Improving Health Outcomes
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Carotid stenosis: the need for a screening programme and surgery in East Kent

Geographical Area covered: East Kent
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)

A service review was undertaken examining the local provision for the management of carotid stenosis. Effectiveness evidence was used to determine for which patients it was appropriate to perform endarterectomy and which high risk patients should be considered for screening. Chandrakumar notes that from a population perspective endartectomy would only reduce the total incidence of stroke by 1%. However, from an individual perspective the procedure can substantially improve health outcome in high risk patients.

Abstract (also published in Volume 1)

East Kent Health Authority undertook a service review as a result of concerns raised by local clinicians regarding the inadequate local provision of services for the screening and surgery for carotid stenosis as a means of preventing stroke. The review included a detailed examination of the evidence available regarding the effectiveness of screening and surgery, current local provision of services and identified the changes necessary to meet the gaps. The study concluded that patients who have had non-disabling strokes and transient ischaemic attacks should have an assessment and screening for carotid occlusion and carotid endarterectomy should be offered for those with 70-99% stenosis. It also concluded that the provider surgical teams should demonstrate the expertise, training and should commit to accurate and complete records, including clinical indications, operative techniques and outcome. Cost benefit analysis was conducted to identify the resource implications.

Introduction:

Why this clinical area was chosen:

East Kent Health Authority decided to undertake a service review regarding the provision of carotid surgery in view of the concerns raised by local clinicians. Neurologists, vascular surgeons and radiologists working in East Kent have recently been expressing an opinion that the secondary prevention of stroke is not being adequately addressed in East Kent. As the evidence became available on the benefits of carotid surgery on patients with severe carotid stenosis from published literature, local clinicians felt that this was a service that should be provided locally. Therefore they approached the Health Authority for additional funding.

Radiologists based at Thanet Healthcare Trust were screening patients for carotid stenosis and were referring them for surgery to teaching hospitals in London. In addition, prior to this case study, local surgeons have also been undertaking carotid artery surgery in numbers fewer than 10 per year. East Kent Health Authority believed that this annual volume of surgery may provide inadequate experience for the surgeons and their teams and may be associated with poor outcome. Therefore concerns were raised regarding the availability and the quality of carotid endarterectomy as means of secondary prevention of stroke. All three Trusts in East Kent were in the process of reviewing vascular surgery and hence there were cost implications for the Health Authority. It became evident that there were variations in access to screening and endarterectomy in the area. For example, residents in Thanet received routine screening whereas others did not. This case study was undertaken to address these issues and inform East Kent Health Authority on the way forward.
Further information that was required:

A Health Service Review was undertaken which examined the following:

A) Local information on incidence and prevalence
An incidence is the fraction or proportion of a group initially free of the condition that develop it over a given period of time. A prevalence is the fraction (proportion) of a group possessing a clinical condition at a given point in time. The incidence of Sub Arachnoid Haemorrhage (SAH) is 0.14 per 1000 per year, Transient Ischaemic Attacks (TIAs) affects new patients at a rate of 0.42 per 1000 per year and the incidence of first or recurrent stroke is 2.40 per 1000 per year. The prevalence of stroke survivors is approximately 6 per 1000 and 3 per 1000 being disabled (Wade 1994). Estimated incidence and prevalence for East Kent were calculated applying these rates to the mid-year population estimates for 1994 and are detailed in table 6.

Table 6: Estimates of Incidence and Prevalence of Cerebro Vascular Accident (CVA) in East Kent (based on the mid year population estimate for 1994 of 582,980).

| Incidence of sub-arachnoid haemorrhage per year | 82 |
| Incidence of transient-ischaemic attacks per year | 244 |
| First or recurrent stroke per year | 1399 |
| Prevalence of stroke survivors in a given year | 3498 |
| Prevalence of people who are disabled due to stroke in a given year | 1749 |

B) Information on the effectiveness of management of carotid stenosis
Prevention
This includes primary prevention and secondary prevention of stroke. Population measures aim to reduce the overall incidence of stroke by screening a targeted subgroup of the population in order to identify and modify risk factors. Special attention needs to be paid to patients who are known to be at an unusually high risk of stroke, the majority of whom are identified by presenting with preliminary TIAs or minor stroke. This secondary prevention, i.e. reduction in risk of second and subsequent stroke, may involve the use of aspirin, anticoagulation and carotid endarterectomy and better control of obesity, smoking and dietary lipids.

