NINDS Traumatic Coma Data Bank: intracranial pressure monitoring methodology

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This report describes the methods used by the Traumatic Coma Data Bank (TCDB) for acquisition and recording of intracranial pressure (ICP) data of severely head-injured patients. Direct computerization of physiological data from all four participating locations within the United States and transmission to a central data bank was found to be logistically complex and costly. A simple manual method for recording ICP, blood pressure, and concomitant ICP therapy at the bedside is described. The method documents the temporal course of these variables for the duration of monitoring. The importance of relating ICP to the therapy intensity level used for ICP management is emphasized. Concomitant analysis of the therapy intensity level is considered imperative in correlative patient studies. The methods described in this report have been in use among all four TCDB hospitals. Examples of ICP data retrieved from the TCDB are presented to illustrate the adequacy of the methods for assessing temporal trends. Of 1030 patients admitted to the TCDB, 654 severely head-injured patients had at least 4 hours of monitoring recorded; elevated ICP (> 20 mm Hg) was observed in 72% of these 654 patients.

Key Words • Traumatic Coma Data Bank • head injury • intracranial pressure • therapy intensity level • blood pressure

The brain swelling that occurs following severe head injury results in depletion of intracranial volume reserve. The concomitant rise in intracranial pressure (ICP) may reach levels sufficient to compromise cerebral perfusion and add further mechanical stress to damaged brain tissue. The introduction of techniques for continuous monitoring of ICP has led to numerous investigations indicating that sustained intracranial hypertension is associated with a poor prognosis.

Normal ICP in humans is about 10 mm Hg. Raised ICP has been defined variously as ICP greater than 15, 20, or 25 mm Hg, based largely on intuitive considerations. Heretofore, no objectively determined critical value has been identified. Recent clinical studies have shown that raised ICP was initially present in two-thirds of patients who were comatose upon admission. The raised ICP recurred or persisted in 50% of patients with mass lesions and remained a problem in one-third of patients with diffuse head injury. Death occurred in one-half of the patients who developed intracranial hypertension or in whom elevated ICP persisted despite surgical decompression, osmotic therapy, and hyperventilation. Thus, ICP remains a critical factor in the neurosurgical management of the severely head-injured patient. One goal of the Traumatic Coma Data Bank (TCDB) was to devise and implement ICP measurement methods as a component of a physiological assessment battery.

As an ideal solution, we considered collecting ICP
data directly from the bedside monitor using an interfaced computer and electronically transferring the ICP data to a central repository. Two of the four centers equipped with computers in the intensive care unit (ICU) conducted a study to test the feasibility of this approach. The transfer of continuously monitored ICP data from neurosurgical patients from Richmond, Virginia, to Galveston, Texas, was accomplished. However, it was concluded that, as a routine procedure, the problems of distant communication using conventional telephone transmission were complex and too costly for serious consideration during the time-frame of the project. It was obvious that preservation of the quantitative approach of ICP recording would require compromise. This strategy led to the development of a manual recording technique of sufficient accuracy to depict the temporal course of ICP. This report describes the methods and procedures used in the assessment, documentation, and recording of ICP as developed by the TCDB.

Intracranial Pressure Recording Method

The cerebrospinal fluid (CSF) pressure measured by the ventricular catheterization method described by Guillaume and Janny and Lundberg is considered the "gold standard" of ICP measurement to which all other techniques are compared. Other methods have been devised in recent years and it is now common and clinically acceptable by many to consider the ICP as that pressure measured in the ventricular, subarachnoid, subdural, or epidural spaces. In addition to these sites, the recent introduction of fiberoptic solid-state catheters allows measurement of ICP directly in brain tissue. The measurement of ICP at the four participating neurosurgical centers was obtained primarily by ventricular catheter referencing to the level of the foramina of Monro or by subarachnoid bolt. Other devices were used sparingly during the time of this study. In either selection, patients were maintained with their head elevated 30° and positioned in the neutral plane.

Selection of ICP Observation Method

Having decided on technical grounds that only a manual method of ICP recording was practical, the question remained as to what feature of ICP should be recorded and by what method. Since it was a common practice at all centers for a nurse to record physiological data extracted from bedside monitors at regular intervals, a study was conducted by one of the centers equipped with computerized monitoring equipment to determine the relationship between nurse- and computer-recorded ICP. Details of this analysis are described in another report. In brief, the ICU nurse observed the ICP monitor at the end of each hour and charted the digital reading of ICP and blood pressure (BP). Simultaneously, bedside monitor values of ICP and BP were transferred and stored by digital computer at 5-second intervals. In this hospital-based study, five patients contributed a total of 347 hours of simultaneous nurse-computer monitoring.

