



Clinical Study of Advanced Hepatocellular Carcinoma (HCC)

**Treated with Sorafenib in Patients of
CMH, Dhaka**

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Introduction

**Hepatocellular
carcinoma
(HCC)**

**Most common primary liver
cancer**

**Commonly found in CLD patients
due to hepatitis B or hepatitis C
infection**

Introduction (contd)

- ❖ New era in the treatment of advanced HCC has been added in 2007 when Sorafenib got FDA approval
- ❖ Generic Sorafenib became available in Bangladesh in 2012.
- ❖ No data is available for patients of advanced primary HCC in Bangladesh.

Morphology

**Unifocal lesion
mostly seen in
patient without
Cirrhosis of liver.**

**Multifocal lesion
mostly seen in
patient with
Cirrhosis of liver**



Tumor Staging Systems

❑ Various systems used to determine the stages of HCC

Most of them describe the prognosis of HCC depending upon :

The severity of underlying liver disease

The size and number of tumor

Extension of tumor into adjacent structures

Presence of metastasis

Primary tumor

TX – primary tu cannot be assessed

T0 – no evidence of primary tu

T1 – solitary tu without vascular invasion

• **T2** – solitary tu with vascular invasion

T3a – multiple tu more than 5 cm

• **T3b** – single or multiple tu of any size involving maj branch of portal vein of hepatic vein

T4 – tu with direct invasion of adjacent organs other than gallbladder or with perforation of visceral peritoneum

