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Evaluation of Chinese updated guideline for acute pancreatitis on management of moderately severe and severe acute pancreatitis☆

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ABSTRACT

Background: /Objectives: The management of acute pancreatitis (AP) in China has undergone major changes since the launch of the updated guideline in 2013. This study aimed to evaluate the impact of this guideline on clinical practice and patient outcome.

Methods: Moderately severe and severe adult AP patients, who were admitted to Peking Union Medical College Hospital from January 1, 2001 to December 31, 2016, were retrospectively included in the study. All enrolled patients were divided into two groups based on the publication date of the updated guideline, as the pre-guideline (Pre) group and post-guideline (Post) group. In-hospital case-fatality rates were compared between two groups after adjusting baseline features, including gender, age, etiology and disease severity. In addition, the associations between specific therapeutic approaches recommended in the updated guideline and in-hospital case-fatality rates were explored.

Results: A total of 475 patients were enrolled in this study, including 273 (57%) in the Pre group and 202 (43%) in the Post group. The adjusted in-hospital case-fatality rate significantly decreased in the Post group (14.3% *vs.* 5.9%, OR 0.39, 95%CI 0.19–0.82). In the post-hoc analysis, the use of enteral nutrition was a protective factor against in-hospital death (OR: 0.08, 95%CI: 0.03–0.18), while open surgery showed an opposite effect (OR: 3.81, 95%CI: 1.06–13.74). Prophylactic antibiotics was not significantly associated with in-hospital death (OR: 1.00, 95%CI: 0.39–2.60).

Conclusions: There was a prominent transition in the management of moderately severe and severe AP after the release of the guideline in China in 2013, which made the prognosis better.

Introduction

Acute pancreatitis (AP) is a common digestive diseases around the world [1], affecting approximately 13–45 per 100,000 patients in the United States [2]. The majority of AP cases are mild, which usually recovered after 5–7 days of conservative treatment. However, approximately 15–20% of patients will suffer a worse outcome. The management of moderately severe acute pancreatitis (MSAP) and severe acute pancreatitis (SAP) patients was complex and has been constantly optimized, featured by the optimal time window for enteral nutrition (EN) and the opposite usage of antibiotics [3]. In this context, appropriate classifications of disease severities and guidelines based on accumulating clinical evidences have been published in recent years, and the most famous one was the revised Atlanta classification (RAC) proposed in 2012 [4]. The Chinese guideline for the management of AP by the Pancreatic Disease Group of Chinese Medical Association was published in 2013, and has been extensively applied in China since then. Based on the RAC criteria, multiple important recommendations were proposed, such as application of fluid resuscitation, proper usage of antibiotics, EN and open surgical intervention [5]. We provided the detailed changes recommended by this guideline in the supplemental material. Furthermore, several studies have compared the differences among guidelines from different medical associations [6], but the impact of this updated guideline in China was unclear. In this study, we aimed at evaluating the overall effect of the

☆ The study was conducted in accordance with the declaration of Helsinki. The IRB of the Peking Union Medical College Hospital approved the study. We make a statement that the written informed have been obtained from all study participants.

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guideline on the prognosis of Chinese AP patients, and tried to decompose the effect into specific recommendations, based on the retrospective data from a tertiary single-center cohort from 2001 to 2016 in China.

Methods

Study design and population

A total of 475 consecutive patients with MSAP or SAP, who were admitted and treated at Peking Union Medical College Hospital (PUMCH), a tertiary medical center in China, from January 1, 2001 to December 31, 2016, were retrospectively recruited in the present study. In order to balance the bias caused by clinicians, two senior fellows (X BAI and M JIN) independently confirmed the diagnosis and severity according to the new guideline, after reviewing the medical data. Disagreement was further discussed with an attending (B LU or H YANG). The diagnostic criteria for MSAP and SAP was based on the 2013 Chinese guideline, which is in line with the RAC. The exclusion criteria were as follows: (1) patients with malignant tumors of the alimentary tract; (2) pregnant patients; (3) age under 18 years old.

The present study was approved by the Institutional Review Board of PUMCH. Patients were treated according to the contemporary guideline, including analgesics, volume repletion, correction of electrolyte disturbance and organ function support.

Data collection

All enrolled patients were divided into two groups based on the sequential order of admission date and publication date of the updated guideline: Pre group and Post group. The demographic data included gender, age and the admission date, while the clinical and imaging information included the etiology, local and systemic complications, and severity evaluation (BISAP [7] and APACHE II [8] scores). The data for the general condition, clinical and imaging information, usage of prophylactic antibiotics and EN, and interventional and open surgical therapy and prognosis were collected through our medical database. “Prophylactic antibiotics” was defined as antibiotics were started without high suspicion of an infection or the result of infection source was negative. While, “interventional therapy” was defined as ultrasound or CT-guided percutaneous catheter drainage. In-hospital death was collected as the clinical outcome.

