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D-Dimer and Ct severity index in evaluation of severity of acute pancreatitis

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Abstract
Background: Coagulative disorder is known to occur in the early phase of acute pancreatitis (AP) and D-dimer is a commonly used clinical parameter of haemostasis. The aim of this study was to assess the value of the plasma D-dimer level as a marker of severity in the days 1, 3, 5 after admission in patients with AP & to study the role of computed tomography in predicting the prognosis of acute pancreatitis & comparing D-dimer levels with Balthazar CT severity index in evaluation of severity of acute pancreatitis.
Method: From September 2015 to September2017, 60 patients admitted for AP were included in this observational study. The D-dimer level was measured on a daily basis during days 1, 3, 5 after admission. The maximum and the mean D-dimer values were used for analysis of multiple organ dysfunction syndrome (MODS), severity of pancreatitis
Need for surgical intervention, outcome of disease. All the above variables are compared with CT severity index in predicting the severity of acute pancreatitis.
Results: Both the maximum and mean levels of D-dimer were significantly different between patients with and without clinical variables such as multiple-organ dysfunction syndrome (MODS), severity of pancreatitis, need for surgical intervention, and outcome of disease. On comparing D dimer levels with CT severity index, CTSI is better in predicting the severity of acute pancreatitis.
Conclusion: D-dimer measurement is a useful, easy, and inexpensive early prognostic marker of the evaluation of severity of acute pancreatitis. CT severity index is better in predicting the severity of acute pancreatitis.

Keywords: D-dimer, acute pancreatitis, Multiple organ dysfunction syndrome, severity of pancreatitis, CT severity index

Introduction
Acute pancreatitis (AP) is an inflammatory condition characterized by variable severity ranging from a mild, self-limited disease to a severe, systemic disease associated with multiple organ dysfunction. Up to 12–25% of the patients develop severe acute pancreatitis (SAP), which has a mortality rate of 8–25% [1]. Mortality in SAP occurs either early, due to an overwhelming inflammatory reaction or late, owing to sepsis-related complications such as septic shock and major bleeding primarily arising from infected pancreatic necrosis. Coagulative derangements and disturbance of the microcirculation are known to occur in the acute phase of AP and are related to its severity [2] Coagulative disorders in these patients may range from scattered intravascular thrombosis to severe disseminated intravascular coagulation (DIC) [3]. In previous studies, some haemostatic system-related parameters have been shown to be potential predictors of AP severity and outcome [2, 4, 5] D-dimer, which is mostly used as an effective diagnostic tool to rule out deep vein thrombosis (DVT) as well as pulmonary embolism (PE) [6, 7]. has been reported to have great predictive power in the early phase of AP. Salomon *et al.* [2] found that the plasma levels of D-dimer were significantly different between patients with uncomplicated pancreatitis and patients with complications. Radenkovic *et al.* [4] suggested that the measurement of plasma levels of D-dimer, irrespective of whether D-dimer concentrations were measured during the first hour of admission or 24 h later, was an accurate method for the identification of patients who would develop organ failure in the further course of AP.
A study was conducted by Dario casas, Rocio Diaz etal in 148 patients who underwent unenhanced and contrast-enhanced helical CT within 72 hr after onset of symptoms of a first

episode of acute pancreatitis. Patients were classified by CT grade and grouped into two categories (mild: grades A, B, C; and severe: grades D and E) that were correlated with complications and death. In the grades including patients with pancreatic necrosis, it was also correlated with complications and death. It was concluded that early unenhanced CT alone was a good indicator of severity of acute pancreatitis in the selected population. CT grade was sensitive for predicting outcome in acute pancreatitis. Pancreatic necrosis, estimated on early, contrast-enhanced CT and seen only in patients having severe disease, was a specific predictor of morbidity and mortality [8].

Erik J Samshu, William Traverse e tall conducted a study in patients admitted with the diagnosis of acute pancreatitis. The index CT scan was used in this study to determine early unenhanced CT alone was a good indicator of severity of acute pancreatitis in the selected population. CT grade was sensitive for predicting outcome in acute pancreatitis. Pancreatic necrosis, estimated on early, contrast-enhanced CT and seen only in patients having severe disease, was a specific predictor of morbidity and mortality [9].

A study was conducted by E J Balthazar, J H Ranson etal to asses the presence and degree of pancreatic necrosis (30%, 50%, or greater than 50%) and was evaluated by means of bolus injection of contrast material and dynamic sequential computed tomography (CT) in 88 patients with acute pancreatitis at initial and follow-up examinations. Pancreatic necrosis was defined as lack of enhancement of all or a portion of the gland. Length of hospitalization, morbidity, and mortality in patients with early or late necrosis (22 patients) were evaluated and compared with the same criteria in the rest of the group. It was found that serious complications occurred in patients who initially had or developed more than 30% necrosis. A CT severity index, based on a combination of peripancreatic index had 2% morbidity, and none died [10].

Erik J Simchuk, L.William Traverso *et al* conducted a study in patients admitted with diagnosis of acute pancreatitis. The index CT scan was used in this study to determine the CT severity index (the CTSI of Balthazar and Ranson). Outcomes measured were death, length of stay (LOS), and need for necrosectomy (NEC). The study concluded that the CT severity index is an applicable and comparable predictor of outcomes in severe pancreatitis [11].

