Impact of primary dressings on healing of venous leg ulcers: a French cohort study from the healthcare insurance database

Objective: Multicomponent bandages (MCBs) are recommended by the French Authority for Health (Haute Autorité de Santé) as first-line treatment for venous leg ulcers (VLUs). A first analysis of the data collected from the French administrative healthcare database (Système National des Données de Santé (SNDS)) on 25,255 patients with a VLU supported superiority of MCBs versus short stretch bandages when considering the healing outcomes and costs associated with closure of these wounds. The aim of this study was to assess how beneficial the primary dressing (technology lipido-colloid nano-oligosaccharide factor (TLC NOSF) or control dressing group (CDG)) could be, when used in combination with MCBs in the treatment of VLUs.

Method: Data from the SNDS were collected for patients meeting the following inclusion criteria: treatment for a VLU with MCBs and with the same dressing type (TLC-NOSF or CDG) during the whole treatment period. Healing outcomes were documented on the global cohorts and propensity score-matched cohorts. The mean healthcare cost and the ecological impact were calculated for those patients healed within the study period.

Results: In total, 12,507 patients met the criteria for treatment with both MCBs and TLC-NOSF dressings (n=1134) versus MCBs and CDG (n=11,373); with 1134 and 2268 patients per group following propensity score matching. Healing outcomes were favourable for the TLC-NOSF group in the global cohort and were enhanced in the propensity score-matched cohorts. At every point of the analysis, the adjusted healing rates were significantly higher in the TLC-NOSF group than in the CDG group (p<0.001). In the propensity score-matched cohorts (n=3402), the healing rate at three months was 52% in the TLC-NOSF group versus 37% in the CDG group (p<0.001). The median healing time was 87 days versus 125.5 days in the TLC-NOSF and CDG groups, respectively (p<0.0001). TLC-NOSF dressings significantly reduced the average treatment cost per healed ulcer (€2099) by 23.7% compared with dressings without TLC-NOSF (€2751) (p<0.001), as well as the resources used.

Conclusion: This SNDS analysis confirms, in the largest real-life study performed in VLU management, the superiority of the TLC-NOSF dressings versus those not impregnated with the NOSF compound. Better clinical outcomes associated with cost savings and a positive ecological impact support the combination of MCBs and TLC-NOSF dressings and should be considered as an optimal standard of care for the global management of VLUs. These outcomes reinforce the current positions of the international guidelines on the use of NOSF impregnated dressings (UrgoStart range; Laboratoires Urgo, France) in this pathology.

Declaration of interest: This study was sponsored by a grant from Laboratoires URGO, France, manufacturers of Urgo K2. SF and IB are employees of Laboratoires URGO. SM, PS and UM have received monetary compensation as speakers for Laboratoires URGO. Data management and statistical analyses were conducted by Median Conseil, France. The study sponsors were not involved in the analysis and interpretation of the data. The authors have no other conflicts of interest to declare.

compression therapy • cost • healing • multicomponent bandages • short stretch bandages • TLC-NOSF dressings • venous leg ulcer • wound • wound care • wound dressing • wound healing

https://doi.org/10.12968/jowc.2024.0189

Venous leg ulcers (VLUs) are the most common lower extremity ulcers and are due to venous insufficiency in nearly 80% of all cases.[1] The burden for patients, health professionals (HPs) and the community is high,[2] with a global prevalence estimated at about 1% of the population in western countries.[3]

The aetiological treatment of VLUs is based on effective compression therapy systems, delivering high compression between 30–40mmHg at the ankle.[1,4–6] Improvement of venous circulation in the legs will support healing of the VLU. In France, the use of multicomponent bandages (MCBs) and short stretch bandages (SSBs) is recognised by the National Authority for Health (Haute Autorité de Santé (HAS)) as being the appropriate treatment for VLUs; however, it also recommends MCBs to be used as first-line treatment.[6]

A study by Meaume et al.,[7] which focused on aetiological treatment of VLUs, was carried out to assess the respective clinical benefits and treatment costs between two types of compression therapy systems, MCBs and SSBs, both available for use by HPs in France.

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Its results confirmed that the healing outcomes achieved in real life with MCBs were significantly superior to those with SSBs. Raw data were analysed for: healing outcomes of the 25,255 selected patients including healing rates at one, three, six and 12 months; healing times; and associated costs in both MCB and SSB groups. At every point of the analysis, the wound healing rates were reported as significantly higher in the MCB group than in those treated with SSBs, notably after three months of treatment, with a healing rate of 42% with MCBs and 35% with SSBs ($p<0.001$). 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 days (interquartile range (IQR): 60–253 days) in the MCB group versus 137 days (IQR: 68–300 days) in the SSB group; and the average treatment cost per patient with a healed ulcer was €2875±3647 in the MCB group and €3580±5575 in the SSB group ($p=0.017$).

