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Iatrogenic Vascular Injuries

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ACTA
UNIVERSITATIS
UPSALIENSIS
UPPSALA
2013

ISSN 1651-6206
ISBN 978-91-554-8597-9
urn:nbn:se:uu:diva-194346

Dissertation presented at Uppsala University to be publicly examined in Auditorium Minus, Museum Gustavianum, Akademigatan 3, Uppsala, Friday, April 12, 2013 at 13:00 for the degree of Doctor of Philosophy (Faculty of Medicine). The examination will be conducted in Swedish.

Abstract

Rudström, H. 2013. Iatrogenic Vascular Injuries. Acta Universitatis Upsaliensis. *Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine* 867. 63 pp. Uppsala. ISBN 978-91-554-8597-9.

Iatrogenic vascular injuries (IVIs) and injuries associated with vascular surgery can cause severe morbidity and death. The aims of this thesis were to study those injuries in the Swedish vascular registry (Swedvasc), the Swedish medical injury insurance where insurance claims are registered, the Population and Cause of death registries, and in patient records, in order to explore preventive strategies.

Among 87 IVIs during varicose vein surgery 43 were venous, mostly causing bleeding in the groin. Among 44 arterial injuries, only 1/3 were detected intraoperatively. Accidental arterial stripping predominated, with poor outcome. Four patients died, all after venous injuries.

IVIs increased over time, and constitute more than half of the vascular injuries registered in the Swedvasc. Lethal outcome was more common (4.9%) among patients suffering IVIs than among non-iatrogenic vascular injuries (2.5%). Risk factors for death were age, diabetes, renal insufficiency and obstructive lung-disease.

Fifty-two patients died within 30 days after IVI. The most common lethal IVIs were puncture during endovascular procedures (n=24, 46%), penetrating trauma during open surgery (11) and occlusion after compression (6). Symptoms were peripheral ischemia (n=19), external bleeding (14), and hypovolemic chock without external bleeding (10). Most died within two weeks (n=36, 69%). After >2 weeks the IVI as a cause of death was uncertain.

Among 193 insurance claims after vascular surgery during 2002-2007, nerve injuries (91) and wound infections (22) dominated. Most patients suffered permanent injuries, three died. Patients with insurance claims were correctly registered in the Swedvasc in 82%.

In 32 cases of popliteal artery injury during knee arthroplasty symptoms were bleeding (n=14), ischaemia (n=7) and false aneurysm formation (n=11). Only twelve injuries (38%) were detected intraoperatively. Patency at 30 days was 97%, but only seven (22%) patients had complete recovery. Six of those had intraoperative diagnosis of popliteal injury and immediate vascular repair.

In conclusion, registration of IVIs is increasing and outcome is often negatively affected by diagnostic and therapeutic delay. Not all fatalities after IVIs are attributable to the injury itself. The most common causes of insurance claims after vascular surgery were nerve injuries, and 82% were correctly registered in Swedvasc.

Keywords: vascular injuries, vascular surgery, vascular trauma, injury, medical error, patient safety, postoperative death, postoperative mortality, patient insurance, varicose vein

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ISSN 1651-6206
ISBN 978-91-554-8597-9
urn:nbn:se:uu:diva-194346 (http://urn.kb.se/resolve?urn=urn:nbn:se:uu:diva-194346)

To Julia and Malte

List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

I Rudström H, Björck M, Bergqvist D. Iatrogenic vascular injuries in varicose vein surgery: a systematic review. World J Surg 2006;30:1-6.

II Rudström H, Bergqvist D, Ögren M, and Björck M. Iatrogenic Vascular Injuries in Sweden. A Nationwide Study 1987-2005. Eur J Vasc Endovasc Surg 2008;35:131-138.

III Rudström H, Bergqvist D, Ahlberg J, Björck M. Insurance Claims after Vascular Surgery in Sweden. Eur J Vasc Endovasc Surg 2011;42:498-505.

IV Rudström H, Bergqvist D, Björck M. Iatrogenic vascular injuries with lethal outcome. (Submitted manuscript)

V Bernhoff K, Rudström H, Gedeborg R, Björck M. Popliteal artery injury in knee arthroplasty - a population based, nationwide study. (Submitted manuscript)

Contents

Abbreviations

AAA	Abdominal Aortic Aneurysm
AE	Adverse Event
CCMI	The County Councils Mutual Insurance Company, The Swedish Patient Insurance (in Swedish: Landstingens Ömsesidiga Försäkringsbolag, LÖF)
EA	Endarterectomy
IVI	Iatrogenic Vascular Injury
KA	Knee arthroplasty
NBHW	National Board of Health an Welfare
NPR	National Population Registry
PAI	Popliteal artery injury
PAOD	Peripheral arterial occlusive disease
SMII	Swedish Medical Injury Insurance (in Swedish: Patientskaderegleringen, PSR)
Swedvasc	The Swedish Vascular Registry
Vv	Varicose vein

Introduction

Primum non nocere, the Latin for "First, do no harm", have for long been an important aim when treating patients. A close approximation to this phrase can be found in the Hippocratic Corpus "to help, or at least do no harm". However, acts with good intentions may have unwanted consequences: all types of acts, decisions (or lack of decisions), medical or surgical interventions, and nursing might cause unwanted effects, or even injury.

Advances in medicine have created numerous invasive methods for diagnosis, treatment, or monitoring, and an increasing number of patients are being exposed to these techniques and consequently, to risk of complications. Health care providers must always consider the possibility of harm that any intervention might cause compared to the potential benefit. This means there are always calculated risks and costs of an intervention. Thus, in the optimal planning of diagnostic procedures and treatments, health care providers need to be aware of the risks and hazards involved.

