

Evaluation of serum procalcitonin levels and changes in hematocrit in prediction of severity of acute pancreatitis

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ABSTRACT

Background: Mortality in severe acute pancreatitis (AP) is 15-30 % while it is only 0-1 % in case of mild AP. Predicting severity of pancreatitis early in the course of disease is critical to maximize therapy and to prevent and minimize organ dysfunction and complications. This study is aimed to explore if serum procalcitonin level and hematocrit values could be used for prognosticating the severity of AP.

Method: The study was a prospective observational study conducted in a tertiary care hospital of North India on 53 consecutive patients admitted with acute pancreatitis. Serum procalcitonin was estimated on Day 1, 3 and 5 and hematocrit levels were noted at the time 0,24,48,72,96 hours and correlated with the severity of acute pancreatitis and outcomes like local and systemic complications and length of hospital stay.

Results: Procalcitonin had sensitivity of 92.9 % and specificity of 100% while hematocrit had 100% sensitivity and specificity of 91.9% for prediction of severity of acute pancreatitis. Procalcitonin value cut-off >0.75 ng/ml had a diagnostic accuracy of 98.10% and hematocrit level cut off of >45.6% had a diagnostic accuracy of 94.10% for correctly predicting the severity of acute pancreatitis.

Conclusion: Procalcitonin and hematocrit values at the time of admission are two simple and convenient biomarkers that can be used to predict severity of acute pancreatitis because of their easy availability, low cost and good diagnostic accuracy as compared with other laboratory parameters and complicated scoring systems.

KEYWORDS: acute pancreatitis, severity, procalcitonin, hematocrit

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INTRODUCTION

Acute pancreatitis (AP) is defined as “an inflammatory process of pancreas with possible peripancreatic tissue involvement and multi organ dysfunction syndrome with increasing mortality rate”^[1]. Severe AP is responsible for about 25 % of all cases, and is associated with one or more of the following: persistent organ failure and other local or systemic complications. Mortality in severe pancreatitis is 15-30 % while it is only 0-1 % in case of mild AP.^[2] Predicting severity of pancreatitis early in the course of disease is critical to maximize therapy and to prevent and minimize organ dysfunction and complications.

Currently available scoring systems such as acute physiology and chronic health evaluation-II (APACHE-II) score, computed tomography severity index (CTSI) and Ranson’s criteria are tedious and cumbersome and rarely used outside of intensive care settings. Besides, these scoring systems require a relatively extended period (more than 48 hours) to predict the severity and this may miss a potentially therapeutic window. Various other markers such as IL 6, procalcitonin and IL 8 are costly and not readily available. Hence it is the need of the hour to find a cost effective and routinely available marker which could predict severity in AP.

There is an emergent need for cheap, easily available and early, predictive markers for severe AP. This study is aimed to explore if serum procalcitonin level and hematocrit values (at admission and follow-up thereafter) could be used for prognosticating the

severity of AP.

MATERIAL AND METHODS

The study was a prospective observational study conducted in a tertiary care hospital of North India. Fifty three consecutive patients admitted with AP were included in the study. AP was diagnosed on the basis of history of pain in abdomen radiating to back and relieved on bending forward associated with tenderness and guarding in upper abdomen plus either of the following two: (1) Rise in serum amylase (N -30-110 U/L) and lipase (N-23-300 U/L) value more than 3 times the normal value (2) Radiological findings suggestive of acute pancreatitis.

Patients excluded were those with recurrent AP, chronic pancreatitis and those patients having other co-existing conditions which can raise procalcitonin levels (e.g. other sources of sepsis, major trauma, major surgical intervention, severe burns, prolonged or severe cardiogenic shock, prolonged severe organ perfusion abnormalities, small cell lung cancer or medullary C cell carcinoma of the thyroid).

