Aetiological treatment of venous leg ulcers with compression therapy: real-life outcomes with two different procedures

Objective: To evaluate the healing outcomes and costs associated with the aetiological management of venous leg ulcers (VLUs) treated with recommended multicomponent bandages (MCBs) and short-stretch bandages (SSBs).

Method: This observational study is a retrospective comparative study (Level 2b), based on the French administrative healthcare database (Système National des Données de Santé, SNDS). It includes patients treated from onset with reimbursed MCBs and SSBs for a VLU episode, between July 2018 and September 2020. Although other compression systems, such as long-stretch bandages, are commonly used for the treatment of VLUs, they are not recommended by health authorities in France and thus, were not considered for this study. A binomial regression model was performed to estimate the adjusted relative risk of wound closure rates at three months for each group, based on potential confounding factors including, notably, age, sex, key comorbidities, and wound dressing size. The mean healthcare cost was calculated for patients whose VLUs healed within the study period.

Results: The reimbursement data (including prescribed compression systems and nursing care) of the 25,255 selected patients were analysed in the study. There were no significant differences between the MCBs and SSBs groups when considering patient characteristics. The healing rates after three months' treatment, were 42% and 35% (p<0.001) in the MCBs and SSBs groups, respectively. When adjusting the statistical model, the chance of healing at three months was still 12% higher with MCBs compared with SSBs (p<0.0001). The median healing time was estimated at 115 (interquartile range (IQR): 60–253) days in the MCB group versus 137 (IQR: 68–300) days in the SSBs group. The average treatment cost per patient with a healed ulcer was €2875±3647 in the MCB group and €3580±5575) in the SSBs group (p=0.0179), due to lower hospital stay and nursing costs in the MCB group. Differences in wound characteristics between the two groups cannot be totally excluded, due to the limited content of the database in terms of clinical data, but should have been addressed, to some extent, through the study selection criteria and the chosen regression model.

Conclusion: In this study, this SNDS analysis seemed to confirm that the healing outcomes achieved in real-life with MCBs were in line with those reported in clinical trials, and superior to SSBs, which reinforces the current position from the guidelines.

Declaration of interest: This study was sponsored by a grant from Laboratoires URGO, manufacturers of Urgo K2 (known as UrgoKTwo in the UK). SB, SF and IB are employees of Laboratoires URGO. SM, PS and UM-P have received monetary compensation as a speaker for Laboratoires URGO. Data management and statistical analyses were conducted by Median Conseil (BT, V-AA). The study sponsors had no involvement in the analysis and interpretation of the data.

cost • compression therapy • healing • multicomponent • short-stretch bandage • venous leg ulcer • wound • wound care • wound dressing • wound healing

The global prevalence of venous leg ulcers (VLUs) is estimated to be about 1% of the population in Western countries.[1] In nearly 80% of all cases, the cause of lower leg ulcers is venous insufficiency.[2]

The aetiological treatment of VLUs (characterised by a systolic ankle pressure index between 0.8–1.3) is based on the implementation of high compression to the lower limb. To be effective, compression systems must reach a pressure between 30–40mmHg at the ankle.[1,3–5] This level of compression will contribute to the reduction of oedema when it is present and the improvement of venous circulation in the legs, leading to complete wound healing.

The French National Authority for Health (Haute Autorité de Santé, HAS) recommends the use of multicomponent bandages (MCBs) as a first line treatment[5] as they represent the gold standard for the aetiological treatment of VLUs.[1,3,4] Beyond providing an adequate level of pressure, they make it possible to obtain an essential level of bandage stiffness on the limb that cannot be obtained by a simple elastic system.[6] Short-stretch bandages (SSBs), also recommended by HAS for the treatment of VLUs, are reimbursed in the same way as MCBs by French National Health Insurance (CNAM).

Sylvie Meaume,[1] MD; **Patricia Senet**,[2] MD; **Benoît Thomé**,[3] Statistician; **Victor-Alexandre Aragno**,[3] Statistician; **Serge Bohbot**,[4] MD, MSc; **Sophie Fortin**,[5] PharmD, MSc; **Isabelle Boucley**,[5] PharmD, MSc*; **Ulrique Michon-Pasturel**,[6] MD; **Hester Colboc**,[1] MD

***Corresponding author email:** i.boucley@fr.urgo.com

1 Geriatry, Dermatology and Wound Healing Department, Rothschild University Hospital, Paris, France. **2** Dermatology and Vascular Medicine Department, Tenon University Hospital, Paris, France. **3** Median Conseil, Pau, France. **4** Global Medical Affairs, Laboratoires URGO, Chenôve, France. **5** Global Regulatory Affairs and Market Access Department, Laboratoires URGO, Chenôve, France. **6** Vascular Medicine Department, Saint-Joseph Hospital, Paris, France.

Chronic (hard-to-heal) wounds, including VLUs, represent a major public health issue, the importance of which is poorly recognised in France.[7] VLUs can take months to heal; the average healing time is estimated to be 210 days according to the French administrative healthcare database (Système National des Données de Santé, SNDS) study directed by Caisse Nationale d'Assurance Maladie (CNAM).[8] Furthermore, the Odyssey randomised controlled trial (RCT), which compared two MCBs (one with two layers, the other with four layers), and for which the primary endpoint was the percentage of leg ulcers healed after 12 weeks, reported healing rates at three months of 44% and 39%, respectively.[9] VLUs can be particularly painful and have a considerable psychosocial impact on the patient.[1] In patients who already experience limited mobility, VLUs contribute to social isolation, the development of anxiety and depression, as well as a significant impairment in their quality of life.[10–13] In addition to the health and social challenges posed by these wounds, there is also a major economic challenge. In 2011, the cost of care in France amounted to >€272 million, accounting only for the care provided in outpatient settings.[8]

To date, the availability of real-life and high-level data on the clinical outcomes of chronic wounds is limited. The CNAM study is the only one that provides information on the healing time and cost of managing venous ulcers in France.[7,8] To our knowledge, no studies have been carried out to quantify and compare treatment costs between products on the French market in parallel with their effectiveness. Although it is recognised that the French medico-administrative database can be used to conduct real-life studies,[14–16] this has not yet been undertaken in the field of wound care.

