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## Assessment of Clinical Outcomes of Patients with Liver Cirrhosis Based on Scoring Systems - A Retrospective Longitudinal Study



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**ABSTRACT** Background: Liver disease accounts for about 2 million deaths worldwide among which 1 million are due to the complications of cirrhosis. As the morbidity and mortality rate associated with Liver Cirrhosis is significantly rising, more research is needed to reduce its severity and improve the QOL of patients. Aim: To evaluate the Child-Turcotte-Pugh (CTP) score and the model for end-stage liver disease (MELD) score in predicting the prognosis of liver cirrhosis and to assess the correlation between the Child Tourette Pugh & MELD scoring system with the complications of liver cirrhosis. Methods: A retrospective longitudinal study was conducted in Caritas hospital, Kottayam among patients above 18 years with liver cirrhosis confirmed by histology, clinical laboratory, and imaging techniques who received treatment between January 2017 to January 2019 enrolled in the study. The essential information was gathered from the patient's medical record, and the clinical condition of the patient was evaluated using the Child-Pugh and MELD grading systems. Data analysis methods such as the paired t-test, Pearson correlation test, and unpaired t-test were used to examine the clinical condition. Result: A total of 200 patients were selected, the majority of them were in the age group of 61-70 years (31.5 %) and were males (91%). There were a total of 295 complications identified in 177 patients. Portal Hypertension was the most predominant complication (31.19%), followed by HE(17.97%), Ascites(18.98%), and Esophageal varices(17.97%). Number of patients was higher in the Child-Pugh class B(59.5%) and MELD scores of range 10-19(50.5%) in the six-month follow-up. As one patient's condition progresses to a higher category in both the Child-Pugh and MELD scoring system, the risk of having complications also increases. MELD score for patients with and without complication is 19.0 and 16.0 respectively. Conclusion: Since liver cirrhosis is a progressive condition, a complete recovery cannot be anticipated; instead, the optimum management for liver cirrhosis is to prevent the disease's progression. The study shows that utilizing a scoring system can help with early disease detection and diagnosis, which is important for halting disease development.



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## INTRODUCTION

As per World Health Organization, liver disease is the tenth most common cause of death in India. It may affect every 1 in 5 Indians. <sup>(1)</sup> Around 10 lakh patients with liver cirrhosis are newly diagnosed every year in India. About 1.28% of all patients who attend the eleven participating hospitals in India had liver disease. <sup>(2)</sup>

Cirrhosis is the histological development of regenerative nodules that are surrounded by fibrous bands in response to chronic liver injury, which involves loss of liver cells and irreversible scarring of the liver. <sup>(3)</sup> Chronic hepatic injury, in combination with environmental and/or genetic factors, may result in fibrosis over time. If the cause of liver damage is not removed or treated, permanent changes in hepatic architecture may occur, resulting in impaired hepatocyte regeneration and loss of hepatic function (i.e., cirrhosis). <sup>(4)</sup> Cirrhosis can cause hepatic dysfunction and/or portal hypertension which can lead to ascites, SBP, varices, hepatic encephalopathy, hepatorenal syndrome, hepatic pulmonary syndrome, and coagulation disorders. Cirrhosis and its complications not only reduce quality of life but also longevity. <sup>(3)</sup>

The Child-Pugh (also known as Child Turcotte Pugh, CTP) score can be used to assess the severity of the condition and describe the clinical state of patients with liver cirrhosis. Five clinical and laboratory criteria were used to categorize patients which include serum bilirubin, serum albumin, ascites, encephalopathy, and prothrombin time. MELD Score incorporates biochemical parameters that include serum bilirubin, prothrombin time, and serum creatinine and can be used as a general prognostic tool for the assessment of patients. MELD scores range from 6 to 40; the higher the score, the higher the 3-month mortality related to liver disease. <sup>(5)</sup>

The Child-Pugh and MELD scoring has frequently been used to predict the prognosis of cirrhotic patients due to its correlation with the severity of the liver disease. <sup>(6)</sup> These scoring systems are valid and easy-to-use tools for classifying the severity of the liver disease. However, they do have a few limitations. The Child-Pugh score's two arbitrary components, ascites and HE might fluctuate depending on the doctor's evaluation, the use of diuretics, and the use of lactulose. Second, when defining coagulopathy and, consequently, liver function in liver cirrhosis, the INR component of the Child-Pugh and MELD scores, which accounts for a portion of both scores, is imprecise. Third, numerous laboratories employ various INR

readings. <sup>(7)</sup> Additional research is required to characterize the prognosis forecasts of the current scores and determine the most accurate technique for prognosis prediction in patients with liver cirrhosis. Aim of our study is to evaluate the Child-Pugh-Turcott (CPT) score and the model for end-stage liver disease (MELD) score in predicting the prognosis of liver cirrhosis and to assess the correlation between the Child Tourette Pugh & MELD scoring system with the complications of liver cirrhosis.

