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GI Bleeding and DOACs: Consensus Panel Findings

Announcer:
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Dr. Fermann:
Hello, my name is Greg Fermann. I currently serve as Professor and Executive Vice Chair of Emergency Medicine at the University of Cincinnati, and the title of my presentation today is GI Bleeding and DOACs: Consensus Panel Findings.

Gastrointestinal bleeding, we commonly describe gastrointestinal bleeding as upper versus lower GI bleeding. Above the ligament of Treitz usually defines upper GI bleeding, most commonly seen as peptic ulcer disease, erosive esophagitis, and less commonly esophageal varices, AVMs, and Mallory-Weiss tears. Lower GI bleeding is commonly defined as below the ligament of Treitz, most commonly diverticulosis and hemorrhoids, but not uncommonly AVMs and intestinal ischemia, as well as colorectal cancers. We commonly subset these into visible versus occult. Occult being defined as the presence of an iron deficiency anemia or positive fecal occult blood test. And then visible, obviously signs of upper or lower GI bleeding, bright red blood per rectum, hematemesis, or hematochezia. The visible also can be sub-segmented into major versus non-major.

So major hemorrhage with respect to the DOAC era has been highly scrutinized, and it's the most common complication of the DOACs in terms of their major bleeding. It may be actually more common with those DOACs that are dosed Q-day versus BID. It's commonly ascribed to the focal anticoagulant effect, the direct caustic effects on the mucosa, along with the systemic anticoagulant effect of the drugs.

We have a couple of trials that specifically look at GI hemorrhage. This one is a multicenter observational cohort study done by my partner, Paul Dobesh, at 354 U.S. hospitals with discharge dates of 2018 to 2022. We included subjects greater than 18 years of age that were hospitalized for anticoagulant-related major bleeding, taking rivaroxaban or apixaban, and were treated with either 4-factor PCCs or andexanet alfa.

The panel on the left describes the characteristics of the overall treatment population. They're aged about 65 years of age. I'm going to point your attention to the comorbidities. Comorbidities of diabetes, heart failure, chronic kidney disease, and liver disease were common in this cohort. On the right panel, you see the massive amount of GI bleeding that was enrolled in this trial. We had 2,200 subjects in the andexanet alfa treated group, 2,200 subjects in the 4-factor PCC treated group. And about 60% of all of these patients had a GI-associated major hemorrhage, with 30% ICH and a smaller minority with compressible, non-compressible, or critical compartment bleeding. I call your attention to time to administration in the bottom of the left panel. That's about 2.5 hours for each group.

If we focus on the GI bleeding subgroup even more, we see that the presentation is commonly to emergency departments, and 82% of the time, a minority were directly admitted or part of a hospital transfer. About 40% of patients were on rivaroxaban with about 60% on apixaban. Average age 65 with a slight predilection for the males. We see about 80% of patients in total were treated, were taking a last

anticoagulant dose of less than 18 hours. Again, the strength of this trial is the numbers: andexanet alfa 1,200 subjects, 4-factor PCCs 1,300 subjects. This is the largest trial to date.

So, we pivot a little bit towards the characterization of GI hemorrhage. Most physicians that treat GI hemorrhage would say there's a gestalt involved with this diagnosis; I know it when I see it. There have been some groups that have actually tried to define it. The American College of Gastroenterology about 10-12 years ago attempted to define major GI hemorrhage as a hemorrhage associated with shock or severe hypotension which is a systolic blood pressure of less than 90, a GI hemorrhage associated with pressor use or surgery, a decrease in hemoglobin of greater than 5, transfusion of greater than 5 units of packed cells, or those associated with death. The ISTH established a research definition that we commonly use. So, we convened a Delphi technique consensus panel made up of a lot of different specialties, including emergency medicine, gastroenterology, as well as vascular specialists to get some consensus on what we mean by GI hemorrhage, especially focusing in the DOAC era and the availability of reversal agents. We reviewed the NICE criteria, which is the large consensus panel group out of the UK that gave recommendations on andexanet alfa use in the UK.

This was published relatively recently in *JACEP Open* in October of this year. And the three predominant findings of this consensus panel are seen on the panel on the right. First, not surprisingly, the definition of GI major hemorrhage is associated with shock, altered mental status, hypotension, tachycardia, cold extremities, cyanosis, diaphoresis, pallor, or delayed capillary refill time. But somewhat surprisingly, we focused also on other parts of the presentation that would influence the decision to use reversal agents, mainly the percentage of total body volume lost. Most influential comorbidities were described as heart failure, kidney disease, and malignancy. And then we also focused on the type of GI hemorrhage as well. In addition, we also came up with a consensus that if reversal agents are selected, they should be delivered in an expedited fashion, ideally within 1 hour of presentation.

So, in summary, hemorrhage is the most common adverse event associated with DOAC use. Major GI hemorrhage is the most common reason for reversal agent use. Hemodynamic collapse, which is signs of shock, plus individual patient characteristics should be considered when deciding to use reversal agents. The most powerful comorbidities identified were chronic kidney disease, heart failure, and malignancy. And if used, there appears to be a consensus that there is a time-to-treatment effect.

Thank you for your attention.

Announcer:
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