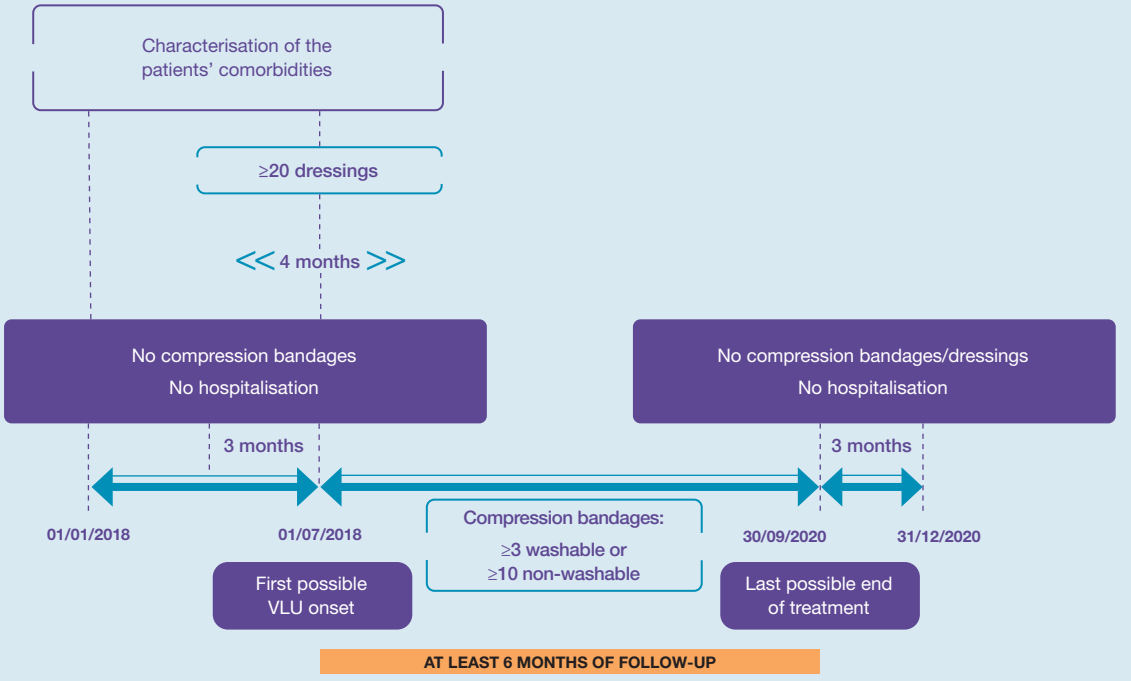
The aim of this study was to provide new data to evaluate the healing outcomes and cost of managing VLUs treated in France with recommended compression systems in real-life, based on the SNDS database (which contains all reimbursement data, including prescribed compression systems and nursing care). The results observed with MCBs recommended by HAS as a first-line treatment[5] were compared to SSBs, also reimbursed for the same indication.[17] Additionally, the analysis was duplicated to compare the most frequently used brands for each type of compression system. Although other compression systems, such as long-stretch bandages, are commonly used for the treatment of VLUs, they are not recommended and not reimbursed in this inducation by health authorities and thus, they were not considered for this study.

Methods

Study design/data source

This retrospective comparative study (Level 2b) was based on data from the SNDS.[18] This database includes all reimbursement data for primary care, types and dates of procedures performed by physicians and health professionals (including nurses), medical devices, and drugs. SNDS is highly representative, covering 99% of the total population of France.[19] It contains data from the Système National d'Information Inter-régimes de

Fig 1. Determination of the venous leg ulcer (VLU) period and main criteria applied over the study period



l'Assurance Maladie (SNIIRAM) for community settings, as well as data from the Programme de Médicalisation des Systèmes d'Information (PMSI) for hospital settings, both covering all socio-professional categories. All data is anonymous and individually linkable to other data for the same person, for example, data from SNIIRAM can be linked to data from PMSI for the same person, even if anonymised.

Ethical approval and scientific approval for study methodology

Access to the SNDS database is heavily regulated. Its use for this study required validation of the protocol by a scientific committee before first submitting to the Health Data Hub (a public structure which has as its objective enabling project coordinators to easily access non-nominative data hosted on a secure platform, in compliance with regulations). The Comité Éthique et Scientifique pour les Recherches, les Études et les Évaluations dans le Domaine de la Santé (CESREES ethics and scientific committee) made recommendations on the methodology, and the national data protection commission, Commission Nationale de l'Informatique et des Libertés (CNIL) gave its approval for data processing and the agreement was signed with CNAM. Finally, the data was extracted for all patients for whom compression of any type was prescribed and delivered between 2018 and 2020.

Patient consent was not required because the data were already registered in and shared by the health insurance system and not specifically gathered for the purpose of this study.

