Impact of renal function on bleeding risk in patients with non-valvular atrial fibrillation treated with direct oral anticoagulants: Subanalysis of the DIRECT registry

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Topic(s):
Oral Anticoagulation

Citation:

[Background]
Renal dysfunction is one of the high bleeding risk factors in patients with atrial fibrillation as presented in the HAS-BLED score. The impact of renal function on bleeding risk is, however, still to be investigated in the era of direct oral anticoagulants (DOAC).

[Methods]
We conducted a single-center prospective observational registry of NVAF patients with DOACs: the DIRECT registry (UMIN000033283). All patients with NVAF (N=2216) who were users of dabigatran (N=648), rivaroxaban (N=538), apixaban (N=599), or edoxaban (N=431) from 2011 to 2017 were enrolled (71.6±10.8 years, mean follow-up duration: 407.2±388.3 days). In the present substudy, all patients were stratified by renal function. Creatinine clearance (CCr) was estimated with the Cockcroft-Gault equations with available creatinine at baseline. Patients were divided into 4 groups based on CCr. (CCr>80, CCr50-80, CCr30-50, and CCr<30). The primary endpoint was major bleeding according to the ISTH criteria. Clinical endpoints were compared between the groups (Kaplan-Meier analysis, Log-rank test). The influence of DOAC type in patients with renal dysfunction was also assessed for the primary endpoints of major bleeding.

[Results]
Kaplan-Meier estimated 2-year major bleeding rate significantly increased as renal function decreased (CCr>80 2.5%, CCr50-80 4.2%, CCr30-50 4.2%, CCr<30 7.8%, Log-rank test p<0.001). However, in patients with apixaban (low CCr 59.6±25.9ml), major bleeding does not appear to increase as renal function decreased (CCr >80 9.2%, CCr 50-80 8.0%, CCr 30-50 10.3%, CCr<30 7.3%, Log-rank test p=0.97).

[Conclusions]
Renal dysfunction increased bleeding risks in NVAS patients with DOACs. Apixaban might be safely used for patients with renal dysfunction.
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[Results] Kaplan-Meier estimated 2-year major bleeding rate significantly increased as renal function decreased (CrCl > 80 2.5%, CrCl 50-80 4.2%, CrCl 30-50 4.2%, CrCl < 30 7.8%, Log-rank test p < 0.001). However, in patients with apixaban (low CrCl 59.6±25.9ml), major bleeding does not appear to increase as renal function decreased. (CrCl > 80 9.2%, CrCl 50-80 8.0%, CrCl 30-50 10.3%, CrCl < 30 7.3%, Log-rank test p = 0.97).

[Conclusions] Renal dysfunction increased bleeding risks in NVAF patients with DOACs. Apixaban might be safely used for patients with renal dysfunction.