PCR113

Patients' Perspectives on Bleeding, Bruising, and Other Key Changes Associated With Antithrombotic Treatment

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BACKGROUND

- Thromboembolic cardiovascular diseases (CVD) are the leading cause of death worldwide[1,2]
  - Common causes of CVD morbidity and mortality include acute coronary syndrome (ACS), stroke (primary and secondary), and atrial fibrillation (AF)[2]
- Antithrombotic therapies, such as antiplatelets, are indicated for CVD conditions, including atherosclerotic ischemic stroke (IS) and ACS, and anticoagulants are indicated for cardioembolic stroke prevention in AF
- However, current antiplatelet and anticoagulant therapies are limited by an increased risk of bleeding, which often makes health care providers hesitant to begin treatment, resulting in many patients who are not adequately treated[3]

OBJECTIVE

- In this study, we assessed patients who self-reported ACS, prior stroke (PS), or AF through qualitative interviews to understand their perspectives on the impacts of antithrombotic therapy and the key changes in signs, symptoms, and functioning experienced with changes in antithrombotic treatments. The main purpose of the interview was to apply the patient perception to the understanding of the best approach for measurement

METHODS

- Individual qualitative interviews were conducted via telephone with patients in the United States, United Kingdom, Germany, and Japan
- Patients were recruited to participate in, gave consent to, and were scheduled for interviews by a recruitment vendor (Global Perspectives) using existing databases, social networks, and clinician referral networks. Interested patients self-reported their health history to determine their eligibility for the interview study
- Interviews were conducted by trained qualitative research interviewers at Evidera using a video conference platform (Microsoft Teams) and lasted for an average of 90 minutes
- Audio files were transcribed and coded using ATLAS.ti software
- Concept codes were used to organize patient expressions by similarity of content and to prepare the data for thematic analysis

CONCLUSION

Most patients with ACS, prior stroke (PS), or AF attributed the bleeding and bruising symptoms they experienced to their antithrombotic treatment. While on a specific treatment, the symptoms they experienced tended to remain constant. However, they have observed that changes in their bleeding and bruising symptoms coincided with changes in their antithrombotic treatment. Therefore, assessment tools must be appropriate in both content and timing to ensure that relevant changes in bleeding and bruising associated with antithrombotic treatments can be adequately assessed to inform treatment-related benefit/risk

References

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3. Ahmed N, et al. *Eur Stroke J*. 2017;2(2):95-102.

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Disclosures

KWW was an employee of Bristol Myers Squibb at the time of the study. AC and MM are employees of Evidera. JF was an employee of Janssen Research & Development, LLC, a Johnson & Johnson Company, at the time of the study. EO and EC are employees of Janssen Global Services, LLC, a Johnson & Johnson Company, and may hold stock in Johnson & Johnson. AK, PG, and BB are employees of and may hold stock in Bristol Myers Squibb.

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RESULTS

- A total of 66 adult patients were interviewed across the 4 countries (**Table 1**)
- The mean age was 60.3 years, and 56.1% were female (**Table 2**)
- A total of 48 (72.7%) patients were currently taking "blood thinners" (28.0% within the last 6 months)

Table 1. Patient Recruitment by Country and Condition

Total by country, n	ACS (n = 23)	PS (n = 20)	AF (n = 23)	Total (N = 66)
US	6	6	6	**18**
UK	5	6	6	**17**
Germany	6	2	5	**13**
Japan	6	6	6	**18**
			Total interviews	**66**

Table 2. Patient Demographic Information

Characteristic	US (n = 18)	UK (n = 17)	Germany (n = 13)	Japan (n = 18)	Total (N = 66)
Age, years					
Mean (SD)	61.3 (7.3)	57.5 (15.1)	61.2 (13.0)	61.3 (11.1)	**60.3 (11.7)**
Gender, n (%)					
Male	3 (16.7)	8 (47.1)	6 (46.2)	12 (66.7)	**29 (43.9)**
Female	15 (83.3)	9 (52.9)	7 (53.8)	6 (33.3)	**37 (56.1)**
Marital status, n (%)					
Single, never married	0	2 (11.8)	1 (7.7)	2 (11.1)	**5 (7.6)**
Living with partner	0	3 (17.6)	1 (7.7)	0	**4 (6.1)**
Married	9 (50.0)	10 (58.8)	8 (61.5)	13 (72.2)	**40 (60.6)**
Divorced	5 (27.8)	1 (5.9)	0	1 (5.6)	**7 (10.6)**
Widowed	4 (22.2)	1 (5.9)	3 (23.1)	2 (11.1)	**10 (15.2)**
Highest level of education, n (%)*					
High school/technical school (or equivalent) or less	0	0	5 (38.5)	17 (94.4)	**22 (33.3)**
Vocational school, some college, graduate school, or certification	18 (100)	16 (94.1)	8 (61.5)	1 (5.6)	**43 (65.2)**
Employment status, n (%)*					
Employed full time or part time	1 (5.6)	10 (58.8)	6 (46.2)	10 (55.6)	**27 (40.9)**
Retired	7 (38.9)	4 (23.5)	5 (38.5)	4 (22.2)	**20 (30.3)**
Unable to work	4 (22.2)	0	0	0	**4 (6.1)**

SD, standard deviation.
*Other categories not shown.

