The European Society for Vascular Surgery

ESVS

Second Vascular Surgery Database Report 2008

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2008

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Message from the President of ESVS

Evidence-based medicine is an essential component of modern practice. As vascular surgeons we can be quite proud of our attempts to base our decisions on large, well-organised, randomised trials, but an important second pillar to our practice is a good knowledge of results from unit and national registries.

A third pillar is a European-wide registry, which has the potential of an enormous database. As we know, results from registries do not always reflect the results of randomised trials, which tend to be performed on selected patients in selected centres. A knowledge of an overall expected outcome in our patients is an essential component of our discussions with healthcare systems throughout Europe. The VASCUNET registry was set up to fulfil this purpose. The enthusiastic instigators of this registry are to be congratulated on its development and deserve our increasing support. By submitting accurate data from all the national registries we can all learn a great deal about our practices.

Many of you are already involved and I would encourage others to expand our database. The VASCUNET Committee work in close collaboration with the European Society for Vascular Surgery and are keen to assist you.

We should be proud of this development.

Mr John Wolfe

President, European Society of Vascular Surgeons

Introduction from the first VASCUNET report

Audit is essential in surgery, where outcomes are dependent on the careful selection of patients and the skills of the surgical and anaesthetic teams. It is important for surgeons and interventionists to know their results and how these compare with others in their field. Those whose outcomes fall short must find and correct the cause whilst those who excel may be able to show others how to improve. It is also important to examine and compare the outcomes of patients in different healthcare systems and in different countries so that we can investigate disparity and learn from each other to help improve outcomes for our patients. Do our patients differ in their characteristics and risk factors? Are there national differences in the way we treat patients and, if so, do these affect outcome?

VASCUNET was originally formed by a group of enthusiasts as a working group within The European Society for Vascular Surgery to exchange ideas and promote discussion between those responsible for the National Registries and other interested individuals in Europe. The first meeting was held in Lisbon in 1997 and since then annual symposia have been held, dealing with such topics as validation, case-mix, quality assurance, computer technology (in particular on-line registration and automated analyses) and legal issues. However, it has always been a common aim that the various databases should somehow be combined to form a common dataset so that international comparisons can be achieved. Whereas, this was essentially a European initiative, interest and enthusiasm from New Zealand and Australia has led to the widening of contributing registries.

The First VASCUNET Report on Abdominal Aortic Aneurysm Surgery results from a pilot project to merge data from existing vascular registries. It is the largest vascular database of its kind, merging data from 33,780 aneurysm repairs from five national registries (The Danish Vascular Registry [1], Swedvasc [2], Swissvasc [3], The UK National Vascular Database [4], The New Zealand Vascular Database [5]) and one large regional registry (The State of Victoria, Australia [6]). The choice of aortic aneurysm repair for this project was pragmatic: it is one of the most common vascular operations, with a single major outcome (survival) and is recorded by all participating registries. The registries have been set up independently and have collected data for different time periods ranging from one to 12 years. The data fields within the individual national databases differ but have many common features that have allowed data merging. Some rely on voluntary contribution (*e.g.* United Kingdom), capturing only half of all the cases performed nationwide whereas those from Denmark and Sweden have much greater levels of participation of over 90%. Validation of the data has been variable (see below) and the definitions of individual data fields have also differed from country to country (see below). For these reasons care must be taken in drawing definitive conclusions from the data at present.

We have shown that it is possible to merge vascular audit data from several countries, collected and stored in different languages and different database systems with different suites of variables. We have deliberately avoided the comparison of national mortality in this first report because of the differences between the databases and questions regarding data validation but it is hoped that such analyses may be possible in the future and will stimulate analysis and discussion, which may lead to future improvements in care.

Such international audit projects are new to vascular surgery but not new to medicine as a whole. A shining example has been the Dialysis Outcomes and Practice Patterns Study, which has compared data on patients with end-stage renal failure in randomly selected units throughout the world for over ten years and has undoubtedly stimulated improvement initiatives within nephrology and vascular access services in several countries [7] (www.dopps.org).

A project in cardiac surgery similar to our initiative has already been undertaken by The European Association of Cardio-Thoracic Surgeons: Their first report was published in 2003 and the project has now grown to include data from 23 national registries from smaller beginnings [8]. We hope that a similar growth in national or regional vascular registries contributing to the VASCUNET database will occur in future years. It is also anticipated that its scope will be widened in future years to include other common vascular procedures such as carotid endarterectomy and stenting and infrainguinal bypass.

We are grateful to Dendrite Ltd for their excellent advice, data merging and analyses and to the Council of the ESVS which has supported and financed the project.

Chris Gibbons

on behalf of the VASCUNET Steering Committee

Introduction to the second VASCUNET report

Audit is the key to improvement. It is essential to compare one's own performance against that of others in the field in order to expose discrepancies and correct deficiencies. Whereas randomised controlled trials give answers to specific questions, large registries can provide a wealth of information on actual practice. The larger the database and the greater the representation, the more accurate is the data and the more generalisable the conclusions.

In this second VASCUNET database report we have recruited data from four more national databases to give a total of ten contributing countries in Europe and Australasia. Data from over 84,000 vascular patients have been analysed making this the largest database of its kind. We have expanded the scope to include not only aortic aneurysm repair but also carotid reconstruction, and for the first time have included comparisons of national outcome data. In order to improve the validity of comparisons and ensure contemporary data, we have restricted the analysis to the last five years.

Whilst, as before, there are discrepancies in the data definitions and the degree of validation between the various national registries, some general conclusions can be legitimately drawn from the data. Some of the analyses have provided further support to the conclusions of certain randomised trials and revealed some surprising national differences in outcome that deserve further investigation.

It is hoped that these results will provide a stimulus for further geographical expansion of the VASCUNET registry and it is anticipated that the scope of the audit will increase further in subsequent years.

Chris Gibbons
on behalf of the VASCUNET Steering Committee

1. Annual reports from the Danish Vascular Registry (Karbase) 2005; see: www.karbase.dk
2. Annual reports from the Swedvasc, 2002-2008; see: http://www.ucr.uu.se/swedvasc/
3. Annual report of the Swissvasc Registry 2005; can be ordered via e-mail: pius.wigger@ksw.ch
4. The Vascular Society of Great Britain and Ireland. Fourth National Vascular Database Report 2004. Dendrite Clinical Systems Ltd, Henley-on-Thames, United Kingdom.
5. The New Zealand Vascular Database; see: www.otago.ac.nz/ouaudit/
6. Beiles CB, Melbourne Vascular Surgical Association Audit Committee. Melbourne vascular surgical association audit. *ANZ J Surg*. 2003; **73:** 69-76.
7. Dialysis Outcomes and Practice Patterns Study; see: www.dopps.org
8. Keogh BE & Kinsman R. First European Adult Cardiac Surgical Database Report 2003. Windsor. The European Association for Cardio-Thoracic Surgery, 2003. Dendrite Clinical Systems Ltd, Henley-on-Thames, United Kingdom.

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The second VASCUNET report

Contents

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Prelude

Basic principles of abdominal aortic aneurysm (AAA) repair

An aneurysm is a permanent localized arterial dilatation with a 50 percent or greater increase over the normal diameter of the affected artery. An abdominal aortic aneurysm is a swelling of the main artery in the abdomen of over 3 cm in diameter. The main risk factors associated for abdominal aneurysms are:

- hypertension (high blood pressure)
- smoking
- elevated cholesterol
- predisposing genetic factors

AAAs are often found during routine medical tests or *via* screening programs. Most patients have no symptoms prior to rupture.

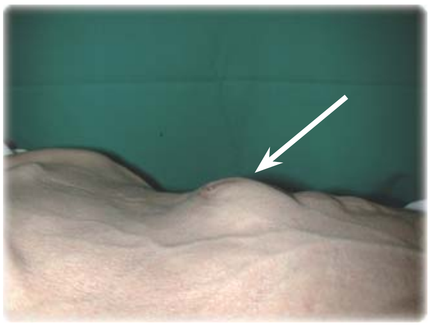


Figure 1.

The photograph shows an abdomen with an abdominal aortic aneurysm (highlighted with an arrow), which is clearly seen through the abdominal wall.

An aneurysm should be treated before the risk of rupture rises significantly. To date there has been no known effective medical treatment. Principally there are two treatment options:

- Open operation
- Endovascular aneurysm repair (EVAR)

The open operation

The traditional way for the last 50 years was the open repair by a direct surgical approach to the artery through an abdominal incision. The normal artery above and below the aneurysm is exposed to permit clamping of the vessel. After clamping the aneurysm is opened by a longitudinal incision. A prosthetic graft made of Dacron or polytetrafluorethylene (PTFE) is sewn to the rim of the normal artery above and below so that the graft lies within the aneurysm sac. After completion the clamps are removed allowing the blood to flow through the graft. The wall of the aneurysm then is closed over the graft for protection.

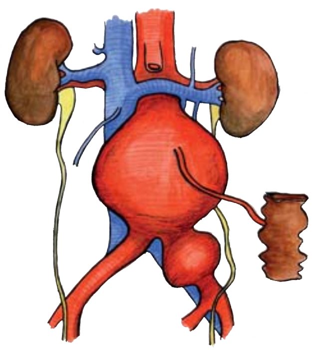


Figure 2A

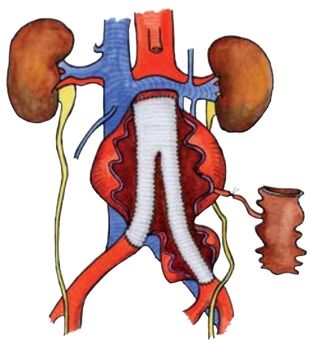


Figure 2B

Figure 2.

Figures 2A and 2B show an abdominal aortic aneurysm before and after surgical repair, using a Dacron graft. The aneurysm arises below the arteries and veins that supply the kidneys and above the iliac (pelvic) arteries. In this case, a trouser graft has been used to replace the aortic aneurysm because there was also an aneurysm affecting the left iliac artery

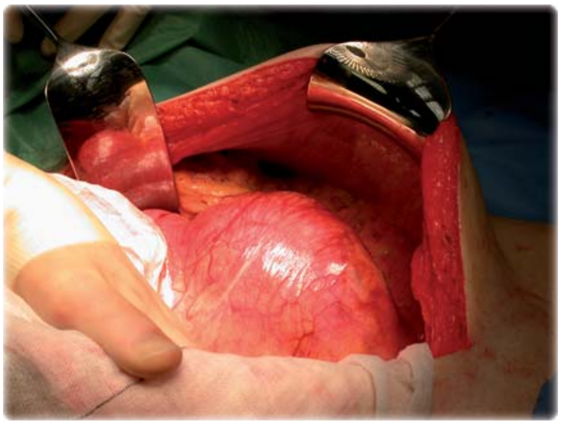


Figure 3.

An incision through the wall of the abdomen allows a clear view of the intact aneurysm.

Endovascular aneurysm repair (EVAR)

During the past 15 years, a keyhole version of aneurysm repair for the aorta has been developed. In this procedure, the inside of the artery is re-lined with a graft (Dacron or PTFE). The graft is supported and held in place by a springy metal alloy framework (stent) sewn to it (stent graft). The device is delivered in two parts each of which are squashed down into a slim delivery tube 6-8 mm in diameter. The parts are brought into position *via* the pelvic arteries from a small incision in each groin and assembled within the aneurysm to form a *trouser* graft. The correct position is checked by X-ray before unfolding the stent-graft. Once delivered, the aneurysm remains in place, but the blood passes through the stent graft within the aneurysm. Thus the pressure is removed from the aneurysm wall that prevents rupture and eventually leads to shrinkage of the aneurysm.

Figure 4.

These diagrams show an endovascular repair (EVAR) of an aneurysm. In figure A the first part of the stent graft is already delivered and the second part is put in place but not yet unfolded (A). Figure B shows a CT-scan with a stent graft in place.

Figure 4A

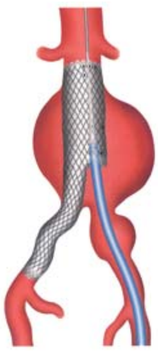


Figure 4B

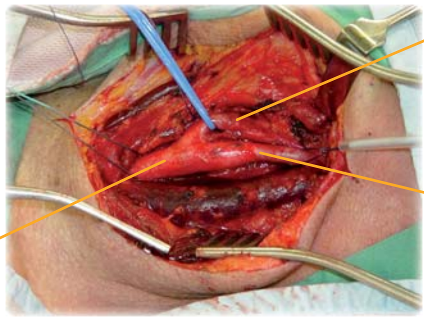
Images reproduced with the kind permission of Thomas Troëng.

The basic principles of carotid artery reconstruction

The brain is supplied blood *via* two carotid arteries and two vertebral arteries which, in most people, have intercommunications between them at the base of the brain, forming the so-called Circle of Willis. The carotid arteries in particular can become narrowed (stenosed) by atherosclerosis, particularly in smokers and diabetics and also in those with a high blood pressure or a raised blood cholesterol level. This disease usually occurs where the common carotid artery divides into its two main branches: the internal carotid artery, which supplies much of the brain and especially the cerebral cortex, and the external carotid artery, which supplies blood to the rest of the head and upper part of the neck (fig 1).

Figure 1.

A photograph taken during carotid endarterectomy showing the anatomy of the carotid bifurcation.



When an internal carotid artery becomes very narrow (usually greater than 70% stenosed so that less than 30% of the diameter remains) clots can form and become dislodged (embolized) into the brain, blocking part of the blood supply to the cerebral cortex. This causes a transient (transient ischaemic attacks or TIA) or permanent stroke (cerebrovascular accident or CVA) with a temporary or permanent numbness, weakness or paralysis of part or all of the opposite side of the body. Speech or understanding of words can also be affected, usually following emboli from the left carotid artery. Similar symptoms can occur when a carotid artery becomes completely occluded by the disease. Small clots can also embolize to the eye causing a transient or permanent interruption of the retinal blood supply resulting in a short lasting (amaurosis fugax) or permanent (central retinal artery thrombosis) blindness in one eye (on the same side as the responsible carotid).

The principles of treatment are to reduce the progression of the underlying arterial disease by smoking cessation, blood pressure control, cholesterol lowering drugs such as statins and control of diabetes and to correct the carotid stenosis by surgical means.

Indications for surgery

Carotid endarterectomy (CEA) is one of the surgical methods most extensively evaluated in large randomized controlled trials. The earlier the intervention, the greater is the benefit in terms of stroke prevention. For this reason efforts are being made to reduce delays in the referral and treatment of symptomatic carotid disease in many countries.

Indications for intervention are

- A stenosis of >70% with relevant symptoms: TIA, CVA with a good recovery, amaurosis fugax or central retinal artery thrombosis.
- A stenosis of >60% in asymptomatic patients below the age of 75 years.

Figure 2.

A carotid angiogram showing a tight stenosis at the origin of the internal carotid artery in a patient presenting with TIA.

In some patients with recurrent symptoms and lesser degrees of stenosis (>50%) surgery may also be indicated particularly when associated with ulcerated or *soft* atherosclerotic plaque. The morphologic diagnosis and degree of stenosis is usually obtained by duplex ultrasound, but angiography (conventional, magnetic resonance or computer tomography) may also be required in some cases (fig 2).

The procedure

Today, open surgery by carotid endarterectomy is the treatment of choice and so far seems to be better than endovascular stent treatment (carotid artery stent, CAS) although further evaluation is ongoing. The principle of carotid endarterectomy (CEA) is to remove the atherosclerotic stenosis to widen the artery. This can be performed in a standard way with a longitudinal incision in the artery (fig 3) or by an eversion technique (fig 4).

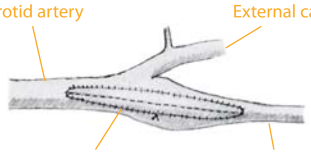


Figure 3.

A diagram showing a standard carotid endarterectomy using a longitudinal arteriotomy with a Dacron patch closure

Figure 4.

Diagrams showing the eversion technique for carotid endarterectomy

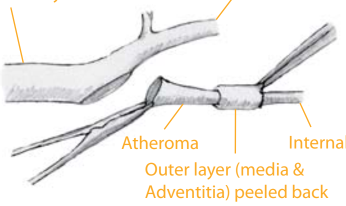


Figure 4a.

The carotid artery is divided and the atheromatous stenosis is removed.

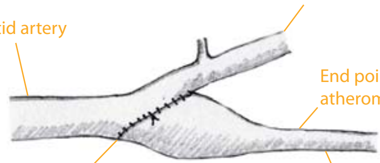


Figure 4b.

The carotid artery is then reanastomosed

One important step in the surgical procedure is to be sure that adequate cerebral circulation is maintained whilst the carotid artery is clamped. This may be accomplished by temporarily inserting a plastic tube (a shunt) into each end of the artery whilst the diseased area is exposed. Because of the anastomosis at the base of the brain most patients can tolerate clamping of one carotid artery without ill effects. However, the problem is to select those patients in need of a shunt (that is to estimate the collateral potential). The most common ways of doing this are:

- Operation under local anaesthesia, *i.e.*, with the patient wide awake.

Or if under general anaesthesia:

- Measuring the stump pressure, that is the back pressure (*via* the circle of Willis) in the internal carotid artery after the common carotid artery has been clamped.
- Using trans-cranial Doppler to measurement the blood flow in the middle cerebral artery.

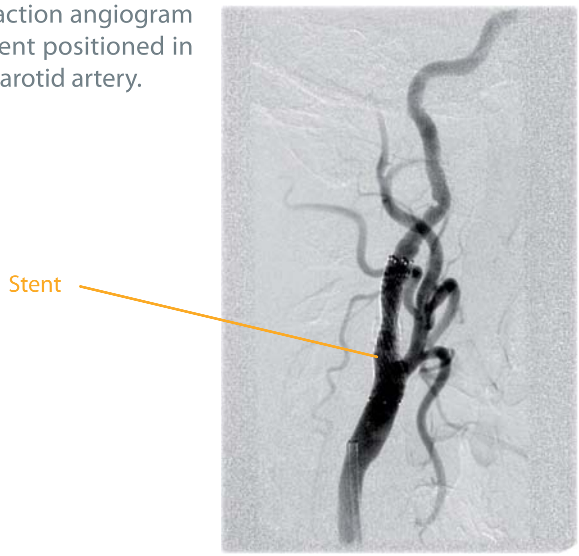
Most patients are already taking acetylsalicylic acid (aspirin) and / or dipyridamole (persantin) when they come to treatment, and many surgeons also add another platelet inhibitor peri-operatively, *e.g.*, clopidogrel or dextran, to reduce the risk of clotting in the artery. Heparin is also commonly injected to reduce clotting whilst the carotid artery is clamped.

The longitudinal carotid artery incision is often closed with a patch (vein, PTFE or Dacron can be used) to widen the artery, especially when the internal carotid artery is small, as is often the case in women, or when there have been technical problems.

Carotid artery stenting (CAS) is performed under X-ray control using local anaesthetic. A metal stent (a tube made from a special wire mesh) is inserted inside the carotid artery *via* a catheter usually passed up from an artery in the groin. When it is in the correct position across the stenosis the stent is deployed to force open the artery and maintain its lumen (fig 5). CAS is currently being evaluated in large randomized studies and should only occasionally be used outside these for cases where open surgery would be problematic, *e.g.*, after radiotherapy to the neck or restenosis after previous carotid endarterectomy. Usually CAS is performed using one of several cerebral protection devices to prevent embolization to the brain whilst manipulating the device inside the artery.

Figure 5.

Digital subtraction angiogram showing a stent positioned in the internal carotid artery.



In addition to a very small risk of post-operative death (most often due to myocardial infarction or stroke), there are local and central complications. The local ones are neck haematoma and cranial nerve damage, which is often reversible (the hypoglossal nerve, the superior laryngeal nerve, the accessory nerve , the mandibular branch of the facial nerve and very rarely the glossopharyngeal or aberrant recurrent laryngeal nerves). Cranial nerve damage may result in (usually temporary) weakness of the tongue, hoarseness, weakness of the angle of the mouth or shoulder weakness.

Central complications in the form of stroke are multi-factorial: ischaemia during clamping, embolism, thrombotic occlusion and bleeding because of hyperperfusion. A usual outcome criterion used in trials is the combined permanent stroke and / or death rate within 30 days of the procedure. It is important to realize that carotid reconstruction is a preventive or prophylactic procedure to avoid stroke in the future and the value for any individual patient is not known – just the statistical risk in a group of patients. The complication rate must therefore be kept very low.

Proposed site for advert

BMS09JO7034_MASTER_A4_Plavix_Ad_AW_HR.pdf

Contributors

The VASCUNET committee would like to extend their thanks to all the countries and hospitals listed below for their efforts in collecting data and also for submitting their data to the VASCUNET database.

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Proposed site for advert
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Table to show the number of cases submitted by each contributor country and the date-range that these cases span.

AAA surgery

Country	Number of hospitals	Number of cases		Date range for data	
		Submitted	Analysed	Submitted	Analysed
Australia	35	3,928	2,312	1999-2007	2003-2007
Denmark	9	7,885	3,533	1996-2007	2003-2007
Finland	2	481	481	2003-2007	2003-2007
Hungary	20	1,054	1,053	2003-2007	2003-2007
Italy	115	13,893	13,893	2003-2007	2003-2007
Norway	22	2,671	2,671	2003-2006	2003-2006
New Zealand	17	3,197	,846	1994-2006	2003-2006
Sweden	47	12,445	4,894	1994-2007	2003-2007
Switzerland	21	1,156	1,156	2005-2006	2003-2006
United Kingdom	98	8,540	5,202	1994-2006	2003-2006
All	**386**	**55,250**	**36,041**		

Carotid surgery

Country	Number of hospitals	Number of cases		Date range for data	
		Submitted	Analysed	Submitted	Analysed
Australia	35	2,620	2,620	2003-2007	2003-2007
Denmark	6	1,570	1,570	2003-2007	2003-2007
Finland	2	618	618	2003-2007	2003-2007
Hungary	20	4,484	4,484	2003-2007	2003-2007
Italy	115	28,780	28,780	2003-2007	2003-2007
Norway	22	920	920	2003-2006	2003-2006
New Zealand	17	568	568	2003-2006	2003-2006
Sweden	47	4,623	4,623	2003-2007	2003-2007
Switzerland	21	885	885	2005-2006	2005-2006
United Kingdom	98	2,956	2,956	2005-2007	2005-2007
All	**383**	**48,025**	**48,025**		

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- Cabrini Hospital, Melbourne
- Cotham Hospital, Melbourne
- Dandenong Hospital, Melbourne
- Epworth Hospital, Melbourne
- Epworth Eastern Hospital, Melbourne
- Frankston Hospital, Frankston
- Geelong Private Hospital, Geelong
- Geelong Public Hospital, Geelong
- Jessie McPherson Hospital, Melbourne
- John Fawkner Hospital, Melbourne
- Knox Private Hospital, Melbourne
- Linacre Hospital, Melbourne
- Masada Hospital, Melbourne
- Monash Hospital, Melbourne
- Northern Hospital, Melbourne
- Peninsula Hospital, Mornington
- Ringwood Private Hospital, Melbourne
- Rosebud Hospital, Rosebud
- Royal Melbourne Hospital, Melbourne
- St. John of God Hospital, Ballarat
- St. John of God Hospital,Geelong
- St. Vincent's Private Hospital, Melbourne
- St. Vincent's Public Hospital, Melbourne
- Valley Hospital, Melbourne
- Warringal Private Hospital, Melbourne
- Western Public Hospital, Melbourne
- Western Private Hospital, Melbourne
- Williamstown Hospital, Melbourne

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- Waikato Hospital, Hamilton
- Hawkes Bay Hospital, Hastings
- Southland Hospital, Invercargill
- Napier Hospital, Napier
- Nelson Hospital, Nelson
- Taranaki Base Hospital, New Plymouth
- Palmerston N. Hospital, Palmerston North
- Rotorua Hospital, Rotorua
- Tauranga Hospital, Tauranga
- Timaru Hospital, Timaru
- Wellington Hospital, Wellington

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- Sykehuset Innlandet HF, Hamar
- Helse Bergen HF, Haukeland universitetssykehus
- St. Olavs Hospital HF
- Universitetssykehuset Nord-Norge HF
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- Rikshospitalet HF, Thoraxkir.avd.
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- Danderyd Hospital, Stockholm
- Eksjö District Hospital
- Eskilstuna County Hospital
- Falun County Hospital
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- Örebro University Hospital
- Örnsköldsvik District Hospital
- Oskarshamn District Hospital
- Östersund County Hospital
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- Sahlgrenska Univ. Hospital, Gothenburg
- Skellefteå District Hospital
- Skövde County Hospital
- Södra Hospital, Stockholm
- Sunderbyn County Hospital
- Sundsvall County Hospital
- Trelleborg District Hospital
- Uddevalla County Hospital
- Umeå University Hospital
- Varberg District Hospital
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- City Hospital Birmingham, Birmingham
- Selly Oak Hospital, Birmingham
- Blackburn Royal Infirmary, Blackburn
- Royal Bournemouth Hospital, Bournemouth
- Princess of Wales Hospital, Bridgend
- Royal Sussex County Hospital, Brighton
- Bristol Royal Infirmary, Bristol
- Frenchay Hospital, Bristol
- Burnley General Hospital, Burnley
- Addenbrookes Hospital, Cambridge
- University Hospital of Wales, Cardiff
- St Helier Hospital, Carshalton
- Countess of Chester Hospital, Chester
- St Richard's Hospital, Chichester
- Colchester General Hospital, Colchester
- Craigavon Area Hospital, Craigavon
- Leighton Hospital, Crewe
- Derbyshire Royal Infirmary, Derby
- Pinderfields General Hospital, Dewsbury
- Doncaster Royal Infirmary, Doncaster
- Dorset County Hospital, Dorchester
- Russells Hall Hospital, Dudley
- Ninewells Hospital, Dundee
- Queen Margaret Hospital, Dunfermline
- University Hospital of North Durham
- Royal Infirmary of Edinburgh, Edinburgh
- Chase Farm Hospital, Enfield
- Frimley Park Hospital, Frimley
- Hairmyres Hospital, Glasgow
- Royal Infirmary Glasgow, Glasgow
- Gloucestershire Royal Hospital, Gloucester
- Diana Princess of Wales Hospital, Grimsby
- Calderdale Royal Hospital, Halifax
- Princess Alexandra Hospital , Harlow
- Hereford County Hospital, Hereford
- Huddersfield Royal Infirmary, Huddersfield
- Hull Royal Infirmary, Hull
- King George Hospital, Ilford
- Raigmore Hospital, Inverness
- Ipswich Hospital, Ipswich
- Leicester Royal Infirmary, Leicester
- Lincoln County Hospital, Lincoln
- Royal Liverpool University Hospital
- University Hospital Aintree, Liverpool
- Barnet General Hospital, London
- Charing Cross Hospital, London
- Hillingdon Hospital, London
- Kings College Hospital, London
- Mayday University Hospital, London
- Royal London Hospital, London
- St George's Hospital, London
- St Mary's Hospital, London
- St Thomas' Hospital, London
- Whipps Cross University Hospital, London
- Manchester Royal Infirmary, Manchester
- James Cook University Hospital, Middlesborough
- Freeman Hospital, Newcastle Upon Tyne
- Newcastle General Hospital, Newcastle Upon Tyne
- Royal Gwent Hospital, Newport
- Northampton General Hospital
- Norfolk & Norwich University Hospital, Norwich
- Queen's Medical Centre, Nottingham
- Royal Oldham Hospital, Oldham
- Peterborough District Hospital
- Derriford Hospital, Plymouth
- East Surrey Hospital, Redhill
- Queen's Hospital, Romford
- Salisbury District Hospital, Salisbury
- Scarborough Hospital, Scarborough
- Northern General Hospital, Sheffield
- Southampton General Hospital
- Southport & Formby District General Hospital, Southport
- Stafford General Hospital, Stafford
- Stirling Royal Infirmary, Stirling
- Sunderland Royal Hospital, Sunderland
- Morriston Hospital, Swansea
- Taunton & Somerset Hospital, Taunton
- Torbay Hospital, Torquay

DENDRITE CLINICAL SYSTEMS

Contributors to the VASCUNET database continued …

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- Sandwell District General Hospital, West Bromwich
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- West Cumberland Hospital, Whitehaven
- Royal Albert Edward Infirmary, Wigan
- Royal Hampshire County Hospital, Winchester
- Arrowe Park Hospital, Wirral
- Wishaw General Hospital, Wishaw
- New Cross Hospital, Wolverhampton
- Worcestershire Royal Hospital, Worcester
- Worthing Hospital, Worthing
- York Hospital, York

Proposed site for advert

Dendrite

The European Vascular Surgery Database

Import, merging and analysis methodology

Each country contributor that had agreed to participate in this project was sent a set of standard instructions on the required format for electronic data transfer (see Appendix for instructions on data submission) together with a list of the requested variables for each procedure. Data files from ten countries (which represented in excess of 100,000 individual patient records from a 386 individual vascular surgery centres), were submitted over the Internet to Dendrite Clinical Systems' offices in the United Kingdom for data processing. The files were received over a four-month period from February 2008 to May 2008 and were imported sequentially onto Dendrite's database platform.

