A multicenter trial of current trends in the diagnosis and management of high-grade pancreatic injuries

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BACKGROUND: Outcomes following pancreatic trauma have not improved significantly over the past two decades. A 2013 Western Trauma Association algorithm highlighted emerging data that might improve the diagnosis and management of high-grade pancreatic injuries (HGPIs; grades III–V). We hypothesized that the use of magnetic resonance cholangiopancreatography, pancreatic duct stenting, operative drainage versus resection, and nonoperative management of HGPIs increased over time.

METHODS: Multicenter retrospective review of diagnosis, management, and outcomes of adult pancreatic injuries from 2010 to 2018 was performed. Data were analyzed by grade and time period (PRE, 2010–2013; POST, 2014–2018) using various statistical tests where appropriate.

RESULTS: Thirty-two centers reported data on 515 HGPI patients. A total of 270 (53%) had penetrating trauma, and 58% went directly to the operating room without imaging. Eighty-nine (17%) died within 24 hours. Management and outcomes of 426 24-hour survivors were evaluated. Agreement between computed tomography and operating room grading was 38%. Magnetic resonance cholangiopancreatography use doubled in grade IV/V injuries over time but was still low.Overall HGPI treatment and outcomes did not change over time. Resection was performed in 78% of grade III injuries and remained stable over time, while resection of grade IV/V injuries trended downward (56% to 39%, $p = 0.11$). Pancreas-related complications (PRCs) occurred more frequently in grade IV/V injuries managed with drainage versus resection (61% vs. 32%, $p = 0.0051$), but there was no difference in PRCs for grade III injuries between resection and drainage.Pancreatectomy closure had no impact on PRCs. Pancreatic duct stenting increased over time in grade IV/V injuries, with 76% used to treat PRCs.

CONCLUSION: Intraoperative and computed tomography grading are different in the majority of HGPI cases. Resection is still used for most patients with grade III injuries; however, drainage may be a noninferior alternative. Drainage trended upward for grade IV/V injuries, but the higher rate of PRCs calls for caution in this practice. (*J Trauma Acute Care Surg.* 2021;90: 776–786. Copyright © 2021 American Association for the Surgery of Trauma.)

LEVEL OF EVIDENCE: Retrospective diagnostic/therapeutic study, level III

KEY WORDS: Pancreas; trauma; pancreatectomy; cholangiopancreatography; algorithm.

Pancreatic trauma presents many challenges. The pancreas is an unforgiving organ, and injuries of all grades can be associated with significant morbidity.[1] Diagnosis is hindered by its retroperitoneal position and limitations of laboratory and imaging tests.[2] Moreover, management of high-grade pancreatic injuries (HGPIs; i.e., American Association for the Surgery of Trauma [AAST] Organ Injury Scale [OIS][3] grades III–V) is fraught: resection is associated with high morbidity rates,[4] but nonresectional management can also be associated with high morbidity, prolonged length of stay (LOS), and the need for multiple interventions.[5,6] Consequently, outcomes related to pancreatic trauma have not improved over the past 25 years.[2]

The rarity of HGPIs has resulted in a lack of experience among practicing trauma surgeons and a dearth of high-quality data guiding management. In 2013, the Western Trauma Association (WTA) published an algorithm for critical decisions in pancreatic injuries.[7] The authors identified several areas with emerging data to potentially change practice. These included the diagnosis of pancreatic injuries and assessment of the integrity of the main pancreatic duct (MPD);[8–11] nonoperative management (NOM) of HGPIs;[5,12,13] the role for pancreatic duct stents;[11,14,15] and the performance of operative peripancreatic drainage in lieu of resection for select HGPIs.[16,17] Subsequent literature further supported increased use of magnetic resonance cholangiopancreatography (MRCP),[18] endoscopic retrograde cholangiopancreatography (ERCP),[19,20] and NOM of select patients.[21,22]

The WTA Multicenter Trials Committee endorsed the current study to characterize the evolving diagnosis and management of HGPIs in recent years. We hypothesized that the use of diagnostic MRCP, therapeutic ERCP and pancreatic duct stenting, operative drainage in lieu of resection, and planned NOM increased over time. We also sought to determine whether pancreas-related complications (PRCs) decreased over time.

PATIENTS AND METHODS

This was a retrospective multicenter study of HGPIs. Inclusion criteria were age 15 years or older, AAST-OIS[3] grades III to V pancreatic injury, and direct admission to participating

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sites between January 2010 and September 2018. Exclusion criteria for outcomes analyses included early deaths (<24 hours) and transfers from other hospitals after laparotomy (LAP) or pancreatic intervention. Adherence to the WTA algorithm[7] was not required.

Data Collection

After institutional review board approval, each site provided deidentified data for patients with pancreatic injuries included in the institution's trauma registry. The case report form included demographic and injury data, diagnostic testing, interventions, and outcomes. The timing and specific findings of imaging studies, operative and endoscopic interventions, and decision making were recorded.

Pancreatic injury grade was recorded for both computed tomography (CT) and intraoperative inspection. When there was a discrepancy between grades, case report forms were evaluated for other information to ascertain a definitive grade (e.g., MRCP or ERCP results); if there was still uncertainty, the site principal investigator was queried and assigned a final grade. Indications for ERCP and pancreatic stenting were recorded as either empiric/prophylactic therapy for a newly diagnosed injury or treatment of a PRC (pancreatic leak, peripancreatic abscess, pancreatic fistula, or delayed pancreatic pseudocyst). Management in the early period (PRE, 2010–2013) was compared with the later period (POST, 2014–2018). The primary outcome of interest was PRCs; pancreas-related mortality was a secondary outcome of interest.

