Pre-treatment with rivaroxaban may expedite cardioversion

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Oral anticoagulant therapy with rivaroxaban is a safe alternative to Vitamin K antagonist (VKA) therapy in patients with atrial fibrillation who are undergoing elective cardioversion to restore a normal heart rhythm, according to results presented today at ESC Congress 2014.

In addition, rivaroxaban may potentially have one important advantage over VKAs, the study suggests.

Findings from the X-VeRT (eXplore the efficacy and safety of once-daily oral riVaroxaban for the prevention of caRdiovascular events in patients with nonvalvular aTrial fibrillation scheduled for cardioversion) trial were presented in a congress Hot Line session.

"The practical advantage of rivaroxaban was demonstrated by the short time to cardioversion compared to patients treated with VKAs," said the study's co-principal investigator Riccardo Cappato, MD, from the University of Milan, in Milan, Italy. However, since time to cardioversion was not a prespecificed outcome of the study, this finding should be interpreted with caution, he added.

While the use of VKAs before and after cardioversion to reduce the risk of clotting is the current standard of care, endorsed by guidelines from the ESC as well as the American Heart Association, American College of Cardiology, and Heart Rhythm Society, a major obstacle to this practice is that at least 3 weeks of treatment is required to achieve adequate anticoagulation," noted co-principal investigator Michael

Ezekowitz MD , PhD, from the Sidney Kimmel Medical School at the Thomas Jefferson University in Philadelphia Pennsylvania.

The pharmacological characteristics of rivaroxaban are particularly useful in the setting of elective cardioversion because it has a rapid onset of action, within 2–4 hours, which can expedite cardioversion, he explained.

X-Vert is the first prospective, randomised trial to examine the safety and efficacy of rivaroxaban compared to VKA therapy in patients undergoing elective cardioversion for the treatment of atrial fibrillation.

It included 1 504 patients from 141 centres and 16 countries, who were scheduled to undergo either electrical (97.6%) or pharmacological (2.4%) cardioversion.

Overall, 1 002 patients were randomised to oral rivaroxaban 20 mg once daily and 502 patients to VKA (warfarin or another VKA at the investigator's discretion, based on local standard of care).

Using established guidelines, patients were assigned to either early (58%) or delayed (42%) cardioversion.

Cardioversion in the delayed group was allowed if at least 3 consecutive weeks of adequate anticoagulation was documented prior to cardioversion. VKA anticoagulation was considered adequate if the international normalised ratio (INR) was maintained in the range of 2.0–3.0 for that time period, while anticoagulation with rivaroxaban was considered adequate by drug compliance of at least 80% for that time period.

Cardioversion in the early group was performed within a target range of one to five days after randomisation, while patients in the delayed

cardioversion group had it performed between 21 and 25 days after randomisation.

The study found that compared to patients taking a VKA, patients treated with rivaroxaban had a similar of risk of the primary composite outcome of stroke or transient ischaemic attack, peripheral embolism, myocardial infarction, and cardiovascular death. This composite outcome occurred in 0.5% of the rivaroxaban group versus 1.02% of the VKA group, a difference that was not considered statistically significant.

In the early cardioversion group, the primary composite occurred in 0.71% of rivaroxaban-treated patients and 1.08% of VKA-treated patients, whereas in the delayed cardioversion group it occurred in 0.24% and 0.93% patients in the rivaroxaban and VKA groups, respectively.

"Although the study was not powered for statistical significance, the Steering Committee felt that a descriptive comparison of 1500 patients would give clinically meaningful information," explained Professor Cappato.

For the primary safety outcome of major bleeding, there was no difference between the rivaroxaban and VKA groups (0.61% vs 0.80%, respectively; RR 0.76).

No clinically important differences in the overall cumulative incidence of adverse events and serious adverse events by treatment assignment or by cardioversion strategy were observed.

In the early cardioversion group, the time between randomisation and cardioversion was similar in both treatment arms (median 1 day), but in the delayed group, patients treated with rivaroxaban had a significantly shorter wait for cardioversion compared to the VKA-treated patients

(median 22 vs 30 days, P

Professor Ezekowitz added that "X-VeRT illustrates the ease of using rivaroxaban in the setting of cardioversion by capitalising on its rapid onset of action."

In conclusion, Professor Cappato noted, "These data are preliminary; however, they offer the first evidence that oral rivaroxaban can be safely used as a possible alternative to VKA therapy for preventing thromboembolic events in patients undergoing elective cardioversion."

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