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Risk of pulmonary embolism in cancer patients receiving anti-EGFR monoclonal antibodies: A meta-analysis

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Background: Cancer patients have a thrombophilic condition predisposing to thromboembolic events such as pulmonary embolism (PE), drug-exposure can increase this risk. Anti-Epidermal Growth Factor Receptor monoclonal antibodies (anti-EGFR MoAbs), Cetuximab and Panitumumab, are beneficial in the treatment of various malignancies, but are burdened by severe and life-threatening harms including PE. We conducted a systematic review and meta-analysis in order to determine the incidence and the risk of PE in cancer patients treated with Cetuximab and Panitumumab.

Material & Methods: Medline, Embase, Web of Science, CENTRAL databases were searched for articles published until October 2014. Eligible studies were randomized phase II and III trials comparing anti-EGFR MoAbs containing regimens with the same regimens without anti-EGFR to treat cancer. Data on PE were extracted. Statistical analyses calculated the incidence of PE, RR and 95% confidence intervals (CIs) by using either random effects or fixed effect models with Mantel-Haenszel method. Subgroup analysis according kind of MoAb was performed. Also, we re-expressed RR in Number Needed to Treat to Harm (NNTH). We used funnel plot to assess potential publication bias.

Results: Bibliographic search provided 6,777 records, after a selection process 6 articles were eligible. A total number of 6,773 patients were considered in our analysis. Patients receiving anti-EGFR MoAbs had a significantly increased risk of severe PE (RR:1.56; 95% CI 1.20 to 2.04) and a a incidence of 4.3% (95% CI 2.7 to 6.0%) vs. 2.7% (95% CI 1.6 to 3.8%). NNTH was 63 (95% CI 35 to 173). Statistical heterogeneity was irrelevant (I^2=0%). Subgroups analyses revealed no differences between Cetuximab and Panitumumab. No publication bias was detected.

Conclusions: The addition of anti-EGFR MoAbs increased the risk of PE by the 56%. Prevention, early recognition and appropriate clinical management of these severe and life-threatening AEs may optimize clinical outcomes reducing morbidity and mortality in cancer patients.

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Readability assessment of package leaflets of biopharmaceuticals available on line: Implications for patient safety

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According to European Directives, the package leaflet is the leaflet containing information for the user which accompanies the medicinal product, and it must be written and designed to be understandable and clearly legible. The aim of this study was to evaluate and compare the readability levels of package leaflets of biopharmaceuticals available on line. Two samples of package leaflets of the same authorized biopharmaceuticals available on line in two years (2007 and 2010) were selected and downloaded from the European Medicines Agency (EMA). Biopharmaceuticals were sorted into 5 product categories according to their source, and into 2 groups according the year of authorization. Five out of the six entire sections of the package leaflets were studied: "1. What X is and what it is used for", "2.What you need to know before you take (or use) X", "3. How to take (or use) X", "4. Possible side effects" and "5. How to store X". Three formulas (SMOG grade, Flesh-Kincaid grade level, and Szigriszt's perspicuity index) were used to obtain readability levels. No significant differences between readability results for the two years studied were observed ($p>0.05$). However, significant differences between readability package leaflet sections in both 2007 and 2010 were found ($p<0.05$). The most difficult section was "4", and the less difficult was "5". Besides, all evaluated package leaflets had a very low degree of readability. Efforts to improve readability of package leaflets of biopharmaceuticals, available from EMA website, must be done to promote patient safety.

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