Institutional Ethics Clearance and informed consent were taken from all patients. Thereafter, a detailed history and clinical examination were done. Relevant biochemical and radiological investigations were done to confirm diagnosis of AP. Severity of the disease was classified as mild, moderately severe and severe according to Revised Atlanta criteria. Organ dysfunction was assessed by modified Marshall scoring at 48 hours and severity estimated as per the revised Atlanta classification criteria.^[1]

Serum procalcitonin was estimated on Day 1, 3 and 5. Whole blood samples were collected and kept at 2-8 °C. After all samples from 53 patients were obtained, they were centrifuged for 20 minutes and the assay was carried out on the supernatant by Human PCT(Procalcitonin) ELISA Kit. This kit was based on sandwich enzyme-linked immune-sorbent assay technology.

Hematocrit levels were noted at the time 0, 24, 48, 72, 96 hours. by analysis on XN-1500 Automated Haematology Analyser. Values of hematocrit and serum procalcitonin were correlated with the severity of AP and outcomes like local and systemic complications and length of hospital stay. Patients were divided into 3 groups based on 24 hours hematocrit change: Low (<10% change), Moderate (10-15% change), & High (>15% change).^[3]

STATISTICAL ANALYSIS

Patient details and investigations were collected on case record sheets and entered in Microsoft Excel Version 2017 (Microsoft Corporation, New York, USA). Results were analysed and statistically evaluated using Microsoft Excel and Statistical Package for Social Sciences (SPSS statistics for Windows, Version 22, Armonk, NY: IBM Corp).

Normality of each variable was assessed by using the Kolmogorov-Smirnov test. Quantitative data is expressed by mean and standard deviation or median with interquartile range and depends on normal distribution. Difference between two groups was tested by Student T test or Mann Whitney U test. Qualitative data was expressed in percentage and difference between the proportions was tested by Chi square test or Fisher's exact test.

Receiver operating characteristics (ROC) analysis was calculated and the area under the curve, the sensitivity, and the specificity was also calculated to analyse the diagnostic accuracy of procalcitonin levels and changes in hematocrit values correlating with outcomes like length of hospital stay, complications and mortality. Sensitivity, specificity, positive predictive value and negative predictive value of procalcitonin levels and changes in hematocrit values was also calculated. Univariate logistic regression was used to calculate odds ratio with 95% CI. 'P' value of less than or equal to 0.05 was considered statistically significant.

RESULT

Fifty-three patients of ≥ 18 years of age admitted to a tertiary care hospital with a diagnosis of AP were included in the study. Detailed history and clinical examination were done. Severity of the disease was classified as mild, moderately severe and severe according to Revised Atlanta criteria. Demographic and clinical characteristics of the patients were as in **Table 1**.

Table 1: Demographic and clinical characteristics of the study population

		Frequency	Percentage(%)
Gender	Male	44	83.02
	Female	9	16.98
Age	<30	15	28.0
	31-40	21	40.0
	41-50	10	19.0
	51-60	6	11.0
	>60	1	2.0
Symptoms	Pain abdomen	53	100
	Nausea/Vomiting	46	86.7
	Abdominal distention	14	26.42
	Fever	9	16.98
	Jaundice	10	18.9

Etiology	Gallstone	39	73.6
	Alcohol related	9	17.0
	Others/Idiopathic	5	9.4
Severity of acute pancreatitis	Mild	39	73.6
	Moderately severe	8	15.1
	Severe acute pancreatitis	6	11.3
Local complications	Nil	42	79.2
	Pancreatic necrosis	8	15.1
	Acute peripancreatic fluid collection	3	5.7
Systemic complications	Nil	39	73.6
	Persistent organ dysfunction	6	11.3
	Transient renal failure	4	7.5
	Transient cardiovascular failure	2	3.8
	Transient respiratory failure	2	3.8
Mortality	No	50	94.3
	Yes	3	5.7
Length of hospital stay	Less than or equal to 5 days	39	73.58
	Between 6-14 days	13	24.53
	More than or equal to 15 days	1	1.89

Procalcitonin and hematocrit values on admission and thereafter on follow-up showed a strong association with severity of AP (p value <0.001) is as shown in **Table 2 (Figure 1 and Figure 2)**. Procalcitonin value cut-off >0.75 ng/ml and hematocrit level cut off of >45.6% had a strong correlation with severity of AP, p value <0.001 (**Table 3**). **Table 4** showed the association of change in hematocrit values with the outcomes of the patients.

