Fibro-Scan versus Child-Pugh Score for the Assessment of Liver Function and Treatment Outcome in Hepatocellular Carcinoma Patients Treated with Sorafenib or Intervention Therapy

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Background and study aim: Prognostic evaluation prior to initiating any form of hepatocellular carcinoma (HCC) management is essential. This study aimed to evaluate the effectiveness of liver stiffness (LS) measurement and Child-Pugh score in predicting outcomes in cirrhosis-related hepatocellular carcinoma patients undergoing sorafenib treatment or other interventional therapy.

Patients and Methods: In total, 100 patients with cirrhosis-related advanced HCC were included in this study. The Child Pugh-score and LS measurements were performed before and after therapy. LS measurements were performed by transient elastography (FibroScan). Patients were treated using either microwave ablation, transarterial chemoembolization, or sorafenib according to the multidisciplinary team's decision. Patients were followed up for hepatic insufficiency post-therapy and treatment outcomes.

Results: The means of LS measurements before and after therapy were 16.1 ± 4.83 kPa and 15.99 ± 5.93 kPa, respectively. There were no statistically significant differences in LS measurements or fibrosis stages before and after therapy. There was a statistically significant difference when comparing outcomes with fibrosis stages and Child-Pugh scores before and after therapy. The cut-off level for LS measurements before therapy for prediction of post-treatment decompensation was 17.75 kPa, with a sensitivity of 73.3 %, specificity of 65 %, positive predictive value of 76 %, negative predictive value of 62 %, and accuracy of 70%.

Conclusion: Liver stiffness measurement can better predict liver decompensation and treatment outcomes in hepatocellular carcinoma patients treated with sorafenib or other interventional non-surgical therapies.

INTRODUCTION

Hepatocellular carcinoma (HCC) is the most prevalent primary liver cancer and ranks as the fifth most common cancer worldwide. HCC is categorized as an advanced cancer when vascular invasion and/or extrahepatic spread are present [1]. Patients with non-advanced HCC exhibit favorable survival outcomes if they receive timely and appropriate management. Unfortunately, owing to the asymptomatic nature of the tumor in its early stages, HCC is typically diagnosed at an advanced stage, where curative treatments are limited [2].

Over the last few years, major progress has been made regarding systemic therapy for advanced HCC. Sorafenib, a multi-tyrosine kinase inhibitor, gained FDA approval for the treatment of advanced HCC after showing survival benefits [3, 4].

Prognostic evaluation before initiating any form of treatment is essential for HCC management.

It is worth noting that liver cirrhosis is a common comorbidity among HCC patients, underscoring the significance of liver function status as a crucial prognostic indicator. The primary clinical prognostic factors utilized in the Barcelona Clinic Liver Cancer (BCLC) staging system to ascertain the natural progression of HCC include tumor burden, liver function, and overall health status. Liver function is typically evaluated using the Child–Turcott-Pugh (CTP) classification system. However, in the most recent update of this staging system, the CTP score has been eliminated as a tool for assessing liver function [5, 6]. Various elastography techniques have been used as effective noninvasive tools for staging fibrosis, diagnosing liver cirrhosis, and evaluating liver status [7-9].

This study aimed to evaluate the effectiveness of liver stiffness (LS) measurement versus CTP scoring in predicting outcomes and post-treatment hepatic decompensation in cirrhosis-related HCC patients receiving sorafenib treatment or other intervention treatment, providing valuable insights into post-intervention prognosis and risk factors for disease progression.

METHODS

Patients` recruitment and assessment:

This study was conducted at the Tropical Medicine and Medical Oncology departments of Zagazig University Hospitals and involved 116 patients with cirrhosis-related advanced HCC between March 2021 and January 2023. The eligibility criteria included patients with (1) cirrhosis-related HCC confirmed by the specific imaging criteria, (2) preserved liver functions, and (3) no prior systemic or intervention therapy for HCC. Twelve patients did not have successful LS measurements because of ascites or morbid obesity. Four patients were lost to the follow-up. Therefore, 100 patients were included in this study.

