

Hospitalization and Death in the First 30 days After Outpatient Lower Extremity Arterial Stenting

Simon Jan, Yann Gouëffic, Olivier Grimaud, Nolwenn Le Meur

▶ To cite this version:

Simon Jan, Yann Gouëffic, Olivier Grimaud, Nolwenn Le Meur. Hospitalization and Death in the First 30 days After Outpatient Lower Extremity Arterial Stenting. CardioVascular and Interventional Radiology, 2022, 45, pp.1441-1450. 10.1007/s00270-022-03193-0. hal-03704186

HAL Id: hal-03704186 https://ehesp.hal.science/hal-03704186

Submitted on 15 Sep 2022

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers. L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

1	Original article
2	Hospitalization and death in the first 30 days after outpatient lower extremity arterial
3	stenting
4	Simon Jan, MD; Yann Gouëffic, MD, PhD; Olivier Grimaud, MD, PhD; and Nolwenn Le
5	Meur, PhD
6	
7	Short title: Early adverse events after outpatient lower limb stenting
8	
9	Affiliations and addresses
10	Simon Jan, MD
11	Observatoire Régional de la Santé, Bretagne, France
12	Address: Immeuble Acropole
13	19 Avenue Charles Tillon
14	35 000 Rennes - FR
15	
16	Yann Gouëffic, MD, PhD
17	Groupe hospitalier Paris St Joseph, Service de chirurgie vasculaire et endovasculaire, F-75014.
18	Address: Hôpital Paris St Joseph, Vascular and endovascular surgical center
19	75014 Paris – FR
20	
21	Olivier Grimaud, MD, PhD
22	Univ Rennes, EHESP, CNRS, Inserm, Arènes - UMR 6051, RSMS - U 1309 – F-35000
23	Rennes, France
24	Address : Écoles des Hautes Études en Santé Publique
25	Département METIS,
26	15 Avenue du Professeur Léon Bernard, CS 74312 35043 Rennes Cedex, FR
27	
28	Corresponding author:
29	Nolwenn Le Meur, PhD
30	Univ Rennes, EHESP, CNRS, Inserm, Arènes - UMR 6051, RSMS - U 1309 – F-35000
31	Rennes, France
32	Address : Ecoles des Hautes Etudes en Santé Publique
33	Département METIS,
34	15 Avenue du Professeur Léon Bernard, CS 74312 35043 Rennes Cedex, FR
35	e-mail: nolwenn.lemeur@ehesp.tr
36	Phone: +33 2 99 02 25 14
37	

1 Abstract

Purpose To compare the safety of outpatient versus inpatient endovascular treatment of lower
extremity arterial disease (LEAD) using real-life data.

4 Materials and Methods

5 This retrospective observational study used real-life data from the French national health data 6 information system on adult patients who underwent stenting for LEAD between 2013 and 7 2016. The outcomes of interest were all-cause mortality, all-cause hospitalization, planned 8 hospitalization, and unplanned hospitalization at day 3 and day 30 after the index endovascular 9 intervention for LEAD revascularization. A propensity score was used to control for indication 10 bias. Outcome rates in outpatient and inpatient settings were compared with the Poisson 11 regression model. Sensitivity analyses were performed by varying the definition of the 12 outcomes of interest.

13 Results During the study period, 26 715 interventions were performed among which 2 819 14 (10.6%) were in outpatient settings. Outpatients were slightly younger than inpatients (64.73 15 ± 10.68 versus 68.10 ± 11.50 , respectively). The percentage of women patients was similar: 16 19.8% in the outpatient group and 27.2% in the inpatient group. Within 30 days after discharge, 17 73 patients (.31%) and 2 (.07%) patients (p = .02) died in the inpatient group and outpatient 18 group, respectively. The death and rehospitalization rate were similar: 3.8 and 3.5 per 1 000 19 person-months for inpatients and outpatients, respectively. No difference was observed after 20 adjusting for patients' case-mix in the regression model (RR = .99; 95% CI [.82-1.19]).

Conclusions Outpatient stenting for LEAD did not present any additional risk of early
 postoperative rehospitalization or death compared with inpatient stenting.

23

Keywords lower extremity arterial disease; endovascular intervention; complication;
outpatient; death; rehospitalization

1 Introduction

2 Lower extremity arterial disease (LEAD) is the third cause of cardiovascular morbidity after 3 coronary artery disease and stroke. LEAD prevalence in \geq 70 adults is estimated at 15-20% 4 [1,2]. Inpatient invasive surgical bypass procedures have been the main treatment for LEAD 5 [3]; however, recent technical progress in minimally invasive surgery, particularly in 6 endovascular revascularization, has contributed to reduce the constraints and risks associated 7 with open surgery (e.g. general anesthesia, long hospital stay, surgical site or hospital 8 acquired infections)[4,5]. Accordingly, the guidelines for vascular and endovascular surgical 9 treatments promote endovascular revascularization instead of open surgery for LEAD [6,7]. 10 Moreover, several studies demonstrated the feasibility of same-day endovascular 11 revascularization (*i.e.* outpatient surgery) [8–11] and the reduced risk of hospital-acquired 12 infections [12]. Consequently, outpatient endovascular revascularization has become the main 13 option for arterial repair in the United States of America (USA) where the Outpatient 14 Prospective Payment System significantly promotes the shift from inpatient to outpatient 15 settings [13]. However, outpatient setting for LEAD remains low elsewhere [14], notably in 16 France where the proportion of outpatients average 5% and stable since 2016. 17 Some studies showed that procedural and postoperative complications of endovascular 18 revascularization within 30 days of surgery occur in 10% to 13% of the patients [15,16]. In 19 addition, outpatient endovascular repair for LEAD does not seem to increase the risk of 20 complications and hospital readmission [8,16–18]; however, the AMBUVASC randomized 21 clinical trial (RCT) showed more readmissions in the outpatient than in the inpatient arm [19]. 22 As real-life patients differ from those enrolled in RCT, the evidence from the AMBUVASC 23 RCT may be insufficient to draw firm conclusions on the risk of readmission after outpatient 24 endovascular revascularization. Therefore, we analyzed real-life hospital discharge data to

