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Results from a prospective real-world multicentre clinical practice of CAS using the CGuard embolic prevention system: the IRONGUARD 2 study

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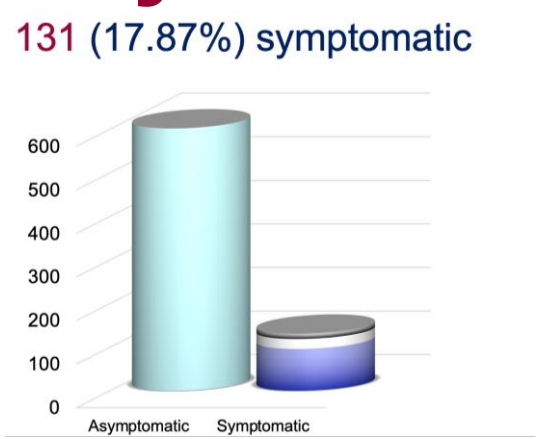
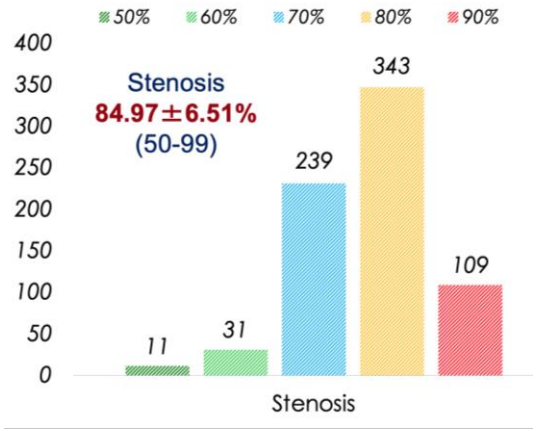
IronGuard2 Study

Aim: to evaluate periprocedural, 30-day, and 12-month outcomes in a prospective series of patients submitted to protected CAS with the **CGuard Embolic Prevention System** (EPS).





Methods: From January **2017** to June **2019** a physician-initiated prospective multispecialty, multicentre study was initiated enrolling 733 consecutive patients admitted for protected CAS and treated using the CGuard EPS in 20 Italian centres.

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Results

@ 24-hour

1 fatal haemorrhagic stroke

(urgent Patient treated for cTIA)

2 Minor Strokes, 6 TIAs

1 AMI

No Death

@ 30-day

1 Minor Stroke, 2 TIAs

1 AMI

No Death

@ 12-month

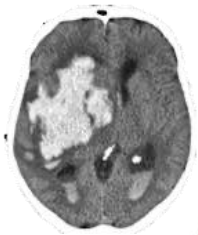
(476/733)

No new strokes

3 TIAs

3 AMIs (2 fatal)

8 Deaths



Cumulative @ 1-month

Stroke rate **0.54%**

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Results

		Incidence without the variable N (%)	Incidence with the variable N (%)	P (OR; 95% CI)
Hypertension		0 (0)	4 (0.64)	1.00 (NA)
Diabetes		2 (0.43)	2 (0.75)	0.56 (1.75; 0.24-12.53)
Dyslipidaemia		1 (0.55)	3 (0.54%)	0.98 (0.98; 0.10-9.51)
Smoking History		2 (0.65)	2 (0.46%)	0.72 (0.70; 0.09-5.04)
Coronary Artery Disease		3 (0.65)	1 (0.35%)	0.59 (1.83; 0.19-17.76)
Octogenarians		3 (0.51)	1 (0.70)	0.76 (1.40; 0.14-13.58)
High clinical risk		2 (0.59)	2 (0.50)	0.91 (1.11; 0.15-7.94)
Symptomatic Stenosis		1 (0.76)	3 (0.49)	0.70 (1.53; 0.15-14.88)
Plaque	Hyperechoic	3 (0.52)	1 (0.61)	0.47 (NA)
	Isoechoic	3 (0.47)	1 (0.93)	
	Hypo-anechoic	3 (0.54)	1 (0.55)	
	Disomogeneous	4 (0.71)	0 (0)	
	Ulcerated	3 (0.43)	1 (2.5)	
	Thin fibrous cap	4 (0.56)	0 (0)	
	Post-CEA restenosis	4 (0.57)	0 (0)	
	Unstable	3 (0.45)	1 (1.44)	0.28 (3.24; 0.33-31.58)
Aortic Arch	Type I	2 (0.54)	2 (0.54)	1.00 (NA)
	Type II	2 (0.43)	2 (0.74)	
	Type III	4 (0.57)	0 (0)	
	Bovine	4 (0.59)	0 (0)	
Tortuosity	None	3 (0.55)	1 (0.51)	1.00 (NA)
	Low	2 (0.45)	2 (0.69)	
	Moderate	3 (0.55)	1 (0.52)	
	Severe	4 (0.59)	0 (0%)	
	Significant	3 (0.62)	1 (0.4)	0.70 (0.64; 0.06-6.20)
Severe Calcification		2 (1.00)	2 (0.37)	0.30 (2.70; 0.37-19.30)
Severe Thrombosis		3 (0.51)	1 (0.68)	0.80 (1.33; 0.13-12.88)
Distal Protection		1 (0.71)	3 (0.50)	0.76 (0.70; 0.07-6.84)
Predilatation		4 (0.70)	0 (0)	1.00 (NA)
Postdilatation		0 (0)	4 (0.65)	1.00 (NA)

At univariate analysis, none of the clinical, anatomical, or procedural characteristic was found to be statistically related to new stroke occurrence during the entire study period, including preoperative symptoms

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Conclusions

- Results from the IRONGUARD-2 suggest that a widespread use of the CGuard-EPS mesh covered stents could guarantee an extremely low periprocedural adverse events rate

- Our data should be validated by a randomized trial, prospectively evaluating results with different stents' configuration

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Thanks to everyone!!!

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IRONGUARD 2

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