



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# Health Technology Assessment of Scheduled Surgical Procedures

## Varicose Vein Surgery

April 2013

*Safer Better Care*

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# 1. Varicose Vein Surgery

## 1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral/treatment thresholds for varicose vein surgery, a high volume scheduled surgical procedure within the publicly funded healthcare system in Ireland. The effectiveness of varicose vein interventions may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled surgical procedures. Details of the background to the request and general methodology are provided in the separate 'Background and Methods' document.<sup>(1)</sup>

The scope of this HTA is to recommend clinical referral and treatment thresholds that can be used in the assessment, referral and surgical management of patients for whom varicose vein surgery is being considered. Input from an expert advisory group, international guidelines, international policy documents and economic evaluations were reviewed to inform the referral criteria. Additionally the resource and budget impact were assessed where appropriate.

## 1.2 Surgical indication

Varicose veins are tortuous, dilated veins that usually occur in the legs, often visibly protruding from under the skin. The precise aetiology of the disease is uncertain, with valvular incompetence and venous hypertension recognised as underlying factors.<sup>(2)</sup> Symptoms related to varicose veins include pain, muscle cramps, swelling, sensations of throbbing or heaviness and fatigue.<sup>(3)</sup> Other complications associated with the disease include skin discolouration, bleeding, thrombophlebitis and ulceration. Some people who do not experience any symptoms may have concerns related to the cosmetic appearance of varicose veins or potential future harms that they may cause.<sup>(4)</sup>

Varicose veins are a common health problem in adult Western populations, with an estimated prevalence of greater than 20% (range 21.8% to 29.4%).<sup>(5)</sup> Approximately 5% (range 3.6% to 8.6%) have venous oedema, skin changes or ulceration.<sup>(5)</sup> Prevalence estimates have varied widely depending on the methodology employed by the study, including factors such as the criteria used to diagnose and the age range, race and geographic location of the study population. The clinical stages of varicose veins have

been classified using the Clinical, Etiological, Anatomical and Pathophysiological (CEAP) system (Table 1.1). Simple varicose veins (CEAP<sup>(6)</sup> classification C<sub>1</sub> – C<sub>3</sub>) are more prevalent in women, with no significant gender differences being reported in the prevalence of severe varicose veins (C<sub>4</sub> – C<sub>6</sub>).<sup>(7)</sup>

**Table 1.1 Clinical stages included in the CEAP classification system<sup>(6)</sup>**

Clinical classification	
<b>C0</b>	no visible or palpable signs of venous disease
<b>C1</b>	telangiectasies or reticular veins
<b>C2</b>	varicose veins
<b>C3</b>	edema
<b>C4a</b>	pigmentation or eczema
<b>C4b</b>	lipodermatosclerosis or atrophie blanche
<b>C5</b>	healed venous ulcer
<b>C6</b>	active venous ulcer
<b>S</b>	symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction
<b>A</b>	asymptomatic

Risk factors for the development of varicose veins that have been identified in the literature include older age, family history, a personal history of phlebitis or clot, obesity, female gender, pregnancy and occupations that involve standing for long periods.<sup>(8)</sup> The evidence for other risk factors such as smoking, oral contraceptive or HRT use, hypertension, physical activity and constipation is inconsistent.

### 1.3 Surgical procedures, potential complications and alternative treatments

There are three main interventional approaches to treating varicose veins: open venous surgery, endovenous surgery and sclerotherapy. Table 1.2 provides a brief overview of each of these treatment options. A number of these procedures may be used in combination during the course of a surgical procedure.

**Table 1.2**    **Interventional treatment options for varicose veins**

Intervention	Description
<p><b>Open surgery</b></p> <p>Ligation and stripping</p> <p>Ambulatory phlebectomy</p>	<p>Open surgical treatment involves the removal of varicose veins to improve appearance, alleviate symptoms and to treat complications. In ligation and stripping procedures the vein is tied off and removed through an incision in the groin or below the knee. Ambulatory phlebectomy is an approach that can be used on its own or in combination with ligation and stripping, where the surgeon makes a series of small incisions along the length of the vein, which is then extracted through these incisions using a phlebectomy hook.</p>
<p><b>Endovenous ablation</b></p> <p>Radiofrequency ablation</p> <p>Endovenous laser ablation</p>	<p>Endovenous ablation is a newer technique for treating varicose veins that involves the insertion of a catheter that generates heat using a radiofrequency generator or laser. The heat damages the inner surface of the vein, creating an occlusion that closes off the vein completely.</p>
<p><b>Sclerotherapy</b></p> <p>Liquid sclerotherapy</p> <p>Foam sclerotherapy</p>	<p>Sclerotherapy uses a similar principle to ablation, except that the damage to the inner lumen of the vein is caused by an irritant liquid or foam rather than heat. The irritant causes inflammation and the development of fibrous tissue that seals off the treated vein.</p>

Complications associated with ligation and stripping surgery include wound complications (3%-10%), nerve injury (7% in patients undergoing stripping

to the knee, 39% in patients undergoing stripping to the ankle) and, rarely, injury to the femoral artery and thromboembolic complications.<sup>(5)</sup> Complications associated with endovenous ablation include bruising (75%), paraesthesia (3%), thrombophlebitis (1.87%) and skin burns (0.46%).<sup>(5)</sup> Recurrence of varicose veins following surgery is common: rates of recurrence ranging from 20% to 80% have been reported between 5 and 20 years after surgery, and it is estimated that 20% of patients presenting to hospital with symptomatic varicose veins have previously undergone surgery.<sup>(5;9)</sup> Repeat procedures are noted to be technically more complicated and demanding than first-time operations.<sup>(5)</sup>

Severe complications after sclerotherapy, such as death, anaphylactic reaction, pulmonary emboli, stroke and large areas of skin necrosis are very rare (<0.01%). Other rare sclerotherapy complications include thrombophlebitis, nerve damage or inadvertent arterial injection of the solution.<sup>(5)</sup> Sclerotherapy has been documented to have poor long-term results with patients having to return for repeat injection following varicose vein recurrence.<sup>(9)</sup>

