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COMPARATIVE STUDY OF IMPACT OF SURVEILLANCE VERSUS NON-SURVEILLANCE STRATEGY ON HEPATOCELLULAR CARCINOMA STAGING & SURVIVAL AT A TERTIARY HOSPITAL

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Abstract

Background: Worldwide, hepatocellular carcinoma (HCC) is the most common primary liver neoplasm, represents the fifth most common cancer in the world, and the third most common cause of cancer-related death. Surveillance has been found to be an effective tool to detect early tumors and expand the applicability of these curative treatment options. Present study was aimed to compare impact of surveillance versus non-surveillance strategy on hepatocellular carcinoma staging & survival at a tertiary hospital. **Material and Methods:** Present study was single-center, prospective, observational, comparative study, conducted in patients of hepatocellular carcinoma with underlying chronic liver disease,. Study population was divided into Group A (detected to have HCC, after at least one year of screening protocol) & group B (had HCC at the time of presentation, but was not on any screening protocol). **Results:** Among 108 patients of hepatocellular carcinoma, 24 patients in group A & 84 patients in group B were studied. There was no significant difference in mean age, gender distribution, comorbidities & addictions of both groups. 66.67% patients in group A were detected in early BCLC stage(stage 0,A,B) whereas only 9.76% patients in group B were detected in early BCLC stage, surveillance leads to early detection of HCC in our cohort (p- 0.00013). Overall median survival in 73 patients who were treated was 12 months whereas median survival in untreated patients was only 4 month. We observed significant improvement of survival in surveillance group as compared to non-surveillance group. Patients detected at early stages had significantly better survival than those detected at late stages. Patients who were treated for HCC has significantly better survival than untreated patients ($p < 0.0001$). **Conclusion:** Surveillance improved detection of HCC at early BCLC

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stage and also detected more tumor within Milan criteria. Surveillance also improved survival & treatment of HCC.

Keywords: surveillance, hepatocellular carcinoma, survival, BCLC stage

Introduction

Worldwide, hepatocellular carcinoma (HCC) is the most common primary liver neoplasm, represents the fifth most common cancer in the world, and the third most common cause of cancer-related death.[1,2] Chronic liver disease is the major risk factor for the development of hepatocellular carcinoma.[3] The increased prevalence of HCC is related to the prevalence of hepatitis B virus (HBV) (450 million) and hepatitis C virus (HCV) (170 million) infections and the growing incidence of fatty liver diseases due to metabolic derangements and alcohol abuse.[4]

Hepatocellular carcinoma is a neoplasm with a dismal prognosis, in part, due to the fact that diagnosis is frequently made at an advanced tumor stage precluding effective treatment. Recently, survival after diagnosis has improved,[5] which is attributed to advances in diagnostic techniques and to the application of various curative treatment options (surgical resection, liver transplantation, and percutaneous ablation).

Since the hepatocarcinogenetic process may evolve for years in a stepwise fashion from premalignant to overt HCC,[6] detection of early, better treatable tumors is made possible by surveillance of patients at-risk. Surveillance has been found to be an effective tool to detect early tumors and expand the applicability of these curative treatment options. Hepatocellular carcinoma has definite risk factors and predisposing conditions enabling surveillance modalities to be easily applied. In addition, the tests employed for surveillance are noninvasive and curative treatments are available when the tumor is detected at an early stage. Present study was aimed to compare impact of surveillance versus non-surveillance strategy on hepatocellular carcinoma staging & survival at a tertiary hospital

Material And Methods

Present study was single-center, prospective, observational, comparative study, conducted in department of Gastroenterology at Bombay Hospital & Institution Of Medical Sciences, Mumbai, Maharashtra, India. Study duration was of 2 years (March 2013 to March 2015). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- All patients of hepatocellular carcinoma with underlying chronic liver disease, who attended the outpatient department or got hospitalized during the study period, willing to participate in present study

Exclusion criteria

- Patients who lost to follow up were contacted telephonically to obtain information about treatment and survival.
- Patients whose information about treatment and survival was not available,
- Patients not willing to participate

Study was explained to patients in local language & written consent was taken for participation & study. Study population was divided into two groups –

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- Group A – Patients of chronic liver disease, detected to have HCC, after at least one year of screening protocol.
- Group B – Patients of chronic liver disease, who had HCC at the time of presentation, but was not on any screening protocol.