The choice of compression system has a great influence on VLU healing outcomes, but other parameters, such as the type of primary dressings used to cover the ulcer wound bed, may also have an impact. It is important to establish the best possible standard of care (SoC) protocol to improve healing outcomes of hard-to-heal wounds and reduce the impact on the patients' impaired quality of life (QoL).

In combination with compression therapy, the use of modern dressings that promote and maintain a moist environment is recommended within international guidelines for the local treatment of VLUs.[1] Primary dressings, including foams and contact layers which are impregnated with NOSF (nano oligosaccharide factor) and those which are not, can be differentiated.

The superiority of technology lipido-colloid (TLC)-NOSF dressings in the local treatment of VLUs compared with a neutral dressing has been demonstrated in two randomised controlled trials (RCTs),[8,9] a pooled analysis of observational studies,[10] and was highlighted in the 2016 European Wound Management Association (EWMA) guidelines.[1] TLC-NOSF dressings have also been shown to positively impact patients' QoL compared to neutral dressings.[11] In 2019 and renewed in 2023, the UK's National Institute for Health and Care Excellence (NICE) recommended, for the first time, the use of TLC-NOSF dressings for treating VLUs,[12,13] due to a higher wound closure rate, improvement of QoL and cost savings. NICE also considered that TLC-NOSF dressings, when incorporated within a pathway of care, were cost-effective compared to SoC.

As well as NICE, other countries have developed health economic models to assess the cost-effectiveness of TLC-NOSF dressings for the treatment of VLUs, including Germany,[14] Spain,[15] Czech Republic[16] and France.[17] All of these countries have highlighted cost-savings when using TLC-NOSF dressings compared with the use of other advanced wound care (AWC) dressings without TLC-NOSF. In addition, the efficacy of TLC-NOSF dressings was evaluated by HAS, which recognised a better clinical added value compared with other AWC dressings (level III and IV for TLC-NOSF dressings versus level V for all others) and a better reimbursement price.

Despite the evidence provided by modelling, the economic burden of VLU treatment is still a challenge in real-world conditions and there is a lack of high-level real-life data. The use of the French administrative healthcare (Système National des Données de Santé (SNDS)) database, which includes all reimbursement data for primary care, types and dates of procedures performed by physicians and HPs (including nurses), medical devices and drugs, is a recognised method to conduct real-life studies.[18–20] To date, the study performed by the French National Health Insurance (CNAM) on 2012 data is the only one providing information on the healing time and the cost of managing venous ulcers in France.[21,22] According to the CNAM, the cost of care provided in outpatient settings in France for the treatment of VLUs amounted to >€272 million in 2011.[22] However, treatment with compression therapy and primary dressings in the global cost of VLUs has never been considered, to the best of our knowledge.

Additionally, an objective of this analysis was to provide new data on the role of the primary dressing treatment, to complement the results of the initial real-life SNDS analysis on healing outcomes and costs of managing VLUs treated in France with recommended compression systems.[7] The results observed with MCBs, recommended by HAS as a first-line treatment,[6] combined with TLC-NOSF dressings (UrgoStart range; Laboratoires URGO, France) will be compared with MCBs combined with the control dressings group (CDG), foams and contact layers, not impregnated with the TLC-NOSF matrix.