### *Conservative treatment options*

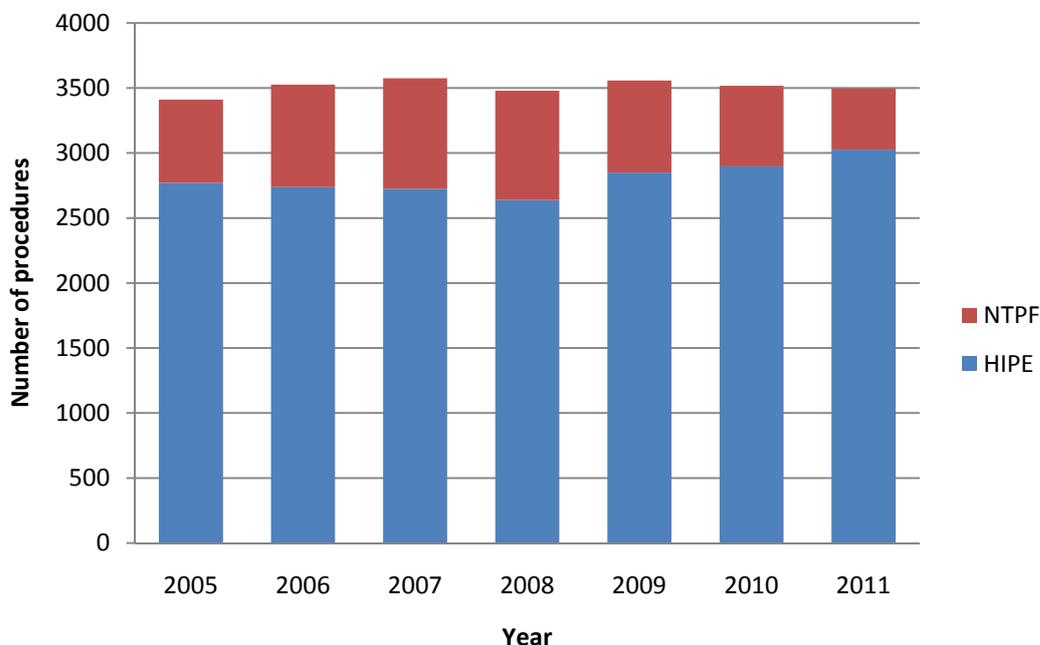
The aim of conservative treatment is to limit the progression of the condition in those who are asymptomatic or who have mild to moderate symptoms and to provide symptom relief. It is also indicated for patients who are unsuitable for surgery for reasons such as pregnancy, deep vein thrombosis or phlebitis.<sup>(10)</sup> Conservative treatment can be divided into three main types: advice and reassurance, control of oedema, and compression therapy. A number of articles highlight the need to reassure patients that varicose veins are unlikely ever to cause them harm and to explain the potential complications of surgical treatment, especially for patients who want treatment for cosmetic reasons or minor symptoms.<sup>(4;11)</sup> Patients are also discouraged from prolonged sitting or standing and advised to elevate the affected limb(s) whenever possible to reduce pressure on impaired vein valves.<sup>(12)</sup> However, a study carried out in the UK in 2006 found that although advice about elevation and exercise is often cited as part of the conservative management of varicose veins, evidence of effectiveness is lacking and provision of this advice is sporadic.<sup>(9)</sup> Compression therapy using elastic stockings or bandages is the basic and most frequently used treatment of varicose veins, venous oedema, skin changes, and ulcerations and is recommended to decrease ambulatory venous hypertension.<sup>(5)</sup> Many patients find wearing these types of garments disagreeable and they tend to

be used regularly only by those who have troublesome symptoms.<sup>(9)</sup> Conservative treatment options do not cure or reverse the effects of the condition, so surgical intervention generally becomes necessary when symptoms begin to significantly impair the patient’s quality of life.<sup>(10)</sup>

### 1.4 Current practice in Ireland

On average, 2,800 varicose vein procedures were performed annually in public hospitals between 2005 and 2011.<sup>(13)</sup> Based on 2011 Health Service Executive (HSE) cost and activity data, vein ligation and stripping surgery accounted for 49% of all vascular surgeries performed that year in public hospitals, and accounted for 15% of the overall vascular surgery costs.<sup>(14)</sup> In addition to activity levels in public hospitals, varicose vein treatment in private hospitals has also been funded for the public healthcare system through the National Treatment Purchase Fund (NTPF), so that in total, approximately 3,500 varicose vein procedures per annum have been provided in recent years (Figure 1.1).

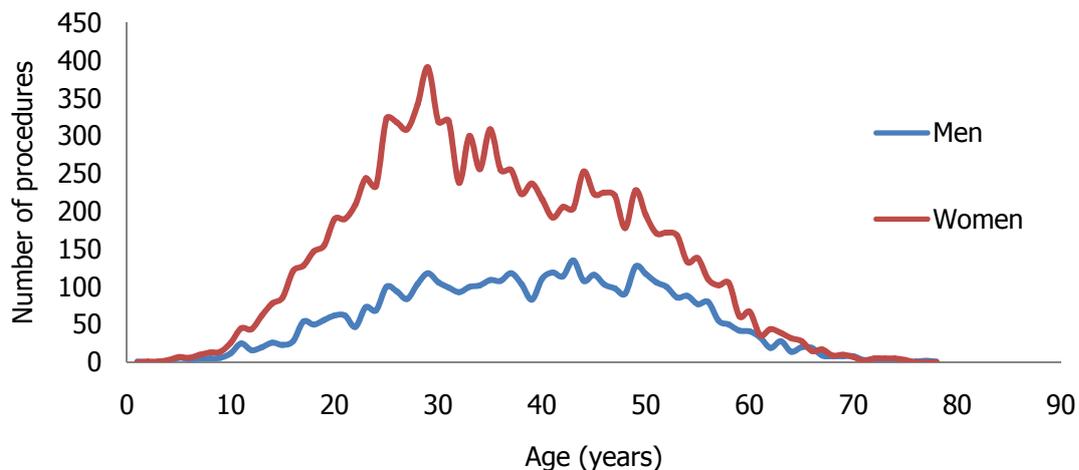
**Figure 1.1 Total number of varicose vein procedures provided by the public health care system, 2005-2011** <sup>(13;15)</sup>



Source: HIPE (Hospital In-Patient Inquiry) Scheme and NTPF (National Treatment Purchase Fund). HIPE data includes all activity in publicly funded hospitals including procedures in patients that used private health insurance.