Patients, materials, and methods

Patients

In this observational study, all consecutive adult patients (age 18 years) with AP (within 72 h from the onset of the disease) hospitalized in JSS Hospital Mysore in department of General Surgery between January September 2015 to September 2017 were studied. Patients who had suffered prior attacks of acute pancreatitis, patients who had received surgical intervention before admission, and patients with a known history of coagulative disorders or a recent history of myocardial infarction or cerebral infarction were excluded from the study. All patients received standard medical therapy [12] and were followed until discharge from the hospital or hospital death.

Data collection

Baseline data including age, sex, aetiology, the Ranson score, and the APACHE II score were recorded on admission. The definitions of organ dysfunction were based on a score of 2 or more in the sequential organ failure assessment (SOFA) scoring system [9] Multiple-organ dysfunction syndrome (MODS) was defined as the combined dysfunction of 2 major organ systems. Pancreatic necrosis was diagnosed according to the results of contrast enhanced computed tomography (CECT) performed at least 48 h after the onset of the disease [10]. Both the SOFA score and APACHE II score were assessed on a daily basis during days 1, 3, 5 days after admission. The development of local complications, such as pancreatic pseudocysts, the computed tomography severity index [10], the use of vasoactive drugs and mechanical ventilation, the duration of hospital and ICU stay, and the need for surgical intervention were also recorded. In all patients, the plasma D-dimer level was determined on admission and days 3, 5 The upper limit of the reference interval for D-dimer was 500 micro g/L. Maximum D-dimer was defined as the highest level reached in all measurements, and the mean D-dimer was defined as the mean level of all measurements. In addition, other routine laboratory parameters such as serum concentrations of creatinine, bilirubin, urea nitrogen, and C-reactive protein (CRP) (all at the Central Laboratory of Jss hospital mysore] were determined at the same time as the plasma D-dimer level was measured, and at other time points.

Statistical analysis

Results were expressed as medians (interquartile ranges), unless mentioned otherwise. Categorical variables were described in absolute numbers and in percentages. Continuous variables were compared using the Mann–Whitney U-test. To establish optimal cut-off points, a receiver operating characteristic (ROC) curve was used. Other tests are Kruskal –Wllis test, independent t test, ANOVA test.

Results

A total of 60 patients with AP were enrolled in this observational study. Table 1 shows the demographic and clinical data of these patients. The incidence rates of organ dysfunction during the episodes of pancreatitis were high: renal dysfunction in 34 patients (56.7%), and pulmonary dysfunction developed in 28 patients (46.6%).

Demographic data.

1. Age / Sex Ratio: Out of 60 patients 53 are male (88%) and 7 are female (12%). Majority of the patients belonged to the age group distribution of 31-50 (45%) and with the next common age distribution being <30 years (33.3%).

Table 1: Age distribution table

		Count	Column N %
age category	<30	20	33.3%
	31-50	27	45%
	51-70	10	16.7%
	>71	3	5%

Table 2: Sex distribution table

		Count	Column N %
Sex	Female	7	12.1%
	Male	53	88.3%

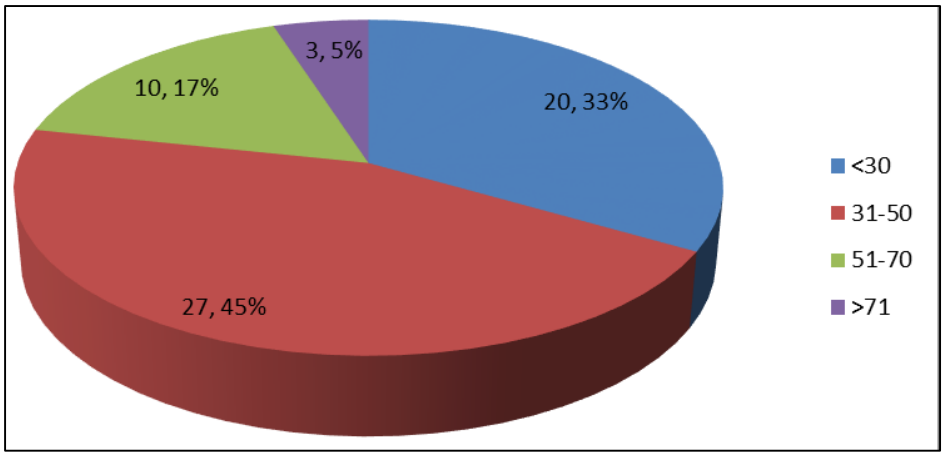


Fig 1: Pie diagram showing age distribution.

