Proposed clinical pathway for nonoperative management of high-grade pediatric pancreatic injuries based on a multicenter analysis: A pediatric trauma society collaborative

Bindi J. Naik-Mathuria, MD, Eric H. Rosenfeld, MD, Ankush Gosain, MD, PhD, Randall Burd, MD, PhD, Richard A. Falcone, Jr., MD, Rajan Thakkar, MD, Barbara Gaines, MD, David Mooney, MD, Mauricio Escobar, MD, Mubeen Jafri, MD, Anthony Stallion, Denise B. Klinkner, MD, Robert Russell, MD, Brendan Campbell, MD, Rita V. Burke, PhD, Jeffrey Upperman, MD, David Juang, MD, Shawn St. Peter, MD, Stephon J. Fenton, MD, Marianne Beaudin, MD, Hale Wills, MD, Adam Vogel, MD, and the Pancreatic Trauma Study Group (PTSG) Collaborators: Stephanie Polites, Adam Pattyn, MD, Christine Leeper, MD, Laura V. Veras, MD, Ilan Maizlin, MD, Shefali Thaker, MD, Alexis Smith, MD, Megan Waddell, MD, Joseph Drews, MD, James Gilmore, MD, Lindsey Armstrong, MD, Alexis Sandler, MD, Suzanne Moody, Brandon Behrens, MD, *and* Laurence Carmant

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BACKGROUND: Guidelines for nonoperative management (NOM) of high-grade pancreatic injuries in children have not been established, and wide practice variability exists. The purpose of this study was to evaluate common clinical strategies across multiple pediatric trauma centers to develop a consensus-based standard clinical pathway.

METHODS: A multicenter, retrospective review was conducted of children with high-grade (American Association of Surgeons for Trauma grade III-V) pancreatic injuries treated with NOM between 2010 and 2015. Data were collected on demographics, clinical management, and outcomes.

RESULTS: Eighty-six patients were treated at 20 pediatric trauma centers. Median age was 9 years (range, 1–18 years). The majority (73%) of injuries were American Association of Surgeons for Trauma grade III, 24% were grade IV, and 3% were grade V. Median time from injury to presentation was 12 hours and median ISS was 16 (range, 4–66). All patients had computed tomography scan and serum pancreatic enzyme levels at presentation, but serial enzyme level monitoring was variable. Pancreatic enzyme levels did not correlate with injury grade or pseudocyst development. Parenteral nutrition was used in 68% and jejunal feeds in 31%. 3Endoscopic retrograde cholangiopancreatogram was obtained in 25%. An organized peripancreatic fluid collection present for at least 7 days after injury was identified in 59% (42 of 71). Initial management of these included: observation 64%, percutaneous drain 24%, and endoscopic drainage 10% and needle aspiration 2%. Clear liquids were started at a median of 6 days (IQR, 3–13 days) and regular diet at a median of 8 days (IQR 4–20 days). Median hospitalization length was 13 days (IQR, 7–24 days). Injury grade did not account for prolonged time to initiating oral diet or hospital length; indicating that the variability in these outcomes was largely due to different surgeon preferences.

CONCLUSION: High-grade pancreatic injuries in children are rare and significant variability exists in NOM strategies, which may affect outcomes and effective resource utilization. A standard clinical pathway is proposed. (*J Trauma Acute Care Surg.* 2017;83: 589–596. Copyright © 2017 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic/care management, level V (case series).

KEY WORDS: Pediatric pancreatic injury; pancreatic trauma; nonoperative management; standard clinical pathway; guideline; practice variability.

The pancreas is the fourth most commonly injured abdominal solid organ in children, yet it remains unclear how pancreatic body transections should be managed. Nonoperative management (NOM) of other solid organ injuries (spleen, liver and kidney) has become the standard of care and is widely accepted as being both safe and effective. Pancreatic body injuries (grade III on the American Association of Surgeons for Trauma [AAST] scale) are debated because distal pancreatectomy is generally well-tolerated and organ preservation is not thought to be as important as it is for the spleen, kidney or liver. Furthermore, leakage of pancreatic enzymes from a primary duct injury can sometimes lead to adverse consequences such as large, symptomatic pseudocysts, pancreatic ascites, pancreatic fistula, or severe pancreatitis. Due to these feared consequences, guidelines in adults are fairly clear, recommending operative control of a grade III injury, which involves pancreatic duct transection, with distal pancreatectomy.[1–3]

