ABALONE

Hospitalisation en AmBulAtoire des patients isoLés à dOmicile pour le traitement de l'artériopathie oblitéraNte des membres inférieurs par technique endovasculairE

PREPS 2020 - NCT05756491

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Disclosures

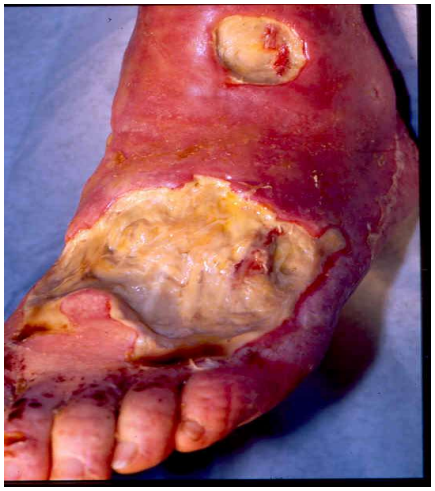
Y. Gouëffic reports:

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

Lower Limb Peripheral Arterial Disease

Claudication

Critical limb threatening ischemia



Aboyans, Eur J Vasc Surg, 2017

Increased demand of hospital care for PAD

Population is aging – Diabetes - Renal insufficiency

*During the preceding decade the number of individuals with PAD, increased by **28.7%** in LMIC and **13.1%** in HIC.*

	People living with peripheral artery disease in year 2000 (thousands)			People living with peripheral artery disease in 2010 (thousands)			Rate of change (2	
	High-income countries	Low-income and middle-income countries	Worldwide	High-income countries	Low-income and middle-income countries	Worldwide	High-income co	Lo mi co
25–29 years	2311	10756	13068	2381	12037	14419	2%	11
30–34 years	2803	11469	14272	2760	12343	15103	-2%	7
35–39 years	3486	11247	14733	3343	13776	17119	-4%	22
40–44 years	4071	11138	15209	3938	14707	18645	-3%	32
45–49 years	4528	11408	15936	4851	14354	19205	7%	25
50–54 years	4907	9902	14808	5503	14100	19603	12%	42
55–59 years	4530	9111	13641	5948	14170	20118	31%	55
60–64 years	5342	9074	14416	6242	11787	18029	16%	29
65–69 years	5287	8416	13704	5547	10124	15670	4%	20
70–74 years	5594	6953	12547	6043	9020	15063	8%	29
75–79 years	4808	4960	9768	5370	7012	12382	12%	41
80–84 years	3107	3015	6123	4723	4396	9118	52	45
85–89 years	2246	1411	3658	3028	2087	5115	34-80%	47
≥90 years	1174	544	1717	1611	864	2474	37-22%	58

Fowkes, Lancet, 2013

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)

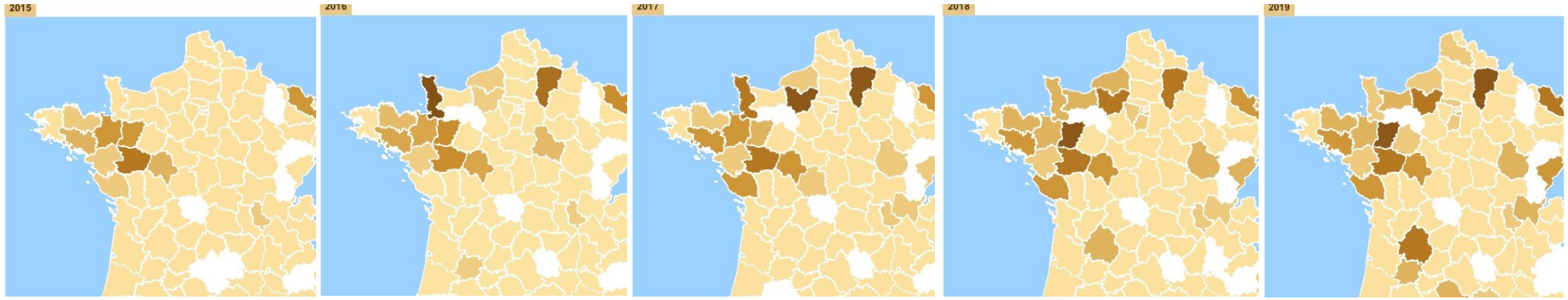
Find ways to optimize the resources, BUT without compromising quality, safety and efficiency of patient care

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

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

Nolwenn Le Meur, Univ Rennes, EHESP, REPERES, EA 7449, F-35000 Rennes, France

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.***

Le Meur, Gouëffic, Eur J Vasc Endovasc Surg, 2022

Issues for the development of outpatients ER for LEAD ?