Table 2: Association of procalcitonin and hematocrit values with severity of acute pancreatitis

	Mild(n=39)	Moderately severe pancreatitis (n=8)	Severe acute pancreatitis (n=6)	P value
Procalcitonin Median(Q1-Q3)				
At admission (Day 1)	0.5(0.4-0.5)	1.05(0.8-1.45)	1.9(1.55-2.875)	<0.001
Day 3	0.3(0.2-0.3)	0.75(0.525-0.9)	1.6(0.875-2.525)	<0.001
Day 5	0.1(0.1-0.2)	0.3(0.2-0.5)	1.05(0.6-2.175)	<0.001
Hematocrit Median (Q1-Q3)				
At admission	38.4(34.8-41.5)	48.4(46.95-52.15)	52.7(51.2-52.8)	<0.001
At 24 hrs	36.4(33.6-38.8)	44.7(44- 47.15)	50.95(49.8-52.4)	<0.001
At 48 hrs	35.8(32.8-37.4)	42.7(40.85-45.25)	49.4(49.8-51.65)	<0.001
At 72 hrs	34.8(32.2-36.6)	40.6(39.05-43.3)	48.6(49.2-51.2)	<0.001

At 96 hrs	34.5(32-36.4)	39.7(38-42.15)	47.6(48.6-49.6)	<0.001
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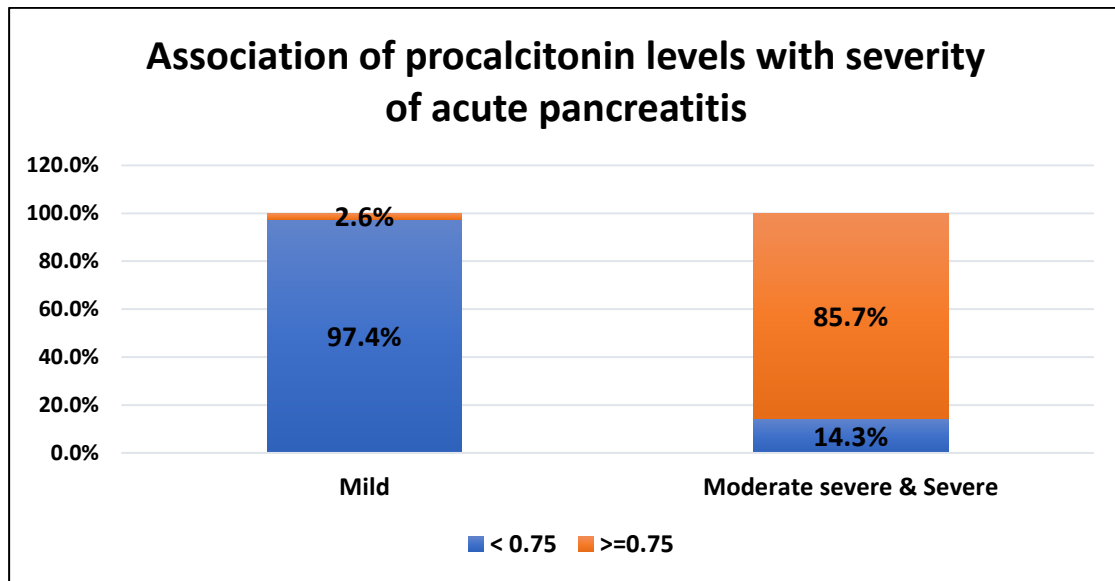


Figure 1: Association of procalcitonin levels with severity of acute pancreatitis.

