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Clinical validity and relevance of accidental puncture or laceration as a patient safety indicator for children☆,☆☆,★

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ABSTRACT

Purpose: Accidental puncture or laceration (APL) has been endorsed as a patient safety indicator and is being used to compare hospital performance and for reimbursement. We sought to determine the positive predictive value (PPV) of APL as a quality metric in a pediatric population.
Methods: We retrospectively reviewed all cases that met APL administrative criteria over 5 years in a quaternary pediatric hospital system. Events were categorized as false positive (FP) or true positive (TP). TP cases were further categorized as "potentially consequential" or "inconsequential". The PPV of APL was calculated, and a z-test was used to provide 95% confidence intervals.
Results: Of the 238 cases identified, 204 were categorized as TP (86%; 95% CI: 80%–90%). Thirty-four of these events (17%) involved injuries that were considered "inconsequential". True events that required repair were identified as "potentially consequential" (n = 170). Thus, the PPV of APL was 71% (95% CI: 65%–77%). Extenuating factors such as adhesive disease or abnormal anatomy were present in 39% of TP cases. Thirty-four cases (14%) were categorized as FP because no documented injury was found.
Conclusions: A large proportion of APL events are either false or clinically irrelevant, thus questioning its usability as a patient safety indicator for children undergoing surgery.
Type of study: Retrospective review.
Level of evidence: IV.

In the past decade, numerous national quality and safety efforts have been developed to improve patient care and to minimize avoidable complications. In 2003, the Agency for Healthcare Research and Quality (AHRQ) published a set of evidence-based patient safety indicators (PSIs) that use administrative discharge data to identify potentially preventable adverse events during hospitalizations. These were subsequently expanded to pediatric quality indicators (PDIs) in order to better address pediatric-specific events [1,2]. These indicators were intended for internal quality measurement and improvement, however, they are increasingly being used for publicized hospital rankings and reimbursement [3–5].

Of particular interest to surgeons is PDI-1, which is defined as any accidental puncture or laceration (APL) during medical care [1]. The validity of APL as a patient safety measure has been questioned. Two validation studies performed in adult populations demonstrated the positive predictive value (PPV) of APL to be approximately 85% to 91%. However, many of the events that are detected are minor injuries that do not require intervention or do not negatively impact patient outcomes [6,7]. Of current quality metrics being faced by surgeons, APL could potentially be construed as a measure of technical proficiency, however, many of these injuries may be a justifiable risk of the procedure or even a result of random chance. While well intended, the use of APL as a quality metric could lead to inappropriate and unfair penalization of surgeons. There is an inherent need for additional rigor and reliability assessment for this specific metric to gain widespread

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; PSI, patient safety indicator; PDI, pediatric quality indicator; APL, accidental puncture or laceration; PPV, positive predictive value; LOS, length of stay; CI, confidence interval; EGD, esophagogastroduodenostomy.

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acceptance. The purpose of this study was to determine the PPV of APL as a quality metric for children undergoing surgery. We also ascertained what types of events this measure is detecting and assessed each event for preventability.

1. Methods

1.1. Study design

We conducted a retrospective review of all cases that met the criteria for PDI-1 at a quaternary pediatric hospital system. The indicator identifies all cases of "accidental cut, puncture, perforation or hemorrhage during medical care" (ICD-9-CM codes E870.0 through E870.9) or "accidental puncture or laceration during a procedure, not elsewhere classified" (998.2). Individual chart review was performed to examine demographic information, diagnoses, operative details, APL type, clinical circumstances surrounding the event, and complications. Complications were defined as prolonged length of stay (LOS), 30-day readmission, need for reoperation, and 30-day mortality. Data sources included discharge summaries, progress notes, and operative notes. Approval for this study was obtained from the Children's Healthcare of Atlanta institutional review board (CHOA IRB #15-084).

1.2. Study population

The study population included all cases of APL in children age 0 to 18 years that occurred between January 2010 and July 2015 at quaternary pediatric hospital system. Our system is a regional referral pediatric health system that consists of two main children's hospitals where surgical procedures are performed. In 2013, the hospital system managed more than 860,849 patient visits, 25,758 hospital admissions, 37,995 surgical procedures (inpatient and outpatient) and 218,231 emergency room visits.