Statistical Analysis

Patient demographics and characteristics are reported using descriptive statistics, including mean, median, interquartile range, and proportions. Continuous variables were compared using analysis of variance and *t* test; for not normally distributed data, Kruskal-Wallis test and Wilcoxon rank sum test were performed. The χ^2 test, Fisher's exact test, two-proportion *z* test, or one-proportion *z* test were used to compare categorical variables. Power analysis of our primary outcome was conducted using two-sample *z* test of equal sample sizes using the parameters: α of 0.05, power of 0.80, and effect size from observed percentages from our data set (Supplemental Digital Content, http://links.lww.com/TA/B893). Statistical significance was defined as p value of <0.05. All statistical tests were performed using R software (version 3.6.3; The R Foundation, Vienna, Austria).

RESULTS

Patients

Thirty-two centers (level I, 30; level II, 2) from the United States, Canada, Australia, and Israel provided complete data on 1,261 patients (Fig. 1), of whom 515 were adults with HGPI (Table 1). The average annual number of HGPI patients from each center ranged from <1 (nine centers) to six (two centers) (Fig. 2). The overall population was 78% male and has a mean age of 34 years with 28 patients (5%) older than 65 years. Mean Injury Severity Score was 29. Two-hundred seventy patients (53%) sustained penetrating trauma. A comparison of blunt and penetrating injury patients is shown in Table 1. The

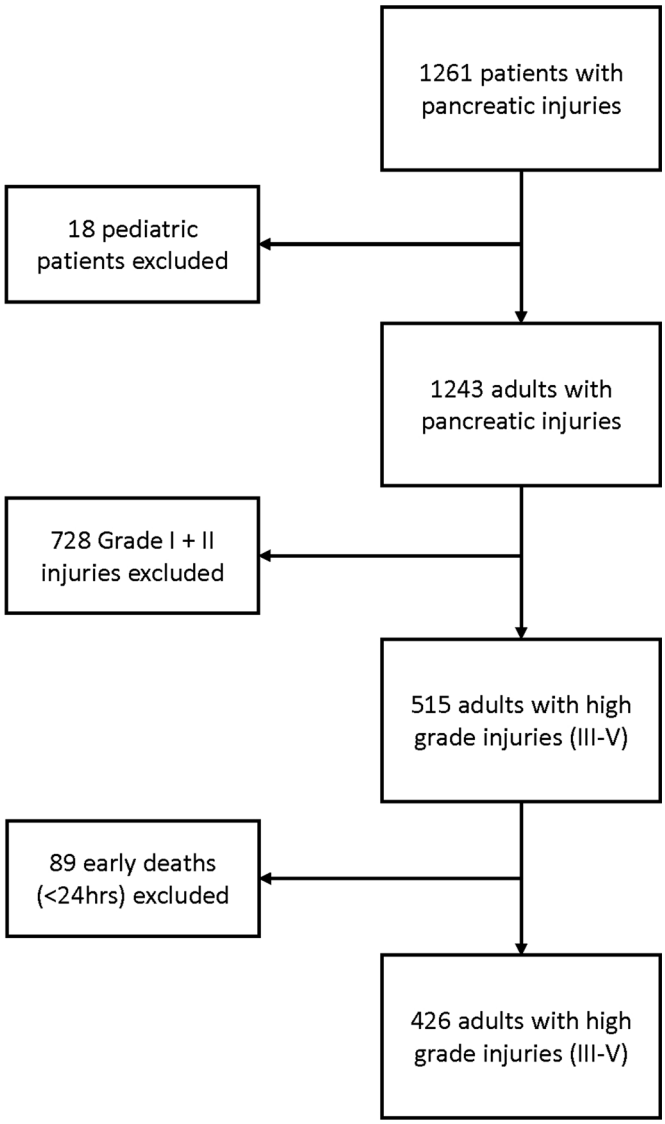

Figure 1. Derivation of final population of adult high-grade (III–V) pancreatic injuries.

percentage of penetrating injuries increased significantly with grade ($p = 0.01$).

Eighty-nine (17%) died within 24 hours: 74 (83%) were attributed to massive blood loss and were mostly intraoperative deaths. The early deaths are included in Table 1 to accurately depict the population and early management and allow comparison with previously published series. However, only the 24-hour survivors (n = 426) were included in analyses of diagnostic evaluation, definitive treatment, and related outcomes.

Imaging

One hundred seventy-six patients underwent initial CT and subsequent LAP. Agreement between CT and operating room injury grades was only 38%: 41% for grade III, 22% grade IV, and 40% grade V. The CT was considered diagnostic of MPD integrity in only 26%. For all HGPI, the use of MRCP and ERCP did not change significantly over time (Table 2). However, among those with grade IV/V injuries, the use of MRCP

TABLE 1. Summary Demographics by Mechanism of Injury, Including Early Deaths

	Blunt	Penetrating	Total	*p*
N = 515	244 (47%)	270 (53%)	514*	0.11
Age, mean (SD)	35.6 (17.2)	32.0 (13.2)	33.7 (15.3)	0.0082
Male sex, n (%)	162 (66)	239 (89)	401 (78)	<0.0001
ISS, mean (SD)	32.0 (15.6)	27.0 (11.8)	29 (14)	0.0001
Grade III, n (%)	183 (75)	173 (64)	356 (69)	0.0073
Grade IV, n (%)	37 (15)	50 (19)	87 (17)	0.31
Grade V, n (%)	24 (10)	47 (17)	71 (14)	0.01
Gunshot wound, n (%)	—	247 (91)	247 (48)	—
Stab wound, n (%)	—	19 (7)	19 (4)	—
Directly to OR, n (%)	70 (29)	230 (85)	300 (58)	<0.0001
FAST examination, n (%)	164 (67)	151 (56)	315 (61)	0.0087
FAST positive, n (%)	95 (58)	95 (63)	190 (60)	0.37
Early deaths, n (%)	37 (15)	51 (19)	88 (17)*	0.26

