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= **W**hat is the **O**ptimal antiplat**E**let and anticoagulant therapy in patients with oral anticoagulation and coronary **S**ten**T**ing (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:	Triple therapy group
OAC + 75mg Clopidogrel qd	OAC + 75mg Clopidogrel qd + 80mg Aspirin qd
1 month minimum after BMS 1 year after DES	1 month minimum after BMS 1 year after DES

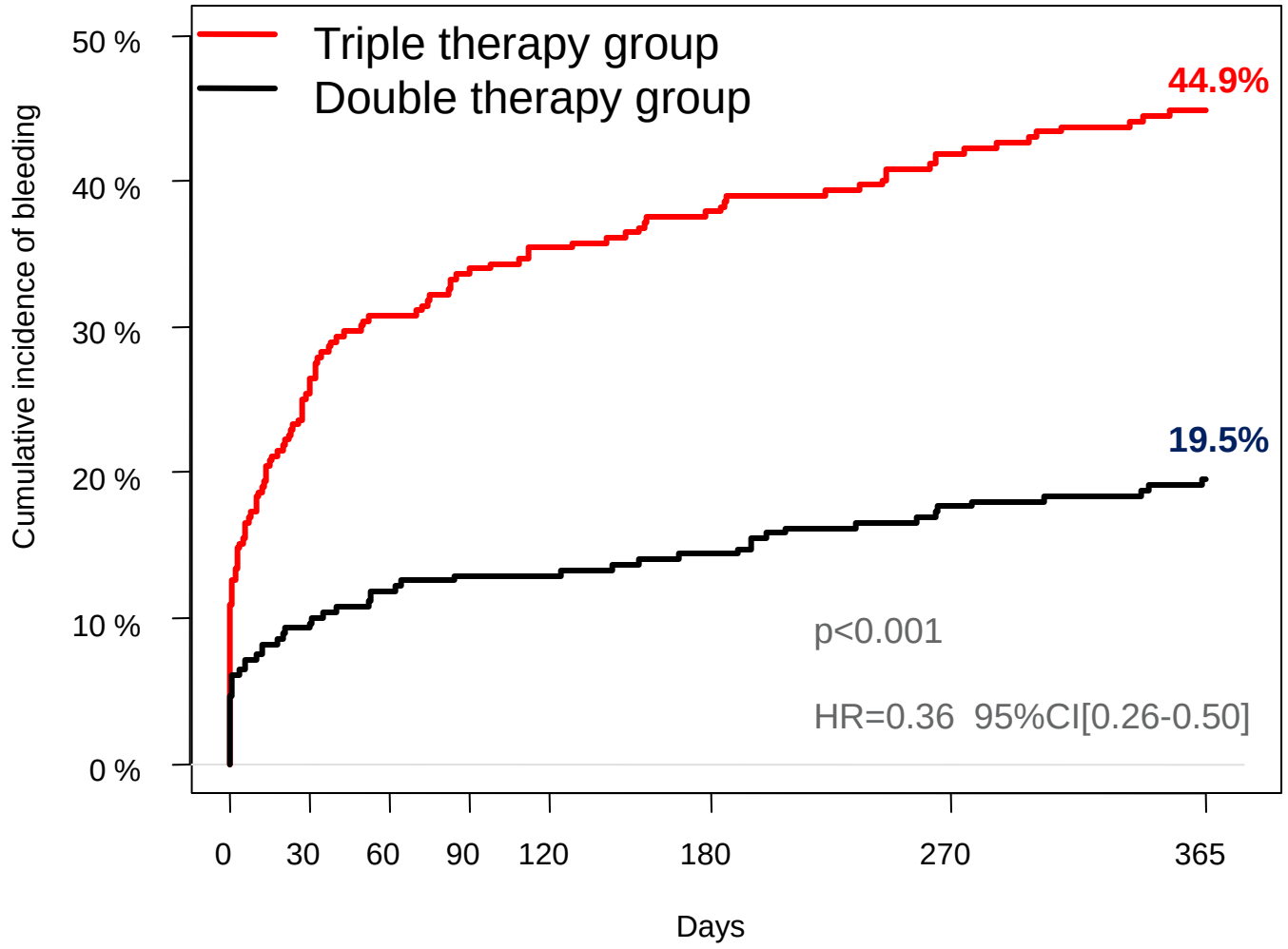
Follow up: 1 year

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

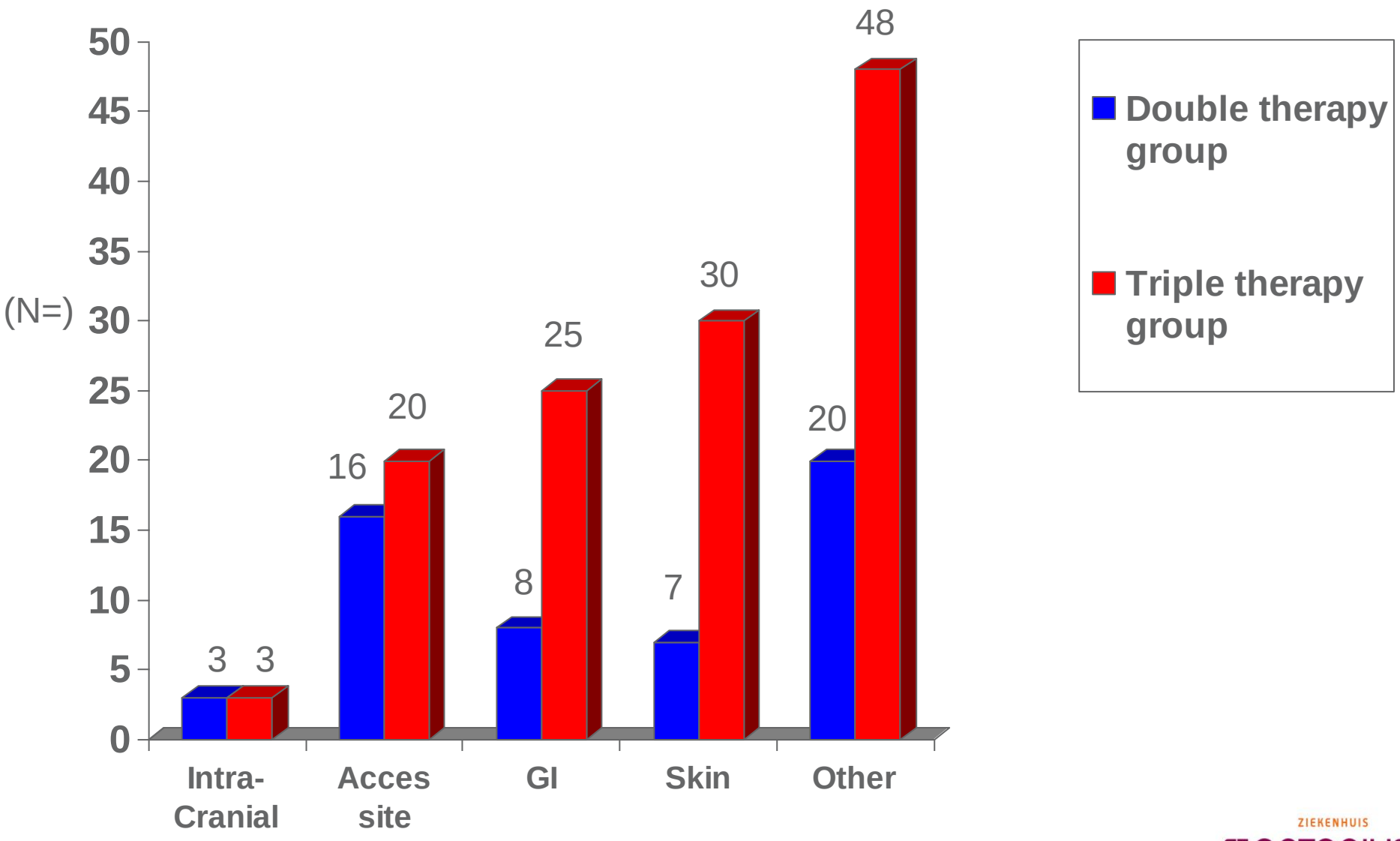
Secondary Endpoints:

