

## Serum procalcitonin as a marker in predicting the severity of acute pancreatitis

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**Abstract**

**Introduction:** Acute pancreatitis is the acute inflammation of pancreatic parenchyma which varies from a mild form to severe necrotizing disease. Most of the episodes are mild and self limiting which subside spontaneously within a few days. In contrast, an ongoing inflammatory process will lead to severe acute pancreatitis in about 15-20% of cases<sup>1</sup>. Severe acute pancreatitis has high morbidity and mortality because of systemic inflammatory changes causing SIRS which will lead to multi-organ dysfunction and death. **Materials and Methods:** A Cross-sectional study was conducted in Inpatients in the General Surgery department, Justice K.S. Hegde Charitable Hospital, of K.S. Hegde Medical Academy, a unit of Nitte (Deemed to be University), Deralakatte, Mangalore. Using Epi info software version 3.01, the minimum sample size required for the study was calculated. Patients diagnosed with AP are categorized into mild, moderately severe, and severe according to Revised Atlanta Criteria. **Results:** Among 94 subjects mild, moderately severe, severe AP was observed in 76,11,7 patients respectively, among them patients aged between 31-40 had the highest incidence in all three groups of AP. We observed that of 94 subjects, 43(42.7%) subjects had hospital stay between 5-10 days, and 20 (20.7%) subjects,31(33.7%) subjects had a hospital stay of <5days,and >10days respectively with a p-value of 0.001. **Conclusion:** Our study demonstrates that serum PCT could not significantly predict the severity of Acute Pancreatitis. We determined serum PCT levels in predicting the severity of AP. There was a male preponderance in the study group (88%). Most of the study subjects were in the 31-40 years group. The majority of the patients had mild AP (76 patients). The majority of the patients had Alcohol-induced AP (58.7%). No statistical significance was found between the serum PCT levels and severity of AP, a p value of 0.218.

**Key Words:** Acute pancreatitis, severe necrotizing disease, multi-organ dysfunction, death.

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**Introduction**

Acute pancreatitis is the acute inflammation of pancreatic parenchyma which varies from a mild form to severe necrotizing disease. Most of the episodes are mild and self-limiting which subside spontaneously within a few days. In contrast, an ongoing inflammatory process will lead to severe acute pancreatitis in about 15-20% of cases<sup>[1]</sup>. Severe acute pancreatitis has high morbidity and mortality because of systemic inflammatory changes causing SIRS which will lead to multi-organ dysfunction and death<sup>[2]</sup>. So early diagnosis of acute pancreatitis is very important to initiate early management and prevention of complications. Currently, the diagnosis of acute pancreatitis is based on typical clinical features (epigastric pain, nausea, vomiting) and measurement of pancreatic enzyme levels in serum (serum amylase or lipase). If the diagnosis is doubtful, patients had to undergo expensive tests like Contrast-Enhanced CT scan which is the gold standard for diagnosis<sup>[3]</sup>.

Patients with sterile necrosis of the pancreas are successfully managed conservatively, patients who had combination of infection of the pancreas with sepsis require intervention (either surgical or radiological)<sup>[4]</sup>. Because of this reason, in recent times there is a growing interest in finding a significant tool for the diagnosis of infective pancreas and sepsis.

Apart from many scoring systems, several biochemical variables are also studied in patients of acute pancreatitis and they have proven to be good predictors of severity of the disease<sup>[4]</sup>. These biochemical variables are of less importance in differentiating infections of the pancreas and associated sepsis from SIRS in the absence of infections. At present, FNAC with radiological guidance is the investigation of choice for the diagnosing pancreatic infections<sup>[4]</sup>. Guided FNAC is expensive and not easily available requiring technical equipment and personal expertise in handling the instrument. A feasible and inexpensive biochemical test to identify patients who might develop pancreatic infections would be helpful<sup>[5]</sup>.

PCT is an inactive precursor of calcitonin in which is the biologically active hormone. Assicot, et al<sup>[5]</sup>, in 1993 noticed high PCT values in septic patients, thus PCT correlates with the inflammatory response of the host to infections. In recent studies PCT increase has shown to predict formation of infected necrosis in patients with acute pancreatitis accurately<sup>[6]</sup>. In some studies, it was found that PCT values within 24 hours of hospital admission was a good predictor of severity of AP and organ failure associated with the AP<sup>[7]</sup>. In some studies estimation of PCT in patients with AP has shown opposite results<sup>[8]</sup>. So usefulness of PCT for predicting the severity of AP is still controversial. Hence this study is conducted to predict the severity of AP based on the serum PCT levels.

