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Original Article

Values of different biochemical indices and clinical scoring systems for the assessment of acute biliary pancreatitis in a Chinese population

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Abstract: Objective: To investigate values of biochemical indices and clinical scoring systems for the assessment of acute biliary pancreatitis (ABP). Methods: Clinical characteristics, laboratory values including procalcitonin (PCT), and radiologic examinations of all ABP patients with mild acute pancreatitis (MAP), moderately severe acute pancreatitis (MSAP), or severe acute pancreatitis (SAP) were recorded within 48 hours after the onset of acute pancreatitis. Scores of the Accuracy of Acute Physiology and Chronic Health Evaluation (APACHE) II, Bedside Index of Severity in Acute Pancreatitis (BISAP), Computed Tomography Severity Index (CTSI), Ranson, Japanese Severity Score (JSS), Pancreatitis Outcome Prediction (POP) Score and Systemic Inflammatory Response Syndrome (SIRS) score were then calculated. The area under the curve (AUC) of the Receiver Operating Characteristic (ROC) curve was used to analyze the predictive values of biochemical indexes and scoring systems for ABP severity and organ failure. Results: The percentage of patients over 60 in the SAP group was higher than in the MAP and MSAP groups. PCT had the highest value for predicting SAP (AUC = 0.84, $P < 0.001$) and organ failure (AUC = 0.87, $P < 0.001$). The AUCs of APACHE II, BISAP, JSS and SIRS for predicting severity were 0.87, 0.83, 0.82, and 0.81, respectively (all $P < 0.001$). As for organ failure, the AUCs were 0.87, 0.85, 0.84, and 0.82, respectively (all $P < 0.001$). Conclusions: PCT has a high value for predicting ABP severity and organ failure. Among the clinical scoring systems, BISAP and SIRS are more suitable for early assessment of AP; while APACHE II and JSS are more suitable for monitoring disease progression after thorough examination.

Keywords: Acute biliary pancreatitis, clinical scoring systems, laboratory tests, prognosis

Introduction

Acute pancreatitis is a common acute abdominal disease, that can cause multiple organ failure or even death with a mortality of 5~10% [1]. Many factors can cause the onset of acute pancreatitis, including biliary tract disease, hyperlipidemia, alcohol addiction, and autoimmune disease. However, biliary disease, especially cholelithiasis, is still the main cause of acute pancreatitis (AP) in China, with an incidence of nearly 55-65% [2, 3]. Although 80%-85% of AP cases have self-limited progression, 15%-20% of the patients may suffer from poor prognosis with a mortality of up to 30% [4].

Clinical studies have reported that about half of deaths in patients with severe acute pancreatitis (SAP) occur during the first week of the disease [5-7]. Acute biliary pancreatitis (ABP) patients usually get biliary tract infection, which further aggravates the body's inflammatory response and the patients are prone to systemic inflammatory response syndrome, multiple organ dysfunction syndrome (MODS), and other complications. Thus, it is vital to evaluate the severity of ABP as soon as possible, to reverse disease progression. This study collected clinical data of ABP patients to comprehensively compare the values of different biochemical values and clinical scoring systems for the assessment of ABP in a Chinese population.

Materials and methods

Study design

This study was approved by the ethics committee of the First Affiliated Hospital of Soochow University. Patients diagnosed with ABP [8]