## **METHODOLOGY:**

### **AIM:**

1. To assess the incidence of complications and to find out the most prevalent one.
2. To evaluate the clinical condition of the patients based on the Child-Pugh Score and MELD score.
3. To assess the correlation between the Child-Pugh & MELD scoring system with the complications of liver cirrhosis.

### **DESIGN AND SETTING OF THE STUDY:**

The study was conducted within the Gastroenterology department in a tertiary care hospital located in Kottayam district in the Central Travancore region of the state of Kerala in India. The hospital is NABH Accredited & ISO 9001:2015 Certified for the quality management system and healthcare procedures. It has an in-patient capacity of 635 beds.

It was a retrospective longitudinal hospital-based study. The admission record was used to identify patients who had been diagnosed with liver cirrhosis. The patient's medical chart was used to acquire all the necessary information that was required for the study. The data was collected by using the data collection form. Liver Cirrhosis was identified in 350 patients. However, 200 patients met the inclusion criteria. 25 patients were excluded due to unavailability of the chart, 75 patients due to lack of follow-up details, 18 of them due to major illness, and 30 and 2 patients due to insufficient data and autoimmune hepatitis respectively.

The sample size was calculated using the formula,  $n = z^2 pq/E^2$ ,

Where  $n$ =sample size,  $z$ = critical value for confidence interval  $p$ =(estimated)proportion of the population which has the attribute in question  $q=1-p$  ,  $E$ =Margin of error(desired level of precision).

The inclusion and exclusion criteria for the patients selected were as follows:

**Inclusion criteria:**

- Patients above 18 years with liver cirrhosis confirmed by histology, clinical, laboratory, or imaging criteria.
- Undergone treatment between 2017-2019 and completed a minimum of six months of follow-up.

**Exclusion criteria:**

- Patients with autoimmune hepatitis.
- Solid organ transplantation.
- Any major illness or disorders that may have interfered with patient treatment, assessment, or compliance with the protocol.
- Patients who are reluctant to follow up or not willing to participate in follow-up.

**DATA ANALYSIS**

The data were presented either as the Mean  $\pm$  Standard Deviation (S.D) or as some patients and percentages. Data storage and analysis were performed using Microsoft Excel and Graph Pad Prism version 9.2.0.

Paired t-test was used to compare the clinical condition of the patient based on the MELD score. Pearson correlation test was done to assess the correlation between Child-Pugh and MELD scores with the complications in the patients. An unpaired t-test was also performed to determine the correlation between the mean MELD score and complications in the patients. All the p values were two-tailed and a significance level of 5% was used.

## RESULTS

### 1. To assess the incidence of complications and to determine the most prevalent one

#### 1.1 Comparison of patients with and without complication

We collected the data of 200 cirrhotic patients who were having a follow-up of a minimum of 6 months. During our study, we examined that, out of these 200 patients, the incidence of at least one complication was found in a total of 177 patients (88.5%). The remaining 23 patients (11.5%) did not report any complications at all (Table 1.1).

**Table 1.1 Comparison of patients with and without complications**

Patients	Number of patients (N=200)	Percentage (%)
With Complication	177	88.5%
Without Complication	23	11.5%

#### 1.2. Determining the most prevalent complication

**Table 1.2: List of complications in patients with LC**

Complications	Number of Complications (N=295)	Percentage (%)
Portal Hypertension	92	31.19
Hepatic Encephalopathy	53	17.97
Ascites	56	18.98
Esophageal Variceal bleed	53	17.97
Fundal varices	8	2.71
Hepato Renal Syndrome (HRS)	11	3.73
SBP	11	3.73
HCC	6	2.03
Hepatic Hydrothorax	4	1.36
Hepato pulmonary syndrome	1	0.34

In our study, we collected the details of complications each patient was experiencing and also examined the most predominant complication. All the reported complications are listed in table 1.2. There were a total of 295 complications identified in 177 patients. More than one complication was found in many patients and the highest number of complications reported from a patient was 5. From the table, it was found that Portal Hypertension was the most predominant complication(31.19%), followed by HE (17.97%), Ascites(18.98%), and Esophageal varices(17.97%). (Figure 1.2)

