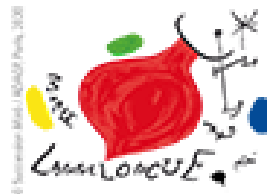


# One day or one night hospital stay for percutaneous angioplasty for PAD patients?

**Y. Gouëffic, MD, PhD**

*Department of vascular and endovascular surgery  
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GROUPE  
HOSPITALIER  
PARIS  
SAINT-JOSEPH



# Disclosures

**Y. Gouëffic** reports:

- **Research funding from** Abbott, General Electric, Veryan, WL Gore
- **Personal fees and grants from** Abbott, Bard, Biotronik, Boston Scientific, Cook, General Electric, Medtronic, Penumbra, Terumo, Veryan, WL Gore (medical advisory board, educational course, speaking)

# Lower arterial extremity disease

**Claudication**



**Critical limb ischemia**



# Endovascular repair *should be the first line of treatment for LEAD*

1-Year Results of a Multicenter  
Randomized Controlled Trial Comparing  
Heparin-Bonded Endoluminal to  
Femoropopliteal Bypass

M.P.J. Reijnen, MD, PhD,<sup>a</sup> Laurens A. van Walraven, MD,<sup>b</sup> Wilbert M. Fritschy, MD, PhD,<sup>c</sup>  
M. J. van den Broek, MD, PhD,<sup>d</sup> Clark J. Zeelregts, MD, PhD,<sup>d</sup> M. Suzanna Lemson, MD, PhD,<sup>d</sup>  
J. H. J. B. Smeets, MD, PhD,<sup>e</sup> Suzanne Holewijn, PhD<sup>f</sup>

Is revascularization and limb salvage always the  
best treatment for critical limb ischemia?

Mark R. Nehler, MD,<sup>a</sup> William R. Hiatt, MD,<sup>b</sup> and Lloyd M. Taylor, Jr, MD,<sup>c</sup> Denver, Colo; and Portland, Ore  
Bypass (BASIL): multicenter  
J Vasc Surg 2003;37:704-8.

Stenting or Surgery for De Novo  
Common Femoral Artery Stenosis

Yann Gouëffic, MD, PhD,<sup>a,b,c</sup> Nellie Della Schiava, MD,<sup>d</sup> Fabien Thaveau, MD, PhD,<sup>e</sup> Eugenio Rosset, MD, PhD,<sup>f</sup>  
Jean-Pierre Favre, MD, PhD,<sup>g</sup> Lucie Salomon du Mont, MD,<sup>h</sup> Jean-Marc Alsac, MD, PhD,<sup>i</sup> Réda Hassen-Khodja, MD,<sup>j</sup>  
Thierry Reix, M,  
Bahaa Nasr, M

ORIGINAL ARTICLES

Shifting Paradigms in the Treatment of Lower Extremity  
Vascular Disease

A Report of 1000 Percutaneous Interventions

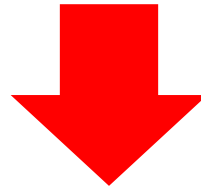
Brian G. DeRubertis, MD, Peter L. Faries, MD, James F. McKinney, MD, Rabih A. Chaer, MD,  
Matthew Pierce, BS, John Karwowski, MD, Alan Weinberg, PhD, Roman Nowygrod, MD,  
Nicholas J. Morrissey, MD, Harry L. Bush, MD, and K. Craig Kent, MD

(Ann Surg 2007;246: 415–424)



## Rationale for same-day discharge

- Increased demand of hospital care (population is aging)
- Hospital budgets constraints (pressure to reduce stay / cost)
- Patients more informed (ask for safe/effective solutions + prompt recovery)



Find ways to optimize the resources, BUT without compromising quality,  
safety and efficiency of patient care

# Issues for the development of outpatients ER for LEAD ?

## **Legal issues**

in case of complications ?

## **Clinical issues**

Safety and efficiency

Lower profile devices 4-5 F

ACD / Manual compression

## **Economic issues**

Societal/hospital perspectives

## **Organization issues**

Ambulatory surgery centers - Office based laboratory procedures

# Guidelines available

## French Guidelines for the Management of Ambulatory Endovascular Procedures for Lower Extremity Peripheral Artery Disease

Yves Alimi,<sup>1,2</sup> Alexandra Hauguel,<sup>3</sup> Laurent Casbas,<sup>4</sup> Pierre-Edouard Magnan,<sup>5</sup> Jean-Luc Pin,<sup>6</sup> Jean Sabatier,<sup>7</sup> Olivier Régnard,<sup>8</sup> and Yann Gouëffic,<sup>3,9,10</sup> On behalf of the French Society of Vascular and Endovascular Surgery (SCVE), Marseille, Nantes, Toulouse, Dijon, Rouen, and Trelaze, France