Diagnosis and investigation of TIA and stroke
A voluntary organisation (Stroke Association) in conjunction with the Health Authority has set up a stroke project which has conducted a number of research studies. One of the studies involved a survey among GPs in Canterbury & Thanet.

Evidence from this Canterbury & Thanet Stroke Project research (Pollock 1993) suggests that General Practitioners do not diagnose TIAs confidently and require specialist advice. This conclusion was reached because a third of the GPs who responded felt that TIA was a difficult diagnosis to make. Stroke due to haemorrhage cannot be reliably separated to those due to infarction on clinical grounds. CT scanning is required when medical intervention is proposed and this now includes the majority of strokes.

Specific medical and surgical treatment
Treatment of patients with previous TIA with Aspirin does reduce recurrence by 20% (UK-TIA Study Group 1991). In all patients identification and treatment of risk factors may reduce recurrence. Carotid endarterectomy reduces the stroke rate in patients, especially those who have already had TIAs or minor strokes and who have a 70-99% carotid stenosis European Carotid Stenosis Trialists Collaboration Group 1991; North American Symptomatic Carotid Endarterectomy Trial Collaboration 1991). Two studies from the USA came to similar conclusions (North American Symptomatic Carotid Endarterectomy Trial Collaboration 1991; Dennis 1987).

Carotid endarterectomy
Patients with carotid stenosis are at increased risk of stroke, particularly if they have already had a “warning” TIA. Less than 15% of stroke are preceded by TIAs and it is likely a maximum of 20% of all TIAs will be eligible for operation. Carotid endarterectomy will reduce the total incidence of stroke by about 1% (Dennis 1987).

The value of carotid endarterectomy was the subject of a European randomized controlled trial which demonstrated that carotid endarterectomy is clearly beneficial in patients who have severe carotid stenosis (70-99%) and have had a TIA or minor stroke attributable to this carotid lesion (European Carotid Surgery Trialists Collaborative Group 1991). Two studies from the USA came to similar conclusions (North American Symptomatic Carotid Endarterectomy Trial Collaboration 1991; Dennis 1987).
It is essential to establish and monitor morbidity/mortality rates of surgical teams which undertake carotid endarterectomy, because the risks of intervention must inevitably be effective against the benefits of long term protection. A British survey found that 61% of surgeons undertaking carotid endarterectomy undertook less than ten a year, a rate which is probably too low to allow reasonable expertise to develop or to be maintained (Murie et al. 1991). Carotid endarterectomy should be undertaken only by surgeons who perform a substantial number (more than 20) of these operations per year. They must have a record of adequate training and experience and must have demonstrated acceptably low morbidity undertaking the operation.

**Indications for carotid endarterectomy**

- Severe stenosis (70 - 99%) of the internal carotid artery in a patient with a history of a TIA or minor stroke attributable to this lesion is a definite indication for carotid endarterectomy;
- There are trials being conducted at present as to the effectiveness of carotid endarterectomy in patients with a history of TIA or minor stroke who have 50-70% stenosis of the appropriate carotid artery. Until these results are available, it is recommended that this should not be considered as an indication.

**Who should be screened for carotid stenosis and by whom?**

The following categories of patients should be considered for screening (Colchester 1996):

- Patients who have had transient ischaemic attacks or non-disabling strokes.
- Patients with severe coronary or peripheral vascular disease, especially those with a cervical bruit.
- Patients with neck bruit with a known high risk of atherosclerosis, e.g. with a strong family history.

Ultrasound screening may be requested by another specialist before involvement of a neurologist but, to minimise the number of patients having invasive procedures unnecessarily, no patient should have x-ray angiography or surgery without a neurologist's opinion.