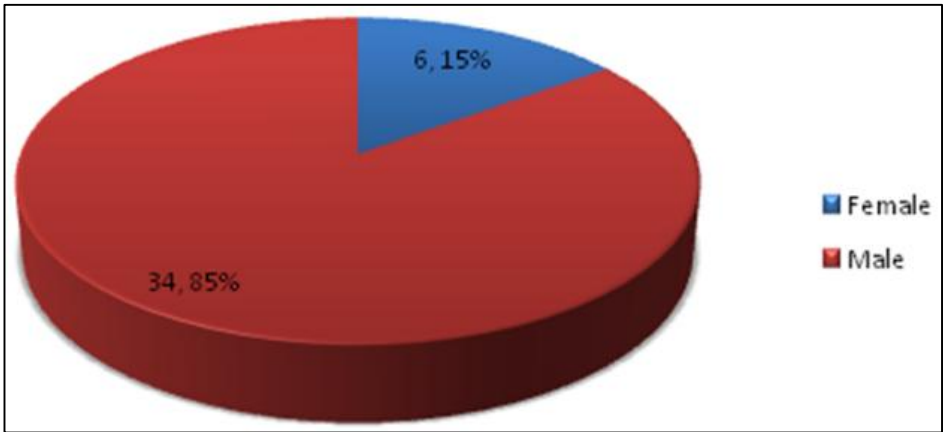


Fig 2: Pie diagram showing sex distribution.

2. Predisposing Factors: Alcohol was the single most common predisposing factor causing pancreatitis in 41 patients (68.3%) in our study. Gallstones were predisposing factor in 13.3% of cases. 4 patients (6.6%) had both alcohol and gall stone as the predisposing factor. 4 (6.6%) patients were idiopathic & 3.3% and 1.6% are due to triglycerides and drug induced respectively.

Table 3: Chart showing etiological factors for acute pancreatitis.

Predisposing factors.	Count	Column Total N %
alcohol	41	68.3%
gallstone	08	13.3%
Alcohol & Gall stones	04	6.6%
Idiopathic	04	6.6%
Triglycerides	02	3.3%
Drug induced	01	1.6%

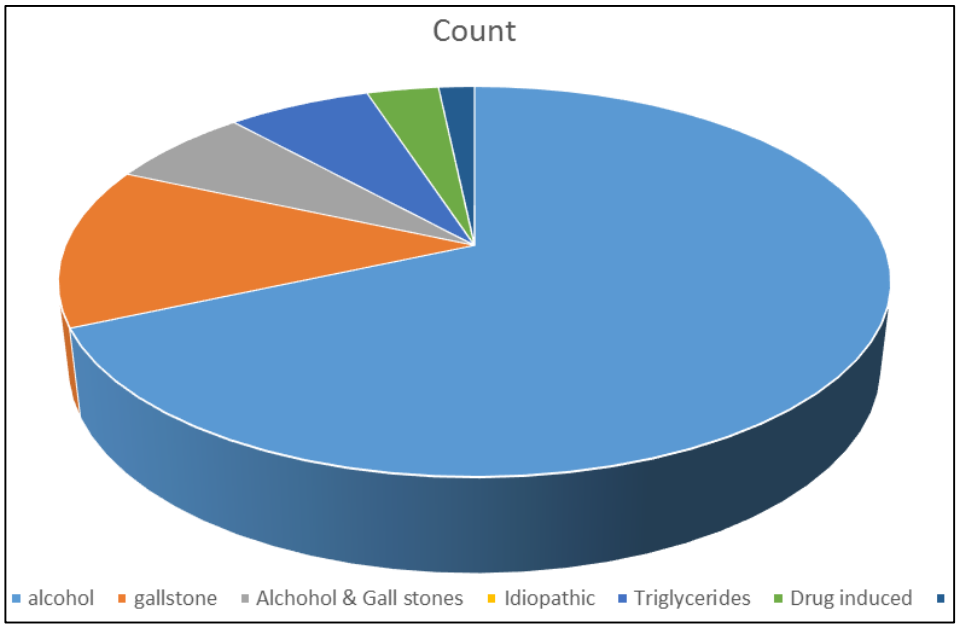


Fig 3: Pie diagram showing etiological factors for acute pancreatitis

3. Clinical characteristics

Table 4: Determining the Clinical characteristics

Severity of pancreatitis	**Mild**	**12**
	Moderately Severe	**14**
	Severe	**34**
Hospital mortality (%)	3(5%)	
Organ dysfunction	40(66.7%)	
MODS	13(21.7%)	
Surgical intervention	10(16.7%)	
Length of hospitalization (days)	13.05	

4. D-dimer and presence or absence of clinical variables

As shown in Table 5, the maximum level of D-dimer was significantly greater in patients who presented with multiple-organ dysfunction syndrome (MODS), severe pancreatitis, need for surgical intervention for necrosectomy. and patients who expired.

Table 5: Values of maximum D-dimer levels in relation to the presence or absence of clinical variables.

Clinical Variables		Max D-dimer day1	Max D dimer day 2	Max D dimer day 3
Organ Dysfuction	No	905	810	1270
	Yes	2895	3150	6700
MODS	No	2010	1986	2100
	Yes	3500	3900	4200
Need for surgical intervention	No	2285	2000	2100
	Yes	2285	2675	3548
Modified outcome	Expired	2650	3900	4200
	Recovered	2270	2000	2100