Société de Chirurgie Vasculaire et Endovasculaire de Langue Française

ARTICLE IN PRESS



Clinical Research

### French Guidelines for the Management of Ambulatory Endovascular Procedures for Lower Extremity Peripheral Artery Disease

Yves Alimi,<sup>1,2</sup> Alexandra Hauguel,<sup>3</sup> Laurent Casbas,<sup>4</sup> Pierre-Edouard Magnan,<sup>5</sup> Jean-Luc Pin,<sup>6</sup> Jean Sabatier,<sup>7</sup> Olivier Régnard,<sup>8</sup> and Yann Gouëffic,<sup>3,9,10</sup> On behalf of the French Society of Vascular and Endovascular Surgery (SCVE), Marseille, Nantes, Toulouse, Dijon, Rouen, and Trelaze, France

**Background:** Ambulatory hospitalization for endovascular repair of lower extremity peripheral arterial disease (PAD) could be a real opportunity to respond to the burden of PAD, to reduce costs, and to improve patients' empowerment. The French Society of Vascular and Endovascular Surgery (SCVE) established guidelines to facilitate the development of ambulatory hospitalization in France.

**Methods:** In 2017, we used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and MEDLINE database to conduct a systematic review of available literature. A total of 448 relevant articles were found. Twelve articles, all published after the year 2000, were included and reviewed by two independent investigators. The SCVE mandated a scientific committee to collectively establish these guidelines.

**Results:** Eligibility for ambulatory management shall be based on the assessment of the triad: (1) patient, (2) procedure, and (3) structure. Comprehensive information and a detailed procedural pathway should be provided for the patient. No age limit is recommended. American Society of Anesthesiologists I, II, and III stable patients are eligible for ambulatory intervention. Specific comorbidities such as severe obesity, sleep apnea, and/or chronic kidney failure should be assessed preoperatively. Critical limb ischemia and complex lesions have not been considered as exclusion criteria. Antiplatelet drug use (aspirin and/or clopidogrel) has not been considered as a contraindication. Femoral ultrasound-guided puncture is recommended. Manual compression or closure devices have been recommended for 7F sheath or less. A minimum of 4 hours of monitoring after percutaneous femoral access is required before discharge.

**Conclusions:** The SCVE guidelines aim to frame the practice of ambulatory endovascular procedures for lower extremity peripheral artery disease and to give vascular interventionalists help in their routine practice.

Financial support and funding: No funding required for this study. No relationships with industry.

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<sup>2</sup>Laboratoire de Biomécanique Appliquée, Faculté de Médecine Nord, UMRT24 IFSTTAR, Aix Marseille Université, Marseille, France.

<sup>3</sup>CHU Nantes, l'institut du thorax, service de chirurgie vasculaire, Nantes, France.

<sup>4</sup>Clinique Sarrus Teinturie, Toulouse, France.

<sup>5</sup>APHM Hôpital La Timone adultes, Marseille, France.

<sup>6</sup>Hôpital privé Dijon-Bourgogne, Dijon, France.

<sup>7</sup>Clinique De L'Europe, Rouen, France.

<sup>8</sup>Clinique St-Joseph, Trelaze, France.

<sup>9</sup>Laboratoire de Physiopathologie de la Réorption Osseuse, Inserm-UN UMR-957, Nantes, France.

<sup>10</sup>Université de Nantes, Nantes, France.

Correspondence to: Pr Yann Gouëffic, CHU de Nantes, service de chirurgie vasculaire, Nantes F-44093, France; E-mail: yann.goueffic@chu-nantes.fr

Ann Vasc Surg 2019; ■: 1–11  
<https://doi.org/10.1016/j.avsg.2019.05.001>

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# Major medical and sociological eligibility criteria

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## Recommendations for eligibility criteria




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| COR | LOE  | Recommendations                                                                                                                                                                                                                                                                                                                         |
|-----|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| I   | C-LD |  1. No limit of age is imposed. The eligibility assessment will be performed on a case-by-case basis, considering physical versus physiological age and socioenvironmental context.                                                                    |
| I   | C-LD |  2. Only ASA I, II, and III stable patients are eligible for ambulatory intervention.                                                                                                                                                                  |
| I   | C-LD |  3. A preoperative assessment of renal function needs to be conducted. If a postoperative hyperhydration is required, the patient should not be eligible for ambulatory intervention, except if intravenous hydration can be organized safely at home. |
| IIa | C-LD |  4. Critical limb ischemia is not considered as an exclusion criterion.                                                                                                                                                                                |
| I   | C-LD |  5. Lesions' complexity is not considered as an exclusion criterion for ambulatory intervention.                                                                                                                                                      |
| IIa | C-LD |  6. In case of anticoagulant therapy, the eligibility will mostly depend on their indication and the patient's risk profile and require a specific evaluation of the risk vs. benefit ratio.                                                         |

