POSTER REFERENCE NUMBER: 207

TREATMENT OUTCOME WITH GENERIC FORMULATIONS OF SOFOSBUVIR PLUS DACLATASVIR IN HEPATITIS C VIRUS GENOTYPE 3 RELATED CHRONIC HEPATITIS PATIENTS

Sonjoy Dey[1], Mamun Al Mahtab[2], Sheikh Mohammad Fazle Akbar[3]

BACKGROUND

Patients with chronic hepatitis C (CHC) infection have a higher risk of liver related complications. Genotype 3 is known as difficult to cure genotype, which is most common in Bangladesh. Branded formulations of direct acting antiviral (DAA) are not available in Bangladesh. We evaluated the safety and efficacy of generic formulations of Sofosbuvir plus Daclatasvir in hepatitis C virus genotype 3 related CHC patients.

METHODS

Treatment-naïve and treatment-experienced patients who were meet the eligibility criteria, were sampled from Department of Hepatology, BSMMU, Bangladesh.

Patients were received Tab Sofosbuvir 400mg plus Tab Daclatasvir 60mg daily for 12 weeks. Key exclusion criteria were creatinine clearance < 30 ml/ min, any evidence of cirrhosis (clinical or imaging study), co-infection with HBV, co-infection with HIV and associated with hepatocellular carcinoma. Outcome was assessed at the end of 4 week (RVR), 12 week (ETR) and 24 week (SVR12).

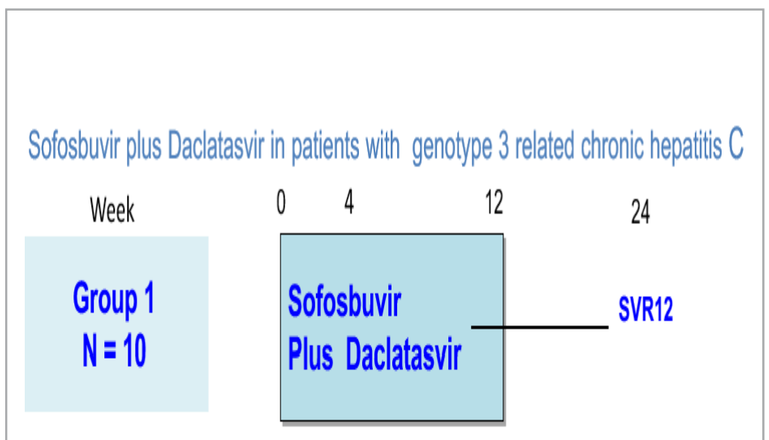
RESULTS

Total 10 patients with HCV genotype 3 related CHC were received treatment. The study population comprised 80 % male and 30 % treatment experienced. At baseline HCV RNA were 70,500-1, 98, 27,500 IU/ml. All patients completed treatment. RVR was achieved in 100%, ETR in 100% but SVR12 in 90%. Most adverse events were headache 30% and fatigue 20%.

Baseline demographics and disease characteristics

Table1: Baseline demographics and disease characteristics

Characteristic	N=10
Male	8 (80%)
Age, median years(range)	43.3 (19-58)
PegIFN/RVB experienced	3(30%)
HCV RNA (range) IU/ml	70,500-1,98,27,500
SGPT, Median (range) IU/ml	224 (184-371)
S bilirubin, Median (range) mg/dl	1.1 (0.5-3.5)
S albumin, Median (range) gm/dl	3.9(3.6-5.5)
PT, Median (range) (Sec)	11.8 (11-14)
Fibroscan, KPa, Median (range)	4.3 (3.5-7.8)



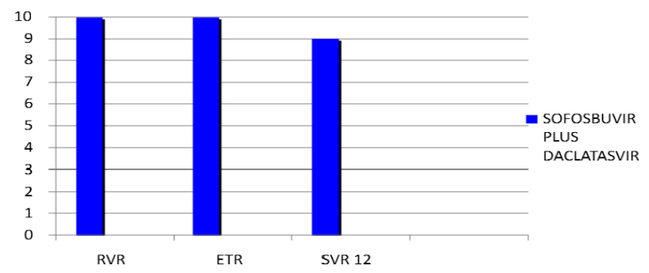


Fig 1: Virologic response during and after treatment with SOFOSBUVIR PLUS DACLATASVIR

Table 2. Adverse events observed during treatment with SOFOSBUVIR PLUS DACLATASVIR

Characteristic	SOF+DAC
Headache	3 (30%)
Fatigue	2 (20%)
Sleep disturbance	1 (10%)
Irritability	1 (10%)

CONCLUSIONS

The HCV regimen with generic formulations of Sofosbuvir plus Daclatasvir for 12 weeks achieved 90% SVR12 and well tolerated in HCV genotype 3 related CHC patients. Definite comment can be made after a large size sample study.

REFERENCES

1 Resident, Department of Hepatology, Bangabandhu Sheikh Mujib Medical University, Bangladesh
2 Department of Hepatology, Bangabandhu Sheikh Mujib Medical University, Bangladesh
3 Department of Medical Sciences, Toshiba General Hospital, Tokyo, Japan

CONFLICTS OF INTEREST

There are no Conflicts of interest to any of the authors.

Contact Information

NAME : Dr. Sonjoy Dey

TEL NO: +8801712243805

EMAIL: sonjoydey_cmc40@yahoo.com

World Hepatitis Summit 2017
SÃO PAULO, BRAZIL 1-3 NOVEMBER