The schematic diagram opposite illustrates the data flow and the complexity of the processes behind the importing and merging of a wide variety of original Source Registry data to produce this second VASCUNET database report. The process of data harvest and data import was represented by two main scenarios:

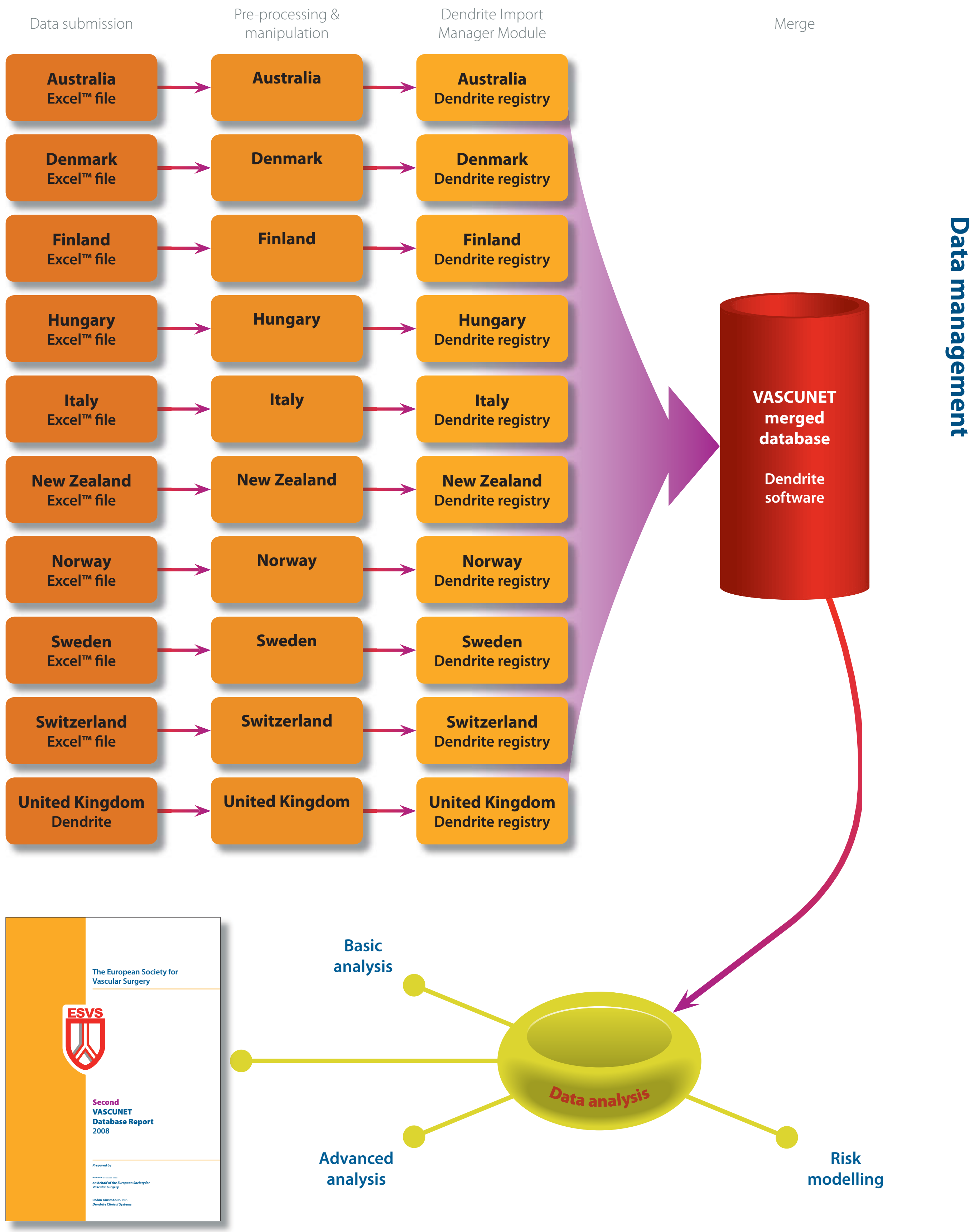
1. Where the national registry is already using Dendrite's national database software for its central registry e.g. the Vascular Society of Great Britain & Ireland's web-based National CEA Database, the data were simply copied across to the Dendrite database as a discrete database.
2. Where the national registry is using a third-party generic or proprietary system such as Microsoft Access™, *e.g*. the Italian National Vascular Surgery Registry, the data were imported into the Dendrite VASCUNET central database using Dendrite's Import Manager Module software. In some cases language translation was also required as in the case of handling the Italian data.

Once all the data had been mapped across into the Dendrite / VASCUNET central data repository, as 10 parallel Import Registries, the data were corresponded across to one common merged database, the so-called target registry.

The correspondence process entailed mapping the response options of the questions in the temporary Import Registries to identical or similar options in the final target VASCUNET registry. Where there were incompatibilities in data definitions or only partial matches between source and target questions, only perfect / near perfect options were mapped. Hence not all the data analyses presented in this report involved data from all 10 of the countries that are represented.

Data merging, manipulation and analysis were carried out using a suite of integrated software systems including Dendrite's proprietary database software, Microsoft Excel™ and Business Objects' Crystal Reports™ using an ODBC link to the Dendrite Registry. Where possible, data from all entries and all countries were used for the basic aggregate data analysis and inter-country comparisons.

A schematic of the processes involved in the production of the VASCUNET merged database



Data submitted

Whereas there was a considerable agreement on the data fields between national registries, not all registries recorded every parameter. The tables on the next two pages show the data fields submitted by each country in a format that was suitable for import, for aortic aneurysm repair and carotid reconstruction, respectively.

AAA surgery

Table to show the data-items submitted in a format that could be imported by each contributor country

	Australia	Denmark	Finland	Hungary	Italy	New Zealand	Norway	Sweden	Switzerland	UK
Demographics										
Age	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Gender	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pre-operative risk factors										
Cardiac disease	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Respiratory disease	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Renal disease	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Hypertension	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗
Smoking	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗
Operative data										
Date-of-operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Urgency	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Aortic findings	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Type of operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Outcomes										
Re-operation	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗
Length-of-stay	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
30-day mortality	✗	✓	✓	✗	✓	✗	✗	✓	✓	✗
In-hospital mortality	✓	✗	✗	✓	✗	✓	✓	✗	✓	✓

Proposed site for advert
AorFix Ballerina Ad ESVS A4.pdf

Proposed site for advert
LeMaitre_Full_4c_Vascunet_6_08.pdf

Carotid surgery

Table to show the data-items submitted in a format that could be imported by each contributor country

	Australia	Denmark	Finland	Hungary	Italy	New Zealand	Norway	Sweden	Switzerland	UK
Demographics										
Age	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Gender	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Disease status										
Symptoms	✓	✓	✓	✓	✗	✓	✗	✓	✓	✓
Percentage stenosis	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Contralateral occlusion	✓	✗	✗	✓	✗	✗	✗	✗	✗	✗
Pre-operative risk factors										
Cardiac disease	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Respiratory disease	✗	✓	✓	✗	✓	✓	✓	✓	✓	✗
Renal disease	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗
Hypertension	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Smoking	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Operative data										
Date-of-operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Urgency	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Procedure	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Type of endarterectomy	✓	✓	✓	✓	✗	✓	✓	✓	✗	✓
Anaesthesia	✓	✓	✗	✗	✓	✗	✗	✗	✓	✓
Shunt	✓	✗	✗	✓	✗	✗	✗	✗	✗	✓
Outcomes										
Re-operation	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗
Stroke	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cranial nerve injury	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Length-of-stay	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
30-day mortality	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓
In-hospital mortality	✓	✗	✗	✓	✗	✓	✓	✗	✓	✓

Data validity

There are two main aspects of validity of registry data:

1. **External validity** concerns generalizability. If virtually all patients with a given disease or procedure in a well-defined population are registered, they will represent the incidence or prevalence in a similar general population, since the data collection is almost complete. Thus registry managers should provide data from an independent source to estimate the degree to which cases in question are registered. A clinical vascular registry should preferably be validated by comparison with administrative hospital data, a national patient index or other data sources with information on hospital stays, procedure codes and diagnostic codes [i, ii].
2. **Internal validity** is the degree to which the registry is correct concerning data on patients actually included. How many patients had a certain degree of heart disease although it was not recorded? What was the definition of hypertension? Were all emergency procedures really acute? According to what definition? Strict definitions of variables are compulsory. Internal validity can be assessed through a study of a sample of patient records where data are re-registered, to evaluate reproducibility. The re-entering of data can be done either by the local centre itself, or as part of an external validation [ii, iii].

The tables on the following pages summarise the work the individual countries are doing for external and internal validity, as well as the definitions of data.

Both the external and internal validity of data is of utmost importance if comparison is to be made between institutions, or in this case, between countries. An important part of the work with the internal validity is to verify that the same definitions and cut-off values are used by the institutions or countries to be compared. That this work is still in the early stages in the VASCUNET collaboration is reflected in the differences seen in the table above, which reveal the need for more uniform variables, definitions and methods of validation. These issues have to be improved, to produce valid and more extensive National reporting of vascular data in the future.

i. Aylin P, Lees T, Baker S, Prytherch D, Ashley S. Descriptive study comparing routine hospital administrative data with the Vascular Society of Great Britain and Ireland's National Vascular Database. *Eur J Vasc Endovasc Surg.* 2007; **33:** 461-465.

ii. Troëng T, Malmstedt J, Björck M. External validation of the Swedvasc registry. A first-time individual cross-matching with the unique personal identity number. *Eur J Vasc Endovasc Surg.* 2008 (In Press)

iii. Laustsen J, Jensen LP, Hansen AK. Accuracy of Clinical Data in a Population Based Vascular Registry. *Eur J Vasc Endovasc Surg.* 2004; **27:** 216–219.

Validity and definitions in the ten registries

The tables on the following pages summarize what the different registries do to safeguard their data validity and how well their definitions of risk factors and outcomes allow for comparison across country borders.

Most of the registries are national, or are regional with coverage of a large proportion of the country. Six out of ten examine their external validity by comparisons with national administrative hospital episode registries. Such a procedure is indispensable to safeguard against biased recruiting to the registry, and the fact that it is not done for all registries could be a source of significant bias when comparing data. If access is admitted to administrative registries such validation is technically simple and not expensive.

Eight registries check their internal validity through studies of a sample by re-registering data or by local checks in each hospital. This is usually a quite laborious and time-consuming task but will of course add to the value of conclusions, and serves as a tool for optimising the data definitions.

Medical risk factors are, to a large extent, obtained from the *patient history* (PH), taken from patient records. However, such a way of data collection can be considered *weak* and is likely to lead to variability within and between registries. Whilst some data definitions, such as that of renal insufficiency, are already similar across the registries, it is hoped that a consensus will gradually develop so that identical data are collected by all countries. This will improve the overall validity of the conclusions and allow more accurate international comparisons.

Whilst death is the ultimate *hard* endpoint, survival statistics may also vary between registries: several registries use 30-day mortality whereas others use in-hospital mortality. These are obtained from patient records and may not differ much in practice. However, deaths may be under-reported as a result of patients who are lost to follow-up. For this reason, data sources other than the hospital records may be preferable.

The presentation of carotid disease and the indications for carotid intervention are relatively *hard* data, as TIA, amaurosis fugax stroke and asymptomatic stenosis are easily distinguishable (although one registry combines TIA and amaurosis fugax). In contrast, the definitions of minor and major stroke are much more variable. Patients who become lost to follow-up may result in the under-reporting of postoperative neurological complications after carotid surgery. It is also well known that independent neurologists detect more post-operative neurological complications than surgeons. Whilst such routine independent neurological assessment is ideal, it is at present impractical except in clinical trials.

This table describes the current practice amongst registries with different degrees of development and experience. Because of this, validity and completeness are naturally imperfect. Similarly, data definitions may be imprecise and differ between registries. This should be taken into account when making international comparisons. Nevertheless, we believe that the data in this report is useful and represent vascular practice in *the real world*. Accuracy is likely to improve over time with more participant registries and with improvement of data definitions and validation methods, through the profitable cooperation in Vascunet.

Data validity

Validity and definitions: AAA surgery

	Australia	Denmark	Finland	Hungary
Scope				
National or regional	Regional	National	Regional, ~30% of the population	National
EVAR included	Yes	Yes	No	Yes
External validation	Compared with the Victorian adverse outcome data	Comparison with the National In-patient registry or operation protocols locally.	Data is compared to the National inpatient registry and missing data completed	No systematic comparison with other data sources
Internal validation of the registry	Internal validation of a 5 % sample from public hospitals	Internal and external re-entry of data for a sample of patient data; performed 1998 and 2006	Data is compared to the National inpatient registry and missing data completed	Internal re-entry of data on a sample of patient data
Definition of risk factors				
Heart disease	PH; ECG / stress test	PH	PH; previously documented MI ± ongoing angina or previous coronary revascularization	Not included
Respiratory disease	Not registered	PH	PH; asthma / COPD	PH
Renal disease	Serum creatinine >180 mmol l^{-1}	Serum creatinine >150 mmol l^{-1} or dialysis	PH; serum creatinine >150 mmol l^{-1} or dialysis	Not included
Hypertension	PH or by WHO-limits for blood-pressure	PH or newly discovered and requiring medication at admission	PH; medication for hypertension or arterial pressure >160/95 mm Hg	Not included
Smoking	PH; Current or Ex-smoker (> 2 weeks)	PH; Never, Ex-smoker (> 6 weeks) or Current	PH; regular smoking within 5 years	Not included
Outcomes				
30-day mortality	No systematic collection of data from other sources; systematic internal validation	Date-of-death obtained from the national population registry 100% reliable	Date-of-death obtained from the national population registry 100% reliable	No data
In-hospital mortality	Collected	As above, 100 %, compared to date of discharge	As above, 100 %, compared to date of discharge	Date of death obtained from the patient's record, 100%reliable
Long-term mortality	Not	As above, data updated monthly for all patients	No data	No data

PH: Patient history; data obtained from the patient history as a current condition / medication.

Italy	Norway	New Zealand	Sweden	Switzerland	UK
National (~ 50% completeness)	National	National	National	All University (5) and larger public hospitals (16)	National, ~50% of all open repairs
Yes	Yes	Yes	Yes	Yes	Patrial
No	No systematic comparison with other data sources.	Comparison with the National In-patient registry in one study	Comparison with the National In-patient registry	No systematic comparison with other data sources	Comparison with the Hospital Episode Statistics in one study
A sample of data is checked for 10 randomly selected participating centres	No	Internal validation of a 10 % sample in one study	Internal re-entry of data on a sample of patient data	Completeness of follow-up checked by each hospital	No
PH; ECG / stress test	PH	PH	PH	PH	PH
PH; spirometry	PH	PH	PH	PH	PH
No; creatinine ranges 1.2-2.4, 2.5-3.5, 3.6-5.9 or >5.9 mg dl^{-1}; dialysis; transplant	Serum creatinine >150 mmol l^{-1}	PH; serum creatinine >150 mmol l^{-1}	PH or serum creatinine >150 mmol l^{-1}	Serum creatinine >150 mmol l^{-1}	Creatinine >150 mmol l^{-1}, dialysis, or transplant
No, controlled with 1 drug, controlled with 2 drugs, controlled with >2 drugs or not controlled	On medication or diastolic systemic blood pressure >110 mmHg	PH	PH* or diastolic systemic blood-pressure >110 mmHg at admission	PH	Not included
Non-smoker, Ex-smoker, Smoker (1 to 5 daily), Smoker (6-20 daily), Smoker (>20 daily)	PH; smoking during last 5 years	PH; current or recent smoker	PH; regular smoking within 5 years	PH; current or previous	Not registered
Date-of-death obtained from the patient record	No systematic collection of data from other sources	Date-of-death obtained from the patient record	Date-of-death from the national population registry, 100% reliable	Date-of-death obtained from the patient record	Date-of-death obtained from the patient record
Date-of-death obtained from the patient record	Obtained from patient record	Collected		From discharge data	
No data are included	Obtained from patient record	Not collected	As above, data updated monthly for all patients	From discharge data	Date-of-death obtained from the patient record

Validity and definitions: carotid surgery

	Australia	Denmark	Finland	Hungary
	Definition of risk factors			
Symptomatic disease	Amaurosis, TIA, stroke	PH: Amaurosis fugax, TIA or stroke	PH: Amaurosis Fugax,TIA (symptoms < 24 hours) or stroke (symptoms > 24 hours)	PH: Amaurosis fugax, TIA (symptoms < 24 hours), minor or major stroke (symptoms > 24 hours), PRIND
	Outcomes			
Post-operative TIA	Registered	Not registered	Registered as yes / no	Registered as yes / no
Post-operative minor stroke	Registered	Included in stroke	Registered as yes / no	Registered as yes / no
Post-operative major stoke	Registered	Included in stroke		Registered as yes / no
Post-operative nerve injury	Registered with outcome	Registered as yes / no	Registered as yes / no	Registered as yes / no

Italy	Norway	New Zealand	Sweden	Switzerland	UK
PH: Asymptomatic or symptomatic	PH: Amaurosis fugax, TIA (symptoms < 24 hours) or stroke (symptoms > 24 hours)	PH: Amaurosis fugax, TIA (symp-toms < 24 hours) or stroke (symptoms > 24 hours)	Amaurosis fugax, TIA, minor stroke	Stroke and TIA (including Amaurosis fugax)	PH: Amaurosis fugax, TIA, stroke or *none of these*
Late ischemic vascular complication	Registered	Registered	Registered as TIA / amaurosis fugax within 30 days – yes / no	Registered together with Amaurosis	Not registered but often recorded under *other complications*
In *cerebrovascular complication* as yes / no	Stroke	Registered	Stroke transient within 30 days	Included in *stroke*	Included in *stroke*
As above	Stroke	Minor and major combined	Stroke- permanent at 30 days yes / no	Included in *stroke*	Included in *stroke*
Nervous Lesion	Registered as yes / no	Registered	Registered as *Local nerve injury* yes / no	Registered as *cranial nerve lesion*	Registered as *Cranial nerve injury* yes / no

Conventions used in the report

There are a number of conventions used in the report in an attempt to ensure that the data are presented in a clear and consistent way. These conventions relate largely to the tables and graphs, and some of these conventions are outlined below.

Conventions used in tables

On the whole, unless otherwise stated, tables in this report record numbers of patient-entries (see the example below representing the data presented graphically in the chart on page 46 from the section on AAA surgery).

		Gender			
		Male	Female	Unspecified	All
Age at surgery / years	<51	345	83	0	**428**
	51-55	625	71	2	**698**
	56-60	1,838	171	0	**2,009**
	61-65	3,842	365	10	**4,217**
	66-70	5,915	720	12	**6,647**
	71-75	7,204	1,116	20	**8,340**
	76-80	6,691	1,186	18	**7,895**
	81-85	3,512	831	9	**4,352**
	>85	813	251	2	**1,066**
	Unspecified	298	87	4	**389**
	All	**31,083**	**4,881**	**77**	**36,041**

The numbers in each table are colour-coded so that patient-entries with complete data for all of the components under consideration (in this example **both** the operation type **and** the aortic findings) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as *unspecified* in purple text. The totals for both rows and columns are highlighted as bold text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value. Yet other tables report average numbers (the patient's age at operation for example) and, again, this is made clear by the use of an appropriate title within the table.

Rows and columns within tables have been ordered so that they are either in ascending order (calendar years; post-operative stay; Low, Medium, High) or with negative response options first (No; No hypertension; Never smoked) followed by positive response options (Yes; Hypertension; Ex-smoker / Smoker).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

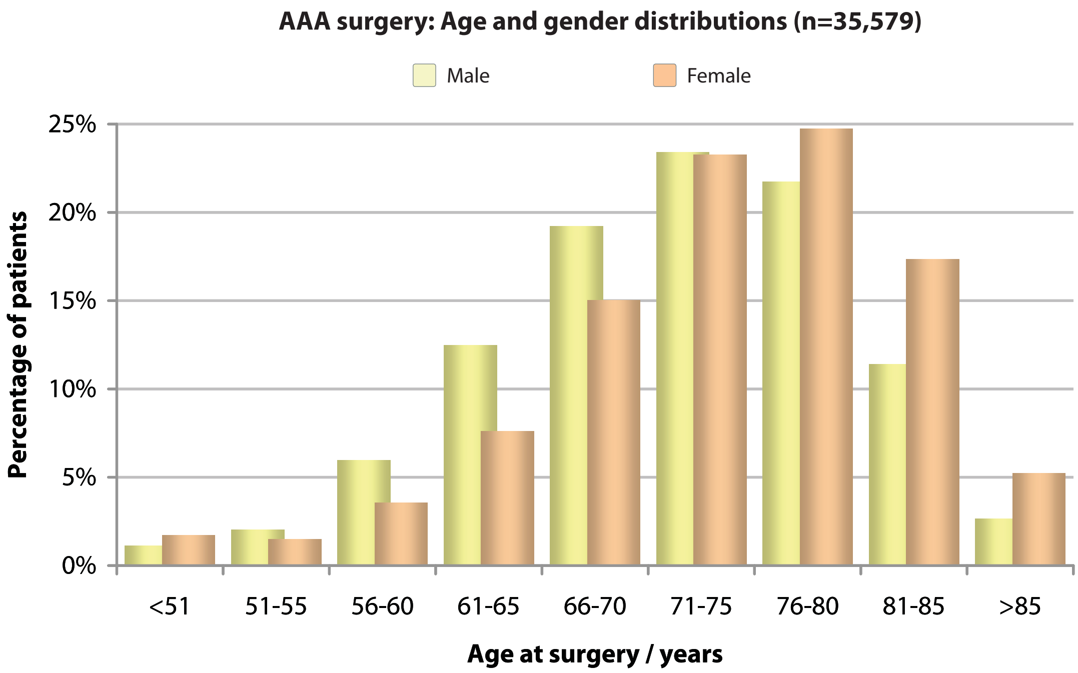
- insufficient space on the page to accommodate both the table and graph
- there would be more rows / columns of data than could reasonably be accommodated on the page (post-operative stay data)
- the tabular data had already been presented elsewhere in the report
- analyses were prepared separately from the preparation of the report by other workers

Conventions used in graphs

The basic principles applied when preparing graphs for the VASCUNET report were based, as far as possible, upon William S. Cleveland's book *The elements of graphing data* [iv]. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: The counts (shown as n= in each graph's title) associated with graphs are affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in the VASCUNET report are graphic representations of results for a particular group (or sub-set) extracted from the database, such as patients with intact aneurysms, patients who had an emergency operation, and so on. This clearly restricts the total number of database-entries available for any such analysis. In addition to this, some entries within the group under consideration have data missing in one or more of the database questions being examined (reported as unspecified in tables); entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph on page 46 (reproduced below), only the patient-entries with both age **and** gender recorded are included in the analysis; this comes to 35,579 patient-entries (345 + 83 + 625 + 71 + 1,838 + 171 + 3,842 + 365 + 5,915 + 720 + 7,204 + 1,116 + 6,691 + 1,186 + 3,512 + 831 + 813 + 251 from examining the table; the 462 patient-entries with one or more unspecified data-items are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals. The width of the confidence interval gives some idea of the statistical certainty around the calculated rate of an event or occurrence. If the confidence intervals around two rates do not overlap, then we can say, with a specified level of confidence, that the rates in these two populations are different; if the bars do overlap, we cannot make such an assertion.

iv. Cleveland WS. The elements of graphing data. 1985, 1994. Hobart Press, Summit, New Jersey, USA.

ESVS

Data analysis

Analyses based on the merged AAA surgery data

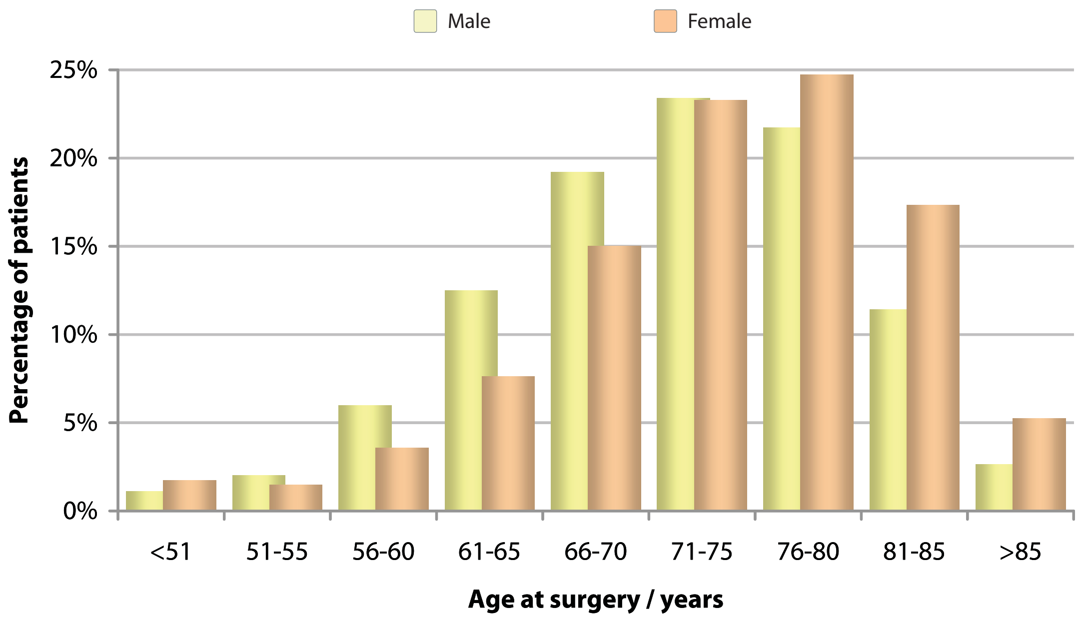
Age at operation

The mean age of patients was 72.1 years. 13.5% of patients were women, who tended to be older (73.9 years cf. 71.8 years).