Statistical model

Raw data was analysed for healing outcomes (healing rates at one, three, six and 12 months and healing time) and cost in both groups: MCBs and SSBs. A statistical model was adapted to study the healing rate at three months considering the potential differences between the two groups; three months was chosen because this is the most commonly used follow-up period to evaluate the efficacy of compression systems used for the treatment of VLUs.[9,20,21]

The studied cohort

This study was based on the population in France with a VLU onset between July 2018 and September 2020, and whose VLU had been treated in the community. Fig 1 shows the main criteria used to determine the treatment period of the patients with VLUs and when it applied to the study period.

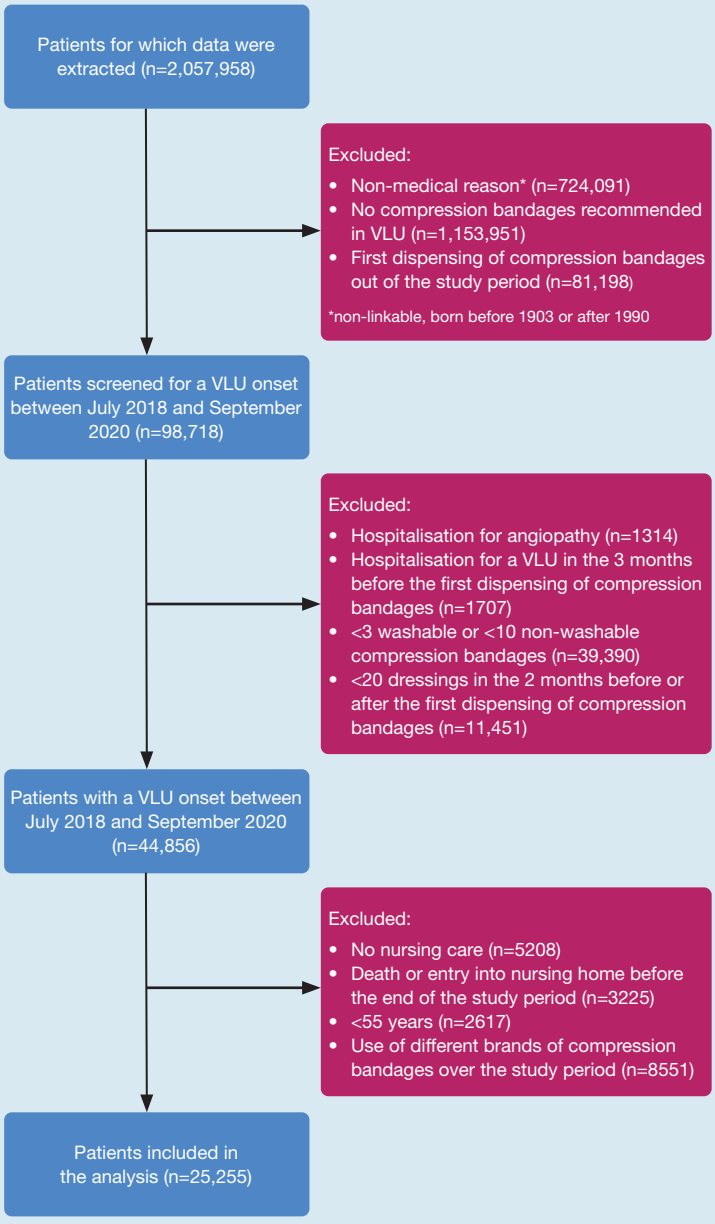
The presence of VLU was identified by the dispensing of:

- A compression system recommended in VLU management:[5] at least three boxes of washable or 10 boxes of non-washable compression systems during the VLU treatment period
- At least 20 dressings over a two-month period preceding or following the first dispensing of the compression system, as previously chosen by Rames et al.,[7] for the methodology of the study used in CNAM's 2014 report.[8]

The VLU onset was determined by the absence of any delivery of a compression system and the absence of hospitalisation for a VLU in the previous three months. Only one VLU onset, i.e. the first VLU that occurred within the study period, could be registered for any patient. Therefore, no recurrence was analysed in the study.

Among the patients who were hospitalised in the three months preceding the initial dispensing of compression bandages, the rare case of a patient

Fig 2. Selection of the study population flowchart. VLU—venous leg ulcer



hospitalised for VLU in the week before the first dispensing was the only exception to the study criteria in order to keep the patient in the analysis.

The selection of patients for inclusion in the analysis is presented in Fig 2.

Data extracted

Data was extracted for all patients in France for whom a compression therapy of any type was reimbursed between 1 January 2018 and 31 December 2020. At baseline, the demographic data of the included patients was extracted (sex, age) as well as their comorbidities (hypertension identified by the dispensing of anti-hypertensive drugs, cardiac insufficiency and diabetes identified by long-term disease categorisation, or malnutrition identified by the dispensing of oral, enteral, or parental nutrition up to six months before inclusion). During the VLU treatment period, the types and brands of compression used were extracted. For MCBs:

- Urgo K2 (Urgo, France)
- Coban 2 (3M, France)
- Kit Biflex (Thuasne, France)
- Profore (Smith+Nephew, France)
- Rosidal Sys (L&R Medical, France)
- VeinoTrain ulcertec (Bauerfeind, France)

For SSBs:

- Rosidal K (L&R Medical, France)

All data relevant for the cost analysis were also detailed.

Outcomes

The primary outcome was the wound healing rate after a maximal follow-up of six months. This included healing rates at one, three and six months. Secondary outcomes included healing rates at 12 months, estimation of the healing time (in days), costs per healed VLU (in euros), identification of the main factors influencing these costs, and the comparison of the outcomes in patients treated with MCBs and in those treated with SSBs.