The average age of patients discharged from public hospitals between 2008 and 2012 following a procedure for varicose veins was 48 years (47 years for women, 50 years for men); approximately 70% were female (Figure 1.2).

**Figure 1.2 Discharges from public hospitals following a varicose vein procedure by age and gender, 2008 - 2012 (HIPE data<sup>(13)</sup>)**



Source: HIPE (Hospital In-Patient Inquiry) Scheme

The breakdown of discharges between 2008 and 2012 according to the principal diagnosis is shown in Table 1.3. As noted, 70% of those treated were female. The majority (98%) of those undergoing a varicose vein procedure did not have significant complications of varicose veins (inflammation or ulceration).

**Table 1.3 Discharges from public hospitals following a varicose vein procedure by procedure code and gender, 2008 - 2012\* (HIPE data<sup>(13)</sup>)**

Principal diagnosis	Male (%)	Female (%)	Total (%)
<b>I830</b> (Varicose veins of lower extremities with ulcer)	63 (0.4%)	64 (0.4%)	127 (0.9)
<b>I831</b> (Varicose veins of lower extremities with inflammation)	33	49	82 (0.6)
<b>I832</b> (Varicose veins of lower extremities with both ulcer and inflammation)	22	28	50 (0.3)
<b>I839</b> (Varicose veins of lower extremities without ulcer or inflammation)	4,155	10,013	14,168 (98)
<b>Total</b>	4,273 (30)	10,154 (70)	14,427 (100)

Source: HIPE (Hospital In-Patient Inquiry) Scheme

Table 1.4 shows the number of varicose vein procedures by HSE region in 2011. Overall, 78% of discharges were completed as day cases in that year, although there was evidence of regional variation with day case rates varying from 71 to 86%.

**Table 1.4 Varicose vein procedures by HSE region 2011 (HIPE<sup>(13)</sup>)**

Health region	Total (%)	Directly standardised rate* (%)	Average Age	% day cases	Average length of stay	Inpatient bed days
HSE Dublin North East	897 (29)	0.09	46.46	79	1.2	225
HSE Dublin Mid Leinster	696 (23)	0.05	45.66	86	1.34	127
HSE South	889 (29)	0.08	48.78	71	1.57	400
HSE West	564 (19)	0.05	49.66	75	1.25	170

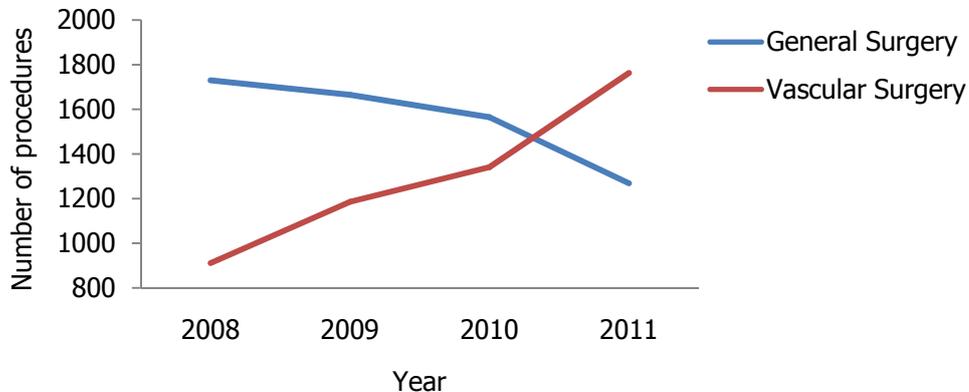
Source: HIPE (Hospital In-Patient Inquiry) Scheme

\*Note: rates are standardised for age and based on area of residence, Census 2011.<sup>(16)</sup>

A breakdown of the type of procedures performed is not readily available from the HIPE data because procedures are classified according to the site of the varicose vein rather than the technique used. Expert opinion<sup>(17)</sup> indicates that the majority of procedures in the public healthcare system are currently performed using ligation and stripping, with endovenous surgery and sclerotherapy techniques being used to a greater degree in private healthcare settings – this reflects international trends towards increased use of less invasive techniques. A survey of the membership of the Vascular Society of Great Britain and Ireland published in 2009 indicated that conventional surgery was the preferred option in both public and private practice (83% and 72%, respectively) at that time with endovenous treatment modalities being offered more frequently in private practice (14% public versus 20% private).<sup>(18)</sup> It is estimated that this difference in the rate of endovenous treatments between public and private settings is even greater in Ireland.<sup>(17)</sup>

Irish hospital data from 2008 to 2011 (Figure 1.3) indicate a trend towards the care of patients with varicose veins being increasingly led by vascular, rather than general surgeons; although of note, some vascular surgeons may be categorised as general surgeons in the HIPE system. There were a total of 98 individual consultant surgeons undertaking varicose vein surgery in Ireland in 2011. The number of procedures per consultant varied widely (median 12; 47% ≤ 10 procedures per year, 8% ≥ 100 procedures per year).<sup>(13)</sup>

**Figure 1.3 Varicose vein procedures in public hospitals by surgical discipline 2008 - 2011 (HIPE data<sup>(13)</sup>)**