*One patient had unknown mechanism.
p Value = blunt versus penetrating.
t Tests and two-proportion *z* tests were performed.
FAST, Focused Assessment with Sonography for Trauma; ISS, Injury Severity Score; OR, operating room.

doubled (9% to 18%, $p = 0.21$) and ERCP quadrupled (6% to 24%, $p = 0.047$). The use of MRCP and ERCP by center is indicated in Figure 2. A comparison of centers managing two or more HGPI cases per year (HIGH) with those managing fewer than two cases per year (LOW) revealed that MRCP was obtained in 9% HIGH versus 15% LOW ($p = 0.08$) and ERCP in 13% HIGH versus 17% LOW ($p = 0.22$).

Definitive Management and Outcomes

Overall, management of HGPIs did not change significantly over time (Table 2). The majority (77%) of grade III injuries were treated with resection, with just 16% having operative drainage alone. There was not a significant difference in PRCs between resection and operative drainage for grade III injuries (Table 3). In contrast, resection for higher-grade (IV/V) injuries trended downward over time (56–39%; $p = 0.11$; Table 2), primarily replaced by operative drainage. There were significantly more PRCs following drainage versus resection (61% vs. 32%, $p = 0.0051$) (Table 3). Compared with penetrating injuries, bluntly injured HGPI patients were less likely to undergo resection and more likely to undergo NOM, but there was no significant difference in the use of operative drainage alone. There was no difference in the incidence of PRCs between blunt and penetrating mechanisms. Management by resection, drainage, and NOM for each center is indicated in Figure 2. Between HIGH and LOW centers, resection was performed significantly more in HIGH centers (73% vs. 64%, $p = 0.03$), while drainage trended toward being used more often in LOW centers (19% vs. 27%, $p = 0.06$); NOM (6% vs. 7%, $p = 0.90$) was not different.

Two hundred twenty-two patients (52%) underwent distal pancreatic resection and survived >24 hours. The resection was stapled without duct suture in 143 (64%), stapled with duct suture in 58 (26%), and sewn in 40 (18%). The PRC rate with the closure techniques was 37%, 47%, and 48%, respectively ($p = 0.31$). The number of PRCs by center is indicated in Figure 2. The PRC rate in centers with two or more HGPI per year (43%) was not different than the rate in lower-volume centers (38%; $p = 0.13$). A 24-hour delay in surgical treatment was associated with a nonsignificant increase in PRCs (50% vs. 31%, $p = 0.08$).

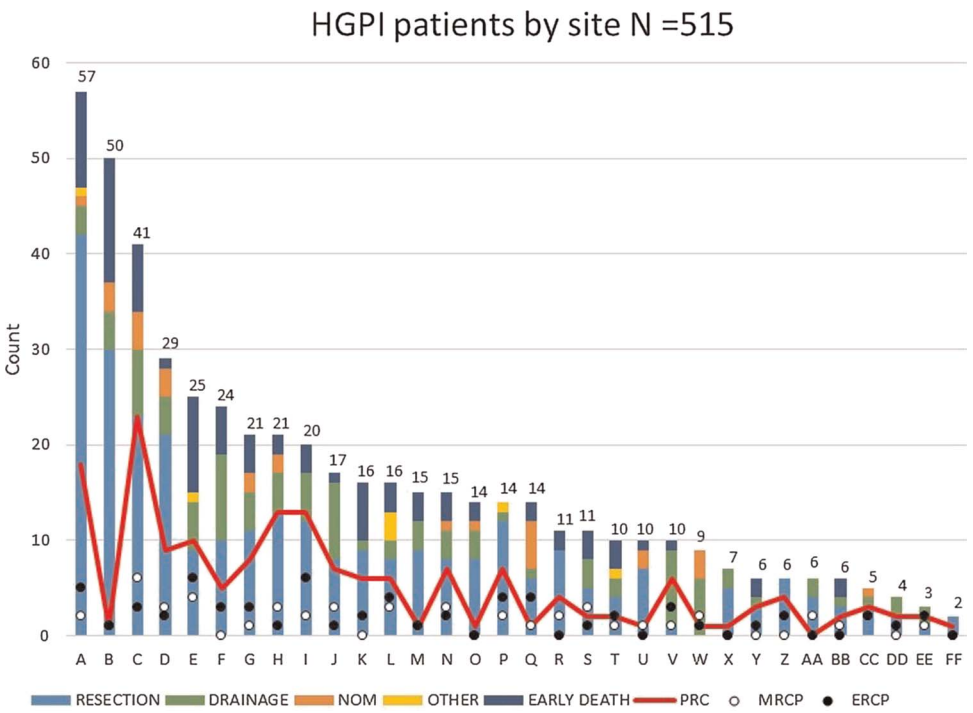

Figure 2. Contribution of patient data by site.