VLU treatment duration and healing time (Fig 1)

VLU treatment initiation was determined by either:

- The first nurse visit after the first compression system was dispensed
- Hospitalisation for VLU in the week before the first compression system was dispensed.

The end of the VLU treatment was determined by the absence of the dispensing of compression bandages and dressings for at least three months, and identified as:

- The day of the last dispensing of dressings and compression bandages, when no follow-up nurse visit was registered afterwards
- The day of the last nursing visit registered in the two months following the last dispensing of dressings or compression bandages.

Patients were considered healed if:

- Their VLU treatment ended before 30 September 2020
- They were not hospitalised for VLU in the three months following the last compression dispensing, to avoid any confusion between recurrence and a continuous episode.
- Their healing time was considered equal to the duration of their treatment. Patients were considered as unhealed if they received bandages or dressings after 30 September 2020.

Statistical analysis

The probability of healing over time was modelled with a Kaplan–Meier curve for all patients and analysed depending on the bandages used (MCBs, SSBs, and the most frequently used used in each group). A Logrank test was used to compare the healing rates between two groups (MCBs versus SSBs, and between the most frequently used brand in each group). A binomial regression model was performed to estimate the relative risk of wound closure rates at three months for each group, adjusted on potential confounding factors which could have an impact on wound healing, notably age, sex, key comorbidities, and wound dressing size. A Wald test was used to assess the significance of these parameters. The level of significance was set at $p<0.05$.

Study perspective and costs

This study was conducted from the CNAM perspective i.e., the costs considered in this study were health insurance costs. All reimbursed costs linked with the VLU episode were considered for those patients who healed within the study period. This included compression systems, dressings, nursing visits, general practitioner (GP) visits, hospital costs, hospitalisation at home (model of care that provides acute-level services in the patient's home with the interventions of a variety of health professionals), and outpatient clinics. Nursing costs for compression and bandages, coded AMI or AMX 2, 4 and 5.1, were identified using the general nomenclature of professional acts.[22] Hospital costs for management of VLUs and grafts were identified through International Classification of Diseases (ICD)-10 coding.[23] The mean costs per VLU healed with MCBs and SSBs were compared, and a Mann–Whitney U test was used to assess the significance of the difference between the two groups. The level of significance was set at $p<0.05$.

Results

Patient characteristics

A total of 25,255 patients were included in the analysis. Their characteristics and comorbidities according to the type of bandages used are described in Table 1. Of the patients, 61% were female. Mean age was 78.62±10.28 years. Despite minor differences in patients' age, sex and comorbidities between the MCBs and SSBs groups, the two populations were well balanced.

In total, 83% of patients were treated with MCBs and 17% with SSBs. The distribution of the different brands of

compression systems is presented in Fig 3, Urgo K2 being the most represented brand among MCBs (88%) and Rosidal K being the only brand representative of SSBs.

Healing outcomes

At every point of the analysis (one, three, six and 12 months), the wound healing rates were reported as significantly higher in the group of patients treated with MCBs than in the one treated with SSBs; most notably after three months of treatment, with a healing rate of 42% with MCBs and 35% with SSBs ($p<0.001$) (Table 2). The healing rates at one month were 11% and 8%; 67% and 60% at six months; and 81% and 78% at 12 months, for MCBs and SSBs, respectively. After one month of treatment, patients treated with MCBs had a 25% greater chance of healing than those treated with SSBs. Even though this gap tended to narrow (17% higher chance to heal with MCBs than SSBs at three months, 11% at six months, and 4% at 12 months), it was always significantly greater for MCBs than for SSBs ($p<0.001$).

The Kaplan–Meier analysis (Fig 4) confirmed a faster healing process with MCBs compared to SSBs as the Logrank test showed significantly different distributions for MCBs and SSBs.

Very similar results were observed in comparing the two most represented brands of MCBs and SSBs, Urgo K2 and Rosidal K, respectively, with significantly different healing distributions and higher healing rates regardless of the treatment duration ($p<0.001$) (Table 4). The median healing time was estimated at 115 (interquartile range (IQR): 59–256) days in the Urgo K2 group versus 137 (IQR: 68–300) days in the Rosidal K group.

After adjusting the model for potential confounding factors (age, size of dressings prescribed and comorbidities, including diabetes, cardiac insufficiency, malnutrition, peripheral arterial disease and hypertension) with a binomial regression model (Table 4), the results remained favourable for the MCBs group, with a 12% greater chance of healing at three months with MCBs compared to SSBs ($p<0.0001$). The exact same difference (12%; $p<0.0001$) was reported in favour of Urgo K2 compared to Rosidal K (the most frequently used brands in each category).

Healthcare costs for healed ulcers

The mean healthcare cost for healed VLUs was calculated based on the 21,655 patients who healed within the study period. The average treatment cost per patient was significantly reduced by 20% in the MCBs group compared to the SSBs group: €2875±3647 and €3580±5575, respectively (Mann–Whitney U test $p=0.0179$), despite higher compression costs in the MCBs group than in the SSBs group (Fig 5). The largest item of expenditure (>40%) in the global cohort was nursing costs: €1687 in the SSBs group and €1222 in the MCBs. Nursing costs were also one of the reduced costs when using MCBs compared to SSBs (a reduction of 28%). Hospital costs were also much lower in the

