

TCT-73**Impact of Routine MicroNet-Covered Embolic Prevention Stent System Use on Contemporary Carotid Revascularization: All-Comer PARADIGM Study**

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BACKGROUND Recent DWI-controlled CARENET study indicated periprocedural cerebral embolization paramount reduction (>50% incidence, >10-fold volume) using a novel MicroNet-covered embolic prevention stent system as compared to conventional CAS, plus no cerebral embolization throughout the healing period.

METHODS PARADIGM [Prospective evaluation of All-comer perCutaneous cArotiD revascularization In symptomatic and increased-risk asymptomatic carotid artery stenosis using CGuard™ Micronet-covered embolic prevention stent system] evaluated feasibility and outcome of routine anti-embolic stent use in unselected pts referred for carotid revascularization. Consecutive referrals were tracked (all-comer six-month sample, industry-independent academic study). Decisions on revascularization (yes/no) and its method were made (CGuard fully available) by a multidisciplinary NeuroVascular Team (neurologist, interventional angiologist, vascular surgeon, cardiologist); asymptomatic pts required ≥1 evidenced lesion-level increased-risk criterion. Outcome analyses were performed by independent CoreLab.

RESULTS Of 97 referrals in 6 months, 24 were deferred (in most - lesion increased risk criteria unmet). Carotid revascularization was thus performed in 73 pts (CAS-only in 67, bilateral in 3, CAS+CEA in 1, CEA in 5), yielding 71 CAS in 68 pts (69±7y, 66% male, 53% symptomatic, 9% emergent CAS in evolving stroke). CGuard was used in 100% of CAS (ie, zero cross-over to other stent/s), proximal/distal EPD use was 35/65%. CAS lesions were thrombus-containing (15%), near-occlusive/string (21%), highly-calcific (23%) (CoreLab). ICA RVD was 4.99±0.96mm, lesion length was 19.9±5.8mm. Diameter stenosis was reduced from 82±9 to only 7±4% (p<0.001); consistent with endovascular reconstruction of the carotid bifurcation with fully maintained ECA patency. Implanted stents were 29.66±0.30 and 39.73±0.34 for nominal 30mm (74.6%) and 40mm length, indicating lack of any foreshortening/elongation. PSV/EDV were 3.8±1.3/1.3±0.7 at B/L vs. 0.70±0.28/0.17±0.07 m/s in-stent (p<0.001). In this increased-risk sample, CGuard technical success was 100% and procedural success was 100%. Death/any stroke/MI rate was 0% at 48h and 0% at 30 days (CEC, independent neurologist and non-interventional cardiologist evaluation).

CONCLUSIONS 1. Over 90% of unselected contemporary carotid artery stenosis patients indicated to require revascularization (Neuro-Vascular Team), including >50% symptomatic presentations, can be treated endovascularly using the MicroNet-covered embolic prevention stent CGuard; this is effective in achieving full endovascular reconstruction of ICA across all-comer lesion subsets in absence of periprocedural and 30-day complications. 2. The PARADIGM study provides accumulating evidence for a novel carotid revascularization decision-making model using the MicroNet-covered embolic prevention stent system as a significant technological advancement translating into maximized patient safety in routine clinical practice.

CATEGORIES ENDOVASCULAR: Stroke and Stroke Prevention

KEYWORDS Carotid, Embolic protection device, Revascularization strategy

TCT-74**Proximal Balloon Occlusion versus Distal Filter Protection in Carotid Artery Stenting: A Meta-Analysis of Clinical Trial Data**

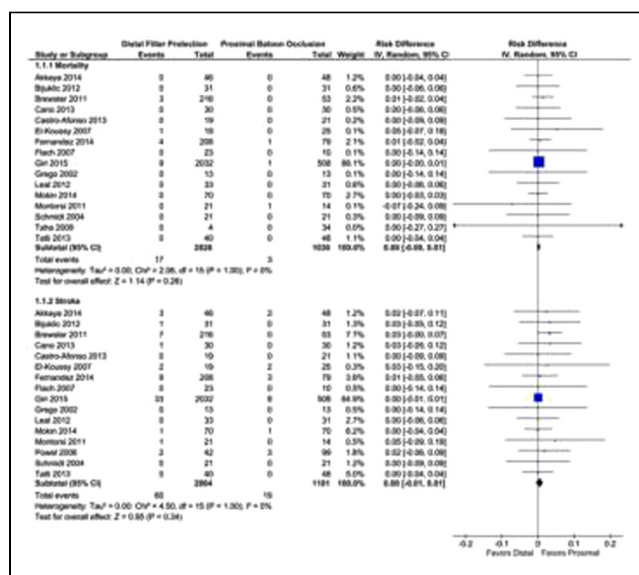
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BACKGROUND Carotid stenting (CAS) is typically performed using embolic protection devices (EPDs) as a means to reduce procedure-related stroke. In this study, we compared procedural complications, morbidity and mortality across two different strategies: distal (D-EPD) and proximal (P-EPD) protection.

