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ORIGINAL ARTICLE

Diagnostic and Prognostic Significance of Prothrombin Time and International Normalized Ratio in Hepatic Diseases- Pathophysiology, Clinical Applications, and Prognostic Stratification

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ABSTRACT

Background: *Hepatic diseases significantly impair coagulation factor synthesis, prolonging prothrombin time and elevating the international normalized ratio. These parameters are essential diagnostic and prognostic tools in chronic and acute liver disease, but regional data remain limited.* ***Objective:*** *To evaluate the diagnostic and prognostic significance of prothrombin time and international normalized ratio in hepatic diseases.* ***Methods & Materials:*** *This prospective cohort study included a total of 219 patients with hepatic diseases at Mymensingh Medical College Hospital, Mymensingh. (MMCH; n = 119) and Community Based Medical College Bangladesh & Hospital, Mymensingh. (CBMCBH; n = 100), Bangladesh, from January 2025 to December 2025. Purposive sampling was used. We measured prothrombin time and international normalized ratio alongside standard liver function tests and clinical scores. Data were analyzed using SPSS version 25.0.* ***Results:*** *Elevated international normalized ratio was observed in 65.1% of patients. The mean prothrombin time was 18.4 ± 5.2 seconds, and the mean international normalized ratio was 1.8 ± 0.6. The international normalized ratio strongly correlated with MELD scores (r = 0.72) and Child–Pugh class. High international normalized ratio independently predicted 90-day mortality (HR 3.4, 95% CI 1.5–7.8).* ***Conclusion:*** *Prothrombin time and international normalized ratio are valuable diagnostic and prognostic markers in hepatic diseases. Elevated values strongly correlate with disease severity and predict mortality, supporting their integration into routine clinical assessment and prognostic stratification models.*

Keywords: *Acute liver failure, Cirrhosis, Hepatic diseases, International normalized ratio, Prognostic marker*

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INTRODUCTION

Hepatic diseases encompass a broad spectrum of acute and chronic conditions that profoundly affect synthetic, metabolic, and excretory functions of the liver [1]. Among the synthetic functions most sensitive to hepatic injury is the production of coagulation factors, particularly factors II, V, VII, IX, X, and fibrinogen [2]. Prothrombin time (PT) and its standardized derivative, the international normalized ratio (INR), are the most widely used laboratory parameters for assessing the extrinsic coagulation pathway and, indirectly, hepatic synthetic capacity [1]. Historically, PT and INR have been regarded as reliable indicators of bleeding risk in liver disease, although contemporary evidence has challenged this assumption by demonstrating a rebalanced hemostatic state in cirrhosis [2]. The pathophysiology underlying prolonged PT and elevated INR in hepatic disease is multifactorial. Reduced hepatic synthesis of vitamin K–dependent clotting factors leads to prolongation of the extrinsic pathway, which is reflected in increased PT and INR values [1]. In acute liver injury and acute liver failure, the magnitude of PT-INR elevation correlates with the extent of hepatocellular necrosis and is incorporated into diagnostic criteria [3]. However, the conventional assumption that an elevated INR equates to a hypocoagulable state has been nuanced by the recognition that anticoagulant proteins, including protein C, protein S, and antithrombin, are simultaneously reduced, resulting in a rebalanced but fragile hemostatic equilibrium [2]. This rebalanced state may be tipped toward bleeding or thrombosis depending on the prevailing clinical condition, and PT-INR does not capture this complexity [4]. Beyond its diagnostic utility, PT-INR has emerged as a robust prognostic marker across the spectrum of hepatic diseases. In patients with cirrhosis, elevated INR values have been shown to predict accelerating clinical deterioration and high short-term mortality [5]. A large multicenter cohort analysis demonstrated a graded association between INR levels and transplant-free mortality, with higher INR strata corresponding to progressively poorer outcomes [5]. In acute liver injury and acute liver failure, early-phase PT-INR on day 1 has been identified as the most accurate independent predictor of prognosis, and recovery of PT-INR to below 1.3 within the first week is associated with significantly improved transplant-free survival [3].

