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RESCUE-ICP TRIAL

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The RESCUE-ICP Trial was one of the most eagerly awaited trials in recent history of neurosurgery. The trial aimed to evaluate the effectiveness of Decompressive Craniectomy (DC) through a randomized, control methodology. Herein, we would like to share the abstract of the trial, and a few comments with regards to its possible shortcomings.

ABSTRACT

Trial of Decompressive Craniectomy for Traumatic Intracranial Hypertension

Peter J. Hutchinson, Angelos G. Kolias, Ivan S. Timofeev, Elizabeth A. Corteen, Marek Czosnyka, and other RESCUEicp Trial Collaborators

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BACKGROUND

The effect of decompressive craniectomy on clinical outcomes in patients with refractory traumatic intracranial hypertension remains unclear. Methods: From 2004 through 2014, we randomly assigned 408 patients, 10 to 65 years of age, with traumatic brain injury and refractory elevated intracranial pressure (>25 mm Hg) to undergo decompressive craniectomy or receive ongoing medical care. The primary outcome was the rating on the Extended Glasgow Outcome Scale (GOS-E) (an 8-point scale, ranging from death to "upper good recovery" [no injury-related problems]) at 6 months. The primary-outcome measure was analyzed with an ordinal method based on the proportional-odds model. If the model was rejected, that would indicate a significant difference in the GOS-E distribution, and results would be reported descriptively. Results: The GOS-E distribution differed between the two groups (P<0.001). The proportional-odds assumption was rejected, and therefore results are reported descriptively. At 6 months, the GOS-E distributions were as follows: death, 26.9% among 201 patients in the surgical group versus 48.9% among 188 patients in the medical group; vegetative state, 8.5% versus 2.1%; lower severe disability (dependent on others for care), 21.9% versus 14.4%; upper severe disability (independent at home), 15.4% versus 8.0%; moderate disability, 23.4% versus 19.7%; and good recovery, 4.0% versus 6.9%. At 12 months, the GOS-E distributions were as follows: death, 30.4% among 194 surgical patients versus 52.0% among 179 medical patients; vegetative state, 6.2% versus 1.7%; lower severe disability, 18.0% versus 14.0%; upper severe disability, 13.4% versus 3.9%; moderate disability, 22.2% versus 20.1%; and good recovery, 9.8% versus 8.4%. Surgical patients had fewer hours than medical patients with intracranial pressure above 25 mm Hg after randomization (median, 5.0 vs. 17.0 hours; P<0.001) but had a higher rate of adverse events (16.3% vs. 9.2%, P=0.03). Conclusions: At 6 months, decompressive craniectomy in patients with traumatic brain injury and refractory intracranial hypertension resulted in lower mortality and higher rates of vegetative state, lower severe disability, and upper severe disability than medical care. The rates of moderate disability and good recovery were similar in the two groups. (Funded by the Medical Research Council and others; RESCUEicp Current Controlled Trials number, ISRCTN66202560.)

CRITIQUE

Although much was expected from this trial, it unfortunately failed to answer most questions that arose from DECRA. It however did help to endorse what the larger fraternity of neurosurgeons already suspected. The critiques have pointed out that the researchers have largely ignored to consider including cranioplasty in the analysis, that almost all survivors of DC will have to undergo and carries very high morbidity. It is essential to consider this procedure with DC while making comparisons with non-operative management while analyzing the cost, and 24-month outcomes, which they later plan to do.

Authors have also not discussed the difference in radiological grading of patients (an important predictors of outcomes). According to their results surgical group had much higher number of patients in class III (a

significant p-value). This difference disappeared on pre randomization radiology, which could be because in a large number of patients (47 and 53) Marshall class is unknown. Can this difference affect final outcomes?

Finally, in 157 patients injury to start of stage 1 therapy delay, was more than 12 hours. Is this delay not too long for severe TBI patients?

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Muhammad Waqas; Study concept and design, protocol writing, data collection, data analysis, manuscript writing, manuscript review
Muhammad shahzad Shamim; Study concept and design, data collection, data analysis, manuscript writing, manuscript review