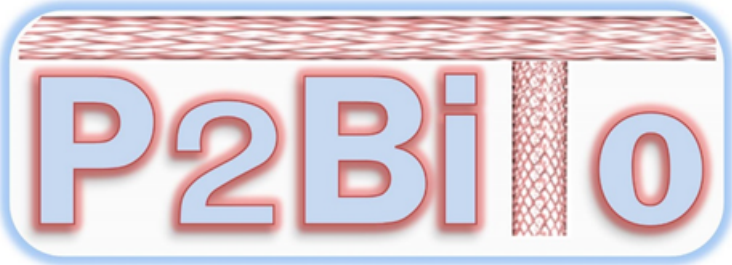
P2Y12 inhibitor utilization in **Bi**furcation and Chronic **T**otal **O**cclusion percutaneous coronary intervention with multiple drug-eluting stent (P2BiTO) registry

ClinicalTrials.gov Identifier: NCT01967615



Project Proposal by

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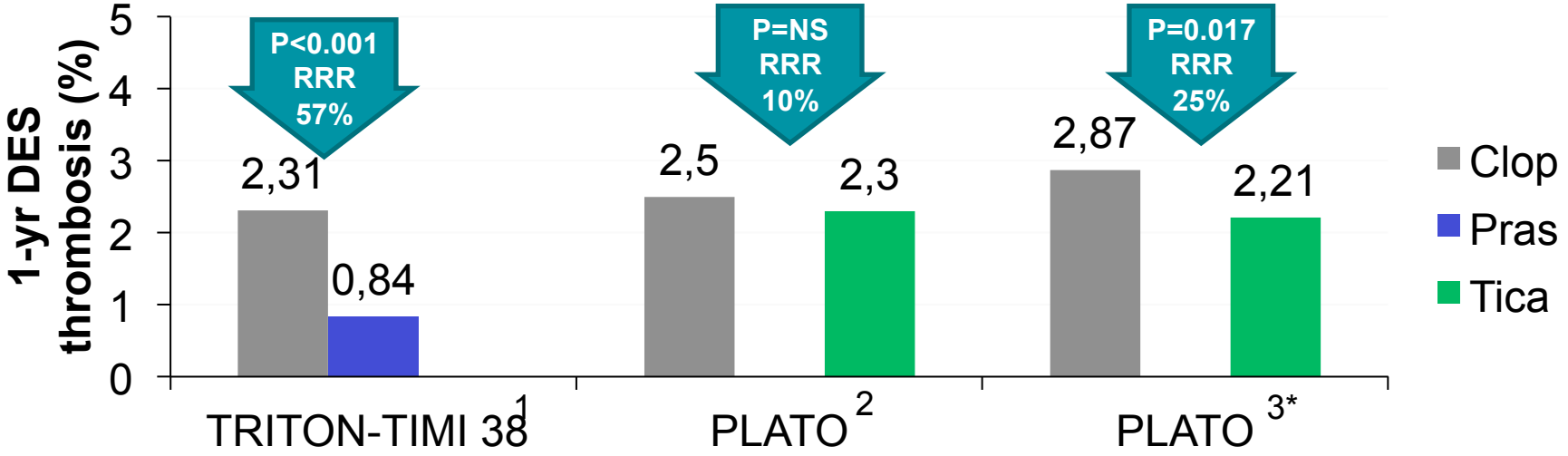
Background - 1

P2BiTO registry

Prasugrel and ticagrelor were both associated with a significant reduction in the risk of MACE in patients undergoing PCI for an ACS, mostly through a reduced stent thrombosis.

The 1-year relative risk reduction (RRR) of definite of probable stent thrombosis in patients receiving a DES were fairly different in TRITON-TIMI 38 and PLATO trials



* taking into account stents either previously implanted or inserted during the course of the trial

1. Wiviott SD et al. N Engl J Med. 2007;357:2001-2015
2. Cannon CP et al. Lancet. 2010;375:283-293
3. Steg PG et al. Circulation 2013;128:1055-65

Background - 2

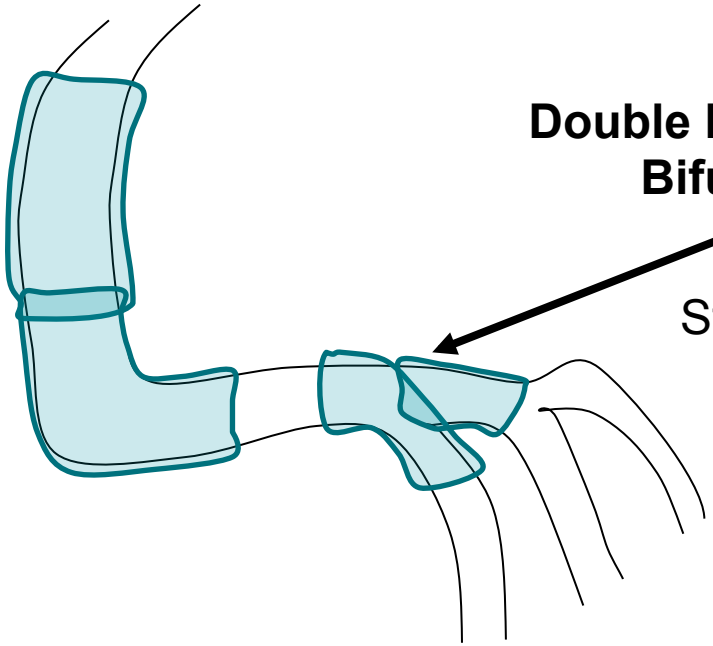
P2BiTO registry

The incidence of DES thrombosis is largely variable according to different lesion settings.

