Improving Health Outcomes

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Varicose veins in North Cumbria

Geographical Area covered: North Cumbria
Focus: Case studies focusing on effectiveness

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Editorial comments on how case study is linked to improving health outcomes: (also published in Volume 1)

The objectives of the varicose vein study described by Tiplady are to demonstrate the practicalities of developing health outcomes jointly with clinicians. They want to improve health outcome by more appropriate selection of patients for varicose vein surgery. They found the literature on the effectiveness of treatments for varicose veins unclear but will use their own study and local consensus to identify factors associated with improved outcome. So far the preliminary examination of results suggests a poor correlation between the outcome of varicose vein surgery as assessed by surgeons and that as assessed by patients using the EuroQol quality of life measures. They conclude that in most cases the treatment of varicose veins is associated with improvement in important symptoms. They hope to use the lessons from this study as a start in developing health outcomes as a contract currency by specifying desired health outcome in contracts as well as volume of activity.

Abstract (also published in Volume 1)

Large numbers of patients in North Cumbria were waiting for treatment of varicose veins, and waiting times were excessive. There was a need for some way of prioritising this work but needs assessment available at the time was unhelpful. Although there was evidence that surgical treatment was associated with better outcomes at five year follow-up, there was no framework that could be used to enable purchasing of treatment according to the clinical characteristics at presentation. Published studies of outcomes of treatment did not address this problem, and there had been little consideration of the patient’s as opposed to the clinician’s views of the benefits of treatment.

We studied the outcome of treatment in 453 patients with varicose veins. All of these patients were treated by the same surgeon with a combination of surgery and compression bandaging. The outcome was measured using the EuroQol, (now EQ-5D) and a simple questionnaire which asked the patient about severity of the veins, the degree of pain, the amount of swelling in the legs, the feelings of tiredness in the legs and appearance. Assessment was carried out before, and six weeks after surgery. These questionnaires were administered by a research assistant. The surgeon completed a separate assessment of outcome.

So far we have obtained complete data on 154 of the patients. The outcomes were generally good, with most patients reporting improvement in several of the symptoms, but some reported no change and a few were worse. There was poor correlation between patient and surgeon in their evaluation of outcome. The EuroQol proved simple to administer, and with minor alterations to one of the questions could prove to be a satisfactory tool for routine use. Data collection is continuing.

The study has shown that outcomes can be measured jointly by purchaser and provider, and the measures could be used as an alternative contract currency. A purchasing policy has been implemented in the district which restricts surgical treatment to patients with moderate or severe symptoms. Further analysis will identify patient characteristics associated with particular outcomes, and this will be used to refine the purchasing policy.

Introduction:
Why this clinical area was chosen:

North Cumbria Health Authority has two local providers, and there were long waiting lists for surgery at both acute hospitals. A significant proportion of the people waiting had varicose veins, and many were approaching limits imposed by National and Regional Charter Standards. The need for some prioritising or rationing of access to treatment for varicose veins seemed clear, but needs assessment studies available at that time were not helpful. It was not possible to estimate incidence rates with confidence, and so it made little sense to attempt to estimate numbers of cases requiring surgery. Discussions between the health authority as a purchaser, and the providers focused increasingly on the question of defining which cases must be offered surgery, and those where there was an element of choice. The use of criteria such as skin changes, oedema, extensive varicosities, pain, eczema, and ulceration select about 10% of incident cases, and could represent the “non-discretionary” cases (Robins et al. 1994). The surgeons thought that this was unlikely to reduce demand for surgery very much, as they believed that they already used criteria similar to these.

The effectiveness of treatments for varicose veins was also unclear. There appeared to be no consensus about what constitutes a good outcome, or about which treatment offers the lowest recurrence rates. A cost-effectiveness study comparing surgery and injection/compression (Chant et al. 1972; Chant et al. 1978) showed that there was no significant difference between the treatments at three years, but by five years, significantly fewer of the patients treated by surgery needed further treatment when compared with those treated by injection/sclerotherapy.

Very few studies have attempted to measure both physical and emotional outcomes to treatment. Jakobsen (1979) used objective clinical measures and subjective criteria reported by the patient. The results suggested that the two evaluations did not correspond. This study used independent observers to seek patient views, and this is probably a better method than asking the views of the staff actually caring for those patients.

Further information that was required:

We decided to assess the outcome of varicose vein surgery, both from the patient’s and the surgeon’s point of view, and to use this information to develop service agreements.