---



# Recommendations regarding the procedure

| Recommendations regarding the procedure |      |                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COR                                     | LOE  | Recommendations                                                                                                                                                                                                                                                                                                                                         |
| I                                       | B-NR |  1. Ultrasound-guided femoral artery puncture is recommended.                                                                                                                                                                                                          |
| IIa                                     | C-LD |  2. Radial or brachial approaches can be used in addition to the femoral approach for complex procedures.                                                                                                                                                              |
| IIa                                     | C-LD |  3. The use of percutaneous closure devices is recommended for ambulatory intervention involving 7F or more sheath and/or in the presence of clinical elements raising concerns to get hemostasis at the puncture point (obesity, coagulation disorder, and so forth). |
| IIa                                     | C-LD | 4. For 7F sheaths or less, manual compression with compression dressing or arterial closure device could be considered.                                                                                                                                                                                                                                 |

## Recommendations for postoperative monitoring

| Recommendations for postoperative monitoring |      |                                                                                                                                                                                                                           |
|----------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COR                                          | LOE  | Recommendations                                                                                                                                                                                                           |
| I                                            | B-R  | 1. A minimum of 4 hours of monitoring after the procedure is required to allow patient's discharge from hospital after approved clinical assessment                                                                       |
| I                                            | C-EO | 2. A medical letter reporting the reason for hospitalization, a brief summary of the procedure and potential complications, as well as the detailed prescriptions and scheduled follow-up has to be issued to the patient |
| I                                            | C-EO | 3. Emergency telephone number, reachable 24/7, has to be provided. Phone call or text message, on the day after the procedure, is recommended and might be charted.                                                       |

# Outpatient PAD rate is driven by the DRG



# Gouvernement urges to save money

*In France, for surgery, the outpatient rate was 36.2% in 2009 and 54% in 2016*

## M Santé

SOCIÉTÉ

SANTÉ

Accès aux soins

Accident thérapeutique à Rennes

Addictions

Financement de la san

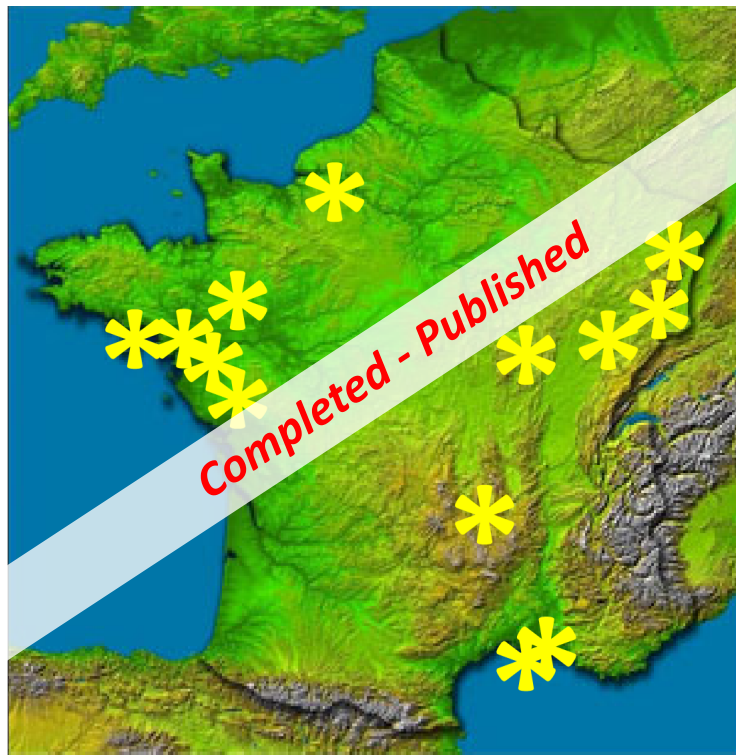
### Buzyn fixe l'objectif de 70 % de la chirurgie réalisée en ambulatoire en 2022

Le recours à l'ambulatoire est encouragé depuis plusieurs années et représente aujourd'hui 54 % des chirurgies.