We aimed to focus at a direct comparison between newer P2Y12 inhibitors in a “worst-case” scenario

Overlapping DES after CTO recanalization

Stent thrombosis 7.5% (3.0 – 57%)



Double DES for “true” Bifurcations

Stent thrombosis 2% (1 – 11%)

4. Valenti R et al. J Am Coll Cardiol. 2013;61:545-550
5. Zimarino M et al. JACC Cardiovasc Interv. 2013;6:687-695

Aims of the Registry

P2BiTO registry

- To obtain an up-to-date descriptive analysis (registry) of the real-world attitude in the management of patients in the worst-case scenario, regardless the clinical setting (ACS or stable CAD)

- To verify the translation of the postulated different reduction in thrombosis rate among various P2Y12 inhibitors (clopidogrel, prasugrel and ticagrelor) in a high-risk setting such as the presence of ≥2 overlapping DES in CTO and bifurcation lesions.

Statistical Analysis
Sample size calculation

P2BiTO registry

- Type I error at 5%; 80% power.
- Assuming a 1-year rate of death, myocardial infarction and stent thrombosis of 12% among patients with “overlapping DES”
- An overall sample size of 578 patients in each group would allow to detect a reduction of 40% in the occurrence of the combined primary end-point
- By estimating a 5% drop-off rate during the 1-year follow-up, 603 patients will have to be enrolled in each arm and therefore a total of 1810 patients will be screened in the study.

P2BiTO - Case Report Form

PT ID:	/	Site

Pt Initials _____ Date of birth ____/____/____ Date of PCI ___ /___ /____

Gender M- ☐ F- ☐ Weight_____ Height_____ Age:____

CLINICAL FEATURES

☐ Registry ☐ Prospective

Hypertension ☐ Diabetes ☐ Smoking (Hx or Present) ☐ Family Hx ☐

Dislipidemia ☐ ☐ CTnI/CTnT ____ (µg/l) ☐ Creatinine ____ (mg/dl or µmol/l)

Baseline Clinical Condition:

NSTE-ACS ☐ Stable Angina ☐ Silent Ischemia ☐

ASA ☐; P2Y12 inhibitor: Clopidogrel ☐ Prasugrel ☐ Ticagrelor ☐

Loading dose ☐ _____ mg ☐ _____ mg ☐ _____ mg

Time before Procedure _____ hh:min _____ hh:min _____ hh:min

Discharge: ASA ☐ Clopidogrel ☐ Prasugrel ☐ Ticagrelor ☐

Statin ☐ Drug _____ dose _____ mg/die

In-hospital Outcome:

☐ Death Urgent revasc ☐ CABG ☐ PCI ☐ Stroke ☐ TIA ☐ Hemopericardium

Peak: CK-MB ____ ☐ CTnI/CTnT ____ (µg/l) ☐ Creatinine ____ (mg/dl or µmol/l)

Repeat Coronary Angiography: **Date ___ / ____ / ____ :**

☐ Normal ☐ Progression ☐ Target ISR ☐ Target Occlusion (☐ side)

Long-term Outcome: **Date ___ / ____ / ____ (by phone call)**

Medication: ASA ☐ Clopidogrel ☐ Prasugrel ☐ Ticagrelor ☐ Statin ☐

☐ Death Revasc ☐ CABG ☐ PCI ☐ Stroke ☐ TIA ☐ Myocardial Infarction

Stent thrombosis ☐ Definite ☐ Probable ☐ Possible

Procedure & Quantitative Coronary Angiography (QCA)

Diseased vessels: LM ☐ 1 ☐ 2 ☐ 3 ☐ Treated vessels: LM ☐ 1 ☐ 2 ☐ 3 ☐

Target Vessel: _____ Reference Diameter : _____ mm Lesion Length : _____ mm

Chronic Total Occlusion

Age >3months or unknown ☐

Blunt stump ☐

Bridging ☐

Bifurcating branch ☐

Technique:

Antegrade ☐

STAR or CART ☐

Retrograde ☐

DES overlapped 1☐ 2☐ 3☐

DES type _____

_____

_____

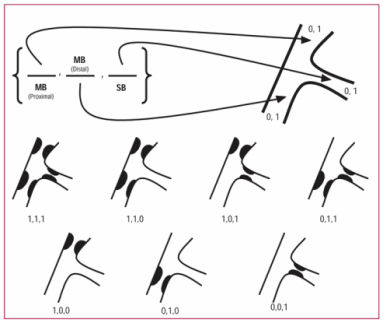
IVUS or OCT ☐

	Baseline	Final
Reference Diam	__.__mm	__.__mm
Lesion Diam	__.__mm	__.__mm
Lesion Diam (side)	__.__mm	__.__mm
TIMI Flow Grade	___ (_side)	__(_side)

Max Balloon Diameter : ___.___ mm

Total Stent Length : _____ mm

Bifurcation



Medina _____ / _____ / _____

Technique:

T (classic or modified) stenting ☐

Crush or minicrash ☐

Touching stents ☐

Kissing or "V" stents ☐

DES type _____

_____

_____

Final Kissing Balloons ☐

IVUS or OCT ☐

Periprocedural GPI: Reopro ☐ Tirofiban ☐ Integrilin ☐ None ☐

Gantt diagram

P2BiTO registry

Activity	Months							
	1-2	3-5	6	18	24	30	31-32	33-36
Central ethical commette approval								
Web site and CRF construction								
Database preparation								
Centers' activation								
Patients' enrolment								
Patients' follow-up								
Data collection								
Statistical analysis								
Manuscript writing and submission								