Evolving Antithrombotic Strategies in Patients With Atrial Fibrillation Undergoing Percutaneous Coronary Intervention: Results From a Survey Among US Cardiologists

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ABSTRACT

Background: Many patients treated with oral anticoagulants for atrial fibrillation undergo percutaneous stent implantation, where dual antiplatelet therapy (DAPT) is also recommended. The current evidence to support triple oral antithrombotic therapy (TOAT) in these patients is limited, and new strategies are being discussed to optimize outcomes.

Hypothesis: There will be variation in antithrombotic strategies in patients with atrial fibrillation needing stenting.

Methods: We surveyed US-based cardiologists serving as clinical investigators in academic sites and posted an online "question of the month" on cardiosource.org.

Results: Seventy-five (10.7%) responses were received to the email survey and 119 to the online question. Bare-metal stenting (BMS) was a priori preferred over drug-eluting stenting (DES) for 50.6% of patients. Only 8.8% of the responders chose newer anticoagulants in addition to DAPT as the preferred oral anticoagulant. For duration of TOAT, 79.4% of physicians recommended stopping DAPT at 1 month when BMS was used in patients presenting without acute coronary syndrome (ACS) vs 57.4% in patients with ACS. In patients implanted with a DES, 73.5% and 76.5% preferred stopping DAPT at 6 to 12 months (no ACS vs ACS, respectively). When asked which of the 2 antiplatelet agents they would recommend stopping after the above durations, 50% chose to quit aspirin.

Conclusions: The survey highlights an interest in the new strategy of dropping aspirin, but the lack of concrete evidence triggers undesired diversity in clinical approaches. High-quality data on the efficacy and safety of such interventions are needed to further consolidate these approaches.

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Introduction

Long-term treatment with oral anticoagulants (OA) is indicated in patients with atrial fibrillation at moderate to high-risk for embolic complications, venous thromboembolism, and many other conditions.[1,2] Many of these patients also have ischemic heart disease,[3,4] which may necessitate percutaneous intervention (PCI) with stent implantation[5] and treatment with dual antiplatelet therapy (DAPT).[6] Although indicated to alleviate the risk of thrombosis and embolism, triple antithrombotic therapy can increase the rate of bleeding in this population.[7,8] The 2011 American College of Cardiology Foundation/American Heart Association/ Heart Rhythm Society (ACCF/AHA/HRS) Focused Update on the management of patients with atrial fibrillation suggests vitamin K antagonists (VKA) plus clopidogrel as the preferred combination in the setting of atrial fibrillation/flutter and PCI (class IIb recommendation, level of evidence C).[2] The 2011 consensus document from the European Society of Cardiology recommends triple oral antithrombotic therapy (TOAT) treatment based on clinical presentation and stent implantation, followed by VKA and clopidogrel.[9] Specifically, in patients with unstable angina/non–ST-elevation myocardial infarction who are indicated for anticoagulation, the 2012 ACCF/AHA Focused Update recommends 12 months of TOAT, with an adjustment of target international normalized ratio (INR) to between 2.0 and 2.5 and use of low-dose aspirin,[10] whereas the European Society of Cardiology (ESC) consensus document recommends TOAT treatment for 6 months in patients presenting with acute coronary syndrome (ACS).[9]

Until recently, only small, retrospective, single-center studies or post hoc analyses from prospective registries were available to assess the benefits and risks of combined antiplatelet and OA treatment after PCI, with variable outcome definitions and time points of assessment.[7,8] The recently published What is the Optimal antiplatElet and anticoagulant therapy in patients with oral anticoagulation and coronary StenTing (WOEST) trial is the first to assess single vs. dual antiplatelet strategies (in addition to anticoagulation) after PCI in a prospective multicenter, randomized, controlled trial, where the intervention arm included VKA and clopidogrel. The results suggest that the use of clopidogrel without aspirin is associated with a significant reduction in bleeding complications and no increase in the rate of thrombotic events.[11]

Given the lack of well-established evidence to support possible approaches, the availability of novel oral anticoagulants (NOACs), and the recent results from the Dutch WOEST trial, we set out to assess the current practice patterns of US-based cardiologists when treating patients on OA who are undergoing PCI.