**C) Current service provision in East Kent**

**Diagnosis and investigation of TIA**

Identification of patients with severe carotid stenosis, selection of those who should be offered endarterectomy, and the surgical service itself, require the co-ordination of several groups of specialists, each of which have to perform to a high standard to justify the service at all. At present, the majority of East Kent cases assessed by a Neurologist with an interest in stroke prevention, and are referred for carotid ultrasound, and if necessary for x-ray angiography and carotid endarterectomy, to experts in London with a proven record of high quality results. Before a decision to commission a comprehensive service locally in Kent, the suitability of local centres to undertake such activity would have to be ascertained.

**Outcome following carotid endarterectomy in East Kent**

Preliminary analysis of data indicates that since 1990 and October 1995, there were 18 carotid endarterectomies performed by Provider Units within East Kent among East Kent residents (table 7).

<table>
<thead>
<tr>
<th>PROVIDER</th>
<th>Number of Carotid Endarterectomies</th>
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<tbody>
<tr>
<td>A</td>
<td>4 1993</td>
</tr>
<tr>
<td>B</td>
<td>10</td>
</tr>
<tr>
<td>C</td>
<td>1 1993</td>
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<td>D</td>
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<tr>
<td>TOTAL</td>
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Table 7: Carotid endarterectomies among East Kent residents
Of the 18 operations performed in East Kent since 1990, analysis of the flat file data showed that one person died (6%) in hospital (male aged 75) two days after an elective admission (16th November 1992). One person (male aged 72 - 6%) was transferred to another consultant episode with the diagnosis of stroke/CVA 7 days after elective admission (24th March 1993). Both of them had carotid endarterectomy as the main operative procedure. This transfer was from a general surgeon to a geriatrician. All patients except the one who died were discharged from hospital alive and none of the subsequent re-admissions had any related diagnosis.

Data validation
Regional flat files are made up of in-patient data sent to the region by the provider units. Following the data validation conducted by the "clearing house", the information is checked and updated regularly by the regional information centre.

D) Changes and facilities which could be needed to develop a comprehensive effective service in East Kent
We estimated the number of people involved at each stage of the screening programme to develop a comprehensive local service that will screen selected patients for carotid stenosis and offer treatment in the form of carotid endarterectomy, the following requirements have to be met:

Ultrasound angiology
It is understood that this expertise is at present available with the Trusts in East Kent. The equipment to perform the tasks are also available. However, the quality of results of carotid ultrasound is known to be highly variable between centres and is very operator dependent. This again is an area EKHA should ensure that satisfactory quality standards are met before commissioning the service.

CT and MRI scanning
Again the equipment and the expertise are available in East Kent.

Laboratory facilities
Existing laboratory facilities are adequate and there is no need for additional equipment.

Clinical neurology
There is a need for an expert neurologist with a special interest on the subject to run a Neurovascular Clinic and to co-ordinate the audit of a new endarterectomy service. Although many patients with carotid disease are already seen by a neurologist, the numbers will rise if the service is developed locally. This has been a problem because of the enormous pressure on the neurology service. However, now that two new Neurologists have been appointed in East Kent, the situation has improved. Furthermore, the number of cases being referred for endarterectomy is rising nationally.

One option is the setting up of a neurovascular clinic with a clinical assistant or a junior doctor working under the supervision of a neurologist. If additional clinical assistant sessions are purchased, then the Neurovascular Clinic may undertake the screening programme and will have minimal adverse effect on the waiting time.

Specialist neuro-radiology
X-ray angiography (Digital Subtraction Angiography) is an essential part of this programme. There are potentially serious complications of cervical/cranial angiography but the risks are low in experienced hands. There are currently no neuroradiologists but there are skilled general radiologists in South Kent Hospitals and Kent and Canterbury Hospital NHS Trust who have the expertise to provide this task. The complication rates must be audited and the risks of angiography must be seen as part of the overall risk of carotid endarterectomy.

Vascular surgery teams to perform carotid endarterectomy
Theatre facilities are already available. There is no need for specialised equipment except standard vascular surgery ones. It would be possible to develop the necessary anaesthetic skills which require more stringent monitoring and more experience.

New vascular surgeons have been appointed at South Kent Hospitals, Thanet Healthcare Trust and at Kent and Canterbury Hospital NHS Trust. It is understood that these surgeons have had training in performing carotid endarterectomy. However, East Kent Health Authority should ensure that satisfactory quality standards regarding training, experience etc. are met before commissioning this service. It should also be emphasised that it is not only the surgeon himself but the supporting team including anaesthetists, theatre staff, and ITU staff who should have adequate training in dealing with these cases.