**Aims and objectives****Aim**

- Estimation of Serum Procalcitonin in Acute Pancreatitis.

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**Objectives**

- To assess the Serum Procalcitonin levels in patients with Acute Pancreatitis.
- To study the association between serum Procalcitonin and severity of Acute Pancreatitis (Revised Atlanta Classification).

**Materials and methods**

**Study design**

Cross-sectional study

**Study setting**

In patients in the General Surgery department, Justice K.S. Hegde Charitable Hospital, of K.S. Hegde Medical Academy, a unit of Nitte (Deemed to be University), Deralakatte, Mangalore-575018.

**Study population**

Patients who are diagnosed with Acute Pancreatitis in Justice K.S.Hegde Charitable Hospital, Deralakatte.

**Sample size**

94

Using EPI info software version 3.01, the minimum sample size required for the study was calculated.

**Study period**

January 2019 to June 2020

**Sampling method**

Every patient who is diagnosed with AP and admitted for the same will be recruited consecutively and purposively till the sample size is attained.

**Results**

The total number of patients included in our study was 94. All the demographic data and risk factors were analyzed and the results are as mentioned below.

**Inclusion criteria**

- Patients admitted with complaints of pain abdomen associated with a serum amylase value more than three times the normal or an increase in serum lipase level and radiological features of AP.
- Patients who are willing to give consent.

**Exclusion criteria**

- The patient who is not consenting to the study.
- The patient presenting with acute on Chronic Pancreatitis.

**Data collection**

Patients diagnosed with AP are categorized into mild, moderately severe, and severe according to Revised Atlanta Criteria.

**Serum Procalcitonin (PCT) Strip test**

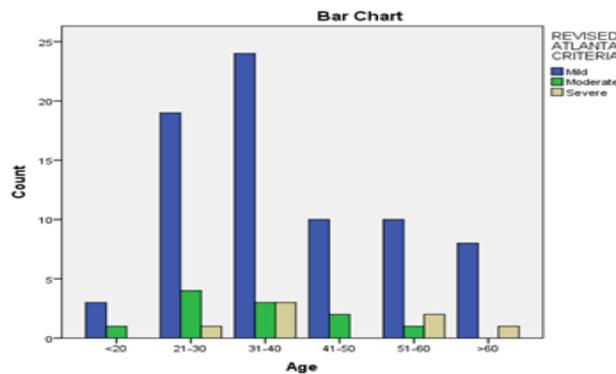
Serum Procalcitonin of less than 0.5 is considered normal. It uses the sandwich principle, wherein there is the formation of an antigen-antibody complex. 3 ml of blood is taken and applied on the PCT strip at room temperature and the result is observed after 20 minutes. With a PCT concentration of >0.5 ng/ml this sandwich complex can be seen as a reddish band. The PCT concentration in the sample is directly proportional to the color intensity of the band. The range of PCT is correlated to three reference concentration (0.5, 2.0, and 10ng/ml).

**Statistical Analysis**

Data were entered in MS-Excel and analyzed in SPSS 20. Descriptive statistics were represented with percentages, mean with SD on the nature of data. Chi-square test, one-way Anova test, Post hoc Tuckey test was done. P<0.05 was considered statistically significant.

**Table 1: Age distribution of study population**

Age	Mild	Moderately severe	Severe	Total
<20	3(4.1%)	1(9.1%)	0(0%)	4(4.3%)
21-30	20(25.7%)	4(36.4%)	1(14.3%)	25(26.1%)
31-40	25(32.4%)	3(27.3%)	3(42.9%)	31(32.6%)
41-50	10(13.5%)	2(18.2%)	0(0%)	12(13%)
51-60	10(13.5%)	1(9.1%)	2(28.6%)	13(14.8%)
>60	8(10.8%)	0(0%)	1(14.3%)	9(9.8%)
Total	76	11	7	94(100%)

