

The evaluation of isotretinoin induced adverse drug reactions

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Background and Aims: Adverse drug reactions (ADRs) are a major cause of morbidity and mortality and have become one of the major health problems. Therefore, assessment, detection, and monitoring of ADRs allow us to prevent and manage ADRs. Currently, isotretinoin is the effective therapy for the treatment of severe recalcitrant nodular acne unresponsive to conventional therapy. It can cause severe adverse reactions and teratogenic effects. Therefore, we conducted this study to assess the rate and pattern of isotretinoin ADRs.

Methods: This was a prospective, cross-sectional study. All patients using isotretinoin from July 2007 to January 2008 were followed up to detect ADRs. Patient demographics, drug history, and the dose of isotretinoin used were recorded. The causality and seriousness of ADRs was also evaluated.

Results: A total of 239 patients using Isotretinoin were entered in the study. More than 90% of patients reported at least one ADR. The most affected system organ was the skin and appendages disorders (91%) with dried lips as the most frequent adverse effect. In this study, we could show there was no significant relationship between the incidence of isotretinoin ADRs with patients' sex, age, weight, dose and treatment period of isotretinoin.

Conclusions: It seems that the incidence of isotretinoin ADRs is not dose-dependent. However, more large and well-designed studies are needed to confirm these findings.

Keywords: Isotretinoin; Adverse drug reactions (ADRs); Severe recalcitrant nodular acne