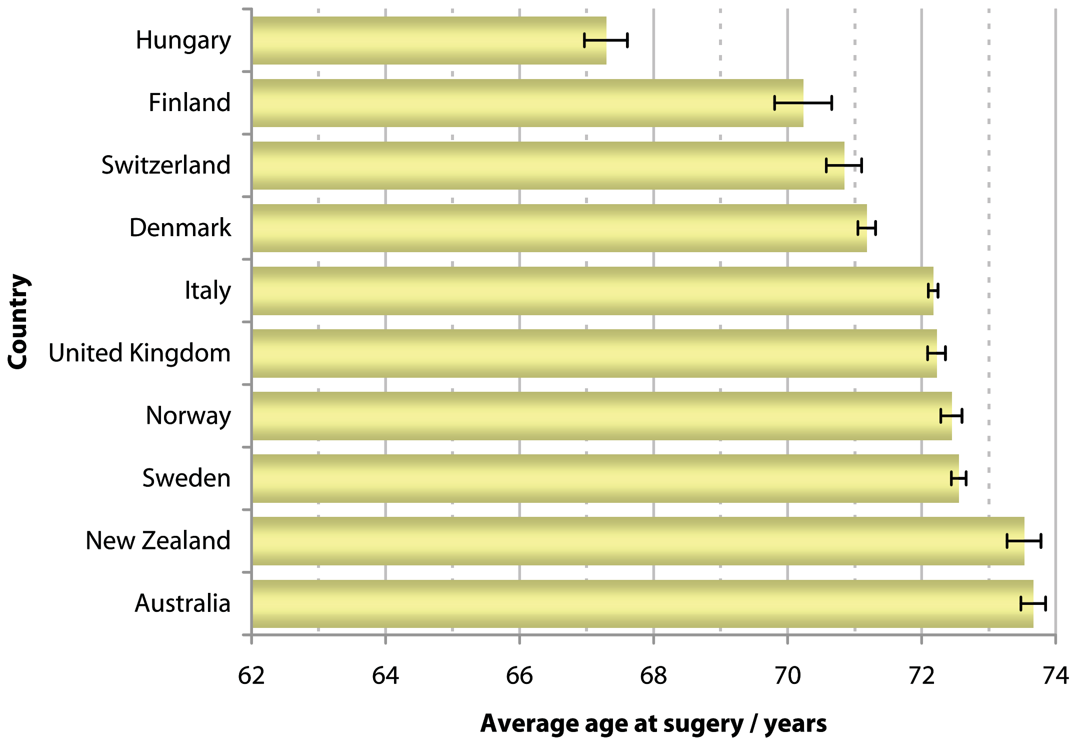
Most patients were in the 65-80 year age group, with women tending to present later than men. In most countries the average patient age was between 70 and 74 years, but the mean age of Hungarian patients was considerably less at 67.0 years. Australian & New Zealand patients were the oldest at 73.6 and 73.5 years respectively. Whether these national differences reflect variation in the disease itself or in patient selection is not known.

		Gender			
		Male	Female	Unspecified	All
Age at surgery / years	<51	345	83	0	**428**
	51-55	625	71	2	**698**
	56-60	1,838	171	0	**2,009**
	61-65	3,842	365	10	**4,217**
	66-70	5,915	720	12	**6,647**
	71-75	7,204	1,116	20	**8,340**
	76-80	6,691	1,186	18	**7,895**
	81-85	3,512	831	9	**4,352**
	>85	813	251	2	**1,066**
	Unspecified	298	87	4	**389**
	All	**31,083**	**4,881**	**77**	**36,041**

AAA surgery: Age and gender distributions (n=35,579)

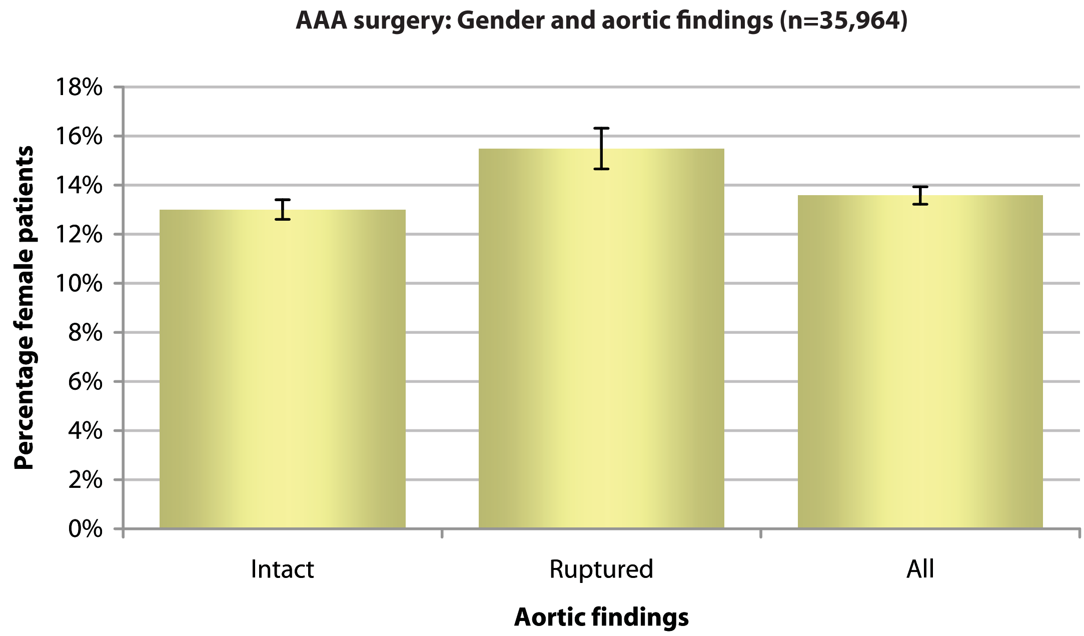


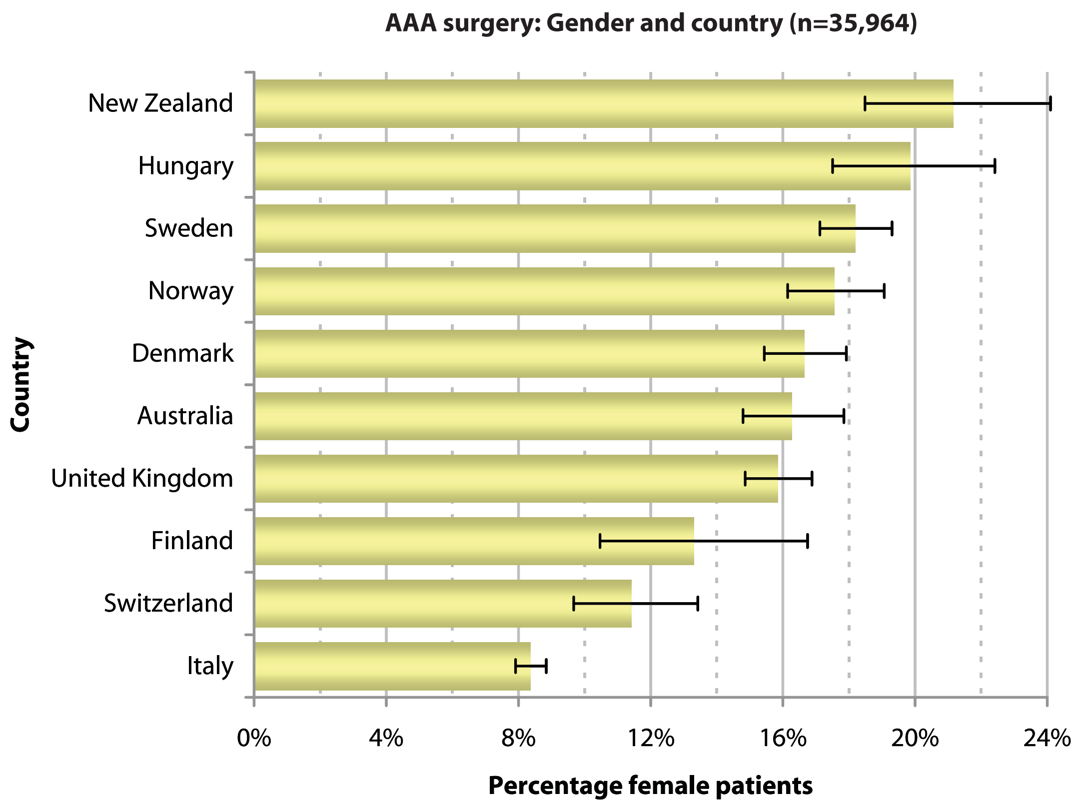
AAA surgery: Average age and country (n=35,652)



Gender

Ruptured aneurysms had a slightly greater percentage of women than intact aneurysms (15.4% *cf.* 13.0%). The percentage of women amongst patients undergoing aortic aneurysm repair varied between countries from 8% in Italy to 21% in New Zealand.



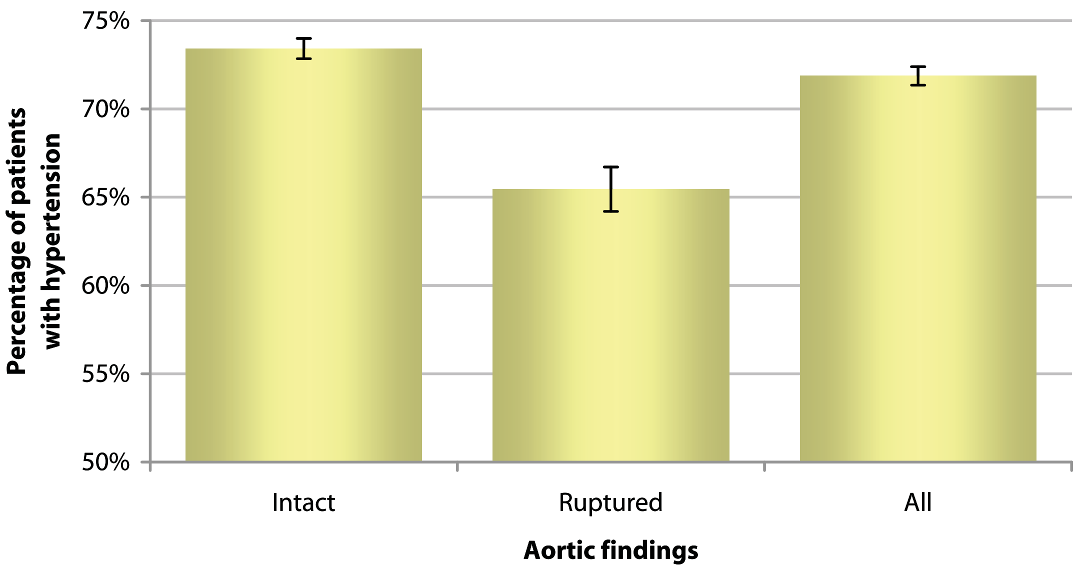


Risk factors

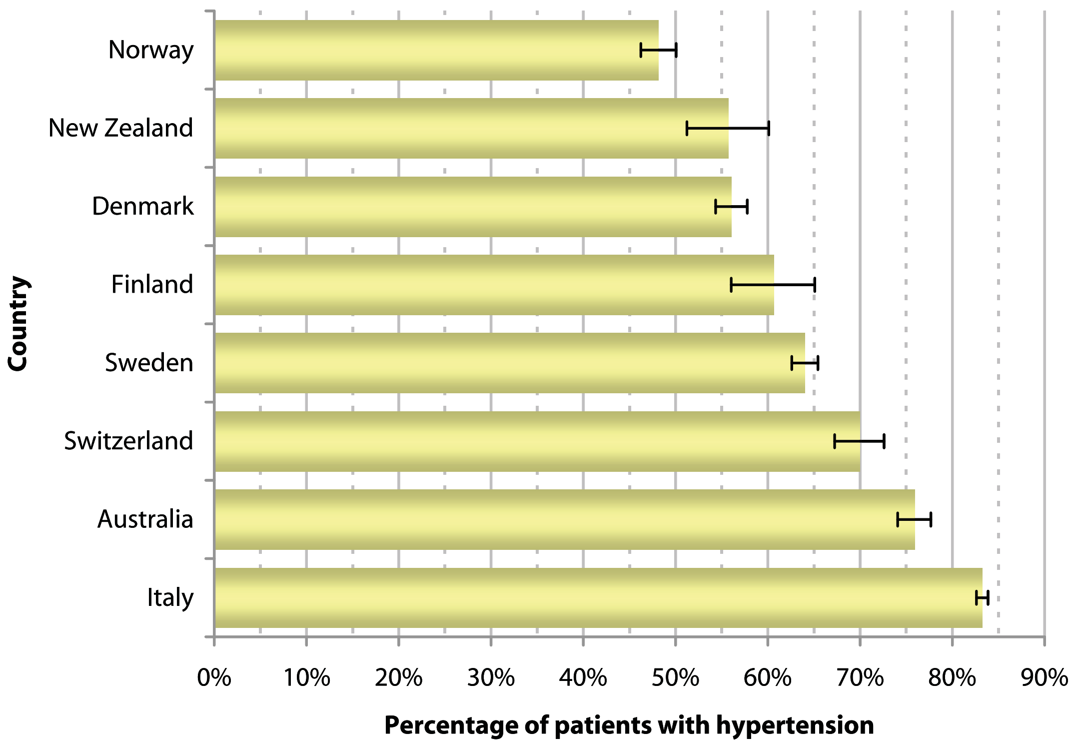
Hypertension

73% of intact aneurysms and 65% ruptured aneurysms had a history of hypertension. National figures for hypertension ranged from 48% (Norway) to 83% (Italy). However the data definitions of hypertension differed greatly between countries (see pages 38-39) and this could have contributed to the differences in incidence.

AAA surgery: Hypertension and aortic findings (n=28,524)

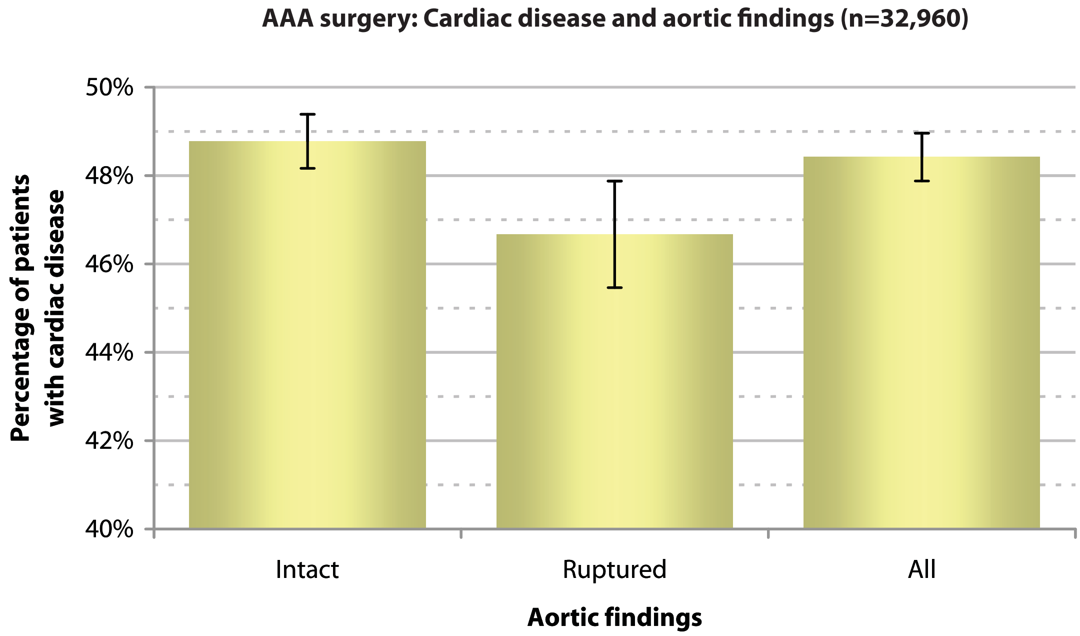


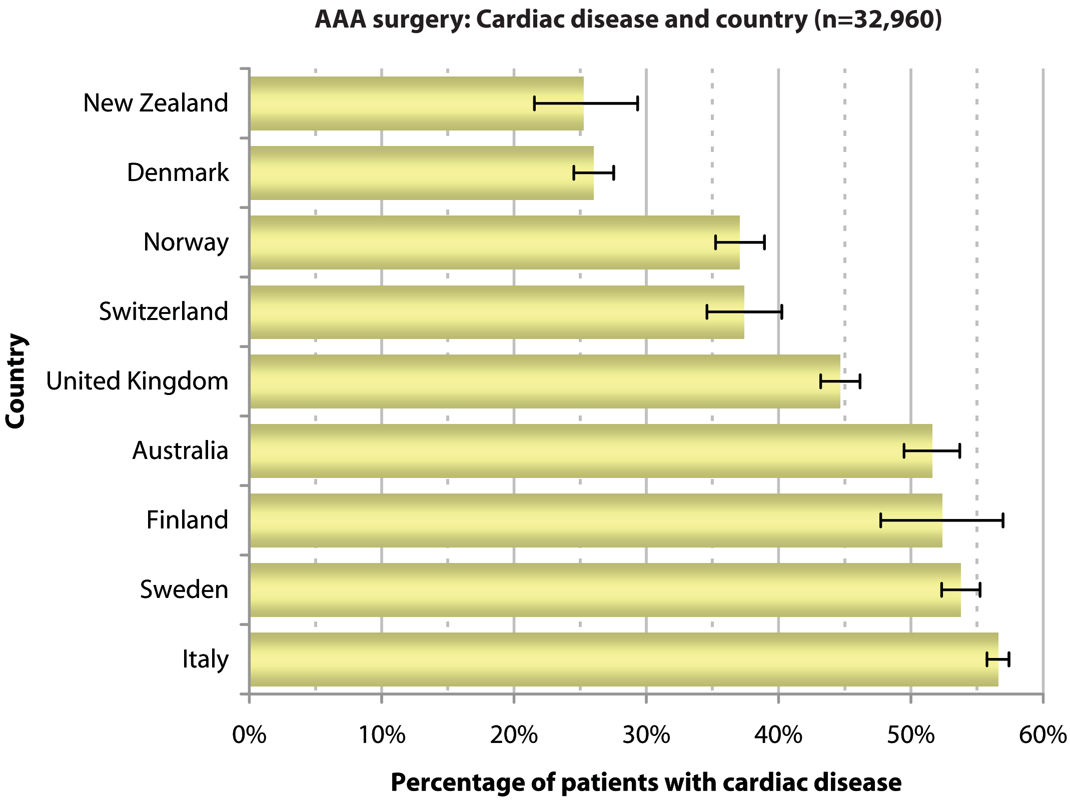
AAA surgery: Hypertension and country (n=28,524)



Cardiac disease

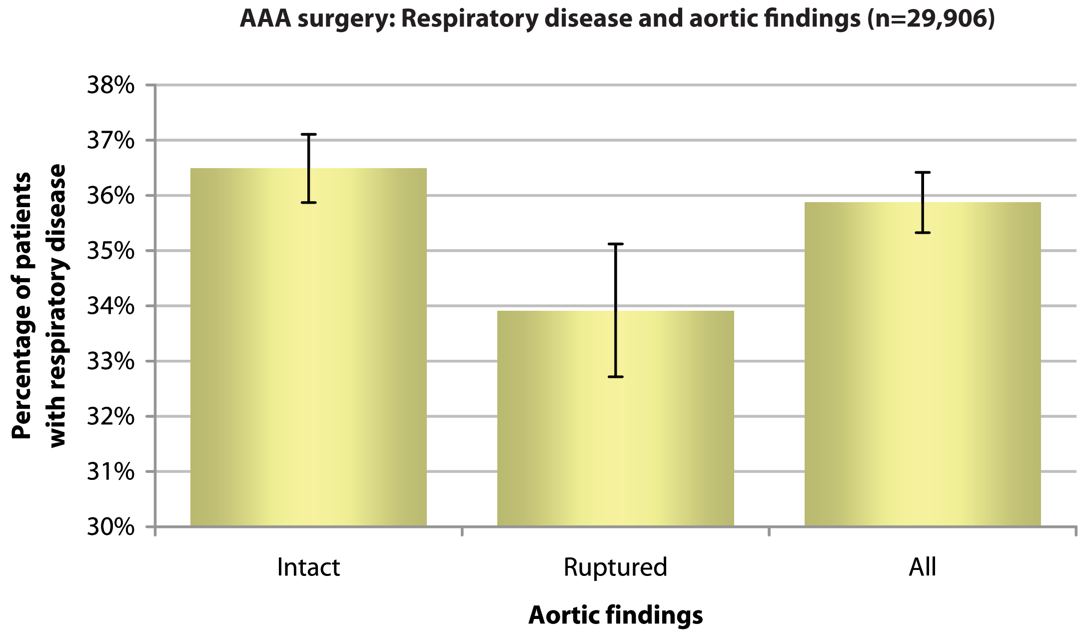
49% of intact and 47 % ruptured aneurysms had known cardiac disease. The percentage of patients with cardiac disease in each registry ranged from 30-55%. Whilst Australia and Italy included not only a past history of cardiac disease but also the results of ECG and stress tests, this is unlikely to explain these national variations.

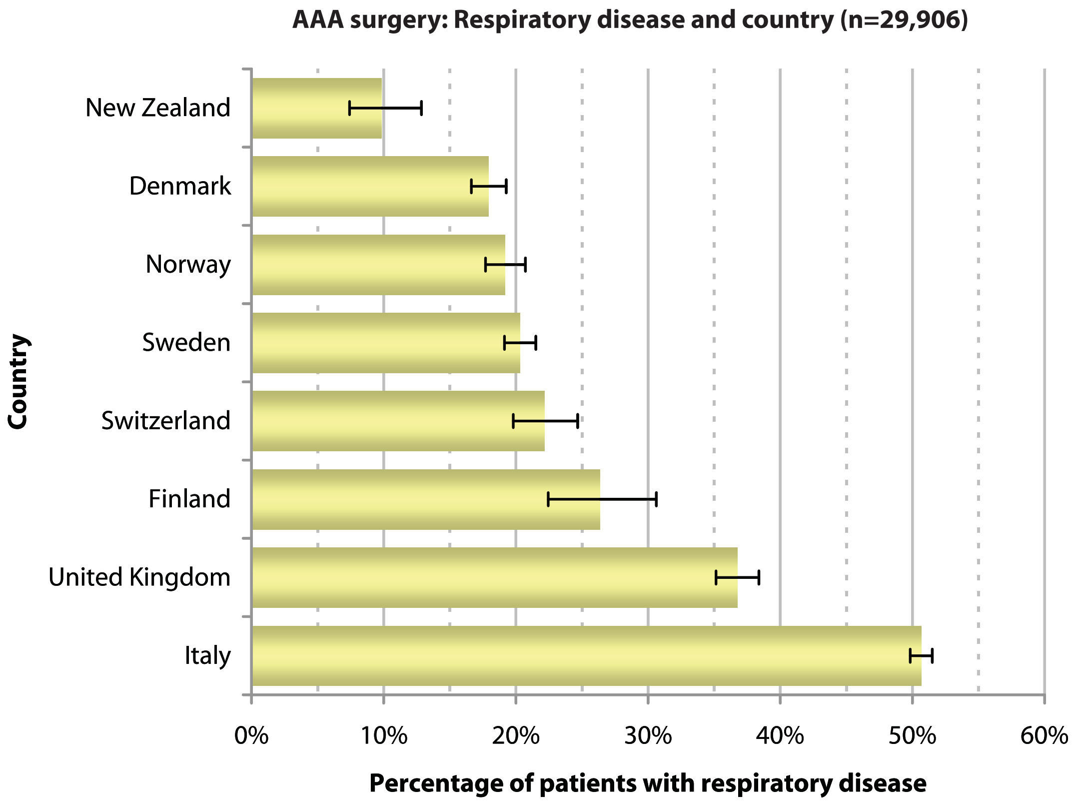




Respiratory disease

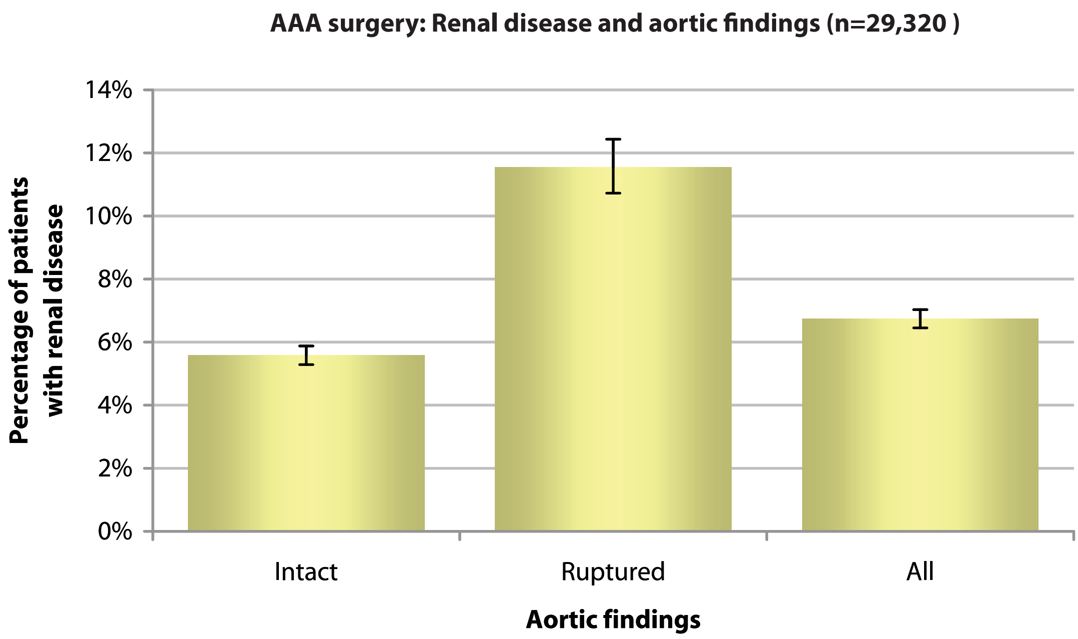
Respiratory disease appeared to be more common in the elective than the ruptured aneurysms. There was a striking national variation in the incidence of respiratory disease form 10% in New Zealand to over 50% in Italy despite similar data definitions.