determine the early readmission and death rates after inpatient and outpatient endovascular
 treatment of LEAD.

3 Materials and Methods

4 Data sources

5 This retrospective observational study was performed using real-life healthcare data extracted 6 from the French national health data system (SNDS). SNDS contains anonymous individual 7 sociodemographic and medical information on >98% of the French population [20]. The 8 medical data include all reimbursed healthcare procedures, such as ambulatory consultations, 9 prescribed drugs, and outpatient and inpatient surgeries.

10 Study population

11 All adult patients who underwent at least one stenting intervention for LEAD between March 12 1, 2013, and June 30, 2016, were included (Fig. 1). The study period started in March to 13 integrate the yearly update of the medical nomenclature coding. The clinical selection criteria 14 were based on twelve surgical procedures identified by the French Classification of Medical 15 *Procedures* (CCAM) and the six main hospital discharge diagnoses identified by the 16 International Classification of Diseases, 10th Revision (ICD10) (Supplementary Table 1). 17 The surgery setting, defined on the basis of the hospital stay duration in the hospital discharge 18 summary, was used to categorize patients into: inpatients (at least one overnight stay) and 19 outpatients (same-day discharge)[21]. To compare homogeneous groups of patients, inpatients with features that would have precluded outpatient surgery were excluded (Fig. 1). 20 21 For each patient, the comorbidity level was computed using hospital discharge data from up 22 to 1 year before the index intervention and the Charlson's comorbidity index coding 23 algorithm [22,23]. Other covariates were the age, the sex, the year of the index surgery, and

the hospital activity, defined by the number of LEAD revascularization procedures performed
 in that hospital between 2013 and 2016.

3 Outcomes

4 The outcomes of interest were all-cause mortality, all-cause hospitalization, planned 5 hospitalization, and unplanned hospitalization at day 3 and day 30 after the index 6 endovascular revascularization for LEAD. All-cause hospitalization included any 7 hospitalization with at least one overnight stay, or admission through the emergency 8 department, or another treatment for LEAD in outpatient setting. Unplanned hospitalizations 9 were considered as postoperative complications and were divided in three categories by two 10 of the authors (SJ: medical doctor and YG: vascular surgeon): endovascular procedure-11 related, cardiovascular comorbidity-related, and other reasons (Supplementary Table 2). 12 Planned hospitalizations included all other causes of admissions. The time to event was 13 calculated as the number of days from the index surgery date to the subsequent hospitalization 14 date. For patients with several readmissions after the index surgery, only the first one was 15 counted and analyzed based on the assumption that the earliest admission was probably 16 related to the index intervention.

17 Statistical analyses

The patients' characteristics were described for the outpatient and inpatients groups. Age was presented as mean and standard deviation. Sex, comorbidities, and year of intervention were described using numbers and percentages. The absolute and relative frequencies of interventions were reported by hospital activity level to highlight any hospital size effect. To determine differences between groups, the standardized difference method was used with the following thresholds for significant differences: low [0.2-0.3[, moderate [0.3-0.8], and high >0.8. To address a possible indication bias within the two groups, the inverse probability

1 treatment weighting (IPTW) was used[24]. Variables included in the propensity score were sex,

2 age, comorbidities, year of intervention, and the hospital activity. Adjustments were considered

3 satisfying when the standardized differences between groups were ≤ 0.1 .

4 Outcomes were summarized for the outpatient and inpatients groups. Unplanned

5 hospitalizations were reported as the cumulative number of events and their relative

6 proportions at day 3 and day 30 days after the index endovascular revascularization. The daily

7 occurrence of outcomes over the 30-day period after the index surgery was plotted in function

8 of the hospitalization type (all-cause, planned, unplanned) and surgery setting.

9 Regression model and sensitivity analysis

A Poisson regression model with robust estimates of the standard errors was used to compare the mortality and hospitalization rates between inpatients and outpatients in the 30 days after the index endovascular revascularization [25]. Although strict selection criteria were used to obtain comparable outpatient and inpatient groups (Fig. 1), IPTW was applied to address possible indication bias in the regression analysis [24].

A sensitive analysis was performed by changing the definition of the outcomes of interest in the Poisson regression model to assess the robustness of the comparison between inpatients and outpatients. The modified definitions were: (i) very early readmission (\leq 3 days); (ii) death or readmission through the emergency department; (iii) readmission related exclusively to the procedure; and (iv) readmission related to cardiovascular comorbidities.

