

ORIGINAL ARTICLE
VENOUS DISEASE

Influence of reimbursement policies on phlebological surgical practice in Belgium between 2007 and 2017

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ABSTRACT

Background: To date, it is unclear how treatment of patients with chronic venous disease (CVD) is influenced by national reimbursement systems. In Belgium, catheters or fibers used for endovenous thermal ablation (EVTA) are reimbursed only once in a lifetime. The potential impact of the Belgian public health insurance reimbursement policy on surgical practice in phlebology needs to be investigated.**Methods:** Billing data available from the Belgian National Institute for Health and Disability Insurance (NIHDI) were used for analyzing the distribution of specific surgical procedures for treating varicose veins and their relative use from 2007 to 2017. The potential influence of age, sex, social status and geographical origin of insured patients on surgical practice in Belgium were studied.**Results:** The annual intervention rate was 343 per 100,000 insured individuals for 2017 with a slight annual increase over the period 2007-2017 (+ 0.83% per year). Patients with limited resources, benefiting from a preferential reimbursement system, had a significantly lower intervention rate than those having the usual system ($P < 0.001$). There was a large geographical variation in the use of care, ranging from 172 to 549 per 100,000 insured in 2017. The number of classic surgical procedures decreased (-6.17% per year) in the period 2015-2017) while EVTA, newly reimbursed in Belgium since 2012, increased during the same period (+ 3.6% per year). This evolution was more pronounced in the north (Flanders) than in the south (Wallonia) of the country. Bilateral treatment increased considerably from 2012 and stabilized at 33% of all surgical interventions in 2016 and 2017.**Conclusions:** Available data of the NIHDI in Belgium highlight remarkable differences in the use of care for CVD, depending on social status and geographical origin of insured patients. The introduction of EVTA techniques has been adopted more rapidly in the north of the country and has led to an increased percentage of bilateral procedures.

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The prevalence of chronic venous disease (CVD) is high, with a multifactorial etiology.¹ The risk factors for its occurrence are age and gender, family history and pregnancies.² A sedentary lifestyle and being overweight aggravate the symptoms.³ The diagnosis is essentially clinical (the 'C' of the CEAP classification, Clinical Etiological Anatomical Pathophysiological classification)⁴ but it should be systematically supplemented by a duplex ultrasound to clarify the anatomy, etiology and pathophysiology, to determine the treatment strategy. The goal of treatment is to reduce the venous hypertension that causes CVD. The variability of clinical presentations accounts for the diverse range of treatments that are offered worldwide. Apart from a conservative approach by means of compression, physical exercise and venotonic medication, there are also a number of potential interventions available, which may be chemical (sclerotherapy and non-thermal non-tumescent techniques), thermal (laser, radiofrequency ablation) or surgical (high ligation, stripping and phlebectomy).⁵⁻⁷ These treatments may be used as single treatments or may be combined. At present, international guidelines recommend endovenous treatments as a first choice for patients with varicose veins and more advanced CVD.^{8,9}

To date, it is still unclear how national reimbursement systems influence treatment of patients with CVD. In Belgium, endovenous thermal ablation (EVTA), mainly laser and radiofrequency ablation, has been reimbursed since 2012.^{10,11} However, there is an important restriction in reimbursement: catheters or fibers used for EVTA are reimbursed only once in a lifetime.

In Belgium 99% of the population has access to a unique system of health care reimbursement,¹² regardless of the type of hospital or institution, public, semi-public or private. Hence the billing data available from the Belgian National Institute for Health and Disability Insurance (NIHDI)¹³ make it possible to analyze the intervention rates and their relative proportion related to age, gender or social status, in a specific field of medicine, for instance varicose veins and CVD. It is also possible to know the type of in-

tervention carried out, their geographical distribution over the country, their evolution over time and the potential influence of changes in reimbursement policies. The NIHDI has started publishing public standard reports on variations in practice since April 2019.^{13,14} This material opens up an opportunity to medical associations, like the Phlebology Working Group of the Belgian Society of Vascular Surgery, to look at their own practice, trying to understand the distribution and evolution of phlebological surgical practice in Belgium over the last 10 years (2007-2017).

