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570 FRAILTY AND DISABILITY IN OLDER PATIENTS AND THE EFFECTS OF APIXABAN ON QUALITY OF LIFE AND DEPRESSIVE SYMPTOMS. THE EXPERIENCE OF THE APULEIO STUDY

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Introduction: The APULEIO study was designed to describe the psychological effects of apixaban in Italian elderly patients with non-valvular atrial fibrillation (NVAF), deep vein thrombosis (DVT) or pulmonary embolism (PE). The existence of implications of treatment on health-related quality of life (HRQL) and mood is among the most important knowledge gaps in cardiovascular care of older subjects. Real-world data on these issues, essential to improve therapy adherence, are lacking. Aim of the present analysis was to evaluate the presence of a different response to oral anticoagulation in the disabled, frail and robust subjects enrolled in the study.
Methods: APULEIO was a multicenter, prospective, observational study including apixaban eligible patients. The 12-Item Short Form Health Survey (SF-12), the Beck Depression Inventory-II (BDI-II) and the Frail non-Disabled (FiND) questionnaire were used to evaluate, respectively, HRQL, depressive symptoms and the presence of disability and frailty. The findings of the baseline and the 6-month evaluation - end of the study - will be presented.
Results: Overall, 376 patients had complete data. Of these, 163 (43.4%), 111 (29.5%) and 102 (27.1%) subjects were, respectively, defined disabled, frail and robust. No differences for reason to anticoagulate were observed by FiND category (p=0.797; overall, AF: 77.1%; DVT/PE: 22.9%). Patients with disability were older (Disabled – D: 79 ±11; Frail - F: 72±12; Robust – R: 72±12 years; p<0.0001), more frequently women (D: 66.9; F: 43.2; R: 24.5%; p<0.0001), with a greater clinical complexity, as expressed by the CHA_2DS_2-VASc score (D: 4.3±1.5; F: 3.2±1.5; R: 2.9±1.6; p<0.0001), and showed a higher heart rate (D: 82±17; F: 77±14; R: 77±15 bpm; p=0.0414). BMI (overall, 27.5±4.7 Kg/m^2; p=0.328), left ventricular ejection fraction (overall, 53±10%; p=0.453), and systolic (overall, 129±15 mmHg; p=0.219) and diastolic (overall, 76 ±10 mmHg; p=0.285) arterial pressure were similar among groups. The incidence of any adverse event was higher in those with disability (D: 14.1; F: 8.1; R: 3.9%; p=0.0190), but the proportion of those with serious adverse events was similar among categories (overall, 6.9%; p=0.105). When studying HRQL, at enrollment, the Physical Health composite score of the SF-12 was significantly different among groups (D: 32.7 ±7.9; F: 42.4±9.3; R: 45.6±8.0; p<0.0001). At the 6-month evaluation (D: 37.0±10.1; F: 43.9±8.8; R: 47.2±7.3; p<0.0001), only the improvement for disabled subjects was significant (p=0.0020). At Baseline, the Mental Health composite score of the SF-12 was lower in disabled and frail patients, when compared to robust ones (D: 46.8 ±9.8; F: 47.7±9.2; R: 51.4±8.6; p<0.0001). After 6 months, once again, only the improvement for disabled subjects (D: 37.0±10.1; F: 43.9±8.8; R: 47.2±7.3; p=0.0004) was significant (p<0.0001) and statistically greater than that observed for frail and robust patients. Regarding depressive symptoms, at enrollment, the BDI-II score was worse in the disabled and frail groups (D: 14.7±9.8; F: 9.0±8.1; R: 4.7±4.5; p<0.0001). At the 6-month assessment, it was possible to observe an improvement (D: 10.5±8.5; F: 6.8±7.8; R: 4.2±4.5; p<0.0001) in disabled (p<0.0001) and frail subjects (p=0.0112), but not in robust ones (p=0.1705).
Conclusions: The APULEIO study demonstrates that disability and frailty are common conditions in older subjects anticoagulated for AF and DVT/PE. Disabled patients present a higher clinical complexity than frail and robust ones. After 6 months of therapy, the use of apixaban is associated with a significant improvement of HRQL in disabled individuals and of depressive symptoms in disabled and frail ones. No changes were found in robust subjects. No differences by group were observed in the incidence of serious adverse events. These findings confirm the efficacy and safety of apixaban also when applying a multidimensional approach to high-risk geriatric populations.