Patients in both groups were subjected to thorough history taking and clinical examination, with emphasis on the presence of jaundice, ascites, portal hypertension, splenomegaly, esophageal varices, and encephalopathy. Diagnosis of chronic liver disease was made on the basis of clinical, biochemical and endoscopic findings. Liver biopsy was done wherever necessary.

The various biochemical investigations were determined at the time of diagnosis. Child-Pugh score and MELD score (Model for end stage liver disease) were calculated for both groups at the time of diagnosis. Also USG, triphasic CT of abdomen or MRI abdomen, endoscopy and liver biopsy reports were noted. Tumor characteristics (size, number, and site) were noted.

Patients were followed prospectively during study period at regular interval. We analyzed retrospectively our prospectively kept data of all subjects of chronic liver disease who attended our referral center during study period and assess adherence to surveillance protocol in them.

The data collected was entered in a Microsoft excel file. Statistical analysis was performed using SPSS software and Sigma plot ver 12. Qualitative data is presented with frequency and Percentage tables. The percentage in group A versus group B was estimated and compared. Categorical variables were expressed as proportions and compared using Chi-square and Fisher's Exact test, as appropriate. A 2-sided $p<0.05$ was considered significant for all analysis. Survival analysis was done using Kaplan Meirer survival curve. Comparison within group was done with the help Logrank test.

Results

108 patients of hepatocellular carcinoma consulted our referral center during study period. 24 patients (22.2%) (group A) were under regular surveillance protocol of 6 monthly ultrasonography with alpha-fetoprotein whereas 84 (78.8%) (group B) patients were not on any surveillance protocol.

Mean age of patients in group A was 60.08±8.75 year and in group B it was 61.45±10.47 year. Both group had predominantly male patients (91.7% in group A & 86.9 % in group B). 58.3% patients were diabetic in group A and 42.9% were diabetic in group B (table 1). 37.5% patients in group A and 39.3% patients in group B were hypertensive. 4.2% patients in group A and 7.1% patients in group B had ischemic heart disease. 25% patients in group A were alcoholic whereas only 4.8% were alcoholic in group B. 8.3% patients in both groups were tobacco chewer. 16.7% and 14.3% patients were smokers in group A and B respectively. There was no significant difference in mean age, gender distribution, comorbidities & addictions of both groups.

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Table No. 1: Demographic profile

	Group		Total (n=108)	p value
	A (n=24)	B (n=84)		
Age (Mean ± SD) (years)	60.08±8.75	61.45±10.48	-	0.560
Male	22 (91.7%)	73 (86.9)	95 (88.0%)	0.729
Female	2 (8.3%)	11 (13.1%)	13 (12.0%)	
DM	14 (58.3%)	36 (42.9)	50 (46.3%)	0.180
HT	9 (37.5%)	33 (39.3%)	42 (38.9%)	0.874
IHD	1 (4.2%)	6 (7.1%)	7 (6.5%)	1.000
Alcoholic	8 (25.0%)	23 (4.8%)	10 (9.3%)	0.567
Tobacco chewer	2 (8.3%)	7 (8.3%)	9 (8.3%)	1.000
Smokers	4 (16.7%)	12 (14.3%)	16 (14.8%)	0.751

Common symptoms observed in present study were loss of appetite (54.6%) followed by weight loss (47.2%), abdominal pain (25.0%), edema feet (15.7%), abdominal distension (13.9%), jaundice (7.4%), fever (3.7%), hematemesis (2.8%) & melena (2.8%). Mean duration of symptoms in group A was 28.00±13.98 days where as in group B it was 52.67±42.09 days, difference was not significant. Symptomatic presentation was significantly more common in group B (69 %) than group A (41.7 %), difference was statistically significant (p -0.014)