NOM started to gain popularity for management of pediatric pancreatic injury in 1987[4] after a case series reported by surgeons from the Hospital for Sick Children in Toronto, Canada.[4] This approach was then supported by a series of similar successful reports. It was found that simply observing these injuries was sufficient, and that symptomatic pseudocysts that developed could be percutaneously drained or resolved spontaneously. Besides pseudocyst, few adverse consequences were reported. For proximal injuries (grades IV and V), the operative options recommended is most often pancreatoduodenectomy (Whipple operation), which is a much more morbid operation than distal pancreatectomy, and may have adverse long-term consequences. Therefore, for these injuries, NOM is generally now the preferred approach in pediatric patients. Controversy, however, remains for grade III injuries.

The evidence-to-date does not provide a clear answer to which option, OM or NOM, leads to superior outcomes for grade III injuries. Given the rarity of these injuries, reports have mostly consisted of small single-center series. The few multicenter series have shown variable results.[5] The largest multicenter study reported better outcomes, such as shortened time to goal feeds and lower pseudocyst formation, with OM.[6] In contrast, a National Trauma Databank (NTDB) review suggested that NOM may lead to better outcomes.[7] The majority of studies have not been able to demonstrate that one of the options leads to significantly superior outcomes than the other. A systematic review and meta-analysis of studies comparing OM to NOM also showed that besides increased pseudocyst formation in NOM, other outcomes were either

Submitted: November 21, 2016, Revised: April 21, 2017, Accepted: April 23, 2017, Published online: June 5, 2017.

From the Texas Children's Hospital (B.J.N-M., E.H.R.); and the Michael E DeBakey Department of Surgery (B.J.N-M., E.H.R.), Houston, TX; Mayo Clinic (D.B.K., S.P.), Rochester, MN; MultiCare Mary Bridge Children's Hospital & Health Center, Tacoma, WA; Children's Hospital of Pittsburgh (B.G., C.L.), Pittsburgh, PA; Le Bonheur Children's Hospital (A.G., L.V.V.), Memphis, TN; Children's Hospital of Alabama (R.R., I.M.), Birmingham, AL; Connecticut Children's Medical Center (B.C., S.T.), Hartford, CT; Hasbro Children's Hospital (H.W., A.S.), Providence, RI; Carolinas HealthCare System (A.S., M.W.), Charlotte, NC; Children's Mercy Hospital (D.J., S.S.P.), Kansas City, MO; Nationwide Children's Hospital (R.T., J.D.), Columbus, OH; Saint Louis Children's Hospital (A.V.), St. Louis, MO; Children's Hospital of Los Angeles (R.V. B., J.U.), Los Angeles, CA; Randall Children's Hospital at Legacy Emanuel (M.J., J.G.), Portland, OR; Boston Children's Hospital (D.M., L.A.), Boston, MA; Children's National Medical Center (R.B.), Washington, DC; University of Utah (S.J.F.), Salt Lake City, UT; Cincinnati Children's (R.A.F.J., S.M.), Cincinnati, OH; Doernbecher Children's Hospital, Oregon Health and Science University (M.J., B.B.), Portland, OR; and Centre Hospitalier Universitaire Sainte-Justine (M.B., L.C.), Montreal, QC, Canada.

This is a Pediatric Trauma Society related manuscript and was presented at the 13th annual meeting of the pediatric trauma society November 11, 2016 in Nashville, TN.

Address for reprints: Bindi J. Naik-Mathuria, MD, Texas Children's Hospital, 6701 Fannin Drive, Suite 1210, Houston, TX 77030; email: bnaik@texaschildrens.org.

DOI: 10.1097/TA.0000000000001576

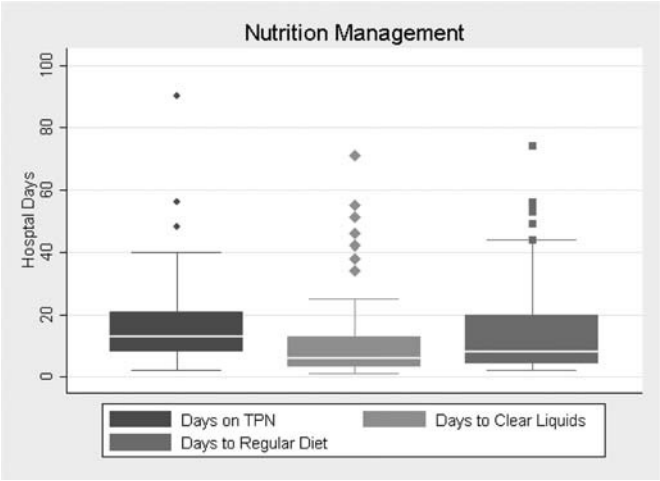

Figure 1. This figure demonstrates the variability in nutrition management.