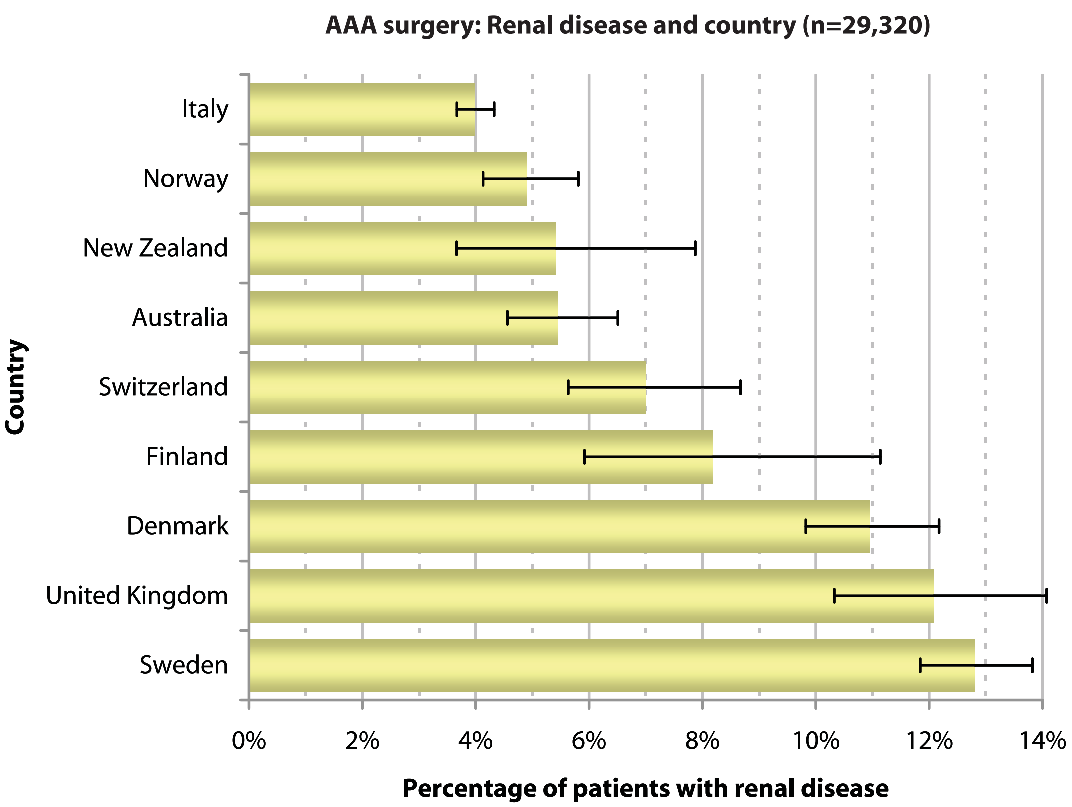




Renal disease

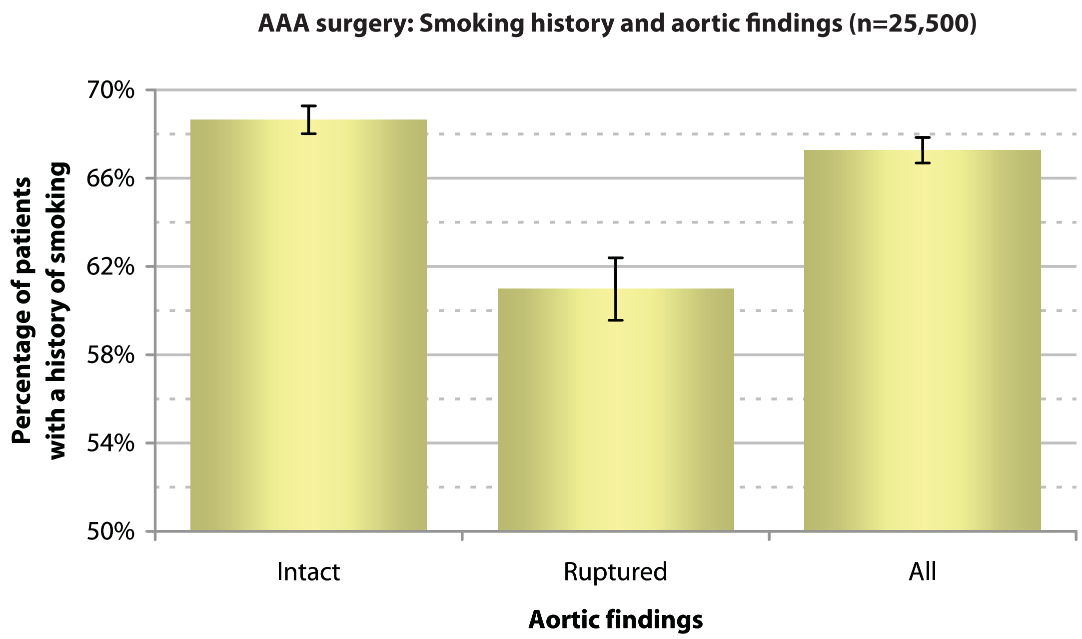
Chronic renal dysfunction was twice as frequent in patients presenting with rupture than in elective aortic aneurysms. National figures ranged from 4% in Italy to 12.8% in Sweden.

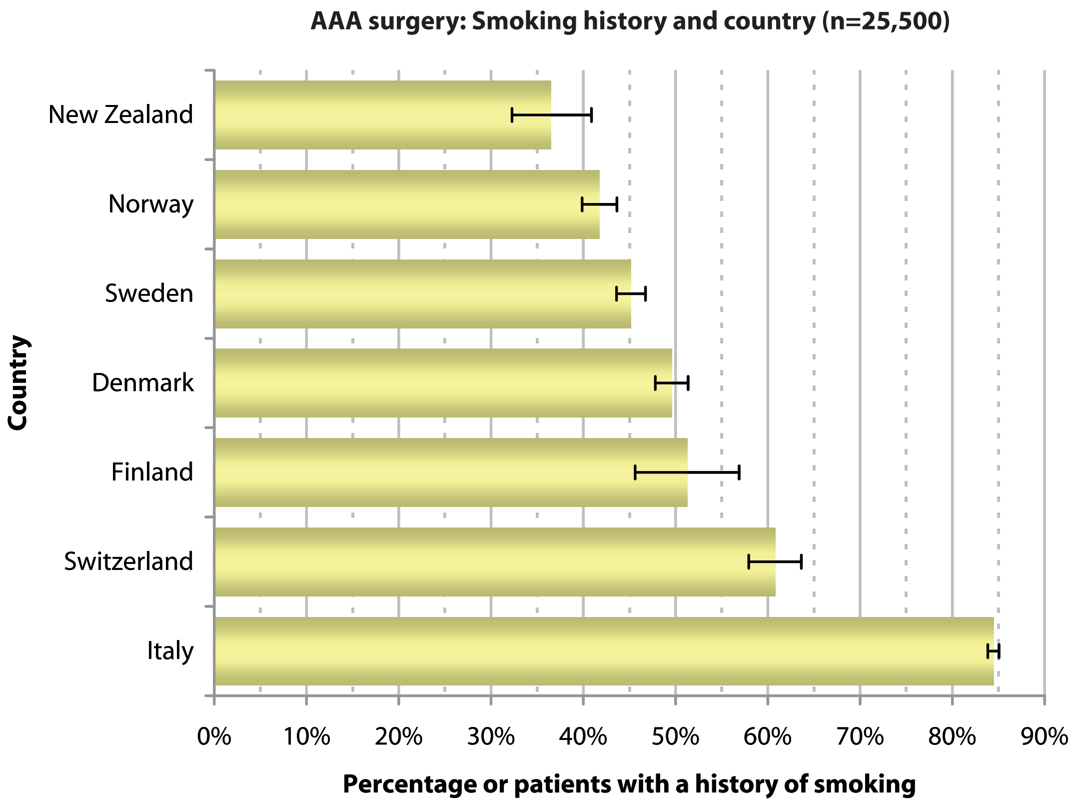




Smoking history

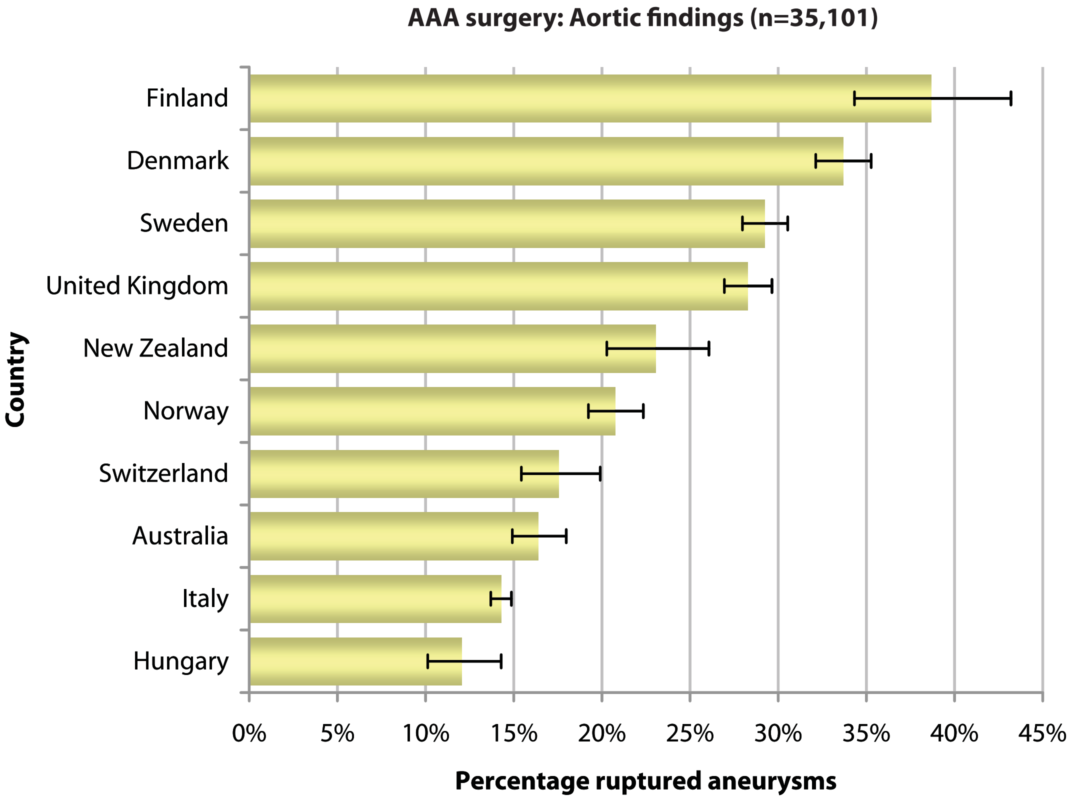
68% of patients with intact aneurysms were smokers in comparison with 61% of patients presenting with rupture. 85% of Italian patients smoked in comparison with 35% of New Zealanders. However, the data definition of smokers varied greatly from country to country so that these data may not be reliable (see page 38-39).





Aortic findings

Overall, 21% of patients with an aortic aneurysm presented with rupture. The percentage of ruptured aneurysms ranged from 12% in Hungary to 38% in Finland. The reasons for this variation are unclear.

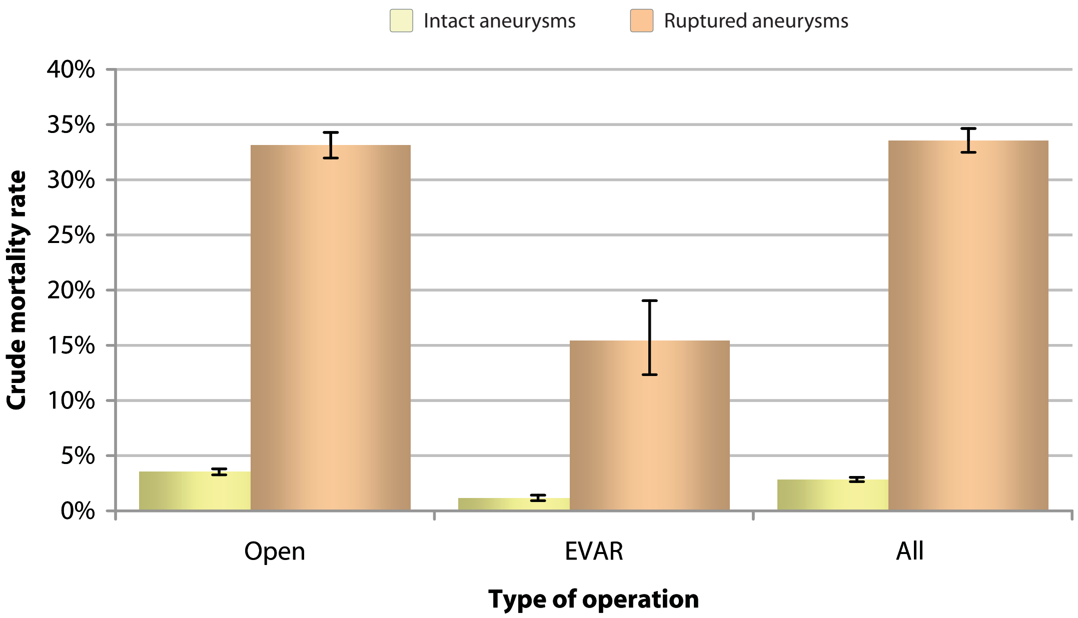


Mortality

The overall mortality of repair was 9.5%. The mortality of surgery was 2.8% for intact aneurysms and 33% for ruptured aneurysms. The mortality of endovascular repair (EVAR) was approximately half that of open repair for both ruptured and intact aneurysms. This is similar to the results of the UK EVAR 1 trial (see ref. 1; page 93).

Aortic findings and type of operation			Mortality: Alive	Mortality: Died	Mortality: Unspecified	Mortality: All
	Intact	Open	17,624	644	203	**18,471**
	Intact	EVAR	7,419	86	73	**7578**
	Intact	Unspecified	1,525	45	16	**1,586**
	Intact	**All**	**26,568**	**775**	**292**	**27,635**
	Ruptured	Open	4,283	2,121	64	**6,468**
	Ruptured	EVAR	401	73	4	**478**
	Ruptured	Unspecified	229	287	4	**520**
	Ruptured	**All**	**4,913**	**2,481**	**72**	**7,466**
	Unspecified	Open	339	24	6	**369**
	Unspecified	EVAR	25	0	3	**28**
	Unspecified	Unspecifiec	487	29	27	**543**
	Unspecified	**All**	**851**	**53**	**36**	**940**

AAA surgery: Crude mortality, aortic findings and procedure type (n=34,737)

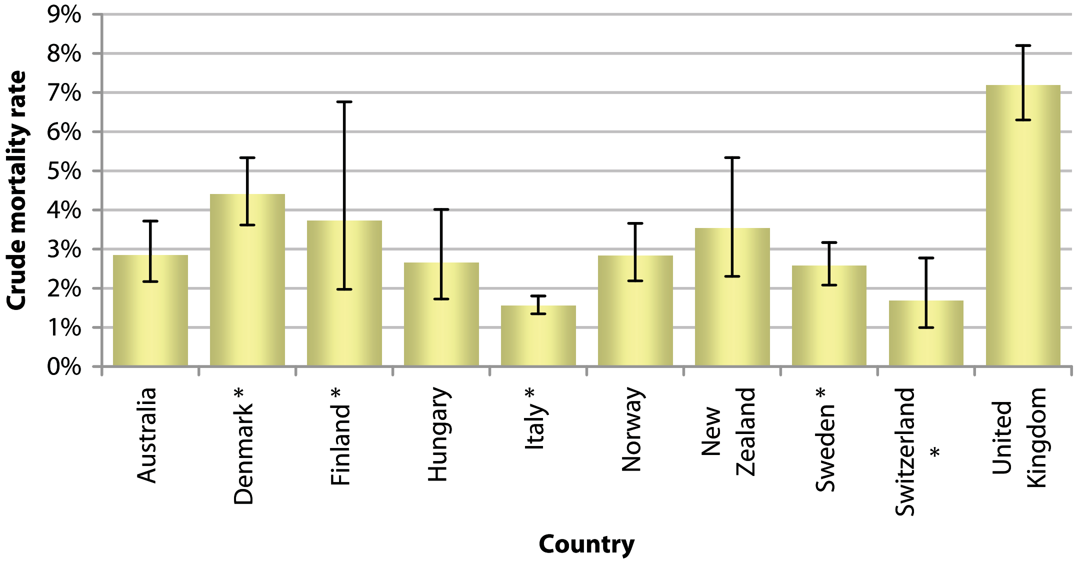


Mortality and country

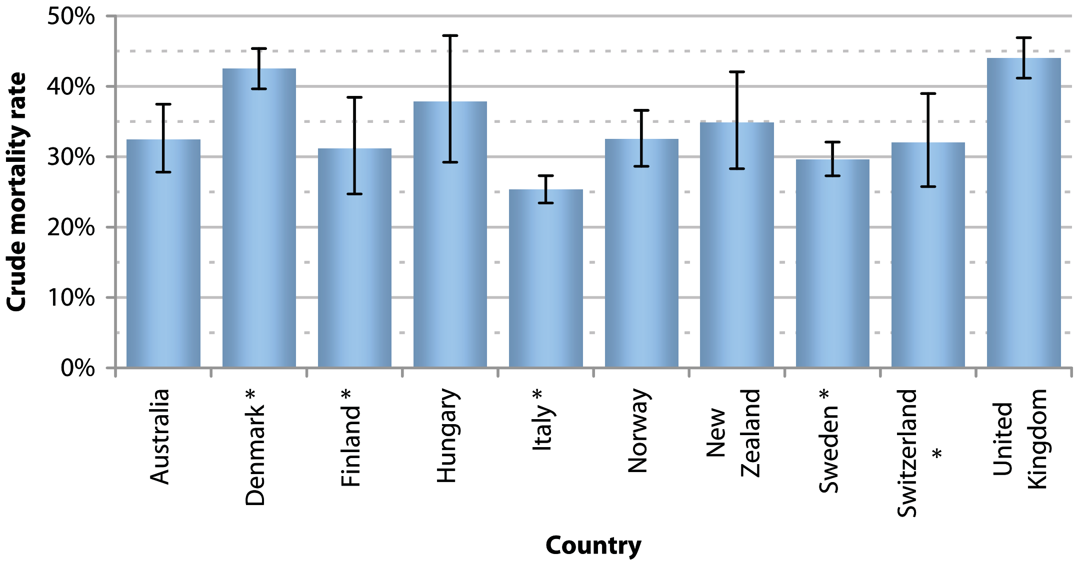
The national mortality of ruptured aneurysm repair varied from 25 to 44%. Similarly, the mortality for open repair of intact aneurysm varied from 1.9 to 7.9% but was significantly greater (7.9%) in the UK than in the other nine registries (1.9-4.5%). The UK results are corroborated by three other national audits published within the last 7 years (refs. 2-4; page 93). The cause for the apparently higher mortality in the UK National Vascular Database is unclear and deserves further study. The national mortality figures for elective EVAR ranged from 0.8-2.7%.

			Mortality			
			Alive	Died	Unspecified	All
Aortic findings and country	Intact	Australia	1,877	55	1	**1,933**
		Denmark	2,217	102	24	**2,343**
		Finland	284	11	0	**295**
		Hungary	845	23	0	**868**
		Italy	11,615	184	99	**11,898**
		Norway	2,056	60	0	**2,116**
		New Zealand	628	23	0	**651**
		Sweden	3,374	89	0	**3,463**
		Switzerland	937	16	0	**953**
		United Kingdom	2,735	212	168	**3,115**
	Ruptured	Australia	256	123	0	**379**
		Denmark	677	500	13	**1,190**
		Finland	128	58	0	**186**
		Hungary	74	45	0	**119**
		Italy	1,472	499	10	**1,981**
		Norway	374	180	0	**554**
		New Zealand	127	68	0	**195**
		Sweden	1,007	424	0	**1,431**
		Switzerland	138	65	0	**203**
		United Kingdom	660	519	49	**1,228**
	Unspecified	Hungary	63	3	0	**66**
		Italy	13	1	0	**14**
		Norway	0	1	0	**1**
		United Kingdom	775	48	36	**859**

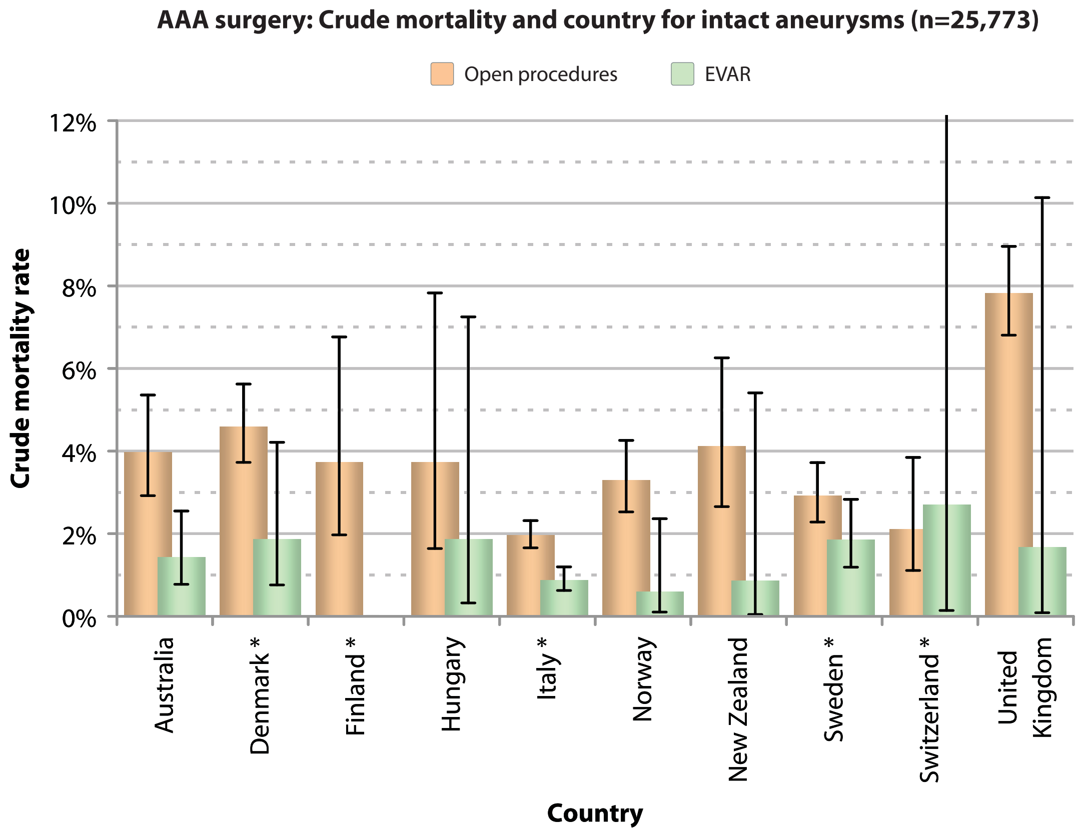
AAA surgery: Crude mortality and country for intact aneurysms (n=27,343)



AAA surgery: Crude mortality and country for ruptured aneurysms (n=7,394)

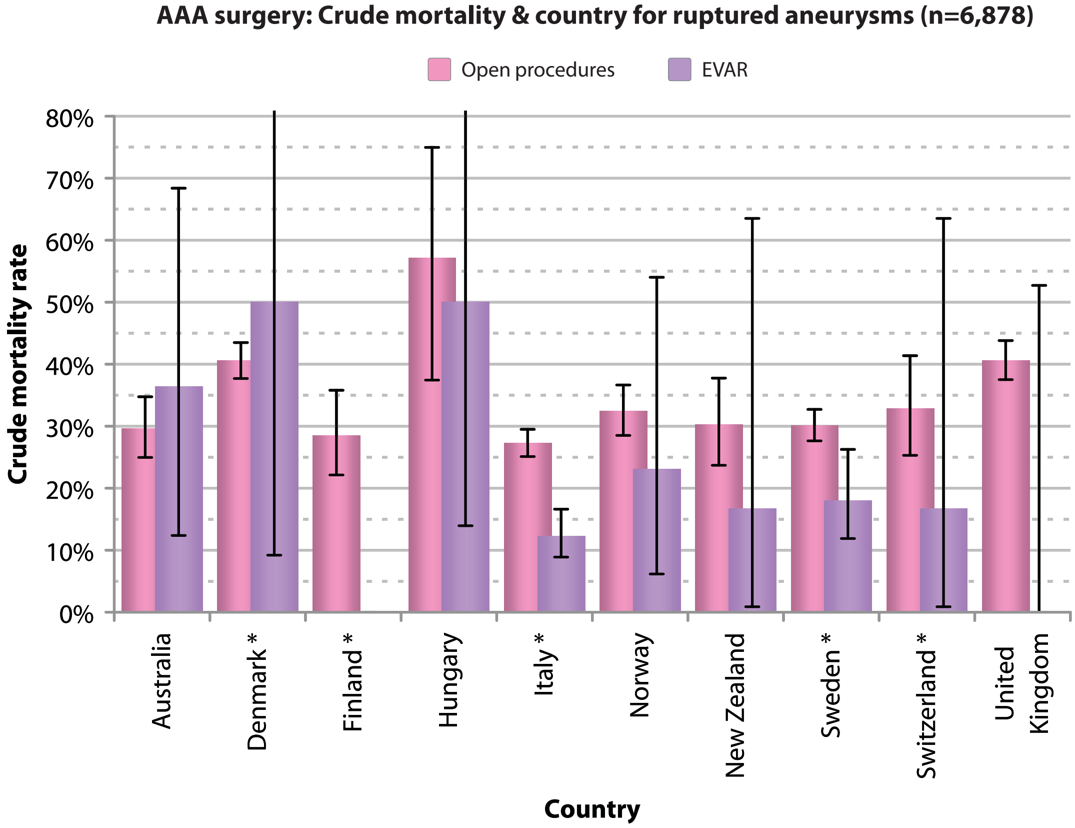


Countries with an asterisk suffix report 30-day mortality, others report in-hospital mortality



Countries with an asterisk suffix report 30-day mortality, others report in-hospital mortality

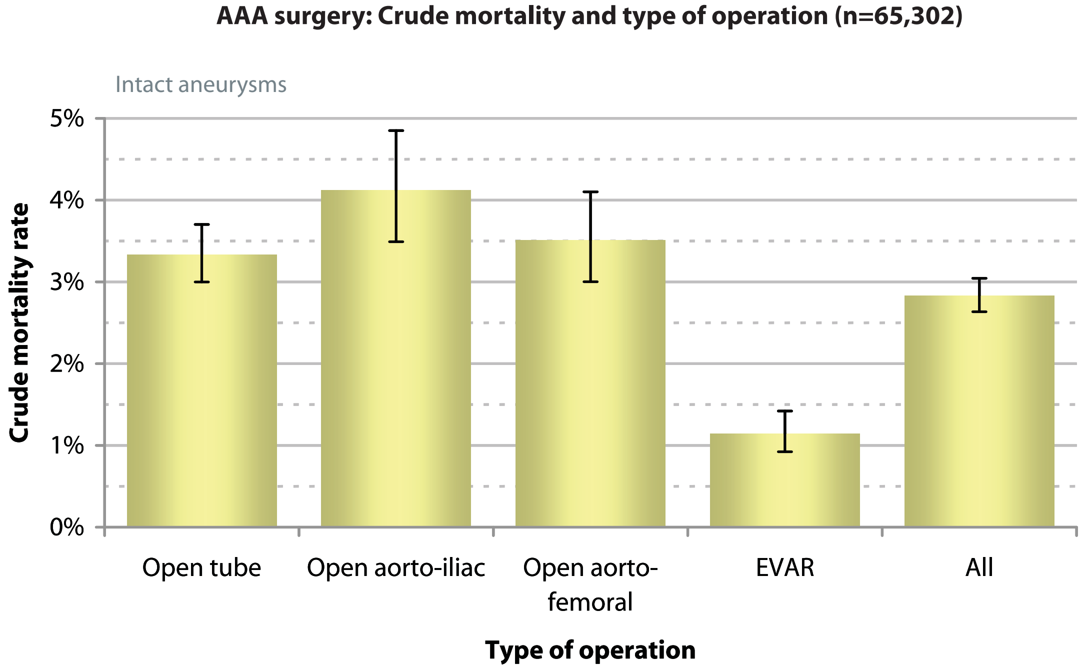
Ruptured aneurysm repair had the highest mortality in Hungary (57% open; 50% EVAR) and lowest in Italy (27% open, 12% EVAR).

