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ORIGINAL ARTICLE

Assessment of Outcome During Hospital Stay in Patients with Decompensated Chronic Liver Disease with Sepsis Using PT-INR To Albumin Ratio (PTAR) Score in a Tertiary Care Hospital of Puducherry

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Abstract

Background: Decompensated chronic liver disease with sepsis is a life-threatening condition and associated with high mortality. Early risk stratification using reliable prognostic score is essential. So, this study aims to classify and assess the treatment outcome of Decompensated Chronic Liver Disease patients with sepsis based on PT-INR to Albumin ratio (PTAR) score. **Methods:** A Hospital based Observational study was conducted in a Government Tertiary care Hospital of Puducherry. A total sample size was calculated to be 107 and the participants those who fulfilled the eligibility criteria were included. On the day of admission PTAR score was calculated to classify the participants as Low risk (PTAR < 0.54), Medium risk (PTAR 0.54 to < 0.82) and High-risk (PTAR ≥ 0.82). Data was analysed using statistical software and chi-square test was applied to find the association between PTAR score and treatment outcome. **Results:** Around 108 participants were recruited and the mean age was 49.48 ± 11.28 (years). Majority of the participants were males 105 (97.2%). The treatment outcome status of the participants shows that 38 (35.2%) died and 70 (64.8%) survived on follow-up till the point of discharge. The classification of patients based on PTAR score shows that 36.1%, 35.2% and 28.7% were in high, medium and low risk category. The mean PTAR score of participants who survived was 0.68 ± 0.38 and those who died was 1.01 ± 0.48. **Conclusion:** PTAR was an accurate tool to predict the outcome status of the decompensated liver disease patients with sepsis. As the PTAR score increases proportionately the risk of mortality increases.

Keywords: Liver diseases, Sepsis, International Normalized Ratio

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Graphical Abstract

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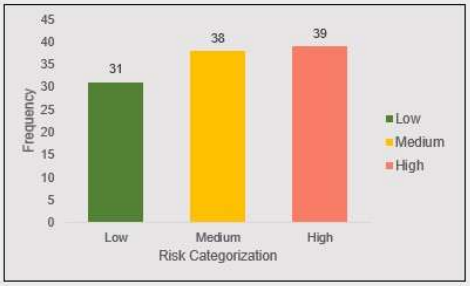
Results:
Proportion of the mortality reported in this study was 35.2%

Figure: Risk classification of Study Participants based on PTAR (N= 108)



Conclusion:
PTAR was an accurate tool to predict the outcome status of the decompensated liver disease patients with sepsis. As the PTAR score increases proportionately the risk of mortality increases.

Introduction

Decompensated liver disease, the advanced stage of chronic liver disease, poses a significant epidemiological burden globally [1]. This stage of liver disease is marked by the onset of serious complications such as ascites, hepatic encephalopathy, variceal bleeding, and jaundice, which lead to high morbidity and mortality rates [1]. According to the World Health Organization (WHO), chronic liver diseases and cirrhosis rank as major causes of death worldwide. Cirrhosis affects more than 100 million people globally [2]. Approximately 5-7% of patients with chronic liver disease develop decompensation annually [2], with the prevalence higher in regions with high rates of hepatitis B and C infections or alcohol consumption [3]. The incidence of decompensated liver disease is rising due to increasing rates of chronic liver conditions such as non-alcoholic fatty liver disease (NAFLD) and alcohol-related liver disease [4].

Sepsis is a life-threatening multiple-organ dysfunction caused by dysregulation of host response to severe infection [5]. In patients with cirrhosis and severe sepsis, high production of proinflammatory cytokines seems to play a role in the worsening of liver function and the development of organ/system failures such as shock, renal failure, acute lung injury or acute respiratory distress syndrome, coagulopathy, or hepatic encephalopathy [6]. Sepsis can develop as an intercurrent event in decompensated cirrhosis, leading to worsening of existing or new-onset decompensation, both of which can lead to

acute on chronic liver failure [6]. Such events increase in-hospital mortality and result in treatment futility even with the best supportive care.