It was found that 83% of the paired observations of computer- and nurse-recorded ICP values differed by less than 6 mm Hg. From the analysis of these data, the mean difference between computer- and nurse-recorded values equaled -1.5 mm Hg, with a standard deviation of 7.8 mm Hg. Based upon this pilot study, it was decided not to record the subjective estimates of hourly high and hourly low ICP. It was concluded that the nurse's "end-hour" recording of the bedside ICP and BP digital values was a good estimate of the ICP and BP history for the entire hour, from which quantitative descriptors of physiological course could be developed.

Duration of ICP Recording

Having selected the ICP feature to record, the next task was to decide upon the duration of ICP recording. Obviously, this decision would have serious implications upon the transmission and storage requirements of the TCDB. It was decided to tailor the recording procedures to standard clinical practice at all centers. With these criteria, it was not possible to define a standard duration of recording since it varied with the severity of injury. For example, the ICP transducers were removed within 72 hours of injury to reduce risk of infection in patients with mild to moderate swelling and no evidence of ICP rise during the first 24 to 48 hours. This decision would limit the ICP recording period to 3 days. However, in patients with moderate brain swelling and sustained high ICP, the duration of recording might extend to several weeks. The shortest duration was associated with patients who died with severe brain swelling and development of uncontrollable ICP (see Fig. 6).

Working within the constraints of clinical practice criteria, we considered concomitant factors that might define a more critical ICP monitoring duration in anticipation of research questions dealing with the pathophysiology of ICP. Survival times from the TCDB pilot-phase data were considered. The survival time for all patients who died during their acute-care period averaged 6.7 days. On the basis of these preliminary data, a maximum ICP recording duration of 10 days was deemed adequate. To insure that this recording period would include all deaths attributed to ICP, we examined survival times in the final main-phase data of 1030 patients. Considering all 145 patients whose primary cause of death was head injury and who had at least 4 hours of ICP monitoring, the median survival time equaled 2.7 days, with an interquartile range of 1.2 to 6.9 days. Given the clinically motivated variability in recording duration, it was concluded from these descriptive statistics that a maximum monitoring duration of 10 days was adequate for TCDB patients manifesting ICP instability soon after injury.

The Therapy Intensity Level Concept

In addition to the problems associated with monitoring, analysis of the data obtained from multcenter
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recording of ICP in head-injured patients is further complicated by the variation in treatment given within centers. Moreover, comparative clinical studies of the pathophysiology of ICP have not addressed the complexities introduced by therapy. This complication is clarified when one compares patients with similar ICP profiles but very different levels of treatment. One patient might require only mild hyperventilation while the other requires barbiturates. The forces driving brain swelling in these patients appear to be different as suggested by the differing aggressiveness of therapy required to control ICP. Therefore, we collected a temporal record of concomitant therapy as well as the temporal record of ICP.

Investigators at the University of California at San Diego introduced the concept of numerically scaling an ICP therapy intensity level. By this technique, it would be possible to quantitatively associate the temporal course of ICP with concomitant therapy. An initial four-level scale was considered, but it was decided that greater resolution was required. Investigators at the Medical College of Virginia developed a new therapy index which provided greater resolution by grading ICP treatment according to a 15-point scale. This new scale was adopted by the TCDB for the course of this study (Table 1).

The development of the 15-point Therapy Intensity Level Scale increased the numerical intervals corresponding to the qualitative stages of increasingly aggressive ICP therapy. Use of sedatives, paralytic agents, mild hyperventilation, or mild ventricular drainage was weighted at one point each. The more aggressive therapy of ventricular drainage exceeding four times per hour or intense hyperventilation resulting in a PaCO2 of less than 30 torr were each weighted at two points. According to this weighting scheme, a maximum score of six was possible without use of osmotic therapy. Use of mannitol was weighted proportionately higher: dosage of less than 1 gm/kg/hr was assigned three points, whereas dosage greater than 1 gm/kg/hr was assigned six points. Thus, considering all combinations, a score of 12 corresponded to maximum conventional therapy. Up to the level of 12, the scoring system is additive. However, use of barbiturates at any dosage level set the Therapy Intensity Level score to its maximum of 15 points (Table 1).

