



# Traumatic Brain Injury Symptom Assessment and Resolution Prediction

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## **Introduction**

Traumatic brain injury (TBI) in children remains a significant public health problem in the United States accounting for 62,000 hospitalizations and more than 560,000 emergency department visits annually [1][2]. Approximately 70%-90% of all TBI are deemed mild TBI. [3] Following TBI, children often exhibit a variety of somatic, cognitive, emotional, and sleep related symptoms that are often not recognized. [4] As many as 35% of children continue to exhibit such symptoms beyond three months and are then defined as having post concussive syndrome (PCS) [5] and for some, symptoms may linger for as long as 1 year. [6]

The goal of this multi-institutional study was to better identify children at risk for prolonged recovery following hospitalization after sustaining a mild traumatic brain injury. This objective was accomplished in partnership with 4 pediatric trauma centers. Together we assessed children with a mTBI using a standardized assessment tool within 48 hours of injury and again at 7 days, 1 month, and 3 months in order to determine if this tool would allow us to predict who is most likely to have persistent symptoms and therefore benefit from referral to a specialized service to improve their outcome.

## **Background**

The symptoms associated with PCS may be overt or not readily recognized by the patient, caregiver, teachers or coaches. [7] The negative effect of PCS can be debilitating and impede the patient's ability to participate in routine activities such as school and sports. [8][9] [3] Persisting cognitive deficits may interfere with executive function and academics. [10] [11] Executive functions include things such as cognitive flexibility, abstract thinking, rule acquisition, initiating appropriate actions and inhibiting inappropriate actions. As a consequence of such deficits, Hooper, et al (2004) reported that 21% of children hospitalized following TBI had not returned to school at one month and 12% for only a portion of the day. These authors note that those children returning to school present

with new deficits and emphasize the importance of early symptom identification and evaluation by rehabilitation services.

Additionally, patients with PCS who return to activities prior to symptom resolution may delay recovery, exacerbate brain injury, or increase risk of mortality due to second impact syndrome. [12] The Centers for Disease Control states “any presentation of lingering and/or persistent symptoms associated with mTBI indicates incomplete recovery and prudent management is indicated, especially pertaining to activities such as work, school, and sports.” (p. 7). [13]

Self or parent reported symptom checklists can be used during hospitalization and at designated intervals post discharge to document severity and the progression or resolution symptoms. [4][14] For example, Nance et al (2009) found that 83.4% of children exhibit an abnormal symptom score during acute hospitalization and 38.1% at the 2-3 week follow-up. Blinman, et al (2009) reported similar findings with 83.6% of children demonstrating abnormal symptom scores during hospitalization and 49% at 2-3 week follow-up. During hospitalization, headaches were the most common symptom and fatigue the most severe. [9] However, at 2 – 3 week follow-up, excess sleep was most commonly reported and trouble falling asleep and nervousness the most severe.

Standardized assessment tools such as the Immediate Post-Concussion Assessment and Cognitive Testing (ImpACT) includes a symptom checklist which provides objective data to support treatment recommendations including inpatient management, discharge instructions, and activity restrictions following discharge. [9][4] However, there is no data to support acute care decisions to determine which patients would benefit from referral to specialty services such as Pediatric Rehabilitation, Sports Medicine, or Occupational, Physical, or Speech Therapy and potentially reduce the rate of PCS.

For example, in sports related concussion, in conjunction with neuropsychological testing, symptom checklists are utilized at 7-10 days and ongoing follow-up, to determine safe return to sports. [16] [17] If an abnormal symptom score is documented, treatment recommendations will include refraining from participation in sports. To date, no threshold for an abnormal symptom score has been identified during hospitalization or which symptoms mandate referral to specialty services.

Numerous symptom checklists are available to document post concussive symptoms. [18] However, no gold standard has been identified. In a systematic review, Alla, Sullivan, Hale & McCrory (2009) identified 6 core symptom checklists that although similar, vary as to the name and number of symptoms included. A majority of these checklists are self or caregiver reported and use a 7-point Likert scale to document severity of symptoms.

