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Original Article

Correlation of Relation of Serum Prolactin Level to Child-Pugh Score in Cirrhosis of Liver in Assessing Disease Severity

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Child-Pugh score
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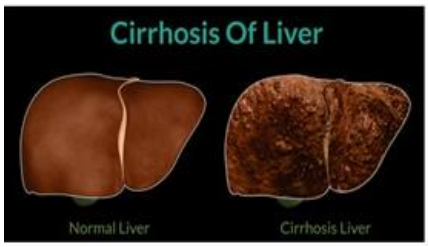
ABSTRACT

Aim: To find the accuracy of prolactin levels and identify the severity and complications.
Materials & Methods: This was a cross-sectional study performed in the Department of Medicine at Sri R.L. Jalappa Hospital and Research Centre.
Participants: The study involves participants who are diagnosed with liver cirrhosis of age above 18 years. Participants with other health complications were excluded from the study.
Interventions: Child pugh scores were compared with serum prolactin levels and the predictive value of serum prolactin was assessed. In the 69 subjects studied mean age was 50.93±8.84 the study population, with the majority of them being males (85.51%) and females 14.49%. The difference in serum prolactin between Child-Pugh scores was statistically significant (P value - < 0.001).
Results: The present study found a significant (P <0.001) higher median prolactin levels in grade 4 hepatic encephalopathy compared to grade 3, 2, and grade 1 (grade 4- 66.00(61.5 to 71.5), grade 3- 47.00(42.0 to 54.0), grade 2-43.00(39.25 to 50.5) and grade 1-40.50(31.25 to 48.25), whereas in cirrhosis cases without hepatic encephalopathy, we found significantly lesser prolactin levels (median- 27.00(range 25.0 to 33.0) compared to cases present with hepatic encephalopathy. The serum prolactin had a sensitivity of 82.61% specificity was 73.91% and diagnostic accuracy was 76.81% in predicting severe child pugh score.
Conclusions: There was a higher frequency of cirrhosis complications in patients who had higher blood prolactin levels at admission. Hence, serum prolactin can be considered as a low-cost, biomarker for liver cirrhosis.

GRAPHICAL ABSTRACT



Child-Pugh Score

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Introduction

India contributed to 18.3% of the two million global liver disease deaths reported in 2015 [1]. In the last four decades, the burden of mortality due to liver cirrhosis is progressively increasing in India due to cultural lifestyle transitions, increased alcohol consumption, a fatty diet, and a lack of exercise [2]. In 2016, chronic liver diseases and cirrhosis accounted for 2.1% of all deaths, and alcohol and viral hepatitis were the two major causes of liver cirrhosis. Alcohol consumption in India doubled between 2005 and 2016 [3]. Globally, cirrhosis is the eleventh leading cause of death. The global burden has been estimated to be 20.7/100,000 in 2015, which is a 13% increase since 2000 [4]. Cirrhosis incidence has increased in Europe and Asia from 2000 to 2015 and has been reduced in some countries, like Japan, due to vaccinations and successful treatment for liver infections. However, its incidence is increasing in other parts of the world due to increased obesity, comorbidities, and alcohol intake [5]. Alcoholic males over the age of 50 with comorbidities like diabetes are at a higher risk of developing cirrhosis. The leading causes around the world were found to be hepatitis C infection and increased alcohol intake, whereas in developing countries, cirrhosis is mainly caused by hepatitis B virus infection. The initial stages of cirrhosis are asymptomatic, making early diagnosis and assessment difficult. The disorder is widely undiagnosed until it becomes complicated which leaves liver transplantation as the only treatment option [6]. Late diagnosis is considered as the main reason for mortality associated with liver cirrhosis. Portal hypertension is considered the main culprit leading to advanced cirrhosis [7]. Adding to the high risk of mortality, it also causes increased healthcare costs due to hospitalization and reduced quality of life [8]. A biopsy is usually considered the gold standard for the diagnosis and staging of cirrhosis. However, biopsy can have sampling errors, high interobserver variability, leading to 33 to 50% diagnostic errors in cirrhosis due to heterogeneity [9]. Liver biopsy has many other disadvantages, including its invasive and painful nature, post-procedure complications, and high cost [10]. Imaging modalities like ultrasonography were considered useful in detecting the morphological characteristics of liver cirrhosis, but they may appear completely normal without any morphological changes [11]. Ultrasonography can diagnose cirrhosis, but its specificity is not 100%. Among non-invasive diagnostic and grading tests for liver cirrhosis, the Child-Pugh scoring system is used for the prediction of mortality. This scoring system requires the assessment of many parameters and has certain limitations. The scoring system has only ten different scores, which does not grade the severity of cirrhosis accurately. The prothrombin time, which is one of the parameters of the Child-Pugh scoring system, varies greatly in testing [12]. The liver is a major organ involved in metabolism, detoxification, and protein synthesis [13]. The production of prolactin hormone by the pituitary gland is controlled by dopamine [14]. Decreased dopamine levels stimulate the pituitary gland and increase the prolactin levels [15]. The increased circulating estrogen owing to reduced excretion by the liver itself has an inhibitory effect on dopamine secretion, thereby stimulating prolactin secretion [13]. Liver dysfunction leads to an increase in circulating concentrations of aromatic amino acids which increase the synthesis of false neurotransmitters like octopamine and phenylethanolamine [14]. These neurotransmitters inhibit dopamine release, leading to increased production of prolactin [16]. Based on the above facts, this study aims to correlate prolactin levels with Child-Pugh's class in assessing the severity of cirrhosis. This will establish the efficacy of serum prolactin levels in assessing severity at an early stage, facilitating easy diagnosis and treatment.