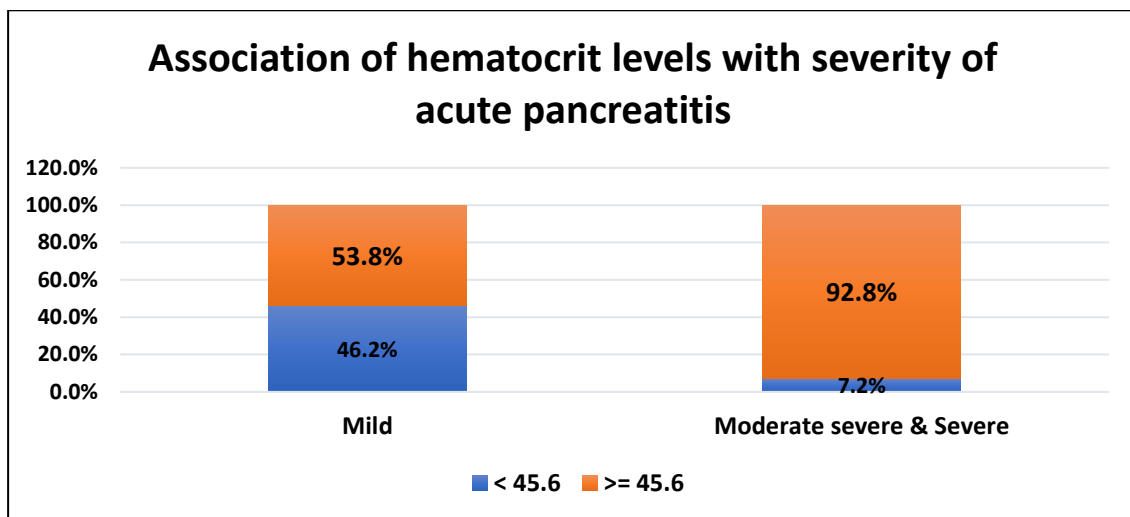


Figure 2:-Association of hematocrit levels with severity of acute pancreatitis.

Table 3: Correlation of procalcitonin levels and hematocrit levels with severity of acute pancreatitis

Table 5: Correlation of procalcitonin levels and hematocrit levels with severity of acute pancreatitis					
	Severity of AP				p value
	Mild		Moderate Severe & Severe		
	Frequency	%	Frequency	%	
Procalcitonin Values					
<0.75	38	97.4%	2	14.3%	<0.001*
>=0.75	1	2.6%	12	85.7%	
Total	39	100%	14	100%	
Hematocrit Values					

< 45.6	18	46.2%	1	7.1%	<0.001 *
>= 45.6	21	53.8%	13	92.9%	
Total	39	100%	14	100%	

* Fisher's exact test

Table 4: Change in hematocrit with outcome of patients in AP

Variables		Percentage Change in hematocrit in 48 hours			P value
		Low (≤10% change)	Moderate (10-15% change)	High (>15% change)	
Severity	Mild(n=39)	17 (32.1%)	22 (41.5%)	0	<0.001
	Moderately severe pancreatitis (n=8)	2 (3.8%)	0	6 (11.3%)	
	Severe acute pancreatitis (n=6)	5 (9.4%)	0	1 (1.9%)	
Complications	No complications	17 (32.1%)	21 (39.6%)	1(1.9%)	<0.001
	With complications	7(13.2%)	1 (1.9%)	6 (11.3%)	
Length of hospital stay	Less than 5 days	17 (32.1%)	21 (39.6%)	1 (1.9%)	<0.001
	5-15 days	6 (11.3%)	1 (1.9%)	6 (11.3%)	
	More than 15 days	1 (1.9%)	0	0	
Mortality	No	21(39.6%)	22 (41.5%)	7 (13.2%)	0.329
	Yes	3(5.7%)	0	0	

Receiver operating characteristic (ROC) curve of procalcitonin and hematocrit levels for predicting severity of AP is as shown in **Figure 3 & 4**. Area under the ROC curve (AUC) at 95% CI, sensitivity, specificity and diagnostic accuracy of procalcitonin and hematocrit levels is as shown in **Table 5**.

