Varicose Vein Surgery

FOR CONSULTATION

13 February 2013
VARICOSE VEIN SURGERY

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1.1 Scope of HTA

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral/treatment thresholds for varicose vein surgery which is 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. 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 thresholds, 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.\(^1\) Symptoms related to varicose veins include pain, muscle cramps, swelling, sensations of throbbing or heaviness and fatigue.\(^2\) 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.\(^3\)

Varicose veins are a common health problem in adult Western populations, with an overall estimated prevalence of \(>20\%\) (range 21.8% to 29.4%).\(^4\) Approximately 5% (range 3.6% to 8.6%) have venous oedema, skin changes or ulceration.\(^4\) 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. Simple varicose veins (CEAP\(^5\) classification \(C_1 - C_3\)) are more prevalent in women, with no significant gender differences being reported in the prevalence of severe varicose veins \((C_4 - C_6)\).\(^6\)

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 and occupations that involve standing for long periods. 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 1.1 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 1.1 Interventional treatment options

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Open Surgery</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Ligation and stripping</td>
<td></td>
</tr>
<tr>
<td>Ambulatory Phlebectomy</td>
<td></td>
</tr>
<tr>
<td><strong>Endovenous Ablation</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Radiofrequency Ablation</td>
<td></td>
</tr>
<tr>
<td>Endovenous Laser Ablation</td>
<td></td>
</tr>
<tr>
<td><strong>Sclerotherapy</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Liquid Sclerotherapy</td>
<td></td>
</tr>
<tr>
<td>Foam Sclerotherapy</td>
<td></td>
</tr>
</tbody>
</table>

Complications associated with ligation and stripping surgery include wound infection (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. Complications\(^{(4)}\) associated with endovenous ablation include bruising (75%), paresthesia (3%), thrombophlebitis (1.87%) and skin burns (0.46%). 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.\(^{(4)}\)

**Conservative treatment options**

The aim of conservative treatment is to limit the progression of the disease in asymptomatic patients or those with mild to moderate symptoms. It is also indicated for patients who are unsuitable for surgery for reasons such as pregnancy, deep vein thrombosis or phlebitis.\(^{(8)}\) 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 explaining the potential complications of surgical treatment, especially for patients who want treatment for cosmetic reasons or minor symptoms.\(^{(3;9)}\) Patients are also discouraged from prolonged sitting or standing and advised to elevate the affected limbs whenever possible to reduce pressure on impaired vein valves.\(^{(10)}\) 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.\(^{(11)}\) 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.\(^{(4)}\) Many patients find wearing these types of garments disagreeable and they tend to be used regularly only by those who have troublesome symptoms.\(^{(11)}\) Conservative treatment options do not cure or reverse the effects of the disease, so surgical intervention generally becomes necessary when symptoms begin to significantly impair the patient’s quality of life.\(^{(8)}\)

### 1.4 Current practice in Ireland

On average, 2,800 varicose vein procedures were performed annually in public hospitals between 2005 and 2011.\(^{(12)}\) In addition to activity levels in public hospitals, varicose vein treatment in private hospitals has also been funded for the public health system through the National Treatment Purchase Fund (NTPF). Data on the numbers of procedures carried out in public hospitals (HIPE) are shown in figure 1.1.
Figure 1.1 Number of varicose vein procedures performed in public hospitals and purchased through the NTPF, 2005-2011 \(^{(12,13)}\)

![Bar chart showing the number of procedures from 2005 to 2011](image)

Note: The HIPE data does not include the additional varicose vein procedures procured by the National Treatment Purchase Fund (NTPF): an estimated 700 additional procedures were procured annually between 2005 and 2011.

The average age of patients with a principal diagnosis of varicose veins discharged from hospitals between 2008 and 2011 was 50 years; approximately 70% were female. Differences between the number of discharges by gender and age group are shown in figure 1.2.

