Understanding Patient Differences in Treating Atrial Fibrillation

National Pharmaceutical Council®

Understanding how treatments can vary in the effects they have across different patient populations is important. A new study published in _Value in Health_ by the Cornerstone Research Group, Institute for Clinical and Economic Review and the National Pharmaceutical Council evaluated the difference in treatment effects for different patient subgroups using anticoagulants to treat atrial fibrillation.

The Issue of "Individual Treatment Effects"

Often, health care is designed assuming patients look like this:

But in the real world, patients look more like this:

That means many different factors can affect how patients will respond to a treatment.

Age Race Gender Other Conditions

Personal Preferences Risk Profile Genetics

Care Setting Social Support Medication Interaction

Does "Average" Exist in Patients With Atrial Fibrillation?

People who have atrial fibrillation, the most common type of heart arrhythmia, face a higher risk of stroke and other heart complications. To reduce risks, many patients are treated with anticoagulants, but those treatments come with known trade-offs between the risk of stroke/systemic embolism (SE) and the risk of bleeding. Treatment decisions are most often made based on what works for the "average" patient. To understand potential patient differences with common treatments, a team of researchers asked:

"Do different anticoagulants have different impacts on different subgroups of people?"

How Researchers Tested the Question

Finding patient differences in any single clinical study can be challenging. Studies are often not large enough or designed to spot these differences.

To answer their question, study authors analyzed data from multiple major clinical trials of treatments known as novel oral anticoagulants (NOACs). In addition to well-known and widely available warfarin as the comparative control, researchers compared four anticoagulants–apixaban, dabigatran, edoxaban, rivaroxaban.

In order to create as comprehensive an evidence network as possible, study authors also used unpublished, but publicly available data submitted to the U.S. Food and Drug Administration (FDA) by manufacturers as part of the regulatory review process. Seventeen percent of the subgroup data for stroke/SE and 52 percent of the data for major bleeding were found only in public submissions to the FDA.

PATIENT SUBGROUPS IN THE STUDY

- Treatment with warfarin (time in therapeutic range)
- Stroke risk (CHADS2 score)
- Age (<75 or ≥ 75 years)
- Gender (male or female)
- Prior use of a vitamin K antagonist (yes or no)
- Prior or current aspirin use (yes or no)

Did Differences Emerge?

In their study, researchers found **298** possible treatment comparisons, based on the different subgroups. Of those possible comparisons, **73 (24.5 percent)** showed big enough differences in outcomes evaluated (stroke/SE or major bleeding) to potentially lead to a change in preferred treatment for patients.

For example:

AGE

For patients older than age 75, the top three preferred treatments, in order, were:	In patients younger than age 75, the top preferred treatments shifted to:
#1 Edoxaban 30 mg	#1 Dabigatran 150 mg
#2 Apixaban 5 mg	#2 Dabigatran 110 mg
#3 Edoxaban 60 mg	#3 Edoxaban 30 mg

PRIOR ASPIRIN USE

| For patients who had used aspirin regimen, the top three preferred treatments, in order, were:	When patients who were not on an aspirin regimen were assessed, the top preferences shifted to:
#1 Edoxaban 30 mg	#1 Apixaban 5 mg
#2 Warfarin	#2 Edoxaban 30 mg
#3 Edoxaban 60 mg	#3 Dabigatran 150 mg

What's the Bottom Line?

For patients with atrial fibrillation, there may be no "one size fits all" approach to treatment. Some patients with the condition may do well on the most commonly used medications, and others may not.

This study shows that both patients with atrial fibrillation and their health care professionals need flexibility in decision-making to select the right treatment option.
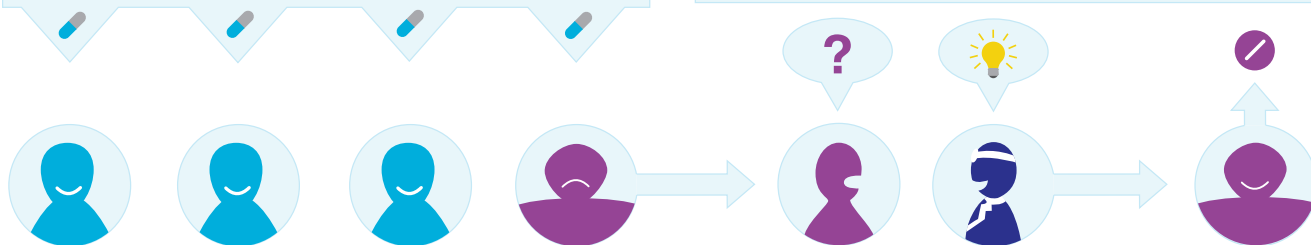
To learn more about individual treatment effects, visit **npcnow.org**.