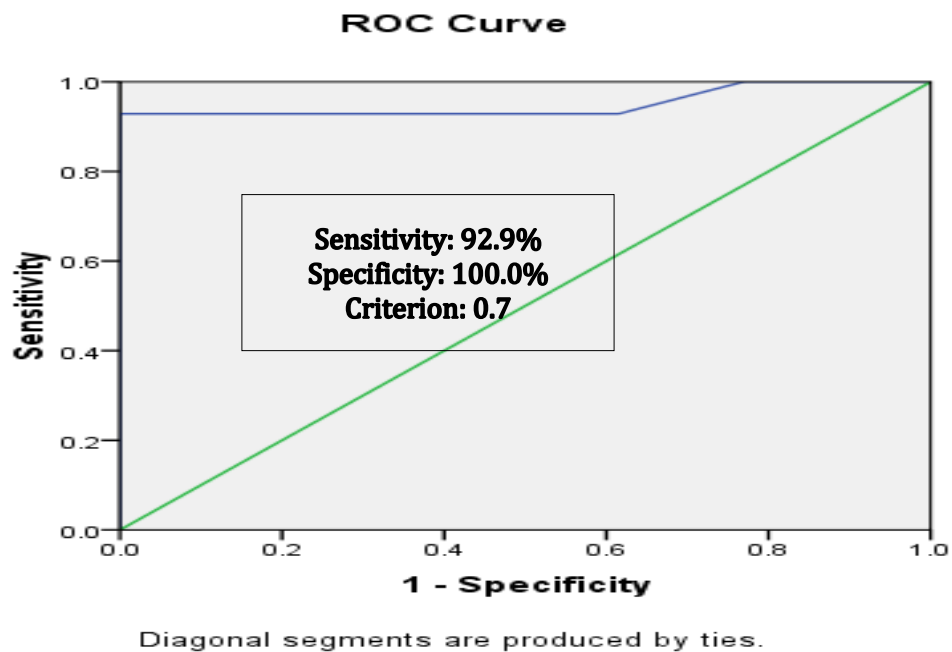


Figure 3:-Receiver operating characteristic curve of procalcitonin level for predicting severity of acute pancreatitis.

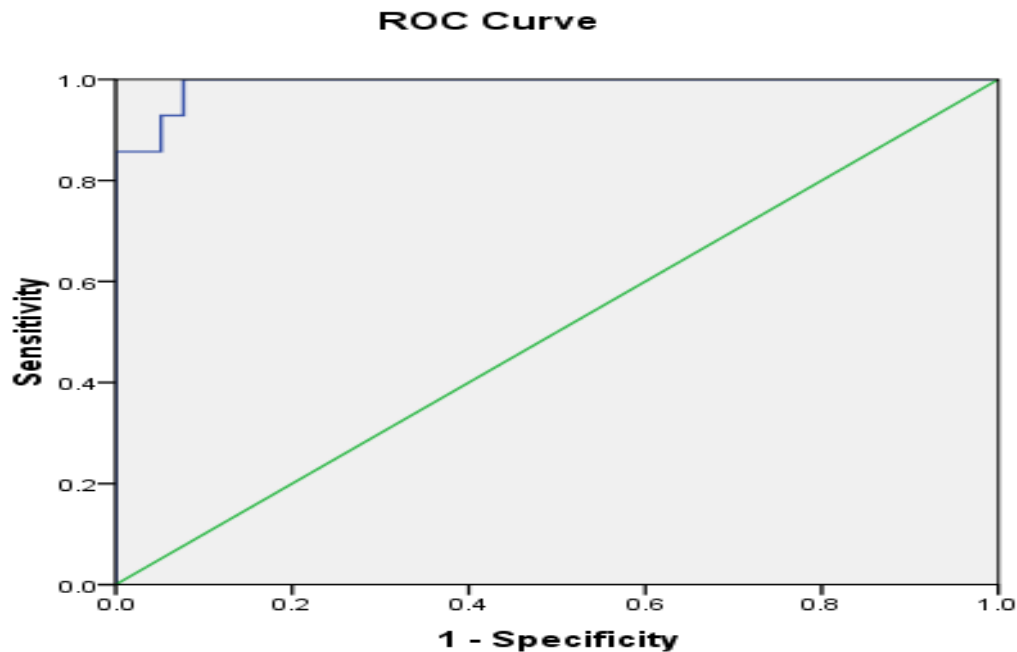


Figure 4:-Receiver operating characteristic curve of hematocrit value for predicting severity of acute pancreatitis.

