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Atrial fibrillation and thromboembolic prophylaxis: focus on the frail oldest patient. How net clinical benefit influences anticoagulant therapy.

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Background: Atrial fibrillation is highly prevalent among the elderly population, which is also frequently prone to thromboembolic complications. Anticoagulant prophylaxis is underused in the elderly due to fear of bleeding, which tends to be more frequent and severe within this group. Randomized controlled trials and several observational studies have shown the comparative effectiveness of direct oral anticoagulant (DOAC) against vitamin K antagonists (VKA), and their superior safety, at least in terms of intracranial bleeding. However, for patients aged 85 or older, there is still insufficient literature, leaving unanswered the question of which prophylaxis to use. Purpose: The aim of the study is to compare the incidence of established outcomes and to investigate the net clinical benefit between DOAC and VKA in patients aged ≥ 85 years. Methods: A cohort of 553 outpatients from the real world began treatment using DOACs at our clinic. The prospective follow-up on average lasted 1.97 years. Main endpoints were stroke and systemic thromboembolism, major hemorrhage, myocardial infarction and mortality for all causes. A sample of the 160 patients aged ≥ 85 years was compared with the remaining younger ones and with a second cohort of 298 outpatients aged ≥ 85 years. Retrospectively analyzed, with follow-ups at our center, who started VKAs; the average time was 2.03 years. The "net clinical benefit" of DOACs against VKAs was calculated as the difference between thromboembolic events with VKAs and with DOACs, minus the difference (weighted by 1.5) between spontaneous intracranial bleeding with DOACs and VKAs. Results: In terms of thromboembolic events, DOACs and VKAs (2.43% p-y vs. 1.82% p-y, p =0.975) have shown comparable efficacy in a higher risk sample (CHA2DS2-VASc score: 5.2 vs. 4.5; p <0.001). There were no differences in spontaneous intracranial hemorrhages (0.81% p-y vs. 1.16% p-y; p =0.419). Major bleeding was more frequent in DOACs (10.11% p-y vs. 4.13% p-y, p <0.05), although they are comparable if we consider patients in VKAs achieving a time in therapeutic range (TTR) <60%. Mortality, in all cases similar (13.75% p-y vs. 9.92% p-y; p =0.778), but was reduced in patients with VKAs therapy, with a TTR = 60%. The net clinical benefit of DOACs compared to VKAs is noticeable in patients with a previous stroke or with CHA2DS2-VASc score <6, while VKAs may be more beneficial to patients with vascular disease or with CHA2DS2-VASc score ≥6. Conclusions: DOACs are as effective in very old patients with atrial fibrillation compared to very old patients receiving VKAs, but they are associated with increased major bleeding. The same is true when compared with younger DOACs users. TTR, representing quality achieved by the anticoagulation with a VKA, can influence the comparison with DOACs. Considering ischemic strokes and spontaneous intracranial hemorrhages, there is however a net benefit for DOACs use in specific categories of elderly patients.