

Evidence-Based Guidelines for Resource Utilization in Children With Isolated Spleen or Liver Injury

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Purpose: This study is intended to resolve the disparity and reach consensus on issues regarding the treatment of children with isolated spleen or liver injuries. To maximize patient safety and assure efficient, cost-effective utilization of resources, it was essential to determine current practice.

Methods: Data from the case records of 856 children with isolated spleen or liver injury treated at 32 pediatric surgical centers from July 1995 to June 1997 were collected. The severity of injury was classified by computed tomography (CT) grade and the data analyzed for intensive care unit (ICU) stay, length of hospital stay, transfusion requirement, need for operation, pre- and postdischarge imaging, and restriction of physical activity. Patients with grade V injuries (2.8%) were excluded leaving 832 patients for detailed review. These data and available literature were analyzed for consensus by the 1998 APSA Trauma Committee.

Results: Resource utilization increased with injury severity (see Table 2). Based on the data analysis, literature search,

and consensus conference, the authors propose guidelines (see Table 3) for the safe and optimal utilization of resources in routine cases. It is important to emphasize that no recommendation falls outside the 25th percentile of current practice at participating centers.

Conclusions: Diversity of treatment, with attendant variation in resource utilization in children with isolated spleen and liver injury of comparable severity is confirmed. This analysis has stimulated a prospective outcomes study with the objective of validating the evidence-based guidelines proposed. This evidence-based study design can bring order and conformity to patient management resulting in optimal utilization of resources while maximizing patient safety.

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INDEX WORDS: Evidence-based guidelines, spleen, liver, injury, trauma.

ALTHOUGH NONOPERATIVE treatment of children with isolated, blunt spleen or liver injury has been universally successful, there is great variation in the management algorithms used by pediatric surgeons. Review of the National Pediatric Trauma Registry and 2 recent surveys of the APSA membership confirms the wide disparity in care acknowledging the limitations of trauma registry and survey reviews.¹⁻³ The evolution and refinement of nonoperative treatment in children with isolated spleen or liver injury has been well documented at individual centers.⁴⁻⁸ However, evidence-based standards or guidelines for intensive care unit (ICU) admission, number of hospital days, the need for pre-discharge

or postdischarge imaging, or the appropriate interval of restricted physical activity remain undefined.

The aims of this study are first to detail the current treatment of children with isolated, blunt spleen or liver injury at pediatric surgical centers by collecting individual case records. Second, we aim to define rational and optimal, evidence-based practice guidelines by expert consensus considering the data analysis and best available literature. The ultimate goal (future studies) is dissemination and implementation of validated, evidence-based guidelines to surgeons, third party payors, and regulatory agencies.

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MATERIALS AND METHODS

Data from the case records of 856 children with isolated spleen or liver injury treated at 32 pediatric surgical centers from July 1995 to June 1997 were collected (Appendix). Twenty-six of 32 centers (81%) reported at least 15 patients. Patients with minor, remote injuries such as nondisplaced, noncomminuted fractures; soft tissue injuries; or less severe solid abdominal organ injuries were included as long as the associated injuries did not influence the variables in this study. The patients were grouped by severity of injury as classified by computed

Table 1. Clinical Parameters in 832 Children With Isolated Spleen or Liver Injury

Age	
1-9 yr	474 (57%)
10-15 yr	308 (37%)
>15 yr	50 (6%)
Gender	65% boys
Diagnosis by CT	99.0% (8 patients taken directly to operating room without imaging)
CT grade	
I	116 (14%)
II	341 (41%)
III	275 (33%)
IV	100 (12%)
Mean Injury Severity Score	12.1

tomography (CT) grade.⁹ The patient cohorts were then analyzed for ICU stay, length of hospital stay, transfusion requirement, need for operation, pre-discharge and post-discharge imaging, and interval of physical activity restriction. Patients with isolated grade V injuries were rare (2.8%) and were excluded leaving 832 patients for detailed analysis. Data were entered using Microsoft EXCEL spreadsheet and analyzed using SPSS (Version 6.12, Chicago, IL). These data and the available literature were analyzed for consensus by the 1998 APSA Trauma Committee. An extensive literature search was performed using Medline.

RESULTS

Clinical parameters in the 832 patients are described in Tables 1 and 2. Five guidelines are proposed for all hemodynamically stable patients. Admission to the ICU is reserved for patients with grade IV injuries only. Children with grades I through III injuries had transfusion rates of only 2% to 10% and operation rates of under 3% supporting the omission of ICU stay. Of note, there

Table 2. Resource Utilization and Activity Restriction in 832 Children With Isolated Spleen or Liver Injury

	CT Grade			
	I	II	III	IV
Admitted to ICU (%)	55.0	54.3	72.3	85.4
No. of hospital days (mean)	4.3	5.3	7.1	7.6
No. of hospital days (range)	1-7	2-9	3-9	4-10
Transfused (%)	1.8	5.2	10.1*	26.6*
Laparotomy (%)	None	1.0	2.7†	12.6†
Pre-discharge imaging (%)	13.9	32.4	34.8	37.9
Post-discharge imaging (%)	29.8	33.7	44.0	43.2
Activity restriction (mean)	5.1 wk	6.2 wk	7.5 wk	9.2 wk
Activity restriction (range)	2-6 wk	2-8 wk	4-12 wk	6-12 wk

*Grade III versus grade IV; *P* < .014.