similar or the data were too poor to assess.[8] In addition, because these studies were retrospective, incomplete data and grouping of outcomes across centers makes the reported data difficult to interpret.

Due to the lack of consensus regarding initial management with OM or NOM for grade III injuries, variability exists in how these patients are managed. Additionally, we previously demonstrated that variability also exists regarding how patients who are treated with NOM (grades III, IV or V) are managed, based on a survey of trauma medical directors at nineteen pediatric trauma centers.[5] This variability likely has developed because of the rarity of these injuries, and because of the lack of a standard management pathway. In contrast, there are many fewer variations in how pediatric surgeons manage liver and spleen injuries since development of consensus guidelines for NOM of liver and spleen injuries.[9]

The purpose of this study was to assess the contemporary management trends of NOM for high-grade pancreatic injuries in children among a multicenter cohort to develop a consensus-based standard clinical pathway for management of these patients.

METHODS

A study group of twenty pediatric trauma centers was established through the Pediatric Trauma Society. Institutional Review Board (IRB) approval for retrospective chart review was obtained at each center. Chart review was performed on children 18 years or younger who were treated for pancreatic injury with clear or suspected duct transection (grades III-V) and were initially managed nonoperatively between the years 2010–2015. Injuries that were not provided a grade by a radiologist were graded retrospectively. Patients who had exploratory laparotomy for other purposes were included, but those with pancreatic resection were excluded. De-identified data were entered into a centralized (RedCap) database. Data were collected on demographics, injury grade, mechanism of injury, laboratory and imaging findings, interventions, time to diet, hospital length of stay, re-hospitalizations, complications, and incidence and management of organized peripancreatic fluid collections. Given that the definition of a "pseudocyst" is variable, we avoided the use of that term, and instead evaluated the formation of an organized peripancreatic fluid collection that was present 7 days or longer after injury.

Analysis was performed using descriptive statistics, Kruskal Wallis and Mann-Whitney for nonparametric data and

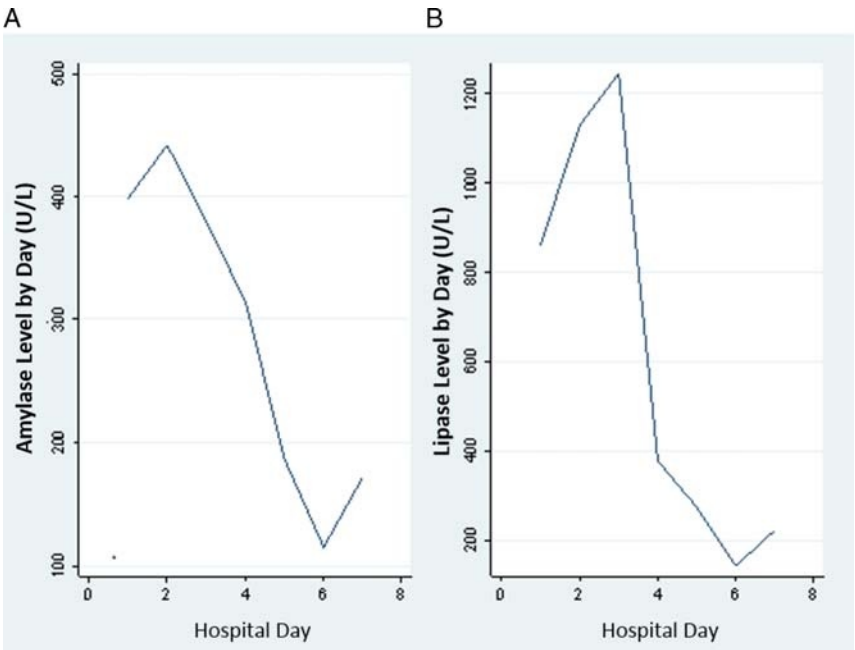

Figure 2. (*A*) Frequency of serial pancreatic enzyme monitoring after baseline level at hospital day 1. (*B*) Trends in serum amylase and lipase levels.