20 All p values < .05 were considered statistically significant. Data management and statistical

analyses were performed using the R statistical software (version 3.6.1) [26].

22 **Results**

- 23 During the study period, 133 992 hospital stays for LEAD stenting were identified (Fig. 1).
- After applying the exclusion criteria, 26 716 hospital stays were considered as potentially

eligible for outpatient management. The propensity score could not be calculated for one
 patient. In total, 26 715 stays were included in the analysis.

3 Patients' characteristics

- 4 Among the 26 715 interventions, 2 819 (10.6%) were performed in an outpatient setting
- 5 (Table 1), and their percentage tended to increase from 2013 to 2016. In the Outpatient group,
- 6 patients were younger (mean age: 64.7 ± 10.68 years vs 68.10 ± 11.50 years), less frequently
- 7 women (19.8% vs. 27.2%), and had fewer comorbidities. Diabetes, cardiovascular and
- 8 chronic obstructive pulmonary diseases were the most frequent comorbidities in both groups
- 9 (11.3% and 22.0%, 10% and 18.5%, 5.1% and 9.1% of outpatients and inpatients,
- 10 respectively).

11 Mortality and hospitalization rates within 30 days

Within 30 days after discharge, 73 (0.31%) and 2 (0.07%) patients died among the inpatients and outpatients, respectively (p = .02) (Table 2). Twenty-six patients died at home without any post-surgery hospitalization; 33 died during their first readmission, and 16 after repeated hospitalizations. The deceased patients were significantly older (mean age 77±13 years), more often men, and had more comorbidities.

17 Within 30 days after discharge, 2 799 patients (n = 281 outpatients, 9.9%, and n = 2518

18 inpatients, 10.4%; p = .35) were readmitted to hospital. Hospitalizations followed a weekly

19 temporal trend (Fig. 2). The first peak of hospitalizations was observed within 5 and 6 days,

20 and then every 7 days. Approximately 50% of all recorded readmissions were within the first

- 21 14 days after discharge. Part of this phenomenon could be explained by the weekend bias in
- 22 hospital discharge reporting. However, it also represented scheduled consultations for post-
- 23 operative surveillance or programmed endovascular revascularization of the other limb. Most
- of these hospitalizations were for LEAD endovascular procedures (n = 1.075; 66.9%),

revascularization by open surgery for LEAD (n = 443; 27.6%), or other revascularization
 interventions (n = 89; 5.5%). These 1 607 (55.9%) hospitalizations were qualified as
 "planned". The remaining 1 267 (44.1%) hospitalizations were qualified as "unplanned" and
 related to postoperative complications.

5 Postoperative complications within 30 days after surgery were reported for 1 267 patients 6 with a significant higher percentage in the inpatient than outpatient group (4.9% vs 3.72%, p 7 $< 1.10^{-5}$). In the inpatient group, the peak of unplanned hospitalizations occurred 5 days after 8 discharge, and about two third of these hospitalizations were within the first 15 days. In the 9 outpatient group, most unplanned hospitalizations occurred within the first 14 days (Fig. 3). 10 Complications were related to the endovascular procedure (23.4% of cases), cardiovascular 11 comorbidities (26%), and other causes (48.3%) (Supplementary Fig. 1). Among the 12 endovascular procedure-related complications, false aneurysm was the most frequent in the 13 outpatient group (22.7% versus 17.2% in the inpatient group), followed by ulcers and 14 gangrene without amputation (18.1% vs 16.4%). Amputations were a more frequent cause of 15 hospitalization in the inpatient group (16.4% vs 4.5% in the outpatient group), suggesting that 16 some patients with severe ischemia were retained in both groups despite our exclusion 17 criteria. Cardiovascular comorbidity-related complications included heart diseases (46%), 18 stroke (1%), and other cardiovascular diseases (43%). These events occurred at similar rates 19 in both groups. Myocardial infarction and stroke represented 11 and 12 complications per 1 20 000 endovascular procedures, respectively. Endovascular procedure-related complications 21 occurred more often in the first week after discharge, whereas cardiovascular comorbidity-22 related complications were spread over time.

23 Early death or readmission

In total, 18 (0.7%) patients died within 3 days after discharge, all of them in the inpatient
group (Table 2). The hospitalization rates within 3 days were comparable between inpatients
(n = 266; 1.1%) and outpatients (n=22; 0.78%)(p = .45). Among these early readmissions,
38% were classified as complementary revascularization procedures (38 angioplasties and 37
revascularization surgeries) and possibly planned interventions. Compared with the 30-day
hospitalizations, early readmissions for complications were more frequently related to the
endovascular procedure than to cardiovascular comorbidities (23% and 19%, respectively).

8 Effect of outcome definition changes

The rates of all-cause hospitalization within 30 days were not significantly different between outpatients and inpatients (p = .88) (Table 3). Results did not change when other causes of hospitalization (e.g., cancer, trauma) were excluded (p = .77), or when only procedure-related complications (p = .52) or comorbidities (p = .53) were considered. Similar results were obtained also for hospitalizations with transfer via the emergency department (p = .06), and for very early hospitalizations within 3 days after the index surgery (p = .46). Only the relative risk of death was reduced to 17% among outpatients.

