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Long and Complex Superficial Femoral Artery (SFA) Lesion Treatments in France: An Analysis of the French Nationwide Claims Database

Tournier C.,[*] Gouëffic Y.,[†] Leboucher C.,[*] Chatellier G.,[†] de Léotoing L.[‡]

[*]Putnam France, Lyon, France, [†]Groupe Hospitalier Paris St Joseph, Paris, France, [‡]W. L. Gore & Associés, Paris, France

RATIONALE

Lower limb peripheral artery disease (LLPAD) is characterized by a decrease in arterial perfusion of the limb due to obstruction and poses a potential threat to the survival of the patient and the limb in question.

Various studies have demonstrated the efficacy of a dedicated covered stent in the endovascular treatment of long and complex femoropopliteal lesions.[1,2,3]

To better evaluate the safety and efficacy of such devices, it is advantageous to use an exhaustive national medico-administrative database in which patients undergoing such treatment can be easily tracked. The French hospital-based medical information database [Programme de Médicalisation des Systèmes d'Information — (PMSI)] enables national hospitalization claims data to be linked at the individual patient level for > 99% of the French population.

OBJECTIVE

The main objective of this study was to compare patients treated for long and complex femoro-popliteal lesions in France with either a covered stent or open surgery.

METHODS

This retrospective population-based study used the PMSI, which covers almost the entire population of hospitalized patients. The PMSI database includes comprehensive hospital-related claims irrespective of the health care insurance system or hospital setting (public/private).

The PICOT model was used as the framework for our research: patient/population (P), intervention (I), control (C), outcomes (O) and timeline (T).

Figure 1 — PICOT methodology

P	• Patients with LLPAD revascularization hospitalized between January 2018 and December 2022 • Diagnoses and procedures coded using ICD-10[§] and the French CCAM[§] procedures classifications
I	• GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface[‖] • Coded using LPPR[§] classification
C	• Open surgery • Procedures were coded using the French CCAM[§] procedures classifications
O	• In-hospital mortality • Amputation rate • Direct costs (National Health Insurance [NHI] perspective) — Costs expressed **in euros (€) as of January 2024 to account for inflation**
T	• Post-operative during **index** stay

To ensure between-group comparability, we conducted a case-control study (1:3) using a propensity score to match with the demographic and clinical characteristics of the index hospital stay (age, gender, disease severity, Charlson score,[4,5] critical limb threatening-ischemia (CLTI), emergency admission, public/private status of establishment and inclusion period by year).

RESULTS

Patient characteristics

***Table 1* — Patient characteristics**

		BEFORE MATCHING			AFTER MATCHING		
		GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface N = 2,248 patients	Open surgery N = 43,467 patients	*P*-value	GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface N = 2,246 patients	Open surgery N = 6,738 patients	*P*-value
Age (years) at inclusion	**Mean ± SD**	72.3 ± 12.0	70.1 ± 12.8	<.0001	72.3 ± 12.0	71.6 ± 11.3	0.0174
Gender	**Men, n (%)**	1,593 (70.9%)	32,208 (74.1%)	0.0007	1,592 (70.9%)	5,084 (75.5%)	<.0001
Length of stay (days)	**Mean ± SD**	5.3 ± 10.3	12.0 ± 14.3	<.0001	5.3 ± 10.3	11.0 ± 12.3	<.0001
ICU admission	**n (%)**	137 (6.1%)	9,255 (21.3%)	<.0001	136 (6.1%)	1,232 (18.3%)	<.0001
ICU duration (days)	**Mean ± SD**	0.4 ± 3.9	1.9 ± 7.5	<.0001	0.4 ± 3.9	1.3 ± 5.4	<.0001
CLTI	**n (%)**	209 (9.3%)	3,632 (8.4%)	0.1167	209 (9.3%)	589 (8.7%)	0.4159
Diabetes	**n (%)**	447 (19.9%)	10,429 (24.0%)	<.0001	446 (19.9%)	1,449 (21.5%)	0.0975
Charlson score	**Mean ± SD**	1.7 ± 1.9	2.2 ± 2.5	<.0001	1.7 ± 1.8	1.7 ± 1.8	0.7738

OUTCOMES

***Table 2* — Outcomes after matching**

	GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface N = 2,246 patients	Open surgery N = 6,738 patients
Death during inclusion stay	31 (1.4%)	231 (3.4%)
Amputation (minor and major)	148 (6.6%)	561 (8.3%)
Minor amputation	118 (5.3%)	420 (6.2%)
Major amputation	39 (1.7%)	167 (2.5%)

All-cause hospital mortality was 1.4% in group 1 (GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface) versus 3.4% in group 2 (open surgery) (OR: 0.39, [95%CI: 0.27-0.58]).