TABLE 2. Interventions and Outcomes in 24-Hour Survivors, PRE Versus POST

	Grade III (n = 321)			Grade IV (n = 66)			Grade V (n = 39)			All HGPIs (n = 426)		
	PRE	POST	*p*	PRE	POST	*p*	PRE	POST	*p*	PRE	POST	*p*
24-h Survivors	124	197	—	19	47	—	15	24	—	158	268	—
Resection, n (%)	93 (75)	154 (78)	0.51	10 (53)	16 (34)	0.37	9 (60)	12 (50)	0.54	112 (71)	182 (68)	0.52
Pancreatectomy, n (%)	92 (99)	152 (99)	1	6 (60)	11 (69)	0.97	2 (22)	1 (8)	0.79	100 (89)	164 (90)	0.82
Pancreaticoduodenectomy, n (%)	0	1 (1)	1	3 (30)	4 (25)	1	6 (67)	10 (83)	0.71	9 (8)	15 (8)	0.95
Proximal pancreatectomy, n (%)	0	1 (1)	1	1 (10)	1 (6)	1	1 (11)	1 (8)	1	2 (2)	3 (2)	1
Operative Drainage, n (%)	20 (16)	31 (16)	0.93	7 (37)	25 (53)	0.23	5 (33)	9 (38)	0.79	32 (20)	65 (24)	0.34
OPP, n (%)	2 (2)	4 (2)	1	0	0	—	0	1 (4)	1	2 (1)	5 (2)	0.94
NOM, n (%)	9 (7)	8 (4)	0.21	2 (11)	6 (13)	1	1 (7)	2 (8)	1	12 (8)	16 (6)	0.51
MRCP, n (%)	12 (10)	23 (12)	0.58	1 (5)	7 (15)	0.52	2 (13)	6 (25)	0.59	15 (9)	36 (13)	0.23
ERCP, n (%)	18 (15)	26 (13)	0.74	2 (11)	12 (26)	0.33	0 (0)	5 (21)	0.15	20 (13)	43 (16)	0.34
Stent, n (%)	12 (10)	23 (12)	0.58	1 (5)	11 (23)	0.18	0 (0)	5 (21)	0.15	13 (8)	39 (15)	0.054
PRC, n (%)	45 (36)	81 (41)	0.37	7 (37)	20 (43)	0.72	5 (33)	12 (50)	0.31	57 (36)	113 (42)	0.22

p Value = PRE versus POST.
Two-proportion *z* tests were performed.
OPP, other pancreatic procedure.

There were 30 late deaths (7%); none were clearly attributed to the pancreas. The subgroup of patients older than 65 years had a similar distribution of injury grades and early death rate compared with those younger than 65 years; however, their late death rate was 33%, compared with 6% among younger adults ($p < 0.0001$).

Endoscopic Management

Sixty-three patients underwent ERCP, and 52 had stents placed: 65% to treat a PRC and 35% for empiric/prophylactic treatment (Table 4). The subgroup with grade IV/V injuries had a significant increase in stent placement from 3% PRE to 23% POST ($p = 0.01$). Eleven (61%) of 18 patients who had prophylactic/empiric stent placement had a PRC. Their LOS was 9 days shorter than those who had stent for treatment of PRC.

DISCUSSION

Recent literature regarding pancreatic trauma has reaffirmed the well-known challenges in diagnosis and surgical treatment of HGPIs and their high-associated morbidity. Unfortunately, current practice guidelines from major trauma organizations in the United States are based on low-quality evidence.[7,23,24] In an effort to improve outcomes, many authors have advocated early use of MRCP and ERCP and suggested an expanded role for NOM, endoscopic pancreatic duct stenting, and nonresectional operative treatment.[5,7–22] In this study, we have collected granular data on a large number of patients with HGPIs across a wide range of trauma centers and describe the current state of pancreatic trauma management. Our findings suggest that (*a*) management seems to be evolving slowly and selectively; (*b*) nonoperative or nonresectional treatment of HGPIs may not improve outcomes as they are intended; and c) there is still much research to be done in pancreatic trauma.

Historically, evolution in trauma care and the adoption of new management strategies has occurred much more rapidly in the aftermath of high-volume, concentrated experiences or the introduction of lifesaving interventions (e.g., damage-control surgery, hemostatic resuscitation, resuscitative endovascular balloon occlusion of the aorta). Thus, it is not surprising that we did not identify a major shift in pancreatic management patterns of all HGPIs over the study period. However, we did find a number

TABLE 3. Pancreas-Related Complications Following Operative Resection vs. Drainage by Grade of Pancreatic Injury

n = 391	Resection	Operative Drainage	Total	*p*
Grade III	247	51	298	
PRC, n (%)	101 (41)	17 (33)	118 (40)	0.32
Grade IV	26	33	59	
PRC, n (%)	8 (31)	18 (55)	26 (44)	0.07
Grade V	21	13	34	
PRC, n (%)	7 (33)	10 (77)	17 (50)	0.01

p Value = resection versus operative drainage.
Two-proportion *z* tests were performed.
PRC, pancreas-related complication.

TABLE 4. Indications for Stent Placement by Pancreatic Injury Grade and Primary Management Strategy

	Patients	Total Stents	Empiric/ Prophylactic	Treatment of PRC	*p*
n (%)	426	51 (12)	18 (35)	33 (65)	—
Grade III, n (%)	321 (75)	34 (11)	14 (41)	20 (59)	<0.0001
Grade IV, n (%)	66 (15)	12 (18)	2 (17)	10 (83)	0.04
Grade V, n (%)	39 (9)	5 (13)	2 (40)	3 (60)	1
Grade IV–V, n (%)	105 (25)	17 (16)	4 (24)	13 (76)	0.03
Resection, n (%)	294 (69)	19 (6)	5 (26)	14 (74)	0.30
Drainage, n (%)	97 (23)	23 (24)	9 (39)	14 (61)	0.60
NOM, n (%)	28 (7)	9 (32)	4 (44)	5 (56)	0.80

p Value = empiric/prophylactic versus treatment of PRC.
Two-proportion *z* tests were performed.
PRC, pancreas-related complication.

of trends in the diagnosis and management of HGPIs that are specific to injury grades and warrant further investigation.