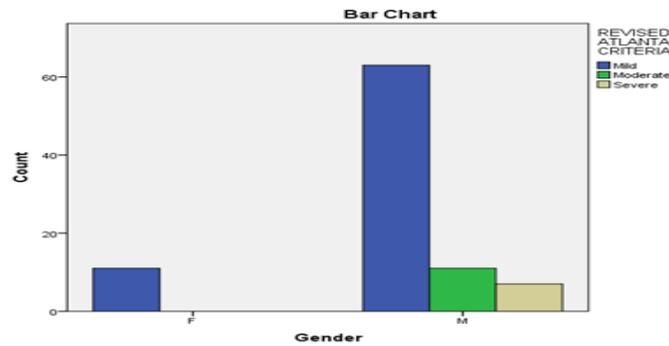


**Fig 1: Age distribution of study population**

Among 94 subjects mild, moderately severe, severe AP was observed in 76,11,7 patients respectively, among them patients aged between 31-40 had the highest incidence in all three groups of AP.

**Table 2: Gender distribution in the study population**

Gender	Frequency	Percent
Male	82	88%
Female	12	12%
Total	94	100%

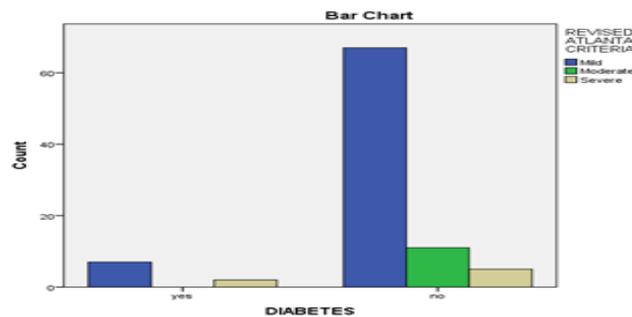


**Fig 2: Gender distribution in the study population**

Among 94 subjects 82 were male i.e 88%, 12 were females i.e 12%. Among males, 63% had mild AP.

**Table 3: Diabetes distribution in the study population**

Diabetes	Frequency	Percentage
Yes	9	9.8%
No	85	90.2%
No	94	100%

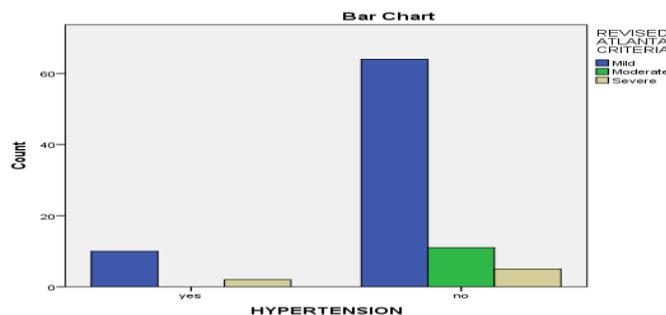


**Fig 3: Diabetes distribution in the study population**

Among 97 subjects, 9 subjects i.e 9.8% had Diabetes Mellitus.

**Table 4: Distribution of systemic hypertension in the study population**

systemic hypertension	Frequency	Percentage
Yes	14	13%
No	80	87%
Total	94	100%



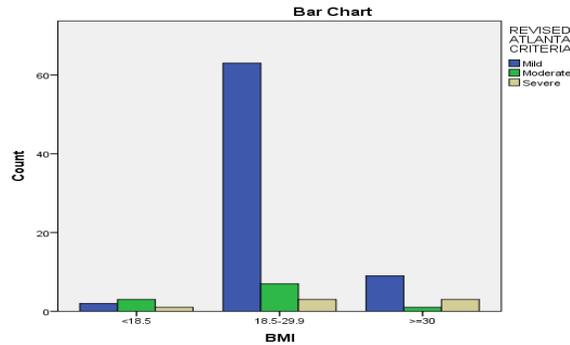
**Fig 4: Distribution of systemic hypertension in the study population**

Of 94 subjects, 14 subjects i.e 13% had systemic hypertension.

**Table 5: BMI distribution in the study population**

BMI	Frequency	Percentage	P-value
<18.5	7	6.5%	

18.5-29.9	74	79.3%	<0.005
>30	13	14.1%	
Total	94	100%	

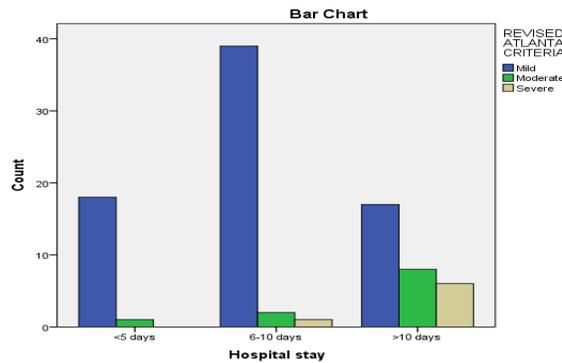


**Fig 5: BMI distribution in the study population**

Out of 94 subjects, 74 subjects i.e 79.3% had a BMI between 18.5-24.9 with a significant p value of 0.005.