A major limitation of the Therapy Intensity Level Scale is that it identifies only the onset of a specific therapy rather than its duration or effect. Each mode of therapy has a different effect profile. For example, drainage results in an immediate fall of ICP when CSF volume is not depleted. The rate of pressure return depends upon many factors, including volume removed, rate of CSF formation, edema clearance, brain compliance and vascular swelling. In contrast, the drug therapy effects rise and then trail off, with a much longer overall course. Moreover, it would be difficult to assign meaning to a therapy intensity level for a 1-hour period since the effectiveness of therapies introduced in the previous hours may overlap. Consideration of the lag in effect of treatment led to a therapy summary over 4-hour time periods rather than hourly.

Each 24-hour physiological recording "day" in the TCDB format was subdivided into six "blocks" of 4 hours' duration. Using 24-hour clock time, the first minute of the first block started after midnight at 00:01. Thus, the TCDB retained maximum time resolution of ICP and BP at 1-hour intervals while therapy intensity level was assessed with 4-hour resolution.

Results

Intracranial Pressure Study Group

A detailed description of the TCDB cohort is reported by Foulkes, et al.2 In brief, the TCDB contained data from 1030 head-injured patients with Glasgow Coma Scale24 scores of 8 or less. Of this group, 654 patients had a minimum of 4 hours of data recording and were available for ICP analysis.

Four exclusion criteria were applied to the full TCDB group of 1030 patients to derive the 654 patients available for ICP analysis (Table 2). The first exclusion was applied to patients who were dead on arrival at the data bank hospital or who died during resuscitation. These patients were not considered a part of the population to which we intend to infer the results of any ICP analyses since there was no treatment opportunity.

Patients with penetrating injuries were excluded since those injuries present sufficiently unique attributes to be studied separately. All patients who never had ICP monitoring were excluded; most of these died before monitoring could begin. The last exclusion criterion involved patients who had less than 4 hours (one block) of ICP monitoring. Four hours is the minimum duration required to have at least one therapy intensity level datum.

The remaining 654 patients had at least one block of ICP monitoring. This number is the largest possible sample available for ICP analysis using these exclusion

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Score</th>
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<tbody>
<tr>
<td>barbiturates</td>
<td>15*</td>
</tr>
<tr>
<td>mannitol</td>
<td>6</td>
</tr>
<tr>
<td>&gt; 1 gm/kg/hr</td>
<td>3</td>
</tr>
<tr>
<td>≤ 1 gm/kg/hr</td>
<td>2</td>
</tr>
<tr>
<td>ventricular drainage</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 4 times/hr</td>
<td>1</td>
</tr>
<tr>
<td>≤ 4 times/hr</td>
<td>1</td>
</tr>
<tr>
<td>hyperventilation</td>
<td>1</td>
</tr>
<tr>
<td>intensive (PaCO2 &lt; 30 mm Hg)</td>
<td>1</td>
</tr>
<tr>
<td>moderate (PaCO2 ≥ 30 mm Hg)</td>
<td>1</td>
</tr>
<tr>
<td>paralysis</td>
<td>1</td>
</tr>
<tr>
<td>sedation</td>
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* Maximum score is 15. Without barbiturates, the score is the sum of the other components.
criteria. We anticipate some ICP questions will require application of additional exclusions. Further exclusions may be motivated by the need for sufficient ICP data per patient to detect findings of interest, such as meaningful time trends, or relationship to outcome.12

Description of ICP Group

The distribution of primary diagnosis for each of the 654 patients is summarized graphically in Fig. 1. Mass lesions were diagnosed in approximately one-third of the patients. The age distribution of the study group is shown in Fig. 2. As in previous studies, most patients fell within the age range of 15 to 35 years. The distribution of the Glasgow Outcome Scale (GOS) scores in the TCDB and the ICP study group is depicted in Fig. 3. Figure 4 shows the Kaplan-Meier product-limit estimated survival distributions of the 654 cohort and of the excluded patients. Most exclusions were among patients who died before ICP monitoring could be initiated (Table 2), and only 12% of these patients survived. The median survival time among the excluded patients was 10.4 hours, with an interquartile range of 2.6 to 40.6 hours. Among the 654 patients in the ICP analysis cohort, less than half died (68% survived) so

![Intracranial Diagnosis](chart1)

**Fig. 1.** Histogram showing the primary intracranial diagnosis of the 1030 total patients in the Traumatic Coma Data Bank and the subgroup of 654 patients selected for intracranial pressure analysis. Miss = missing an intracranial diagnosis; NVP = diffuse injury with no visible pathology on computed tomography scan; Diff. = diffuse injury with cisterns present and < 5-mm shift; Swell = diffuse injury with swelling and cisterns compressed or absent; Shift = diffuse injury with shift > 5 mm; EM = evacuated mass lesion; and NEM = nonevacuated mass lesion.