All complications, adverse events (AE) and medical errors are potentially harmful, represent a failure, and should be kept to a minimum. Complications due to omission or failure to follow accepted practice or an AE due to substandard care should not be accepted, and continuous prevention strategies and active quality policies are required to avoid such events. These kind of adverse events are potentially avoidable and should be kept to a minimum, and their non-existence is a hypothetic goal. However, avoidable, unpredictable complications render treatment planning with risk calculation difficult, or even impossible.

An examination of the cause and outcome of AE after healthcare interventions will assist in the development of prevention strategies to minimise the frequency and severity of patient injuries. Therefore, the first step in creating more effective and safe care systems is the identification of an AE or a pattern of events.

A special group of iatrogenic injuries affect the vascular system and are associated with vascular surgery (open and endovascular interventions). Iatrogenic vascular injuries may cause severe morbidity and even death. Besides individual suffering, iatrogenic injuries cause additional cost to the health care system, and long- term community costs secondary to permanent disability (Persson 2005). Data on vascular trauma from civilian experiences (non-war) are dominated by injuries of iatrogenic origin (Bergqvist1984; Bergentz 1989; Golledge 1995; Pongratz 2011). However, for civilian vascu-

lar trauma, there is international variation in the proportions of iatrogenic vascular trauma and the difference between countries probably reflects the incidence of violence in the societies studied (Fingerhut 2002; Risberg 1996).

Epidemiology

The nature of iatrogenic injuries in healthcare was not well recognised until the last decades of the 20th century. In the mid-1980s, the American Society of Anaesthesiologists initiated a number of programs, one of which was the Closed Claims Project, to improve patient safety and prevent anaesthetic injuries (Cheney 1999). The situation needed reforming due to the increasing cost of liability claims. The Harvard Medical Practice Study in 1991 revealed an iatrogenic injury rate of 3.7% in hospital admissions in the USA (Brennan 1991). The Quality in Australian Health Care Study (QAHCS) reported that 16.6% of hospital admissions were associated with an iatrogenic patient injury. The high incidence of iatrogenic injuries indicated that morbidity due to healthcare is a public health problem, and the lack of sufficient patient safety is unlikely to be a problem confined to Australia and the United States (Vincent 1999, Wilson 1995). In a British study (Vincent 2001), the incidence of adverse events was 10.8% of all admissions in two hospitals in the London area: the incidence was higher in general surgery (14.1%) than in general medicine (8%) and obstetrics (7%). About half of the AEs were considered preventable with current standard of care.

In the UK, the most common cause of litigation claims after general surgery is AE after varicose vein (Vv) surgery (Campbell 2002), with nerve injury being the dominating cause of complaint (Markides 2008). Vessel injury is a less common but serious complication of Vv surgery; when it occurs, it often causes severe morbidity (Liddicoat 1975; Tennant 1995; Critchley 1997; Frings 2001).

Iatrogenic vascular injuries

Although iatrogenic vascular injuries (IVI) are considered rare, there are reports of increasing IVI incidence, which represents an important cause of vascular trauma (Bergqvist 1987; Golledge 1995; Fingerhut 2002; Giswold 2004). The increase in incidence appears associated with the introduction of percutaneous transluminal angioplasty (PTA) and cardiac catheterisation (Bergqvist 1987; Lazarides 1998). The number of endovascular procedures increases each year (Bergqvist 1997), and with the improved materials and devices and growing experience, there is an accompanying widening range of indications. However, the increasing numbers of percutaneous endovascular procedures performed may reflect the increasing number of complica-

tions, especially at the access site (Oweida 1990; Nehler 1998). Vascular injuries from peripheral endovascular procedures requiring open surgery range between 1% and 4% of all injuries (Bolia 2005), and the frequently used closure devices do not appear to decrease the frequency of angiographic access site complications (Koreny 2004; Meyerson 2002).

Vascular injuries in orthopaedic surgery were reported as early as in the 1950s (Ross 1951) during both open meniscectomy and operations for femoral fracture (Stein 1956). Vascular injuries during knee arthroplasty have also been reported (Calligaro 2003; Holmberg 1996; Rush 1987): popliteal artery injuries can be dramatic and are potentially dangerous due to poor collateral circulation around the knee joint. Abdominal surgical procedures such as in surgery for intestinal malignancy or in gynaecologic pelvic operations with close topographic relation to important vessels are also potential causes of iatrogenic vascular injuries.

In Sweden during the period 1986 to 1990, Jonung et al (1995) estimated 20% of all vascular injuries to be IVI; however, the incidence of IVIs in Sweden is uncertain and the outcome is not well established.

Symptoms and Diagnosis

An IVI can occur at any time and without warning during various types of interventions, and usually requires urgent management. The injuries can manifest through a wide range of symptoms, which are expected to be known by a vascular surgeon, such as open or closed bleedings, thrombosis, or an intimal flap dissection with impaired circulation and ischemic signs from the affected organ or limb. In cases of arterial damage with a self-limiting bleeding, a false aneurysm (pseudoaneurysm) might form because of counter pressure in the surrounding tissues. The symptoms of an IVI can initially be mild with a risk of diagnostic delay. In injuries with open bleeding or with acute severe ischemia, the diagnosis is often obvious. Local symptoms can be an expanding, painful mass, accompanied with symptoms of nerve compression, such as anaesthesia or paralysis. The long-term sequelae can be chronic ischemia, pseudoaneurysm, or arterio-venous fistulae.