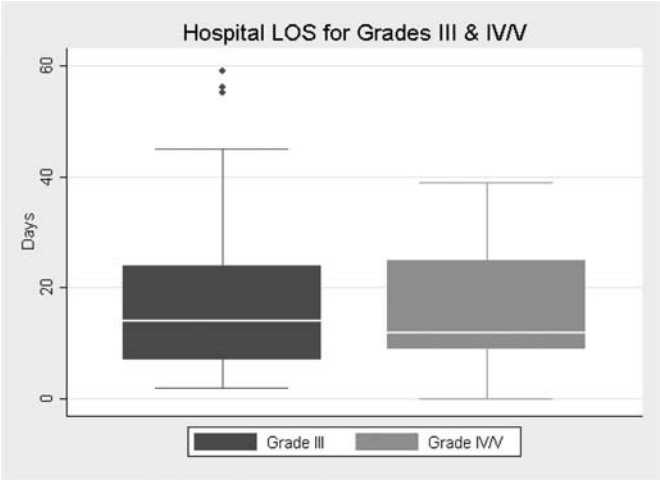

Figure 3. This figure demonstrates the similarity in hospital length of stay between distal (grade III) and proximal (grades IV–V) pancreatic injuries, as well as increased variability in grade III injuries.

χ^2 or Fisher's exact for categorical data. Stata software was utilized, and significance was considered at $p < 0.05$. After analysis of clinical management strategies, those employed for more than 50% of patients were incorporated into a proposed standard clinical pathway. Using the Delphi method, an expert panel of reviewers (the trauma medical directors who are authors of this manuscript) came to a consensus to refine the proposed pathway.

RESULTS

I. Patient Demographics and Injury Details

Eighty-six pediatric patients were treated at twenty pediatric trauma centers (range, 1–8 per center) over this five-year period. Most (67%) of patients were male, and the median age was 9 years (range, 1–18 years). Per the AAST scale, 63 patients (73%) had a grade III injury, 20 (24%) had a grade IV injury, and 3 (3%) had a grade V injury. The majority of injuries were acute, as median time from injury to presentation was 12 hours (range, 0.5–120 hours, n = 63). Median ISS was 16 (range 4–66, n = 74). In the majority of patients (63%), the pancreas was the only injured organ. Six (7%) patients had laparotomy for other indications, or exploration of pancreatic injury without pancreatic resection. The most common injury mechanism overall was bicycle handlebar injuries 31 (41%). Other mechanisms included: low-velocity abdominal trauma (21%), motor vehicle accidents (16%), nonaccidental trauma (NAT) (13%), falls (6%), and other (3%).

II. Clinical Management

All patients had a computed tomography (CT) scan and serum pancreatic enzyme levels measured at presentation to the trauma center, or before transfer to the trauma center. All patients were admitted and NOM was attempted. Magnetic resonance cholangiopancreatogram (MRCP) was obtained in 29% of patients at presentation in addition to CT scan and was only discordant in six patients. Endoscopic retrograde cholangiopancreatogram was performed in 24% (21 patients), at a median time of 5 days. A stent (at duct transection site or ampulla) was placed in 53%.

Complete data on feeding practices was available for 70 patients. Of these, 54 (77%) were started on total parenteral nutrition (TPN), 22 (31%) were started on jejunal feeds, and 16 (23%) received both TPN and jejunal feeds. A clear liquid diet was started at a median of 6 days (range, 1–71 days; n = 70) and regular diet at a median of 8 days (range, 2–74 days; n = 70) (Fig. 1). The most common reason for diet advancement was improvement of tenderness or nausea (66%), but 34% waited until pancreatic enzymes downtrended in addition to symptom improvement. The median days on TPN was 13 (range, 2–91). There was one significant outlier: a patient who was on TPN for 90 days who was a 2-year-old with NAT who had a severe traumatic brain injury and multiple other injuries who had pain with clear liquids and was discharged to the rehabilitation unit on TPN.

