



MAARIT HEIKKINEN

The Vascular Surgical Service

Review of the 1990s
and Future Prospects



ACADEMIC DISSERTATION

To be presented, with the permission of
the Faculty of Medicine of the University of Tampere,
for public discussion in the small auditorium of Building K,
Medical School of the University of Tampere,
Teiskontie 35, Tampere, on February 7th, 2003, at 12 o'clock.

Acta Universitatis Tampensis 909
University of Tampere
Tampere 2003

ACADEMIC DISSERTATION

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<http://granum.uta.fi>

Cover design by
Juha Siro

Printed dissertation
Acta Universitatis Tamperensis 909
ISBN 951-44-5565-7
ISSN 1455-1616

Electronic dissertation
Acta Electronica Universitatis Tamperensis 229
ISBN 951-44-5566-5
ISSN 1456-954X
<http://acta.uta.fi>

Tampereen yliopistopaino Oy Juvenes Print
Tampere 2003

To Mika, Jarna and Leevi

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by their Roman numerals:

I Heikkinen M, Salenius J, Auvinen O. Trends of vascular service in a well defined geographical area in 1990s. *Annales Chirurgiae et Gynaecologiae* 2000; 89: 285-291

II Heikkinen M, Salenius J, Auvinen O. Projected workload for a vascular service in 2020. *European Journal of Vascular and Endovascular Surgery* 2000;19: 351-355

III Heikkinen M, Salenius J, Auvinen O. Ruptured abdominal aortic aneurysm in a well-defined geographical area. *Journal of Vascular Surgery* 2002; 36: 291-296

IV Heikkinen M, Salenius J, Zeitlin R, Saarinen J, Metsänoja R, Auvinen O. Carotid artery stenosis – a challenge for a vascular surgeon. (submitted)

V Heikkinen M, Salenius J, Zeitlin R, Saarinen, J, Suominen V, Metsänoja R, Auvinen O. Fate of AAA patients referred to a vascular surgical unit due to AAA. *Scandinavian Journal of Surgery* 2002;91:345-352

VI Heikkinen M, Salenius J, Saarinen, J, Laurikka J, Suominen V, Metsänoja R, Zeitlin R, Auvinen O. Regional differences in the utilization of vascular surgical service and incidences of amputations in a well-defined geographical area. *European Journal of Surgery*, accepted

ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
ABI	Ankle Brachial Index
ACAS	Asymptomatic Carotid Atherosclerosis Study
ACST	Asymptomatic Carotid Surgery Trial
ADAM	Aneurysm Detection and Management
AF	Amaurosis Fugax
AK	Above Knee
BK	Below Knee
CEA	Carotid Endarterectomy
CLI	Chronic Critical Leg Ischaemia
ECST	European Carotid Surgery Trial
EBM	Evidence Based Medicine
FHDR	Finnish Hospital Discharge Registry
HCE	Health Care Expenditures
HTIA	Hemispheric Transial Ischaemic Attack
IC	Identity Code
ICD	International Classification of Diseases
NASCET	North American Symptomatic Carotid Endarterectomy Trial
PAOD	Peripheral Arterial Occlusive Disease
PTA	Percutaneous Transluminal Angioplasty
RAAA	Ruptured Abdominal Aortic Aneurysm
SLI	Symptomatic Leg Ischaemia
SPSS	Statistical Package for the Social Sciences
TASC	Trans Atlantic Consensus Document
TAUH	Tampere University Hospital
TIA	Transient Ischaemic Attack
VRIS	Vascular Registry in Southern Sweden
U.S.A.	United States of America

INTRODUCTION

The development of vascular surgery began about 50 years ago. In Finland the Finnish Vascular Surgical Society was founded in 1996 and 1.1.1999 vascular surgery became an independent specialty, as in most of the countries in the European Union. Thereafter vascular surgery has been a surgical specialty similar to orthopaedy, gastroenterology, urology, general surgery, paediatric, hand, plastic and cardiothoracic surgery.

The three main goals of vascular surgical activity are to obviate the need for amputations and prevent strokes and ruptures of abdominal aortic aneurysms. Large randomized studies were published in the last decades providing guidelines for treatment of carotid artery stenosis and abdominal aortic aneurysms. Also the treatment and outcome of critical leg ischaemia has undergone a change during the last two decades and an aggressive reconstruction policy has been found to reduce amputation incidence.

As the relative and absolute number of elderly persons will increase during coming decades, the workload of the vascular service will grow significantly. Resources available for health care do not increase similarly, which emphasizes the importance of the cost-effectiveness of chosen treatment in the future. If the treatment of vascular diseases is evidence-based, the net economic impact is often positive.

To optimize the appropriateness and efficacy of treatment, continuous quality control of results and evaluation of treatment criteria is necessary. Consistent quality control of the vascular surgical service requires a functioning vascular registry. By linking information in various registries, vascular, hospital and cause-of-death, it is possible to review the past and analyze the success of treatment as a whole as well as to plan the future of the vascular surgical service. This study was undertaken to review the function of the vascular surgical service during the last decade and to map out the prospects of the service for the next two decades.

REVIEW OF THE LITERATURE

1. Evidence-based medicine

Owing to the lack of awareness of relevant research, decision-making in health care is based on pathophysiological principles, personal observation and intuition, this resulting in wide variation in practice between healthcare workers (Olantunbosun et al. 1998). Clinicians looking up the solution to a clinical problem will in most cases go to only one or two articles or reviews and usually, without formal critical appraisal, pick the solution they like (Meakins 2002). Evidence-based medicine (EBM) integrates the best available data from clinical research into clinical practice to enhance the quality of clinical decisions and achieve the best possible outcome (Knotterus and Dinant 1997, Olatunbosun and Edouard 1997).

The infrastructures of EBM are the levels of evidence and grades of recommendation for research articles. Fletcher and Sackett first introduced these concepts in 1979 in the context of recommendations regarding periodic health examination (Canadian task force on periodic health examination 1979). The concepts have gone through numerous iterations. The levels of evidence for therapy progress from systematic reviews of randomized control trials of high quality and the grades of recommendation (A, B, C, D) are founded on the quality, of the evidence as defined by its level (Meakins 2002). This grading is intended to help clinicians to understand the sources whence statements in, for example, guidelines are derived.

Most physicians are aware of EBM, they hold views on its current promotion and perceive its usefulness in the day-to-day management of patients (McColl et al. 1998, Olatunbosun et al. 1998). Doctors have, however, a low level of awareness of the extract journals, review publications and databases relevant to it (McColl et al. 1998). Also the understanding of terms used in EBM is partial (McColl et al. 1998, Woodcock et al. 2002, Young et al. 2002). The perceived major barriers to practising evidence-based medicine are lack of personal time, personal and organizational inertia, attitudes of colleagues, patients' expectations and the absence of hard evidence (McColl et al. 1998). There is also some measure of concern among physicians regarding evidence-based medicine, for example "evidence-based medicine is time-consuming", "evidence-based

medicine ignores clinical experience” and it leads to “erosion of physician autonomy” (Olatunbosun et al. 1998).

In the last decade, many important questions in vascular surgery were resolved. Large randomized multicentre studies clarified the indications for surgery of high-grade symptomatic carotid stenosis and small AAAs (ESCTCG 1991, NASCET Collaborators 1991, The UK Small Aneurysm Trial Participants 1998). In all areas of vascular surgery, however, EBM data is not available; a number of areas await results of future research. For example, asymptomatic carotid stenosis is still in so-called gray area, and the benefit of carotid endarterectomy in asymptomatic patients with carotid stenosis is controversial (Barnett et al. 2002). Many questions also attend the diagnosis and management of AAAs. Is population screening cost-effective in reducing deaths from rupture? Are there smaller groups of patients whose treatment would be more beneficial in other ways than those concluded in large randomized studies, for example the treatment of AAA in low-risk patients with long life expectancy, male patients with high-grade asymptomatic stenosis? The answers to these questions are open and will remain so until results from further randomized controlled trials are available.

2. Main vascular surgical diseases

2.1. Chronic critical limb ischaemia

2.1.1. Definition

Chronic critical limb ischaemia (CLI) is the term used to define cases where chronic arterial disease has resulted in rest pain in the foot, or ischaemic skin lesions, either ulcers or gangrene (The TASC Working Group 2000). In 1954 Fontaine and associates proposed a simple clinical classification in which patients with chronic limb ischaemia were divided to four groups. Stages I and II comprised asymptomatic patients with PAOD and those with claudication respectively. Ischaemic rest pain but no skin lesions was defined as stage III peripheral arterial occlusive disease (PAOD), and patients with skin lesions as stage IV PAOD. Patients with critical limb ischaemia belong to stage III or stage IV (Fontaine et al. 1954).

According to the Trans Atlantic Inter-Society Consensus Document on the Management of Peripheral Arterial Disease (The TASC Working Group 2000), the definition of CLI is based on a patient having chronic ischaemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease (The TASC Working Group 2000). The term critical limb ischaemia implies chronicity and is to be distinguished from acute limb ischaemia. The suggested inclusion criteria in TASC for CLI were absolute ankle pressure below 50-70 mmHg or reduced toe pressure (<30-50 mmHg) or reduced trans cutaneous oxygen pressure (<30-50 mmHg).

2.1.2. Incidence and prevalence

Information on the incidence of CLI is sparse. In the best estimates, the rate has been calculated on the basis of the development of CLI in claudication patients or the incidence of amputations in the population. Roughly, of 100 claudicants, one develops CLI annually (Catalano 1993). Calculated on the basis of claudication, annual incidences per million inhabitants in Western countries have ranged from 400 to 600 (Catalano 1993, the Vascular Society of Great Britain and Ireland 1995). Huntington and colleagues (2000) studied the workload incurred by lower limb occlusive arterial disease in the North of England in 19 hospitals providing vascular services for 2.33 million people. In one year, 85 patients per 10⁵ inhabitants were admitted to hospital because of leg ischaemic symptoms. Legs with intermittent claudication accounted for 55 % and CLI 45 % of admissions.

The incidence of CLI can also be estimated on the basis of the amputation incidence in a given region. Assumptions have been that 90 % of major amputations are performed for ischaemia and that 25 % of patients with CLI undergo a major amputation (Second European Consensus Document on Chronic Critical Leg Ischaemia 1992, The TASC Working Group 2000). Estimates range between 100-1000 per million per year (Table 1). This method is however somewhat inaccurate, in that the amputation incidence is affected by a number of factors, for instance the activity of vascular surgery in the region.

The data on the prevalence of critical lower limb ischaemia alone are sparse. In 1995 the Vascular Surgical Society of Great Britain and Ireland estimated the prevalence of CLI in Britain and Ireland to be 1 in 2500 of the population annually (0.04 %). There are few studies, which reporting the prevalence of chronic lower limb ischaemia as a whole. Canales and colleagues (1991) found a prevalence of 8.8 % in men and 4 % in the population over 59 years of age in a Spanish region. Skau and Jönsson (1993) studied the prevalence of symptomatic leg ischaemia (SLI) in the Vadstena community, Sweden. The overall prevalence

of SLI in the age group 50-89 years was 4.1 %, ranging from 1.5 % at 50-59 years to 7.1 % at 70-79 years (Skau and Jönsson 1993).

Luther studied the treatment of CLI in the Vasa area from the 1970s to the 1990s. He found the incidence of new interventions undertaken due to CLI to have increased from 107/million inhabitants/year in 1970-1974 to 379/million inhabitants/year in 1990-1994 (Luther 1997).

2.1.3. Risk factors

The incidence of peripheral arterial occlusive disease (PAOD) increases with age (Bloor 1961, Luther 1994). In 1994 Luther found, that the incidence of major amputations was over three times higher in octogenarians than in the age groups 65-70, 70-75 and 75-80 years old.

Cigarette smoking is a significant independent risk factor both for developing PAOD and in its progression (Auerbach and Garfinkel 1980, DaSilva et al. 1979, Kannel and Shurtleff 1973, Liedberg and Persson 1983). Smoking also worsens the prognosis of arterial reconstruction (Lassila and Lepäntalo 1988, Powell and Greenhalgh 1992). In contrast with its relationship to coronary disease and stroke, previous smoking appears to have a long legacy of increased risk of PAOD (Fowler et al. 2002).

In Western populations the prevalence of diabetes is 3 % to 5 % (Alwan and King 1992, King et al. 1998, Vilbergsson et al. 1997). Diabetes is an independent risk factor associated with PAOD (The Vascular Surgical Society of Great Britain and Ireland 1995). Diabetics are some 10 times more likely to need an amputation than nondiabetics (Da Silva 1979, Bendick et al. 1983, Bild et al. 1989, Most and Sinnock 1983). Diabetic atherosclerosis is also more diffuse and more severe, and manifests itself at an earlier age than atherosclerosis in nondiabetic patients (Gensler et al. 1965, Strandness et al. 1964). Also, diabetics have to undergo amputation on the average earlier than nondiabetics (Christensen 1976, Hansson 1964, Hierton and James 1973).

2.1.4. Natural history

The natural history of CLI is difficult to describe because most subjects suffering from it undergo some form of intervention. Patients not suitable for active treatment are the only cases yielding unmanipulated outcome data, but may not represent the whole CLI group. A large proportion of these are patients whose clinical status is so poor or atherosclerosis so widespread that arterial reconstruction is not feasible.

TABLE 1

Incidence¹ of amputations and estimated CLI-incidence²

Authors	Publication year	Region	Study period
Kald et al.	1989	Sweden	1980-1982
Ebskov et al.	1994	Denmark	1983-1990
Lindholt et al.	1994	Viborg, Denmark	1989-1990
Dormandy and Ray	1996	UK	
Hallett Jr. et al.	1997	Minneapolis, U.S.A.	1973-1993
Morris et al.	1998	Tayside, Scotland	1993-1994
Luther et al.	1999	Finland	1993-1994
Pohjolainen and Alaranta	1999	Southern Finland	1995
Feinglass et al.	1999	U.S.A.	1996
Galland et al.	1999	West Midlands, UK	1994-1995
Galland et al.	1999	Oxford, UK	1994-1995
Pernot et al.	2000	Limburg, Netherlands	1994
The GLEASG ⁷	2000	Tochigi, Japan	1995-1999
The GLEASG ⁷	2000	Madrid, Spain	1995-1997
The GLEASG ⁷	2000	Montgomery, U.S.A.	1995-1997
The GLEASG ⁷	2000	Navajo, U.S.A.	1995-1998
Eskelinen et al.	2001	Seinäjoki and Ähtäri, Finland	1997-2000
Nazim	2001	Poland	1996
Witso et al.	2001	Trondheim, Norway	1994-1997
Trautner et al.	2001	Leverkusen, Germany	1990-1998
Dillingham et al.	2002	Maryland, U.S.A.	1986-1998
Chen et al.	2002	Taiwan	1997

¹ Incidence expressed as number of cases per 10⁵ inhabitant per year² Calculated on the basis of assumptions presented in

the Second European Consensus Document on Chronic Lower Limb Ischaemia (25 % of CLI-patients undergo major amputation)

³ AK=above or through knee⁴ BK=below knee, knee joint intact⁵ Only vascular amputations included in the study⁶ Age-adjusted to standard European population⁷ The Global Lower Extremity Amputation Study Group⁸ 25 % knee disarticulations⁹ 39 % knee disarticulations

Amputation Incidence	AK ³ /BK ⁴	Diabetics %	Proportion of vascular amputations (%)	Estimated CLI incidence ²
46	1.6	45	95	175
30 ⁵		25	100	120
30.9	1.7	43		111
30				108
30.6	0.6			120
14.4	0.5	27	90	52
21.6 ⁵		63	100	86
16.0	1.0	49	80	46
25.0	1.6			90
15.2				55
12.3				44
17.1	1.2 ⁸	43	86	62
3.8 ⁶		33		14
2.8 ⁶		80		10
19.2 ⁶		64		69
43.9 ⁶		90		193
22	1.4	39	80	70
19.9 ⁵	2.9	49	100	80
27.4	2.3 ⁹	34	87	99
15	2.0	76		54
25.1 ⁵	1.1	43	100	100
8.8	0.4	53	79	28

In different series, the proportion of cases in which revascularization had been attempted prior to amputation varies between 23 and 97 % (Eskelinen et al. 2001, Holdsworth 1997, Luther 1994, McGrath et al. 1983, Taylor 1991, The I.C.A.I. Group 1997). The treatment of critical ischaemia has become more aggressive during recent decades and the proportion of patients not undergoing vascular intervention before amputation has decreased during that time (Karlström 1997, Luther 1994). In the evaluation of the treatment of critical lower limb ischaemia during 1970-1994 in the Vasa region (Finland), Luther found a dramatic decrease in the proportion of patients undergoing primary amputation (Luther 1997). The primary choice of treatment for patients presenting with new CLI was amputation in almost 100 % in the early 1970s. In 1980-84, 30 % had reconstruction and in 1990-94 the corresponding figure was 64 % (Luther 1997).

Lepäntalo and Mätzke (1996) studied the outcome of unreconstructed chronic critical leg ischaemia in 105 patients with 136 critically ischaemic legs. One year mortality was 54 % and 46 % of the critically ischaemic legs had been amputated; 28 % were alive with the nonamputated leg. In a study of 37 nonreconstructed patients with CLI, Jivegård and colleagues (1995) reported 35 % to be alive at one year with the nonamputated leg. In trials of pharmacotherapy for CLI, with patients not suitable for arterial reconstruction or in whom reconstruction has failed, less than half have been alive without major amputation after 6 months (Norgren et al. 1990, Bliss et al. 1991).

Bertele and colleagues (1999) assessed the impact of patient history, cardiovascular risk, manifestations of the disease and specific invasive and pharmacological interventions on mortality, amputation rate and persistence of CLI in 1560 patients with CLI. In that series, about one-quarter were considered inoperable on account of local disease (12.2 %), general condition (6.0 %) or both (5.3 %). The overall one-year mortality was 19.1 %, 12 % had been amputated and 47.8 % had persistent CLI. Age affected all clinical outcomes: each year of age increased the risk of dying within 6 or 12 months by about 5 %, the risk of needing amputation by about 2 % and the probability of not recovering from CLI by about 1 %. A history of myocardial infarct or stroke was a strong predictor of mortality, while previous amputations did not predict a poorer outcome in terms of mortality or amputation or CLI resolution (Bertele et al. 1999).

The reported one-year mortality in unselected patients with CLI has been around 20 %, 2-year mortality 32-44 % and 5-year mortality 56 % (the I.C.A.I. Group 1997, Wolfe 1986, Wolfe 1997)

2.1.5. Treatment

All patients with ulcers, gangrene or pain in the foot possibly associated with PAOD should be considered urgent cases and treatment should take place in a unit, which has a vascular specialist (Audit Committee of the Vascular Surgical Society of Great Britain and Ireland 1996, The TASC Working Group 2000). Since foot ischaemia is one of the determinants in the development – and the most important factor preventing healing – also in diabetic foot ulcers, thorough assessment of the lower limb arterial tree should be routinely performed (Lepäntalo et al. 2000). In further investigations the anatomy of arterial disease is to be ascertained and coexisting diseases in other systems evaluated (The TASC Working Group 2000). Infections, pain and possible thrombosis need urgent treatment. If an ischaemic and infectious leg, gas or septic gangrene, causes an immediate threat to a patient's survival, an immediate major amputation is mandatory (The TASC Working Group 2000).

The primary aim in treatment is revascularization to provide sufficient blood flow to relieve ischaemic symptoms and lesions. Revascularization of the lower extremity remains the treatment of choice for most patients with significant arterial occlusive disease (Griffith and Gallum 1988, Hallett et al. 1997, Hobson et al. 1985, Luther 1997, Perler 1995, The Audit Committee of the Vascular Surgical Society of Great Britain and Ireland 1996, The TASC Working Group 2000). Conservative treatment may be used only in patients with unreconstructable arterial changes, when there are contraindications to reconstruction or as a temporary treatment while planning for reconstruction (Luther 1997). Choice between an endovascular and a surgical procedure depends largely on the precise level and extent of the arterial disease. When two techniques of revascularization give equivalent short-term and long-term benefit, the technique with the least morbidity and mortality should be preferred (The TASC Working Group 2000). However, legs with critical ischaemia frequently have multisegment disease and are therefore seldom candidates for endovascular repair. No comparative data on long bypass vs. subintimal recanalization are available. There is also substantial disagreement among surgeons and radiologists with regard to the appropriateness of surgery or angioplasty for severe limb ischaemia, this stemming from the absence of an evidence base (Bradbury et al. 2002). It means that the same patients may receive entirely different treatment depending on which hospital and consultant they attend (Bradbury et al. 2002).