It is therefore possible to develop this service locally with the minimal extra resources. However, before a long term policy is established, East Kent Health Authority should request the providers to demonstrate the quality of the available facilities and to confirm their co-operation with a prospective two year audit. Audit of
the Endarterectomy Service should be undertaken over a two-year period to establish the appropriateness of the cases receiving surgery, the morbidity and mortality and to consider the possible causes of complications that have arisen. The service could then be launched and would be monitored over a two-year period by an independent team with input from the Department of Public Health Medicine. The long term policy, including the balance between the commissioning service from major centres in London and locally within East Kent would be reviewed at the end of the first and second years.

Data validity studies:

Summary findings from initial work:

Changes which were made:

As a result of this case study, it was agreed that there should be local services developed. A health service review of the stroke/neurorehabilitation services is being undertaken at the same time. Therefore, the results of this study were included in the Review and the following recommendations are being made to the East Kent Health Authority.

1. To establish a neurovascular clinic to co-ordinate existing activity. This clinic would provide advice on all aspects of primary and secondary stroke prevention. Patients with possible carotid stenosis would be screened; appropriate patients would be selected for more specialised investigation (DSA) and interventions (carotid endarterectomy or angioplasty); and data for monitoring referral outcomes would be audited to assist long term planning.

2. To commission a comprehensive local service for management of patients with carotid artery disease to provide: Neurovascular clinic and multidisciplinary meeting for selection of patients for specialised procedures (investigation and surgery).

   - Improved ultrasound services for carotid stenosis screening
   - Improved neuro-imaging (DSA, MRA, and MRI) for selected cases
   - Carotid endarterectomy

Each component of the local service would require structured audit and a two year accreditation process. These would be co-ordinated through the multidisciplinary meeting and independently monitored by the East Kent Health Authority. Long term commissioning decisions would be reviewed in the light of this audit. The district co-ordinator, once identified, will play a major role in ensuring the provision and the quality of the service.

How changes will be monitored:

It has been recommended that the stroke/neurorehabilitation health service review group will continue to exist as a service implementation group. It will be the responsibility of this group to monitor the implementation and ensure changes do take place.

In addition, the strategy document also recommends the appointment of stroke prevention co-ordinators to co-ordinate the activities across East Kent. It is expected that this co-ordinator will monitor the implementation of these changes. All components of a local service should be reviewed after a two-year period of prospective audit, and consideration should then be given to commissioning any components in East Kent which had not reached a designated standard from alternative sites. It is also important that if this service is to be commissioned, then the provider units should ensure each specialist’s commitment to accurate and complete records, including clinical indications, techniques and outcome. The surgical risks should not exceed those set out by the Committee on Carotid Surgery Standards of the American Heart Association’s Stroke Council. These standards are a combined perioperative morbidity and mortality of 5% when the indication is TIA rising to 7% in patients who have had minor stroke and are having surgery to prevent severe strokes. The target should be to achieve significantly better results than this.

The audit process itself should be carried out to a high standard. This should be organised by a Consultant designated as the stroke prevention co-ordinator for East Kent and independently monitored by the East Kent Health Authority.
Resource Implication:

A) Resource implications of setting up such a service
If a policy of screening and surgery is implemented, approximately 100 people (96) will require carotid endarterectomy per year. Life table analysis from the North American study showed that at the end of three years, 97% will not have stroke following surgery compared to 83% in the non-surgery group. Hence, if 100 people were operated upon, at the end of three years, only three would have had strokes compared to 17 if surgery is not offered. We estimated the cost implications of the policies of surgery or no surgery together with the potential costs and benefits from carotid endarterectomy over a longer time frame. The costs were based on the incidence expected for each cohort but with the assumption that savings from reducing the number of longer term disabled would continue for the full period instead of being limited to three years. By Year 9, the annual cost savings were greater than the cost of surgery and screening although it would be several more years before the cumulative savings outweighed the initial costs.

