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[™] Micronetcovered 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 (allcomer 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 increasedrisk 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%), nearocclusive/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 $7\pm4\%$ (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 procedurerelated 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 12 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.

	Distal Filler Pr		Proximal Baloon C			Risk Difference	90sh 20/Revenue
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BluAh: 2912		31	0	21	0.6%	8-90 (-8-96, 0.06)	
Breventer 2011	1	246	0	53	2.2%	0.01 [-0.02, 0.04]	
Carso 2013		30			0.5%	\$120 (-0.06, 0.06)	
Casto-Alanso 2013		19	ø	21	0.3%	8-00 (-0.09, 0.09)	
El Koulety 2007	1	19	0	25	0.1%	£063-627, 0.1#j	
Fernandez 2014	4	208		79	2.1%	8-01 (-0.82, 0.04)	
Flach 2007		25	0	10	0.1%	8.80 (-5.14, 0.14)	
Get 2015		2002		508	80.1%	8 90 (-0.00, 0.01)	
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Leal 2012		23	0	31	0.8%	6.001-0.06, 0.061	
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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	
Bijuklic 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	
Pieniazek 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