Le Monde.fr avec AFP | 05.10.2017 à 18h36

# AMBUVASC trial

French multicenter randomized and controlled medico-economic trial to evaluate the cost efficiency of outpatient endovascular vs conventional hospitalization for PAD intervention (



Investigator initiated study

PI: Prof. Yann Gouëffic

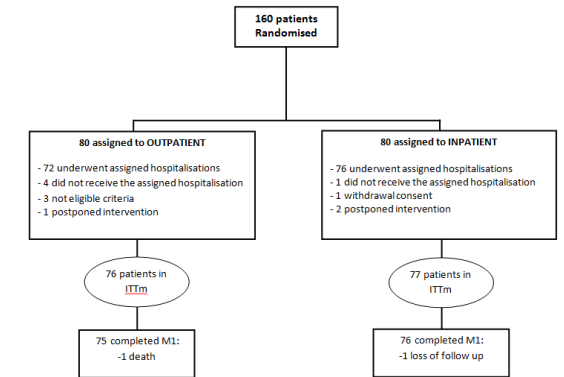
Sponsor: Nantes university hospital

**13 centers** : CHU de Nantes, CHU de Rennes, CH de La Roche sur Yon, CHU de Dijon, CH de Colmar, Clinique de l'Europe, Rouen Clinique Océane, Vannes Clinique de la porte de l'Orient, Lorient CHU de Besançon, CHU de Strasbourg, Hôpital Nord AP-HM La Timone AP-HM, CHU de Saint Etienne.



# AMBUVASC RCT safety

ClinicalTrials.gov Identifier: NCT02581150



|                                           | AMBULATORY<br>(n = 76) | CONVENTIONAL<br>(n=77) | P value |
|-------------------------------------------|------------------------|------------------------|---------|
| Death*, n (%)                             | 1                      | 0                      | NS      |
| Same-day discharge, n (%)                 | 66 (89)                | NA                     | NA      |
| Re-hospitalisation within 24 hours, n (%) | 0                      | NA                     | NA      |
| Reinterventions, n (%)                    | 4 (5)                  | 1 (1)                  | 0.81    |
| Perioperative complications**, n (%)      | 15 (20)                | 14 (18)                | 0.81    |

\* Not related to the device, the procedure or the peripheral arterial disease; \*\* Related to the intra and post operative complications; NA: not applicable; NS: not significant

# Mean costs estimation per item and per patient

## Initial stay

(outpatient vs inpatient)

- Costs of the intervention: 1789•73€ vs 1642•07€

*The difference is mostly due to the mean cost of the arterial closure device*

- Hotel cost: 1 481•39€ vs 1698•79€

## Follow-up

(outpatient vs inpatient)

- All follow-up costs in the conventional hospitalisation arm exceed those of the outpatient arm except for domestic help and rehospitalisation.

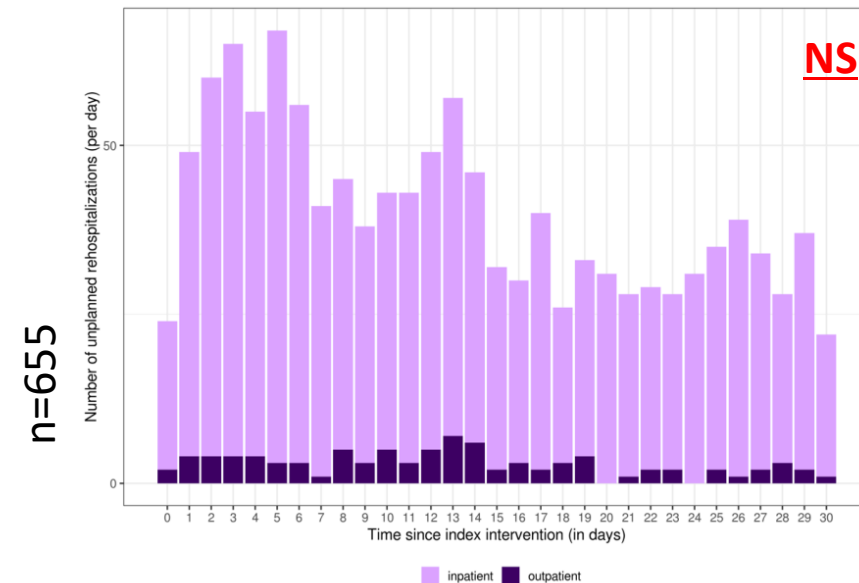
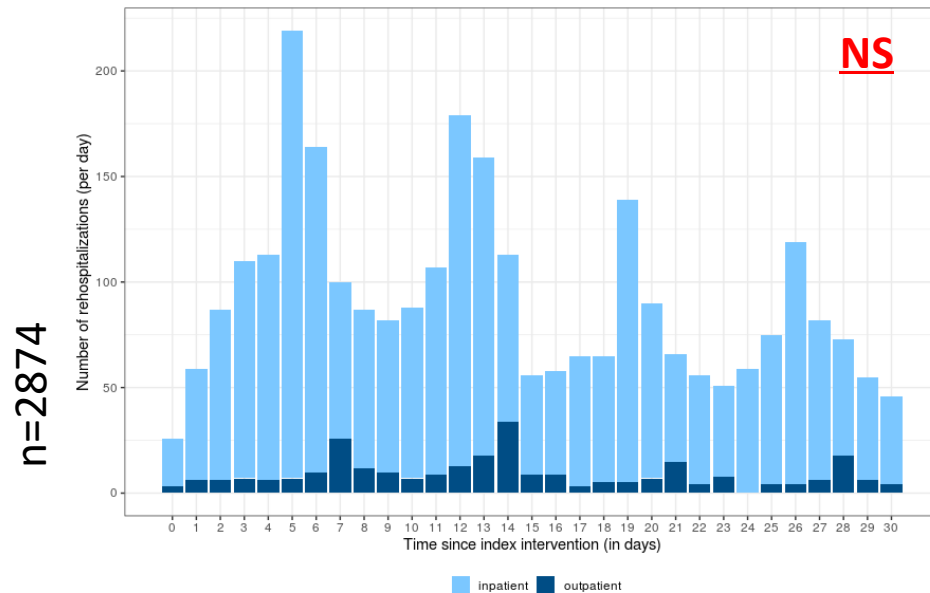
- Re-hospitalisation costs: 302•83€ vs 0€ (*3 re-hospitalisation vs 0*)