Two common tools are the Post-Concussion Scale within the ImPACT and the Rivermead Post Concussion Symptoms Questionnaire (RPQ). The Post-Concussion Scale (ImPACT) is a 22 item checklist utilizing a 0-6 Likert scale that measures the patient's current perception of symptoms. [16] The RPQ addresses 16 symptoms that the patient rates the severity of current symptoms compared to premorbid levels on a scale of 0-4. [19]

At Cincinnati Children's, the Post-Concussion Scale (ImPACT) score is documented for all patients age 5 years and older admitted to Trauma Services following a mild TBI. Within 24-48 hours following injury the symptom score is obtained via self-report or from the parent. Among our pilot group of patients assessed, 68% had an abnormal score at the initial evaluation and 25% remained abnormal at 7-10 day follow up. However, research is needed to identify the acute symptoms or total score predictive of increased risk of prolonged deficits to facilitate referral for treatment. [20][2] Prompt identification of post concussive symptoms will enhance early referral, treatment and care and may ultimately decrease the rate of Post Concussive Syndrome at three months post-injury. [4]

Environmental factors have also been shown to affect recovery after TBI. Family functioning influences recovery and acts to moderate the effects of injury severity on cognitive and social recovery after pediatric TBI. [21] Socioeconomic resources, social supports, and better family functioning have been shown to buffer or reduce the adverse effects of TBI on executive functions and social problem solving skills. [22] Elucidating the role of family functioning related to symptom recovery after pediatric TBI is an important step towards determining the optimal environment needed to facilitate recovery.

Additionally, individual characteristics, including genetics, would also likely factor strongly into the recovery process. Phenotypes are determined by the interaction of environmental stimuli with genetic inheritance. A genetic predisposition to prolonged recovery could provide further explanation of the variability in outcomes after TBI. Various genes have been implicated in recovery after TBI in adults, [23] however, the relationship of genetics to recovery after pediatric TBI needs to be explored. Characterization of the genetic association with recovery from TBI could provide insight to potential mechanisms of recovery and identify possible targets for interventions to improve recovery. Additionally, the genetic influence on treatment effects needs to be examined to better elucidate potential responses to interventions. [24] Thus, investigations considering both individual (i.e., genetic) and environmental (i.e., family and treatment interventions) influences on recovery are essential to better understand the trajectory of recovery and to provide optimal interventions to maximize recovery following pediatric TBI.

There is clearly a clinical need to reliably identify those children with a mild TBI that are most likely to have delayed recovery. Once patients at risk are reliably identified it will be possible to study whether present interventions or new interventions can reduce the time to full recovery (comparative effectiveness research).

Our **overall objective** of this multi-institutional prospective study was to better identify children at risk of prolonged recovery after mild traumatic brain injury (TBI) requiring inpatient admission.

***Specific Aims:***

**Aim 1:** Analyze the ability of the ImPACT symptom score performed within 48 hours of sustaining a minor traumatic brain injury /concussion to predict resolution of post-concussion symptoms at 7 days, 1 month and 3 months after injury.

*Hypothesis 1:* Children with symptoms scores above 30 on the ImPACT post-concussive symptom scale less than 48 hours after injury will be more likely to experience persistent symptoms 3 months after injury compared to an orthopedic injury (OI) group. This will allow for the prediction of the nature of outpatient resources (clinician follow up, subsequent testing, cognitive therapy, etc.) that will most likely benefit each child suffering a mild traumatic brain injury.

**Aim 2:** Analyze the effect of family environment on the trajectory of symptom recovery after mild TBI and OI in children, as measured by the McMaster Family Assessment Device

*Hypothesis 2:* Positive family functioning will decrease the association of high symptom scores on the ImPACT post-concussion assessments with persistent symptoms 3 months after injury. Additionally, positive family function will have a greater effect in the TBI group compared to the OI group.

**Aim 3:** Collect and bank salivary DNA samples for future genetic analyses

*Hypothesis 3:* Individuals with certain genetic polymorphisms will be more likely to have persistent symptoms 3 months after injury and the genetic influence will be more pronounced in the TBI group compared to the OI group.

## Methods

This was a prospective, multi-institutional, non-randomized cohort study. Children with mild traumatic brain injury (mTBI) were included as the study group and children with mild orthopedic injury from a non-decelerating injury were included as a control group. A mild orthopedic injury control group was utilized as a reliable comparison group. Deceleration injuries were excluded from the control group as these may be associated with mTBI. Children with positive head CT findings not requiring operative intervention yet meeting all other inclusion criteria were included.