Treatment and Prevention

At some stage, a surgeon will be confronted with an iatrogenic vascular injury or a severe adverse event. If the surgeon is not familiar with vascular problems, assistance and advice from a vascular surgeon is required. The reduction in frequency and severity of both AEs and IVIs through prevention, timely recognition, and adequate treatment is fundamental; however, the treatment strategy and surgical approach will vary depending on the type

and location of the injury. Such a preventive strategy can only be successful if high-risk medical and surgical interventions and patients with a high risk of AE are identified. Increased knowledge of IVIs and AEs in vascular surgery among health care personnel, especially in the different fields of surgery, is essential for good risk management and safe clinical practice. Consequently, several questions are frequently raised, including whether there are common patterns or specific anatomic areas that are dominant, where patients with IVI come from and how they can be treated, and whether it is possible to improve outcome.

Sources of data

There are different methods for identifying and studying AEs and injuries within health care and different possible sources of data. The Swedish vascular registry, Swedvasc, has been used in various studies, and could be a potential source of data for identifying and analysing IVIs. Since 1994, the registry has had nationwide coverage, and the unique personal identification number can be used with the Swedish population registry to determine the exact date of death. Other methods, used in previous international studies, are analyses of malpractice claims and litigation claims. Patient injury claims can offer rich data, and Sweden has a unique system of a national, no blame, patient insurance system. After review by medical experts, patients in Sweden are entitled to compensation from the County Councils' Mutual Insurance Company (LÖF) for injuries received due to medical error. The Mutual Insurance Company receives around 9000 claims each year (County Councils' Mutual Insurance Company's annual report 2009). All files are saved and categorised by speciality; however, these registries have not previously been used for analysing AEs in vascular surgery or IVIs. Another national Swedish reporting system, HSAN (Malpractice Inspectorate) and Lex Maria, collects information about medical errors that cause injury to patients. This system forms part of negligence monitoring of health care personnel, and the register contains malpractice reports and communication between the authorities, the claimant, and the care provider. HSAN processes around 6000 cases each year, however, as part of a punitive system, it is probably highly selective with claims being biased by severity (Vincent 2006). Since January 2011 patients can complain or report errors to the National Board of Health and Welfare. Focus after that has changed from a punitive system towards a system of analysis and investigation of the care process, together with the involved care providers, in order to prevent similar events in the future.

Terms and Definitions

Adverse Event	injury or complication or a non-desirable outcome caused by the healthcare delivered, rather than by the disease from which the patient suffered. While all adverse events result from medical management, not all are preventable and due to medical error.
Close Call	a medical error not leading to an injury or adverse event. Is synonymous to sentinel event or near mishap.
Iatrogenic	injury caused by the healthcare system. It originates from the Greek word for the art of healing –iatreia.
Medical Error	a failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error of planning). Errors can happen in all stages in the process of care, from diagnosis, to treatment, to nursing and caring.
Preventable	an error in management or accident due to the failure to follow accepted practice and expected performance at an individual or system level.
Safe care	freedom from accidental injury and non-preventable adverse events kept at a minimum.

Aims of the thesis

The overall aim of the investigation was to characterize iatrogenic vascular injuries and serious complications after vascular surgery, in Sweden, and to identify preventive strategies.
The specific aims were:

To investigate the nature and consequences of deep vascular injuries during varicose vein surgery based on a systematic literature review (Study I)

To study the epidemiology, anatomic distribution and time trends of vascular injuries with emphasis on iatrogenic vascular injuries, in relation to the vascular surgery volume, reported to the Swedvasc registry (Study II)

To investigate factors associated with the outcome of IVIs registered in the Swedvasc (Study II)

To estimate the incidence and causes of adverse events, leading to insurance claims for injury, in relation to vascular surgery in Sweden (Study III)

To validate the registration of SMII cases of vascular surgery in Swedvasc (Study III)

To characterize IVIs with lethal outcome and evaluate the relationship between IVIs and postoperative mortality (Study IV)

To describe the mechanisms behind popliteal artery injuries during knee arthroplasty, to identify risk factors associated with adverse outcome, and identify preventive strategies (Study V)

Material and Methods

Study I

This analysis of severe iatrogenic vascular complications during varicose vein surgery is based on 81 cases identified in international medical publications. A systematic literature research was performed in the Medline/PubMed identifying papers dealing with varicose vein surgery and complications. Search terms such as varicose vein, surgery, vascular injuries and complications were used, in combinations. Papers in English, French, German, and the Scandinavian languages published after 1945 were scrutinized, as were their reference lists to identify further possible articles of interest. The long time period was chosen to gain maximum number of case reports. There have not been any great advances or variations in Vv surgery, prior the recently introduced endovenous heat treatments (Endovenous laser and radiofrequency). The papers identified were of two types: papers briefly dealing with vascular complications in series of varicose vein surgery and papers with more detailed case reports of vascular injuries. A structured protocol was designed before the review, and filled in retrospectively with variables such as injury mechanism, anatomic location, patient characteristics, symptoms of vascular injury, time to diagnosis and to repair, type of repair and outcome.

Study II

This analysis of vascular injuries, due to iatrogenic or non-iatrogenic trauma, was based on Swedvasc data. No attempts were made to retrieve complete case-records from the various hospitals. A total of 138 289 open vascular or endovascular surgical procedures were reported to the Swedvasc during the period of January 1987 until December 2005 (by March 2006). Of these were 1793 registered with vascular trauma as indication for surgery and after exclusion of cases with incorrect personal identification numbers or duplicates.