The aim of the present study was therefore to better understand phlebological practice in Belgium by addressing several questions. Are Belgian data consistent with international epidemiological data? What can we learn about surgical practice in phlebology in Belgium? Did this practice evolve in line with international recommendations? Is it possible to identify factors influencing the evolution of Belgian phlebological practice? Finally, as endovenous techniques have been reimbursed in Belgium since the end of 2012,^{10,11} to what extent has reimbursement policy influenced the establishment of these techniques in Belgium?

Materials and methods

Billing (reimbursement) codes of specific phlebological surgical procedures in Belgium were selected for this study.¹⁵ Interventions consisting of sclerotherapy only were excluded. There are 10 surgical reimbursement codes and two codes for reimbursement of equipment (Table I). Three codes are certified for phlebectomy invoicing, one code for small saphenous vein (SSV) ablation, five codes for great saphenous vein (GSV) ablation, one code for bilateral varicose veins ablation and another one for surgical ligation of perforating veins. There are no specific codes for endovenous techniques available so far. Therefore, to calculate the number of thermal ablations performed, we additionally queried the billing codes related to reimbursement of specific equipment used for these endovenous techniques. We should also note that the present analysis is

TABLE I.—*Reimbursement codes of venous surgery in Belgium.*

Codification	
1619190-161921	All equipment used for complete single or bilateral Endovenous treatment of varicose veins of the lower Limbs with laser or radiofrequency during the treatment 238173-238184, 238210-238221, 238276-238280 Of the classification of the billing codes (nomenclature) (since 2014)
688996-689500	All equipment used for complete single or bilateral Endovenous treatment of varicose veins of the lower Limbs with laser or radiofrequency during the treatment 238173-238184, 238210-238221, 238276-238280 Of the classification of the billing codes (nomenclature) (2012-2014)
238070-238081	Ligation, fulguration or resection: one varicose vein
238092-238103	Ligation, fulguration or resection: two or three varicose veins
238114-238125	Ligation, fulguration or resection of more than three varicose veins
238136-238140	Total removal of the small saphenous vein
238151-238162	High ligation of the great saphenous vein
238195-238206	High ligation and total resection of one of the two saphenous veins
238210-238221	High ligation and stripping of the great and small saphenous vein
238232-238243	High ligation and ligation, fulguration or resection of varicose veins
238276-238280	Bilateral resection of the great or small saphenous vein
238291-238302	Total sub-aponeurotic ligation of the perforating veins of a lower limb

based on the hypothesis that only one of the selected codes is invoiced to the same patient on the same day, because the reimbursement rules stipulate a priori that they cannot be cumulated.

The research addressed a variety of techniques for varicose veins and their rate of use based on age, gender, social security status and geographical origin during the period 2007-2017. Belgium can be subdivided into 43 districts and globally into 3 main regions (Flanders, Wallonia and Brussels). The results comparing regions were standardized by age group, gender, and social security status.¹³ The social security status of insured persons indicates whether they have a low income and are eligible for an enhanced reimbursement of health care (preferential system) or they have a normal reimbursement system. In 2016, 18.9% of the insured were covered by the preferential system (PS) of reimbursement.¹⁶

Statistical analysis

The data presented in this document are based on the entire population. Therefore, descriptive statistics (mean, median), were used to illustrate the techniques applied for treatment of varicose veins in Belgium.

Whenever descriptive statistics highlighted potentially interesting differences between regions, techniques and periods, hypotheses derived from these observations were tested by performing several statistical analyses on the data. In general, analyses with a variable of geographical location were performed on standardized data.¹³ While the data for the entire population could be analyzed, data per insured was not available. Therefore, the rate of use of care was computed per district, as well as per age category, gender and reimbursement type, and used for statistical testing. To investigate whether or not there was a trend break between the period 2007-2017 and 2015-2017 (overall and by region), regression coefficients were compared using a *t*-test that takes into account the standard error of each regression coefficient and the number of years used in the regression. Additionally, to investigate whether the geographical distribution differed between the beginning and end point of the measurements, the coefficients of variation (*i.e.* the ratios of the standard deviation to the mean, expressed as a percentage, to measure relative variability) from 2007-2009 and 2015-2017 were compared using χ^2 test for an asymptotic distribution.¹⁷ These analyses were conducted based on the overall rate of interventions and for each technique used separately.