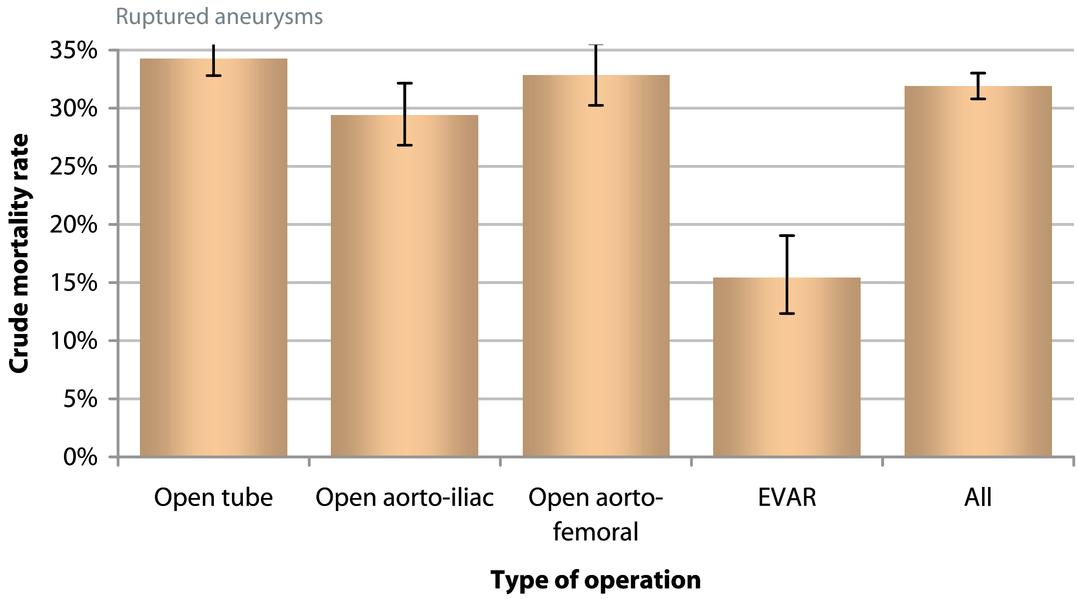


Countries with an asterisk suffix report 30-day mortality, others report in-hospital mortality

Mortality and type of operation

For open repair bifurcated grafts and tube grafts had similar mortalities in both ruptured and intact aneurysms.

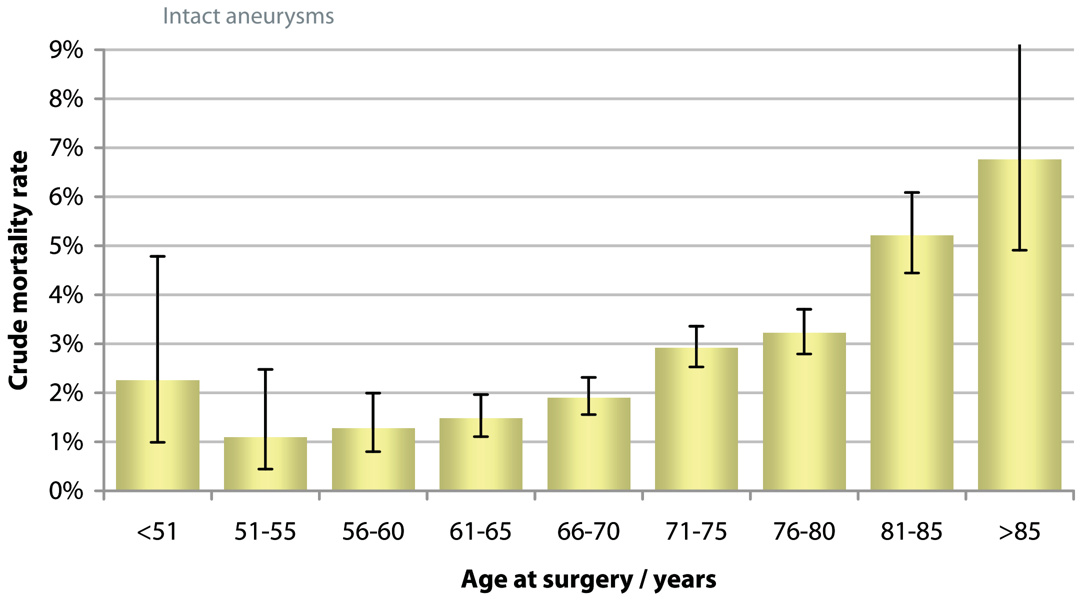


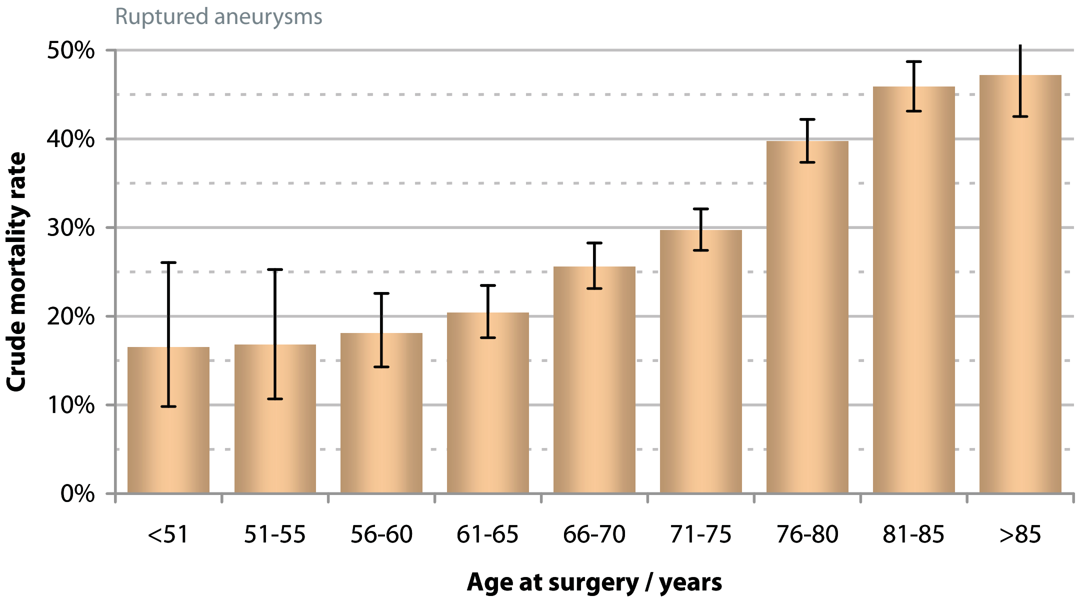


Mortality and age at surgery

Increasing age is an important adverse determinant of mortality in both ruptured and intact aneurysms.

AAA surgery: Crude mortality and type of operation (n=34,367)

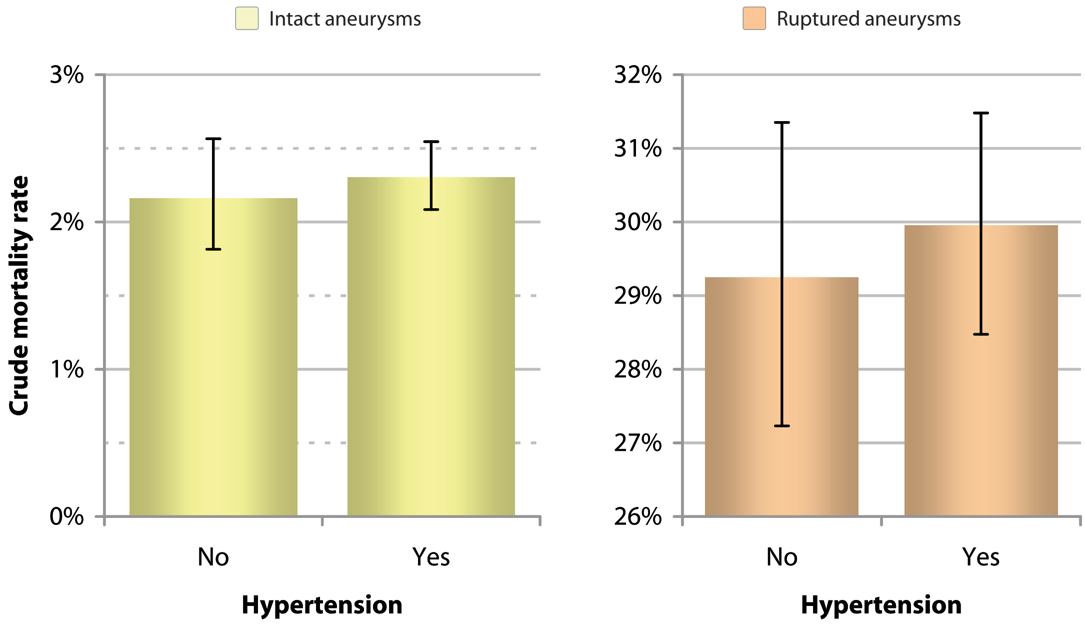




Mortality and hypertension

Hypertension did not affect mortality of intact or ruptured aneurysm repair.

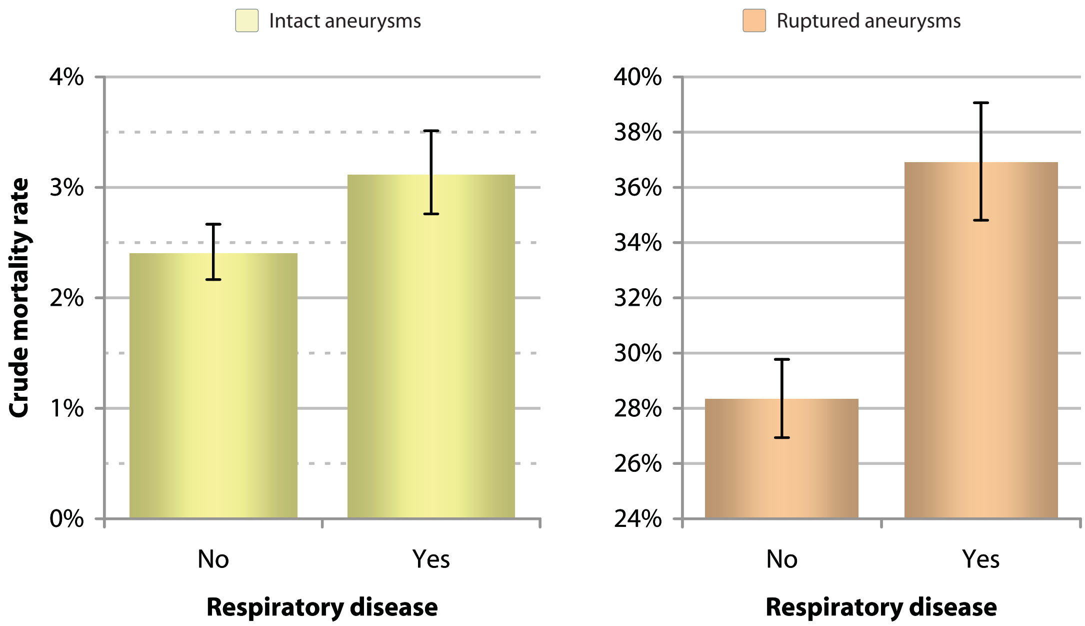
AAA surgery: Crude mortality and hypertension (n=28,372)



Mortality and respiratory disease

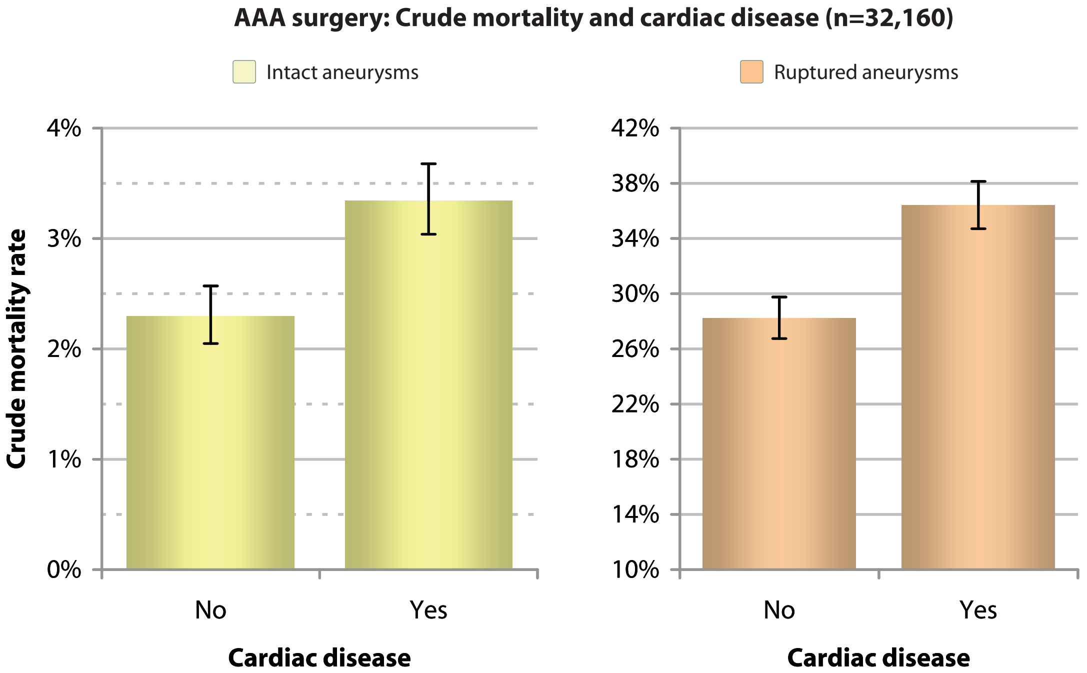
A history of respiratory disease adversely affected mortality of intact and ruptured aneurysm repair.

AAA surgery: Crude mortality and respiratory disease (n=29,224)



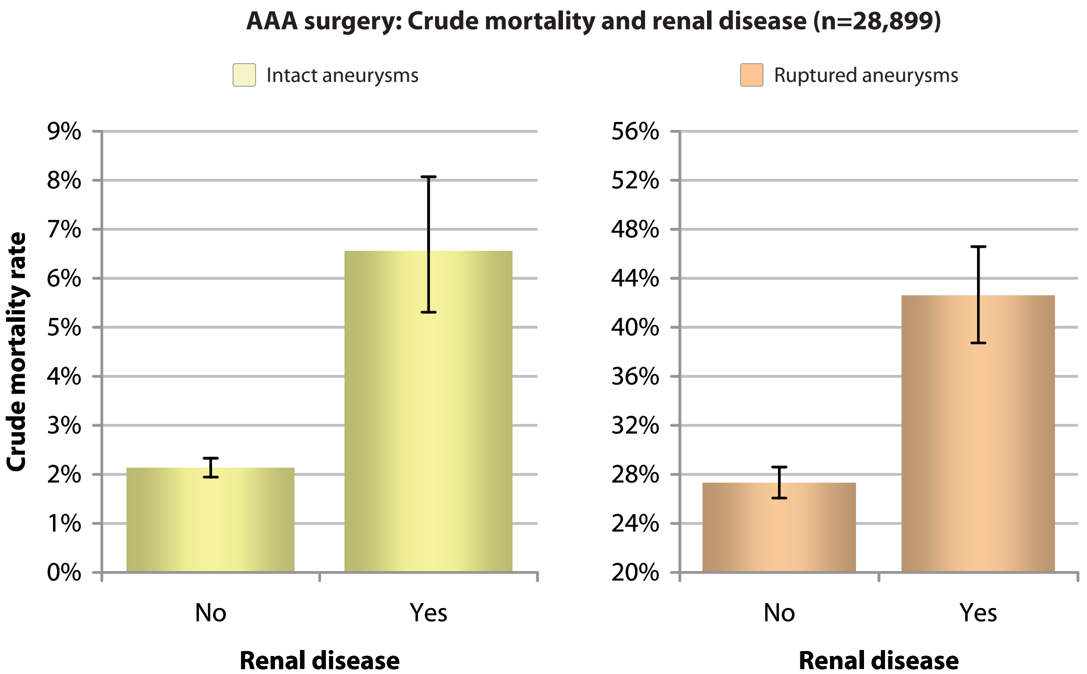
Mortality and cardiac disease

Cardiac disease, as expected, was found to adversely affect mortality of intact and ruptured aneurysm repair.



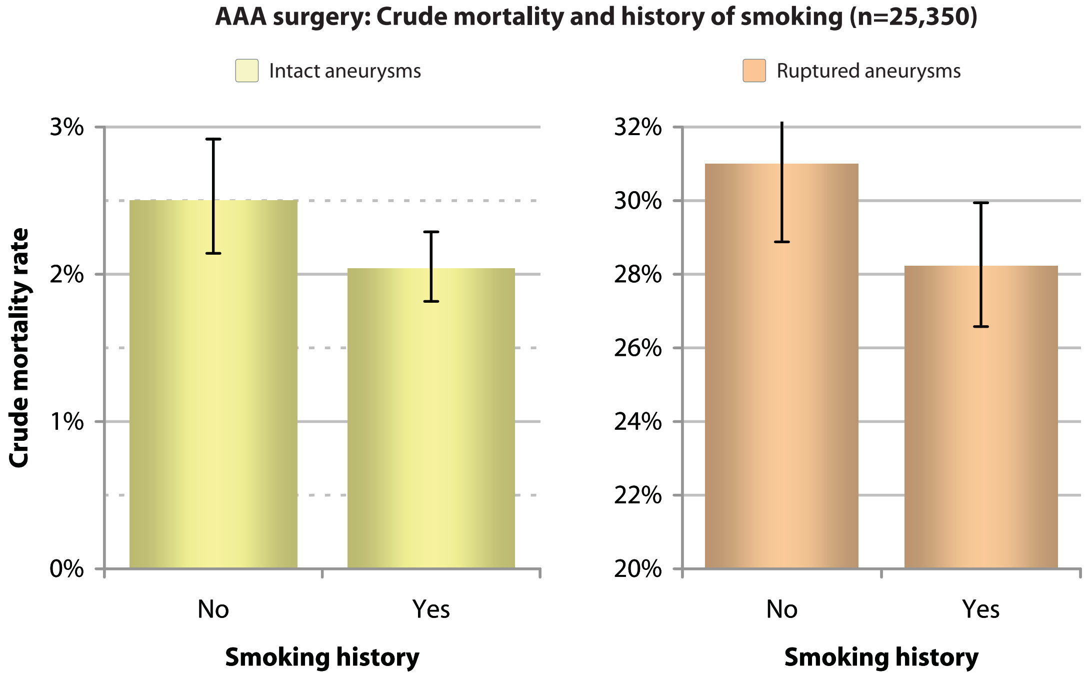
Mortality and renal disease

After increasing age, renal failure had the greatest effect on mortality of intact and ruptured aneurysm repair.



Mortality and a history of smoking

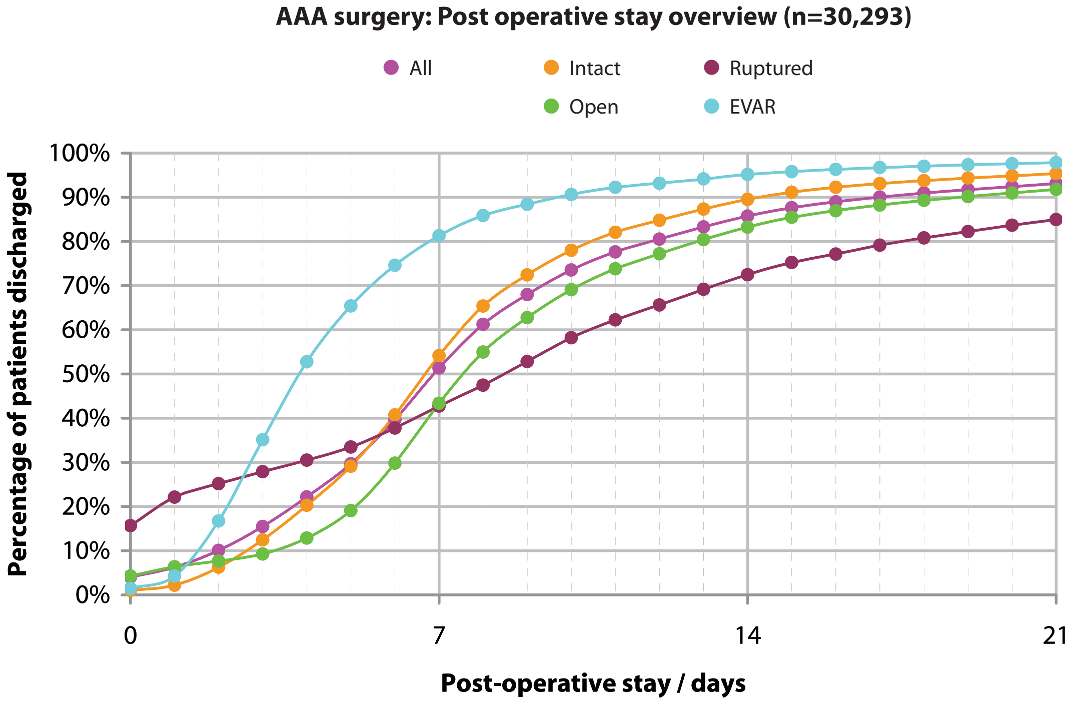
Smoking seemed, if anything, to reduce the mortality of aneurysm surgery. However, whilst the data definitions for smoking varied widely, the reasons for this apparent protective effect are unclear and could be spurious.



Post operative stay

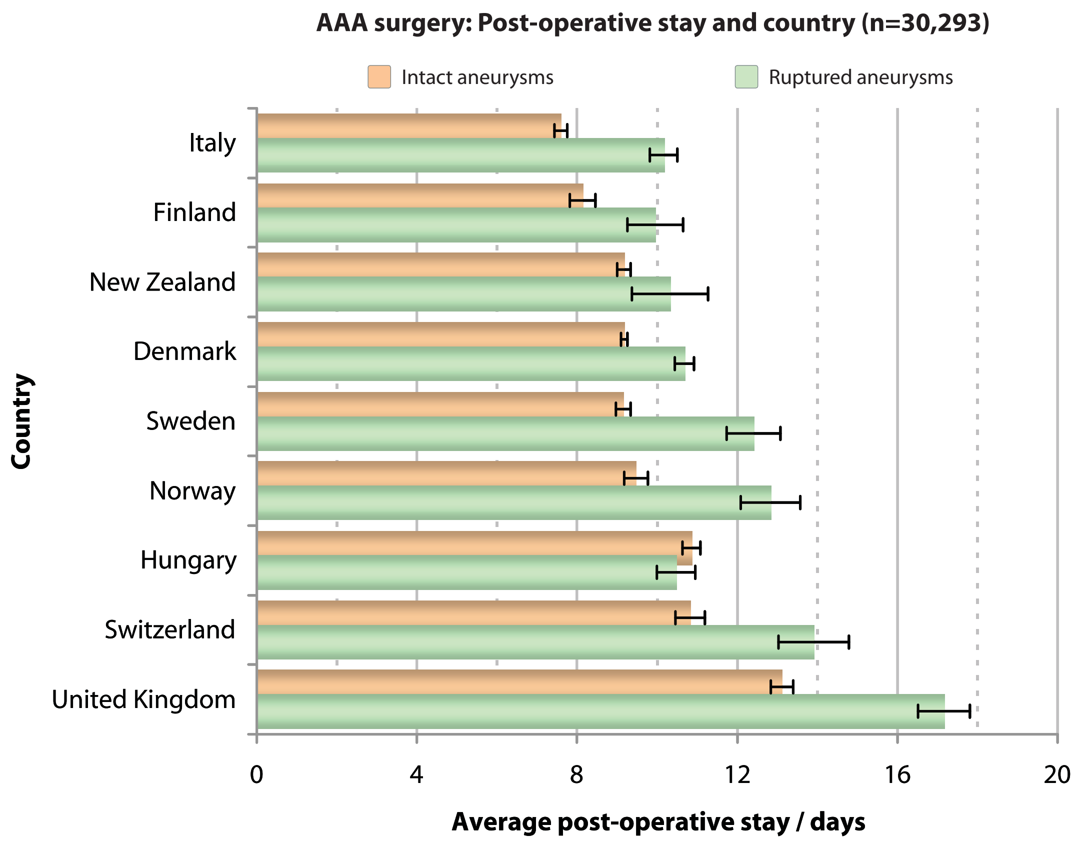
Post-operative stay overview

The average post-operative length-of-stay was substantially less for endovascular than open repair (5.9 days cf. 10.8 days). The length-of-stay for ruptured aneurysms was the longest (12.1 days).



Post-operative stay and country

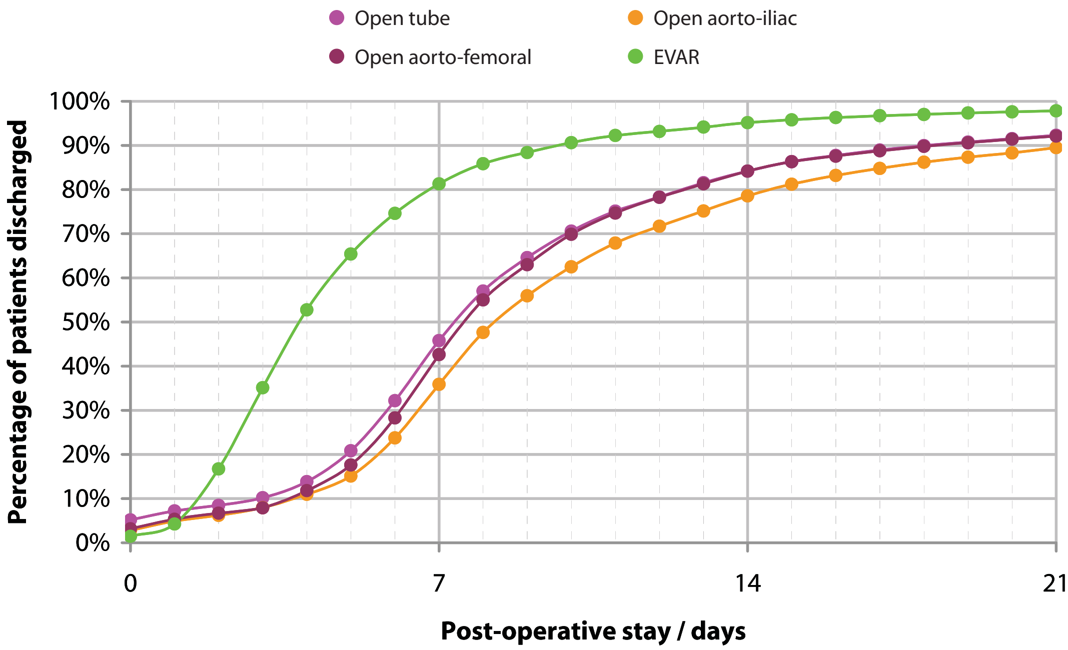
The post-operative length-of-stay was greatest in the United Kingdom (14.1 days) and least in Italy (8.0 days).



