
Guardian Availability in Children Evaluated in the Emergency Department for Blunt Head Trauma

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Abstract

Background: Enrolling children in research studies in the emergency department (ED) is typically dependent on the presence of a guardian to provide written informed consent.

Objectives: The objectives were to determine the rate of guardian availability during the initial ED evaluation of children with nontrivial blunt head trauma, to identify the reasons why a guardian is unavailable, and to compare clinical factors in patients with and without a guardian present during initial ED evaluation.

Methods: This was a prospective study of children (<18 years of age) presenting to a single Level 1 trauma center after nontrivial blunt head trauma over a 10-month period. Physicians documented patient history and physical examination findings onto a structured data form after initial evaluation. The data form contained data points regarding the presence or absence of the patient's guardian during the initial ED evaluation. For those children for whom the guardian was not available during the initial ED evaluation, the physicians completing the data forms documented the reasons for the absence.

Results: The authors enrolled 602 patients, of whom 271 (45%, 95% confidence interval [CI] = 41% to 49%) did not have a guardian available during the initial ED evaluation. In these 271 patients, 261 had reasons documented for lack of guardian availability, 43 of whom had multiple reasons. The most common of these was that the guardian did not ride in the ambulance (51%). Those patients without a guardian available were more likely to be older (mean age, 11.4 years vs. 7.6 years; $p < 0.001$), be victims of a motor vehicle collision (MVC; 130/268 [49%] vs. 35/328 [11%]; $p < 0.001$), have a Glasgow Coma Scale (GCS) score <14 (21/269 [7.8%] vs. 11/331 [3.3%]; $p = 0.02$), and undergo cranial computed tomography (CT) scanning (224/271 [83%] vs. 213/331 [64%]; $p < 0.001$). Multivariate analysis identified similar independent risk factors for lack of guardian presence.

Conclusions: Nearly one-half of children with nontrivial blunt head trauma evaluated in the ED may not have a guardian available during their initial ED evaluation. Patients whose guardians are not available at the time of initial ED evaluation are older and have more severe mechanisms of injury and more serious head trauma. ED research studies of pediatric trauma patients that require written informed consent from a guardian at the time of initial ED evaluation and treatment may have difficulty enrolling targeted sample size numbers and will likely be limited by enrollment bias.

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Many barriers exist to conducting research involving acutely ill or injured children. One of the initial challenges that must be met is obtaining informed consent.¹ This is particularly challenging in the emergency department (ED). Interventional trials involving children require written informed consent from the patient's guardian (as well as written assent from the child if the child is of the appropriate age). Such a consent process is not possible when the guardian is unavailable.

For research studies pertaining to patients who are critically ill or injured, however, exception from written informed consent for clinical research may be sought under the appropriate circumstances.^{2,3} To qualify for and implement an exception from informed consent, a given study must meet certain rigorous federal requirements, which in themselves present nontrivial barriers to implementation.^{4,5}

Observational studies, which are of minimal risk to the patient, as they do not involve any intervention or alteration in patient care, may receive a waiver of informed consent from many institutional review boards (IRB). In fact, waiver of informed consent may even be sought for minimal-risk randomized controlled trials meeting specific requirements,⁶ although some IRBs may require written informed consent for such studies.⁷ Therefore, the availability of a guardian to provide informed consent is important for the conduct of both interventional trials and observational studies in children when consent is required. Absence of the guardian may hinder successful patient enrollment and result in biased enrollment, although the magnitude and effect of this problem is unclear.

The objectives of this study were 1) to determine the rate of guardian availability during the initial ED evaluation of children with nontrivial blunt head trauma, 2) to identify the reasons why the guardian is unavailable, and 3) to compare clinical factors in those patients with and without a guardian present during initial ED evaluation. We hypothesized that a substantial portion of children with head trauma will not have a guardian available at initial ED evaluation and that children without a guardian available will be more significantly injured than those who have a guardian present.