METHODS MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials were queried from January 1998 through May 2015. Only studies comparing (D-EPD) and (P-EPD) were included. Two independent reviewers selected and appraised studies and extracted data in duplicate. Random-effects meta-analysis was used to pool outcomes across studies. Heterogeneity of treatment effect among studies was assessed using the I² statistics. Publication bias was assessed using inspection of funnel plots. The primary endpoints included mortality and stroke. Secondary endpoints included new cerebral lesions on diffusion-weighted magnetic resonance imaging (DW-MRI), contralateral lesions on DW-MRI, transient ischemic attacks (TIA) and internal carotid artery spasm.

RESULTS A total of 12281 patients were included from eighteen studies (13 prospective and 5 retrospective) comparing (D-EPD) and (P-EPD) in the setting of CAS. Mean age was 69 years and 64% of patients were male. No evidence of publication bias was detected. There was no significant difference between the two modalities in the risk of stroke (risk difference [RD] 0.0, 95% confidence interval [CI] -0.01 to 0.01) or mortality (RD 0.0, 95% CI -0.01 to 0.01) nor was there any difference in the incidence of new cerebral lesions on DW-MRI, contralateral DW-MRI lesions, TIA or ICA spasm.



Study/Year	Study Type	Study Primary Endpoint(s)	Distal Filter Protection							Proximal Balloon Occlusion						
			N	TIA	Stroke	New Cerebral Lesions	Contralateral Lesions on DW MRI	Mortality	ICA Spasm	N	TIA	Stroke	New Cerebral Lesions	Contralateral Lesions on DW MRI	Mortality	ICA Spasm
Akkaya 2014	Prospective (Randomized)	New cerebral lesions on DW-MRI	46	0	3	30	3	0	N/A	48	0	2	19	2	0	N/A
Bjuklic 2012	Prospective (Randomized)	New cerebral lesions on DW-MRI	31	0	1	27	9	0	N/A	31	0	0	14	2	0	N/A
Cano 2013	Prospective (Randomized)	New cerebral lesions on DW-MRI	30	0	1	19	11	0	N/A	30	0	0	20	8	0	N/A
Castro-Afonso 2013	Prospective (Randomized)	New cerebral lesions on DW-MRI	19	1	0	3	3	0	N/A	21	1	0	10	3	0	N/A
El-Koussy 2007	Prospective (Randomized)	New cerebral lesions on DW-MRI	19	0	2	6	1	1	N/A	25	0	2	7	5	0	N/A
Grego 2002	Prospective (Randomized)	Stroke/TIA/Mortality	13	0	0	N/A	N/A	0	3	13	0	0	N/A	N/A	0	3
Leal 2012	Prospective (Randomized)	New cerebral lesions on DW-MRI	33	0	0	13	2	0	N/A	31	0	0	4	0	0	N/A
Montorsi 2011	Prospective (Randomized)	New cerebral lesions on DW-MRI	21	0	1	9	N/A	0	N/A	14	0	0	2	N/A	1	N/A
Schmidt 2004	Prospective (Randomized)	Stroke/TIA	21	1	0	N/A	N/A	0	N/A	21	0	0	N/A	N/A	0	N/A
Taha 2009	Prospective (Randomized)	New cerebral lesions on DW-MRI	4	N/A	N/A	2	1	0	N/A	34	N/A	N/A	26	11	0	N/A
Tatli 2013	Prospective (Randomized)	Stroke/TIA/Mortality	40	1	0	N/A	N/A	0	9	48	0	0	N/A	N/A	0	1
Flach 2007	Prospective (Observational)	New cerebral lesions on DW-MRI	23	0	0	8	0	0	N/A	10	0	0	4	0	0	N/A
Brewster 2011	Retrospective (Observational)	Stroke/MI/Mortality	216	N/A	7	N/A	N/A	3	N/A	53	N/A	0	N/A	N/A	0	N/A
Fernandez 2014	Restrospective (Observational)	Stroke/MI/Mortality	208	0	9	N/A	N/A	4	N/A	79	0	3	N/A	N/A	1	N/A
Giri 2015	Restrospective (Observational)	Stroke/Mortality	2032	N/A	33	N/A	N/A	9	N/A	508	N/A	8	N/A	N/A	1	N/A
Mokin 2014	Retrospective (Observational)	Stroke/TIA/Mortality	70	1	1	N/A	N/A	0	N/A	70	1	1	N/A	N/A	0	N/A
Pleniazek 2008	Prospective (Randomized)	Stroke/Mortality	396	N/A	N/A	N/A	N/A	N/A	13	139	N/A	N/A	N/A	N/A	N/A	0
Powel 2006	Retrospective (Observational)	Stroke/TIA/Mortality	42	0	2	N/A	N/A	N/A	12	99	1	3	N/A	N/A	N/A	2

CONCLUSIONS In patients undergoing CAS, both D-EPD and P-EPD appear to provide similar levels of protection from peri-procedural stroke, TIA and mortality.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Carotid artery stenting, Protection devices, Stroke