Vascular trauma is classified as iatrogenic and non-iatrogenic according the mechanism of injury, and non-iatrogenic trauma is subdivided into blunt or penetrating trauma. Subgroup analyses were performed based on these three trauma mechanisms, furthermore on gender, age, time-period, survi-

vors (i.e. no date of death within 30 days after surgery), anatomic distribution and type of repair.

Mortality data (date of death) were obtained by cross-reference to the Swedish Population Register, with follow up until 5th of November 2006, by using the unique personal identity code (with permission from the national data-security authority). This results in complete data for survival and making it possible to analyse long-term survival.

Co-morbidities and risk factors such as hypertension, diabetes mellitus, chronic obstructive pulmonary disease, cerebral vascular disease, renal disease, former vascular surgery or amputation due to peripheral ischemia are registered at the primary operation for the vascular injury according to the Swedvasc protocol. Other variables registered prospectively are vascular segments involved among arterial injuries (not for vein or graft injuries), type of operation and graft, survival and complications.

The incidence was estimated from January 1994 when Swedvasc reached national coverage. The following 12 years until December 2005 were divided in 3 four-year periods. Time trends in incidence and crude numbers were analysed between these time intervals. We considered the increasing population of Sweden, from 8 816 000 in January 1994 to 9 053 000 in January 2006.

Study III

In this study we analysed injuries and adverse events (AE) related to vascular surgery, leading to an insurance claim (IC). All ICs related to vascular surgery reported to the Swedish Medical Injury Insurance (SMII) from January 2002 to the end of December 2007 were included. A total of 193 cases of preventable and non-preventable AE were identified during the study period. All medical records and documentation sent to the SMII for each case and the SMIIs closed decision were collected. The material was reviewed and coded in a structured protocol for type of procedure and disease, type of injury and adverse event, the cause of injury and injury claim, as well as the outcome of the injury. The cases from the SMII were cross-matched with Swedvasc through the unique personal identification number used in both databases, and could therefore be put in relation to vascular surgery in Sweden and cases of core vascular surgery missing in Swedvasc could be identified. During the 6-year study period 58,358 cases were registered in Swedvasc. Varicose vein surgery is not reported to the registry. The reviewer (a specialist in general and vascular surgery) needed access to all information and was therefore not blinded to the final outcome.

Study IV

This study of IVIs with lethal outcome within 30 days is based on case records, death certificates and registry data (the Swedvasc registry, the Swedish population registry and the Swedish registry of cause of death). Similar to Study II the subjects were identified through the Swedvasc, and included all cases registered with iatrogenic trauma as indication for vascular surgery 1987 - May 2008 (n=1084). Complications after open and endovascular vascular surgery should be registered as complications and not as IVIs in the Swedvasc, according to the instructions of the registry. When such a procedure is performed by a radiologist, however, some vascular surgical departments do register it as an IVI, others as a complication. When the endovascular procedure is performed on a non-vascular surgical patient, such as a cardiology patient undergoing a PCI, all injuries are registered as IVIs.

By crosschecking the unique personal identification number from the Swedish Vascular Registry with the Swedish Population Registry all patients who died within 30 days after surgery (n= 56) were identified and of these were 52 (93%) case-records retrieved from various hospitals. Death certificates were collected from the Swedish registry of cause of death (the Swedish Board of Health and Welfare). Clinical data were obtained from medical records, the Swedvasc registry, the Swedish population registry, and the Cause of death registry as well as from death certificates.

Analyses were performed about the mechanism of injury, and who inflicted the vascular injury repaired by a vascular surgeon. When scrutinizing the case records we could evaluate if the death was directly related to the registered iatrogenic vascular injury or if death was more related to the disease from which the patient suffered previous to the injury or AE, rather than by the injury itself. It was also possible to evaluate if the injury was an avoidable consequence of the treatment or care process. The death certificates revealed if the cause of death was established by an autopsy or not.

Study V

In this study we focused on iatrogenic injuries of the popliteal artery during orthopaedic knee arthroplasty. Clinical data were obtained from the Swedvasc registry, the LÖF registry and patients case records. The Swedish vascular registry (Swedvasc) was searched for iatrogenic injuries at the popliteal artery segment, i.e. surgery on the segments with registered right or left sided in-flow and out-flow between the common femoral artery and calf arteries (n=114). These cases were checked if they had an orthopaedic case report at their local hospitals by cross checking their unique personal number. The national Swedish patient insurance, LÖF (former County Councils' Mutual Insurance Company) database of orthopaedic surgery was searched

as well, by ICD-10 for popliteal artery injury and knee arthroplasty (n=4). Cases identified in the Swedish patient insurance registry were all except one identified in Swedvasc. In total, 115 unique iatrogenic popliteal artery injuries were identified between 1987-2011. It was possible to analyse 110 patients (95.7%) where case-records could be retrieved. Among those 110 patients, 53 patients suffered iatrogenic popliteal artery injury during orthopaedic surgery, 32 injuries in 32 patients were associated with knee arthroplasty. Prospective data from the databases was supplemented with retrospectively analysed case-records.

