

Introduction

Traditional stereotactic RF thalamotomy has been used with success in medication refractory tremor-dominant Parkinson’s disease. Recently, transcranial MR guided focused ultrasound (MRgFUS) has been used to successfully perform thalamotomy for essential tremor. We designed a double blinded, randomized controlled trial to investigate the effectiveness of MRgFUS thalamotomy in tremor-dominant PD.

Methods

Patients with medication refractory, tremor-dominant Parkinson’s disease were enrolled in the two center study and randomized 1:2 to receive either a sham procedure or treatment. After the 3 month blinded phase, the sham group was offered treatment. Outcome was measured with blinded CRST and UPDRS ratings. The primary outcome compared improvement in hand tremor between the treatment and sham procedure at 3 months. Secondary outcomes were measured with UPDRS and hand tremor at 12 months. Safety was assessed with MRI, adverse events, and comprehensive Neurocognitive assessment.

Results

Twenty-seven patients were enrolled and seven were randomized to a sham procedure. For the primary outcome assessment, there was a mean 52.6% improvement in hand tremor from MRgFUS thalamotomy at 3 months compared to a 16.7% improvement from the sham procedures (p=0.019). The 1yr tremor scores at 1yr follow up showed a reduction in tremor scores of 41.8% (p=0.002) and a mean reduction in medicated UPDRS motor scores (part III) of 3.1 (p=0.007). Twenty seven patients completed the primary analysis. Following blinded 3 month assessment, 3 patients opted for DBS, 3 were lost to follow up, 1 patient opted for no treatment.

Conclusions

Transcranial MRgFUS demonstrates a trend towards improvement in hand tremor, and a clinically significant reduction in mean UPDRS. A significant placebo response was noted in the randomized trial.

Learning Objectives

To understand the potential role of MR guided focused ultrasound thalamotomy in the treatment of medication-refractory, tremor-dominant Parkinson’s disease