Statistical analysis

Categorical variables were presented in percentage, and analyzed using Chi-square or Fisher’s exact test. Continuous variables were presented as mean ± standard deviation, and analyzed by *t*-test for normally distributed variables and rank-sum test for non-normally distributed variables. Multivariable logistic regression analysis was performed to evaluate the effect of the updated guideline on the in-hospital death, adjusting variables including age, severity, gender, and etiology. A two-sided *P*-value <0.05 was considered statistically significant. The statistical analysis was performed using SPSS 24 (IBM, Chicago, IL, USA).

Results

Differences in clinical features and outcomes between the Pre and Post groups

A total of 475 patients were enrolled in the present study. Among these patients, 273 (57%) patients were assigned to the Pre group, while 202 (43%) patients were assigned to the Post group. The details of the clinical differences between these two groups are illustrated in Table 1. There was no significant differences in gender, age and distribution of disease severities between these two groups ($P > 0.05$). A change in etiology over time was noted, and more hypertriglyceridemia-induced AP were diagnosed, accompanied by a decrease in AP caused by the biliary stones ($P < 0.01$). The prevalence of local complications was similar (88.3% *vs.* 91.1%, $P > 0.05$), and the APACHE II and BISAP scores were also comparable between these two groups (10.8 ± 6.6 *vs.* 11.0 ± 7.2 and 2.3 ± 0.9 *vs.* 2.2 ± 1.0, both $P > 0.05$). For systemic complications, the prevalence of circulatory failure and multiple organ dysfunction syndrome (MODS) significantly increased in the Post group (7.3% *vs.* 18.3% and 15.4% *vs.* 23.8%, both $P < 0.01$), unlike the respiratory failure or renal failure (42.1% *vs.* 47.0% and 22.3% *vs.* 24.8%, both $P > 0.05$). The in-hospital case-fatality rate significantly decreased (14.3% *vs.* 5.9%, $P < 0.05$). In the multivariable regression model, improved prognosis was observed in patients from the post-guideline group (Table 2, OR: 0.39, 95% CI: 0.19–0.82, $P < 0.05$).

Comparison of therapeutic utilizations in the Pre and Post groups

Four specific therapeutic measures emphasized in the updated guideline were compared, including EN, prophylactic antibiotics, interventional therapy and open surgery (Table 3). The application of interventional therapy and EN was not significantly different (11.4% *vs.* 10.4% and 55.3% *vs.* 53.0%, both $P > 0.05$), but patients in the Post group received earlier EN (16.8 ± 10.4 *vs.* 6.7 ± 4.3 days (time from admission to EN initiation), $P < 0.01$). The use of prophylactic antibiotics in the Post group was significantly reduced (98.2% *vs.* 45.5%, $P < 0.001$), but the proportions of pancreatic infective necrosis were comparable (16.8% *vs.* 11.4%, $P > 0.05$). In patients with biliary AP, the use of prophylactic antibiotics presented a dramatic decrease in the Post group (100% *vs.* 56.1%, $P < 0.001$), while the proportions of infective necrosis were similar (13.8% *vs.* 12.3%, $P > 0.05$). Data in the alcoholic and hypertriglyceride types showed similar results, i.e. decreased usage of prophylactic antibiotics in Post group with a similar incidence of infective necrosis (Table 3). In the same time, the utilization of open surgery also decreased significantly in the Post group (8.1% *vs.* 1.0%, $P < 0.001$), but no significant difference was observed in the patients managed by interventional therapy or open surgery (16.1% *vs.* 10.9%, $P > 0.05$).

The analysis of potential factors and therapies associated with in-hospital death

The result of the multivariable logistic regression (Table 4), with disease severity and the three main therapeutic measures as the variables, revealed that SAP was an important factor for the in-hospital death (OR: 12.93, 95% CI: 5.40–30.91, $P < 0.001$). In the aspect of therapies, the use of EN was a protective factor against in-hospital death (OR: 0.08, 95% CI: 0.03–0.18, $P < 0.001$), while open surgery had an opposite effect (OR: 3.81, 95% CI: 1.06–13.74, $P < 0.05$), and prophylactic antibiotics played an insignificant role (OR: 1.00, 95% CI: 0.39–2.60, $P > 0.05$).

Discussion

To our knowledge, the present study was the first to focus on the impact of the updated Chinese guideline of AP on real-life clinical practice in China. Our study indicated the updated guideline has resulted in clinical benefit in patients with MSAP and SAP in a tertiary medical center, which may be related to the increased EN utilization and decreased open surgical intervention.

Table 1
Differences of clinical features, complications and outcomes between the Pre and Post groups.

