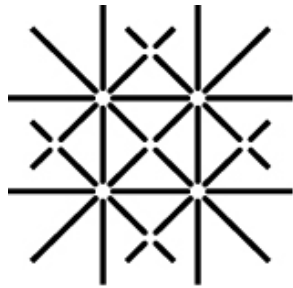


Development and Pilot Validation of a New Questionnaire to Assess Patient Knowledge about New Oral Anticoagulants (NOACs)



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Abstract

Background: New oral anticoagulants (NOACs) have been developed to replace the complex and time-consuming therapy with vitamin-K antagonists (VKAs). The advantages of NOACs are the minimized interaction potential with drugs and food, no need for regulatory blood monitoring and a fast onset of action. But the NOACs have a short half-life time and therefore an increased risk for thromboembolic events after the omission of few doses. Thus, adherence to NOACs is critically important. Patient education and leaflets are helpful instruments to improve adherence. Ahead of a patient education, relevant knowledge gaps should be detected to provide tailored patient education. Therefore a validated questionnaire is needed.

Objective: The aim of this study was to develop and pilot validate a questionnaire to assess patient's knowledge about NOACs, and to develop a patient information leaflet containing all important information about NOACs.

Methods: During a literature review in 2015, a list of question for the assessment of patient knowledge about NOACs was compiled. This list of questions was presented to ensure content validity to an expert panel of physicians, pharmacists and nurses. The expert panel had to chose within the scope of two online forms and one discussion round the relevant questions for patient knowledge. These questions were compiled to the questionnaire to assess patient knowledge about NOACs. The questionnaire was validated in a pilot validation study with patients of the hospital Bruderholz concerning feasibility, comprehension, acceptability and precision according to Fitzpatrick's Guidelines [1998].

In addition a patient information leaflet containing information about NOACs was created according the Alberts' Guidelines [1992].

Results: The expert panel evaluated 17 questions of the list of questions as relevant for patient knowledge, but they requested the combination of several questions and the generation of two further questions. The questionnaire to assess patient knowledge about NOACs contained 15 questions. In the pilot validation study participated 62.5% (n=5) of the requested patients, thereof all were female and the mean age was 83.4 ± 7.9 years. The participating patients assessed the questionnaire regarding comprehension and feasibility with excellent marks. The number of correct responses increased after the information about NOACs statistically significant by about a third.

The leaflet contained information about NOAC subdivided in the following issues: *'Reason for intake'*, *'Effect of the anticoagulant'*, *'Anticoagulation-Card'*, *'Intake instructions'*, *'Side effects'*, *'Situations for the doctor'*, *'Information for the doctor'* and *'Precautions'*.

Conclusion: The questionnaire to assess patient knowledge about NOACs encountered on acceptability and seems comprehensible and feasible. Moreover, he could be used to detect gaps of knowledge and to increase patient knowledge about NOACs.

But to complete the validation of the questionnaire, additional patients must be included.