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134. Prevention of Risk by Education of Patients and Medical Staff: a Propos of a Study on Oral Anticoagulant Treatment

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Introduction: Oral anticoagulant treatment (OAT) is a widely used therapy. In France, it is estimated that nearly half a million of patients are treated by OAT each year. The benefit of OAT is well demonstrated in various cardiovascular diseases. Bleeding complications account for the first cause of hospitalisations for adverse drug reactions in France.[1] The incidence of haemorrhage is clearly raised when the INR, which is the recommended indicator of OAT optimal use, is above the therapeutic zone[2] (value of target INR ranging between 2 and 4.5 according to the indications). However, in many cases, despite patient's high INR, no clinical symptom of haemorrhage occurred. This implies that other factors have to be associated so that haemorrhage occurs.

Aim of the study: In this study roles of patients and of medical staff as cause of excessive anticoagulation by OAT leading to bleeding are assessed. Identifying the avoidability of overanticoagulation was also attempted.

Methods: This study analysed 62 patients hospitalised with an INR > 5. The inclusion of patients was prospective (cohort of patients from 01/01/2006 to 21/04/2006) with a systematic review of patients with high INR. The patients were separated into two groups: patients with a symptomatic haemorrhage and patients without evidence of bleeding.

Results: During this period, 18 (29%) cases of haemorrhage due to OAT administration were reported. 13 (21%) were considered as serious cases and four drug-related deaths occurred. 38% of the serious cases seem to be avoidable and attributable to a low quality of management.

Medical staff inadequate use of OAT was identified as wrong indications, INR persistently outside the therapeutic zone, drug interactions.Patients misuses were due to low compliance, misunderstanding of the prescription, non adherence to medical advices.

Conclusion: These data confirm that OAT needs to be more strictly controlled in order to better avoid adverse effects. Risks are probably underestimated by physicians and pharmacists. Information given to patients seems too frequently insufficient or unsuitable. Improvement of patient education and physician involvement are necessary.

References

1. Pouyanne P, et al. Admissions to hospital caused by adverse drug reactions: cross sectional incidence study. BMJ 2000; 320: 1036

2. Oden A, et al. Oral anticoagulation and risk of death: a medical record linkage study. BMJ 2002; 325: 1073-5