The study was part of a larger project in North Cumbria developing outcomes in health care contracts.

The study started in 1995, and patients are still being entered. All patients with varicose veins referred to one local surgeon with a special interest were to be included in the study. Each patient was asked to complete two simple questionnaires at the initial out patient consultation, and at six weeks after treatment. Treatment consisted of ligation and stripping of the varicose veins with compression bandages being applied post operatively. Doppler ultrasound was available to aid diagnosis. A separate study was being carried out to evaluate three different types of bandages, but it was not thought that this would affect our results. We developed a simple questionnaire for the patients to complete which asked questions about severity of the veins, the degree of pain, the amount of swelling in the legs, the feelings of tiredness in the legs and appearance. These symptoms were rated on a score for 0 - 10, best to worst. We decided quite arbitrarily on a sample size of 500 patients because we were anxious to collect as much data as possible, and the surgeon suggested this target. We are now well on the way to achieving that.

We also asked each patient to complete the EuroQol (now known as EQ-5D) a quality of life measure being developed in a European collaboration of health economists (The EuroQol Group 1990). The EuroQol consists of seven dimensions of quality of life:

- mobility
- self-care
- usual activities
- pain/discomfort
- anxiety/depression
- health now versus health one year ago
- health today.

Each of these dimensions is rated on a scale from 0 to 5, (worst to best) apart from the question about current health (health today) which has a scale from 0 to 100.
In addition to these structured questionnaires, patients were asked about how much difference they had expected the treatment to make, whether or not they wished to see the consultant after treatment, and questions about post-operative problems such as bruising.

The surgeon rated each case on a simple single severity score, from 0 - 10. In addition, the surgeon indicated whether the veins were primary or recurrent, and whether any previous treatment had been given. The treatment used was recorded, together with any complications and the surgeon’s own assessment of the expected outcome.

Our key objectives were to:

- demonstrate the practicalities of developing outcomes jointly with the clinicians;
- improve outcome by more appropriate selection of patients for varicose vein surgery;
- develop outcomes as a contract currency, specifying desired outcome in contracts as well as volume of activity.

So far, 453 patients have been entered into the study, and complete data (i.e. before and after questionnaires) has been obtained on 154. One hundred people had treatment, and of the fifty-four who were not treated, twenty-five had no discernible varicose veins.

Women outnumbered men by about 2 to 1, with an age range from under 20 years to over 80 years. The modal age was between 50 and 59 years. Slightly more than 60% of all the patients had primary varicose veins and about 35% were recurrent. Surgery was planned for 62% of the referrals, injection treatment (sclerotherapy) in 18%, and compression bandaging in a further 7%. Varicose veins were not found in 25 of the referrals, 14 patients refused treatment, contra-indications for surgery were found in only four, and only one patient was deemed to be seeking surgery entirely for cosmetic reasons.

The outcomes of treatment were generally good. Most of the patients reported improvements over the six week period of observation in several areas. Only very few patients reported poorer scores after treatment. Leg pain, tiredness and swelling showed quite marked improvements over the six week period of observations, with the majority of patients reporting changes in scores of four or five points. Most patients assessed the appearance of their legs as having improved. The surgeon’s assessment of the outcome was that there was a reduction in the severity of varicose veins in most of the patients, but eight showed no change and nine had some degree of worsening. Surprisingly, there was poor correlation between patient and surgeon assessment of the outcome. There were 88 cases where the outcome had been assessed both by the patient and the surgeon, and the correlation coefficient (Pearson’s R), was 0.270, suggesting that even though patients and doctors generally agree that there has been improvement after treatment, they have differing perceptions of exactly what aspect of health status have changed. We will carry out more detailed analysis when the study is complete, and will be looking at whether this finding can be explained by patient characteristics or the severity of the varicose veins.

As our follow up was relatively soon after surgery at six weeks, it is possible that post operative problems such as bruising and swelling may have resulted in some patients having a lower score post-operatively than before.