Clinical issues

Safety and efficiency

Lower profile devices 4-5 F

ACD / Manual compression

Economic issues

Societal/hospital persepctives

Legal issues

in case of complications ?

Organization issues

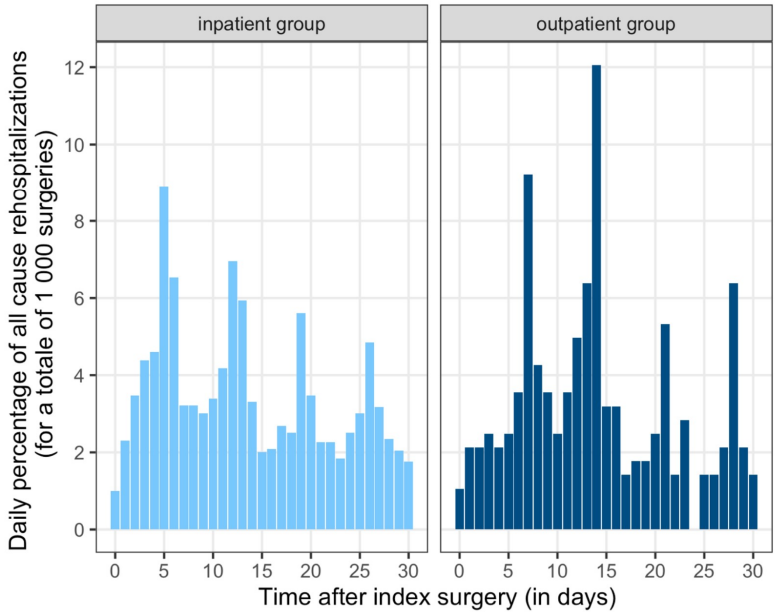
Ambulatory surgery centers - Office based laboratory procedures - Physicians

Outpatient stenting for lower limb PAD did not present any additional risk of early postoperative rehospitalization or death compared with inpatient stenting.

Retrospective observational study with real-life data from the French national health databasse

Patients who underwent stenting for lower limb PAD between 2013 and 2016.
A propensity score was used to control for indication

26 715 interventions / 2 819 (10.6%) outpatient hospitalization



Jan, Gouëffic, Cardiovasc Intervent Radiol, 2022

Guidelines for Outpatient for Lower Limbs PAD

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

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

SCVE | Société de Chirurgie Va: Endovasculaire de Langue

ARTICLE IN PRESS

ELSEVIER

Clinical Research

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

Yves Alimi,[1,2] Alexandra Hauguel,[3] Laurent Casbas,[4] Pierre-Edouard Magnan,[5] Jean-Luc Pin,[6] Jean Sabatier,[7] Olivier Régnard,[8] and Yann Gouëffic,[3,9,10] 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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[3]CHU Nantes, l'institut du thorax, service de chirurgie vasculaire, Nantes, France.
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[7]Clinique De L'Europe, Rouen, France.
[8]Clinique St-Joseph, Trelaze, France.
[9]Laboratoire de Physiopathologie de la Résorption Osseuse, Inserm-UN UMR-957, Nantes, France.
[10]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

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Major medical and sociological eligibility criteria

Recommendations for eligibility criteria		
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.

Alimi, Ann Vasc Surg, 2019

Recommandations 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.

Alimi, Ann Vasc Surg, 2019

Recommandations 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.

Alimi, Ann Vasc Surg, 2019

SFAR guidelines

- American Society of Anesthesiologists status 1-3 (stable)

- Good comprehension and cooperation of the patient with regard to hospitalization

- To spend the first night accompagnied after the procedure alone

- To live <1 hour from a medical facility

- To be reachable by telephone on the day before and after the intervention

- To remain hospitalized in the event of a complication.

