Special Topic: A study on varicose vein treatments, Patient Reported Outcome Measures (PROMs) in England, April 2009 to March 2015

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This product may be of interest to members of the public and other stakeholders to enable them to gain an understanding of the range of services available and make informed decisions about providers.

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Executive Summary

Patient Reported Outcome Measures (PROMs) have been collected for varicose vein treatment along with three other conditions since 2009/10. Patients undergoing PROMs-eligible varicose vein treatment are asked to complete a questionnaire before treatment and again three months after treatment.

There are a number of different ways that varicose veins can be treated, ranging from surgical removal to more modern, less invasive techniques. In many cases these different techniques are used in combination with one another within the same episode of care.

In July 2013, the National Institute for Health and Care Excellence (NICE) issued guidance recommending the adoption of these new techniques where appropriate, in preference to traditional surgical methods.

The purpose of this PROMs special topic is to look at the differences in outcome between these treatments as reported by the patient on their PROMs questionnaires.

Key Facts

• The proportion of varicose vein procedures being performed which are covered by the National Institute for Health and Care Excellence (NICE) guidance has increased since PROMs began in 2009/10, primarily due to the increase in endothermal procedures in preference to conventional surgery.

• The proportion of varicose vein procedures being performed which are covered by NICE guidance varies considerably by provider from 0 per cent to nearly 100 per cent. Providers which perform a large number of varicose vein procedures are more likely to offer the procedures covered by the NICE guidance.

• Participation in PROMs varies by procedure type, with patients undergoing surgical treatment more likely to participate than endothermal or sclerotherapy treatment patients.

• Health gain varies by the type of procedure (or combination of treatments) used. Surgical treatments show the highest health gains after treatment, followed by endothermal procedures then foam sclerotherapy. Patients undergoing foam sclerotherapy on average score greater health gain than other types of sclerotherapy, according to the five year sample of finalised data in this report.

• Complications following treatment vary considerably by treatment type. Patients who undergo surgery procedures are more likely to report post-operative complications such as wound problems or bleeding than patients who undergo endothermal or foam sclerotherapy treatment.
Introduction

Varicose veins\(^1\) are veins beneath the skin of the leg that become swollen and enlarged because the delicate valves in them stop working. This means that blood flows the wrong way – down the leg, instead of upwards. This produces a head of pressure which makes the veins bulge and which can lead to symptoms and sometimes other more serious problems.

Varicose vein symptoms can range in severity. For many people varicose veins are primarily a cosmetic problem and they are therefore excluded from treatment in the NHS. Symptoms of heaviness, aching and itching may be mild or severe; if severe they may justify referral for NHS treatment. Some people get complications from the high pressure in their varicose veins which, include skin damage ulceration and bleeding in which case treatment on the NHS is recommended.

There are a number of different ways of treating the varicose veins. The conventional method is surgery, where the affected vein is ‘stripped’ and varicose veins are removed through tiny incisions (phlebectomies or avulsions). In recent years newer, less invasive techniques have been developed such as foam sclerotherapy, where a substance is introduced into the vein to close them off and endothermal ablation (radiofrequency or laser), where localised heat is used to seal the vein, instead of surgical stripping.

In July 2013, the National Institute for Health and Care Excellence (NICE) issued guidance\(^2\) recommending a hierarchical approach to treatment where endothermal ablation, either radiofrequency or laser, should be considered first. If this treatment is unsuitable, foam sclerotherapy (a type of sclerotherapy where foam is injected into the vein to under ultrasound imaging guidance) should be offered. Finally surgery should be offered in cases where foam sclerotherapy is unsuitable. Commonly, combinations of treatment are used, in particular endothermal ablation in combination with either surgical phlebectomies or foam sclerotherapy.

The purpose of this PROMs special topic is to look at the differences in outcome between these treatments as reported by the patient on their PROMs questionnaires.

