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

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1 **Original article**

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

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6

7 **Short title:** Early adverse events after outpatient lower limb stenting

8

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1 **Abstract**

2 **Purpose** To compare the safety of outpatient versus inpatient endovascular treatment of lower
3 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 \pm 10.68 *versus* 68.10 \pm 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]).

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

23

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

26

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 ≥ 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

1 determine the early readmission and death rates after inpatient and outpatient endovascular
2 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,
20 inpatients with features that would have precluded outpatient surgery were excluded (Fig. 1).
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

1 the hospital activity, defined by the number of LEAD revascularization procedures performed
2 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***

18 The patients' characteristics were described for the outpatient and inpatients groups. Age was
19 presented as mean and standard deviation. Sex, comorbidities, and year of intervention were
20 described using numbers and percentages. The absolute and relative frequencies of
21 interventions were reported by hospital activity level to highlight any hospital size effect.
22 To determine differences between groups, the standardized difference method was used with
23 the following thresholds for significant differences: low [0.2-0.3[, moderate [0.3-0.8], and high
24 >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***

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

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

20 All p values $< .05$ were considered statistically significant. Data management and statistical
21 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).

24 After applying the exclusion criteria, 26 716 hospital stays were considered as potentially

1 eligible for outpatient management. The propensity score could not be calculated for one
2 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***

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

17 Within 30 days after discharge, 2 799 patients ($n = 281$ outpatients, 9.9%, and $n = 2 518$
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
24 of these hospitalizations were for LEAD endovascular procedures ($n = 1 075$; 66.9%),

1 revascularization by open surgery for LEAD (n = 443; 27.6%), or other revascularization
2 interventions (n = 89; 5.5%). These 1 607 (55.9%) hospitalizations were qualified as
3 “planned”. The remaining 1 267 (44.1%) hospitalizations were qualified as “unplanned” and
4 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***

1 In total, 18 (0.7%) patients died within 3 days after discharge, all of them in the inpatient
2 group (Table 2). The hospitalization rates within 3 days were comparable between inpatients
3 (n = 266; 1.1%) and outpatients (n=22; 0.78%)(p = .45). Among these early readmissions,
4 38% were classified as complementary revascularization procedures (38 angioplasties and 37
5 revascularization surgeries) and possibly planned interventions. Compared with the 30-day
6 hospitalizations, early readmissions for complications were more frequently related to the
7 endovascular procedure than to cardiovascular comorbidities (23% and 19%, respectively).

8 *Effect of outcome definition changes*

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

16

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
13 characteristics.

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

1 epidemiological and public health studies [20]. The second strength is the longitudinal
2 dimension over a 3-year period allowing the recording of the rare events that are
3 complications after endovascular surgery. Third, the propensity score weighting based on the
4 patient's comorbidity helped matching the two groups in the context of a real-life dataset.
5 Finally, this study demonstrates the interest of analyzing real-life data to complement the
6 findings of randomized trials, such as AMBUVASC, on the safety of outpatient surgery.
7
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

1 overestimation of the complication rate [27]. Finally, few socio-demographic data are
2 available in our database. For instance, social isolation, which is an exclusion criterion for
3 outpatient care due to the potential risk of postoperative complications, could not be
4 considered. Socially isolated patients should have been only in the inpatient group, but we
5 could not identify them and thus we may have overestimated the number of comparable
6 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.

16

1 **Author contributions**

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

7

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12

13 **Compliance with Ethical Standards**

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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
23 approved by the Institutional Review Board of the SNDS (agreement #201) and the National
24 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.