Regional lymph node

NX – regional lymph cannot be assessed

N0 – no regional lymph metastasis

N1 – regional lymph metastasis

Distant metastasis

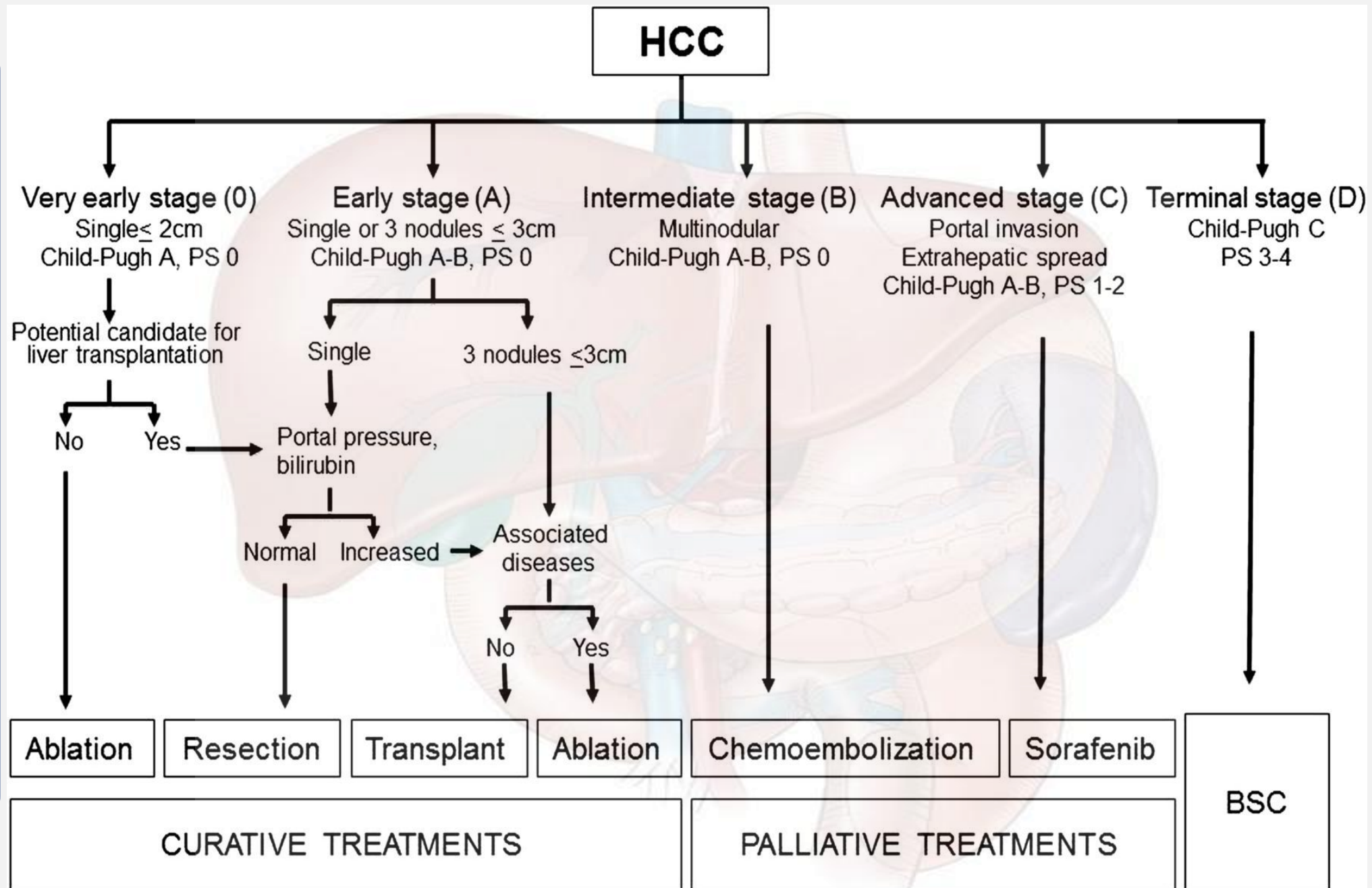
• **M0** – no distant metastasis

• **M1** – distant metastasis

Barcelona Clinic Liver Cancer System

- ❑ Considers in combination of tumor burden, hepatic function and performance status.
- ❑ Can provide not only the prognosis but also the treatment algorithm .

BCLC Staging and Treatment Strategy



Purpose of the Study

- ❑ To evaluate the efficacy of TKI Sorafenib on the patients of advanced and non resectable primary HCC in Bangladeshi patients
- ❑ Efficacy was observed in terms of overall survival, median survival, drug compliance and common toxicities.

Methodology

- ❑ Patients were randomly selected in admitted patients from Medical Oncology Department of Combined Military Hospital, Dhaka
- ❑ They have received TKI Sorafenib for HCC as first line or second line therapy.

Methodology (contd)

- ❑ The patients received Sorafenib 200 mg - 400 mg twice daily till disease progression ceases or increases and there was no unacceptable toxicities.

Methodology (contd)

- ❑ Following variables were considered to assess the disease status of the patients before & after treatment with Sorafenib:

Serum bilirubin

Serum albumin

Prothrombin time

AFP

USG

CBC

CT scan

Ascites, PS

Study Design

Eligibility criteria
**Histologically/
Cytologically confirmed,
Non-resectable tumour**
Stage- C
ECOG PS : (1 -2)
Good organ function

**Sorafenib
400 mg bid**



- ❖ Major endpoints
- ❖ Overall Survival
- ❖ Quality of Life

Results and Discussion

Total Patients



32 (advanced hepatocellular carcinoma)

Treatment Period



June 2012 to July 2017 (CMH, Dhaka)

Sex



Male- 87.5%, Female- 12.5%

Primary Endpoint



Median Overall Survival

Median Age of Enrolled Patients



55 years

Results and Discussion (contd)

- ❑ In 24 months of follow-up period from the date of Sorafenib taken, the overall survival of the patients ranged from 12 to 764 days.
- ❑ Median overall survival was found to be 141 days or 4.7 months with Sorafenib therapy.
- ❑ The overall survival was more than 4 months in 53.1 % patients.

Common toxicities

Anorexia

Rash and mucositis

Weakness

HTN

Yellow coloration of
skin, Mucosa

Diarrhoea

Comparison with the International Studies of Sorafenib in HCC patients

	Dhaka CMH	Denmark ^[3]	Spain ^[1]	Korea ^[4]	UK ^[5]	Turkey ^[2]
Overall survival range	12 to 764 days	4 to 777 days	N/A	14–452 days	N/A	N/A
Median Overall Survival	141 days or 4.7 months	162 days	321 days	141 days	123 days	336 days

Recommendations

- ❑ According to this study **Sorafenib** is recommended **first line** drug for the treatment of advanced HCC.
- ❑ Initially the patients cannot tolerate the full dose of **800 mg** a day. Gradual increase of dose from **200 mg to standard 800 mg** per day is well tolerated.

