

## 2015 Winter Cardiology Conference Review

American Heart Association Scientific Sessions •

American Society of Hematology • European Society of Cardiology

### AHA 2015

## Warfarin Associated With Poorer Outcomes Compared With New Oral Anticoagulants

Laura Joszt

**D**espite the fact that warfarin is more easily reversible, bleeding complications with the therapy are associated with longer stays in the hospital and higher mortality than dabigatran and rivaroxaban, according to a poster presented at the American Heart Association Scientific Sessions.

The researchers analyzed claims of adults with atrial fibrillation who were hospitalized for bleeding after starting warfarin, dabigatran, or rivaroxaban. Outcomes were length of stay in the hospital, intensive care unit (ICU) admission, length of ICU stay, and all-cause mortality. Patients treated with warfarin had worse outcomes than those treated with new oral anticoagulants.

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## Xarelto Reduced Risk of Fatal Bleeding for Patients With Renal Disease

Laura Joszt

**P**atients with atrial fibrillation and renal disease who were treated with rivaroxaban (Xarelto) had less of a risk of fatal bleeding, according to a study presented at the American Heart Association Scientific Sessions.

Major bleeding occurs more often in atrial fibrillation patients with renal disease, but when these patients were treated with rivaroxaban, the rate of major fatal bleeding was identical to patients without renal dysfunction (0.09 per 100 person-years for both groups). The incidence of major bleeding was slightly higher (4.52 per 100 person-years) among pa-

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## Warfarin Produces Worse Outcomes Than NOACs *(Continued from page 1)*

“Little is known about the relative outcomes of bleeding complications during warfarin therapy compared to bleeding complications during treatment with dabigatran or rivaroxaban,” the authors wrote.

Warfarin users were older and had more comorbidities than dabigatran or rivaroxaban users, the researchers found. However, after adjusting, warfarin was still associated with a 2.2 mean day increase in hospital stay compared with dabigatran and a 3.1 mean day increase compared with rivaroxaban.

“Our results are completely the opposite of what we thought we would find when we did this study,” Blake Charlton, MD, told Medpage Today. “We were really, really surprised by these findings.”

In addition, after more than 3 years of follow-up, the researchers found a 17% adjusted mortality in the warfarin group

compared with 13% for the dabigatran group and 6% in the rivaroxaban group. However, 30- and 90-day mortality rates did not differ significantly.

The researchers also analyzed subgroups: patients with chronic kidney disease, heart failure, more than 7 comorbidities, hemorrhagic stroke, major gastrointestinal bleed, patients older than 75 years, patients without ICU admission, and patients restarting anticoagulants after discharge. They found that in every subgroup, warfarin was associated with longer hospitalization.

“However, because patients treated with newer oral anticoagulants are younger and healthier, randomized trials are necessary to better understand these unexpected differences in bleeding-related outcomes,” the authors concluded. ●

## Xarelto Reduced Fatal Bleeding Risk *(Continued from page 1)*

tients with kidney disease compared with those who did not have kidney disease (2.54 per 100 person-years).

The researchers presumed that the higher rate of major bleeding in the group of patients with renal disease may be a result of the confounding effects of comorbidities, according to Medpage Today.

However, Captain Sally Tamayo, MD, head of cardiology at the Naval Medical Center in Portsmouth, Virginia, said she found it reassuring that the mortality was the same for patients on rivaroxaban with and without renal disease.

The researchers analyzed Department of Defense electronic medical records and identified 44,793 beneficiaries who experienced major bleeding and required hospitalization. Of the 6921 members diagnosed with renal disease, 312 patients experienced major bleeding.

Most (85%) of the major bleeding occurred in the gut for patients regardless of whether or not they had renal impairment. Patients with renal disease were usually treated with lower doses of rivaroxaban, with half of the group receiving 20 mg daily, 43.5% receiving 15 mg, and 6.2% receiving a 10-mg dose. In comparison, 73% of patients without renal dysfunction were treated with the 20-mg dose, and only 21.1% were given the 15-mg dose.