†Grade III versus grade IV; *P* < .0001.

was a significant difference in the rate of transfusion (grade III, 10.1% v grade IV, 26.6%; *P* < .014, χ^2) and operation (grade III, 2.7% v grade IV, 12.6%; *P* < .0001, χ^2) supporting the clinical relevant increase in severity from grade III to grade IV. Further statistical analysis was not performed because this would not influence proposed guidelines.

The proposed number of hospital days and weeks of physical activity restriction were chosen by determining what was done safely in at least 25% of the patients entered in the study. Less than half of the patients underwent pre- or post-discharge follow-up imaging studies, thus supporting our recommendation of no follow-up imaging in routine cases.

Based on the data analysis, literature search, and consensus conference, we propose the guidelines in Table 3 for the safe and optimal utilization of resources in routine cases. It is important to emphasize that no recommendation falls outside the 25th percentile of current practice at participating centers.

DISCUSSION

Evidence-based medicine involves integrating current best evidence (medical literature) with clinical expertise and patient preferences in making decisions about the care of individual patients. Evidence-based methodology is the emerging cornerstone of the clinical practice guideline process. Recently, several trauma societies have developed practice guidelines using evidence-based methodology.¹⁰

There are no randomized, controlled trials (Class I evidence) regarding optimal resource utilization in children with isolated spleen or liver injury. Therefore, using evidence-based methodology, standards of care cannot be proposed in the absence of class I data. Formal consensus development techniques utilizing expert opinion is required to develop practice guidelines whenever

Table 3. Proposed Guidelines for Resource Utilization in Children With Isolated Spleen or Liver Injury

	CT Grade			
	I	II	III	IV
ICU stay (d)	none	none	none	1
Hospital stay (d)	2	3	4	5
Pre-discharge imaging	none	none	none	none
Post-discharge imaging	none	none	none	none
Activity restriction (wk)*	3	4	5	6

*Return to full-contact, competitive sports (ie, football, wrestling, hockey, lacrosse, mountain climbing) should be at the discretion of the individual pediatric trauma surgeon. The proposed guidelines for return to unrestricted activity include "normal" age-appropriate activities.

there is lack of adequate evidence (class I).^{11,12} Our study utilizes evidence from multiple sources including published, nonrandomized trials (class II evidence), historical controls, and expert clinical experience and consensus (class II and III). Thus, the term *guidelines* is appropriate for the proposed recommendations.

To define evidence-based guidelines for children with spleen or liver injury assuring efficient, cost-effective utilization of resources while maximizing patient safety, it was essential to determine current practice. This detailed review of 832 patients confirmed the diversity of treatment, with attendant variation in resource utilization, in children with isolated spleen and liver injury of comparable severity. A unique aspect of our study is strict stratification of patients by injury severity (CT grade). This allowed for a more rational analysis of resource utilization. Despite the diversity, clear patterns emerged showing a continued decrease in the resources used without a compromise in safety or outcome.

Several descriptive studies have recommended shorter ICU and hospital stays in children with stable spleen or liver injury.^{8,13,15} Gandhi et al¹⁶ showed significant reduction of hospital stay in children with spleen injury after adopting a clinical pathway. Their recommendations for hospital stay and interval of activity restriction did not stratify for injury severity. The evidence in our study for eliminating ICU admission in stable patients with grades I through III injury is current transfusion rates of only 2% to 10% and operation rates of under 3% in this cohort. Intensive care unit admission for patients with grade IV injuries is supported by the significant increase in the rate of transfusion and operation than in children with less severe injuries. It is imperative to emphasize that these proposed guidelines assume hemodynamic stability. The extremely low rates of transfusion and operation document the stability in the study cohort of patients.

The safe interval of restricted physical activity after solid organ injury has been debated for nearly 30 years. Many have used radiological "healing" as criteria for allowing children to return to normal physical activity.¹ Controversy exists over the need for follow-up imaging before and after discharge in children with successful nonoperative treatment of spleen or liver injury and the potential significance of these studies on limitation of physical activity.^{17,18} Attempts to define the time required for healing of the injured spleen by imaging studies have been inconclusive. Lynch et al¹⁹ reviewed 58 patients who had nonoperative treatment of blunt splenic injuries diagnosed by abdominal CT. All children were studied by ultrasonography (US) before discharge and subsequently at 4- to 6-week intervals. The time to US "healing"

correlated roughly with CT grade of injury, notwithstanding assessment of healing by imaging studies can be misleading and unreliable in defining a safe interval for restriction of physical activity.

