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Title **Amotosalen (Intercept®) for the Inactivation of Pathogens for Transfusion Therapy**

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Reference 2009 June. www.gencat.cat/salut/depsan/units/aatrm/pdf/in_amotosalen_intercept_aatrm_2009ca.pdf

Aim

To analyze scientific evidence related to the efficacy, effectiveness, and safety of amotosalen plus ultraviolet light for the inactivation of pathogens in plasma and platelets for transfusion therapy.

Conclusions and results

Three randomized clinical trials (RCT) were selected for platelets, two RCTs and a quasiexperimental study for plasma, and three hemosurveillance studies. Generally, the quality of methodology in the clinical trials of amotosalen was considered good. The RCTs showed no statistically significant differences with respect to post-transfusion platelet recovery on transfusion of similar amounts of platelets in the intervention and control groups. Moreover, it was demonstrated that treatment with amotosalen plus ultraviolet light did not alter platelet hemostatic capacity. Regarding plasma, studies on patients with acquired coagulopathy, congenital coagulopathy, or thrombotic thrombocytopenia purpura did not show statistically significant differences between the intervention and control groups. Treatment-related adverse effects, serious adverse effects, and the deaths observed during treatment were also similar in both groups.

In Spain, plasma inactivated with methylene blood is used in approximately 61% of autonomous communities, whereas fresh frozen plasma subjected to quarantine is used in the rest of autonomous communities. Only the Red Cross Hospital in Madrid uses amotosalen in plasma. Regarding platelets, no pathogen inactivation technique is used in 77% of autonomous communities and the remaining 33% use amotosalen as a pathogen inactivation technique. The use of platelets inactivated with amotosalen would represent an estimated cost increase of 3 359 808.8 euros for 2009 as compared to 2008.

The systematic review showed that amotosalen is effective and safe for pathogen inactivation in plasma and platelets for use in transfusion. In addition, the results from active hemosurveillance subsequent to its commercialization showed good patient (adult and pediatric) tolerance in 14 493 transfusions of platelet concentrations treated with amotosalen.

Methods

Scientific evidence available up to April 2009 was systematically reviewed using the main biomedical databases. Randomized clinical trials were selected. Two reviewers assessed the quality of the methodology, the classification of the evidence, and the degree of recommendation of the studies based on the Scottish Intercollegiate Guidelines Network (SIGN) criteria, and then they synthesized the scientific evidence. To ascertain the current situation of pathogen inactivation in plasma and platelets in Spain, one transfusion center in each autonomous community was contacted to request information. Finally, the impact on the budget of the hypothetical use of amotosalen in platelets was analyzed.

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