### *Inclusion Criteria Study Group:*

- Admitted within 48 hours of injury to a participating hospital with a diagnosis of head injury
- Age 5-16 years old (inclusive)
- Admission Glasgow Coma Scale (GCS) of 13-15
- Patients with or without a head CT (positive head CT findings other than those requiring operative intervention will be included)

### *Exclusion Criteria Study Group:*

- Head CT finding requiring operative neurosurgical intervention
- Focal neurologic deficit
- Concurrent injury with Abbreviated Injury Score of > 2
- Pre-morbid neurologic or psychiatric disorder

### *Inclusion Criteria for Control Group:*

- Evaluated in the Emergency Department or admitted within 48 hours of injury to Cincinnati Children's with a diagnosis of isolated bone fracture
- Age 5-16 years old (inclusive)
- Abbreviated Injury Score of < = 2



*Exclusion Criteria Control Group:*

- Any symptoms or sign of head injury
- Concurrent injury with Abbreviated Injury Score of > 2
- Any traumatic findings on head CT, including extracranial injuries (head CT not required for inclusion or exclusion).
- Significant deceleration mechanism (e.g. motor vehicle collision or fall from greater than 6 feet)
- Pre-morbid neurologic or psychiatric disorder

Study group participants were identified by daily review of the in-patient trauma service patient list at each participating institution. If all inclusion criteria were met, the parent(s) and children were approached for consent and assent (when appropriate). The initial post-concussive symptom assessment was administered within 48 hours of injury and results were recorded via a secure on-line data collection program. Repeat administration of the symptom assessment tool was then performed on-line at 7-10 days post-injury, 28-32 days (1 month) post-injury, and 86-94 days (3 months) post-injury (Aim 1). In the event that the child had a scheduled follow up appointment at one of the prescribed time points the follow up assessment occurred during that visit. An email reminder was sent 24 hours in advance of the follow up time period and a follow up phone call was placed if, within 24 hours of the close of the follow up window, the on-line assessment has not been completed. Those reached by phone were given the opportunity to perform the assessment via the phone or to go on-line to complete the tool. Those without computer access were still included in the study and had their follow up evaluations performed over the phone by research staff at Cincinnati Children's. At least three phone call attempts were made at each time point to ensure maximal participation/compliance with follow up. After completion of all three follow-up assessments a five dollar gift card was mailed to the participants. To assess family functioning, the McMaster Family assessment device (FAD) was

administered to the parents/primary care givers during the initial 48 hours post-injury during hospitalization.

Control patients were identified by review of the Emergency Department census for the prior 24 hours as well as review of the in-patient trauma and orthopedic service census at Cincinnati Children's. Once identified the same procedure as described above for the study group was followed for initial and follow up administration of the post-concussive symptom assessment.

DNA collection (Aim 3) occurred only at Cincinnati Children's. During hospitalization, enrolled patients were asked to participate in the DNA collection portion of the study and indicated consent for this portion in the Parental Permission form. Once consented, a salivary DNA sample was collected. The Oragene (DNA Genotek, Ottawa, Ontario, Canada) DNA self-collection kit was used. Saliva was self-collected by spitting into an Oragene cup. Coordination of purification and storage of DNA samples was conducted by the CCHMC genetics core. DNA will be extracted using the manufacturer's recommended procedure.

## **Results**

Over the study period, a total of 101 subjects were enrolled from 5 pediatric trauma centers, including 66 mTBI and 35 OI patients. All OI patients were enrolled at the primary investigation site. The distribution of mTBI patients enrolled per facility ranged from 3% - 60.4%. Demographics are summarized in Tables 1a and 1b. There were no significant differences between groups for age, gender, or history of prior TBI.

**Table 1a. Demographic Data of TBI Patients**

	All	Site A	Site B	Site C	Site D	Site E
<b># of Participants</b>	66	10	26	20	7	3
<b>Gender</b>	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
<i>Male</i>	46 (69.7)	9 (90)	17 (65.4)	13 (65)	5 (71.4)	2 (66.7)
<i>Female</i>	20 (30.3)	1 (10)	9 (34.6)	7 (35)	2 (28.6)	1 (33.3)
<b>Mean Age (years)</b>	10.6	13.1	9.7	10.4	9.9	13.3
<b>Previous Head Injury</b>						
<i>Never</i>	58	8	24	19	4	3
<i>2 Weeks</i>	1	1	0	0	0	0
<i>4 Weeks</i>	0	0	0	0	0	0
<i>3 Months</i>	0	0	0	0	0	0
<i>6 Months</i>	1	0	1	0	0	0
<i>Past Year</i>	3	0	1	0	2	0
<i>Did Not Answer</i>	3	1	0	1	1	0
<b>Pre-Injury School Difficulties</b>						
<i>None</i>	54	9	25	12	5	3
<i>Very Little</i>	4	0	1	3	0	0
<i>Somewhat</i>	4	0	0	3	1	0
<i>To a Great Extent</i>	1	0	0	1	0	0
<i>Did Not Answer</i>	3	1	0	1	1	0