Methods

Ethical considerations and patient consent

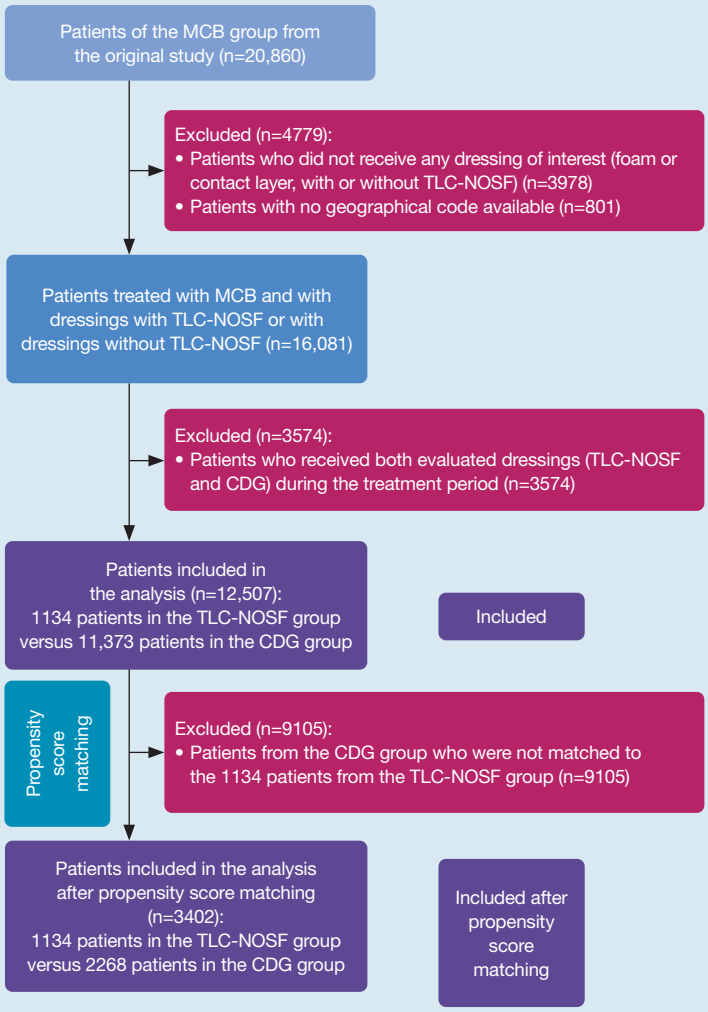
Access to the SNDS database was given for the original study after the approval of the Comité Ethique et Scientifique pour les Recherches, les Etudes et les Evaluations dans le Domaine de la Santé (CESREES), number TPS 3224648 bis, dated 18 March 2021. Patient consent was not required because the data were already registered in and shared by the health insurance system and not specifically gathered for the purpose of this study.

The original SNDS study

The methodology and results of the original SNDS study have been mentioned in the introduction and detailed in a previous publication.[7] Only the main elements will be described here.

The initial analysis was a retrospective comparative study (grade 2b) which was based on data from the exhaustive French SNDS database.[23] The data were extracted for all patients for whom compression of any type was prescribed and delivered between 2018 and 2020.

Fig 1. Selection of the study population flowchart. CDG—control dressing group; MCB—multicomponent bandage; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor



Methods of the current analysis

Study design/data source

The findings of the original study confirmed the superiority of MCBs compared with SSBs in terms of healing outcomes and cost savings.[7] This second analysis was carried out to assess the primary dressings' benefits, with or without TLC-NOSF matrix, when used in combination with MCBs. We have considered the healing outcomes, healthcare resources and costs associated with the aetiological management of VLUs. Foams and contact layer dressings were included because they are reimbursed for the same indication. Other types of dressings, in particular silver dressings, were not considered as a criterion for patients' selection but could be used in both groups, for a short period of time within the study period, if deemed necessary by the physician.

The healing outcomes (healing rates at one, three, six and 12 months, and healing time) were analysed in both the TLC-NOSF and CDG groups, on the global cohort and after propensity score matching. The matching was based on potential confounding factors, including age, sex, key comorbidities and wound dressing size. The ecological impact was measured by the reduction of nursing visits, compression bandages and boxes of dressings used for healed ulcers, depending on the type of dressings used on the adjusted populations. The cost analysis was performed for healed ulcers on the two groups matched by the propensity score.

The studied cohort

This study was based on the population in France with a VLU onset between July 2018 and September 2020, and whose VLUs had been treated in the community setting with MCBs (including 88% with the UrgoK2 compression therapy system; Laboratoires URGO, France) 20,860 patients of the MCB group from the original study. Patients who did not receive any dressing of interest (foam or contact layer, with or without TLC-NOSF) and patients with no geographical code available were excluded from the analysis. Patients who received both evaluated dressings of interest within the study period, with and without TLC-NOSF, were also excluded from the analysis.

The selection of patients included in the analysis is presented in the detailed flowchart (Fig 1).

Data extracted

The data were extracted for all patients in France for whom MCBs and any foam or contact layer dressings were reimbursed between 1 January 2018 and 30 September 2020.

At baseline, the following data were extracted for all included patients:

- Demographic data: sex and age
- Wounds characteristics:
  1. Estimated area of dressing at first application
  2. Infection estimated by the delivery of silver dressings
- Comorbidities:
  1. Hypertension identified by the dispensing of anti-hypertensive drugs
  2. Cardiac insufficiency, diabetes, peripheral artery occlusive disease and haemostasis disorder identified by the long-term disease categorisation
  3. Malnutrition identified by the dispensing of oral, enteral or parenteral nutrition up to six months before inclusion
  4. Analgesic or anti-inflammatory treatment
- Types of dressings used:
  1. In the TLC-NOSF group: foam or contact layer with TLC-NOSF (UrgoStart range)
  2. In the CDG group: foam or contact layer without TLC-NOSF (all dressings were reimbursed in the foam and contact layer categories)
- Relevant data for the cost analysis, detailed below.