1 Discussion

2 According to our study, rehospitalization after endovascular stenting occurs in more than 1 in 3 10 patients with LEAD during the perioperative period. However, when using real-life 4 hospital discharge data, it is difficult to disentangle between readmissions in the framework of 5 the planned care trajectory and true postsurgical complications. Based on our medical 6 expertise, early complications related to the endovascular procedure and to cardiovascular 7 comorbidities were rare (<3%) and were not associated with the setting (inpatient/outpatient 8 surgery), when adjusting for the patients' case-mix. Unsurprisingly, early readmissions 9 (within 3 days) were often related to the procedure, whereas late readmissions (within 4 to 30 10 days) were more associated with cardiovascular comorbidities. The mortality rate was 11 significantly lower in the outpatient group, although we cannot exclude that this might be 12 explained by the remaining differences observed after adjustment for the patient baseline characteristics. 13

14

15 Comparison of our results with other studies is difficult because different health care systems 16 have different outpatient surgery definitions and organization. For instance, in the USA, the 17 type of care (outpatient/inpatient) depends mainly on the facility [27]. Outpatient care is often 18 provided in independent ambulatory surgery centers or in office-based surgeries. In France, 19 outpatient surgery units remain under the administrative control of hospitals and no financial 20 incentive was given before 2019 to promote outpatient endovascular surgery. Nevertheless, 21 we excluded high-risk patients using medical criteria similar to those of other 22 studies[8,11,19,27] (i.e. the American Society of Anesthesiology score and recent guidelines 23 [28]). Moreover, the number of patients with diabetes was lower than in most previous studies 24 (11% and 22% of patients in the outpatient and groups compared with 25% to 33% of 25 patients[8]). This difference might be the result of overall differences in population health or

1 might be linked to our stringent criteria to obtain comparable inpatient and outpatient groups 2 (exclusion of patients with arterial wounds and of patients with intercurrent conditions, such 3 as stroke, coronary artery disease in the last 3 months or hospitalization in the previous 4 month). For example, we excluded patients with pain at rest. Nevertheless, our rate of 5 postoperative hospitalizations for complications within 30 days was relatively similar to that 6 of previous studies [11,17]. In our study, the percentage of post-operative deaths and 7 complications was 2.5%, whatever the surgery setting, and 1.8% for outpatients only. 8 Spiliopoulos et al. reported rates of 1.4% for major complications and 2.7% for minor 9 complications (without need of treatment or consequences) in their multi-center study on the 10 safety and feasibility of day-case endovascular procedures for the management of peripheral 11 arterial diseases [11]. Lin et al. followed 1568 outpatients who underwent office-based 12 endovascular arterial interventions, and found a postoperative complication rate of 1.5% [17]. 13 Overall, these findings are consistent. although our population coverage may slightly differ 14 because we focused on patients with LEAD, while other studies included patients with 15 broader profiles of peripheral arterial diseases. Using Medicare data (a design closer to that of 16 our study), Turley et al. found higher all-cause hospitalization rates at 30 days but their 17 patients were significantly older and with more comorbidities [27]. Similarly, Ali et al. found 18 higher rates of unplanned readmissions, but their study population had a more complex 19 clinical background (diabetes, critical limb ischemia with tissue loss)[16]. In our study, the 20 mortality rate at 30 days was .07% among outpatients, which is significantly lower than the 21 rate in the studies by Lin et al. and Turley et al (0.9%, and 0.18%, respectively) [17,27]. 22 Again, this could be partly explained by the younger mean age of our patients. 23

24 The main strength of this study is its nation-wide coverage based on data from the French 25 national healthcare information system. This data source has been previously used for many

11

epidemiological and public health studies [20]. The second strength is the longitudinal
dimension over a 3-year period allowing the recording of the rare events that are
complications after endovascular surgery. Third, the propensity score weighting based on the
patient's comorbidity helped matching the two groups in the context of a real-life dataset.
Finally, this study demonstrates the interest of analyzing real-life data to complement the
findings of randomized trials, such as AMBUVASC, on the safety of outpatient surgery.

8 The study is limited by the lack of clinical details on the hospital stays. Therefore, we could 9 not identify the patients initially scheduled for outpatient surgery whose hospital stay was 10 converted to inpatient surgery (i.e., outpatient who finally stayed one or more nights). This 11 may have underestimated the number of scheduled outpatients and of very early 12 complications (within hours). However, to control for this bias, we excluded all patients who 13 presented postoperative complications before hospital discharge. Moreover, the LEAD 14 clinical stage was not available in our database (no symptom listed). To minimize this 15 limitation, we excluded patients with critical limb ischemia and tissue loss because they were 16 less likely to be offered outpatient surgery. However, with this approach, we may have 17 underestimated the complications in the inpatient group. In addition, we did not have 18 information on the surgery approach (laterality, route, artery treated) and this did not allow us 19 to formally link the initial surgical procedure with the subsequent hospitalization(s). Indeed, 20 this population presents a high secondary hospitalization rate at 30 days for contralateral 21 surgery [29], which makes it more difficult to identify the true complications. In our study, 22 secondary interventions carried out within one month concerned nearly 6% of the patients 23 who had undergone angioplasty. To control for this limitation, we categorized all 24 postoperative causes of hospitalization and limited the follow-up period to 30 days because 25 we think that a 1-year follow-up, as done in the study by Turley *et al.*, might lead to an

ACCEPTED MANUSCRIPT / CLEAN COPY

overestimation of the complication rate [27]. Finally, few socio-demographic data are
available in our database. For instance, social isolation, which is an exclusion criterion for
outpatient care due to the potential risk of postoperative complications, could not be
considered. Socially isolated patients should have been only in the inpatient group, but we
could not identify them and thus we may have overestimated the number of comparable
inpatients.

