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The Efficacy of Combined Sofosbuvir and Daclatasvir in Treating Hepatitis C Patients – A Preliminary Report

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BACKGROUND

The combination of sofosbuvir and daclatasvir can be used for treating all genotypes of hepatitis C. As such, genotype testing can be skipped, making this combination more attractive for hepatitis C elimination protocols.

The combination of both drugs in a single tablet (Sovodak) has been first available in Iran and is already tested in a small population of 100 patients, all cirrhotic[1].

In this study we test this combination in over 1000 subjects including all genotypes, cirrhotics, non-cirrhotics, HIV coinfection, and other subgroups.

Table 1:
Baseline characteristics of patients enrolled*

	Count	Percent
Genotype:		
1 (a/b)	702	45.5%
2	13	0.8%
3 (a/b)	594	38.5%
4	11	0.7%
Mixed	7	0.5%
Unknown/untypable	217	13.9%
No cirrhosis	583	50.7%
Compensated cirrhosis	513	44.6%
Decompensated cirrhosis	53	4.6%
Treatment naïve	762	77.5%
Previous interferon-based failure	186	18.9%
Previous sofosbuvir-based failure	31	3.2%
Renal failure	59	3.9%
Hemodialysis	47	3.1%
Post transplant (kidney/liver)	28	1.8%
HIV coinfection	134	11.8%

CONCLUSIONS

This is by far the largest study on the efficacy of sofosbuvir and daclatasvir in treating hepatitis C.

The efficacy of this combination and the ease of use (one pill a day) makes Sovodak an excellent choice for treating all cases of hepatitis C.

Due to the uniformity of treatment regimen across genotypes it might not even be necessary to check the genotype in the future. This is especially useful in elimination programs where the elimination of any single test would have an enormous effect on the budget.

This fact, combined with the low price of Sovodak, makes this treatment very attractive for HCV elimination programs.

Pilot studies for HCV elimination are already underway in Iran using this combination.

*This is a preliminary report. There are many unchecked and missing data and some records might be duplicate.

METHODS

The aim of the study is to include at least 1000 subjects with hepatitis C including subjects with cirrhosis, co-infection with HIV or HBV, renal failures, and post-transplant subjects.

Patients are treated with a single fixed dose combination pill containing 60 mg daclatasvir and 400 mg sofosbuvir (Sovodak 60/400, RojanPharma, Tehran, Iran) taken once daily for 12 weeks.

For subjects with cirrhosis, weight-based ribavirin (1000 mg daily if less than 75 kg or 1200 mg if 75 kg or over) is also added. If ribavirin is contraindicated, the treatment will be extended to 24 weeks with Sovodak alone.

The dose of daclatasvir is modified to 30 or 90 mg (Sovodak 30/400 or Sovodak 90/400) in subjects on anti-retroviral treatment (HIV) if required due to drug interaction.

Subjects with renal failure receive the same treatment (without ribavirin) but are followed weekly.

Response to treatment is assessed 12 weeks after the end of treatment with a sensitive assay (SVR12).

RESULTS

Until now 1542 subjects have been enrolled, 1012 have finished the treatment and 619 have been followed for 12 weeks after end of treatment (time frame for SVR12).

Mean age of patients is 48.7 years and 80.5% are male. The characteristics of patients enrolled in the study are given in table 1.

Side effects included headache, fatigue, diarrhea and pruritic rash. None of these side effects was severe enough to require dose modification or discontinuation of treatment. None of the patients receiving ribavirin required change in dose because of anemia. Of particular interest is lack of side effects among renal failure patients, even those under hemodialysis.

The overall SVR rate (per-protocol) among the 619 patients reaching this time point is 97.7%. The rates in different subgroups are given in table 2.

Table 2:
Sustained viral response in patients completing treatment (per-protocol)*

	Number	Number achieving SVR	SVR percent
Total	**619**	**605**	**97.7%**
Genotype			
1 (a/b)	**342**	**336**	**98.2%**
2	**5**	**4**	**80.0%**
3 (a/b)	**227**	**222**	**97.8%**
4	**4**	**4**	**100%**
Mixed	**3**	**3**	**100%**
Unknown	**38**	**36**	**94.7%**
No cirrhosis	**218**	**213**	**97.7%**
Compensated Cirrhosis	**254**	**246**	**96.9%**
Decompensated Cirrhosis	**15**	**15**	**100%**
Renal failure	**17**	**17**	**100%**
Hemodialysis	**13**	**13**	**100%**
Treatment naïve	**182**	**173**	**95.1%**
Previous interferon failure	**77**	**75**	**97.4%**
Previous sofosbuvir failure	**12**	**11**	**91.7%**
Post-transplant	**9**	**8**	**88.9%**
HIV coinfection	**6**	**6**	**100%**

REFERENCES

1. The Efficacy of 12 Weeks of Sofosbuvir, Daclatasvir, and Ribavirin in Treating Hepatitis C Patients with Cirrhosis, Genotypes 1 and 3. Hepat Mon 2017;17(1): e44564.

CONFLICTS OF INTEREST

SM has received research funding from Rojan Pharma. SM and HP have received travel grants from Rojan Pharma. ANB is a shareholder in Rojan Pharma.

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