

Efficacy and safety of dabigatran versus warfarin in patients with non-valvular atrial fibrillation

WCY Lau, EW Chan, ICK Wong

The University of Hong Kong, Hong Kong, Hong Kong

Dabigatran, a direct thrombin inhibitor, is the first new oral anticoagulant approved for the prevention of stroke in patients with non-valvular atrial fibrillation (NVAf) as an alternative to warfarin. However, the clinical effectiveness and adverse events concerning the use of dabigatran are not well described outside clinical trial setting. The aim of this study was to compare the efficacy and safety of dabigatran and warfarin in patients with NVAf in the real-world clinical practice.

Patients newly diagnosed with NVAf from 2010 through 2013 and received dabigatran or warfarin were identified from the Clinical Data Analysis and Reporting System (CDARS), a population-wide database managed by the Hong Kong Hospital Authority which serves over seven million people in Hong Kong. The outcomes of interest were occurrence of ischaemic stroke, intracranial haemorrhage (ICH), gastrointestinal haemorrhage (GIH), and all-cause mortality among the treatment groups. Patients with history of any outcomes were excluded from the analysis. Propensity-score (PS) matching at 1:1 ratio and cox proportional-hazards regression were used to compare the risk of outcomes in terms of hazard ratio (HR) between treatment groups.

Preliminary results indicated that 4049 and 1281 eligible patients receiving warfarin and dabigatran were identified from CDARS respectively. Of these, 1261 PS-matched pairs were included in the analysis. The use of dabigatran was associated with a reduced risk of ICH (HR=0.25; 95% confidence interval [CI]=0.07-0.89) and all-cause mortality (HR=0.58; 95%CI=0.37-0.92) when compared to warfarin, with no significant differences in the risk of GIH (HR=1.08; 95%CI=0.63-1.86) and ischaemic stroke (HR=0.86; 95%CI=0.51-1.47). In the subgroup analysis for the elderly population (age≥75), similar results were found (Table 1). In conclusion, this study showed that the use of dabigatran was associated with a lower risk of ICH and all-cause mortality; and similar risk of GIH and ischaemic stroke when compared to warfarin.

Table 1 Results of the cox proportional-hazards regression analysis after propensity-score matching

Outcomes	Overall cohort		Elderly population (age≥75)	
	Hazard ratios	95% CI	Hazard ratios	95% CI
	Dabigatran (n=1261) vs. Warfarin (n=1261)		Dabigatran (n=662) vs. Warfarin (n=662)	
Ischaemic stroke	0.86	(0.51-1.47)	0.58	(0.28-1.22)
Intracranial haemorrhage	0.25	(0.07-0.89)*	0.17	(0.04-0.75)*

Gastrointestinal haemorrhage	1.08	(0.63-1.86)	1.56	(0.83-2.93)
All-cause mortality	0.58	(0.37-0.92)*	0.39	(0.22-0.68)*

*p<0.05.