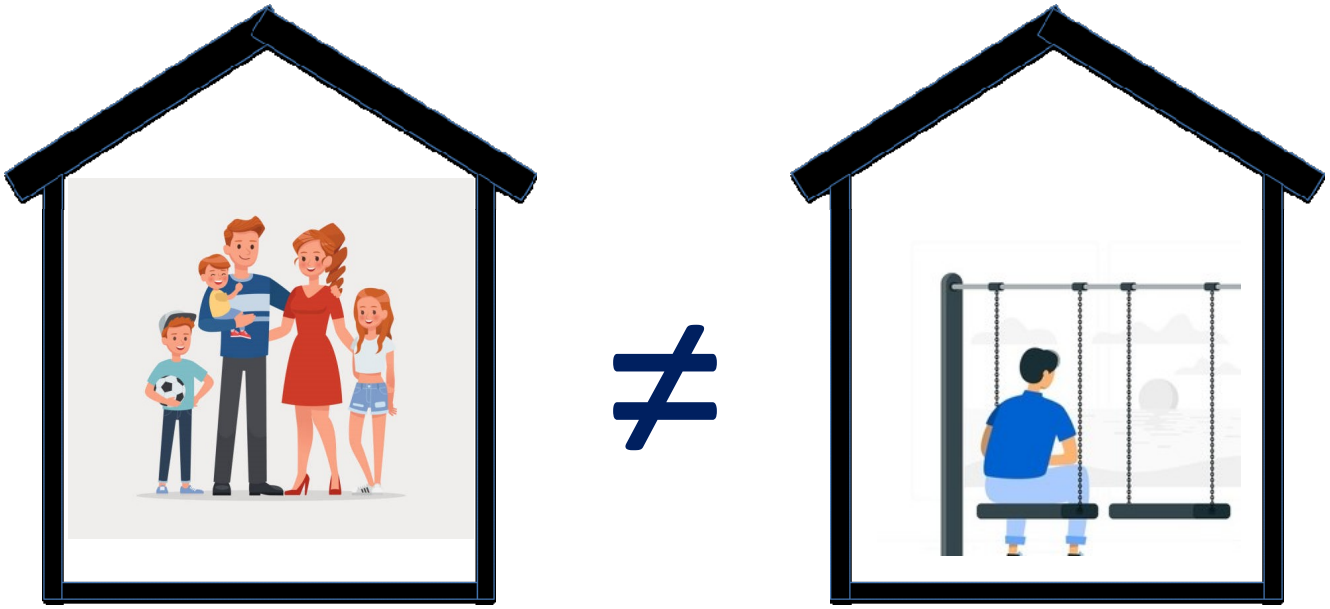
Contribution of healthcare resources and population characteristics in the development of endovascular LEAD interventions in outpatient setting *(multivariate analysis)*

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

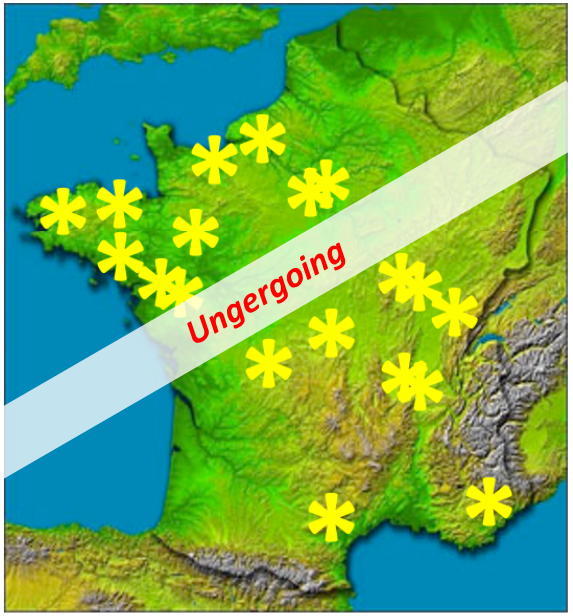
Le Meur, Gouëffic, Eur J Vasc Endovasc Surg, 2022

Isolated patients suffer from a social exclusion and an innovating health care exclusion



ABALONE

Outpatient Hospitalization of Unaccompanied Patients at Home for Endovascular Treatment of Peripheral Arterial Disease. *(PREPS - ClinicalTrials.gov Identifier: NCT05756491)*