Haruki et al in 2018, created an objective liver function scoring model named the prothrombin time-international normalized ratio (PT-INR) to albumin ratio (PTAR) [7]. Albumin is the most abundant plasma protein synthesized by the liver, crucial for maintaining oncotic pressure and serving various transport functions [8]. Hypoalbuminemia is a marker of poor prognosis in liver disease and sepsis. Clotting factors are synthesized in liver, its damage leads to prolonged PT/INR [8]. Sepsis can exacerbate coagulation abnormalities by causing disseminated intravascular coagulation (DIC) further prolonging PT/INR [9]. On integration of two critical aspects of liver function (clotting factor synthesis and albumin production) PTAR score offers a comprehensive prognostic indicator. A potentially valuable tool for assessing the liver function and predicting the mortality in patients with Decompensated Chronic Liver Disease with sepsis [7]. PTAR tool is an established tool and successfully applied in the condition of critically ill sepsis patients [10] and Hepatitis B associated decompensated liver disease patients to predict the mortality and prognosis [11]. But there are very few studies conducted in Indian setting to establish the significance of PTAR score in predicting the treatment outcome among decompensated chronic liver disease patients with sepsis. The evidence generated in this study will be helpful to identify the Decompensated Liver Disease patients with Sepsis at risk for mortality and plan the best course of action for preventing the mortality. The study objectives were to classify and assess the treatment outcome of Decompensated Chronic Liver Disease patients with sepsis based on PT-INR to Albumin ratio (PTAR) score.

Methodology

A Hospital based Observational study (Longitudinal study) was conducted between July 2022 to June 2024 in a Government Tertiary care Hospital of Puducherry. All the patients with decompensated chronic liver disease with presumed sepsis admitted in the medical wards of a tertiary care institute were considered for the study. Based on the findings by Sreeraj S et al the proportion of mortality in low risk PTAR score group was 14.3% (p) [12], considering 7% absolute precision (d), 5% alpha error, 10% non-response rate the final minimum sample size estimated by $N=Z_{1-\alpha/2}^2 \times p(1-p)/d^2$ (Cochran`s formula for single proportion) [13] was 107. Convenient sampling was used to recruit the participants. The inclusion criteria were participants of either gender diagnosed with Decompensated Liver Disease with presumed sepsis and those who score ≥ 2 in quick Sequential Organ Failure Assessment (qSOFA). The exclusion criteria were age less than 18years and greater than 90years, those with hospital stay of less than 24hours and patients on anti-coagulant therapy. Convenient sampling method was applied to select the 108 eligible participants for the study.

Written informed consent was obtained from the legally eligible relative and re-consent was taken from the patient on return of consciousness. qSOFA score [14] was calculated at the time of admission for all patients with Decompensated Chronic Liver Disease patients and presumed infection. The parameters of

qSOFA score are Respiratory rate ≥22/ min, change in mental status, systolic blood pressure ≤ 100 mm/Hg with each score of 1. Participants with a qSOFA score ≥ 2 was considered as sepsis and included in the study. qSOFA score was a validated tool with the accuracy of 73.3% and specificity of 81.1% [15]. A pre-tested, content validated semi-structured questionnaire was used to collect the demographic data, clinical data, laboratory parameters, investigation information's and outcome of the participant. On the day of admission, the Prothrombin time-Albumin Ratio (PTAR) score was calculated to classify the participants as Low risk group (PTAR < 0.54), Medium risk group (PTAR 0.54 to < 0.82) and High-risk group (PTAR ≥ 0.82). The participants were treated appropriately as per the European Association for the Study of the Liver (EASL) guidelines and followed up for their outcome (Discharged/ Expired) until their duration of stay in the hospital. Then outcome was assessed for different risk categories classified by PTAR score.

Data entry was made in MS EXCEL 2019 and analysed using IBM SPSS software version 21.0, Chicago, USA. Numerical variables were represented in Mean ± Standard deviation and categorical variable was represented in proportions. The Chi-square test/ fisher`s exact test was applied to find the association between PTAR score and treatment outcome, other factors. p Value less than 0.05 was considered as statistical significance.

Ethical clearance was obtained from the Institutional Ethical Committee before the start of the study (GHIEC/2022/149). Participants/ legally eligible relatives were informed about the study and written informed consent form was obtained. The confidentiality of the information collected was ensured by the principal investigator.