Diagnosis

Delays in diagnosis and treatment of pancreatic injury are associated with increased morbidity.[1] The pitfalls of clinical diagnosis and laboratory evaluation have been well described, particularly with regard to the identification of HGPI.[2,7,22,24,25] In the current study, pancreatic enzymes were not measured with any regularity; the diagnosis was made by either imaging or operative inspection.

Imaging

Computed Tomography

The accuracy of CT for diagnosis of MPD injury is known to be suboptimal.[4,10] The most telling data point in the current study was that, in only 26% of cases, the CT was considered diagnostic of MPD integrity. Recognizing the limitations of CT, a number of "pearls and pitfalls" have been described.[26] Contrast-enhanced, multidetector-row computed tomography (MDCT) is superior to nonhelical CT scanning. With widespread availability of 64-channel and higher MDCT scanners, continuous acquisition (also known as "whole body") protocols have gained favor over segmental scanning. Following the arterial phase, portal venous phase images of the upper abdomen are important to evaluate the solid organs. However, peak enhancement of the pancreas is during a late arterial/early portal venous phase (the pancreatic parenchymal phase).[27] This phase may be too sensitive: Wong et al.[28] reported six of six true positives in the portal venous phase but two false positives in the pancreatic parenchymal phase. On the other hand, a more recent series incorporating portal venous phase scanning reported just 36% accuracy.[29]

To aid in CT interpretation, Gordon et al.[26] separated findings into those that are indirect, highly sensitive, but nonspecific (e.g., peripancreatic fluid, fat stranding) and those that are direct, highly specific, but relatively insensitive (e.g., pancreatic lacerations, contusions, active hemorrhage). Increased risk of MPD injury is associated with lacerations involving greater than 50% of the width of the pancreas, pancreatic contusions, and active hemorrhage. As many as 40% of CT scans in patients with pancreatic injury may be interpreted as normal.[26] Minimal retroperitoneal fat makes identification of subtle defects more difficult; concurrent abdominal injury with hemorrhage may be attributed to nonpancreatic injury; and close apposition of fragments of a lacerated pancreas may hide the defect. On the other hand, some normal variants may be misinterpreted as pancreatic injury, including pancreatic clefts, which appear hypoattenuating and can be read as lacerations, or fatty replacement of the pancreas in obese or elderly patients, which may appear as pancreatic contusions.[26] Computed tomography is likely more accurate after 8 to 12 hours, as fluid, edema, and inflammation progress.[7,24–26] If a patient has no initial indication for LAP, but there remains clinical suspicion, a repeat contrast-enhanced MDCT is recommended.

In sum, CT is the primary imaging modality for diagnosing pancreatic injury but still is not sufficiently accurate to identify MPD injuries early. Recognizing its limitations will help in its interpretation and usage. If there are findings concerning for MPD injury but the patient does not have other indications for LAP, cholangiopancreatography should be considered.

Magnetic Resonance Cholangiopancreatography

The main determinant of pancreas-related morbidity is MPD disruption.[1,14,30] The use of MRCP in trauma was first described in 1999,[8] and a case series in 2000 reported 100% clinical utility.[9] Because it is noninvasive and provides visualization of distal ducts beyond the injury, MRCP is recommended before ERCP for diagnosis of MPD injury.[7,11,24] Given the importance of evaluating MPD integrity and the degree to which MRCP usage has increased in other clinical scenarios, it is somewhat surprising that it was not used more frequently in the current series. Unfortunately, the accuracy of MRCP has been called into question, for trauma and nontrauma applications.[31] A recent multicenter study from the pediatric Pancreatic Trauma Study Group[18] reported that MRCP was not superior to CT for determination of MPD integrity in children. Further study is warranted.

Endoscopic Retrograde Cholangiopancreatography

A role for ERCP in trauma was first proposed in 1976 by Gougeon et al.,[32] and it remains the criterion standard for assessment of pancreatic duct integrity. Advances in cross-sectional imaging have limited, but not eliminated, the need for ERCP for diagnosis. In this series, ERCP was usually performed after MRCP to confirm ductal injury and to place stents. Pancreaticographic classification of ductal injuries appears to be a useful tool in selecting patients for NOM and in planning interventions.[11,33,34] The therapeutic role of ERCP is discussed hereinafter.

Operative Inspection

The majority (58%) of patients in this study were triaged directly to the operating room. Assessment of the MPD requires complete exposure of the pancreas.[25] Intraoperative criteria for ductal injury described by Heitsch et al.[30] include complete pancreatic transection, direct visualization of duct injury, laceration through more than half the diameter of the pancreas, central pancreatic perforation, or severe maceration of the pancreas. Pancreatography would seem to offer a more objective means of evaluating the MPD, but it has largely fallen out of favor because of logistical challenges and potential morbidity.[25] Indeed, Schellenberg et al.[35] reported a series in which 94% of patients were managed based on visual inspection alone; 6% had intraoperative pancreatography, and the studies were all inconclusive. The Memphis group promoted a simplified management guideline based on visual inspection in 1997[16] and validated it over the next several years.[17] However, intraoperative inspection is not completely accurate, and postoperative imaging was common in the current series: CT was obtained in 41%, MRCP in 6%, and ERCP in 15%.