The discriminatory power of procalcitonin (AUC 0.951; 95% CI: 0.862-1.000) and discriminatory power of hematocrit (AUC 0.964; 95% CI: 0.921-1.000) was excellent. Procalcitonin value cut-off >0.75 ng/ml had a diagnostic accuracy of 98.10% and hematocrit level cut off >45.6% had a diagnostic accuracy of 94.10% for correctly predicting the severity of AP. Procalcitonin levels had a sensitivity of 92.9% and 100.0% specificity while hematocrit levels had a sensitivity of 100.0% and specificity of 91.9%.

Table 5: Receiver operating characteristic curve of procalcitonin and hematocrit levels for predicting severity of acute pancreatitis.

Severity of acute pancreatitis	Procalcitonin	Hematocrit
Area under the ROC curve (AUC)	0.951	0.964
Standard error	0.046	0.022
Confidence interval	0.862-1.000	0.921-1.000
P value	<0.001	<0.001
Cut off	0.75	45.6
Sensitivity (95% CI)	92.9%	100.00%
Specificity(95% CI)	100.0%	91.90%
PPV(95% CI)	100.0%	82.4.0%
NPV(95% CI)	97.50%	100.00%
Diagnostic accuracy	98.10%	94.10%

DISCUSSION

In the present study, majority of the patients (83.02%) were males and only 16.98% were females. Similar results were seen in studies by Kashid et al ^[4] where males were 70.91% and females were 29.09%, Choudhuri et al ^[5] had 66.6% males and 33.4% females and Pupelis et al ^[6] had 73.7% males and 26.3% females. The mean age of patients in our study was 38.4 years and is comparable to the study by Kashid A et al ^[4] where the mean age was 35 years. Choudhuri et al ^[5] found it to be 44.8 years and Buchler et al ^[7] found it to be 55.1 years.

In the present study, gallstones related AP (73.6%) was the most common cause of AP followed by alcohol intake which was seen in 17% patients. This was comparable to the study by Sand J ^[8] at Finland. In other studies also, gall stone was the main etiological factor like Buchler et al ^[7] found it in 45% patients and Kashid A et al ^[4] found it in 36.4% patients. The percentage

of idiopathic cases were comparable.

In the present study, abdominal pain was the predominant presenting complaint seen in 100 % of the study population, followed by nausea/vomiting in 87% of cases while the least common presenting complaints were fever (17%) and jaundice in 19% of patients. The clinical features in the present study were comparable to the study by Kashid A et al ^[4] who also found pain abdomen to be the commonest symptom (92.73%) cases followed by nausea/vomiting in 60% cases. He also found fever in 20% cases and jaundice in 7.27% which were similar to our results.

In our study, 39 patients (73.6%) had mild AP, 8(15.1%) had moderately severe and 6 patients (11.3%) had severe AP. However, other studies had a higher proportion of severe disease like Kashid et al ^[4] had 47.27% severe disease, Choudhuri et al ^[5] had 52.3% severe cases and Buchler ^[7] had 42% cases of severe pancreatitis.

The PCT level is considered a valuable predictive factor for severity of AP and also a predictor of risk of developing infective pancreatic necrosis. ^[9-11] Rau et al ^[12] found that best PCT cut-off level for predicting infected necrosis (IN) of pancreas or persisting pancreatic sepsis was obtained at \geq or =1.8 ng/ml. Woo SM et al ^[13] proposed PCT level of 1.77 ng/ml to be the best cut-off value for predicting severe AP. Chen et al ^[14] also found a cut-off PCT level is 1.39 ng/mL to predict severe cases of AP. Mofidi et al ^[15] also concluded that values of procalcitonin concentration of 0.5 ng / ml and more are pathological. This value can be used to predict the severity of AP and the development of infected pancreatic necrosis in the course of the disease. Kasian VV ^[16] suggested that elevated procalcitonin levels (> 0.5 ng / ml) at the time of hospitalization can predict the severity of AP peritonitis and help change the treatment tactics accordingly to prevent the risk of purulent-septic complications. In our study, we found cut-off values > 0.75 ng/ml to predict moderately severe and severe AP.