**Table 6: Hospital stay in subjects**

Hospital stay	Frequency	Percentage	P-value
<5 days	20	20.7%	
5-10 days	43	42.7%	0.001
>10 days	31	33.7%	
Total	94	100%	



**Fig 6: Hospital stay in subjects**

We observed that of 94 subjects, 43(42.7%) subjects had hospital stay between 5-10 days, and 20 (20.7%) subjects, 31(33.7%) subjects had a hospital stay of <5days, and >10days respectively with a p-value of 0.001.

**Table 7: Etiology of AP**

Etiology	Frequency	Percentage	P-value
Alcohol induced	55	58.7%	0.154
Gallstone induced	19	19.6%	
ERCP induced	2	2.2%	
Trauma	1	1.1%	
Unknown	17	18.5%	
Total	94	100%	

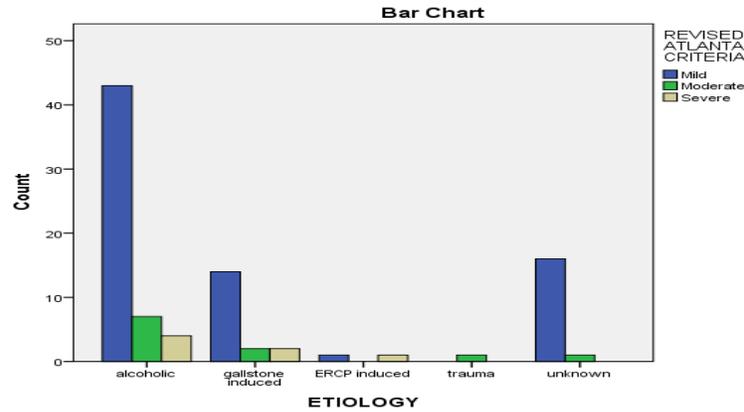


Fig 7: Etiology of AP

In our study, as depicted in the above picture, 55 (58.7%) subjects had alcohol-induced AP, 19 (19.6%) subjects had Gallstone induced AP, 2 (2.2%) subjects had ERCP induced AP, 1 (1.1%) subject had trauma-induced AP, 17 (18.5%) subjects had unknown etiology.

Table 8: Serum Procalcitonin levels in the study population

Serum Procalcitonin	Mild	Moderately severe	Severe	Total	P-value
>0.5	50 (62.2%)	5 (45.5%)	3 (42.9%)	58 (62.0%)	
>2.0	26 (33.8%)	6 (54.5%)	4 (57.1%)	36 (38%)	
Total	76	11	7	94 (100%)	0.218

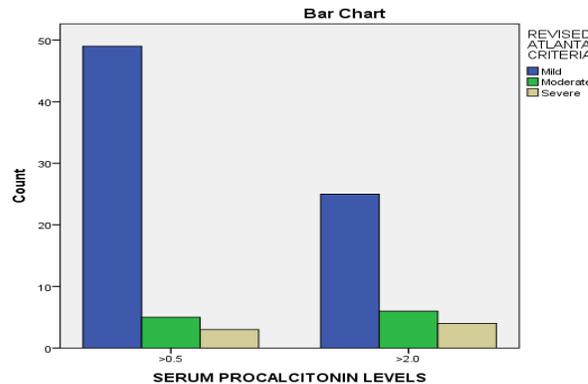


Fig 8: Serum Procalcitonin levels in the study population

In our study, as depicted in the above figure out of 94 subjects, 58 (62.0%) subjects had serum PCT levels >0.5ng/ml (50, 5, 3 subjects in mild, moderately severe, severe AP respectively).

36 (38%) subjects had serum PCT levels >2.0ng/ml (26, 6, 4 subjects in mild, moderately severe, severe AP respectively) with a insignificant p value of 0.218.