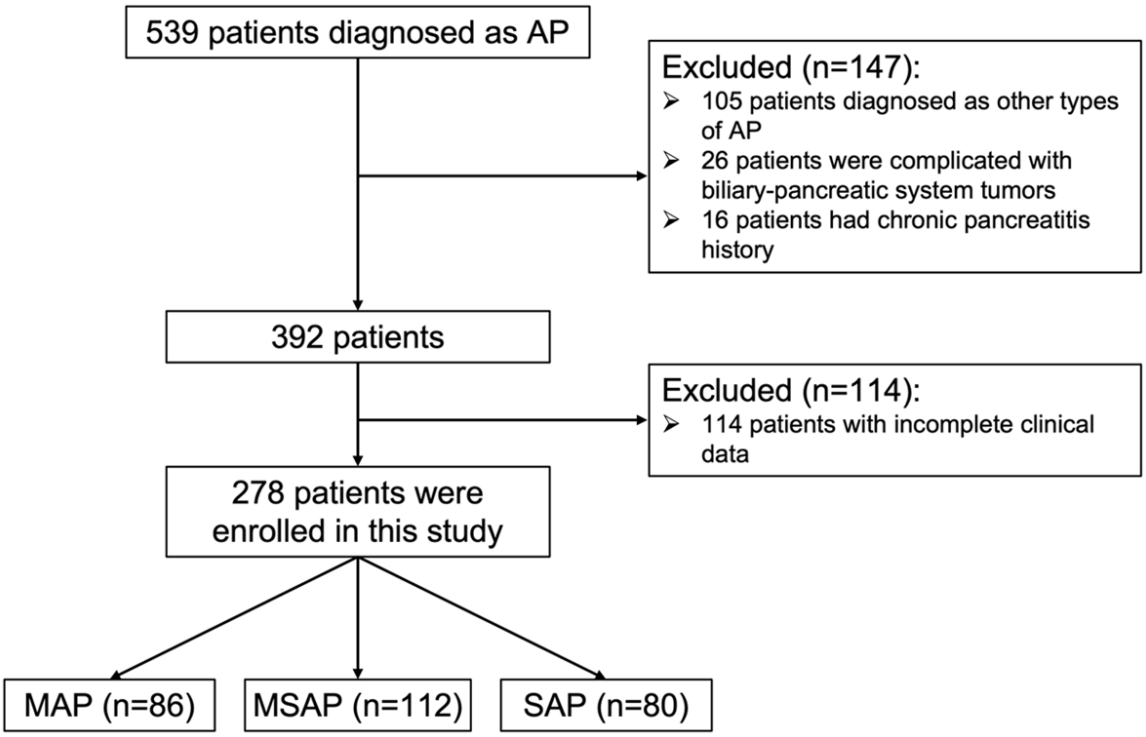

Figure 1. Selection of patients with acute biliary pancreatitis included in this study. Note: AP: acute pancreatitis; MAP: mild acute pancreatitis; MSAP: moderately severe acute pancreatitis; SAP: severe acute pancreatitis.

Table 1. Demographic and clinical data of patients with acute biliary pancreatitis

	MAP (n = 86)	MSAP (n = 112)	SAP (n = 80)	*P*-value
Gender (Male/Female)	45/41	64/48	45/35	*P = 0.783*
Age (years)				*P* < 0.001
< 60	47 (54.65%)	50 (44.64%)	29 (36.25%)	
≥ 60	39 (45.35%)	62 (55.36%)	51 (63.75%)	
BMI (kg/m^2)	21.42 ± 2.35	22.44 ± 2.24	22.45 ± 1.93	*P = 0.941*
Source of stones (%)				*P = 0.884*
Gallstones	25 (29.07%)	29 (25.89%)	20 (25.00%)	
Choledocholithiasis	34 (39.53%)	45 (40.18%)	29 (36.25%)	
Gallstones + Choledocholithiasis	27 (31.40%)	38 (33.93%)	31 (38.75%)	
Medical history				*P = 0.998*
Smoking history (%)	21 (24.42%)	30 (26.79%)	20 (25.00%)	
History of alcohol consumption (%)	16 (18.60%)	22 (19.64%)	16 (20.00%)	
COPD (%)	6 (6.98%)	5 (4.46%)	5 (6.25%)	
Hypertension (%)	26 (30.23%)	31 (27.68%)	23 (28.75%)	
Diabetes (%)	11 (12.79%)	12 (10.71%)	8 (10.00%)	

Note: MAP: mild acute pancreatitis; MSAP: moderately severe acute pancreatitis; SAP: severe acute pancreatitis; BMI: body mass index; COPD: chronic obstructive pulmonary disease.

from Jan 2016 to Dec 2018 in the First Affiliated Hospital of Soochow University and Zhangjiagang First People's Hospital were selected based on the following inclusion criteria: (1) patients had abdominal pain characteristics as AP; (2) patients had serum amylase and/or lipase level 3 times higher than the upper limit; (3) patients had AP features as indicated by radiography; (4) patients had gallstone and/or choledocholithiasis as indicated by

Table 2. Comparison of biochemical indicators among different classifications of acute biliary pancreatitis