Materials and Methods

This was a cross-sectional study conducted in the Department of Medicine, R.L. Jalappa Hospital and Research Centre, Tamaka, Kolar. Patients over the age range of 18 years old, diagnosed with cirrhosis of the liver were included in the study. Patients with cranial surgery, pituitary or hypothalamic disease, chronic renal failure,

seizure disorders, and chest wall trauma were excluded from the study. The sample size was calculated using G*Power Software version 3.1.9.7 and it came to be 69 subjects. Patients fulfilling inclusion criteria were considered and informed written consent was obtained from all the subjects. All the patients were examined carefully, and investigations like CBC, RFT, serum electrolytes, serum prolactin levels, LFT, urine routine, HCV, HBsAg, PT/apTT/INR, and USG abdomen were performed.

Statistical analysis

Descriptive analysis was carried out for quantitative variables, frequency, and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagrams, pie diagrams, and cluster bar charts. For non-normally distributed quantitative parameters, medians and interquartile range (IQR) were compared between study groups using the Mann-Whitney U test (2 groups). For non-normally distributed quantitative parameters, medians and interquartile range (IQR) were compared between study groups using the Kruskal Wallis Test (P-value) (>2 groups). The Chi-square test was used for the comparison of the two groups. The utility of serum prolactin in predicting the severity of the Child-Pugh Score was assessed by receiver operative curve (ROC) analysis. The area under the ROC curve along with its 95% CI and P-value are presented. Based on the ROC analysis, it was decided to consider 39.5 as the cut-off value. The sensitivity, specificity, predictive values, and diagnostic accuracy of the screening test with the decided cut-off values along with their 95% CI were presented. A P-value of <0.05 was considered statistically significant.

Results and Discussion

In our study, the minimum age is 33 and the maximum age is 66 years. 59 (85.51%) participants were male, and the remaining 10 (14.49%) participants were female. Among the study population, 18 (26.09%) participants had mild ascites, followed by moderate 13 (18.84%) and severe 7 (10.14%). Among the study population, 46 (66.67%) participants had an etiology of alcohol, 7 (10.14%) had Nash, and 16 (23.19%) had viral etiology. The bilirubin levels ranged from 2.90 to 12 (95% Confidence Interval (CI) 4.47 to 5.45). The albumin (g/dl) ranges between 1.70 g/dl and 5.20 g/dl (95% CI 3.08 to 3.48). The prothrombin time (sec), ranges between 11 sec and 30 sec (95% CI 17.93 to 20.24). The international normalized ratio ranges between 1 and 3.40 (95% CI 1.72 to 1.95). Among the study population, class A, B, and C all the child-Pugh scores were with an equal distribution of 23 (33.33%) each. Among the study population, 10 (14.49%) participants had hepatic encephalopathy grades 1, 6 (8.70%) had grade 2, 13 (18.84%) had grade 3, and 7 (10.14%) had grade 4. The prolactin minimum level was 22 and the maximum level was 77 (95% CI 36.40 to 42.99). The mean child Pugh score was 8.74±3.11 ranging between 5 to 15 (95% CI 8.01 to 9.47).