Grading

While research in pancreatic trauma is hampered by low numbers of cases, it is undermined by inaccurate grading. Accurate grading of pancreatic injuries is critical for meaningful research in this area. As an example, a recent analysis of American College of Surgeons Trauma Quality Improvement Program (TQIP) data reported that just 42% of penetrating grade III pancreatic injuries were managed with pancreatic resection.[36] This is in stark contrast

to the current study (87% resection in penetrating cases) and the recent AAST trial[4] (84% resection of grade III overall), both of which were contemporaneous with the TQIP study period but which based analyses on data confirmed by record review. This raises questions about the accuracy of injury coding in administrative databases. We encourage individual trauma centers to be more vigilant with regard to coding in their trauma registries and encourage multicenter studies in this arena to pay particular attention to the accuracy of grading.

Management

The three most common management strategies are operative resection, operative drainage without resection, and NOM, with or without endoscopic or percutaneous interventions. There were more resections performed in the HIGH centers than the LOW centers. Overall, there was no change in management over time, but there were differences between injury grades.

Operative Management

Grade III Injuries

Distal pancreatectomy became the preferred treatment for grade III injuries in the 1970s, based on the lower occurrence of PRCs compared with drainage alone,[30,37] and it is still recommended in current guidelines.[7,23,24] The management algorithm proposed and validated by the Memphis group[16,17] reported lower morbidity among those with distal injuries who were drained (11%) compared with those who underwent distal pancreatectomy (26%). However, it is important to note that the Memphis patients had intraoperative assessment and resection based on the Heitsch et al. criteria,[30] so those who had drainage alone were unlikely to have MPD injury (i.e., they likely had grade II injuries). In the current series, 78% of patients underwent resection and 16% had drainage. The difference in PRC rates between resection (41%) and drainage (33%) was not significant ($p = 0.32$), raising the possibility that drainage of grade III injuries may be noninferior to resection. Given the high rate of PRCs after distal resection in this and other published series,[4,16,17] the definitive management of grade III injuries should be studied prospectively, with careful attention paid to assessment of MPD integrity.

Nonoperative management of pancreatic injuries gained popularity after a 1987 report from Toronto's Hospital for Sick Children.[38] Several case series in children have been reported, with mixed results.[5,6,39,40] There are a paucity of data on NOM in adult patients with HGPI,[12,13,21] and just 5% of the patients in the current series were managed in this way, with significant mortality. However, there may be a subset of selected patients with pancreatic ductal injury for whom NOM with or without adjunctive pancreatic sphincterotomy and/or stenting will result in better outcomes.[11,15,20] For example, patients who are physiologically well and have ductal injury with leakage that is contained within the pancreatic parenchyma may be reasonable candidates.[11,33,34] Most investigators currently recommend surgery in the setting of documented MPD transection, but this should be explored in a controlled clinical trial.

Grade IV Injuries

The 2016 Eastern Association for the Surgery of Trauma guidelines[23] conditionally recommended resection for grade IV injuries. Resection may involve "extended" distal/near-total pancreatectomy (65% of resections in the current series) or more complex resections.[25] Extended distal pancreatectomy for grade IV injury appears to be safe as long as 20% of the gland is preserved to avoid endocrine dysfunction.[37] Two patients underwent proximal pancreatic resection, which has generally fallen out of favor because the pancreaticoenteric anastomosis can be morbid and it may also be associated with early endocrine dysfunction.[41] Pancreaticoduodenectomy was performed in seven patients, although it is not generally considered appropriate for a grade IV injury. The Memphis experience[16,17] suggests that drainage alone is associated with improved outcomes for pancreatic head injuries overall. For this reason, the WTA algorithm[7] recommended drainage, and the recent World Society of Emergency Surgery-AAST guideline[24] favors it as well. However, outcomes in the setting of a documented transected MPD in the head are unclear. In the current series, there was an increasing tendency over time to drain grade IV injuries (53% from 37%), but numbers remain small and the outcomes raise concerns with PRC rates of 31% for resection versus 55% for operative drainage ($p = 0.07$). This requires further study.

Grade V Injuries

Grade V injury is, fortunately, uncommon. Truly massive injury to the head of the pancreas will require pancreaticoduodenectomy. This can be performed safely in trauma patients;[42–44] however, in the setting of physiologic compromise, it is most prudent to perform initial damage control and stage the procedure.[7,43,45] Of note, operative drainage alone was performed in 36% of patients and was associated with a 77% rate of PRCs. This approach has been described for combined pancreaticoduodenal injuries,[46–48] but patients must be appropriately selected.

We analyzed the highest-grade injuries (IV and V) together and found a chronological trend away from resection (56–39%; $p = 0.11$). Of note, there was a significantly higher rate of PRCs following operative drainage (61%) as compared with resection (32%) ($p = 0.0051$). While the trend toward nonresection was not statistically significant, this was likely a result of our studying being underpowered for this outcome. This calls for an evaluation of these management strategies in a controlled clinical trial.

Endoscopic Management

ERCP/Stenting

Based on success in healing pancreatic duct disruptions in various pancreatic disorders, ERCP has been used to manage early traumatic MPD disruptions and posttraumatic PRCs.[11,15,19,20] Pancreatic sphincterotomy and/or stent placement can eliminate the 30- to 40-mm Hg pancreatic duct sphincter pressure and allow unimpeded forward flow of pancreatic juice into the duodenum.[15] Series from San Francisco[15] and Cape Town[19] reported successful endoscopic management of 50% to 79% of patients. Of note, those with pancreatic strictures were less amenable to endoscopic treatment and required surgery in 58% of cases.[19] Kong et al.[49] reported a reduction in PRCs (26% vs. 46%) and improved success of NOM (91% vs. 70%) with endoscopic placement of pancreatic stents or nasopancreatic drains. Recently, Kim et al.[20] reported a 34-year

series in which they managed 43 cases of pancreatic ductal disruption. The ductal injury was missed by CT in 41% of cases. They selected treatment based on CT or ERCP result. They reported a very high rate of PRCs (67–76% in the three treatment groups). Kim et al.[20] and Bhasin et al.[11] both mention a concerning association of early pancreatic stenting with pancreatic duct strictures. Clearly, more research is warranted in this area.