	MAP (n = 86)	MSAP (n = 112)	SAP (n = 80)	*P* value
ALT (U/L)	91.36 ± 45.56	87.22 ± 42.35	98.30 ± 45.11	*P = 0.231*
AST (U/L)	92.25 ± 41.70	97.86 ± 53.49	105.85 ± 56.17	*P = 0.228*
Ca (mmol/L)	2.08 ± 0.22	1.84 ± 0.20	1.71 ± 0.14	*P* < 0.001
CRP (mg/L)	110.00 ± 36.71	141.14 ± 39.96	161.55 ± 51.50	*P* < 0.001
LPS (U/L)	393.99 ± 98.56	372.76 ± 100.99	367.93 ± 107.36	*P = 0.206*
PCT	0.48 ± 0.25	1.71 ± 0.42	2.02 ± 0.43	*P* < 0.001

Note: MAP: mild acute pancreatitis; MSAP: moderately severe acute pancreatitis; SAP: severe acute pancreatitis; ALT: alanine aminotransferase; AST: aspartate aminotransferase; Ca: calcium; CRP: C reactive protein; LPS: Lipopolysaccharide; PCT: procalcitonin.

Table 3. Values of biochemical indicators for predicting SAP in acute biliary pancreatitis

	AUC	Sensitivity	Specificity	95% *CI*	Optimal threshold value	*P* value
CRP	0.70	0.65	0.71	0.63-0.77	147	*P* < 0.001
Ca	0.81	0.70	0.81	0.76-0.87	1.8	*P* < 0.001
PCT	0.84	0.91	0.67	0.79-0.88	1.5	*P* < 0.001

Note: SAP: severe acute pancreatitis; AUC: area under the curve; CI: Confidence Interval; CRP: C reactive protein; Ca: calcium; PCT: procalcitonin.

Table 4. Values of biochemical indicators for predicting organ failure in acute biliary pancreatitis

	AUC	Sensitivity	Specificity	95% *CI*	Optimal threshold value	*P* value
CRP	0.76	0.74	0.79	0.70-0.82	136	*P* < 0.001
Ca	0.82	0.84	0.72	0.77-0.87	1.8	*P* < 0.001
PCT	0.87	0.88	0.78	0.82-0.91	1.4	*P* < 0.001

Note: AUC: area under the curve; CI: Confidence Interval; CRP: C reactive protein; Ca: calcium; PCT: procalcitonin.

Table 5. Comparisons of AUCs among different biochemical indicators for predicting SAP and organ failure

ROC	SAP		Organ failure	
	Z value	*P* value	Z value	*P* value
PCT *vs* Ca	0.67	*P* = 0.502	1.53	*P = 0.127*
PCT *vs* CRP	3.34	*P* < 0.001	2.86	*P = 0.004*
Ca *vs* CRP	2.54	*P = 0.011*	1.55	*P* = 0.121

Note: AUC: area under the curve; ROC: receiver operating characteristics; SAP: severe acute pancreatitis; CRP: C reactive protein; Ca: calcium; PCT: procalcitonin.

radiological examination. The exclusion criteria included: (a) patients had biliary-pancreatic system tumors; (b) patients had chronic pancreatitis; (c) patients had hyperlipidemia, ERCP-related or other factors causing pancreatitis; (d) patients had incomplete data (**Figure 1**).

Data collection

The clinical, biochemical, and radiologic data of ABP patients were collected. The clinical data included sex, age, body mass index (BMI), smoking history, alcohol consumption history, and past medical history. The relevant laboratory or radiologic examinations, including serum amylase, serum calcium, alanine aminotransferase (ALT), aspartate aminotransferase (AST), C reactive protein (CRP), procalcitonin (PCT), and arterial blood gas, were recorded within 48 h after the onset of the disease. All patients were treated according to the guidelines for diagnosis and treatment of acute pancreatitis in China [8]. For MSAP and SAP patients, organ function maintenance and early nutritional support were strengthened.