B) Effect of purchasing carotid endarterectomy surgery on other surgical activity
To identify the opportunity costs of surgery if the assumption is made that each procedure takes approximately 3 hours, then 100 procedures in one year will require two theatre sessions and surgical team’s time per week. Therefore, if endarterectomy is not purchased, then it will release two theatre sessions per week. This could result in other procedures which could be carried out during this time. Some estimates are as follows:

In one year, instead of carotid endarterectomy, one of the following could be carried out:

100 Major surgery (e.g. Aortic Aneurysm)
or
300 Moderate surgery (e.g. Cholecystectomy)
or
600 Intermediate surgery (e.g. Hernia Repair)

If carotid endarterectomy is not purchased, there will be approximately £280,000 available to purchase other services. If this £280,000 is made available for rehabilitation, then one of the following services could be purchased:

Type of care provided in a nursing home for one person with long term disability for 11 years
or
Type of care provided in a nursing home for 11 people with long term disability for 1 year
or
Purchase approximately 14 W.T.E. Physiotherapist
or 14 W.T.E. Occupational Therapist
or 14 W.T.E. Speech Therapist

Practical lessons learnt:

As part of this case study and as part of the consultation process, all the Vascular Surgeons were consulted. There was wide support for the study and recognition of the work undertaken. As providing the service locally is likely to result in extra costs, the implementation of the recommendations may prove to be difficult. The support of the GPs is crucial in the implementation as without their support, and the support of the locality commissioning teams, it will be difficult to provide a local service.

The difficulty of establishing appropriate process and outcome measures were identified. However, there was evidence from existing literature for standards to be maintained based on those set out by the Committee on Carotid Surgery Standards of the American Heart Association Stroke Council. Cost benefit analysis was found to be difficult in view of the number of assumptions that had to be made.

Conclusion:

- From a population perspective carotid endarterectomy will reduce the total incidence of stroke by no more than 1%. Other measures (lifestyle modification, and treatment of risk factors like hypertension) to reduce stroke risks in carotid disease are very important;
- From an individual perspective, carotid endarterectomy substantially reduces the stroke rates in patients suffering from TIs or minor strokes who have severe carotid stenosis (70 - 99%). Failure to commission the service altogether would be a service deficiency in healthcare;
- Patients who have had non-disabling strokes and TIs should have an assessment and screening for carotid occlusion if carotid endarterectomy is being purchased;
If the stenosis is severe (70 - 99%), then carotid endarterectomy could be offered; Most carotid endarterectomies on East Kent patients are performed in London; Expertise, facilities and equipment to establish such a service are already in existence in East Kent. If this service is to be developed in East Kent, it is important that the provider surgical teams should demonstrate the expertise, training and the availability of resources and each aspect of the service should be audited to establish its own morbidity and success rates. Each surgeon should commit himself to accurate and complete records including clinical indications, operative techniques and outcome. Carotid endarterectomy should not be performed by a surgical team which has a combined perioperative morbidity and mortality of more than 5% where the indication is TIA and more than 7% where the indication is prevention of severe stroke in people who have had minor strokes.

References:

B) Carotid stenosis: the need for a screening programme and surgery in East Kent


Organisational Context:

Population health outcome assessments focus attention on health gain and what action is likely to be effective in achieving health gain. Health outcome assessments are important because they provide the scientific basis with which Health Authorities can justify their policies and ordering of priorities. They provide the argument on which to allocate the funds available for health services; namely, to achieve the greatest health gain possible within the financial constraints. Individual GPs and hospital clinicians may have a different set of priorities and a powerful set of arguments for more resources relating to the best interests of the patients under their care. It is only by structuring the evidence about health gain and allowing health authorities to make prioritising decisions based on relevant information that a proper balance can be found between competing claims to the same resources. East Kent Health Authority takes a very pro-active view on using health gain and health outcome as a basis for developing strategies and implementing service changes. It has carried out a number of health service reviews across East Kent and uses these to undertake commissioning as a tool to effect changes. Population health outcome assessments focus attention on health gain and what action is likely to be effective in achieving health gain. Health outcome assessments are important because they provide the scientific basis with which Health Authorities can justify their policies and ordering of priorities.
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