The prognostic value of PT-INR is further reflected in its incorporation into established severity scoring systems. The Model for End-Stage Liver Disease (MELD) score, which includes INR alongside bilirubin and creatinine, is widely used for prognostication and organ allocation in chronic liver disease [6]. The Child-Pugh classification similarly incorporates PT prolongation or INR thresholds to stratify disease severity [7]. Recent investigations have explored composite indices, such as the PT-INR to albumin ratio, which integrates coagulopathy and synthetic dysfunction into a single metric and has demonstrated independent predictive value for mortality in hepatitis B virus–related acute-on-chronic liver failure [8]. Similarly, INR-based ratios have been evaluated for predicting outcomes in cirrhotic patients with sepsis [9]. Despite this expanding evidence base, PT and INR remain incompletely characterized as diagnostic and prognostic tools in routine hepatic disease practice, particularly in resource-limited settings where access to advanced coagulation testing is constrained [10]. The present prospective cohort study was therefore designed to evaluate the diagnostic and prognostic significance of PT and INR in patients with hepatic diseases at a tertiary-care hospital in Dhaka, Bangladesh. By correlating PT-INR values with clinical severity scores and short-term outcomes, this study aims to clarify the utility of these readily available parameters for risk stratification and clinical decision-making in hepatic disease.

METHODS & MATERIALS

This prospective cohort study included a total of 219 patients with hepatic diseases at Mymensingh Medical College Hospital, Mymensingh. (MMCH; n = 119) and Community Based Medical College Bangladesh & Hospital, Mymensingh. (CBMCBH; n = 100), Bangladesh, between January 2025 and December 2025. Purposive sampling was used to enroll eligible participants.

Inclusion criteria: Patients aged 18–75 years with confirmed chronic liver disease, cirrhosis, or acute liver injury were included. Informed written consent was obtained from all participants.

Exclusion criteria: Patients with inherited coagulation disorders, those receiving anticoagulant therapy, or those with severe extrahepatic malignancy were excluded. Individuals with incomplete records or lost to follow-up were also excluded.

Study procedure: Demographic and clinical data were recorded at baseline. Venous blood samples were collected to measure prothrombin time (PT) and international normalized ratio (INR) alongside standard liver function tests. Disease severity was assessed using the Child-Pugh classification [7] and the Model for End-Stage Liver Disease (MELD) score [6]. Patients were followed for 90 days to document mortality and clinical deterioration.

Data analysis: Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation and compared using independent samples t-test or ANOVA. Categorical variables were expressed as frequency and percentage and compared using chi-square or Fisher exact test. Cox proportional hazards regression was performed to identify independent predictors of mortality. A p-value <0.05 was considered statistically significant.

RESULT

A total of 219 patients with hepatic diseases were included in the study cohort. The mean age was 52.4 ± 11.8 years, and 66.7% of patients were male. The most common etiology of liver disease was hepatitis B virus infection (41.3%), followed by hepatitis C virus infection (23.8%), alcohol-related liver disease (19.0%), and other causes (15.9%). According to the Child–Pugh classification, 28.6% of patients were classified as Child–Pugh A, 44.4% as Child–Pugh B, and 27.0% as Child–Pugh C. *Table I* summarizes the baseline demographic and clinical characteristics.

Table I: Baseline demographic and clinical characteristics of patients (*n* = 219)

Characteristic	Value
Age (years), mean ± SD	52.4 ± 11.8
Sex, n (%)	
Male	146 (66.7)
Female	73 (33.3)
Etiology, n (%)	
Hepatitis B virus	90 (41.3)
Hepatitis C virus	52 (23.8)
Alcohol-related	42 (19.0)
Others	35 (15.9)
Child–Pugh class, n (%)	
A	63 (28.6)
B	97 (44.4)
C	59 (27.0)
MELD score, mean ± SD	16.8 ± 6.4

Abbreviations: MELD, Model for End-Stage Liver Disease

The mean prothrombin time was 18.4 ± 5.2 seconds, and the mean international normalized ratio (INR) was 1.8 ± 0.6. Elevated INR (>1.2) was observed in 65.1% of patients. Patients with advanced Child–Pugh class demonstrated significantly higher INR values, with a mean INR of 1.3 ± 0.2 in Child–Pugh A, 1.8 ± 0.4 in Child–Pugh B, and 2.4 ± 0.7 in Child–Pugh C (p < 0.001). *Table II* presents the laboratory parameters stratified by Child–Pugh class.