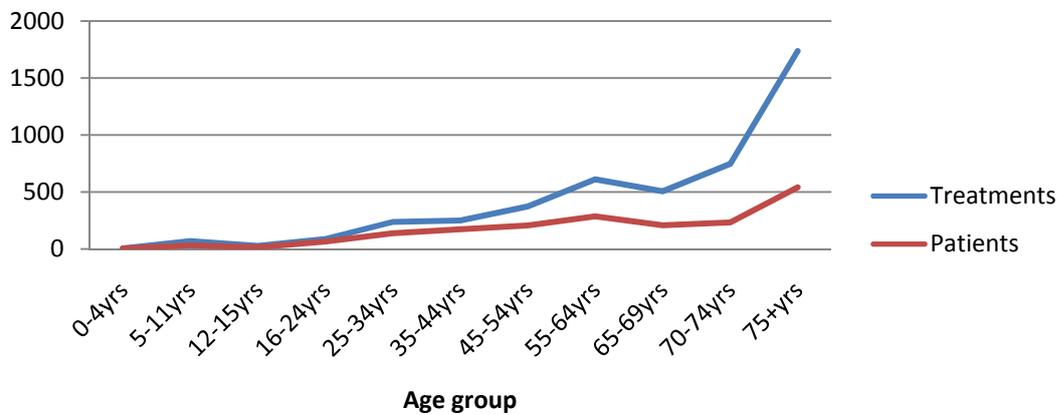


*Note: ICD procedure codes: 3250001, 3250401, 3250700, 3250800, 3250801, 3251100, 3251400; speciality codes: 2600 (general surgery), 2604 (vascular surgery).*

Patients with varicose veins who require treatment are generally referred for an outpatient consultant appointment by their general practitioner (GP). At present, there are no standardised referral criteria that are routinely used to prioritise such referrals. GPs can request that an individual referral is prioritised if the patient is in urgent need of attention; approximately 1% of hospital admissions for varicose vein procedures were made on an emergency basis between 2008 and 2011.

Sclerotherapy may be administered under local anaesthetic either in a hospital setting or by GPs in the primary care setting. Primary Care Reimbursement Service (PCRS) data<sup>(19)</sup> indicate that approximately 4,600 sclerotherapy injections were provided by almost 700 different GPs for 1,902 patients in primary care in 2011 (Figure 1.4). Patients with multiple varicose veins may have treatment staggered into a number of sessions.

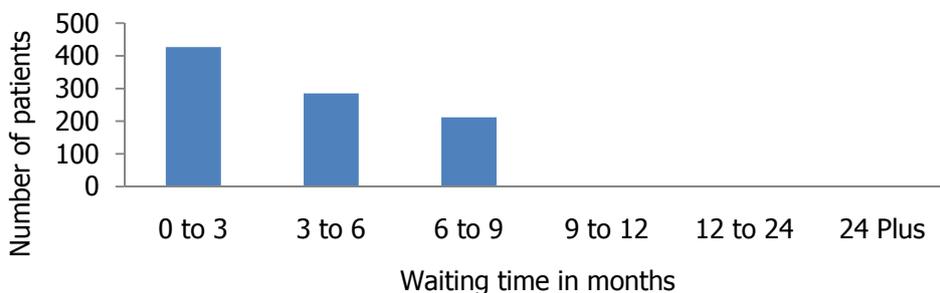
**Figure 1.4 Sclerotherapy activity reimbursed by the PCRS by patient age group (2011)<sup>(20)</sup>**



Source: PCRS (Primary Community Care Reimbursement Service of the HSE)

Accurate data on the current average waiting time for an outpatient appointment is unavailable. However, an October 2012 performance report from the HSE indicates that 47.8% of all new outpatient referrals (across all disciplines) wait longer than six months to be seen, with 28.9% waiting longer than 12 months.<sup>(19)</sup> According to the Patient Treatment Register (PTR) collated by the NTPF, there were 928 people on hospital waiting lists for treatment of varicose veins in September 2012, with over half (54%) waiting longer than three months (Figure 1.5).

**Figure 1.5 Number of patients and waiting times for varicose vein surgery (NTPF data as of September 2012)<sup>(21)</sup>**



Source: NTPF (National Treatment Purchase Fund)

There is a lack of data on the severity of varicose vein disease in those referred for outpatient review. As noted in Table 1.2, available data indicate that only approximately 10% of patients who underwent surgery in public hospitals in 2011 had varicose veins that were complicated by the presence of ulceration and/or inflammation. More detailed information on the patient population, such as the type, prevalence and severity of other varicose vein symptoms or complications, is lacking. An Irish survey<sup>(22)</sup> carried out in 2005 to examine the factors influencing patients seeking consultation for surgery for varicose veins found that the main reasons were pain (59%), appearance (41%), itching (38%), swelling (24%) and heaviness (22%). However, the sample size was small (n=78) and the study was limited to a single clinic in Dublin.

## 2. Clinical referral/treatment threshold

### 2.1 Review of the literature

A systematic review of the literature was conducted to identify international clinical guidelines on the treatment of varicose veins, health policy documents describing treatment thresholds that are in place in other health systems, and economic evaluations of the introduction of treatment thresholds for varicose veins. The search strategy is described in detail in Appendix 1 accompanying the Background and Methods document. A summary of the results of the search is shown in Table 2.1.

**Table 2.1 Search results summary**

Type of evidence	Number of relevant results
Clinical guidelines	5 <sup>(5;23-26)</sup>
Literature reviews	7 <sup>(4;10;27-31)</sup>
Health policy documents	10 <sup>(32-41)</sup>
Cost-effectiveness studies	3 <sup>(9;42;43)</sup>

### 2.2 Clinical evidence

A systematic search for clinical guidelines for the treatment of varicose veins identified four published guidelines<sup>(5;23-25)</sup> and one guideline<sup>(26)</sup> that is due to be completed in July 2013. Seven review papers<sup>(4;10;27-31)</sup> that included

information on the conservative management of varicose veins were also identified.