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\(^1\) [http://www.nhs.uk/conditions/Varicose-veins/Pages/Whatarevaricoseveins.aspx](http://www.nhs.uk/conditions/Varicose-veins/Pages/Whatarevaricoseveins.aspx)

\(^2\) [http://www.nice.org.uk/guidance/cg168](http://www.nice.org.uk/guidance/cg168)
Varicose Vein activity summary

The range of treatment types for varicose veins have been reviewed and grouped into a few main categories. The following analysis shows the number of episodes in each of these categories and where more than one method of treatment has been used the different categories are listed together. Please refer to appendix 1 for full details of the clinical coding for varicose veins.

**Figure 1.1: Number\(^a\) of varicose vein episodes\(^b\) in 2014/15 showing the proportion by procedure type.**

- **Endothermal Ablation**: 9,000 episodes
- **Surgery**: 7,500 episodes
- **Endothermal Ablation & Minor Procedures**: 5,600 episodes
- **Foam Sclerotherapy**: 5,000 episodes
- **Minor Procedures**: 2,000 episodes
- **Endothermal Ablation & Foam Sclerotherapy**: 1,000 episodes
- **Other Sclerotherapy**: 800 episodes
- **Endothermal Ablation & Surgery**: 700 episodes
- **Surgery & Minor Procedures**: 500 episodes
- **Endothermal Ablation & Other Sclerotherapy**: 200 episodes

\(^a\) Numbers in the above chart have been rounded to the nearest 100.

\(^b\) Procedure types which were recorded with fewer than 150 episodes have been suppressed for this chart. Please see Special Topic Reference Table for full details.

Endothermal ablation has the greatest number of episodes reported in 2014/15 with over a quarter (27.7 per cent) of all episodes (9,100 out of 32,700). Over a quarter (25.6 per cent) of episodes (8,400 out of 32,700) have a combination of treatment types, for example endothermal ablation and foam sclerotherapy. The row titled ‘Minor Procedures’ refers to phlebectomies and avulsions, an area of treatment with declining support from medical professionals.

To simplify further analysis, where an episode of care has multiple treatment types they have been allocated according to the following hierarchy:
1) Where an episode contains endothermal ablation, allocate to endothermal ablation;
2) Then, where an episode contains surgery, allocate to surgery;
3) Then, where an episode contains foam sclerotherapy, allocate to foam sclerotherapy;
4) Finally, where an episode contains other sclerotherapy, allocate to other sclerotherapy.

**Activity over time.**

The overall numbers of varicose veins treated in the NHS has decreased from a maximum of 35,600 when PROMs began in 2009/10 over time until a minimum in 2012/13, and increased to just below 32,700 in 2014/15. Figure 1.2 below shows the number of varicose vein procedures by year, plotted with the proportion that fall into each category.

**Figure 1.2: Number of varicose vein episodes by year showing the proportion by procedure type, 2009/10 to 2014/15.**

The chart shows a clear trend toward procedures covered by NICE guidance primarily due to a move away from surgery toward the less invasive endothermal ablation. In 2009/10 surgery accounted for just under 50 per cent of procedures; by 2014/15 this has decreased to just under 25 per cent. The opposite effect can be viewed with endothermal ablation which accounts for over 50 per cent of procedures in 2014/15.

The proportion of other treatments (foam and other sclerotherapy and other minor procedures) has remained relatively steady between 20 and 25 per cent with the proportion of foam sclerotherapy procedures increasing slightly from around 13 per cent in 2009/10 to 15.5 per cent in 2014/15.
Participation

Participation in PROMs is voluntary and patients are under no obligation to take part. Participation is estimated simply by dividing the total number of questionnaires by the number of procedures, i.e. a hospital trust which undertook 100 varicose vein procedures and returned 85 pre-operative varicose vein questionnaires would have a participation rate of 85 per cent.

In 2013/14, participation in PROMs for varicose vein patients was 40.5 per cent, this is much lower than participation for the other PROMs procedures. In 2013/14, the latest finalised year of PROMs data at the time of publication, average participation across all four PROMs procedures was just over 76 per cent, with hip and knee replacement surgery at nearly 86 per cent and 94 per cent respectively.