PI: Prof. Y. Gouëffic

Methodologist: Prof. G. Chatellier

Sponsor: Groupe Hospitalier Paris Saint Joseph

20 centers: *Hôpital privé du Confluent, Nantes , Clinique Mutualiste de la porte de Lorient, CHU de Nice, CHU de Caen, Centre Hospitalier Saint Grégoire, CHU de Brest, Hôpital Privé Dijon Bourgogne, Clinique Esquirol Saint Hilaire, Agen, Hôpital Universitaire Ambroise Paré, Boulogne Billancourt, CHU de NantesMédipôle Lyon Villeurbanne (Centre de consultation Léon Blum, Villeurbanne ; Centre de consultation Clinique du grand large, Décines), CHU Besançon, Clinique de l'Europe, Rouen, CHU de Clermont Ferrand, #CHU Dijon Bourgogne, Centre Hospitalier de Béziers, Centre Hospitalier, Saint-Brieuc, Hôpital Privé Francheville, Périgueux and* Groupe Hospitalier Paris Saint Joseph

ABALONE

Outpatient Hospitalization of Unaccompanied Patients at Home for Endovascular Treatment of Peripheral Arterial Disease. *(PREPS - ClinicalTrials.gov Identifier: NCT05756491)*

Main objective

The objective of the study is to increase the rate of outpatient hospitalization for the LEAD endovascular repair by including the isolated patients.

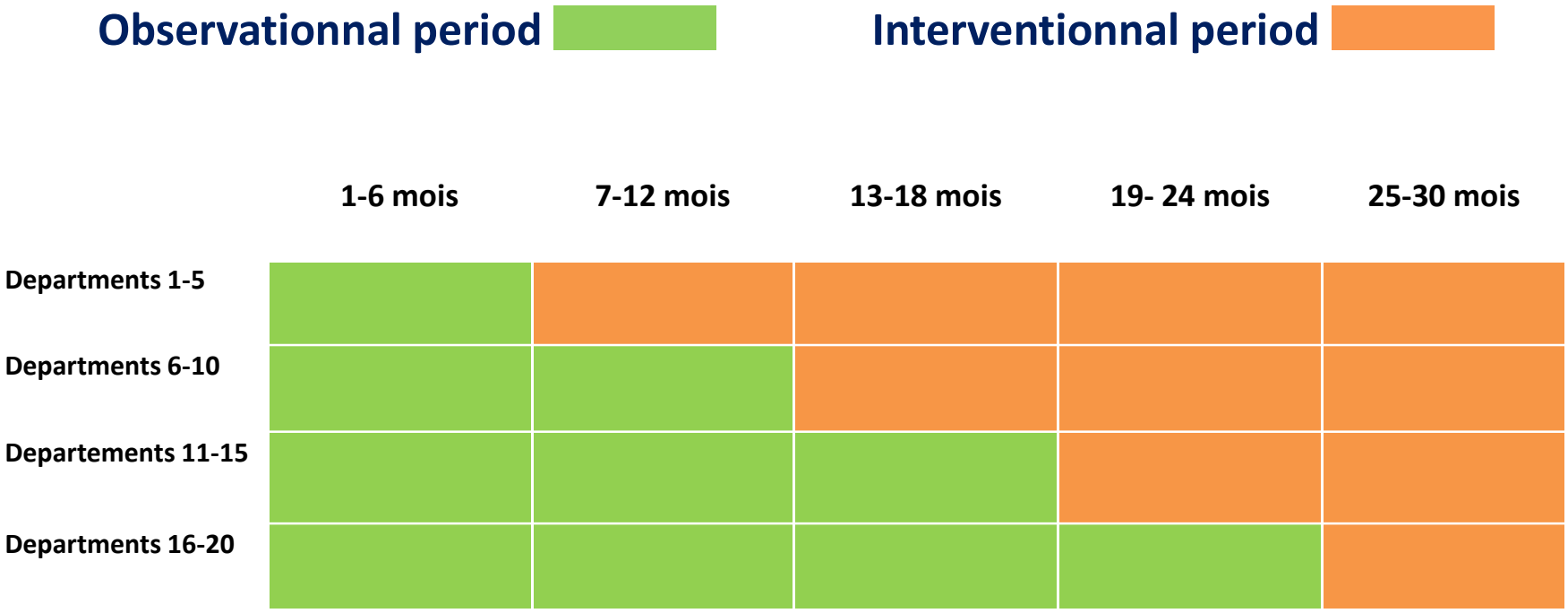
Primary endpoint

The rate of outpatient hospitalization for the LEAD endovascular repair at the end of the intervention period.

