Still using "aspirin or nothing" for AF patients with frailty? ETNA-AF-Europe shows frailty corresponds to higher mortality but not neurological bleeding with edoxaban anticoagulation in routine care

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Background: Clinicians are encouraged to anticoagulate frail and older patients. Both groups were underrepresented in pivotal AF stroke prevention trials. Large, more geographically generalizable data are needed for safety and treatment efficacy in these groups. Aim: ETNA-AF-Europe registry assessed key clinical outcomes and risk scores in frail and older patients compared to their counterparts.

Methods: ETNA-AF-Europe is a large, prospective, post-authorisation, observational study of patients with AF being prescribed edoxaban. The registry captured frailty as a single, mandatory field as perceived by physicians. Baseline characteristics evaluation and 1-year outcomes of patients were extracted by presence of frailty and age (≥ vs. <80 years) using descriptive analyses.

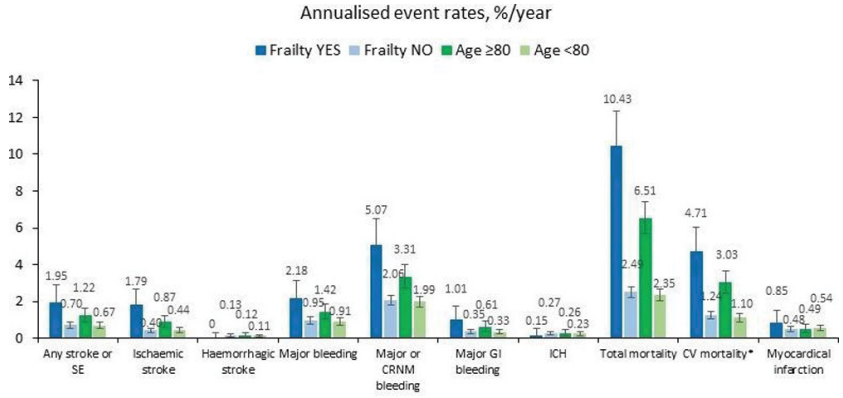
Results: Of, 13,090 enrolled patients, 10.6% were considered frail with coding complete for 12,212 patients. Whilst 27.9% of patients were aged ≥80, of these only 25.3% were frail. Frail patients differed from non-frail and had similar baseline characteristics to those aged ≥80 years. Frail patients were more frequently female, with lower BMI and higher HAS-BLED risk score (Table), and incurred the highest rates of overall and cardiovascular deaths and major bleeding, even more than those aged ≥80 (Figure). Despite this, intracranial haemorrhage (ICH) was surprisingly low and comparable.

Conclusions: In this large, Europe wide group of patients with AF anticoagulated with edoxaban, patients considered frail by physicians are not always older. A clinical frailty perception is associated with a 4-fold higher short-term mortality. Whilst major bleeding is higher in this frail cohort, ICH is comparably low. The HAS-BLED score in frail patients prescribed edoxaban, appears to predict non-neurological bleeding. These data provide confidence for prescribing edoxaban in frail AF patients to prevent stroke.

Baseline demographics

n (%) or mean ± SD	Frailty Yes 1392 (10.6%)	Frailty No 10820 (82.7%)	Age ≥80yrs 3651 (27.9%)	Age <80yrs 9439 (72.1%)
Age, years, Mean ± SD/ median (IQR)	81.5±7.1 / 82 (78; 86)	72.5±9.3 / 74 (67; 79)	84.0±3.5 / 83 (81; 86)	69.6±7.8 / 71 (66; 76)
BMI, kg/m^2	26.6±5.2	28.3±5.1	26.7±4.3	28.6±5.3
(calc.) CrCl ± CG, mL/min	54.2±21.7	77.2±30.5	52.7±17.5	82.9±30.2
(calc.) CHA_2 DS_2 -VASc	4.1±1.3	3.0±1.4	4.0±1.1	2.8±1.4
(calc.) mod. HAS-BLED	3.1±1.1	2.5±1.1	2.6±1.0	2.4±1.1
Frailty*	1392 (100.0)	0	922 (25.3)	469 (5.0)
Age >80 years	922 (66.3)	2472 (22.8)	3651 (100.0)	0
Current AF type				
Paroxysmal	573 (41.2)	6020 (55.7)	1689 (46.4)	5349 (56.8)
Persistent	303 (21.8)	2646 (24.5)	830 (22.8)	2328 (24.7)
Long-standing persistent & permanent	515 (37.0)	2142 (19.8)	1124 (30.9)	1740 (18.5)

*Frailty was reported as perceived by the investigator. CrCl, creatinine clearance; IQR, interquartile range; SD, standard deviation.



*Sensitivity analysis. CV, cardiovascular; CRNM, clinically relevant non-major; GI, gastrointestinal; ICH, intracranial haemorrhage; SE, systemic embolism.

One-year outcomes