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Evaluation of Prognostic Markers in Patients of Acute-on-Chronic Liver Failure and Decompensated Cirrhosis

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Abstract : In the current era, with increasing availability of liver transplant across the country, comes a lacuna of prioritizing the patients presenting to the hospital for liver transplant. Such prioritization, although done on a standard basis by MELD (The Model for End-Stage Liver Disease) score in various countries for optimization of transplant waiting list, such scores show discrepancy in predicting acute in hospital mortality, as they do not take into account sepsis, inflammatory states and MODS. This is a comparative study, with aim and objectives to study the descriptive clinico-laboratory markers of prognosis and their relationship with acute mortality (within 30 days of admission) and in patients of decompensated cirrhosis and acute-on-chronic liver failure and to determine and compare the diagnostic performance of these clinico-laboratory markers to ascertain acute mortality (within 30 days of admission). **Methodology:** The patients were divided into two groups based on inclusion and exclusion criteria as subgroup A-Cirrhosis and subgroup B-Acute-on-chronic liver failure, and prognostic indicators including presentation during admission, SIRS criteria, QSOFA score, serum C-reactive Protein, neutrophil to lymphocyte ratio, serum sodium levels and MELD score were assessed in terms of 30 day mortality from admission. **Conclusion:** In patients of cirrhosis presenting features along with inflammatory markers are better prognostic indicators than the traditionally used MELD score. However, in patients of ACLF, where inflammatory markers are non-specifically increased, the MELD score appears to be the better prognostic marker for mortality.

Key Words: Cirrhosis, acute-on-chronic liver failure, MELD score, Neutrophil to lymphocyte ratio, C-reactive Protein, QSOFA, SIRS, Serum Sodium, Prognostic Markers, mortality.

Introduction

With availability of liver transplant in major metro cities in India, there is a dire need to prioritize the liver transplant waiting list for patients who suffer from end stage liver disease. The end stage liver disease includes a wide spectrum of patients including those suffering from acute liver failure, decompensated cirrhosis and a more recently defined acute-on-chronic liver failure. Out of these, acute liver failure has well established criteria for prognostication, however, the latter sub-groups which have an underlying chronic liver injury as a common factor, MELD score has been used to prognosticate patients and triage the liver transplant waiting list. However, since the MELD score has been classically designed and validated for risk of 3 month mortality, other markers which could identify the risk of short term mortality would be more suitable for prioritizing the transplant waiting list. However, currently MELD score is the standard of prognostication and prioritization as no extensive data on other markers is currently available. In a recent study by Peng *et al.* (2016) it was demonstrated evidently that there lies a discrepancy between MELD score and mortality outcomes in cirrhotic patients, and in order to focus determinants of short term mortality acute parameters including neutrophil to lymphocyte ratio (Zhang *et al*., 2016; Kalra *et al.*, 2017) those fulfilling SIRS criteria, a high C-reactive protein (Ha *et al.,* 2011; Kwon *et al.,* 2015; August *et al*., 2017) , those fulfilling QSOFA (Osatnik *et al.,* 2018) score, and a low Serum Sodium levels Kim *et al.* (2009; 2018) have shown a promising utility, and in some studies (Zhang *et al.,* 2016 and Kalra *et al.,* 2017) non inferior to MELD score in decompensated cirrhosis. Some of these markers have been studied in patients of acute-on-chronic liver failure. This study aims to determine the sensitivity, specificity and

diagnostic accuracy of these markers, including MELD score to identify risk of 30 day in-hospital mortality and its possible utility in two sub groups (decompensated cirrhosis and acute-on-chronic liver failure) for predicting acute mortality and their possible role in prioritization of waiting list.

Aim and Objectives:

1. To study the descriptive clinico-laboratory markers of prognosis and their relationship with acute mortality (within 30 days of admission) and in patients of decompensated cirrhosis and acute-on-chronic liver failure.

2. To determine and compare the diagnostic performance of these clinico-laboratory markers to ascertain acute mortality (within 30 days of admission).