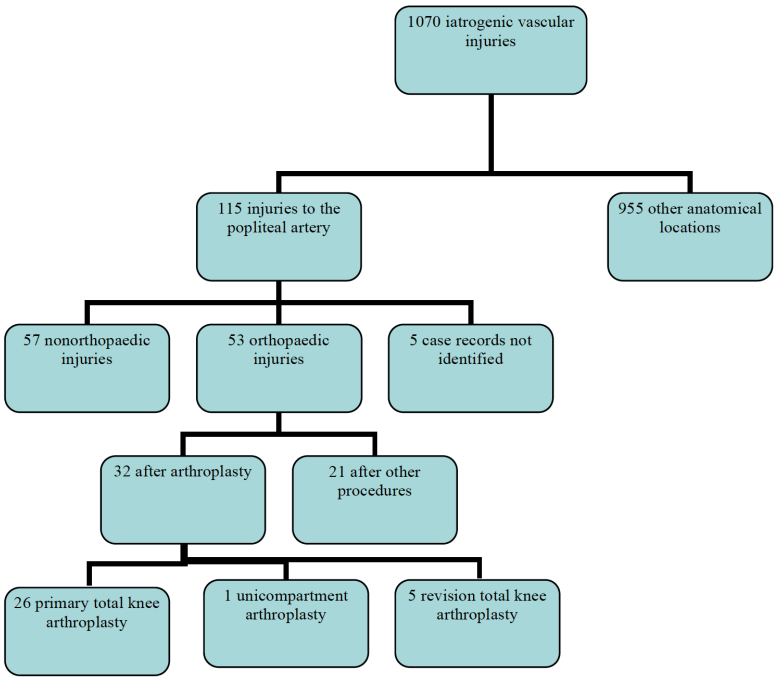


Figure 1. Retrieval of cases

Both orthopaedic and vascular surgical case-records were analyzed according to the mechanism of injury, time to detection, time and method to restore the circulation, use of tourniquet and outcome.

Long-term survival was obtained by cross matching the patients' unique personal identification number with the Swedish Population Registry (On January 7, 2013).

Comments

In Study I we analyse severe vascular injuries associated with varicose vein (Vv) surgery. This is a very rare complication and even large centres of Vv surgery might never encounter this AE in a prospective study. To capture these exceptionally rare but dreaded AEs we used a systematic review of literature and case reports. The majority of identified papers were case reports, forming a cohort. It is essential to remember that there is likely to be a substantial underreporting and there is no possibility to assess the incidence, when the population at risk is unknown.

In Study II, IV and V an iatrogenic vascular injury was defined as a major vessel injury inflicted by the health care, needing an open or endovascular repair involving a vascular surgeon or interventionist, thus being eligible for reporting to the Swedvasc. This definition of IVIs excludes patients who die before arrival of the vascular surgeon, or if she/he is not contacted at all.

In study III the incidence of insurance claims relates largely to routine and frequently performed surgical procedures, but it is possible to assess the incidence of claims on vascular surgery registered in Swedvasc and identify high-risk procedures for insurance claims in validated core vascular surgery. Rare complications are difficult to study prospectively or by retrospective medical record review, even from multiple institutions. To study the closed claims of the SMII therefore provides an effective approach to data collection on injuries that occur in many different institutions.

However, not all IC in vascular surgery and Vv surgery reflect medical negligence. There is also a possibility of underreporting. Minor events are not reported, but might still be a substantial economic burden for the health care system due to their frequency in routine clinical care. Inadequate knowledge about the insurance system might also influence the frequency of claims. Another limitation of claim analyses is that data in claim files are for legal purposes and lack important medical variables. In SMII, however, which is not a punitive system, the full medical records are available.

County Councils' Mutual Insurance Company

In cases of malpractice and complications associated with substandard care, patients in Sweden are entitled to compensation from the County Councils' Mutual Insurance Company, the Patient Insurance (Patientförsäkringen LÖF) under the Patients Injury Act (Patientskadelagen 1996:799). The Patient Insurance turns over approximately 1 billion SEK per year. The Swedish Medical Injury Insurance (SMII) (PSR in Swedish) is responsible for the entire investigation (until 2010-01-01, after that included in the responsibility of LÖF) and collates all medical documents and case records. The SMII receives approx 9000 insurance claims per year. Medical experts re-

view all claims and if the expert opinions advise that the standard of care is inferior to that expected, or there was a failure to adhere to accepted practice, and which resulted in the patient suffering harm, economic compensation is paid. About 45% of all insurance claims are considered to represent preventable injuries, and the claimant receives economic compensation (The Patient Insurance annual report 2009, Persson 2005).

The Database of the SMII is organised by specialty, type of surgery associated with the claim and complication. Since 2010-01-01 SMII is a part of County Councils Mutual Insurance Company.

Swedvasc

The Swedish vascular registry, Swedvasc, started in 1987. Since 1994 all 42 hospitals performing vascular surgery in Sweden participate and the registry has a nationwide coverage. Responsible surgeons, or in some centres specially trained staff members, register the hospital, procedures, and patient specific data, such as comorbidities, risk factors and 30-day follow-up. Every procedure needs registration of an indication and the indications of vascular injury is subdivided into iatrogenic, blunt and penetrating trauma. The registry has been the main source of data in several previous studies (Kragsterman 2004, Mani 2009).

The Swedvasc has been internally and externally validated and compared with the In-Patient Registry, used for reimbursement, showing that the reporting rate of core vascular surgery is higher than 90 percent and with great validity of data. The follow-up rate at 30 days also exceeds 90 percent (Björck 2002, Kragsterman 2006, Ravn 2007, Wanhainen 2008, Troëng 2008).