Table 9: Comparison of mild, moderately severe, severe AP using One-way Anova and Posthoc Tukey Test

	Mild (n=76)	Moderately severe (n=11)	Severe (n=7)	ONE WAY ANOVA		POSTHOC TUKEY TEST		
				F value (*=welch test)	P VALUE	Mild vs Moderately severe difference (p-value)	Mild vs Severe difference (p-value)	Moderately severe vs Severe difference (p-value)
Age	40.19±14.32	32.36±12.49	42.29±14.61	1.622	0.203	7.83 (0.206)	-2.1 (0.926)	-9.92 (0.32)
BMI	22.61±2.26	20.92±3.2	23.58±3.46	1.655*	0.235	1.69 (0.094)	-0.97 (0.583)	-2.66 (0.073)
HOSPITAL STAY	8.19±3.42	14.73±7.35	22.14±12.59	7.857*	<b>0.008</b>	-6.54 (<0.001)	-13.95 (<0.001)	-7.42 (0.01)

Comparison of Age was done between the three groups. Severe group had the highest mean age of 42.29 years and the moderately severe group had the lowest mean age of 32.36 years. This was not statistically significant p value of 0.203. Posthoc Tukey tests compared mild and moderately severe groups and showed that it was

not statistically significant (p value: 0.206). Mild and severe group comparison was also not statistically significant (p value: 0.926). Moderately severe and severe group comparison was also not statistically significant (p value: 0.32). BMI comparison between the 3 groups showed that severe group had the highest mean BMI of 23.58

Kg/m<sup>2</sup> and moderately severe group had the lowest BMI of 20.91 Kg/m<sup>2</sup>. The difference was not statistically significant (p value: 0.235). Posthoc Tukey test compared mild vs moderately severe group (p value: 0.094), mild vs severe groups (p value: 0.583) and moderately severe vs severe groups (p value: 0.073) and concluded that it was statistically insignificant.

Comparing hospital stay in the three groups showed that the severe group had the longest stay of 22.14 days, while the mild group had the shortest stay of 8.19 days, which was statistically significant (p value: 0.008). Posthoc Tukey tests compared mild vs moderately severe group (p value <0.001), mild vs severe group (p value <0.001) and moderately severe vs severe group (p value: 0.01). It showed that all 3 comparisons were statistically significant.

#### Discussion

Acute Pancreatitis is a common clinical condition leading to emergency admission. AP places a substantial burden on the health care system. The severity of the disease varies from mild to severe. Mild cases are associated with or without organ dysfunction, which can be managed conservatively. SAP has a severe inflammatory response, which leads to a number of local and systemic complications. Severe AP can progress rapidly, which causes SIRS, MODS, which requires prolonged hospital stay and interventions and it is associated with increased morbidity and mortality. Recently, the number of new cases of AP is increasing with a high mortality rate.

Scoring of AP plays an important role for many reasons. The physician gets to know about the severity of the disease. It also helps in comparison of severity within and between patient series. It helps to include patients in new trials with novel treatments or interventions. There are numerous scoring systems (Ranson score, APACHE II, Balthazar, Early Warning Score (EWS), BISAP score) for assessing the severity of AP. These scoring systems use multiple parameters that are difficult for the immediate assessment of the severity of AP. In patients with severe AP, the scoring systems used at present are often inadequate, severe AP is characterized by rapidly progressive multiple system organ dysfunctions[7].

Serum biomarkers like lipase and amylase on admission, cannot predict the severity of the disease. The condition can be very serious, but the enzymes may be only mildly increased (<3 times increase). So, there is scope for novel biomarkers to predict the severity of AP rapidly in order to start treatment. It can help in reducing complications and to improve survival rates. Many studies concluded that serum Procalcitonin predicts the severity of the AP and also helpful in predicting the prognosis of AP. Our study assesses serum PCT to predict the severity of AP[8].

Our study included 94 subjects, the presence of AP is confirmed by measuring Serum amylase and lipase, then serum PCT is assessed using a strip test. The subjects are categorized into mild, moderately severe, severe based on Revised Atlanta criteria 2012. Most of the patients underwent an ultrasound abdomen and only a few of them underwent CECT abdomen and pelvis.