Results

Characteristics of the Study Participants:

Table 1. General Characteristics of Study Participants (N= 108)

Variable		**n (%)**
Age (in years)	≤ 45	44 (40.7)
	> 45	64 (59.3)
Gender	Male	105 (97.2)
	Female	3 (2.8)
Smoking Addiction	Present	7 (6.5)
	Absent	101 (93.5)
Alcohol Addiction	Present	103 (95.4)
	Absent	5 (4.6)
Glasgow Coma Scale score	15	47 (43.5)
	<15	61 (56.5)

Duration of hospital stay	<7 days	64 (59.3)
	≥ 7 days	44 (40.7)
Treatment Outcome Status	Discharged	70 (64.8)
	Expired	38 (35.2)

Around 108 participants were recruited based on the eligibility criteria. The mean age of the study participants was 49.48 ± 11.28 (years) with age distribution in the range of 26- 87 (years). The proportion of the participants more than 45 years were 64 (59.3%). Majority of the participants were males 105 (97.2%). The distribution of the addiction behaviour that includes smoking and alcohol among the study participants were 7 (6.5%) and 103 (95.4%) respectively. Of the 108 participants recruited 64 (59.3%) spent less than a week of hospital bed days. The mean duration of hospital stay was 6.33 (± 3.21) days with the range distribution of 2- 18 days. The treatment outcome status shows that around one-third of the participants 38 (35.2%) died and 70 (64.8%) were discharged alive (Table 1).

Figure 1, represents the symptomology of the study participants on the day of admission. Most of the participants had more than one symptom at presentation. Almost all the participants 108 (100%) had ascites. The second most common presenting symptom was breathing difficulty 69 (63.9%). This was followed by jaundice 67 (62%), altered sensorium 55 (50.9%) and dark urine 46 (42.6%). The least reported symptom was blood in stools. 3 (2.8%).

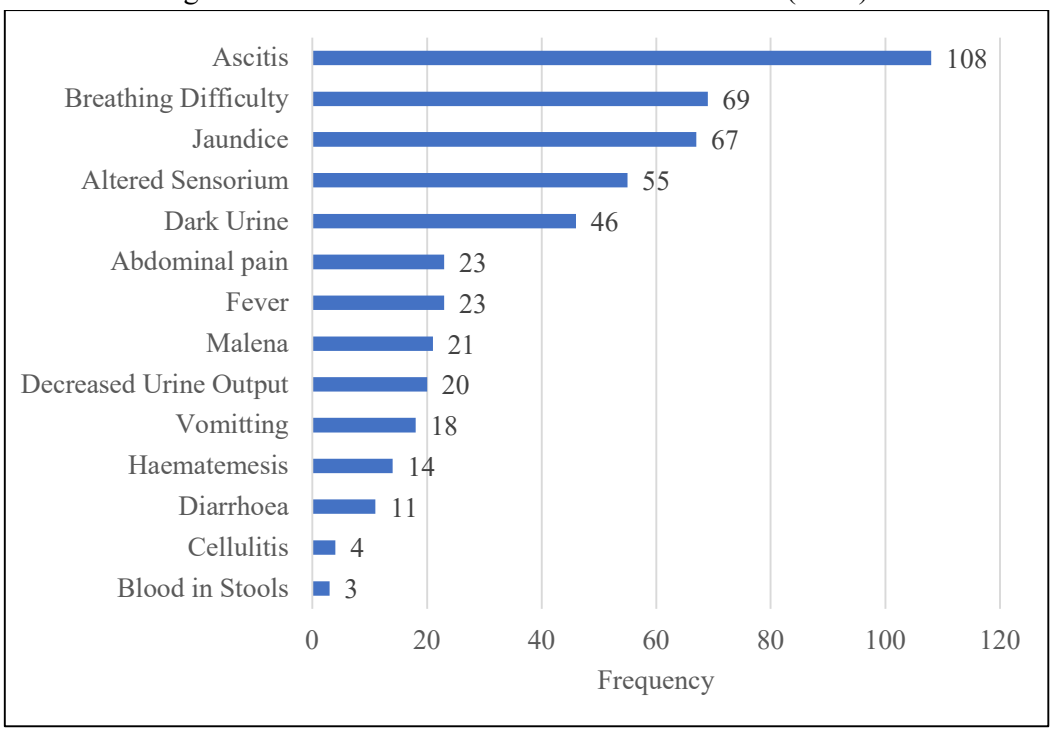


Figure 1. Distribution of Clinical Presentation at the Time of Admission (N=108). *Multiple responses type

Classification of patients based on PTAR

The quick Sequential Organ Failure Assessment (qSOFA) shows that majority of the participants 91 (84.26%) scored 2 and around 17 (15.74%) scored 3. The Prothrombin Time-INR to Albumin Ratio (PTAR) was used to risk categorize the study participants at the time of the admission and it shows that around one-third of the participants 39 (36.1%) and 38 (35.2%) were categorized as high risk and medium risk respectively and 31 (28.7%) of the participants were classified as low-risk group (Figure 2).

