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Implications Associated With Integrating Both Real-World Data and Clinical Trial Data Into Clinical Practice: AF Considerations

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Caso:
This is CME on ReachMD. I am Dr. Valeria Caso, and today I will identify the challenges in using real-world evidence when making clinical decisions in everyday practice for the management of AF or VTE.

So what we know from the clinical randomized trials is that DOACs are good drugs. They are working extremely well. They have a high safety profile compared to vitamin K. They are not inferior to vitamin K. So when you really think about this, everything should set up, no question, because we have good drugs, we have good possibility to treat our patients.

But, however, in the real world there are some limitations for the drugs. And we know, for example, from observational and real-world data, that the better is the adherence. For example, from the ARISTOPHANES study. This is a study on Medicare data, showing that the adherence is much better by when you use DOACs. It's even better when you use apixaban because patients have a lower risk to bleed compared to others, like with rivaroxaban and dabigatran. And this is also compared in other real-world studies where we see sometimes patients switch from one drug to the other. We know that from the ATHENS study that switching from, for example, apixaban to rivaroxaban, there's a higher risk of bleeding and a higher risk of having ischemic event. Probably for the better risk profile of apixaban compared to rivaroxaban. So there is a higher adherence for the patients.

So what I really want to share with you, and I think this is the most important message: we have excellent drugs. We have some who are safer, and when you have higher safety, better safety, you have better adherence. And this will not also only reduce US ischemic risk, but also will reduce the risk of bleeding. And this, clearly, will lead to better adherence because patients are afraid of taking drugs when anticoagulation is involved.

So when we are going to real-world evidence, we know how important these data are, because real-world evidence, you are moving from randomized trials where you have highly selected patients. If you look at the mean age of the randomized trials, it's not the age that we see with our patients. So, for example, taking the ARISTOPHANES study where we have data from Medicare, so we see what is happening in the real world. It clearly shows us that patients who are on DOAC compared to with those who are on vitamin K antagonists have a much better safety and efficacy profile. Efficacy, why? Because we know that it's not – the DOAC is not inferior to vitamin K, but probably this is due to a better adherence because we know from real world that maintaining the INR between 2 and 3 is almost impossible for all the time that is needed to have a good effect.

So, for example, another very important aspect is about switching because we know our patient will switch if all for the reason because they don't tolerate the drug or because they want – sometimes they want to change from once daily to twice daily or vice versa. And it's very important to have data on what happens in real world by switching. The ATHENS study shows us clearly that switching from

rivaroxaban to apixaban was safer and more efficacious. And what was even more important, patients were more adherent to treatment.

And this didn't happen because we could expect maybe switching from twice daily to once daily the adherence increased. But this was not the case. Again, there was no change in adherence from apixaban once daily to rivaroxaban.

So, again, here clearly in real world, we don't have strong evidence which is the same as a randomized trial, but we are collecting and collecting more data. And you see the growing evidence on the importance of real-world evidence on what is going on with our patients, because as soon as you move from the wonderful world of the randomized trials to the real world, this is not the same. So when you have well tolerated that drug, then you have safety and then you have efficacy.

The most important message that I want to deliver to you is that DOACs are safer than vitamin K, but this is something that you clearly know. And you have to choose the drug which is most tolerated by patients. So it's important that you find the one who has the best safety profile, because the safety and efficacy profile will lead to a better adherence.

This is all what I wanted to deliver for you today, and thank you for tuning in.

Announcer:
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