In this study, 7 (10.14%) participants had varices, and 7 (10.14%) participants had spontaneous bacterial peritonitis

The median prolactin of mild samples was 43.50 (40.0 to 48.75), it was 52.00 (40.0 to 58.0) in moderate, it was 58.00 (44.0 to 68.5) in severe, and it was 27.00(25.0 to 30.0) in absent of ascites. The median difference of prolactin across ascites was statistically significant with a P-value of <0.001 (Table 1).

The median prolactin of hepatic encephalopathy grade 1 samples was 40.50 (31.25 to 48.25), 43.00 (39.25 to 50.5) in grade 2, 47.00 (42.0 to 54.0) in grade 3, 66.00 (61.5 to 71.5) in grade 4, and 27.00 (25.0 to 33.0) in absent hepatic encephalopathy grade. The median difference in prolactin across hepatic encephalopathy grades was statistically significant with a P-value <0.001 (Table 2). The median prolactin was 46.00 (44.0 to 50.0) in varices and 35.00 (27.0 to 46.75) in no varices. The median difference of prolactin between varices was statistically significant with a P-value of 0.0108. The median prolactin was 46.00 (39.5 to 64.5) in spontaneous bacterial peritonitis and 36.00 (27.0 to 46.75) in no spontaneous bacterial peritonitis. The median difference in prolactin between spontaneous bacterial peritonitis was statistically significant with a P-value of 0.0147.

Table 1: Comparison of prolactin with ascites in the study population (N=69)

Parameter	Ascites (Median (IQR))				Kruskal Wallis Test (P-value)
	Mild (N=18)	Moderate (N=13)	Severe (N=7)	Absent (N=31)	
Prolactin	43.50(40.0 to 48.75)	52.00 (40.0 to 58.0)	58.00 (44.0 to 68.5)	27.00 (25.0 to 30.0)	<0.001

Table 2: Comparison of prolactin with hepatic encephalopathy grade in the study population (N=69)

Parameter	Hepatic Encephalopathy Grade (Median (IQR))					Kruskal Wallis Test (P-value)
	Grade 1 (N=10)	Grade 2 (N=6)	Grade 3 (N=13)	Grade 4 (N=7)	None (N=33)	
Prolactin	40.50(31.25 to 48.25)	43.00(39.25 to 50.5)	47.00(42.0 to 54.0)	66.00(61.5 to 71.5)	27.00(25.0 to 33.0)	<0.001

Table 3: Comparison of serum prolactin with Child-Pugh score in the study population

Serum Prolactin	Child Pugh Score		Chi square	P-value
	Severe (N=23)	Mild to Moderate (N=46)		
High (>=39.5)	19 (82.61%)	12 (26.09%)	19.798	<0.001
Low (<39.5)	4 (17.39%)	34 (73.91%)		

In sever Child-Pugh score, 19 (82.61%) participants were high serum prolactin and 4 (17.39%) were low serum prolactin. In mild to moderate Child-Pugh score, 12 (26.09%) participants were high serum prolactin and 34 (73.91%) were low serum prolactin. The difference in serum prolactin between Child-Pugh score was statistically significant with a P-value <0.001 (Table 3).

The serum prolactin had a sensitivity of 82.61% (95% CI 61.22% to 95.05%) in predicting severe Child-Pugh Score as shown in Figure 1. Specificity was 73.91% (95% CI 58.87% to 85.3%), false positive rate was 26.09% (95% CI 14.27% to 41.13%), false negative rate was 17.39% (95% CI 4.95% to 38.78%), positive predictive value was 61.29% (95% CI 42.19% to 78.15%), negative predictive value was 89.47% (95% CI 75.20% to 97.06%), and the total diagnostic accuracy was 76.81% (95% CI 65.09% to 86.13%) (Table 4).