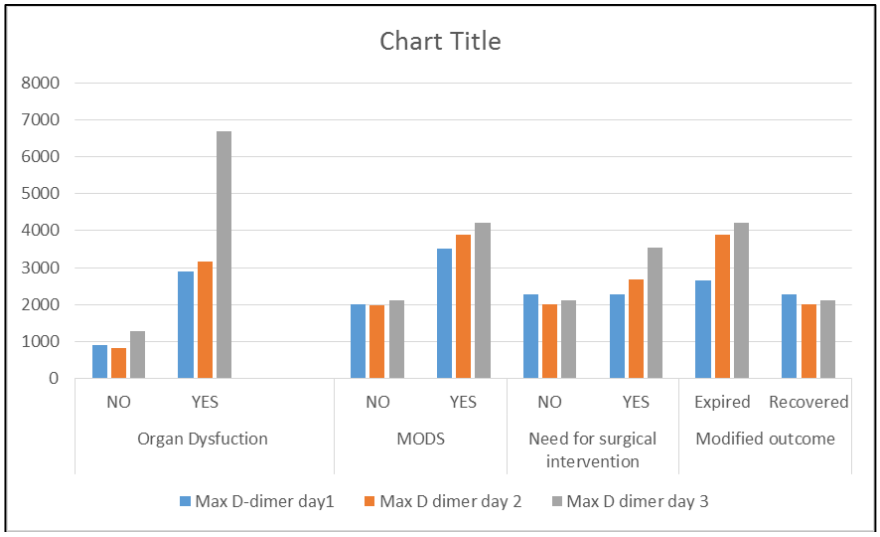


Fig 4: Values of maximum D-dimer levels in relation to the presence or absence of clinical variables.

The mean D-dimer levels showed tendencies similar to those of the maximum D-dimer levels in relation to clinical variables (Table 6). Thus, the utility of the maximum D-dimer level seemed to be equivalent to the mean level as a marker of the severity of AP.

Table 6: Values of mean D-dimer levels in relation to the presence or absence of clinical variables.

Clinical variables		Mean D dimer
Organ dysfunction	NO	793
	YES	3403
MODS	NO	1979
	YES	3867
Need for surgical intervention	NO	2076
	YES	2946
modified outcome	Expired	3867
	Recovered	2031

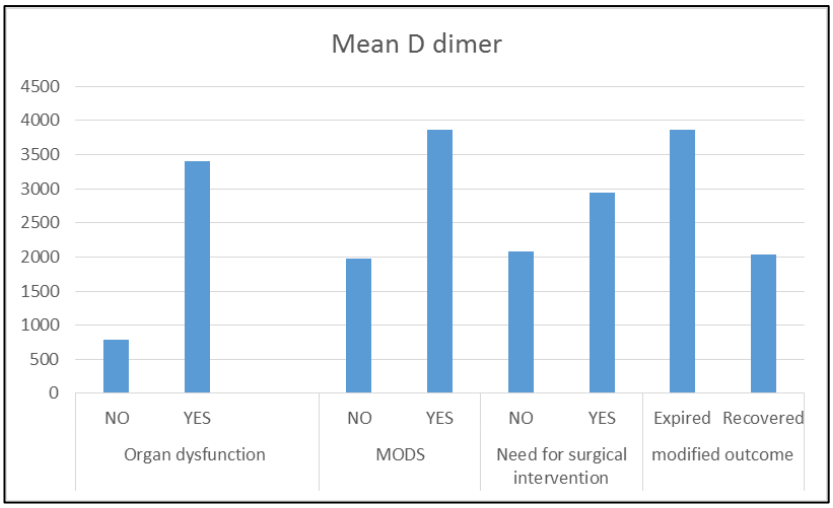


Fig 5: Values of mean D-dimer levels in relation to the presence or absence of clinical variables

5. CT severity index and presence or absence of clinical variables.

CT severity index is significantly greater in patients who require who has severe pancreatitis, Multiple Organ dysfunction syndrome, need for surgical intervention, and who expired.

Table 7: CT severity index and presence or absence of clinical variables.

Clinical variables		Mean CT Severity index
Organ dysfunction	No	4.30
	Yes	8.27
MODS	No	6.36
	Yes	9.60
Need for surgical intervention	No	6.40
	Yes	9.20
modified outcome	Expired	6.36
	Recovered	9.60

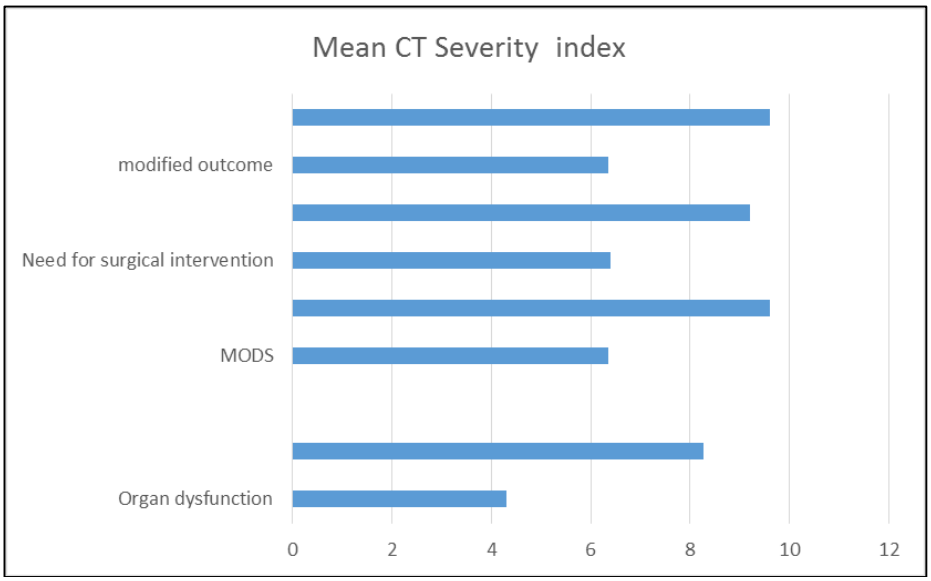


Fig 6: CT severity index and presence or absence of clinical variables.