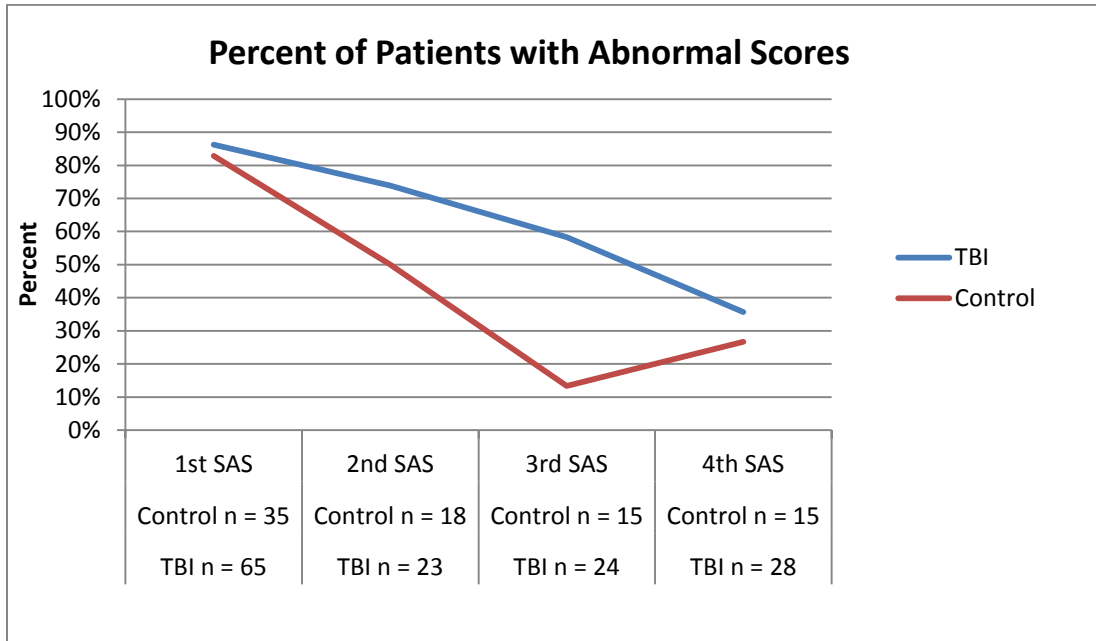
The initial symptom score was completed by 97% of subjects. The percentage of mTBI and OI patients completing assessments at the designated time interval were 34.8% (23/66) vs 51.4% (18/35) at 7-10 days, 36.4% (24/66) vs 42.9% (15/35) at 1 month, and 42.4% (28/66) vs 42.9% (15/35) at 3 months respectively. A total of 8 (12.1%) mTBI and 6 (18.8%) OI patients completed all 4 symptom assessments. Patients were lost to follow-up due to lack of parent response to email reminders and/or inability to contact patient/family at the appropriate time intervals despite repeated attempts.

**Table 1b. Demographic Data of Control Patients**

	n (%)
<b># of OI Participants</b>	35
<b>Gender</b>	
<i>Male</i>	24 (68.6)
<i>Female</i>	11 (31.4)
<b>Mean Age (years)</b>	10.9
<b>Previous Head Injury</b>	
<i>Never</i>	31
<i>2 Weeks</i>	1
<i>4 Weeks</i>	0
<i>3 Months</i>	1
<i>6 Months</i>	0
<i>Past Year</i>	2
<b>Pre-Injury School Difficulties</b>	
<i>None</i>	33
<i>Very Little</i>	2
<i>Somewhat</i>	0
<i>To a Great Extent</i>	0

Overall, the percent of patients with an abnormal PCS score, both mTBI and OI, decreased over time (**Figure 1**). Although scores decreased, it is important to note that at 3 months 35.7% of mTBI and 26.7% of OI patients remained symptomatic. The most common initial symptoms reported in the mTBI group were fatigue (45), headaches (44), and drowsiness (44) and the OI patient's fatigue (30), drowsiness (23), and feeling slowed down (21).

