

Spotlights on CLEAR III

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Editorial

Intracerebral hemorrhage (ICH) accounts for 8-13% of all strokes and is the most frequent fatal form of stroke and has the highest level of morbidity of any stroke subtype.

For patients with both intracerebral hemorrhage and intraventricular hemorrhage (IVH), expected mortality is 50-80% and good functional outcomes in less than 20%.

A common question for both Neurologists and Neurosurgeons is how to manage patients with ICH less than 30 ml with large intraventricular hemorrhage with obstruction of the third and fourth ventricle.

CLEAR Phase III trial (The Clot Lysis: Evaluating Accelerated Resolution of Intraventricular Hemorrhage) [1] a randomized, double-blinded, placebo controlled, multiregional study was set up to obtain information from a population of 500 non traumatic ICH subjects with intraventricular hemorrhage (IVH), regarding the benefit (or lack thereof) of IVH clot removal on subject function as measured by modified Rankin Scale (mRS).

The Modified Rankin Scale (mRS) runs from 0-6, running from perfect health without symptoms 0 to death 6.

0 - No symptoms.

1 - No significant disability. Able to carry out all usual activities, despite some symptoms.

2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.

3 - Moderate disability. Requires some help, but able to walk unassisted.

4 - Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.

5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent.

6 - Dead.

Acute hydrocephalus is a possible cause for deterioration in patient with ICH and IVH (3) and when it is documented by serial

CT scan [2], external ventricular drainage (EVD) is the mainstay of neurosurgical management [4,5].

The trial was designed to elucidate the role of thrombolysis via the ventricular drain in evacuating IVH, with the goal of improving mortality and functional outcomes.

1.0mg of alteplase were administered via the intraventricular catheter every 8 hours for up to 12 doses with saline bolus serving as placebo

2 take away findings:

A-The primary endpoint, mRS \leq 3 at 6 months follow up was achieved by 117 (48%) patients in the alteplase group and 110 (45%) in the saline group. The difference was not statistically significant,

However the second finding was positive:

B-46 fatalities were reported in in the alteplase group compared to 73 fatalities in the saline group amounting to a 50 percent reduction in the death rate.

Finally, no major differences in bleeding in the tpa versus placebo were reported.

References

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