6. Comparing CT severity index with D dimer in predicting the severity of acute pancreatitis.

The maximum and mean levels of D dimer for the variables MODS, Organ dysfunction, need for surgical intervention, and mortality are compared with ct severity index in predicting the severity of acute pancreatitis by plotting area under curve, ROC curves, P values.

Area under curve: The area under curve for mean and max D dimer values for the variables MODS, organ dysfunction, need for surgical intervention, and Mortality are explained.

The area under curve of mean and max D-dimer levels for MODS are 0.743 &0.727 and p values are 0.013 & 0.020 which is statistically not significant (p value <0.005 is significant) are explained in table 8

Table 9: Area under curve of Mean and maximum D dimer for MODS.

Test Result Variable(s)	Area	p	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
MeanDDimer	.743	.013	.604	.882
MaxDDimer	.727	.020	.589	.866
D Dimer day 1	.711	.031	.562	.860
D Dimer day 3	.773	.005	.639	.907
D Dimer day 5	.741	.014	.608	.873

The area under curve of mean and max D-dimer levels for surgical intervention are 0.650 and 0.654 and p values are 0.176 0.166 which is statistically not significant (p value <0.005 is significant) are explained in table 10

Table 10: Area under curve for Mean and Max D dimer values for need of surgical intervention.

Test Result Variable(s)	Area	p	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
MeanDDimer	.650	.176	.497	.803
MaxDDimer	.654	.166	.499	.809
D Dimer day 1	.567	.543	.402	.733
D Dimer day 3	.653	.169	.497	.808
D Dimer day 5	.685	.095	.540	.830

The area under curve of mean and max D-dimer levels for mortality are 0.720 and 0.719 and p values are 0.025 & 0.024 respectively. Which is statistically not significant (p value <0.005 is significant) are explained in table 11

Table 11: Area under curve for Mean and Max D dimer values for mortality.

Test Result Variable(s)	Area	p	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
MeanDDimer	.720	.024	.574	.865
MaxDDimer	.719	.025	.574	.863
D Dimer day 1	.615	.238	.457	.773
D Dimer day 3	.739	.014	.594	.884
D Dimer day 5	.756	.009	.627	.885

The area under curve of mean and max D-dimer levels for organ dysfunction are 0.964 and 0.945 and p values are 0.001 & 0.001respectively. Which is statistically significant (p value <0.005 is significant) are explained in table 12

Table 12

Test Result Variable(s)	Area	Cut off	Sen	Spe	p	Asymptotic 95% Confidence Interval	
						LB	UB
MeanDDimer	.964	1790	95	92.1	.000	.914	1.000
MaxDDimer	.945	2400	95	89.5	.000	.871	1.000

ROC Curves For D dimer values and MODS, mortality, need for surgical intervention and organ dysfunction are shown in figures 7, 8, 9, 10

