SAFETY OF TRIPLE THERAPY WITH TELAPREVIR IN HEPATITIS C EXPERIENCED HAEMOPHILIACS

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Introduction and Objectives:

Cure rates of chronic hepatitis C patients with advanced fibrosis or cirrhosis by pegylated interferon and ribavirin are unsatisfactory. Recent reports provide promising results with increased sustained response rates with the addition of protease inhibitors. Few data on safety and tolerability in patients receiving triple therapy are available. For patients with hereditary haemorrhagic disorders infected with hepatitis C, data are lacking.

Preliminary safety data on triple anti- HCV therapy are reported, in haemophilia patients HCV positive, previous treated with double therapy.

Patients and Methods:

- A total of 5 HCV infected haemophilia pts, mean age 42 years (38-51) were treated with triple regimen which included the protease inhibitor **telaprevir.**
- All had already received previous double anti-HCV therapy and they had not achieved SVR.
- They also had advanced fibrosis Score evaluated by measuring liver Stiffness using Fibroscan. Patients characteristics are shown in Table 1.

Treatment schedule:

- Pegylated interferon a-2a 180μg/week
- Ribavirin 1000-1200mg daily
- Telaprevir 750mg tid. Telaprevir was administered for the first 12 weeks and then stopped.

Total treatment duration was 48 weeks, for those who had virological response at 4, 12, 24 weeks.

Results:

❑All pts completed treatment

Table 1. Characteristics of the patients included in the triple HCV therapy

	1	2	3	4	5
Haemophilia Severity	A severe	A mild	A mild	B severe	B moderate
Age	42	38	39	51	40
Liver Fibrosis Fibroscan Stiffness (kPa)	14.3	10.3	9.3	21.3	16.8
Previous anti-HCV therapy	Non Responder	Non Responder	Relapser	Non Responder	Relapser

Safety

- Severe adverse events were not observed.
- Anaemia was present in all patients.
  - Median decrease in haemoglobin was 3gr/dl (2,5-4,4).
  - ➢*During the triple therapy, ribavirin-dose was reduced in 3/5 patients and was returned in the initial dose after cessation of telaprevir. No transfusions or Erythropoetin administration was added.*
  - Median PLT during therapy was 128.000 (range 72000-185000)
  - Neutrophils ranged between 1400-4100 (median 2700).
- Mild general symptoms were reported
  - fatigue and anorexia (5 pts).
  - haemorrhoids (2 pts)
  - Nausea (1 pt).
  - No dermatological events were present, except mild itching after bathing.
- Biochemical abnormalities were observed only in 2 patients and included:
  - Increased uric acid (1 pt)
  - Hypertriglyceridemia and low potassium levels (1 pt)

Efficacy

- All 5 patients responded to therapy during the first 12 weeks of therapy.
- After cessation of telaprevir 3/5 were HCV-RNA negative at 24 and 48 weeks (1F3, 2F4)
- So far 2/5 patients have achieved SVR.

Conclusion:

Our preliminary data with triple anti –HCV therapy which included a protease inhibitor in haemophiliacs, is associated with the same risk of define adverse events as the patients in other risk groups. A follow up of higher number of patients is needed to confirm these data.