Douglas Zipes, MD, past president of the American College of Cardiology, told Medpage that the study highlights the link between the heart and the kidney, although the mechanisms are not yet clear as to why patients with heart disease and kidney disease do worse than patients with only heart disease. ●

# Getting Out of the Car Best for Blood Pressure, Weight Control, Study Results Say

Mary K. Caffrey

New research supports the idea that adding steps to your day can help control blood pressure, prevent weight gain, and perhaps prevent diabetes.

Two studies that looked at using a car less—by moving to walkable neighborhoods or by using public transportation—were presented at the 2015 Scientific Sessions of the American Heart Association meeting in Orlando, Florida. Both showed that walking for routine errands and commuting is healthier than using the car.

The first study, from the Institute for Clinical Evaluative Services in Toronto, Canada,<sup>1</sup> comes from a team that has produced other studies on the health effect of “walkable neighborhoods.” This one found that those who moved to a walkable neighborhood had a 54% lower risk of high blood pressure after at least 4 years than those who moved to a place that still required use of a car.

The second study, from the Moriguchi City Health Examination Center in Osaka, Japan,<sup>2</sup> examined health status based on how commuters got to work. Compared with drivers, those who used public transportation were 44% less likely to be overweight, 27% less likely to have high blood pressure, and 34% less likely to have diabetes.

In September 2015, US Surgeon General Vivek H. Murthy, MD, MBA, issued a “Call to Action” on walking. He said that adding just 22 minutes of exercise a day could make a difference in lowering high blood pressure and preventing chronic conditions like diabetes and obesity. Walking is especially helpful for those who haven’t been exercising at all and need a place to start, Dr Murthy said. Walking helps control blood pressure, the main risk factor in heart disease, which is the leading cause of death in the United States. High blood pressure is also the leading indicator for stroke, which is the fifth leading cause of death, according to the AHA.

**Walkable neighborhoods matter.** In this study, researchers compared 1057 pairs of adults from the Canadian Community Health Survey for the years 2001 to 2010. Pairs moved from a low-walkability neighborhood to a high-walkability one or from one low-walkability neighborhood to another.

To gauge “walkability,” researchers used WalkScore, a tool that rates neighborhoods from 1 to 100 based on accessibility on foot to destinations such as stores, parks, and schools. Places that scored 90 had “high walkability.” The matched groups were balanced on 16 factors such as age, income, marital status, and body mass index. Researchers used electronic health records to obtain

subjects’ hypertension measures. Researchers noted they did not have detailed dietary information on the pairs.

Lead author Maria Chiu, MSc, PhD, said the pairs were followed for a total of 11 years and a median of 4 years. Pairs were remarkably well matched, including for factors such as alcohol use and vegetable consumption. Dr Chiu said the study used the propensity score method to control for confounders such as education, income, and marital status. At a press conference, she said she was surprised at the magnitude of difference in the rate of hypertension: the incident rate of hypertension was 8.6 per 1000 person-years among those who moved from low-walkability to high-walkability neighborhoods, while it was 14.9 per 1000 person-years among those who moved between low-walkability neighborhoods in the same period.<sup>1</sup>

As they have in other work, the study’s authors said their findings are a call on planners and elected officials to take walkability into account when approving neighborhood design. “We need to set people up for success by making walking instead of driving the more convenient and enjoyable choice,” Dr Chiu said.

**The bus beats the car.** Researchers from Moriguchi, Osaka, Japan, studied

5908 commuters who were identified from a larger group of 16,397 commuters during their annual health checkup in 2012. The subjects were asked about both the level activity at their workplace and how they got to work.

Controlling for work activity, age, gender, and smoking status, the researchers found that those who took public transportation had better health measures than those who drove to work, either by car or motorbike. The analysis showed that those taking public transportation were much less likely to be overweight, (odds ratio [OR] = 0.56; 95% CI, 0.45-0.69;  $P < .0001$ ), had lower prevalence of hypertension (OR = 0.73; 95% CI, 0.59-0.90;  $P = .0035$ ), and lower prevalence of diabetes (OR = 0.66; 95% CI, 0.44-0.99;  $P = .0427$ ), after adjusting for covariates.<sup>2</sup>

To their surprise, researchers found that those taking the bus or the train had better measures for diabetes, high blood pressure, and weight control than even commuters who walked or biked to work. The researchers speculated that the bus and train commuters were actually walking more steps to get to work than those with shorter commutes.