In some cases in which the risks of revascularization are high and the chances of success low, there is a place for a primary major amputation or noninterventional therapy (Luther 1997). Re-do vascular reconstructive procedures are also of benefit in limb salvage and the preservation of ambulatory ability (DeFrang et al. 1995). Since failure of a lower extremity revascularization does not predispose the patient to a higher level of amputation or multiple

amputations (Bloom and Stewick 1988, Whittaker et al. 2001), initial attempts at vascular reconstruction of the lower extremity are indicated.

The impact of pharmacological therapies on the outcome of CLI has proved limited. Prostanoids have been shown to have beneficial effects on rest pain; they might promote ulcer healing and prevent the need for amputations (Norgren et al. 1990, UK Severe Limb Ischaemia Study Group 1991, Guilmot and Diot 1991). The TransAtlantic Inter-Society Consensus for the management of peripheral arterial disease recommends the use of prostanoids in patients who have a viable limb in which revascularization procedures are impossible, carry a poor chance of success or have previously failed, and particularly when the alternative is amputation (The TASC Working Group 2000)

2.1.6. Amputation

Unreconstructable arterial disease is generally due to the progressive nature of the underlying atherosclerotic occlusive condition. If the distal vessels cannot be found by means of modern imaging techniques, especially in the setting of advanced distal ischaemia associated with a low ABI (<0.30), vascular reconstruction is often impossible and major amputation inevitable (Howell et al. 1989, Wolfe and Wyatt 1997, The TASC Working Group 2000). Nonambulatory patients with fixed, irremediable flexion contracture, who require a stable, pain-free limb that can be used for positioning in bed or wheelchair and PAOD patients with terminal or near terminal co-morbid conditions, will gain no benefit from revascularization procedures (Johnson et al. 1995, Humphreys et al. 1995). Primary amputation is the best choice in these patient groups (Johnson et al. 1995, Luther 1997).

Secondary amputation is indicated when vascular intervention is no longer possible or when the limb continues to deteriorate despite the presence of a patent reconstruction (The TASC Working Group 2000). The most common indication for secondary amputation is bypass thrombosis, accounting for nearly 50 % of such cases (Reifsnnyder et al. 1997, Schina et al. 1994, Wahlberg 1994). Failure of limb salvage despite patent bypass is the second common diagnosis (Reifsnnyder et al. 1994).

Using the figures available for progression of claudication, total major amputations in the United Kingdom may be about 30 per 10^5 per annum (Dormandy and Ray 1996). This compares with estimates of 47 per 10^5 per annum in Sweden, 25 per 10^5 per annum in Denmark (Ebskov et al. 1994, Kald et al. 1989) and 25 per 10^5 per annum in the United States (Feinglass et al. 1999). The incidence of major amputations due to vascular disease in Finland was 21.6 per 10^5 inhabitants during the years 1993-1994 (Luther et al. 2000) (Table 1).

2.2. *Ischaemic cerebrovascular disease*

2.2.1. Symptoms

Transient ischaemic attacks (TIA) represent embolic events with recovery presumably related to collateral flow to ischaemic regions or dissolution of thrombus or platelet debris (Fisher 1958, Lhermitte et al. 1970, Millikan et al. 1955, Whisnant et al. 1954). Hemispheric symptoms often involve sensory or motor deficits in the extremities contra-lateral to the affected artery. Amaurosis fugax (AF) is a transient ipsilateral monocular blindness secondary to ischaemia of the retina or optic nerve. Symptoms last from a few minutes up to 24 hours and they completely resolve (Millikan and Siekert 1955). In ischaemic stroke prolonged ischaemia causes the death of neuronal tissue, leading to a focal neurological deficit which does not clear up within 24 hours (Sundt et al. 1987).

A patient with symptomatic carotid artery disease is at significant risk of continued ischaemic symptoms and cerebral infarction. Patients experiencing TIAs have an approximately 7 % annual stroke risk (Baker et al. 1968, NASCET Collaborators 1991, Barnett et al. 1998) and patients experiencing stroke have an annual recurrence risk up to 20 % (Acheson and Hutchinson 1971, Baker et al. 1968, Robinson et al. 1968, Sacco et al. 1982). The risk of stroke is higher in patients who have had hemispheric TIA (HTIA) compared to those suffering amaurosis fugax (Streifler et al. 1995, Benavente et al. 2001). The risk of ipsilateral stroke at 2 years was 17 % with amaurosis fugax and 44 % with hemispheric TIAs ($p=0.02$) in patients with high-grade carotid stenosis. The relative risk of ipsilateral stroke (AF compared with HTIA) has been found to be 3.23 (Streifler et al. 1995).

2.2.2. Epidemiology

Stroke is the third leading cause of death in the Nordic countries (Salenius and Kuukasjärvi 1997). Cerebral infarction comprises about 80 % of all strokes in Scandinavia (Immonen-Räihä et al. 1997, Numminen et al. 1996, Samuelsson et al. 2001). The incidence of stroke in Finland is about 200 per 10^5 inhabitants per year (Mähönen et al. 2000, Numminen et al. 1996, Sivenius 1982) and the age-adjusted incidence has decreased by 20 % during 1972-1991. Stroke incidences in Western countries and changes in these incidences are presented in Table 2. The incidence is higher in men than in women (Immonen-Räihä et al. 1997, Mähönen et al. 2000, Feigin et al. 1995). Sivenius and colleagues (1982) studied the epidemiology of stroke in East Central Finland and found that its incidence was almost 3-fold in men compared to women in the age group 35-54 years, double in the age group 55-64 years and 1.5-fold at 65-74. In the age group of 75 years and over, the incidence was slightly higher in women compared to men (Sivenius 1982).

TABLE 2

The incidence¹ of strokes and changes in it in Western countries

Authors	Publication year	Study region	Study period
Terent	1988	Soderhamn, Sweden	1975-1986
Lindenström et al.	1992	Copenhagen, Denmark	1976-1988
Kagan et al.	1994	Oahu, Japan	1969-1985
Feigin et al.	1995	Novobirst, Russia	1982-1992
Numminen et al.	1996	Several districts, Finland	1972-1991
Carolei et al.	1997	L'Aquila, Italy	1994
Ellekjaer et al.	1997	Innherred, Norway	1994-1996
Kolominsky-Rabas et al.	1998	Southern Germany	1994-1996
Lackland et al.	1998	South Carolina, U.S.A.	1990
Lackland et al.	1998	South Carolina, U.S.A.	1990
Morikawa et al.	2000	Oyabeand Fukuoba, Japan	1977-1991
Mähönen et.	2000	Finland	1991-1994
Johansson et al.	2000	Lund-Orup, Sweden	1983-1995
Gibbs et al.	2001	United Kingdom	1992-1996
Appelros et al.	2002	Scandinavia	1999-2000

¹ Incidence expressed as number of cases per 10⁵ inhabitant per year² Age-adjusted to European population³ Age-adjusted to the U.S.A. white population in 1970⁴ Calculated from age-adjusted figures

There are fewer reports on TIA incidence compared to stroke incidence in the literature and reported incidences vary considerably depending on the methodology used. Reported figures vary between 40–330 per 100 000 inhabitants per year (Gibbs et al. 2001, Lemesle et al. 1996, Sempere et al. 1996, Lauria et al. 1996, Matias-Guiu et al. 1994, Fratiglioni et al. 1989)

Mean stroke incidence	Change during the study period	Proportion of ischaemic strokes (%)	Trend during the study period ⁴
323	290-353	61	Increasing (22 %)
214			No significant change
353	510-240	73	Decreasing (53 %)
219 ³			Decreasing (14 %)
	241-192	79	Decreasing (20 %)
228 ²		80	
232 ²		74	
134 ²		79	
211 ³		85	
293 ³		85	
	207-235	65	Decreasing (27 %)
190 ²			
147 ²	134-158	74	Increasing (14 %)
151			
254 ²			

In the U.S.A. the prevalence of stroke increased from 1.4 % to 1.9 % from the 1970s to the 1990s. During the same period the number of persons with a history of stroke increased by 60 % (Muntner et al. 2002). In a door-to-door survey in three towns in Spain Matias-Guiu and colleagues (1994) found a prevalence of stroke of 2.2 % and a prevalence of TIA of 1.3 %. In a questionnaire survey in Italy, Fratiglioni and colleagues (1989) found a TIA prevalence of 6.6 %.

2.2.3. Symptomatic clinical trials

Three prospective randomized clinical trials on carotid endarterectomy versus best medical management for the treatment of symptomatic patients with ipsilateral carotid artery stenosis were independently initiated during the 1980s and the results were published during the 1990s (ESCTCG 1991, Mayberg et al. 1991, NASCET Collaborators 1991).

North American Symptomatic Carotid Endarterectomy Trial

The North American Symptomatic Carotid Endarterectomy Trial (NASCET) compared medical therapy (325-1300 mg aspirin) versus medical therapy plus carotid endarterectomy (NASCET Collaborators 1991). The degree of stenosis was determined by comparison of the narrowest linear diameter of the affected vessel with the diameter of the normal internal carotid artery beyond the carotid bulb. A total of 659 patients with 70-99 % symptomatic carotid stenosis from 50 centers were randomized. The cumulative risk of ipsilateral stroke at 2 years was 26 % in the medical group and 9 % in the surgical group, for an absolute risk reduction of $17.0 \% \pm 3.5 \%$. An absolute risk reduction of $10.6 \% \pm 2.6 \%$ was realized for major or fatal ipsilateral stroke (13.1 % medical, 2.5 % surgical). The operative risk of stroke or death was 5.8 %. The benefit of surgery over medical therapy alone remained clear when all strokes and deaths were combined in outcome analysis ($p < 0.001$). (NASCET Collaborators 1991)

The benefit of surgery compared to medical treatment in patients with 50-69 % carotid stenosis has been found to be clearly less than that seen in patients with more severe stenosis (Barnett et al. 1998). The five-year risk of fatal or nonfatal ipsilateral stroke among patients with stenosis of 50 to 69 % was 22.2 % in the medical group and 15.7 % in the surgical group ($P=0.045$). The absolute risk reduction was 6.5 % and the number needing to be treated to prevent one stroke was 15. Kaplan-Meier stroke-free survival curves for surgical and medical groups overlaps in 95 % confidence interval areas, which means reduced benefit (Barnett et al. 2002). There were also subgroups who gained more benefit from CEA: those 75 years and older, men, patients with recent symptoms (within three months), patients with more severe stenosis, history of stroke (rather than TIAs) and patients with hemispheric symptoms rather than amaurosis fugax (Alamowitch et al. 2001, Barnett et al. 1998, Streifler et al. 1995). Radiographic findings which predicted greater benefit from carotid endarterectomy compared to medical treatment included the presence of intracranial stenosis, nonlacunar lesion and the absence of collateral vessels (Henderson et al. 2000, Inzitari et al. 2000, Kapelle et al. 1999).

European Carotid Surgery Trial

The European Carotid Surgery Trial (ECST) was also a prospective randomized trial, involving approximately 80 participating centers. The method for determining the degree of stenosis from the angiogram was different in ECST compared to NASCET. Severity was determined by comparison of the narrowest linear diameter of the vessel in question with the normal diameter of the carotid bulb. In the treatment of patients with 80-99 % carotid stenosis (which translates to 70 % to 90 % stenosis on NASCET criteria), 574 patients were randomized. The Kaplan-Meier estimate of the frequency of a major stroke or death at 3 years was 26.5 % for the control group and 14.9 % for the surgery group, an absolute benefit from surgery of 11.6 %. Thus about 9 patients had to be treated by surgery for one more patient to be alive and free of major stroke at 3 years. If the analysis is restricted to disabling strokes, the number needed to treat is 18 (ECSTCG 1998). The operative risk of stroke or death was 7.0 %.

Among the patients with moderate or mild stenosis (0 % - 80 %; 0-70 % as measured by the NASCET method), no statistical difference was achieved between patients treated medically and surgically (ECSTCG 1991, ECSTCG 1998). However, in the group of patients with 70-79 % stenosis, it seemed that males over 70 years of age would gain benefit from surgery (ECSTCG 1998).

Veterans Affairs Cooperative Symptomatic Trial

A third prospective randomized multicenter trial of endarterectomy versus medical management was initiated in 16 university-affiliated Veterans Affairs medical centers (Mayberg et al. 1991). The study was terminated when the NASCET and ECST results were published. At this point, 189 patients with symptomatic carotid stenosis over 50 % by NASCET criteria had been randomized. This study also showed a stenosis-dependent effect with benefit of CEA in higher-grade stenosis (>70 %).

Indications for carotid endarterectomy in symptomatic carotid stenosis, conclusion

The above-mentioned studies justify the use of CEA in patients with symptomatic stenosis, from 70 % to 90 % measured by the NASCET method, who do not have specific exclusion criteria when operated on by surgeons who have a low (<6%) major stroke and death morbidity and mortality rates. In the case of 50-70 % stenosis the evidence is uncertain and especially in low-risk patients CEA is not justified.

Asymptomatic carotid stenosis

Three large studies have been reported on surgery versus medical therapy for asymptomatic carotid artery stenosis (The CASANOVA Study Group 1991, Executive Committee for the Asymptomatic Carotid Atherosclerosis Study 1995, Hobson et al. 1993). In the Carotid Artery Stenosis with Asymptomatic Narrowing Operation Versus Aspirin (CASANOVA) trial 410 patients with 50 to 90 % asymptomatic carotid stenosis were randomized into a surgical (n=206) or a medical (n=204) group. Using death and stroke as endpoints, the study found no difference in outcome between the surgical and the nonsurgical group (The CASANOVA Study Group 1991).

In the Veterans Affairs Cooperative Study Group 444 patients with asymptomatic carotid stenosis greater than 50 % on angiography were randomized for surgery (n=211) or nonsurgical therapy (n=233). Patients were followed for a mean 48 months. The endpoint in the study was an ipsilateral neurologic event (TIA, AF, stroke). In the nonsurgical group the rate of ipsilateral neurologic events was 20.6 % and surgical event rate 8.0 %, giving an absolute risk reduction rate of 12.6 % ($p<0.001$). There was no difference between the groups when the endpoints of all strokes or death were evaluated. (Hobson et al. 1993)

The Asymptomatic Carotid Atherosclerosis Study (ACAS) included 1662 patients with asymptomatic carotid stenosis 60 % or over as measured in NASCET (ECACAS 1995). Patients with coronary artery disease were excluded from the study. All patients in conservative treatment received 325 mg aspirin daily. Altogether 825 patients with angiographically determined tight carotid stenosis were randomized into a surgical group and 834 to a medical group. The overall perioperative stroke or death rate was 2.3 %, including 1.2 % angiography-related complications. At 2.7 years the estimated 5-year absolute risk reduction was 5.9 %. The estimated 5-year risk of ipsilateral stroke or any perioperative stroke or death was 11 % for the medical group and 5.1 % for the surgical ($p=0.04$). In terms of any stroke or death, the difference was not statistically significant. Also when endpoint was major ipsilateral stroke or any perioperative major stroke or perioperative death, the difference in outcome between surgical and medical group was not significant. The risk reduction was more apparent in men than in women and was independent of degree of stenosis or disease in the contralateral artery. (ECACAS 1995)

Indications for carotid endarterectomy in asymptomatic carotid stenosis; conclusion

As there was no significant difference in the incidence of major ipsilateral stroke or any perioperative major stroke or perioperative death between patients receiving the best medical treatment and surgery and since the rate of perioperative complications was exceptionally low in ACAS, operation of asymptomatic carotid stenosis would appear to remain a controversial issue without clear evidence of benefit.

2.2.4. Mortality

Clinical studies have revealed an association between carotid stenosis and death (Hennerici et al. 1987, Norris et al. 1991). In the Tromsø Study, 248 subjects with suspected carotid stenosis and 496 controls were followed for almost four years (Joakimsen et al. 2000). The relative risk of death in cases with carotid stenosis was 2.72 (95 % CI 1.57-4.75) and carotid stenosis was a strong and independent predictor of death. Moreover there was a dose-response relationship between degree of stenosis and risk of death. A carotid bruit, which is highly correlated with carotid stenosis, has been found to be associated with a 1.7-2.2-fold-higher relative risk of death (Wolf et al. 1981, Wiebers 1990). Most subjects with carotid stenosis die from coronary artery disease and several studies have found carotid stenosis to be a stronger predictor of cardiac death than of death caused by cerebral stroke (Hennerici et al. 1987, Norris et al. 1991, Wiebers et al. 1990). In the Cardiovascular Health Study ICA stenosis had a strongly positive risk ratio for 5-year mortality (Fried et al. 1998). However, this ratio decreased substantially after adjustment for other variables, suggesting further that this measure is a marker for serious atherosclerosis throughout the vasculature, rather than being a direct cause of death (Fried et al. 1998).

2.3. Abdominal aortic aneurysm

2.3.1. Definition

Abdominal aortic aneurysm (AAA) has been defined in several ways. Johnston and colleagues suggested in 1991 the following definition of an arterial aneurysm: "An aneurysm is permanent localized (i.e. focal) dilatation of an artery having at least 50 % increases in diameter compared to the expected normal diameter of the artery in question" (Johnston et al. 1991). Being much

easier to apply in practice, a widely used definition of abdominal aortic aneurysm is a diameter of 3.0 cm or more (Holdsworth 1994, Lederle et al. 1997, Scott et al. 1991, Simoni et al. 1995, The UK Small Aneurysm Trial Participants 1995). Lederle and colleagues (1997) studied the relationship of age, gender, race and body size to infrarenal aortic diameter in approximately 70 000 subjects who had no previous history of AAA and no ultrasound evidence of AAA. They found that these factors were associated with infrarenal aortic diameter (IAD), but that the effects were small. Female sex was associated with a 0.14 cm reduction in IAD and black race with a 0.01 cm increase in IAD. They concluded that “age gender, race, and body size have statistically significant but small effects on IAD. Use of these parameters to define AAA may not offer sufficient advantage over simpler definitions (such as an IAD \geq 3.0 cm) to be warranted” (Lederle et al. 1997). The most widely used upper limit for a normal aorta is an aortic diameter of 2.5 cm (Liddington and Heather 1992), while 2.5 cm to 2.9 cm has been defined an abdominal aortic dilatation. (Morris et al. 1994, Simoni et al. 1995). In the fixed definition, the normal variation in aortic size is not taken into consideration and may cause certain inaccuracy at individual level.

2.3.2. Epidemiology

The exact incidence of asymptomatic AAAs in a population is difficult to determine, since it requires a sequential screening survey of the same population. Wilmink and colleagues (2001) studied the incidence of AAA by screening 4070 men over the age of 50 in the Huntingdon district twice. They found an incidence of new aneurysms of 350 per 10⁵ person-years (95 % CI 2.8-4.4). The highest incidence of new aneurysms was found in the 60- to 69-year-old age group (Table 3).

TABLE 3

Incidence of new aneurysms¹ in subjects who had an aortic diameter <3 cm and were rescreened after an average 5.5 years

Age	n at risk	py ² follow up	n new AAA	Incidence	95 % CI
50-59	1601	9270	17	1.8	1.1-2.9
60-69	1278	7144	37	5.2	3.7-7.0
70+	727	3584	17	4.7	2.8-7.4
Total	3606	20013	71	3.5	2.8-4.4

¹ A new aneurysm is defined as a growth in aortic diameter exceeding 5 mm in an aorta initially smaller than 3 cm

² Py=person-years

Modified from: Wilmink et al. 2001

Lederle and colleagues performed US screening twice at a four years' interval with 2622 subjects, 50-79 years old, with no previous AAA, and found a 4-year incidence rate of 2.6 % (Lederle et al. 2000).

Other studies have been based on autopsy or hospital discharge registers. The reported incidence per 10^5 person-years varies from 3 in women to 117 in elderly males (Table 4). In men, the incidence of AAA begins to increase at the age of 50 (Akkersdijk et al. 1991, Melton et al. 1984, Wilmink et al. 2001). In women, the aorta enlarges later and the incidence begins to increase at the age of 60 years (Akkersdijk et al. 1991, Melton et al. 1984, Sonesson et al. 1993). The incidence of AAA has increased during the past few decades (Eickhoff 1993, Gillum 1995, Melton et al. 1984). A part of this rise can be explained by the development of new diagnostic models such as ultrasound and computer tomography, and their increasing use. It has been estimated that a part of the increase is true, since the incidence of death from AAA increased steadily from the 1950s to the 1980s (Bengtsson et al. 1992, Fowkes et al. 1989, Norman et al. 1991, Reitsma et al. 1996).