Before active treatment initiation, the patients underwent a thorough evaluation, including history, clinical examination, laboratory investigations, viral markers, and radiological studies. The CTP score was calculated based on its specific parameters to assess liver function. Liver stiffness was measured using transient elastography (FibroScan Echosens). Patients with HCC were treated using either microwave ablation (MWA), transarterial chemoembolization (TACE), or sorafenib, according to the multidisciplinary team's decision. Patients were treated with 400 mg sorafenib twice daily until either disease regression or the occurrence of adverse events. If sorafenib side effects occurred, the dose was reduced or stopped according to the severity of adverse events.

LS measurements were performed for all patients within one week before therapy or intervention one month after intervention therapy, and 3 months after sorafenib treatment. LS was measured by transient elastography after 6 hours of fasting. An M-sized probe transducer was used in this study. The results were measured in Kilo Pascals (kPa). A median of 10 valid measurements was approved [10].

Post-intervention assessment:

Post-intervention assessment focused on the prognostic value of LS measurement in predicting liver decompensation and HCC progression, compared with the CTP score. The study also analyzed the risk factors for post-intervention liver decompensation and HCC progression or regression. Patients were followed up for hepatic insufficiency post-therapy and HCC status, correlating LS measurements with CTP scoring. Multiphasic liver computed tomography (CT) was regularly performed to monitor treatment responses.

Statistical analysis:

Data collected were statistically analyzed using SPSS 26.0 (SPSS Inc., Chicago, IL, USA). The paired samples t-test, Wilcoxon ranked signed test, and Chi-square test were used for data analysis. The validity of LS measurement and CTP score was tested using ROC curve analysis. Statistical significance was set at $P < 0.05$.

RESULTS

The present study included 100 patients with advanced HCC and compensated cirrhosis, with a mean age of 56.3 years (range: 45-69 years). About two-thirds of the cases (70%) were male, 30% were diabetic, and 12% were hypertensive Serology tests revealed that 98 patients have positive HCV antibodies, 16% of the cases were positive for HBsAg, and only 2% were positive for HBc Ab. Approximately 44% of the patients were on sorafenib therapy at a dosage of 800

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mg/day, while 28% were on a dose of 400 mg/day. Hand and foot rashes were observed in 44% of the cases as a side effect of sorafenib, and diarrhea was reported in 36%.

Liver injury after sorafenib

Regarding liver function, there was a significant increase in the mean values of both bilirubin and ALT levels and a significant decrease in mean albumin levels after therapy compared to baseline values. In terms of complete blood counts, there was a significant decrease in neutrophil and platelet counts after therapy, whereas no significant change was observed in total WBC counts. Additionally, the median INR values significantly increased after therapy. The median value of creatinine after therapy was 1 (range: 1-2), and the median hemoglobin value was 10.5 (range: 9.1-11.5).

Pathological characteristics of HCCs

Triphasic CT abdomen revealed that more than half of the diagnosed tumors (56%) were multiple. Portal vein thrombosis was found in 58% of cases, lymph node metastasis in 34%, and distant metastasis in 22%. Bone metastasis was observed in 10% of cases, both pulmonary and lung metastases in 8%, and paraspinal metastases in 2%. There was a decrease in the median AFP level after therapy.

Prognostic indicators

There was no statistically significant difference in the CTP scores before and after therapy. The majority of patients (88%) had a CTP score of A before treatment. More than half of the patients (54%) retained a CTP score of A, 20 % had a score of B, and 26 % had a score of C. Only 14 % of patients had mild ascites before therapy. Post-therapy, mild ascites developed in 22 % of patients, moderate ascites in 28 %, and marked ascites in only two cases.

The means of LS measurements before and after sorafenib therapy were 16.1±4.83 kPa and 15.99±5.93 kPa, respectively and the range was between 6.5 and 28.5 kPa. There were no statistically significant differences in the LS measurements or fibrosis stages before and after therapy (Table 1).