Secondly, to investigate whether technique, region, gender or preference scheme significantly influenced differences in utilization rate in 2017, a 4-way ANOVA with technique (3 levels: phlebectomy, perforating veins surgery, high ligation and stripping), region (3 levels: Brussels, Flanders, Wallonia), gender (2 levels) and reimbursement system (2 levels) was used. For this analysis the raw data (not standardized) were studied. Testing effects were based on the type III sum of squares as the data were unbalanced and the reported p-values were corrected for multiple testing using the Tukey-Kramer method.

Finally, to further investigate uni- and bilateral interventions another 4-way ANOVA was used with type intervention (2 levels: uni- and bilateral), region, gender and reimbursement system.

All statistical analysis were performed using SAS/EG 9.4 and Excel 2016 (Microsoft Office Professional Plus 2016).

Statistical significance was accepted at $P < 0.05$.

Results

Overall intervention rates

The main results of the study are summarized in Table II. For classic surgery (high ligation and stripping), EVTA, perforating vein surgery and phlebectomy the annual mean intervention rate was 343 per 100,000 insured individuals for 2017, giving 37,333 interventions per year (for a total population of 11.000.000 inhabitants). Not taking into account phlebectomies and other interventions for small varicose tributaries, the rate falls to 229 per 100,000 insured. The average expenses for varicose veins surgery exceeded 10 million euro per year. The vast majority of the interventions were carried out by surgeons (99%).

The mean age of the patients was 53.4 years (SD=13.8), 53.2 years (SD=13,6) for women and 54.2 years (SD=13.9) for men. Seventy percent of the interventions were carried out within the range of 40 to 69 years, regardless of gender.

For 2017, 74.6% of these procedures were done for women (P<0.001). This female predominance was observed for all age groups. This difference did not vary according to geographical region.

Most varicose vein surgery was performed on an outpatient basis (mainly day surgery) (91.5%). However, there were marked regional differences with a lower rate of one

day hospitalization in Brussels and Wallonia (87%) and 94% in Flanders. Day hospitalization has been progressing for 10 years, having increased from 79 to 91% on average.

The global rate of use of care was 364 per 100,000 insured persons for those under the regular reimbursement system whereas it was 250 per 100,000 for insured persons with PS (P<0.001) (Figure 1). Additionally, there was a significant two-way interaction for gender and reimbursement type (PS) (P<0.001). Comparisons showed that there was a significant lower average rate of use of care between reimbursement system for women (P<0.001) but not for men (P=0.46). The two-way interaction for region and gender and region and reimbursement type was not significant (both p ≥ 0.05).

During the period from 2007 to 2017, we observed a slight increase in the rate of interventions (+ 0.83% per year). During the period, 2015 to 2017, however, the number of interventions diminished by 3.86% per year with no differences between regions (Figure 2). This difference in trends between periods was statistically significant (P<0.01).

Large geographical disparities were observed in the use of care: in 2017, it ranged from 172 to 549 per 100.000 insured in the different districts (Figure 3).¹¹ Interestingly, the coefficient of variation (39%, over the period 2007-2009) decreased significantly in more recent years (19%, for the years 2015-2017) (P<0.001) (Table II).

TABLE II.—Summary of main study results.

	Varicose veins Total	High ligation and stripping	Thermal ablation	Phlebectomy	Perforator veins	Unilateral surgery	Bilateral surgery
General use of care							
Average number of interventions per year	37,333	23,085	12,257	12,326	1922	15,231	7854
Standardized rate of interventions per 100,000 insured	342.79	211.97	112.54	113.18	17.65	139.85	72.12
Average age (years)	53.43	53.17	52.73	53.6	55.48	53.39	52.73
Percentage women	74.63	69.69	71.96	84.27	72.01	67.70	73.55
Percentage of ambulatory interventions	91.46	89.37	90.46	95.61	90.01	91.29	85.64
Ratio of preferential regime to general regime	0.69	0.67	0.63	0.71	0.72	0.69	0.64
Trends							
Trend (2007-2017): % increase (+) or decrease (-) per year	+0.83%	+1.84%	+7.69%	-0.35%	-2.11%	+0.24%	+6.04%
Trend (2015-2017): % increase (+) or decrease (-) per year	-3.86%	-6.12%	+3.60%	+2.42%	-11.49%	-8.27%	-1.46%
Statistically significant difference?	P<0.01	P<0.001	P<0.01	P<0.01	P<0.001	P<0.001	P<0.001
Evolution of the coefficient of variation (by district)							
Coefficient of variation (%) (2007-2009)	38.97	23.94	NA	90.93	162.88	28.65	38.4
Coefficient of variation (%) (2015-2017)	18.99	21.33	47.48	44.58	121.22	25.21	38.8
Statistically significant difference?	P<0.001	NS	NA	P<0.001	NS	NS	NS
Expenses							
Average annual expenses (€)	€10,064 999	€ 7103 584	€ 1425 606	€ 1023 870	€ 511 939	€ 3506 751	€ 3596 833
Average cost of interventions (€)	€ 269.60	€ 307.71	€ 116.31	€ 83.07	€ 266.36	€ 230.24	€ 457.96
Main health care providers							
Percentage surgeons	99.16	99.84	100.00	97.75	99.95	99.77	99.97