The most recent clinical guideline (2011) was developed by the Society for Vascular Surgery and the American Venous Forum.<sup>(5)</sup> This recommends that the CEAP<sup>(6)</sup> (Clinical-Etiology-Anatomy-Pathophysiology) classification is used for patients with varicose veins (recommendation 6.1). It also recommends that compression therapy is used for symptomatic patients, for healing venous ulcers and as an adjuvant treatment for the prevention of ulcer recurrence. However, the practice guidelines recommend against compression therapy as the primary treatment in patients who are candidates for saphenous vein ablation (recommendation 9.2). This recommendation is primarily based on a randomised controlled trial (RCT) and cost-effectiveness analysis<sup>(9)</sup> carried out in 2006 in the UK (REACTIV trial). A total of 1,009 patients were recruited: Group 1 comprised of 34 patients (minor varicose veins with no reflux) who were randomised to conservative management or injection sclerotherapy; Group 2 comprised of 77 patients (moderate below knee varicose veins with reflux) who were randomised between surgery and injection sclerotherapy; Group 3 comprised of 246 patients (severe varicose veins that were above the knee or below the knee with reflux) who were randomised between conservative treatment and surgery; the remaining 652 patients formed the observational arm. The CEAP classification was not used to classify patients, however, those with cosmetic thread veins (C<sub>0</sub>-C<sub>1</sub>) were excluded as were those with a history of ulcer or current ulceration (C<sub>5</sub>-C<sub>6</sub>). Patients with skin changes (C<sub>4</sub>) were classified as severe disease and were limited to Group 3 or the observation arm. Those patients included in Group 1 (sclerotherapy vs. conservative treatment) and Group 2 (surgery vs. sclerotherapy) who were considered to have mild and moderate disease, respectively therefore could be assumed to have a CEAP classification of C<sub>2</sub>-C<sub>3</sub>.

Group 1 comprised 34 patients with minor below knee varicose veins whose main symptoms were related to cosmetic appearance and aching and who did not have any evidence of reflux or complications. No serious complications were observed in either group. Results at one-year follow-up indicated that sclerotherapy was associated with a significant improvement in cosmetic appearance (85% vs 14% of patients had no cosmetic concerns or considered that there had been cosmetic improvement,  $p < 0.05$ ), aching (69% vs 28% of patients had no aching or considered that their symptoms had improved,  $p < 0.05$ ) and the anatomical extent of varicose veins (84.6% undergoing sclerotherapy showed improvement vs 28.6% undergoing

conservative treatment,  $p < 0.05$ ). Patients dissatisfaction was higher for those who received conservative treatment compared to those who underwent sclerotherapy (57% vs 8%,  $p < 0.05$ ). There were no significant differences in health-related quality of life (HRQoL) scores at one year, but the sample size was insufficient to exclude a clinically significant difference.

The REACTIV trial also compared patients with moderate varicose veins randomised to receive either surgery or liquid injection sclerotherapy (Group 2). Results indicated that there were no significant differences between surgery and sclerotherapy with respect to changes in symptoms at one year, but surgical treatment was significantly more likely to result in improved anatomical clearance of the varicose veins. Surgery resulted in improved HRQoL at one year on EQ-5D and VAS measures compared with sclerotherapy. There was no significant difference in patient satisfaction at one year. Group 3 of the REACTIV trial randomised patients with severe varicose veins (patients with significant skin changes or reflux  $> 1$  second and above-knee varicose veins  $> 5$  mm in diameter of any varicose veins in upper third of thigh and below-knee varicose veins  $> 5$  mm in more than one quadrant) to receive either surgery or conservative treatment. The study found that of those randomised to conservative treatment, many were dissatisfied and, by the end of the third year of follow-up, over half (51.6%) had chosen to withdraw from conservative treatment and undergo surgery. The surgical arm of the trial showed better results for symptoms, anatomical extent, HRQoL and patient satisfaction at one-year follow-up. The complication rate of those randomised to surgery was 16.9% compared to 1.7% for those randomised to conservative treatment.

Recommendations<sup>(24)</sup> developed by the Venous Forum of the Royal Society of Medicine (UK) in 2010 also support the use of the CEAP<sup>(6)</sup> classification system. They recommend that patients with uncomplicated disease ( $C_0 - C_3$ ) whose primary concern is cosmetic should not normally be treated in the public healthcare system. Uncomplicated ( $C_1 - C_3$ ) patients with oedema or symptoms that: 1) are likely to be due to chronic venous insufficiency; 2) have not responded to conservative treatment; or 3) are impairing the patient's quality of life should be referred to a vascular surgeon for clinical and duplex ultrasound examination. Urgent referral is recommended for patients with superficial thrombophlebitis, bleeding from varicosities and complicated ( $C_4 - C_6$ ) disease.

Guidelines for appropriate referral from general to specialist services<sup>(25)</sup> produced by the UK's National Institute for Health and Care Excellence (NICE) in 2001 included specific guidance in relation to varicose veins (Table

2.2). The minimum threshold for a routine referral is for patients with 'troublesome symptoms attributable to their varicose veins, and/or they and their GP feel that the extent, site and size of the varicosities are having a severe impact on quality of life.'

**Table 2.2 NICE referral advice for the management of varicose Veins**

Referral timing	Patient profile
<b>Seen immediately*</b>	Patients who are bleeding from a varicosity that has eroded the skin
<b>Seen urgently**</b>	Patients who have bled from a varicosity and are at risk of bleeding again
<b>Seen soon**</b>	Patients who have an ulcer which is progressive and/or painful despite treatment
<b>Routine appointment</b>	Patients who have an active or healed ulcer and/or progressive skin changes that may benefit from surgery
	Patients with recurrent superficial thrombophlebitis
	Patients with troublesome symptoms attributable to their varicose veins, and/or they and their GP feel that the extent, site and size of the varicosities are having a severe impact on quality of life.

Source: NICE (National Institute for Health and Care Excellence)

Key: \* within 1 day. \*\* Health authorities, trusts and primary care organisations should work to local definitions of maximum waiting times in each of these categories. A maximum waiting time of two weeks was considered to be appropriate for urgent referrals.