Classification of patients

Patients meeting the criteria were divided into a mild acute pancreatitis (MAP) group, moderately severe acute pancreatitis (MSAP) group, and SAP group according to AP severity [8]. Organ failure of patients in the MSAP and SAP

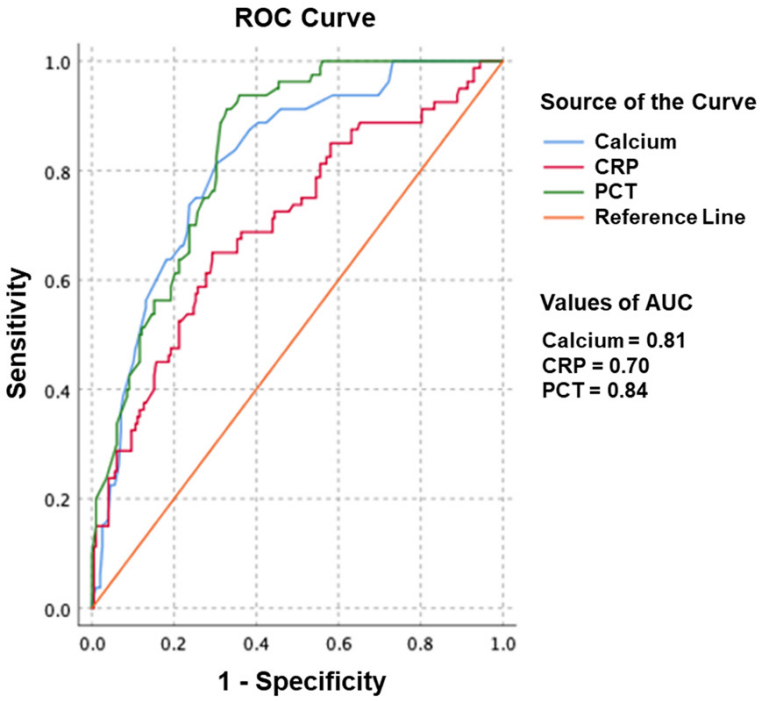

Figure 2. Values of biochemical indicators for predicting SAP in acute biliary pancreatitis. Note: ROC: receiver operating characteristics; AUC: area under the curve; CRP: C reactive protein; PCT: procalcitonin.

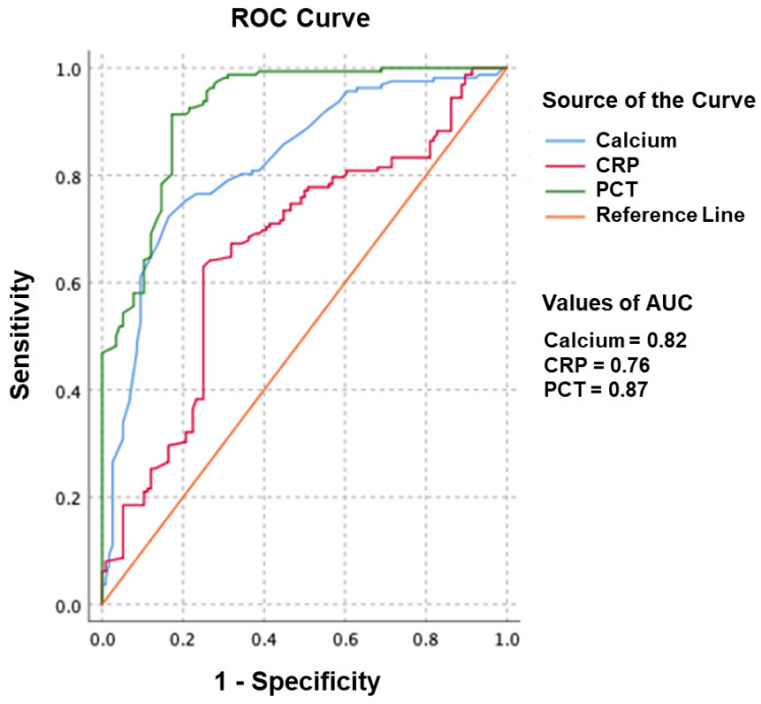

Figure 3. Values of biochemical indicators for predicting organ failure in acute biliary pancreatitis. Note: ROC: receiver operating characteristics; AUC: area under the curve; CRP: C reactive protein; PCT: procalcitonin.

groups was determined according to the modified Marshall score [1].

Assessments

Acute Physiology and Chronic Health Evaluation (APACHE) II, Bedside Index of Severity in Acute Pancreatitis (BISAP), Ranson, Japanese Severity Score (JSS), Pancreatitis Outcome Prediction (POP), Systemic Inflammatory Response Syndrome (SIRS), and Computed Tomography Severity Index (CTSI) scores were used to evaluate the severity of ABP.