Outcomes

The primary outcomes included the wound healing rates at one, three, six and 12 months, as well as an estimation of the healing time (in days), determined in the same way as in the original analysis. Secondary outcomes were the mean treatment costs per healed VLU (in euros), the difference of treatment costs between the two groups and the ecological impact.

Statistical analysis

The probability of healing over time was modelled with a Kaplan–Meier curve for all patients and analysed depending on the dressings used (TLC-NOSF or CDG). A log-rank test was used to compare the healing rates between the two groups. Healing time was compared between both groups and the significance of the difference was determined with both log-rank and Wilcoxon–Mann–Whitney tests. A Wilcoxon test was also performed to assess the p-value for the difference in treatment costs between patients of the TLC-NOSF group and the CDG group.

In addition, propensity score matching was used to reduce the effects of confounding factors by matching all the patients of the TLC-NOSF group with similar patients from the CDG group. This method is commonly used to reduce bias from observational cohorts as a randomisation process was not performed.[24]

Ecological impact due to consumption of healthcare resources

The mean number of healthcare resources used, including nursing visits, compression systems and evaluated dressings for the treatment of ulcers, was calculated based on the adjusted population of 3011 patients who healed within the study period. For each resource, the significance of the difference between the two groups was calculated with a Wilcoxon–Mann–Whitney test.

Cost analysis perspective and parameters

The cost analysis was conducted from the CNAM perspective on the two groups matched by the propensity score. All reimbursed costs linked with the VLU episode were considered for the patients who healed within the study period. This included compression systems, dressings of interest, other dressings, nursing visits, general practitioner (GP) visits and hospital costs. Nursing costs for compression and dressing changes, coded AMI or AMX 2, 4 and 5.1, were identified using the general nomenclature of professional acts.[25] Hospital costs for management of VLUs and grafts were identified through ICD-10 coding.[26] The mean costs per VLU healed with MCBs and dressings with or without TLC-NOSF were compared and a Wilcoxon–Mann–Whitney test was used to assess the significance of the difference between the two groups.

Results

Patient characteristics

Initially included for the analysis were 12,507 patients. In addition to the aetiological treatment with MCBs, most of these patients (11,373 patients, 91%) were treated with the foams or contact layer dressings without TLC-NOSF while the remainder (1134 patients, 9%) were treated with TLC-NOSF dressings.

Table 1. Patient characteristics

	TLC-NOSF	CDG	Total
Number of patients	1134	11,373	12,507
Mean age, years	77.90	78.58	78.51
Standard deviation, years	10.33	10.29	10.29
Percentage of female patients	62	62	62
Mean MRMI score	4.05	4.35	4.32
Standard deviation	2.31	2.39	2.38
Hypertension, %	35	32	32
Cardiac insufficiency, %	15	20	19
Diabetes, %	29	30	29
Malnutrition, %	5	4	4
Haemostasic disorder, %	0	0	0
Analgaesic or anti-inflammatory treatment, %	49	53	53
CMU-C, ACS or C2S beneficiaries*, %	6	6	6
ALD† 3: peripheral artery occlusive disease, %	4	6	6
AAH‡ beneficiaries, %	1	2	2
Mean APL§ indicator for general practitioners	4.13	4.14	4.14
Mean number of nurses in the living area	436	451	449
Deprivation quintile (1 wealthier; 5 most deprived), %			
1	13	12	12
2	16	16	16
3	19	18	18
4	22	24	24
5	30	30	30
Delivery of silver dressings, %	7	7	7
Dressing size at first delivery (adhesive border excluded), %			
≤100cm²	40	39	39
>100cm²	60	61	61

