THE START-ANTIPLATELET REGISTER

A MULTICENTER OBSERVATIONAL PROSPECTIVE STUDY TO ASSESS THE RISK-BENEFITS OF ANTIPLATELET THERAPY IN ACS PATIENTS

Gruppi attualmente attivi nel registro:

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START REGISTRY

EXPORT PAZIENTI START ANTIPLATELET 23.01.2018

N° TOTALE PAZIENTI	**1442**
MASCHI	1040 (72%)
FEMMINE	402 (27.8%)
ETA' MEDIA	67
FOLLOW UP - <6 mesi - 6 mesi - 1 anno	**971** (67.3%) 15 177 779

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Papers

START REGISTRY

- **Patti G**, Cavallari I, Antonucci E, Calabrò P, Cirillo P, Gresele P, Palareti G, Pengo V, Pignatelli P, Ricottini E, Marcucci R. Prevalence and predictors of dual antiplatelet therapy prolongation beyond one year in patients with acute coronary syndrome. PLoS One. 2017 Oct 23;12(10):e0186961.
- **Calabrò P**, Gagnano F, Di Maio M, Patti G, Antonucci E, Cirillo P, Gresele P, Palareti G, Pengo V, Pignatelli P, Pennacchi M, De Servi S, De Luca L, Marcucci R.
  Changes in the epidemiology and therpaeutic management of patients with ACS in real world practice: evidence from two consecutive multicenter Italian registries, *Sumitted*
- **Cirillo P**, Di Serafino L, Patti G, Antonucci E, Calabrò P, Gresele P, Palareti G, Pengo V, Pignatelli P, Marcucci R.
  Gender-related differences on the choice of antiplatelet therapy and its impact on one-year clinical outcome in patients presenting with Acute Coronary Syndrome: Insights from the START *Antiplatelet* Registry.
  Submitted

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Papers

- **Marcucci R:** real-world Eventi trombotici ed emorragici al follow-up di 12 mesi
- **Gresele P** : Sottonalisi pazienti con PAD
- **Gresele P**: shifting tra diversi antiaggreganti
- **Pengo V**: rischio trombotico/emorragico negli anziani
- **Patti G** : correlazione tra diverse formule di stime della clearance creatinina ed eventi avversi trombotici ed emorragici

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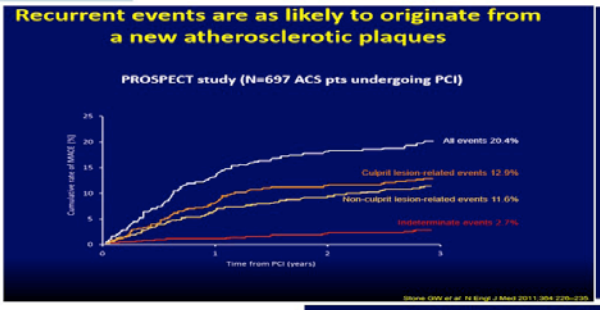
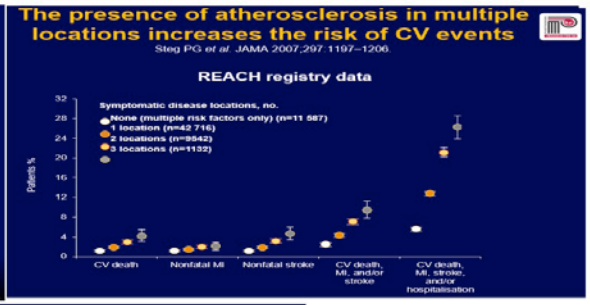
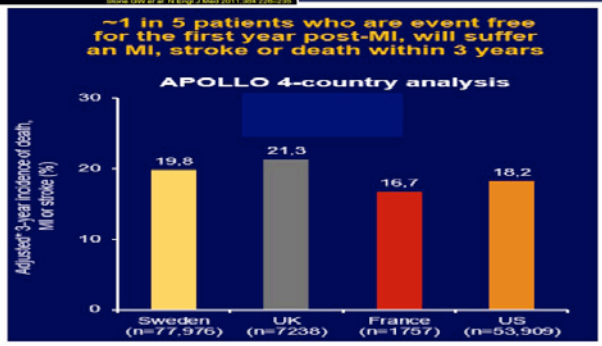
Algorithm For the Use of Antithrombotic Therapy in ACS

	ACS	Discharge	2 Weeks to 12 Months	12 Months and Beyond
ASA	ASA 75 – 100 mg daily in all patients — Class of Recommendation I			
$P2Y_{12}$ Inhibitor	Ticagrelor or Prasugrel* preferred over Clopidogrel but caution if prior stroke/TIA, low body weight, advanced age — Class of Recommendation I			Consider continuing (Ticagrelor 60 or Clopidogrel) if tolerating & high-risk — Class of Recommendation IIb
PAR-1 Antagonist			Consider adding to ASA+Clopidogrel if high-risk features, no prior stroke/TIA	
Rivaroxaban 2.5 mg		Consider adding to ASA+Clopidogrel if no prior stroke/TIA — Class of Recommendation IIb		