Estimates of the prevalence of AAA can be obtained from population screening surveys and autopsy studies. Both methods yield fairly similar figures when similar age and sex groups are compared (Pleumeekers et al. 1994). According to autopsy series and ultrasound screening, the prevalence of AAAs (≥ 30 mm) in Western countries is 3 % to 10 % in the population over 50 years of age (Table 5). In Veterans Administration screening studies of more than 120000 patients aged 50 to 79 years, the prevalence of AAA over 30 mm was 4.2 % and AAA over 40 mm 1.3 % (Lederle et al. 1997, Lederle et al. 2000) (Table 6). Prevalence in men begins to rise after 50 years of age and reaches its peak at the age of 80-89 years (Wilmink et al. 1999) (Table 7).

The incidence of ruptured AAAs has also increased during recent decades (Drott et al. 1992, Eickhoff 1993, Mealy and Salman 1988, Wilmink et al. 1998). The reported incidences in the UK population vary between 9 and 21 per 10^5 person-years (Choksy et al. 1999, Mealy and Salman 1988). In Scandinavia, the latest reported incidences have been about 6 per 10^5 person-years (Bengtsson and Bergqvist 1993, Kantonen et al. 1999) (Table 8). The incidence increases after the age of 50 in men and after the age of 60 in women (Bengtsson and Bergqvist 1993) and the overall male: female ratio is 6:1 (Choksy et al. 1999).

TABLE 4

Reported incidences¹ of abdominal aortic aneurysms (> 29 mm)

Author	Publication year	Region	Study method
Melton et al.	1984	Minnesota, U.S.A.	CDR+HR
Melton et al.	1984	Minnesota, U.S.A.	CDR+HR
Castleden and Mercer	1985	Western Australia	A
Castleden and Mercer	1985	Western Australia	A
Lilienfeld et al.	1993	Minneapolis, U.S.A.	HR
Lilienfeld et al.	1993	Minneapolis, U.S.A.	HR
Gillum	1995	U.S.A.	HR
Reitsma et al.	1996	Netherlands	HR
Reitsma et al.	1996	Netherlands	HR
Magee et al.	1997	Oxford, UK	HR
Lederle et al.	2000	U.S.A.	US
Spark et al.	2001	Bradford, UK	HR
Wilmink et al.	2001	Huntingdon, UK	US

A=Autopsy study

CDR=Cause-of-death registry

HR=Hospital Records

US=Ultrasound screening

M=Male

F=Female

¹ Incidence expressed as number of cases per 10⁵ inhabitants per year² Mean incidence during the study period, no longitudinal data presented³ Study based on screening of the same population twice

Sex	Age group	Study period	Incidence in the beginning of study period	Incidence at the end of study period
M	All age-groups	1951-1980	11.2	45.3
F	All age-groups	1951-1980	4.2	19.7
M	> 55	1971-1981	74.8	117.2
F	> 55	1971-1981	17.5	33.9
M	All age-groups	1979-1984		49.3
F	All age-groups	1979-1984		12.0
M+F	>65	1979-1992	75.6	139.4
M	All age-groups	1972-1992	3.7	37.6
F	All age-groups	1972-1992	1.2	5.5
M+F	All age-groups	1996	3.6	3.6
M	50-79	1990s		650 ³
M+F	>55	1990-1997		27.0 ²
M	>55	1991-1998		350 ³

TABLE 5

Reported prevalences of abdominal aortic aneurysms

Authors	Publication year	Study period	Study region
Darling et al.	1977	1952-1975	Massachusetts, U.S.A.
Rantakokko et al.	1983	1959-1979	Turku, Finland
Holdsworth	1994		Northumberland
Bengtsson et al.	1992	1958-1986	Malmö, Sweden
Bengtsson et al.	1992	1958-1986	Malmö, Sweden
Krohn et al.	1992		Oslo, Norway
Simoni et al.	1995	1991-1994	Genoa, Italy
Simoni et al.	1995	1991-1994	Genoa, Italy
Scott et al.	1995	1989-1995	Chisester, UK
Scott et al.	1995	1989-1995	Chisester, UK
Wilmink et al.	1999	1991-1996	Huntingdon, UK
Lederle et al.	2000	1993-1997	U.S.A.
Singh et al.	2001	1994-1995	Tromsö, Norway
Singh et al.	2001	1994-1995	Tromsö, Norway
Chichester Aneurysm Screening Study	2001	1988-	Chichester, UK
Viborg Aneurysm Screening Study	2001	1994-	Viborg, Denmark
Western Australian AAA Program	2001	1996-	Western Australia
Multicenter Aneurysm Screening Study	2001	1997	UK

A=Autopsy study

US=Ultrasound

M=Male

F=Female

Study method	Screened population/ Number of autopsies	Sex	Age group	Prevalence (%)
A	24 000	M+F	All age groups	1.9
A	22 765	M+F	All age groups	1.0
US	628	M	65-79	6.7
A	45 838	M	All age groups	4.3
A	45 838	F	All age groups	2.1
US	1 246	M	>60	8.2
US	741	M	65-75	8.8
US	860	F	65-75	0.6
US	6 433	M	65-80	7.6
US	4 682	F	65-80	1.3
US	9 658	M	>50	5.4
US	126 196	M	50-79	4.2
US	2 955	M	25-84	8.9
US	3 363	F	25-84	2.2
US	2 212	M	65-74	7.7
US	4 861	M	65-74	3.9
US	12 203	M	65-83	7.2
US	27 121	M	65-74	4.9

TABLE 6

Prevalence of abdominal aortic aneurysm by diameter¹

Diameter, cm	First Cohort n=73 451	Second Cohort n=52 745	Combined Group n=126 196
≥ 3.0	3366 (4.6)	1917 (3.6)	5283 (4.2)
≥ 4.0	1031 (1.4)	613 (1.2)	1644 (1.3)
≥ 5.0	368 (0.50)	203 (0.38)	571 (0.45)
≥ 5.5 ²	224 (0.30)	118 (0.22)	342 (0.27)
≥ 6.0	137 (0.19)	75 (0.14)	212 (0.17)
≥ 7.0	48 (0.07)	28 (0.05)	76 (0.06)
≥ 8.0	22 (0.03)	10 (0.02)	32 (0.03)

¹ Data given as number (percentage) of subjects² The diameter at which surgery was offered in the surveillance arms of the Aneurysms Detection and Management trial in the United Kingdom Small Aneurysm Trial

Modified from: Lederle et al. 2000

TABLE 7

Prevalence (%) of abdominal aortic aneurysms by age group detected on first screen in men over the age of 50 years in Huntingdon

Age group	50 to 59	60 to 69	70 to 79	80 to 89	>90
No. screened	4116	3107	1814	573	48
AAA > 29 mm	1.2	5.1	10.3	12.4	8.3
95 % CI	0.9-1.6	4.3-5.9	8.9-11.7	9.7-15.1	0.5-16.2
AAA > 49 mm	0.05	0.4	1.5	2.8	0
95% CI	0.01-0.15	0.2-0.7	0.9-2.0	1.4-4.1	0

Modified from: Wilmink et al. 1999

2.3.3. Risk factors

Older age, male gender, positive family history, smoking, hypercholesterolemia, peripheral arterial occlusive disease, coronary artery disease and white race have been found to be associated with AAAs, age, gender and smoking having the largest impact on their prevalence (Allardice et al. 1988, Auerbach and Garfinkel 1980, Lee et al. 1997, Wilmink et al. 1999, Lederle et al. 1988, Lederle et al. 2000, Wolf et al. 1995). A positive family history has been found in 15 % to 25 % of patients undergoing AAA repair (Johansen and Koepsell, 1986, Tilson and Seashore 1984, Verloes et al. 1995, Webster et al. 1991). The prevalence of AAA in the population with PAOD is about 5-fold compared to that without PAOD (Allardice et al. 1988, Berridge et al. 1989, Wolf et al. 1995).

2.3.4. Natural history

Most aneurysms expand over time (Berstein and Chan 1984, Cronenwett et al. 1985, Littooy 1989, Grimshaw et al. 1994). One major factor affecting the dilatation rate is the maximum size of the aneurysm (Gadowski et al. 1994, Sterpetti et al. 1987). A proportion of 17-58 % remains stable for several years (The UK Small Aneurysm Trial Participants 1998, Nevitt et al. 1989, Glimåker et al. 1991). The median growth rate is about 2-3 mm (Cronenwett et al. 1985, Darling et al. 1991, Lederle et al. 2002, Nevitt et al. 1989, Vardulaki et al. 1998). Only 20 % grow over 4 mm per year (Nevitt et al. 1989, The UK Small Aneurysm Trial Participants 1998, Vardulaki et al. 1998). Lederle and group (2000) found in surveillance of 576 patients with small AAA (40 to 54 mm, follow-up 3.5 to 8.0 years) that a larger initial diameter and the absence of diabetes were significant univariate predictors of an increased rate of enlargement.

The strongest known predictor of rupture is the maximal diameter of the aneurysm (Glimåker et al. 1991, Nevitt et al. 1989, Reed et al. 1997). The risk increases exponentially with the diameter of the aneurysm and it starts to increase significantly when an AAA exceeds 50 mm in diameter (Darling et al. 1977, Darling et al. 1991, Nevitt et al. 1989, Szilagyi 1972). Smoking and hypertension are also associated with a higher risk of aneurysm rupture (Cronenwett et al. 1985, Powell and Brown 2001, Sterpetti et al. 1991). The rupture risk for AAAs less than 40 mm is 0-0.4 % per year; 40 to 49 mm, 0.5 % to 5 % per year; 50 to 59 mm, 3 % to 11 % per year; 60 to 69 mm, 9 % to 18 % per year; 70 to 79 mm, 20 % to 30 % per year and more than 80 mm, 30 to 50 % per year (Brown and Powell 1999, Darling et al. 1977, Guirguis and Barber 1991, Jones et al. 1998, Lederle et al. 2002, Law et al. 1994, Reed et al. 1997, Sterpetti et al. 1991).

TABLE 8

Reported incidences¹ of ruptured abdominal aortic aneurysms

Authors	Publication year	Study period	Region
Mealy and Salman	1988	1979-1986	Worthing, UK
Mealy and Salman	1988	1979-1986	Worthing, UK
Drott et al.	1992	1952-1959	Göteborg, Sweden
Drott et al.	1992	1980-1988	Göteborg, Sweden
Bengtsson and Bergqvist	1993	1971-1986	Malmö, Sweden
Bengtsson and Bergqvist	1993	1971-1986	Malmö, Sweden
Eickhoff	1993	1977-1990	Denmark
Scott et al.	1995	1989-1994	Chichester, UK
Magee et al.	1997	1996	Oxford, UK
Wilmink et al.	1999	1991-1996	Huntingdon
Wilmink et al.	1999	1991-1996	Huntingdon
Kantonen et al.	1999	1991-1994	Finland
Chosky et al.	1999	1986-1995	Huntingdon
Chosky et al.	1999	1986-1995	Huntingdon
Scott et al.	2002	1989-1998	Chichester, UK

¹ Incidence expressed as number of cases per 10⁵ inhabitant per year

A=Autopsy reports

CDR=Cause-of-death register

HR=Hospital records

VR=Vascular registry

Method	Sex	Age group	Mean incidence
CDR+HR	F	All age-groups	6.2
CDR+HR	M	All age-groups	23.1
A+CDR+HR	M+F	All age-groups	1.0
A+CDR+HR	M+F	All age-groups	6.8
A+CDR+HR	M	All age-groups	8.4
A+CDR+HR	F	All age-groups	3.0
HR	M+F	All age-groups	5.7
CDR+HR	M	65-80	435
HR	M+F	All age-groups	3.6
CDR+HR	M	> 50	62
CDR+HR	F	> 50	14
A+CDR+VR	M+F	All age-groups	6.1
CDR+HR	M	All age-groups	17.8
CDR+HR	F	All age-groups	3.0
CDR+HR	F	65-80	20.2

Powell and Brown (2001) analyzed the risk factors associated with aneurysm rupture in 2257 patients with AAA participating in the UK Small Aneurysm Trial. In this cohort there were 103 cases of aneurysm rupture. The risk of rupture was independently and significantly associated with female sex, larger initial aneurysm diameter, current smoking and higher mean blood pressure. Age, body mass index, serum cholesterol level and ABI pressure index were not associated with an increased risk of aneurysm rupture (Powell and Brown 2001).

In an 8-year follow-up analysis of the UK Small Aneurysm Trial (2002), where 527 patients were assigned to the surveillance group, the risk of rupture of AAA was four times as high among women as among men.

2.3.5. Management

The progression of aortic wall degeneration, aneurysm formation and possible rupture cannot be prevented medically. So far the only available means of treating AAA is graft replacement, either by open surgical procedure or by endovascular grafting (Freeman and Leeds 1951, Dubost et al. 1952, Parodi et al. 1991). Reconstruction of asymptomatic AAAs is a prophylactic intervention designed to prolong life and avoid rupture. Thus, appropriate decision-making requires an estimation of AAA rupture risk versus elective operative risk (Hollier et al. 1992). Since most AAAs never rupture, elective repair is undertaken only when the risk is considered high. The risk of rupture is extremely small in AAAs with a diameter less than 4.0 cm (Law et al. 1994). Reconstruction of these aneurysms is not justified. In cases where these aneurysms grow and the risk of rupture concomitantly increases, these patients should be kept under surveillance. When the risk of death due to rupture exceeds the mortality attending elective surgery, aneurysms should be repaired electively if the patient has no contraindications. If the operative mortality is increased because of patients' co-morbidity, a higher threshold for operative treatment is suggested (Cronenwett et al. 2000). If life expectancy is limited or operative risks exceed the risk of aneurysm rupture, the patient should not be operated (Cronenwett et al. 2000).

The right threshold for AAA reconstruction has been a subject of debate since the beginning of the 1990s. Some surgeons suggested elective surgery for a patient of any age with an aneurysm of 4 cm or more in diameter (Collin 1987, Hollier et al. 1992) while others suggested that the risk of death due to rupture in aneurysms over 5.0-6.0 cm in diameter exceeds mortality in elective surgery and such aneurysms should be repaired electively if the patient has no contraindications (Ballard et al. 1992, Scott et al. 1993). To ascertain the best management of AAAs in the grey area, 4.0 to 5.5 cm in diameter, the UK Small Aneurysm Trial and the Aneurysm Detection and Management (ADAM) Study

were begun in the mid-1990s (Lederle et al. 1994, the UK Small Aneurysm Trial Participants 1995).

The results of the UK Small Aneurysm Trial were published in 1998 and gave crucial information on the treatment of aneurysms 4.0-5.5 cm in diameter. In that study, 1090 patients with an AAA 40 to 55 mm in diameter were randomized for either surveillance or early elective surgery. The mean follow-up was 4.6 years. In the surveillance group, AAA was operated if the diameter increased up to 5.5 cm, increased more than 10 mm per year, or became tender or ruptured. Survival in the two groups, survival did not differ significantly ($p=0.56$). The estimated absolute risk of death by 6 years was 0.3 % greater in the early surgery group than in the surveillance group (n.s.). The 30-day postoperative mortality in the early surgery group was 5.8 %. In total, 61 % of patients kept under surveillance eventually underwent elective surgical repair. The 30-day mortality in these patients was 7.1 %. The UK Small Aneurysm Trial showed that ultrasonographic surveillance for AAAs under 5.5 cm in diameter is safe, and early surgery does not provide a long-term advantage (the UK Small Aneurysm Trial Participants 1998). In long-term outcome analysis of the UK Small Aneurysm Trial there was no difference in mean survival between the groups, although after eight years total mortality was lower in the early surgery group. This difference may probably be attributed in part to beneficial changes in life style adopted by members of the early surgery group (the UK Small Aneurysm Trial Participants 2002).

Lederle and associates (2002) also compared in a large randomized study (ADAM) immediate repair with surveillance of small aortic aneurysms (4.0-5.5 cm in diameter). The mean duration of follow-up was 4.9 years in 569 patients who underwent immediate repair and 567 patients under surveillance. They were likewise unable to show any benefit from early surgery: There was no significant difference between the two groups in the primary outcome or the rate of deaths from any cause. In the early surgery group, in-hospital mortality after elective repair was 2.7 %; 62 % of the surveillance group had undergone AAA repair by the end of the study with an in-hospital death rate of 2.1 % (Lederle et al. 2002).

In both of the above studies, the proportion of women was small. In the UK Small Aneurysm trial, in 17 % of women the diameter of the AAA was less than 55 mm. The results of these trials may thus not be applicable to women (Lederle et al. 2002, UK Small Aneurysm Trial Participants 2002).

For patients with symptomatic AAA, invasive treatment is usually appropriate in view of the high mortality rate associated with rupture or thrombosis and the higher likelihood of limb loss associated with peripheral embolism.

2.3.6. Survival after AAA repair

Perioperative mortality after AAA repair depends upon case mix (Bradbury et al. 1998, Kantonen et al. 1997). The reported 30-days operative mortality for elective open aneurysm repair in different series varies between 0.2 and 9.6 % (Crawford et al. 1981, Golden et al. 1990, Jaakkola et al. 1996a, Johnston and Scobie 1988, Kantonen et al. 1997, Katz et al. 1994, Zarins and Harris 1997). In Finland mortality according to the national vascular registry after 929 elective repairs of AAA was 5.1 % and varied between hospitals from 0 % to 15 % (Kantonen et al. 1997). In 156 acute non-ruptured cases the mean mortality was 13.5 % ranging from 0 % to 33 % between hospitals (Kantonen et al. 1997). Corresponding mortality figures from the Swedish vascular registry, Swedvasc, for elective asymptomatic, elective symptomatic and acute repair of non-ruptured AAA are 4.0 %, 6.4 % and 10.9 % (Bergqvist et al. 1998).

Early mortality after ruptured AAA surgery averages 50 % (Bergqvist et al. 1998, Gloviczki et al. 1992, Johnston et al. 1994, Kantonen et al. 1997, Katz et al. 1994). The mortality depends markedly upon the patient's haemodynamic condition before operation. In an evaluation of outcome of 4103 ruptured AAA repair on the basis of the Swedvasc registry in 1987-1995 the 30-day mortality was 21.9 % if patients did not have shock and 45.9 % in those with shock (Bergqvist et al. 1998). Operative mortality is, however, not a reliable measure when comparing results between the units, since it is affected largely by criteria for operability (Kantonen et al. 1997).

The 5-year survival after successful elective AAA repair is about 70-80 % and the 10-year survival rate about 40 % (Crawford et al. 1981, Koskas and Kieffer 1997, Norman et al. 1998, Olsen et al. 1991, Vohra et al. 1990, Yasuhara et al. 1999). If long term mortality is compared to the age- and sex-standardized normal population, the overall survival after AAA reconstruction is found to be reduced (Hollier et al. 1984, Norman et al. 1998, Yasuhara et al. 1999). The increased mortality is mostly caused by atherosclerotic manifestations (Hollier et al. 1984, Norman et al. 1999, Yasuhara et al. 1999). The causes of death after AAA reconstruction has been cardiac disease (36-44 %), cancer (15-25 %), rupture of another aneurysm (8-11 %), stroke (7-9 %) and pulmonary disease (6-15 %) (Crawford et al. 1981, Hollier et al. 1984, Norman et al. 1998, Yasuhara et al. 1999). Koskas and Kieffer (1997) found age, cardiac disease, carotid disease, renal disease, aneurysm extent, suprarenal extension, and external iliac involvement to be independent risk factors predictive of late mortality after elective AAA reconstruction.

Norman and colleagues in a population-based series studied long term survival in 1475 patients (1257 men and 218 women) who had undergone AAA repair and survived more than 30 days. After elective surgery the survival of women but not of men was significantly poorer. It also emerged that the survival

curve for patients less than 80 years of age was significantly inferior to the matched normal population, but the curve for the octogenarians rose as their survival was better than that of the matched normal population (Norman et al. 1998).

Stonebridge and colleagues compared long-term survival after successful repair of ruptured (n=227) and nonruptured (n=311) abdominal aortic aneurysms. The overall survival rate at 8 years was 43.6 % and during the follow-up there was no significant difference in survival between ruptured (40.5 %) and nonruptured (n=45.2 %) cases (Stonebridge et al. 1993).

3. Aims in vascular surgery

Chronic lower limb ischaemia can be divided into claudication and critical limb ischaemia (CLI) according to the severity of the ischaemia. Claudication is a relative indication for revascularization, as the stage of ischaemia is not limb-threatening. If, however, claudication is severe, significantly worsening the quality of life, coping at work or living independently and conservative treatment is not successful, invasive treatment may be indicated (The TASC Working Group 2000). In such cases the aim is to improve the quality of the patient's life significantly, preserve ability to work or live at home without continuous help. Critical limb ischaemia is a limb-threatening condition which often, without revascularization procedures, leads to loss of limb (Juergens et al. 1960, Wolfe 1986). The aim of the treatment of CLI is to obviate the need for amputations and thereby to preserve patients' mobility and prevent institutionalization.

