compare extent of tumor resection between the two study arms. It was a prospective, randomized, outcome assessor and statistician blinded, two arm (*A: IOMRI, n = 25 and B: 2D-F, n = 25*), parallel group clinical trial. 4 patients from IOMRI group cross-over to 2D-F group and were consequently analyzed in latter group, based on modified intent to treat method. A total of 50 patients were enrolled till completion of trial ($n = 25$ in each study arm). Demographic profile and baseline parameters were comparable among the two arms ($p > 0.05$) except for higher number of endoscopic procedures and experienced neurosurgeons (>10 years) in arm B ($p = 0.02$, 0.002 respectively). Extent of resection was similar in both study arms (*A, 94.9% vs B, 93.6%; p = 0.78*), despite adjusting for experience of operating surgeon and use of microscope/endoscope for surgical resection. We observed that use of IOMRI helped optimize the extent of resection in 5/20 patients (25%) for pituitary tumor resection in-group A. Present study failed to observe superiorty of IOMRI over conventional 2D-F guided resection in pituitary macroadenoma surgery. By use of this technology, younger surgeons could validate their results intra-operatively and hence could increase EOR without causing any increase in complications.

1. Introduction

Pituitary tumors are more commonly seen in males between third and sixth decades. They account for 10–16.7% of all primary brain tumors [1–3]. Clinically and endocrinologically they are subdivided as functional (70%) or non-functional (30%) [4]. Microsurgical excision has been the mainstay of symptomatic pituitary tumors causing hormonal hyper-secretion or mass effect on visual pathways, pituitary stalk and ventricular system or invading cavernous sinus causing cranial neuropathies/headache [1,4]. Conventional pituitary surgery is performed under two dimensional fluoroscopic (2D-F) guidance. Advances in the field of intraoperative imaging, especially intraoperative magnetic resonance imaging (IOMRI) has led to its increasing usage during this surgery. This technology is expensive but supposedly helps a surgeon in safely improving the extent of resection. We have conducted a randomized two arm parallel group clinical trial to evaluate the superiority of IOMRI over conventional 2D-F in pituitary macroadenoma surgery. Primary objective of the study was to compare extent of tumor resection (EOR). Secondary objective was to compare in hospital complication rate, visual and hormonal profile till 3 month follow up.

2. Material and methods

2.1. Study design

The current study was designed as a prospective, randomized, outcome assessor and statistician blinded, two arm (*A: IOMRI, n = 25 and B: 2D-F, n = 25*), parallel group clinical trial (Fig. 1) based on updated CONSORT guidelines [5]. Pituitary macroadenoma patients meeting inclusion criteria were enrolled from June 2012 to December 2014. Single follow up was done after 3 months of

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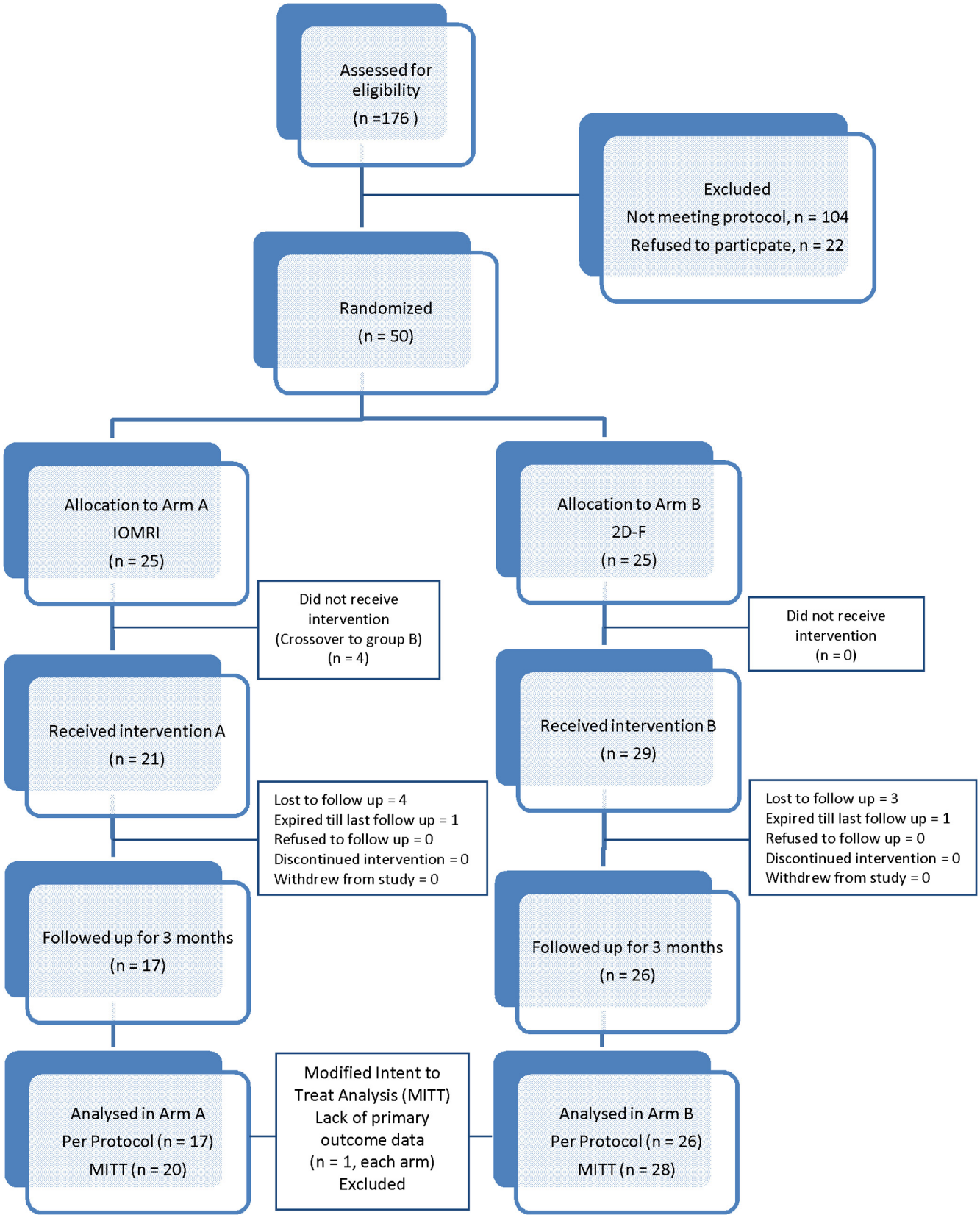

Fig. 1. Trial tree for two-arm parallel group randomized trial in accordance with updated CONSORT guidelines. IOMRI – Intra-operative magnetic resonance imaging; 2D-F – 2-Dimensional fluoroscopic.

enrollment. The study was approved by institutional ethics committee (*IEC/T-180/04.05.2012 for all prospective cases to be recruited with effective from 04.06.2012 and IESC/T-24/30.12.11 & RT-02/02.03.12 for approval of recruitment of functional tumors as well with effective from 03.12.12*). Present study was approved by national council for medical research for working under *Good Clin-*