Safety assessment of triple therapy treatments in chronic hepatitis C

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Background

Efficacy of chronic hepatitis C genotype 1 treatment has been improved with protease inhibitors (PI) telaprevir and boceprevir. However, triple therapy PI, peginterferon alfa and ribavirin has increased the number, type and severity of adverse events.

Purpose

Assessing the triple therapy safety in the first 12 weeks of treatment with telaprevir and boceprevir used for chronic hepatitis C treatment in clinical practice.

Materials and Methods

Patients treated telaprevir and boceprevir

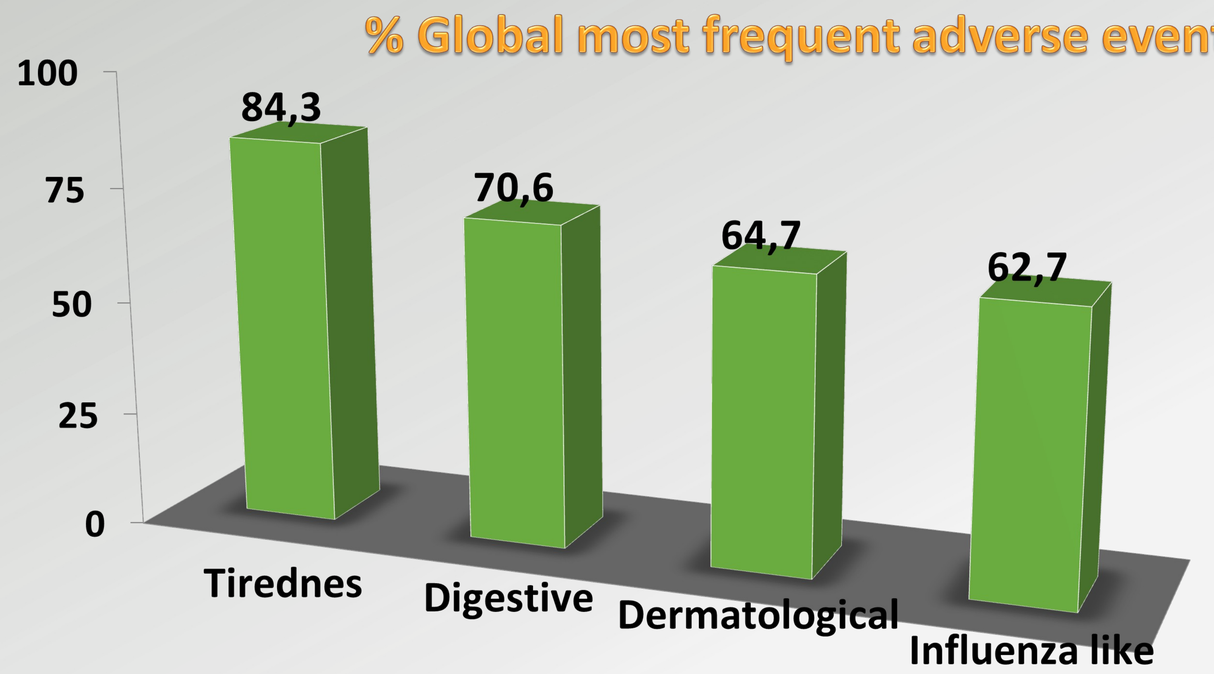
Interviewed monthly receiving treatment in the Outpatient Care Unit

March – September 2012

- ✓ Predefinided questionnaire
- ✓ Anemia, neutropenia and thrombocytopenia also were included as adverse effects if the patient had been treated for any of them

Results

- ✓ Telaprevir 34 patients
- ✓ Boceprevir 17 patients
- ✓ All patients had at least one adverse event on any of the visits



Adverse event	Telaprevir (%)	Boceprevir (%)	Adverse event	Telaprevir (%)	Boceprevir (%)
Influenza like illness	61.8	64.7	Oral disorders	32.4	33.3
Tiredness	85.3	82.4	Hemorrhoids	64.7	0.0
Mood disorders	32.4	70.6	Tachycardia	2.9	23.5
Digestive disorders	67.7	76.5	Libido decreased	2.9	11.8
Dermatological disorders	70.6	52.9	Edema	11.8	11.8
Hair lost	5.9	17.7	Anemia	55.9	47.6
Non productive cough	8.8	29.4	Neutropenia	17.7	11.8
Itchy eyes	0.0	5.9	Thrombocytopenia	14.7	5.9

Conclusion

Safety in the first 12 weeks of triple therapy results in a high frequency of adverse events. Information of possible side effects and how to prevent or treat them is important for patients. Since commercialization of PI is recent, it is also important to communicate and register every new adverse event not identified in clinical trials.