It is not possible to directly determine participation by procedure type. This is because when the patient completes the questionnaire, often weeks or months before the procedure, type of treatment the patient will eventually have is not always known and therefore not recorded on the PROMs questionnaire. We can only determine the type of treatment once the PROMs questionnaire data has been linked to the HES activity record.

For the purposes of this analysis, participation has been estimated by looking at the proportion of each type of procedure (as recorded in HES), which link to a pre-operative questionnaire and applying this to the overall participation rate for varicose veins.

Figure 2.1: Estimated participation rate by procedure type: 2013/14.

Figure 2.1 above shows that conventional surgery has by far the highest estimated participation rate at 51.4 per cent, followed by minor procedures. Participation among foam sclerotherapy patients is roughly half that of surgery at 27.4 per cent, followed by other sclerotherapy at the bottom with 22.6 per cent. This could potentially be because foam and other sclerotherapy treatments are relatively newer treatments and were not as widely adopted by providers when the PROMs began to be measured in 2009.
Demographics

Age and sex

When reviewing the demographic makeup of the individuals undergoing varicose vein procedures we have looked at the potential differences between men and women of all ages, how many episodes there have been and then looked at the all the different procedure types to investigate if there is any difference in the demographic make up for the different procedure types.

We have focused on 3 procedure types; surgery, endothermal ablation and foam sclerotherapy in line with the NICE recommendations. Reviewing the total number of episodes of each type over the period since PROMs reporting began 2009 until the latest finalised HES data 2015.

**Figure 3.1 Number of varicose vein episodes by age and sex with relative procedure data 2009-2015**

Figure 3.1 above shows there are a greater number of episodes for females of all ages, this is in line with expectation due to previous PROMs analysis.

Figure 3.1 also shows surgery to be consistently the most common procedure over the six year period for those under 70. However when looking at those individuals over 70 there appears to be a shift toward endothermal ablation becoming more prevalent than surgery and for those over 80 foam sclerotherapy also appears to overtake surgery along with endothermal ablation as the more common option for both men and women.
Distribution of varicose vein surgeries by Clinical Commissioning Group

Mapping rates of PROMs eligible varicose vein treatments by CCG of residence for 2013/14, as previously shown in the annual report\(^3\) and in this document, Appendix 2; there are certain inferences we can draw from the data. In particular:

- Rates appear to be higher in urban areas (in particular, some parts of London and some CCGs in and around Birmingham), whereas rates for other procedures are generally lower in urban areas.
- Rates are generally higher across the north of England (and in particular in the north west) than in other parts of England. A substantial proportion of varicose vein procedures are carried out in outpatient clinics, which are not eligible for PROMs. The consistently higher rates seen in the north of England may suggest that some regions have been quicker than others to either increase the proportion of varicose vein treatment provided or apply cosmetic exclusions to these procedures.

\(^3\) [http://www.hscic.gov.uk/catalogue/PUB17876](http://www.hscic.gov.uk/catalogue/PUB17876)
Analysis by provider

The proportion of procedures covered by NICE guidance varies significantly by provider – an NHS Trust or independent sector hospital. Figure 3.2 shows the procedures that are covered as a proportion of all varicose vein procedures, plotted against the total volume of varicose vein procedures. Each dot on the scatter plot represents one organisation.

Figure 3.2: Proportion of procedures covered by NICE guidance by provider and volume of total procedures: 2014/15

The proportion of procedures covered by NICE guidance in 2014/15, the latest finalised year of HES, varies considerably by provider from 0 per cent to nearly 100 per cent.

Among the providers that perform relatively few varicose vein procedures, there is a wide variation in the proportion of NICE recommended procedures, although there is a large number of providers that perform either no or very few of these procedures.

Providers which perform a large number of varicose vein procedures are more likely to have a higher proportion of procedures that are covered by NICE guidance. It is likely that providers which undertake a large number of varicose vein procedures are more willing to invest in specialist equipment for the foam sclerotherapy and endothermal procedures than those that do very few overall.
Health Outcome

Patients undergoing PROMs-eligible varicose vein surgeries are asked to complete a questionnaire before and after surgery. The questionnaires contain a number of different measures ranging from general health questions to questions specific to varicose veins.

