

**Orbital Atherectomy System (OAS) with Angioplasty  
for CLI Treatment. Budget Impact Analysis:  
From a Modelling Approach to a Hospital Reality in  
Italy**

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# Orbital Atherectomy System (OAS) with Angioplasty for CLI Treatment. Budget Impact Analysis: From a Modelling Approach to a Hospital Reality in Italy.

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- **AIM:** To determine whether the use of OAS in calcified infrapopliteal lesions for CLI patients can be a cost-saving / cost-effective technology for Italian regional health institutions compared vs BA alone.
- **METHOD:** Budget Impact and cost-effectiveness models were developed with clinical and healthcare utilization data from CALCIUM 360 trial (2) and current cost data at Maria Cecilia Hospital. Existing OAS modelling analysis determined cost-savings of OAS+BA vs current treatment for infrapopliteal calcified lesions only in the US (1), but never before in Europe. By considering the resource usage per CLI patient at Maria Cecilia Hospital, and the consumable unit costs, the model was prepared to demonstrate cost savings and cost effectiveness for the hospital and regional healthcare system.
- **RESULTS:** The analysis suggests that the strategy OAS+BA is associated with 12-month cost savings up to 498,800€ for every 100 procedures to the hospital. The economic value of OAS+BA is related to a reduced need for major amputation, mortality, TLR/TVR and the cost of end-of-life care despite higher upfront costs. OAS+BA shows superiority in incremental LYGs vs BA alone (0.32 LYGs per year). Results were consistent compared to the current US literature.(1) (2)

	ENDOVASCULAR STRATEGY CLI	
	OAS+BA	BA
COST OF PROCEDURE (€)		
INCREMENTAL TIME COSTS OF PROCEDURE (€)		
PERIOPERATIVE EVENTS COSTS (€)		
COSTS TLR/TLV 12 MONTHS (€)		
MORTALITY COSTS 12 MONTHS		
TOTAL		
INCREMENTAL COSTS @12m per patient		

1. Shammas NW, Lam R, Mustapha J, Ellichman J, Aggarwala G, Rivera E, Niazi K, Balar N. Comparison of orbital atherectomy plus balloon angioplasty vs. balloon angioplasty alone in patients with critical limb ischemia: results of the CALCIUM 360 randomized pilot trial. J Endovasc Ther. 2012 Aug;19(4):480-8. doi: 10.1583/JEVT-12-3815MR.1. PMID: 22891826.

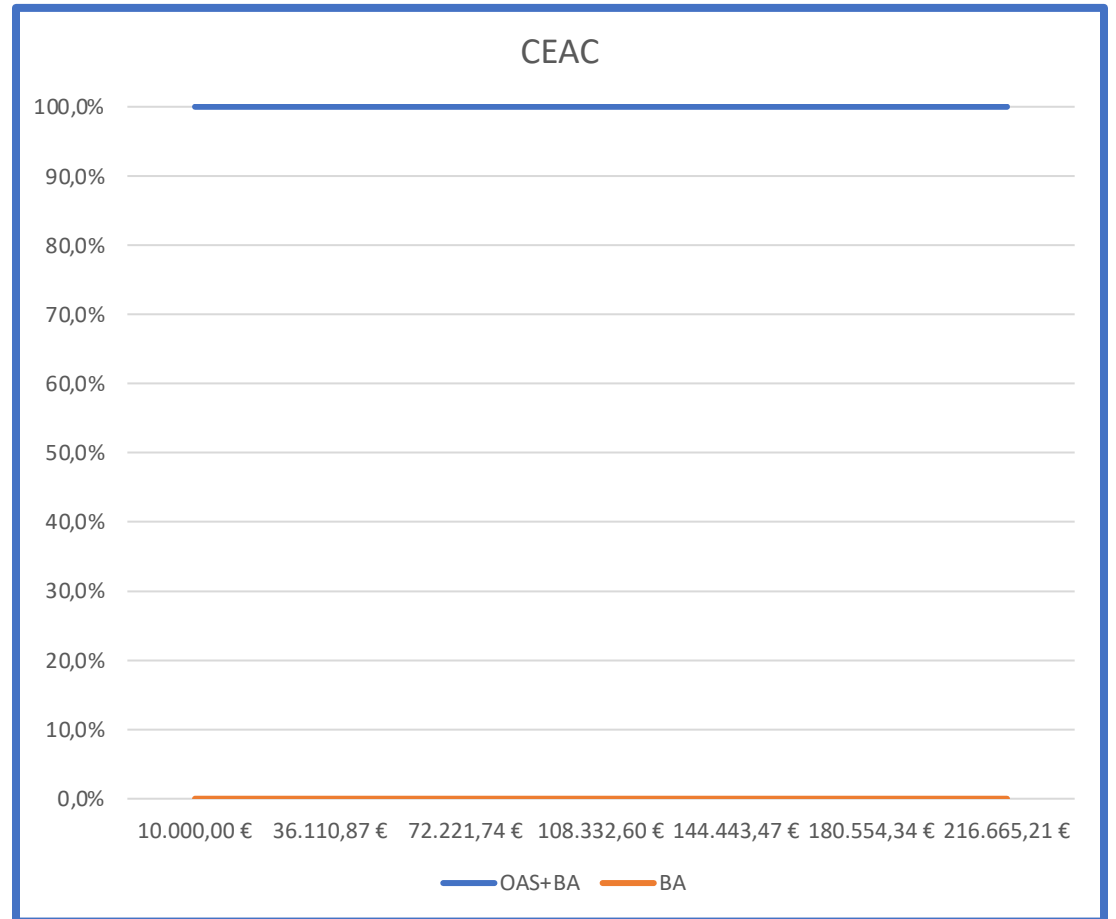
2. Shammas NW, Boyes CW, Palli SR, Rizzo JA, Martinsen BJ, Kotlarz H, Mustapha JA. Hospital cost impact of orbital atherectomy with angioplasty for critical limb ischemia treatment: a modeling approach. J Comp Eff Res. 2018 Apr;7(4):305-317. doi: 10.2217/ce-2017-0070. Epub 2017 Oct 26. PMID: 29072090.