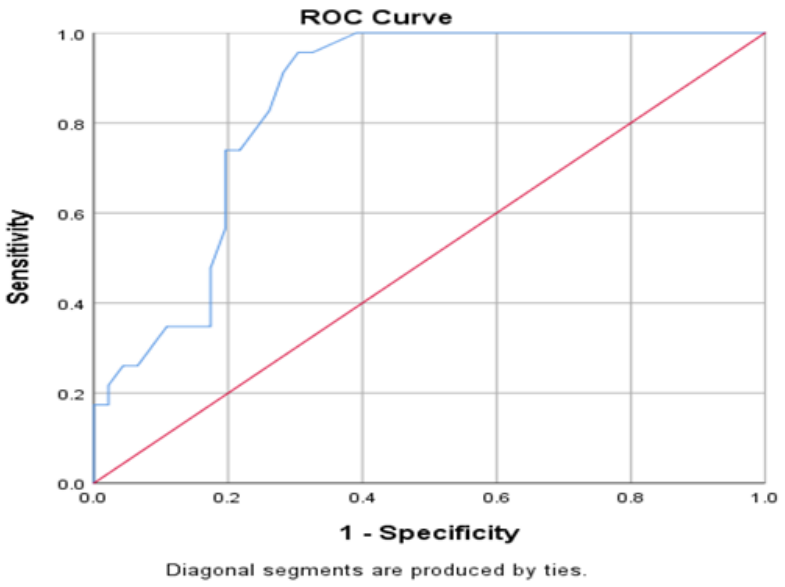

Figure 1: Receiver operating curve for serum prolactin in predicting severity

Table 4: Area under curve

Variable	Area under the curve	Std. Error[a]	P-value	Asymptotic 95% confidence interval	
				Lower Bound	Upper Bound
Serum Prolactin	0.845	0.046	0.000	0.755	0.934

The present study was a cross-sectional study with 69 subjects. The majority of them are males (85.51%) and females 14.49%. Balakrishnan *et al.* (2017) involving 60 patients, also found male predominance (83%) and females only 17%, were between the ages of 40 and 50. Hepatitis B infection (9%), followed by alcoholic liver disease (73%) were the two most frequent causes of cirrhosis in this research [17].

In comparable research conducted on 70 patients by Velissaris *et al.* (2008) where 26 subjects had cirrhosis and the remaining were enrolled as controls, with a mean age of the cirrhosis subjects was 64.6 ± 9.5 years with a 2:1 male to female ratio. Six individuals had cirrhosis of the liver and thirteen had viral hepatitis out of a total of 60 patients with liver disease who tested positive for HBsAg [15].

A recent study by Animesh *et al.* (2022) involved 70 subjects with a mean age of 47 ±13 years, male predominance (ratio: 4:1). Punekar *et al.* (2022) involved 60 subjects with a mean age of 44.9±12.8 years and male predominance (86.7%) and female 13.3%.

Khalil *et al.* (2020) studies found mean prolactin levels to be 18.76±9.14 ng/ml, the mean albumin level was 3.08±0.85 g/dl, the mean total bilirubin level was 2.6±1.3 mg/dl, mean Prothrombin time 8.9±5.54 second.

Child-Pugh score and serum prolactin

In the present study, the distribution of classes A, B, and C was equal with 33.33% each in each class. The mean child-Pugh score was 8.74±3.11 in the study population. According to Khalil *et al.* [20], the mean Child-Pugh score was 9.16±3.16.

Punekar, P. *et al.* [19] studies observed that of a total of 60 patients, 60% were classified as having Class B, 31.7% had a Child-Pugh Class C, and only 8.3% were Class A. Velissaris *et al.* (2008) found class A in 24.3%, class B in 22.9%, and class C in 42.9%. Another study by Jha found class A in 34.3%, class B in 22.9%, and class C in 42.9%. Balakrishnan *et al.* (2017) found 10% in Class A, 40% in Class B, and 50% in Class C. In the present study, with a severe Child-Pugh score, 82.61% of participants had high serum prolactin and 17.39% had low serum prolactin. In mild to moderate Child-Pugh score, 26.09% of participants had high serum prolactin and 73.91% had low serum prolactin. The difference in the levels of serum prolactin when compared to Child-Pugh score was statistically significant with a P-value of <0.001.