The Aberdeen Varicose Vein Questionnaire (AVVQ) is a thirteen item measure (with patients asked to respond to some questions separately for each leg), that is combined into an index ranging from 0 (the best possible score) to 100 (the worst possible score). The measure asks patients about pain and irritation, the impact of varicose veins on their regular activities and the location of their varicose veins (patients are asked to draw these on a diagram).

All patients are also asked to complete two general measures, the EQ-5D Index and the EQ – Visual Analogue Scale (EQ VAS)

The EQ-5D Index is a five item measure that asks patients about their:
• ability to pursue their usual activities;
• current experience of anxiety and/or depression, if any;
• current experience of pain and discomfort, if any;
• mobility, and;
• ability to wash and dress themselves (self-care).

Patients’ responses to the EQ-5D questions are combined to give a score ranging between -0.594 and 1, with ‘1’ representing full health on the Index. This is a simple measure that is common across all PROMs procedures and therefore enables a comparison of how different procedures affect patients’ overall health.

The EQ – Visual Analogue Scale (EQ VAS) is a single-item ‘thermometer’-style measure which asks patients to rate their general health at the time of completion on a linear scale from 0 to 100, with 100 representing the best possible state of health.

There are two ways of looking at outcomes based on these measures; (1) the proportion of patients that report an improvement in score post operatively and (2) the difference in score, or health gain, between the post-operative questionnaire and the pre-operative questionnaire.
Figure 4.1 shows that in 2013-14, the latest year of finalised data, surgery had the highest proportion of patients reporting an improvement for EQ-5D at over 55 per cent and the Aberdeen Varicose Vein Questionnaire (AVVQ) just below 90 per cent. However, it is important to note that the other procedures do not differ greatly from surgery in 2013-14 for EQ-5D, with the smallest average improvement 46.8 per cent for foam sclerotherapy and the largest 57.8 per cent for surgery and the 95 per cent confidence interval shows an overlap between the procedures making it difficult to confirm the difference. The proportion of patients reporting an improvement in the AVVQ is spread between other sclerotherapy with 72.9 per cent and surgery at 89.3 per cent, with the 95 per cent confidence interval showing it is possible to state that surgery does have a higher rate of improvement.

For the EQ-VAS foam sclerotherapy scores the highest improvement rate, with 40.5 per cent, while at 37.2 per cent endothermal ablation shows the smallest improvement. However, it is important to note the overlapping confidence intervals for the treatments measured by the EQ-VAS indicating a large variance between individual scores means that the differences between treatment types are not significant.
Proportionally more patients report improvement on the AVVQ than on the more general EQ-5D Index and the EQ VAS. This is probably because this measure focuses on issues directly affected by the condition than do the more general measures.

**Average Health Gain**

Figure 4.2 below shows that the largest health gain, as measured by the Aberdeen Varicose Vein Questionnaire (AVVQ), are for patients who undergo conventional surgery at nearly 9 points, followed by endothermal ablation at 7.6 points.

Minor procedures and foam sclerotherapy treatment have similar outcomes at between 6.43 and 6.24 point respectively. Given that the 95 per cent confidence intervals for these two procedures overlap, it is not possible to say that minor procedures outperform foam sclerotherapy at this level of significance.

The AVVQ score ranges from 0 – 100 and the average health gain measured in Figure 4.2 effectively shows a five to nine point average improvement by procedure.

**Figure 4.2: Average health gain measured by Aberdeen Varicose Vein Questionnaire (AVVQ) by procedure type 2009/10 – 2013/14.**

![Average health gain measured by procedure type](image)

Finally, the lowest health gain is for the other sclerotherapy group. However the wide confidence intervals indicate the relatively low volumes of procedures in this category compared to the other groups.
Average health gain as measured by the EQ-5D, figure 4.3 are much closer together, with little difference between the groups apart from other sclerotherapy which has an average health gain marginally but significantly lower than the other categories. The confidence intervals around the health gains for the EQ-5D are wider than those for the AVVQ indicating a greater variance, or spread of health gain between the patients.