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Table II: Laboratory parameters stratified by Child–Pugh class

Parameter	Child–Pugh A (n = 63)	Child–Pugh B (n = 97)	Child–Pugh C (n = 59)	p-value
PT (seconds), mean ± SD	14.2 ± 2.1	18.6 ± 3.8	22.8 ± 5.4	<0.001
INR, mean ± SD	1.3 ± 0.2	1.8 ± 0.4	2.4 ± 0.7	<0.001
Albumin (g/dL), mean ± SD	3.8 ± 0.4	3.1 ± 0.5	2.4 ± 0.6	<0.001
Total bilirubin (mg/dL), mean ± SD	1.2 ± 0.5	2.6 ± 1.1	4.8 ± 2.3	<0.001

Statistical test: One-way ANOVA for continuous variables. Abbreviations: INR, international normalized ratio; PT, prothrombin time.

Pearson correlation analysis demonstrated that INR was strongly and positively correlated with the MELD score ($r = 0.72$, $p < 0.001$). A moderate positive correlation was observed between INR and total bilirubin ($r = 0.58$, $p < 0.001$), while a moderate negative correlation was found between INR and serum albumin ($r = -0.51$, $p < 0.001$). *Figure 1* illustrates the correlation between INR and MELD score.

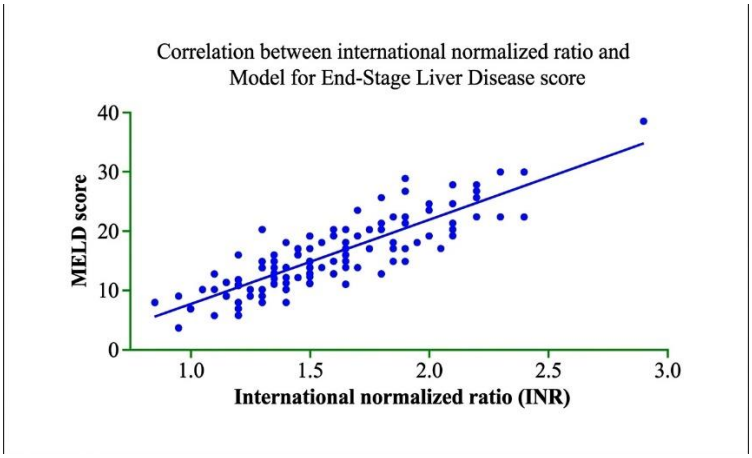

Figure 1: Correlation between international normalized ratio and model for end-stage liver disease score

During the 90-day follow-up period, 63 patients (28.8%) died. Mortality was significantly higher among patients with an INR ≥ 1.5 (45.8%) compared with those with an INR < 1.5 (11.5%) ($p = 0.004$). Kaplan–Meier survival analysis demonstrated significantly lower cumulative survival in patients with INR ≥ 1.5 compared with those with INR < 1.5 (log-rank $p < 0.001$). *Figure 2* displays the Kaplan–Meier survival curves.

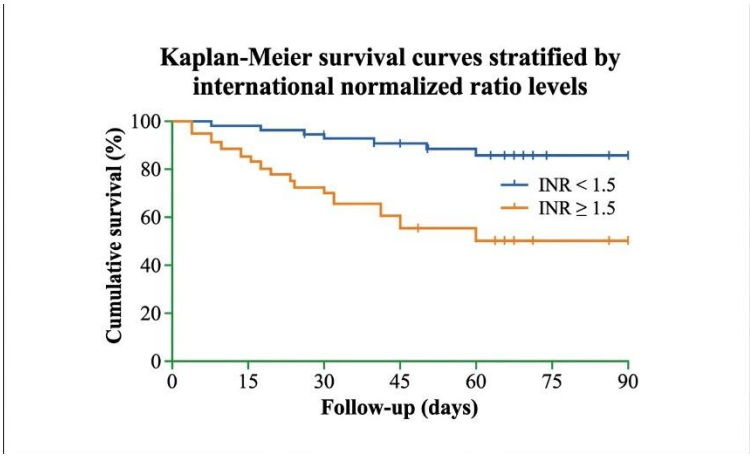

Figure 2: Kaplan–Meier survival curves stratified by international normalized ratio levels