Of 57 grade IV/V injuries that were not resected in the current series, ERCP was performed in 19 (33%) and stents placed in 17 (89%). We expected an increase in stent placement, and this was true in the POST period for grade IV/V injuries. Somewhat surprisingly, only 24% were placed early. The rate of PRCs was high after early stenting, but LOS was 9 days shorter compared with those receiving stents for treatment of complications —this needs to be studied prospectively.

In sum, earlier endoscopic evaluation and interventions warrant investigation for HGPI management. The current consensus seems to be that a transected MPD will likely require surgery, and this may optimize long-term outcomes. However, pancreaticographic classification of injuries may refine decision making.

Outcomes

Pancreas-Related Complications

Because the primary risk factor for PRC is injury to the MPD,[1,14,30] and essentially all HGPI patients have MPD injury, it is not surprising that the PRC rate was not different between injury grades and was similar to the 47% incidence in the recent AAST study.[4] There was no difference in PRCs between blunt and penetrating injuries, or HIGH versus LOW centers. Among those who underwent distal resection, we found no difference in PRC rate between patients who were stapled versus sewn, nor did we find any benefit to suturing the duct. In the AAST study,[4] stapled anastomoses had significantly lower abscess plus pseudocyst/fistula rates (30%) compared with sewn (48%) or stapled plus sutured (37%). This is in contrast to previous studies in elective pancreatectomy, but comparing trauma and elective surgery is not necessarily valid.[50] One point raised by Byrge et al.[4] was the finding that the use of 3.5-mm staples was associated with the lowest leak rate, and this warrants further study.

Based on our data, operative drainage may be a noninferior alternative to resection for grade III injuries but may result in worse outcomes in grade IV/V injuries.

Strengths

This multicenter trial represents a broad spectrum of trauma centers and is, to our knowledge, one of the largest reported series of HGPI outside of administrative database studies. We were able to collect more granular data than what is available in such databases and had opportunities to clarify interventions and timelines. Thus, we have reliable data that are generalizable.

Limitations

This study was retrospective in design and suffers from all the limitations of such studies. Specific to this study, injury grading may have been inaccurate because CT scanning, intraoperative assessment, and MRCP all have shortcomings and trauma registry data may not be correct. Definitive management may have been influenced by factors other than the injury grade, and our ability to determine clinical decision making was limited. Similarly, outcomes such as LOS, overall morbidity, discharge disposition, and late mortality could not be interpreted because they are influenced by many factors that could not be assessed. The recording of PRCs was based on retrospective review rather than prospective documentation with strict definitions. There was no requirement to follow the WTA algorithm, although this resulted in a more realistic picture of current management.[7] Data may not be representative of management across the country because the majority was collected from academic centers with WTA members. However, a broad range of centers is represented, so these data and the conclusions should be generalizable. The study period ended in October 2018, so more recent data are not included and it is possible that ongoing evolution in care is occurring.

Many comparisons were underpowered to draw firm conclusions. Based on low event rates among HGPIs overall, power analysis indicates that we would need to enroll the following numbers of patients in each group to confirm statistical significance for the hypothesized changes in management: diagnostic MRCP (953), ERCP (2,157), pancreatic duct stenting (318), operative drainage (1,680), and NOM (2,542). To achieve statistical significance based on a 6% change in PRCs among all HGPIs over time would require 1,035 patients in each group (Supplemental Digital Content, http://links.lww.com/TA/B893). On the other hand, analysis of the rate of PRCs of operative resection versus operative drainage for grade IV and V injuries was adequately powered with just 93 patients: power, 0.81.

Summary/Future Directions

The results of this study indicate there has not been a significant change in the overall management of HGPIs in adults from 2010 to 2018. However, there are evolving trends that call into question some recommendations in current guidelines. For example, the 2013 WTA pancreatic injury algorithm recommends resection for grade III injuries and drainage for grade IV injuries, yet the current data suggest that drainage may be a noninferior alternative for grade III injuries, but drainage of grade IV and V injuries may result in worse outcomes. The recognition that CT scanning is suboptimal for MPD assessment should prompt consideration of early pancreatography. Increasing interest in NOM has stemmed from reports in pediatric patients, but application to adult patients is premature. Management of HGPIs appears to vary between HIGH and LOW centers; while PRC rates are not different, the influence of practice patterns and volume is confounded by low numbers and the differences in blunt/penetrating ratio and warrants further study.

AUTHORSHIP

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DISCLOSURE

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DISCUSSION

BABAK SARANI, M.D. (Washington, District of Columbia): Thank you, Dr. Burlew. I'd like to start by thanking the Association for the privilege of discussing this paper and, also, I congratulate the authors on a very well-written manuscript. But I have to say, given that the lead author graduated from the George Washington School of Medicine, that's almost expected and a given.

The authors carried out a 32-center, multi-national, retrospective study involving over 500 patients with the goal of evaluating the role of magnetic resonance imaging and either pancreatic duct stenting or peripancreatic drainage as a compared to resection in the management of Grade 3 and higher pancreatic injury.

They compared the management strategy and outcomes associated with that before and after publication of the Western Trauma Association algorithm for management of this type of injury. I have a few questions.

You divided patient demographics based on blunt and penetrating mechanism of injury, but you report the outcomes in amalgam, as a single cohort. Is it fair to lump these two mechanisms together?

