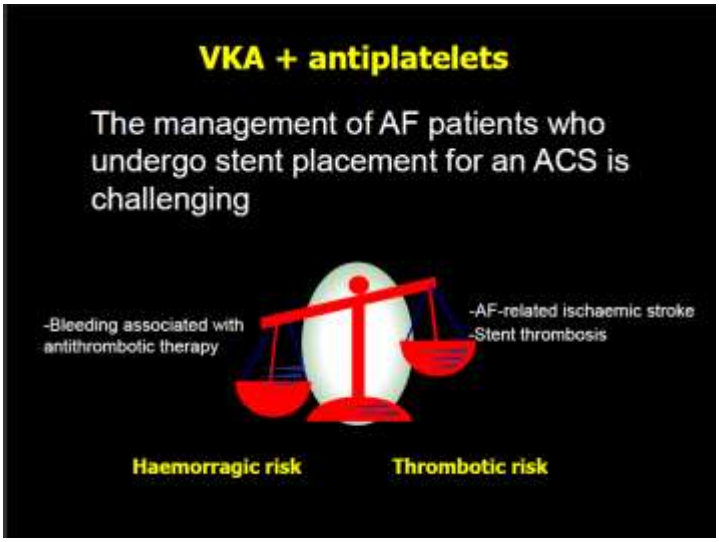
PIONEER AF-PCI trial: Rivaroxaban VS. Warfarin post-PCI in AF patients.

ELSayed Farag MD,FSCAI
Zagazig University ,Egypt

- Approximately 20–45% of patients with AF have evidence of coronary artery disease, and depending on the presentation, a proportion of these patients require coronary revascularization with either PCI or coronary artery bypass grafting .
- Among ACS patients undergoing PCI, approximately 5% to 21% of patients have concomitant AF.

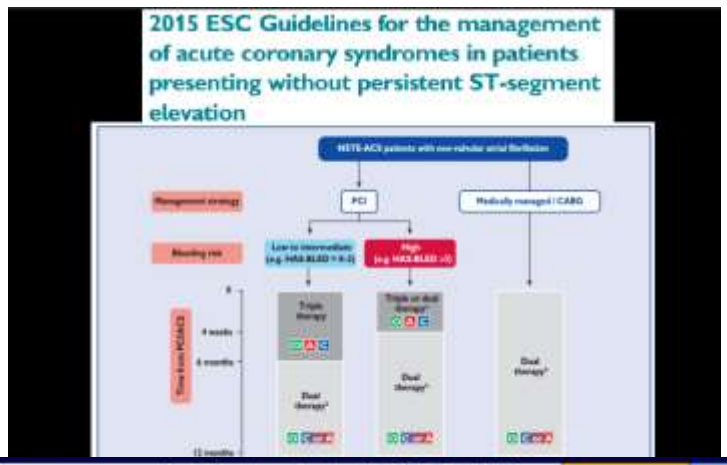


Thrombosis is an enemy but bleeding is not a friend

HAS-BLED

	Clinical characteristic*	Points awarded
H	Hypertension	1
A	Abnormal liver/renal function	1-2
S	Stroke	1
B	Prior major bleeding or predisposition	1
L	Labile INR	1
E	Elderly (>65)	1
D	Drugs/alcohol concomitantly	1-2

