

#### Disclosures

Consultant agreements Terumo SilkRoad Medical W.L. Gore & Associates Research and education support W.L. Gore & Associates

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# Pharmacology and TCAR

- Role of anti-platelet therapy
- Chronic anticoagulation population
- Acute anticoagulation and reversal
- Alternate agents



## **TF-CAS RCT**

First author	Outcome	Aspirin + heparin	Aspirin + clopidogrel	p valu
McKevitt [25]	30-day incidence of adverse neurological events	25%	0%	0.02
	Bleeding complication	17%	9%	0.03
Dalainas [26]	30-day incidence of adverse neurological events	16%	2%	< 0.05
	Bleeding complication	4%	2%	NS
	Subacute stent thrombosis	2%	0%	NS

All Patients	ITT (n=692)	PP (n=632)
Death	3 (0.4%)	1 (0.2%)
Stroke	13 (1.9%)	4 (0.6%)
Stroke/death	16 (2.3%)	5 (0.8%)
Myocardial infarction	6 (0.9%)	6 (0.9%)
Stroke/death/myocardial infarction	22 (3.2%)	11 (1.7%)
Cranial nerve injury	10 (1.4%)	8 (1.3%)
Technical success	690 (99.7%	
Procedural success*	668 (96.5%	
Symptomatic patients	ITT (n=180)	complia
Death	1 (0.6%)	/
Stroke	8 (4.4%)	1 (0.6%)
Stroke/death	9 (5.0%)	1 (0.6%)
Myocardial infarction	1 (0.6%)	1 (0.6%)
Stroke/death/myocardial infarction	10 (5.6%)	2 (1.2%)
Asymptomatic patients	ITT (n=512)	PP (n=467)
Death	2 (0.4%)	1 (0.2%)
Stroke	5 (1.0%)	3 (0.6%)
Stroke/death	7 (1.4%)	4 (0.9%)
Myocardial infarction	5 (1.0%)	5 (1.1%)
Stroke/death/myocardial infarction	12 (2.3%)	9 (1.9%)
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CLINICAL TRIAL Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease

- n = 632 high-risk
- 70% operators TCAR-naïve
- Medical therapy protocol deviation
  most common
- Neurologist or NIHSS-trained RN
  evaluation
- Demonstrates low penalty learning curve

#### Preoperative

- Standard best medical therapy
  - High-dose statin (atorvastatin 80 mg qd equivalent)
  - Dual antiplatelet therapy
- TEG platelet mapping or Plavix VerifyNow / Aspirin inhibition testing
- Verify compliance day of surgery
- Defer non-compliant asymptomatic cases

### Plavix Non-Responder

- Clopidogrel P2Y12 prodrug\_\_\_\_\_
- 30-64% of patients with sub-therapeutic result
- VerifyNow versus plateletmapping TEG



Quality Initiative				
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Outcome	All	Clopidogrel	Ticagrelor	P value
Cranial nerve injury	15/10,211 (0.1)	14/9832 (0.1)	1/379 (0.3)	.545
Major bleeding event	297 (2.4)	291 (2.4)	6 (1.4)	.175
Stroke/death	176 (1.4)	172 (1.4)	4 (0.9)	.393
Stroke	155 (1.3)	153 (1.3)	2 (0.5)	.14
Ipsilateral stroke	131 (1.1)	129 (1.1)	2 (0.5)	.227
Death	38 (0.3)	36 (0.3)	2 (0.5)	.536
TIA	67 (0.5)	61 (0.5)	6 (1.4)	.013
Ipsilateral TIA	58 (0.5)	52 (0.4)	6 (1.4)	.004
Stroke/TIA	216 (1.7)	208 (1.7)	8 (1.9)	.828
Stroke/MI/death	234 (1.9)	227 (1.9)	7 (1.6)	.706
MI	70 (0.6)	66 (0.6)	4 (0.9)	.294
Acute CHF	47 (0.4)	46 (0.4)	1 (0.2)	.622
Dysrhythmia	184 (1.5)	177 (1.5)	7 (1.6)	.792
Reperfusion syndrome	23 (0.2)	23 (0.2)	O (0)	.365
Access site complication requiring intervention	328 (2.6)	321 (2.7)	7 (1.6)	.189
Postoperative LOS >1 day	3699 (30)	3553 (30)	146 (34)	.042
Postoperative LOS >2 days	1831 (15)	1760 (15)	71 (17)	.261





## Chronic AC and DAPT

- Known strong benefit to DAPT in TF-CAS and TCAR patients (like PCI)
- Increased hemorrhagic risk to long-term DAPT / AC
- Limit duration of triple therapy to 30 days
- Aspirin dose less than 100 mg qd
- Patient and risk-specific
- Antiplatelet therapy loading kinetics

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# BRIDGE Trial

- RCT perioperative bridge with LMWH versus placebo
- VKA therapy
- Non-valvular atrial fibrillation
- Undergoing elective operations or invasive procedure

Dutcome	No Bridging (N=918)	Bridging (N=395)	P Value
	number of pati		
Primary			
Arterial thromboembolism	4 (0.4)	3 (0.3)	0.01*, 0.73†
Stroke	2 (0.2)	3 (0.3)	
Transient ischemic attack	2 (0.2)	0	
Systemic embolism	0	0	
Major bleeding	12 (1.3)	29 (3.2)	0.005†
Secondary			
Death	5 (0.5)	4 (0.4)	0.88†
Myocardial infarction	7 (0.8)	14 (1.6)	0.10†
Deep-vein thrombosis	0	1 (0.1)	0.25†
Pulmonary embolism	0	1 (0.1)	0.25†
Minor bleeding	110 (12.0)	187 (20.9)	<0.001†



	No protamine (n – 944), No. (%)	Protamine (n – 944), No. (%)	Relative risk (95% CI)	P valu
Primary outcomes				
Access site bleeding complication	78 (8.3)	26 (2.8)	0.33 (0.21-0.52)	<.001
Interventional treatment	34 (3.6)	9 (1.0)	0.26 (0.13-0.54)	<.001
Blood transfusion	37 (3.9)	11 (1.2)	0.30 (0.15-0.58)	<.001
Stroke or death	21 (2.2)	15 (1.6)	0.71 (0.37-1.39)	.32
Secondary outcomes				
Stroke	19 (2.0)	10 (1.1)	0.53 (0.24-1.13)	.09
Death	7 (0.7)	5 (0.5)	0.71 (0.23-2.25)	.56
Transient ischemic attack	10 (1.1)	4 (0.4)	0.40 (0.13-1.28)	.11
Myocardial infarction	8 (0.8)	4 (0.4)	0.50 (0.15-1.66)	.25
Congestive heart failure	3 (0.3)	4 (0.4)	1.33 (0.30-5.96)	.71
Hemodynamic instability				
Hypotensive	121 (14.9)	129 (16.1)	1.06 (0.83-1.35)	.50
Hypertensive	138 (16.7)	148 (18.1)	1.13 (0.90-1.43)	.45
Cl. Confidence interval.				

### Summary

- Targeted DAPT with inhibition assay testing or consider switch to ticagrelor
- Limit triple therapy to 30 days
- Seldom bridge patients, wound check prior to restart AC (same as CEA)
- Protamine = better outcomes
- Integrate medical management into perioperative protocols, testing and service

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