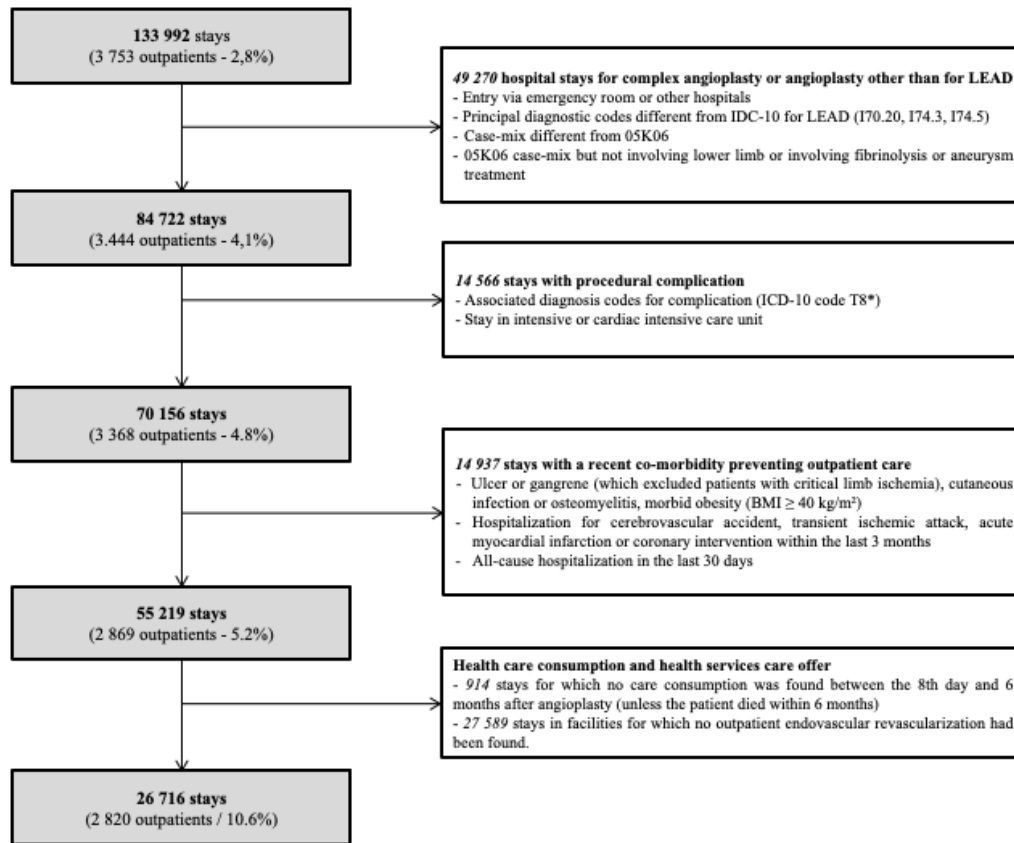
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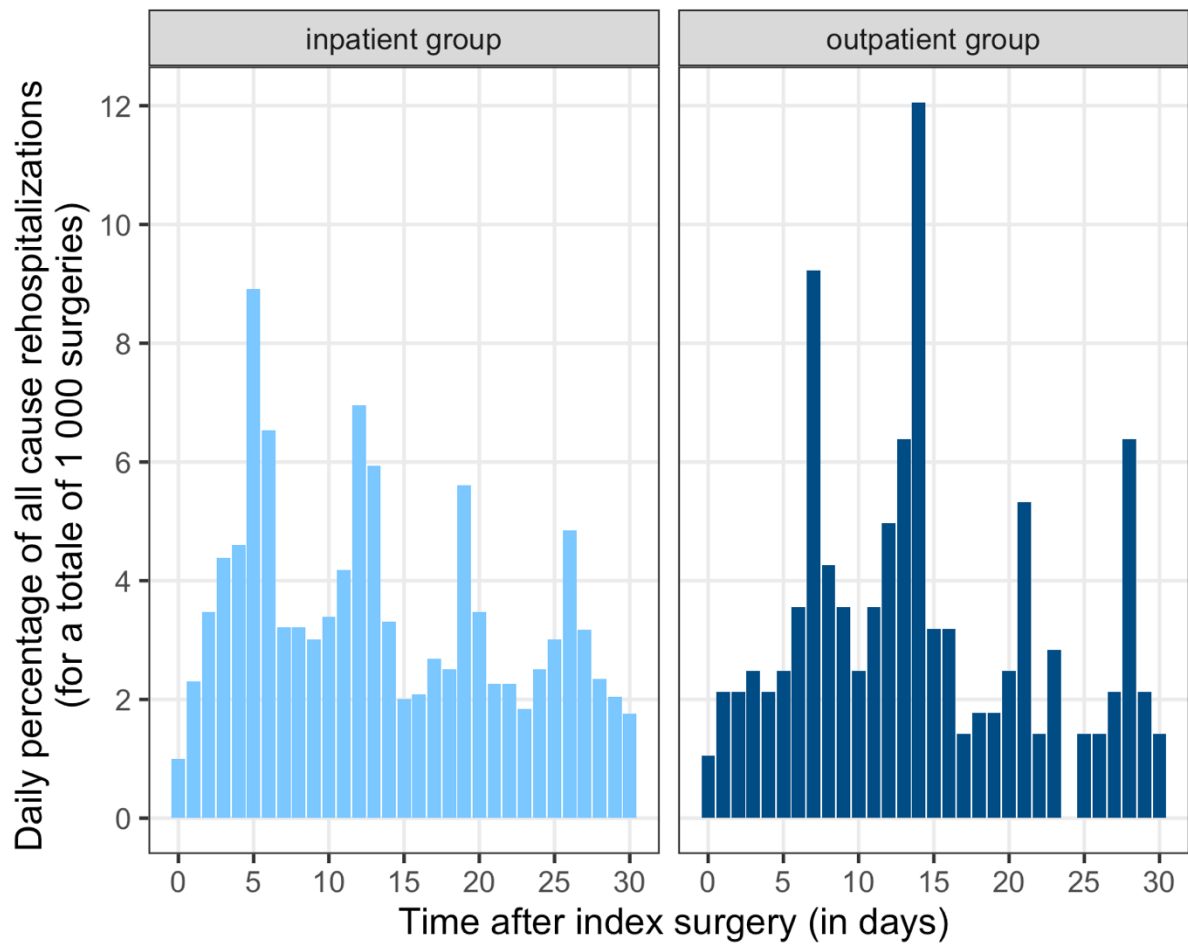
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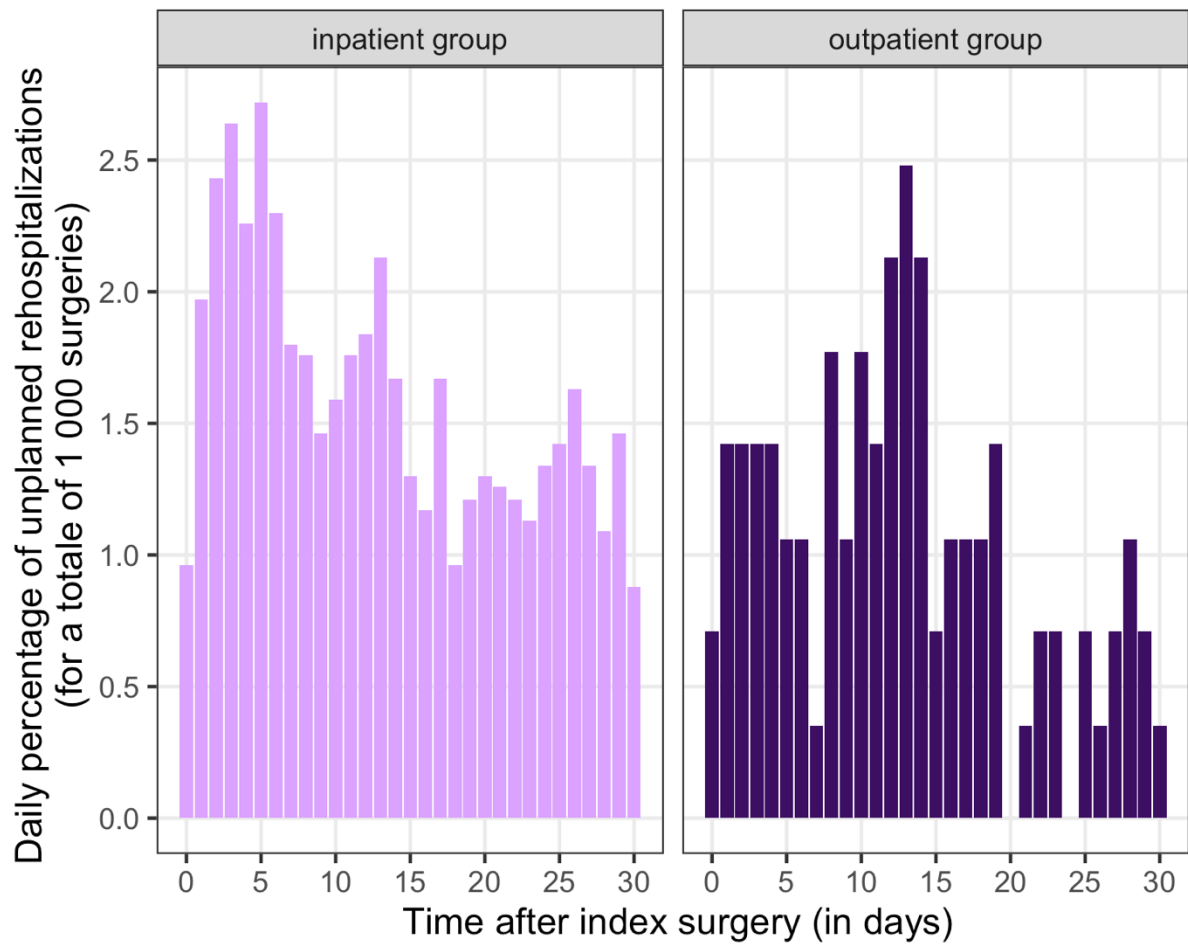
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2 **Fig. 1** Flow diagram for the selection of comparable hospital stays for outpatient and inpatient
3 lower limb stenting in patients with LEAD