Table No. 2: Symptoms

Symptoms	Group		Total	P value
	A (n=24)	B (n=84)		
Loss of appetite	9(37.5%)	50(59.5%)	59 (54.6%)	0.056
Weight loss	5(20.8%)	46(54.8%)	51 (47.2%)	0.003
Abdominal pain	2 (8.3%)	25 (29.8%)	27 (25.0%)	0.035
Edema feet	4(16.7%)	13(15.5%)	17 (15.7%)	1.000
Abdominal distension	1(4.2%)	14(16.7%)	15 (13.9%)	0.182
Jaundice	1 (4.2%)	7 (8.3%)	8 (7.4%)	0.681
Fever	1(4.2%)	3(3.6%)	4 (3.7%)	1.000
Hematemesis	0(0.0%)	3(3.6%)	3 (2.8%)	1.000
Malena	0(0.0%)	3(3.6%)	3 (2.8%)	1.000
Duration of symptoms (days) (mean ± SD)	28.00 ± 13.98	52.67 ± 42.09	-	0.072
Symptomatic presentation	10 (41.7%)	58 (69.0%)	68 (63.0%)	0.014

Most common etiology of underlying CLD was Hepatitis B seen in 41.67% of patients in group A and 40.48% patients in group B. Second most common etiology in group A was alcohol (25%) followed by hepatitis C (12.5%). Second most common etiology in group B was hepatitis C (20.24%) followed by alcohol (15.48%) and cryptogenic (15.48%).

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Table no 3: Etiology of underlying chronic liver disease

ETIOLOGY	Group		Total
	A (n=24)	B (n=84)	
HBV	10 (41.67%)	34(40.48)	44(40.74%)
HCV	3(12.5%)	17(20.24%)	20(18.52%)
Alcohol	6(25.0%)	13(15.48%)	19(17.59%)
Cryptogenic	2(8.33%)	13(15.48%)	15(13.89%)
NASH	1(4.17%)	7(8.33%)	8(7.4%)
Others	2(8.33%)	0(0.0%)	2(1.9%)

In group A, 37.5%, 62.5% and 0% patients had CTP class A, B and C respectively. In group B, 45.2%, 45.2% and 9.5% patients had CTP class A, B and C respectively. Distribution of CTP class in both the group was statistically not significant. Varices were present in 79.2% and 68.9% patients in group A and B respectively. Ascites was seen in only 16.7% and 28.6% patients in group A and B respectively. Mean CTP score and mean MELD score (Model for end Stage Liver Disease) in both groups was not significantly different.

Table No. 4: Status of underlying chronic liver disease

	Group		Total	P value
	A (n=24)	B (n=84)		
CTP class (CHILD-PUGH SCORE)				
A	9 (37.5%)	38 (45.2%)	47 (43.5%)	0.159
B	15 (62.5%)	38 (45.2%)	53 (49.1%)	
C	0 (0.0%)	8 (9.5%)	8 (7.4%)	
Mean CTP score	6.88±1.19	7.02±1.76	-	0.698
Mean MELD score	13.28±4.29	12.50±5.33	-	0.513
Presence of varices	19(79.2%)	42(68.9%)	61(71.8%)	0.341
Presence of ascites	4(16.7%)	24(28.6%)	28(25.9%)	0.365

Most of patients in both groups had single tumor nodule (50% in group A and 54.9% in group B). 25% and 13.4% patients in group A and B respectively, had two tumor nodules. 24.4% patients in group B had portal vein thrombosis whereas only 4.2% patients in group A had portal vein thrombosis. Distant metastasis was seen at presentation in 11% and 4.2% patients in group B and A respectively. Portal lymph node involvement was also more common in group B (26.8%) than group A (8.3%). At the time of diagnosis, 79.2% patients in group A were within Milan criteria whereas only 22% patients in group B were fulfilling Milan criteria. AFP > 400 ng/ml was seen in 46.4% patients in group B as compared to only 16.7% patients in group A. 83.3% and 53.6% patients in group A and B respectively had AFP < 400 ng/ml.

