The WOEST Trial: First randomised trial comparing two regimens with and without aspirin in patients on oral anticoagulant therapy undergoing coronary stenting

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The WOEST Trial = What is the Optimal antiplatelet and anticoagulant therapy in patients with oral anticoagulation and coronary Stenting (clinicaltrials.gov NCT00769938)

Disclosures/Conflict of interest: none
Background

1/ Long term oral anticoagulant therapy (OAC) is obligatory (class I) in:
   - most patients with atrial fibrillation
   - patients with mechanical heart valves

2/ Over 30% of these patients have concomitant ischemic heart disease
   When these patients need to undergo percutaneous coronary stenting,
   there is also an indication for aspirin and clopidogrel

3/ Triple therapy (OAC, aspirin and clopidogrel) is recommended according
   to the guidelines but is also known to increase the risk of major bleeding
   Major bleeding increases mortality

4/ No prospective randomized data available
Aim of the study

To test the hypothesis that in patients on OAC undergoing PCI, clopidogrel alone is superior to the combination aspirin and clopidogrel with respect to bleeding but is not increasing thrombotic risk in a multicentre two-country study (The Netherlands and Belgium)
### Study Design

**1:1 Randomisation:**

**Dual therapy group:**
- OAC + 75mg Clopidogrel qd

1 month minimum after BMS
1 year after DES

**Triple therapy group**
- OAC + 75mg Clopidogrel qd + 80mg Aspirin qd

1 month minimum after BMS
1 year after DES

**Follow up:** 1 year

**Primary Endpoint:** The occurrence of all bleeding events (TIMI criteria)

**Secondary Endpoints:**
- Combination of stroke, death, myocardial infarction, stent thrombosis and target vessel revascularisation
- All individual components of primary and secondary endpoints
Primary Endpoint: Total number of bleeding events

- **Triple therapy group**: 44.9%
- **Double therapy group**: 19.5%

**p<0.001**

**HR=0.36  95%CI[0.26-0.50]**

Days

Cumulative incidence of bleeding

- **n at risk:**
  - 0 days: 284
  - 30 days: 253
  - 60 days: 244
  - 90 days: 241
  - 120 days: 241
  - 180 days: 236
  - 270 days: 226
  - 365 days: 208
Locations of TIMI bleeding: Worst bleeding per patient

- GI=gastrointestinal; Other bleeding consists of eye, urogenital, respiratory tract, retroperitoneal, mouth, PM pocket bleeding

Intra-Cranial
Access site
GI
Skin
Other
Double therapy group
Triple therapy group

(N=)

3 3
16 20
8 25
7 30
20 48
Secondary Endpoint

MI=any myocardial infarction; TVR= target vessel revascularisation (PCI + CABG); ST= stent thrombosis

MI=any myocardial infarction; TVR= target vessel revascularisation (PCI + CABG); ST= stent thrombosis
Conclusions

1. **First randomized trial** to address the optimal antiplatelet therapy in patients on OAC undergoing coronary stenting

2. **Primary endpoint was met**: as expected, OAC plus clopidogrel causes less bleeding than triple antithrombotic therapy, but now shown in a randomized way

3. **Secondary endpoint was met**: with dual therapy there is no excess of thrombotic/thromboembolic events: stroke, stent thrombosis, target vessel revascularisation, myocardial infarction or death

4. **Less all-cause mortality** with dual therapy
Implications

We propose that a strategy of oral anticoagulants plus clopidogrel, but without aspirin could be applied in this group of high-risk patients on OAC when undergoing PCI