# Endovascular Strategy

		COST OF PROCEDURE (€)	INCREMENTAL TIME COSTS OF PROCEDURE (€)	PERIOPERATIVE EVENTS COSTS (€)	COSTS TLR/TLV 12 MONTH (€)	MORTALITY COSTS 12 MONTHS	TOTAL	TOTAL WO MORTALITY
Endovascular Strategy	OAS+BA	€ 2.683,15	€ 71,11	€ -	€ 1.732,91	€ -	€ 4.487,17	€ 4.487,17
	BA	€ 400,07	-	€ 12,40	€ 5.172,86	€ 3.893,83	€ 9.479,17	€ 5.585,33

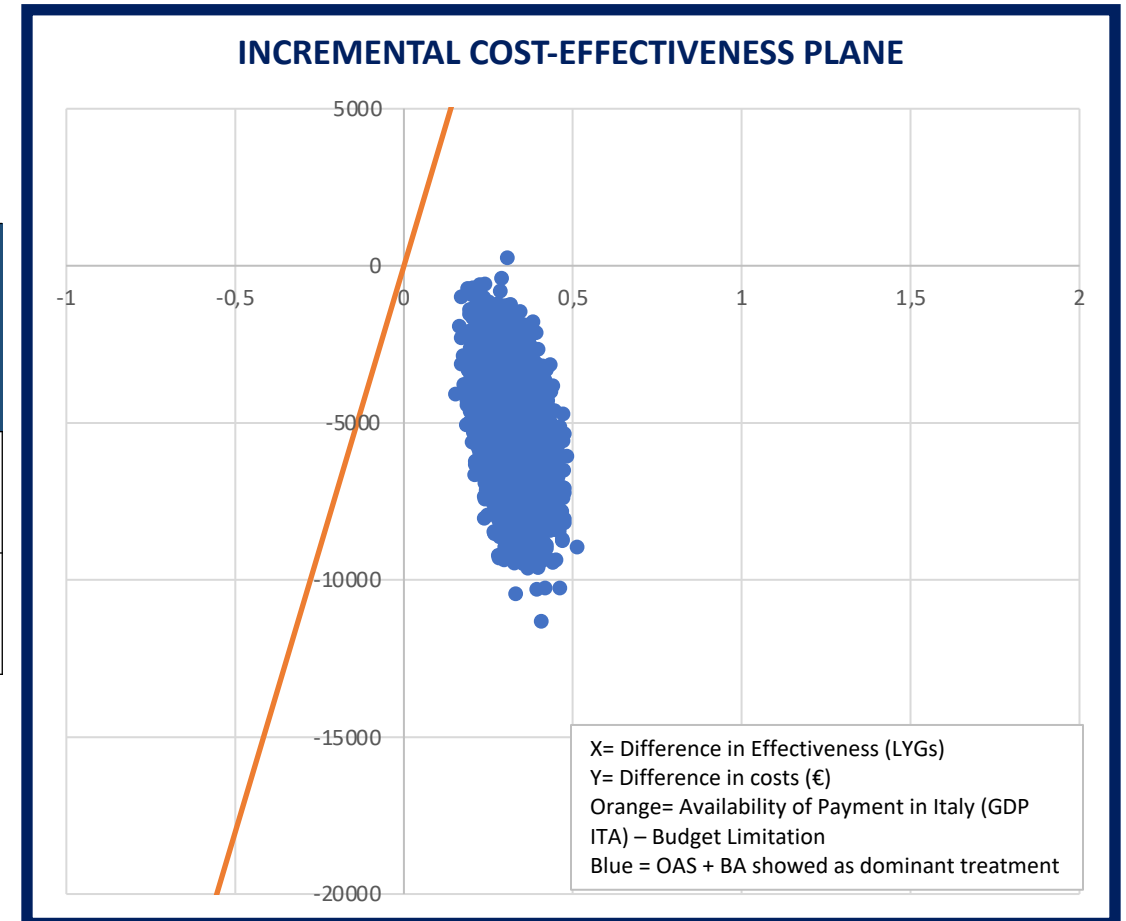
# Incremental cost-effectiveness analysis