Six patients had oral diet initiation longer than 50 days. Two of them had large, persistent pseudocysts, one of whom ended up requiring a cystgastrostomy. Other reasons for avoiding oral diet for a prolonged period were listed as "elevated enzymes" in two and "surgeon preference" in the remainder. The majority of patients (85%) were discharged home on a regular diet (n = 80). Data on TPN or jejunal feeds at discharge were not reported for all patients, but of those reported, 11 of 62 patients

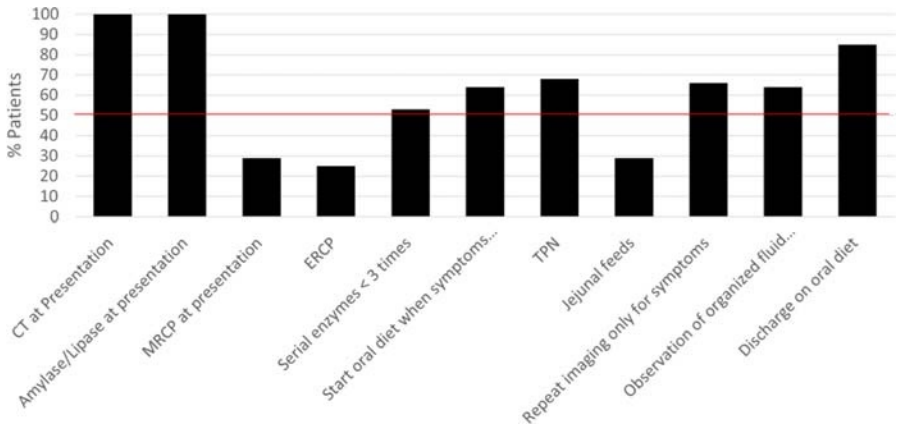

Figure 4. Summary of clinical management across centers.

TABLE 1. Differences in Serum Pancreatic Enzymes, Time to Regular Diet, and Hospital Length of Stay Among Patients With Distal Pancreatic Injury (AAST Grade III) and Proximal Pancreatic Injury (AAST Grade IV or V)

	AAST Grade III (n = 63 Total)	AAST Grade IV/V (n = 23 Total)	*p*
Initial median amylase: median (range), U/L	399 (27–2,500) (n = 55)	392 (68–2,424) (n = 20)	0.95
Initial median lipase: median (range), U/L	997 (71–12,933) (n = 56)	714 (71–12,646) (n = 22)	0.70
Peak median amylase: median (range), U/L	538 (105–4932) (n = 24)	1325 (261–2424) (n = 7)	0.29
Peak median lipase: median (range), U/L	2130 (71–46,004) (n = 55)	2047 (71–136,450) (n = 21)	0.67
Time to regular diet: median (range), d	8 (2–52) (n = 52)	11 (3–44) (n = 18)	0.27
Hospital length of stay, mean (SD), d	17.7 ± 14.2 (n = 61)	15.9 ± 11.3 (n = 23)	0.92

were discharged with TPN and 5 of 52 patients on jejunal feeds. Patients with organized peripancreatic fluid collections took significantly longer to tolerate a regular diet than those without (11 vs. 8 days; $p = 0.01$, n = 60). However, TPN use was not significantly higher ($p = 0.14$ n = 79) in this subgroup.

The median serum enzyme levels at presentation were: amylase, 399 U/L (range, 27–2,500; n = 75) and lipase, 861 U/L (range, 41–12,933; n = 78). After the initial set, serial serum pancreatic enzyme levels were obtained more than three times for 47% of patients, ranging from 0 to 27 times. For the majority (88%) of patients, both serum amylase and lipase levels were serially followed at least one additional time. The median number of either serial serum amylase or lipase level check was three times. Figure 2 demonstrates the trend of serum