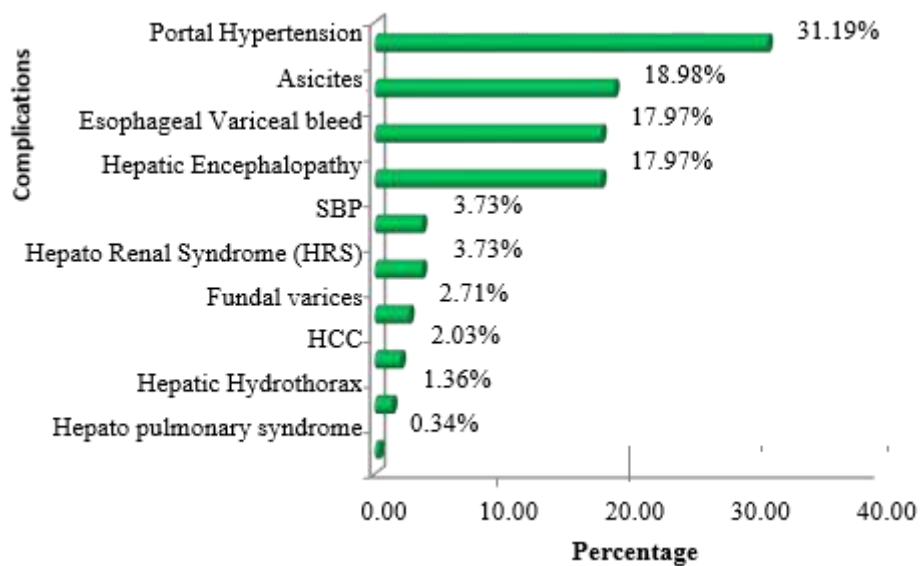


Figure 1.2: Represents various complications

2. To evaluate the clinical condition of the patient based on Child-Pugh and MELD score

2.1. Based on Child- Pugh Score:

Table 2.1: Baseline and Follow-up Child-Pugh score

Child-Pugh Score	Baseline (N=200)	Percentage (%)	Follow up (N=200)	Percentage (%)
A	37	18.5	32	16
B	116	58	119	59.5
C	47	23.5	49	24.5

Child- Pugh Scores (A, B, C) of both baseline & 6-month follow-up values were recorded for each patient. The score was categorized as A, B, and C based on the increasing order of severity. It was observed that the majority of the patients were in Child-Pugh Category B

(58%) during baseline and 59.5% in the follow-up (Table 2.1) (Figure 2.1). We also observed a decrease in several patients in the mild category (A) from 37 to 32 and an increase in the number of patients in the moderate (B) and severe (C) categories during follow-up.

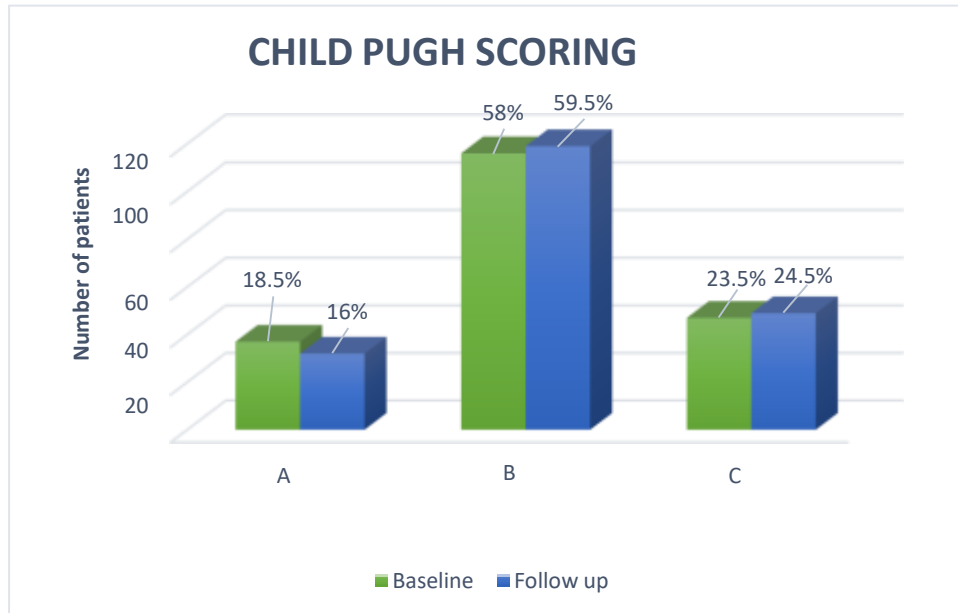


Figure 2.1: Represents baseline and follow-up Child Pugh Score

2.2 Based on MELD score:

Table 2.2.1: Number of patients in baseline and follow-up MELD score

MELD SCORE*	Baseline N=200	Percentage	Follow-up N=200	Percentage
≤9	13	6.50%	13	6.50%
10-19	107	53.50%	101	50.50%
20-29	72	36%	67	33.50%
30-39	7	3.50%	17	8.50%
≥40	1	0.50%	2	1%

2.2.2 Number of patients in baseline and follow-up MELD score

(\*Patients were categorized into 5 groups based on the MELD score (≤9 is the mild MELD category, 10-19 & 20-29 are the moderate MELD category, 30-39 & ≥40 are thesevere MELD category).

MELD scores (baseline and 6 months follow-up) were collected for each patient from the patient’s record and they were classified into various groups as shown in the table.