NS: not significant; NA: not applicable.

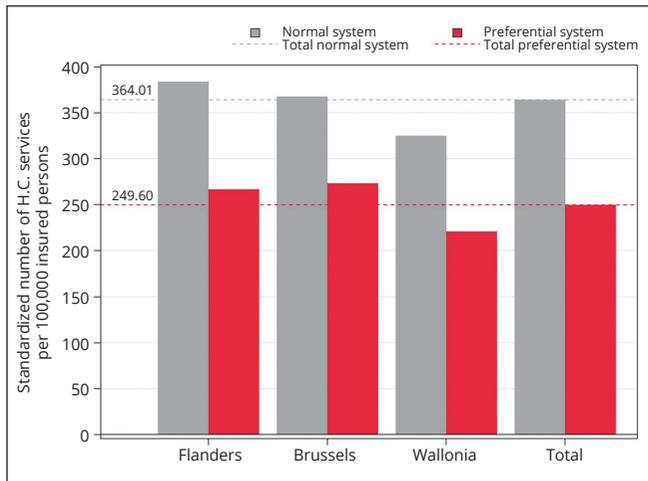


Figure 1.—Comparison of intervention rate for chronic venous disease according to social security status by region (2017). H.C. services: health care services (for varicose veins and more advanced chronic venous disease); TOTAL: the whole country Belgium; normal system: patients benefiting from the usual reimbursement; preferential system: patients with a low income, benefiting from enhanced reimbursement of health care services.

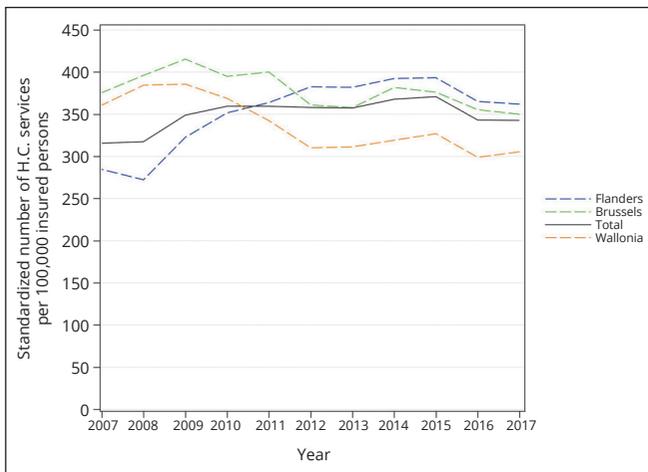


Figure 2.—Evolution of intervention rate for chronic venous disease by region (2007-2017). H.C. services: health care services (for varicose veins and more advanced chronic venous disease); TOTAL: the whole country Belgium.

Variations according to techniques

Of all the surgical interventions for CVD, 62% concerned surgical interventions on saphenous trunks, by stripping or endovenous techniques. Phlebectomies also represented one third of the procedures (33%), while perforator ligation was declared in 5% of cases. The proportion of minimally invasive, laser or radio-frequency interventions, counted for 53% of interven-