“If it takes longer than 20 minutes one way to commute by walking or cycling, many people seem to take public transporta-

*Those who took public transportation had better health measures than those who drove to work*

tion or a car in urban areas of Japan,” said lead author Hisako Tsuji, MD, director of the Moriguchi City Health Examination Center. She said physicians should ask their patients how they get to work.

The team noted the limits of its study: most who used public transportation were women, and most drivers were men. They did not know if their findings would apply in the United States, where more commuters are already overweight. The average age of the study participants was 49 to 54 years.

## References

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## ASH 2015

# Treatment Patterns of Deep Vein Thrombosis and Pulmonary Embolism

Laura Joszt

**P**hysicians are sticking with what they know when it comes to prescribing treatment for deep vein thrombosis (DVT) and pulmonary embolism (PE). A poster presented at the American Society of Hematology annual meeting found that the most common treatment remains a parenteral anticoagulant (PAC) with warfarin despite the arrival of a the new treatment option rivaroxaban.

Researchers from Boston Health Economics Inc and Boehringer Ingelheim Pharmaceuticals, Inc studied hospital administrative claims data from more than 600 hospitals for patients 18 years or older who had a primary discharge diagnosis of DVT and/or PE in order to evaluate characteristics and treatment patterns.

“Given the relatively recent introduction of novel oral anticoagulants (NOACs), it is essential to understand the demographic and clinical characteristics of DVT/PE patients receiving these therapies,” the authors wrote.

The study included 46,214 patients, with 54% receiving the primary diagnosis of PE, 38% receiving the diagnosis of

DVT without PE, and 8% receiving the diagnosis of DVT with secondary PE.

The most common treatment was PAC and warfarin (70%), followed by PAC alone (16%), PAC and rivaroxaban (6%), PAC plus warfarin and rivaroxaban (4%), warfarin alone (1%), rivaroxaban alone (1%), and no anticoagulant treatment (2%).

Using a logistic regression, the researchers determined that patients with a primary PE diagnosis, a primary DVT diagnosis with a secondary PE diagnosis, receipt of thrombolytic drugs, the presence of renal disease, and receipt of care in an urban hospital were significantly more likely to receive rivaroxaban with PAC and/or warfarin compared to rivaroxaban alone.

“Our findings indicate that the standard of care (PAC + warfarin) remains the dominant treatment regimen despite the availability of newer NOACs,” the authors concluded. “Future studies of treated patients with DVT and/or PE should examine whether these preliminary observations of treatment patterns change with increased clinical experience with NOACs.” ●

# Rivaroxaban Safe and Effective in Cancer Patients With Thrombosis

Laura Joszt

**A**lthough rivaroxaban was approved by the FDA in 2012, a knowledge gap has remained about how it works with cancer patients. A recent study, presented at the American Society of Hematology annual meeting, focused specifically on the safety and efficacy of the therapy when used among cancer patients.

Gerald Soff, MD, of Memorial Sloan Kettering Cancer Center, and colleagues studied 200 patients with cancer-associated thrombosis and treated them with rivaroxaban. They found that the rate of major bleeding was very low at 1.6% and the rate of recurrent thrombosis was just 4.4%, he told *ecancertv*. In addition, they did

not see any loss in efficacy, safety, or mortality compared with the older generation of anticoagulants. Dr Soff explained that rivaroxaban also had significantly better patient satisfaction because it is a pill instead of an injection and it costs less.

This study was the first to study rivaroxaban looking only and specifically at cancer patients, although there have been previous studies where cancer patients were studied as a subgroup, which also found that rivaroxaban provides safety and efficacy.

Dr Soff concluded that for patients who do not have a contrain-

dication to the drug, they can be treated with rivaroxaban for their thrombosis with a “reasonable reassurance” of safety and efficacy. However, Dr Soff pointed out that like all anticoagulants, rivaroxaban requires that the provider understands the drug and how it works in order to know when to use it and when not to use it.