Methods

An invitation letter was sent electronically to a network of interventional cardiologists practicing in the United States who serve as investigators in clinical trials managed by the site management team at the Harvard Clinical Research Institute, Boston, Massachusetts. The participating physicians were asked to complete the email survey (Table 1). Additionally, an online "question of the month" was posted on the Cardiosource.org website for a 4-week period. The data obtained included estimates of the prevalence of the condition, and physicians' preferences to stent class, anticoagulation type, and antiplatelet treatment (type and duration). Data were collected at a central location (SurveyGizmo.com, Boulder, CO). Descriptive results (n, %) are presented.

Table 1. Email Survey Questionnaire

1.	In your practice as a cardiologist, what is your estimate of the percentage of patients who have atrial fibrillation/flutter that necessitates anticoagulation and who undergo stent implantation?
2.	How often will you opt to implant a BMS in a patient with atrial fibrillation/flutter on OA indicated for stent implantation?
3.	Which anticoagulant in the setting of triple antithrombotic treatment is your preferred choice?
4.	How long will you continue treatment with triple antithrombotic treatment in the following setting? (a) ACS + DES, (b) no ACS + DES, (c) ACS + BMS, (d) no ACD + BMS.
5.	Which antiplatelet agent will you prefer to drop first?
6.	When will you stop the second antiplatelet agent (ie, treat with OA only)?
7.[a]	For a patient with AFib undergoing DES implantation, which is your preferred strategy? (a) triple antithrombotic treatment for 1 year, (b) triple antithrombotic treatment for 1 month followed by anticoagulation + aspirin, (c) triple antithrombotic treatment for 1 month followed by anticoagulation + clopidogrel, (d) WOEST-like strategy: anticoagulation and clopidogrel for at least 1 month (BMS) or 12 months (DES or ACS)

Abbreviations: ACS, acute coronary syndrome; AFib, atrial fibrillation; BMS, bare-metal stent; DES, drug-eluting stent; OA, oral anticoagulant; WOEST, What is the Optimal antiplatElet and anticoagulant therapy in patients with oral anticoagulation and coronary StenTing.
[a]This question was a part of the survey and concurrently posted on cardiosource.org.

Results

The invitation letter with the link to the email survey was sent to via email in February 2013 to 710 investigators. Over a period of 2 weeks, 75 responses were received (10.7%). An online "question of the month" was posted concurrently at Cardiosource.org with 119 responders.

Sixty-nine percent of responders (52/75) estimated that 5% to 10% of patients in their clinical practice undergoing PCI have atrial fibrillation or flutter that necessitates anticoagulation. Twenty percent (15/75) estimated this rate to be 10% to 20%. When asked which stent class is preferable in the population, 37% (28/75) would choose bare-metal stents (BMS) over drug-eluting stents (DES) as the preferred stent in the majority (>66%) of their patients. Overall, BMS is a priori the preferred stent of choice in 50.6% of these patients.

With regard to what anticoagulant to use in patients with atrial fibrillation, the majority of responders (53%, 36/68) opted to retain the same OA regimen used prior to PCI, whereas 38% (26/68) specifically preferred warfarin over other treatment options. Only 8.8% (6/68) preferred NOAC

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Table 2. Triple Therapy Treatment Duration (n = 68 Responses)

Clinical Scenario	1 Month	3 Months	6 Months	12 Months
DES implantation, ACS	8.8% (6)	14.7% (10)	20.6% (14)	55.9% (38)
DES implantation, no ACS	8.8% (6)	17.6% (12)	35.3% (24)	38.2% (26)
BMS implantation, ACS	57.4% (39)	13.2% (9)	11.8% (8)	17.6% (12)
BMS implantation, no ACS	79.4% (54)	14.7% (10)	2.9% (2)	2.9% (2)

Abbreviations: ACS, acute coronary syndrome; BMS, bare-metal stent; DES, drug-eluting stent.