Table 1. Patient characteristics

	Total	MCBs	SSBs
Patients, n	25,255	20,860	4395
Age, years, mean±SD	78.62±10.28	78.37±10.29	79.81±10.14
Female, %	61	62	58
MRMI* score, mean±SD	4.37±2.39	4.26±2.37	4.86±2.43
Long-term disease, %	70	69	77
Diabetes, %	30	29	33
Cardiac insufficiency, %	19	18	23
Hypertension, %	31	32	23
Malnutrition, %	5	5	7

MCBs—multicomponent bandages; *MRMI score-mortality-related morbidity index, predictive of all-cause mortality[24]; SD—standard deviation; SSBs—short-stretch bandages

Table 2. Healing rates and relative risk between MCBs and SSBs, Logrank test

Treatment duration, months	Healing rate		RR	95% CI	p-value
	MCBs	SSBs			
1	0.11	0.08	1.25	1.13–1.39	<0.001
3	0.42	0.35	1.17	1.12–1.22	<0.001
6	0.67	0.60	1.11	1.08–1.14	<0.001
12	0.81	0.78	1.04	1.03–1.06	<0.001

CI—confidence interval; MCBs—multicomponent bandages; RR—relative risk; SSB—short-stretch bandages

Table 3. Median healing time (days) depending on the type of bandage

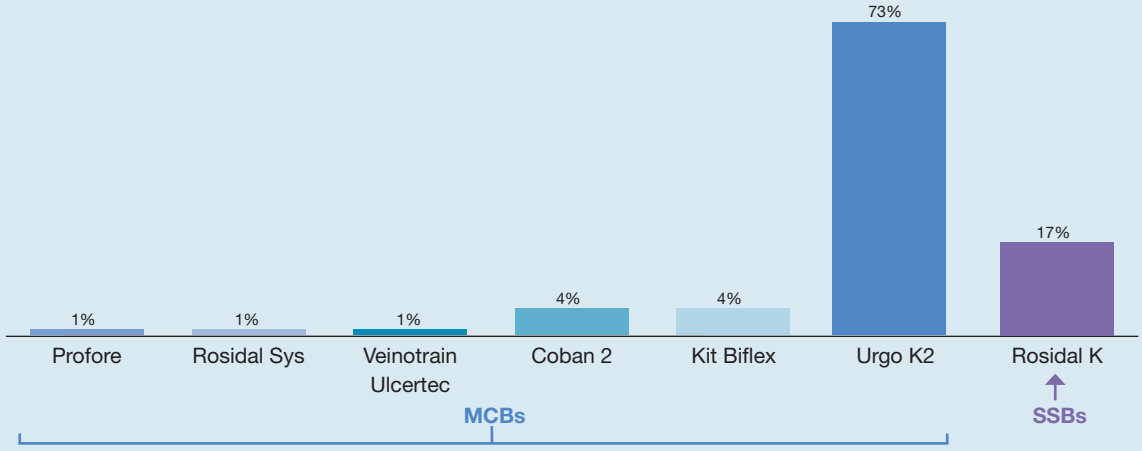
Type of bandage	Median	Lower quartile	Upper quartile
Short-stretch	137	68	300
Multicomponent	115	60	253

Table 4. Healing rates and relative risk between Urgo K2 and Rosidal K, Logrank test

Treatment duration, months	Healing rate		RR	95% CI	p-value
	Urgo K2	Rosidal K			
1	0.11	0.08	1.27	1.14–1.41	<0.001
3	0.41	0.35	1.17	1.12–1.22	<0.001
6	0.66	0.60	1.10	1.08–1.13	<0.001
12	0.81	0.78	1.04	1.02–1.06	<0.001

CI—confidence interval; RR—relative risk

Fig 3. Proportion of patients per bandage brand. MCBs—multicomponent bandages; SSB—short-stretch bandages



MCBs group (4% of mean cost of healed ulcer) compared to the SSBs group (20% of mean cost of healed ulcer). The cost of dressings was also reduced, though to a lesser extent, when using MCBs versus SSBs. Hospitalisation at home and GP visit costs were similar in both groups. Outpatient clinics costs were <1% in both groups.

Discussion

To our knowledge, this study compared for the first time the two most frequently used types of compression systems, with the same reimbursement indication,[17] in real-life practice for the treatment of VLUs in France. To do so, only the CNAM reimbursement data, recorded in the SNDS, could answer this question nationwide. The SNDS database is commonly used to collect real-world evidence to guide public decisions[18] and can also be used for international comparisons.[25] The use of this medical administrative claim database is strictly regulated: the public health interest of the study is mandatory, and the methodology must notably be approved by an ethics committee. Having access to

Table 5. Binomial regression model depending on the type of compression: RR and 95% CI, Wald-test p-value

Variables	Level	RR	95% CI	p-value
Intercept	—	0.630	0.548–0.724	<0.0001
Type of bandage	MCBs vs SSBs	**1.124**	1.077–1.174	<0.0001
MRMI score	1 point	0.990	0.982–0.998	0.018
Age	5 years	0.987	0.978–0.997	0.006
Hospitalisation at the beginning of treatment	Yes or no	0.696	0.500–0.969	0.032
Diabetes	Yes or no	0.911	0.879–0.943	<0.0001
Cardiac insufficiency	Yes or no	0.931	0.892–0.971	0.001
Malnutrition	Yes or no	0.892	0.825–0.965	0.004
Delivery of high absorption dressings	Yes or no	0.814	0.786–0.843	<0.0001
Delivery of small size dressings	Yes or no	1.123	1.088–1.158	<0.0001
Delivery of silver dressings	Yes or no	0.901	0.848–0.957	0.001
Universal Health Coverage	Yes or no	0.894	0.836–0.956	0.001
Peripheral artery occlusive disease	Yes or no	0.862	0.807–0.921	<0.0001
Allowance for adults with disabilities	Yes or no	0.772	0.667–0.893	0.001
Use of painkillers or anti-inflammatory drugs	Yes or no	0.815	0.791–0.840	<0.0001