Carotid endarterectomies and abdominal aortic aneurysm reconstructions constitute prophylactic surgery, where the procedure itself does not usually make the patient's subjective condition better. The aim of the treatment is to prevent severe symptoms or death in the future. Without treatment carotid artery stenosis may lead to stroke and abdominal aortic aneurysm may rupture, an event involving extremely high total mortality.

Acute limb ischaemia is an urgent condition which leads to irreversible tissue changes within a few hours without revascularization procedure and to death if the ischaemic period is prolonged. The aim of treatment is to prevent amputations and patient death.

4. Structure of health care service in Finland

Finland has a population of 5.2 million and an area of 338 000 square kilometers. The state and municipalities are responsible for providing social and health services to their citizens. Every municipality, alone or in federation with others, organizes social services, primary health care and specialized hospital care for its inhabitants. Primary health care takes place mainly in health care centres, which anyone can contact for outpatient services. To obtain specialized hospital services (except emergency care), the patient must be referred from a health centre general practitioner or private physician. In practice, specialized care is provided by the hospital districts, which own the hospitals. Each municipality must be affiliated to one of these hospital districts.

Vascular surgical units are secondary or tertiary referral centres. Vascular surgery is performed in 5 university hospitals, 16 central hospitals and three district hospitals. University hospitals serve their own population as referral centres for the region. The private health care sector in Finland is small, especially in the context of vascular surgical procedures.

5. Vascular registries

5.1. History

The most conclusive data on the value of a medical or surgical procedure come from randomized trials (Barnes 1989). It is, however, also important to assess the outcome of treatment in routine care, i.e. the results on a population basis which reflect the conditions for “unselected” patients (Troeng et al. 1987). To improve results in vascular surgery, it is important to evaluate earlier results and complications. This requires evaluation of various pre- and postoperative risk factors and indications for treatment, as well as an assessment of the different operative and nonoperative modalities (Jensen et al. 1992). Every vascular surgeon should be aware of own results and complication frequency and be able to compare them with certain standards. Such continuing quality control guarantees a high level of vascular surgical activity. With advances in computer technology it has become possible to carry out even large scale data storage and analysis on personal computers.

The first multisurgeon computerized registry was established in Cleveland in 1975 to monitor risks and outcomes of common vascular operations (Plecha et al. 1979). The first Nordic vascular registry, the Vascular Registry In Southern Sweden (VRISS), subsequently Swedvasc, started in Sweden at the beginning of

1987 (Troeng 1992). The aims of the Swedish registry were to monitor practice, changes in and outcomes of vascular surgery in routine care on a population basis, to safeguard a high level of data quality, to establish a basis and a starting-point for scientific studies and to develop techniques for quality development (Bergqvist et al. 1994). Later on vascular registries were also established in Norway, Denmark and Finland (Myhre 1992, Jensen et al. 1992, Salenius et al. 1992).

3.2. Finnvasc registry

Since the vascular registry in Sweden was established and commenced in 1987 the initiative was taken to form an extensive vascular registry in Finland (Salenius et al. 1992). The first Finnvasc pilot study was organized in four university clinics and four central hospitals in November 1989. After the experiences of this pilot study, regular recording of surgical and interventional procedures in vascular diseases commenced on January 1st 1991 (Salenius et al. 1992). The common Finnvasc record form was a modification of that used by Karmody and by the VRISS (Karmody et al. 1983, Karmody et al. 1984, Plecha et al. 1979, Troeng 1987). Data comprised patient's identification, procedure indication and risk factors, operation code with anatomy and possible graft materials, clinical status of patient at discharge and 30-day follow-up (Salenius et al. 1992). All data were recorded on printed paper forms and mailed to the central registry in Tampere University Hospital, where the information was fed into the computer. All vascular procedures, including endovascular procedures and access surgery, were registered. Primary amputations and surgery for varicose veins were excluded (Salenius et al. 1992). The Finnvasc registry was in function during the period 1991-1999. Thereafter Finnish legislation did not allow national medical registries, which were not fixed by law.

6. Age structure of population and projected changes in the next decades

6.1. Western countries

The older population has been expanding since the turn of the century and will continue to do so until about 2030, at which time it is expected to stabilize as a percentage of the total population (Pegels et al. 1990). The total population of England and Wales is projected to rise by 4 % between 1994 and 2034, within which the population aged 60 to 74 is projected to increase by 48 %, those aged 75 to 84 by 59 % and those aged 85 and over by 102 % (Gambrill and Wood 1996). In 1998, 12.7 % of the population in the United States was more than 65 years of age. For 2020, the projected proportion is 16.5 % and 20 % in 2035. The

projected increase in the number aged 65 and over up to the year 2020 is 56 % from the year 1998 (U.S. Census Bureau 2000). In Japan the proportion of the population over 65 years of age was 14.1 % in 1994 and the estimated proportion for the year 2020 is 25.5 %. The total increase in the number of elderly people up to the year 2020 is 85 % compared to the year 1994 (Statistic Bureau of Japan 1995).

6.2. Finland

Statistics Finland has information on the population in the past years. It also makes predictions concerning changes in the Finnish population. The latest forecasts have been made in 1998 and 2000. Forecasts are made for the whole country, but also for different subregions, the smallest unit being a single municipality. The forecasts have been calculated on the basis of assumptions of fertility and mortality.

To cover the influence of variation in fertility, the municipalities have been divided into 160 fertility areas on the basis of the total fertility rate for three previous years. Age-specific fertility rates have been calculated for each municipality group for the same years. To establish the influence of mortality, the country has been divided into three mortality areas on the basis of life expectancy by region for the three previous years. Age-specific mortality rates have been calculated for the same years. The annual mortality coefficients have been obtained by calculating how much mortality changed from the years 1981-1985 to 1992-1996 (Statistics Finland 1998).

In Finland the age structure is similar to that in other Western countries. In 2000, the population over 65 years of age was about 777 000 and comprised 15.0 % of the total population. The projected figure for 2020 is 1 217 000, 22.9 % of the projected total population. The expected increase in the number of population over 65 years of age from 2000 to 2020 is 56.7 % (Table 9).

TABLE 9

Population projection in Finland according Statistics Finland

Year	Age group			Total
	<15	15-65	>65	
2000	936333	3467584	777198	5181115
2010	851482	3501398	915069	5267949
2020	832925	3266650	1217821	5317396

7. Vascular surgical workload

Chronic lower limb ischaemia is the major indication for vascular procedures in Finland and other Scandinavian countries (Paaske 1999, Paaske 2000). At the beginning of the 1990s it was an indication for a vascular surgical or endovascular procedure in 57 % of cases in Finland (Salenius et al. 1992), 48.1 % in Sweden (Bergqvist et al. 1998) and over 50 % in Denmark (The Danish Vascular Registry 1997). The proportion of endovascular procedures in the treatment of chronic limb ischaemia has been higher in Finland than in the other Nordic countries (Paaske 1999). The greatest difference has been in the rate of percutaneous transluminal angioplasties (PTA) made below the inguinal ligament, where there was a five-fold difference between Finland and Denmark (Paaske 1999).

Carotid surgery made up 10.3 % of all vascular procedures in Finland in 1995 (Salenius et al. 1998). There was marked regional variation in the rate of carotid surgery which varied between 2.0 and 17.0 per 10^5 inhabitants between the university regions (Salenius et al. 1998). The rate of carotid endarterectomies is higher in Finland than elsewhere in Scandinavia (Paaske 1999, Salenius et al. 1998). Asymptomatic carotid stenosis was an indication for operation in 18 % of all CEAs in Finland during 1995 and in 8.1 % in the Swedvasc material from the years 1987 to 1995 (Bergqvist et al. 1998, Salenius et al. 1998).

Abdominal aortic aneurysms are the third major indication group for vascular surgery, comprising in Finland about 8 % of all procedures. The incidence has been about 6-8 per 10^5 inhabitants (Salenius et al. 1998, Paaske 1999), which is lower than in the other Nordic countries (Bergqvist et al. 1998, the Danish Vascular Registry 1997, Paaske 1999).

Two remaining notable indication groups are acute limb ischaemia and access surgery, which comprised about 9 % and 6 % respectively of the total vascular surgical workload in Finland at the beginning of 1990s (Salenius et al. 1992). Together these five indication groups (chronic lower limb ischaemia, carotid surgery, abdominal aortic aneurysms, acute limb ischaemia and access surgery) comprised over 90 % of the total vascular surgical workload in Finland in the 1990s. The number of vascular surgical procedures per 10^5 inhabitants in Denmark, Sweden and Finland are presented in table 10.

TABLE 10

Number of vascular surgical procedures per 10⁵ inhabitants in Denmark, Sweden and Finland

a. Open vascular surgical procedure for carotid artery

Authors and publication year	Study period	Denmark	Sweden	Finland
Bergqvist et al.	1998	1987-1995	6.5-12.2 ¹	
Salenius et al.	1998	1995		10.5
Paaske	1999	1997	3.0	9.1 ²
Paaske	2000	1998	3.4	
Paaske	2001	1999	3.5	10.6

b. Open vascular surgical procedure for nonspecific infrarenal aortic aneurysm

Author and publication year	Study period	Denmark	Sweden	Finland
Bergqvist et al.	1998	1987-1995	5 - 14 ¹	
Salenius et al.	1998	1995		8.0
Paaske	1999	1997	12.9	6.1 ²
Paaske	2000	1998	12.5	
Paaske	2001	1999	11.1	7.6

c. Open vascular surgical procedure for chronic lower limb ischaemia

Author and publication year	Study period	Denmark	Sweden	Finland
Salenius et al.	1998	1995		29.6
Paaske	1999	1997	35.3	28.2 ²
Paaske	2000	1998	37.7	
Paaske	2001	1999	35.0	36.0

d. Endovascular treatment chronic lower limb ischaemia

Author and publication year	Study period	Denmark	Sweden	Finland
Salenius et al.	1998	1995		31.7
Paaske	1999	1997	15.4	36.6 ²
Paaske	2000	1998	17.5	
Paaske	2001	1999	17.2	35.6

¹ Variation between Swedish health care regions

² The figure from the year 1996

8. Health economics

The costs of the health services have been a topical issue in national and international policy debates on health care in recent years. Health care expenditure (HCE) has increased constantly. The affecting factors have been the ageing of the population, the development of medical technology and changes in the epidemiology of diseases (Gerdtham et al. 1993). The continuous increase in HCE has prompted interest in the quality of health care and the cost effectiveness of health services. The growth of HCE has been most significant in the older age groups (Gerdtham 1993). In 2000, the proportion of HCE in the gross national product was 6.6 % in Finland compared to 13.0 % in the USA, 7.5 % in Norway and 8.3 % in Denmark (OECD 2002).

Vascular surgical patients are usually elderly (Trout 1997). In consequence of the changes in age structure to be anticipated in the future, the number of patients will probable increase. In peripheral vascular disease the most economical solution, in terms of overall costs, is often active treatment of the independently living patient. Luther (1997) documented the total cost of primary amputation in patients living in an institution (nursing home) or at home. He also calculated the costs of reconstructive surgery, including all the costs of both alternatives including redo surgery, surveillance and eventual later amputation. His analysis showed, that it is more economical to treat critical limb ischaemia in an independently living patient with vascular reconstruction than amputation. The additional costs per survival year over the preoperative year were 12 000 euros in the reconstruction group also embracing the amputations necessitated by failed graft, while the costs per survival year for independently living patients who underwent primary amputation were 25 000 euros ($p < 0.001$). The costs per survival year were only 7500 euros for patients who survived without amputation. The corresponding figure for institutionalized patients who underwent primary amputation was 7000 euros corresponding.

Ruptured abdominal aortic aneurysm is a lethal condition and elective treatment with the right indications prevents AAA deaths. The advantages of elective operations are obvious: the fatality is 2 - 6 % while the fatality due to ruptured AAA is 75-95 % (Kantonen et al. 1999, the UK Small Aneurysm Trial Participants 1998). Ascher and colleagues studied the outcome and costs of ruptured versus elective AAA repair in comparable groups of 10 patients. They calculated that potential average savings accruing from one patient undergoing elective AAA repair rather than ruptured AAA repair were 93 139,21 US dollars in 1993 (Ascher et al, 1999). Patel and colleagues (2000) studied the cost-effectiveness of repairing ruptured abdominal aortic aneurysms in a hypothetical cohort of 72-year-old patients with ruptured AAA either undergoing open surgical repair or with no intervention. In their base-case analysis, the repair of

ruptured AAAs was cost-effective with an incremental cost-effectiveness ratio of 19 754 US dollars. In sensitivity analysis, cost-effectiveness was influenced only by alterations in operative mortality. If the operative mortality exceeded 88 %, repair of ruptured AAAs was no longer economically justifiable.

In carotid surgery the main aim is stroke prevention. It has been concluded in large randomized multicenter studies that operation of six high-grade carotid stenoses prevents one stroke (NASCET Collaborators 1991, ECSTCG 1991). Strokes are the third leading cause of death in Western countries (Salenius and Kuukasjärvi 1997) and a prominent cause of disability. Reviews of the financial impact of stroke for a calendar year were estimated to be 41 billions direct and indirect cost in the U.S. in 1990 in terms of 1990 dollars (Taylor et al. 1996). The cost-effectiveness ratio (US dollars per QALY) of CEA for symptomatic patients with 70 % to 99 % ICA stenosis is reported to be 4 600 (Kuntz and Kent 1996). Cost-effectiveness ratios of vascular surgical procedures and common medical practices are presented in Table 11.

Differences in health care expenditure across countries are substantial, irrespective of how they are measured (Gerdtham et al. 1992). This is also true when comparing the relatively homogeneous industrialized market economies (OECD countries) (Gerdtham et al. 1992). Several regression analyses based on cross-sectional data have been used to explain the differences observed in health care expenditure across countries (Gerdtham et al. 1992, Kleiman 1974). A common result of these studies is that per capita income is statistically the most significant factor determining health care expenditure. Other explanatory variables were urbanization, share of public financing in total expenditure, share of inpatient care expenditure in total expenditure, and remuneration of doctors working in outpatient care (Gerdtham et al. 1992).

As well as internationally, there are often wide variations in health expenditure from one region to another in a given country. Häkkinen and Luoma (1995) found that in Finland the difference between municipalities in health care expenditures per capita can be over 100 %. They found the most important determinants of health care expenditure to be income level of local population, the amount of central government subsidy, allocative efficiency (the mix of care between institutional and non-institutional), productive efficiency of service providers, and factors associated with the need for services (age structure, morbidity) (Häkkinen and Luoma 1995).

TABLE 11

The cost-effectiveness ratios for common medical practices

Authors and publication year		Medical intervention	CE-ratio (\$/QALY)
Stange and Sumner	1978	Hemodialysis for end-stage renal disease	60 044 ¹
Weinstein and Stason	1982	CABG for left main disease	10 500 ¹
Kuntz and Kent	1996	CEA for symptomatic patients with 70% to 99% ICA stenosis	5 070 ¹
Kuntz and Kent	1996	CEA for asymptomatic patients with 60% to 99% ICA stenosis	64 700 ¹
Huber et al.	1997	Routine cell-saving device for hepatocellular carcinoma	133 000 ¹
Sarasin et al.	1998	Orthotopic liver transplantation for hepatocellular carcinoma	151 000 ¹
Patel et al.	2000	Open surgical repair of RAAA	11 870 ¹
Soisalo-Soininen et al.	2001	Screening for familial AAAs	6 300
Kaminota	2001	Hemodialysis for end-stage renal disease	77 000
Kaminota	2001	Kidney transplantation for end-stage renal disease (cadaveric donor transplant)	18 700
Bosch et al.	2002	Endovascular repair of AAA	9 905
Gaspoz et al.	2002	Aspirin for secondary prevention of coronary heart disease	11 000
Gaspoz et al.	2002	Clopidogrel for secondary prevention of coronary heart disease	130 000
Paniagua et al.	2002	Cardiopulmonary resuscitation after in-hospital cardiac arrest in octogenarians	63 015
deVries et al.	2002	Bypass surgery for intermittent claudication compared with exercise therapy	311 000

¹ Cost-effectiveness ratios adjusted to 2000 US dollars using the consumer price index

CE-ratio=Cost-effectiveness ratio

CABG = Coronary artery bypass grafting

CEA = Carotid endarterectomy

ICA = Internal carotid artery

QALY = Quality-adjusted life year

AIMS OF THE PRESENT STUDY

1. To define the workload of a vascular surgical unit and the major changes in it during the 1990s (I, III, IV, V, VI)
2. To estimate the influence of population changes during the next two decades on the needs of the vascular service (II, III)
3. To evaluate how the current evidence-based indications based on large multicenter studies fit with treatment (III)
4. To analyze how treatment guidelines in practice follow evidence-based guidelines based on large multicenter studies (IV)
5. To analyze the success of a vascular surgical service in offering the intended treatment (III)
6. To study regional differences in utilization of the vascular surgical service between geographically defined areas and the impact of regional differences on the outcome of critical lower limb ischaemia (VI).
7. To analyze the benefits of a vascular service (V, VI)

PATIENTS AND METHODS

1. Data sources and their reliability

1.1. Hospital registries

All patient attendances at Tampere University Hospital are recorded in the central register with information on patients' ID, domicile, referring institution and up to four diagnoses according to the International Classification of Diseases (ICD). The dates of outpatient visits or when admitted the dates of admissions and discharges are recorded. In the case of an outpatient visit, a brief reason for the visit is also recorded. The physician responsible for the care of patients during hospital stay assigns the diagnoses and corresponding ICD code of diseases. From 1967 discharges from hospitals in Finland have also been recorded in the nationwide Finnish Hospital Discharge Register (FHDR) managed by the National Research and Development Centre for Welfare and Health (STAKES, previously the National Board of Health), whose validity has been studied several times. Completeness of register data has been found to be very good and numerical data accurate (Mähönen et al. 1997) and reliable enough to be used in epidemiological studies (Leppälä et al. 1999, Mähönen et al. 1997, Rapola et al. 1997).

1.2. Cause of death registry

The Finnish cause-of-death registry is part of Statistics Finland. The death certificate contains data on patients' IC and domicile and the date, place and cause of death. The physician who treated the deceased during his/her final illness determines the diagnoses and ICD codes. The death certificate contains the immediate cause of death, the intermediate cause of death and the underlying cause of death as well as other contributing diseases. From 1983, inclusion of a short case history in the certificate has been obligatory. This abstract includes information on the death and its circumstances so as to justify all cause-of-death diagnostic and other conclusions entered in the certificate. A separate entry on autopsy must be also filled (done/not done; medical/medico legal; code for the autopsy).

The routine Finnish mortality statistics have been found to be reasonably good (Lahti and Penttilä 2001, Mähönen et al. 1999). Finland has had the highest autopsy rate in Nordic countries (Saukko 1995). In 1995 30.8 % of all entries were based on autopsy (Lahti and Penttilä 2001). In the same year 63 % of death certificates were based on examinations in hospital within specialized health care and on the whole nearly 84 % of certificates on hospital examination prior to death (Lahti and Penttilä 2001). The latter proportion rose to 90 % in the 65-74 year age group (Lahti and Penttilä 2001). Cardiovascular diseases were fairly stable as to the validation procedure, with a false positive rate of 20.2 % and false negatives 23.1 %. Net change was 3.8 % (95% CI 2.6-5.2) and was not statistically significant.

1.3. Vascular registry of Tampere University Hospital

As a part of the national Finnvasc registry, a local vascular registry has been kept in Tampere University Hospital (TAUH) from the beginning of 1990. The data collected have been identical with the Finnvasc data. The completeness of the local registry has been checked yearly by comparing the data to the anesthesia register, and missing procedures have been collected from patients' case records; data validity has not however been evaluated. The validity of the national Finnvasc register has been ascertained twice (Lepäntalo et al. 1994, Kantonen et al. 1997). In assessment of the first-year Finnvasc data quality, there was 92 % agreement for most recorded variables, with rerecording within the study (Lepäntalo et al. 1994). In the second audit, where the years 1991-1994 were assessed (Kantonen et al. 1997), data agreement was 93 %. Regarding specific variables in the registry, the risk factors were the variable most differing (85 % data agreement). The best data agreement was in surgical complications, non-surgical complications and non-vascular reoperations (95 %, 97 % and 98 % respectively). Data input error was 1.5 %.

2. Study region and population

Pirkanmaa is a hospital district with about 440 000 inhabitants and an area of 14 300 square kilometers in southern Finland. The total population increased by 4.8 % in the 1990s. The age structure is near the Finnish average. The number of the population over 65 years of age was on average 66 000 (15.0 %). The number of population over 65 years has increased by 15.6 % in the last decade.