More number of patients were within the MELD category 10-19(53.50% in the baseline and 50.50% in the follow-up). The data suggest that the number of patients within the mild MELD category ( $\leq 9$ ) remains the same and those in moderate MELD categories (10- 19,20-29) decreased for both baselines and follow values. However, there was a substantial increase in the number of patients within the follow-up group of very severe MELD categories (30-39,  $\geq 40$ .) when compared with the baseline value. (Figure 2.2.1).

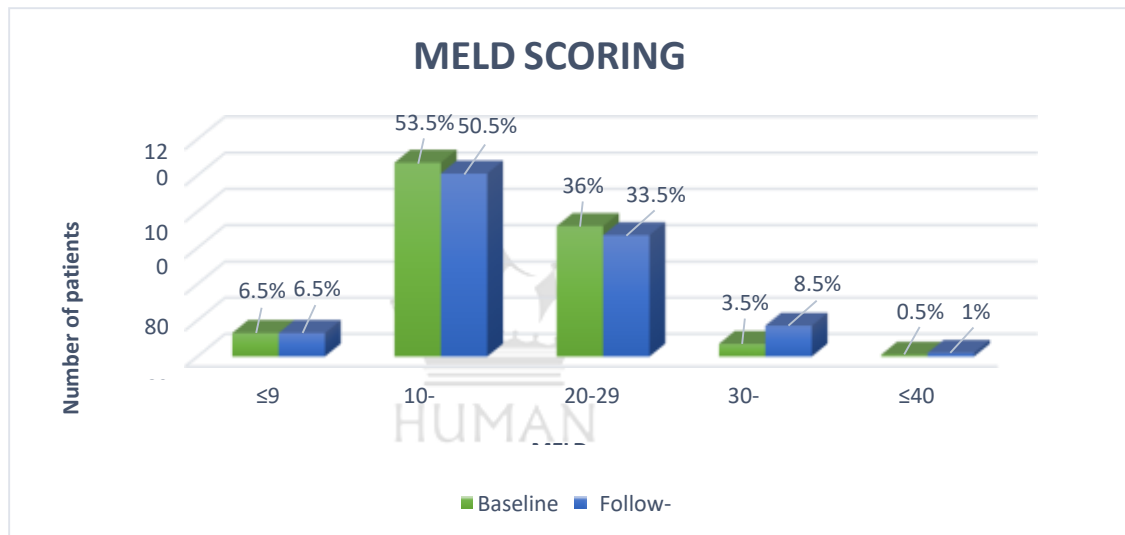


Figure 2.2.1: Represents MELD score (Baseline & Follow up)

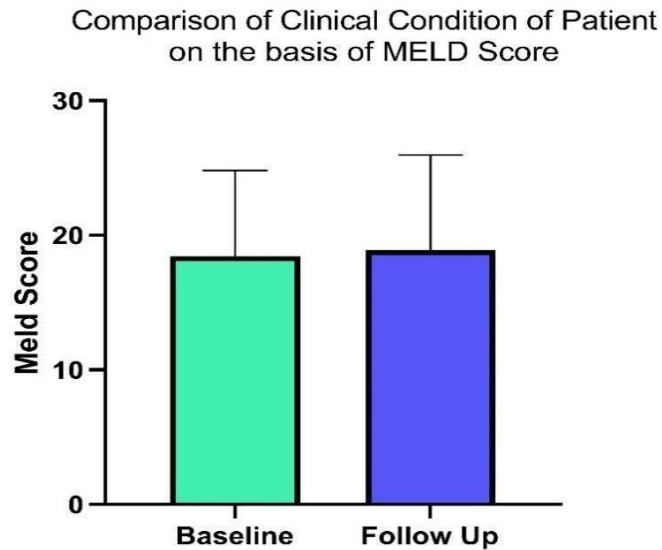
### 2.3 Comparison of MELD scores of Sample Populations during Baseline and Follow up

Table 2.2.2. Comparison of MELD scores in baseline & followup. (One Sample Paired t-Test; 95% CI)

Mean $\pm$ SD(Baseline)	Mean $\pm$ SD(Follow-up)	p-value
18.44 $\pm$ 6.38	18.89 $\pm$ 7.07	0.1757



It was found that the mean (SD) score of baseline MELD was 18.44(6.38) and that of follow-up was 18.89(7.07). The two-tailed p-value of both follow-up and baseline MELD was 0.1757 ( $P > 0.05$ ) and was not significantly different (Table 2.2.2) (Figure 2.2.2).



