CHARACTERISTICS AND OUTCOMES OF PATIENTS WITH OR WITHOUT A BLEEDING EVENT: RESULTS FROM THE TRIPLE ANTIPLATELETS FOR REDUCING DEPENDENCY IN ISCHAEMIC STROKE (TARDIS) TRIAL

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Background
Intensive antiplatelet therapy following acute cerebral ischaemia was associated with increased bleeding in the TARDIS trial of intensive antiplatelet therapy. We compared the characteristics and outcomes of patients with or without bleeding events in the TARDIS trial.

Methods
TARDIS compared one month of intensive antiplatelet therapy with guideline in patients with acute non-cardioembolic ischaemic stroke or transient ischaemic attack. Information on bleeding events and functional outcome by day 90 were assessed centrally blinded to treatment assignment. Outcomes were analysed using adjusted ordinal logistic regression and multiple regression.

Results
Bleeding event data are available for 3072/3096 (99.2%) patients, of whom 444 (14.5%) suffered a bleed. Compared to the rest, patients with a bleed were more likely to: be female (43.0% vs. 36.0%, p=0.005); have presented with sensory loss (39.4% vs. 33.7%, p=0.019); have a higher pre-morbid modified Rankin Scale score (>0: 19.8% vs. 15.2%, p=0.014) and have had a qualifying event of ischaemic stroke (73.0% vs. 71.5%, p=0.009). Patients with a bleed were also less likely to have been taking either aspirin (22.5% vs 27.1%, p=0.043) or combined aspirin and dipyridamole (1.4% vs. 3.0%, p=0.049) prior to their qualifying event. By day 90, patients with a bleed were more dependent (mRS, p=0.002), disabled (Barthel Index, p<0.001), cognitively impaired (tMMSE, p=0.027) and had a poorer quality of life (EQ-5D-HSUV, p=0.007) and mood (Zung depression scale, p=0.001).

Conclusions
Patients with a bleeding event were more dependent at baseline and had a poorer outcome by day 90.

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