The size of the total population in 2020 projected by Statistics Finland is 475 000 (6.2 % increase from year 2000) and the projected number of people over 65 years of age is 108 048 (53.8 % increase from the year 2000). In 2000, 15.7 % of the total population were over 65 years; the proportion will be 22.7 % in 2020 (Table 12).

TABLE 12
Population projection in Pirkanmaa according Statistics Finland

Year	Age group			Total
	<15	15-65	>65	
2000	77563	299242	70246	447051
2005	76574	305602	74764	456940
2010	73799	308782	82096	464677
2015	73240	300135	97409	470784
2020	73408	293508	108048	474964

There are 33 municipalities (34 until the year 2000) in the region, which have their own health care centres. Vascular surgical referrals from health care centres, district hospitals and the private sector come to the vascular surgical unit of TAUH, where all vascular surgical consultations and procedures take place. Also there are five district hospitals where no arterial surgery or interventions are undertaken. In the Pirkanmaa region there is no arterial surgery or interventions in the private sector. In one city, Tampere, there are vascular surgeons with private practice mostly for varicose vein surgery.

The Pirkanmaa health district is divided into 11 municipality federations, which buy health care services from Tampere University Hospital (Figure 1). The demographic information on these municipality unions is presented in Table 13.

TABLE 13

The basic data¹ from the 11 municipality unions in Pirkanmaa region

	Population, N	> 65 years, %	Urban, %	Rural, %
1	31444	14.2	68.2	31.8
2	49679	13.7	74.3	25.7
3	17967	20.4	0.0	100.0
4	21985	17.7	37.2	62.9
5	56072	12.2	94.3	5.7
6	25533	18.0	61.6	38.4
7	7421	14.9	100.0	0.0
8	13525	19.3	67.3	32.7
9	178595	14.7	100.0	0.0
10	21382	15.4	100.0	0.0
11	6255	18.8	0.0	100.0
Total	429858	15.0	81.8	18.2

¹ Average from the 1990s

Urban, % = The percentage of population living in urban environment

Rural, % = The percentage of population living in rural environment

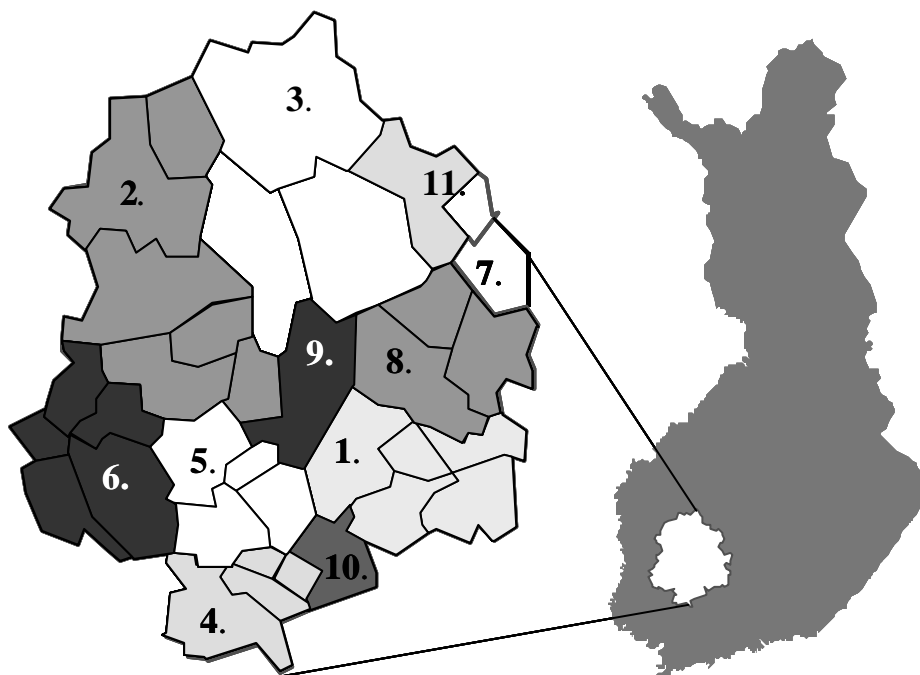


FIGURE 1. *The Pirkanmaa hospital district and the 11 municipality federations*

3. Vascular surgical procedures

3.1. Data collection

In the first study, the material in the local vascular registry for the years 1990-1997 was analyzed. Data for the years 1991-1996 were complete. Preliminary data from the years 1990 and 1997 were available. These preliminary data were checked against the hospital register data and missing procedures sought from patients' case records.

3.2. Patients

The total number of vascular procedures during the period 1990-1997 was 5019. Of these procedures, 3363 (67.0 %) were surgical and 1656 (33.0 %) endovascular. The mean age was 66.3 (SD 1.7) years and surgical patients were on average 3.5 years younger than endovascular patients, 66.3 (SD 12.7) and 65.2 (SD 13.0) years, respectively. The majority of the patients were male (60 %); in the surgical and endovascular groups the proportion of men was 66 % and 51 % respectively.

In the surgical group the elective procedures amounted to 74 % and emergency operations 26 %, in the endovascular group the corresponding figures were 87 % and 13 %. Primary procedures were performed in 87 % and secondary in 13 % of the surgical cases and in the endovascular group in 89 and 11 %, respectively.

The most common indications for a procedure were claudication (n=1367, 27.2 %), critical lower limb ischaemia (n=995, 19.8 %), supra-aortal ischaemia (n=633, 12.6 %), access surgery (n=592, 12.0 %), acute limb ischaemia (n=441, 8.8 %) and abdominal aortic aneurysm (n=432, 8.6 %). The most common surgical procedures were carotid endarterectomy (n=581, 17.2 %), reconstruction of therapeutical arteriovenous fistula (n=547, 16.2 %), open AAA reconstruction (n=413, 12.2 %), femoropopliteal bypass (n=350, 10.4 %) and aortoiliac or aortofemoral bypass for PAOD (n=186, 5.5 %). Almost half of the endovascular procedures were PTA of a stenosed arterial segment without stenting (n=765, 46.2 %), followed by recanalization and PTA of an occluded arterial segment without stenting (n=384, 23.2 %). PTA with stenting was done in 306 cases (18.4 %) and thrombolysis in 77 (4.6 %).

4. The first vascular surgical outpatient visits

4.1. Data collection

All first outpatient visits to the vascular surgical unit in the years 1990, 1992, 1994, 1996 and 1998 were selected from the central register of TAUH with information on identity code (IC), date for the visit, age, sex, reason for the consultation, diagnosis, patient's municipality and the institution the patient was referred from. Each record was checked to confirm the diagnosis for the visit. Patients were divided according to the main reason for the vascular surgical consultation into five groups: chronic lower limb ischaemia, arterial aneurysms, supra-aortal vascular diseases, venous diseases and other.

4.2. Patients

The total number of vascular surgical outpatient visits during the years 1990, 1992, 1994, 1996 and 1998 was 3802. The mean age of patients was 65.5 years (SD 13.5, range 13-96) and 55.1 % were male. The main indications for the vascular surgical consultation were chronic lower limb ischaemia (62.7 %, n=2383), venous problem (13.2 %, n=503), supra-aortic vascular problem (11.7 %, n=445) and arterial aneurysm (6.3 %, n=239). A closer evaluation was made among patients with chronic lower limb ischaemia (study VI), carotid stenosis or bruit (study IV) and abdominal aortic aneurysm (study V)

The data were subsequently supplemented with first outpatient visits due to chronic lower limb ischaemia during the years 1991, 1993, 1995, 1997 and 1999 to cover the whole decade (Study VI). Cases where the reason for the visit was claudication were excluded to reach patients with critical lower limb ischaemia. The total number of outpatient visits included was 3300. The mean age of patients was 69.0 years (SD 12.3, range 16-100) and 55.3 % were male.

5. Amputations

5.1. Data collection

All amputations performed in Pirkanmaa during the years 1990-1999 were sought from the central registries of Tampere University Hospital and five district hospitals; data noted IC, procedure codes and dates, up to four diagnoses and patient's municipality, age and sex. Each record was checked to confirm

diagnosis and amputation level. Major amputations with the diagnosis of vascular disease or diabetes were included in the study. Minor amputations, amputations due to trauma or tumour and patients from outside Pirkanmaa were excluded. IC and amputation level checking was done to prevent multiple amputations on the same leg.

5.2. Patients

After confirmation of diagnoses and amputation level, 1022 amputations were included in the study, 676 (66.1 %) above-knee and 346 (33.9 %) below-knee. The mean age of patients was 75.6 years (SD 11.1, range 32-101); 47.1 % were male. The proportion of diabetics was 27.1 %.

6. Patients' case records and cause-of-death registry

6.1. Study III

All patients operated due to RAAA during the period 1990-1999 were selected from the local Finnvasc registry. According to ICs, data were collected from patients' case records, which provided information with regard to age, sex, diameter of AAA at the time of rupture, previous examinations and imaging of AAA, as well as the 30-day outcome of the procedures.

Information on all patients who had died due to RAAA during the years 1990-1997 was obtained from the Cause-of-death registry of Statistics Finland. Data included patient's IC, date, place and all causes of death as well as the method by which the cause of death had been determined.

When calculating the RAAA incidence in Pirkanmaa, the data from the Cause-of-death and the local Finnvasc registry were combined. All patients from outside Pirkanmaa were excluded. ICs were crosschecked and one patient had only one entry into the study. Incidence was calculated as the number of new RAAAs per 10⁵ inhabitants.

6.2. Study IV

Case records of the 239 patients with arterial aneurysm were studied to reach patients with AAA. A patient was included in the study if the infrarenal aorta exceeded 2.9 cm. A total of 194 patients were included, 168 (86.6 %) men and

26 (13.4 %) women. The mean age was 70.7 (SD 7.0, range 36-88). Information was collected on all outpatient visits, hospital admissions, examinations, procedures for AAA and follow-up after procedure. Attention was paid to the management of intended treatment and the natural course of disease. According to the IC, Statistics Finland provided information on the date and causes of death until the end of August 2000. The mean follow-up was 56 months (SD 32, range 0-137).

6.3. Study V

The case records of 445 patients with supra-aortic vascular disease were studied and patients with carotid stenosis or asymptomatic carotid bruit were included in the study. The number of patients included was 400. From case records, information on all examinations and procedures for the carotid arteries as well as findings in ultrasound or carotid angiography were noted. Attention was also paid to the indications for the procedures. In 2 cases it proved impossible to obtain all the necessary information.

Indications for CEA were divided to three groups: appropriate, uncertain or inappropriate. An indication was considered appropriate for symptomatic carotid stenosis ≥ 70 %, uncertain for symptomatic 50-70 % stenosis or ≥ 60 % asymptomatic stenosis or inappropriate for < 50 % symptomatic stenosis and < 60 % asymptomatic stenosis. The degree of stenosis was assessed by angiography and measured as in NASCET. Patients with indefinite symptoms (e.g. headache, vertigo, indefinite transient disability) were considered asymptomatic.

Statistics Finland provided the information on the date and causes of death until the end of August 2000. The mean follow-up after the first outpatient visit to a vascular surgeon was 43 months (SD 22, range 0-131).

7. Projection of the workload in 2020

To make a projection on the workload of the vascular service in 2020, the mean annual incidence of the procedures in the Finnvasc registry during 1990-1997 was calculated in three age groups (<45 , 45-65 and >65). Estimation of the RAAA rate was made by calculating the annual incidences in the population at 5-year intervals. The final forecast was calculated on the basis of these incidences and population projection for the next two decades.

8. Regional differences in utilization of the vascular surgical service

The regional differences in the utilization of the vascular service were analyzed on the basis of the 3300 outpatient visits due to chronic (critical) lower limb ischaemia. Pirkanmaa was divided into 11 regions on the basis of the prevailing municipality federations (Figure 1, Table 13). The incidences of new consultations as well as the amputation incidence were calculated for each municipal union. The incidence of new consultations was defined as the number of all new outpatient visits due to chronic lower limb ischaemia to the vascular surgical unit per 10^5 inhabitants per year. The incidence of major amputations was defined as the number of all major amputations per 10^5 inhabitants per year.

To evaluate regional differences, the incidences of new consultations and major amputations were age-standardized. The total population of Pirkanmaa was used as a standard population.

To evaluate the influence of the vascular surgical service, the correlation between the incidence of new consultations and amputations was calculated in patients 15-85 years of age. Amputations for patients over 85 years of age were excluded because most of these patients are immobilized with no possibilities for vascular reconstruction.

9. Statistical analysis

Results are expressed as mean and SD. The significance of differences between groups was tested by unpaired Student's t-test. Proportions and incidences were compared by chi-square test. To assess the degree and significance of correlation, the correlation coefficient was calculated by Pearson's test. Cumulative survival was calculated using the Kaplan-Mayer method. Statistical significance for univariate analysis of differences between subgroups was determined by log rank test. Differences between incidences were tested using the chi-square test. Changes over time were evaluated by linear regression analysis. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 7.0 and 9.0. The p-values less than 0.05 were considered significant.

RESULTS

1. The workload of a vascular surgical unit and major changes in it during the 1990s

1.1. Invasive treatment

1.1.1. Surgery

The mean annual number of vascular procedures during the years 1990-1997 was 420, varying between 330 in 1990 and 538 in 1995. The mean annual incidence, as expressed in the number of procedures per 10^5 inhabitants, was 97.4. The mean age increased 3.0 years during the period, from 63.6 years (SD 13.3) to 66.6 years (SD 13.6) ($p=0.003$). The incidence of major indications and the proportions of indications in the total workload are presented in Table 14.

The most significant increase was seen in the surgical treatment of critical lower limb ischaemia: the number of procedures increased from 24 in 1990 to 72 in 1997 and the proportion of critical limb ischaemia among all surgical procedures increased from 7.3 % to 16.6 % during the eight-year period. Also the ratio of surgical vs. endovascular treatment increased constantly from 0.33 in 1990 to 1.63 in 1997 (Figure 2). The median hospital stay was 7 days (range 0-120), decreasing from 9 days in 1990 to 6 days in 1997 ($p<0.0001$).

1.1.2. Endovascular treatment

The mean annual number of endovascular procedures was 207, varying between 156 in 1997 and 255 in 1992. The mean annual incidence was 47.9 per 10^5 inhabitants. The mean age of endovascular patients was 65.2 years (SD 13.0) and did not change markedly during the study period. The incidences and proportions of main indications during the study period are presented in Table 15.

The main changes over the period were seen in the treatment of acute limb ischaemia: the number of procedures increased from 3 in 1990 to 13 in 1995. The number for critical lower limb ischaemia was at maximum in 1992, when 97

TABLE 14

*Indications for vascular surgical procedures during 1990-1997*a) Number of the procedures per 10⁵ inhabitants

	1990	1991	1992	1993	1994	1995	1996	1997	Total
AAA, nonruptured	7.1	9.8	8.6	10.5	6.5	8.7	6.4	7.5	8.1
AAA, ruptured	4.2	2.8	4.9	7.2	2.8	4.8	4.8	3.4	4.4
Acute limb ischaemia	11.8	10.1	11.4	10.5	10.9	11.3	10.1	10.2	10.8
Claudication	12.0	10.5	9.8	15.1	10.9	24.4	23.1	12.7	14.9
Critical limb ischaemia	5.6	7.5	10.7	9.1	11.3	16.8	16.0	16.4	11.7
Supra-aortal ischemia	14.4	10.8	18.0	21.1	17.4	25.1	18.3	17.1	17.8
Access surgery	13.2	14.1	14.9	14.2	14.4	18.9	26.1	20.9	17.1
Other	9.4	11.7	16.1	15.6	9.7	13.8	14.0	10.7	12.6
Total	77.7	77.3	94.5	103.2	83.8	123.8	118.7	99.0	97.4

b) Proportion (%) from the total surgical workload

	1990	1991	1992	1993	1994	1995	1996	1997	Total
AAA, nonruptured	9.1	12.7	9.1	10.1	7.7	7.1	5.4	7.6	8.4
AAA, ruptured	5.5	3.6	5.2	7.0	3.3	3.9	4.0	3.4	4.5
Acute limb ischaemia	15.2	13.0	12.1	10.1	13.0	9.1	8.5	10.3	11.1
Claudication	15.5	13.6	10.4	14.6	13.0	19.7	19.5	12.9	15.3
Critical limb ischaemia	7.3	9.7	11.4	8.8	13.5	13.6	13.5	16.6	12.0
Supra-aortal ischemia	18.5	13.9	19.0	20.5	20.7	20.3	15.4	17.2	18.3
Access surgery	17.0	18.2	15.8	13.8	17.1	15.2	22.0	21.1	17.6
Other	12.1	15.2	17.0	15.1	11.6	11.1	11.7	10.8	12.9
Total	100	100	100	100	100	100	100	100	100

AAA=Abdominal aortic aneurysm

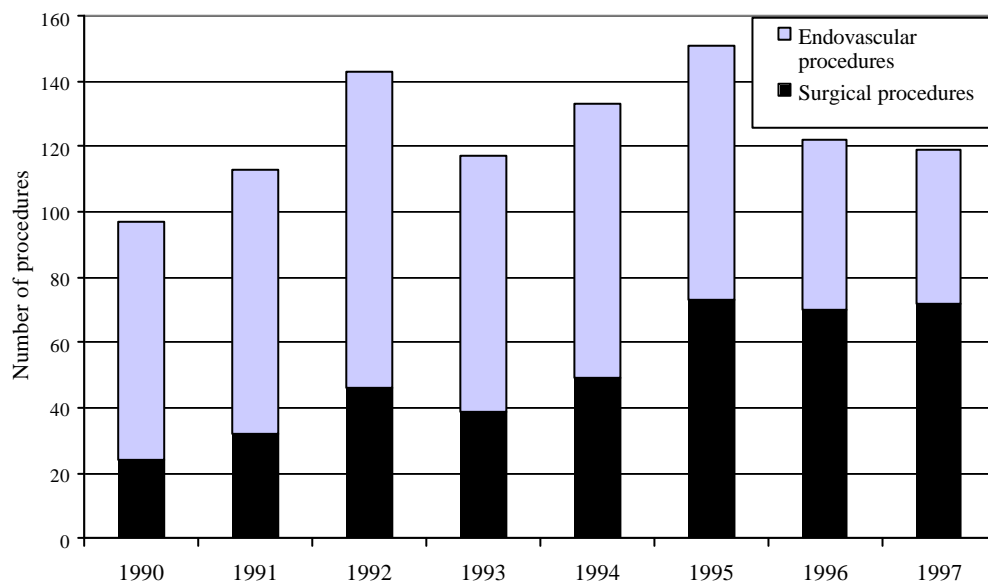
FIGURE 2. *Number of surgical and endovascular procedures in treatment of critical lower limb ischaemia during 1990-1997*

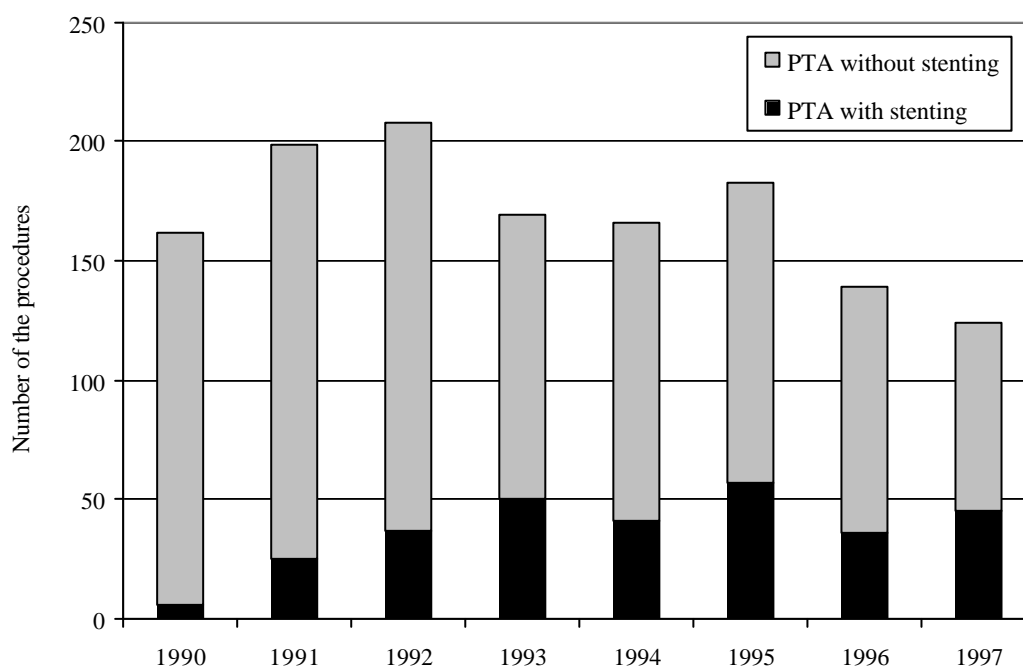
TABLE 15

*Indications for endovascular procedures during the years 1990-1997*a) Number of the procedures per 10⁵ inhabitants

	1990	1991	1992	1993	1994	1995	1996	1997	Total
Acute limb ischaemia	0.7	0.9	1.9	2.1	2.5	3.0	2.5	2.3	2.0
Claudication	25.0	30.7	30.3	22.3	21.3	27.9	22.2	18.4	24.7
Critical lower limb ischaemia	17.2	19.0	22.6	18.1	19.4	18.0	11.9	10.7	17.1
Supra-aortal ischaemia	0.9	0.5	0	0.9	0.2	0.9	0.5	0.5	0.6
Other	2.4	2.8	4.7	4.0	5.8	2.8	2.7	3.6	3.6
Total	46.1	53.9	59.5	47.4	49.3	52.5	39.8	35.5	47.9

b) Proportion (%) from the total endovascular workload

	1990	1991	1992	1993	1994	1995	1996	1997	Total
Acute limb ischaemia	1.5	1.7	3.1	4.4	5.1	5.7	6.3	6.4	4.2
Claudication	54.1	57.0	51.0	47.1	43.2	53.1	55.7	51.9	51.6
Critical lower limb ischaemia	37.2	35.2	38.0	38.2	39.4	34.2	29.9	30.1	35.6
Supra-aortal ischaemia	2.0	0.9	0	2.0	0.5	1.8	1.1	1.3	1.1
Other	5.1	5.2	7.8	8.3	11.7	5.3	6.9	10.3	7.5
Total	100	100	100	100	100	100	100	100	100

FIGURE 3. *Use of stent in percutaneous transluminal angioplasty during 1990-1997*

procedures were undertaken. Thereafter the number decreased constantly being 47 in 1997. In the endovascular treatment of chronic lower limb ischaemia, stenting gained popularity during the study period: the number of PTAs with stenting increased from 6 in 1990 to 45 in 1997 and proportion of stenting in PTAs increased from 3.7 % to 36.2 % during 1990-1997 (Figure 3). Endovascular grafting for AAA was initiated in 1997 and 10 procedures were undertaken during that year.