1.3. Analysis

We categorized cases as true or false positive. False-positive cases were those that met the PDI-1 criteria based on administrative billing data review; however, no APL was identified upon detailed chart abstraction. True-positive cases had a confirmed APL event on chart abstraction. The PPV of PDI-1 for any event was calculated. True-positive cases were then further categorized as "potentially consequential" or "inconsequential". Those injuries that generally require repair were labeled as "potentially consequential" (e.g., puncture or laceration to the gastrointestinal or urinary tract or injury to a blood vessel that could not be ligated with impunity) and those that generally do not require repair were labeled as "inconsequential" (e.g., serosal tear to abdominal organs, injury to a blood vessel that could be ligated with impunity, or a dural tear that did not require repair). This categorization was independent of actual patient outcome and was intended to serve as a descriptive tool. We acknowledge that some injuries that were labeled as "inconsequential" may be treated differently by individual physicians (i.e., some physicians may repair injuries such as serosal tears and some may not). Additionally, many of the "potentially consequential" injuries did not affect patient outcomes in any way, however, if unrecognized or left unrepaired could have potentially negatively affected the patient.

Outcomes for each event were reviewed to determine if the patient suffered any complication as a result of the APL event. A literature review was performed for median LOS for procedures of interest and these parameters were used to support the concept of longer than expected length of stay. Because of the broad spectrum of cases identified, LOS was not assessed against controls. A z-test was used to calculate 95% confidence intervals (CIs).

2. Results

Using the defined criteria for the APL indicator, 238 events were identified among the estimated 209,000 cases performed in our system (0.1% event rate). Upon review of the medical record, 204 (86%; 95% CI: 80%–90%) cases were confirmed to have a documented APL event during the same episode of care. The majority of APL events (88%) occurred in the operating room setting and involved an abdominal or pelvic procedure (56%, Table 1).

2.1. False-positive cases

Thirty-four cases (14%) were identified as false positive, because there was no apparent APL event associated with the designated hospitalization found upon detailed chart abstraction. These cases were further categorized as those because of coding inaccuracies, those that were present on admission, and those that were nonaccidental events (Fig. 1). For those cases that were coded inaccurately, no event was found that could explain why the case was coded as an APL event. There were 7 cases in which a nonaccidental incision such as an "arteriotomy" or a "durotomy" was inappropriately coded as an APL event. In these cases, the surgeon used language such as "the dura was opened" or "arteriotomy was made". When read in context, it is clear that these were purposeful steps of the operation and did not represent APL events. The remaining 8 cases were found to have APL events but were present prior to admission to our facility. Among these cases, 1 patient had a penile glans injury and was transferred to our center for further management, 2 patients had pneumoperitoneum from a spontaneous bowel perforation which was the indication for operation, 1 patient underwent rigid bronchoscopy for an airway foreign body and a tracheal laceration caused by the foreign body was noted on examination of the trachea, 1 patient had a repair of a urethral injury that had occurred during a previous hospitalization, 1 patient had a rectal injury from a sacrococcygeal teratoma excision performed at an OSH and was transferred for further management, and 2 patients had colonic perforations from a colonoscopy performed at outside centers.

Table 1
Characteristics of all patients who met criteria for PDI-1 at CHOA between 2010 and 2015.

Characteristic	APL verified (n = 204)	APL not verified (n = 34)
Age, years (mean ± SD)	6.47 ± 6.5	6.10 ± 6.32
Male gender, n (%)	119 (58)	22 (65)
Race/ethnicity, n (%)		
White, non-Hispanic	80 (39)	16 (47)
African American, non-Hispanic	74 (36)	15 (44)
Hispanic	34 (18)	2 (6)
Asian, non-Hispanic	9 (4)	0 (0)
Other/missing	7 (3)	1 (3)
Setting in which APL occurred, n (%)		
Operating room	179 (88)	–
Catheterization laboratory	7 (3)	
Emergency department	1 (.5)	
Radiology suite	6 (3)	
Bedside	6 (3)	
Endoscopy	5 (2.5)	
Anatomic region of the APL/purported APL, n (%)		
Head	18 (9)	9 (26)
Neck	6 (3)	2 (6)
Chest	43 (21)	5 (15)
Abdomen/pelvis	115 (56)	12 (35)
Spine	12 (6)	1 (3)
Upper extremity	1 (1)	1 (3)
Lower extremity	8 (4)	4 (12)
Factors associated with APL, n (%)		
Scar tissue/lysis of adhesions	72 (35)	21 (62)
Abnormal anatomy	8 (4)	0 (0)