METHODS

Study Design

This was a prospective, observational study of children (<18 years of age) presenting to a single Level 1 trauma center after nontrivial blunt head trauma from December 2005 through September 2006. The study was approved by the human subjects review committee at the participating institution and received a waiver of written informed consent.

Study Setting and Population

Patients were eligible for study enrollment if they suffered nontrivial blunt head trauma. Trivial head trauma was defined by ground-level falls and if patients struck their head against stationary objects and had no signs or symptoms of traumatic brain injury (TBI). Patients were excluded if they presented more than 24 hours

after the time of injury, had a preexisting neurologic disease preventing reliable neurologic assessment, or were transferred from another hospital with prior cranial imaging.

Study Protocol

Emergency physicians documented patient history and physical examination findings onto a structured data form after initial ED evaluation. The data form contained data variables regarding the presence or absence of the patient's guardian during the initial ED evaluation. A patient's guardian was considered not present if a guardian was not available during the treating physician's initial ED evaluation of the patient. For those children for whom the guardian was not available during the initial ED evaluation, the physician responsible for the patient's care documented the reasons for these absences. The decision to obtain cranial computed tomography (CT) scans and disposition decisions were made at the discretion of the treating physicians and were not dictated by study protocol. TBI on CT scan was defined as the presence of any of the following: intracranial hematoma, cerebral contusion, subarachnoid hemorrhage, pneumocephalus, cerebral edema, diastasis of the skull, or skull fracture depressed by at least the thickness of the skull. The medical records of patients admitted to the hospital were reviewed to determine hospital outcomes. The guardians of patients discharged from the ED were contacted at least 1 week after the ED visit to assess clinical status and identify any TBI not identified during initial ED evaluation.

During the study period, all patients presenting to the ED with traumatic mechanisms of injury were screened for study eligibility. Data on CT rate and the presence of TBI were collected on those patients eligible but not enrolled ("missed" patients). No data, however, were collected on guardian availability of these missed patients.

Outcome Measures

The primary outcome measure was the presence or absence of the patient's guardian during initial ED evaluation. The secondary outcome measure was the reason(s) for the guardian's absence.

Data Analysis

We used simple descriptive techniques to describe the study population, including 95% confidence intervals (CIs) where appropriate; asymptotic CIs are presented for differences in prevalence rates, while exact CIs were calculated for proportions. We compared continuous variables between patients for whom a guardian was present or absent using Student's *t*-test, and categorical data using chi-squared test or Fisher's exact test in cases of small cell sizes. Patients in whom CT scanning was not performed and who were well at follow-up were assumed not to have a TBI for purposes of this analysis. Bivariate odds ratios (ORs) for the risk of the guardian being unavailable were calculated for patient age categories and mechanisms of injury. Patient age categories, mechanisms of injury categories, and Glasgow Coma Scale (GCS) score were then entered into a multiple logistic regression analysis to determine

independent association with guardian absence. Data analysis was performed with SAS statistical software, Version 9.1 (SAS Institute Inc., Cary, NC; 2007).

RESULTS

During the study period, we enrolled 602 (77.4%) of 777 eligible patients. Enrolled patients had a mean age of 9.4 ± 5.9 years. The mechanisms of injury, which were available for 596 of these patients, were as follows: motor vehicle collisions (MVC) in 165 (28%), falls in 149 (25%), automobile versus pedestrian or bicycle in 85 (14%), assault in 51 (9%), other wheeled transport crash in 32 (5%), fall from bicycle in 27 (5%), sports injuries in 21 (3%), object struck head in 20 (3%), ran into object in 8 (1%), and other mechanisms of injury in 38 (6%).