The intervention

To allow uncompagnied patient to have access to outpatient hospitalisation

Stepped-wedge design



SeniorAdom, the VYV Group's telecare solution

GROUPE VYV

1st mutual health player in France

3 professions: Health, insurance & retirement / Housing / Care & Support

A reason for being: **the right to health**

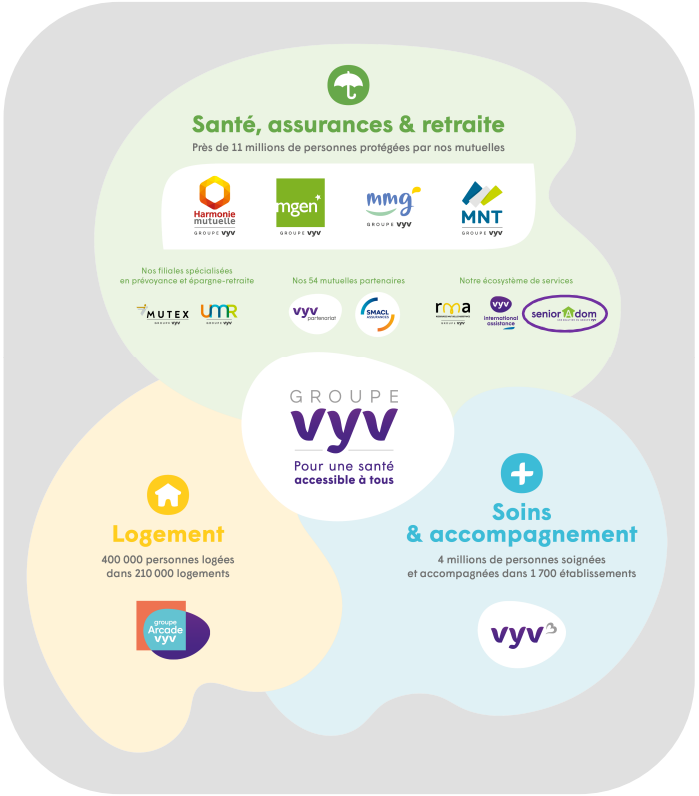
seniorAdom

Created in **2013**

Integrated to the Groupe VYV in **2018**

Innovative telecare solutions

A set of listeners **available 24/7** in mainland France



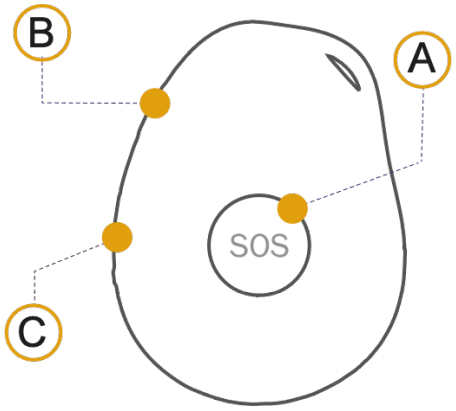
Groupe hospitalier Paris Saint-Joseph
Soignez, accompagnez, innovez, formez

GROUPE VYV

seniorAdom
UNE SOLUTION DU GROUPE VYV

The telecare device « NOMADE »

Remote assistance



A Geolocatable call
B Call button to
C Speakers and microphones

Integrated GPS

Call-in and call-out

Multi-operator Sim card included

Included battery (2 to 7 days battery life)

