PIONEER AF-PCI: should we change practice?

Ph. Gabriel Steg
DHU-FIRE, Hôpital Bichat, Assistance Publique – Hôpitaux de Paris,
Université Paris – Diderot, INSERM U-1148, Paris, France,
French Alliance for Cardiovascular clinical Trials
& Imperial College, Royal Brompton Hospital, London, UK
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

• These are difficult studies: the trial was well done and the investigators must be congratulated
Main finding: RVRX-based regimens, combined with either $\text{P2Y}_{12}$ 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 $\text{P2Y}_{12}$, 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?
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

<table>
<thead>
<tr>
<th>HR (95% CI) for stroke</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Riva + P2Y_{12} vs. VKA + DAPT: 1.07 (0.39-2.96)</td>
<td>0.891</td>
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<tr>
<td>Riva + DAPT vs. VKA + DAPT: 1.36 (0.52-3.58)</td>
<td>0.530</td>
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Reassuring that stroke rates were low overall
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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

**PIioneer AF-PCI**
VRVX reduced dose + APT

Dewilde W et al. *Lancet* 2013

Gibson CM et al. *NEJM* 2016
The WOEST strategy (but not RVRX-based strategies) reduces MACE

**WOEST**
VKA + clopidogrel

**PIioneer AF-PCI**
RVRX reduced dose + APT

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3. The RVRX strategies were not compared to the “WOEST” strategy
4. The trial does not provide reliable information on the duration of antiplatelet therapy, because duration was not randomly assigned
5. The recurrent hospitalisation data are interesting and potentially important but come from a post-hoc analysis and therefore must be viewed as hypothesis-generating.
PIioneer Af PCI: an important trial but should we change practice?

• PIONEER AF-PCI is an important and robust contribution to the currently limited evidence base regarding AF and PCI and provides critical information on the safety of RVRX-based strategies.

• 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?