A Cochrane systematic review<sup>(28)</sup> published in 2011 concluded that there was 'insufficient high quality evidence to determine whether or not compression hosiery or stockings are effective in the sole and initial treatment of varicose veins without healed or active venous ulceration'. This review, which only included randomised controlled trials involving patients with a CEAP<sup>(6)</sup> classification of C<sub>2</sub> – C<sub>4</sub>, did, however, find that many studies showed a subjective improvement in symptoms for people wearing compression stockings, but there was a high risk of bias associated with this outcome since it was not made by comparing one randomised arm of a trial with a control group. Evidence of poor initial compliance with the use of stocking (approximately 30% drop-out rate reported) was counterbalanced by

speculation by the authors that a long-term compliance rate of 70% is relatively good for a treatment. No serious or long-term side effects were noted, but the authors did highlight the need for appropriate training in those fitting compression stockings as adverse effects can arise if they are incorrectly applied or used in patients with peripheral vascular disease. The conclusions of this review were in line with an earlier systematic review on compression hosiery for uncomplicated varicose veins carried out in 2009.<sup>(31)</sup>

Another recent (2011) systematic review<sup>(27)</sup> included a number of studies examining conservative treatment of varicose veins in various populations. Abramowitz<sup>(44)</sup> (1973) found that in pregnant women with lower leg varicosities, liquid sclerotherapy was superior to conservative management with compression stockings in cosmetic results and symptomatic relief. Viarengo<sup>(45)</sup> (2007) randomised patients with active venous ulcers for over a year to either laser ablation or compression therapy and found that the laser group had higher healing rates at three months (63% versus 12%,  $p=0.001$ ) and 12 months (82% versus 24%,  $p=0.001$ ). Three included studies<sup>(9;46;47)</sup> reported clinical outcomes for surgery versus conservative management. Two<sup>(46;47)</sup> involved patients with complicated varicose vein disease (CEAP<sup>(6)</sup> classification C<sub>6</sub> or an open or recently healed ulcer). In both of these studies there was no difference detected in healing rates between surgery and conservative management and in one,<sup>(46)</sup> surgery was associated with a reduced rate of recurrence (31% for surgery and 56% for conservative treatment,  $p<0.01$ ). The results of the other included study (REACTIV trial<sup>(9)</sup>) were described earlier in this section. The REACTIV trial was also identified as the sole included study involving conservative treatment in an earlier systematic review<sup>(10)</sup> published in 2008.

Discussion on conservative management in two other review articles state that compression therapy can be employed as a primary treatment for patients with symptomatic varicose veins<sup>(29)</sup> and that good communication with patients about the risks and benefits of different treatment options is fundamental.<sup>(4)</sup> The importance of reassuring patients that, for most people, varicose veins are unlikely ever to cause harm and that treatment is not essential is highlighted.<sup>(4)</sup> However, the idea that no treatment is needed for people with uncomplicated varicose veins<sup>(4;48)</sup> is challenged by some<sup>(49)</sup> who contend that treatment should not be rationed on the basis of complications alone since 'the negative effect of uncomplicated varicose veins on quality of life is comparable to that of veins with complications short of ulceration, confirming the need for intervention in this group'.<sup>(50)</sup> The difficulty in establishing a cut-off point for treatment is further highlighted by a 2011

systematic review by Warmuth,<sup>(30)</sup> which concluded that based on the available evidence it was not possible to define a border between medically necessary and cosmetically desired interventions.

### *Treatment thresholds*

Health policy documents have been published in a number of countries laying out the criteria for eligibility for different types of varicose vein treatment. In general, the purpose of these policies is to prioritise patients who stand to gain the most clinical benefit for the resources required to provide a particular treatment, while ensuring that others are directed towards alternatives that are also both clinically and cost-effective. A summary of health policies by country is provided in Table 2.3.

**Table 2.3 Policies for restricting access to, or reimbursement for, varicose vein treatment by country**

Country	Policy
<b>Netherlands</b>	In the Netherlands, the CVZ is responsible for assessing whether or not certain treatments should be covered under their universal health insurance system. In 2010 it produced a policy document <sup>(34)</sup> reporting that that 'in cases with a confirmed haemodynamic disorder or a severe complication, the treatment of varicose veins is a medical necessity and not primarily cosmetic in nature. This applies to varicose veins referred to as C <sub>2</sub> – C <sub>6</sub> in the CEAP classification used for varicose veins. It does not apply to varicose veins referred to as C <sub>0</sub> and C <sub>1</sub> in the CEAP classification. As a rule, the treatment of these varicose veins is not an insurable provision under the Health Insurance Act because these are generally cosmetic interventions.
<b>UK</b>	In the UK, decisions regarding funding for medical services within the public health system (NHS) are made by Primary Care Trusts (PCTs). There are 146 PCTs in total, each responsible for the provision of services within a defined geographical area. Survey data <sup>(18)</sup> indicate that, as of 2009, treatment for cosmetic reasons was made available in a small minority of PCTs. To be eligible for treatment in most areas, patients need to have varicose veins with

complications such as ulcers, phlebitis, bleeding or skin changes such as lipodermatosclerosis or varicose eczema. Many stipulate that symptoms must also have failed to respond to conservative treatment over the course of three to six months.<sup>(51;52)</sup> More recently, referral criteria have tended to include troublesome symptoms that are significantly impairing patients' quality of life or preventing them from taking part in work/education activities or performing vital domestic or carer duties.<sup>(53;54)</sup> There are also examples of PCTs that stipulate that the patients need to have a body mass index (BMI) less than 30<sup>(55)</sup> or 32<sup>(56)</sup> before being eligible for treatment. Some PCTs have recommended that all patients are classified using the CEAP classification system,<sup>(57)</sup> with the usual cut-off point for treatment being C<sub>2</sub> or C<sub>3</sub> unless the patients has significant symptoms. However, explicit thresholds based on CEAP classification are not used in the majority of published PCT threshold documents.

**USA**

Given the way in which the US healthcare system is organised, centralised policy documents relating to eligibility for varicose vein treatment are not produced. However, individual health insurance companies have published guidelines on eligibility for reimbursement. Some of the major insurers have applied criteria that include a mixture of physical examination, clinical history and physiological measurement. For example, Aetna<sup>(32)</sup> stipulate that reimbursement is available for patients with ultrasound documented venous insufficiency where 1) reflux duration is  $\geq 500$ ms; 2) vein diameter  $\geq 4.5$ mm; and 3) the presence of complications such as ulceration, bleeding, phlebitis or severe pain and swelling that has not responded to conservative treatment is documented. Policies that differ slightly (such as specifying a minimum vein diameter of 3.0mm<sup>(33)</sup>) were also identified as part of the literature search, along with others that focused solely on symptoms and complications and did not include specific requirements for reflux duration and vein diameter. All policies reviewed stated that treatment was not covered for patients in whom the intervention is cosmetic and/or not medically necessary.