Abdominal CT also has been used to follow-up children with healing spleens. Pranikoff et al²⁰ studied 25 children who had undergone nonoperative treatment of CT-documented blunt splenic injuries. Follow-up CT scans at 6 weeks postinjury showed healing in 10 of 13 (77%) of grade I and II injuries, whereas only 1 of 12 (8%) grade III or IV had normal appearance. These investigators recommended 3 months of restricted activity for all patients. Studies indicate that follow-up CT may show inhomogeneity in the healing spleen for a longer interval than ultrasound. Again, the appearance of the spleen on imaging studies does not necessarily correlate with the integrity of the spleen and, therefore, offers little help to the clinician in advising the period of restricted physical activity after injury.

Our data show that less than 50% of patients currently undergo follow-up imaging in the 32 participating centers without sequelae. Our recommendation is that no routine follow-up imaging be obtained. Rather, focused imaging based on clinical symptoms is encouraged.

The impact of developing clinical guidelines on costs can be significant. Our findings have stimulated a prospective study at the 32 participating centers with the objective of validating the 5 proposed evidence-based guidelines. If validated, the guidelines will have direct economic relevance by eliminating unnecessary ICU days, hospital days, and imaging studies while enhancing patient satisfaction in safely returning to normal activities.

This evidence-based study design can bring order and conformity to patient management resulting in optimal utilization of resources while maximizing patient safety. The rapidly changing health care environment has put new pressures of accountability on physicians. There is a great need and opportunity to apply evidence-based methodology in pediatric surgery to enhance the care for our patients. Evidence-based studies such as this will allow pediatric surgeons to proactively define optimal care rather than to be reactive responding after the fact to the concerns of others with less expertise and differing motivations.

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APPENDIX: PARTICIPATING PEDIATRIC SURGICAL CENTERS

Participating Centers	Contacts	Participating Centers	Contacts
Babies & Children's Hospital of New York	Steven Stylianos/Jeanne Rubsam	Wylar Children's Hospital, Chicago	Mindy Statter
Boston Children's Hospital	Dennis Lund/Carole Atkinson	Yale University Medical Center	Robert Touloukian/John Seashore
Buffalo Children's Hospital	James Gilbert/Graidi Keleher		H.G. Andrews/Connie Cunningham
Children's Hospital of Alabama	William Hardin/Geni Smith	Loma Linda Children's Hospital	
Children's Hospital of Pittsburgh	James Lynch/Mary Gardner	Egleston Children's Hospital, Atlanta	Richard Ricketts/Mary Shepherd
Children's Memorial Hospital	Stephen Almond/Marti Barthel	Cook County Children's Hospital	Hernan Reyes/Rosalyn Dembek
Cincinnati Children's Hospital	Victor Garcia/Nicole Panaro	Hemby Pediatric Trauma Inst, Charlotte	Robert Attorri/Arlene Jacobs
Dallas Children's Hospital	Barry Hicks/Jan Johnson	Mercy Hospital of Pittsburgh	Michael Hirsch/Dorene Carter
Dartmouth-Hitchcock Medical Center	David Mooney	Geisinger Clinic	Cyndy Graves/Karen Johnston
Connecticut Children's Med Ctr, Hartford	Richard Weiss	Univ of Iowa	Anthony Sandler/Michele Alpin
Johns Hopkins Medical Center	Charle Paidas/Lucinda Berent	Hasbro Children's Hospital, Providence	Francois Luks
Kosair Children's Hospital, Louisville	Mary Fallat	Children's Hospital, Greenville	James DeCou
Rainbow Babies & Children's Hospital, Cleveland	Enrique Grisoni	Children's Hospital of Oklahoma	David Tuggle/Denise Taylor
Riley Children's Hospital, Indianapolis	Tres Scherer/Mary Kay Mitchell	Bay State Medical Center	Barry Sachs/Pat Letourneau
St Louis Children's Hospital	Robert Foglia/James Wood	Marshall University, W Va	Bonnie Beaver/Bryan Springer
University Hospital of Jacksonville	J.J. Tepas/Pam Pieper	Duke University	Keith Oldham
		Georgetown University	Burton Harris
		Medical Univ of S Carolina*	Andre Hebra/Jill Evans
		Morristown Memorial*	Kerry Bergman/Ira Jacobs

*Data submitted after study closure.

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Discussion

R.H. Pearl (Peoria, IL): In the original work on splenic injuries, physiological response to transfusion was the thing that got a child to the operating room. If you stabilized on saline and then 40 mL/kg of blood or less,

you did not undergo an operation; if you did not stabilize you did.