![Age at Injury](chart2)

**Fig. 2.** Histogram showing the age at injury of the 1030 Traumatic Coma Data Bank patients and the subgroup of 654 patients selected for intracranial pressure analysis. The proportion of patients excluded within each age group is fairly constant across the age groups.

![Glasgow Outcome Score](chart3)

**Fig. 3.** Histogram showing the Glasgow Outcome Scale scores in the 1030 Traumatic Coma Data Bank patients and the subgroup of 654 patients selected for intracranial pressure analysis. Most of the excluded patients died.

**TABLE 2**

<table>
<thead>
<tr>
<th>Reason for Exclusion</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>died before resuscitation</td>
<td>137</td>
</tr>
<tr>
<td>penetrating injury</td>
<td>167</td>
</tr>
<tr>
<td>no ICP monitoring</td>
<td>319</td>
</tr>
<tr>
<td>monitored for &lt; 4 hrs</td>
<td>17</td>
</tr>
<tr>
<td>cumulative exclusions</td>
<td>376</td>
</tr>
<tr>
<td>remaining patients</td>
<td>654</td>
</tr>
</tbody>
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*ICP = intracranial pressure.
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the median survival time is undefined; however, 25% of the 654 had died by 417 hours postinjury.

Synchronization of ICP and Therapy Intensity Level

To illustrate the need for a quantifiable therapy scale, the ICP profiles of two head-injured patients included in the TCDB were plotted (Fig. 5). The ICP- and therapy intensity level-recording formats were as described above. The temporal courses of the ICP during the first 7 days postinjury were quite similar for the two patients. The ICP course of both patients was quite variable, with transient elevations to 35 mm Hg during the first 48 hours. After that, the ICP in both patients was maintained below 25 mm Hg. However, despite comparable ICP profiles, there was a dramatic difference in the Therapy Intensity Level scores. One patient (Case A) required three doses of mannitol during the first 72 hours, as indicated by the Therapy Intensity Level exceeding a score of six. In this patient, scores of 11 and 12 indicate that mannitol administration exceeded 1 gm/kg/hr during the first 24 hours and was coincident with the maximum elevation of ICP. For the succeeding 5 days, the Therapy Intensity Level score remained at 6 or below, indicating that osmotic therapy was not required and the ICP in this patient could be managed by a combination of sedation, hyperventilation, and drainage. In Case B, however, maximum conventional ICP therapy was required during the first 24 hours. Thereafter, barbiturates were used to control ICP for the next 5 days. Both patients recovered and were classified as having a “moderate” GOS score at 6 months postinjury.

From these data, it is reasonable to assume that the degree of brain swelling in these patients was markedly different although, from the standpoint of ICP classification, they would generally fall in the same category. Under these circumstances, despite similar ICP profiles, the Therapy Intensity Level score should be higher in patients with reduced compliance and “tight brains.” This relationship was demonstrated by Maset, et al., who measured brain compliance in head-injured patients by the pressure-volume index (PVI) and observed higher Therapy Intensity Level scores with reduced PVI.

Definition of ICP and Monitoring Devices Used

According to the TCDB definition, ICP is the “end-hour” value indicated by the bedside ICU monitor and recorded by the ICU nurse. The ICP data form differentiated between ICP recorded by ventriculostomy, subarachnoid bolt, epidural, and “other” devices. Of the

![Graph of Survival Time (Days) vs Probability](attachment:image)

**Fig. 4.** Kaplan-Meier product-limit estimated survival functions for the 654 patients in the intracranial pressure analysis group (upper curve) and for the excluded patients (lower curve). The survival function gives the probability of postinjury survival to time, t.

![Graph of Therapy Intensity Level (TIL) and ICP](attachment:image)

**Fig. 5.** The intracranial pressure (ICP) profiles of two patients selected to illustrate need for an ICP therapy index. The ICP temporal course of both patients is quite similar during the first 7 days postinjury and, in both patients, transient elevations of 35 mm Hg occurred during the first 48 hours. The ICP of Case A (left) was controlled by three doses of mannitol during the first 72 hours (6 < Therapy Intensity Level < 12). In Case B (right), maximum conventional therapy was followed by barbiturate administration to control ICP (Therapy Intensity Level score 15). The difference in ICP management is clearly indicated by the Therapy Intensity Level score.
654 patients in the TCDB available for ICP analysis. ICP monitoring was by ventricular catheters alone in 257 patients and by subarachnoid bolts alone in 275; 110 patients had monitoring by multiple pressure-measuring devices and the remaining 12 patients by fiberoptic devices. The ICP data used in this analysis was obtained from the pressure device used for ICP management.