**Figure 2.2.2: Comparison of the clinical condition of the patient based on the MELD score**

1. To evaluate the correlation between Child-Pugh and MELD score with complications of liver cirrhosis.

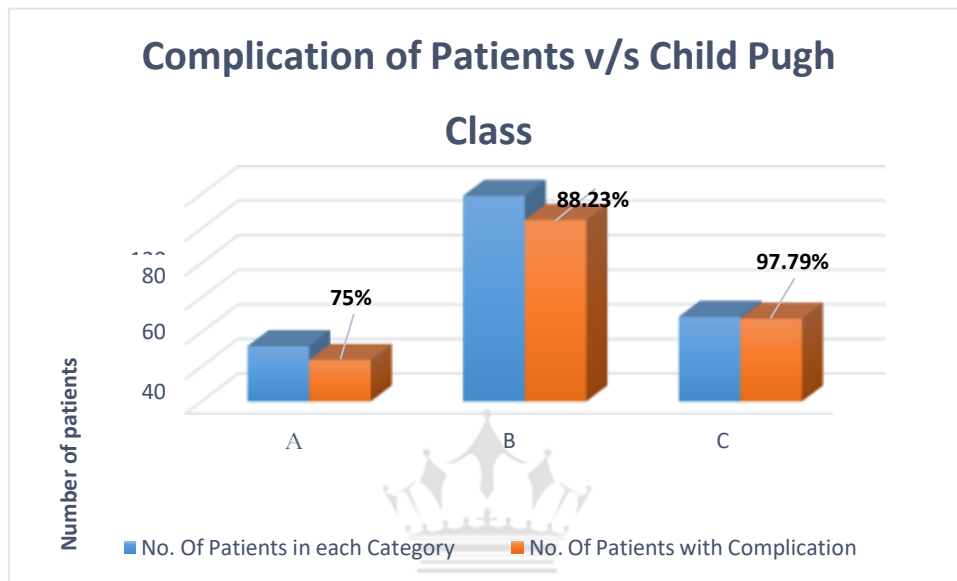
**1.1 Complications of patients based on the Child- Pugh Scoring system**

**Table 3.1. Complications of patients based on Child-Pugh Scoring System.**

ChildPugh Class	N=200	n=177	Percentage (%)	r value	p-value
A	32	24	75	0.9943	0.0341
B	119	105	88.23		
C	49	4338	97.79		

N= Number of Patients in each Category, n=Number of Patients with Complication

In the Child-Pugh Score Categorization, the prevalence of occurrence of complications was higher in Class C with 48 patients out of a total of 49 patients in this category, (97.79%) whereas, in Child-Pugh Classes A and B, it was 24 out of 32 patients(75%) and 105out of 119 patients(88.23%) respectively(Table 3.1). Pearson Correlation test was done to assess the correlation between the number of patients in each category and with several patients with complications in each category. The test was considered statistically significant with (*p-value 0.0341*) and a correlation coefficient *r value of 0.9943*.



**Figure 3.1. Represents complications of a patient with liver cirrhosis based on Child-Pugh classification.**

3.2. Individual complications based on Child Pugh Score categories

Table 3.2. Individual complications based on Child Pugh Score categories

Complication	Child- Pugh Score					
	AN (N=38)		B(N=169)		C(N=88)	
	n	%	n	%	N	%
Esophageal Variceal bleed	14	36.84	31	18.34	8	9.09
Fundal Bleeding	2	5.26	6	3.55	0	0.00
Portal Hypertension	14	36.84	55	32.54	23	26.14
Hepatic Encephalopathy	3	7.89	31	18.34	19	21.59
Ascites	3	7.89	33	19.53	20	22.73
Hepato Renal Syndrome (HRS)	0	0.00	3	1.78	8	9.09
Hepato Cellular Carcinoma (HCC)	1	2.63	1	0.59	4	4.55
SBP	0	0.00	6	3.55	5	5.68
Hepatic Hydrothorax	1	2.63	3	1.78	0	0.00
Hepato pulmonary syndrome	0	0.00	0	0.00	1	1.14