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Table No. 5 Tumor characteristics

Tumor characteristics	Group		Total	P value
	A (n=24)	B (n=84)		
No of tumor nodule				
• Single	12 (50.0%)	45 (54.9%)	57 (53.8%)	0.539
• Two	6 (25.0%)	11 (13.4%)	17 (16.0%)	
• Three	1 (4.2%)	4 (4.9%)	5 (4.7%)	
• Multiple	2 (8.3%)	15 (18.3%)	17 (16.0%)	
• Multicentric HCC	3 (12.5%)	7 (8.5%)	10 (9.4%)	
Portal vein thrombosis	1 (4.2%)	20 (24.4%)	21 (19.8%)	0.039
Distant metastasis	1 (4.2%)	9 (11.0%)	10 (9.4%)	0.450
Portal LN involvement	2 (8.3%)	22 (26.8%)	24 (22.6%)	0.093
Patients within Milan criteria	19 (79.2%)	18 (22.0%)	37 (34.9%)	0.000
AFP>400 ng/ml	4(16.7%)	39(46.4%)	43 (39.8%)	0.009

Staging of all HCC patients was done using OKUDA staging, CLIP score and BCLC staging.. 41.7% and 35.4% patients in group A and B respectively, had OKUDA stage I. Majority of patients in both the group had OKUDA stage II (58.3%- group A, 59.8%- group B) 4.9% patients in group B had OKUDA stage III. Distribution of CLIP score (Cancer of the Liver Italian Program) in both groups, mean CLIP score in group B (2.05±1.26) was significantly higher than group A (1.41.1.10).

When patients were classified based on BCLC staging (Barcelona Clinic Liver Cancer), we observed significant difference in staging of both group (p value- 0.000). Majority of patients in group A had BCLC stage A (62.5%), while majority of patients in group B had BCLC stage C (76.8%) at the time of diagnosis. BCLC stage 0 was seen in 4.2% patients of group A and none in group B. 13.4% patients in group B had BCLC stage D, whereas only 4.2% patients in group A had BCLC stage D. Thus, patients in surveillance group were detected at earlier BCLC stage than patients in non- surveillance group.

Table No. 6: Staging of HCC

	Group		Total	P value
	A (n=24)	B (n=84)		
Okuda Stage				
I	10 (41.7%)	29 (35.4%)	39 (36.8%)	0.502
II	14 (58.3%)	49 (59.8%)	63 (59.4%)	
III	0 (0.0%)	4 (4.9%)	4 (3.8%)	
Mean CLIP Score	1.41±1.10	2.05±1.26	-	0.028
PT BCLC stage				
0	1 (4.2%)	0 (0.0%)	1 (0.9%)	
A	15 (62.5%)	5 (6.1%)	20 (18.9%)	
B	0(0.0%)	3(3.7%)	3(2.8%)	
C	7 (29.2%)	63 (76.8%)	70 (66.0%)	
D	1 (4.2%)	11 (13.4%)	12 (11.3%)	

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We also analyzed the ability of surveillance to detect HCC patients at an early stage. 66.67% patients in group A were detected in early BCLC stage(stage 0,A,B) whereas only 9.76% patients in group B were detected in early BCLC stage. Similarly, 79.17% patients in group A were fulfilling Milan criteria whereas only 21.95% patients in group B were fulfilling Milan criteria. Thus, surveillance leads to early detection of HCC in our cohort (p- 0.00013).

Table No. 7: Ability of surveillance for early detection of HCC

Early stage HCC	Group A (n=24)	Group B (n=82)	P value
Okuda I +II	24(100%)	78(95.12%)	0.00013
CLIP 0-3	23(95.83%)	70(85.37%)	
BCLC 0,A,B	16(66.67%)	8(9.76%)	
Pt within Milan criteria	19(79.17%)	18(21.95%)	

All patients in group A received treatment. Only 60.5% patients received treatment for HCC in group B. 39.5% patients received only palliative care. 26. 25% patients in group A underwent liver transplant whereas only 3.7% patients in group B underwent liver transplant 58.3% and 34.6% patients in group A and B received locoregional therapy respectively. TACE was the most commonly used locoregional therapy (45.8% in group A and 19.8% in group B). 25% and 23.5% patients in group A and B respectively, received only sorafenib because they were unsuitable for other treatment options. Overall median survival in 73 patients who were treated was 12 months whereas median survival in untreated patients was only 4 month.