Post-operative stay and graft type

The use of a bifurcated graft, whether aorto-iliac or aortobifemoral, had little effect on the post-operative length-of-stay.

AAA surgery: Post operative stay and graft type (n=27,899)

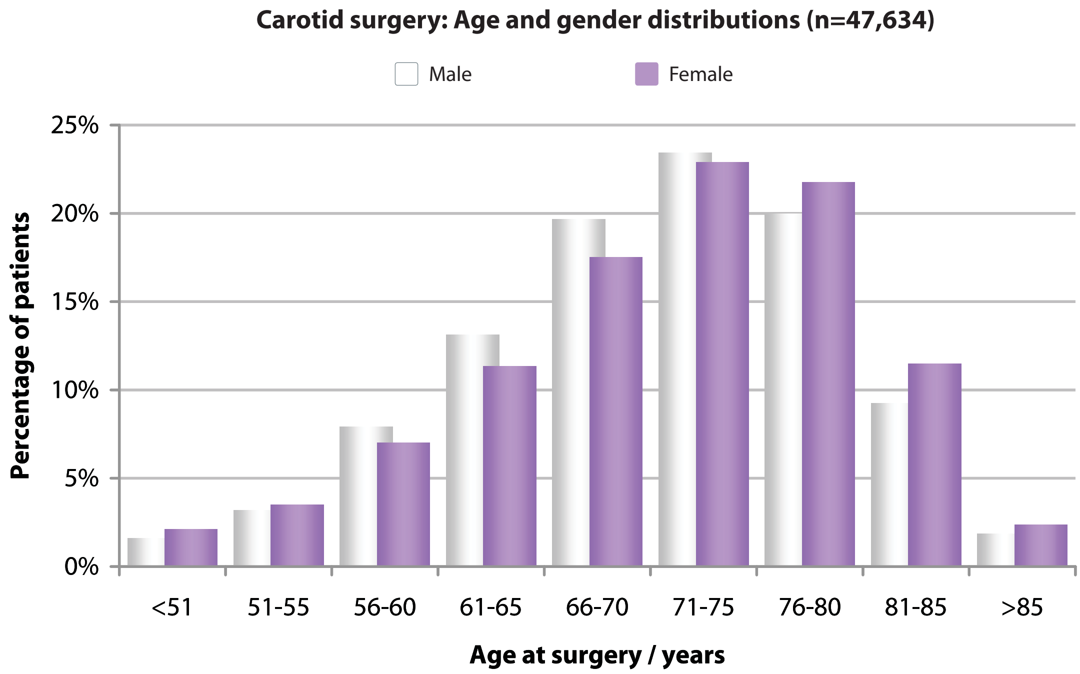


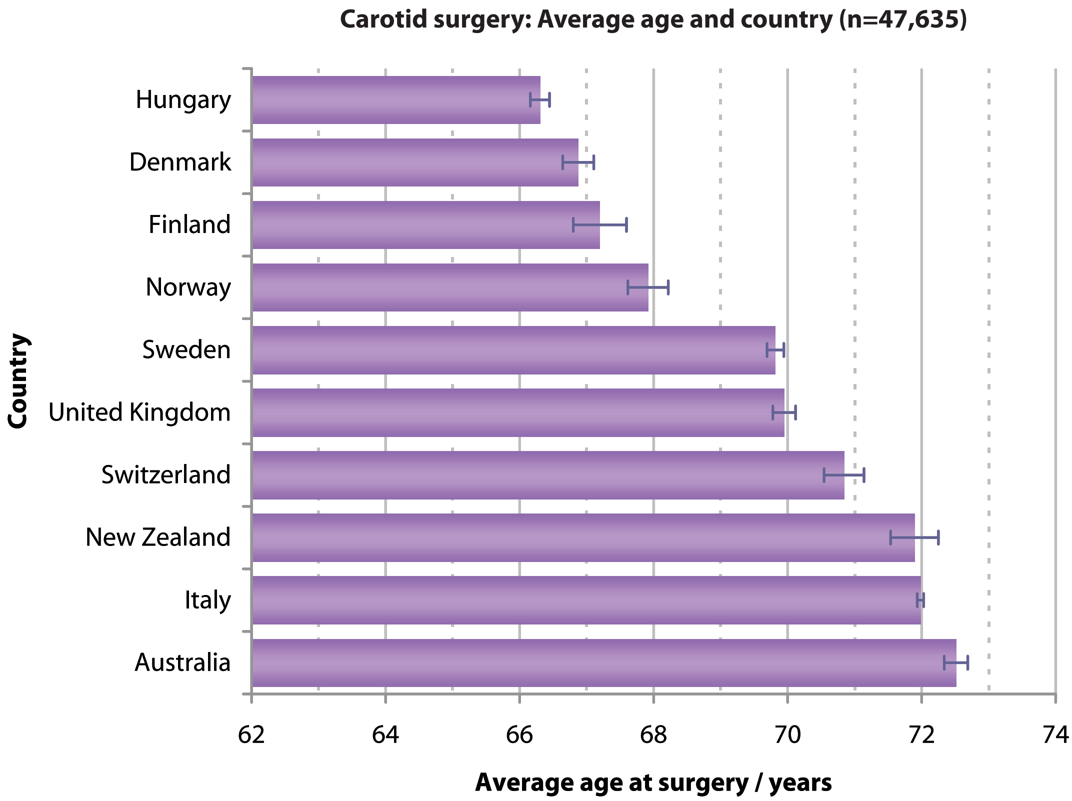
Analyses based on the merged carotid surgery data

Age at operation

32% of all patients undergoing carotid surgery were women. The mean age was similar for men (66.9 years) and women (66.9 years). As shown on the facing page, the average age varied between registries from 66.3 years in Hungary to 72.5 years in Australia.

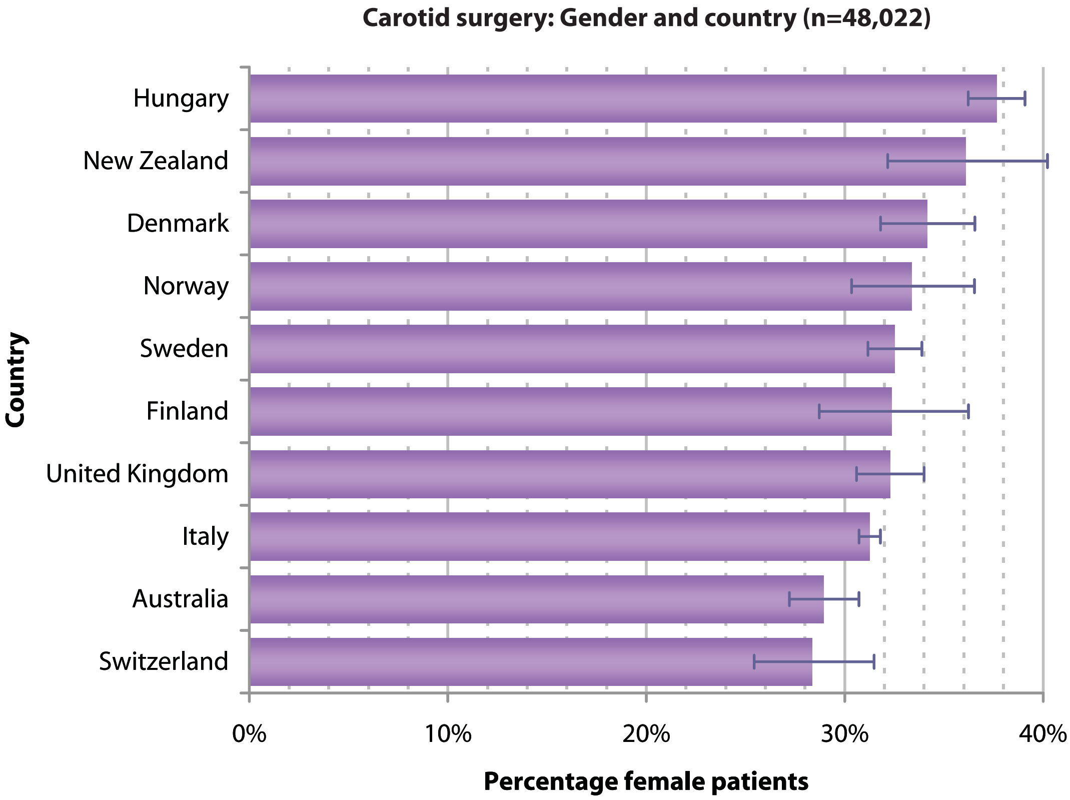
		Gender			
		Male	Female	Unspecified	All
Age at surgery / years	<51	491	299	0	**790**
	51-55	962	497	0	**1,459**
	56-60	2,409	997	0	**3,406**
	61-65	3,946	1,617	0	**5,563**
	66-70	6,003	2,509	0	**8,512**
	71-75	7,211	3,340	1	**10,552**
	76-80	6,166	3,183	0	**9,349**
	81-85	2,857	1,669	0	**4,526**
	>85	568	350	0	**918**
	Unspecified	273	108	1	**382**
	All	**30,886**	**14,569**	**2**	**45,427**




Carotid surgery: Average age and country (n=47,635)
Country
Hungary
Denmark
Finland
Norway
Sweden
United Kingdom
Switzerland
New Zealand
Italy
Australia
62
64
66
68
70
72
74
Average age at surgery / years

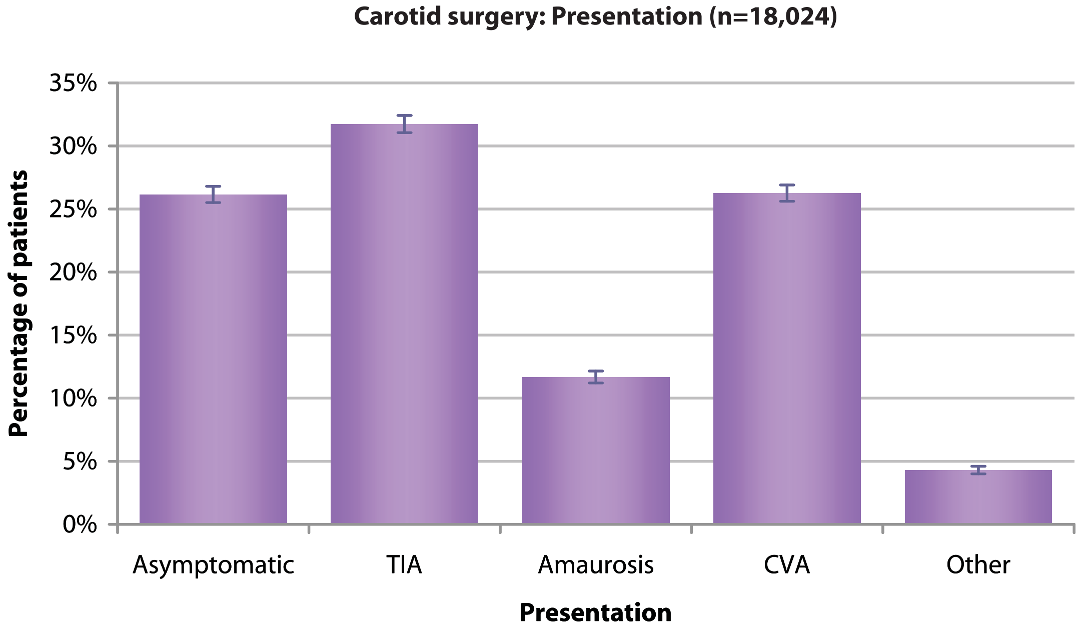
Gender

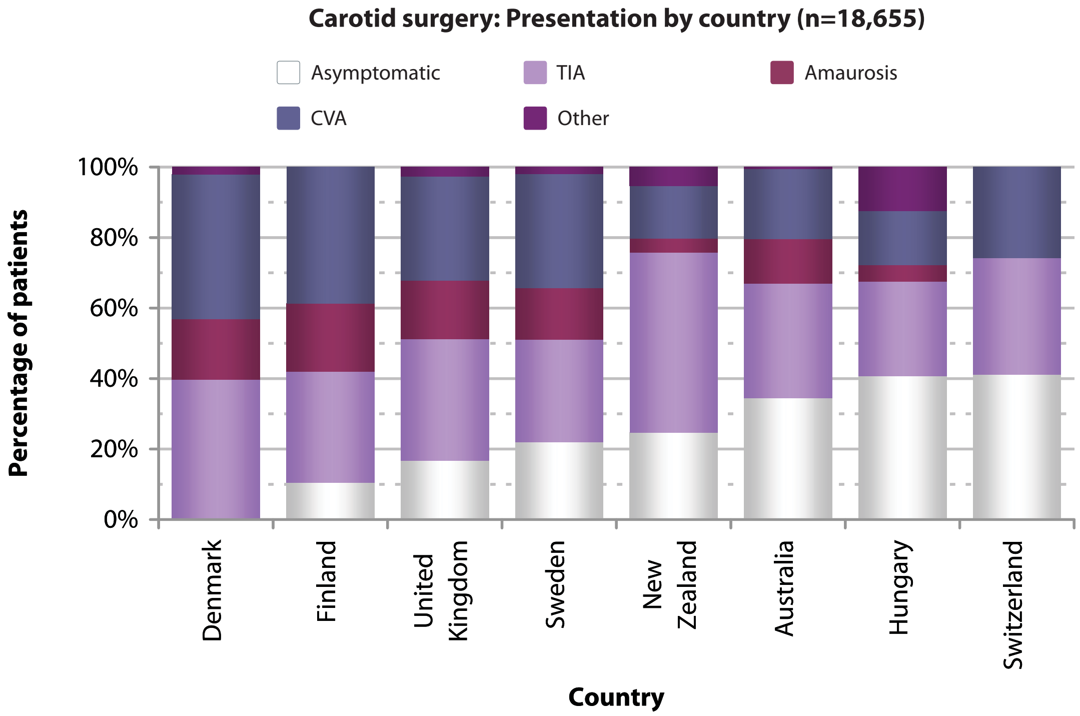
The proportion of women undergoing carotid surgery ranged from 27.6% in Switzerland to 37.4% in Hungary.



Presentation

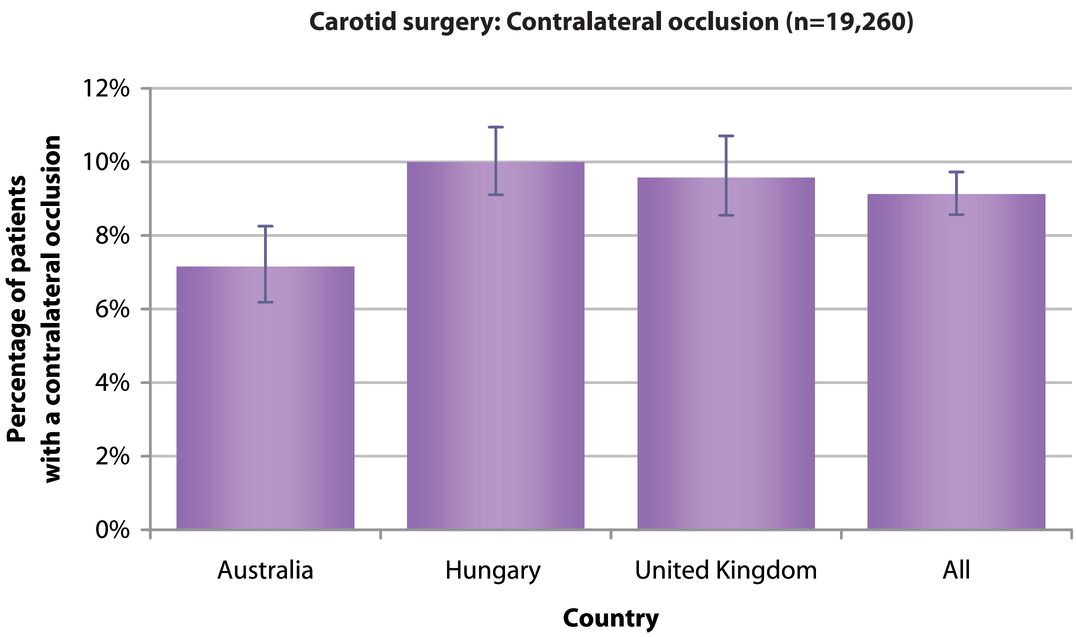
Most patients undergoing carotid reconstruction were symptomatic and only 26% were asymptomatic in the combined data. The percentage of asymptomatic patients varied from 0% in Denmark to 40% in Switzerland and Hungary. The apparent absence of amaurosis fugax in Switzerland is explained by the fact that it was included within the TIA group in the Swiss registry. Italy was not included in this graph as its registry only recorded patients as symptomatic or asymptomatic. Around 66% of the Italian patients were asymptomatic.





Contralateral occlusion

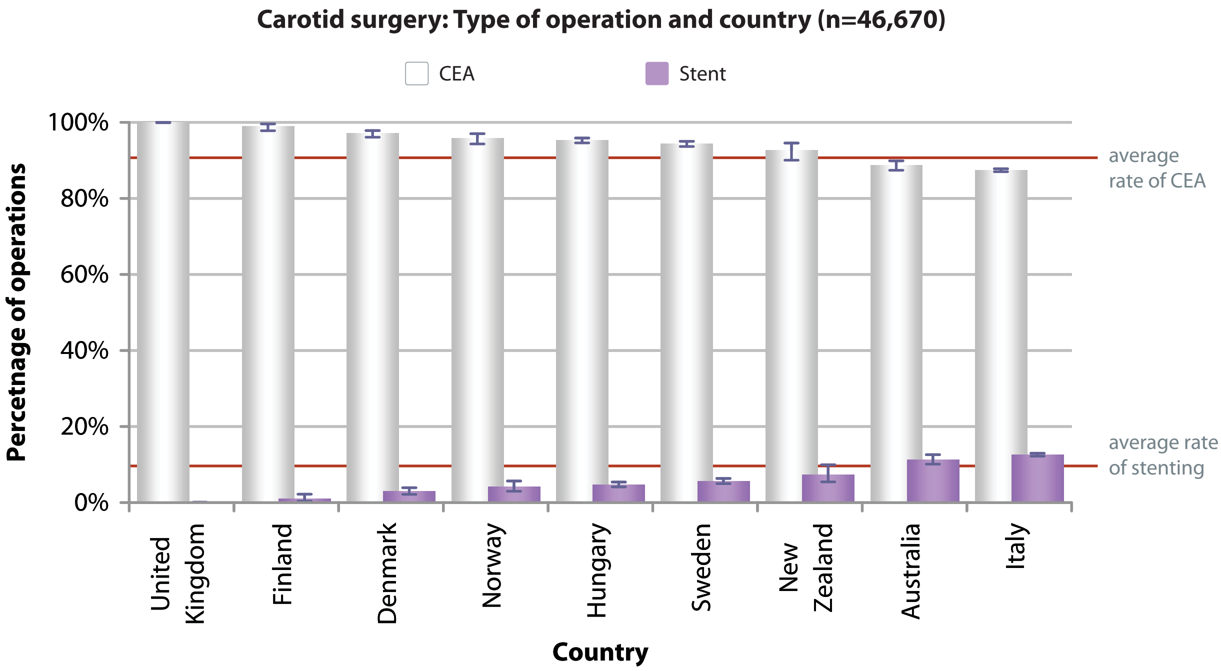
The three countries recorded contralateral occlusion. The average percentage was 9%.



Operation

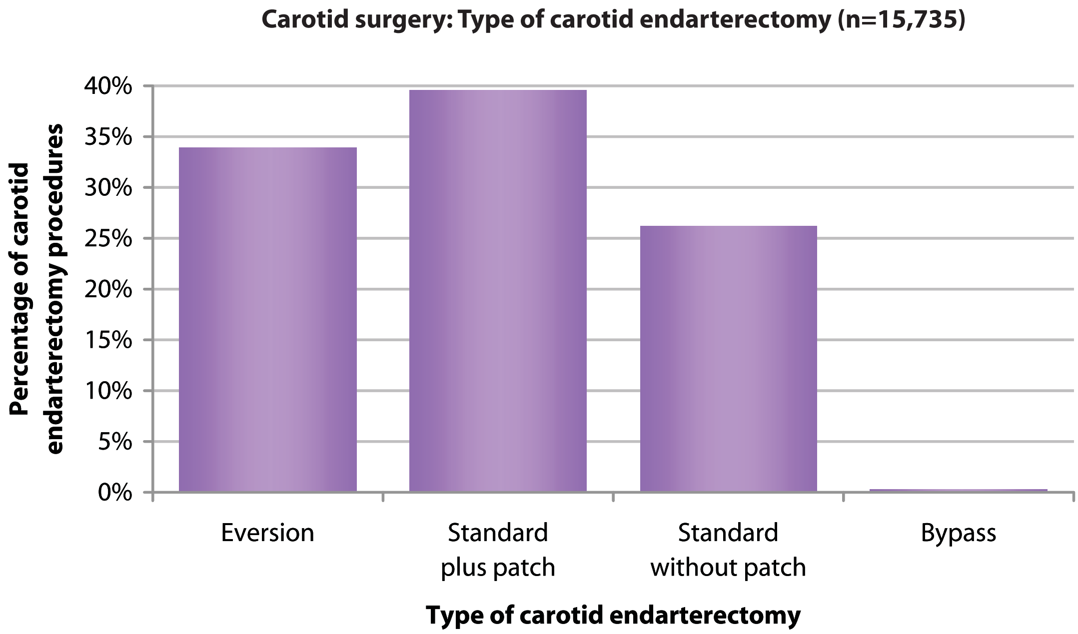
Type of operation

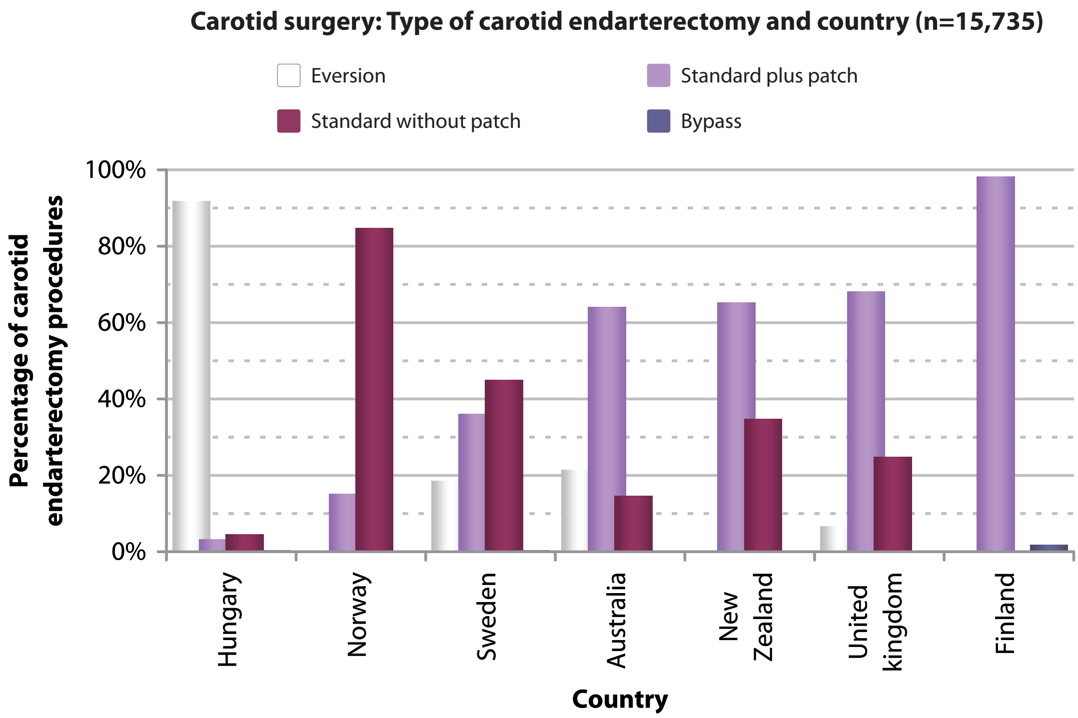
Overall 10% of patients underwent carotid stenting and 90% carotid endarterectomy. Stents were not recorded in the United Kingdom registry, but in the remaining nine countries the percentage of stents varied from 1% in Finland to 12% in Australia and Italy.



Type of carotid endarterectomy

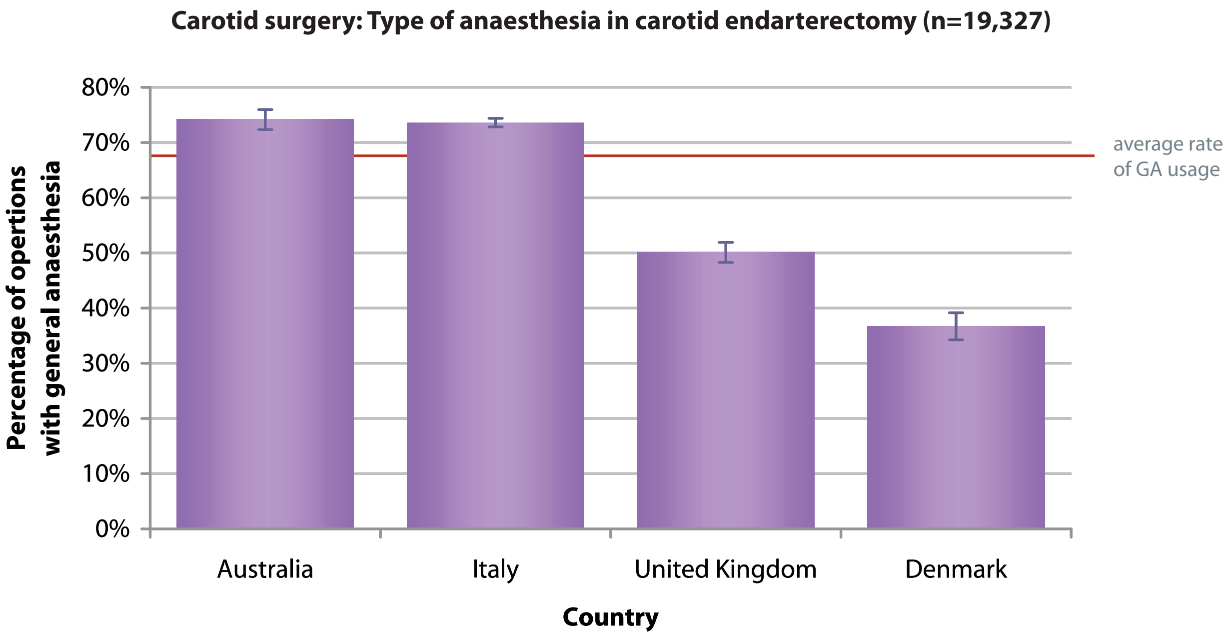
The method of carotid endarterectomy was not included in the Danish, Italian or Swiss data files in a format suitable for import. Of the patients in other registries 34% underwent eversion endarterectomy, 40% standard endarterectomy with a patch and 26% without a patch. The method used differed greatly between countries: in Hungary 90% underwent eversion endarterectomy, whereas Finland, New Zealand and Norway did not use the eversion technique at all. Patches were rarely used in Norway, but were always used in Finland.