Materials and Methods

The study was a prospective, descriptive and observational study, for which ethical clearance was taken from institutional ethical committee, Gandhi Medical College, Bhopal (Ethical Clearance for study-3626-28/mc/iec/2018 dated 30/1/2018) and included the indoor patients admitted under department of medicine, Gandhi Medical College Bhopal, India, who fulfilled selection criteria (inclusion and exclusion). A written informed consent was taken and their clinical and laboratory parameters at the time of admission and during the course of hospital stay were recorded. These patients were followed up till a period of 1 month from admission to note outcomes during January 2018 to July 2019. The Participants admitted were divided into two groups- Group A: Decompensated cirrhosis and Group B : Acute- on-chronic liver failure.

Sub-group A: Decompensated Chronic Liver disease, inclusion criteria - A Patient of Cirrhosis as proven by histology or by clinic-radiological criteria fulfilling at-least 2 out of 3

a. In-homogenous Hepatic Surface with Splenomegaly

b. Portal Hypertension on Radiological Finding

c. Platelet counts less than 100,000/m3 or Variceal Changes in Endoscopy.

Criteria for Exclusion: 1. Acute Hepatitis 2. Hematological disorders 3. Hepatocellular Carcinoma 4. Other concurrent malignancies 5. Immunocompromised state.

Sub-group B: Acute-on-chronic Liver Failure (Sarin *et al.,* 2008; Wlodzimirow *et al.,* 2013; Lei *et al*., 2017) inclusion criteria-was defined as acute hepatic insult manifesting as jaundice and coagulopathy, complicated within 4 weeks by ascites and/or encephalopathy in a patient with previously diagnoses or undiagnosed liver disease. (Jaundice with Serum bilirubin >5mg/dl and coagulopathy INR>1.5 and development of ascites and/or encephalopathy as determined by physical examination).

The Prognostic markers which were noted include- 1.Main event of hospitalization, 2. Neutrophil to Lymphocyte ratio (Sarin *et al.,* 2008; Zhang *et al*., 2016). 3. SIRS, 4. C-reactive protein (Ha *et al.,* 2011; Kwon *et al*., 2015; August *et al.,* 2017). 5. QSOFA (Ha *et al.,* 2011) score, 6. Serum Sodium levels (Osatnik *et al.,* 2018; Kim *et al.,* 2008 & 2009). 7. MELD score. These were evaluated in the two different subgroups as prognostic markers of acute mortality in the patients (within 30 days of admission).

Data Analysis:The parameters of all three subgroups and their outcomes were analysed separately for three sub-groups. Using in Microsoft Excel 365 and IBM SPSS version 25. In the categorical data sets Chi square test and for continuous variables student's t-test was utilized. Receiver Operator Curve analysis for each variable of each subgroup was performed determine the diagnostic accuracy and comparison with other variables.

Results

There were 90 patients who fit the criteria for decompensated cirrhosis with mean age was 47.12 (± 12.71years) of which 73 were males and 17 being female between the age group of 18-70 years, whereas 40 patients fulfilled criteria for ACLF, The mean age of patients of acute-on-chronic liver failure (n=20) observed under this study was 40 +15 years, with 16 males (x=37.4±15.14 years) and 4 females (x=52±13.7 years). A higher mortality was noted in patients of ACLF (45.0% n=18) as compared to the patients admitted for cirrhosis (24.4%, n=22).

1. Main event of hospitalization

There was a significant higher mortality noted amongst patients primarily with hepatic encephalopathy, variceal bleed than due to uncontrolled ascites or other causes in patients of decompensated cirrhosis, however, no difference

between the mortality was noted with respect to primary event for hospitalization amongst patients with ACLF (Table-1).

Table - 1. Main event of hospitalization in decompensated cirrhosis.

Decompensated Cirrhosis		**Acute on Chronic Liver Failure**	
Uncontrolled Acites (n=30, Mortality =10%)	$\chi^2 = 7.732$	Uncontrolled Acites (n=12 , Mortality =24%)	$\chi^2 = 0.804$
Hepatic encephalopathy (n=33, Mortality 60.6%)	P = 0.038	Hepatic encephalopathy (n=14, Mortality 70.8%)	P = 0.381
Variceal Bleed (n=26, mortality =23.1%)		Variceal Bleed (n=16, mortality =55.1%)	
Others (n=1, mortality 0%)		Others (n=0, mortality 0%)	
Total mortality- 24.4%, n= 90		Total mortality- 24.4%, n= 90	

2. For patients fulfilling SIRS Criteria, a higher mortality was noted amongst patients with cirrhosis, however not amongst those with acute-on-chronic liver failure (Table-2).