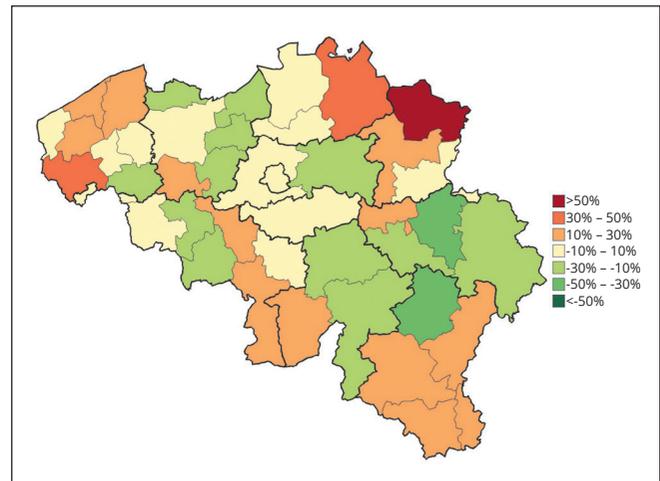


Figure 3.—Geographical variations in surgical interventions for chronic venous disease in Belgian districts (2017). The color scale indicates the coefficient of variation, which is expressed as a percentage: orange and red colors indicate districts with more use of care for chronic venous disease than the mean for Belgium, green colors those with less.¹¹

tions on the saphenous trunks, representing 33% of all interventions.

Trends in utilization rates were quite different from one technique to another (Table II).

There was a significant decrease in high ligation/stripping as well as in perforator ligation in 2015-2017 compared to the whole decade (for both $P < 0.001$). On the other hand, there was a significant increase in the use of phlebectomies ($P < 0.01$). The use of EVTA techniques, which were not reimbursed before 2012, was increasing fast with a rate of 3.6% per year during 2015-2017.

Variations in techniques showed great disparities between regions: based on the intervention rate for 2017 the four-way ANOVA showed a significant main effect for region, ($P = 0.03$). The average rate of use for high ligation and stripping was significantly higher in Wallonia than in Flanders ($P < 0.001$), whereas the rate of EVTA was lower in Wallonia than in Flanders ($P < 0.001$). The average phlebectomy rate was significantly larger in Flanders than in Wallonia ($P < 0.001$).

Unilateral versus bilateral interventions on saphenous trunks

A total of 7.854 bilateral interventions were carried out in 2017, representing 34% of all saphenectomy interventions, regardless of the technique used (endovenous or surgical). These procedures are performed less frequently in an ambulatory setting (only in 85%).

Examining possible trends in the last decade, we found a slight divergence between unilateral and bilateral interventions. Unilateral interventions were stable in the last decade (+0.24% / year) but decreased sharply in the last period (-13.18%/ year 2015-2017). The bilateral ones, which had been growing since 2007 (+6% per year), were decreasing slightly since 2015 (-1.46%) especially in Wallonia (-4.78% over 2015-2017). As a result, the percentage of bilateral procedures, which had been stable between 2007 and 2012 (22%), increased sharply from 2012 onwards and then stabilized at 33% in 2016 and 2017. Figure 4 shows the evolution of the bilateral surgical intervention rate per 100,000 insured persons over the period 2007 to 2017 for the entire country as well as the variations recorded by region.

Based on the rate of use of interventions on saphenous trunks for 2017 the four-way ANOVA showed a significant main effect for the type of intervention (uni- versus bilateral), ($P < 0.001$). The average rate of use of unilateral interventions was still significantly higher than that of bilateral interventions ($P < 0.001$).

There was also a significant effect for region, ($P < 0.001$). Comparisons indicated that there was a significant difference in average rate of use of bilateral procedures between Flanders and Wallonia ($P < 0.001$) and between Flanders and Brussels ($P = 0.001$) (Figure 4). The average rate in Brussels and Wallonia did not differ significantly ($P = 0.36$).

Discussion

This study analyzed the variation in utilization of several surgical techniques for treating varicose veins in Belgium,