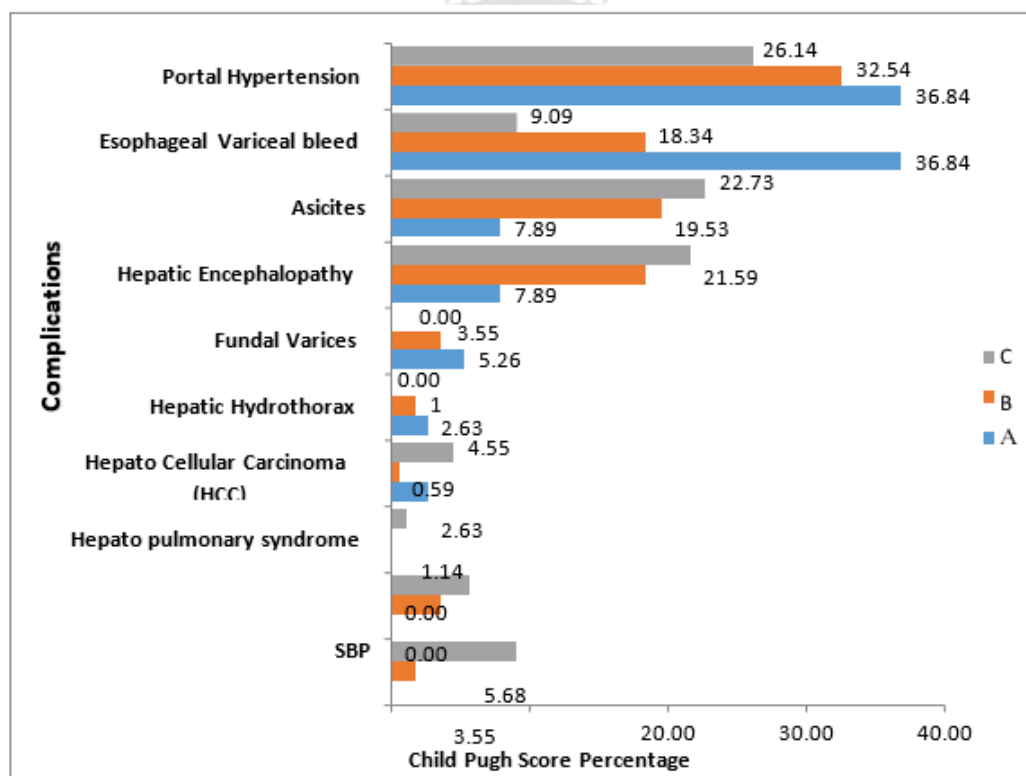


Figure 3.2. Represents Child-Pugh Score-based individual complications of patients with liver cirrhosis.

3.2. Complications of patients based on the MELD scoring system.

Table 3.3: Complications of patients based on the MELD scoring system

MELD SCORE	N=200	n=177	Percentage (%)	r value	p-value
≤9	13	11	84.61	0.995	<0.001
10-19	101	86	85.14		
20-29	67	61	91.04		
30-39	17	17	100		
≥40	2	2	100		

N= Number of Patients in each Category, n= Number of Patients with Complication.

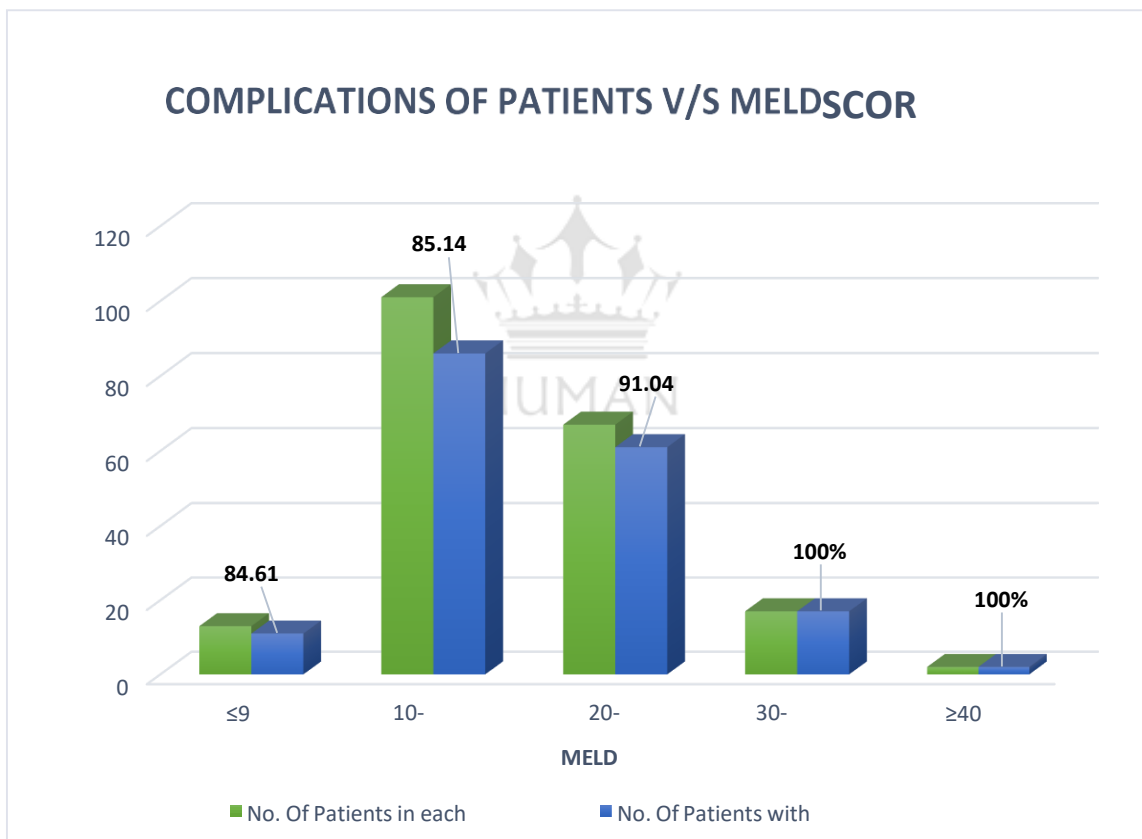


Figure 3.3 Represents complications of patients based on the MELD scoring system.