- 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

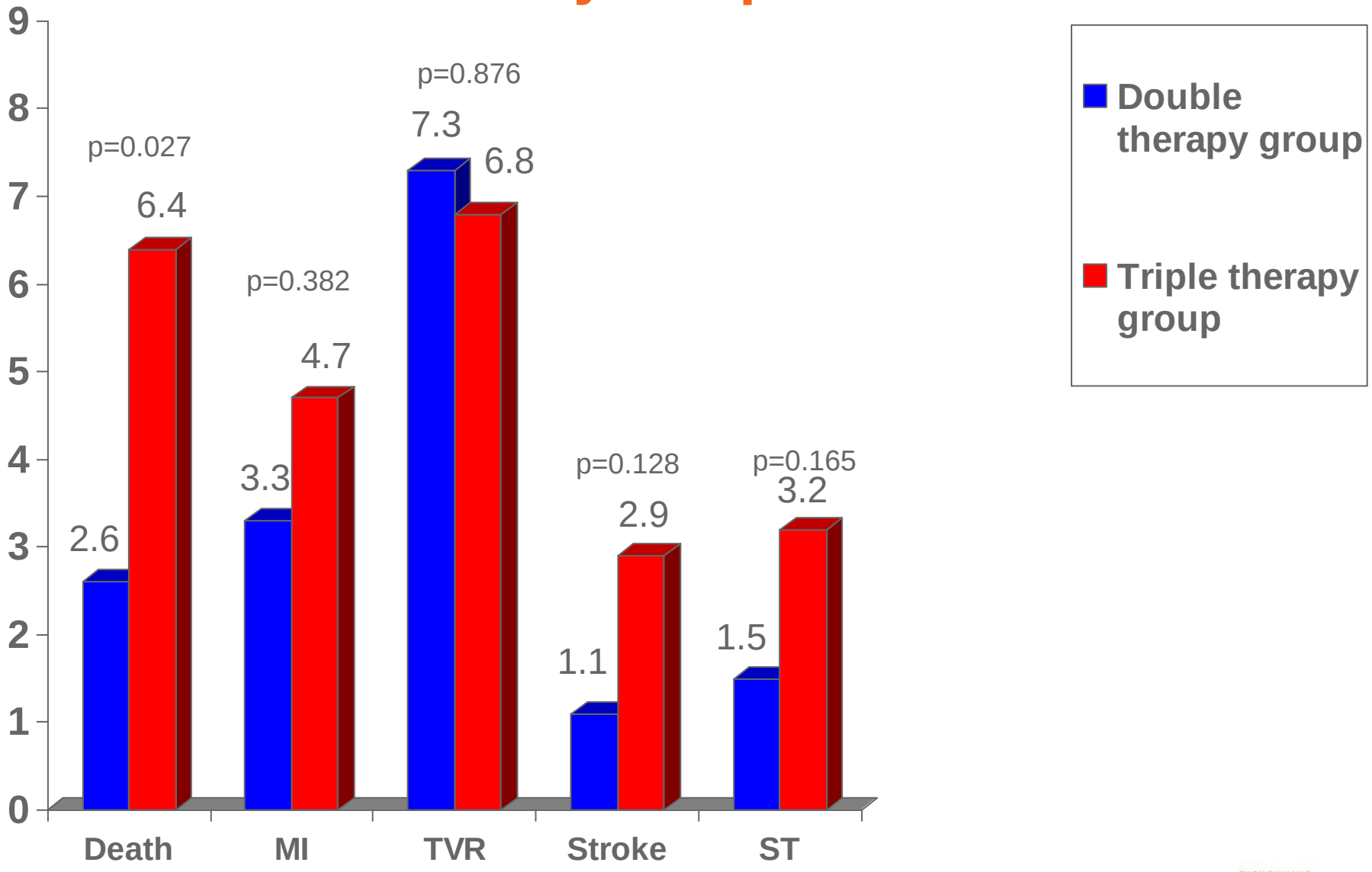


Locations of TIMI bleeding: Worst bleeding per patient



GI=gastro intestinal; Other bleeding consists of eye, urogenital, respiratory tract, retroperitoneal, mouth, PMpocket bleeding

Secondary Endpoint



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

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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