Subjects of Phase I Study of Transcranial MR-guided Focused Ultrasound Thalamotomy See Reduced Tremor, Improved Quality of Life

NEW ORLEANS (April 29, 2013) — Research findings offered today during the 81st American Association of Neurological Surgeons (AANS) Annual Scientific Meeting show that the use of transcranial MR-guided focused ultrasound for producing a thalamotomy can have significant positive effects on subjects suffering from essential tremor.

A preliminary clinical trial suggested that acoustic energy could be delivered precisely to generate a focal stereotactic ablation deep within the brain. In an FDA-approved clinical trial, 15 patients with medication-refractory essential tremor underwent transcranial MR-guided focused ultrasound thalamotomy targeting the Vim nucleus. Adverse events were recorded throughout the study, with comprehensive neurologic assessments for sensation, gait, strength and balance. A 160-point validated rating scale of tremor was used to assess the procedure’s efficacy on the subjects, and a quality-of-life-in-essential-tremor questionnaire was obtained at pre, three-months and twelve-months post treatment. In addition, MR assessments were made of the lesions at one day, one week, one month and three months. The results of this study, The One Year Results of a Phase I Study of Transcranial MR Guided Focused Ultrasound Thalamotomy for the Treatment of Medication Refractory Essential Tremor, will be presented by William Jeffrey Elias, MD, FAANS, from 2:31-2:39 p.m. on Monday, April 29.

Co-authors are Diane Huss, PhD; Johanna Loomba, BS; Mohamad Khaled, MD, MS; Eyal Zadicario, MSc; Scott Sperling, PhD; Robert Frysinger, PhD; Binit Shah, MD; Madaline Harrison, MD; and Max Wintermark, MD.

Those results showed a 67 percent reduction in contralateral hand tremor at one year. This unilateral reduction of tremor in the dominant hand resulted in substantial improvements in daily disabilities (83 percent) and quality of life as assessed by clinicians and the subjects. Adverse events from the therapy were minimal and consisted mostly of mild paresthesia of the face or hand, but it is important to note that this preliminary feasibility study was not powered to determine the true safety and efficacy of the treatment. The researchers concluded that this initial investigation of transcranial MR-guided focused ultrasound thalamotomy seems feasible and safe enough to proceed with more comprehensive clinical trials. The study’s presenting author, William Jeffrey Elias, MD, FAANS, noted that the investigators “plan to follow these patients annually just as we do in our clinic with other movement-disorder procedures. We also are planning a long-term follow-up for our next multi-center and international clinical trial, which is scheduled to begin this summer.”

Dr. Elias added that “it is important to realize from these results and those of other tremor procedures that tremor suppression in the dominant hand, even if it is 75 percent on a rating scale, translates to very significant improvement in functional abilities. Our patients experienced almost no residual disabilities in day-to-day activities with this degree of tremor suppression.” He also noted that the researchers were “extremely surprised” by the amount of interest the tremor community had in this clinical trial. “We have been contacted by more than 2,000 people with tremor, which I think reflects their desire for more treatment options than we currently offer.”

Disclosure: William Jeffrey Elias, MD, FAANS, disclosed that the Focused Ultrasound Surgery Foundation provided grant/research support and an honorarium.

Media Representatives: The 2013 AANS Annual Meeting Press Kit includes releases on highlighted scientific research, AANS officer and award winners, National Neurosurgery Awareness Week, and other relevant information about this year’s program. Those releases also will be posted under the Media area on the 2013 AANS Annual Scientific Meeting website (http://www.aans.org/Annual+Meeting/2013/Main/Media.aspx). If you would have interest in a topic related to neurosurgery or would like to interview a neurosurgeon — either on-site or via telephone — during this year’s event, please contact John Iwanski, AANS Director of Member and Public Outreach, via the onsite press room at (504) 670-4910.
About the 2013 AANS Annual Scientific Meeting: Attended by neurosurgeons, neurosurgical residents, medical students, neuroscience nurses, clinical specialists, physician assistants, allied health professionals and other medical professionals, the AANS Annual Scientific Meeting is the largest gathering of neurosurgeons in the nation, with an emphasis on the field’s latest research and technological advances. A record-breaking 1,003 scientific abstracts were presented for review at the 2013 AANS Annual Scientific Meeting, and the scientific presentations given at this year’s event represent cutting-edge examples of the incredible developments taking place within the field of neurosurgery. Additional information about the AANS Annual Scientific Meeting and the Meeting Program can be found at http://www.aans.org/Annual Meeting/2013/Main/Home.aspx.

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