	Pre group (n = 273)	Post group (n = 202)	*P* value
Demographics			
Male (n%)	181 (66.3)	121 (59.9)	0.152
Age ($\bar{x}$±s, years)	50.2 ± 16.9	47.3 ± 16.7	0.071
Etiology (n%)			0.005
Biliary	116 (42.5)	57 (28.2)	
Alcoholic	33 (12.1)	24 (11.9)	
Hypertriglyceride	50 (18.3)	58 (28.7)	
Others	74 (27.1)	63 (31.2)	
Severity			
MSAP (n%)	145 (53.1)	124 (61.4)	0.072
BISAP ($\bar{x}$±s)	2.3 ± 0.9	2.2 ± 1.0	0.629
APACHE II ($\bar{x}$±s)	10.8 ± 6.6	11.0 ± 7.2	0.617
Local complication (n%)	241 (88.3)	184 (91.1)	0.324
Systemic complication (n%)	140 (51.3%)	104 (51.5%)	0.965
MODS	42 (15.4)	48 (23.8)	0.021
Circulatory failure	20 (7.3)	37 (18.3)	0.000
Respiratory failure	115 (42.1)	95 (47.0)	0.287
Renal failure	61 (22.3)	50 (24.8)	0.540
In-hospital death (n%)	39 (14.3)	12 (5.9)	0.004

$\bar{x}$±s mean ± standard deviation; MSAP, moderately severe acute pancreatitis; MODS, multiple organ dysfunction syndrome;

Table 2
The adjusted analysis based on the baseline features for the association of guidelines with in-hospital death.

	OR value	95% CI	*P* value
Post group	0.39	0.19–0.82	0.013
SAP	9.68	4.18–22.42	0.000
Female	0.88	0.45–1.76	0.727
Etiology			0.001
Biliary	reference		
Alcoholic	0.51	0.17–1.56	0.237
Hypertriglyceride	0.18	0.02–1.46	0.109
Others	2.50	1.21–5.17	0.013
Age (years)	1.00	0.98–1.03	0.596

SAP, severe acute pancreatitis.

In studies conducted in the past decades, nutritional support has been approved as a necessity in patients with MSAP and SAP, which are unlikely to resume oral intake within one week [9]. It has been generally accepted that EN can help maintain the intestinal barrier and prevent bacterial translocation from the gut [10]. EN, rather than parenteral nutrition, is recommended for patients with MSAP and SAP, who cannot tolerate oral feeding due to the results of several trials and meta-analyses [11–13]. Despite recent evidence showed that EN within three days is a protective measure against secondary infection [14], further investigations are warranted. The present study presented a usage rate for EN between the Pre and Post guideline groups in our center was similar (55.3% *vs.* 53.0%, $P > 0.05$). However, the timing of EN administration was much earlier in the Post group (16.8 ± 10.4 *vs.* 6.7 ± 4.3 days, $P < 0.01$) following the recommendations of the updated guideline recommendation. Although early usage of EN has been confirmed to improve the prognosis, we recognized a subgroup of patients with AP who couldn't tolerate early EN in clinical practice, how to solve their dilemma remaining a challenge for physicians. Choice(s) of formula types and routes of nutrition treatment for them will be worthwhile directions for further studies. In addition, the multiple regression analysis confirmed that the use of EN was an independent protective factor against the in-hospital death of AP (adjusted OR: 0.08, 95% CI: 0.03–0.18, $P < 0.001$), indicating the clinical benefit of the updated guideline.

Extrapancreatic infection is a common complication associated with AP-related mortality, occurring in up to 20% of patients with AP [15,16]. It has been generally accepted that when an infection is suspected, antibiotics should be started without any doubt while the source of the infection is being determined [12]. Although prophylactic antibiotics are not recommended in the updated guideline, regardless of the type or disease severity of AP, there are some conflicting results from systematic reviews, especially in acute necrotizing pancreatitis (ANP). A 2015 meta-analysis,

Table 3
The comparison of the therapeutic utilizations in the Pre and Post groups.

	Pre group (n = 273)	Post group (n = 202)	*P* value
EN (n%)	151 (55.3)	107 (53.0)	0.613
Timing of EN ($\bar{x}$±s, days)	16.8 ± 10.4	6.7 ± 4.3	0.000
Prophylactic antibiotics (n%)	268 (98.2)	92 (45.5)	0.000
Biliary	116 (100)	32 (56.1)	0.000
Alcoholic	32 (97.0)	9 (37.5)	0.000
Hypertriglyceride	47 (94.0)	23 (39.7)	0.000
Infective necrosis (n%)	46 (16.8)	23 (11.4)	0.114
Biliary	16 (13.8)	7 (12.3)	0.783
Alcoholic	5 (15.2)	4 (16.7)	0.877
Hypertriglyceride	9 (18.0)	5 (8.6)	0.148
Interventional therapy (n%)	31 (11.4)	21 (10.4)	0.768
Open surgery (n%)	22 (8.1)	2 (1.0)	0.001
Interventional therapy or open surgery (n%)	44 (16.1)	22 (10.9)	0.104

$\bar{x}$±s, mean ± standard deviation; EN, enteral nutrition.