*Prasugrel only for patients treated with PCI





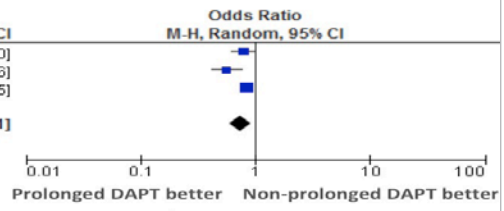


Extended Duration Dual Antiplatelet Therapy in Pts with MI: a study-level meta-analysis of CRTs

MACE

Study	Prolonged DAPT Events	Total	Non-prolonged DAPT Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
CHARISMA	126	1903	161	1943	30.8%	0.78 [0.62, 1.00]
DAPT	69	1805	117	1771	24.8%	0.56 [0.41, 0.76]
PEGASUS-TIMI 54 Tica 60 mg	487	7045	578	7067	44.4%	0.83 [0.74, 0.95]
Total (95% CI)		**10753**		**10781**	**100.0%**	**0.74 [0.60, 0.91]**
Total events	682		856			

Heterogeneity: Tau² = 0.02; Chi² = 5.50, df = 2 (P = 0.06); I² = 64%
Test for overall effect: Z = 2.81 (P = 0.005)

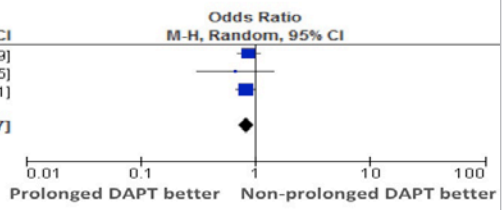


Approximately 50% of MI benefit unrelated to index vessel revasc./ST

Cardiovascular death

Study	Prolonged DAPT Events	Total	Non-prolonged DAPT Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
CHARISMA	142	4735	163	4743	42.6%	0.87 [0.69, 1.09]
DAPT	11	1805	16	1771	3.8%	0.67 [0.31, 1.45]
PEGASUS-TIMI 54 Tica 60 mg	174	7045	210	7067	53.7%	0.83 [0.67, 1.01]
Total (95% CI)		**13585**		**13581**	**100.0%**	**0.84 [0.72, 0.97]**
Total events	327		389			

Heterogeneity: Tau² = 0.00; Chi² = 0.42, df = 2 (P = 0.81); I² = 0%
Test for overall effect: Z = 2.32 (P = 0.02)



Patti G. Am Heart J 2016

Extended Duration Dual Antiplatelet Therapy in Pts with MI: a study-level meta-analysis of CRTs

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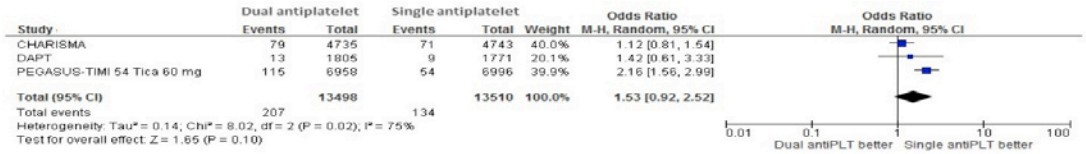
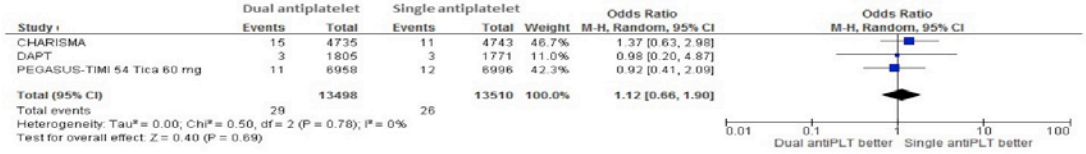
Major bleeding



Fatal bleeding



Patti G. Am Heart J 2016

PEGASUS-TIMI 54 EU label population:

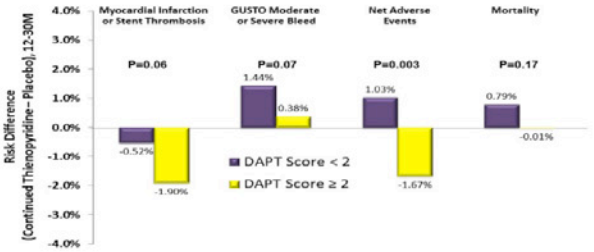
Ischemic outcomes – Patients with ≤2 years from qualifying MI or ≤1 year from prior ADP receptor inhibitor treatment