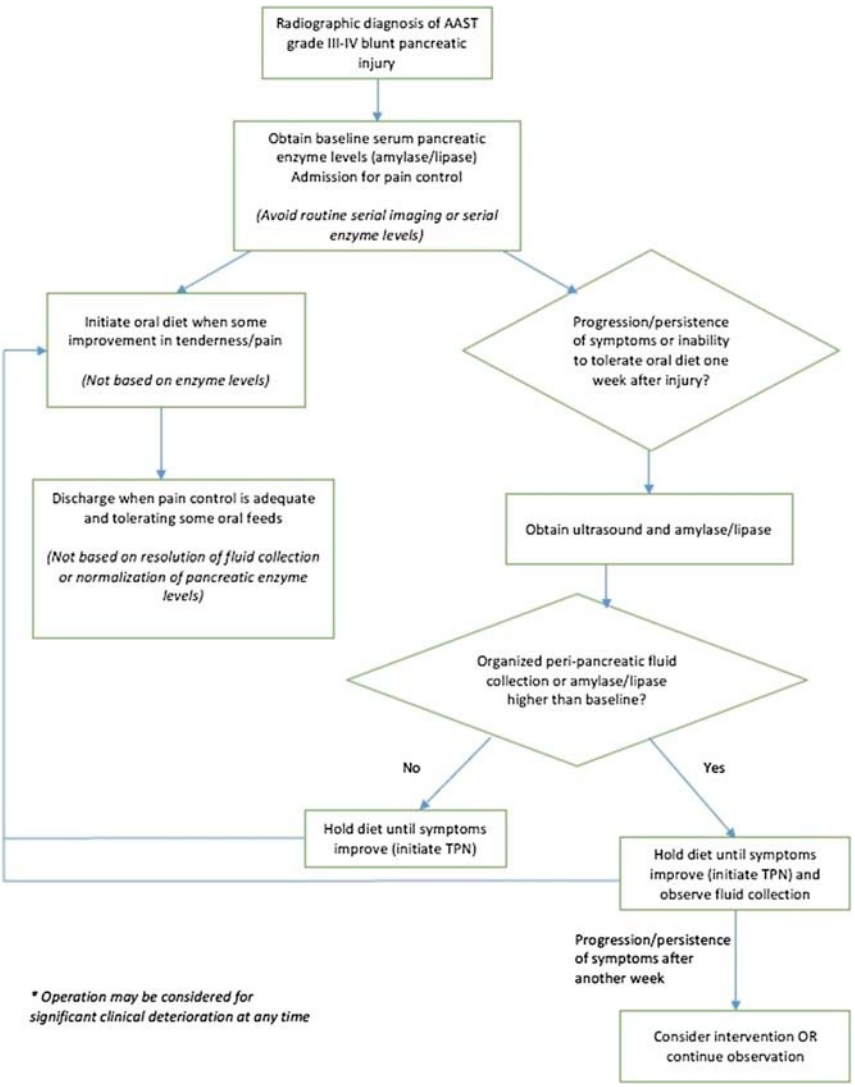

Figure 5. Proposed clinical pathway for NOM of blunt pancreatic injury in pediatric patients.

amylase level, which peaked 2 days after admission, and lipase level, which peaked 3 days after admission.

After the initial CT scan, repeat imaging was obtained in 63 (n = 84) of the patients; 14% for fever, 29% for pain, 37% for routine follow-up, and the rest for other reasons. The median number of repeat imaging studies was 2 (range, 0–6), and the most common study was ultrasound (44%).

III. Organized Peripancreatic Fluid Collection Development and Management

An organized fluid collection that was present 7 days or longer after injury was identified in 42 patients at a median of 12 hospital days (range, 7–42 days). Most collections were identified by repeat imaging obtained for symptoms, rather than for routine follow-up. Most (64%) were observed, and the rest underwent early intervention: 24% percutaneous drain, 2% percutaneous aspiration, and 10% internal drainage via ERCP and stent. Ultimately, 26% (11 patients) received a definitive drainage procedure for persistent pseudocyst (seven operative cystgastrostomy, one distal pancreatectomy, one Roux-en-Y cystjejunostomy, and two endoscopic cystgastrostomy).

IV. Outcomes

Resolution of abdominal tenderness was reported in 52 patients. The median day of pain resolution was 7 (range, 2–287 days). The median hospitalization length of stay was 13 days (range, 0–88 days). Regarding hospital length of stay, five patients stayed longer than 50 days. Four of them had symptomatic pseudocysts, of whom two required a delayed intervention. Two were patients with NAT, who likely had prolonged admission due to multiple injuries. Notably, there were no significant differences in hospital length of stay between patients with pancreatic head injuries (grades IV or V) or pancreatic body injuries (grade III) (Fig. 3).

The readmission rate was 89%. Twenty-eight percent of patients were readmitted for abdominal pain, nausea/vomiting, or inability to tolerate an oral diet (12 of these had multiple readmissions). Nine patients were readmitted for procedures (drains, ERCP, cyst-gastrostomy, or distal pancreatectomy). Two patients were readmitted for PICC line infection.