Among the 602 enrolled patients, 271 (45%, 95% CI = 41% to 49%) did not have a guardian available during the initial ED evaluation. Age and mechanism of injury data for patients with and without a guardian available on initial ED evaluation are presented in

Table 1. History of loss of consciousness and traumatic amnesia, frequency of low initial GCS scores, frequency of CT scans, and TBI outcomes for patients with and without guardians available on initial ED evaluation are presented in Table 2. Patients who were involved in MVCs were less likely to have a guardian available, whereas those patients presenting after a fall were more likely to have a guardian available. Patients without a guardian available were more severely injured, as they were more likely to have all the following markers of injury severity: traumatic amnesia (assessed among children at least 3 years old), loss of consciousness, a lower initial GCS score, and likelihood to undergo cranial CT scan. Patients without a guardian available were also more likely to have documented TBIs on CT scan and undergo neurosurgical procedures, although these differences were not statistically significant.

The multiple logistic regression analysis identified several independent variables associated with guardian absence and is presented in Table 3. Increasing patient age, MVC mechanism, and severity of head injury were

Table 1
Comparisons of Age and Injury Mechanisms among Patients with a Guardian Available at Initial ED Evaluation and Those without a Guardian Available

Clinical Finding	Guardian Unavailable (n = 271)	Guardian Available (n = 331)	Difference (95% CI)	p-Value
Age (years)				
Mean (\pm SD)	11.4 \pm 5.5	7.6 \pm 5.6	3.8 (2.9, 4.7)	<0.001
<2	24/271 (9%)	73/331 (22%)	-13% (-19, -8)	<0.001
2-4.99	28/271 (10%)	60/331 (18%)	-8% (-13, -2)	0.008
5-12.99	80/271 (30%)	123/331 (37%)	-8% (-15, -0.1)	0.049
13-17.99	139/271 (51%)	75/331 (23%)	29% (21, 36)	<0.001
Mechanism of injury*				
MVC	130/268 (49%)	35/328 (11%)	38% (31, 45)	<0.001
Automobile vs. pedestrian/bicycle	33/268 (12%)	52/328 (16%)	-4% (-9.1, 2.0)	0.22
Fall	30/268 (11%)	119/328 (36%)	-25% (-32, -19)	<0.001
Age (mean) for MVC patients	11.3 \pm 5.7	8.4 \pm 5.8	2.9 (0.7, 5.0)	0.01
Age (mean) non-MVC mechanisms	11.5 \pm 5.4	7.6 \pm 5.6	3.9 (2.8, 5.0)	<0.001

CI = confidence interval; ED = emergency department; MVC = motor vehicle collision; SD = standard deviation.
*Mechanism of injury available on 596 patients.

Table 2
Comparisons of Clinical Findings among Patients with a Guardian Available at initial ED Evaluation and Those without a Guardian Available

Clinical Finding*	Guardian Unavailable (n = 271)	Guardian Available (n = 331)	Difference (95% CI)	p-Value
Traumatic amnesia†	95/194 (49%)	59/183 (32%)	17% (7, 26)	0.001
Loss of consciousness	121/229 (53%)	93/305 (30%)	22% (14, 31)	<0.001
GCS score < 14	21/269 (7.8%)	11/331 (3.3%)	4.5% (0.7, 8.2)	0.02
CT scan obtained	224/271 (83%)	213/331 (64%)	18% (11, 25)	<0.001
TBI on CT scan	20/271 (7.4%)	13/331 (3.9%)	3.5% (-0.3, 7.2)	0.06
Neurosurgical procedure	3/271 (1.1%)	0/331 (0%)	1.1% (-0.1%, 2.4)	0.09

CI = confidence interval; CT = computed tomography; ED = emergency department; GCS = Glasgow Coma Scale; TBI = traumatic brain injury.
*Some data points not available for all patients.
†Traumatic amnesia assessed only for children aged 3 years and older.

all independently associated with guardian absence during initial ED evaluation.