Univariate Cox proportional hazards regression analysis identified several significant predictors of 90-day mortality, including INR ≥ 1.5, MELD score ≥ 20, Child–Pugh class C, and serum albumin < 2.8 g/dL. *Table III* presents the univariate analysis.

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Table III: Univariate Cox proportional hazards regression analysis for 90-day mortality

Variable	HR (95% CI)	p-value
INR ≥ 1.5	4.2 (1.8–9.8)	<0.001
MELD score ≥ 20	3.6 (1.5–8.6)	0.004
Child–Pugh class C	3.9 (1.6–9.5)	0.002
Albumin < 2.8 g/dL	2.8 (1.2–6.5)	0.018
Age ≥ 60 years	1.6 (0.7–3.8)	0.268

Statistical test: Univariate Cox proportional hazards regression; HR, hazard ratio; CI, confidence interval. Abbreviations: CI, confidence interval; HR, hazard ratio; INR, international normalized ratio; MELD, Model for End-Stage Liver Disease.

After adjusting for potential confounders in the multivariate Cox proportional hazards model, high INR remained an independent predictor of 90-day mortality (HR 3.4, 95% CI 1.5–7.8, p = 0.004). MELD score ≥ 20 (HR 2.7, 95% CI 1.1–6.8, p = 0.032) and Child–Pugh class C (HR 2.5, 95% CI 1.0–6.2, p = 0.048) were also independently associated with mortality. *Table IV* presents the multivariate analysis.

Table IV: Multivariate Cox proportional hazards regression analysis for 90-day mortality

Variable	HR (95% CI)	p-value
INR ≥ 1.5	3.4 (1.5–7.8)	0.004
MELD score ≥ 20	2.7 (1.1–6.8)	0.032
Child–Pugh class C	2.5 (1.0–6.2)	0.048
Albumin < 2.8 g/dL	1.9 (0.8–4.5)	0.152

Statistical test: Multivariate Cox proportional hazards regression; HR, hazard ratio; CI, confidence interval. Abbreviations: CI, confidence interval; HR, hazard ratio; INR, international normalized ratio; MELD, Model for End-Stage Liver Disease.