7 Conclusions

8 Using real-life data, we found that outpatient endovascular revascularization for LEAD does 9 not present any additional risk compared with inpatient surgery. Readmissions and deaths at 10 30 days following LEAD stenting in outpatient settings are rare (<3%), although patients are 11 older and often have several comorbidities. Moreover, early complications do not seem to be 12 associated with the surgery setting. The mortality and complication rates after outpatient 13 endovascular surgery for LEAD should not prevent vascular surgeons to propose it to their 14 patients, when possible. Nevertheless, more data are needed to confirm its efficiency as 15 already highlighted by the AMBUVASC RCT.

1 Author contributions

Simon Jan, Yann Gouëffic and Nolwenn Le Meur were involved in the conception and design
of the study. Simon Jan and Nolwenn Le Meur wrote the article with critical revision were by
Yann Gouëffic and Olivier Grimaud. Statistical analysis and interpretation of the data were
performed by Simon Jan and Nolwenn Le Meur. All four authors approved the final version of
the article.

7

8 Acknowledgements

9 The authors would like to acknowledge INDS and CNAMTS for support in accessing the
10 data. We would like to thank Elisabetta Andermarcher for editing and proofreading this

11 manuscript. We would like to thank Mathilde Lefort for her advises on the statistical methods.

12

13 Compliance with Ethical Standards

14 **Funding:** This work was supported by the French Health Products Agency as part of the

15 PEPS platform and the TRACKEDAYS project (TRAjectory of Care for Knowledge on

16 Endovascular DAY Surgery).

17 **Conflict of interest statement:** Y. Gouëffic reports research funding from Bard, General

18 Electric, Medtronic, WL Gore, personal fees and grants from Abbott, Bard, Biotronik, Boston

19 Scientific, Medtronic, Penumbra, Terumo, Vygon, WL Gore (medical advisory board,

20 educational course, speaking). None of these funds was used for the present work. The other

21 authors declare that they have no competing interests.

22 Ethical approval: For this type of study formal consent is not required. This study was

approved by the Institutional Review Board of the SNDS (agreement #201) and the National

Authority Review Board for data protection (CNIL agreement #1968571).

25 Informed consent: For this type of study informed consent is not required

26 **Consent for publication:** For this type of study consent for publication is not required.

1 References

- 2 1. Fowkes FGR, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al.
- 3 Comparison of global estimates of prevalence and risk factors for peripheral artery disease in
- 4 2000 and 2010: a systematic review and analysis. Lancet. 2013;382:1329–40.
- 5 2. Song P, Rudan D, Zhu Y, Fowkes FJI, Rahimi K, Fowkes FGR, et al. Global, regional, and
- 6 national prevalence and risk factors for peripheral artery disease in 2015: an updated
- 7 systematic review and analysis. Lancet Glob Health. 2019;7:e1020–30.
- 8 3. Antoniou GA, Georgiadis GS, Antoniou SA, Makar RR, Smout JD, Torella F. Bypass
- 9 surgery for chronic lower limb ischaemia. Cochrane Database Syst Rev. John Wiley & Sons,
- 10 Ltd; 2017;4:CD002000–CD002000.
- 11 4. Indes JE, Pfaff MJ, Farrokhyar F, Brown H, Hashim P, Cheung K, et al. Clinical outcomes
- 12 of 5358 patients undergoing direct open bypass or endovascular treatment for aortoiliac
- 13 occlusive disease: a systematic review and meta-analysis. J Endovasc Ther. 2013;20:443–55.
- 14 5. Sullivan TM, Taylor SM, Blackhurst DW, Langan EM, Cull DL, Carsten CG, et al. Has
- 15 endovascular surgery reduced the number of open vascular operations performed by an
- 16 established surgical practice? Journal of Vascular Surgery. 2002;36:514–9.
- 17 6. Halliday A, Bax JJ. The 2017 ESC Guidelines on the Diagnosis and Treatment of
- 18 Peripheral Arterial Diseases, in Collaboration With the European Society for Vascular
- 19 Surgery (ESVS). European Journal of Vascular and Endovascular Surgery. 2018;55:301–2.
- 20 7. Stoner MC, Calligaro KD, Chaer RA, Dietzek AM, Farber A, Guzman RJ, et al. Reporting
- 21 standards of the Society for Vascular Surgery for endovascular treatment of chronic lower
- extremity peripheral artery disease. Journal of Vascular Surgery. 2016;64:e1–21.
- 8. Hauguel A, Maurel B, Bague N, Gouaillier-Vulcain F, Costargent A, Chaillou P, et al.
- 24 Management of ambulatory (day case) endovascular procedures for peripheral arterial
- disease. J Cardiovasc Surg (Torino). 2017;58:293–304.
- 9. Payne SP, Stanton A, Travers P, Glenn D, Hanel KC. Outpatient angioplasty: 4-year
 experience in one practice. Ann R Coll Surg Engl. 1997;79:331–4.
- 10. Akopian G, Katz SG. Peripheral angioplasty with same-day discharge in patients with
 intermittent claudication. J Vasc Surg. 2006;44:115–8.
- 30 11. Spiliopoulos S, Karnabatidis D, Katsanos K, Diamantopoulos A, Ali T, Kitrou P, et al.
- 31 Day-Case Treatment of Peripheral Arterial Disease: Results from a Multi-Center European
- 32 Study. Cardiovasc Intervent Radiol. 2016;39:1684–91.
- 33 12. Daryapeyma A, Hammar U, Wahlgren CM. Incidence of Healthcare Associated Infections
- 34 After Lower Extremity Revascularization Using Antibiotic Treatment as a Marker. European
- 35 Journal of Vascular and Endovascular Surgery. 2016;51:690–5.
- 36 13. Jones WS, Mi X, Qualls LG, Vemulapalli S, Peterson ED, Patel MR, et al. Trends in
- 37 Settings for Peripheral Vascular Intervention and the Effect of Changes in the Outpatient

