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Released: 06/20/2023
Valid until: 06/20/2024
Time needed to complete: 1h 34m

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Audience Q&A

Announcer:
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Dr. Gibler:
So I wanted to follow up on a question that - for each of the panelists, as far as is there any volume of intracranial hemorrhage that you - below which you would not - that or below which you would not anticoagulant? I mean, reverse anticoagulation? Could you all each answer that in your experience? And I'd be very interested in the audience, what their thoughts were too. You want to start with that, Adrian?

Dr. Parry-Jones:
Well, I think David's case makes a strong case for it.

Dr. Gibler:
You can see the emergency physician's concern in David's - yeah, in David's case.

Dr. Parry-Jones:
Yeah. So I mean, I'd go back to the point I made before, which is that they've got so much to lose. And I think you obviously you have to balance risks and benefits, don't you. And I think we have touched on the risk of thromboembolic compound complications with the reversal agents. But if you look in the trials, those were often quite late on. So they're unlikely to be to do with the reversal agent specifically, but rather to do with the reemergence of the patient's underlying thrombotic risk.

So, you know, and I think also, there's - if you look at the data altogether, there is a meta-analysis which brings it all together, but the quality of the studies is very different. So if you run a prospective clinical trial, then the monitoring for events is going to be much better and you'll see a higher rate, whereas if it's a retrospective sort of note review study, you're going to miss a lot of them. So I think that's uncertain as well. But you've got to balance that against the risk of hematoma expansion. But I think, for me, usually I'd err on the side of treating them.

Dr. Seiffge:
A short answer, I totally agree with Adrian, to be honest. There's no lower limit. I would probably set an upper limit, so a patient who already has at least 100 or 90 mL of bleeding, so very large bleeding, probably even 60 mL. So these patients, if they tend to expand, I would treat. I would consider those patients probably not to reverse, because they already have a very poor prognosis probably, that's probably an upper limit, but not a lower limit. Because those are those patients that have much to lose.

Dr. Gibler:
And Natalie, I'm going to pick your brain both ways with first a non-traumatic ICH, and then a traumatic ICH. Are there patients with trauma that, first, with a non-traumatic bleed with anticoagulation, is there any patient you wouldn't treat?

Dr. Kreitzer:
I think the one that I might not treat would be the person who potentially, you know, describes their fall as being yesterday, for example, with a thought that they've probably had that period of time to allow.

Dr. Gibler:
So time would be the one thing that would prevent you from –

Dr. Kreitzer:
Potentially, yeah.

Dr. Gibler:
-potentially treating. But if the - if it was non-traumatic, you would say reverse the anticoagulation?

Dr. Kreitzer:
Correct.

Dr. Gibler:
Are there any other questions from the audience for the panel? Yes. Yes, please.

Male:
I just want to say thank you all four for doing this. That has been very helpful for me. I do have a question. Mostly, I think I just want to hear you talk about this, if you would. I feel personally pretty confident that the direct reversal agents idarucizumab and andexanet alfa actually have a biomarker response. But can I hear you - I'd love to hear you four kind of discuss a little bit more the impact on clinical outcome. And I know this has been kind of alluded to several times, I think, David, that you presented some data on this, but still think digesting it is something that is difficult, especially when I'm presenting this information to a hospital administrator to now purchase a medication that is expensive.

Dr. Parry-Jones:
Well, yeah. Well, I mean, I think I was just going to say that in terms of the impact on outcome, you're trying - you have to remember you're trying to prevent a complication, aren't you. So you're trying to stop them getting worse. And yeah, the trials don't have long-term outcome data. So you've shown some of the propensity score match studies and so on. But I don't know, what do you think?

Dr. Seiffge:
Yeah, I think if - I totally understand your problem or the situation because this is a bit less sexy to sell, to be honest. We all know about thrombectomy cases where we go in for ischemic stroke and go in for thrombectomy, and we see a patient, we treat them with a quite expensive treatment. But all of us have experienced these cases where patients walk out only to stroke 2 days later, which came in severely disabled, so have an immediate idea what you did, how beneficial it was, and for, as Adrian said, preventing a complication, which in long term will pay out one day.

It's very it's much more difficult to sell because it's not visible. And what we know from all these ICH studies is that improvement takes time, so they don't improve on day 2 or day 3, they usually improve on day 30, 3 months, 6 months, 1 year, because all these studies need so long follow-up. And it's very difficult to explain to a hospital patient – to administration people, I agree. But I think it's - I don't have a real argument, other than that what I just said. And if there could be a problem.

Dr. Gibler:
I don't know if you have anything to add?

Dr. Kreitzer:
Yeah. So you mentioned whether, you know, this does have a good biomarker response, which was, you know, the primary endpoint for the ANNEXA-3 study as well as in the ANNEXA-4, one of the two endpoints. Within that was also hematoma expansion. There was moderate correlation with the change in biomarker, the anti-factor Xa activity level, with the patients specifically an intracranial hemorrhage, not as much for the GI bleeds and other sites of hemorrhage. So that is certainly there. And the other piece with that ANNEXA-4 study is, I believe the median time from presentation to when patients receive the reversal agent was quite long, it was several hours, as I believe it was like 6 hours. So some of that piece may have been missed.

Dr. Seiffge:
But I think it's a really good point also to strengthen that, in the studies treating ICH patients, we always need long-term outcomes to assess outcomes actually and to give patients time to recover. And to actually measure the benefit that you might achieve in the acute phase, the 30 days is probably too short. To see these effects, we probably need to measure 3 months, 6 months, 12 months in the studies to see that the effect that we've done in the acute phase.

Dr. Gibler:
Any other questions that I'm missing? Nope.

I wanted to really thank our speakers. It was wonderful. Very, very intellectually stimulating and really well done, as far as a presentation of the evidence. So I want to thank doctors Kreitzer, Seiffge, and Parry-Jones for being here today. And I wanted to thank everyone here for adding to this discussion by your expertise. So thank you so much. And we, once again, very much appreciate you being here, and enjoy the rest of the conference. Thank you.

Announcer:
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