2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation

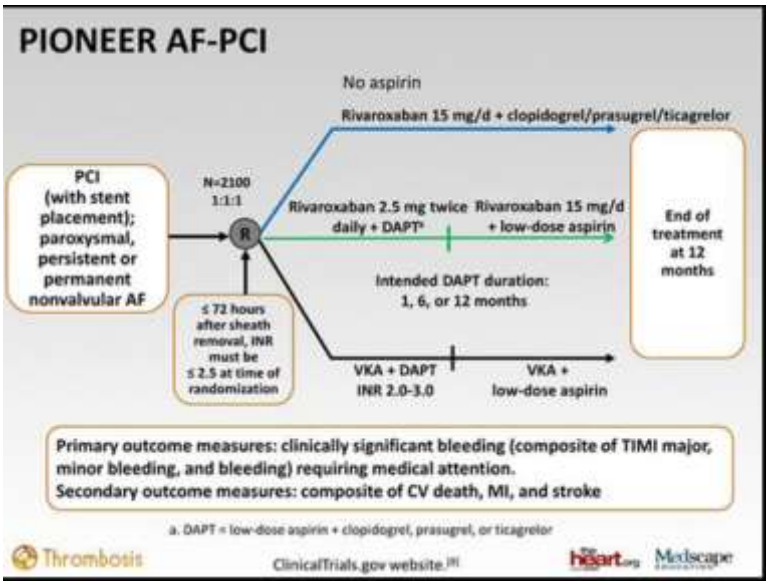


Following coronary revascularization in patients with CHA_2DS_2-VASc score of ≥2, it may be reasonable to use clopidogrel concurrently with oral anticoagulants, but without aspirin	IIb	B

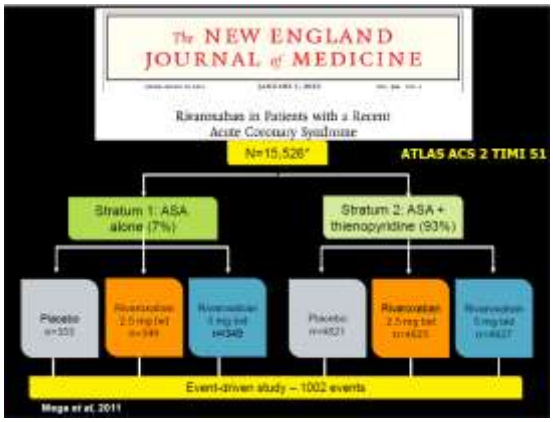
AF and PCI: an important issue

- Oral anticoagulants are needed for preventing stroke
- Antiplatelet therapy is needed for preventing stent thrombosis
- Combining OAC and APT increases bleeding
- Therefore, there is a need to clarify the optimal combination regimen in terms of choice of agents, dose and duration
- Pioneer AF-PCI is the first randomized trial to address the issue with NOACs. Given the safety and convenience advantages of NOACs over VKA, this is important

PIONEER AF-PCI



Part of the rationale for the rivaroxaban 2.5 mg BID dose was its previous association with reduced stent thrombosis in the ATLAS ACS 2 TIMI 51 trial.



FACT

Pioneer AF-PCI : interpretation

Main finding : RVRX-based regimens, combined with either $P2Y_{12}$ or DAPT, reduced bleeding compared to VKA and DAPT.

1. **The RVRX regimens used reduced doses**
   - The RVRX dose was reduced to either 15 mg daily with $P2Y_{12}$, or to 2.5 mg bid with DAPT
   - These doses were neither tested nor approved in the SPAF indication
   - Thus, reduced bleeding when compared to full dose VKA is not surprising
   - The real question is: does this preserve the efficacy of anticoagulation to prevent stroke ?

EgSC EGYPTIAN SOCIETY OF CARDIOLOGY

FACT French Alliance for Cardiovascular Trials

Pioneer AF-PCI : interpretation

Main finding : RVRX-based regimens, combined with either $P2Y_{12}$ or DAPT, reduced bleeding compared to VKA and DAPT.