Statistical analysis

SPSS 22.0 software was used for statistical analysis. Continuous data with a normal distribution were expressed as mean ± standard deviation (SD). Categorical data were expressed as numbers (percentages). One-way ANOVA analysis was used to compare the data among groups. The predictive value was calculated by the ROC curve, and the AUC, as well as the optimal threshold, sensitivity, and specificity for prediction of SAP and organ failure by each biochemical index and scoring system. Medcalc software 10.2 was used to compare AUCs among different biochemical indexes and scoring systems by *z*-test. *P*-value < 0.05 was considered significant.

Results

General characteristics of ABP patients

A total of 278 patients were included in the study, including 86 patients with MAP, 112 patients with MSAP, and 80

Table 6. Comparisons of different scoring systems in patients with acute biliary pancreatitis

	MAP (n = 86)	MSAP (n = 112)	SAP (n = 80)	*P* value
APACHE II	4.90 ± 1.56	8.30 ± 1.68	10.39 ± 1.97	*P* < 0.001
BISAP	1.27 ± 0.58	2.61 ± 0.63	3.25 ± 0.74	*P* < 0.001
CTSI	1.01 ± 0.71	3.73 ± 1.07	4.11 ± 0.71	*P* < 0.001
Ranson	1.57 ± 0.73	2.85 ± 1.08	3.21 ± 0.81	*P* < 0.001
JSS	0.99 ± 0.87	3.04 ± 1.13	3.98 ± 1.10	*P* < 0.001
POP	4.97 ± 1.91	10.22 ± 1.90	11.26 ± 2.79	*P* < 0.001
SIRS	0.66 ± 0.64	1.78 ± 0.99	2.54 ± 0.79	*P* < 0.001

Note: MAP: mild acute pancreatitis; MSAP: moderately severe acute pancreatitis; SAP: severe acute pancreatitis; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

Table 7. Value of different scoring systems for predicting the severity of acute biliary pancreatitis

	AUC	Sensitivity	Specificity	95% *CI*	Optimal threshold value	*P* value
APACHE II	0.87	0.86	0.74	0.84-0.92	9	*P* < 0.001
BISAP	0.83	0.86	0.65	0.78-0.88	3	*P* < 0.001
CTSI	0.79	0.87	0.63	0.73-0.84	4	*P* < 0.001
JSS	0.82	0.75	0.77	0.78-0.88	4	*P* < 0.001
Ranson	0.73	0.79	0.63	0.68-0.79	3	*P* < 0.001
POP	0.76	0.76	0.63	0.71-0.82	10	*P* < 0.001
SIRS	0.81	0.88	0.63	0.76-0.86	2	*P* < 0.001

Note: AUC: area under the curve; CI: Confidence Interval; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

Table 8. Value of different scoring criteria for predicting organ failure in acute biliary pancreatitis

	AUC	Sensitivity	Specificity	95% *CI*	Optimal threshold value	*P* value
APACHE II	0.87	0.74	0.80	0.82-0.91	8	*P* < 0.001
BISAP	0.85	0.74	0.84	0.80-0.89	3	*P* < 0.001
CTSI	0.79	0.89	0.73	0.73-0.86	3	*P* < 0.001
JSS	0.84	0.77	0.78	0.79-0.89	3	*P* < 0.001
Ranson	0.76	0.64	0.72	0.70-0.82	3	*P* < 0.001
POP	0.80	0.84	0.71	0.74-0.86	9	*P* < 0.001
SIRS	0.82	0.77	0.82	0.77-0.87	2	*P* < 0.001

Note: AUC: area under the curve; CI: Confidence Interval; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

patients with SAP. The percentage of patients over 60 in the SAP group was significantly higher than that in the MAP group and MSAP group (*P* < 0.001) (**Table 1**).

Comparison of biochemical indexes in ABP patients

Serum calcium level in the SAP group was significantly lower than that in the MAP and MSAP groups (*P* < 0.001), while CRP and PCT in the SAP group were significantly higher than those in MAP and MSAP groups (*P* < 0.001). There were no significant differences in ALT, AST, or LPS among the three groups (*P* > 0.05), as shown in **Table 2**.