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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)



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2 **Fig. 3 :** Daily percentage of unplanned hospitalizations after the index LEAD endovascular
 3 stenting in the outpatient and inpatient groups (n=655)

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1 *Supplementary Information*

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

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

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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

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1 **Supplementary Table 2: Medical procedures (CCAM) and associated diagnosis**
 2 **precluding outpatient surgery for exclusion of LEAD patients.**
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CCAM – procedure code	GROUP LABEL
DDAF003, DDAF004, DDAF006, DDAF007, DDAF008, DDAF009, DDPF002	Dilatation of coronary artery with stenting
DDAF001, DDAF010, DDFF001, DDFF002	Dilatation of coronary artery without stenting
DDQH009, DDQH010, DDQH011, DDQH012, DDQH013, DDQH014, DDQH015, DDQJ001, DDRH001	Coronary artery imaging and treatments
DGAF005, DGAF007, DGAF008, DGLF001, DGLF002, DGLF005, DGPF001, DGPF002, DHAF004	Dilatation of coronary artery, abdominal or arterial bypass toward lower limb
EBAF001, EBAF010, EBAF011, ECAF001, ECAF002, ECAF003, ECAF004, ECJF001, ECLF003, ECLF004	Dilation of the carotid artery
ECNF001, ECNF002, ECPF002, ECPF003, ECPF005, ECSF002, ECSF004	Fibrinolysis or thrombectomy of upper limb artery
EDAF001, EDAF005, EDAF007, EDAF008, EDAF009, EDAF010, EDJF002, EDLF004, EDLF006, EDLF007, EDPF002, EDPF003, EDPF005, EDPF006	Fibrinolysis or thrombectomy of abdominal or aorto-ilio-fémoral path
EDAF001, EDAF005, EDAF007, EDAF008, EDAF009, EDAF010, EDJF002, EDLF004, EDLF006, EDLF007, EDPF002, EDPF003, EDPF005, EDPF006	Dilatation of renal or digestive artery
EDSF004, EDSF005, EDSF009, EDSF010, EDSF012, EDSF013, EDSF014, EDSF016	Embolization
EEJF001, EELF002, EENF001, EENF002, EESF001, EESF006, EESF007	Selective or hyper-selective in situ fibrinolysis or embolization of an artery or arterial bypass
EFPF001, EGAF002, EGPF001, ENAF001, ENAF002, ENFF001, ENNF001, EZAF002	Recanalization of the external iliac vein or Intraluminal dilation of a non-anatomic limb arterial bypass
EQLF003, GLLD003, GLLD012, EQLF002, FELF004, GLLD008, FELF003, JVJF002, DCJB001, JVJF005, YYYY015, YYYY020, YYYY001, YYYY002	Intensive care unit
ICD10 – associated diagnosis	Diagnosis
E66*	Obesity
L97, L984	Chronic ulcer of lower limb
I21, I22, I23, I24	Myocardial infarction
I60, I61, I62, I63, I64	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

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1 **Supplementary Table 3: Categorization of rehospitalizations as complications using**
 2 **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: EESF***, 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: S70.0, S70.1, S80.0, S80.1
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 revascularization	GHM root: 05M12
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 procedure	DP: I97.8, T81.7, T82.3, T82.7, Z09.0, Z48.0, Z48.8 or CCAM: EDCA004, EEGA001-2

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

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1 **Supplementary Table 4: Characteristics of patients and hospitals at the index**
 2 **endovascular revascularization after propensity score weighting**