- Prospective Payment System. Journal of the American College of Cardiology. 2015;65:920–
 7.
- 3 14. Nickinson A, Birmpili P, Weale A, Chetter I, Boyle J, Loftus I, et al. What is the current
- 4 practice for managing patients with chronic limb-threatening ischaemia in vascular surgery
- 5 services? A survey of UK vascular surgeons. annals. 2021;rcsann.2021.0075.
- Medical Advisory Secretariat. Stenting for peripheral artery disease of the lower
 extremities: an evidence-based analysis. Ont Health Technol Assess Ser. 2010;10:1–88.
- 8 16. Ali TZ, Lehman EB, Aziz F. Unplanned return to operating room after lower extremity
 9 endovascular intervention is an independent predictor for hospital readmission. Journal of
- 10 Vascular Surgery. 2017;65:1735-1744.e2.
- 11 17. Lin PH, Yang K-H, Kollmeyer KR, Uceda PV, Ferrara CA, Feldtman RW, et al.
- 12 Treatment outcomes and lessons learned from 5134 cases of outpatient office-based
- 13 endovascular procedures in a vascular surgical practice. Vascular. 2017;25:115–22.
- 14 18. Oskui PM, Kloner RA, Burstein S, Zhiroff K, Kartub BR, Economides C, et al. The
- 15 Safety and Efficacy of Peripheral Vascular Procedures Performed in the Outpatient Setting.
- 16 The Journal of Invasive Cardiology. 2015;27:7.
- 17 19. Gouëffic Y, Pin JL, Sabatier J, Alimi Y, Steinmetz E, Magnan P-E, et al. A Cost
- 18 Effectiveness Analysis of Outpatient versus Inpatient Hospitalisation for Lower Extremity
- 19 Arterial Disease Endovascular Revascularisation in France: A Randomised Controlled Trial.
- 20 European Journal of Vascular and Endovascular Surgery. Elsevier; 2021;61:447–55.
- 20. Tuppin P, Rudant J, Constantinou P, Gastaldi-Ménager C, Rachas A, de Roquefeuil L, et
- 22 al. Value of a national administrative database to guide public decisions: From the système

23 national d'information interrégimes de l'Assurance Maladie (SNIIRAM) to the système

24 national des données de santé (SNDS) in France. Revue d'Épidémiologie et de Santé

- 25 Publique. 2017;65:S149–67.
- 26 21. Lemos P, Jarrett P, Philip BK, International Association for Ambulatory Surgery, British
- 27 Association of Day Surgery. Day surgery: development and practice. Portugal; International
- 28 Association for Ambulatory Surgery; London: British Association of Day Surgery; 2006.
- 29 22. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying
- 30 prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis.
- 31 1987;40:373–83.
- 32 23. Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi J-C, et al. Coding
- Algorithms for Defining Comorbidities in ICD-9-CM and ICD-10 Administrative Data:
 Medical Care. 2005;43:1130–9.
- 24. Cole SR, Hernan MA. Constructing Inverse Probability Weights for Marginal Structural
 Models. American Journal of Epidemiology. 2008;168:656–64.
- 37 25. Cameron AC, Trivedi PK. Microeconometrics using Stata. Rev. ed. College Station, Tex:
- 38 Stata Press; 2010.

- 1 26. R Core Team. R: A Language and Environment for Statistical Computing [Internet].
- 2 Vienna, Austria: R Foundation for Statistical Computing; 2020. Available from:
- 3 https://www.R-project.org/
- 4 27. Turley RS, Mi X, Qualls LG, Vemulapalli S, Peterson ED, Patel MR, et al. The Effect of
- 5 Clinical Care Location on Clinical Outcomes After Peripheral Vascular Intervention in
- 6 Medicare Beneficiaries. JACC: Cardiovascular Interventions. 2017;10:1161–71.
- 7 28. Alimi Y, Hauguel A, Casbas L, Magnan P-E, Pin J-L, Sabatier J, et al. French Guidelines
- 8 for the Management of Ambulatory Endovascular Procedures for Lower Extremity Peripheral
- 9 Artery Disease. Annals of Vascular Surgery [Internet]. 2019 [cited 2019 Jul 17]; Available
- 10 from: http://www.sciencedirect.com/science/article/pii/S0890509619303498
- 11 29. Rockley M, Kobewka D, Kunkel E, Nagpal S, McIsaac DI, Thavorn K, et al.
- 12 Characteristics of high-cost inpatients with peripheral artery disease. J Vasc Surg. 2020;
- 13
- 14