Table no 8: Treatment

	Group		Total	P value
	A (n=24)	B (n=84)		
TREATED for HCC	24(100.0%)	49(60.5%)	73 (69.5%)	0.001
Liver transplant	6(25.0%)	3 (3.7%)	9 (8.6%)	0.004
Locoregional therapy	14 (58.3%)	28 (34.6%)	42 (40.0%)	
RFA	1(4.2%)	4(4.9%)	5(4.8%)	
TACE	11(45.8%)	16(19.8%)	27(25.7%)	
TARE	0(0.0%)	2 (2.5%)	2 (1.9%)	
Combination	2 (8.3%)	6 (7.4%)	8 (7.6%)	
No	10 (41.7%)	53 (65.4%)	63 (60.0%)	
Only Sorafenib	6 (25.0%)	19 (23.5%)	25 (23.8%)	

Impact of surveillance on survival:

We observed significant improvement of survival in surveillance group as compared to non-surveillance group [p = 0.0002, Hazard ratio- 3.4488, 95% CI(2.0483 to 5.8068)].

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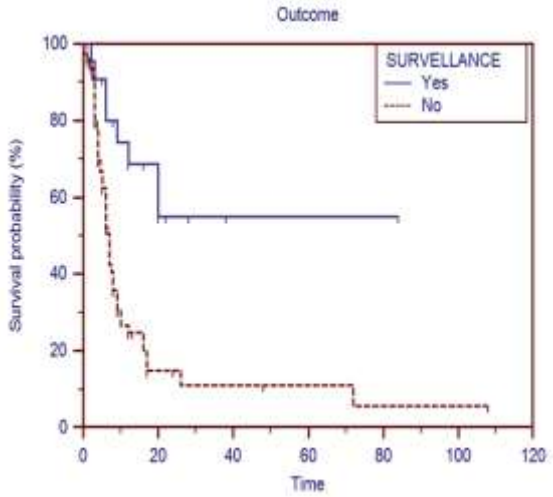

Figure 1: Impact of surveillance on survival

We also compared survival in HCC patients detected at early stage (BCLC stage 0, A, B) and those detected at late stage (BCLC stage C, D). Patients detected at early stages had significantly better survival than those detected at late stages [$p < 0.0001$, Hazard ratio-11.28, 95% CI(6.7226 to 18.9141)].

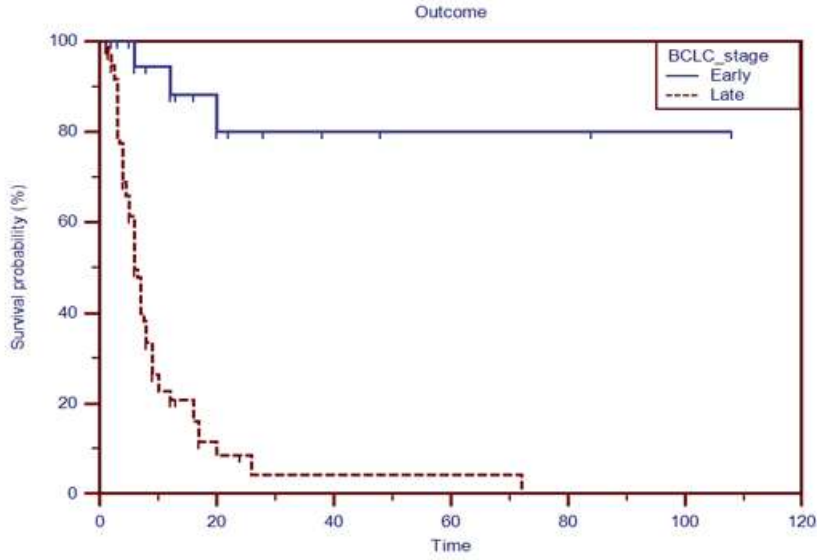

Figure 2: Survival in patients detected at early stage Vs late stage

Patients who were treated for HCC has significantly better survival than untreated patients ($p < 0.0001$). Mean follow up in group A was 18.5±22.37 months while group B mean follow up in group B was 8.94 ± 14.94 (p value- 0.17). Overall follow up was 11.12 months per person. We did multivariate analysis of following factors: Age, gender, symptomatic presentation, surveillance, diabetes mellitus, BMI, portal vein thrombosis, AFP>400 ng/ml, patient within Milan criteria, BCLC staging, treatment and liver transplant. Early BCLC stage detection was independently associated with improved survival.