Table 3. Preferred Treatment Strategies in Patients With Atrial Fibrillation Undergoing Drug-Eluting Stent Implantation (Combined Email and Online Surveys, n = 184)

Treatment Strategy	Responses, N = 184
Triple antithrombotic therapy for 1 year	29.9% (55)
Triple antithrombotic therapy for 1 month followed by OA and aspirin	13.6% (25)
Triple antithrombotic therapy for 1 month followed by OA and clopidogrel	29.3% (54)
WOEST-like strategy: anticoagulation and clopidogrel for 12 months	27.2% (50)

Abbreviations: OA, oral anticoagulant; WOEST, What is the Optimal antiplatElet and anticoagulant therapy in patients with oral anticoagulation and coronary StenTing.

as the routine first-line treatment in this clinical scenario. Responders commented on the lack of supporting clinical data for the new agents when combined with DAPT, and cited lack of reversibility of NOAC compared to warfarin as reasons for their choice of treatment.

Table 2 summarizes the preferences toward the duration of triple therapy in different clinical scenarios (with and without ACS, BMS vs DES implantation). As shown, the type of stent appeared to be the most influential factor: the majority of responders continuing triple therapy for 6 to 12 months following DES, whereas 1-month duration was the preferred approach following BMS. Overall, half (34/68) of the responders preferred to stop aspirin and half preferred to stop clopidogrel after the initial triple antithrombotic therapy phase. Although 69% (47/68) preferred to continue at least 1 antiplatelet therapy indefinitely, 31% of responders preferred to stop the second antiplatelet therapy between 6 and 12 months after the intervention.

We asked in both the email and online surveys what is the respondent's single preferred treatment strategy for patients treated with OA and implanted with DES. As shown in Table 3, there was great interest in dropping 1 of the 2 antiplatelet agents after either 1 month (42.9%) or immediately (27.2%). Of these, approximately two-thirds of respondents would discontinue aspirin, whereas one-third would discontinue clopidogrel.

Discussion

We conducted 2 simultaneous surveys to assess US cardiologists' practice patterns in patients atrial fibrillation/flutter treated with OA who undergo PCI. A substantial percentage of interventional cardiologists would consider implantation of BMS over DES in this setting for the majority of their patients, suggesting concern over the safety of enhanced and prolonged antithrombotic therapy. In patients at high risk for bleeding, the North American and European recommendations suggest that DES should be totally avoided (and BMS used).[12] In a recent single-center study, BMS was used in 81% of patients with atrial fibrillation (AF) undergoing PCI, and its use was not associated with any clear disadvantages compared to DES. Only 22% of the patients in this study received OA at hospital discharge.[13] In another single-center study, BMS was associated with higher risk of revascularization post-PCI when compared to DES in the setting of ceasing aspirin use at 1 month.[14] In our survey, more physicians are likely to cease 1 antiplatelet therapy at 1 month in patients implanted with BMS, whereas in patients receiving DES the majority of physicians will transition at 6 to 12 months, a pattern that has been documented prior to the emergence of NOAC and the WOEST results.[15] Stent type was found to have stronger influence on duration of DAPT, possibly due to the fact that the majority of benefit from DAPT in patients with DES is in the first few months.[16] Interestingly, although the prior guidelines have suggested stopping clopidogrel after the minimal duration poststenting, we observed a strong interest in the new strategy of discontinuing aspirin. In our email survey, it was an even split between aspirin or clopidogrel as the single antiplatelet agent alongside an OA, whereas in the online survey, it was a 2:1 preference for stopping aspirin and continuing clopidogrel and anticoagulation. As such, a substantial proportion of responders are adopting the WOEST strategy of clopidogrel and OA after stent implantation with or without 1 month of DAPT.