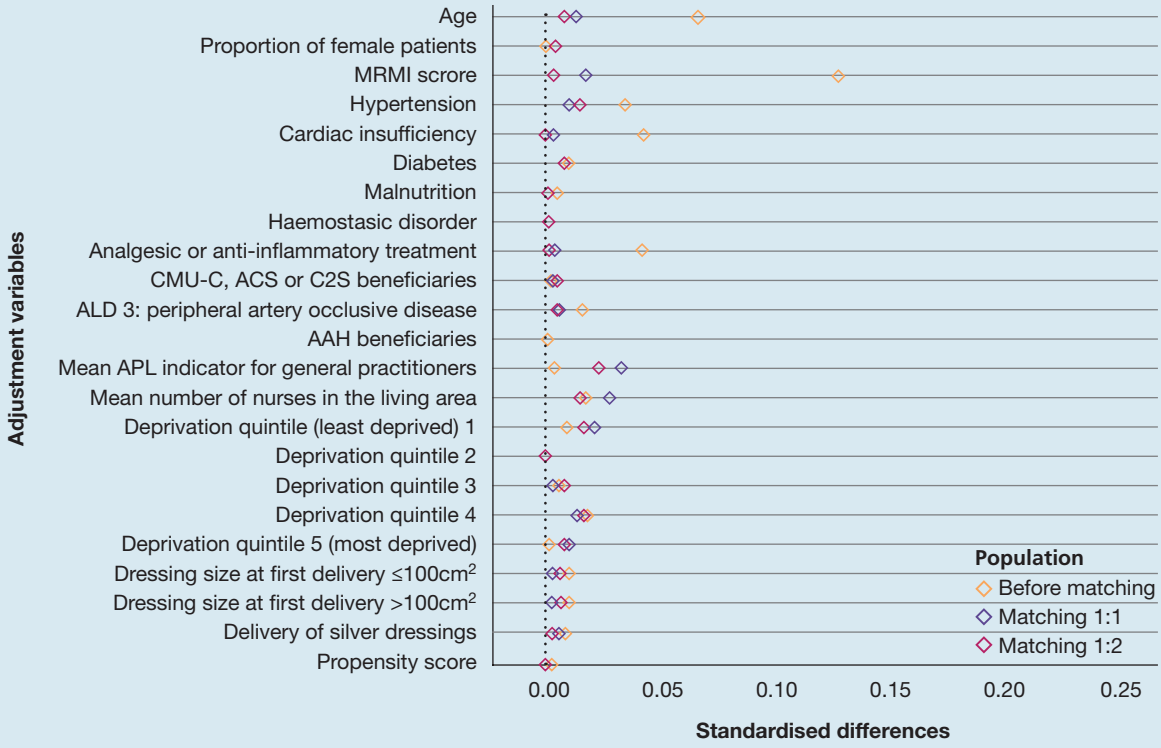
*Specific health insurance regimens; †Classification for long-term diseases; ‡Disabled adult allowance; §The Localized Potential Accessibility Indicator (APL) was developed to measure the spatial fit between the supply and demand for primary care at a fine geographic level. MRMI—mortality-related morbidity index, predictive of all-cause mortality[24]

Their characteristics and comorbidities according to the type of bandages used are described in Table 1; 62% of patients were female and the mean age was 78.52±10.29 years. The minor differences in patients' age, sex and comorbidities between the two groups (TLC-NOSF and CDG) allowed both populations to be considered broadly similar.

Propensity score

In order to reduce the differences between the two groups and thus any potential bias, a propensity score was calculated with a binomial regression and all the patients' characteristics mentioned above were considered. The matching possibilities were assessed with 1:1 and 1:2 matching. Fig 2 shows the standardised differences for each of the adjustment variables, before

Fig 2. Standardised differences in adjustment variables between the TLC-NOSF and CDG groups before matching, after matching 1:1 and after matching 1:2. AAH—Allocation Adulte Handicapé (allowance for disabled adults); ALD 3—Affection Longue Durée 3 (long-term diseases classification 3); APL—localised potential accessibility; CDG—control dressing group; CMU-C, ACS or C2S—health insurance regimens; MRMI—mortality-related morbidity index; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor



and after matching with both options.

As the patients' characteristics of both groups were similar, it was possible to match each patient of the TLC-NOSF group to two patients of the CDG group (1:2 matching). In this way, all of the initial 1134 patients in the TLC-NOSF group could be compared to 2268 patients from the CDG group with the same baseline characteristics as the TLC-NOSF patients. The propensity score matching resulted in an adjusted population of 3402 patients, to bring further balance to the global cohort of 12,507 patients.

Table 2. Healing rates and relative risk between dressings with and without TLC-NOSF on the total cohort of 12,507 patients

Treatment duration, months	Healing rate, %		RR	95% CI	p-value
	TLC-NOSF (n=1134)	CDG (n=11,373)			
1	11	8	1.31	[1.09; 1.57]	0.004
3	52	38	1.39	[1.31; 1.48]	<0.001
6	80	66	1.23	[1.19; 1.27]	<0.001
12	92	81	1.12	[1.10; 1.15]	<0.001

CDG—control dressing group; CI—confidence interval; RR—relative risk; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor

Healing outcomes

All of the healing outcomes presented in this analysis were from the overall study population and were adjusted using the propensity score.

The wound healing rates observed at every point of the analysis (one, three, six and 12 months) were reported as being similar for the total cohort of patients and after propensity score matching. In both cases, they were significantly higher in the TLC-NOSF group than in the CDG group (Tables 2 and 3). Thus, only the most accurate results after adjusting the population using propensity score matching are fully detailed in this article.

The results in favour of the TLC-NOSF group are particularly notable in the latter case, after three months of treatment, with a healing rate of 52% with TLC-NOSF dressings and 37% with dressings without TLC-NOSF ($p<0.001$) (Table 2).