Outcome	Ticagrelor 60 mg bid N=5388		Placebo N=5391		Hazard ratio (95% CI)	*P* value
	n	3 year KM%	n	3 year KM%		
Composite of CV death, MI or stroke	373	7.9	463	9.6	0.80 (0.70–0.91)	0.001
CV death	119	2.6	167	3.6	0.71 (0.56–0.90)	0.0041
MI	230	4.8	274	5.6	0.83 (0.70–0.99)	0.041
Stroke	71	1.5	95	2.0	0.74 (0.55–1.01)	0.058
All-cause mortality	206	4.4	256	5.4	0.80 (0.67–0.96)	0.018

Dellborg M et al. *Eur Heart J* 2017;38(suppl):794–795

DAPT score

Variable	Points
Patient Characteristic	
Age	
≥ 75	-2
65 - <75	-1
< 65	0
Diabetes Mellitus	1
Current Cigarette Smoker	1
Prior PCI or Prior MI	1
CHF or LVEF < 30%	2
Index Procedure Characteristic	
MI at Presentation	1
Vein Graft PCI	2
Stent Diameter < 3mm	1



P values are for comparison of risk differences across DAPT Score category (interaction).

this analysis suggests that patients with DAPT score ≥ 2 gets more CV benefits with DAPT with relatively lower risk of bleedings, so they are candidates for extended DAPT.

Low DAPT Score (< 2)
NNT to prevent ischemia = 153
NNH to cause bleeding = 64

High DAPT Score ≥ 2
NNT to prevent ischemia = 34
NNH to cause bleeding = 272

PLOS ONE

RESEARCH ARTICLE

Prevalence and predictors of dual antiplatelet therapy prolongation beyond one year in patients with acute coronary syndrome

Giuseppe Patti[1]*, Ilaria Cavallari[1], Emilia Antonucci[2], Paolo Calabrò[3], Plinio Cirillo[4], Paolo Gresele[5], Gualtiero Palareti[2], Vittorio Pengo[6], Pasquale Pignatelli[7], Elisabetta Ricottini[1], Rossella Marcucci[8]

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PLOS ONE | https://doi.org/10.1371/journal.pone.0186961 October 23, 2017

START-ANTIPLATELET Registry

- Prospective, observational, spontaneous registry performed in 7 Italian institutions (Pol. CBM di Roma; Ospedale Monaldi di Napoli; Federico II di Napoli; AOU Careggi di Firenze; AOU di Padova; AOU di Perugia; Clinica Medica Università Sapienza di Roma)
- First patient enrolled in January 2014

INCLUSION & EXCLUSION CRITERIA

Inclusion criteria (consecutive enrollment):
- Age ≥18 years
- Admission for ACS (either STEMI or NSTE-ACS) in two pre-defined working days per week at each site (i.e.,Tuesday and Friday)
- Written informed consent for study participation

No explicit exclusion criteria

STUDY DESIGN

ACS

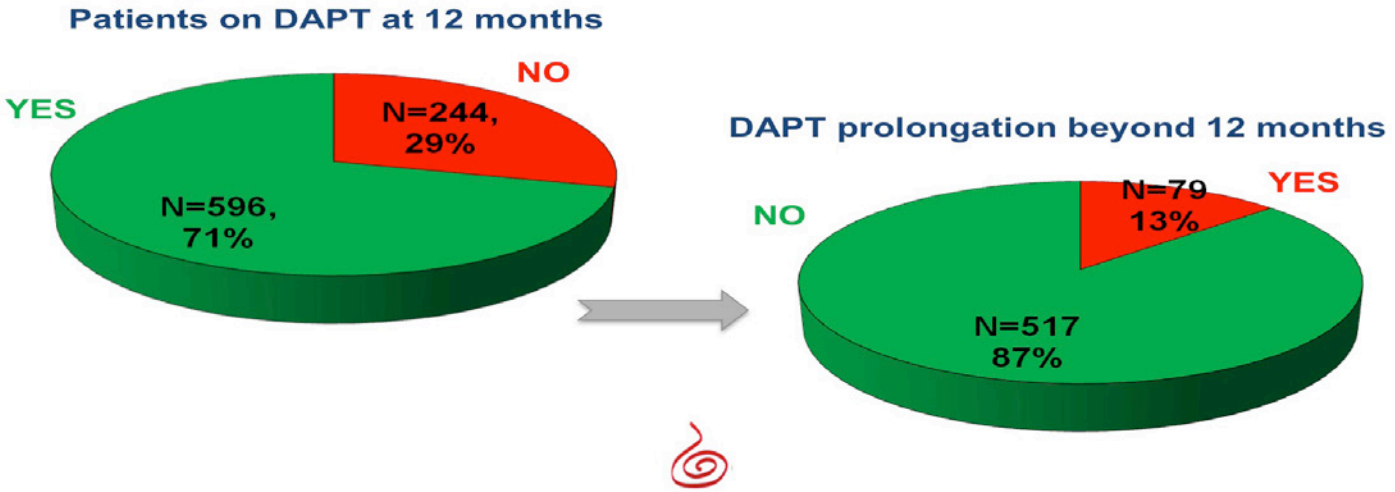
Baseline Visit *In-hospital*
- Demographic data
- Risk factors
- Medical treatment