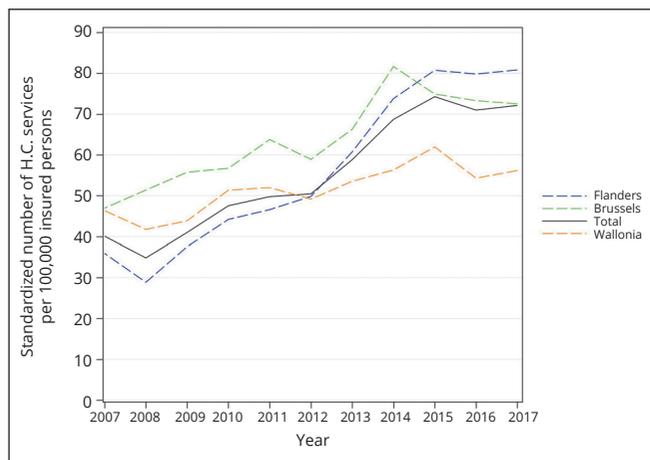


Figure 4.—Evolution of bilateral interventions rate for chronic venous disease by region (2007-2017). H.C. services: health care services (for varicose veins and more advanced chronic venous disease); Total: the whole country Belgium.

based on registered billing information. We looked at the global use of care and the influence of patient-related variations, such as age, gender, social status (based on the reimbursement system covering individual patients) and geographical origin. Globally, there was a large female preponderance, the underprivileged social classes used less care than expected and there was a remarkably large geographical disparity in care. Differences in the use of certain techniques like phlebectomies and the use of endovenous procedures were mainly based on geographical location, being more frequently used in Flanders than in Wallonia.

Global use of care for varicose veins

In 2017, 343 patients per 100,000 insured underwent a treatment for varicose veins (C2-C6). This may seem quite high, if compared to data from the international literature, where such numbers are usually rather cited for more severe cases of CVD (C3-C6).¹⁸⁻²¹ It should be pointed out, however, that intervention rate falls to only 229 per 100,000 if interventions for varicose tributaries are not included.

A decreasing rate of interventions has been observed starting in 2015. The same evolution has also been described in other European countries.²² The diminishing number of interventions cannot be accounted for by an epidemiologic change. The underlying hypothesis is that the reduction seen is associated with the increased application of techniques which cannot be detected by looking at the existing codes for surgery: for instance, it is most likely that ultrasound-guided foam sclerotherapy (UGFS), not included in the coding system yet, is gradually replacing surgical techniques for treating refluxing saphenous trunks in certain indications, conform international guidelines.^{8, 9}

Despite recent stabilization of the use of care after an unexplained period of sustained growth between 2009 and 2011, the rate of use has remained particularly high in Flanders in comparison with both Wallonia and Brussels (Figure 2). One of the reasons may be that in Flanders the use of endovenous interventions is more established, than in the two other regions. Since the side-effects, especially pain after the procedure, are less pronounced after endovenous treatment, the threshold to be treated may be lower for patients in Flanders.

Patient related variations

Women are over-represented in the use of care for varicose veins, since they account for about three-quarters of interventions. This is even more pronounced for phlebectomy,

where the rate rises to 85%. These figures are seen in every region in Belgium and for the different types of insured persons. Epidemiological studies show that venous disease is more common among women than men.²³ In Belgium the female/male ratio is at the upper end of the range seen internationally, where the ratio tends to be more about 2 to 1. This raises the question of relative underuse of care by men, or relative overuse by women.

The median age at which patients undergo operations for varicose veins is 54 years, both for men and for women, for all techniques and across all regions. This result was expected in view of the natural history of CVD, which becomes worse with age, balanced against surgical risks.²⁴⁻²⁹

A third type of variability in practice is quite remarkable: patients belonging to the most underprivileged social classes, covered by the PS, are clearly under-represented in all the categories studied. Access to care, including surgery, endovenous techniques and phlebectomy is almost 50% lower in this group. These differences are surprising in comparison with other studies on variability in practice in Belgium, where social status did not seem to influence the use of care.¹³ Moreover, the difference is significant only for women. It is therefore difficult to link this lower rate to difficulties in access to care only. An explanation would be that, among these social classes, treatment for CVD is rather considered as an unnecessary luxury. This difference in use of care is regrettable since late treatment, at more severe stages of CVD, entails more risks of deterioration in socio-professional and quality of life terms and also has adverse economic consequences.³⁰

Finally, major geographical disparities are seen in the use of care for varicose veins. This variability appears to reveal large differences between treatment practice over the country. Obviously, these cannot be accounted for by epidemiology of CVD or by international recommendations. It is difficult to conclude whether these regional differences are rather linked to specific surgical practices³¹ or to patients' habits.