In-hospital amputation occurred in 6.6% versus 8.3% of patients in group 1 (GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface) and group 2 (open surgery) (OR: 0.78, [95%CI: 0.64-0.94]), respectively.

COSTS

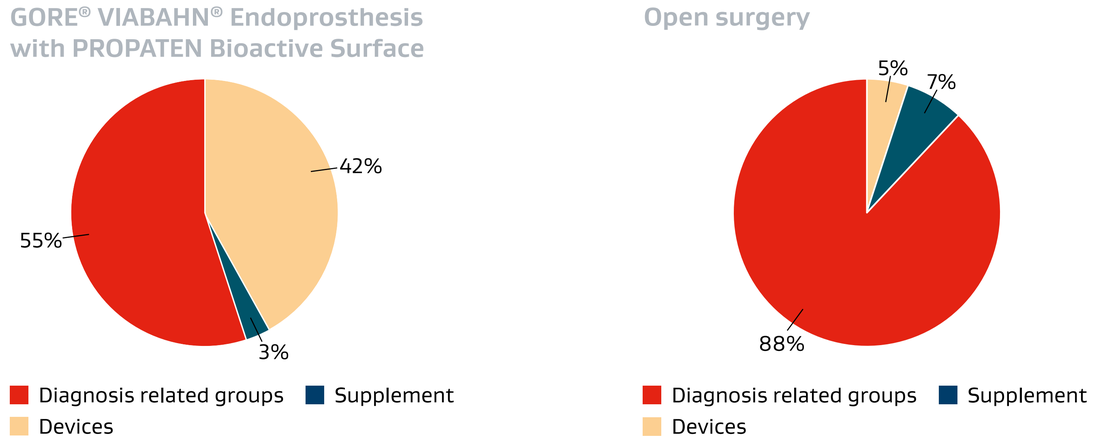
The associated costs were €6,954 (IQR: €5,569–€9,587) in group 1 and €8,575 (IQR: €6,577–€12,957) in group 2 (non-significant difference).

***Table 3* — Costs**

Cost at inclusion (expressed in euros (€) as of January 2024)	GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface N = 2,246 patients	Open surgery N = 6,738 patients
Q1	€5,569	€6,577
Median	**€6,954**	**€8,575**
Q3	€9,587	€12,957

The costs are detailed in the figure below.

***Figure 2* — Details of costs**



CONCLUSION

In this real-world nationwide cohort of LLPAD patients, the risk of both in-hospital mortality and major amputation was lower in those treated with the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface, a dedicated vascular endoprosthesis, than in their matched counterparts who underwent open surgery, while the costs were 19% lower.

Main strength

Large sample size

45,715 patients included — of whom 2,246 in the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface arm and 6,738 in the open surgery arm — were available for propensity score matching between the two treatments.

Main limitation

Absence of detailed clinical information in the PMSI

- The precise characteristics of the lesions, such as the location, calcification or the length, are not documented.
- Cholesterol, hypertension and tobacco are poorly coded in the PMSI-MCO and could not be reliably retrieved.
- CLTI was used as a proxy for the description of the LLPAD severity, as the ICD-10 codes for LLPAD do not offer precise information on the severity of the disease; critical patients might be underestimated.
- The PMSI database does not mention the side on which the index intervention has been performed; thus, amputations and interventions could have involved any vessel or the contralateral limb, resulting in overestimations compared to other prospective registries.

Information for comparing the long-term outcomes of both treatments is still missing.
A further analysis of data from the present cohort is planned.

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[§] ICD-10: International Classification of Diseases 10th Revision; CCAM: Classification Commune des Actes Médicaux; LPPR: Liste des Produits et Prestations Remboursables.

[‖] As used by Gore, PROPATEN Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

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