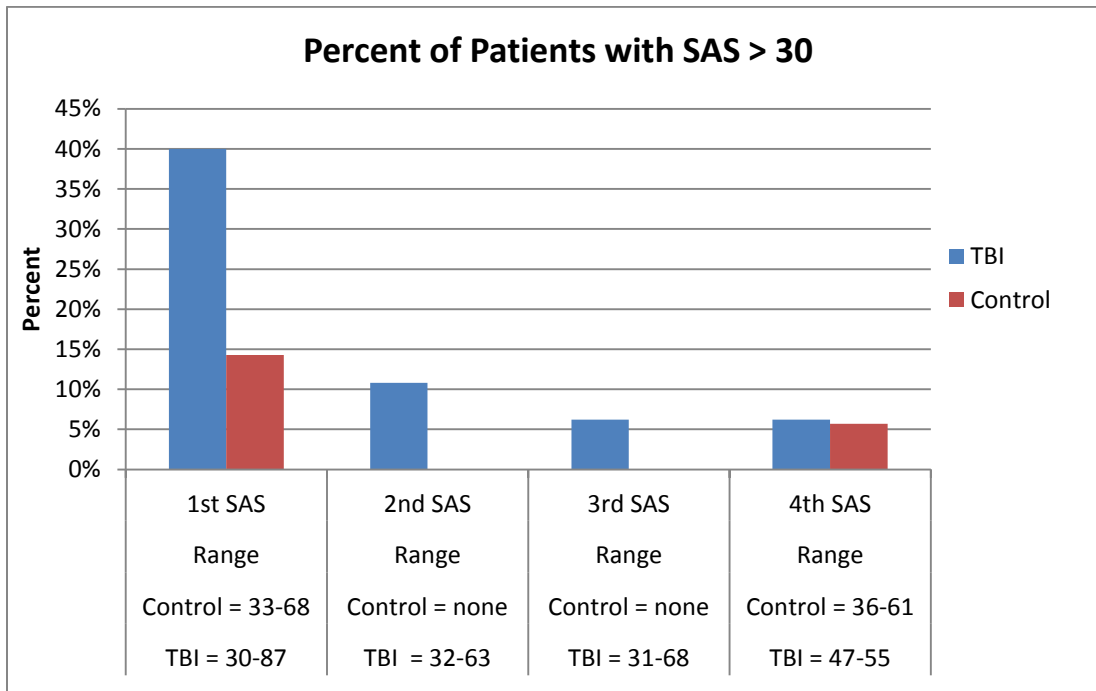
**Figure 1. Percent of Patients with Abnormal Scores**



At 7 - 10 days, the most common PCS for the mTBI patients were feeling slowed down (78.3%), fatigue (69.6%), and headaches (65.2%). Alternatively, the OI group reported fatigue (44.4%), sadness (38.9%), and feeling slowed down (38.9%). Over time, the most common persistent mTBI symptoms at 3 months were being more emotional (39.3%), feeling foggy (39.3%) and difficulty with concentrating and remembering (35.7%). The OI patients reported irritability, nervousness, being more emotional, and feeling slowed down (26.7%).

Analysis of symptom scores identified 26 (40%) mTBI patients and 5 (14.3%) OI patients with initial symptom scores greater than or equal to 30. This decreased to 7 (10.8%) at 7-10 days and 4 (6.2%) at 1 and 3 months for mTBI patients. A symptom score greater than or equal to 30 was reported by 2 OI patients (5.7%) but only at 3 months. Refer to Figure 2.

**Figure 2. Percent of Patients with SAS > 30.**



Comparing patients at initial evaluation and again at 7-10 days, four distinct categories were identified: 1) a normal symptom score at both time points (mTBI: 2/23 vs OI: 4/18); 2) a decline of an abnormal initial symptom score to within normal range (mTBI: 5/23 vs OI: 6/18); 3) a decreased symptom score from baseline but persistently abnormal (mTBI: 10/23 vs OI: 4/18); and 4) an increased symptom score from baseline (mTBI: 6/23 vs OI: 4/18). No mTBI patients (5) and 7/8 OI patients with a normal symptom score at 7 – 10 days became symptomatic.

It is important to note that not every patient completed the symptom assessment at each time interval. However, by one month 33.3% (8/24) of mTBI patients and 13.3% (2/15) of OI patients demonstrated improvements in their PCS score but remained abnormal. Interestingly, twenty-five percent (6/24) of mTBI patients had increased symptom scores at 1 month. No patients in the OI group demonstrated increased symptom scores at 1 month. The trajectory of symptom resolution continued to improve in most patients by 3 months, although 17.9% (5/28) of mTBI and 6.7% (1/15) of OI patients