1

2 Fig. 1 Flow diagram for the selection of comparable hospital stays for outpatient and inpatient

3 lower limb stenting in patients with LEAD



2 Fig. 2 Daily percentage of all-cause hospitalizations (planned and unplanned readmissions)

3 after the index LEAD endovascular stenting in the outpatient and inpatient groups (n=2,874)





3 stenting in the outpatient and inpatient groups (n=655)

Supplementary Information

- 1 2 3 4 Hospitalization and death in the first 30 days after outpatient lower extremity arterial
- stenting

5 Supplementary Table 1: Medical procedure (CCAM) for inclusion of LEAD patients

6

CCAM	LABEL			
DGLF001	Aortobisiliac bifurcated stent-graft stent placement by transcutaneous arterial approach			
DGLF002	Aorto-uniiliac covered stent, transcutaneous arterial			
EDAF003	Intraluminal dilatation of the common iliac artery and / or external iliac artery with stenting, by transcutaneous arterial approach			
EDAF006	Intraluminal dilatation of the internal iliac artery with stenting, transcutaneous artery			
EDLF004	Stent-graft placement in the common iliac artery and / or the external iliac artery with embolization of the internal iliac artery by transcutaneous arterial delivery			
EDLF007	Stent-graft placement in the internal iliac artery or extradigestive branch of the abdominal aorta via the transcutaneous arterial approach			
EDPF006	Recanalization of the common iliac artery and / or the external iliac artery with stent graft placement, transcutaneous arterial			
EEAF002	Intraluminal dilatation of a lower extremity artery with intraluminal dilatation of the common iliac artery and / or the ipsilateral external iliac artery with stenting, by the transcutaneous arterial approach			
EEAF004	Intraluminal dilatation of a lower extremity artery with stent grafting by transcutaneous arterial artery			
EEAF006	Intraluminal dilatation of several lower extremity artery with stent graftings by transcutaneous arterial artery			
EELF002	Stent-graft placement in lower extremity artery via transcutaneous arterial approach			
EEPF001	Recanalization of a lower extremity artery with stenting, by transcutaneous arterial approach			

Supplementary Table 2: Medical procedures (CCAM) and associated diagnosis precluding outpatient surgery for exclusion of LEAD patients.

CCAM – procedure code	GROUP LABEL	
DDAF003, DDAF004, DDAF006, DDAF007, DDAF008,	Dilatation of coronary artery	
DDAF009, DDPF002	with stenting	
DDAF001, DDAF010, DDFF001, DDFF002	Dilatation of coronary artery	
	without stenting	
DDQH009, DDQH010, DDQH011, DDQH012, DDQH013,	Coronary artery imaging and	
DDQH014, DDQH015, DDQJ001, DDRH001	treatments	
DGAF005, DGAF007, DGAF008, DGLF001, DGLF002,	Dilatation of coronary artery,	
DGLF005, DGPF001, DGPF002, DHAF004	abdominal or arterial bypass	
	toward lower limb	
EBAF001, EBAF010, EBAF011, ECAF001, ECAF002,	Dilation of the carotid artery	
ECAF003, ECAF004, ECJF001, ECLF003, ECLF004		
ECNF001, ECNF002, ECPF002, ECPF003, ECPF005,	Fibrinolysis or thrombectomy	
ECSF002, ECSF004	of upper limb artery	
EDAF001, EDAF005, EDAF007, EDAF008, EDAF009,	Fibrinolysis or thrombectomy	
EDAF010, EDJF002, EDLF004, EDLF006, EDLF007,	of abdominal or aorto-ilio-	
EDPF002, EDPF003, EDPF005, EDPF006	fémoral path	
EDAF001, EDAF005, EDAF007, EDAF008, EDAF009,	Dilatation of renal or digestive	
EDAF010, EDJF002, EDLF004, EDLF006, EDLF007,	artery	
EDPF002, EDPF003, EDPF005, EDPF006		
EDSF004, EDSF005, EDSF009, EDSF010, EDSF012,	Embolization	
EDSF013, EDSF014, EDSF016		
EEJF001, EELF002, EENF001, EENF002, EESF001,	Selective or hyper-selective in	
EESF006, EESF007	situ fibrinolysis or	
	embolization of an artery or	
	arterial bypass	
EFPF001, EGAF002, EGPF001, ENAF001, ENAF002,	Recanalization of the external	
ENFF001, ENNF001, EZAF002	iliac vein or Intraluminal	
	dilation of a non-anatomic limb	
	arterial bypass	
EQLF003, GLLD003, GLLD012, EQLF002, FELF004,	Intensive care unit	
GLLD008, FELF003, JVJF002, DCJB001, JVJF005,		
YYYY015, YYYY020, YYYY001, YYYY002		
ICD10 – associated diagnosis	Diagnosis	
E66*	Obesity	
L97, L984	Chronic ulcer of lower limb	
121, 122, 123, 124	Myocardial infarction	
160, 161, 162, 163, 164	Stoke	
G45	Transient ischemic attack	
I7001, I7021, I7081 and R02	Arteriopathy with gangrene	
M86, A46, L02, L03, L04, L08, L303, L304	Osteomyelitis and skin	
	infection	