In the present study, mean hematocrit at the time of admission was 38.42 % in mild pancreatitis, 49.4 % in moderate and 52.73 % in severe AP. Similar results were seen by Meena SK et al ^[17] the mean hematocrit of the patients at the time of admission was 36.62% in mild, 42.31% in moderate, 47.67% in severe AP. Brown et al also had similar results where haematocrit at admission $\geq 44\%$ was associated with severe pancreatitis and the patients developed necrotizing pancreatitis and organ failure. ^[18, 19]

It was also seen that moderate change in hematocrit values (between 10-15%) in the first 48 hours was associated with minimum complication rate (1.9% or 1 out of 53 cases). Hematocrit change less than 10% or more than 15% in the first 48 hours was associated with 13.2% (7 cases) and 11.3%(6 cases) complication rate respectively (ref Table 4). Other studies also had similar findings. Brown et al also concluded that failure to decrease the HCT within the first 24 hours of admission proved to be a significant risk factor for developing pancreatic necrosis and organ failure. ^[18, 19]

Baillargeon et al ^[20] also indicated that the maximum level of the HCT within the first 48 hours of admission could be reliably used to identify the patients who might eventually develop infection of the final pancreatic necrosis. They concluded that hemoconcentration with an admission hematocrit \geq or = 47% or failure of admission hematocrit to decrease at approximately 24 h were strong risk factors for the development of pancreatic necrosis.

Woo et al ^[13] in his study found that the range of admission duration of patients were 4 to 41 days. However, serum PCT did not show definite relation to the length of hospital stay. It had effective p-value ($p=0.021$) but only with possible association due to low R square level ($r^2=0.127$). However, in our study procalcitonin levels had a significant correlation with length of hospital stay ($p<0.001$). Rau et al ^[12] also found length of hospital stay was 8 days (1-129 days) which correlated well with the PCT levels. Dias et al ^[21] found a strong correlation between plasma PCT (by Pearson's coefficient value of 0.892, p value <0.001) at admission and total hospital stay.

In the present study, majority (79.2%) of patients did not have any local complications. Pancreatic necrosis was present in 15.1% of patients and peri-pancreatic collection in only 5.7% patients. However, Choudhuri et al ^[5] found pancreatic necrosis in 40.5% and Buchler ^[7] et al found it in 42.5%. Majority (73.6%) of patients did not have any systemic complications. Persistent organ failure was seen only in 11.3% of our patients. However, higher percentage was found in other studies like Kashid A et al ^[4] found persistent organ failure in 29% cases, Choudhuri et al ^[5] found in 40.5% cases and Buchler ^[7] found it in 36.28% cases. This maybe because most patients in our study had mild disease.

In the present study, we found hematocrit of 45.6% to have a high prediction of severe AP. Gray et al ^[22] in 1965 reported that hemoconcentration at admission was a poor prognostic sign in patients with AP, but Talamini et al ^[23] did not find significant differences of Hct levels obtained within 24 h of admission in survivors and non-survivors of AP. On the other hand, the classic study of Ranson ^[24] found that a fall in hematocrit level by greater than 10% after 48 h of therapy had a better outcome and decreased mortality.

