

POSITION: STRATEGIES TO IMPROVE TBI MANAGEMENT – NEW APPROACHES

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Finding additional improvements to the limited panel of treatment options for TBI management remains challenging. However, recent reports from interdisciplinary working groups consisting mostly from neurologists, neurosurgeons, neuropsychologists, and biostatisticians, state that to create improvements in TBI treatment, important methodological lessons from the past must be taken into account in future clinical research. An evaluation of neuroprotection intervention studies conducted in the last 30 years has determined that methodological design flaws are major reasons why pharmacological agents fail to demonstrate efficacy.

Almost all the inconclusive studies used a single outcome measure approach. This classic approach in clinical TBI trials cannot capture all clinical relevant functional information in survivors of any kind of TBI. Even survivors of mild to moderate TBI may experience lifelong disturbances in the physical, behavioral, emotional, cognitive (memory, attention, reasoning, communication and planning), motor, sensory, perception and social domains of life that may affect specific or global functioning.

Leading interdisciplinary research groups recently highlighted the multidimensional nature of TBI, such as, e.g., the International Mission on Prognosis and Clinical Trial Design in TBI (IMPACT), stating that “outcome after TBI is by definition multidimensional” or the US Traumatic Brain Injury Clinical Trials Network Group, pointing out that “multiple measures are necessary to address the breadth of potential deficits and recovery following TBI”.

Multidimensional analysis opens a completely new direction for clinical and statistical thinking and is perhaps much closer to the complicated reality of outcome after traumatic brain injury than the previous “one-criterion paradigm” which ruled clinical research on neuroprotective treatments for the last decades. It is thus fortunate that new data analysis procedures are now available that are appropriate for the multidimensional concept. These procedures are robust with respect to every data situation and highly efficient with multiple target criteria. Furthermore, these procedures produce easily interpretable results (global test as well as global treatment effect).

The multidimensional strategy is expected to become a key development in TBI clinical research, opening up new horizons for TBI management.