**New Zealand** Guidelines for the management of varicose veins in primary care in New Zealand<sup>(35)</sup> include referral criteria for various subgroups of patients. For those whose principal complaint is unsightly appearance, the recommended action is to provide simple reassurance or conservative treatment to prevent or slow down progression. Onward referrals to a surgeon or for sclerotherapy for these patients can only be made to the private sector. Onward referral within the public sector for patients with unilateral oedema, ache, heaviness and superficial thrombophlebitis is only recommended when conservative treatment has failed or symptoms are severe, chronic and/or preventing activities of daily living. Varicose vein patients with more serious complications (venotensive skin signs or post-thrombotic syndrome) are referred to specialist nursing and surgical services in the public system.

Evidence of the impact that introduction of referral and treatment thresholds has had on other health services is limited, particularly in regard to the wider impact on waiting times and the demand for alternative services. However, there are longitudinal data on changes in varicose vein treatment in the UK over the time period when PCTs were implementing the policies outlined in Table 2.3. Analysis of UK hospital episode statistics for varicose vein treatment between 1998 and 2008<sup>(58)</sup> shows that over the course of that decade there has been a 34% decline in patients receiving varicose vein treatment in hospitals. Data on conventional varicose vein surgery show that waiting times for surgery had fallen by 59%, along with an overall decline in demand of 52% in women and 43% in men. Harris<sup>(59)</sup> examined the varicose vein workload and casemix before and after the introduction of clinical referral criteria in a single PCT in the UK by comparing two six-month periods in 2000 and 2002/2003. The minimum clinical criteria introduced for surgery included skin changes, ulceration, two or more episodes of thrombophlebitis or bleeding. Results showed that following the introduction of the threshold there was a 37% decrease in the number of procedures performed (134 vs 85,  $p=0.001$ ) and the average age of treated patients rose from 49 to 58 years ( $p=0.007$ ). No significant difference in the type of surgeries performed was observed.

Data from a study<sup>(18)</sup> comparing survey data from 1999 and 2009 show that rationing of access to varicose vein surgery has limited the number of

surgeons who are permitted by their PCT to operate where the indication is cosmetic (20%) or symptomatic (68%). The authors also conclude that rationing at a PCT level has led to regional variation in the availability of services and contributed towards differences in public and private practice. This difference is manifested in both the indications for treatment and the range of treatments offered. The degree to which inferences regarding prospective changes in service delivery in Ireland can be drawn from retrospective data from the UK is debatable. Therefore, it is advisable that these results are interpreted cautiously, with due consideration given to the differences in health service organisation and to the likely contribution of changes in the treatment of varicose veins that were taking place over the same time period (e.g. move towards day case surgery and the emergence of endovenous treatment modalities).

### **2.3 Cost-effectiveness evidence**

Three economic evaluation reports<sup>(9;42;43)</sup> comparing conservative management of varicose veins to alternative interventions were identified, two of which reported data from the same study.<sup>(9;43)</sup> In the other study,<sup>(42)</sup> conservative care was taken to be equivalent to no treatment and the cost of conservative care assumed to be negligible. As such, conservative treatment was used merely as a baseline rather than acting as a meaningful comparator to surgery.

The remaining economic evaluation is the cost-effectiveness analysis carried out alongside the randomised controlled trials (RCTs) conducted as part of the UK NHS REACTIV trial<sup>(9)</sup> that was described previously (Section 2.2). The economic analysis, based on 2002-2003 NHS treatment costs, concluded that standard surgical ligation and stripping of varicose veins is clinically and cost-effective for patients with severe varicose veins (above the knee or below the knee with reflux) compared to conservative treatment with an estimated ICER of £7,175 per QALY over a two-year period. Using a 10-year time horizon, economic modelling predicted an ICER of £1,936 per quality of life year (QALY). For patients with moderate disease (below knee varicose veins with reflux), there were insufficient data to carry out an economic analysis based on the trial. However, economic modelling predicted that while delivering only a small overall benefit, injection sclerotherapy is a cost-effective treatment for moderate varicose veins (£3,388/QALY). However, surgery is predicted to provide a greater benefit at a lower cost per QALY for this cohort. In patients with minor varicose veins without reflux, injection sclerotherapy is predicted to provide a small average benefit, and was cost-

effective compared to conservative treatment with a predicted ICER of £3,500 per QALY.

No Irish data on the cost-effectiveness of different varicose vein treatments or international studies that directly compared conservative treatment to varicose vein surgery were identified.

## **2.4 Budget impact and resource implications**

The average cost-per-case for inpatient and day case surgery was obtained from the 2013 'Ready Reckoner' published by the National Casemix Programme that reports the inpatient and day case activity and costs for the 39 hospitals that participated in the National Casemix Programme in 2011.<sup>(14)</sup> This indicates that the average cost of varicose vein surgery (vein ligation and stripping) is €3,810 for inpatient cases and €2,211 for day case surgery. DRG-based costs for sclerotherapy and endovenous treatments provided in an outpatient setting are not routinely reported. Since the majority of interventions carried out in public hospitals in Ireland are ligation and stripping procedures, the available information is sufficient to provide an estimate of the budget impact of varicose vein treatment and the likely effect of any given change in the number of procedures performed annually. Based on this information, the estimated cost of varicose vein treatments in Irish hospitals (79% day case, 21% inpatient) was approximately €8.3 million in 2011. In addition, there were approximately 4,600 sclerotherapy injections provided for 1,902 patients in primary care in 2011. This equated to a cost of approximately €125,000 in 2011 as the PCRS reimbursement fee for this procedure in primary care is €31.67 per procedure.<sup>(19)</sup>