Our study has shown that outcomes following a variety of treatments in patients with varicose veins have improved. These assessments have been done by the patients themselves and the surgeon, and there is a reasonably high level of agreement about the assessments. Most of these patients were presenting for the first time, but a significant proportion had recurrent varicose veins. The measures of outcome we have used have been simple, and have used before and after techniques to avoid the difficulty of the non-availability of baseline data. Nevertheless, the reduction in symptoms such as tiredness, pain and swelling are important measures of outcome. Further work is need to determine which of these symptoms are most important, and possibly to determine the relationship between subjective and objective measures of outcome. Some of the difficulties in interpreting the correlation of surgeon and patient assessments may be related to observer bias, and this could probably be reduced by observers other than the surgeon responsible for the treatment carrying out the assessments.

We have looked at outcome related to subjective measures of severity, particularly the presence of eczema, ulceration and severe oedema. These data are still being analysed, and we are looking at outcome in these groups compared with patients where these indicators of severity were absent.
Data validity studies:

No attempts were made to validate this data.

Summary findings from initial work:

Changes which were made:

We are confident that this locally-based project will lead to better contracts for the treatment of varicose veins. There are two main areas in which we think this will happen.

Firstly, we will work towards contracts which specify the degree of outcome expected following treatment for varicose veins. This, of course, will be something that can only be done after completion of the study and following extensive discussions with local clinicians. However, our experience so far is that we believe this will be possible, and indeed welcomed, by the surgeons. We will probably propose a contract for the mean change in health status for this group of patients as a whole, and the intention is that there would be some adjustment of the contract if this was not achieved. This is still some way ahead, and it is too early to discuss penalties for failure to achieve quality targets. The first stage would be to include these outcomes in the contract, to share the results and to review targets accordingly. The questions of sanctions for failure to meet these targets could only be considered as confidence in the process has developed.

The second way that we will use this data is to reach agreement on which patients with varicose veins should be treated, and those where treatment may be deferred or rejected, according to the availability of resources. This requires more detailed analysis of the data to identify predictors of good and bad outcome. We will be identifying factors associated not only with improvement in outcome, but also where there is no change, or where outcome worsens.

Because of the pressures on the surgical contracts we decided to implement a purchasing policy to restrict treatment for varicose veins. Discussions were held with a small group of surgeons from both acute trusts, and they all agreed that a difficult decision had to be made. We agreed that surgery should only be offered to patients with specific symptoms or signs related to their varicose veins, namely, pain, skin changes (eczema and or ulceration) or ankle oedema. This excludes asymptomatic varicosities, and mild symptoms without skin changes. The policy was presented to the health authority in public, and with the support of the local trusts, approved. The policy is being given wide circulation within the district, and has been in operation now for only a few weeks. It does appear to be resulting in a fall in referrals by GP’s, and surgeons now feel that they have an agreed basis to turn down requests for surgery.

We also intend to explore the possibility of demonstrating that the much maligned efficiency formula could be improved by weighting activity data by outcome. There is much criticism of this formula because it completely fails to account for improvement in health resulting from any treatment, and which can penalise health authorities for what appears to be inefficient medical care.

How changes will be monitored:

If outcome measures become part of contracts, then they will be included in our normal contract monitoring activities. This involves monthly discussion with our providers, adjustment of targets as part of contract negotiations. We will also expect more detailed clinical study to be carried out as part of the clinical audit programme. This is funded directly by the health authority, and the forward programme is agreed jointly with the clinical audit committees.

We will work with the provider to audit the policy of restricted access to treatment, looking at how selection for surgery matches the health authority’s purchasing policy.

Outcomes as part of the contract would be subject to regular reports to the commissioning meetings.

Resource Implication:

The research assistant attended the outpatient clinics specially held for patients with varicose veins. Data preparation and entry into the survey database was carried out separately. In total, about two days per month were needed for these activities. The total cost of the outcomes project, was £65,000 over a two year period.
Maintaining data collection in this study will require about 4 hours of administrative support each week. We would recommend that this should be at a fairly senior level, such as A & C Grade 5, in order to ensure high quality of work.

Practical lessons learnt:

The measurement of outcomes after treatment for varicose veins can be done relatively simply, and most importantly, can be a joint project between purchaser and provider. The research project has strengthened relationships between Public Health and clinical medicine, and has led to a greater confidence in discussions about clinical effectiveness and prioritising health care. It was never our intention to use this information to shift contracts to other providers if the outcome of treatment had not been satisfactory, nor did we mean to compare results with other surgeons. If however, information like this was available from other providers we would have felt justified in raising the issue.

The study was part of a larger project on health outcomes, and was generously supported by a grant from the Northern Regional Health Authority research and development funds. Without this support only a limited study would have been possible.