The median hospital stay was 2 days (range 0-56) and it decreased from 2 days to 1 day during the study period

1.2. Vascular outpatient service

The mean annual number of first outpatient visits to a vascular surgical unit was 760 and the trend was increasing during the years (Table 16). The incidence increased from 158.2 in 1992 to 192.1 in 1998 ($p<0.05$). The mean age of patients increased from 60.4 years (SD 14.3, range 22-93) to 68.5 (SD 12.7, range 15-94) ($p<0.05$).

Most significantly increased consultations due to chronic lower limb ischaemia, from 334 in 1990 to 571 in 1998. The mean annual incidence was 110.1 per 10^5 inhabitants and it increased from 78.6 in 1990 to 129.2 in 1998 ($p<0.05$) (Table 16).

The most significant change was seen in the number of patients with a venous problem, the number decreased from 207 in 1990 to 38 in 1998. The decreasing coincided with the decision at the beginning of the 1990s to transfer varicose surgery to district hospitals.

1.3. Ruptured abdominal aortic aneurysm

The mean annual number of ruptured abdominal aortic aneurysms (RAAAs) in Pirkanmaa was 26.7, varying from 24 in 1991 to 36 in 1995; 78.3 % were men ($n=173$) and 21.7 % women ($n=48$). The mean annual incidence was 6.3 per 10^5 inhabitants, ranging between 5.1 and 8.2. The incidence in males was 10.5 and in females 2.7. The male: female ratio decreased with age (Table 17).

The mean age of RAAA patients was 73.9 (SD 9.9, range 29-97). Women were 7 years older on average than men ($p<0.0001$); 111 patients (50.2 %) received operative treatment and 51 patients (23.1 %) survived.

TABLE 16

Number and incidence¹ of new vascular surgical outpatient visits in the five main groups

a) Number

	1990	1992	1994	1996	1998	Total
Arterial aneurysms	35	49	51	55	49	239
Chronic lower limb ischaemia	334	426	500	552	571	2383
Supra-aortal vascular disease	77	68	101	97	102	445
Venous disease	207	108	82	68	38	503
Other	44	27	32	40	89	232
Total	697	678	766	812	849	3802

b) Incidence

	1990	1992	1994	1996	1998	Total
Arterial aneurysms	8.2	11.4	11.8	12.6	11.1	11.0
Chronic lower limb ischaemia	78.6	99.4	115.7	126.3	129.1	110.1
Supra-aortal vascular disease	18.1	15.9	23.4	22.2	23.1	20.6
Venous disease	48.7	25.2	19.0	15.6	8.6	23.2
Other	10.4	6.3	7.4	9.2	20.1	10.7
Total	164.1	158.2	177.3	185.8	192.1	175.6

¹ Incidence expressed as the number of new outpatient visits per 10⁵ inhabitants per year

TABLE 17

Incidence¹ of ruptured abdominal aortic aneurysm in three age groups

Age	Male	Female	Total
<65	2.1	0.1	1.1
65-80	55.5	8.8	28.9
>80	138.0	28.5	57.5
Total	10.5	2.7	6.3

¹ Incidence=Number of cases per 10⁵ inhabitants per year

2. The need of the vascular surgical service in 2020

2.1. Main changes in the vascular surgical workload

The mean annual number of vascular surgical procedures was 627 during the period 1990-1997. On the basis of this figure, the projected increase in the number of vascular surgical procedures is 40.5 % up to the year 2020 (Figure 4). In the main indication groups the projected increase is as follows: claudication 35.4 %, critical limb ischaemia 44.2 %, carotid surgery 34.0 %, abdominal aortic aneurysms 40.7 %, acute limb ischaemia 45.0 % and access surgery 27.4 %.

2.2. Ruptured abdominal aortic aneurysm

According to this calculation the mean annual number of RAAAs will increase by 49.6 % up to the year 2020 compared to the mean annual amount during 1990-1997. The most significant increase will be in the age group of 65-80 years (Figure 5). The overall annual incidence in the total population will increase from 6.3 to 8.9 / 10⁵.

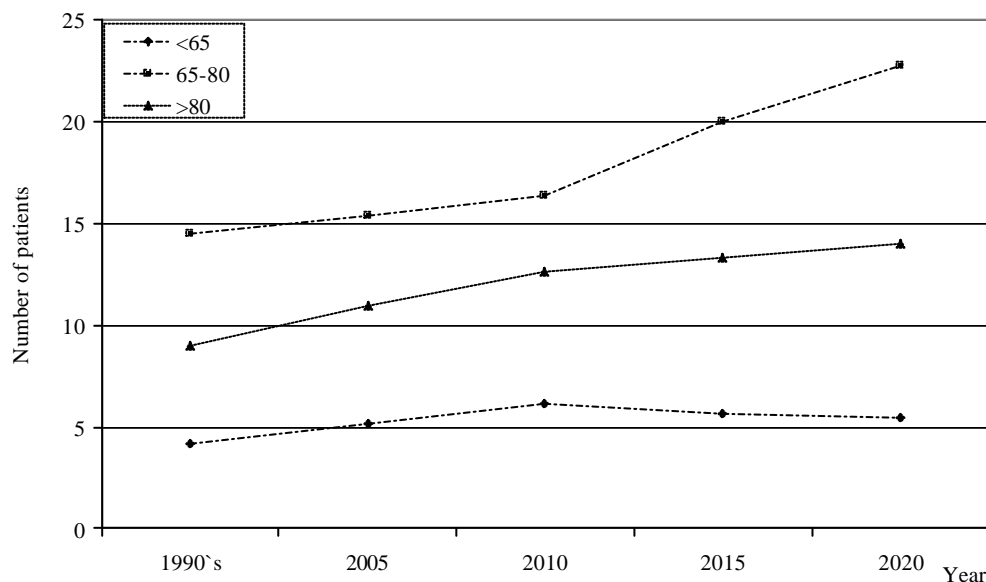


FIGURE 5. Annual number of patients with ruptured abdominal aortic aneurysm in next two decades in three age groups

3. AAA diameter at the time of rupture

During the 10-year period, 1990-1999, 166 patients were operated on for RAAA in Tampere University Hospital, 141 men (85 %) and 25 (15 %) women. Their mean age was 70.1 years (SD, range), and there was no significant difference between the genders.

The maximum diameter of AAA at the time of rupture was examined from the case records. The information was available from ultrasound scanning or computer tomogram performed preoperatively in 160 cases. The median diameter was 7 cm. There were 7 men (5.2 %) and 6 women (24.0 %) with a diameter of less than 5.5 cm, the current threshold indicator for elective surgery ($p=0.003$, Figure 6).

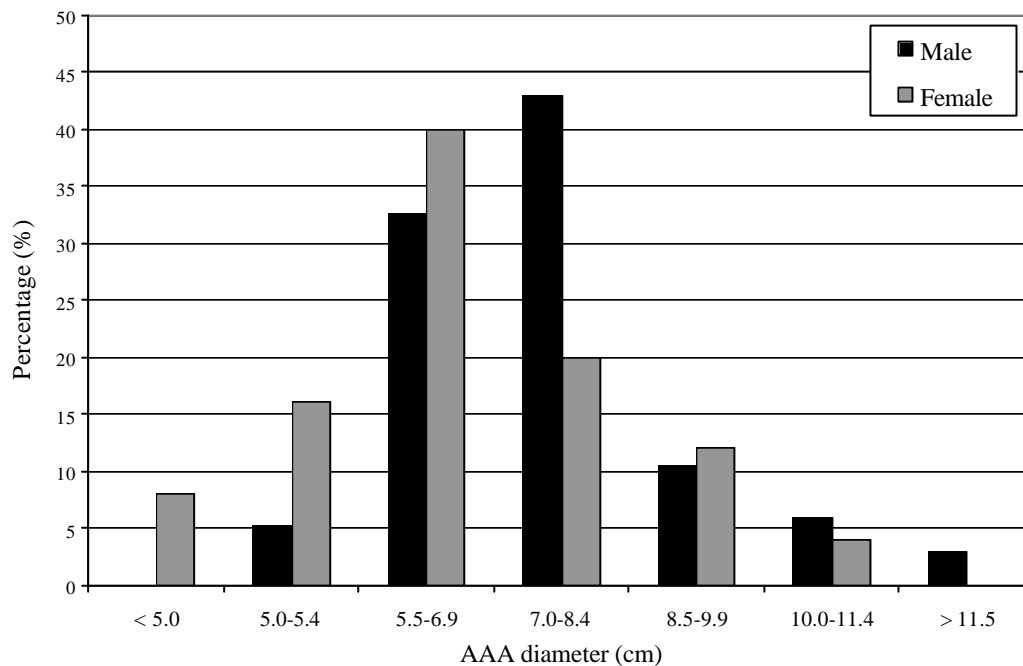


FIGURE 6. Maximal diameter of AAA at the time of rupture, proportions of sizes in both genders

4. Appropriateness of carotid surgery

Altogether totally 400 new consultations because of carotid stenosis or carotid bruit were arranged during the years 1990, 1992, 1994, 1996 and 1998. The mean annual incidence was 18.5 per 10⁵ inhabitants. Patients' mean age increased from 64.7 in 1990 to 68.9 years in 1998 (<0.05). A revision of case history was made in 398 cases. Nearly half (46.2 %, n=184) of the patients had had a carotid-related neurologic event before the consultation (stroke, TIA or amaurosis), nearly a third had had indefinite symptoms (27.9 %, n=111) and one in four patients (25.9 %, n=103) was totally asymptomatic. Angiography was performed in 280 (70.4 %) cases and 198 (49.7 %) carotid arteries were operated.

The number of carotid endarterectomies was 193. An appropriate indication was found in 31.6 (n=61) operations, uncertain in 57.0 % (n=110) and inappropriate in 11.4 % (n=22). Mostly, the uncertain and inappropriate indications concerned asymptomatic carotid stenosis (Table 18). About half of the CEA patients had originally been referred to the vascular surgical unit by a neurologist (52.8 %, n=102), while the other half (47.2 %, n=91) came from a health care centre, the private sector or other specialists in TAUH. The indication for CEA was more often appropriate if the original consultation had taken place in a neurological unit (43.1 %) compared to other referral origins (18.7 %) (p=0.002).

TABLE 18

Appropriateness of indications for carotid endarterectomy

Appropriateness	Stenosis	N	%
Appropriate	Symptomatic >70 %	61	31.6
Uncertain	Asymptomatic >60 %	72	37.3
	Symptomatic 50-70 %	38	19.7
Inappropriate	Asymptomatic <60 %	18	9.3
	Symptomatic <50 %	4	2.1
Total		193	100

N=number of patients

5. The success of the intended elective treatment of AAA

Of the 166 patients operated for RAAA in Tampere University Hospital during the period 1990-1999, 18 (10.2 %) had previously documented AAA and 9 (5.1 %) were waiting for preoperative examinations or elective procedure. One patient had waited for 2 years and it seemed obvious that there was an error in the calling system. The other 8 patients had waited between 2 weeks and 5 months (median 6 weeks).

6. Regional differences in utilization of the vascular surgical service and benefits of the service

6.1. Chronic lower limb ischaemia

6.1.1. Trends during the 1990s

The age-standardized annual number of new vascular surgical consultations varied between 62.1 and 120.1 and the trend was increasing during the last decade (Figure 7). The annual age-standardized amputation incidence ranged between 22.5 and 37.9 and the trend was clearly decreasing (Figure 7).

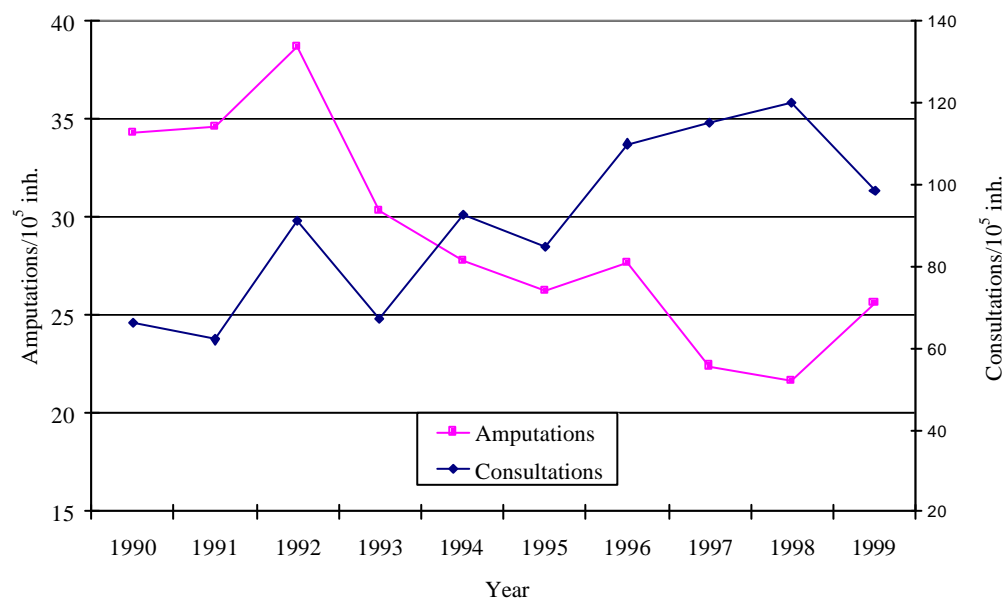


FIGURE 7. The age-standardized¹ incidence of new vascular surgical consultations and amputations during 1990s (¹Age-standardized between the years as whole population in Pirkanmaa during 1990s as standard population)

6.1.2. Regional differences in utilization of the vascular surgical service

The mean annual incidence of new consultations in the vascular surgical outpatient unit due to chronic lower limb ischaemia was 84.0 per 10⁵ in the population over 15 years of age between 1990 and 1999. In the 11 municipality federations the age-standardized incidence varied between 60.7 and 111.1 per 10⁵ inhabitants ($p < 0.001$). During the same period, the mean annual incidence of vascular major amputations was 21.3 per 10⁵ inhabitants in the total population.

6.1.3. Correlation between consultations and amputations

The mean annual consultation incidence in the age group 15-85 years was 78.0 per 10⁵ inhabitants, range 52.4-104.7 in municipality federations ($p = 0.009$). The mean annual amputation incidence in the same age group was 20.6 per 10⁵ inhabitants; the age-adjusted rate varying from 10.2 to 24.8 ($p = 0.009$). An inverse trend emerged between incidences of consultations and below-knee amputations ($R = -0.68$). In femoral amputations no such correlation was seen ($R = -0.21$) (Figure 8). The highest negative correlation was between consultation activity and amputations among diabetics' below-knee amputations ($R = -0.70$) (Figure 9).

6.2. Abdominal aortic aneurysm

Of the 194 cases referred to the vascular surgical unit due to AAA, 116 reached 5.0 cm as a maximum diameter of AAA. Of these patients, 93 were actively treated, that is, preoperative examinations were started. Twenty-three patients had too many risk factors to operative treatment or refused active treatment, which led to conservative treatment. According to the treatment mode, patients were divided into 2 groups: Intention to treat (group 1) or no intention to treat (group 2). These groups were comparable in aneurysm diameter at the beginning of follow-up (mean diameter 5.9 cm and 6.0 cm respectively). The proportion of females was 11.8 % in group 1 and 30.4 % in group 2 ($p = 0.04$) and the group 1 was 4.4 years younger than the group 2 (mean ages 70.0 and 74.3 years respectively). The cumulative 1/5/8 RAAA-rates (including mortality due to elective surgery) in groups 1 and 2 were 0.10/0.11/0.14 and 0.10/0.52/1.00 respectively (Figure 10).

