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Patient-Relevant Bleeding Events Among Patients Taking Anticoagulant Medication

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Disclosures

- *I am an employee of and have a financial stake in Anthos Therapeutics [privately held company]*

Learning objectives

Understand the day-to-day bleeding problems (defined as bleeding not requiring medical intervention) experienced by patients on anticoagulants, and the impact on daily activities, emotional well-being, and adherence

Review key results from a global survey on the impact of *patient-relevant bleeding* (PRB) events, including questions about their experiences, the effect on their emotions, and how it made them feel about their anticoagulant therapy.

The impact of bleeding events on quality of life for patients taking anticoagulation is not well studied

- Bleeding events or bruising that do not require medical intervention are often referred to as “minor” bleeding events, but even minor bleeds may be relevant to patients
- The term “minor” may also reduce HCP-patient communication on this type of bleeding
- We suggest using the term patient-relevant bleeding (PRB) events instead of ‘minor’ bleeding
- The impact of these PRB events among patients taking anticoagulant medications is underreported, poorly understood, and has not been well described

The objectives of this study were to explore the impact of PRB events in patients taking anticoagulants on:

- Daily activities
- Emotional well-being
- Adherence

Global survey of 3,000+ patients prescribed anticoagulants



Under the leadership of **StopAfib.org** and the **National Blood Clot Alliance (NBCA)**, a comprehensive patient questionnaire intended to gain quantitative and qualitative insight on the impact of Patient-Relevant Bleeding (PRB) events, which we defined as bleeding not requiring medical intervention.

Aims of Patient Survey: To explore the impact of PRB events on daily activities, emotional well-being, and adherence in patients taking anticoagulants

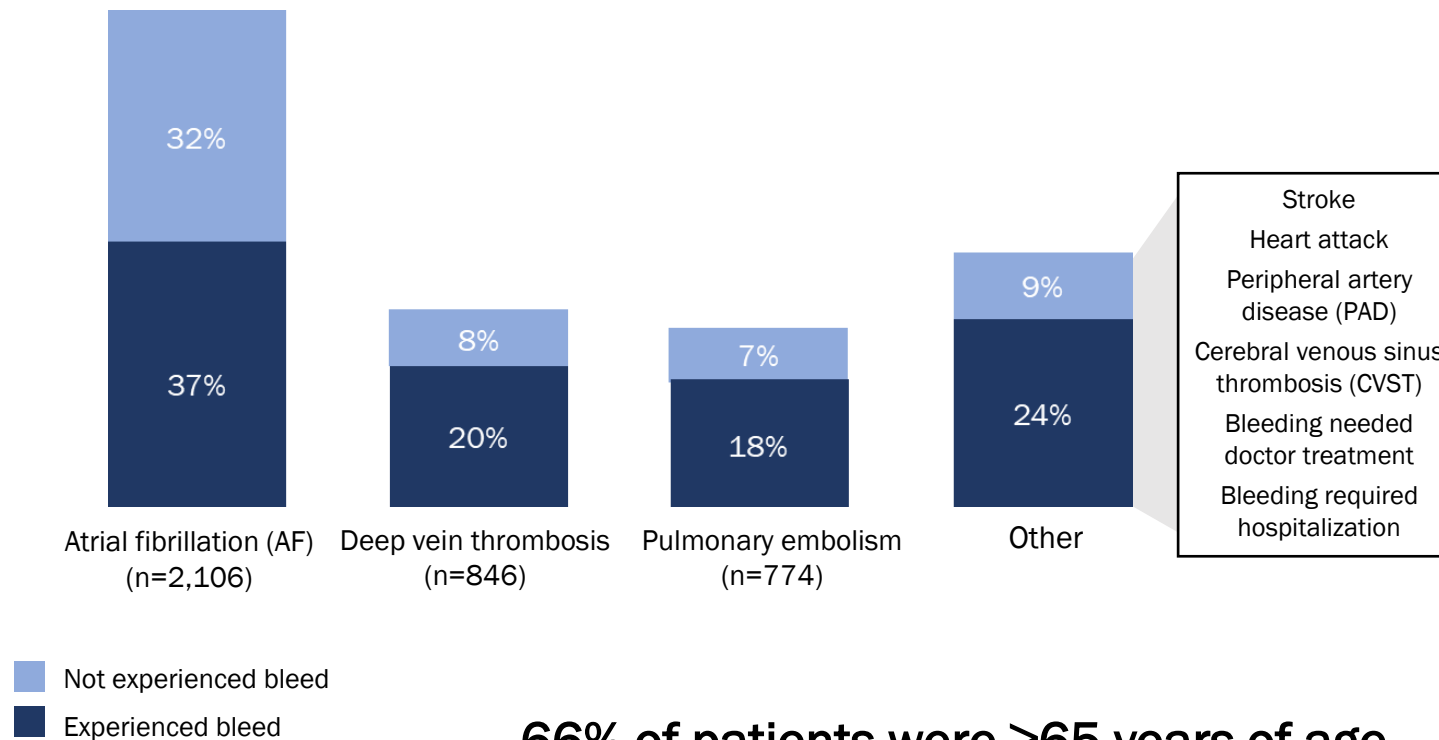
- Participants aged ≥ 21 years currently taking anticoagulants were included (warfarin, low molecular weight heparin, or direct oral anticoagulant)
- The online survey was made available in November 2022 and is accessible globally (English language only)
- No personally identifiable information collected

