

SSC Subcommittee Project/Collaborative Project

NAME OF PROJECT: Patterns of prescription of oral anticoagulants in the elderly population for the treatment of deep vein thrombosis

Subcommittee: Predictive/Diagnostic Variables

Person responsible (Chair / Principal Investigator):

Dr. Camila Masias (Miami Cancer Institute, Baptist Health South Florida)

Description Abstract:

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Suggested length is 2-3 paragraphs

Variability has been observed in the treatment of acute deep venous thrombosis (DVT) in older patients. While literature regarding the use of DOACs for stroke prevention in patients with non-valvular atrial fibrillation calls for dose adjustments in anticoagulants in patients older than 80 with either 1) weight less than 60 kg OR serum creatinine ≥ 1.5 mg/dL (133 μ mol/L), current guidelines for the management of VTE do not recommend any dose changes for older patients. However, treating elderly patients is challenging due to perceived risks including concern for a higher bleeding risk, poly-pharmacy, drug toxicity, fall risk and compliance. Moreover, older patients were underrepresented in the landmark clinical trials that led to the approval of apixaban and rivaroxaban for the treatment of acute VTE.

Understanding physician prescription behaviors for DOACs to treat DVT among the elderly is relevant as the elderly population is increasing over the next decades, and because DVT incidence increases with age. Mortality associated with venous thromboembolism is higher in the elderly, and the countervailing concern, the risk of major bleeding with anticoagulation also increases with age. Understanding the patterns of prescription of anticoagulation in older patients with DVT is the first step to assess the need for future clinical trials specific to this population.

The aim of this project is to understand physician prescribing patterns for elderly patients with acute DVT.

Design and methodology (Data expected to collect, sample size and statistical analysis):

Describe concisely the research design and methods for achieving these goals. Suggested length 2-3 paragraphs

Methods: We will perform a survey of providers to assess their preferences when prescribing anticoagulants for with the treatment of acute DVT in the elderly.

Sample size: Leveraging power calculations by Dalmaijer, et.al [1] and preliminary data from a similar survey of DOAC prescribing behaviors, we anticipate almost 100% accuracy for detecting the correct number of clusters, and 90% or better chance of accurately classifying each respondent in the correct subgroup. Recruiting 200 respondents for this survey would allow for the identification of 5 subgroups, with approximately 40 respondents per subgroup. Therefore we aim to recruit at least 200 respondents including providers from different specialties (Emergency Medicine, Hematology and Internal Medicine) and geographic areas.

Survey Development: The survey will be revised by all members of the SSC ISTH subcommittee.

Analysis: We will perform logistic regression to explore factors associated with dosing behaviours among the elderly. Considering dosing behaviours, we will use k-means clustering and minimize the silhouette score while maintaining sufficient cluster size to assess for clustering of behaviours. We will assess for

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clustering of clinicians by characteristics around dose reduction decision-making. Descriptive statistics will be used to describe the clusters.

Study population (Inclusion, exclusion, eligibility) (patient population; recruitment of participating institutions/physicians and subjects; minimum number needed; expected number):

Not applicable - no study subjects will be enrolled.

Expected timeline:

We aim to present our methodology and if possible preliminary outcomes at ISTH2022 in London, at the Predictive and Diagnostic Variables in Thrombotic Disease Standardization Subcommittee meeting. Furthermore, we intend to publish a paper summarizing our findings in a peer-reviewed journal; prioritizing Journal of Thrombosis and Haemostasis (JTH) or RPTH.

Expected outcomes (ie. publications):

Publication type (SSC Communication, Guidance document or original article):

The results of this study will be published in a peer-reviewed journal. In the manuscript, we will report the results of the survey in relationship to provider preferences. We also aim to provide with next steps related to this delicate population.

Description of project set/up and management, needed infrastructure and resources (summary):

This project will involve the co-chairs of the Predictive/Diagnostic Variables SSC and Predictive /Diagnostic SSC members with expertise in this research. To achieve the objective, individual co-chairs will contribute time to the refinement of the survey, data extraction, and reporting of the measures captured in the standard set for VTE. Endorsement by the ISTH would be valuable to improve the impact of this work.

1. Dalmaijer ES, Nord CL, Astle DE. Statistical power for cluster analysis. arXiv preprint arXiv:2003.00381. 2020 Mar 1.