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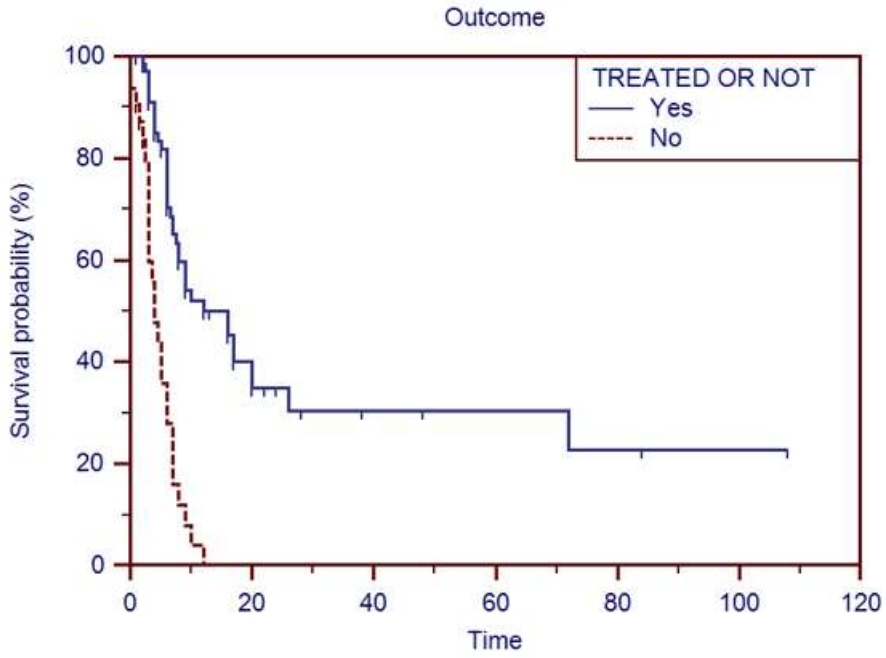

Figure 3: Survival in patients who received treatment for HCC

Discussion

HCC is becoming major public health problem in India due to the rising incidence and high mortality. Most of HCCs are detected at advanced stage limiting treatment option. Surveillance is important tool for early detection of HCC. 108 patients of hepatocellular carcinoma with underlying chronic liver disease were included in our study. There were 24 cases of newly diagnosed hepatocellular carcinoma during cumulative 968.09 person-years of follow-up and incidence rate of 1.63% per year. In study by Paul S.B. *et al.*,[7] during a cumulative 563 person years follow-up nine cases of HCC (all males) were detected with an annual incidence rate of 1.6%.

The frequency of HCC in a cirrhotic may vary depending upon underlying etiology of cirrhosis, such as HBV, HCV, alcohol and nonalcoholic fatty liver disease.[8] AASLD and EASL recommend surveillance for patients with cirrhosis of varying etiologies, to be offered when the risk of HCC is 1.5% per year or greater. In our cohort, incidence rate in patients of liver cirrhosis secondary to HBV, HCV, alcohol and others was >1.5%. Previous study including 322 patients of autoimmune hepatitis reported the risk of HCC among AIH patients with cirrhosis as 1.9% per year.[9] Thus, cirrhosis secondary to other etiologies like autoimmune hepatitis also merits regular surveillance.

Age of presentation of HCC in our study was around fifth and sixth decade. Mean age of patients in group A and group B was 60.08±8.75 year and 61.45±10.47 year respectively. Studies from India have shown the maximum incidence of HCC in the fifth to sixth decade.[10,11] Both group had predominantly male patients. 91.7% and 86.9% patients in group A and group B were male respectively. The male preponderance is similar to previous Indian studies.[10,12] The male: female ratio for HCC in India is reported as 4:1.[12] Demographic profile of patients in both group was similar.

HCCs detected when symptomatic are associated with a poor prognosis. When HCC presents with clinical symptoms, the tumor is typically very far advanced and the patient has few

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therapeutic options. Sandip Pal *et al.*,[13] found that most of the HCCs were diagnosed in cirrhotic and at an advanced stage which limited the therapeutic options. Symptomatic presentation was significantly more common in group B (69%) than group A (41.7%) (p-0.014). Previous Indian study reported symptomatic presentation in 91.6% of patients with mean duration of symptoms 5.0 ± 6.5 months.[10] Improvement in diagnostic techniques has improved detection of HCC at asymptomatic stage.