“But there is no evidence right now that there is a problem using it in the cancer niche, and if anything, we seem to see favorable safety and efficacy compared to the standard of care,” Dr Soff said. ●

## New Hematology Drugs: Progress and Challenges Discussed at the 57th ASH Meeting

*Surabhi Dangi-Garimella, PhD*

**A**n early session on the first day of the 2015 annual meeting and exposition of the American Society of Hematology in Orlando, Florida, saw presentations on the promise of newly approved hematology/oncology agents in addition to the challenges that clinicians face in treating patients with these drugs. Physicians with clinical experience using these agents discussed the appropriate population, dosing, side effects, and adverse events presented by the real-world use of the molecules.

Chaired by Mikkael A. Sekers, MD, MS, from the Cleveland Clinic, participants included Kenneth A. Bauer, MD, from the Beth Israel Deaconess Medical Center; Anjali S. Advani, MD, from the Leukemia Program at Cleveland Clinic; and Sagar Lonial, MD, Winship Cancer Institute, Emory University School of Medicine.

### Idarucizumab

The first presentation by Dr Bauer introduced idarucizumab (Praxbind), a humanized monoclonal antibody indicated for patients with dabigatran (Pradaxa) for reversal of the anticoagulant effects of dabigatran. Developed by Boehringer Ingelheim Pharmaceuticals, idarucizumab is used in emergency surgery or urgent procedures and to protect against life-threatening bleeding. Preclinical studies have shown that idarucizumab protects patients from bleeding when treated with the direct oral anticoagulant (DOAC) dabigatran.

“Idarucizumab, a fully humanized antibody fragment, or Fab, has high affinity specifically for dabigatran and has shown no non-specific binding to other agents,” said Dr Bauer, echoing results presented at the meeting of the American Heart Association last month.

Presenting updates from the REVERSE-AD (Reversal Effects of Idarucizumab on Active Dabigatran) study, which led to the drug’s approval, Bauer said that the management of dabigatran-related major bleeding using reversal agents can prove challenging.

REVERSE-AD included 90 patients treated with idarucizumab, who were divided into 2 cohorts. Group A included 51 patients who had uncontrolled bleeding with dabigatran, while those in

group B were 39 patients who needed emergency surgery or procedure following dabigatran treatment. The patients were administered 5 g intravenous idarucizumab, back-to-back in 2 separate infusions over 0 to 15 minutes. Within minutes of administration, idarucizumab normalized either elevated dilute thrombin time (dTT) or elevated ecarin clotting time (ECT), the study reported.

“The primary endpoints of maximum percent reversal of anticoagulant effect of dabigatran, based on central-lab assessment of dTT or ECT within 4 hours of idarucizumab,” explained Dr Bauer. “Secondary endpoints were cessation of bleeding in group A and hemostasis during procedure in group B.”

Although dTT normalized in 98% of group A and 93% of group B patients, ECT normalized in 89% of group A and 88% of group B patients, Dr Bauer showed.

“Safety issues are a concern with idarucizumab,” said Dr Bauer, including some thrombotic events observed within 3 days and 4 events later on. There may have been no cases of hypersensitivity, but the trial saw 18 deaths, 9 in each group. “But deaths were primarily related with comorbidities that these very sick patients suffered from,” Dr Bauer added.

An ideal treatment strategy for the management of dabigatran complications, according to Dr Bauer, includes:

- Discontinue or hold dabigatran treatment
- Supportive care (with IV fluids, packed red blood cells)
- Activated charcoal within 2 hours of treatment
- Localization management of bleeding site
- Administer idarucizumab

He then listed some challenges associated with using reversal agents with DOACs, including:

- Insufficient data on whether supportive measures suffice or whether invasive procedures may be necessary
- Quantitative assays for DOACs are not yet available

“For intracerebral bleeding, early presentation to a health-care facility, prompt diagnosis, and prompt administration of an effective reversal agent is critical to improve outcomes,” Dr Bauer concluded.