The cost-effectiveness acceptability curve				
% INTERACTIONS OAS+BA	% INTERACTIONS BA	THRESHOLD	OAS+BA	BA
100,00%	0,00%	10.000,00 €	100,0%	0,0%
		36.110,87 €	100,00%	0,00%
		72.221,74 €	100,0%	0,0%
		108.332,60 €	100,0%	0,0%
		144.443,47 €	100,0%	0,0%
		180.554,34 €	100,00%	0,00%
		216.665,21 €	100,00%	0,00%



# Incremental cost-effectiveness analysis

	TOTAL COSTS	INCREMENTAL COSTS	EFFECTIVENESS (LIVING PATIENTS)	INCREMENTAL EFFECTIVENESS INCREMENTAL LYG	ICER IN TERMS OF INCREMENTAL COST PER LYG
OAS+BA	4493,48		1		
BA Solo	9481,67	-4988,19	68%	32%	-15775,22

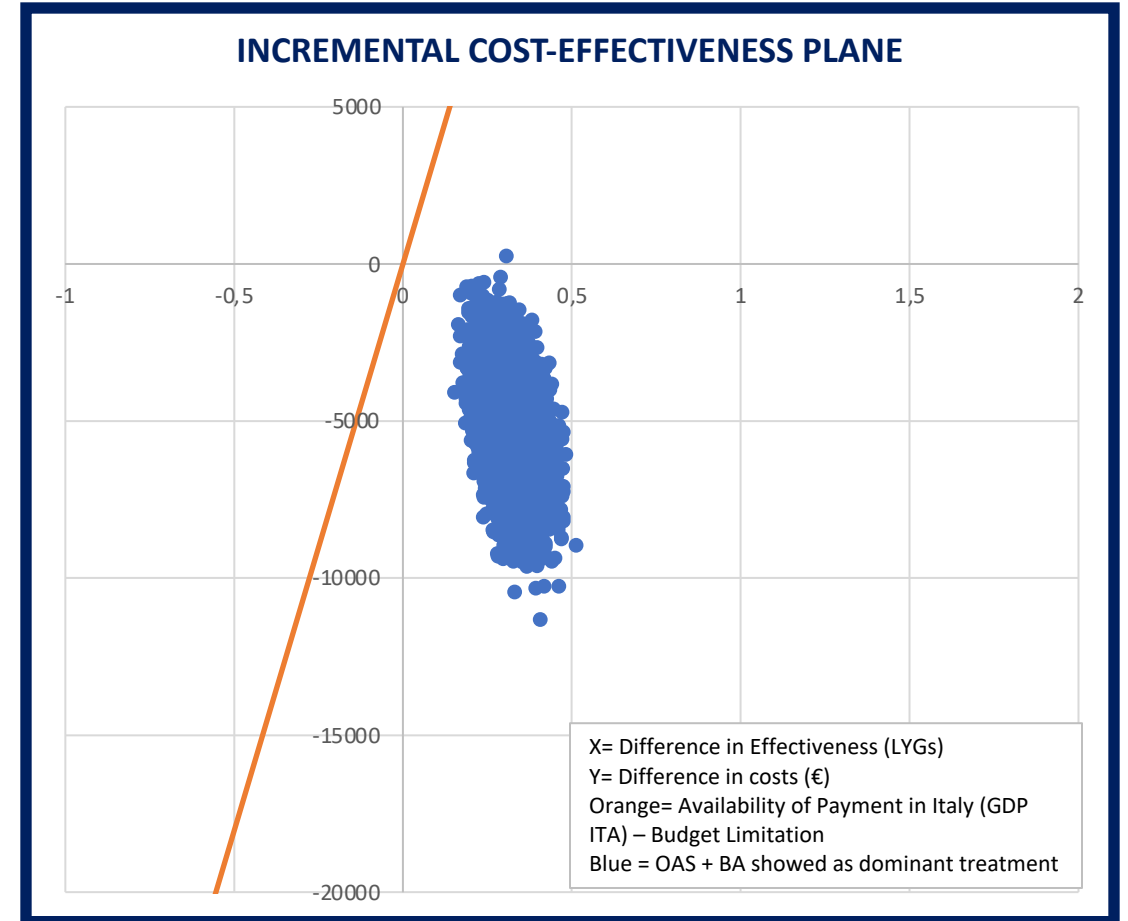


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## **CONCLUSIONS:**

- OAS+BA is associated with 12-month cost savings up to 498,800€ for every 100 patients to the hospital.
- OAS+BA shows superiority in incremental LYGs vs BA alone. (0.32 LYGs per year)
- OAS+BA is cost-effective vs BA alone. Therefore, OAS+BA is the dominant treatment option in 100% of selected patients.
- Understanding the availability of Payment (GDP Italy), OAS + BA should be the treatment of choice for these types of patients regardless of budget.



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