Anaesthesia for carotid endarterectomy

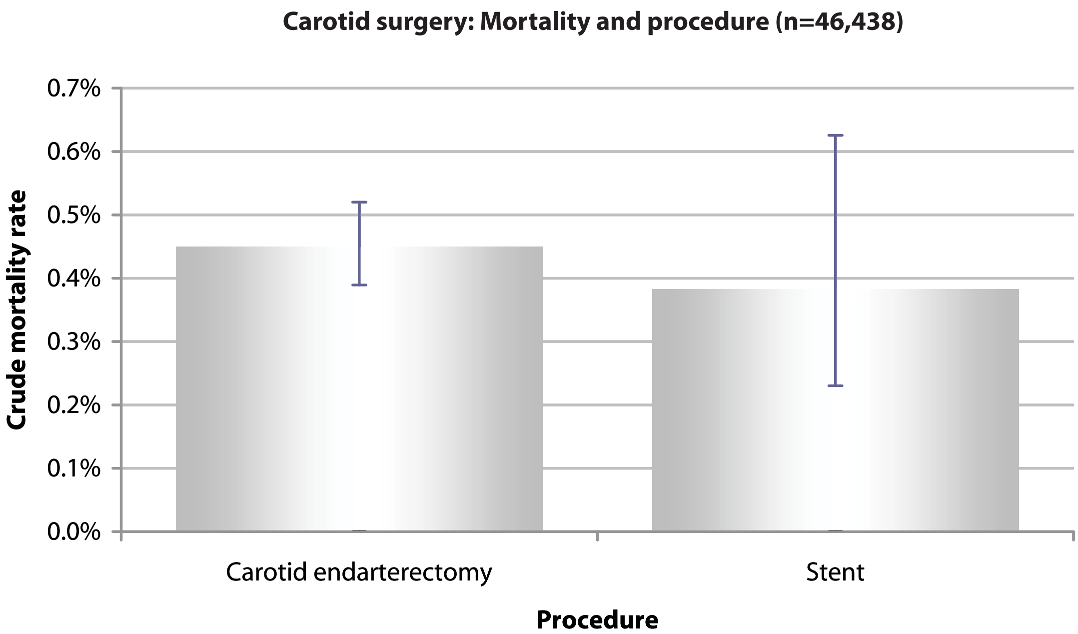
In the four countries recording the type of anaesthesia, general anaesthesia was used in 68% of patients. Local anaesthesia was preferred in Denmark whereas general anaesthesia was preferred in Australia and Italy.



Mortality

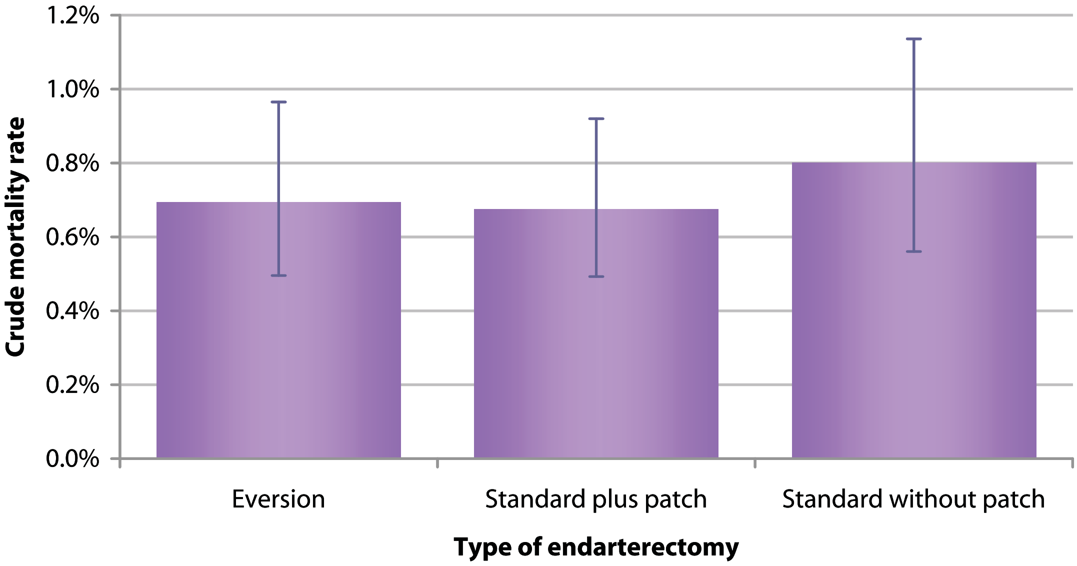
Mortality and procedure

The overall mortality of carotid endarterectomy was 0.45% compared with 0.38% for carotid stents, but this difference was not statistically significant (p=0.60).

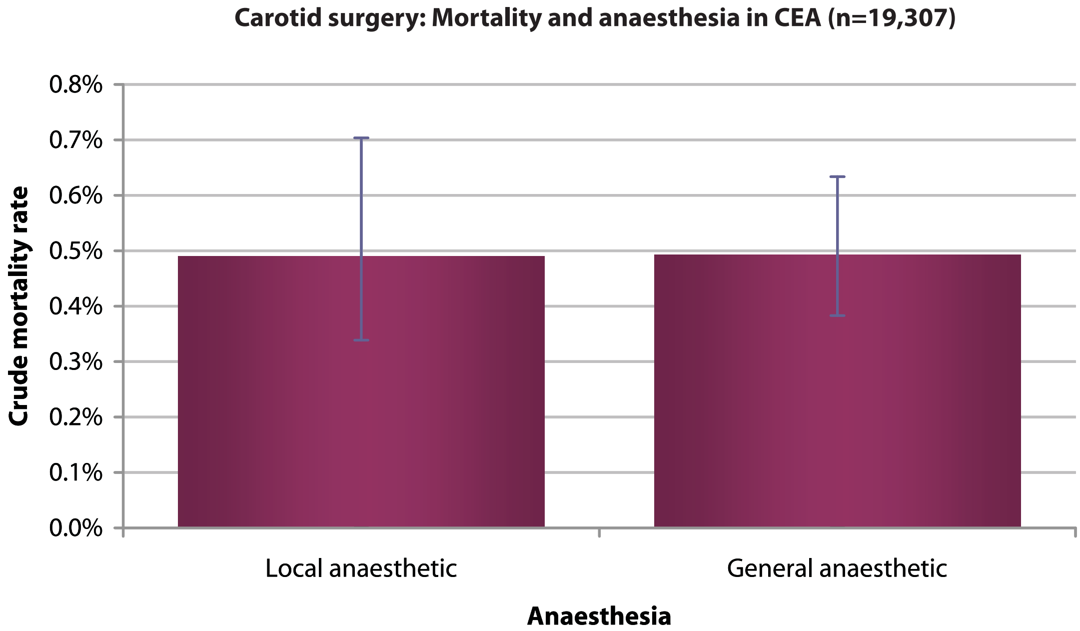


The method of carotid endarterectomy had no effect on mortality.

Carotid surgery: Mortality and type of carotid endarterectomy (n=15,684)



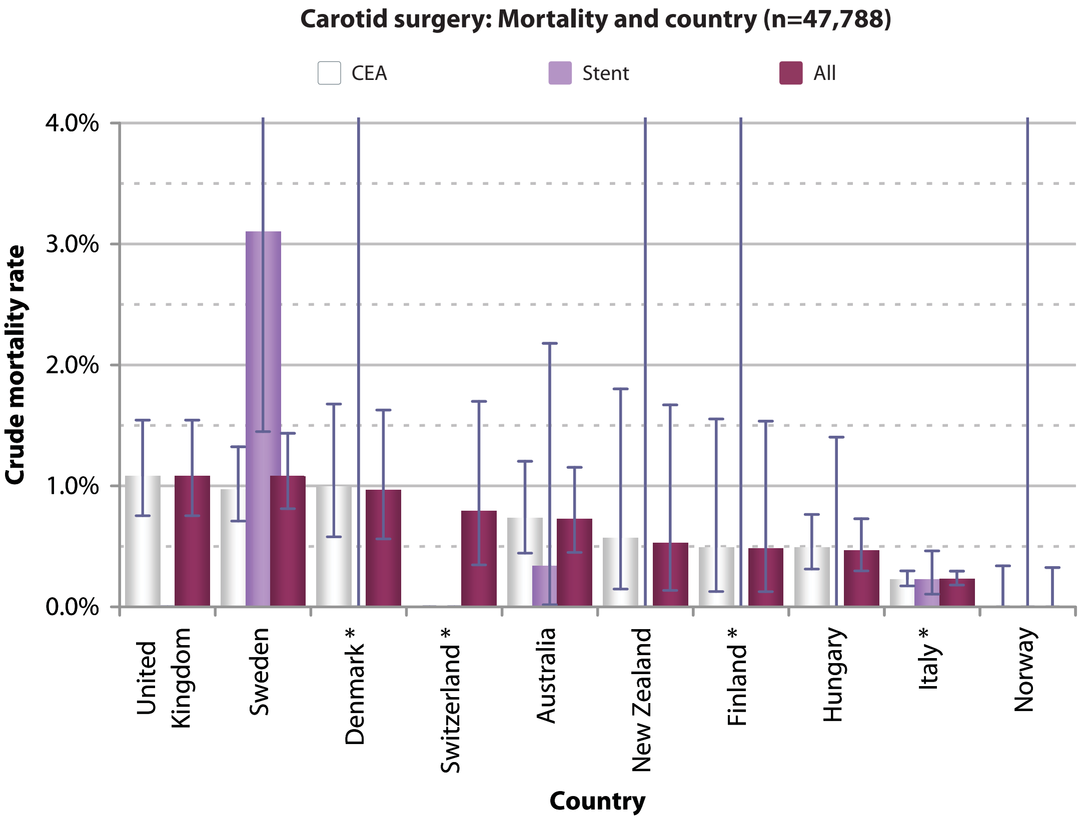
Mortality was almost identical for general and local anaesthesia.



Mortality and country

National mortality varied from 0.2% in Italy to approximately 1% in UK, Sweden and Denmark. In Sweden there appeared to be an excess mortality for carotid stents at 3.1%, but confidence limits were wide and mortality for stents and carotid endarterectomy were equivalent in all other countries.

		Mortality			
		Alive	Died	Unspecified	All
Country	Australia	2,600	19	1	**2,620**
	Denmark	1,538	15	17	**1,570**
	Finland	615	3	0	**618**
	Hungary	4,463	21	0	**4,484**
	Italy	28,496	66	218	**28,780**
	Norway	920	0	0	**920**
	New Zealand	565	3	0	**568**
	Sweden	4,573	50	0	**4,623**
	Switzerland	878	7	0	**885**
	United Kingdom	2,924	32	0	**2,956**



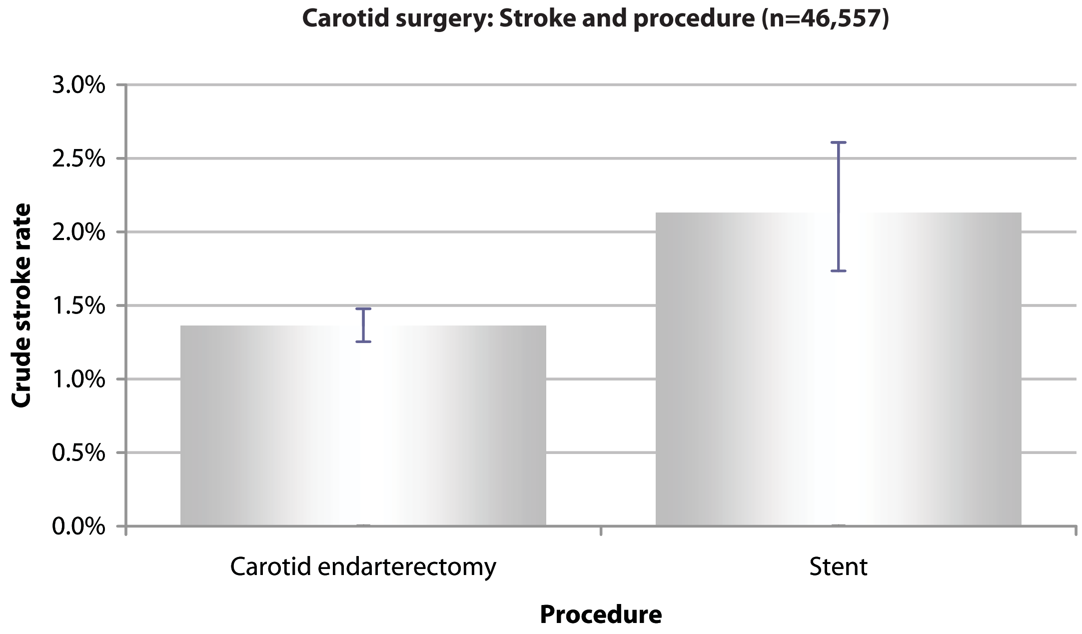
Countries with an asterisk suffix report 30-day mortality, others report in-hospital mortality

Stroke

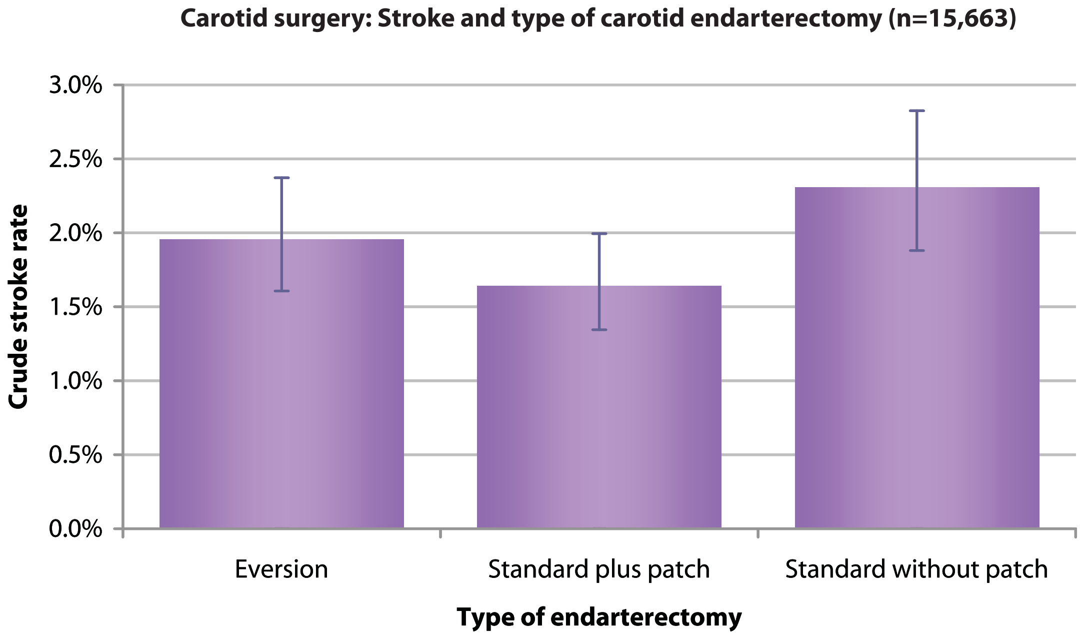
Stroke and procedure

Several countries recorded stroke as major or minor, disabling or non-disabling. The data definitions of the subdivisions of stroke varied considerably, so for the purpose of this report peri-operative strokes were considered as a single category.

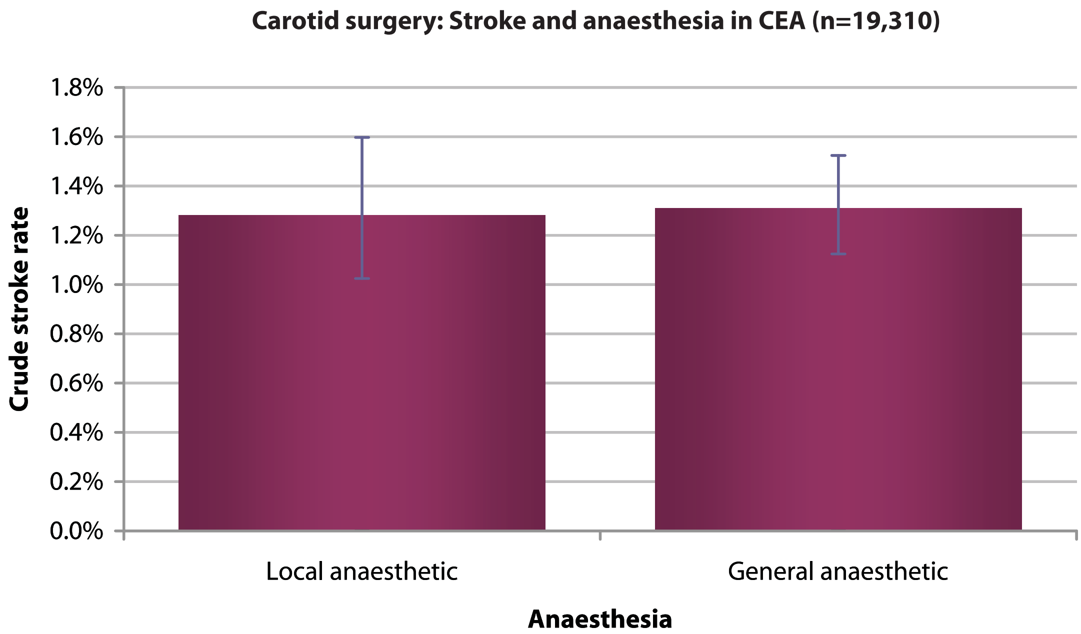
There were significantly more strokes after carotid stenting than endarterectomy (2.1% *versus* 1.3%; Chi-squared 6.3, $p<0.0001$). This is of particular interest in view of the current controversy regarding the safety of carotid stenting.



We were unable to demonstrate a significant difference in stroke rate between the three methods of carotid endarterectomy.



Stroke rates were almost identical between patients undergoing carotid endarterectomy under general and local anaesthesia.

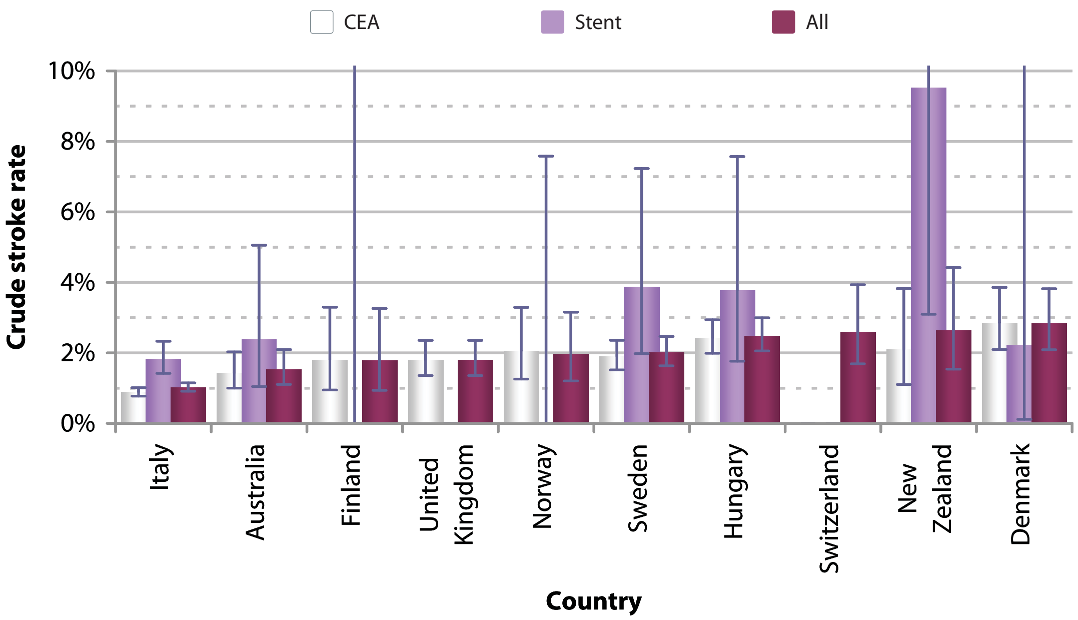


Stroke and country

Overall stroke rates for carotid reconstruction (including both endarterectomy and stents) were least in Italy (1%) but 5 / 10 countries had stroke rates of 2-3%. The stroke rate of carotid endarterectomy ranged from 0.9% in Italy to 1.8% in Denmark, whereas that of carotid stenting ranged from 1.8-9.4% with the highest recorded in New Zealand.

		Stroke			
		No	Yes	Unspecified	All
Country	Australia	2,580	40	0	**2,620**
	Denmark	1,508	44	18	**1,570**
	Finland	607	11	0	**618**
	Hungary	4,357	111	16	**4,484**
	Italy	28,411	294	75	**28,780**
	Norway	896	18	6	**920**
	New Zealand	553	15	0	**568**
	Sweden	4,530	93	0	**4,623**
	Switzerland	862	23	0	**885**
	United Kingdom	2,903	53	0	**2,956**

Carotid surgery: Stroke and country (n=47,909)

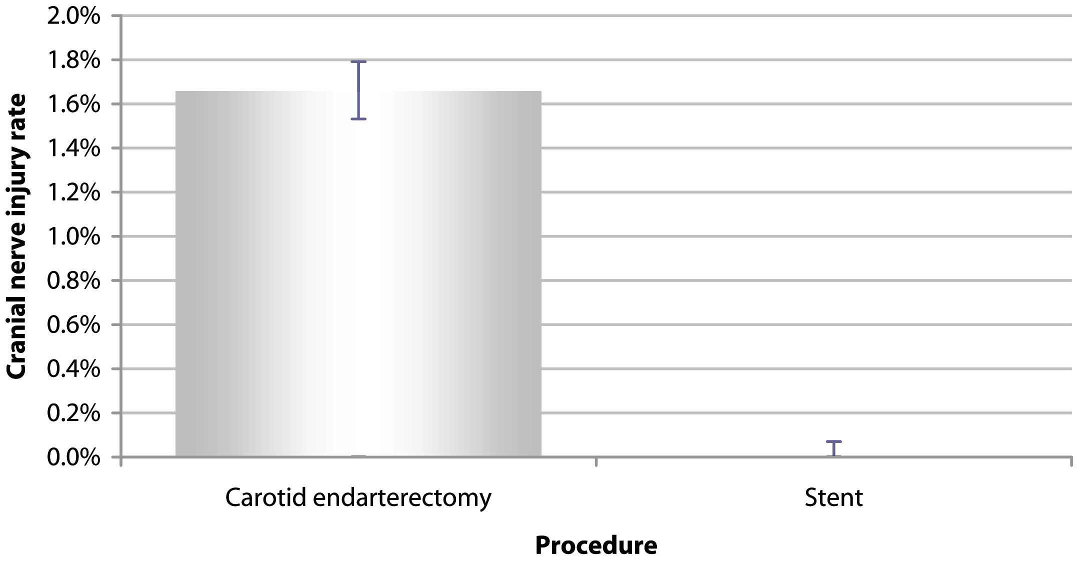


Cranial nerve injury

Cranial nerve injury and procedure

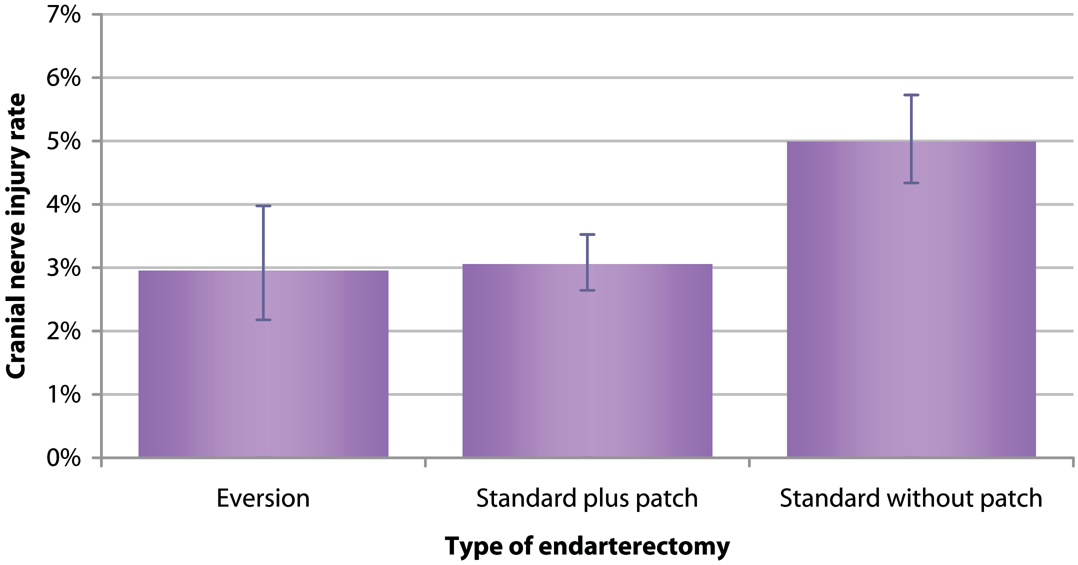
Cranial nerve injury was recorded in 1.6% of carotid endarterectomies. This is a surprisingly low percentage as most previously published studies have reported an incidence of cranial nerve lesions of about 6% (see ref. 16, page 93). It is likely that they have been under-reported in many cases either because they have gone unrecognised or because, as with most cranial nerve lesions, they were temporary.