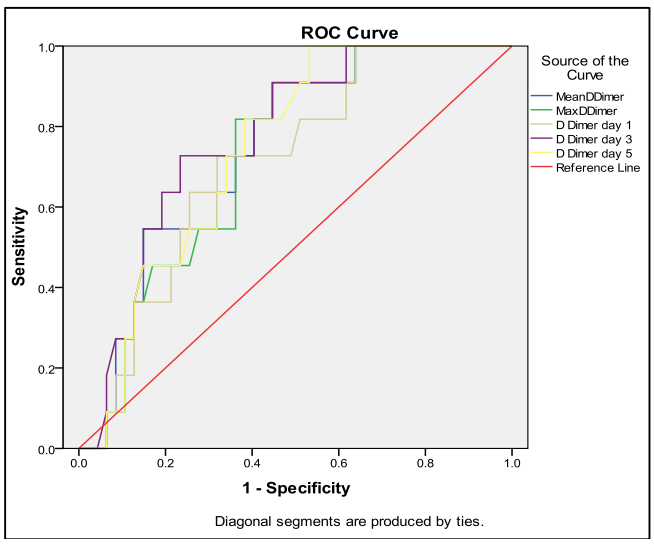


Fig 7: ROC curve in predicting the MODS

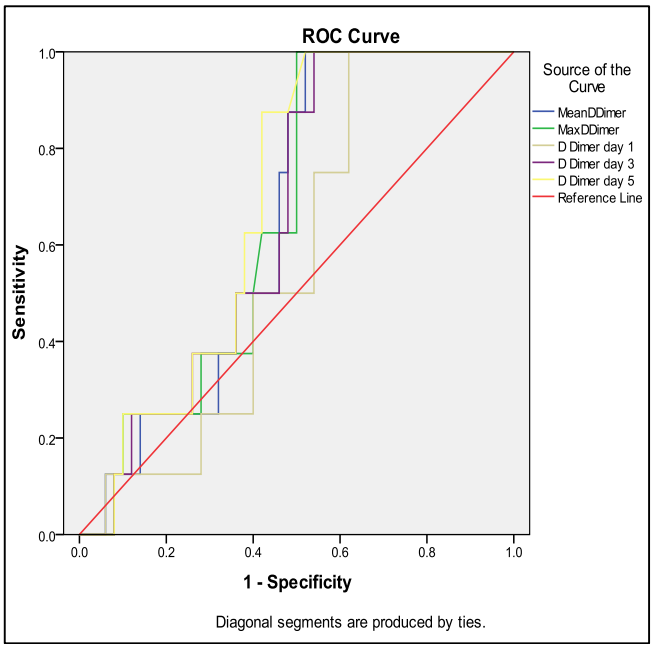


Fig 8: ROC curve in need of surgical intervention

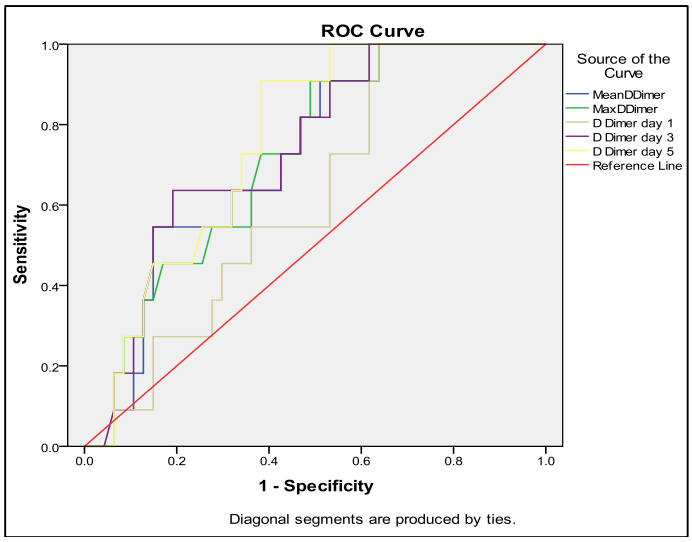


Fig 9: ROC curve for predicting the Mortality

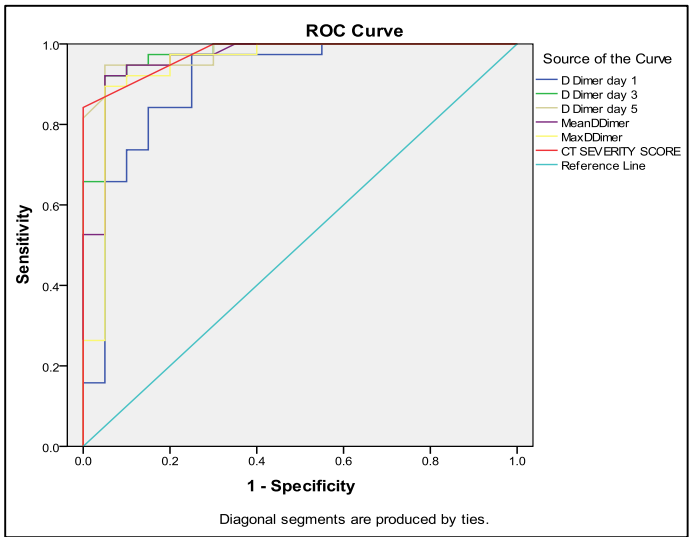


Fig 10: ROC curve for predicting organ dysfuction.

The area under curve CT severity index for the variables MODS, organ dysfunction, need for surgical intervention, and Mortality are explained.

The area under curve for CT severity index in predicting the MODS is 0.825 and p value is 0.001 which is statistically significant (p value <0.005) is shown in table 13.

Table 13: Area under curve of CT severity index in predicting MODS

Test Result Variable(s)	Area	p	Asymptotic 95% Confidence Interval				
			Lower Bound	Upper Bound	Cut off	Sen	spe
Ct Severity Score	.825	.001	.713	.937	7	100	54.2

The area under curve for CT severity index in predicting the Mortality is 0.813and p value is 0.001 which is statistically significant (p value <0.005) is shown in table 14.

Table 14: Area under curve of CT severity index in predicting Mortality.

Area	p	Asymptotic 95% Confidence Interval	
		Lower Bound	Upper Bound
.813	.001	.701	.926

The area under curve for ct severity index in need for surgical intervention is .740 and p value is 0.001 which is statistically significant (p value <0.005) is shown in table 15.

Table 15: Area under curve of CT severity index in predicting need of surgical intervention.

Test Result Variable(s)	Area	Cut off	Sen	Spe	p	Asymptotic 95% Confidence Interval	
						LB	UB
Ct Severity Score	.887	8	77.4	92.6	.001	.800	.974

The area under curve for CT severity index in predicting the Organ dysfunction is 0.976 and p value is 0.001 which is statistically significant. Is shown in table 16.

Table 16: Area under curve of CT severity index in predicting organ dysfunction.

Test Result Variable(s)	Area	Cut off	Sen	Spe	p	Asymptotic 95% Confidence Interval	
						LB	UB
Ct severity score	.976	8	100	84.2	.000	.947	1.000

ROC curves of CT severity index in predicting MODS, Organ dysfunction, need for surgical intervention and mortality are shown in Fig 11, 12, 13, 14.

