Major bleeding with antithrombotic agents: a 2012-2015 study using the French nationwide Health Insurance Database (SNIIRAM) linked to emergency departments records within five areas. Rationale and design of SACHA study

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| Résumé en anglais | Bleeding represents the most recognised and feared complications of antithrombotic drugs including oral anticoagulants. Previous studies showed inconsistent results on the safety profile. Among explanations, bleeding definition could vary and classification bias exist related to the lack of medical evaluation. To quantify the risk of major haemorrhagic event and event-free survival associated with antithrombotic drugs (Vitamin K Antagonist [VKA], non-VKA anticoagulant [NOAC], antiplatelet agent, parenteral anticoagulant) in 2012-2015, we linked the French nationwide Health Insurance database (SNIIRAM) with a local "emergency database" (clinical and biological data collected in clinical records). In the VKA-NOAC comparison, a Cox regression analysis will be used to estimate the hazard ratio of major haemorrhagic event adjusted on gender, modified HAS-BLED score and comorbidities. A distinction on the type of major haemorrhagic event (intracranial, gastrointestinal and other haemorrhagic events) was made. We present here the study protocol and the databases linkage results. Using six linkage keys, among 3,837,557 hospital visits identified in SNIIRAM, 5264 have been matched with a major haemorrhagic event identified in the "emergency database", thus clinically confirmed. The 1090 unmatched haemorrhagic events could be explained by the fact that patients were not extracted in the SNIIRAM database (patients living in accommodation establishment with internal use pharmacy, military people with specific insurance...). We showed the value of SNIIRAM enrichment with a clinical database, a necessary step to categorise haemorrhagic events by a clinically relevant definition and medical validation; it will allow to estimate more accuracy each type of haemorrhagic event. This article is protected by copyright. All rights reserved. |

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