The effect of the introduction of treatment thresholds is difficult to quantify with any precision, but it is possible to examine the consequences of varying the number of referrals for treatment made each year, to assess the likely effect this would have on waiting lists, service capacity and costs. If current levels of service provision were maintained, a threshold that had the effect of reducing the number of referrals by 30% would eliminate the waiting list in one year. Conversely a threshold that increased the absolute number of annual referrals by 10% would result in the number of patients on the waiting list rising to 1,270. There are a number of important limitations associated with these calculations. These include the fact that it only includes hospital activity and does not take account of the costs and resource implications of transferring the care of patients who do not meet the criteria for surgery. Another is that it does not consider the impact on the outpatient

appointment waiting lists, since data on the number of people waiting for a consultant appointment specifically for varicose veins is unknown. However implementing referral criteria would potentially reduce the number of unnecessary hospital outpatient appointments leading to a more efficient use of resources and a reduction in waiting times for patients. Across all specialities, approximately 38% of individuals seen in outpatient clinics, through the NTPF, were referred back to their GP without receiving surgical treatment between 2005 and 2011.<sup>(15)</sup> This overall average may not be indicative of patients referred for varicose vein treatment. The most recent NTPF data for vascular surgery specifically (2007, 2008 and 2009) shows wide variation in the percentage of patients who received an outpatient appointment who subsequently proceeded to surgery (34%, 70% and 80%, respectively).<sup>(60)</sup> According to Casemix<sup>(14)</sup> data, in 2011 the average cost of an outpatient appointment in the HSE was €130 – no breakdown of cost by clinical specialty was available at the time of preparing this report. The use of clear referral criteria for varicose vein surgery could lead to a reduction in the number of patients being referred for outpatient review who are unlikely to meet surgical treatment criteria at that time. This in turn would allow more efficient use of outpatient resources, improving access for those meeting the criteria and shortening the elective surgical journey without causing harm or reducing benefit.

The impact of potential treatment thresholds on surgical activity rates is less certain and would depend on how different the criteria used are from current practice. In the UK, where stringent reimbursement criteria were implemented by many primary care trusts because of funding restrictions (see Section 2.3), a 37% to 49% decrease in the numbers of procedures performed occurred<sup>(58;59)</sup> while the average age of treated patients rose from 49 to 58 years. According to HIPE data, the average age of patients undergoing varicose vein surgery in Ireland between 2008 and 2012 was 48 years. Although not categorised by CEAP classification, recorded principal diagnoses suggest that only 2% of patients undergoing treatment have significant complications of varicose vein disease (C<sub>4</sub> – C<sub>6</sub>). If however the intention is to maintain current surgical activity levels, then a stated threshold that reflects existing best practice should be used.

## **2.5 Advice on clinical referral/treatment threshold**

Taking account of the available evidence that exists in relation to the treatment of varicose veins, the following threshold criteria are advised for referral and treatment within the publicly funded healthcare system in Ireland:

The presence of varicose veins does not in itself indicate a need for surgery.

Patients with no visible or palpable signs of venous disease, those with telangiectasies or reticular veins and those with asymptomatic varicose veins without complications who are seeking treatment for primarily cosmetic reasons should not be routinely referred for treatment.

Patients with complicated varicose veins, or those who are experiencing pain, heaviness, throbbing or other symptoms resulting in significant impairment in quality of life or the patient's ability to perform essential work, education, domestic or carer activities and whose condition cannot be adequately managed in primary care should be referred for surgical outpatient review.

Patients who are not referred for surgery should remain under the care of their primary care practitioner and be reassessed as appropriate.

These criteria are designed to distinguish between patients with simple varicose veins who should be routinely referred for treatment and those who should not, based on the severity of symptoms and their impact on patients' quality of life and functional ability. Patients that present with acute complications (e.g., bleeding from a varicosity that has eroded the skin, acute severe ascending thrombophlebitis of the great saphenous vein) or severe complications (e.g., ulceration that is progressive or painful despite treatment) of varicose vein disease should continue to be referred for urgent or rapid assessment and treatment in line with current best practice.

## **3. Discussion**

Definitive evidence on which to base a referral threshold for interventional treatment (conventional surgery, endovenous surgery or sclerotherapy) as opposed to conservative treatment (advice, reassurance and compression therapy) is unavailable. There is general consensus that asymptomatic patients with no visible or palpable signs of venous disease (C<sub>0</sub>) or those with

telangiectasies or reticular veins (C<sub>1</sub>) are a low priority for interventional treatment. Similarly, there is little debate that symptomatic patients experiencing serious symptoms associated with chronic venous disease, such as oedema, skin changes or venous ulcers (generally C<sub>3</sub> – C<sub>6</sub>) need to be referred for a consultant appointment to assess all the options in regard to management of this disease. Where guidelines and health policy documents have primarily varied is in the management of patients who lie between these two groups. Policy documents produced in other healthcare systems over the last number of years generally stipulate that patients must have complicated varicose vein disease or symptoms that are significantly impairing their quality of life or functional ability, and that these symptoms have failed to respond to conservative therapy.

The specified threshold is consistent with those in use internationally and reflects current practice in the referral of patients with varicose veins. Since not all varicose vein patients are suitable candidates for conservative treatment options, the threshold omits the need for patients to have failed conservative treatment prior to being referred. However, conservative management should be considered as a first-line treatment option. The threshold does not specify what constitutes a significant impairment in quality of life due to varicose vein-related symptoms or how this should be measured. The implementation of such a threshold would therefore require agreement on the definition of a significant impairment in quality of life and how this should be documented, preferably using a validated instrument. This definition should take consideration of the resultant resource demands and competing priorities in the area of vascular surgery.

There is considerable uncertainty in relation to the impact of referral or treatment thresholds on resource use. Other countries that have implemented treatment criteria that restrict access to surgery to only those with the most clinically severe disease have observed a decrease in the numbers of procedures performed annually, a reduction in the number of people on waiting lists and an increase in the average age of treated patients. The degree to which these results are relevant or transferrable to the Irish setting is unclear. At present almost half of all vascular surgeries are to treat varicose veins and they account for 15% of the expenditure in this area.

The use of stated referral criteria should bring greater transparency, allowing for more efficient audit to ensure that there is equity of access to beneficial care. Limited current data suggest that 30% to 50% of patients referred to surgical outpatients (across all disciplines) do not proceed to surgery and are

referred back to primary care. Reducing the rate of referral of patients who do not proceed to surgery should release capacity and resources at the tertiary care level, so that the patients with greater clinical need get speedier access to outpatient review and surgery, without causing harm or reducing benefit.

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George's Lane  
Smithfield  
Dublin 7

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