Fistula development was reported in two patients. One developed after washout and drain placement, which ultimately required distal pancreatectomy, and the other did not resolve after endoscopic stenting and later also required distal pancreatectomy.

Other reported complications were: pancreaticoduodenal pseudoaneuryms requiring angiography and thrombin injection (one patient), portal vein thrombosis requiring anticoagulation (one patient), pancreatitis (reported in only one patient), small bowel obstruction after delayed operation (one patient), NJ tube clogging/displacement (four patients), drain site infection (one patient), and PICC line infection (two patients). One patient developed a pneumothorax during percutaneous aspiration of an organized fluid collection. There were no deaths.

Development of diabetes was reported as "no" or "unknown" in the 69 patients for whom these data were reported, but follow-up times were not reported. Time to return to school was 30 days (median), but these data were only available for 22 patients.

V. Predictors of Outcomes

A comparison of the characteristics and outcomes of patients based on injury grade is demonstrated in Table 1. Based on these data, proximal injuries (IV and V) were not significantly correlated with pancreatic enzyme levels, organized peripancreatic fluid collection development, and did not predict longer time to regular diet or longer hospital stay compared to grade III injuries. However, given the small numbers, these insignificant differences may be due to insufficient power.

In addition to injury grade, neither initial nor peak serum amylase or lipase levels were predictive of development of an organized peripancreatic fluid collection or persistent pseudocyst: amylase, 697 U/L no pseudocyst versus 715 U/L pseudocyst ($p = 0.73$); lipase, 3,177 U/L no pseudocsyt versus 1685 U/L pseudocyst ($p = 0.24$).

VI. Development of a Standard Clinical Pathway

Figure 4 illustrates the clinical management strategies described above. Based on the strategies that were used more than 50% of the time, an expert, consensus-based standard clinical pathway was developed (Fig. 5).

DISCUSSION

Pediatric surgeons have debated for decades about whether operative or NOM is the optimal way to manage blunt pancreatic injuries; specifically, AAST grade III injuries. The data presented in this study represent the largest series of patients managed with NOM that only includes injuries with duct transection and are not obtained from the NTDB. In the most recent NTDB article,[10] 514 patients treated with NOM were included, only 16% were AAST grades III-IV. The inaccuracy of large database data is highlighted in this study, because operative management by location is reported as involving the tail in 50% and the body in 85% of grade IV injuries, which by definition only includes disruption of the pancreatic head.

Given the rarity of these injuries, we felt it is important to combine data from multiple centers, and performed a detailed retrospective chart review of patients managed with NOM at pediatric trauma centers, where surgeons are generally well versed in latest management trends and keep current with the literature in the field. In our previous survey study of these centers, variations in management had been discovered, and the data from this study confirm this finding. After diagnosis of pancreatic injury by CT scan and elevated pancreatic enzyme levels, there is discrepancy in the use of MRCP or ERCP to confirm ductal disruption (which can be difficult to ascertain from CT scan in pediatric patients,[10] as well as in adult patients,[11,12]) in how often serial pancreatic enzymes are monitored, in feeding practices, and in how pseudocysts are identified and managed.

The fact that only a quarter of the centers obtained MRCP or ERCP may be due to lack of access to these modalities. Additionally, if CT scan is sufficient to demonstrate a ductal injury then surgeons may not feel that further confirmation of MRCP is necessary. The utility of ERCP for pediatric pancreatic injury is still under debate. It does serve value in confirming ductal integrity, but whether or not stenting the duct makes a therapeutic difference is not clear.[13]

Serial monitoring of pancreatic enzyme levels was also variable. While elevated levels indicate injury and ongoing pancreatic inflammation, it has not been shown that peak levels predict course of disease, although they may predict pseudocyst formation.[14] In our data, we found no correlation between initial or peak enzyme levels and injury grade or pseudocyst development. It appears that some surgeons use decreasing enzyme levels as an indicator of when to start an oral diet, whereas others are not. Some are checking levels until they normalize, whereas others are likely managing patients based on symptoms than serum enzyme levels. Furthermore, the grade of injury did not correlate with higher enzyme levels. We therefore suggest that trending serial enzymes are unlikely to have much clinical application in NOM of these injuries, but comparison to initial levels after injury may be of benefit when assessing for worsening pancreatitis in patients with progressive symptoms.