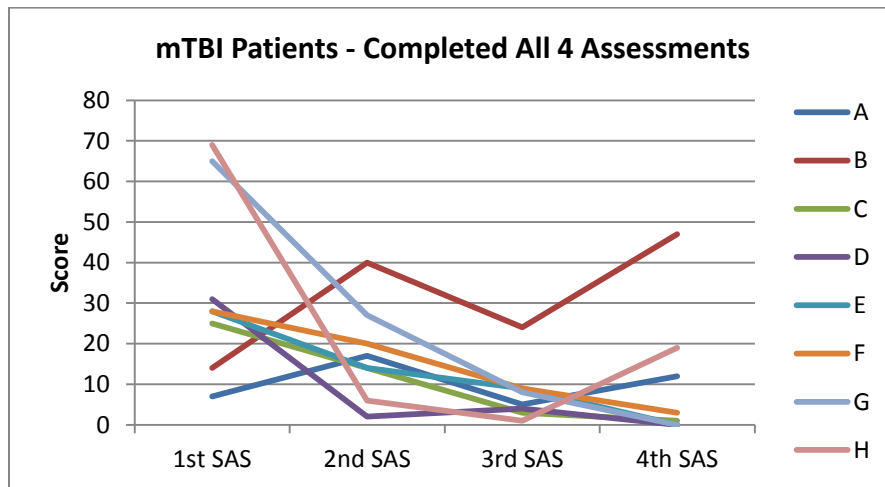
remained abnormal. Of this cohort, the 2 mTBI patients that completed the 7 – 10 day assessment had abnormal scores, whereas the OI patient was normal. Refer to Table 2 for mean symptom scores.

**Table 2.**

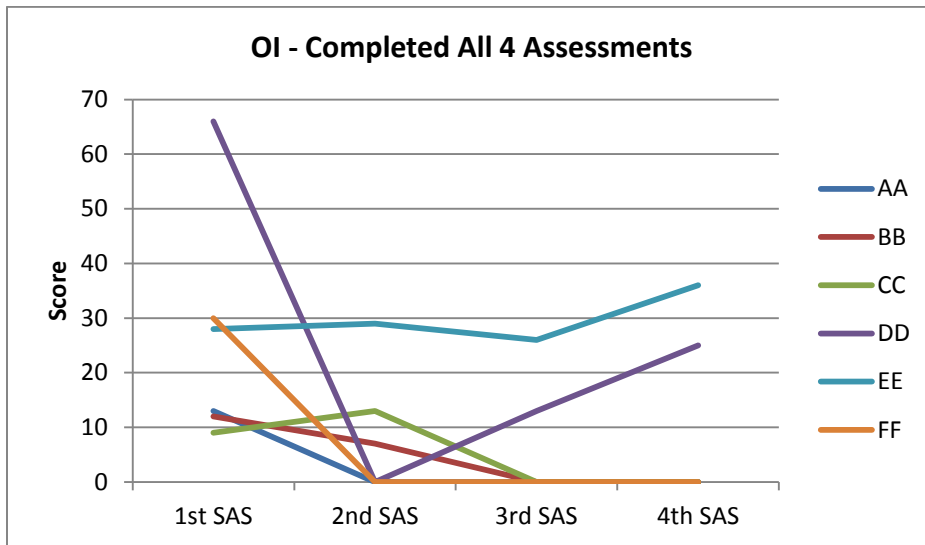
	mTBI Patients				OI Control Patients			
	SAS Scores		Abnormal Scores		SAS Scores		Abnormal Scores	
	Mean ( n)	Range	% (n)	Range	Mean (n)	Range	%(n)	Range
<b>24-48 Hours Post Injury</b>	27.2 (65)	0-87	86.2 (56)	7-87	18.4 (35)	0-66	82.9 (29)	7-66
<b>7-10 Days Post Injury</b>	21.0 (23)	0-63	73.9 (17)	6-63	8.7 (18)	0-29	50 (9)	7-29
<b>1 Month Post Injury</b>	15.2 (24)	0-68	58.3 (14)	8-68	3.3 (15)	0-26	13.8 (2)	13-26
<b>3 Months Post Injury</b>	11.6 (28)	0-55	35.7 (10)	7-55	10 (15)	0-61	26.7 (4)	22-61

The cohort of mTBI and OI patients that completed all 4 symptom assessments demonstrated abnormal symptom scores on the initial assessment (**Figures 2a and 2b**). The majority of mTBI patients were symptomatic at 7 – 10 days (87.5%; mean score: 17.5; range: 2 – 40). At 1 and 3 months post injury, 3 subjects actually demonstrated significantly worse symptoms. Of the 6 OI patients, 50% demonstrated PCS at 7-10 days, and 33.3% at 1 and 3 months.

**Figure 2a. Mild TBI Patients that Completed All Symptom Assessments**



**Figure 2b. OI Patients that Completed All Symptom Assessments**



Ten subjects agreed to the DNA collection but the majority of patients deferred to participate in this aspect of the study. Primary reasons were due to dry mouth, nausea and vomiting, lack of interest, or patients were ineligible because of the contraindication of swabbing the mouth for the DNA collection within 30 minutes of eating.