In the present study, procalcitonin had sensitivity of 92.9 % and specificity of 100% while hematocrit had 100% sensitivity and specificity of 91.9% for prediction of severity of AP. The discriminatory power of both procalcitonin (AUC 0.951; 95% CI: 0.862-1.000) and that of hematocrit (AUC 0.964; 95% CI: 0.921-1.000) was excellent. Procalcitonin value cut-off >0.75 ng/ml had a diagnostic accuracy of 98.10% and hematocrit level cut off of $>45.6\%$ had a diagnostic accuracy of 94.10% for correctly predicting the severity of AP. Rau et al ^[12] suggested that monitoring of procalcitonin allows early and reliable assessment of

clinically relevant pancreatic infections and overall prognosis in AP. In their study, ROC curve analysis showed a PCT level of ≥ 3.500 ng/ml was 7% sensitive and 88% specific for the prediction of development of infected necrosis with multiorgan dysfunction syndrome (MODS) or non-survival ($p < 0.01$).

In study by Kumar et al, ^[25] receiver operating characteristic curve showed the area under curve of serum procalcitonin was higher (area under curve: 0.887, Confidence interval: 0.825-0.948) compared to computed tomography severity index scoring system, Ranson's score and C-reactive protein in predicting the severity of AP. The best cut-off value of serum procalcitonin to predict severe AP was 0.9 ng/ml with 92.6% sensitivity, 80.3% specificity. Dias et al ^[21] found that cut off for plasma PCT of >2 ng/mL was found to be 100 % sensitive and 100 % specific for predicting the progression to severe AP.

In the present study, hematocrit level cut off of $>45.6\%$ had a diagnostic accuracy of 94.10% for correctly predicting the severity of AP. In the study by Lankisch, ^[26] sensitivity and specificity of the hematocrit cut-off level of 43.0% for male and 39.6% for female patients to detect necrotizing pancreatitis were 74% and 45%, respectively. The positive predictive value was 24% and the negative predictive value 88%. They tried receiver operating characteristics (ROC) curve values for many cut-offs for hematocrit but these did not result in any ideal levels.

Koutroumpakis et al ^[27] found admission hematocrit $\geq 44\%$ to be the most accurate in predicting persistent organ failure (AUC: 0.67 and 0.71, respectively) and pancreatic necrosis (0.66 and 0.67, respectively). In a pooled analysis, admission hematocrit $\geq 44\%$ was associated with an odds ratio of 3.54 and 5.84 for persistent organ failure, and 3.11 and 4.07, respectively, for pancreatic necrosis. Bohara et al ^[28] found area under ROC curve for haematocrit at admission was 0.713 (P value 0.175, 95 % CI 0.536 - 0.889) and that for haematocrit at 24 hours of admission (figure 2) was 0.917 (P value 0.008, 95 % CI 0.813 – 1.00). Coordinates of ROC curve shows that cut-off value of 44 % is 100 % sensitive and 88.9 % specific in prediction of severity of pancreatitis for hematocrit at 24 hours of admission.

Remes-Troche ^[29] also analyzed the hematocrit at 24 h after admission. They constructed ROC curves that displayed cut- off values of Hct to define hemoconcentration at risk for severity in agreement with those previously reported by others. ^[27,28]

Limitations of our study include a relatively small sample size which may not be adequate to find cut-offs of procalcitonin and hematocrit values for predicting severity of AP. Also, ours being a tertiary care hospital, many of the cases were already treated at other centres before being referred to us which could have an impact on the admission levels of procalcitonin and hematocrit. A similar study with relatively large sample size and at multiple centres would be required to get more accurate cut-offs of procalcitonin and hematocrit for predicting severity of AP with a better diagnostic accuracy.

CONCLUSION

The study concluded that procalcitonin had sensitivity of 92.9 % and specificity of 100% while hematocrit had 100% sensitivity and specificity of 91.9% for prediction of severity of AP. The discriminatory power of both procalcitonin and that of hematocrit was excellent. Procalcitonin value cut-off >0.75 ng/ml had a diagnostic accuracy of 98.10% and hematocrit level cut off of $>45.6\%$ had a diagnostic accuracy of 94.10% for correctly predicting the severity of AP. Procalcitonin and hematocrit values at the time of admission are two simple and convenient biomarkers that can be used to predict severity of AP because of their easy availability, low cost and good diagnostic accuracy as compared with other laboratory parameters and complicated scoring systems.

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