The value of biochemical indicators for predicting SAP

ROC curve analysis showed that CRP, calcium and PCT had statistical significance in predicting acute severe biliary pancreatitis (all *P* < 0.001). Among these, the AUC value predicted by PCT (0.84) was the largest (**Tables 3**, **5**; **Figure 2**).

Value of biochemical indicators for predicting organ failure

Of the 278 ABP patients, 162 had organ failure. ROC curve analysis showed that CRP, calcium, and PCT had significance for predicting organ failure (all *P* < 0.001). The AUC value predicted by PCT (0.87) was the largest (**Tables 4**, **5**; **Figure 3**).

Comparison of different scoring systems in ABP patients

By comparing the scoring systems, it was found that all

Table 9. Comparison of AUCs among different scoring systems for predicting SAP and organ failure

ROC	SAP		Organ failure	
	Z value	*P* value	Z value	*P* value
APACHE II *vs* BISAP	1.48	*P* = 0.140	0.95	*P* = 0.342
APACHE II *vs* CTSI	3.37	*P* = 0.001	2.91	*P = 0.004*
APACHE II *vs* Ranson	4.94	*P* < 0.001	3.67	*P* < 0.001
APACHE II *vs* JSS	2.14	*P = 0.040*	1.33	*P* = 0.184
APACHE II *vs* POP	3.75	*P* < 0.001	2.61	*P = 0.009*
APACHE II *vs* SIRS	2.05	*P = 0.040*	1.70	*P* = 0.090
BISAP *vs* CTSI	1.49	*P* = 0.137	2.07	*P = 0.038*
BISAP *vs* Ranson	2.82	*P = 0.005*	2.82	*P = 0.005*
BISAP *vs* JSS	0.20	*P* = 0.845	0.34	*P* = 0.735
BISAP *vs* POP	2.41	*P = 0.016*	1.99	*P = 0.047*
BISAP *vs* SIRS	0.75	*P* = 0.451	0.86	*P* = 0.388
CTSI *vs* Ranson	1.50	*P* = 0.125	1.15	*P* = 0.249
CTSI *vs* JSS	-1.41	*P* = 0.159	-1.67	*P* = 0.095
CTSI *vs* POP	0.69	*P* = 0.492	-0.34	*P* = 0.734
CTSI *vs* SIRS	-0.80	*P* = 0.424	-0.76	*P* = 0.449
Ranson *vs* JSS	-2.72	*P = 0.007*	-2.26	*P* = 0.024
Ranson *vs* POP	-0.84	*P* = 0.403	-1.31	*P* = 0.191
Ranson *vs* SIRS	-2.10	*P = 0.036*	-1.65	*P* = 0.099
JSS *vs* POP	2.03	*P = 0.043*	1.48	*P* = 0.140
JSS *vs* SIRS	0.48	*P* = 0.630	0.72	*P* = 0.470
Pop *vs* SIRS	-1.48	*P* = 0.139	-0.57	*P* = 0.571

Note: ROC: receiver operating characteristics; SAP: severe acute pancreatitis; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

scores in the SAP group were higher than those of the MAP group and MSAP group (all $P < 0.001$) (**Table 6**).

Value of different scoring systems for predicting SAP

The ROC curve was used to further analyze the value of different scoring systems for predicting SAP. It was found that the AUC values could be ranked as APACHE II > BISAP > JSS > SIRS > CTSI > POP > Ranson (all $P < 0.001$) (**Tables 7**, **9**; **Figure 4**).

Value of different scoring systems for predicting organ failure

For the prediction of organ failure, AUC values of the scores were ranked as APACHE II > BISAP > JSS > SIRS > POP > CTSI > Ranson (all $P < 0.001$) (**Tables 8**, **9**; **Figure 5**).

Discussion

Acute pancreatitis is an inflammatory disease originating from the pancreas that may involve peripancreatic tissues and multiple organs [9]. Acute biliary pancreatitis (ABP) is the most common type of acute pancreatitis in China [2, 5]. Such patients often get biliary tract infection, resulting in a dangerous progression to multiple organ failure, and even death within the first week of the disease [2, 5]. However, in reality, about 44% of ABP patients cannot be identified in time [10]. In order to reverse the progression of the disease and improve the prognosis of patients, accurate assessment of ABP at the early stage of the disease is crucial.