One involves a crushing injury while the other is more of a penetrating and blast injury with transection of the parenchyma and/or duct.

The breakdown between the penetrating and the blunt cohorts was almost 50/50 so the data, naturally, do lend themselves to evaluating the cohort separately.

Question Number 2. You divided the outcomes based on the date of injury, specifically, before and after publication of the Western Trauma algorithm, but this decreases the number of patients in each analyzed cohort which, in turn, impacts your ability to detect a small difference in the outcome.

I did not see an actual power analysis for the paper. So given that your study really did not detect a difference in the primary outcome, would you consider carrying out a power analysis to see what sample size you would need to do so and if you could combine the cohorts to achieve that power?

Based on your results it would appear that the Western Trauma algorithm really did not impact management anyway, which is somewhat expected given the delay between publication and change in practice. Lastly, ultimately, the fundamental question that we have to answer as trauma surgeons is what do you do when confronted with a high-grade pancreatic injury. Does your study help guide this decision?

Your results state that essentially any pancreatic duct transection should be treated with resection as compared to drainage or ECRP stenting alone.

Based on preexisting reports and now your manuscript, do you think this is the approach that we should espouse for all patients with this type of pancreatic injury?

Overall, the study's findings are certainly quite interesting in the sense that they challenge and corroborate previous studies challenging the traditionally accepted rule of resection for all high-grade pancreatic injuries.

I, thus, applaud you, Dr. Biffl, and your colleagues on your work and completely support your recommendation for prospective studies to further assess this injury pattern.

WALTER L. BIFFL, M.D. (San Diego, California): Dr. Sarani, I would like to thank you for your kind remarks and insightful questions- and, mostly, for sending me the questions ahead of time so I could do some analyses and come up with actual answers.

The blunt and penetrating patients are very different, and I described some of the key differences in the presentation. We had gotten to that in a roundabout manner; it was not an a priori planned analysis. We were interested in the accuracy of imaging so we separated out those who went directly to the OR without

imaging- they turned out to be mostly penetrating trauma patients. There were some differences between the two groups in demographics; however, we did not separate them for all the analyses because, as you alluded to in other questions, the subgroups get small enough that statistical analysis is challenging and inconclusive.

That being said, when you sent me your questions we analyzed specifically by the mechanism of injury for the management and outcomes. We found that the blunt injured patients were less likely to undergo a resection and more likely to undergo non-operative management; but there was not a statistical difference in the number who underwent operative drainage alone.

Blunt injured patients more frequently had MRCP. There was no change in management over time among the blunt or penetrating injured groups. And as far as outcomes, there was no difference in pancreas related complications between blunt and penetrating patients. Of note, the recent AAST multi-center study did find penetrating mechanism of injury to be associated with an increased risk of pancreatic fistula or pseudocysts so this is definitely an area for future study.

The second question was about comparing management in the two time periods. It was our original primary purpose that we wanted to evaluate current management and determine whether it had changed over time. We had no delusions that our algorithm would change management overnight. But some of these data had been around for five or ten years, and there were more publications over the couple of years after we published the algorithms.

We divided the study period into before and after the publication date of the algorithm, which seemed less arbitrary than dividing at other time points.

Moreover, going back any further in time, there would have been some practical problems given what we got from some institutions' trauma registries. I think when you go back earlier than 2010 people struggle to come up with good data.

We did not see an immediate change in management but there were some interesting trends. The study was underpowered to draw firm conclusions. As it was a retrospective study, we had not performed a priori power analysis- but we did some power analyses.

We found, for example, that to demonstrate a significant difference over time in the use of drainage for Grade 4 injuries – and I remind you, they did increase in this study from 37 percent to 53 percent in the two time periods – we would have to have 300 patients in each group to have a significant difference. To determine whether the use of MRCP increased significantly for all high-grade injuries, we'd need nearly a thousand patients for each sample; and to identify a difference in drainage, we would need over 1,600 patients per sample. This is due to the low event rate.

We did not analyze outcomes by time period as there was no reason to think that the complications after a resection would have changed over the eight-year period. But there are still issues with the power to draw firm conclusions so, hence, the need for future prospective studies.

That leads to the final question – what should we do with the high-grade injuries. I think for the Grade 3 injuries data going back to the 1970s suggests that resection offers better outcomes compared with drainage.

There has been nothing published since then that has really changed that conclusion and nothing in our study to change that. So I think that's a take-home message.

The surgical options for Grade 4 injuries are complex. Drainage to the pancreatic head has been shown by the Memphis group to be a reasonable approach overall.

And Dr. Sarani, you and your colleagues looked at the TQIP database and concluded that non-resectional management may be a viable option for Grade 3 and 4 injuries.

But what we lack right now are well-controlled studies comparing resection and drainage in patients who have an actual, documented laceration of the main pancreatic duct or true Grade 4 injuries. Our data suggests a higher complication rate in that setting so it needs to be studied prospectively. And, finally, I believe doing ductal imaging with MRCP or ERCP will open the door for less invasive management strategies. Thank you for your questions.

MATTHEW MARTIN, M.D. (San Diego, California): Wait – what do you think of this data in light of the previous presentation of the pediatric multicenter study utilizing non-operative management almost exclusively, even for ductal injuries? Great work.

WALTER L. BIFFL, M.D. (San Diego, California): Yes, that was an interesting presentation. I would have some concerns with adopting that in adults at this time. A non-resectional strategy can commit people to multiple interventions and it raises the question why you would not just go in and resect. This is where ductal imaging comes in. If it's just a side branch, they may be more likely to get through it without a major issue. Another area to study.