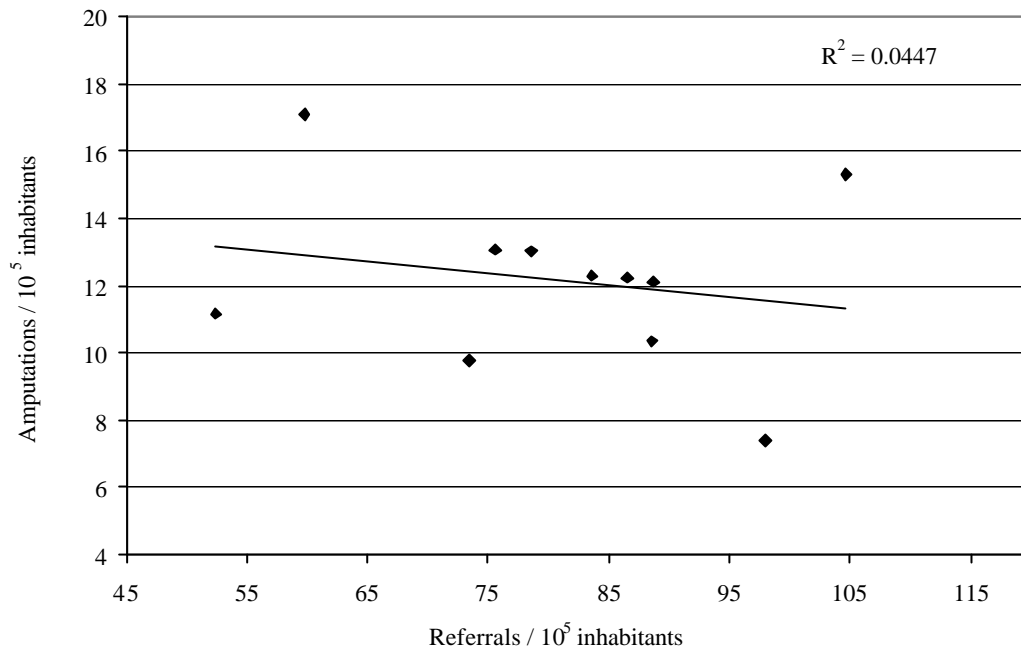


FIGURE 8. *The age-standardized annual incidences of new vascular surgical consultations and above-knee amputations among patients 15-85 years of age in the 11 regions ($R = -0.21$; $P = 0.53$)*

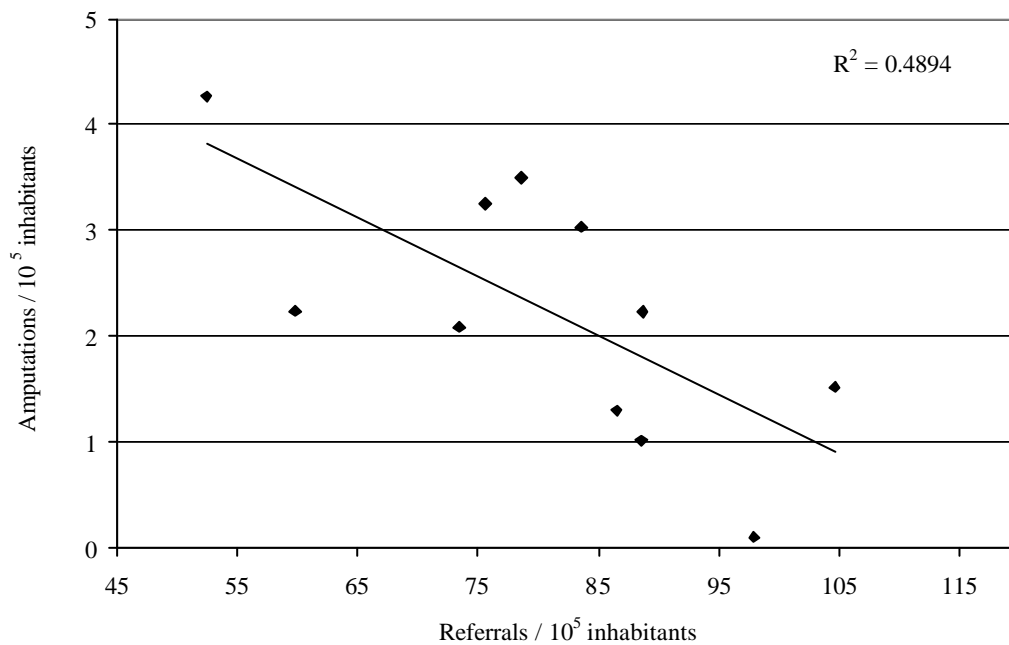


FIGURE 9. *The age-standardized annual incidences of new vascular surgical consultations and diabetics' below-knee amputations among patients 15-85 years of age in the 11 regions ($R = -0.70$; $P = 0.02$)*

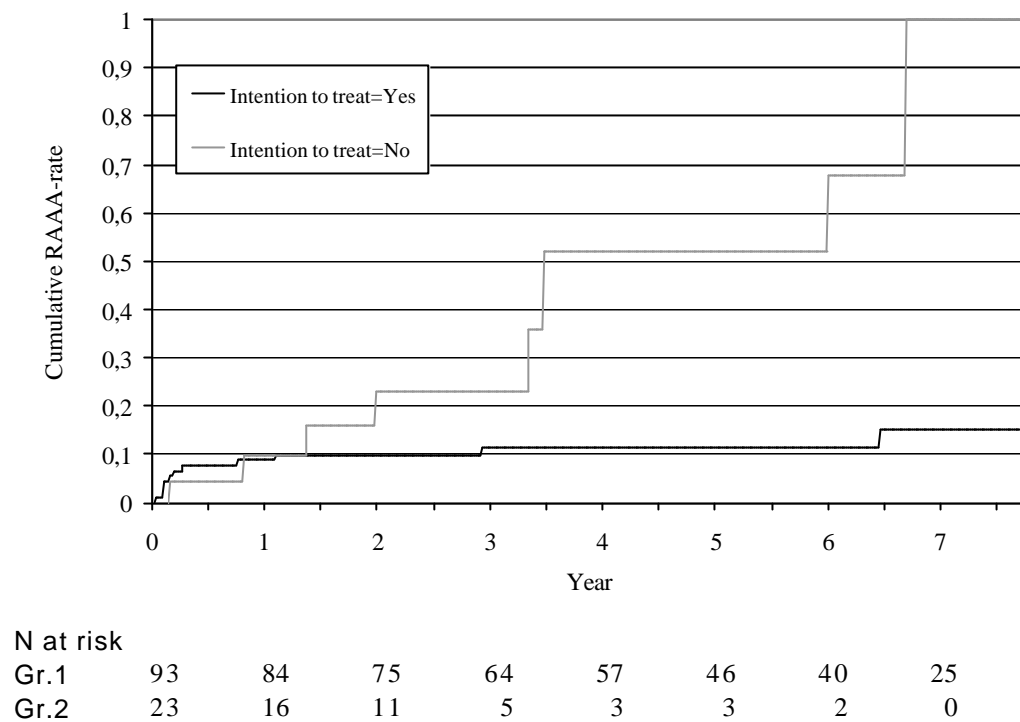


FIGURE 10. *Kaplan-Meier estimates of probable AAA rupture or postoperative death after elective repair in patients with who were actively treated or not (unfit for or refused elective repair). $P=0.001$ by the log-rank test*

¹ Includes RAAs and mortality due to elective AAA repair

DISCUSSION

1. Workload of the vascular surgical service and major changes in it during the 1990s

1.1. Limitations

The study on the workload of vascular service was based on large registries, the local Finnvasc registry and the computerized hospital registry, which gives rise to inaccuracy in results. The main problems are possible lack of information and miscoding of procedures. By merit of the annual checking system for vascular procedures, the local Finnvasc registry is highly comprehensive. Kantonen and colleagues (1999) audited the validity of the national Finnvasc registry by comparing the originally recorded Finnvasc forms and the set of recorded forms filled in later. The overall data agreement in Tampere University Hospital was over 95 %, which we consider as accepted level of accuracy in the present study. In several studies hospital registries have been assessed as reliable enough to be used in epidemiological studies (Leppälä et al. 1999, Mähönen et al. 1997). The diagnostic accuracy in vascular disease in hospital discharge registers in Finland has been found to be very high (90 – 95 %) and false positive cases are rare (Leppälä et al. 1999, Rapola et al. 1997). Also the completeness of the FHDR is very good and numerical data highly accurate (Mähönen et al. 1997).

In the study of the workload of the vascular surgical outpatient clinic, information on the private sector was not available. In Pirkanmaa there is a private vascular outpatient service in one city, Tampere. The size of this sector is relatively small and if invasive examinations or procedures are needed, patients are referred to the vascular surgical unit of TAUH. For this reason, the lack of information concerns mainly claudication patients, whose treatment has been solely conservative.

1.2. Workload in vascular surgical activity during the 1990s

The mean number of vascular procedures in the Pirkanmaa region was 145.3 per 10⁵ inhabitants and 33 % comprised endovascular procedures. Almost half of the vascular procedures (47.1 %) were for chronic lower limb ischemia. The proportion is in accordance with other Scandinavian reports from the 1990s (Bergqvist et al. 1998, the Danish Vascular Registry 1997). The

claudication/critical limb ischaemia ratio was, however, high in our material, 1.4, while in Sweden it ranged between various regions from 0.62 to 1.23 in 1987-1993 (Bergqvist et al. 1998). This difference is in fact due mostly to the high incidence of procedures for claudication in our material. The incidence of procedures for critical limb ischaemia was 28.8 per 10⁵ inhabitants in our hospital. In comparison, the incidence ranged between 11.7 and 37.0 in Swedish hospital districts according to Swedvasc. The incidence of procedures for claudication was 39.6 per 10⁵ inhabitants in our unit compared to 11.9 – 30.6 in Swedish hospital districts. On the basis of these figures we may conclude that claudication was accepted as an indication for procedure rather liberally in our region during the 1990s.

In the treatment of chronic lower limb ischaemia, the proportion of endovascular treatment has been higher in Finland than in other Nordic countries (Paaske 1999). In this study, endovascular procedures constituted 61.1 % of treatment measures for chronic lower limb ischaemia. The proportion decreased during the period from 70 % to 50 % but was still relatively high at the end of the period. In Swedvasc (1987-1996) the proportion of endovascular procedures ranged from 32.8 to 54.4 % between health care regions and in Denmark it was about 20-25 % (Bergqvist et al. 1998, the Danish Vascular Registry 1997). In Denmark, however, the absolute and relative number of endovascular procedures for lower limb ischaemia was on the increase during the years 1993-1997, being about 30 % at the end of the period. Despite this increasing trend, the proportion was clearly lower than that in our figures. One explanation behind the high proportion of endovascular procedures may be the high number of claudicants in our material: claudication is more often accepted for endovascular treatment. In Denmark the number of all PTAs to lower extremity vessels (including aorto-iliacal and peripheral PTAs) was 15.3 per 10⁵ inhabitants in 1997. In the same year, 1997, the rate of endovascular procedures undertaken for chronic lower limb ischaemia in our hospital was 29.1 per 10⁵ inhabitants; 18.7 due to claudication and 10.7 due to critical limb ischaemia.

The amount of carotid surgery has traditionally been high in our hospital, as can also be seen also in this study. The incidence of surgery for carotid stenosis was 17.4 per 10⁵ inhabitants (symptomatic stenosis 14.5 and asymptomatic stenosis 2.8 per 10⁵ inhabitants). The incidence in the whole of Finland was 9.1 in 1996 and in other Nordic countries 3.0-6.8 per 10⁵ inhabitants (Paaske 1999). The proportion of asymptomatic stenosis was relatively high in our series when compared to other units in Scandinavia. In some centres in Finland as well as in other Scandinavian countries, asymptomatic stenosis is not generally accepted at all as an indication for procedure (Salenius et al. 1998, Bergqvist et al. 1998). In Swedvasc, asymptomatic stenosis constituted 8.1 % of indications during the period 1987-1995, ranging 0-13 % between health care regions (Bergqvist et al. 1998).

A clear increase was seen in the number of first vascular surgical outpatient consultations during the 1990s. This increase was larger than could be expected on the basis of ageing of the population alone, especially in chronic lower limb ischaemia (Figure 7). During the same period a number of measures were taken to improve the vascular surgical services. In 1996 the Finnish Vascular Society was founded. A year after Michael Luther's academic dissertation, a cost benefit analysis of critical limb ischaemia, was referred to on the national television and Duodecim published a special issue on vascular surgery. These events increased the awareness of the treatment of critical lower limb ischaemia and other vascular diseases.

2. Changes in the vascular surgical workload in the next two decades

Our projection is based solely on the change in the age structure in the future assuming that indications for procedures remain stable. However, indications for procedures in fact undergo changes as new treatment methods are developed and new data from randomized clinical trials are published. During the study period, claudication and asymptomatic carotid stenosis were operated relatively frequently in our unit. Nowadays the indications are clearly stringent and our projection may be overestimated in this respect. Asymptomatic carotid stenosis is a controversial issue and at the time, debate on this issue continues. The Asymptomatic Carotid Surgery Trial (ACST) is ongoing. Its aim is to determine whether CEA and appropriate best medical treatment can improve stroke-free survival time when compared with best medical treatment alone (Halliday et al. 1994) and results of it may have an impact on the indications for asymptomatic stenosis. The benefit of surgery in symptomatic high-grade carotid stenosis has been established in randomized multicentre studies and the criteria are evidence-based.

Also the indications for AAA repair have changed in the last decade. After publication of the results of the UK Small Aneurysm Trial, the threshold for elective AAA repair was settled at 5.5 cm (The UK Small Aneurysm Trial Participants 1998). Long-term analysis, together with our study suggest however that there may be evidence for operating female AAAs earlier than at a diameter of 5.5 cm (The UK Small Aneurysm Trial Participants 2002). The indication may thus in that respect undergo changes in the future. Screening of AAAs has been under discussion during the last decade. If screening proves to be a cost-effective method in preventing RAAAs, it will change the projected RAAA incidence, but also the number of elective procedures for AAA and the need for outpatient surveillance capacity.

Critical limb ischaemia is a clear indication for a procedure in a mobile independently living patient. If techniques improve and graft materials develop, an even higher proportion of patients with critical limb ischaemia may be operated in the future.

In our projection we have not calculated or taken into consideration the trends in treatment activity during the last decade. For example the trend was clearly increasing in the operative treatment of critical lower limb ischaemia, and if this is taken into account, it would have increased the projection in this respect. On the other hand, the trend was decreasing in the endovascular treatment of critical limb ischaemia, which, if considered, would bring the projected number down from that calculated on the basis of mean volume in the 1990s alone.

Our projection is based on the population projection by Statistics Finland. Several factors affect the population and these have been taken into consideration as carefully as possible in the calculation (Statistics Finland 2001). However it inevitably contains some inaccuracy, this concerning all projections, and has to be accepted.

The influence of changes in risk factors in the future can only be speculated. The most prominent hazards are hyperlipidaemia, diabetes, hypertension and tobacco smoking. Several promising articles on lipid-lowering therapies and the impact of drugs on atherosclerotic manifestations have been published. Lipid-lowering therapy have reduced the need for PTCA/CABG in patients with abnormalities in lipid metabolism (Sacks et al.1996, Shephard et al. 1995, The Post Coronary Artery Bypass Graft Trial Investigators 1997, The Scandinavian Simvastatin Survival Study 1994). To achieve a clear reduction in the need for vascular procedures would require almost complete adherence to lipid-lowering drug therapy by all patients with atherosclerosis as well as the much larger group of individuals with asymptomatic disease. The success of lipid therapy is not complete even if the drug has been started. A rapid decrease in the prevalence of other risk factors is also unlikely. The incidence of diabetes has constantly increased (Hyppönen 2000, Podar 2001, Green 2001). Also overweight has become more common and constituted a clear risk factor for diabetes (Hyppönen 2000, Kautiainen et al. 2002).

Projections regarding the need for health care services in the next decades are scarce. Johansen and associates (1996) have estimated the increase in the overall number of patients and hospital days up to 2016. In their study the calculated increase in the number of patients was 52 % compared to the years 1990-1991 and in the number of hospital days 83 % compared to the same years. Compared to our figures these are roughly similar. In the Pirkanmaa health care region a local estimate has been made of the need for health care services in 2010 (Luoto

et al. 2002). The investigators calculated the projection with and without trends from the 1990s. In their projection, which takes consideration of trends, the need for internal inpatient visits per 1000 inhabitants will increase from 42.21 (average from the years 1997-99) to 55.18 in 2010 (increase 30.7 %) and the number of internal outpatient visits per 1000 inhabitants from 180 to 308.5 (71.4 %). The projected increase in surgical inpatient visits per 1000 inhabitants was from 55.89 to 68.78 and outpatient visits from 122.67 to 198.85 (62.1 %). The magnitude of the increase is clearly higher than in our calculation, as the trend was clearly increasing in the last decade.

The mean annual costs of vascular surgical index procedures to the municipalities, when calculated on the basis of current (year 2002) charges, were 2.20 million euros in the 1990s, which was 4.0 euros per inhabitant and 7.4 euros per inhabitant 15-64 years of age. Using the same expense values and our projection of the vascular surgical workload, the mean annual costs would be 3.04 million euros, 6.6 euros per inhabitant and 10.4 euros per inhabitant 15-64 years of age (in year 2002 euros). However, it is likely that resources in health care will not increase along with the aging population and increasing needs for health care services. Despite this, we must be able to maintain good quality in health care. This emphasizes the importance of appropriate indications for various treatment methods. If treatment is evidence-based, the patient has a right to it and no one must be left without treatment simply to save money. Usually evidence-based treatment also saves money in long term, for example carotid surgery prevent strokes and treatment of critical limb ischaemia prevents amputations, and when patient selection is appropriate, also gains economical benefit (Luther 1997). It is important to understand the relationship between cost and net economic impact. On the other hand we must be carefully when considering procedures for patients whose treatment is not evidence-based. Vascular surgery, when indications are appropriate, can reduce total costs but when used inappropriately, serves to increase costs. In our study there was a relatively large number of patients whose indication for treatment was in the so-called "grey area" or whose treatment was not indicated in terms of evidence-based treatment: the proportion of asymptomatic carotid stenosis and claudication was high when compared to other hospitals. By cutting down these procedures, considerable resources will be released for the increasing needs of other sectors. In our hospital we have instituted a projection to standardize and equalize the indications for procedures in the vascular surgical unit.

3. AAA diameter at the time of rupture

3.1. Limitations

In study III aortic diameter at time of rupture was sought retrospectively from case histories. As diameter was measured mostly by ultrasound prior to emergency surgery, there may be a certain degree of inaccuracy. Measurements were made by several radiologists and measurement methods were not standardized. Both US and CT measurements of the infrarenal aorta are subject to interobserver variability (Jaakkola et al. 1996b, Wanhainen et al. 2002). However, the median diameter was 7 cm, which correlates with that established in other studies (Reed et al. 1997) and diameters ranged at normal distribution in both women and men. All ultrasound examinations were made by a radiologist or trainee radiologist, which lends greater accuracy to the examination than when made by some other physician.

3.2. Diameter of AAA at the time of rupture and evidence-based guidelines

Results of the UK Small Aneurysm Trial published in 1998 showed reliably that ultrasonographic surveillance for small abdominal aortic aneurysms is safe, and that early surgery provide no long-term survival advantage in AAAs of 4.0-5.5 cm in diameter (The UK Small Aneurysm Trial participants 1998). In the Cochrane library this has been the only trial that has fulfilled the criteria for inclusion (Ballard et al. 2002). The guidelines for AAA treatment have not distinguished between genders, being the same for men and women. In the present study, however, we found a significant difference in AAA diameter in the rupture situation: 24 % of women were under the threshold for current evidence-based operative treatment (5.5 cm) compared to 5 % in men ($p=0.004$). A problem in AAA studies has been the small proportion of women. Since the incidence and prevalence in women is significantly lower, several studies have even been made only in men. There were 188 women in the UK Small Aneurysm Trial. The long-term analysis was recently published and attention was also paid to differences between the genders: the risk of rupture was four times as high among women than among men and the study included a considerable proportion of women (17 %), for whom the threshold of 5.5 cm in diameter for the repair of an aneurysm may have been too high (The UK Small Aneurysm Trial Participants 2002). The conclusion in the long-term analysis was that “at least for men, surveillance remains a justifiable policy until the threshold of 5.5 cm in diameter is reached”.

It is tempting to recommend a lower threshold for AAA repair in women on the basis of these results, but it remains unclear what the right threshold would

be. With these difficult questions we are again in a “grey area” of evidence. In our material the threshold of 5.0 cm in women would have covered 92 % of all cases and only 2 patients (8.0 %) would have been under the threshold for elective AAA repair. Because female AAA patients are older than men, the operative risk is also in many cases higher. The basic guideline in aneurysm surgery must be remembered: the risk of rupture must be higher than the operative risk. Large studies among women would be needed obtain answers on this. On the basis of recent findings however, we recommend that elective AAA repair be considered in women with low operative risk and long life expectancy when the AAA diameter exceeds 5.0 cm.

4. The success in realization of evidence based treatment in practice

4.1. Limitations

The study of the treatment of patients referred to the vascular surgical unit due to carotid stenosis or asymptomatic bruit was a retrospective analysis of patient case records, which implies certain limitations to the study. The treatment decision and reasons behind it were evaluated on the basis of the vascular surgeon’s notes from each visit. Nonetheless, carotid symptoms were well reported in the case records and there were usually clear notes as to whether the patient had had symptoms such as amaurosis fugax, TIA and stroke or not. Also postoperative complications were carefully reported, also if there had been none.

4.2. Evidence-based medicine in practice

The amount of information available to health care professionals is huge. To establish evidence-based medicine, it would be important to distinguish information derived from a high level of scientific evidence above other forms of information. Asymptomatic carotid stenosis has been under debate since the publication of the ACAS study and it remains a controversial issue. In the United States CEA was recommended in the guidelines of the American Heart Association for carotid endarterectomy (Moore et al.1995, Biller et al. 1998) as a proven indication for patients with asymptomatic carotid stenosis with a surgical risk <3 % and life expectancy of at least 5 years. On the other hand the guidelines of the Canadian Neurosurgical Society in the same time considered asymptomatic carotid stenosis to be an uncertain indication (Findlay et al. 1997). The enthusiasm prompted by the publication of ACAS to operate asymptomatic stenosis also came in for criticism (Barnett et al. 1996, Perry et al. 1997), above all by reason of the lack of any significant difference in the incidence of major

ipsilateral stroke or any perioperative major stroke or perioperative death between medically treated patients and surgical patients in ACAS (Barnett et al. 1996). Also the perioperative stroke and death rates were exceptionally low in ACAS (2.3 % including a 1.2 % arteriography complication rate). If the perioperative rate had been 4.5 %, no real surgical benefit would have been achieved in the first 5 years postoperatively (Barnett et al. 1996). The defenders of operative treatment of high-grade asymptomatic stenosis emphasize the importance of individual patient care. They suggest that asymptomatic stenosis should be operated in high-risk patients when operative morbidity and mortality is low (Castaldo 1999). Some of the latest guidelines, however, do not recommend automatically an operative approach to asymptomatic carotid stenosis until new data support CEA (Feasby 2000, Llinas et al. 2001, Barnett et al. 2002). The ongoing ACST study, where 3600 asymptomatic patients will be randomized, aims to clarify the indications for surgery in cases of asymptomatic carotid stenosis and help identify high-risk groups in whom the benefits of surgery and of the best medical treatment would be increased (Halliday et al. 1994).