Higher **intervention** and **re-hospitalisation** costs the total mean cost per patient of the outpatient procedure exceeds that of conventional hospitalisation by 187•83€ [95% CI -275•68; 651•34]



# Acute care hospitalization and death after LEAD endovascular stenting in outpatient versus inpatient setting in the first 30 days (n=26715)

The death and rehospitalization: 3.5% vs 3.8% (p=.88)



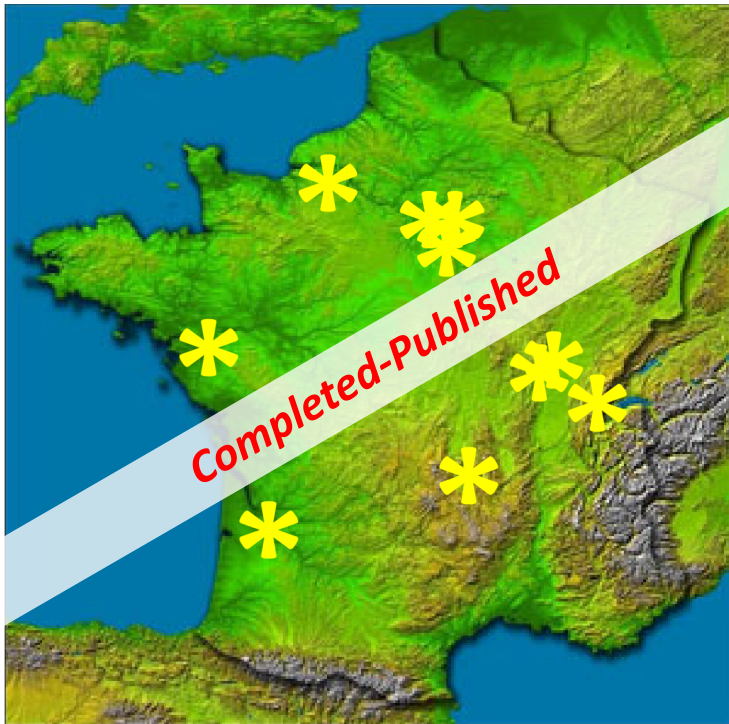
*Retrospective observational study - Real-life data from the French national health data information system  
Endovascular procedures for LEAD between 2013 and 2016 - Propensity score analysis*

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

# FREEDOM OP

French prospective multicenter registry to assess safety and feasibility of femoral manual compression for outpatient endovascular with PAD interventions

(ClinicalTrials.gov Identifier: NCT03185052)



**PI: Prof. Yann Gouëffic**

**Sponsor: Nantes university hospital**

**10 centers : CHU de Nantes; Clinique de Fontaine les Dijon; Clinique de l'Europe; HEGP; CHU Dijon; CHU Clermont-Ferrand; CHU Bordeaux; Hôpital Ambroise Paré; CHU de Besançon; Institut Mutualiste Montsouris**