Of the 101 subjects enrolled in the study, 83 (82.2%) completed the McMaster Family Assessment Device (FAD) including 57 mTBI and 26 OI patients. The FAD provides a global rating of the overall general function of the family that ranges from 1 (healthy) to 4 (unhealthy). The mean general function score for all subjects was in the range of healthy (1.69). The percentage of patients with an unhealthy score ( $\geq 2$ ) was 19.3% (11/57) of mTBI and 38.5% (10/26) of OI patients. Unfortunately, analysis of patients who were post-concussive at each symptom assessment is limited due to attrition and subsequently hindered our ability to analyze the FAD score as it relates to symptom recovery. Three mTBI patients at 1 month and 1 mTBI patient at 3 months had abnormal scores and unhealthy FAD scores. This compares to 4 OI patients at the same time intervals.



## Discussion

Symptom assessments are a valuable tool to document PCS and to monitor resolution over time following an mTBI. [9] [4] [25] Identification of symptoms is also important to facilitate appropriate patient/family education and to offer reassurances, which have been positively associated with a decline in symptom reporting. [26] [27] This is critical because PCS such as headache or vomiting are more readily apparent, but less conspicuous symptoms like difficulty concentrating, feeling foggy, irritability, fatigue, nervousness, or sleep problems are frequently unrecognized by parents [7] and health care professionals but are equally important to identify.[28]

This study sought to determine if early symptom assessment scores predict risk for suffering prolonged symptoms following a mild traumatic brain injury in children. In this multicenter pediatric study 58% of children at 1 month and nearly 36% of children at 3 months post injury had persistent symptoms compared to 14% and 27% of OI control patients. Additionally, results indicate that the symptom assessment score at 24-48 hours post-injury may not be as useful in predicting long term symptoms as originally hypothesized. On the contrary, the results of this study suggest that both the symptom score at 7-10 days post injury and a worsening symptom score between the first and second assessment may be predictive of prolonged symptoms.

Response rates were low for both the one and three month assessment with 37% and 43% for the head injury group respectively and 43% for both time points in the control group. However, if it is assumed that all subjects who did not respond were symptom free, our rate of symptoms at 1 and 3 months for the brain injured group would decrease to 22% and 15% and 6% and 11% for the control group. This is likely optimistic as parents may not recognize PCS [29] [30] or associate them to the head injury. [7]

Previous research suggests that early symptom assessments to identify PCS may also predict recovery. [31] [32] Evaluation of children presenting to the ED following mTBI, found that the presence of headaches in the ED, in addition to adolescent age and admission to the hospital were acute predictors for PCS. [31] Nausea, dizziness, and disorientation were also predictive of persistent PCS. [21] Data from our study of hospitalized children suggests that the trend of an increasing symptom assessment score and absolute score at 7-10 days post injury may more reliably predict prolonged symptoms. Of the 8 children who completed the assessment at each time point, 66% of those abnormal at 3 months had an increasing symptom score at 7-10 days compared to 24-48 hours. In addition, for the entire cohort, no patient with persistent symptoms at 1 or 3 months had a normal score at 7-10 days from injury. Furthermore, nearly 50% of those with an abnormal score at 7-10 days remained symptomatic at 3 months. Utilizing this information it may be possible to identify children at risk for prolonged recovery and more appropriately direct their follow up care. This would not only reduce unnecessary visits to specialists, but also decrease associated health care costs and family stressors related to time required to take off from work. Most importantly, prompt identification of children with abnormal scores at 7-10 days can expedite referral to specialists for symptom management and ensure safe return to recreational and sports activities. [15]

Data from the family assessment tool, although limited, indicates that family support structure may be tightly associated with recovery of symptoms after discharge from the hospital. This finding supports similar prior studies of children recovering from mild to severe traumatic brain injury. [33] [34][35] The persistence of symptoms at each time point (at 1 and 3 months post injury) in families with elevated scores on the family assessment device supports the crucial importance of a supportive home environment to maximize recovery. Further study is recommended to understand the interplay between family support and recovery to allow the development of targeted interventions to optimize all aspects of recovery and shorten symptom duration.

## Limitations

In spite of some interesting and provoking results, the relatively small number of enrolled patients limits this study. Despite initial commitment by 7 centers to participate, only 4 ultimately remained involved. Primary barriers to participation included a lack of available and trained staff to enroll patients, obtain consent, and perform the initial assessment using the on-line survey tool. During the study period, several sites experienced staff turnover, which required training of new staff on the study protocol. In at least one instance, the new staff member had not completed mandatory human subject research training (i.e. CITI training), which delayed their ability to enroll by several months. In addition, one center held their ACS site review and went live with their electronic medical record system during the study enrollment period limiting the amount of time staff dedicated to this study. This also limited staff ability to identify patients for enrollment.