Of the 271 patients without a guardian available during initial ED evaluation, 261 had one or more reasons given for this unavailability; 43 listed multiple reasons, and there were a total of 319 reasons documented for this unavailability. These reasons are presented in Table 4. The most common reason for guardian unavailability was transport of patient to the ED by emergency medical services (EMS), with the guardian not present in the ambulance. In 24% (63/261) of cases where the guardian was unavailable, the guardian was also injured and was either transported to a different hospital or transported to the same hospital but unavailable for history/consent, or the location of the guardian was not known.

A total of 175 of the 777 patients eligible were inadvertently not enrolled (enrollment rate = 77.5%). Of the 602 enrolled patients 437 (73%, 95% CI = 69% to 76%) had CT scans performed. This rate was similar to that of the 143 missed patients, in whom 92 (64%, 95% CI = 56% to 72%) had CT scans performed. The rate of TBI in patients enrolled (33/602; 5.5%, 95% CI = 3.8% to 7.6%) was similar to the rate in the missed patients (7/143; 4.9%, 95% CI = 2.0% to 9.8%).

DISCUSSION

This study demonstrates that a substantial percentage of children with nontrivial blunt head trauma present initially to the ED without a guardian present. Furthermore, older age, MVC, and more severe head injury are all independently associated with guardian absence. These findings have important implications for conducting clinical research on acutely ill or injured children in the ED.

A prior survey suggested that 2% to 3% of all pediatric patients present to EDs without a guardian.⁸ That study was particularly focused on children who present to the ED on their own for medical treatment. The current study, however, focused on initial ED evaluation of a specific population (i.e., children with nontrivial head trauma), which in great part explains the large difference in prevalence rates of guardian presence. In most of the cases in this study, a guardian or other family member ultimately presented to the ED or the hospital to be involved in the patient's care. However, in many cases, the time delay for guardian arrival would preclude the patient from enrollment into a study requiring written informed consent before an intervention or data collection. In fact, if guardian written informed consent had been required at the time of initial evaluation, more

Table 3
Bivariate and Multivariate Association for the Risk of Guardian Not Being Available in the ED

Clinical Variable	Bivariate OR (95% CI)	Multivariate OR (95%CI)
Age 2–4.99 (vs. age <2)	1.42 (0.75, 2.70)	1.03 (0.49, 2.16)
Age 5–12.99 (vs. age <2)	1.98 (1.15, 3.40)	1.68 (0.89, 3.17)
Age 13–17.99 (vs. age <2)	5.64 (3.29, 9.67)	4.13 (2.13, 8.02)
GCS < 14 (vs. GCS ≥ 14)	2.46 (1.17, 5.21)	3.60 (1.52, 8.54)
Automobile vs. pedestrian/bicycle (vs. fall)	2.52 (1.39, 4.55)	1.60 (0.85, 3.04)
Assault (vs. fall)	5.23 (2.64, 10.36)	2.07 (0.95, 4.49)
Other wheeled transport (vs. fall)	1.55 (0.65, 3.70)	0.79 (0.31, 1.99)
Bicycle (vs. fall)	1.67 (0.67, 4.18)	0.95 (0.35, 2.53)
MVC (vs. Fall)	14.73 (8.52, 25.47)	9.68 (5.44, 17.25)
All other mechanisms (vs. fall)	1.98 (1.09, 3.61)	1.23 (0.64, 2.35)

Age is measured in years. Outcome is relative odds of the guardian being not available during initial ED evaluation and treatment.
CI = confidence interval; ED = emergency department; GCS = Glasgow Coma Scale; MVC = motor vehicle collision; OR = odds ratio.
Bold font indicates the three independent predictors of the outcome.