**5F compatible stents and drug eluting balloon catheters**

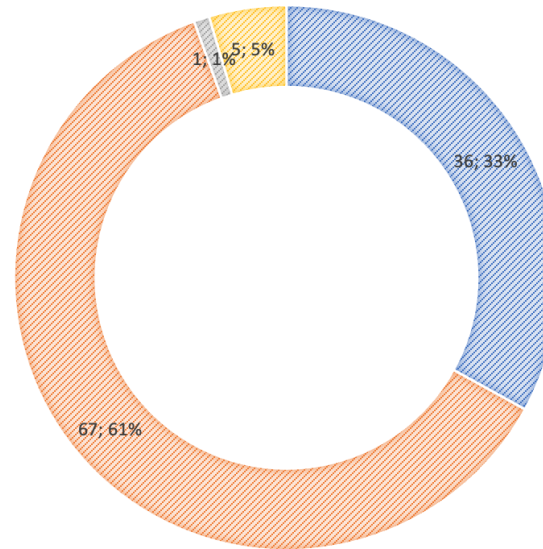
## Inclusions

September 2017 – August 2019

109 patients

Mean age :  $66 \pm 10$  y

Diabetes: 31%



■ 2 ■ 3 ■ 4 ■ 5 ■

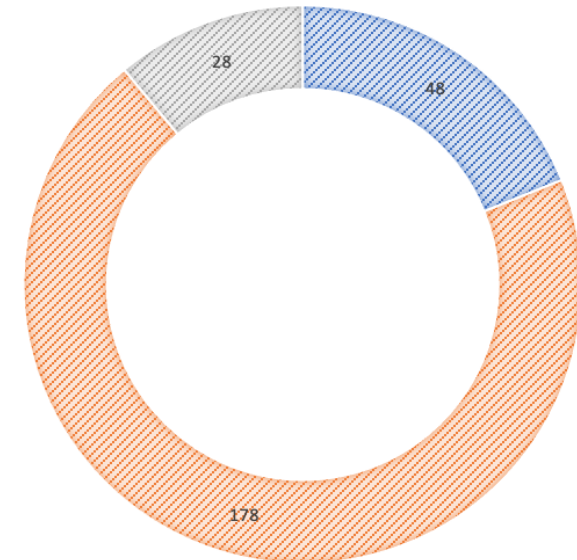
## Procedures

Local anesthesia: 63%

technical success was 97%.

Mean manual compression duration:  $13 \pm 4$  mn

Mean procedure duration:  $65 \pm 32$  mn



■ Lésions iliaques ■ Lésions fémoropoplitées ■ Lésions sous-gonales

## Follow up

- No rehospitalisation was carried out within 24 hours after discharge.
- No major cardiovascular event, including death, was observed.
- The patients were significantly improved in term of clinical status ( $p < 0.0001$ ) and hemodynamic ( $p < 0.0001$ ) in comparison to baseline.

## Freedom OP take home message

FREEDOM OP showed that manual compression is feasible and safe for same-day discharge after LEAD revascularization with 5F sheath femoral approach.

## STEP

French prospective multicenter randomized trial to assess the superiority of Femoseal<sup>®</sup> versus Proglide<sup>®</sup> for endovascular PAD interventions (*PHRC-IR ClinicalTrials.gov Identifier: NCT03192033*)



**PI:** Prof. Yann Gouëffic

**Sponsor:** Nantes university hospital

**6 centers :** CHU de Nantes; CHU d'Angers; CHU de Brest; CHU de Poitiers; CHU de Rennes; CH de la Roche/Yon; Superiority study: Femoseal<sup>®</sup> (Terumo) versus Proglide<sup>®</sup> (Abbott).