**Figure 4.3: Average health gain measured by EQ-5D by procedure type 2009/10 – 2013/14.**

Average health gain as measured by the EQ-VAS (not plotted) is close to zero for varicose veins as a whole. Although there are small differences between the different treatment types, none are significant due to the large variances in other factors between each patient.
Complications following treatment

In addition to questions relating to health related quality of life, patients are also asked a number of questions post-operatively about whether or not they experienced any common complications following treatment. Figure 5.1 below shows the proportion of patients, by procedure type, that indicated that they had experienced one or more of the following complications, wound problems, bleeding, urinary problems and allergy/reaction to a drug.

Figure 5.1: Proportion of patients who reported a post-operative complication by procedure type 2009/10 – 2013/14.

Patients who undergo surgical type procedures are more likely to report any post-operative complication than endothermal or sclerotherapy treatment patients, with just over 31 per cent of surgery patients indicating that they had experienced one or more complications compared to 16 per cent for endothermal ablation and nearly 11 per cent for foam sclerotherapy.

The main complications experienced by varicose vein patients are wound problems and bleeding. Both urinary problems and allergic reaction problems are reported by a very small proportion of patients irrespective of treatment type.

Wound problems are reported by 20.8 per cent of surgery patients compared to 7.7 per cent and 6.6 per cent for endothermal ablation and foam sclerotherapy patients respectively. For bleeding the figures are 18.4 per cent for surgery compared to 8.8 per cent for endothermal ablation and 2.3 per cent for foam sclerotherapy.
Further information

PROMs Guide

For more details on the background to the PROMs programme and an overview of data collection, processing, scoring and linking, refer to A Guide to PROMs Methodology, which is available at http://www.hscic.gov.uk/proms.

Hospital Episode Statistics

For more information about Hospital Episode Statistics, and to access the many published analyses and datasets, please visit the HES homepage at http://www.hscic.gov.uk/hes.

Acknowledgements


Contributions

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Dr. Hannah Patrick and Prof. Bruce Campbell - National Institute for Heath and Care Excellence (NICE).
Prof. Gerard Stansby – The Newcastle upon Tyne NHS Foundation Trust.

Useful links

Varicose Veins on NHS Choices
http://www.nhs.uk/conditions/Varicose-veins/Pages/Whatarevaricoseveins.aspx

NICE guidance on varicose vein treatment
http://www.nice.org.uk/guidance/cg168

NICE guidance on endothermal ablation
http://www.nice.org.uk/guidance/ipg8 - Radiofrequency ablation.
http://www.nice.org.uk/guidance/ipg52 - Laser ablation

NICE guidance on foam sclerotherapy
http://www.nice.org.uk/guidance/ipg440
### Appendix 1: Clinical Coding

<table>
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<tr>
<th>OPCS Code</th>
<th>Description</th>
<th>Treatment Group</th>
<th>NICE Guidance</th>
<th>Notes</th>
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<td>Endothermal Ablation</td>
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<td>Foam Sclerotherapy</td>
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<td>Vein graft</td>
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<td>L87.5</td>
<td>Local excision of varicose vein of leg</td>
<td>Minor procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L87.6</td>
<td>Incision of varicose vein of leg</td>
<td>Minor procedures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2: Varicose Vein Episode Map

Varicose vein treatments per 100,000 people aged 10 and over\textsuperscript{a,b} by Clinical Commissioning Group place of residence\textsuperscript{c}, 2013/14

\textsuperscript{a} Rates are calculated using the Mid-2013 Population Estimates for Clinical Commissioning Groups (CCGs) in England by Single Year of Age and Sex, using the population aged 10 years and over. Accompanying data tables may be found in the data pack.

\textsuperscript{b} About a fifth of CCGs fall into each category; any CCGs that fall on the category boundaries are placed in the lower category.

\textsuperscript{c} Episode counts used in calculating these rates are based on CCG of residence, derived from patients’ postcode of residence. Postcode of residence was unknown or located in another U.K. country for 318 of the 26,201 PROMs eligible varicose vein episodes carried out in 2013/14.