Among the sites that did participate, overall enrollment reached only 65 patients, far short of the predicted enrollment of 1,273. One factor identified that limited enrollment was the length of the family assessment device (FAD). Many families that expressed initial interest in participating refused stating it was too time consuming. Enrollment was also hindered by the relatively short hospital stay of less than 24 - 48 hours and many eligible patients were discharged before they could be enrolled. This primarily occurred on the weekend when study staff was not present to enroll eligible patients. Although a response rate of over 60% at 3 months post injury is consistent with similar long term follow up studies, only 8 of 65 (12%) subjects that completed assessments at each of the 4 time points. [36] This occurred despite an internet-based system that sent reminders to the families and allowed the ability to complete the assessments on-line. The majority of families required a follow up call from research staff to complete the assessment.

In order to allow for additional enrollment, the research team was granted a six-month extension by the ODPS Grants Committee.

### **Conclusions and Recommendations**

Although most children recover quickly from mTBI, a proportion will have symptoms at 3 months post injury. Assessment of symptom scores at 7-10 days may be a useful tool for predicting those children at risk for prolonged symptoms. In addition, understanding the family support system and providing additional resources may further promote recovery. Additional prospective data will be essential to further evaluate the reliability of this assessment approach and the ability to ultimately reduce the duration of symptoms among this cohort.

### **Information/Qualifications**

This study was led by members of Trauma Services at Cincinnati Children's Hospital Medical Center. The Trauma Medical Directors and Program Managers at four of the pediatric trauma centers committed to this project and provided direct supervision at each site.

The principal investigator, Richard A. Falcone, Jr., MD, MPH, is currently an Associate Professor of Surgery and the Medical Director of the Level I Pediatric trauma program at Cincinnati Children's. He has an extensive background in trauma research including epidemiologic studies, quality of care studies and design and evaluation of injury prevention programs. In addition to the accomplishments listed on his curriculum vitae, he has previously successfully completed several similar funded projects. He has previously led and been involved with numerous multi-disciplinary projects and is experienced in collaborating such efforts.

Brad Kurowski, MD, MS is an Assistant Professor of Pediatrics and Physical Medicine and Rehabilitation at CCHMC. He has completed residency training in Physical Medicine and Rehabilitation (PM&R) and completed a fellowship in Pediatric Rehabilitation Medicine (PRM). He has the clinical expertise to

develop and perform studies evaluating pediatric TBI. Recently, he has successfully obtained a NIH-sponsored K-12 grant exploring the association of catecholamine-related polymorphisms with recovery from early childhood TBI.

Becky Cook, CNP, DNP is currently a trauma nurse practitioner at Cincinnati Children's and has extensive experience caring for pediatric trauma patients in the inpatient and outpatient setting. She is actively involved in the development and evaluation of evidenced based guidelines and research. Her role will be to facilitate data collection and to contribute her knowledge and experience with TBI for interpretation of this data.

Margie Koehn, CSTR has been the trauma registrar at Cincinnati Children's for the past 20 years and is a recognized expert in trauma data management. Her expertise in exporting appropriate data from our database in formats that allow rapid analysis will be essential. In addition, Ms. Koehn has extensive experience in secure database creation to allow a high level of safety and confidentiality of all of our data.

Suzanne Moody, MPA, is currently the Clinical Research Coordinator for Trauma Services at Cincinnati Children's Hospital Medical Center. She has extensive experience in trauma data management, data analysis, project management as well as interacting with our IRB. Her role on this project will be as research coordinator and she will work closely with the Principal Investigator. Her background in data analysis and research coordination will allow for the timely completion and interpretation of this important study.

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**Total Project Expenditures**

<b>Budget Description</b>	<b>Total Project Expenditures</b>
<b>Personnel Costs</b>	
Trauma Staff	\$47,599.96
<b>Materials &amp; Supplies</b>	
None	\$0
<b>Equipment Purchases</b>	
None	\$0
<b>Contractual Services</b>	
Development of Web based collection system	\$17,250.00
Data collection support at participating centers \$2,000 X 3 hospitals	\$6,000.00
Genetic collection kits	\$2,405.00
<b>Meetings/Events</b>	
None	\$0
<b>Other</b>	
Incentive gift cards	\$500.00
<b>Total Project Expenditures</b>	<b>\$73,754.96</b>
<b>Unused Amount Returned to ODPS</b>	<b>\$5,837.04</b>