## Experimental group: Femoseal®

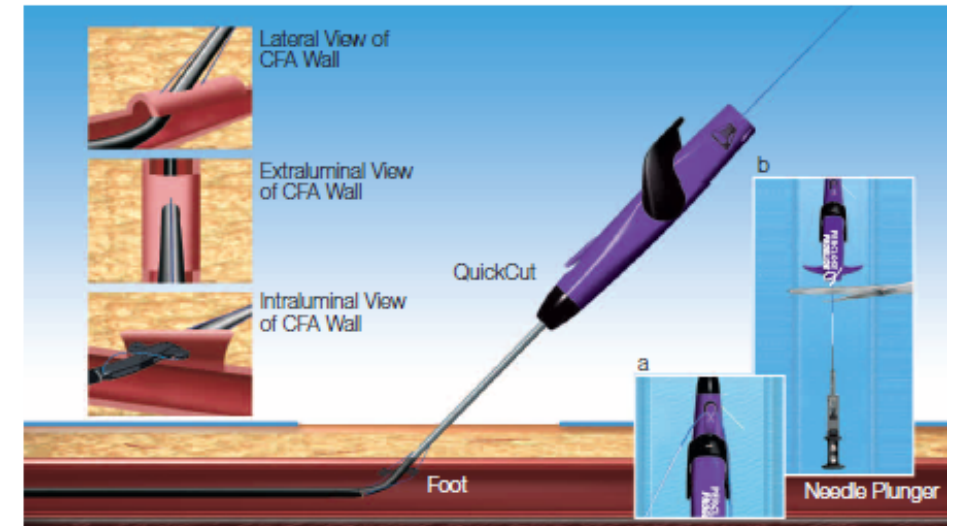
*Terumo Corp., Tokyo, Japan*



The FemoSeal® VCD features a sandwich design: an intraluminal anchor and an extraluminal disc joined by a bioabsorbable suture.

## Control group: ProGlide®

*Abbott Laboratories, Abbott Park, Ill, USA*



The ProGlide® VCD involves a direct suture on either side of the arterial incision site, using a needle and polypropylene thread.



## STEP primary endpoint: VCD technical success

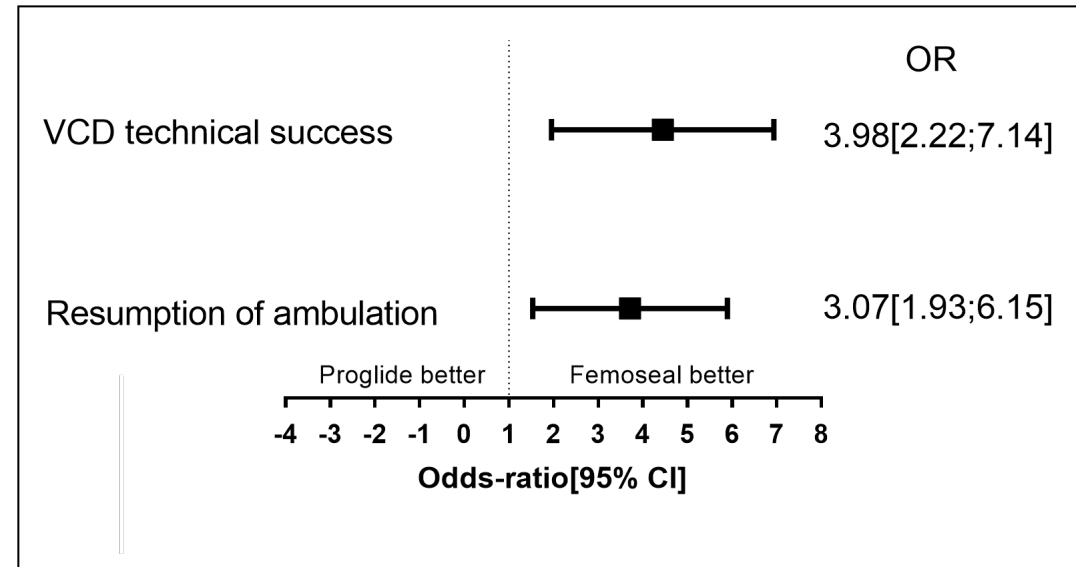
*In ITT analysis, VCD deployment was technically successful in 90 FS (80%) and 58 PG (50%) patients (odds ratio: 3.99; 95%CI: 2.22 to 7.14;  $p < 0.0001$ )*