Prescribed
anticoagulant | **3,072**

Experienced
bleeding problem | **1,815 or 59%**

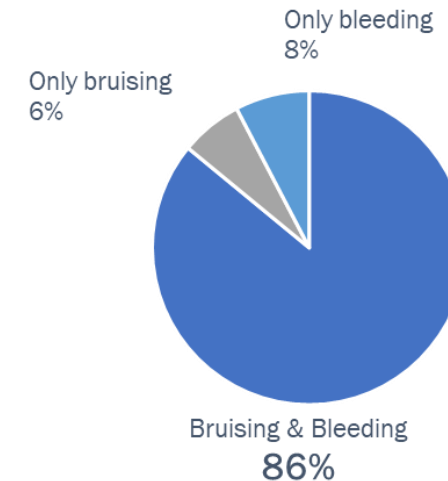
Bleeding problems reported across multiple diagnoses, with AF patients experiencing the highest rates

Patient-reported diagnosis
(patients may report more than one, n=3,072)



66% of patients were ≥65 years of age

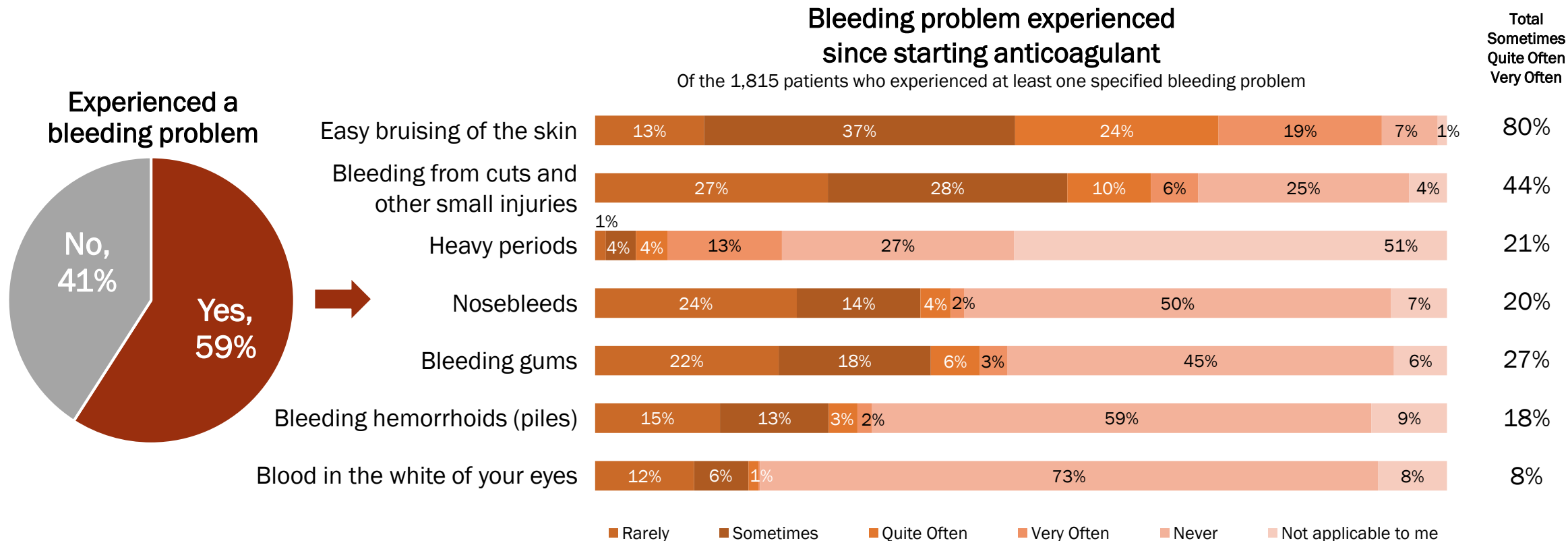
86% of those with a bleeding problem experienced both bleeding and bruising



On average patients reported experiencing 3.3 of the specified types of bleeds or bruising since starting their current treatment

Base = 3,072 completed the survey of which 1,815 (59%) experience bleeding problems on current treatment. Patients who experienced a bleeding problem completed the full survey to understand the impact of those bleeds
 Source: Global survey of patients prescribed a blood thinning product, Insocius, Nov 2022