Table - 2 . Prognostic utility of SIRS in predicting acute (30 day) mortality.

Decompensated Cirrhosis			**Acute on Chronic Liver failure**		
Mortality in patients fulfilling SIRS Criteria (n=28)	60.7% (n=17)	X^2= 28.9 P< 0.001	Mortality in patients fulfilling SIRS Criteria (n=22)	54.5% (n=12)	X^2= 0.900 P=0.406
Mortality in patients not fulfilling SIRS Criteria (n=62)	8.1% (n=5)		Mortality in patients not fulfilling SIRS Criteria (n=18)	33.3% (n=6)	
Total Mortality (n=90)	24.4% (n=22)		Total Mortality (n=40)	45.0% (n=18)	
Area under the Curve – (AUROC)	0.805	P<0.001	Area under the Curve – (AUROC)	0.606	P=0.379
Sensitivity	77.3%	At cut off SIRS fulfilled	Sensitivity	66.7%	At cut off, SIRS Fulfilled
Specificity	83.8%		Specificity	54.5%	
PPV	60.7%		PPV	54.5%	
NPV	8.1%		NPV	33.3%	
Diagnostic Accuracy	31.1%		Diagnostic Accuracy	55.0%	

3. A significantly higher mortality was noted amongst patients of cirrhosis fulfilling QSOFA criteria, however, no difference between mortality was seen amongst those fulfilling QSOFA criteria, or not in patients of ACLF (Table-3).

Table – 3. Prognostic utility of QSOFA score in Predicting acute (30 day) mortality

Decompensated Cirrhosis			**Acute-on-Chronic Liver failure**		
Mortality in patients fulfilling QSOFA Criteria (n=32)	59.4% (n=19)	X^2= 32.804 Ƥ< 0.001	Mortality in patients fulfilling QSOFA Criteria (n=24)	58.3% (n=14)	X^2= 2.155 Ƥ=0.197
Mortality in patients not fulfilling Q-SOFA Criteria (n=58)	5.2% (n=3)		Mortality in patients not fulfilling Q-SOFA Criteria (n=16)	25.0% (n=4)	
Total Mortality (n=90)	24.4% (n=22)		Total Mortality (n=40)	45.0% (n=18)	
Area under the Curve –(AUROC)	0.836	Ƥ<0.001	Area under the Curve – (AUROC)	0.662	Ƥ=0.166
Sensitivity	86.4%	At cut off, fulfilling QSOFA	Sensitivity	77.8%	At cut off, fulfilling QSOFA
Specificity	80.9%		Specificity	54.5%	
PPV	59.4%		PPV	58.3%	
NPV	5.20%		NPV	25%	
Diagnostic Accuracy	35.6%		Diagnostic Accuracy	60%	

4. Similar results were noted with NLR, with higher mortality rates in patients of Cirrhosis with NLR more than 5, where as in patients of ACLF no difference was noted amongst NLR sub groups (Table-4).

Table - 4. Prognostic utility of Neutrophil to Lymphocyte Ratio in Predicting acute (30 day) mortality

Decompensated Cirrhosis			**Acute-on-Chronic Liver failure**		
Mortality in patients with NLR < 2 (n=16)	00.0% (n=0)	X^2= 25.784 P value < 0 001	Mortality in patients with NLR < 2 (n=6)	0% (n=0)	X^2= 3.594 P value < 0 232
Mortality in patients with NLR 2-5 (n=52)	15.4% (n=8)		Mortality in patients with NLR 2-5(n=22)	45.5% (n=10)	
Mortality in patients with NLR > 5(22)	63.4% (n=14)		Mortality in patients with NLR >5(n=12)	66.7%) (n=16)	
Total Mortality (n=90)	24.4% (n=22)		Total Mortality (n=40)	45.0% (n=18)	
Area under the Curve – (AUROC)	0.802	Ƥ<0.001	Area under the Curve – (AUROC)	0.707	Ƥ<0.001
Sensitivity	63.6%	At cut off NLR>5	Sensitivity	100%	At cut off NLR 2-5
Specificity	88.2%		Specificity	27.3%	
PPV	63.6%		PPV	52.9%	
NPV	11.8%		NPV	0	
Diagnostic Accuracy	24.4%		Diagnostic Accuracy	85%	