CI—confidence interval; MCBs—multicomponent bandages; MRMI—Modified Rivermead Mobility Index; RR—relative risk; SSBs—short-stretch bandages

these data is of high value because it can provide data from 99% of the population in France.[19] In our case, data from >25,000 patients were studied—this is highly representative of the real-world population and ensures major statistical significance. Patients with a VLU were selected following a similar methodology to the study of Rames et al.[7] This study was used by the CNAM in its report to France's Minister of Health in 2014.[8] However, some additional criteria were used to address the limitations identified in the Rames study:

- Patients with a minimum number of compression systems over the treatment period were considered to reduce the risk of including other indications than VLU (arterial ulcer, mixed ulcer, oedema of any aetiology, etc.)
- All patients were studied from VLU onset to analyse one full VLU treatment per patient
- Patients had to be followed up by nurses to limit the risk of compression systems not being correctly applied by relatives or not applied at all.

Most patients with VLUs were covered by this method and to ensure both groups were comparable, those patients who switched their compression treatment over the study period were not analysed. Thus, the studied cohort only comprised patients wearing a unique compression system used in first-line treatment, from the onset of the VLU to the end of the treatment period.

Unsurprisingly, and in line with HAS's recommendation for the first-line treatment in this indication, MCBs were the most represented compression systems in the analysed cohort. Most of the MCBs were two-component systems, Urgo K2 being the most frequently used. Despite SSBs being recommended by HAS as a secondary treatment option for the same VLU indication, it can be observed in real life that these bandages are still dispensed to a substantial proportion of patients as a first-line treatment in this indication (17%, more than all the MCBs systems other than the most represented one).

In addition, some of the findings from the study of this cohort of patients are aligned with populations studied in previous RCTs. The healing rate at three months in the MCBs group (41%) matched with the results of Urgo K2 in the Odyssey RCT (44%).[9] Indeed, healing rates at three months are the most clinically relevant according to the literature.[9,20,21] The chance of healing at three months in the MCBs group was 17% greater than the chance of healing at three months in the SSBs group (p<0.001), which represents a significant improvement in healing rate for patients. When adjusting the model for confounding factors, the results were still positive for MCBs, with a 12% greater chance of healing at three months compared to SSBs. A faster healing rate—22 days quicker in this study—with MCBs compared to SSBs is significant when considering the patient's quality of life; three weeks free of nursing care and a quicker return to a more normal life. These results are concordant with the HAS recommendations of using MCBs as a first-line treatment and reinforces the accuracy of the guidelines for compression, that should remain the current practice for health professionals in France.

Moreover, the reduction in healing time leads to a lower global cost of treatment. From the CNAM perspective, using MCBs could save 20% of the amount allocated to healing a VLU compared to using SSBs. This difference can be explained by the decrease in the number of nursing care and medical visits as well as

Fig 4. Product-limit failure curves with 95% Hall–Wellner Bands. SSBs—short-stretch bandages; MCBs—multicomponent bandages

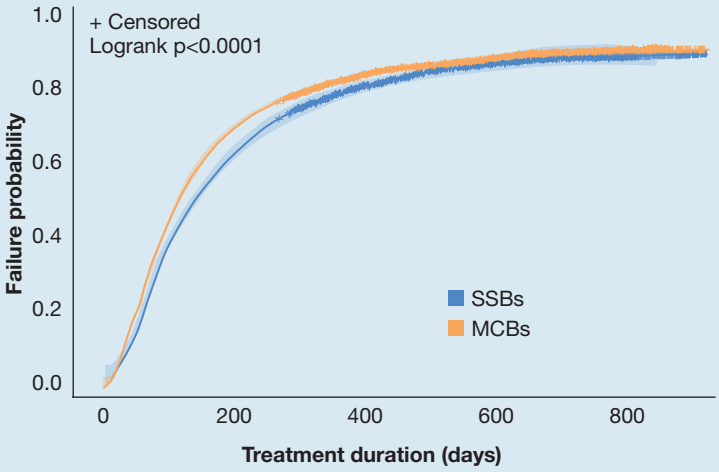
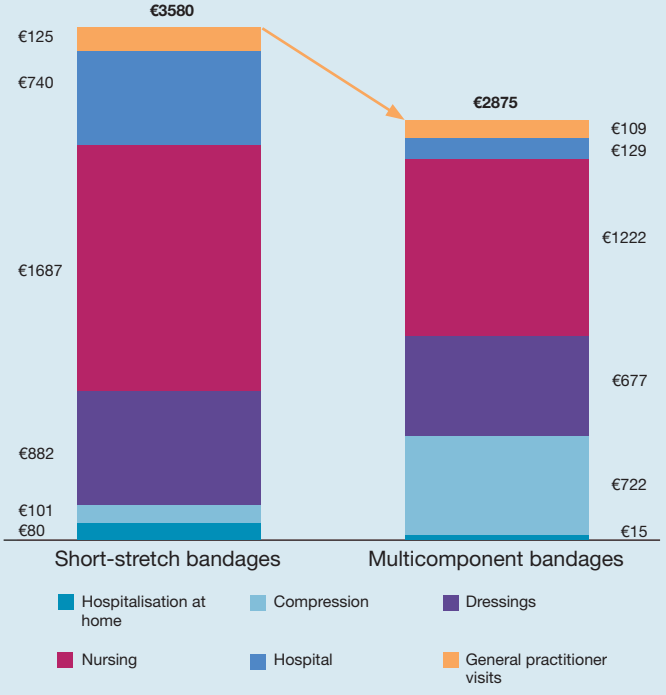


Fig 5. Mean cost per patient per healed ulcer (€) depending on the bandage type. Costs <1% are not shown in the graphic



reduced hospitalisations and fewer dressings used despite higher compression costs. Healing time and cost analysis also support the current recommendations from HAS[5] as well as expert consensus.[1,3,4]

This study only evaluated the efficacy of the products; however, management of VLUs should also consider other parameters, such as safety, ease of use or patients comfort to optimise concordance.