- The top 2 symptoms rated as "worst" in patient interviews were bruising easily (n = 11) and bleeding skin (n = 9; **Table 3**)
- The emotional impacts due to bleeding and bruising that were reported by patients included anxiety, worry, concern, embarrassment, frustration, self-consciousness, and annoyance
- When thinking about starting new "blood thinners," patients with PS reported worrying about the increased need to avoid injuries, consequences if they needed surgery, and having the "blood thinner" fail to prevent repeat strokes (**Table 4**)

Table 3. Symptoms Identified by Patients as Their "Worst" Ones and Example Quotations

Symptom	Symptom identified as their "worst," n (%)	Example quotations describing what makes it their "worst"
Bruising easily	11 (16.7)	• *Because in the summer, I don't wear any clothes with long sleeves. So, if I get bruises on my arms or elbows, I don't know how I could hide them… I have 2 bruises right now. Maybe I notice a new bruise every 2 weeks… I notice bruises on my legs* • *Because it's so visual. People are always asking me, what have you done to yourself? Where have you bruised your arm? Why are your legs so bruised?... it's just the constant, people asking, why are you bruised?* • *It makes me feel old. It's purely a vanity thing. It just reminds me I'm more fragile than I'd like to remember*
Bleeding skin	9 (13.6)	• *It's because I have to be constantly careful not to get injured. It's very burdensome that I have to constantly worry and have to be careful. It is burdensome that you have to live with that kind of concern in your everyday life* • *Because it affects my daily life. When you have just a tiny thing on your finger, you start bleeding right away if you're taking blood thinners, and the clothes you're wearing might be ruined* • *First of all, just the embarrassment that you have blood that soaked through your clothes. Could be anywhere from a little spot to being pretty major, close to me needing to get emergency room attention. And the fact that my life has changed, that I can't do activities that I used to for the fear of losing my balance and falling, creating a blood clot, or the opposite, for any too much internally and the skin*

Table 4. What Worries Patients the Most About Starting a New "Blood Thinner"?

ACS	PS	AF
• *Potentially long-term effects… Ultimately, related to how long you can be on it when it's not healthy to be on it anymore, if that's correct, what the alternative is and how effective the alternative is* • *That it's not doing its job properly* • *Well, what worries me most is the fact that I cannot undergo surgical procedures. I have to avoid injuries at all cost, especially the kind of injury that would require a surgery*	• *Just being too coagulated or anticoagulated, having my blood be maybe too thin and having a bleeding event or being in an accident and not being able to control it* • *Duration of the treatment. How long do I have to continue taking this medication? I did ask the doctor once and the doctor said, "for a very long time," but he didn't really specify how many more years. Maybe I need to take this medication until I die. That's really worrying* • *I make a lot of business trips and I might forget to take the medication with me. If I forget to take it, I'm always afraid that I might experience another stroke*	• *Possible bleeding. I can't get injured. That is most worrying. Also, I can't undergo any surgical procedures while I'm taking [apixaban]. For example, including dental treatment* • *If it didn't work and I was to have some kind of TIA, or whatever that's called* • *The only thing I would be worried about is [if] for some reason it was no longer available. Not a worry, but even with fairly good insurance, it is still a very expensive drug* • *If I accidentally experience an injury, I have to be worried because the wound will not stop bleeding. So, I would be worried about prolonged bleeding*

TIA, transient ischemic attack.

- Sixty-two (93.9%) of the 66 patients interviewed reported bleeding (skin, urine/feces, vomit, nosebleeds, and menstrual)
- Thirty-seven (56.1%) of the 66 patients interviewed who reported bleeding of the skin attributed it to either their "blood thinner" or both their "blood thinner" and their condition (**Table 5**)
- Forty-nine (74.2%) of the 66 patients interviewed reported bruising easily and having internal bruising
- Fifty (75.8%) of the 66 patients interviewed who reported bruising attributed it to either their "blood thinner" or both their "blood thinner" and their condition (**Table 5**)
- While bleeding and bruising were reported as symptoms experienced during the cardiovascular event and the recovery period, these symptoms were reported to be most prominent during the patients' experience of preventive care (**Table 5**)
- Both negative and positive changes were described relative to having medications changed by their clinicians
  - Negative changes related to treatment with "blood thinners" included excessive bruising, prolonged bleeding from cuts and lab work, nosebleeds, emotional burden, changes in daily activities to avoid bleeding, fatigue, weakness, muscle soreness, nausea, and lightheadedness
  - Positive changes related to treatment with "blood thinners" included reduced signs and symptoms of their underlying condition (including chest pain, irregular heartbeat, shortness of breath, fatigue, tiredness, and weakness) and other treatment effects, such as headache, dizziness, nausea, reflux, and heartburn. Global changes, such as an overall impact on quality of life and a positive improvement on mental health, were also mentioned, as well as a greater sense of security that risk for CVD events was reduced and, for some, feeling better from improved blood flow

Table 5. Symptoms Reported by Attribution and Timing of Experience

	Patients believe symptom is more related to, n*		Stage where symptom was most prominent, n†		
Symptom description	Condition	"Blood thinner"	During event	During recovery	During preventive care
Bleeding: skin	0	37	5	9	33
Bleeding: into urine/feces, coughing, vomiting	1	4	2	1	4
Bleeding: nosebleeds	2	19	3	5	17
Bleeding: heavy menstruation (females only)	1	1	0	1	1
Bruising easily	6	44	8	13	38
Internal bruising	1	1	1	0	1

*Patients were allowed to report >1 type of bleeding.
†Some patients indicated all times they had symptoms rather than selecting the most prominent time period.