Our results demonstrated wide variability in feeding strategies for these patients, with only 29% initiating jejunal feeds and 68% initiating TPN. The majority of patients were started directly on an oral diet after improvement in abdominal tenderness. The median days to clear liquids were 6 days and regular diet was 8 days, but there were significant outliers, which did not always correspond to patients who had persistent pseudocyst problems. Notably, higher injury grade did not correlate with prolonged diet initiation. It seems likely that a few surgeons are choosing to avoid starting an oral diet early on for fear of worsening symptoms of pancreatic inflammation or duct leakage. Based on these results, we recommend attempting starting an oral diet rather than jejunal or parenteral nutrition when oral diet is tolerated.

A high proportion of patients had an organized peripancreatic fluid collection at 7 days. Although these might be early pseudocysts, we have chosen not to label these as such. Repeat imaging (generally with ultrasound) was obtained for symptoms the majority (66%) of the time rather than for routine monitoring, which makes it slightly less likely that asymptomatic fluid collections were identified. Initial management of organized fluid collections was also variable, with observation and percutaneous drainage being the most common practices. Oral feeds were generally withheld longer in patients after identification of organized fluid collections. Since only a minority of collections persisted and required intervention and most were observed, we recommend attempting observation when these fluid collections are first identified.

There were generally few complications in this large cohort of children with high-grade injuries who were managed with NOM. However, the hospital readmission rate was very high (almost 90%). We were unable to ascertain outcomes regarding quality of life, return to school, or development of pancreatic insufficiency, which reflects the limitations of a retrospective chart review. Thirteen percent of patients required definitive procedures (operation or endoscopic cystgastrostomy) to drain symptomatic pseudocysts, which could be considered failure of NOM. Although there were no cases reported in this review, it should be noted that there is always the possibility of a missed associated injury such as a bowel injury when managing patients with high-grade pancreatic injuries nonoperatively, and this should be carefully considered when choosing this approach.

There are key limitations of this study. The retrospective nature led to some incomplete data, especially at centers who do not have complete electronic medical records. Additionally, suppositions may have been made in some cases when not clearly stated in the hospital chart, such as reason for starting diet. Finally, since all patients were managed nonoperatively and the use of ERCP is low, there is the possibility that some may not have had ductal transection and therefore grade II injuries were included in this cohort, which may affect the outcomes described as these injuries generally follow a milder course.

In summary, through this large, multicenter review of NOM for pancreatic injuries in children, we have demonstrated the variations in contemporary management trends. Given that most centers are treating only a few of these patients per year, and the lack of guidance in the current evidence in this field, this variability is not surprising. In addition to the incidence of complications, the majority of studies available in the current literature that compare OM to NOM report the outcomes of length of hospital stay, duration of TPN, and time to diet. With varying practice patterns, these outcomes may not reflect consequences of disease progression, which makes prior comparisons difficult to interpret.

Using the data compiled in this multicenter study, which comprise the largest series of high-grade blunt pancreatic injuries managed with NOM, we have proposed a consensus-based, standard clinical pathway. Minimizing variability in patient care is vital to compare and evaluate outcomes, allows for more effective resource utilization, and tends to decrease adverse events. We plan to utilize and validate the proposed pathway during a planned multicenter prospective trial in which outcomes of OM and NOM will be compared specifically for grade III injuries, from which we hope to definitively answer the question about which management strategy leads to superior outcomes for these vulnerable patients.

AUTHORSHIP

B.J.N.-M. is the principle investigator and participated in study conception, design and implementation, analysis of results, primary author of manuscript (drafting and critical revision). E.H.R. made significant contribution to study design, data acquisition, coalescence, analysis and interpretation, secondary author of manuscript (drafting and critical revision). A.V., A.G., R.B., R.A.F., R.T., B.G., D.M., M.E., M.J., A.S., D.B.K., R.R., B.C., R.V.B., J.U., D.J., S.S.P., S.J.F., M.B., H.W. made significant contribution to study design, data acquisition at each center, provided expert consensus panel to develop standard clinical pathway, provided significant manuscript drafting and critical revision. Pancreatic Trauma Study Group (PTSG) collaborators: S.P., A.P., C.L., L.V.V., I.M., S.T., A.S., M.W., J.D., J.G., B.B., L.A., A.S., S.M.., B.B., L.C. participated in data acquisition at each center, input into manuscript drafting and critical revision.

DISCLOSURE

The authors declare no conflicts of interest.

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