

various brain pathological conditions correctly. Therefore, we take a closer look at the waveform of ICP in the several pathologic condition. The data of ICP waveform (ICPWF) was monitored in water intoxicated rat model and continuous infusion model using Biopac MP150 system (BIOPAC USA). On cite of clinical, the ICP data of 16 trauma patients and 9 cerebrovascular disease patients in whom ICPWF was monitored continuously by ICP express<sup>®</sup> (Codman USA). Differential ICPWF was calculated using LabChart<sup>®</sup> Software (AD instrument, USA).

Continuous monitoring of ICPWF showed clarify waveform change and the change over time of the pressure. Single ICPWF was expressed as 3-phase wave (P1, P2, P3), 3-phase wave was reflected as U1, U2, U3 in the differential ICPWF. In accordance with increased ICP Continuous infusion as interstitial edema model demonstrates high amplitude ICPWF and elevated P1, U1. In contrast, water intoxication as cellular edema model showed low amplitude ICPWF, numerous b wave and U2 elevation during high ICP. Also in clinical cases, ICPWF were divided roughly into two groups. One group showed the increased U1, there was a tendency to include increased ICP patients with a massive hematoma. Another elevated U2 group tended to be more common in cases of severe traumatic brain injury and cerebral infarction patients.

Although mean ICP was the same degree, the difference of ICPWFs was observed in different pathogenic brain condition: extracellular edema and intracellular edema. It suggests ICP waveform analysis will be more valuable for assessment of brain's pathological condition like several type of brain edema.

#### Key words

differentiated intracranial pressure waveform

#### A1-13

### FACTORS ASSOCIATED WITH CLINICIAN ADHERENCE TO PEDIATRIC TRAUMATIC BRAIN INJURY GUIDELINES: A QUALITATIVE STUDY

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Evidence-based medicine may be influenced by provider beliefs and competencies, professional norms, and managerial support. This study assessed factors specific to adherence to the Brain Trauma Foundation pediatric traumatic brain injury (TBI) guidelines. We conducted nineteen focus groups with physicians (n = 54) and nurses (n = 74) who treat pediatric patients with TBI at six pediatric-trauma centers (Chicago, Columbus, Los Angeles, Pittsburgh, and Seattle). Sessions were transcribed and examined using content analysis to identify themes related to guideline adherence. Barriers and facilitators of clinical adherence to the pediatric TBI guidelines were identified. Three domains emerged: 1) the implementation and agreement of institutional protocols with the guidelines, 2) inter- and intra-department communication and decision making, and 3) and perceived guideline credibility and practicality. Dissemination and accountability struc-

tures used to implement institutional protocols, and the level of agreement between protocols and TBI guidelines influenced clinical decisions. Communication and decision making were affected by the quality of platforms for inter- and intra-department communication and the establishment of common treatment goals. Clinicians reported value in clear care pathways, identified and accessible decision makers, departmental liaisons, and provider consensus of guideline application in local practice. Guideline credibility was rooted in the perceived strength of the evidence, and alignment with clinical experience and training. Practicality was determined by applicability to the patient. Identifying remediable provider and organizational factors that impact guideline adherence will inform changes to pediatric TBI care pathways and the development of future TBI treatment recommendations.

#### Key words

adherence, guidelines, qualitative, TBI

#### A1-14

### COMPARATIVE STUDY OF OUTCOME MEASURES AND ANALYSIS METHODS FOR TRAUMATIC BRAIN INJURY TRIALS

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Batteries of functional and cognitive measures have been proposed as alternatives to the Extended Glasgow Outcome Scale (GOSE) as the primary outcome for traumatic brain injury (TBI) trials. We conducted a study to compare GOSE and a battery of functional and cognitive measures.

Several analytic methods were evaluated for each outcome. Using data from a randomized trial, we simulated multiple treatment effects (0, 5, 7.5, and 10 percentage point improvement in favorable outcome on GOSE and a corresponding deficit reduction for other measures) across multiple outcome measures. Patients with complete data (n=331) were sampled with replacement (bootstrapping) to generate 10,000 samples for each treatment effect (n=400 patients/group). We calculated the percentage of samples where the null hypothesis was rejected to estimate the power for each outcome with a suite of analytic techniques. Type-I error was estimated by analyzing the simulation with 0% treatment effect.

All analytic techniques had appropriate rates of Type-I error ( $\leq 5\%$ ). Accounting for baseline prognosis, either by using sliding dichotomy for GOSE or using regression-based methods substantially increased the power over the corresponding analysis without accounting for prognosis. The highest power was obtained using multivariate proportional odds regression to analyze GOSE or using regression-based adjusted analysis of the battery of functional and cognitive measures, assuming equal treatment effect across all components. Analyzing GOSE using the fixed dichotomy provided the lowest power for both unadjusted and regression-adjusted analyses.

Our findings are limited to situations where the assumption of equal treatment effect across all measures is satisfied. This may not be true in an actual clinical trial.

Accounting for baseline prognosis is critical to attaining high power in phase-III TBI trials. The choice of primary outcome for future trials should be guided by the domain of brain function an intervention is likely to impact and the feasibility of data collection.

#### Key words

clinical trial, Glasgow Outcome Scale, outcome measures, research design, statistical data analysis, traumatic brain injury