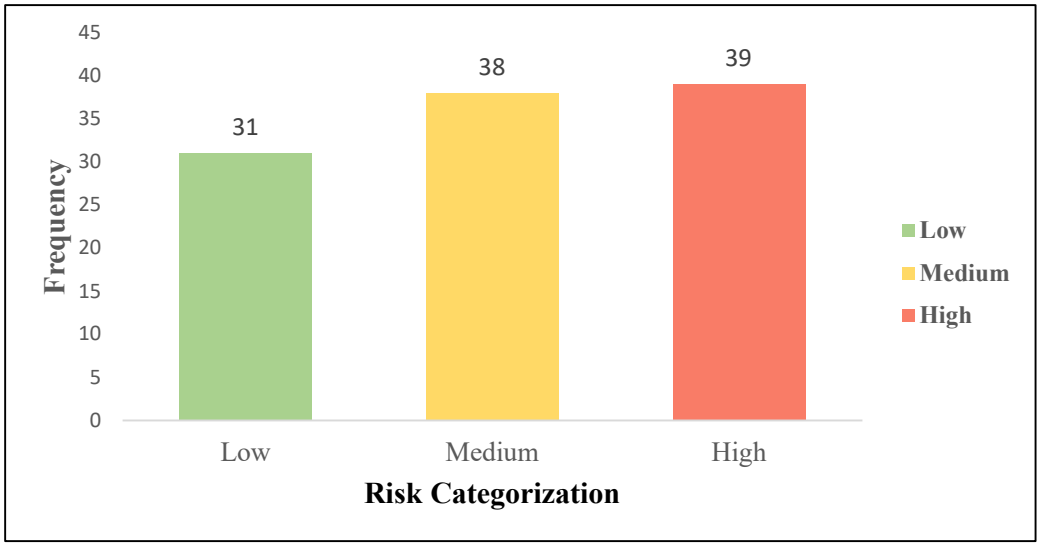


Figure 2. Risk classification of Study Participants based on PTAR (N=108)

Association between PTAR Risk Categorization and treatment outcome:

Table 2. Association between PTAR Risk Categorization and Treatment Outcome Status

Outcome Status	Expired	Discharged	**Chi-Square Value**	**p Value***
High Risk	24 (61.5)	15 (38.5)	18.59	0.000
Medium Risk	11 (28.9)	27 (71.1)		
Low Risk	3 (9.6)	28 (90.3)		

*Chi-Square test

The number of participants expired in the high-risk group was more than half 24 (61.5%) compared to only less than one-tenth 3 (9.7%) in the low-risk group. Vice versa, the proportion of participants discharged were 90.3% in the low-risk group compared to only 38.5% in the high-risk group based on PTAR score risk categorization. Among participants in the medium risk group also the proportion of

participants discharged were more than the expired (71.1% vs 28.9%). These differences were found to be statistically significant (p Value 0.000). [Table 2]

Factors associated with the unfavourable treatment outcome

Table 3 shows that the proportion of participants with treatment outcome status 'expired' was nearly doubled (26.6% to 47.7%) when it was compared between the participants duration of hospital stay of less than 7 days with participants of hospital stay more than or equal to 7 days. Also, the proportion of participants expired increases with decrease in Glasgow Coma Scale score (23.4% vs 44.3%). Duration of hospital stay and level of consciousness are associated with treatment outcome status and these association were also statistically significant. The other factors that include age, gender, smoking and alcohol addiction behaviour of the study participants has no association with the treatment outcome status. (p Value >0.05)

Table 3. Association between General Characteristics and Treatment Outcome (N=108)

Factor		**Expired**	**Discharged**	**p Value**
Age	> 45	22 (34.4)	42 (65.6)	0.832#
	≤ 45	16 (36.4)	28 (63.6)	
Gender	Male	37 (35.2)	68 (64.8)	1.000*
	Female	1 (33.3)	2 (66.7)	
Smoking Addiction	Present	5 (62.5)	3 (37.5)	0.126*
	Absent	33 (33.0)	67 (67.0)	
Alcohol Addiction	Present	37 (35.9)	66 (64.1)	0.467*
	Absent	1 (20.0)	4 (80.0)	
Duration of hospital stay	≥ 7 days	21 (47.7)	23 (52.3)	**0.024#**
	<7 days	17 (26.6)	47 (73.4)	
Level of Consciousness	GCS (<15)	27 (44.3)	34 (55.7)	**0.024#**
	GCS (15)	11 (23.4)	36 (76.6)	