The goal of prescribing antithrombotic therapy is to reduce the risk of coronary thrombotic events (such as myocardial infarction or stent thrombosis).[6] VKAs are a well-established intervention in patients with AF or flutter with a moderate risk for embolic events.[2] Unfortunately, DAPT is not sufficient for stroke prevention, as seen in the Atrial Fibrillation Clopidogrel Trial with Irbesartan for Prevention of Vascular Events (ACTIVE-W) trial.[17] Conversely, anticoagulation and aspirin are inferior to P2Y12 inhibition with clopidogrel or ticlopidine for prevention of stent thrombosis and cardiovascular events.[18–21] Thus, some combination of anticoagulation (for stroke prevention) and antiplatelet therapy (for cardiac protection) is warranted. The optimal combination regimen is not well defined.

Three NOACs are now also approved in the United States for stroke prevention in patients with nonvalvular atrial fibrillation, based on large randomized controlled trials.[22–24] However, the addition of an antiplatelet agent to VKA[25] or NOAC[26] increases the risk of bleeding, including in patients undergoing PCI, as was reported in multiple registries.[27–29] The net benefit of combining OA and antiplatelet agents in the setting of PCI is not well addressed in the clinical literature. The 2011 ACCF/AHA/HRS Focused Update on the management of patients with atrial fibrillation suggests VKA plus clopidogrel as the preferred combination in the setting

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of atrial fibrillation/flutter and PCI, but the suggestion does not go as far as specifying the type of implanted stent.[2] The 2010 consensus document of the ESC Working Group on Thrombosis, endorsed by the European Heart Rhythm Association and the European Association of Percutaneous Cardiovascular Interventions, recommends different durations of TOAT based on the clinical scenario (ACS vs elective) and stent type, with TOAT treatment not extending beyond 6 months, followed by VKA and clopidogrel and finally VKA alone.[9] These guidelines, however, are not firmly based on direct evidence. It can be assumed that until more robust evidence is presented, many US-based physicians will hesitate to follow these guidelines. There are currently no data to address a clinician's reasons for nontreatment.

The results from the WOEST trial are the first to signal the net benefit of a combination of VKA and clopidogrel over triple therapy in a randomized fashion. Despite being small and unpowered to detect differences in outcomes other than major bleeding such as coronary end points, its results seem to be what many interventionalists are eager to adopt—a new strategy that can reduce bleeding and potentially improve outcomes for this high-risk group of patients who constitute 5% to 7% of their practice.[30]

Limitations

Our survey is small in size and confined in scope, and as such can be argued to be non-representative of the surveyed population. Email surveys of health professionals are known to have low response rates compared with other modalities,[31,32] with reported rates as low as 9%.[33] Despite its size and low response rate, our survey is unique in emphasizing trends in this evolving field. This survey was not designed to capture reasons leading to current practice patterns. As such, it should be regarded as hypothesis generating. Additional insight will be useful to better portray this apparent shift in treatment patterns.

Conclusion

As shown in the current survey, practice patterns appear to be shifting to adjust for the emerging data. An undesired variability in practice exists, and as many as 30% of the patients who are admitted for PCI with OA are discharged without it.[34,35] This has been attributed to patients' medical history, admission course, and need for dual antiplatelet therapy after PCI.[34] Interestingly, these studies show that OA and a single antiplatelet drug have been prescribed in 2.5% to 7.5% of the patients.[34,35] Our data suggest that many more physicians are now ready to adopt this strategy. Ongoing randomized trials are being conducted to address this question and include the Anticoagulation in Stent Intervention (MUSICA-2 trial, NCT01141153, 300 low- to moderate-risk AF patients randomized to VKA and dual antiplatelet therapy vs dual antiplatelet therapy alone) and the Triple Therapy in Patients on Oral Anticoagulation after Drug Eluting Stent Implantation (ISAR-Triple trial, NCT00776633, 600 AF patients implanted with DES randomized to 6 weeks vs 6 months clopidogrel treatment with OA and aspirin). These are likely to provide valuable information. However, additional large (ideally with several thousand patients) prospective randomized studies are warranted to further establish the efficacy and safety of various combination regimens, to determine the duration and type of antiplatelet therapy, and to establish the role of NOAC in patients treated with OA who undergo PCI.

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