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TELAPREVIR: ADVERSE EVENTS IN CLINICAL PRACTICE

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BACKGROUND

- The addition of telaprevir to peg-interferon and ribavirin represents a new therapy for hepatitis C(HCV) associated with an improvement in treatment response rates and an impairment of the safety profile.

PURPOSE

- To evaluate the safety of telaprevir-based therapy in patients for HCV infection in real clinical practice in a specialty hospital.

MATERIALS AND METHODS

- Prospective and observational study of patients who start telaprevir from April through September 2012.Data were collected at each treatment visit at the hospital pharmacy through clinical interview and revision of analytical parameters.

RESULTS

- We enrolled 14 patients treated with telaprevir, 9 monoinfected and 5 co-infected. All patients were between 18 and 70 years old ,had HCV genotype-1 infection and had at least stage-3 of liver fibrosis (metavir score).Only two patients had received no previous treatment. In the pre-treated group, 42% of the patients had a previous relapse, 33% had a partial response, and 25 % had no response.

Anemia	69%	Grade 2 (8.0 – <10.0g/dL)	54%
		Grade 3-4(<8,0g/dL)	8%
Thrombocytopenia	69%		
Neutropenia	77%		
Hyperbilirrubinemia	46%		
Increased tryglicerides	46%		
Increased ferritin	54%		
Increased GGT	46%		
Photosensitivity	23%		
Fatigue	100%		
Depression	69%		
Reduction appetite	77%		
Nausea	30%		
Diarrhea	46%		
Vomiting	38%		
Haemorrhoids	77%		
Rash and pruritus	69%		

- 43% of patients required ribavirin dose reduction due to anemia (hemoglobin<10g/dl).
  - 23% of patients needed erythropoietin-stimulating agents due to anemia(hemoglobin<8,5 g/dl even though the ribavirin dose reduction).
  - 8% of patients required blood transfusion.
  - Discontinuation of telaprevir occurred in one patient because of rash. No patients discontinued treatment because of anemia.

CONCLUSIONS

- The safety profile of telaprevir was consistent with the findings in clinical trials. However, most of the adverse events were reported more frequently in patients in real clinical practice compared with previous results in clinical trials.With these serious and frequently adverse events may be an opportunity for pharmacist involvement to improve safety of this treatment.