新規経口抗凝固薬はワルファリンと比べても遜色はない(Abstract 1875)

新規経口抗凝固薬はワルファリンと同じように脳梗塞を予防するが出血を起こしにくい

New oral anticoagulants provide same stroke prevention as warfarin but cause less bleeding

非ビタミンK拮抗経口抗凝固薬（NOAC）は、ワルファリンと同じように脳梗塞を予防するが頭蓋内出血を起こしにくい、という43,000人超の心房細動患者を対象にした観察研究が2016年ESC Congressで発表された。研究では、NOAC（ダビガトラン、リバーロキサバン、アピキサバン）を"リアルワールド"においてワルファリンと比較した。1年以内の脳梗塞リスクは、NOAC群とワルファリン群で同等であり、2.0～2.5%の範囲であった。1年後の頭蓋内出血リスクは、ワルファリン治療群（0.6%）に比べ、ダビガトランおよびアピキサバン治療群で有意に低かった（0.3～0.4%）。

Full Text

The new oral anticoagulants provide the same stroke prevention as warfarin but cause less intracranial bleeding, reports an observational study in more than 43 000 patients presented at ESC Congress 2016 today by Dr. Laila Staerk, a research fellow at Herlev and Gentofte University Hospital, Denmark.

"Atrial fibrillation is associated with a five-fold risk of stroke, potentially leading to disability and death," said Dr. Staerk. "In the next four decades, the number of patients with atrial fibrillation is expected to triple so the number of Europeans diagnosed could rise to a staggering 25 to 30 million."

Patients with atrial fibrillation are treated life-long with oral anticoagulation to reduce their risk of stroke. But treatment with non-vitamin K antagonist oral anticoagulants (NOACs) and vitamin K antagonists (warfarin) is a double-edged sword, because it lowers the risk of stroke at the cost of increased bleeding risk. Intracranial bleeding is a particular fear.

With several treatment options available the clinical question of which one to use has often been asked. Dr. Staerk said: "There has been a need to investigate safety and effectiveness of NOACs versus warfarin in a 'real world' population and our Danish registries provide this opportunity."

The current study compared the risk of stroke and intracranial bleeding with NOACs (dabigatran, rivaroxaban and apixaban) versus warfarin in a 'real world' setting. The study was conducted at The Cardiovascular Research Centre at Herlev and Gentofte University Hospital in Denmark. It included 43 299 patients with atrial fibrillation who were recruited from Danish nationwide administrative registries.

Some 42% of patients were taking warfarin, while 29%, 16% and 13% were taking dabigatran, apixaban and rivaroxaban, respectively. During follow up, stroke occurred in 1054 patients and there were 261 intracranial bleedings.

The researchers found that the risk of having a stroke within one year was similar between the NOAC and warfarin groups, and ranged from 2.0 to 2.5%. At one year the risk of intracranial bleeding was significantly lower in patients treated with dabigatran and apixaban (0.3 to 0.4%) compared to those treated with warfarin (0.6%).

Dr. Staerk said: "The inclusion and exclusion criteria in our study were broadly similar for patients initiating NOACs or warfarin, and this gave a straightforward opportunity to directly compare the treatment regimens, which is in contrast to the randomized trials. The results suggest that although they have similar effects in preventing stroke, dabigatran and apixaban were associated with a safer use regarding the absolute one-year risk of intracranial bleeding."

She added: "Our results complement the large randomized phase III trials by providing 'real world' data on stroke and intracranial bleeding with NOACs versus warfarin since fragile patients were not excluded from our nationwide cohort. For example, patients with increased risk of bleeding, liver disease, and chronic kidney disease are less represented in trials."

Dr. Staerk concluded: "Registry studies have some limitations such as the observational design, residual confounding, and confounding by drug indication. In the future it would be exciting to see a head-to-head randomized trial performed to compare the different NOAC treatments in patients with atrial fibrillation."

Velux Foundations supported the study.

Conference News