*Fisher`s Exact test, # Chi-square test

Discussion

Total 108 participants of decompensated liver disease who scored more than or equal to 2 in qSOFA scoring and fulfilled the eligibility criteria were recruited for the study. PTAR score was applied to risk categorize the patients and discharge status of all the participants were recorded. It was found 31 (28.7%) were in low risk, 38 (35.2%) in medium risk and 39

(36.1%) in high-risk group. The proportion of mortality observed among the study participants were 38 (35.18%) of which 24 (61.5%) were in high risk, 11 (28.9%) in medium risk and 3 (9.6%) in low-risk group.

The mean age of the participants reported to the hospital with decompensated liver disease was 49.28 ± 11.28 years. A study conducted in a tertiary care hospital of Nepal by Bhattarai et al. [16] by recruiting 754 decompensated cirrhotic patients also showed that the mean age of decompensated cirrhosis was 54 ± 11.51 years. Studies from Indian region of Kolkata (2014) and Assam (2016) by Ray et al. [17] and Bhattacharyya et al. [18] also revealed that the mean age of decompensated liver disease admitted in a tertiary care hospital is near to our findings of 48.4 years and 45.8±10.45 respectively. Decompensated liver disease typically manifests in middle age due to the cumulative effects of various risk factors that includes hepatitis virus infection, alcohol, and the progression of liver damage over time [19]. The comorbidities also play a key role such as diabetes, hypertension, and cardiovascular diseases, which can exacerbate liver damage and contribute to decompensation [19].

Our study findings reflect that incidence of decompensated liver disease is higher in male group (97.2%) compared to the female. This is well known and does not appear to be changing with years. This might be because of the variation in distribution of most common risk factor 'alcohol addiction' for decompensated liver disease between the gender. This fact was supported by the evidence from national wide survey (National Family Health Survey- 5) [20], of India that men aged 15 years and above who consume alcohol was 18.8% compared to the women aged 15 years and above who consumed alcohol was 1.3%.

The proportion of total mortality reported in this study was 35.2% on following 108 participants to the point of outcome (discharge/ expired). On comparison a similar proportion 35.4% was observed in a hospital-based study by Sreeraj et al. [12] among the participants of cirrhosis of liver with sepsis.

The PTAR score has been investigated for its prognostic value in patients with decompensated liver disease. In our study the mean PTAR score of participants who survived was 0.68 ± 0.38 and those who died at the end of treatment was 1.01 ± 0.48. On comparison, the study by Zhang et al. [21] (2022) in the China among HBV associated decompensated cirrhosis indicates the mean PTAR score for those who died was 0.58 (0.42-0.77) compared to those survived 0.45 (0.37-0.58). Similarly in the same geographical region another study by Cai er al. [11] in 2021 indicate the mean PTAR score among those who died was 0.62 (0.55- 0.82) higher than those who survived 0.43 (0.35-0.54). These evidences suggest that a higher PTAR score is associated with worse prognosis and higher mortality rates [11,21].

The mortality rate observed across different risk categories based on PTAR score was 61.5%, 28.9% and 9.6% among high risk, medium risk and low risk group respectively. This data indicates that the proportion of mortality was higher in high risk and gradually steps down as the category becomes medium and low risk. On comparison with the study by Sreeraj et al. [12] shows that mortality rate was 76.93%, 23.08% and 14.29% among the high risk, medium and low risk category respectively.

This trend was similar to our findings. The strengths of our study were first of this kind in South Indian population and it is a prospective study. The limitations are lack of dynamic observation of PTAR score progressively during the hospital stay, a single-centre hospital-based study and influence of comorbidities like diabetes, immunocompromised conditions in the outcome were not studied.

Conclusion

The proportion of mortality reported among decompensated liver disease patients with sepsis in our study was 35.1%. The risk of mortality increases with increase in PTAR score that is participants those classified as high-risk. The factors associated with unfavourable treatment outcome are longer duration of hospital stay and decreased level of consciousness. To conclude the PTAR was an accurate tool to predict the outcome status of the decompensated liver disease patients with sepsis. It is easily calculated and could help the physicians in early identifications of patients with high risk of mortality and plan an appropriate aggressive management

Ethical Approval

Ethical clearance was obtained from the Institutional Ethical Committee before the start of the study (GHIEC/2022/149).

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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