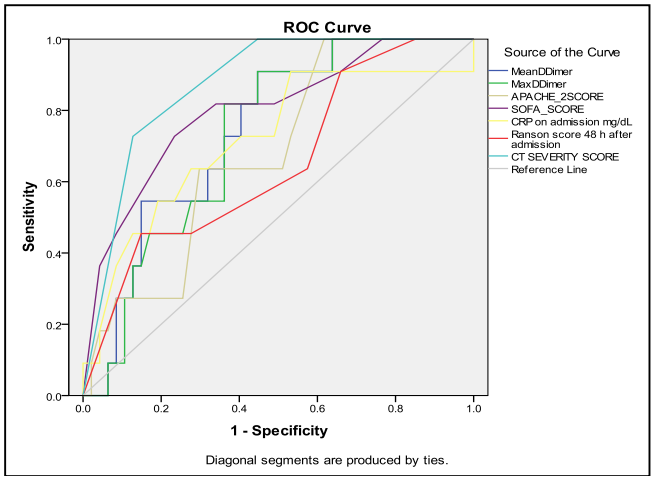


Fig 11: ROC curve in predicting the MODS.

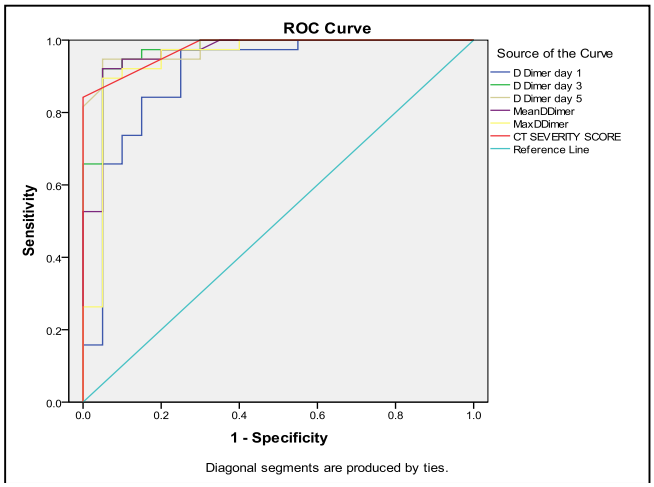


Fig 12: ROC curve in predicting the organ dysfuction.

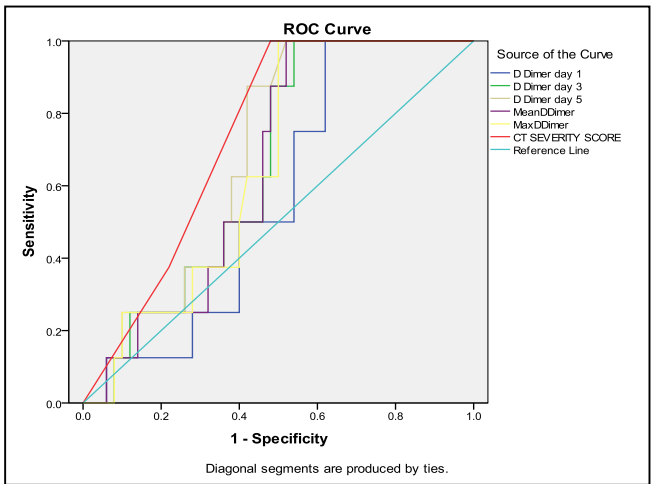


Fig 13: ROC curve in predicting the need for surgical intervention

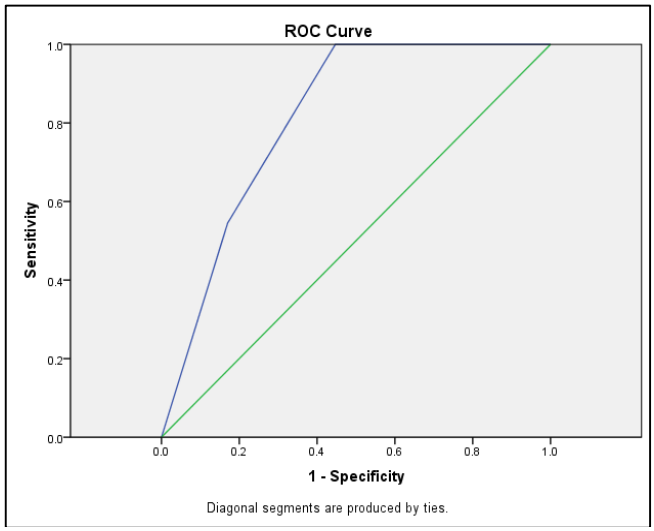


Fig 14: ROC curve in predicting the Mortality

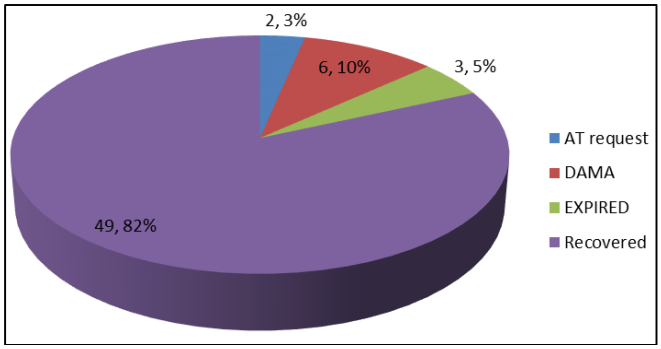
9. Management

All 40 patients (100%) are managed conservatively.