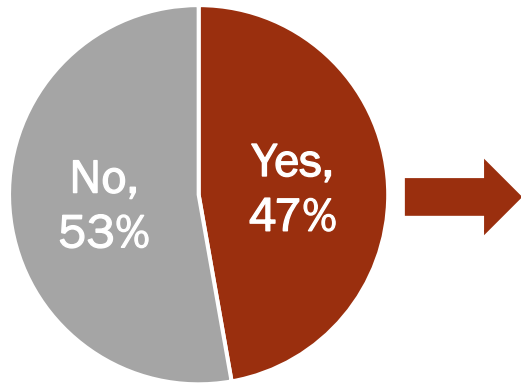
59% of patients reported experiencing a bleeding problem since starting an anticoagulant



Base = 1,815 (59%) experiencing a bleeding problem on current treatment.
 Percents rounded to nearest whole number.
 Patients able to select more than one medicine within each class, totals may be greater than 100%.
 Source: Global survey of patients prescribed a blood thinning product, Insocius, Nov 2022

47% of patients acknowledged bleeding may have an emotional impact

Do bleeding problems affect your emotions?

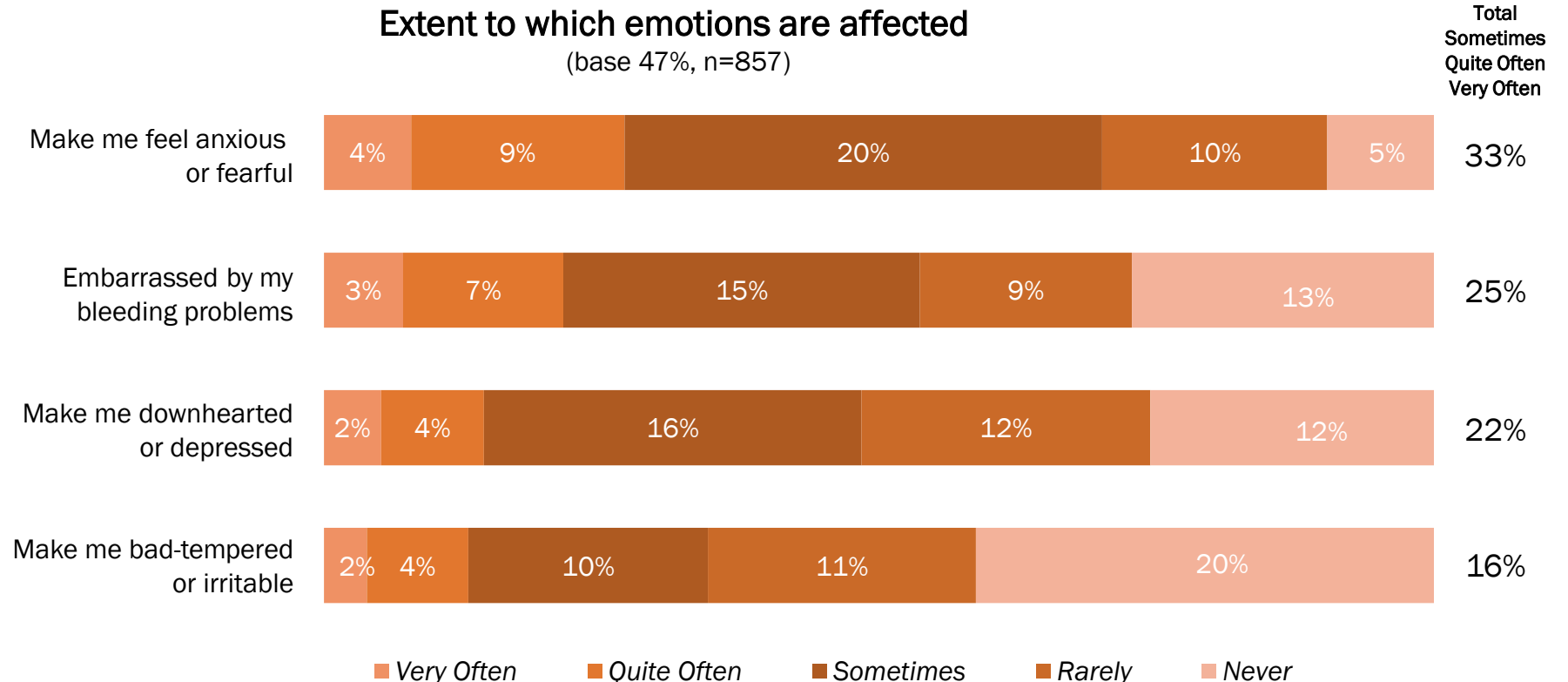


Patients reported underlying fears or concerns related to:

- Fatal accident or bleed
- Injuries such as car accident or fall
- Being alone and 'bleeding out'
- Doctor won't consider their serious bleed to be serious
- Potential for another clot

Extent to which emotions are affected

(base 47%, n=857)



Previous experience of a bleed requiring medical attention heightens the emotional impact

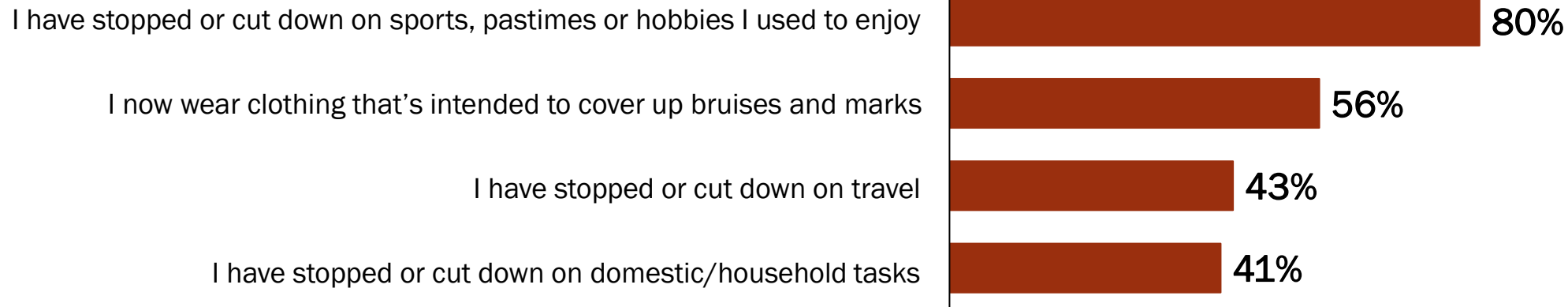
A substantial proportion of patients adjusted their lifestyles to reduce risk or hide bleeding

54%

Reported adjusting their lifestyles to reduce risk of bleed

Patients reported they spend less time doing hobbies or traveling and wear clothes to cover marks or bruises

Of the 54% of patients who adjusted their lifestyles:

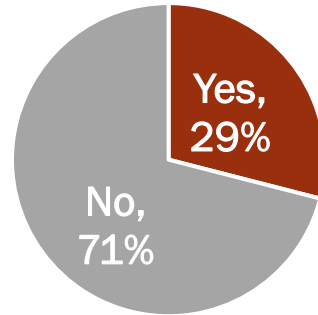


Other reported (<20%):

- I have stopped or cut down on shaving/personal grooming
- I do less socializing
- I have made changes in my work/profession
- I usually avoid outdoor activities like swimming where my bruises or marks would be visible to others

Bleeding problems often lead patients to want to pause treatment or reduce their anticoagulant dose

Have your bleeding problems made you feel like you want to stop taking anticoagulant?



Of the 29% of patients who considered stopping or changing the dose of their anticoagulant:

Have asked their doctor to pause, stop, or reduce the dose of their anticoagulant

45%

Have stopped, paused, or reduced the dose of their anticoagulant without first consulting your physician

25%

Of those who stopped, paused, or reduced the dose of their anticoagulant themselves, later informed their doctor

16%

"I'd be embarrassed. I feel that I can manage it myself"

"I stopped for a few days because I was going to the dentist"

Reasons for not telling their doctor:

"I only stopped for a day or two whilst the bleeding stopped"

"I have not seen my doctor since reducing my dosage. I intend to tell him soon"

Conclusion: Patient impact is significant

Survey shows the impact of PRB events on patients' quality-of-life and adherence to anticoagulant therapy

- Patients withdraw from an active, healthy lifestyle to minimize bleeding risk
- Women stay at home during menstrual bleed due to fear of heavy periods
- Patient-reported emotional burden includes fear of a future bleed they are unable to control
- Without informing their HCP, some patients temporarily stop taking their anticoagulant medication
 - Other studies suggest that consequences of poor adherence include a nearly **5X increased risk of thrombotic event** but NO decrease in bleeding risk compared to fully adherent patients¹

Instead of referring to these events as “minor”,
we propose the term “patient-relevant bleeding (PRB)”
to more appropriately reflect their impact and clinical significance

Clinical Significance

Need for a new generation of anticoagulants

In patients with atrial fibrillation being treated with an anticoagulant:

- Major bleeds are critical, but **ALL** bleeds matter
- Bleeding and bruising that are relevant to patients, but may not require medical attention, should be considered relevant to the prognosis and clinical care of patients with atrial fibrillation
- Patient-relevant bleeding* has a significant impact on the quality of life of patients and may lead to poor adherence, leaving patients at a high risk for experiencing a stroke

These data highlight the need for a new generation of anticoagulants that reduce the risk of stroke and VTE, with substantially less bleeding than the existing agents

Acknowledgments

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