Table 4
Reasons* Why a Guardian Was Not Available during Initial ED Evaluation

Reason	n	% (95% CI)
Guardian did not ride in the ambulance	134	51% (45, 58)
Guardian location unknown	59	23% (18, 28)
Guardian did not bring the child to the ED	53	20% (16, 26)
Guardian injured and transported to same hospital but unavailable	34	13% (9, 18)
Guardian injured but location unknown	16	6% (4, 10)
Guardian injured and transported to different hospital	13	5% (3, 8)
Other reason	10	4% (2, 7)

Ten patients with unavailable guardian did not have available reasons documented.
CI = confidence interval; ED = emergency department.
*A total of 319 reasons documented in 261 patients for whom guardian was unavailable.

than 40% of the study's enrolled patients would not have been able to participate. As a result, the time needed to recruit the needed study sample size would nearly double.

The most substantial implication if written informed consent had been required, however, was biased patient enrollment and its effects on the generalizability and conclusions of the study. Children who were older, those who were victims of MVCs, and the more significantly injured children would have been preferentially excluded if guardian consent was required. In studies of this type, this may result in findings that are biased, as the most severely injured and those who are victims of MVCs would not be included in the analysis. Furthermore, the generalizability of the results of such a study to children who are older, who are victims of MVCs, and who have more severe head injuries would be limited.

The study also describes the reasons why a guardian was not available during initial ED evaluation and treatment of this pediatric head trauma population. Injured children are often transported by the EMS system and the guardian does not frequently ride to the ED in the ambulance. In many instances, the guardian would arrive to the ED by private transportation after initial evaluation and treatment. Furthermore, if the guardian was injured in the same event (especially MVCs), they were often transported for medical care and not available for history/consent during the child's initial ED evaluation. The study site serves as both an adult and a pediatric trauma center; thus many of the guardians were transported to the same center as the child. For free-standing children's hospitals that care for pediatric trauma patients but do not provide adult trauma care, the likelihood that an injured guardian would be available during initial ED evaluation (or even later in the child's ED care) would be lower, as the injured guardian would typically be transported and treated at a different facility.

We have focused this discussion primarily on the issues relating to consent for research in injured children. However, lack of guardian availability has important clinical and research implications for other ED pediatric populations as well. Obtaining a detailed medical history is difficult (and at times impossible) in younger children without the presence of the guardian and may be challenging even in older, more sophisticated children. In addition, obtaining consent for invasive procedures, including those ED procedures that may be time-sensitive, requires guardian availability. The Committee on Pediatric Emergency Medicine of the American Academy of Pediatrics has previously stated that urgent/emergent medical care should not be delayed due to inability to obtain guardian consent.⁹ This study demonstrates the impact and importance of this policy in acutely injured children.

LIMITATIONS

The study was conducted at a single Level 1 trauma center that provides care to both injured adult and injured pediatric patients. The results may not be generalizable to all centers providing care to injured chil-

dren. As previously discussed, nearly one-fourth of the instances in which the guardian was not available were due to the fact that the guardian was also injured in the same mechanism of injury (usually a MVC). The study site receives a high percentage of trauma patients following MVCs. Centers that have a lower percentage of trauma patients as a result of MVCs may have a lower rate of guardian unavailability. The study focused on children with acute blunt head trauma, and the results may be less generalizable to children with other acute medical and traumatic conditions. We did not collect the time between patient arrival and guardian arrival to the ED (if they in fact did arrive). We only collected the frequency of guardian availability during initial ED evaluation and treatment, when clinical decisions are initially made, as we were seeking the impact of this frequency on research studies requiring consent at the time of initial evaluation/management. Finally, a relatively small number of patients had documented TBIs. Thus, our ability to demonstrate statistical differences in the presence or absence of TBIs or the need for neurosurgery between patients with and without a guardian available at initial ED evaluation was limited, but trended in the anticipated direction.

CONCLUSIONS

Nearly one-half of children with nontrivial blunt head trauma evaluated in the ED may not have a guardian available during their initial ED evaluation. Patients whose guardians are not available in the ED are older, have more severe mechanisms of injury and more severe head trauma. ED research studies of pediatric trauma patients that require written informed consent from a guardian at the time of initial evaluation and treatment may have difficulty enrolling targeted sample size numbers and will likely be limited by enrollment bias.

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