6-month FUP
- Medical treatment
- Drug-related side effects
- Adverse events

12-month FUP

Prevalence of DAPT Prolongation Beyond 1 Year

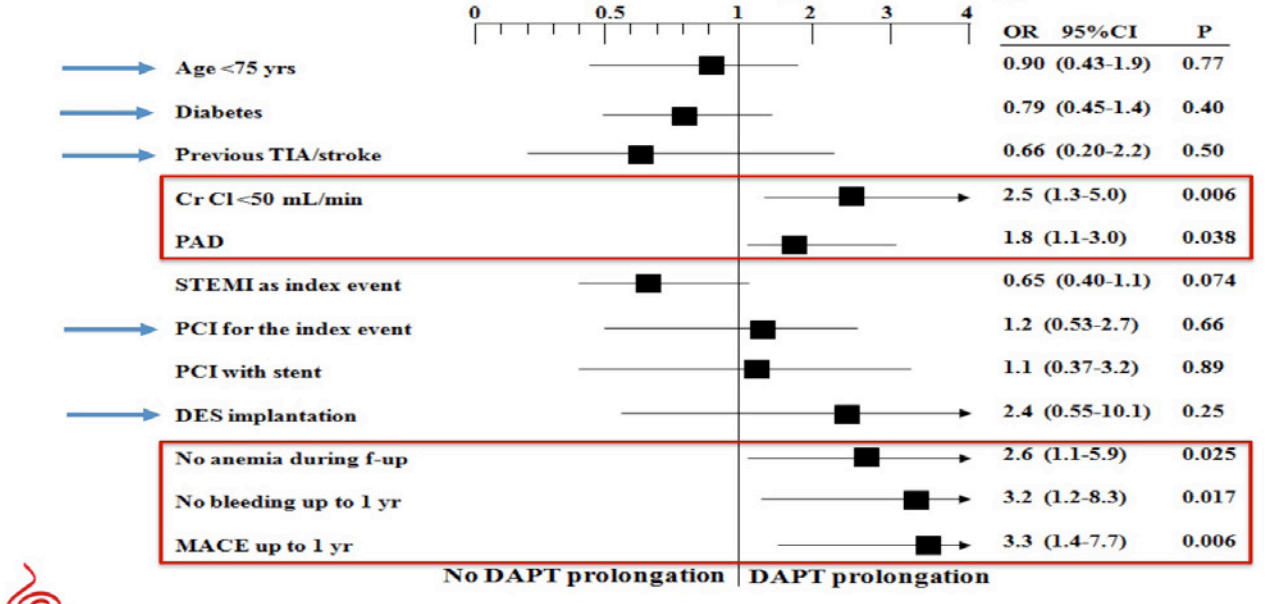
840 ACS patients with 1-year complete FUP by January 31, 2017



Population Features

	No DAPT prolongation (N=517)	DAPT Prolongation (N=79)	P value
Therapy for index event			
Medical therapy	22 (4)	4 (5)	0.98
CABG	6 (1)	0	0.72
PCI	489 (95)	75 (95)	0.89
PCI with stent	463 (90)	72 (91)	0.82
PCI with DES	406 (79)	66 (84)	0.38
Antithrombotic therapy up to 1-year			
Aspirin	517 (100)	79 (100)	-
Clopidogrel	**145 (28)**	**39 (49)**	**<0.001**
Ticagrelor	**265 (51)**	**28 (35)**	**<0.001**
Prasugrel	107 (21)	12 (16)	0.32
Triple therapy	-	-	
Any bleeding up to 1-year	87 (17)	5 (6)	0.025
MACE up to 1-year	23 (4)	9 (11)	0.022

Odds Ratio for DAPT Prolongation Beyond 1 Year



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Summary & Conclusions

- This study provides a real-world snapshot about the diffusion of prolonged DAPT beyond one year after ACS in Italy (~13% of patients)
- Independent predictors of DAPT prolongation beyond one year were moderate-to-severe renal failure, PAD, no anemia or bleeding events during follow-up and recurrent ischemic events
- No significant relationship between age, presence of diabetes, type of strategy and DES implantation was observed