In consequence of these controversies in the literature regarding high-grade asymptomatic carotid stenosis, the vascular surgeon in practice may have had difficulties in everyday work in creating clear guidelines and indications for surgery. We therefore defined the operative treatment of asymptomatic stenosis in our unit as uncertain. First, all guidelines, which recommend the treatment of asymptomatic high-grade carotid stenosis stress that, the combined perioperative death and stroke rate should be under 3 % (Moore et al. 1995, ECACAS 1995). It was higher in our unit, which should have prompted debate on the issue. Secondly, the published trials in the case of asymptomatic stenosis do not justify operative treatment of asymptomatic stenosis automatically in all patients. In ACAS, where the stroke rate was smaller in the surgical compared to medical group, the benefit was clearly smaller in women. The statistical methods have also been criticized; different analysis methods would have shown no clear benefit from the surgery (Barnett 1996).

About half of the CEAs in our study were done under uncertain indications for CEA (57 %) and a great number were asymptomatic. Wong and colleagues studied the appropriateness of carotid indications in Edmonton during the years 1991-1995 (Wong et al. 1997). They found an uncertain indication in 49 % of cases, and in their series too most of the patients in question were asymptomatic cases (Wong et al. 1997). They subsequently started a prospective study to determine whether the distribution and presentation of the results of the previous audit along with published practice guidelines and notification of ongoing monitoring could influence the performance of CEA in their region (Wong et al. 1999). The second study involved 185 patients during the period 1996-1997. As a result, the rate of appropriate indications rose from 33 % to 49 %, uncertain

indications did not change (49 % versus 47 %) and inappropriate indications dropped from 18 % to 4 % (Wong et al. 1999). The proportion of high-grade asymptomatic patients was still high in the second study; in fact it increased. In a third study, where 249 CEA patients in the same region in 1997-1998 were evaluated, Wong and colleagues found that the proportion of uncertain asymptomatic patients was even higher. They concluded that despite the designation CEA for asymptomatic stenosis as uncertain in the guidelines and the expression of serious concern on the part of the authorities regarding this group of patients, growing interest in operating asymptomatic patients continued (Lubkey et al. 2000).

In the present study, clearly inappropriate indications for carotid surgery were found in 11 % of patients. In the treatment of these patients there has been no controversy since the large studies mentioned: Operative treatment of asymptomatic stenosis <60 % or symptomatic <50 % is not evidence-based. On the basis of the available literature, these patients should not have undergone CEA. In retrospect it is impossible to establish the reasons for operation decisions; in many cases the patient's own wish is for surgery. In these cases the vascular surgeon's duty is to tell the facts and decide on conservative treatment. The most crucial point is that the vascular surgeon master the facts. Continuous educational meetings with discussions of the latest publications as well as the setting and revising of indications within the unit together with all vascular surgeons are important in achieving this. Wong and associates (1999) found a clear decrease in inappropriate indications in their region after attention was drawn to the issue; proportion decreased in the first step from 18 % to 4 % and in the second step to 2 % (Wong et al. 1997, Wong et al. 1999, Lubkey et al. 2000). They showed that after identifying areas of concern, an educational campaign and further prospective surveillance clearly reduced the number of inappropriate indications while increasing the use of appropriate indications.

In the present study the indication for CEA was more often appropriate if the patient came via a neurologist as against coming directly to the vascular surgeon. One reason for this is probably that patients with stroke are usually referred first to a neurological clinic and from there for vascular surgical consultation. Patients with asymptomatic carotid stenosis or bruit, in turn, are often referred primarily to a vascular surgeon from the health care centres. However, our findings emphasize the importance of co-operation between the two specialties in the treatment of ischaemic cerebrovascular disease.

5. Success in the achievement of intended treatment and comparison of treatment results

It has been estimated that about half of abdominal aortic aneurysms will expand and rupture if not electively treated (Nevitt et al. 1989). Open aortic repair however is major surgery with a mortality rate of about 5 %. Comparison of results of aortic surgery between hospitals is difficult, as patient selection has an impact on perioperative complications (Bradbury et al. 1998, Kantonen et al. 1997). In units where only healthy patients with a low-risk factor profile are operated, operative mortality and morbidity are low, but the RAAA incidence and mortality are high. On the other hand, the threshold for operative repair should be raised in high-risk patients, in view of the high operative risks: the risk of aneurysm rupture should always be higher than the mortality attending operative treatment, otherwise it will increase total mortality in the population by elective aneurysm repair. The ideal parameter for comparison of the success of elective treatment of AAAs between hospital regions would be the total number of AAA deaths in a region divided by the total number of AAAs in a region. AAA deaths should include those caused by AAA ruptures and elective surgery for AAAs. Such a parameter is, however, impossible to calculate because the total AAA rate is unknown. Moreover the prevalence of risk factors may vary between regions. Comparison of RAAA mortality in the total population is not a reliable means of measuring the success of elective treatment, as AAA incidence may vary between regions. At this time there is no easy parameter which could be reliably applied between vascular surgical units in a comparison of the results of elective treatment of AAAs.

A further reason why operative mortality is in itself insufficient in determining success in elective treatment is that it gives no indication as to how many patients in active elective treatment have actually died. Mortality among patients intended to treat also describes the availability of hospital places to achieve the intended treatment. The figure includes RAAAs under surveillance and also those emerging while waiting for elective procedure. In our material the number of such deaths was 1.7 % of all patients for whom treatment was intended. In fact the proportion of patients assigned for treatment but not attaining to an elective operation before RAAA would be a reliable figure for evaluating the quality of the vascular surgical services in terms of capacity to offer timely treatment for AAA, and such a parameter would be comparable between hospitals.

In quality control, it is important to establish the reasons underlying ruptures of aneurysms under active elective treatment. Some aneurysms may rupture before they reach the threshold for elective repair. This is acceptable if the thresholds for elective treatment are appropriate. In turn, the RAAAs emerging during long intervals prior to elective operation or due to errors in information

transfer or treatment chain are unacceptable and call for further efforts to improve the whole treatment process. The number of such deaths should be zero. In our study on all RAAA patients operated in TAUH during the 1990s, the median time from operative decision to rupture was 6 weeks. In two cases it was unacceptably high.

Although not necessarily comparable between units, operative mortality is of course an important parameter which should be continuously evaluated and compared with that in other units, with results in the literature as well as with results in the unit in question over time. If mortality is higher than in other hospitals, the reasons should be analyzed: what is the quality of pre- and postoperative care and surgical techniques, are too high-risk patients operated and what has been the aneurysm diameter in these high-risk patients. In AAA surgery likewise the appropriateness of indications can be evaluated. On the other hand, if operative mortality is extremely low, the proportion of patients excluded from elective surgery in view of high risks and the patient selection should be revised. If these are comparable with other units, a hospital can be satisfied with good results. During recent years, interest has focused on the development of audit systems standardizing patient data to allow meaningful comparison of patients undergoing operations (Prytherch et al. 1998). The Portsmouth Physiological and Operative Severity Score for enumeration of morbidity and mortality (P-POSSUM) was first developed for use in a comparative audit in a large series of general surgical patients. Later two models based on the P-POSSUM methodology (physiological and operative, and physiology only) were developed for use in vascular surgery (V-POSSUM) (Prytherch et al. 2000, Prytherch et al. 2001). These equations have accurately predicted both mortality and morbidity after arterial surgery (Earnshaw et al. 1999, Prytherch et al. 2000, Treharne et al. 1999). The models have proved useful in elective aneurysm surgery (Prytherch et al. 2001), but have nonetheless failed to fit emergency AAA repair (Prytherch et al. 2001).

6. Regional differences and benefits of vascular service

6.1. Limitations

This study was based on extensive hospital records from one university hospital and five district hospitals. As stated, information from the private sector would increase the number of vascular surgical outpatient visits, but the proportion is relatively small and concerns mostly claudication. Critical limb ischemia is treated in the university hospital and patients from the private sector are referred

there when angiography or procedures are needed. Also this study focuses on regional differences and private outpatient clinics are available to all and are not restricted to patients' domicile. Amputations are performed exclusively in the included six hospitals, none in the private sector.

The correlation between vascular surgical consultation incidence and amputation incidence was calculated in the population 15-85 years; 20.6 % of amputations were undertaken patients over 85 years. Most of the primary amputations done due to poor general status of immobilized institutionalized patients or nonreconstructable vessels are among this group. Such patients are not suitable for the vascular reconstruction and vascular surgical service cannot influence amputation among these patients. We therefore did not include these patients in order to avoid a confusing factor in the analysis. In a study by Eskelinen and colleagues (2002) the proportion of patients outside vascular reconstructions due to poor condition among all patients undergoing amputation was about 30 % and it increased from under 20 % in 1997 to over 50 % in 2000. Of course not all patients over 85 years of age are necessarily unsuitable for reconstruction and, as have been concluded by Luther, elderly patients should be considered for reconstruction if available because the results are not poorer and they usually cannot be rehabilitated to use a prosthesis (Luther and Lepäntalo 1997).

6.2. Regional differences in the use of vascular surgical services and influence of high vascular surgical consultation activity on amputation incidence

The age-adjusted regional differences in consultation activity between municipality unions were relatively high. The reason for this variation is probably multifactorial. Differences may stem from regional variation in health care policy, variations in individual physicians' threshold in referring patients further and differences in availability of health care services affected by the number of doctors in a region. There might also be regional differences in patients' threshold for seeking help in their health problems. Within the framework of the present study the reasons for differences in referral patterns remain obscure.

The proportion of urban compared to rural areas varies from 0 % to 100 % between the municipality unions in Pirkanmaa. The proportion of the population over 65 years of age is typically higher in rural areas. In the three most markedly rural municipality unions the proportion over 65 years of age varied from 17.7 to 20.4 % and in the three most urban unions the corresponding proportion ranged from 14.7 to 15.4 %. By reason of age standardization, however, the amputation incidences are comparable despite the differences in age structures between the

regions. Niemann and colleagues studied regional variation in the use of diagnostic coronary angiographies between urban and rural regions in Denmark (Niemann et al. 2000). They found angiography activity for ischaemic heart disease to be two to three times lower in rural than in urban areas ($p < 0.01$); this was the case in all age groups and both genders. In the present study no such phenomenon could be seen in referral incidences. The high proportion of rural areas in a municipality union was not associated with low consultation incidence and likewise a high level of urbanization was not associated with a high incidence in consultations. There was also no evidence that distance from the university hospital affected consultation activity; in the two most distant municipality unions the consultation incidences were above the average.

The differences in age-standardized amputation incidences were also marked, varying from 13.5 to 30.5 per 10^5 inhabitants in the population over 15 years of age. There was no association between urban or rural areas in high or low amputation incidences. High regional differences in amputation incidence have also been found in other studies: Wrobel and colleagues found an 8.6-fold variation in the lower extremity major amputation rate in diabetics and 6.7-fold in individuals without diabetes across 306 hospital referral regions (Wrobel et al. 2001). The group did not study the reasons behind this variation but speculated that the explanation might lie in systemic variations in preventive care and treatment decision-making. Luther and colleague studied regional differences in amputation rates and vascular surgical activity in Finland. Amputation incidences ranged from 14 to 33 per 10^5 inhabitants. They also found even greater variation in endovascular and surgical treatment of CLI between the regions; the incidence of arterial intervention varied between 7.2 and 35.3 and that of infrapopliteal reconstructions between 0-12.5 per 10^5 inhabitants annually (Luther et al. 1999). Their main finding was the correlation between a high incidence of infrapopliteal surgical arterial reconstructions and a low incidence of below-knee amputations (Luther et al. 1999). Similar results were seen in a Danish study, where regional vascular surgical activity, as indicated by the number of reconstructions per 10^5 inhabitants in 1990, correlated with the percentage decrease in amputation rate from 1983 to 1990. The correlation was statistically significant ($R=0.65$) (Eickhoff 1993). Michaels and colleagues compared amputation rates between regions with high and low volumes of arterial reconstructive surgery. In the high-volume areas more patients had been referred from elsewhere, they did more arterial reconstructions and had a lower amputation rate (Michaels et al. 1994). In the present study there was an inverse correlation between the rates of below-knee amputations and the first outpatient visit to the vascular surgical unit. The correlation is probably partly attributable to the leg-saving influence of vascular surgical treatment. It also underlines the importance of vascular surgical consultation in cases with critical limb ischaemia.

Of crucial importance in the treatment of critical limb ischaemia in health care centres and other institutions outside the vascular surgical clinics is that patients be referred for vascular surgical consultation, where the possibilities of vascular reconstructions are determined. Vascular surgical consultation should be undertaken within 2 weeks if a new skin lesion in diabetics shows no tendency to heal (Lepäntalo et al. 2000). In 1994 Lindholt and colleagues found that in 1986-1987 only 19 % of patients were evaluated by a vascular surgeon before amputation, and the proportion increased to 49 % in 1989-1990. In the same period the number of distal reconstructions rose by 43 % and the frequency of major amputations decreased by 25 %, from 40.9 to 30.9 per 10⁵ inhabitants annually. However, in the later study period the proportion of patients undergoing amputation without vascular surgical consultation was still relatively high. In an analysis of 50 diabetics, Bardwell and Olczak (1999) found half of the amputations to have been performed without doppler studies and angiography. Also the time of consultation is important. Severity of preoperative ischaemia influences the outcome of reconstruction and if there is extensive tissue loss, amputation is inevitable despite successful revascularization (Luther and Lepäntalo 1997). Eskelinen and colleagues found in a material of 169 lower limb major amputations that some 8 % had been referred to a vascular surgeon too late to avoid amputation despite successful revascularization (Eskelinen et al. 2001).

The proportion of diabetics decreased with age, being 40 % in patients under 65 years. The negative correlation was most evident in diabetics' below knee amputation. In diabetics, good conservative treatment and foot care is of crucial importance. A diabetic foot clinic takes care of conservative treatment of diabetics' foot problems in Tampere University Hospital. Several large clinical centres have experienced a 50 % reduction in the rate of amputations among individuals with diabetes after the implementation of improved foot care programs (Edmonds 1986). One reason for the more pronounced decrease in amputations among diabetics in the present study might have been the more forceful conservative treatment along with vascular surgical treatment in patients referred to the university hospital.

A decreasing AK/BK ratio has been held to be a sign of successful vascular surgical activity (Sayers et al. 1993). When the ratio falls, relatively fewer AK amputations and more BK amputations are undertaken. In the present study the ratio was relatively high and it did not fall during the period while the amputation rate decreased. The AK/BK amputation ratio is not an ideal indicator for success in vascular surgical activity. Previous studies as well as the present have concluded that vascular surgical activity reduces the BK amputation rate, not AK amputations (Luther 2000). It has also been surmised that the reason behind this is that AK amputations are often undertaken in cases of immobilized patients because it is the "amputation of choice" in these patients (Luther 1997, TASC 2000). Thus, if vascular surgical activity is "ideal" and comprehensive in

a region, the amount of BK amputations would be very low, while that of AK amputations would remain constant, applying specifically immobilized patients with poor health and beyond vascular surgery. Thus the ratio of AK/BK amputations would be high.

The curve for the AK/BK ratio is maybe U-shaped: at first, when vascular surgical activity commences, the ratio decreases, more BK amputations being done instead of AK amputations for mobile patients. The number of AK-amputations decreases, but that of BK amputations does not fall as rapidly or at first may even increase. Such a phenomenon was seen for example in Denmark during the period 1983 to 1990, when the percentage of AK amputations decreased in favour of more distal levels (Ebskov et al. 1994). When vascular surgical activity further increases, the number of BK amputations decreases, but the number of AK amputations reaches the “basic level” and ceases to fall. At the same time the AK/BK ratio starts to increase and reaches the maximum, when AK amputations are done basically only to patients outside vascular surgery and BK amputations are at minimum level with the maximal activity of vascular surgical service.

6.3. Elective treatment of abdominal aortic aneurysms

In study V we analyzed the cumulative RAAA rate in two groups of patients with an AAA diameter more than 5.0 cm: those who were intended for treatment and those who were not (Figure 10). The group “not intended to treat” were high-risk patients and those who declined elective treatment. With a moderate quality of elective treatment it is easy to lower the total mortality in cases of patients with large AAA, because the mortality in cases of untreated ruptured aneurysm approaches 100 %. In the ideal treatment of AAAs, the area between the survival curves presented in Figure 10 is as large as possible and the area under the lower survival curve as small as possible.

The mean size of AAA was about the same in the two groups. However, the proportion of women was higher in the group 2. Also, patients in the group 2 were mostly old patients with one or more concomitant diseases. These factors may cause that the risk of AAA rupture was basically higher in the group 2 and in that respect, the two groups are not exactly comparable. However, it is impossible to perform a study like this with two randomized groups.

CONCLUSIONS

1. Treatment of chronic lower limb ischaemia constitutes about half of the total vascular surgical workload and together with abdominal aortic aneurysms, carotid surgery, acute limb ischaemia and access surgery comprises almost 90 % of the total workload. Major changes during the 1990s were an increase in the activity of surgical treatment of critical lower limb ischaemia and a doubling of vascular surgical outpatient consultations due to chronic lower limb ischaemia.
2. According to our estimation, the need for the vascular service will increase by over 40 % during the next two decades and the most marked increase will be in the treatment of critical lower limb ischaemia.
3. Large multicentre studies may not recognize small subgroups whose evidence-based treatment may differ from the main group as exemplified by the high proportion of women with ruptured AAA and aortic diameter under 5.5 cm.
4. Implementation of evidence-based practice is difficult and its principles may be realized with a delay in the everyday practice of a vascular surgeon.
5. The vascular surgical service was able to provide the intended treatment by and large as scheduled, but unfortunately in an extensive organization the individual patient may not obtain intended treatment in an appropriate time. An evaluation of success in achieving intended treatment in the health care organization is important to ensure minimal mortality or morbidity due to underlying vascular disease among patients awaiting intended treatment.
6. There is considerable regional variation in the utilization of the vascular surgical service. A reflection of this is the variability in outcome of critical lower limb ischaemia and amputation rate between regions.
7. The vascular surgical service cuts down the number of RAAA deaths and amputations.

ACKNOWLEDGEMENTS

This study was carried out at the Department of Surgery, Tampere University Hospital and at the Medical Faculty, Tampere University during years 1997-2002

I wish to express my deepest gratitude to my supervisor, Docent Juha Salenius, M.D., for introducing me into the interesting world of vascular surgery and vascular registries. Besides scientific work, Juha has been an example of a skillfull vascular surgeon. Juha has always had time to teach, give advice and support during these years.

My sincere thanks go to Professor Markku Järvinen, M.D. and Docent Isto Nordback, M.D. Head of the Department of Surgery, Tampere University Hospital, for providing working facilities for this study.

I also thank Docent Ossi Auvinen, M.D., the previous Head of the Department of Surgery for giving me opportunity to work at the department and for support for my scientific work.

Professor Mauri Lepäntalo, M.D. and Docent Mikko Hippeläinen M.D. were the official referees of my thesis and gave me very valuable advice and constructive criticism. I really appreciate the intensive discussions with them about the current thesis. I am grateful to them for an improved manuscript.

A thesis is not a result of the work of an individual, and in this sense I owe my warmest thanks to my co-workers and co-authors, Jukka Saarinen, M.D., Velipekka Suominen, M.D., Rainer Zeitlin, M.D. and Jari Laurikka, M.D. for the constructive discussion, ideas and also for sharing and preventing the depression that is sometimes raising its head during a scientific work. I am also truly grateful to Riina Metsänoja for the help with statistical analysis.

The help of professor Arnold Miller, M.D., in careful reviewing of the manuscript is gratefully acknowledged.

I am grateful for Robert McGilleon (M.A.) for the revising the English language.

I wish to thank Jorma Hannukainen M.D., who with his extensive knowledge of vascular surgery and great skills in the art of surgery set the example which guided me into the field of surgery in the first place. Without Jorma this study would have never began.

I wish to thank the personnel in the Medical Library and the Medical Record Center in Tampere University Hospital for their practical assistance. My special thanks go to Anneli Jokela and Anneli Keinonen, whose quick help the last meters before final was of crucial importance.

Finally, I wish to express my warmest loving gratitude to my husband Mika and our children Jarna and Leevi. You are the most valuable things in my life and without your love this work would not have been successful.

The Medical Research Fund of Tampere University Hospital financially supported this study.

Permission to reproduce the original articles was kindly granted by the Finnish Surgical Society and Elsevier Science

Tampere, January 2003

Maarit Heikkinen

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