Definition of risk factors in the Swedvasc registry and in Studies II, IV and V

- Diabetes mellitus; treatment with diet, oral medication or insulin
- Cerebrovascular disease; present or previous neurological events such as stroke, TIA, RIND or amaurosis fugax
- Obstructive lung disease; Asthma or Chronic Obstructive Pulmonary Disease (COPD)
- Hypertension; medication or diastolic blood-pressure >110 mmHg
- Cardiac disease; history of cardiac operation, myocardial infarction, heart failure, angina pectoris, atrial fibrillation or signs of ischemia on ECG
- Previous vascular surgery; open or endovascular procedure or amputation due to peripheral ischemia

- Renal insufficiency; serum creatinine >150 µmol/l
- Smoking; a well-known risk factor for future health problems, but it is difficult to obtain valid data from the patients regarding their smoking habits by interview only, biochemical verification is needed. It is also poorly registered with a high proportion of missing values. Thus, we decided to exclude data on smoking in all our analyses.

Statistical analyses

Statistical analyses were performed in SPSS Statistics 17.0-19.0 (SPSS Inc., Chicago, IL, USA). Data are presented as numbers and proportions (%), mean and median values. In the evaluation of preoperative risk factors for 30-day outcome, and differences between cohorts, proportions were compared by the chi-square test and expressed in terms of odds ratios with 95% confidence intervals (study II, study III). Distributions were first tested with Levene's test for equality of variances, and if symmetrically distributed, compared by two-tailed Student's t-test. Long-term survival rates were compared using the Kaplan-Meier method, the generalised Wilcoxon test for univariate analyses and Cox regression analysis for multivariate models. The anatomic distribution in arterial injury cases and arterial surgery overall was compared by indirect standardisation to overall rates, with expression of standardised morbidity ratios (SMRs) between observed number of vascular injury cases involving each anatomical site, and the expected number based on the overall vascular injury percentage and the number of vascular surgery cases involving that site, for the three indications studied.

SMI = n Observed surgery injuries / n Expected injuries, where n Expected injuries = (n total surgery specific anatomic segment / n Swedvasc total) x n Injuries total.

Ethical considerations

The individuals participating in these studies were not informed and most likely would not have benefitted from being reminded of the injury or adverse outcome. In the application of Ethical approval we argued that they might even suffer from us asking them about informed consent to review their charts. We also argued that the importance of this investigation to prevent future IVIs and AEs was so great that it was almost unethical not to investigate. The Research Ethics Committee accepted this position. However, according to the rules of the Swedvasc informed consent is required from all patients prior to registration, with the exception of fatal cases, which are

exempted. Individuals could not be identified in published papers and identity in data files was erased and replaced with a case number. Concerning the lethal cases, we considered contacting relatives to the deceased as a new psycho-emotional trauma and creating discomfort by sad memories and trespassing integrity.

In these studies data were analysed, with the permission granted by the Steering Committee of the Swedvasc. The ethical considerations for studies II-V were presented to the Research Ethics Committee of the Uppsala/Örebro Health Care region, which approved the studies II-V.

Results

Study I

In Study I we analysed reported iatrogenic vascular injuries in varicose vein surgery, identified in a literature review. A total of 50 papers were identified (40 papers after 1970). Of these were 46 papers detailed case reports of 81 patients with 87 iatrogenic vascular injuries. Of the 36 patients where age was given, the median age was 37 (range18–69) years. In Table 1 the types of the 87 injuries are shown. More than one injury was described in 6 patients: two had bilateral arterial injury, one had bilateral vein injury, and three had combined arterial and venous injury.

Table 1. Type of vascular injury complicating varicose vein surgery

Type of injury		Number
Venous injuries		**43**
	Laceration of the femoral vein	14
	Ligation of the femoral vein	4
	Division of the femoral vein	13
	Stripping of the femoral vein	4
	Resection of the femoral vein	2
	Laceration of the popliteal vein	4
	Stripping of the popliteal vein	1
	Resection of the popliteal vein	1
Arterial injuries		**44**
	Crushing of the femoral artery	4
	Division of the femoral artery	14
	Rupture of the femoral artery	1
	Incision in the femoral artery	2
	Resection of the femoral artery	6
	Stripping of the femoral artery	17
Total: all injuries		**87**

Diagnostic delay

Of the 87 cases, the injury was detected at the varicose vein operation in 41 (47%), usually because of bleeding problems. In 36 (41%) there was a diagnostic delay and in the remaining 10 (12%) cases, there was no information on time to diagnosis, Table 2. Especially in cases with arterial injury causing ischemia, there was often a diagnostic delay, with misinterpretation of the

symptoms and signs of ischemia. Only 13/44 (30%) arterial injuries were detected preoperatively compared with 28/43 venous injuries (65%). Seven cases escaped in-hospital detection.

Table 2. Time to diagnosis

	Number
Peroperatively	41 (47%)
Within eight hours	14 (16%)
More than 12 hours	22 (25%)
Unclear time to diagnosis	10 (12%)

Treatment

Treatment varied from none (n=13), venous ligature (n=5), suture (n=12), to reconstructive solutions (n=54). None treatment was especially in the earlier years in the case of ischemia, or ligation in case of bleeding. In later time more complex reconstructive solutions appear, including distal by-pass with the stripped or the contralateral great saphenous vein or a synthetic graft, both on the arterial and venous sides. The surgical treatments are summarized in table 3.