The healing rates at one month were 11% and 8%; at six months 80% and 65%; and at 12 months 92% and 81%, in the TLC-NOSF group and CDG group, respectively. After one month of treatment, the patients treated with TLC-NOSF dressings already had a >31% greater chance of healing than those treated with dressings without TLC-NOSF. At three months, this gap was even higher, with a 43% greater chance of healing with TLC-NOSF dressings than dressings without

TLC-NOSF. Even though this difference tended to narrow after six months (23% at six months and 13% at 12 months), it was still significantly higher for patients treated with TLC-NOSF dressings than with dressings without TLC-NOSF. Moreover, six additional months were required in the CDG group to reach the healing rate of 80% which was met at six months in the TLC-NOSF group.

The log-rank test used with the Kaplan–Meier analysis showed significantly different distributions for dressings with and without TLC-NOSF (Fig 3), which confirmed that the healing process was significantly more effective with TLC-NOSF dressings compared to dressings without TLC-NOSF.

The median healing time for VLUs was estimated at 87 days (IQR: 52–152 days) in the TLC-NOSF dressings group versus 125.5 days (IQR: 66–263 days) after propensity score matching in the CDG group (Table 4). The difference corresponds to a healing time decreased by 31% in the group with TLC-NOSF dressings compared to the control group. The log-rank test confirmed that the difference between both groups was significant (p<0.0001).

Ecological impact for healed ulcers

The mean number of healthcare resources used for the treatment of ulcers was observed on the adjusted population of 3011 patients who healed within the study period.

Using MCBs and TLC-NOSF dressings led to savings for all resources compared to the use of MCBs and control dressings (Table 5):

- The mean number of nursing visits was reduced by 21% (p<0.001)
- The mean number of compression systems was reduced by 12% (p=0.176)
- The mean number of dressings of interest was reduced by 44% (p<0.001).

Healthcare costs for healed ulcers

The mean healthcare cost for the treatment of ulcers was calculated based on the adjusted population of 3011 patients who healed within the study period. The average treatment cost per patient was significantly reduced—by 24%—when using TLC-NOSF dressings compared to foams and contact layer dressings without TLC-NOSF: €2099±2228 and €2751±3437, respectively (p<0.001) (Fig 4).

In both groups, all dressings taken together accounted for almost 20% of treatment costs. Dressings of interest (foams/hydrocellular dressings and contact layers) represented only a small proportion of the mean cost per patient: 12% in the CDG group and 13% in the TLC-NOSF group.

The largest items of expenditure in this cohort were nursing care and compression costs. Nursing care represented 45% of costs in both groups, distributed as follows: €941 and €1242 in the TLC-NOSF and CDG groups, respectively, representing a 24% cost reduction.

Table 3. Healing rates and relative risk between dressings with and without TLC-NOSF after propensity score matching (n=3402)

Treatment duration, months	Healing rate, %		RR	95% CI	p-value
	TLC-NOSF (n=1134)	CDG (n=2268)			
1	11	8	1.31	[1.05; 1.63]	0.020
3	52	37	1.43	[1.32; 1.54]	<0.001
6	80	65	1.23	[1.18; 1.28]	<0.001
12	92	81	1.13	[1.10; 1.16]	<0.001

CDG—control dressing group; CI—confidence interval; RR—relative risk; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor

The second biggest item was compression costs: 30% or €625 in the TLC-NOSF dressings group and 26% or €711 in the group without TLC-NOSF (a reduction of 12% when using TLC-NOSF dressings). In the same way, all of the other items (dressings of interest, other dressings, hospitalisation and GP visits) were reduced when using TLC-NOSF dressings compared with dressings without TLC-NOSF. The larger percentage of savings when using TLC-NOSF dressings applied to costs for hospital and other dressings used (reduction of around 50% for both items). In conclusion, in this analysis, using TLC-NOSF dressings to heal VLUs generated less cost, including costs allocated to the wound dressings.

Discussion

The analysis of the SNDS database considering a large cohort of patients presenting with a VLU treated with the same category of compression systems (MCBs) has established that the nature of the primary dressings (with or without TLC-NOSF matrix), can make a difference in terms of clinical outcomes. Patients treated with TLC-NOSF dressings for the duration of care to complete healing had better outcomes, including wound closure rates and time to healing, than patients

Fig 3. Kaplan–Meier curve: cumulated healing rate depending on the treatment duration (days). CDG—control dressing group; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor

