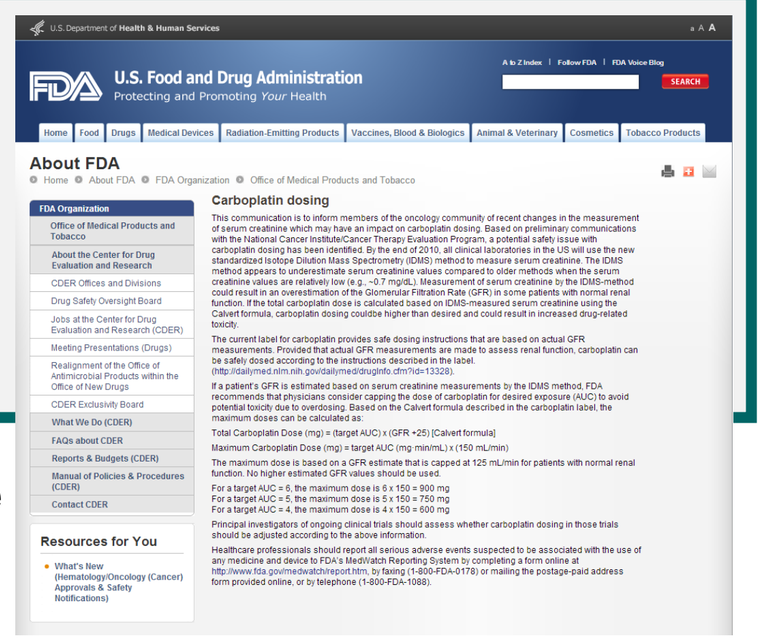
COMPLIANCE WITH FDA RECOMMENDATIONS ABOUT OVERDOSING WITH CARBOPLATIN

C. Martinez-Diaz, S. Fenix-Caballero, C. Palomo Palomo, M.J. Gandara-LadrondeGuevara, E.J. Alegre-DelRey, M.A. Blanco Castaño, J.F. Lopez-Vallejo, J. Diaz-Navarro, J.M. Borrero Rubio, E. Rios-Sanchez. E.

Hospital Universitario Puerto Real, Hospital Pharmacy, Puerto Real Cádiz, Spain.

BACKGROUND

At the end of the year 2010, FDA issued an alert regarding the utilisation of one new method for serum creatinine determination. This method provided an insufficient dosing over previous methods, most especially in serum creatinine value ≤0.7mg/dl. This could mean an increase in dosing and toxicity of carboplatin. It was therefore recommended the use of fixed maximum doses for each target AUC value.



PURPOSE

① To determine compliance with FDA recommendations about carboplatin dosage

② To assess the toxicity emerged at doses higher tan recommended.

MATERIALS AND METHODS

Data from Farmis® database

- Overall number of patients
- Carboplatin courses
- Sex and age
- Diagnosis
- Overdosage percentage.

From January 2011 to September 2013

Overdosage courses were selected

carboplatin dosing >900mg for a target AUC=6
carboplatin dosing >750mg for a target AUC=5
carboplatin dosing >600mg for a target AUC=4

In the event of an overdosing, blood tests before the next course were sought.

Pharmacological toxicology (neutropenia and thrombocytopenia) and the need to delay the chemotherapy course were evaluated.

RESULTS

A total of 195 patients

763 carboplatin courses → 2% overdosed

Patients afected by overdosing: 3 women and 4 men, with an average of 48 years.

Type of cancer: lung (N=2), stomach (N=1), ovary (N=2) and unknown origin (N=2).

Chemotherapy courses	Overdosage percentage	¿Need to delay the next chemotherapy course? (1 week)	Adverse events
1	2%	No	-
5	3%	Yes, N=2	Neutropenia, grade 1 (N=3) Neutropenia, grade 2 (N=1)
2	7%	Yes, N =1	Neutropenia, grade 3 (N=1)
1	9%	No	-
1	10%	No	-
2	13%	No	-
1	15%	No	-
3	20%	Yes, N =1	Neutropenia, grade 3 (N=1)
1	22%	No	-
1	29%	No	-

Of the eighteen next chemotherapy courses with excess dosage, 22.2% were delayed.

CONCLUSIONS

While the rate of implementation is rather high, it is necessary to set up an automated alert system based on FDA recommendations.

Neutropenia was the only adverse event resulting in delays of chemotherapy; with no thrombocytopenia.

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