10. Outcome

49 patients (81.7%) recovered by the time of discharge while 6 patients (10%) got discharged against medical advice as their condition worsened and attenders didn't want to continue treatment. 2 patients (3.3%) got discharge at request and 3 patients (5%) expired.

		Count	Column N %
Outcome	AT request	2	3.3%
	Dama	6	10%
	Expired	3	5%
	Recovered	49	81.7%



Conclusion

Sixty patients of diagnosed Acute Pancreatitis were admitted to J.S.S Hospital over a period of 2 years and the study of these patients revealed, Majority of the patients belonged to the age group distribution of 31-50 (45%) and with the next common age distribution being <30 years (33.3%) and with male predominance 53 (88.3%).

Most common symptom of acute pancreatitis was pain abdomen, which was seen in all patients with pain radiating

to back in majority (65%) of cases. The other associated symptoms were vomiting predominantly and sometimes fever and jaundice. On examination all patients had abdominal tenderness and guarding.

Alcohol was the single most common predisposing factor causing pancreatitis in our study. Gallstones were next common predisposing factor. Definite relationship exists between alcoholism, gallstone and pancreatitis.

The exact mechanisms by which diverse etiological factors induce an attack are still unclear, but once the disease process is initiated, common inflammatory and repair pathways are invoked. There is a local inflammatory reaction at the site of injury, which, if marked, leads to a systemic inflammatory response syndrome, and it is this systemic response that is believed to be ultimately responsible for the majority of the morbidity and mortality.

Henceforth new biological markers which are markers of systemic inflammation can be used as an alternative to Multifactorial scoring systems, as the Ran son's prognostic signs, the Glasgow score, and APACHE II which are evaluated only 48 h after admission, which is too late for therapeutic decision-making.

Pro inflammatory cytokines are considered to be important in the pathogenesis of severe acute pancreatitis.

In our study we assessed the role of D dimer a marker of haemostasis in predicting the prognosis of acute pancreatitis. Prognosis is evaluated by Predicting the development of MODS, organ dysfunction, need for surgical intervention and mortality also compared with CT severity index in predicting the severity of acute pancreatitis.

On evaluating the role of mean and maximum D dimer and CT severity index in predicting the MODS, p values of mean and maximum D dimer are 0.013 & 0.020 which is statistically not significant, P value of CT severity index in predicting the MODS is 0.001 which is statistically significant (p value <0.005).

On evaluating the role of mean and maximum D dimer and CT severity index in predicting the need of surgical intervention the p values are 0.176, 0.166 which is statistically not significant (p value <0.005 is significant), P value of CT severity index in predicting the MODS is 0.001 which is statistically significant (p value <0.005).

On evaluating the role of mean and maximum D dimer and CT severity index in predicting the organ dysfunction the cut off values are 1790 and 2400 microgram /L respectively the p values are 0.001 which is statistically significant (p value <0.005 is significant), the sensitivity and specificity of mean and maximum D dimer values and CT severity index in predicting the organ dysfunction are 95%, 92.1% & 95 %,89.5% respectively, P value of CT severity index in predicting the MODS is 0.001 which is statistically significant (p value <0.005), cut off value is 8 and sensitivity and specificity are 100% and 84.2%.

On evaluating the role of mean and maximum D dimer and CT severity index in predicting mortality the p values are p values are 0.025 & 0.024 respectively. Which is statistically not significant (p value <0.005 is significant), P value of CT severity index in predicting the mortality is 0.001 which is statistically significant (p value <0.005).

In patients with acute pancreatitis, D dimer level at admission per se do not predict development of MODS, need for surgical intervention and mortality but could predict the development of organ dysfunction. On contrary CT severity index predicted the development of MODS, need for surgical intervention, and mortality and predicted better than D dimer in development of organ dysfunction. Hence CT severity index is better in predicting the severity of acute pancreatitis than D dimer level.

Summary

Early diagnosis of severe acute pancreatitis is important for the timely initiation of intensive support treatment, identifying complications as soon as possible and for the transferring of patients to specialized centres.

The severity of acute pancreatitis cannot always be reliably identified by clinical approaches at the time of admission to hospital Various biochemical parameters, computerized tomography and certain scoring systems are used for this purpose and to determine the need for intensive care. The Ranson and Acute Physiology and Chronic Health Evaluation (APACHE) II scoring systems are frequently used to identify the severity of pancreatitis, but they are not practical because they require a number of parameter measurements to be concluded during scoring.

For early prognosis in acute pancreatitis patients, various markers such as α1-antitrypsin, urinary trypsinogen activating peptide, amyloid A and C-reactive protein (CRP) have been determined.

D-dimer is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis and is reported as marker of severity.

A prospective study is conducted from October 2015 to October 2017, 60 patients presenting with acute pancreatitis in department of general surgery JSS hospital. Out of total 60 patients 34 patients had severe pancreatitis. 20 patients developed ARDS 34 patient had AKI, 13 patient developed MODS. 10 patients developed local complications. By CT 36 patient had pancreatic necrosis. Mortality was there in 3 patients.

Declarations

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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