Limitations

As with all analyses using data from the SNDS database, the results of this study may have some limitations, as this database does not contain all the relevant clinical data,[26] such as wound characteristics and, in particular, wound area and the duration of the wound. In addition, it is relevant to question if the two types of compression systems were used on the same types of VLUs and we cannot exclude the probability that ulcers of mixed aetiology are included in the SSBs group (due to the lack of detail related to wound characteristics in the SNDS database.

Similarly, it cannot be excluded that the increased costs of hospitalisation, dressings and nursing care in the SSBs group are influenced by other factors, in addition to the longer duration of treatment in this group, such as potentially greater wound severity. Nonetheless, the wound duration and area at treatment initiation—which are the most impactful parameters on the healing process[27–30]—were controlled for in this study by considering only the first VLU to occur, from the beginning of its treatment for all patients; therefore, in both groups only very recent VLUs and wound dressing size were included in the binomial regression model. Other parameters, such as tobacco use or body mass index, may have had an impact on wound healing but are less important and are unfortunately not documented in the SNDS database. Moreover, to avoid considering leg ulcers of mixed aetiology, the binomial regression model included the proportion of peripheral arterial disease in both the MBC and SSBs groups.

Some limitations are also due to the observational design of the study, the disadvantages of which, including the increased risk of potential bias and confounding factors, have been discussed in other publications.[31,32]

However, this methodology also has many strengths. It grants the ability to measure the efficacy of health products in real-world conditions[33] and it is the only type of study that allows access to such large cohorts of patients.[18]

Conclusion

The analysis of the SNDS real-life data assessed the healing outcomes achieved with two compression therapies in VLU management and confirmed the superiority of MCBs compared to SSBs. The choice of the compression system has an important influence on wound healing outcomes and cost of treatment. Deeper analysis should be performed to better understand the influence of other parameters in VLU management. This would help in determining the best standard of care protocol, with clinical data from real-life, to promote more efficient and effective management of VLUs for patients. **JWC**

References

1 Franks PJ, Barker J, Collier M et al. Management of patients with venous leg ulcers: challenges and current best practice. J Wound Care 2016; 25(Suppl 6):S1–S67. https://doi.org/10.12968/jowc.2016.25.Sup6.S1

2 Agale SV. Chronic leg ulcers: epidemiology, aetiopathogenesis, and management. Ulcers 2013; 2013:1–9. https://doi.org/10.1155/2013/413604

3 O'Donnell TF Jr, Passman MA, Marston WA et al.; Society for Vascular Surgery; American Venous Forum. Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2014; 60(2 Suppl):3S–59S. https://doi.org/10.1016/j.jvs.2014.04.049

4 Kelechi TJ, Brunette G, Bonham PA et al. 2019 guideline for management of wounds in patients with lower-extremity venous disease (LEVD). J Wound Ostomy Continence Nurs 2020; 47(2):97–110. https://doi.org/10.1097/WON.0000000000000622

5 Haute Autorité de Santé. [Medical compression in chronic venous disease. 'BUTS' (Bon Usage des Technologies de Santé [Good use of health technologies]) [In French]. 2010. https://tinyurl.com/3sn3y5kt (accessed 18 September 2023)

6 Partsch H, Schuren J, Mosti G, Benigni JP. The Static Stiffness Index: an important parameter to characterise compression therapy in vivo. J Wound Care 2016; 25(Suppl 9):S4–S10. https://doi.org/10.12968/jowc.2016.25.Sup9.S4

7 Rames O, Sebo S, Pecault R. [Chronic wounds in France: prevalence, characteristics and trends. Improving the organization of care after hospital discharge.] [In French]. JPC 2014; 92:12–18. https://tinyurl.com/mr37htc6 (accessed 18 September 2023)

8 Caisse Nationale d'Assurance Maladie. [Improving the health system and manage expenses: report to the Minister for Social Security and Parliament on the evolution of charges and products of Health Insurance (Assurance Maladie) for 2014] [In French]. 2013. https://tinyurl.com/mtd4eadp (accessed 18 September 2023)

9 Lazareth I, Moffatt C, Dissemond J et al. Efficacy of two compression systems in the management of VLUs: results of a European RCT. J Wound Care 2012; 21(11):553–565. https://doi.org/10.12968/jowc.2012.21.11.553

10 Green J, Jester R, McKinley R, Pooler A. The impact of chronic venous leg ulcers: a systematic review. J Wound Care 2014; 23(12):601–612. https://doi.org/10.12968/jowc.2014.23.12.601

11 Jones J, Barr W, Robinson J, Carlisle C. Depression in patients with chronic venous ulceration. Br J Nurs 2006; 15(Sup2):S17–S23. https://doi.org/10.12968/bjon.2006.15.Sup2.21237