Carotid surgery: Cranial nerve injury and procedure (n=42,095)

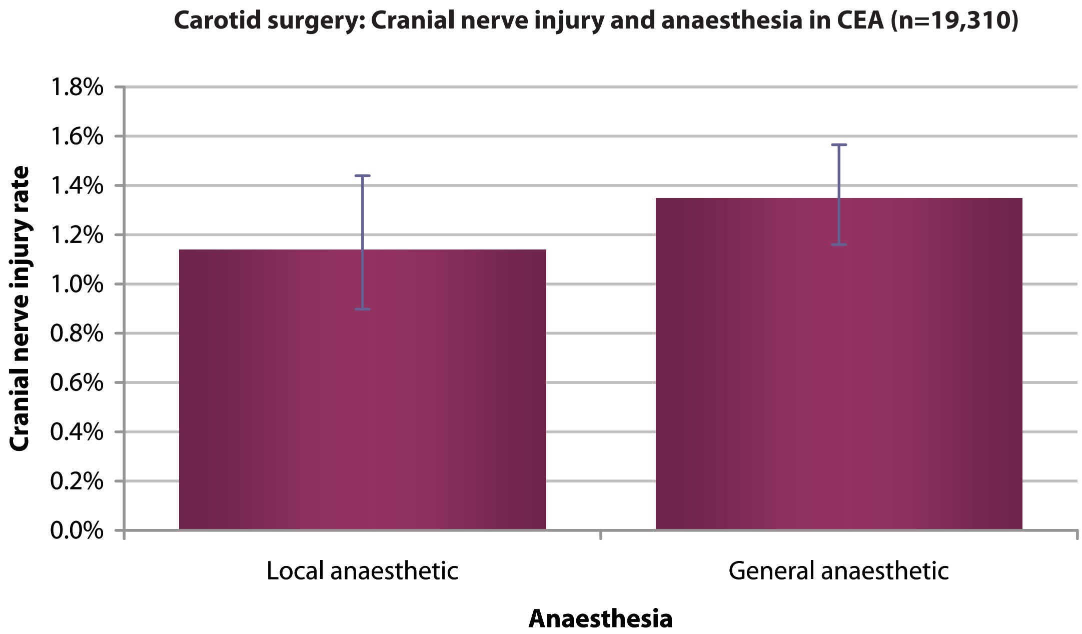


Of those patients in which the type of endarterectomy was recorded cranial nerve injuries were recorded in 3% of eversion procedures and 3% standard with a patch. For reasons that are not clear, a greater number of cranial nerve injuries (5%) were found after those treated by a standard endarterectomy without a patch.

Carotid surgery: Cranial nerve injury and type of carotid endarterectomy (n=11,512)

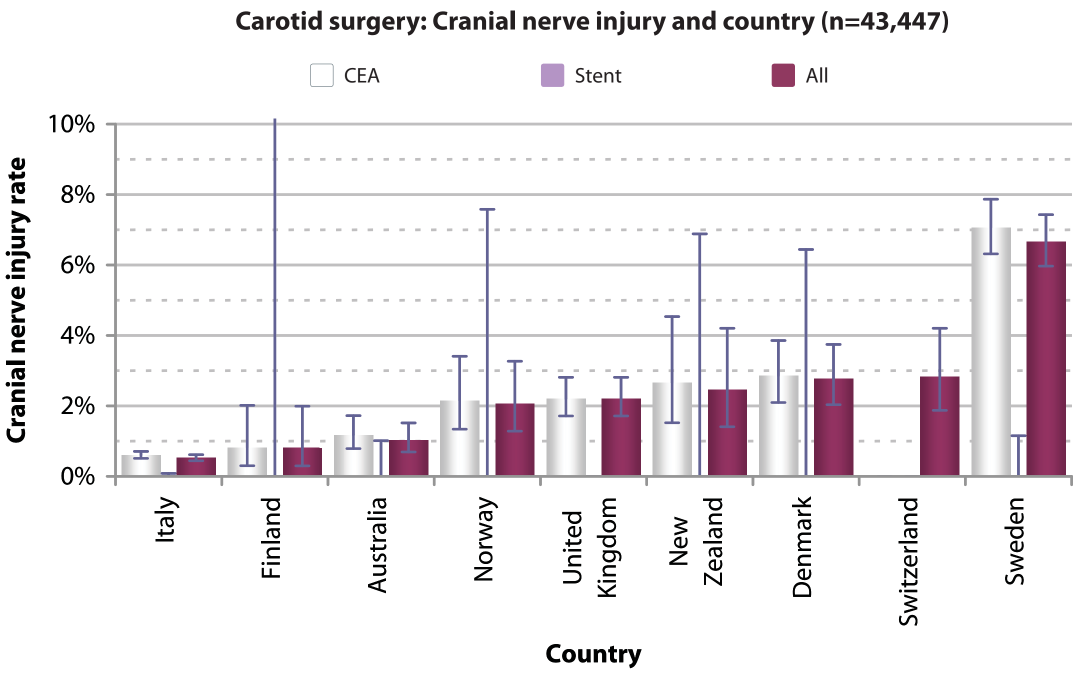


The incidence of post-operative cranial nerve lesions was unaffected by the type of anaesthesia.



Cranial nerve injury and country

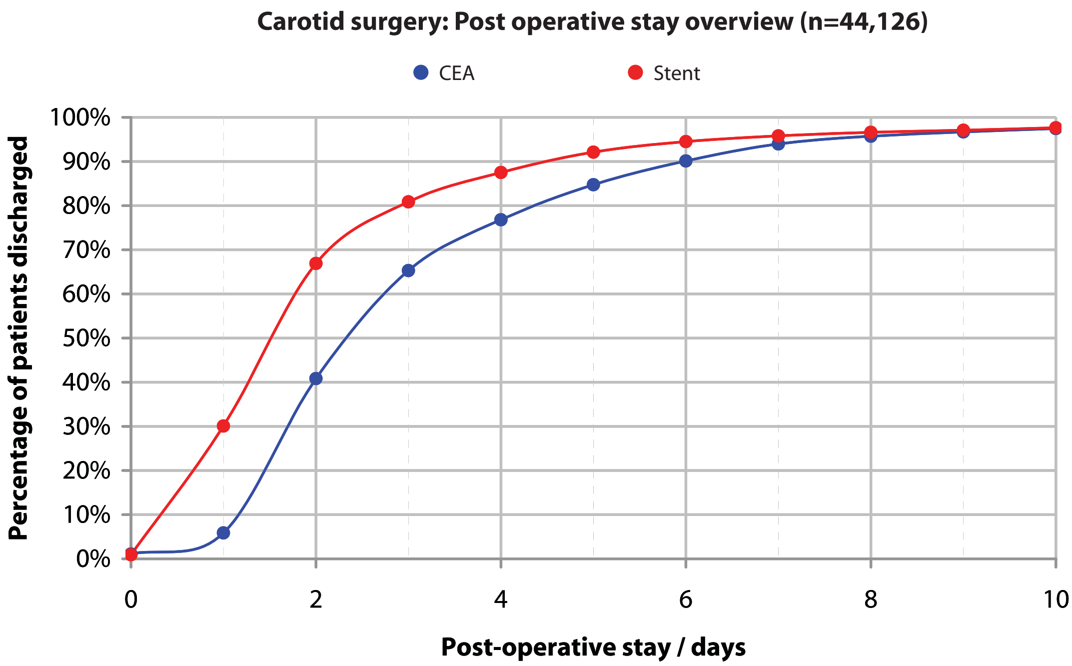
The highest rate of cranial nerve injury was reported in Sweden at 7%. However, this is more in keeping with published reports (see ref. 16, page 93) and since most patients in the Swedish registry were examined post-operatively by a neurologist this could represent a true reflection of the incidence of cranial nerve lesions in other countries.



Post-operative stay

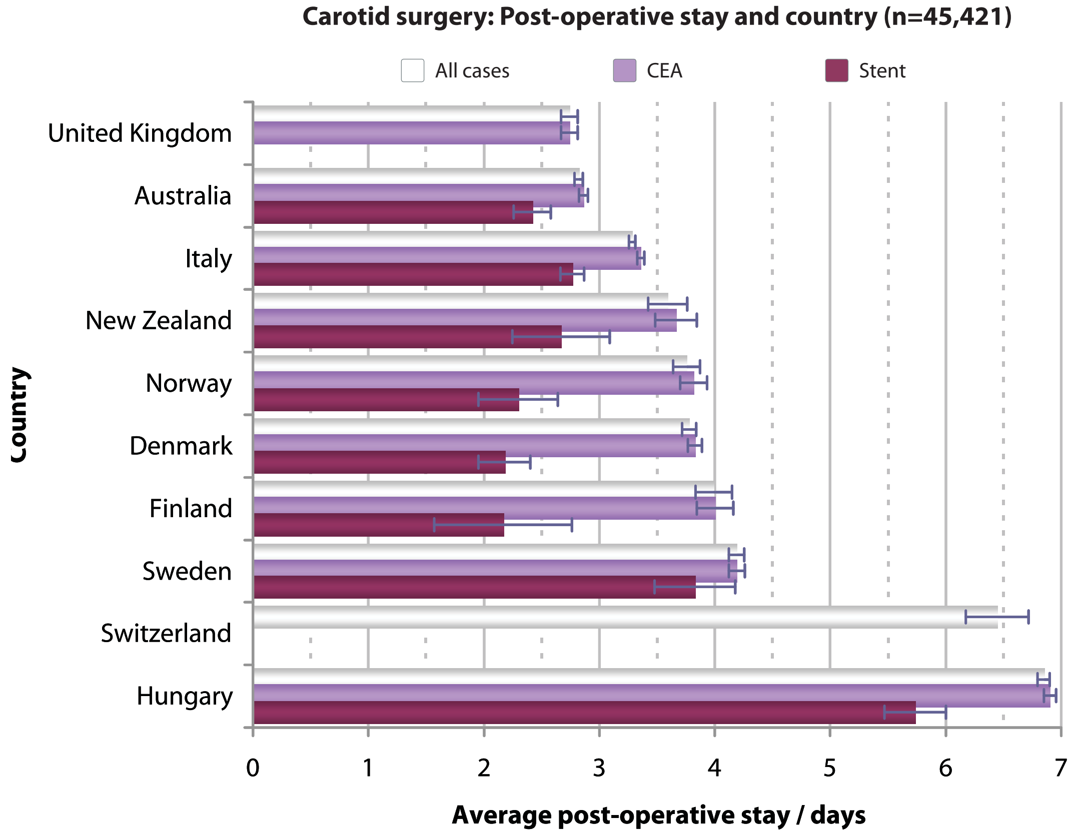
Post-operative stay and procedure

The post-operative length-of-stay was significantly less for carotid stents than endarterectomy (average of 2.9 days *versus* 3.7 days).



Post-operative stay and country

Post-operative length-of-stay was considerably greater in Hungary and Switzerland than the other registries.



Summary and conclusions

In this second VASCUNET database report data from 55,250 aortic aneurysm repairs and 48,025 carotid reconstructions were submitted from 8 national (Denmark, Hungary, Italy, Sweden, Switzerland, Norway, United Kingdom) and 2 large regional (Australia and Finland) databases. Data analysis was restricted to patients receiving treatment within the last 5 years (2003-2007 inclusive) so that 36,041 and 48,025 patients, respectively, were analysed in the aortic and carotid groups. There was a good correlation between the data fields collected by each registry although data definitions varied slightly from country to country.

For the first time national outcome data were compared. Whereas some countries recorded 30-day mortality (Denmark, Finland, Italy, Sweden, Switzerland) others recorded in hospital mortality (Australia, Hungary, New Zealand, Norway, United Kingdom). However any difference between these parameters is likely to be small.

Some form of data validation was performed by eight registries, but not by Norway and the United Kingdom.

Aortic aneurysm repair

Of the 36,041 records analysed 35% were submitted by Italy. 13.5% of patients were women, although the percentage of women was greater in ruptured than elective aneurysms. As expected, the average age of the men was less than that of women with aortic aneurysms (71.8 years *versus* 73.9 years). The percentage of women undergoing aortic aneurysm repair varied to a surprising degree between countries from 8% in Italy to 21% in New Zealand. This surprising difference merits further investigation. The mean age of patients undergoing AAA surgery varied from country to country with Hungary having the youngest (67.4 years) and Australia the oldest patients (73.7 years).

Patients with ruptured aneurysms had apparently lower incidences of hypertension, respiratory and cardiac disease, but a higher incidence of significant renal disease than those undergoing elective repair. Renal disease seemed to be more prevalent in some of the northern European countries (Sweden, United Kingdom and Denmark), although this observation may partly be explained by differences in definition. International collaboration may result in more uniform definitions in the future, facilitating analyses. There were slightly fewer smokers amongst the patients with ruptured than intact aneurysms. Italy had the highest proportion of smokers as well as cardiac disease and pulmonary disease.

Most registries included both open and endovascular repairs but EVAR was not recorded in Finland and only partially captured in the United Kingdom. The overall mortality for elective surgery was 3% and was significantly less for EVAR than open repair (1% *versus* 4%). This confirms the results of the EVAR 1 trial [1]. The mortality of ruptured aneurysm was 34% and was significantly less for EVAR than open repair (15% *versus* 33%).

The mortality of both intact and ruptured aneurysm repair was significantly increased by advancing age, cardiac, respiratory and renal disease but not apparently by smoking or the use of a bifurcated graft. The data on smokers may not be reliable as definitions varied somewhat between countries, resulting in considerably heterogeneous groups.

The mortality of intact open aneurysm repair was significantly greater in the United Kingdom than other countries at 7.9%. The other 9 countries had mortality rates ranging from 1.9% in Italy to 4.5% in Denmark (average for all 10 registries 3.5%). The cause for this apparently high mortality in the United Kingdom National Vascular Database is unclear, particularly since the mortality of EVAR and ruptured aneurysms in the UK was similar to that of the other registries. In the United Kingdom there was an excess of` renal disease, but otherwise risk factors appeared similar to those of other countries and it seems unlikely that renal disease could be solely responsible for the excess elective mortality. Whilst there are undoubted limitations to merging data from different registries, the observed mortality of unruptured aortic aneurysm repair in the United Kingdom is corroborated by other studies [2,3,4] and it is also of note that the mortality in the United Kingdom Small Aneurysm Trial [5] was substantially greater than that of a similar trial in the USA [6]. This discrepancy deserves further study.

The mean post-operative length of stay was greater for intact than ruptured aneurysms and strikingly reduced for EVAR in comparison with open repair.

The United Kingdom had significantly longer hospital stays than other countries for both intact and ruptured aneurysms. For elective aneurysm repair the average length of stay was 13 days for the United Kingdom in comparison with 7.5 days for Italy.

Carotid reconstruction

Of the 48,025 carotid reconstructions analysed 60% were submitted from Italy. This would suggest that the incidence of carotid reconstruction is higher in Italy than in the other countries.

The mean age for carotid reconstruction was 70.8 years and was slightly greater for men (70.6 years) than women (71.2 years). The mean age for reconstruction ranged from 66.3 years in Hungary to 72.5 years in Australia. 32% were women with the greatest proportion in Hungary (37%) and the least in Switzerland (28%).

The indication for carotid reconstruction was not recorded in Italy. Of the other nine registries, 26% of patients were asymptomatic, 32 % had a history of TIA, 15% amaurosis fugax and 26% prior stroke. Asymptomatic patients were most common in Hungary and Switzerland (40%) rare in Denmark and Finland (0% and 10% respectively).

Amongst the three countries that recorded the state of the contralateral carotid artery 9% were occluded.

Carotid stents were not recorded in the United Kingdom national database but comprised 10% of all cases with 12% stents in Italy and 11% in Australia.

The method of carotid endarterectomy was recorded by 7 countries (15,735 patients): eversion endarterectomy was used in 34%, standard endarterectomy with patch 39% and without patch 26%. The surgical method was country dependent: eversion endarterectomy was used in over 90% in Hungary but not used at all in Finland and Norway. Patches were preferred in Australia, New Zealand, United Kingdom and Finland but not in Sweden and Norway. Four countries recorded the type of anaesthesia: general anaesthesia was used in about 73% of cases in Australia and Italy, 50% in United Kingdom and 36% in Denmark. Such national differences in technique may also reflect changes in opinion with time and it will be of interest to find out whether they persist in future audits.

The mortality of carotid endarterectomy was 0.45% and was unaffected by the endarterectomy method or type of anaesthesia. The mortality of carotid stenting was not significantly different from carotid endarterectomy (0.39%). Mortality ranged from about 1% in the United Kingdom, Sweden and Denmark to less than 0.5% in Finland, Hungary, Italy and Norway.

The peri-operative stroke rate was 1.4% for carotid endarterectomy in comparison with 2.1% for carotid stenting. This difference was statistically significant ($p<0.0001$). This result is of particular interest in view of the controversy regarding the morbidity of carotid stenting and the differing results of the various randomised trials comparing carotid endarterectomy and stenting [7, 8, 9, 10, 11, 12, 13, 14, 15]. The incidence of perioperative stroke following carotid endarterectomy was unaffected by the method used or the type of anaesthesia.

National stroke rates for carotid endarterectomy ranged from 0.9% for Italy to 2.8% for Denmark.

Cranial nerve injury was recorded in 1.6% of carotid endarterectomy. This was unaffected by the type of anaesthesia but appeared to be greater for the standard approach without a patch than eversion or patched standard endarterectomy. There is no apparent reason for this, which may be due to confounding factors. Cranial nerve injury seemed to be much greater in Sweden (7%) than other countries (range 0.6-2.8%). However, this figure is perhaps more in line with published reports [16] and the apparent discrepancy could be due to differences of definition, particularly as the majority of cranial nerve injuries are temporary, or thoroughness of follow-up. In Sweden all peripheral nerve injuries are registered, including the common cutaneous nerve injuries. Furthermore, in most Swedish centres patients are examined at 30 days by neurologists who are likely to identify more cranial nerve injuries than surgeons.

The mean post-operative length of stay was greater for carotid endarterectomy (3.7 days) than stenting (2.9 days) and was substantially longer in Hungary and Switzerland than in other countries

Conclusions

The second VASCUNET database report has combined the data from the registries of ten countries to form the largest vascular registry to date.

It has confirmed the results of randomised trials showing the reduction in mortality of aortic aneurysm repair by using endovascular methods and confirmed that advancing age, cardiovascular, renal and respiratory disease are all important risk factors for surgical mortality. The mortality of elective open aortic aneurysm repair was found to be greater in the United Kingdom than all other countries but the reasons for this observation remain unclear.

For carotid surgery there was no difference in mortality between endarterectomy and stenting, but stenting seemed to be associated with a slightly higher stroke rate. Neither the endarterectomy method nor the type of anaesthesia appeared to influence morbidity or mortality to a significant degree. In view of the latter, the results of the GALA trial will be of great interest when they become known.

Many of these results are thought-provoking, and merit further focused research efforts. Whilst the VASCUNET database is still in the development phase, it has shown the usefulness of international audit and it is hoped that this will expand both geographically and in the scope of the audit in years to come.

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ESVS

Database form

The European Society for Vascular Surgery database forms

The following pages represent the full AAA surgery and carotid surgery datasets sent out to the contributors when the request for data was first made in January 2008.

This incarnation of the VASCUNET project represents a significant step forward, since the scope of the project was widened to include carotid surgery data as well as the AAA surgery data that formed the basis for the first report released in July 2007.

Contributors will be sent copies of the datasets, with any revisions, as part of the next request for data, together with a full set of data definitions and a data-file specification to further smooth to the processes of importing and merging the data so that more time may be spent on the analysis phase of the next report.

Changes to the AAA surgery dataset

After reviewing the completeness of data submitted for the first VASCUNET report, it seemed logical to adjust the AAA surgery dataset. The principal aim was to reduce the complexity of the dataset even further in an attempt to further encourage participation and to accommodate some of the differences in the scope and breadth of data held in the national databases sending their data for inclusion in the merged database. Questions were either removed completely from the dataset or adjusted to remove some complexity:

- The diabetes risk factor was removed; this was probably a mistake as this is an important risk factor that many national registries include in their own datasets, and will probably be reinstated for the next version of the dataset
- The question on beta blockers was removed; very few countries held these data in their national registries
- Likewise, the question on statins was removed as very few contributors were able to submit these data
- Maximum aneurysm diameter was also removed from the dataset, again because data on this parameter were rare in the submitted data files
- The type of operation question was simplified in that the two options relating to EVAR procedures previously requested (EVAR bifurcated modular and EVAR aorto uni-iliac) were merged into a single option labelled EVAR
- The question detailing conversions from the EVAR technique to the open approach was removed
- Most of the questions in the outcome section were removed (myocardial infarction, stroke, graft infection, graft occlusion, other re-operation, major amputation) leaving the patient's post-operative status as the sole outcome in the database

The new carotid surgery dataset

The new carotid surgery dataset will undoubtedly undergo the same processes of review and modification following careful consideration of the analyses presented in this report. For example, very few countries were able to supply data on whether or not the patient had had a contra-lateral occlusion; this question might be a candidate for excision from the next version of the carotid surgery dataset.

It is clear, however, that it is important to have at least one measure of outcome other than mortality, and the next evolution of the dataset might focus around making these outcome measures more robust and compatible with the datasets currently collected in the contributor countries.

AAA surgery dataset

European Society for Vascular Surgery
AAA database form
Version 2.0

ESVS

Demographics and other identifiers

Hospital number			
Date of birth	dd / mm / yyyy		
Gender	○ Male	○ Female	○ Unknown
Country			
Hospital			

Pre-operative risk factors

Cardiac disease	○ No	○ Yes
Respiratory disease	○ No	○ Yes
Renal failure	○ No	○ Yes
Diabetes	○ No	○ Yes
Hypertension	○ No	○ Yes
Smoking	○ No	○ Yes

Operative data

Date of operation	dd / mm / yyyy	
Operative urgency	○ Elective	○ Emergency
Aortic findings	○ Ruptured	○ Intact
Type of operation	○ Open tube ○ Open aorto-iliac	○ Open aorto-femoral ○ EVAR

Outcomes at 30 days

Reoperation	○ No	○ Yes
Date of discharge	dd / mm / yyyy	
In-hospital mortality	○ Alive	○ Dead
Patient status at 30 days	○ Alive	○ Dead

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Carotid surgery dataset

European Society for Vascular Surgery

Carotid surgery database form

Page 1; Version 2.0

Demographics and other identifiers

Hospital number	
Date of birth	dd / mm / yyyy
Gender	○ Male ○ Female ○ Unknown
Country	
Hospital	

Disease status

Symptoms	○ Asymptomatic ○ Amaurosis ○ TIA ○ Other
Stenosis	%
Contralateral occlusion	○ No ○ Yes

Pre-operative risk factors

Cardiac disease	○ No ○ Yes
Respiratory disease	○ No ○ Yes
Renal failure	○ No ○ Yes
Hypertension	○ No ○ Yes
Smoking	○ No ○ Yes

Operative data

Date of operation	dd / mm / yyyy
Previous ipsilateral carotid intervention	○ No ○ Yes
Previous contralateral carotid intervention	○ No ○ Yes
Operative urgency	○ Elective ○ Emergency
Procedure	○ Carotid endarterectomy ○ Carotid stent

Additional data for carotid endarterectomies

Type of carotid endarterectomy	○ Eversion ○ Standard without patch ○ Standard plus patch ○ Bypass
Anaesthesia	○ General ○ Local (including regional)
Shunt	○ No ○ Yes

DENDRITE CLINICAL SYSTEMS

DENDRITE CLINICAL SYSTEMS

European Society for Vascular Surgery
Carotid surgery database form
Page 2; Version 1.0

ESVS

Hospital number	
Date of operation	dd / mm / yyyy

Outcomes

Reoperation	○ No	○ Yes
Date of discharge	dd / mm / yyyy	
Stroke	○ None ○ TIA	○ Major stroke ○ Minor stroke
Cranial nerve injury	○ No	○ Yes
In-hospital mortality	○ Alive	○ Dead
Patient status at 30 days	○ Alive	○ Dead

DENDRITE CLINICAL SYSTEMS

ESVS

Submission of data

Submission of data to the ESVS database

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Scope of this appendix

This appendix outlines the basic requirements for data submission from hospitals/national registries for successful import into the VASCUNET European Vascular Surgery Database. It covers:

1. Minimum requirements for file-formats
2. Minimum requirements for each row of data
3. Minimum requirements for supporting documentation

File formats

Individual anonymised patient records are required, not aggregate data analyses.

In many cases the data must be viewed and manipulated in third-party software prior to import. This allows for detailed examination of the data so that the final import database is the best fit to the database structure of the central registry. It also allows some pre-import manipulation of the data to create the cleanest final import possible. The data also have to be transmuted into a file-format that is suitable for import a tab-delimited text file.

The most common acceptable source data formats; include:

- Microsoft Access™
- Microsoft Excel™
- Tab-delimited text files

However, any file that can be demonstrated to be compatible with standard Microsoft packages would also be acceptable. Comma-delimited files are not generally acceptable as the comma is used to sub-delimit fields where more than one response option may be selected. Comma-delimited files may be accepted as long as there are no multiple-response fields with comma delimiters or sub-delimiters other than commas.

Where there is more than one table of source data to be imported, it is essential that the tables of data required in the final import product are identified and that the inter-relationships between these tables are recorded explicitly, including the indices that are used to link the tables. This requirement applies most frequently to Access™ databases, but also applies to other file formats where data from multiple files are to be migrated into the VASCUNET central registry database.

Minimum requirements for each row of data

The minimum requirements for data submitted to the VASCUNET database are:

- The first row in each data file or table must contain headers
- Each row of data in each file / table must include an unique patient identifier [i]
- Each row of data in each file must include a key-date as an index (admission, operation, *etc*. For the VASCUNET database the key-date is the date-of-operation) [ii]
- Numbers containing decimals should be presented with a decimal point (.) signifying the decimal position and without comma thousand separators *e.g.*, 10000.245
- Dates should be presented in long date format, dd/mm/yyyy
- Where a data item may contain multiple responses each of those responses must be separated by a comma only
- It is important that soft carriage-returns are removed from the data before delivery to the VASCUNET database. These control characters cause configuration problems when the data are transferred into the file format that acts as the substrate for the import process as the carriage return is reserved as a row (record) delimiter

Requirements for supporting documentation

A full data dictionary is required, particularly where abbreviations or encoding systems have been used. This dictionary should include supporting information on the relationship between the individual data-items and patient's progress *i.e.*, are the data pre-operative, post-operative *etc*.

Where data are maintained in a language other than UK English, a full translation of all the headers and data items must also be provided. It is important to have full explanations for all headers:

- The meaning of the header
- The type of data [iii]

Where data-items are coded (0, 1; Y, N; *etc.*) a comprehensive set of data definitions should be supplied with, and at the same time as, the data to be imported [iv].

i. If the data file lacks unique identifiers such as a Hospital number or a Department number, then there must be sufficient patient-specific data to generate an unique identifier. An indication of the nature of the unique identifier is very important *i.e.*, is the identifier an hospital number, a national number or a database row ID. The minimum data fields would be the patient's surname, forename, date-of-birth and gender. In such cases, if an examination of the data demonstrates that there are a number of duplications then this methodology and the whole data submission will be rejected. The unique patient identifier may be absent in individual data-files from a multiple file suite as long as there is a database key that allows the patient-records to be linked back to an unique identifier in one of the data-files.

ii. Any row of data that lacks a key date will not appear in the final import. Null values in this field will be treated as missing and, as such, removed at the time of import.

iii. Type of data should include the clinical sense of the data (pre-operative, operative, post-operative, *etc.*), the scope of the data (mutually exclusive data, multiple choice data, date data, free text *etc.*).

iv. Any data point that contains data options not included in the accompanying data definition documentation will be treated as an error and, as such, removed at the time of import.

Proposed site for advert

Advert IVR ESVS.pdf

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