Table 3. Surgical treatment of iatrogenic vascular injuries in varicose vein surgery

Type of repair	**Number**
Venous injuries	
Suture	9
Patch	3
Venous ligature	5
Venous end-to-end anastomosis	6
Venous bypass	12
Unclear	3
No treatment	5
Subtotal: all venous injuries	43
Arterial injuries	
Suture	3
Patch	2
Arterial end-to-end anastomosis	6
Arterial bypass	23
Unclear	2
No treatment	8
Subtotal: all arterial injuries	44
Total: all injuries	87

Follow-up

In 20 (25%) patients there was no follow-up mentioned making it difficult to evaluate the long-term results. In 22 (27%) patients there was a follow up during the hospital stay only. In the remaining 38 (47%) patients the follow up varied from 1-6 months (19 patients), 7-12 months (6 patients) and more than 12 months (14 patients).

Of the 22 patients who were followed up during the hospital stay, 15 were amputated and four were dead. All four cases of vascular injuries with lethal outcome had a vascular injury on the deep venous system. Of the 30 patients with venous reconstructions with follow-up after discharge (range 3–60 months), 10 developed severe deep vein thrombosis or post-thrombotic syndrome. In patients with deep vein injury during disconnection between the short saphenous vein and the popliteal vein, the risk of developing post-thrombotic syndrome was even higher (3/3).

In the subgroup of inadvertent arterial stripping (n=17), five patients (30%) went to major amputation. If the arterial stripping included an artery distal to the superficial femoral artery (n=11) only two (18%) were without severe morbidity (i.e. major amputation, pareses, toe amputation, atrophic muscles, or occluded graft). Both patients with favourable outcome had the earliest diagnosis and reoperation (< 8 hours) in the group (median 13 hours, range 6–216).

Comments

This report is mainly based on case reports, and most likely biased towards dramatic injuries and arterial injuries. Thus the incidence could not be estimated given that the number of patients at risk is unknown, and underreporting must be suspected. The largest prospective study (Frings 2001) could identify only seven venous injuries and no arterial injury among nearly 40,000 varicose vein operations, revealing that deep vascular injuries are rare and indicating venous injuries out number arterial injuries.

Study II

In study II the epidemiology of vascular injuries registered in the Swedvasc, with special focus on Iatrogenic Vascular Injuries (IVIs) and time-trends was analyzed.

A total of 1853 open or endovascular operations in 1791 patients with the indication of vascular injury were registered in the Swedvasc 1987 to 2005. Of the1853 vascular injuries 888 (48%) were caused by IVIs in 856 patients, and of the 965 non-iatrogenic injuries (non-IVIs), 530 (55%) were caused by penetrating and 435 (45%) by blunt trauma, 514 and 421 patients respectively.

The average number of vascular injuries increased from 87 in 1994 to 180 in 2005. The proportion caused by iatrogenic trauma increased, from 41% during the 4-year-period 1994-1997 to 51% 2002-2005, figure 2. While the number of annually registered procedures was stable during this 12-year period, the proportion of procedures for IVI increased from 0.57 to 0.79% from the first to the last 4-year period, table 4.

The average annual incidence of vascular injury was 1.2 per 100 000 inhabitants during 1994-1997 and increased to 1.6 per 100 000 inhabitants 2002-2005.

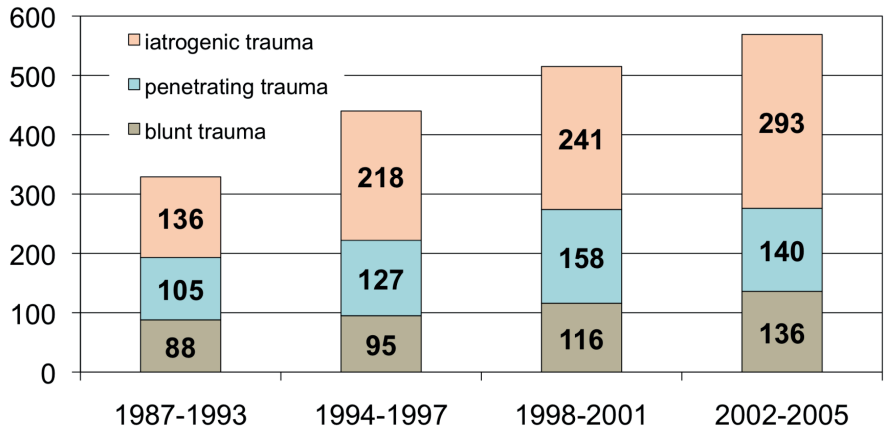


Figure 2. Vascular injuries (1853 cases) depending on type of trauma during four time periods.

Table 4 Proportion of vascular surgery caused by iatrogenic vascular injuries.

	Registered procedures of vascular surgery overall	IVI	%
1987-1993*	23830	136	0.57
1994-1997	38912	218	0.56
1998-2001	38246	241	0.63
2002-2005	37301	293	0.79
Total	138289	888	0.64

*Not yet national coverage

Patient characteristics

In the group of patients suffering iatrogenic vascular injuries the gender distribution was balanced (49% men), but men predominated among non-IVIs (76%). Median age among patients suffering IVIs was 68 years (range 3-92), compared to the median age of non-IVIs, 36 years (range 0-97).

The rates of co-morbidities among patients with IVI were cardiac disease in 58%, hypertension in 44%, and renal dysfunction (creatinine > 150 mmol/l) in 18%.

Anatomic distribution of injuries

Of the 888 procedures for IVI 768 (86%) were arterial compared to 96% of the 965 procedures for non-IVIs. The anatomic distribution of arterial IVIs is illustrated in Figure 3.