5. A significantly higher mortality was seen in patients with C reactive protein more than 10 mg/dl amongst patients with cirrhosis and ACLF. However only 2 patients out of 40, amongst patients of ACLF had C reactive protein less than 10 mg/dl, and both patients succumbed (Table-5).

Table – 5. Prognostic utility of C -Reactive Protein in Predicting acute (30 day) mortality

Decompensated Cirrhosis			**Acute on Chronic Liver failure**		
Mortality in patients with C - reactive protein > 10mg/dl(n=40)	52.5%(n=21)	X^2= 30.685 Ƥ< 0.001	Mortality in patients with C - reactive protein > 10mg/dl(n=38)	42.1(n=16)	X^2= 30.685 Ƥ< 0.001
Mortality in patients with C - reactive protein < 10mg/dl(n=50)	2.0%(n=1)		Mortality in patients with C - reactive protein < 10mg/dl(n=2)	100%(n=2)	
Total Mortality (n=90)	24.4%(n=22)		Total Mortality (n=40)	45.0%(n=18)	
Area under the Curve –(AUROC)	0.838	Ƥ<0.001	Area under the Curve – (AUROC)	0.556	Ƥ= 0.423
Sensitivity	95.5%	At cut off , C reactive Protein > 10 mg/dl	Sensitivity	89%	At cut off , C reactive Protein > 10 mg/dl
Specificity	72.1%		Specificity	0.0%	
PPV	52.5%		PPV	42.1%	
NPV	2.00%		NPV	0%	
Diagnostic Accuracy	44.4%		Diagnostic Accuracy	40%	

6. A higher mortality was noted amongst patients with lower serum sodium levels amongst patients with Cirrhosis, however no significant difference was seen in patients with ACLF (Table-6).

Table - 6. Prognostic utility of Serum Sodium Levels in Predicting acute (30 day) mortality

Decompensated Cirrhosis			**Acute on Chronic Liver failure**		
Mortality in patients with Serum Sodium < 130 mMol/l (n=41)	39.0% (n=16)	X^2= 9.971 Ƥ=0.005	Mortality in patients with Serum Sodium < 130 mMol/l (n=24)	41.1% (n=10)	X^2= 0.971 Ƥ =0.025
Mortality in patients with Serum Sodium 130 to 135 mMol/l (n=30)	6.7% (n=2)		Mortality in patients with Serum Sodium 130 to 135 mMol/l (n=10)	50% (n=5)	
Mortality in patients with Serum Sodium > 135 mMol/l (n=19)	21.1% (n=4)		Mortality in patients with Serum Sodium > 135 mMol/l(n=6)	50% (n=3)	
Total Mortality (n=90)	24.4% (n=22)		Total Mortality (n=40)	45% (n=18)	
Area under the Curve – (AUROC)	0.652	Ƥ<0.001	Area under the Curve – (AUROC)	0.502	Ƥ=0.450

Decompensated Cirrhosis			**Acute on Chronic Liver failure**		
Sensitivity	72.7%	At cut off Serum Sodium levels less than 130 mMol/L	Sensitivity	27.3%	At cut off Serum Sodium levels less than 130 mMol/L
Specificity	63.2%		Specificity	54%	
PPV	39.0%		PPV	41%	
NPV	12.2%		NPV	72.9	
Diagnostic Accuracy	45.6%		Diagnostic Accuracy	21.2%	

1. Using MELD score, a higher MELD score was associated with higher mortality in both Cirrhosis and ACLF patients (Table-7).

Table - 7. Prognostic utility of MELD Score in predicting acute (30 day) mortality.