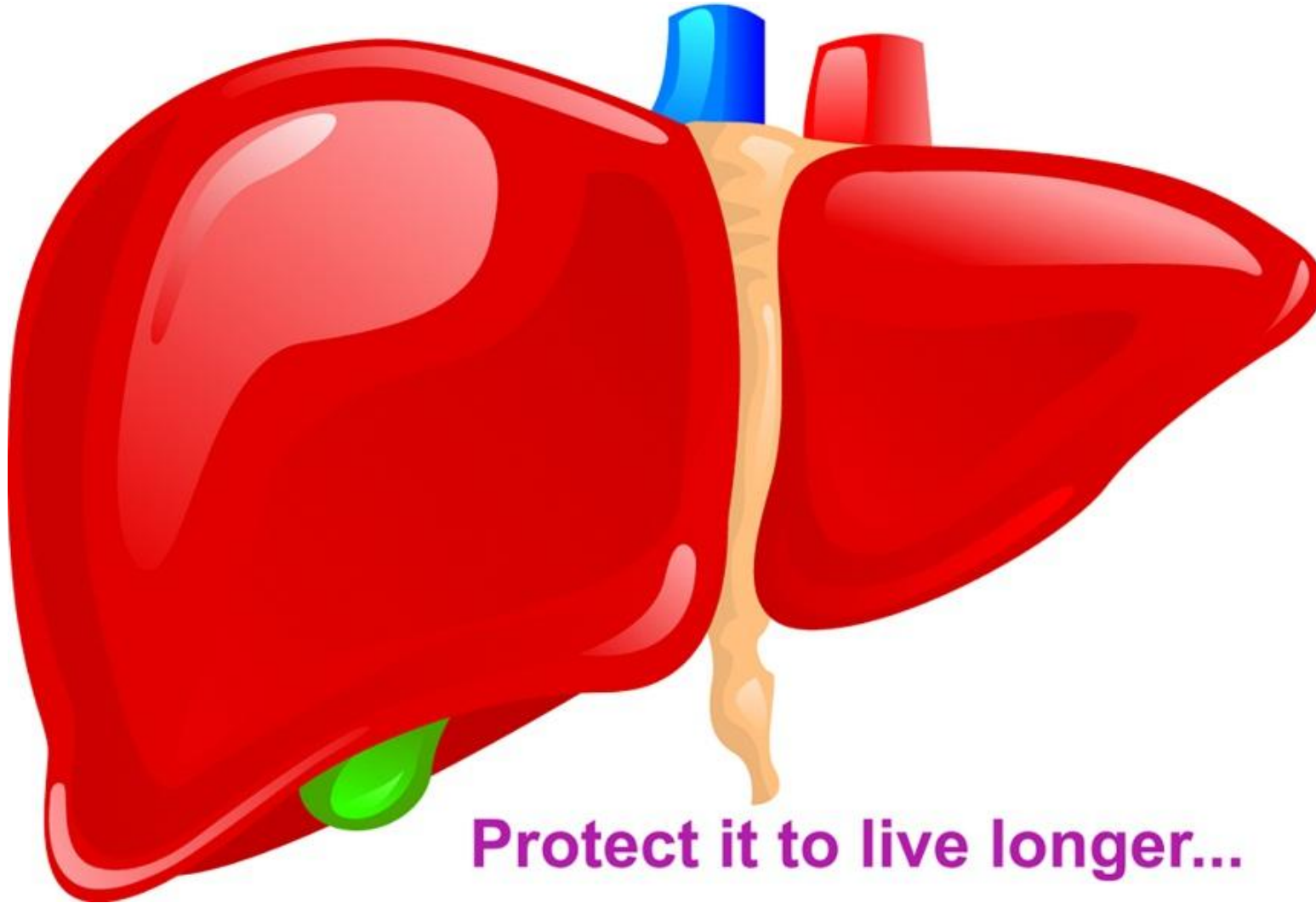
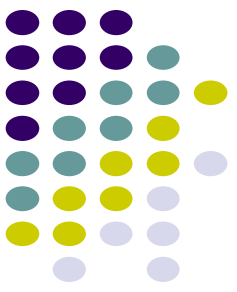
Recommendations

- ❑ There might have some specific gene mutation like **EGFR, ALK, BRAF, HER-2, KRAS** etc, which could be more sensitive to Sorafenib or any other TKI.
- ❑ In future further **gene profiling** will guide us precisely.

References



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