In systemic review on prognostic factors in HCC which included 23, 968 patients from 72 studies, the most robust predictors of death were portal vein thrombosis, tumour size, alpha-fetoprotein and Child–Pugh class.[14] In our study, portal vein thrombosis was more common in group B (24.4%) than group A (4.2%). Similarly AFP >400 ng/ml was seen more commonly in group B (46.4%) than group A (16.7%). These poor prognostic factors in addition to advanced stage presentation may be contributory to poor survival in group B.

The BCLC staging has been widely used as the standard means of assessing the prognosis for patients with HCC.[15] When patients were classified based on BCLC staging, we observed, significant number of patients were detected in early stage in group A as compared to group B (p value- 0.000). Thus, patients in surveillance group were detected at earlier stage than patients in no surveillance group. In one retrospective study, surveillance doubled the detection of HCC at early stage of BCLC (25.4% vs. 11.9% $P = 0.000$).[16] Anita Kohli *et al.*,[17] noted that patients with cirrhosis who underwent HCC surveillance were found more likely to be diagnosed with HCC that was either potentially curable (BCLC Stage 0/A) or with HCC eligible for treatment with life-prolonging therapies (Stage B/C disease) than patients who did not undergo surveillance.

We observed significant improvement of survival in surveillance group as compared to non-surveillance group [p = 0.0002, Hazard ratio- 3.4488, 95% CI(2.0483 to 5.8068)]. Also, patients detected at early stages had significantly better survival than those detected at late stages [p < 0.0001, Hazard ratio- 11.28, 95% CI(6.7226 to 18.9141)]. A retrospective study from India which included 164 HCC patients, also observed, patients diagnosed at an earlier stage of HCC lived significantly longer after diagnosis than patients diagnosed at a later stage (Stage 0/A: 15.6 ± 14.2 months vs. Stage B/C: 9.43 ± 19.7 months vs. Stage D: 5.59 ± 11.9 months; p = 0.0006).[17] Paul *et al.*,[11] had also reported in their study that treated patients had longer median survival compared to untreated ones (16 months vs. 7 months, p < 0.05). Thus, surveillance can be considered useful tool to improve survival of HCC patients only if patients receives appropriate treatment for HCC.

On multivariate analysis, we observed early BCLC stage detection to be the independent predictor of survival. BCLC was created initially as a staging system to guide treatment indication but it is also able to stratify patients according to prognosis. Its stratification capacity has been validated in Italy,[18,19] and a study performed in the United States[20] has shown that it is superior to the other proposed systems, including CLIP, CUPI, JIS, GETCH and Okuda. In our study early BCLC staging was found to correlate with improved survival of HCC patients irrespective of age, gender, surveillance, DM, obesity, portal vein thrombosis, AFP >400 ng/ml, treatment for HCC, liver transplant or tumor within Milan criteria. Surveillance significantly improved detection of patients in early BCLC stage. Thus, surveillance of chronic liver disease is important tool to improve management and survival of HCC patients.

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Surveillance is useful tool for early detection of HCC in cirrhotics. Treatment of HCC especially early stage patients with curative treatment option like liver transplant can improve survival. Locoregional therapy and liver transplant should be used as treatment modality in suitable patients. Increasing awareness about surveillance in physician treating HCC patient is necessary to improve outcome. BCLC stage should be used for assessing prognosis and making treatment decisions in HCC patients.

Our study has few limitations. Number of patients in surveillance group was less. Lead time bias and length bias cannot be completely excluded. Poor prognostic factor like AFP >400 ng/ml and portal vein thrombosis was more common in non-surveillance group. These factors may be contributory to poor survival seen in non-surveillance group in addition to advanced stage presentation.

Conclusion

Majority of patients in surveillance group were detected in asymptomatic stage. Portal vein thrombosis and AFP >400ng/ml was more common in non-surveillance group. Surveillance improved detection of HCC at early BCLC stage and also detected more tumor within Milan criteria. Surveillance also improved survival & treatment of HCC. Early BCLC stage detection was independently associated with improved survival in HCC.

Conflict of Interest: None to declare
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