Choice of surgical procedure

Four types of surgical interventions were included: high ligation and stripping, endovenous techniques, phlebectomy and surgical ligation of perforating veins. The first three account for approximately equal shares. Ligation of perforating veins, which accounts for only 5% of interventions, is only carried out in certain regions. Variability in practice appears to be mostly geographical rather than being linked to patient characteristics.

The high level of variability over the country in the use

of phlebectomies can be questioned. Is it due to local surgical practice, to the replacement of this technique by UGFS or to differences in interpretation of the nomenclature?

Replacement of stripping by endovenous techniques

Surgical techniques to treat symptomatic saphenous incompetence have been evolving over recent years and international guidelines now recommend endovenous techniques as the first treatment choice.^{8, 9, 32-35} These minimally invasive EVTA techniques have been reimbursed in Belgium since the end of 2012 and are used without difference for specific age groups, gender or type of reimbursement system (usual or PS). The observed variability is essentially related to the patient's geographical location: the implementation of endovenous techniques does not seem to be as rapid in Wallonia as in Flanders. It can be hypothesized that this will change over time, as these techniques become more established, also in the south of the country.

Along with the introduction of endovenous techniques, there has been a significant increase in bilateral interventions, from 22% in 2007, which corresponds to general epidemiological data, to 33% in 2017. This increase was significantly more striking in Flanders than in Wallonia. The fact that endovenous equipment is eligible for reimbursement only once in a patient's lifetime in Belgium carries a risk of encouraging over-treatment, by excessive scheduling of bilateral interventions from the outset, also in cases where only a unilateral treatment may have been needed. Offering treatment of the contralateral leg without proper indication is not supported by any international guideline.

Limitations of the study

Several possible biases and limitations should be highlighted, mainly directly linked to the Belgian coding and billing system.

First, sclerotherapy could not be analyzed in the present study. Indeed, there is only one reimbursement code for sclerotherapy, which covers the various indications and techniques used, from micro-sclerotherapy for minor telangiectasia and reticular veins (C1) up to UGFS of saphenous trunks. It is not possible to differentiate between indications for treatment (clinical and duplex ultrasound findings) based on the billing codes. Hence, we were not able to measure the use of UGFS, although this is nowadays an essential technique in the management of CVD. Invoicing practices probably vary from one clinician to another, and a code for sclerotherapy may be linked to a duplex ultrasound or even to a phlebectomy code. This, of course, is a wrong interpretation of the reimbursement

rules, due to the absence of a proper coding for reimbursement of UGFS and makes a proper evaluation of the impact of UGFS in Belgium impossible.

Second, the rate of use for endovenous interventions may have been underestimated, related to the fact that reimbursement of EVTA techniques is only allowed to be certified once in a patient's lifetime. If a patient needs to undergo a second operation using again an endovenous technique, the healthcare institution has to provide the catheter or fiber and equipment without any reimbursement and the intervention is usually coded as 'classic' surgery. Hence in the present study such cases were erroneously added to the wrong category of treatment technique. We estimate, however, that the impact of such errors is not very significant, since reimbursement for the equipment in Belgium only began recently and hence not so many patients will have undergone a second intervention already since the end of 2012.

Third, endovenous treatment of the small saphenous vein only is not eligible for reimbursement, unless the small saphenous vein is treated at the same time as the great saphenous vein. It is unknown if and how surgeons certify these interventions.

Fourth, the rate of use can be influenced by the number of procedures by patient during the same year (more procedures the same day, or more procedures during the same year). We have not studied whether there have been one or more interventions for a single patient in a single year, which may have slightly influenced the results.

Finally, the rate of use can be influenced by the surgeons' habits or his/her workplace. In this study the geographical criteria are linked to the patient's geographical origin and not the geographical location of the place of treatment. However, it is likely, but not certain, that most patients choose a health care institution close to their home for treatment of CVD.

Conclusions

In 2017, 343 patients per 100,000 insured underwent a treatment for varicose veins in Belgium, representing a stable situation over the last 10 years. Although there is access to health care for all inhabitants, there is a strikingly lower use of care for varicose veins by individuals with a low income. Endovenous techniques have been implemented at a faster pace in the north than in the south of the country. There are remarkably more bilateral varicose veins procedures than in surrounding countries. The wide geographical variations in treatment techniques may depend more on the surgeon's habits or patients' expectations than on international scientific guidelines.

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