Age (> 69 years old), BMI ≥ 30 kg/m^2 and alcohol consumption are independent risk factors for acute pancreatitis, and these patients are more likely to develop SAP [11, 12]. Our study found that the percentage of patients aged ≥ 60 in the SAP group was significantly higher than those of the MAP and MSAP groups, indicating that elderly patients with biliary pancreatitis were more likely to progress to SAP. However, BMI and drinking habits showed no statistical difference among MAP, MSAP, and SAP groups in our study, which probably was because our study mainly focused on the AP patients with cholelithiasis. However, it is inaccurate to evaluate the severity of ABP solely based on the patient's past history or clinical data. A combination of relevant biochemical and/or radiologic examinations is required to assist in the evaluation.

Besides general conditions, many biochemical indexes are changed in ABP. Whether such indexes can be used to monitor disease progression needs further study. For example, CRP is an acute phase inflammatory protein that is mainly secreted following inflammatory stimulation and has been widely used to monitor the severity of AP for decades. However, several studies have found a limitation of CRP in prediction of infected necrosis and organ failure [13, 14]. Subsequently, Rau *et al*. noticed that

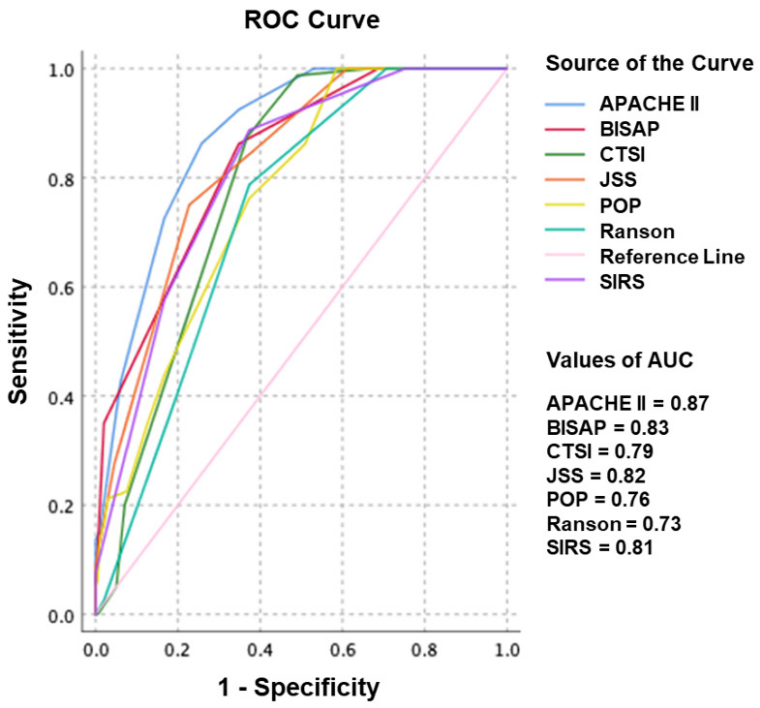

Figure 4. Values of different scoring systems for predicting SAP in acute biliary pancreatitis. Note: ROC: receiver operating characteristics; AUC: area under the curve; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

PCT was highly correlated with the severity of AP [15]. A later study claimed that the sensitivity and specificity of PCT for the prediction of SAP were 72% and 86%, respectively [16]. However, a study also indicated that PCT has limited application value for early prediction of SAP [17].

As an important factor involved in the occurrence and development of pancreatic inflammation, serum calcium has received more attention in clinical application. In order to further explore and clarify the value of biochemical indicators such as CRP, PCT, and serum calcium for predicting the prognosis of ABP, we measured ALT, AST, serum calcium, CRP, LPS, and PCT levels in ABP patients. The results showed that CRP and PCT levels were positively associated with the severity of ABP, while serum calcium levels were negatively associated with severity. By comparing the AUC values of CRP, PCT, and serum calcium levels, it was found that PCT had the largest AUC for predicting SAP and organ failure. Based on the fact that PCT has a great advantage for reflecting the body's infection, and most ABP patients have concurrent biliary tract infection, the results of this study suggest that PCT has a high application value for predicting ABP severity and organ failure. PCT is superior to CRP and serum calcium.