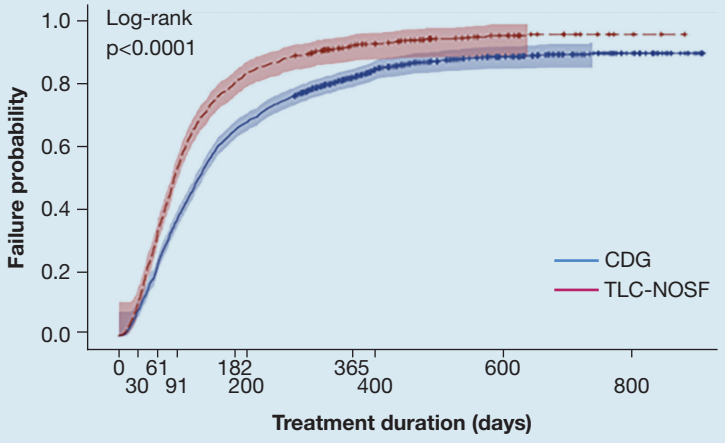


Table 4. Median healing time (days) depending on the evaluated dressings

	Median (days)	Lower quartile (days)	Upper quartile (days)	Significance of the difference between TLC-NOSF and CDG (p-value)
TLC-NOSF (n=1134)	87.0	52	152	
CDG after propensity score (n=2268)	125.5	66	263	<0.0001
CDG (n=11,373)	123	64	257	<0.0001

CDG—control dressing group; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor

who received the control dressings without TLC-NOSF. While patients treated with MCBs and dressings without TLC-NOSF (CDG group) had better healing outcomes (median healing time: 125.5 days) than patients from the initial study treated with SSBs (median healing time: 137 days),[7] the time to heal was reduced further when using MBCs and TLC-NOSF dressings (median healing time: 87 days) as SoC.

In addition, the use of TLC-NOSF dressings as a first-line treatment for hard-to-heal wounds has shown substantial improvement in terms of wound closure rate when used earlier in the episode of care. Early implementation of the TLC-NOSF dressings will lead to improved clinical outcomes. This has been demonstrated in a post hoc analysis of the Explorer double-blind RCT[27] in diabetic foot ulcers (DFUs) and more recently in German real-life studies including DFUs, pressure ulcers and VLUs.[28,29]

In this SNDS study, patients had prescriptions for dressings, either with or without TLC-NOSF, from the start of their VLU treatment. The healing rate at three months, which is the most relevant according to the literature in VLU treatment,[30,31] observed in the TLC-NOSF dressings group was concordant with the results on leg ulcers (≤1 month) of the German observational study of Augustin et al.[28] published in 2021, with healing rates at three months with and without TLC-NOSF of 52.4% and 52.9%, respectively.

The selection of the type of primary dressings, in addition to the aetiological treatment, has also demonstrated a significant impact in real life on mean treatment costs. Health economic models based on RCT data[12,13,32,33] have previously been performed to demonstrate cost savings achieved when using TLC-NOSF dressings for the treatment of hard-to-heal wounds. However, cost-effectiveness data regarding TLC-NOSF dressings were not yet supported in real-life conditions. The cost savings observed in this SNDS study are consistent with those reported by the NICE recommendations[13] (€652 per healed ulcer versus £541 or €633 (authors' conversion) per patient per year, respectively).

Similar to the reduction in healing time, the costs of care were also reduced for patients treated with MCBs combined with control dressings without TLC-NOSF (mean treatment cost: €2751) compared with patients treated with SSBs (mean treatment cost: €3580). This difference was even greater for patients treated with MCBs combined with TLC-NOSF dressings (mean treatment cost: €2099). The significant reduction of the healing time between the groups with and without TLC-NOSF leads to a reduction of the overall cost to heal a VLU as well as a reduction of resources used, leading to a positive ecological impact. The cost of the dressing of interest is quite low (<15%) in the total cost of treatment and despite a higher unit price, using TLC-NOSF instead of CDG dressings, leads to fewer costs allocated to dressings.

To ensure the results are attributable to the dressing, the patients who switched between dressings with and without TLC-NOSF over the study period were not analysed. The studied cohort was only composed of patients treated with MCBs and a unique type of dressing of interest (TLC-NOSF or CDG) for first-line treatment and consistently applied from the first delivered prescription to the end of the treatment period.

These results are aligned with current guidelines[1] and the French health care authorities which recommend MCBs as a first-line compression therapy for VLUs (versus SSBs)[6] and the highest level of clinical evidence for TLC-NOSF (versus other dressings) in the aetiological and local treatment of VLUs, respectively. This study revealed that in France, between 2018 and 2020, only 9% of patients treated for a VLU with MCBs were using TLC-NOSF dressings in combination. Introducing this complete protocol within care pathways, as per NICE recommendations, the use of TLC-NOSF dressings[13] will improve everyday practice for HPs and improve patients' QoL.

