ORIGINAL ARTICLE

The HIPOGAIA study: Monitoring of oral anticoagulation with vitamin K antagonists in the municipality of Gaia[☆]

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Abstract

Introduction: Anticoagulant therapy is an effective measure in preventing thromboembolic adverse events. Of the diseases in which this treatment is indicated, atrial fibrillation (AF) has the highest incidence worldwide, with a prevalence of 1.5-2%.

Objectives: To assess the quality of monitoring of patients with non-valvular AF under oral anticoagulation with vitamin K antagonists in Vila Nova de Gaia healthcare units.

Methods: This was a retrospective observational analytical study of the population registered at the 37 healthcare units of the Vila Nova de Gaia and Espinho health center area under oral anticoagulation with vitamin K antagonists during 2014. The data were collected using TAONet® software. The variables studied were health units, age, gender, INR value, time in therapeutic range (TTR) and medication. TTR was calculated for each patient using the Rosendaal linear interpolation method. It was stipulated that each patient should have undergone at least six INR measurements. Data were analyzed using Microsoft Excel® 2010 and SPSS® version 21, using descriptive and inferential statistical techniques.

Results: A total of 479 patients with non-valvular AF were studied, corresponding to 5883 INR tests. Mean TTR was 67.4±6.5%, and 35.3% of patients exhibited poor control (TTR <60%).

Discussion: Our study showed moderate control of coagulation parameters, but better than in many international clinical trials and in another Portuguese observational study. Nevertheless, there is still room for improvement in anticoagulation monitoring in primary health care.

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Estudo HIPOGAIA: monitorização da hipocoagulação oral com dicumarínicos no concelho de Gaia

Resumo

Introdução: A terapêutica com anticoagulantes é uma medida eficaz na prevenção de eventos tromboembólicos. Das patologias que requerem este tratamento, a fibrilhação auricular (FA) é das que tem maior expressão a nível mundial, com uma prevalência de 1,5-2%.

Objetivos: Aferir a qualidade da monitorização de doentes com FA não valvular sob anticoagulantes dicumarínicos, nas unidades funcionais (UF) do concelho de Gaia.

Material e métodos: Estudo observacional retrospetivo analítico. População: doentes inscritos nas 37 UF dos ACeS Gaia e Espinho-Gaia sob hipocoagulação com dicumarínicos, durante o ano de 2014. Fonte dos dados: TAOnet®. Variáveis estudadas: ACeS, UF, idade, género, INR, tempo em intervalo terapêutico (TTR) e terapêutica. O TTR foi calculado pelo método de interpolação linear de Rosendaal. Foram consideradas no mínimo seis visitas por doente. Tratamento estatístico: Microsoft Excel® 2010 e SPSS®21.

Resultados: Foram estudados 479 doentes com FA não valvular, o que correspondeu a 5883 registos. O TTR médio foi de 67,4% ($\pm$6,5). Apresentaram mau controlo da hipocoagulação (TTR < 60%) 35,3% dos doentes.

Discussão: O nosso estudo revela um padrão de controlo de hipocoagulação moderado, mas superior ao encontrado noutros estudos. No entanto, consideramos que ainda há um grande potencial de melhoria nos cuidados de hipocoagulação prestados nos cuidados de saúde primários.

Introduction

Anticoagulant therapy is an effective measure in preventing thromboembolic adverse events. Of the diseases in which this treatment is indicated, atrial fibrillation (AF) has the highest incidence worldwide, with a prevalence of 1.5-2%.[1] According to the FATA study, overall AF prevalence in eight Vila Nova de Gaia family health units (FHUs) was 1.29%.[2] AF can cause major hemodynamic changes but prognosis is mainly determined by associated thromboembolic phenomena, which have a significant impact on morbidity and mortality. Stroke, the leading cause of death and disability in Portugal, is five times more common in AF patients.[3,4]

There are two types of anticoagulant drugs, vitamin K antagonists (VKAs) (warfarin and acenocoumarol) and the new oral anticoagulants (NOACs) (notably dabigatran, rivaroxaban and apixaban). Only the first type require monitoring of international normalized ratio (INR).

VKAs inhibit the production of vitamin K epoxide reductase, thus preventing reconversion to an active form and reducing gamma-carboxylation of glutamic acid residues at sites near the end-terminal of coagulation factors II (prothrombin), VII, IX and X. They also inhibit vitamin-K dependent carboxylation of protein C and its cofactor protein S.[5]

VKAs have been used for 70 years and were until recently considered the gold standard treatment. They are inexpensive and there is solid evidence that they prevent thromboembolic events in AF patients, one study showing that warfarin reduced ischemic and hemorrhagic stroke by 62% compared to placebo.[6] They are also effective in deep vein thrombosis, pulmonary embolism, acute coronary disease requiring stenting, rheumatic valve disease (in the presence of AF or a history of embolism), antiphospholipid syndrome (with history of arterial or venous thrombosis), and valve disease in patients with mechanical or biological prostheses.[7] They are also used to prevent thromboembolism following orthopedic surgery.

Nevertheless, there are certain difficulties with the use of VKAs, including a narrow therapeutic window, genetic factors causing interindividual differences in elimination kinetics, and environmental factors such as adherence to therapy, drug interactions and vitamin K dietary intake that can affect their absorption, pharmacokinetics and pharmacodynamics.

Monitoring the effect of these drugs is therefore essential to achieve and maintain adequate levels to prevent thrombotic events while minimizing the risk of bleeding complications. This is done by measuring prothrombin time as expressed by the INR.[8,9]

There are various ways to monitor oral anticoagulant therapy: (1) in a hospital environment (anticoagulation clinics) by a physician, generally a specialist in hematology or hemotherapy or with experience in the area; (2) in a primary care setting, by a general practitioner (GP), generally the patient's own (routine medical care); (3) in a private laboratory with experience in the area; (4) by the patients themselves using point-of-care devices (self-testing), either self-monitoring, in which patients perform the test at home and then contact their center for dose adjustment, or self-management, in which patients perform the test at home and adjust the dose themselves if necessary.[9]