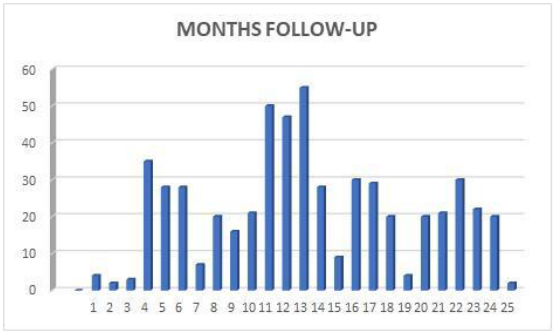

FIGURE 3 MONTH FOLLOW-UP total population

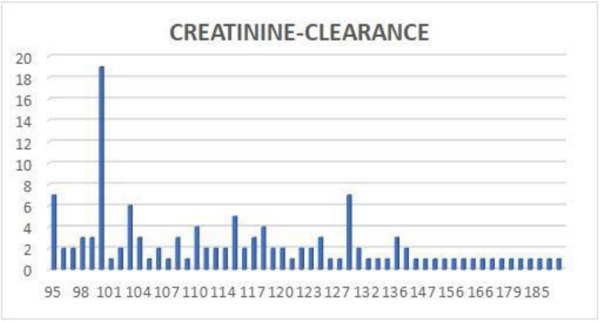

FIGURE 4 High Creatinine Clearance population

Results: It has not been reported any case of Stroke, Systemic Embolism, or Major Bleeding during the follow-up time of the patients treated, both in the main group and in the subpopulation of patients with creatinine clearance above 95 ml/min. 3% of patients (17) had complications with Edoxaban, of which 12 had discontinued treatment for this cause.

Conclusions: This is a sample of 552 patients and more than 26 months of follow-up. In the analyzed subpopulation of patients with creatinine clearance greater than 95 ml/min, the good results of Edoxaban are confirmed since they have not presented any stroke recurrence or systemic embolism or major or clinically relevant hemorrhage.

PB0004 | Comparison of Peak and trough Concentrations of Dabigatran, Rivaroxaban and Apixaban with the Published Expected Values in Patients with Non Valvular Atrial Fibrillation

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Background: Direct oral anticoagulants (DOACs), dabigatran, rivaroxaban and apixaban, have been increasingly used for the prevention and treatment of thromboembolic diseases in recent years. However, peak and trough concentrations of these DOACs in certain clinical indications are still insufficiently investigated.

Aims: The aim was to assess both peak and trough plasma concentrations of all three DOACs in patients treated for non valvular atrial fibrillation (NVAF) and to compare our own results with the first published expected values.

Methods: The study included plasma samples from patients treated for NVAF and taking dabigatran (N=37), rivaroxaban (N=28) and apixaban (N=36). Blood samples were taken on the same day to obtain both trough (immediately prior the next drug dose) and peak (two hours after drug administration) DOACs concentrations. Rivaroxaban and apixaban concentrations were measured using chromogenic anti-FXa assay (Innovance anti-FXa, Siemens Healthineers, Germany) calibrated with specific calibrators for rivaroxaban and apixaban (Hyphen BioMed, France). Dabigatran was measured using commercial chromogenic method (Innovance DTI assay, Siemens Healthineers, Germany). All coagulation assays were performed on Behring Coagulation System XP (BCSXP) analyser

TABLE 1 Results for dabigatran, rivaroxaban and apixaban peak and trough concentrations in NAVF patients

	N	Dosing regimen	Median (95%CI) and interquartile range (IQR) ng/mL	P	Published expected values (ng/mL) Gosselin et. al. Thromb Haemost 2018;118:437-50.	Within expected values	Below expected values	Above expected values
Dabigatran peak	37	150 mg twice a day	201 (136-239) 117-258	<0.001	175 (117 - 275)	27/37 0.73	6/37 0.16	4/37 0.11
Dabigatran trough	37		101 (59-139) 52-160		91 (61 - 143)	26/37 0.70	6/37 0.16	5/37 0.14
Rivaroxaban peak	28	20 mg once a day	171.5 (134-246) 122-277	<0.001	249 (184 - 343)	21/28 0.75	3/28 0.11	4/28 0.14
Rivaroxaban trough	28		35 (23-89) 19-103		44 (12 - 137)	22/28 0.79	2/28 0.07	4/28 0.14
Apixaban peak	36	5 mg twice a day	180 (164-203) 153-224	<0.001	171 (91 - 321)	28/36 0.78	5/36 0.14	3/36 0.08
Apixaban trough	36		89 (72-126) 56-135		103 (41 - 230)	28/36 0.78	4/36 0.11	4/36 0.11

(Siemens Healthineers, Germany). Statistical analysis was done using Mann-Whitney test by MedCalc Statistical Software version 11.5.1. The study was funded as an integral part of the Croatian Science Foundation research project IP-2016-06-8208.