Geolocation by relatives

Security perimeter: entry and exit of configurable zone

Waterproof button

Groupe hospitalier Paris Saint-Joseph
Soignez, accompagnez, innovez, formez

GROUPE VYV

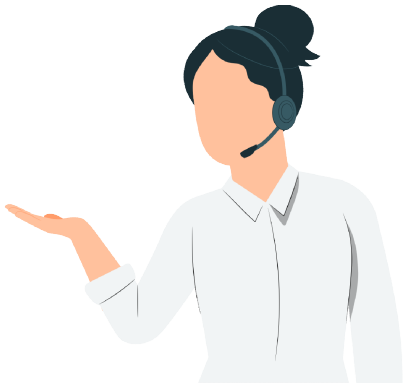
senior Adom
UNE SOLUTION DU GROUPE VYV

The advantages of VYV telecare

The strenght of Groupe VYV

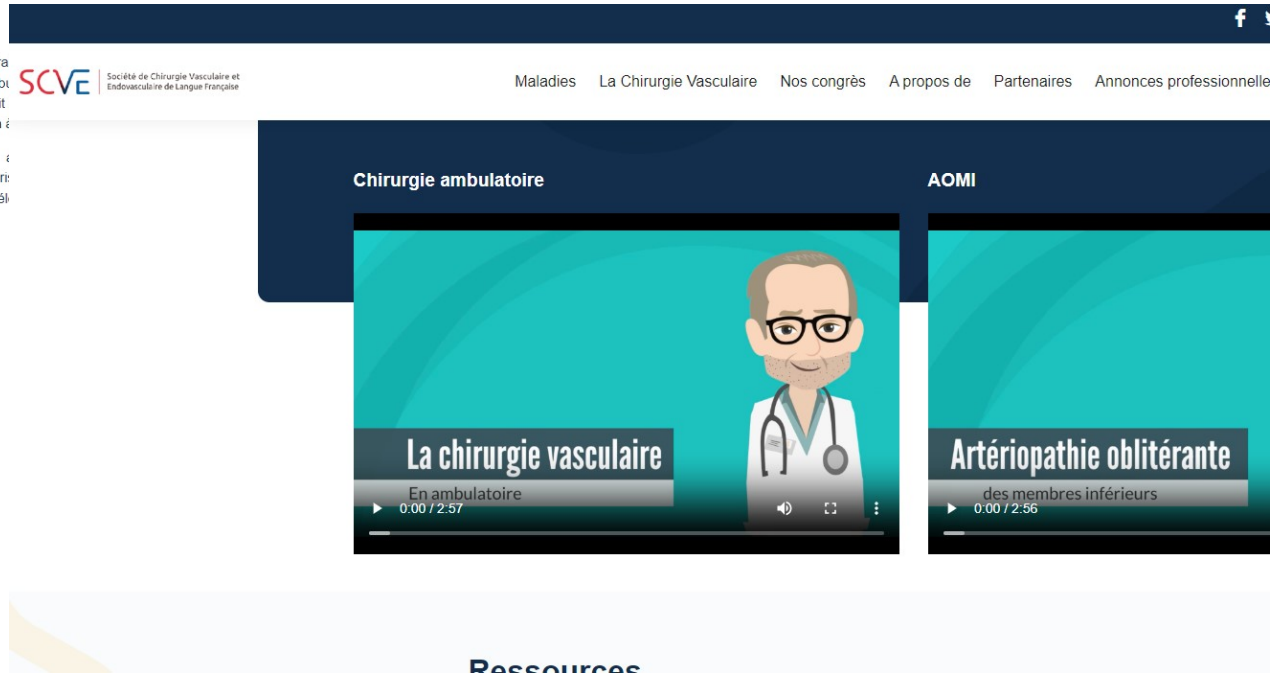
A listening platform **available 24/7**

Listeners **trained specifically in the ABALONE study**

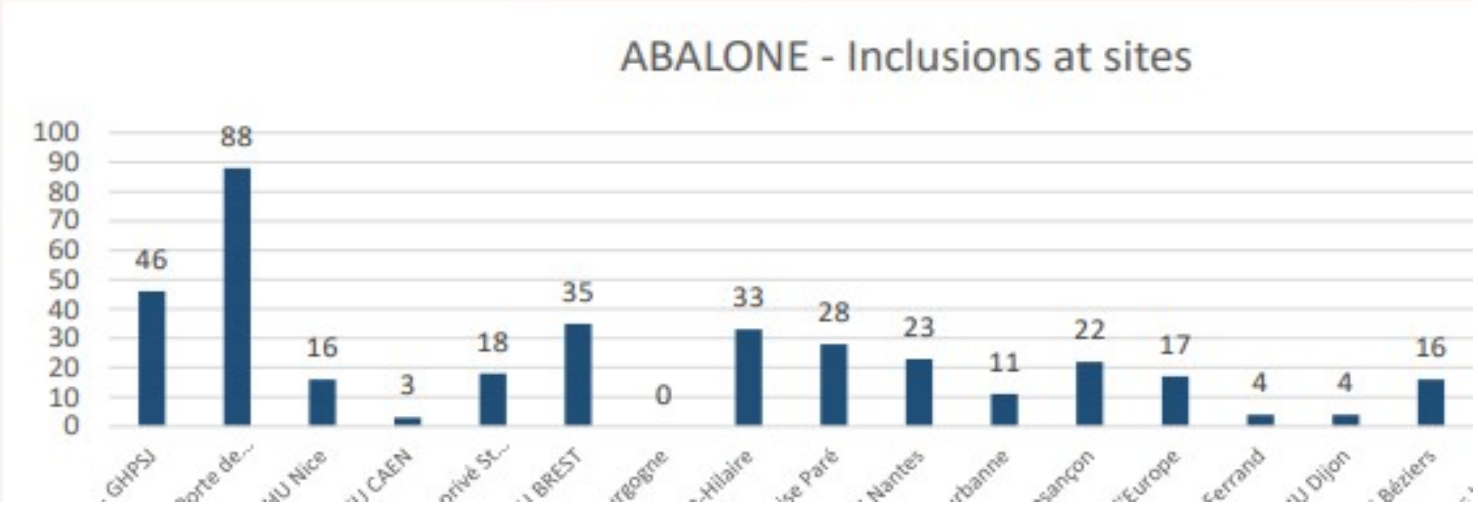


SCVEbinar 2 : ENDOPROTHESES


Espace mem
SCVE
Société de Chirurgie Vasculaire et Endovasculaire de Langue Française
Maladies
La Chirurgie Vasculaire
Nos congrès
A propos de
Partenaires
Annonces professionnelles
Abalone
Nos spo
Protocole
ABALONE
Hospitalisation en ambulatoire des patients non accompagnés à domicile pour le traitement de l'AOMI par technique endovasculaire
Aujourd'hui, la prise en charge d'un tra
des membres inférieurs (AOMI) en ambu
patients qui sont accompagnés la nuit
accompagnant est un critère d'exclusion
Le protocole ABALONE propose
hospitalisation en ambulatoire en sécuri
d'hospitalisation grâce à un service de tél


SCVE
Société de Chirurgie Vasculaire et Endovasculaire de Langue Française
Maladies
La Chirurgie Vasculaire
Nos congrès
A propos de
Partenaires
Annonces professionnelle
Chirurgie ambulatoire
La chirurgie vasculaire
En ambulatoire
0:00 / 2:57
AOMI
Artériopathie oblitérante
des membres inférieurs
0:00 / 2:56
Ressources

Recruitment: Observationnal Phase on 30SEP2023



Take home messages

- Safety of outpatients hospitalization for lower limbs PAD endovascular procedures has been demonstrated.

- SFAR and SCVE guidelines help to prevent post operative complications

- Outpatients hospitalization for lower limbs PAD endovascular procedures could be extended by using dedicated devices and preventing post operating complications