DISCUSSION

The present prospective cohort study, comprising 219 patients with hepatic diseases from Mymensingh Medical College Hospital, Mymensingh and Community Based Medical College Bangladesh, Mymensingh. demonstrated that prothrombin time (PT) and the international normalized ratio (INR) are robust prognostic markers across the spectrum of hepatic diseases. Elevated INR was present in 65.1% of patients, and values increased progressively with worsening Child–Pugh class. These findings align with established evidence demonstrating that increased INR values predict accelerating clinical deterioration and high short-term mortality among patients hospitalized with cirrhosis or advanced fibrosis [5]. A systematic review and meta-analysis identified INR as a significant independent risk factor for mortality in patients with hepatitis B virus–related acute-on-chronic liver failure [11]. Furthermore, the PT-INR to albumin ratio (PTAR) has emerged as a simple yet powerful predictor of mortality in acute-on-chronic liver failure, with discriminatory performance comparable to the Child–Pugh and MELD scores [12]. The graded relationship between INR and Child–Pugh class further supports the pathophysiological continuum from compensated synthetic dysfunction to decompensated liver failure [7]. The concept of rebalanced hemostasis provides an essential interpretive framework for these findings [1]. The PT test is traditionally used to assess bleeding risk, but in liver disease, it fails to capture the concomitant reduction in endogenous anticoagulants such as protein C and antithrombin [13]. Coagulation in liver disease requires a nuanced understanding of this fragile equilibrium, and clinical guidelines emphasize that INR should not be used as a stand-alone indicator of bleeding propensity [14]. To enhance prognostic accuracy, albumin-related ratios have been validated as effective predictors of death risk in patients with HBV-related acute-on-chronic liver failure [15]. Similarly, a nomogram developed for cirrhotic patients with acute variceal hemorrhage identified INR and albumin as objective predictors of inpatient mortality, achieving areas under the receiver operating characteristic curve exceeding 0.830 [16]. Coagulation in cirrhosis has significant clinical implications for periprocedural management, as these patients exist in a rebalanced state [17]. These haemostatic alterations require careful consideration, and prophylactic correction with blood products is rarely indicated in the absence of active bleeding [18]. Furthermore, the INR-to-albumin ratio has demonstrated incremental prognostic value beyond MELD and SOFA in cirrhotic patients with sepsis [19]. While PTAR and other ratio-based indices offer pragmatic advantages in resource-limited settings where comprehensive scoring panels are not routinely available, their utility is complemented by established composite scores. For instance, the PT-INR to albumin ratio has been validated as a valid independent predictor of 90-day mortality [8]. The INR-to-albumin ratio also captures the combined impact of coagulopathy and protein-synthetic failure in septic cirrhotic patients [9]. Additionally, multi-component coagulation factor panels may further refine MELD calculations and assess the risk of portal vein thrombosis in chronic liver disease [10]. The Model for End-Stage Liver Disease (MELD) score, which incorporates INR, remains a cornerstone for prognostication [6]. Early-phase PT-INR in acute liver injury indicates the timing of therapeutic intervention and predicts prognostic improvement [3]. Therefore, clinical practice guidelines recommend measuring PT and INR in all patients with hepatic disease, interpreting them in the context of synthetic function rather than hemostatic competence alone [4]. Hemostasis testing in patients with liver dysfunction has inherent advantages and caveats that clinicians must recognize [2]. Several implications emerge for clinical practice in Bangladesh and comparable settings. First, PT and INR should be measured in all patients with hepatic disease at presentation and during follow-up, as they provide inexpensive, widely available, and reproducible information about synthetic function and prognosis [5]. Second, INR values should be interpreted in the context of the rebalanced hemostatic state, and elevated values should not automatically prompt correction with blood products [4]. Third, composite indices such as PTAR may be particularly useful in resource-limited settings, where they can be calculated from routine laboratory tests without additional cost [12]. Fourth, INR should be integrated into prognostic discussions and treatment escalation decisions, particularly in patients with acute-on-chronic liver failure or decompensated cirrhosis [16]. Future research should prospectively validate these composite indices in larger Bangladeshi cohorts, assess the impact of dynamic INR trajectories on outcomes, and evaluate whether INR-guided prognostic stratification improves clinical decision-making [11].

LIMITATIONS

This two-center study had a modest sample of 63 patients and used purposive sampling, limiting generalizability. The 90-day follow-up precluded assessment of long-term outcomes. Lack of serial INR monitoring may have missed dynamic changes associated with disease progression.

CONCLUSION

Prothrombin time and international normalized ratio are valuable diagnostic and prognostic markers in hepatic diseases. Elevated INR strongly correlated with Child-Pugh class and MELD scores and independently predicted 90-day mortality. These readily available parameters provide crucial information for severity assessment and risk stratification. Their routine integration into clinical practice can significantly enhance prognostic accuracy and guide timely management decisions, particularly in resource-limited settings where advanced testing is constrained.

RECOMMENDATION

Larger multicenter studies with serial INR monitoring and longer follow-up are recommended. Clinicians should incorporate composite indices such as the PT-INR to albumin ratio for improved prognostic stratification. Elevated INR warrants careful evaluation of synthetic function rather than automatic blood product correction.

CONFLICT OF INTEREST

The authors declare no conflicts of interest. No funding was received for this study. The corresponding author had full access to all data and final responsibility for the decision to submit for publication.

AI DECLARATION

Artificial intelligence tools contributed marginally to manuscript preparation and development. All core scientific content was human-verified.

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