Table 4
The analysis of potential factors and therapies associating with in-hospital death.

	OR value	95% CI	*P* value
Open surgery	3.81	1.06–13.74	0.041
EN	0.08	0.03–0.18	0.000
SAP	12.93	5.40–30.91	0.000
Prophylactic antibiotic	1.00	0.39–2.60	0.993

EN, enteral nutrition; SAP, severely acute pancreatitis.

including six randomized controlled trials with a total of 397 ANP patients, revealed that early prophylactic antibiotics (commencement with 48 h after admission) improved the mortality (7.4% *vs.* 14.4%, OR 0.48, 95% CI: 0.25–0.94) and reduced the incidence of infected pancreatic necrosis (16.3% *vs.* 25.1%, OR: 0.55, 95% CI: 0.33–0.92), when compared to controls [17]. It is interesting that an analysis conducted on a Japanese nationwide database, which included 3354 eligible SAP patients, reached an opposite conclusion, revealing the methodological limitations of the above meta-analysis [18]. Due to the mixed evidence on the role of prophylactic antibiotics in AP, several unresolved questions remain, such as the proper timing for antibiotic administration in AP [19]. In the present study, the result revealed no benefit of prophylactic antibiotic use for in-hospital death in MSAP and SAP. Meanwhile, there was a tremendous decrease (98.2% *vs.* 45.5%) in the use of prophylactic antibiotics in all types of AP in the present cohort. However, the prevalence of infective necrosis remained similar (16.8% *vs.* 11.4%) under these circumstances. Biliary AP has been considered as high susceptibility for infection in the past, and some textbooks in China continue to recommend the use of routine prophylactic antibiotics for this subtype. In order to elucidate this question, the present subtype analysis revealed that the decrease in prophylactic antibiotic use did not increase the infective necrosis in the biliary AP subtype. The “mis-use” of antibiotics in AP appears to be a common phenomenon worldwide [20,21]. A report in UK presented approximately 20% inappropriate prescriptions during the six-month nationwide survey [20]. More real-world evidence and risk-based guidance in the future may aid clinicians better use of antibiotics in treating patients with AP.

During the 1980s, most MSAP patients underwent open surgical intervention, but the results were unsatisfactory. In the 1990s, the concept of a conservative, non-surgical approach to severe ANP was developed, but was not generalized [22]. At present, it is recommended to postpone surgery for as long as possible and initiate an early transfer to a specialist center for multidisciplinary management [23]. Many centers have reported that a conservative approach and the avoidance of open necrosectomy resulted in lower mortality [24,25]. Open surgery is reserved for concomitant intra-abdominal complications. The present result revealed that less open surgery leads to a better prognosis, and this remained consistent with the change in trends and guidelines with time [26,27]. It is noteworthy that the evaluation for the effects of open surgery in the real world is not as easy as expected due to the variable conditions in practice. Abdominal compartment syndrome, and suspected enteric perforation or bleeding are the absolute indications for surgery in our center. Meanwhile, the updated guideline recommends that acute peripancreatic fluid collection (APFC) and acute necrotic collection (ANC) without infection are not indications for invasive therapy. Our result showed 4 patients with APFC and ANC during 2001–2006 in Pre group were implemented by ultrasound or CT-guided percutaneous catheter drainage, while none in the Post group. Besides, in the Pre Group, indications for total 22 cases of open surgery were gastrointestinal bleeding (1 case), infected necrosis (9 cases), wall-off necrosis (2 cases), necrotic collection (5 cases) and pancreatic pseudocyst (5 cases). Notably, there was only 1 for infected necrosis and 1 for wall-off necrosis in the Post Group. The investigators exerted their utmost efforts to eliminate the deviation from the co-factors, but there were still some limitations in the present study. First, this was a retrospective analysis conducted on a 16-year database. Second, the rehydration in the initial phase of treatment in AP is an important procedure of management due to the retrospective nature of the study. However, this could not be precisely calculated. Third, the stricter administrative policy of antibiotics in China may make the usage more appropriate. Otherwise, the supplementation of data through long-term follow-up would improve the study results.

In the present study, the present condition and change in the trend in AP treatment patterns in China were analyzed based on the database of a tertiary medical center. The differences between the pre- and post-updated guideline of AP in China were elaborated indicating the transition of management pattern and improved patient prognosis in MSAP and SAP after the release of the updated guideline.

Declaration of competing interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pan.2020.09.013.

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