Figure 1.2 Varicose vein discharges for men and women by age 2008 - 2012 (HIPE data\(^{(12)}\))

![Line chart showing discharges by gender and age](image)

The breakdown of discharges according to the presence of ulcers, inflammation, or both is shown in table 1.2.
Table 1.2 Discharges with varicose veins and/or ulceration and inflammation, 2008 - 2012 (HIPE data(12))

<table>
<thead>
<tr>
<th>Principal diagnosis</th>
<th>Male (%)</th>
<th>Female (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I830 (Varicose veins of lower extremities with ulcer)</td>
<td>257 (5)</td>
<td>311 (3)</td>
<td>568 (3)</td>
</tr>
<tr>
<td>I831 (Varicose veins of lower extremities with inflammation)</td>
<td>214 (4)</td>
<td>305 (3)</td>
<td>519 (3)</td>
</tr>
<tr>
<td>I832 (Varicose veins of lower extremities with both ulcer and inflammation)</td>
<td>312 (6)</td>
<td>428 (4)</td>
<td>740 (5)</td>
</tr>
<tr>
<td>I839 (Varicose veins of lower extremities without ulcer or inflammation)</td>
<td>4,261 (84)</td>
<td>10,241 (91)</td>
<td>14502 (89)</td>
</tr>
<tr>
<td>Total</td>
<td>5,044 (31)</td>
<td>11,285 (69)</td>
<td>16,329 (100)</td>
</tr>
</tbody>
</table>

Between 2008 and 2011 more women were treated for varicose veins than men (69% vs 31%). The majority of all varicose vein patients admitted to hospital do not have either inflammation or ulceration (89%) and gender differences in treatment rates are greater in this group than in the other three diagnostic groups.

Table 1.3 Varicose vein procedures and average patients age by health region 2011 (HIPE data(12))

<table>
<thead>
<tr>
<th>Health Region</th>
<th>Total (%</th>
<th>Treatment rates (%)</th>
<th>Average Age</th>
<th>% Day cases</th>
<th>Average length of stay</th>
<th>Inpatient bed days</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>999 (28)</td>
<td>0.098</td>
<td>47.75</td>
<td>77</td>
<td>5.93</td>
<td>1375</td>
</tr>
<tr>
<td>Mid East</td>
<td>881 (25)</td>
<td>0.067</td>
<td>49.28</td>
<td>85</td>
<td>6.77</td>
<td>900</td>
</tr>
<tr>
<td>Southern</td>
<td>947 (27)</td>
<td>0.081</td>
<td>49.85</td>
<td>69</td>
<td>2.65</td>
<td>768</td>
</tr>
<tr>
<td>Western</td>
<td>678 (19)</td>
<td>0.063</td>
<td>52.47</td>
<td>69</td>
<td>4.21</td>
<td>872</td>
</tr>
</tbody>
</table>

Table 1.3 shows the number of varicose vein procedures by region for the last full year for which records are available (2011). Overall, 75% of discharges were completed as day cases in that year. Of the discharges that were not completed as day cases (862 out of 3,506), 80% (681) were associated with a hospital stay of less than three days (range 1 to 207 days).

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\(^{(14)}\) 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 is supported by (primarily UK) data from a survey\(^{(15)}\) of the membership of the Vascular Society of Great Britain and Ireland, which indicate that conventional surgery remains the preferred option in both public and private practice (83% and 72% respectively) with endovenous treatment modalities being offered more frequently in private practice (14% public versus 20% private). It is estimated that this difference in the rate of endovenous treatments between public and private settings is even greater in Ireland.\(^{(14)}\) Sclerotherapy is also carried out by general practitioners (GPs) in the primary care setting. PCRS data\(^{(16)}\) from 2010 indicate that 4,800 such procedures were carried out in Ireland that year, up from 4,499 in 2009. Irish hospital data from 2008 to 2011 (Figure 1.3) also indicates a trend towards the care of patients with varicose veins being increasingly led by vascular, rather than general surgeons.

**Figure 1.3** Speciality of consultant associated with principal diagnosis for procedures carried out between 2008 and 2011 (HIPE data\(^{(12)}\))

![Figure 1.3](image)

*Note: ICD procedure codes: 3250001, 3250401, 3250700, 3250800, 3250801, 3251100, 3251400; Speciality Codes: 2600 (General Surgery), 2604 (Vascular Surgery)*

There were a total of 98 individual consultants taking charge of varicose vein treatments carried out in Ireland in 2011. The number of procedures per consultant varied widely (median 12; 47% \(\leq\) 10 procedures per year, 8% \(\geq\) 100 procedures per year).\(^{(12)}\) 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 and a small proportion of hospital admissions for varicose vein procedures are made on an emergency basis (~1% of all admissions between 2008 and 2011). 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.\(^{(17)}\) As of September 2012, there were 928 people on hospital waiting lists for treatment of varicose veins, with over half (54%) waiting longer than three months (figure 1.4).

**Figure 1.4  Number of patients and waiting times for varicose vein treatment (NTPF data as of September 2012\(^{(18)}\))**

Available data indicate that approximately 10% of patients received treatment for varicose veins that were complicated by the presence of ulceration and/or inflammation (Table 1.2). 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\(^{(19)}\) 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. A summary of the results of the search are shown in table 2.1.