Supplementary Table 3: Categorization of rehospitalizations as complications using
 groupage of diagnosis, procedures, grouping of patients by a medical expert

Categories of complications	Diagnostic (ICD10 codes) / Medical procedures CCAM / GHM (patient grouping algorithm based on ICD10 and CCAM codes)				
Endovascular procedure-related					
complication					
hemorrhage	DP: D62, K66.1, T81.0, R57.1, N50.1, Z51.3 or GHM root: 21C05 or 05C18				
aneurysm	DP: I72.*, I77.2 or CCAM: EESE*** EDPA001_EDPA005				
gangrene, ulcer (without amputation)	DP: I70.21, I70.81, L97, R02, S81.8, S91.3 GHM root not in 05C12 or 05C13				
amputation	GHM root: 05C12 or 05C13				
embolism and thrombosis	DP: I74.3, I74.4, I74.5				
lower limb contusion	DP: \$70.0, \$70.1, \$80.0, \$80.1				
lower limb pain	DP: M79.6, M79.65, M79.66				
	CCAM: AJFA001-2-3, AJFC001-2				
sepsis	DP: A41.0, A41.5				
acquired arteriovenous fistula	DP: I70.0				
Heart diseases					
heart failure and circulatory shock	DP: I50, R57.0 or GHM root: 05M09				
other coronary artery diseases	DP: I24, I25 or GHM root: 05M16				
angor	DP: I20 or GHM root: 05M06				
arrhythmia	DP: I44, I45, I47, I48 or				
-	GHM root: 05M08				
myocardial infarction	DP: I21 or				
	GHM root: 05K05, 05M04				
chest pain	DP: R07 or GHM root: 05M13				
cardiac arrest with death	GHM: 05M22E				
Stroke					
Strokes constituted	DP: I60, I61, I63				
	GHM root: 01M30, 01M31, 01M36				
transient ischemic attack	GHM root: 01M15, 01M16				
Other cardiovascular diseases					
peripheral vascular disorder without	GHM root: 05M12				
revascularization					
syncopes and lipothymias	GHM root: 05M05				
phlebitis	DP: I80 or GHM root: 05M07				
high blood pressure	GHM root: 05M15				
pulmonary embolism	GHM root: 04M10				
Other reasons					
other complications related to the	DP: I97.8, T81.7, T82.3, T82.7, Z09.0, Z48.0, Z48.8 or				
procedure	CCAM: EDCA004, EEGA001-2				
DP: principal diagnosis : CCAM Franch nomenclature of modical procedures : CUM: homegoneous					

DP: principal diagnosis ; CCAM French nomenclature of medical procedures ; GHM: homogeneous group of patients

1 Supplementary Table 4: Characteristics of patients and hospitals at the index

2 endovascular revascularization after propensity score weighting

	Outpatients (n = 2.819)	Inpatients (n = 23.896)	Standardized differences ^a
Age in years (mean ± SD)	67.37 (10.73)	67.74 (11.52)	0.033
Women – n (%)	738.3 (26.1)	6324.3 (26.5)	0.009
Comorbidities – n (%)			
Myocardial infarction	142.2 (5.0)	1140.2 (4.8)	0.012
Congestive heart failure	288.3 (10.2)	1843.9 (7.7)	0.086
Stroke (hemiplegia excluded)	159.3 (5.6)	1228.3 (5.1)	0.021
Dementia	26.3 (0.9)	167.2 (0.7)	0.026
Chronic obstructive pulmonary disease	299.3 (10.6)	2083.1 (8.7)	0.063
Connective tissue disease	11.3 (0.4)	126.2 (0.5)	0.019
Peptic ulcer	6.3 (0.2)	90.2 (0.4)	0.028
Mild liver failure	1992.3 (70.4)	16600.9 (69.5)	0.019
Diabetes without complications	32.0 (1.1)	235.1 (1.0)	0.014
Diabetes with organ damage	330.2 (11.7)	2489.9 (10.4)	0.040
Hemiplegia	29.2 (1.0)	183.7 (0.8)	0.028
Moderate or severe kidney failure	150.1 (5.3)	1044.3 (4.4)	0.043
Cancer	78.7 (2.8)	646.8 (2.7)	0.004
Moderate or severe liver failure	10.1 (0.4)	67.2 (0.3)	0.013
Metastatic solid tumor	13.0 (0.5)	94.2 (0.4)	0.010
HIV with or without AIDS	8.5 (0.3)	55.7 (0.2)	0.013
Year of intervention - n (%)			0.040
2013 ь	658.2 (23.2)	5600.1 (23.4)	
2014	806.2 (28.5)	7187.9 (30.1)	
2015	895.0 (31.6)	7241.3 (30.3)	
2016°	472.2 (16.7)	3865.9 (16.2)	
Number of interventions by hospital activity level ^d			0.082
≤ 100	189.7 (6.7)	1716.6 (7.2)	
100-200	692.6 (24.5)	5241.4 (21.9)	
200-300	359.0 (12.7)	3422.1 (14.3)	
300-400	446.6 (15.8)	3982.5 (16.7)	
400-500	219.5 (7.8)	1643.5 (6.9)	
> 500	924.3 (32.6)	7889.0 (33.0)	

Supplementary Figure 1: Number of deaths and postsurgical acute care hospitalizations for complications after LEAD endovascular stenting, whatever the clinical setting (n=1, 267)