Duda AG, et al. studied 40 subjects to study the prognostic value of acute phase proteins and PCT in AP prognosis. They found that 67.5% were male and 32.5% were female, with a median age of 47.45 years. Rau BM, et al[3] included 104 subjects for Early Assessment of Pancreatic Infections and Overall Prognosis in Severe Acute Pancreatitis by Procalcitonin (PCT), and it was found that 73(70%) were male and 31(30%) were female with a median age of 50 years. In our study out of 94 subjects, 84(88%) were male and 12(12%) were female, most of the subjects were between 31-45 years with a median age of 45. Hence AP is more commonly seen in the male[9].

Shera I A, et al. studied 115 subjects for correlation of elevated serum PCT levels with severity of AP and found that 64(55.7%) subjects had BMI between 18.5-25 kg/m<sup>2</sup>. Another study done by Khanna A K, et al. who studied 72 subjects, found that 55(74%) subjects had BMI between 18.5-24.9 kg/m<sup>2</sup>. In our study out of 94 subjects, 74(79.3%) subjects had BMI between 18.5-24.9 kg/m<sup>2</sup> with a significant p value of 0.005.

Tian F, et al. studied 153 patients, found that hospital stay for severe vs mild AP was 13.21 ± 2.01 vs 8.52 ± 1.5 days respectively, P <

0.05. Kim BG, et al. studied 50 patients, found that Hospital stays for mild vs severe AP was 11.5 vs 18.5 days respectively. In our study, we analyzed 94 subjects and found that patients with severe AP required prolonged hospital stay with a duration of 22.14 days, and mild AP patients 8.19 days, with a significant p value of 0.008. Thus severe AP requires prolonged hospital admission for appropriate management of complications. AP has various causes with varying frequencies in different countries. The common causes of AP are gall stones followed by alcohol. Together they contribute to 80 % of all cases of AP. Riche F C, et al[42] studied 48 patients found that etiology for pancreatitis is ethanol-induced in 25 subjects, gall stone induced in 16 subjects, others in 11 subjects. Dias B H, et al. analyzed 50 subjects found that in 50 % of the patients, alcohol was the cause, while in 26 %, gallstone was the cause of AP. 20 % of the patients, had no obvious etiological factor and were diagnosed as idiopathic AP. Shera I A, et al. studied 115 patients and found out that some of the causes of AP were gallstones in 53.9% of the patients, ethanol in 25% case, idiopathic in 14.8% patients, drug induced in 5.2% cases, increased calcium in 1.7% of the patients, hyper triglyceridemia in 0.9% and post ERCP AP in 1.7% of the cases. Cho J Het al. studied 153 subjects and found that AP was due to gallstones in 49.7 % patients, alcohol in 32.7 % patients, and unknown cause in 15.7 % patients. In our study we analyzed 94 subjects, we observed that etiologies for AP were, alcohol-induced in 55(58.7%), Gallstone induced 19(19.6%), ERCP induced in 2(2.2%), trauma-induced 1(1.1%), 17(18.5%) had unknown etiology. Our study showed a male predominance in the ethanol group compared with the biliary group, and patients were younger in the alcohol group compared to a biliary group, however, this was not statistically significant. Biliary group had less severe AP which may be due to early ERCP which could have halted AP progression. In many patients with gall stone induced AP, there is spontaneous stone passage and hence, ERCP is not necessary. Endoscopic retrieval of CBD stone is required if there is no spontaneous passage of stone. The severity of gall stone induced AP, prognosis and the course of the disease could be complicated by acute cholangitis and cholestasis. Urgent ERCP to remove CBD stones may reduce gall stone induced AP in patients who have an associated acute cholangitis. These interventions could have led to an improvement in the clinical course of the disease in gall stone induced AP. In comparison, alcoholic AP patients are given conservative management like Nil by Mouth, fluid resuscitation and vitals monitoring.

PCT is a long-life 116- amino-acid propeptide of calcitonin which is secreted by kidney cells, hepatocytes, lung tissue, pancreatic cells and thyroid C cells. During infection, PCT is circulated in the blood stream without a concomitant increase of calcitonin.