### Table 2.1  Search results summary

<table>
<thead>
<tr>
<th>Type of evidence</th>
<th>Number of relevant results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical guidelines</td>
<td>5 (4;20-23)</td>
</tr>
<tr>
<td>Clinical reviews</td>
<td>7 (3;8;24-28)</td>
</tr>
<tr>
<td>Health policy documents</td>
<td>10 (29-38)</td>
</tr>
<tr>
<td>Economic analyses</td>
<td>3 (11;39;40)</td>
</tr>
</tbody>
</table>

#### 2.2  Clinical evidence

A systematic search for clinical guidelines for the treatment of varicose veins identified four published guidelines\(^4;20-22\) and one guideline \(^23\) that is due to be completed in July 2013. Seven review papers\(^3;8;24-26;28;41\) 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\(^4\). This recommends that CEAP\(^5\) (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 reoccurrence. 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 and cost-effectiveness analysis\(^11\) carried out in 2006 in the UK (REACTIV trial), which included a comparison of conservative management and sclerotherapy in patients with mild varicose veins. The study population 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 1 year follow up indicate that sclerotherapy is 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 HRQoL scores at 1 year, but the sample size was insufficient to exclude a clinically significant difference.

Recommendations\(^{(21)}\) developed by the Venous Forum of the Royal Society of Medicine (UK) in 2010 also support the use of the CEAP\(^{(5)}\) classification system. They recommend that patients with uncomplicated disease 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 patients 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\(^{(22)}\) produced by the UK’s National Institute for Health and Clinical Excellence (NICE) in 2001 included specific guidance in relation to varicose veins. 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 provides full details on the different categories of patients and how their referral to specialised services be managed.
Table 2.2  NICE referral advice for varicose veins

<table>
<thead>
<tr>
<th>Referral timing</th>
<th>Patient profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seen immediately*</td>
<td>Patients who are bleeding from a varicosity that has eroded the skin</td>
</tr>
<tr>
<td>Seen urgently**</td>
<td>Patients who have bled from a varicosity and are at risk of bleeding again</td>
</tr>
<tr>
<td>Seen soon**</td>
<td>Patients who have an ulcer which is progressive and/or painful despite treatment</td>
</tr>
<tr>
<td>Routine appointment</td>
<td>Patients who have an active or healed ulcer and/or progressive skin changes that may benefit from surgery</td>
</tr>
<tr>
<td></td>
<td>Patients with recurrent superficial thrombophlebitis</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

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. The advisory group considered a maximum waiting time of 2 weeks to be appropriate for urgent referrals.

A Cochrane systematic review\(^{(25)}\) 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\(^{(5)}\) classification of C\(_2\) - C\(_4\), 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 (~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 fact that adverse effects can arise if compression stockings are incorrectly applied or used in patients with peripheral vascular disease and the need for appropriate training for those fitting them. The conclusions of this review were in line with an earlier systematic review on compression hosiery for uncomplicated varicose veins carried out in 2009.\(^{(28)}\)

Another recent (2011) systematic review\(^{(24)}\) included a number of studies examining conservative treatment of varicose veins in various populations.
Abramowitz (42) (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 (43) (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 3 months (63% versus 12%, p=0.001) and 12 months (82% versus 24%, p=0.001). Three included studies (11;44;45) reported clinical outcomes for surgery versus conservative management. Two (44;45) involved patients with complicated varicose vein disease (CEAP (5) classification C6 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 (44), 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 (11)) 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 (8) 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 (26) and that good communication with patients about the risks and benefits of different treatment options is fundamental. (3) 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. (3) However, the idea that no treatment is needed for people with uncomplicated varicose veins (3;46) is challenged by some (47) 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”. (48) The difficulty in establishing a cut off point for treatment is further highlighted by a 2011 systematic review by Warmuth (49), 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