Balakrishnan *et al.* (2017) show that 73.33% of the patients had elevated blood prolactin levels, and patients in higher Child-Pugh classes had higher prolactin levels as well (B and C). This was consistent with research by Arafa[n] *et al. (*2012) that found prolactin levels rose as the Child-Pugh class rose from A to C. Furthermore, Animesh *et al.* (2022) showed that class C (78.5%) had mean prolactin of 43.638 ng/ml, and usual serum prolactin levels were found in all class A subjects. Hence, they found a significant (P-value < 0.001) higher score with Child-Pugh class C. Similarly in the present study, a significantly higher prolactin was found in Class C compared to Class A and Class B.

Serum prolactin levels in patients with etiology and complications of cirrhosis

The present study found significant (P-value <0.001) higher prolactin levels in severe ascites cases compared to mild and moderate cases and compared to cases without ascites ((median/ range: severe- 58.00 (44.0 to 68.5), moderate-52.00 (40.0 to 58.0), mild-43.50 (40.0 to 48.75), and no ascites -27.00 (25.0 to 30.0)). In contrast to our study findings, Khalid *et al.* (2017) found no significantly higher prolactin levels with severity of ascites (severe: 21.06±5.32 ng/dl, moderate: 20.05±9.06, mild: 13.67±6.48, no ascites-18.13±11.38 ng/dl). Punekar *et al.* (2022) also found no significant association between prolactin level and ascites.

The present study found a significant (p<0.001) higher median prolactin levels in grade 4 hepatic

encephalopathy compared to grade 3, 2, and grade 1 (grade 4-66.00 (61.5 to 71.5), grade 3-47.00 (42.0 to 54.0), grade 2-43.00 (39.25 to 50.5) and grade 1-40.50 (31.25 to 48.25), whereas in cirrhosis cases without hepatic encephalopathy we found significantly lesser prolactin levels (median-27.00 (range 25.0 to 33.0) compared to cases present with hepatic encephalopathy.

Khalid *et al.* (2017) found a significant ($p<0.001$) association of higher levels of prolactin to higher grades if hepatic encephalopathy (grade 4-32.66±2.76, grade 3-30.37±1.8, grade 2-23.87±1.96, grade 1-17.54±4.3, no hepatic encephalopathy-13.22±6.32). In contrast to our findings, Punekar *et al.* (2022) found no significant association between prolactin level and hepatic encephalopathy.

In the current study, we found that significantly higher prolactin levels were associated with varices compared to no varies. In contrast, Punekar, P. *et al.* [19] found no significant association. Similarly, median prolactin was significantly higher in spontaneous bacterial peritonitis compared to no spontaneous bacterial peritonitis. According to our study, individuals with liver cirrhosis sequelae such as hepatic encephalopathy, varices, and spontaneous bacterial peritonitis had higher blood prolactin levels. This was in line with research by Balakrishnan et al. (2012) and Koller *et al.* (2009) discovered that patients with greater ascites and encephalopathy stages had higher prolactin levels.

Predictive value of prolactin in predicting the severity of liver cirrhosis

The serum prolactin had a sensitivity of 82.61%, a specificity of 73.91%, a false positive rate of 26.09%, a false negative rate of 17.39%, a positive predictive value of 61.29%, a negative predictive value of 89.47%, and the total diagnostic accuracy of 76.81% in predicting severe Child-Pugh score.

Jha *et al.* (2021) evaluated the predictive value of prolactin in the mortality of the liver cirrhosis subjects. They found a sensitivity of 40%, specificity of 73.3%, positive predictive value of 66.7%, and negative predictive value of 47.8%.

Conclusion

Since blood prolactin levels and the Child-Pugh scoring system have a strong correlation, the study demonstrates that serum prolactin levels in individuals with liver cirrhosis can be used as a marker for the severity of the condition. In addition, it shows that individuals with problems such as hepatic encephalopathy, and ascites have considerably higher serum prolactin levels and that the severity increases with prolactin level. As a result, we draw the conclusion that serum prolactin levels can be employed as a helpful prognostic marker and a precursor for cirrhosis-related complications.

Limitations and recommendations

(1) The primary limitation of this study is the existence of confounding variables, such as undetected comorbid diseases, which may result in elevated prolactin levels.

(2) A further drawback is the smaller sample size and study design.

(3) Future research is also necessary to compare prolactin levels to the other complications like hepatopulmonary syndrome and hepatorenal syndrome. It is possible to conduct cohort studies to examine the connection between high levels of prolactin and death rates.

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No potential conflict of interest was reported by the authors.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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