Dias B H, et al. studied 50 subjects and concluded that with a cut-off value of PCT >2 ng/mL, SAP could be predicted with 100 % sensitivity and specificity. Back K, et al. analyzed 162 patients and concluded that PCT had more accuracy in predicting SAP (sensitivity: 92%, specificity: 84%) when compared to CRP or APACHE-II score or Ranson score at 24 hours. Bezmarevic M, et al. studied serum PCT and IAP for predicting the severity of AP in 51 subjects and concluded that Sensitivity/specificity at 24 h after admission was 86%/63% for PCT and 75%/77% for IAP. Shera I A, et al. studied 115 patients and found that PCT at 0.42 ng/ml could differentiate between mild and moderately severe pancreatitis (sensitivity: 65%, specificity: 89.9%). When the cut-off value was fixed at 0.53 ng/ml, it could differentiate between moderately severe and SAP with 81.3% sensitivity and 55% specificity. Frasquet J, et al. studied 41 subjects and concluded that serum PCT does not predict the severity of AP. A study conducted by Kim BG, et al. which included 50 patients comparing BISAP score and serum PCT to predict AP severity, concluded that BISAP score ≥ 2 predicted SAP with an accuracy of 84%. It was superior to the PCT, with an accuracy of 76% in predicting SAP. Pezilli R, et al. studied Serum Amyloid A, Procalcitonin, and C-Reactive Protein in Early Assessment of Severity of Acute Pancreatitis in 31 patients and concluded that the SAA was significantly more sensitive (76.8%) in assessing the

severity of AP when compared to PCT which had a sensitivity of 21.7% and CRP which had a sensitivity of 60.9%. But, PCT (Specificity: 83.2%) and CRP (Specificity: 89.1%) was more specific than SAA (Specificity: 69.3%). Both SAA and CRP, had comparable accuracy and efficiency. Both SAA and CRP had more accuracy and efficiency than PCT, which was significant. In our study, we analyzed 94 subjects and found that 58(62.0%) subjects had serum PCT levels >0.5 ng/ml (50, 5, 3 subjects in mild, moderate, severe AP respectively) and 36(38%) subjects had serum PCT levels >2.0ng/ml (26, 6, 4 subjects in mild, moderate, severe AP respectively) with an insignificant p value of 0.218.

Serum PCT is also used to predict bowel strangulation, Cosse C, et al. analyzed Serum Procalcitonin in patients of small bowel obstruction for Predicting the Failure of Conservative Management and the Need for Bowel Resection and found that Procalcitonin levels were higher in the Surgically managed group than in the Conservatively managed group and concluded that PCT can help predict conservative management failure and occurrence of bowel ischemia in SBO patients. Markogiannak is H, et al. studied 242 patients to predict bowel ischemia and necrosis in patients with bowel obstruction with the aid of PCT. PCT levels were significantly more in bowel ischemia group than non-ischemic group (P value of 0.0001). PCT levels were also significantly more in the necrosis group than in the non necrosis group (P value of 0.0001). Thus, they concluded that PCT on presentation is very useful for the diagnosis of intestinal ischemia and necrosis in acute bowel obstruction.

A systematic review and meta-analysis conducted by yang S K, et al. consisting of 18 studies including 1827 patients on the Significance of serum procalcitonin as a biomarker for detection of bacterial peritonitis found that sensitivity and specificity of serum PCT for the diagnosis of bacterial peritonitis were 0.83 and 0.92 respectively and concluded that PCT determination may be a comparatively sensitive and specific test for the diagnosis of bacterial peritonitis.

Cosse C, et al. studied 150 patients for detecting Serum Procalcitonin (PCT) levels in postoperative ischaemic colitis. They found that PCT level less than 2 µg/L was seen in 85% of Stage 1 cases, whereas PCT level of 4-8 µg/L was observed in 63% of Stage 2 cases and PCT level more than 8 µg/L was seen in 70% of Stage 3 cases. There was a strong correlation between Favier stage and PCT levels, thus concluding that PCT is strongly correlated to Stage 2 or Stage 3 postoperative ischaemic colitis requiring surgery[10].

#### Limitation

The sample size was less. Undiagnosed inflammatory conditions could have influenced serum PCT levels, which could have had a confounding effect in my study.

#### Conclusion

Our study demonstrates that serum PCT could not significantly predict the severity of Acute Pancreatitis. We determined serum PCT levels in predicting the severity of AP. There was a male preponderance in the study group (88%). Most of the study subjects were in the 31-40 years group. The majority of the patients had mild

AP (76 patients). The majority of the patients had Alcohol-induced AP (58.7%). No statistical significance was found between the serum PCT levels and severity of AP, a p value of 0.218.

#### Acknowledgement

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**Conflict of Interest: Nil Source of support: Nil**