Treatment outcome

As shown in Table 2, more than half of the cases (60%) showed regression (48% partial regression and 12% complete regression), whereas 40% showed progression (34% complete progression and 6% stationary course).

There was a statistically significant difference when comparing between outcome and fibrosis stages before and after therapy as before therapy, with nearly 87.5 % of stage F2 patients showing regression, about 66.7 % of stage F3 patients showing regression, and half of F4 stage patients showing regression. After therapy, approximately 83.3 % of stage F2 and F3 patients showed regression, and 36 % of F4 stage patients showed regression (Table 3).

Table 4 shows a statistically significant difference in outcomes and CTP scores before and after therapy. Before therapy, nearly 63.6 % of CTP A patients and 33.3 % of CTP B patients showed regression. After therapy, approximately 96.3 % of CTP A patients and 40 % of CTP B patients showed regression.

ROC curve analysis was performed to test the predictive value of LS measurement in HCC patients treated with sorafenib or intervention therapy for liver function after systemic treatment or intervention therapy. The cut-off level for LS measurements before therapy was 17.75 kPa, with a sensitivity of 73.3%, specificity of 65%, positive predictive value (PPV) of 76%, negative predictive value (NPV) of 62%, and accuracy of 70% (Table 5) (Fig. 1).

Table 6 shows that analysis by the ROC curve was performed to test the predictive value of sorafenib or intervention therapy in hepatocellular carcinoma patients regarding CTP score. The CTP score before therapy had a sensitivity of 93.3%, specificity of 20%, PPV of 63.6%, NPV of 66.7%, and accuracy of 64%. The CTP score after therapy had a sensitivity of 86.7%, specificity of 95%, PPV of 96.3%, NPV of 82.6%, and accuracy of 90% (Fig. 2).

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Table (1): Baseline and after-therapy Liver stiffness measurements and fibrosis stages of the studied group

Characteristic	Study group (n=100)		
Baseline measurements (kPa) Mean ±SD Range	16.1±4.83 (8-26.5)		
After therapy measurements (kPa) Mean ±SD Range	15.99±5.93 (6.5-28.5)		
P value*	0.829		
Fibrosis stage before	F2	16	16
	F3	24	24
	F4	60	60
Fibrosis stage after therapy	F1	2	2
	F2	12	12
	F3	36	36
	F4	50	50
P value†	0.303		

SD, standard deviation; kPa, Kilo Pascals.
P value > 0.05 is considered statistically non-significant.
*Paired samples t-test.
†Wilcoxon signed-ranks test.

Table (2): Outcome of the studied group (n=100)

Category		No.	%
Outcome resolution	Complete regression	12	12.0
	Partial regression	48	48.0
	Stationary coarse	6	6.0
	Progression	34	34.0
Outcome	Regression	60	60
	Progression	40	40

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Table 3. Relation between outcome results and fibrosis stage of the studied groups

Variables			Outcome		P value*
			Regression	progression	
Fibrosis stage before	F2	N	14	2	0.018
		%	87.5%	12.5%	
	F3	N	16	8	
		%	66.7%	33.3%	
	F4	N	30	30	
		%	50.0%	50.0%	
Fibrosis stage after therapy	F1	N	2	0	< 0.001
		%	100.0%	0.0%	
	F2	N	10	2	
		%	83.3%	16.7%	
	F3	N	30	6	
		%	83.3%	16.7%	
	F4	N	18	32	
		%	36.0%	64.0%	

P value < 0.05 is considered statistically significant.
*Chi-square test.

Table 4. Relation between outcome results and CTP score of the studied groups

Variables			Outcome		P value*
			Regression	progression	
CTP score before	A	N	56	32	0.044
		%	63.6%	36.4%	
	B	N	4	8	
		%	33.3%	66.7%	
CTP score after therapy	A	N	52	2	< 0.001
		%	96.3%	3.7%	
	B	N	8	12	
		%	40.0%	60.0%	
	C	N	0	26	
		%	0.0%	100.0%	

CTP, Child–Turcott-Pugh score.
P value < 0.05 is considered statistically significant.
*Chi-square test.

