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Meta-analysis or systematic review

Title: Role of Cerebral Embolic Protection with Transcatheter Aortic Valve Replacement: An Updated Metaanalysis of Randomized Controlled Trials

Description: Stroke risk with TAVR remains a legitimate reason for increase morbidity and mortality, Despite improvement in device design and experience with TAVR rates of stroke are at the least comparable to SAVR. With the recent PROTECT TAVR trial carries largest number of embolic protection device use. We perform a MA of all RCT that compared use of embolic protection to no embolic protection when using TAVR to look at

pooled estimate of the role of such devices in TAVR era.

Role of Cerebral Embolic Protection with Transcatheter Aortic Valve Replacement: An Updated Meta-analysis of Randomized Controlled Trials

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Abstract poster

Creighton

School of Medicine

Role of Cerebral Embolic Protection with Transcatheter Aortic Valve Replacement: An Updated Meta-analysis of Randomized Controlled Trials

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Background

The role of cerebral embolic protection (CEP) in patients undergoing transcatheter aortic valve replacement (TAVR) to prevent embolization of thrombotic or calcified debris remains a topic of debate despite multiple randomized controlled trials (RCTs). Recently, the PROTECTED TAVR trial was published. The current metaanalysis aimed to aggregate RCTs that examined all available forms of CEP devices to date.

Results

Six studies with a total of 3621 patients (CEP n= 1874, no CEP n= 1747) met our inclusion criteria (mean age 79.5 years, 58.6% male, average STS score 3.76). CEP was not associated with a significant reduction of stroke at 30 days (Relative risk RR: 0.75; 95% CI: 0.52, 1.08; P= 0.12; Absolute Risk Difference ARD: -0.75%; 95% CI: -1.8%, 0.3%). No difference in 30-day all-cause mortality with CEP vs no CEP use, RR: 0.93; 95% CI: 0.41, 2.11; P= 0.86. The magnitude and direction of effect were consistent when limiting analysis to trials that utilized Sentinel® device.

Conclusion.

In this comprehensive meta-analysis of all RCTs to date, use of CEP devices in patients undergoing TAVR was not associated with a significant reduction in 30-day stroke or all-cause mortality.

Methods

PubMed, Cochrane Central, and EMBASE were searched for RCTs comparing CEP versus no CEP in patients undergoing TAVR. The primary outcome was 30-day stroke. The secondary outcome was 30-day all-cause mortality. Search and reporting were according to PRISMA guidelines. Random effects model with DL tau estimator were used for pooled effect. Heterogeneity was assessed using I² test. All analyses were performed by R studio.

			CEP	No	CEP			
Study	Device	Events	Total	Events	Total	Risk Ratio	RR	95%-CI
Outcome = 30 Day St	roke							
PROTECTED TAVR	SENTINEL	34	1501	43	1499		0.79	[0.51; 1.23]
SENTINEL	SENTINEL	13	231	10	110		0.62	[0.28; 1.37]
CLEAN-TAVI	SENTINEL	4	50	4	50	+	1.00	[0.26; 3.78]
MISTRAL-C	SENTINEL	0	32	2	33	•	0.21	[0.01; 4.13]
EMBOL-X	EMBOL-X	0	14	0	16			
DEFLECT-III	TriGuard	2	46	2	39		0.85	[0.13; 5.74]
Common effect mode		53	1874	61	1747	•	0.75	[0.52; 1.07]
Random effects mode	el					•	0.75	[0.52; 1.08]
Heterogeneity: $I^2 = 0\%$								
Test for Significance p	= 0.12							
Outcome = 30 Day Al	l cause Mort	ality						
PROTECTED TAVR	SENTINEL	8	1501	4	1499		2.00	[0.60; 6.62]
SENTINEL	SENTINEL	3	234	2	111	_	0.71	0.12; 4.20]
CLEAN-TAVI	SENTINEL	0	50	1	50		0.33	[0.01; 7.99]
MISTRAL-C	SENTINEL	1	32	3	33		0.34	[0.04; 3.13]
DEFLECT-III	TriGuard	1	46	2	39		0.42	[0.04; 4.50]
Common effect mode	1	13	1863	12	1732	\Rightarrow	0.93	[0.43; 1.99]
Random effects mode	el					\rightarrow	0.93	[0.41; 2.11]
Heterogeneity: $I^2 = 0\%$								
Test for Significance p	= 0.86							
						0.1 0.51 2 10		