Groupe hospitalier Paris Saint-Joseph
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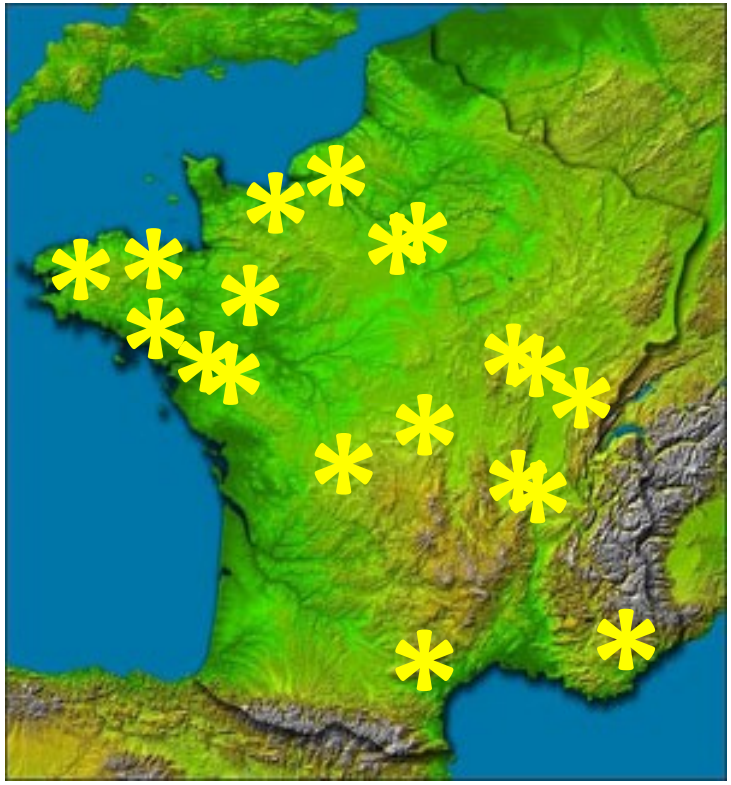
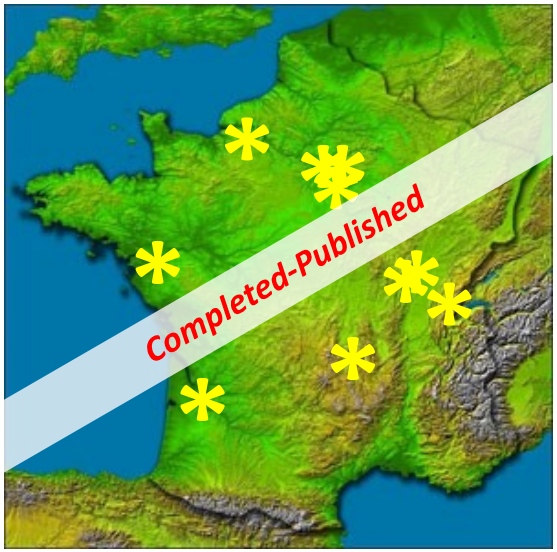


STEP

French prospective multicenter randomized trial to assess the superiority of Femoseal® versus Proglide® 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® (Terumo) versus Proglide® (Abbott).

Gouëffic, Cardiovasc intervent Radiol, 2021

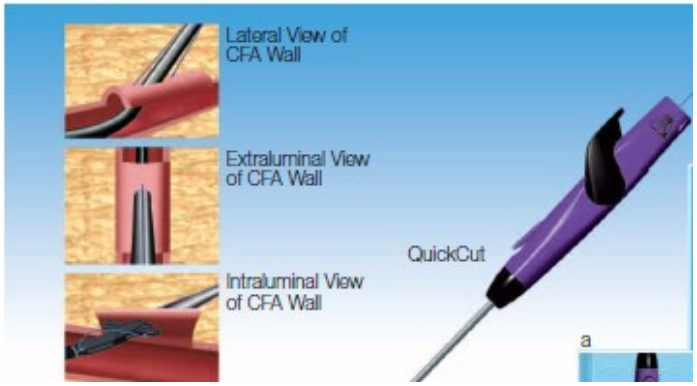
Experiemental group: Femoseal®

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



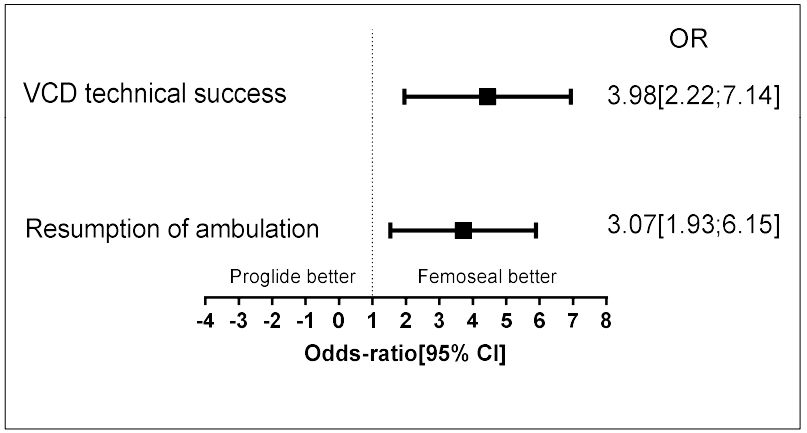
The ProGlide® VCD involves a direct suture on either side of the arterial incision site, using a needle and polypropylene thread.

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



Gouëffic, Cardiovasc intervent Radiol, 2021