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Table 5. Predictive value of liver stiffness measurements in HCC patients treated with sorafenib or intervention therapy regarding liver function

Variables	AUC	95% CI	Cut off	Sensitivity	Specificity	PVP	PVN	Accuracy
Baseline (kPa)	0.747	0.648-0.847	17.75	73.3%	65%	76%	62%	70%
After therapy (kPa)	0.835	0.742-0.928	15.75	83.3%	80%	86.2%	76.2%	82%

kPa, Kilo Pascals; AUC, Area under the curve; CI, Confidence Interval; PVP, Predictive value for positive; PVN, Predictive value for negative.

Table 6. Predictive value of sorafenib or intervention therapy in HCC patients regarding CTP score

Variables	AUC	95%CI	Sensitivity	Specificity	PVP	PVN	Accuracy
CTP score baseline	0.567	0.449-0.684	93.3%	20%	63.6%	66.7%	64%
CTP score after therapy	0.952	0.906-0.998	86.7%	95%	96.3%	82.6%	90%

CTP, Child-Turcott-Pugh score; AUC, Area under the curve; CI, Confidence Interval; PVP, Predictive value for positive; PVN, Predictive value for negative.

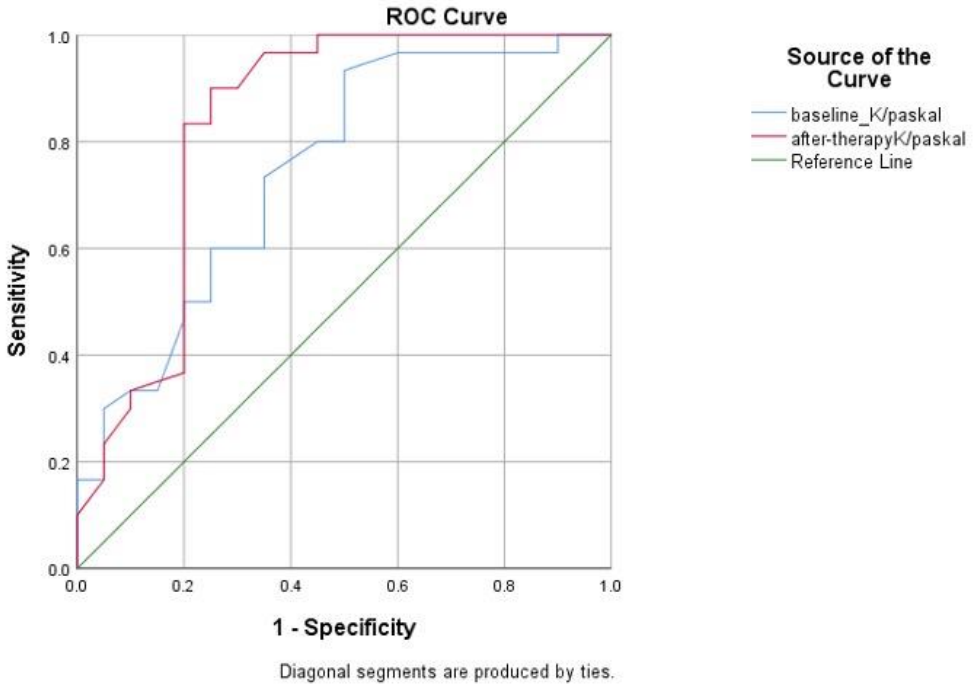

Figure 1. Roc curve analysis showed the predictive value of liver stiffness measurements in HCC patients treated with sorafenib or intervention therapy regarding liver function.