This SNDS study is the largest evaluation of a cohort of patients with VLUs. It is also the first time, to the authors' knowledge, that the combination of MCBs and different types of dressings (with or without the TLC-NOSF matrix) have been considered. Neutral dressings, which are not impregnated with TLC-NOSF, are routinely prescribed in the management of VLUs

Table 5. Mean number of resources used per patient per healed ulcer depending on the evaluated dressings

	CDG after propensity score matching (n=2268)	TLC-NOSF (n=1134)	Total	% reduction between CDG and TLC-NOSF	Significance of the difference between CDG and TLC-NOSF (p-value)
Nursing visits (mean)	80.80	63.67	74.78	21%	<0.001
Compression systems (mean)	41.55	36.59	39.80	12%	0.176
Dressings of interest (mean)	92.67	51.48	78.15	44%	<0.001

CDG—control dressing group; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor

and are considered by many HPs as being equivalent in their influence on wound healing. There is no clear evidence to support the use of one neutral dressing over another, as demonstrated by the Cochrane review of O'Meara and Martin-St James.[34] This is probably the reason why the benefits in terms of healing outcomes have always been attributed to the compression therapy used and not the primary dressings. This study highlights the benefits, in real life, of choosing an appropriate compression therapy system in conjunction with a specific evidence-based primary dressing for first-line treatment of VLUs. This study shows that—all other things being equal (including the same type of compression)—the management of VLUs with TLC-NOSF dressings instead of neutral dressings without TLC-NOSF generates better clinical outcomes, costs savings and may lead to a positive ecological impact.

Limitations

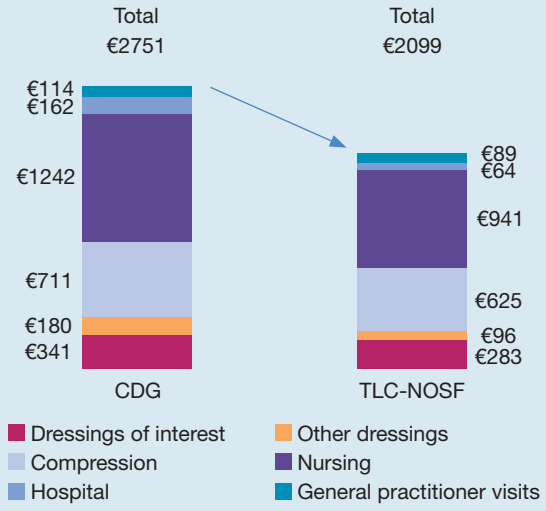
As with every analysis from real-word evidence, results may have some limitations. The identification of a specific population and the definition of exposure periods may be difficult when performing studies on the SNDS database because of its structure and the nature of the data recorded.[35] In this analysis, it was particularly challenging because the SNDS database does not contain all relevant clinical data,[36] such as wound characteristics (wound area and duration of the treated VLU), which may impact the healing process, as they are identified as being healing prognosis factors.

In this study, the patients were committed to either the group with or without TLC-NOSF, depending on the prescriptions for foams/hydrocellular dressings and contact layers. This selection did not exclude the potential prescriptions of other dressings, in both groups, such as antimicrobial dressings; that they were prescribed in only 7% of the patients, in both groups and for a short period of time, is not likely to have had any significant impact on the final results documented in this study.

The cost study did not consider any health economic modelling and was only based on the data observed during the study period for healed ulcers. A cost-effectiveness analysis could be performed to take into consideration different cohorts, cost items, other perspectives and time horizons.

Other limitations that could impact healing were not considered, including tobacco use and body mass index, as this information is not captured within the SNDS database. Nonetheless, this methodology also offers many advantages, the most important being the ability to measure the efficacy of healthcare products in real-world conditions[37] on large cohorts of patients.[23]

Fig 4. Mean cost per patient per healed ulcer (euros(€)) depending on the dressing type. CDG—control dressing group; MCB—multicomponent bandage; TLC-NOSF—technology lipido-colloid nano-oligosaccharide factor



Conclusion

The original study of the SNDS real-life data, which assessed the healing outcomes achieved with two compression therapies in VLU management, has established the superiority of MCBs compared to SSBs. The clinical efficacy of MCBs can be enhanced with use of the most appropriate advanced wound care dressing. This second SNDS analysis has documented superior healing outcomes when combining MCBs with TLC-NOSF dressings versus control dressings. This study is fully concordant with the results of previous clinical studies using TLC-NOSF dressings, thus supporting the combination of MCBs with TLC-NOSF dressings used as first-line treatment for VLUs. This combination of aetiological and local treatments should lead to cost savings, already supported by previously published health economic models, and in addition should positively impact the environment due to the reduction of resources used.

Improved clinical outcomes associated with cost savings and a positive ecological impact reinforce the position that the combination of MCBs and TLC-NOSF dressings may represent an optimal SoC for the treatment of patients with VLUs. JWC

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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 primary dressing to treat a patient presenting with a VLU?
- What, if any, influence do you think the choice of the primary dressing has on achieving healing for your patient?

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