Results: Concentrations for all three DOACs ranged as follows: dabigatran (peak 14-415 ng/mL; trough 0-237 ng/mL); rivaroxaban (peak 90-417 ng/mL; trough 1-188 ng/mL) and apixaban (peak 60-385 ng/mL; trough 13-221 ng/mL) with statistically significant differences between peak and trough concentrations (P< 0.001) for all three DOACs (Table 1). Peak and trough concentrations obtained in our study for all three DOACs conformed with published expected values for most samples analyzed (Table 1).

Conclusions: The study showed a good agreement of both peak and trough concentrations for dabigatran, rivaroxaban and apixaban with the published expected values in NVAF patients.

PB0005 | The Impact of an Educational Intervention in Patients with Atrial Fibrillation Treated with Warfarin: Protocol of a Clinical Trial

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Background: Atrial fibrillation (AF) is the most common sustained arrhythmia worldwide. Warfarin is an oral anticoagulant widely prescribed for prevention of stroke in patients with AF. Despite its benefits, the achievement of the goals of pharmacotherapy depends on patient involvement. Educational interventions can contribute for anticoagulation control.

Aims: To describe the protocol of a clinical trial designed to evaluate the effect of a patient-centered educational strategy focused on low-income patients with poor anticoagulation control.

Methods: Patients ≥18 years with AF, on warfarin for at least six months and time in therapeutic range (TTR) < 60% will be recruited at two anticoagulation clinics (ACs) in Brazil. Patients from one of them will be allocated to the intervention group and patients from the other to the control group. Intervention group will attend educational sessions based on a patient-centered care approach, and the control group will receive usual care. The intervention will be based on Paulo Freire's theory, practices involving health empowerment and individuals with limited socioeconomic status. The intervention is estimated to last five months. TTR will be the primary outcome and knowledge and self-reported non-adherence to warfarin therapy will be secondary outcomes. The outcomes will be measured before intervention and at times after intervention (Figure 1). The calculated sample size indicated 85 patients in each group. This study was approved by the Research Ethics Committee of Universidade Federal de Minas Gerais (UFMG) - CAAE 65928316.3.0000.5149. All participants signed an informed consent.

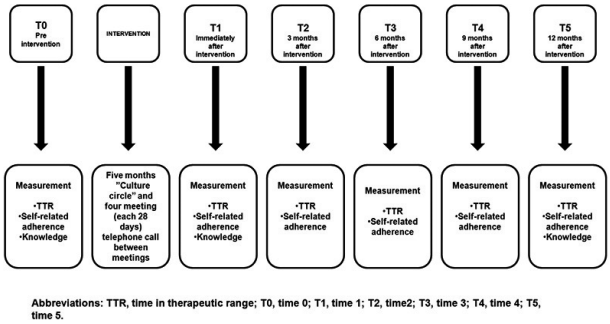

FIGURE 1 Depicts a flowchart of the study phases

Results: Currently, 239 and 134 eligible patients were identified in the control and intervention ACs, respectively. After randomization, 85 patients were invited in each clinic. The intervention will be provided in April 2019.

Conclusions: Our findings are expected to improve anticoagulation effectiveness in low-income regions.

Acknowledgments: This study received support from Programa de Pós-graduação em Medicamentos e Assistência Farmacêutica - UFMG, CNPq, CAPES e FAPEMIG.

PB0006 | Oral Anticoagulant Therapy in Patients with Atrial Fibrillation and Flutter in Macedonia

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Background: Acenocumarol is the most consumed oral anticoagulant therapy (OAT) in Macedonia, used for prevention of arterial embolism in some cardiovascular diseases (CVD) like atrial fibrillation and flutter (AFF), cardiomiopathia (CMP), valvular heart disease etc.

Aims: The aim of the study is to evaluate how many of the patients with AFF on OAT had INR in therapeutic range, and to compare INR values when venous and capillary blood was used.

Methods: This is a retrospective study performed in the Institute of transfusion medicine (ITM) by using data from our outpatient