1. The RVRX regimens used reduced doses
2. **This trial did not establish (or even test) noninferiority of RVRX-based strategies vs VKA + DAPT for stroke prevention**

	HR (95% CI) for stroke
Riva + $P2Y_{12}$ vs. VKA + DAPT :	1.07 (0.39-2.96) p=0.891
Riva + DAPT vs. VKA + DAPT :	1.36 (0.52-3.58) p=0.530

Reassuring that stroke rates were low overall

EgSC EGYPTIAN SOCIETY OF CARDIOLOGY

FACT French Alliance for Cardiovascular Trials

Pioneer AF-PCI : interpretation

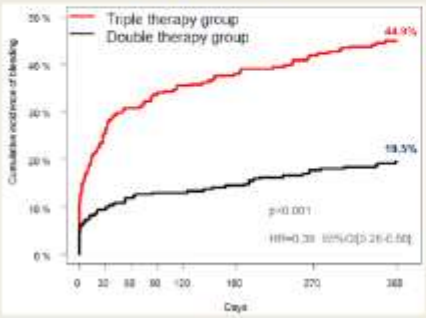
Main finding : RVRX-based regimens, combined with either $P2Y_{12}$ or DAPT, reduced bleeding compared to VKA and DAPT.

1. The RVRX regimens used reduced doses
2. This trial did not establish noninferiority of RVRX-based strategies vs VKA + DAPT for stroke prevention
3. **The RVRX strategies were not compared to the "WOEST" strategy of VKA + clopidogrel alone**

Both strategies reduce bleeding compared to VKA + DAPT

WOEST

VKA + clopidogrel



Dewilde W et al. *Lancet* 2013

PIONEER AF-PCI

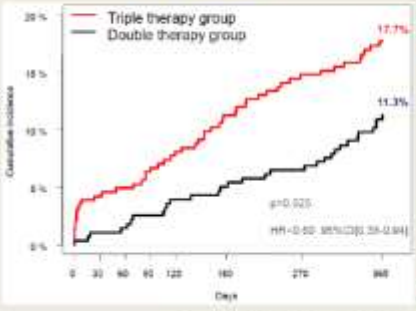
RVRX reduced dose + APT

Gibson CM et al. *NEJM* 2016

The WOEST strategy (but not RVRX-based strategies) reduces MACE

WOEST

VKA + clopidogrel



Dewilde W et al. *Lancet* 2013

PIONEER AF-PCI

RVRX reduced dose + APT

Gibson CM et al. *NEJM* 2016

FACT

Pioneer AF-PCI : interpretation

Main finding : RVRX-based regimens, combined with either $P2Y_{12}$ or DAPT, reduced bleeding compared to VKA and DAPT.

1. The RVRX regimen used reduced doses
2. This trial did not establish noninferiority of RVRX-based strategies vs VKA + DAPT for stroke prevention
3. The RVRX strategies were not compared to the "WOEST" strategy
4. **The trial does not provide reliable information on the optimal duration of antiplatelet therapy, because duration was not randomly assigned**

Results of the PIONEER AF-PCI Trial

Keith AA Fox MBChB

- Considering both safety and practical use, the reduced dose of rivaroxaban 15 mg OD plus single antiplatelet therapy could become the approach of choice once approved.
- Currently, rivaroxaban 2.5 mg BID is approved in Europe for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome with elevated cardiac biomarkers, and it has not been tested for stroke prevention in patients with AF.

Take home message

- Triple therapy (OAC, clopidogrel and aspirin) for PCI in AF leads to unacceptable bleeding. possibly, aspirin maybe skipped.
- The most recent guidelines mandate for most AF patients undergoing PCI triple therapy for the shortest periodas clinically acceptable.
- For AF patients undergoing PCI the NOACs seem preferable because of their safety profile, but randomized trial data are necessary to support this.
- PIONEER AF-PCI now provides the first new evidence to support the use of a NOAC in patients with AF who require PCI, with rivaroxaban-based treatment strategies demonstrating improved safety.
- PIONEER–AF-PCI is not powered to detect differences in stroke rates…
- It will still remain uncertain if rivaroxaban 2.5 mg b.i.d. would adequately reduce strokes in AF, even when combined with antiplatelet agents…

- My question to the panel: Should we change practice on the basis of this trial and adopt a RVRX-based strategy for AF patients receiving stents ?