Onset and Duration of ICP Monitoring

During the pilot development of the TCDB, interest was expressed by all participating investigators in monitoring and recording ICP as rapidly as possible. Data collection procedures were designed accordingly. Among the cohort of 654 patients, the median transport delay from time of injury to admission to the TCDB centers was 1.3 hours, with an interquartile range (the middle 50%) extending from 0.8 to 3.0 hours. The interval between admission and ICP monitoring is attributable to transfer, emergency room management, computerized tomography, surgery, and ICU stabilization. In the cohort of 654 patients, this delay segment had an interquartile range of 2.8 to 6.8 hours with a median delay of 4.5 hours. Summing these components, the median total delay for the 654 patients was 6.7 hours, with an interquartile range of 4.5 to 10.0 hours.

The distribution of the duration of ICP monitoring for the 654 patients in the ICP analysis cohort is shown in Fig. 6. Most of these patients who died while being monitored did so soon after injury, resulting in shorter monitoring durations. The remaining patients either survived or died more than an hour after monitoring was discontinued.

TCDB Patients With Raised ICP

In TCDB patients with at least 4 hours of ICP monitoring, 72% had at least one "end-hour" ICP observation above 20 mm Hg. A more detailed description of the relationship of ICP elevation to outcome is described elsewhere.12

Discussion

The main objective of the ICP monitoring component of the TCDB was to develop a practical method for prospectively documenting the temporal course of ICP from four centers within the United States. The methods described in this report, although limited by practical considerations, have been tested, compared with on-line computerized recording results, and shown to be sound.23 The accuracy of documentation of these events by the neurosurgical nurse is remarkable, given that the data collection was conducted during the intensive care of severely head-injured patients in the clinical setting, particularly when these tasks are superimposed during the early hours of ICU stabilization. To the best of our knowledge, the TCDB effort represents the first attempt at multicenter systematic recording and documentation of ICP data.

Computerized procedures for recording ICP have been described by many investigators.6,8,22,23,25,26 All of these systems extract physiological data at high sampling rates and have the advantage of automated acquisition, storage, and processing. The greatest advantage is that there are many fewer restrictions on the type of ICP analysis conducted. Analysis may focus on the more slowly varying ICP baseline or on changes in ICP pulse pressure. Pulsatile analyses, or even within-hour trend analyses, cannot be performed using the TCDB collection procedures. It is geared specifically for ICP and cerebral perfusion pressure trends manifested over longer time periods, such as 4-hour blocks or even days.

At a few head-injury centers, clinicians have used within-hour high and low ICP values to characterize the ICP temporal course and judge the effectiveness of treatment. The TCDB recording format of ICP does not include high and low values of ICP reached within the hour. Nevertheless, high and low ICP values documented during the hour are of clinical importance when brief time periods are assessed. These high and low values are best measured by a computer system because of the frequent sampling required to assess them accurately. For example, using the TCDB recording format, the variability of ICP during a 4-hour period would be expressed by only four "end-hour" values. A patient might exceed an ICP mannitol treatment threshold within a given hour without that excursion being revealed by the "end-hour" value. Thus, for short-term

Fig. 6. Distribution of the duration of intracranial pressure (ICP) monitoring for the 654 patients in the ICP analysis cohort. Patients who died while being monitored are represented in the hatched portion of the bars. Most of these deaths occurred soon after injury, resulting in shorter monitoring durations. The remaining patients (solid portion of the bars) either survived or died more than 1 hour after monitoring was discontinued.
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assessment of ICP, high and low values have clinical relevance, yet they may be reliably determined only by frequent sampling. The “end-hour” system of ICP recording is one which is best suited for characterizing the temporal course over longer time periods and provides a reasonably accurate profile with minimal equipment and personnel requirements.

Conclusions

This report documents the methods used for recording ICP and therapy directed toward ICP management. The final recording format represents the culmination of a 3-year effort which evaluated several approaches to the problem of describing intracranial hypertension. Practical limitations required that many ICP features such as plateau wave identification, pulsatile changes, trends, and immediate response to therapy were not documented in order to arrive at an ICP measure which was objective, easily implemented, and yet statistically meaningful. In our view, a major strength of the ICP component of the TCDB is simply that the physiological time course of the head-injured patient is available within a relational data base linking pathophysiology with treatment. This data base allows correlative studies of ICP with other critical parameters obtained and systematically recorded from the moment of injury and throughout the acute management period. It is hoped that information gained from these studies will contribute to our understanding of ICP in traumatic head injury.

References


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