Decompensated Cirrhosis			**Acute on Chronic Liver failure**		
MELD score in mortality group (n=22)	Mean (19.64±6.63)	Students T test= 3.517 Ꝑ< 0.001	MELD score in mortality group (n=18)	Mean (34.89±7.11)	Students T test= 3.487 Ꝑ=0.004
MELD score amongst survivors (n=68)	Mean (14.24±4.95)		MELD score amongst survivors (n=22)	Mean (25.27±4.67)	
Total Mortality (n=90)	24.4%(n=22)		Total Mortality (n=40)	45%(n=18)	
Area under the Curve – (AUROC)	0.740	Ꝑ<0.001	Area under the Curve – (AUROC)	0.879	Ꝑ=0.0049
Sensitivity	63.6%	At cut off MELD score >17.5	Sensitivity	77.8%	At cut off MELD score >32.5
Specificity	75.0%		Specificity	90.9%	
PPV	45.2%		PPV	87.5%	
NPV	13.6%		NPV	16.7%	
Diagnostic Accuracy	34.4%		Diagnostic Accuracy	40%	

Table - 8. Prognostic markers in cirrhosis and their diagnostic performance

	SIRS	**QSOFA**	**Neutrophil to lymphocyte ratio >5**	**C - Reactive Protein levels more than 10 mg/dl**	**Serum Sodium Levels less than 130mMOL/L**	**MELD score >17.5**
AUROC	0.805	0.836	0.802	0.838	0.652	0.740
Sensitivity	77.3%	86.4%	63.6%	95.5%	72.7%	63.6%
Specificity	83.8%	80.9%	88.2%	72.1%	63.2%	75.0%
Diagnostic Accuracy	31.1	35.6	24.4%	44.4%	45.6%	34.4%

Table - 9. Prognostic markers in Acute-on-chronic liver failure and their diagnostic performance

	SIRS	**QSOFA**	**Neutrophil to lymphocyte ratio >5**	**C-Reactive Protein levels more than 10 mg/dl**	**Serum Sodium Levels less than 130mMOL/L**	**MELD score >32.5**
AUROC	0.606	0.662	0.707	0.556	0.502	0.879
Sensitivity	66.7%	77.8%	100%	89%	27.3%	77.8%
Specificity	54.5%	54.5%	27.3%	0.0%	54%	90.9%
Diagnostic Accuracy	55.0%	60%	85%	40%	21.2%	40%

Discussion

Amongst patients of cirrhosis the AUROC, sensitivity, and diagnostic accuracy of prognostic markers signify that the markers of inflammation such as SIRS, QSOFA, NLR > 5, C-reactive proteins more than 10 mg/dl have a higher AUROC than the MELD score, the highest being for C-reactive Protein levels. In terms of sensitivity where C-reactive protein had a highest sensitivity, followed by QSOFA, SIRS, Serum Sodium levels, whereas NLR and MELD had a low sensitivity to predict 30 day mortality. In terms of Specificity, NLR had the highest specificity, followed by SIRS, QSOFA, C-reactive Protein levels, MELD score and Serum Sodium Levels. Diagnostic accuracy in terms of identifying 30 day mortality the C-reactive Protein and serum sodium levels had highest accuracies, whereas NLR had the lowest.

The above results along with the significant difference between presentation during admission suggests that in patients with cirrhosis, 30 day mortality can be better predicted by presentation during admission with higher mortality amongst those presenting with hepatic encephalopathy or UGI bleed, and secondly by markers of inflammation such as C-reactive protein, QSOFA, NLR, SIRS, and serum sodium levels better than the MELD score.

In patients of acute-on-chronic liver failure the presenting complains during admission did not significantly predict mortality. In terms of prognostic markers the AUROC reveals that MELD score was better predictor of mortality at 30 days than the inflammatory markers and had a high specificity of 90.9%, and diagnostic accuracy of 40%. It may be stated that in patients of ACLF, as the acute component is common in all the patients and thus markers of inflammation are raised non-specifically all the patients, the mortality is better predicted by MELD score, rather than the inflammatory markers.

Conclusion

In patients of cirrhosis presenting features along with inflammatory markers are better prognostic indicators than the traditionally used MELD score. However, in patients of ACLF, where inflammatory markers are non-specifically increased, the MELD score appears to be the better prognostic marker for mortality.

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