### Additional VCDs:

FS: 0 patients; PG: 23 patients

### Need for MC:

FS: 19 patients; PG: 45 patients



# The spatial-temporal variations of LEAD endovascular revascularization in outpatient settings

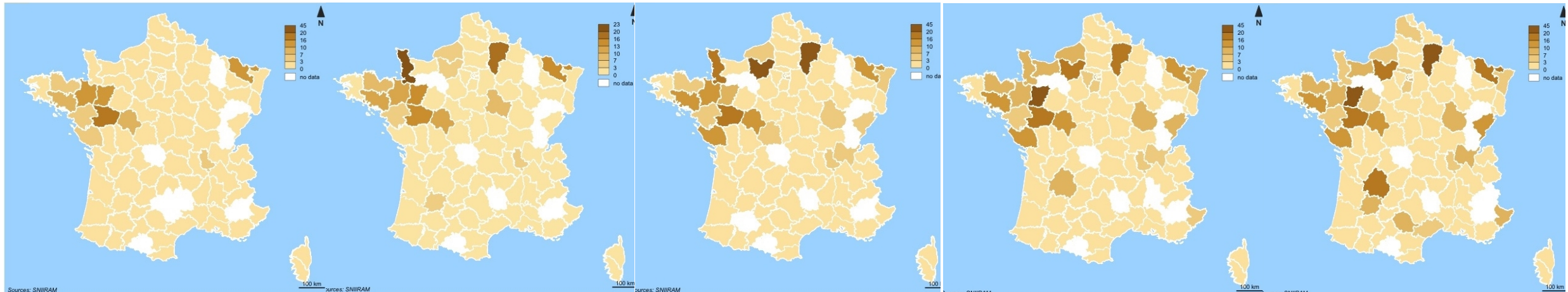
2015

2016

2017

2018

2019



Nevertheless, the percentage of endovascular interventions in outpatient settings remained extremely low in 2015 and 2019, relatively to inpatient: 1.66% and 4.03% respectively.

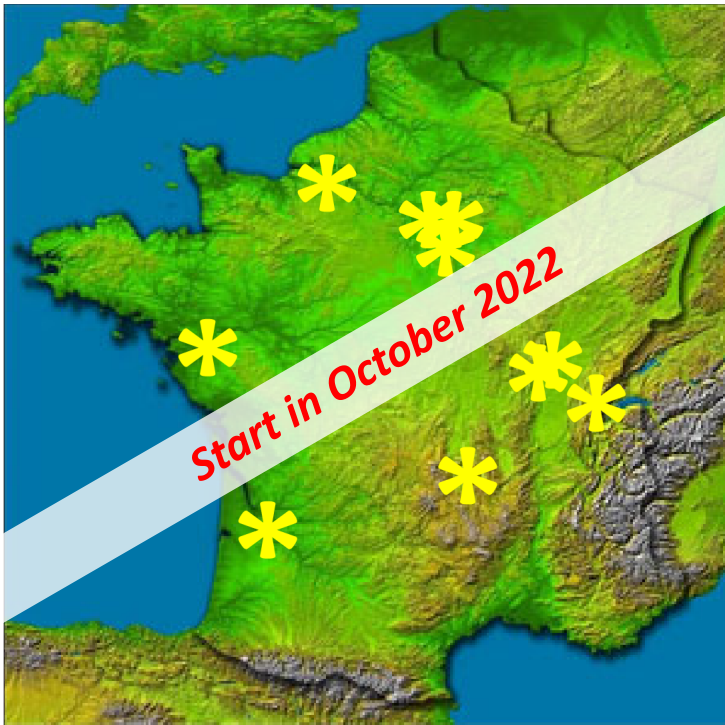
# Contribution of healthcare resources and population characteristics in the development of endovascular LEAD interventions in outpatient setting *(multivariate analysis)*

An increase of the proportion of elderly single-man household **reduces by 38%** the odds for a department to belong to the clusters of significant outpatient activity.

|                                                        | OR [95%CI]       | p-value |
|--------------------------------------------------------|------------------|---------|
| Population characteristics                             |                  |         |
| Proportion of 60 year-old or more                      | 1.40 [1.15-1.69] | 0.001   |
| Venous thromboembolic disease mortality rate           | 1.15 [1.00-1.31] | 0.04    |
| Proportion of single-man household aged 75 or more     | 0.62 [0.39-0.99] | 0.04    |
| Poverty rate of people aged 50 to 59 year-old          | 0.76 [0.56-1.02] | 0.07    |
| Healthcare resources                                   |                  |         |
| Density of care professionals per 100 000 inhabitants: |                  |         |
| pharmacy                                               | 1.04 [0.99-1.09] | 0.07    |
| nurse                                                  | 0.98 [0.97-0.99] | 0.01    |

# ABALONE

*Hospitalisation en AmBulAtoire des patients isoLés à dOmicile pour le traitement de l'artériopathie oblitérante des membres inférieurs par technique endovasculaire*



**PI:** Prof. Yann Gouëffic

**Sponsor:** Groupe hospitalier Paris Saint Joseph

**20 centers**

**2000 patients**

**RCT - Stepped-wedge design**

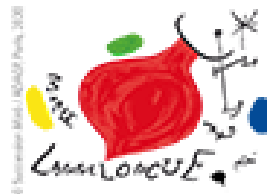
## Take home message

- Outpatient management is **safe** and **efficient**.
- Enforced **patient selection, pre-assessment visits, trained practitioners, adequate structures** and **high quality post-procedure monitoring** to detect early complications are required
- Proper **guidelines** have been settled in order to help vascular experts supervise their practice in the most appropriate and safe conditions.

# One day or one night hospital stay for percutaneous angioplasty for PAD patients?

**Y. Gouëffic, MD, PhD**

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Groupe Hospitalier Paris Saint Joseph, Paris, France.*



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