Out of the total patients taken, all the patients in the MELD score range  $\geq 30$  have complications. Pearson correlation test was done to find the association between the numbers of patients in each category versus the number of patients with complications. Pearson

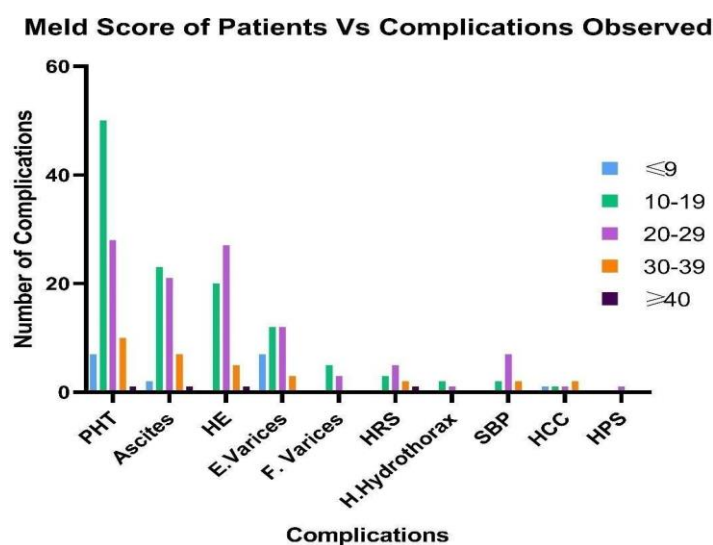
Correlation coefficient ( $r$ ) was found to be 0.995 and it was statistically significant with a  $p$ -value  $<0.001$ .

### 3.3. Individual complications of patients according to MELD Score.

**Table 3.4: Individual complications of patients according to MELD Score.**

Complications	$\leq 9$	10-19	20-29	30-39	$\geq 40$
Portal hypertension	7	50	28	10	1
Ascites	2	23	21	7	1
Hepatic encephalopathy	0	20	27	5	1
Esophageal varicealbleeding	7	12	12	3	0
Fundal varicealbleeding	0	5	3	0	0
Hepato renalsyndrome	0	2	4	2	1
Hepato adrenalsyndrome	0	1	1	0	0
Hepatic hydrothorax	0	2	1	0	0
SBP	0	2	7	2	0
HCC	1	1	1	2	0
Hepatopulmonarysyndrome	0	0	1	0	0

Portal hypertension was more prevalent in the 10-19 range ( $n=50$ ) of the MELD scoring system followed by the 20-29 range ( $n=28$ ). Individual complications of patients according to MELD score are given in Table 3.4.



**Figure 3.4.:** Represents the MELD Score based on individual complications of patients with liver cirrhosis

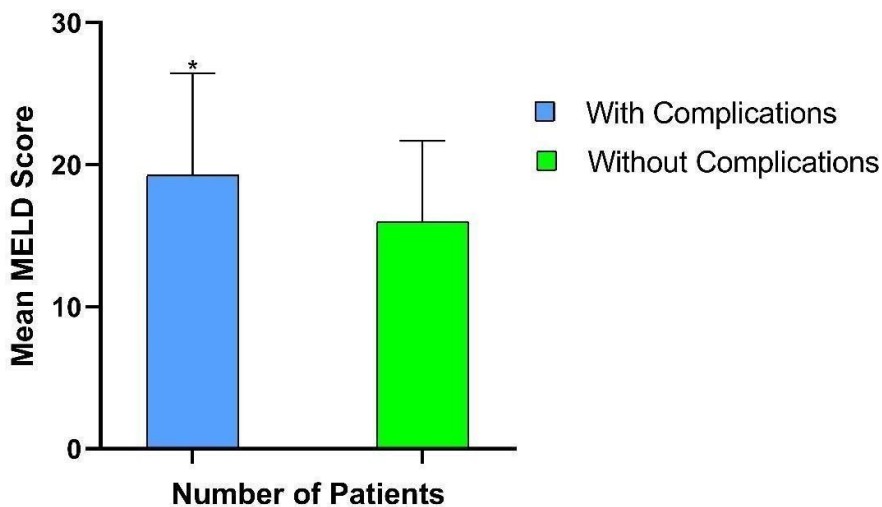
**3.5. Correlation between mean MELD Score and Complications of patients with liver Cirrhosis.**

**Table 3.5 Correlation of Mean MELD Score and Complications in liver cirrhosis patients**

Complications	N	Mean ± S.D.	p-value
Yes	177	19.27 ± 7.165	0.037
No	23	16.00 ± 5.673	

Here, the Unpaired t-test was done and the *p-value* was found to be 0.037( $p < 0.05$ ), so we can conclude that a significant difference between the variable. The mean value of patients with complications was found to be 19.27 and for those without complications was 16.00. From the mean value, we can say that patients who have complications lead to a higher average of MELD scores. MELD score for patients with complications is 19.27 and for not having complications is 16.0.