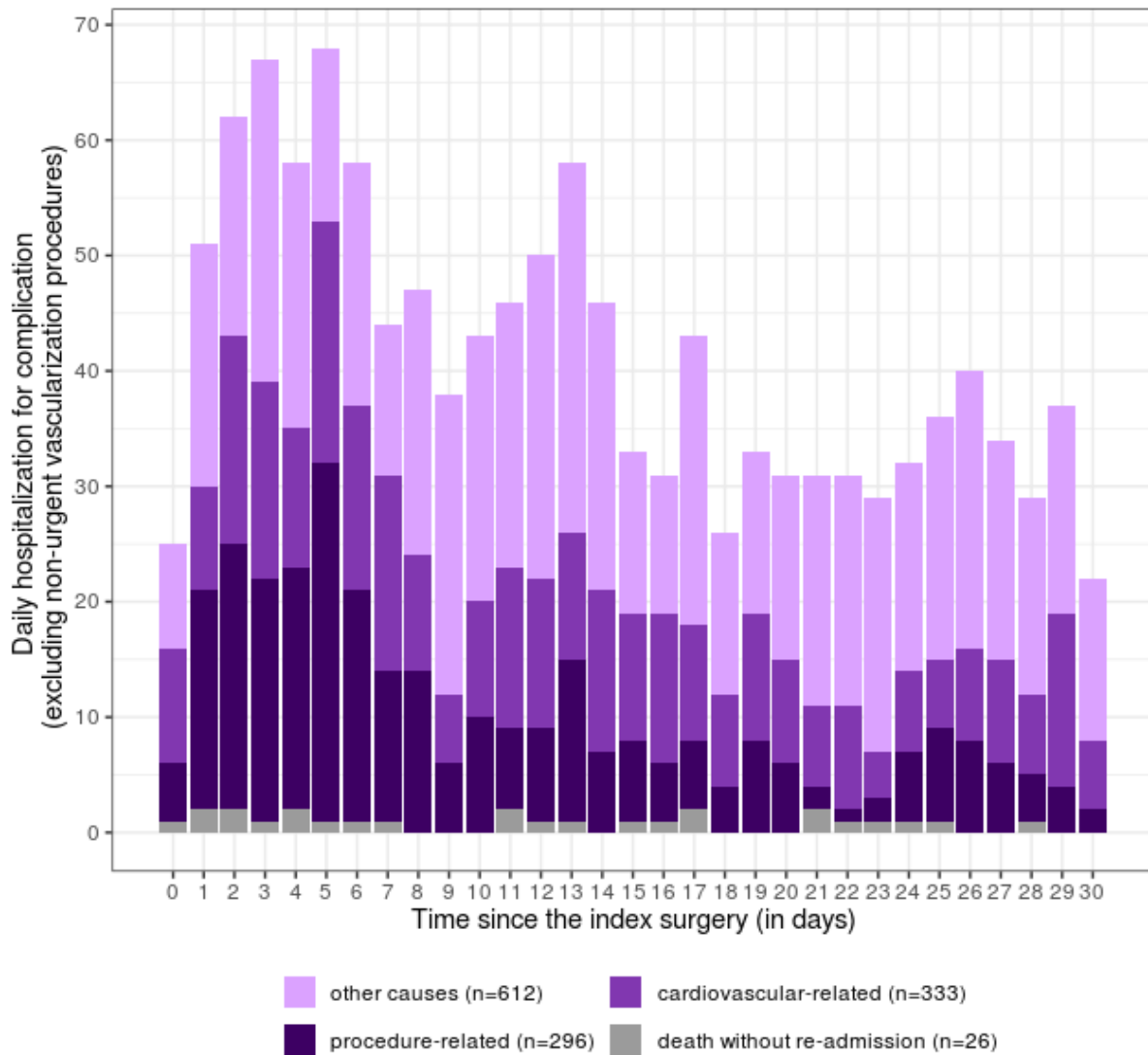
	Outpatients (n = 2.819)	Inpatients (n = 23.896)	Standardized differences ^a
Age in years (mean ± SD)	67.37 (10.73)	67.74 (11.52)	0.033
Women – n (%)	738.3 (26.1)	6324.3 (26.5)	0.009
Comorbidities – n (%)			
Myocardial infarction	142.2 (5.0)	1140.2 (4.8)	0.012
Congestive heart failure	288.3 (10.2)	1843.9 (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 ^b	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 ^c	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)	

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2 **Supplementary Figure 1: Number of deaths and postsurgical acute care hospitalizations**
3 **for complications after LEAD endovascular stenting, whatever the clinical setting (n=1,**
4 **267)**

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