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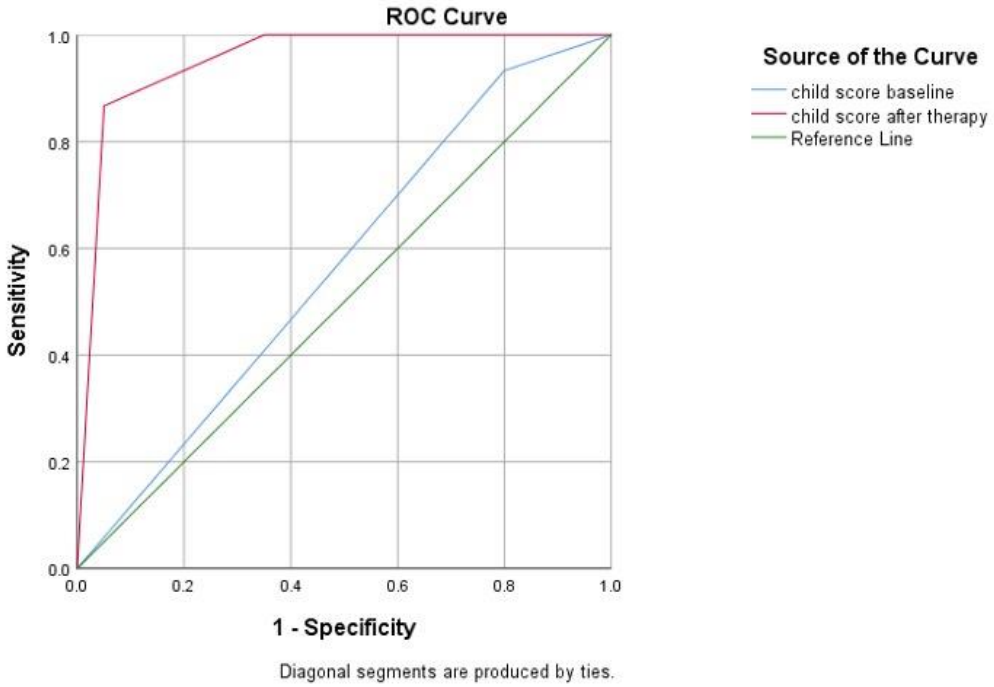

Figure 2: Roc curve analysis showed the predictive value of sorafenib or intervention therapy in HCC patients regarding the Child-Turcott-Pugh score.

DISCUSSION

This study compared the predictive capabilities of LS measurement using transient elastography and the established CTP scores for liver status and treatment outcomes following systemic and other interventional non-surgical HCC therapies. The LS measurement demonstrated moderate accuracy in anticipating liver decompensation before treatment. The CTP score proved superior in predicting this outcome, both before and after therapy. Interestingly, significant variations in outcomes were observed between different CTP score categories, unlike fibrosis stages assessed by transient elastography, which remained consistent pre- and post-treatment [11, 12].

A liver biopsy is considered to be the gold standard for liver assessment. It is invasive and impractical, especially in patients with advanced HCC patients and hepatic decompensation [13]. Consequently, the Barcelona Clinic Liver Cancer (BCLC) staging system and CTP scoring systems are commonly used to select patients for sorafenib treatment or other intervention therapies [14, 15].

Our findings revealed a strong correlation between CTP score and response to sorafenib, with Child A patients exhibiting the highest HCC regression rates. This aligns with previous studies that reported improved overall survival in Child A patients. Therefore, clinical assessment often relies on a widely used CTP score [15,16]. Due to several limitations, the CTP score has been removed from the updated staging systems [17, 18]. Therefore, more reliable and dependent methods are needed for the accurate assessment of liver functions in HCC patients to obtain better treatment outcomes.

LS measurement by transient elastography is a non-invasive tool with the potential to replace clinical scoring systems for assessing liver fibrosis. In the present study, there was a statistically significant difference between the outcome and LS measurements before and after therapy, with better outcomes in patients with F2 and F3 stages of liver fibrosis. Our study found no significant change in LS measurements or fibrosis stages following sorafenib therapy, despite the initial high prevalence of advanced fibrosis (F4). This may be due to population differences, genetic variations, and the etiology of cirrhosis. In contrast, Hung et al. found a significant reduction in liver stiffness after short-term sorafenib treatment in a more advanced patient population [19]. However, in this study, liver stiffness measurements were performed using acoustic radiation force impulse elastography and not by transient elastography (Fibro-Scan), as in our study.