I have several questions. The first is on the physiological response to transfusion. Are you looking at it in the

children that undergo transfusion regarding how much blood is transfused before an operation is performed?

The second question regards grade V injuries. We had 2 children with grade V liver injuries who remained symptomatic in terms of discomfort in the right upper quadrant but stable physiologically, and both returned to the hospital emergently at 10 days. One bled to death and 1 went to the operating room and was saved, but these are the kinds of injuries that I think are different from those that are less severe. In the splenic grade V injuries, we never had a child come back or rebleed with a grade V injury of which I am aware. Also, all children went to the operating room in 5.4 hours or less. Did the children in your study stabilize quickly and then not go to the operating room after the first 6 to 12 hours or did you have any patients reported to you that had delayed bleeding that would be watched in a different way than children who were taken to the operating room emergently.

S. Stylianos (response): We tried to be careful. We really chose a very specific cohort of patients. These were not children who were involved in high-speed motor vehicle accidents. These were children who fell off the jungle gym or fell off the slide. Therefore, the number of grade V patients was so small that we could not make any comments. However, in terms of operation rate, of 832 patients, less than 40 went to the operating room, and every one of them went within 12 hours. So these children behaved in a predictable manner. I do not think there is a risk in terms of the ICU issue that we brought up.

A. Hays-Jordan (Memphis, TN): I wondered if you had any data on what percentage of the patients, after they were discharged from the hospital, reinjured their liver or spleen and at what time did that happen? Was it after their activity restriction, and how many weeks or months later did it happen?

S. Stylianos (response): In the retrospective part of this study there were no reinjury events that were recorded in those 832 patients. In the prospective part of the study, which will be presented hopefully next year, we are allowing for a 4-month follow-up interval before enrolling the patients. The reason we have only 100 enrolled so far is that each of the clinicians is holding on to those data sheets for 4 months to see if there are any untoward events after discharge.

From the Floor: What evidence is there in the literature that CT grading is the criterion we should use to stratify our patients? In my experience, it is the physiological grade of the patient that determines how you should treat them. A bad CT scan does not mean they have to go to the ICU or the operating room. It is the ones who are hemodynamically unstable, not responding to conven-

tional transfusion, that end up needing a higher level of treatment.

S. Stylianos (response): That is a very good point. The cohort of these 832 patients are children with isolated injuries. So these were children who were very rapidly stabilized and admitted to the hospital. Only very few never stabilized and went to the operating room within 12 hours.

D.W. Vane (Burlington, VT): I think this is exactly the type of research that needs to be done prospectively on this problem, but I have a real issue with the way some of the data were collected. You stated in your discussion that all patients requiring operations went within 12 hours of being admitted. Unfortunately, CT grading does not really apply to spleens but does apply to livers, so one question is how did you determine how to incorporate patients physiologically into the CT grading of spleens?

The other question regards patients with grade III splenic injuries associated with physiological instability initially and are resuscitated. Are you proposing that those unstable patients not go to the intensive care unit, even after resuscitation, which brings their blood pressure to normal?

S. Stylianos (response): First, we used AAST-defined criteria for CT grading. Second, the proposed guidelines are not and were never meant to be issues that are fixed in stone as indicated throughout the manuscript. Generally, children who suffer traumatic spleen or liver injuries are stabilized quickly, if not already stable, and are followed up through their hospital course. Any patient who falls outside of the realm of this normal response needs to be treated on an individual basis. The same is true with imaging. A child who has a liver injury and a week later is febrile and has a right upper quadrant pain obviously needs imaging.

D.W. Vane: But your statement is that patients with grade III spleens not go to the ICU. And the problem with the study is that you are not making a determination on the physiological status of the patient but rather just the grade on the CT scan, which, in children, is not accurate. This is going to allow third-party payers to look at the CT grade and deny reimbursement for an ICU stay. The issue of just sticking with an x-ray study and determining a plan of treatment is probably not the best way to approach the problem.

S. Stylianos (response): I believe the inference is that in these isolated spleen and liver injuries that the grade and the physiology correlate quite nicely, but it will be very important, as these guidelines are disseminated, to make that point, and we certainly will do that.

H.R. Ford (Pittsburgh, PA): When you looked at the grade III and IV patients who required operations, did you try to stratify according to whether they were treated in a level 1 pediatric trauma center, one that is approved

by the American College of Surgeons or some kind of a state credentialing system? When we did a multivariate analysis in the State of Pennsylvania, we saw that most of the severely injured children who were operated on, grade IV or V or grade III, actually were treated in a

nonlevel 1 pediatric trauma center. They were treated predominantly in an adult trauma center.

S. Stylianos (response): That was not evaluated in this study, but as we move forward with these projects, clearly stratification is going to have to be done.