### Blinatumomab

Introducing the case of an adult acute lymphoblastic leukemia (ALL) patient in her clinic, Dr Advani explained that while overall survival (OS) for pediatric ALL patients is very encouraging, “Novel approaches are needed for treating adult ALL patients. The 3-year OS for 759 adults enrolled in a Cancer and Leukemia Group study is low—it’s an unmet need,” said Dr Advani. She explained that while 80% of ALLs are B-cell subtype, most are pre-B ALL and that CD19 has been a particularly attractive target for new therapies that are being developed.

“Blinatumomab is unique in that it’s an anti-CD19 antibody, but it is a bispecific T-cell engager antibody. Of the 2 arms of this antibody, 1 engages the B-lymphoblast and the other the anti-CD19 antibody,” Advani said. So the molecule can act as a bridge, she explained. Blinatumomab (Blinicyto) was approved late last year for the treatment of ALL.

A major challenge, in Advani’s opinion, is the need for continuous drug infusion with blinatumomab, a complication with treatment that arises due to the short half-life of the drug. Short-term IV infusion schedules with blinatumomab were disappointing, Advani said.

Some early results with the drug found an 80% rate of complete response in patients on blinatumomab, Advani showed. A follow-up study published in *Lancet Oncology* showed promising results in adult patients with relapsed or refractory B-precursor ALL. The trial, Advani said, recruited 189 patients who were Philadelphia chromosome (Ph)-negative, heavily-pretreated, and almost 70% had a bone marrow blast count that was  $\geq 50\%$ .

“While response rate was lower in this multi-center trial, it’s important to note that these were more heavily pretreated patients,” Advani said, explaining the results. Whereas a complete response was observed in 43% of patients, minimal residual disease response was high, observed in 82% of trial participants.

The most significant side effects, from blinatumomab include fever, headache, and febrile neutropenia. Dr Advani then pointed out several management issues with blinatumomab.

- Short half-life necessitates a continuous infusion: 4 weeks on and 2 weeks off. This calls for a very compliant patient.
- In trials, bag changes are required every 48 hours, which can create logistical issues.
- The drug is expensive: \$89,000 per month of therapy. Health plans need prior authorization for drug use.

- Patients may need hospitalization for at least 2 days.
- Neurologic toxicity is observed in about 50% patients; severe incidences are, however, rare.

Dr Advani said that she is part of a phase 2 study that is currently recruiting elderly ALL patients who are either Ph+ or Ph-, for treatment with blinatumomab in combination with prednisone, vincristine, methotrexate, 6-mercaptopurine, also known as POMP. “We have hopes of improving patient outcomes with this combination,” she said.

“Blinatumomab is a new class of bispecific T-cell-engaging antibodies with significant activity in B-ALL that can hopefully improve outcomes,” she concluded.

### Panobinostat

The last molecule, introduced by Dr Lonial, was panobinostat, a histone deacetylase inhibitor (HDAC) approved earlier this year for the treatment of patients with multiple myeloma.

“It is very important to know how to use drugs once they have been approved,” said Dr Lonial, underscoring the importance of real-world experience with drugs. Some other drugs currently being developed in the HDAC inhibitor class include vorinostat, givinostat, ricolinostat, and romidepsin, he said.

A unique feature of myeloma cells, according to Dr Lonial, is that they continue with their normal function, unlike most other cancerous cells whose normal cellular functions are compromised. “Myeloma cells continue to produce antibodies, which can then be used as a biomarker to measure response,” he explained.

Dr Lonial showed that although preclinical data with panobinostat, generated by various groups, has confirmed the drug’s activity, preliminary data from animal models has shown antiosteoclast activity of panobinostat. The study published in *Blood* in 2013 by Richardson et al, presenting results from the PANORAMA 2 trial, showed that panobinostat could resensitize refractory patients to a combination of bortezomib and dexamethasone, Dr Lonial explained.

“Best responders, based on subgroup analysis, were patients with high-risk disease and those who had been heavily exposed to prior therapies, including bortezomib and IMiD,” Dr Lonial said.

