EE546

Improved Outcomes and Cost Savings with a New-Generation Balloon Expandable Covered Stent in Aorto-Iliac Occlusive Disease: Preliminary Results Overview from an Italian Perspective

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OBJECTIVE

- Aortoiliac occlusive disease (AIOD) is a severe vascular condition requiring effective revascularization strategies to restore blood flow and prevent complications.
- This analysis simulates the economic impact of a new-generation balloon expandable covered stent for treating AIOD in the Italian health care setting compared to alternative covered stents.

METHODS

A cost-analysis model was used to simulate AIOD patient outcomes from the preoperative phase through intraprocedural and postoperative events. The model compared a new-generation balloon expandable covered stent (VBX Stent Graft) with the market-share weighted average of alternative covered stents available in Italy *(Figure 1)*.

To obtain device-specific variable estimates, extracted data were pooled by weighting the values based on the sample size of the reporting studies. The clinical data used for the analysis are reported in *Table 1*; values for the alternatives were obtained by weighting device-specific estimates based on their relative market share.

Table 1 – Clinical inputs[h]

Outcome	New-generation balloon expandable covered stent	Alternatives (weighted average)
Myocardial infarction (at 30 days)	0.22%	0.49%
Major amputation (at 18 months)	0.02%	3.06%
Freedom from TLR (at 36 months)	92%	83.39%

Cost inputs

Number of stents required

The analysis assumed that the number of stents used in a procedure depends on the lesion length. The distribution of lesion lengths (45.20 +/- 14.40 mm) was derived from the pivotal trial of the new-generation balloon expandable covered stent in AIOD.[1]

The number and size of device needed was estimated according to the stent sizes available for each device and the extra stent length required for margin safety and stent overlap.

Acquisition costs for the hospital

The acquisition costs for each considered device type and size were determined from public hospital tenders in Italy; the average price of the alternatives was calculated based on market shares established by national market research.

Complication management costs

The costs associated with medical procedures required to manage clinical complications related to vascular and cardiac interventions *(Table 2)* were estimated from health care cost evaluations and DRG tariffs.[2,3]

Late complications (myocardial infraction, major amputation and target lesion revascularization) are not covered by the DRG tariff for the index intervention and accrue extra costs for the Health System in the follow-up.

Table 2 – Complication management costs

Complication	Unit cost
Myocardial infarction	€ 3,897
Major amputation	€ 11,031
Target lesion revascularization	€ 12,073

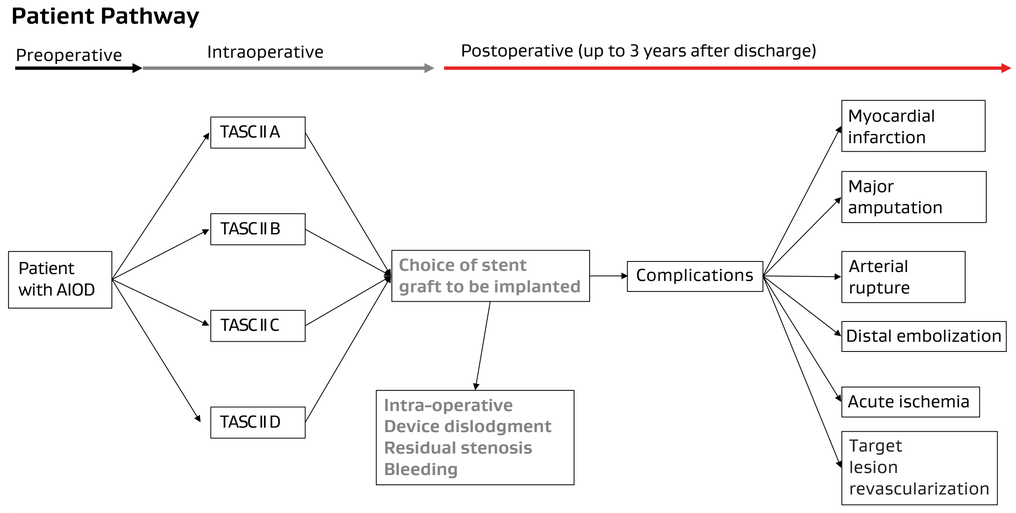
Assessment of uncertainty

Uncertainty was assessed using deterministic and probabilistic sensitivity analyses (DSA and PSA).

For DSA, one-way testing of +/- 20% of base case values was performed.

For PSA, the simulation was repeated 1,000 times with random sets of input values sampled from their respective probability distributions.

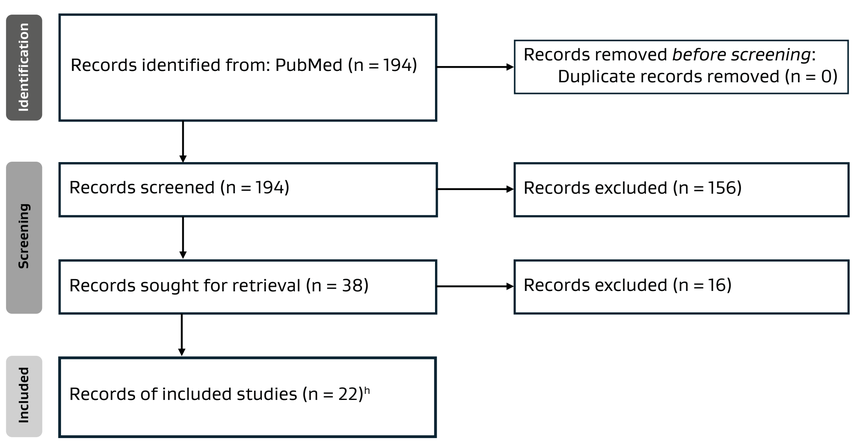
Figure 1 – Simulated patient pathway



Clinical inputs

A systematic literature review in PubMed was conducted and the search strategy included both MeSH terms and free-text terms related to arterial occlusive diseases. To ensure the inclusion of relevant interventions, terms like “balloon expandable”, “covered stent”, “stent graft” and specific device names were searched. The search was limited to articles published in English. Search strategy and selection results are presented in *Figure 2*.

Figure 2 – Search results and study selection process



RESULTS

	New-generation balloon expandable covered stent	Alternatives	Difference
Cost of devices			
Mean number of devices required	1.02	1.16	-0,14
Total costs	€ 3,196	€ 2,273	€ 924
Cost of complications management			
Myocardial infarction	€ 9	€ 19	€ -11
Major amputation at 18 months	€ 2	€ 337	€ -335
TLR at 3 years	€ 966	€ 2,005	€ -1,039
Total costs	€ 977	€ 2,361	€ -1,384
Overall 3-year cost per patient	€ 4,173	€ 4,634	€ -461

- The total mean cost per patient over a 3-year period was estimated at €4,173 for the new-generation balloon expandable covered stent compared to €4,634 for the alternative stents, resulting in average cost savings of €461 per patient (*Table 3*).
- Results were stable when the main sources of uncertainty were tested: in DSA, none of the extreme input values changed the overall conclusion of the analysis; cost savings were indicated in 93% of the PSA simulations (95% credible intervals).

CONCLUSIONS

- This simulation shows reliable clinical outcomes for the new-generation balloon expandable covered stent, including lower rates of myocardial infraction, major amputation and target lesion revascularization over 36 months.
- It may represent a cost-effective treatment for AIOD in Italy, with the model suggesting potentially reliable clinical outcomes and low overall treatment costs.
- This analysis may provide supportive evidence for the new-generation balloon expandable covered stent for improving patient care and reducing health care expenditure compared to existing options.

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[h] Access the publications via this QR code or under https://gmd.cm/EE546

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