**Mean MELD Score Vs Complications**



**Figure 3.5 Mean MELD Score and Complications of liver cirrhosis patients.**

**DISCUSSION**

We collected all the complications associated with liver cirrhosis from the patient’s medical record. The severity of liver cirrhosis was assessed based on Child-Pugh and MELD scoring system. We then identified the correlation between these scoring systems and the complications of liver cirrhosis to determine the condition of the patient.

About 88.5 % of patients were identified with at least one complication during the follow-up period of 6 months. The remaining patients (11.5%) were not having any complications at all. The increased percentage of patients with complications might be due to the progressive nature of cirrhosis.<sup>[8]</sup> All those patients who had at least one complication of liver cirrhosis can be considered to have decompensated cirrhosis. However, the patients who had no complications reported are having compensated cirrhosis. Special attention has to be given to all the patients in the compensated stage to limit the progression of liver damage by early detection as well as treatment of any incident complications.<sup>[3]</sup> This helps in preventing the progression of liver cirrhosis into the decompensated stage thereby improving the patient's quality of life.

Among the identified complications, Portal hypertension was the predominant one. PHT is considered the life-threatening complication of cirrhosis, accounting for increased morbidity and mortality.<sup>[9]</sup> This agrees with the study conducted by Raquel A *et al* which also concluded PHT is a highly prevalent complication of cirrhosis.<sup>[10]</sup>

In our study, we used two scoring systems namely the Child-Pugh Score and MELD score to assess the patient's condition. Scores were collected for the baseline and follow-up values. Baseline values are those values collected at the time of diagnosis of cirrhosis and follow-up values are those collected after a 6-month follow-up.

While assessing the Child-Pugh score and MELD score, it was observed that there was a decrease in the number of patients from the mild category of both Child-Pugh and MELD score and all those patients within the mild categories had migrated towards the severe categories during follow-up. This suggests that the clinical condition of the patient was deteriorating. The worsening of the patient's condition is due to the progressive nature of cirrhosis. The damage that took place in the liver due to cirrhosis cannot be reversed, which further increases the incidence of complications. Thus, special attention should be given to limiting the progression of cirrhosis, such as treating the underlying causes.<sup>[11]</sup> thereby limiting the migration of patients towards the severe MELD and Child-Pugh scores.

Moreover, it was also found that as one progresses to an advanced Child-Pugh category, the risk of having complications also increases, and it was stated using the Correlation test. The study conducted by Tsois *et.al.*<sup>[12]</sup> suggested that the Child-Pugh scoring system could predict the development of complications and mortality rate. Portal Hypertension accounts for

the highest number of complications associated with liver cirrhosis. An unpaired t-test was done and it was found that the mean MELD score of patients with complications was 19 and for those without complications was 16.

Furthermore, in MELD score categorization, as the score range increases, several patients with complications are higher concerning the number of patients in that category. A higher MELD score before liver transplantation was associated with a greater risk of complication rate and mortality according to a study performed by Fang Yi *et.al*.

## **SUMMARY**

The important findings of our study are as follows:

Child-Pugh class B (59.5%) and MELD score of the range 10-19(50.5%) showed a higher number of patients in the six-month follow-up. The risk of having complications increases as one patient's condition progresses to a higher category in both Child-Pugh and MELD scoring systems. MELD score for patients with complications was found to be 19 and for those without complications was found to be 16.

## **CONCLUSION:**

Since liver cirrhosis is a progressive disease, we could not expect a complete cure for the disease. An important way to manage LC is to prevent the progression of the disease to advanced decompensate stages. This necessitates the significance of early detection and diagnosis of the disease thereby preventing the progression to the next stage. And this can be achieved by using the scoring systems that are used in this study.

## **ABBREVIATIONS:**

CTP: Child-Turcotte-Pugh, HCC: Hepato Cellular Carcinoma, HE: Hepatic Encephalopathy, HRS: Hepato Renal Syndrome, MELD: Model For End-Stage Liver Disease, SBP: Spontaneous Bacterial Peritonitis.

## **DECLARATIONS:**

1. Ethics Approval: This study was ethically and scientifically approved by Caritas Hospital Ethical Committee.



2. Consent for publication: Not applicable
3. availability of data and materials: Data will be made available upon reasonable request.
4. Competing interests: No competing interests to declare.
5. Funding: We received no funding.
6. Author's contribution: All authors have complete access to the study data.
7. Acknowledgments: Not applicable.

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