<table>
<thead>
<tr>
<th>Country</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Netherlands</strong></td>
<td>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 they produced a policy document(31) 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 C2, C3, C4, C5 and C6 in the CEAP classification used for varicose veins. It does not apply to varicose veins referred to as C0 and C1 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.”</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td>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(15) 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 also stipulate that symptoms must also have failed to respond to conservative treatment over the course of 3 to 6 months.(50;51) 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.(52;53) There are also examples of PCTs that stipulate that the patients needs to have a BMI less than 30(54) or 32(55) before being eligible for treatment. Some PCTs have recommended that all patients are classified using the CEAP classification system,(56) with the usual cut-off point for treatment being C2 or C3 unless the patients has significant symptoms. However explicit thresholds based on CEAP classification are not used in the majority of published PCT threshold documents.</td>
</tr>
<tr>
<td><strong>USA</strong></td>
<td>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(29) stipulate that reimbursement is available for</td>
</tr>
</tbody>
</table>
patients with ultrasound documented venous insufficiency where 1) reflux duration is \( \geq 500\text{ms} \) 2) vein diameter \( \geq 4.5\text{mm} \) 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\(^{(30)}\)) 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\(^{(32)}\) 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 compression 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 is 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\(^{(57)}\) shows that over the course of that decade there has been a 34% decline in patients presenting for an intervention for varicose veins. 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\(^{(58)}\) examined the varicose vein workload and case mix 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 clinical criteria introduced 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 (\( p=0.007 \)). No significant difference in the type of cases performed was observed.
Data from a study\(^{(15)}\) comparing survey data from 1999 and 2009 show that rationing of access to varicose vein treatment 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 daycase surgery and the emergence of endovenous treatment modalities).

### 2.3 Cost-effectiveness evidence

Three economic evaluation reports\(^{(11;39;40)}\) comparing conservative management of varicose veins to alternative interventions were identified. Two of these reported data from the same study.\(^{(11;40)}\) In the other study\(^{(39)}\), 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 performed as part of the REACTIV trial\(^{(11)}\) that was described previously (see section 2.2). This trial was set in the UK (NHS) and included three arms, only one of which (group 1) involved conservative treatment as a comparator. In this group the population comprised 34 patients with mild varicose veins (cosmetic appearance, aching, with no evidence of reflux or complications), who were randomised to conservative treatment (n=18) or sclerotherapy (n=16). The difference between the mean cost per patient for conservative treatment and sclerotherapy was £81 (conservative treatment £52, sclerotherapy £133).

Given the small number of patients involved in this arm of the trial it was necessary to develop an economic model to assess the cost-effectiveness based on the different QALY gains associated with the outcomes of these treatments (described previously, see section 2.2). This analysis concluded that:\(^{(11)}\)
- In patients with minor varicose veins and no reflux, injection sclerotherapy provides a small incremental benefit of about 0.044 QALY (about 16 days of quality-adjusted survival).
- The additional benefit is at an incremental cost of about £155, giving an ICER of about £3,500 per QALY.
- The results are robust to univariate and multivariate sensitivity analysis, with all tested parameters providing incremental cost effectiveness ratios well below a willingness-to-pay threshold of £30,000 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 2012 ‘Ready Reckoner’ published by the National Casemix Programme that reports the inpatient and daycase activity and costs for the 38 hospitals that participated in the National Casemix Programme in 2010.\(^{[59]}\) This indicates that the average cost of varicose vein surgery (vein ligation and stripping) is €3,556 for inpatient cases and €2,158 for day case surgery. DRG-based costs for sclerotherapy and endovenous treatments are not routinely calculated. The PCRS reimbursement fee for sclerotherapy carried out in primary care is €31.67.\(^{[16]}\) 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 (75% day case, 25% inpatient, see section 1.4) was approximately €8.5 million in 2011.

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 the above 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 specialties, 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.\(^{(13)}\) The overall average may not be indicative of varicose vein treatment however, since 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).\(^{(60)}\) According to Casemix\(^{(61)}\) data, in 2010 the average cost of an outpatient appointment in the HSE was €139 – no breakdown of cost by clinical specialty is currently available. 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 would allow more efficient use of outpatient resources, improving access for those meeting the criteria and shortening the elective surgical journey without increasing 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%–49% decrease in the numbers of procedures performed occurred.\(^{(57;58)}\) 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 health system in Ireland:
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 varicose veins 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.

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. Those with more serious varicose vein disease and complications such as ulceration, progressive skin changes and/or bleeding should continue to be referred for further assessment and treatment in line with current best practice in the management of this condition.

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 (C0) or those with telangiectasies or reticular veins (C1) 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 C3 – C6) 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. The primary source of evidence regarding conservative versus interventional treatment in this group comes from a 2006 RCT that reported better outcomes associated with sclerotherapy compared with compression therapy plus advice on lifestyle, diet and exercise. There are important limitations associated with this study however, such as the small
number of patients involved (N=34). 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.

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. However, the degree to which these results are relevant or transferrable to the Irish setting is unclear.

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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