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Most HCC develops in patients with cirrhotic liver; therefore, evaluation of hepatic reserve and liver function is essential for selecting the HCC treatment protocol and is strongly associated with post-treatment outcomes and hepatic decompensation [4, 20]. We identified a pre-therapy LS measurement at a cut-off value of 18 kPa with 70 % accuracy in predicting liver decompensation after HCC treatment. This aligns with the BAVENO criteria for portal hypertension, which is a known risk factor for decompensation in patients undergoing hepatic resection. The strong association between high LS measurements and poor prognosis in HCC is likely due to advanced fibrosis, cirrhosis, and associated portal hypertension [21]. Similarly, Lee et al. identified MRE-assessed LS as a more potent biomarker for predicting post-hepatectomy liver failure [22]. In addition, Kim et al. showed that MRE-assessed LS is a strong predictor of severe hepatic injury after sorafenib treatment. Patients with LS measurement > 7.5 kPa before treatment showed a markedly increased risk of severe hepatic injury than patients with LS measurement ≤ 7.5 kPa [23].

In comparison to the CTP score, LS measurement has a better predictive value for prediction of liver decompensation, AUC for LS measurement, and CTP score: 0.747 and 0.567, respectively, indicating a better predictive value for LS measurement. In addition, the CTP score contains subjectively dependent items. This and other factors led to the removal of the CTP score from the most recent prognostic score. Inconsistent with our results, Procopet., et al. observed that LS measurement had a performance like that of hepatic venous pressure gradient (HVPG) measurement in predicting 3-month post hepatectomy decompensation in patients with early HCC suitable for liver resection [24]. Similarly, a study by Ngai et al. showed that LS measurement is a significant adverse predictor of survival in patients with advanced HCC, which is independent of BCLC stage and albumin-bilirubin (ALBI) grade, which is dependent on liver function such as the CTP score [25].

These results suggest that LS measurement using transient elastography is a valuable tool for assessing liver disease severity and predicting outcomes in patients with HCC after treatment. Transient elastography is a simple, non-invasive tool that is now available in most centers and can accurately measure liver stiffness.

This study was a single-center study and included, to some extent, a small number of patients; therefore, further multiple centers research with a large number of patients is needed to determine the optimal use of LS measurement in HCC patients with liver cirrhosis.

CONCLUSION

In conclusion, liver stiffness measurement can better predict liver decompensation and treatment outcomes in HCC patients treated with sorafenib or other interventional no-surgical therapies. Better treatment outcomes were observed in patients with stages F2 and F3 fibrosis. LS measurement at a cut-off value of 18 kPa before treatment has 70 % accuracy in predicting liver decompensation after HCC treatment.

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Ethical approval:

This study was approved by the local institutional review board of the Faculty of Medicine, Zagazig University (ZU-IRB #8015/7-2-2021). Informed consent was obtained from all the patients.

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Author Contributions: We declare that all listed authors have made substantial contributions to all the following three parts of the manuscript:

-research design, acquisition, analysis, or interpretation of data.

-drafting the paper or revising it critically.

-approving the submitted version.

We also declare that no one who qualifies for authorship has been excluded from the list of authors.

HIGHLIGHTS

- Liver function is usually evaluated using the Child-Turcott-Pugh (CTP)

classification system. However, in the most recent update of this staging system, the CTP score has been eliminated as a tool for assessing liver function in hepatocellular carcinoma patients.

- This study compared the predictive capabilities of liver stiffness measurement using transient elastography and the established CTP scores for liver status and treatment outcomes following systemic and other interventional non-surgical HCC therapies.
- Our results suggest that liver stiffness measurement using transient elastography is a valuable tool for assessing liver disease severity and predicting outcomes in patients with HCC after treatment.

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