12 Persoon A, Heinen MM, van der Vleuten CJ et al. Leg ulcers: a review of their impact on daily life. J Clin Nurs 2004; 13(3):341–354. https://doi.org/10.1046/j.1365-2702.2003.00859.x

13 Le Gloanec H, Boye T, Placidi E. [Causes of non-adherence to compression therapy in the treatment of venous ulcers] [In French]. Phlebologie 2017; 70(2):38–48. https://tinyurl.com/ysb47y4j (accessed 18 September 2023)

14 Dumas E, Laot L, Coussy F et al. The French Early Breast Cancer Cohort (FRESH): a resource for breast cancer research and evaluations of oncology practices based on the French National Healthcare System Database (SNDS). Cancers (Basel) 2022; 14(11):2671. https://doi.org/10.3390/cancers14112671

15 Baudot FO, Aguadé AS, Barnay T et al. Impact of type 2 diabetes on health expenditure: estimation based on individual administrative data. Eur J Health Econ 2019; 20(5):657–668. https://doi.org/10.1007/s10198-018-1024-9

16 Opatowski M, Brun-Buisson C, Touat M et al. Antibiotic prescriptions and risk factors for antimicrobial resistance in patients hospitalized with urinary tract infection: a matched case-control study using the French health insurance database (SNDS). BMC Infect Dis 2021; 21(1):571.

https://doi.org/10.1186/s12879-021-06287-1
17 Caisse Nationale d'Assurance Maladie. [List of reimbursable products and services] [in French]. https://tinyurl.com/3sc3f6dm (accessed 18 September 2023)
18 Tuppin P, Rudant J, Constantinou P et al. Value of a national administrative database to guide public decisions: from the Système National d'Information Interrégimes de l'Assurance Maladie (SNIIRAM) to the Système National des Données de Santé (SNDS) in France. Rev Epidemiol Sante Publique 2017t; 65(Suppl 4):S149–S167. https://doi.org/10.1016/j.respe.2017.05.004
19 Bezin J, Duong M, Lassalle R et al. The national healthcare system claims databases in France, SNIIRAM and EGB: powerful tools for pharmacoepidemiology. Pharmacoepidemiol Drug Saf 2017; 26(8):954–962. https://doi.org/10.1002/pds.4233
20 Haesler E. Evidence summary: venous leg ulcers: multi-layer compression bandaging. Wound Practice & Research 2019; 27(1):49–51. https://doi.org/10.33235/wpr.27.1.49-51
21 Szewczyk MT, Jawień A, Cierzniakowska K et al. Comparison of the effectiveness of compression stockings and layer compression systems in venous ulceration treatment. Arch Med Sci 2010; 5(5):793–799. https://doi.org/10.5114/aoms.2010.17097
22 Caisse National d'Assurance Maladie. [General nomenclautre of professional acts] in force since the UNCAM decision of March 11, 2005] [In French]. https://tinyurl.com/2p8c3dr8 (accessed 18 September 2023)
23 World Health Organization. ICD-10 Version: 2019. International statistical classification of diseases and related health problems. 10th revision. 2019. https://icd.who.int/browse10/2008/fr (accessed 11 September 2023)
24 Constantinou P, Tuppin P, Fagot-Campagna A et al. Two morbidity indices developed in a nationwide population permitted performant outcome-specific severity adjustment. J Clin Epidemiol 2018; 103:60–70. https://doi.org/10.1016/j.jclinepi.2018.07.003
25 Sbidian E, Mezzarobba M, Shourick J et al. Choice of systemic drugs for the management of moderate-to-severe psoriasis: a cross-country comparison based on national health insurance data. Acta Derm Venereol 2021; 101(6):adv00473. https://doi.org/10.2340/00015555-3765
26 Scailteux LM, Droitcourt C, Balusson F et al. French administrative health care database (SNDS): the value of its enrichment. Therapies 2019; 74(2):215–223. https://doi.org/10.1016/j.therap.2018.09.072
27 Gelfand JM, Hoffstad O, Margolis DJ. Surrogate endpoints for the treatment of venous leg ulcers. J Invest Dermatol 2002; 119(6):1420–1425. https://doi.org/10.1046/j.1523-1747.2002.19629.x
28 Kantor J, Margolis DJ. A multicentre study of percentage change in venous leg ulcer area as a prognostic index of healing at 24 weeks. Br J Dermatol 2000; 142(5):960–964. https://doi.org/10.1046/j.1365-2133.2000.03478.x
29 Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? Am J Med 2000; 109(1):15–19. https://doi.org/10.1016/S0002-9343(00)00379-X
30 Phillips TJ, Machado F, Trout R et al. Prognostic indicators in venous ulcers. J Am Acad Dermatol 2000; 43(4):627–630. https://doi.org/10.1067/mjd.2000.107496
31 Hess AS, Abd-Elsayed A. Observational studies: uses and limitations. In: Abd-Elsayed A (ed). Pain. Springer, Cham. 2019. https://doi.org/10.1007/978-3-319-99124-5_31
32 Boyko EJ. Observational research opportunities and limitations. J Diabetes Complications. 2013; 27(6):642–648. https://doi.org/10.1016/j.jdiacomp.2013.07.007
33 Haute Autorité de Santé (HAS). Real-world studies for the assessment of medicinal products and medical devices. HAS Guidelines. 2021. https://tinyurl.com/3ekwndyw (accessed 11 September 2023)

Reflective questions

- What challenges do you face in the diagnosis and management of patients with a venous leg ulcer (VLU)?
- What criteria do you consider when selecting a compression system to treat a patient with a VLU?
- How do you ensure you achieve an effective level of pressure for each patient when you apply a compression system?