BOCEPREVIR AND TELAPREVIR: SAFETY

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Background

Protease inhibitors boceprevir and telaprevir were approved by the European Medicines Agency in July and September 2011 respectively for the treatment of hepatitis C genotype 1 in combination with peginterferon and ribavirin (tri-therapy).

Purpose

To describe the safety of boceprevir and telaprevir in clinical practice.

Material and method

All patients who received tri-therapy previous commercialization (compassionate use) of boceprevir and telaprevir to September 2012 were included. Data collected were: drugs administered for tri-therapy, analytical parameters (hemoglobin, neutrofils and platelets) and subjective adverse effects. Patients were educated by the pharmacist about the medications with the initiation of tri-therapy and interviewed about adverse effects monthly with each refill of tri-therapy.

Results

Of the 36 patients with chronic hepatitis C included, 16 were treated with telaprevir and 20 with boceprevir. The most frequent adverse reactions were anemia, neutropenia and thrombocytopenia.

Protease inhibitor	Total patients	Anemia	Neutropenia	Thrombocytopenia
		Nº patients (%)		
Boceprevir	20	17 (85)	14 (70)	15 (75)
Telaprevir	16	11 (69)	6 (38)	13 (81)

Anemia was managed with ribavirin dose reduction (7 patients), erythropoiesis-stimulating agents (11 patients) and packed cells (7 patients).
Neutropenia and thrombocytopenia were controlled with peginterferon dose reduction (2 patients) and granulocyte colony- stimulating factor (4 patients).
Other adverse effects were fatigue or discomfort (16 patients), insomnia (5 patients), fever (5 patients), pruritus (4 patients), dysgeusia, headache, nausea, diarrhea and irritability. Eight patients had to discontinue treatment due to adverse reactions which were not controlled with dose adjustment or supportive drugs.

Conclusions

All adverse events observed were reported in the EMA studies. It is very important to have a close collaboration between the physician and the pharmacist for medication management, so that adverse reactions not described in the drug information will be reported to health agencies.