The major toxicities observed with panobinostat include diarrhea and fatigue (asthenia). Whereas grade 3 or 4 diarrhea has been consistently observed across studies, the combination of panobinostat with bortezomib is what may be causing these grade 3 or 4 toxicities, Dr Lonial clarified. “So there is a need for better partners with panobinostat, and our options include carfilzomib and ixazomib,” which he said are currently being evaluated in the clinic. ●

*“Novel approaches are needed for treating adult acute lymphoblastic leukemia patients.”*

## Post-Marketing Surveillance of Rivaroxaban Finds the Drug “Inherently Safe”

Laura Joszt

**R**esearch on the post-marketing surveillance of rivaroxaban found that the drug was as safe as determined from the results of the anticoagulant’s randomized controlled trial.

A poster presented at the European Society of Cardiology’s annual congress in London looked at almost 40,000 people taking rivaroxaban, after it was approved by the FDA, to determine how often they bled and what the consequences were, explained W. Frank Peacock IV, MD, from Baylor College of Medicine in a video interview with MD Magazine.

“When you have a randomized controlled trial, you have a very refined population of people with a certain age and a certain risk factor profile that is well described,” he said. “When you roll out to the public and all doctors anywhere can use it, you’re not always certain they’re going to apply it right and that risk-benefit analysis may change.”

He added that sometimes when a drug is rolled out to the public, there are “strange little things” that happen. In the case of this study, that did not occur.

“We wanted to make sure that the results that we had in real life look like the results that we had when we studied it in a randomized controlled trial,” Dr Peacock said.

The study found that of the nearly 40,000 people in the study, 970 had a bleed and most of them had a gastrointestinal bleed. In addition, 35 people died, mostly from intracranial hemorrhages. Dr Peacock added that the bleed rate was about 2.89 for 100 patient years and the risk of dying was 0.1.

“This is all statistically consistent with what we saw in the trials, and it goes to show you that these drugs are inherently safe,” he said. ●

## XANTUS Study: Rivaroxaban Prevents Stroke in Patients With Atrial Fibrillation

Laura Joszt

**U**sing rivaroxaban (Xarelto) in a patients with nonvalvular atrial fibrillation (NVAF) can reduce rates of stroke and major bleeding, according to the result of the XANTUS study.

XANTUS is the first large, international, prospective study describing the use of rivaroxaban for stroke prevention in a broad NVAF patient population. The study results were published in *European Heart Journal*.

The single-arm, observational study evaluated the safety and effectiveness of rivaroxaban for stroke prevention. The researchers studied 6784 patients with NVAF across Europe and Canada in routine clinical practice. Patients were followed up for 1 year or until 30 days after premature discontinuation.

A majority of patients (96%) did not experience major bleeding, all-cause death, or stroke/systemic embolism. Stroke occurred in 0.7% of patients per year, fatal bleeding in 0.2% per year, and critical organ bleeding in 0.7% per year. Treatment and dosing were decided on by the treating physician and 5336 patients received 20 mg once daily, 1410 received 15 mg once daily, and 35 received another dose.

“The findings reaffirm the positive benefit-risk profile of rivaroxaban established in the phase III clinical trial ROCKET AF, in

which rivaroxaban was shown to provide effective stroke prevention with a similar overall bleeding profile and significantly lower rates of the most feared intracranial and fatal bleeds compared with vitamin K antagonists,” XANTUS principal investigator A. John Camm, MD, professor of clinical cardiology in the Cardiovascular and Cell Sciences Research Institute at St George’s University of London, said in a statement.

According to the study, major bleeding, all-cause death, and thromboembolic events occurred at higher incidence rates for the 15 mg once daily dose compared with the 20 mg once daily dose.

At the end of the study, the researchers found that 5096 (75%) of patients reported to their physicians that they were “very satisfied” or “satisfied” with their treatment. Premature discontinuation only occurred among 7.9% of patients, with the main reason being an adverse event.

“These real-world insights from XANTUS complement and expand on what we already know from clinical trials, and provide physicians with reassurance to prescribe rivaroxaban as an effective and well-tolerated treatment option for the broad range of patients with AF seen in their everyday clinical practice,” said Dr Camm. ●