Although we have shown how simple data can be very useful for measuring outcome, as a routine tool to clarify purchasing decisions, it is not without cost. Our project had a full time research worker and the support of enthusiastic and energetic staff in the hospital. Collecting these data routinely will require a modest investment, and we are currently exploring how this could be achieved.

The EQ-5D proved to be easy to use, most patients finding it straightforward. The question on the patient’s current state of health used a scale from 0 to 100, and some patients found the scale difficult. With encouragement, this problem was overcome, but we think that a shorter, scale, possibly with 10 points would achieve greater compliance. As a routine tool the EQ5-D has much to commend it. Like most health scales it may be insensitive to small changes in status, and may need to be supplemented by more specific outcome measures. We have been using the EQ5-D in other arms of this outcomes project and have found that the elderly and mentally ill have great difficulty in self assessment. And we therefore abandoned its use in these groups.

In many health authorities the treatment of varicose veins has often been seen as contentious. However, our study has shown that in most cases the treatment is not simply cosmetic, but is associated with improvement in more important symptoms as well as more objective signs. In some respects, we have only shown what the surgeons knew all along, but it has been extremely useful to affirm the health gain following treatment. We now feel we have powerful data to claim a higher place for varicose veins in the purchasing priorities of a health authority. We will also have data that will help us to control the total expenditure on varicose veins according to evidence of outcome, and if prioritising or rationing decisions have to be made, then these will be fair.

We believe quite strongly that outcomes should be measured, and that it is a major responsibility of the purchaser of care to ensure that this is done, and that contracts should take outcomes into account. We are now discussing with the surgeon a contract for varicose vein surgery which specifies who should have surgery, and what outcomes are expected.

Conclusion:

It is too soon to say whether the use of outcome measures is going to be embedded in the organisational framework of North Cumbria Health Authority. This will depend upon further discussions about the nature and content of the contracts using the outcome measures we have determined in this study. It will also require a way of collecting the data on a routine basis, which is not yet finalised.

We have discussed the project quite widely during its life so far, and have held a seminar for senior managers of the health authority, including the commissioning team. There was much support for progress towards outcome-based contracts, but as yet, no clear agreement as to how that could be done. That will be addressed in the next phase of the project, which will address these issues over the coming months.

References:

A) Varicose veins
Organisational Context:

The key people in the varicose vein study were the public health department and the lead vascular surgeon in the acute hospital trust. The development of clinical outcomes as part of the Authority’s business is in its infancy, and this study could not have gone ahead without the enormous commitment of the surgeon involved. The research was led by the public health department, and the major enabling factor which got the whole study off the ground was the appointment of a full-time research worker, funded by the research and development division of the Northern Regional Health Authority. Without this support only a limited study would have been possible.

The development and use of outcome indicators in purchasing remains something of a holy grail for health authorities. North Cumbria Health Authority, in company with many others, is at an early stage in its use of outcomes to support its purchasing strategy. The health authority is now committed to an evidence-based purchasing plan, and has stated that it requires good evidence that any changes from existing patterns of service will improve outcomes. All changes in clinical services are subjected to critical appraisal and will only progress to consideration for funding if there is good evidence adduced for their benefits. This work cannot be carried out globally on all aspects of the health authorities purchasing portfolio, which would require a level of resources out of all proportion to the benefit. By concentrating on areas of change, that is to say on the margins the health care programme, it is possible to incorporate the results of detailed consideration of outcomes.

In North Cumbria this work has been largely stimulated and led through the public health department, but it relies heavily on commitment from other directorates, and most importantly, by the clinicians in the trusts. Our experience has been that a collaborative approach to outcomes affirms the clinical work in a major way. Consultants want to demonstrate that what they do improves health, and is good value for money. The common purchasing currency of service activity is viewed with disdain by clinicians, and the absence of outcome measures from the efficiency index emphasises this difficulty. What the clinicians would like to see are contracts that demonstrate that their care is effective, both in health and financial terms. We are working confidently towards contracts that specify the expected outcomes of health care, and we hope to include quantified targets to achieve this. These are sensitive areas and there needs to be extensive collaborative work between health authorities and Trusts. We believe that the liaison at a clinical level is the key feature in progress, and health authorities will need strong clinical support themselves in public health, primary care, nursing and other clinical areas. At a time when health authority management costs are continually under scrutiny, the importance of a health led strategy cannot be over-emphasised.