Along with the continuous study of AP, multiple scoring systems have been proposed to evaluate AP severity and prognosis. These all use past medical history, clinical symptoms, laboratory tests, and imaging. Different scoring systems have their own advantages and disadvantages in view of the different contents included in these systems. For example, the first proposed Ranson score requires a secondary assessment within 48 hours, and the amount of alkali loss and fluid loss are not regularly evaluated in primary hospitals, which limits its application in the early stages of the disease [18]. The APACHE II score proposed later has the advantages of being more objective and can be evaluated daily, but it also has the disadvantages of numerous indices and complicated calculations [19]. In addition, some indices of these scoring systems are overlapped or interspersed with each other, namely, SIRS is included in BISAP. Therefore, if the scoring systems with representative significance and high predictive value can be selected from among the numerous scoring systems, the actual clinical workload can be greatly reduced and repeated labor can be avoided. In this study, we found that the AUC of the scores were: APACHE II > BISAP > JSS > SIRS for predicting severe ABP and organ failure. However, the APACHE II score and JSS score contain many items, and their accuracy depends on thorough laboratory or imaging examinations, thus their application in an emergency or early onset of the disease is limited. In contrast, the BISAP score and SIRS score are characterized by fewer scoring items and faster calculation. In particular, the SIRS score only requires patients' vital signs and white blood cell count,

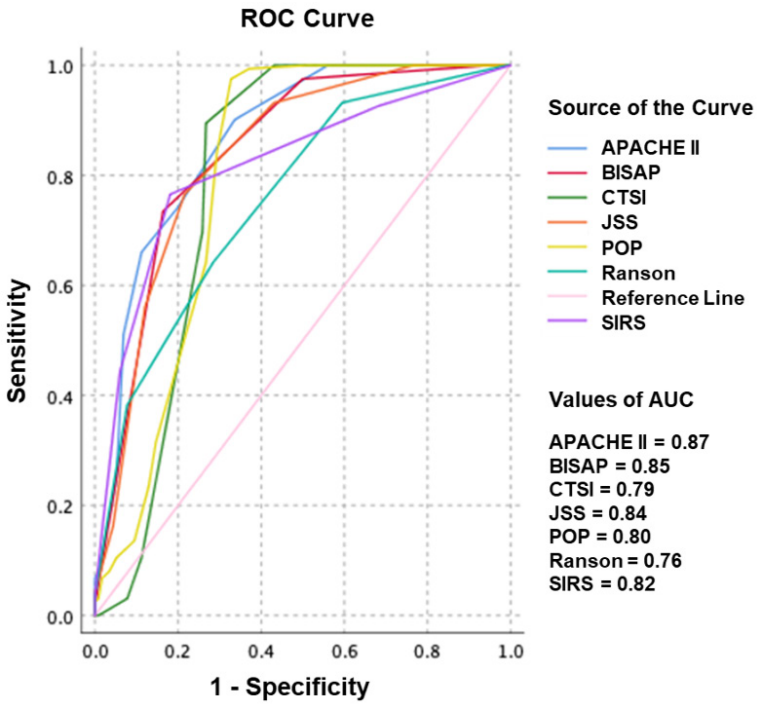

Figure 5. Values of different scoring systems for predicting organ failure in acute biliary pancreatitis. Note: ROC: receiver operating characteristics; AUC: area under the curve; APACHE II: Acute Physiology and Chronic Health Evaluation II; BISAP: Bedside Index of Severity in Acute Pancreatitis; CTSI: Computed Tomography Severity Index; JSS: Japanese severity score; POP: Pancreatitis Outcome Prediction; SIRS: systemic inflammatory response syndrome.

which greatly facilitates emergency or early disease assessment and intervention.

There were several deficiencies in this study, such as: a. the sample size in this study is not large enough; b. this study was a retrospective analysis, and prospective analysis must be further conducted to clarify the value of different scoring systems and serum markers for prediction of acute biliary pancreatitis; c. with the rapid development of artificial intelligence, AI could be introduced to screen and verify the accuracy of a prediction system.

Conclusions

ABP patients in the study aged more than 60 years were more likely to progress to SAP. In individual laboratory tests, PCT had a high value in predicting SAP and organ failure. Among the different scoring criteria, BISAP score and SIRS score were most conducive to early assessment and intervention of the disease; while APACHE II score and JSS score were more suitable for monitoring and follow-up.

Disclosure of conflict of interest

None.

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