Directly Acting Antiviral Agents (DAA) In The Treatment Of HCV Infected Haemodialysis Patients- 4 Years' Experience From A Tertiary Care Hospital

Dr Sreenidhi H C , Dr Shivendra Singh, Dr Manjit Pal Singh, Dr Khushbhoo Rani,
Department of Nephrology
Institute of Medical Sciences BHU Varanasi

BACKGROUND

- HCV infection in HD population is associated with poorer prognosis when compared with sero-negative HD patients
- HCV infection is associated with relative immunosuppression and requires multiple transfusions
- In the last decade with the discovery of DAA there has been significant paradigm in the management of HCV in HD patients
- The current study was done to evaluate the safety and efficacy profile of DAA for HCV infection in HD patients at a tertiary care hospital

AIM-To study the safety profile and efficacy of DAA in newly diagnosed HCV infected HD patients

STUDY DESIGN

PROSPECTIVE OBSERVATIONAL STUDY

STUDY PERIOD- Oct2016 - Oct 2020

INCLUSION CRITERIA-
HD patients aged ≥18 years who were newly diagnosed with HCV infection

EXCLUSION CRITERIA-
- **HepB/HIV coinfection**
- **prior malignancy**
- **pregnant females**
- **not consenting**

INVESTIGATIONS

- **COMPLETE BLOOD COUNT**
- **RENAL FUNCTION TEST**
- **LIVER FUNCTION TEST**
- **SERUM ALBUMIN**
- **TOTAL PROTEIN**
- **ELASTOGRAPHY OF LIVER**
- **HCV QUANTITATIVE PCR**
- **HCV GENOTYPING BY PCR**

Epidemiological data

PATIENTS TREATED WITH SOFOSBUVIR BASED DAA -THERAPY

DAA REGIMENS

- **Sofosbuvir 400mg & Ledipasvir90mg *(genotype 1,4,5 &6)***
- **Sofobuvir400mg & Daclatasvir60mg *(genotype 3)***
- **Sofosbuvir 400mg & Velpatasvir 100mg *(pan genotype)***

DEFINITION

Diagnosis of HCV – presence of HCV virus in serum by quantitative PCR

SVR (sustained virological response) defined as undetectable viral RNA with real time PCR

Institute ethics committee approval and consent taken from all study participants

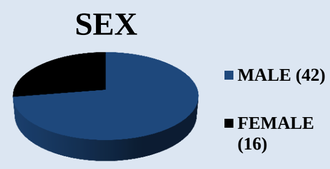
FOLLOW UP

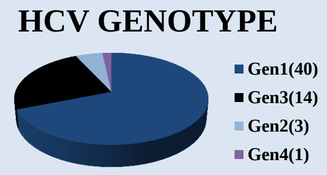
- ***CBC,RFT & LFT monitored every monthly.***
- ***HCV quantitative PCR done at 12 weeks and 24 weeks***
- ***Patients observed for adverse drug reactions, requirement of blood transfusion and additional erythropoietin doses***
- ***Patients were followed up for a period of 24 weeks***

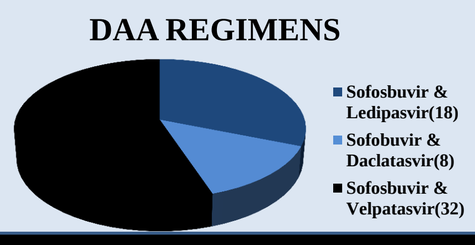
Statistical analysis done with SPSS Statistics software version 28.

RESULTS

Total patients- 58







- **5 patients had evidence of cirrhosis at initiation of therapy**
- **Baseline characteristics was similar between different HCV genotypes**
- **18 patients received Sofosbuvir & Ledipasvir, 8 patients received Sofosbuvir & Daclatasvir and 32 patients received Sofosbuvir & Velpatasvir**
- **At 12 weeks of therapy, 51 (87.9%) patients achieved SVR**
- ***At 24 weeks all 58(100%) patients achieved SVR***
- **6 patients had generalized hyper pigmentation ,4 patients required additional erythropoietin therapy and 2 patients required blood transfusion during therapy**
- **No serious adverse reactions seen**

SR NO	VARIABLE	HCV GEN1 N=40	HCV GEN3 N=14	HCV GEN2&4 N=4	P value
1	AGE (years)	47.53±5.53	52.71±16.06	40.33±15.94	0.22
2	SEX(M/F)	29:11	10:4	3:1	0.9
3	DUARTION OF HD (yrs)	1.9±0.94	1.84±0.78	1.83±0.37	0.9
4	SGOT (U/L)	44.10±18.8	42.21±15.05	51.0±20.42	0.56
5	SGPT(U/L)	43.90±20.9	41.29±16.61	45.00±19.46	0.81
6	SER ALBUMIN(g/dl)	3.49±0.50	3.48±0.69	3.63±0.73	0.81
7	CIRRHOSIS	3	1	1	0.74
8	TYPE 2 DM	10	4	2	0.86
9	HEMOGLOBIN(g/dl)	9.42±1.43	9.76±1.06	9.76±2.35	0.78
10	HCV VIRAL LOAD (U/ml)	2993178.07± 5588406.1	1169641.78± 2571038.5	3545001.33±559 8588.93	0.69
11	DAA REGIMENS	Sofosbuvir&Ledipasvir(16) Sofosbuvir&Velpatasvir(24)	Sofosbuvir&Daclatasvir(8) Sofosbuvir&Velpatasvir(6)	Sofosbuvir&Ledipasvir(2) Sofosbuvir&Velpatasvir(2)	

CONCLUSION

DAA therapy is efficacious in achieving SVR in HCV infected patients with very good safety profile. By 12 weeks of therapy 87.9% patients achieved SVR and by 24 weeks 100% patients achieved SVR .There is no difference in between the DAA regimens. In the resource poor setting, where HCV genotyping is difficult, pan genotypic Sofosbuvir & Velpatasvir combination can be considered for therapy.

References
- European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2018 J Hepatol, 69 (2) (2018), pp. 461-51
- Borgia SM, Dearden J, Yoshida EM, et al. Sofosbuvir/velpatasvir for 12 weeks in hepatitis C virus-infected patients with end-stage renal disease undergoing dialysis. J Hepatol. 2019;71(4):660-665