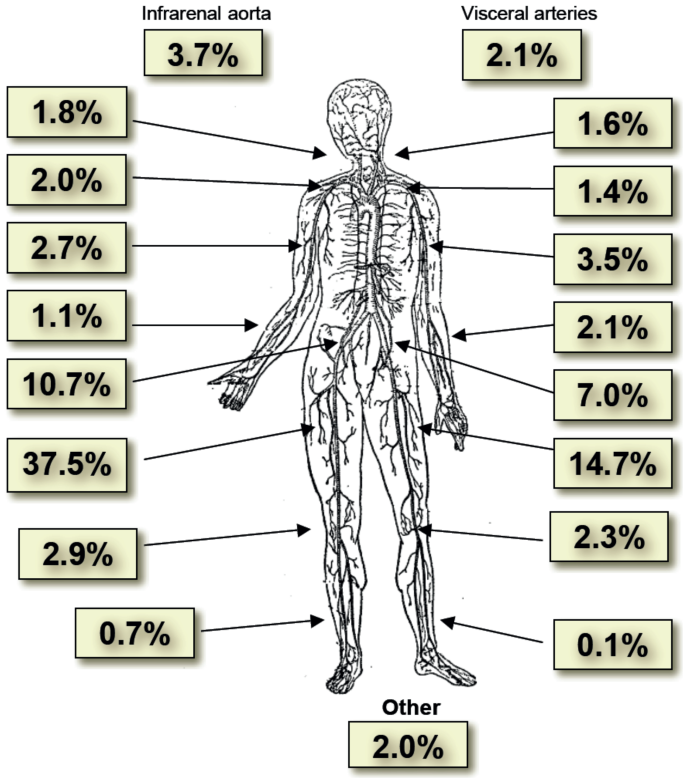


Figure 3. Sites of arterial iatrogenic vascular injuries, in total 768 cases.

I order to evaluate differences in the anatomic distribution between arterial surgery due to vascular injuries and arterial surgery overall in the Swedvasc a Standardised morbidity ratio (SMR) was used. The difference between observed and expected number of cases on involved arterial segments was calculated. The arterial segment with the highest SMR of vascular injuries overall was the vertebral artery (SMR=15.0). Among the iatrogenic vascular injuries the vertebral (SMR=6.5), the subclavian/axillary (SMR=3.2), the internal iliac (SMR=2.5) and the visceral (SMR=2.0) arteries had the highest SMR.

Type of vascular repair

Emergency repair was performed in 75% of the IVIs and in 93% of the non-IVIs.

Among IVIs the most common surgical procedure was direct suture repair of the vessel (39%), followed by bypass or interposition graft (19%), thrombo-embolectomy (11%), endovascular repair (9%), exploration only (8%), patch angioplasty (6%) and direct repair with end-to-end anastomosis (3%). When reconstruction was performed with a bypass, interposition graft or a patch, prosthetic material (61% PTFE) was used in 150 (55%), vein in 108 (39%) and composite grafts in 16 (6%) cases. Endovascular repair increased during the study-period: from 4.6% (1994-1997) to 15% (2002-2005) (Table 5).

Table 5. Endovascular repair of IVIs

	PTA	Stent	Stentgraft	Trombolysis	of total IVIs	%
1987-1993*	4				139	2.9%
1994-1997	10				217	4.6%
1998-2001	21		1	1	241	9.5%
2002-2005	24	9	8	4	294	15%

* Not yet national coverage

Outcome

After 30 days 110 patients (13%) of the 846 patients with IVIs still were hospitalized and 42 (4.9%) were dead. The patients who died within 30 days were older and had more comorbidities than survivors (Table 6) and it was more common with an IVI on an abdominal or a cervical artery than a peripheral artery injury ($p=0.0016$, OR=2.9, 95% CI: 1.5-5.6).

The most common surgical complications were bleeding, wound infection and graft occlusion (5-6%). The patients with early fatal outcome had a worse patency of their vascular reconstructions with a higher occlusion rate (7/38) than among survivors (36/754, $p < 0.001$). At 30 days 66 cases (8%) were lost to follow-up with respect to complications. There were no lost cases in survival data due to the unique personal identification code and cross check with the Swedish population registry.

Table 6. Co-morbidities and risk-factors for 30-day mortality

Co-morbidity	N°. at risk*	N°. (%) with co-morbidity survivors	N°. (%) with co-morbidity non-survivors	OR	P**
Diabetes mellitus	648	97 (16%)	11 (37%)	3.1 (1.5-6.5)	0.003
Renal impairment	669	106 (17%)	14 (44%)	3.9 (2.0-7.7)	<0.001
COPD[1]	640	55 (9%)	7 (23%)	2.9 (1.3-6.9)	0.013
Age > 68	849	376 (47%)	29 (69%)	2.6 (1.3-4.9)	0.004
Cardiac disease	722	397 (58%)	24 (65%)		0.41
Hypertension	643	267 (44%)	16 (52%)		0.38
Previous v.s.[2]	699	268 (40%)	15 (46%)		0.55
Male gender	852	388 (48%)	20 (47%)		0.97

* N° at risk is the number of patients with data regarding this particular risk-factor, which was missing in a proportion of cases. **$\chi 2$ –test comparing cases with lethal outcome within 30 days. [1] Chronic obstructive pulmonary disease; [2] vascular surgery

An association between co-morbidities and long-term mortality among IVIs was found. Diabetes, previous vascular surgery and renal impairment appeared to be risk factors, independent of age and other co-morbidities.

There were no differences in 30-day mortality and long-term survival between teaching hospitals and county hospitals, after adjustments for age.

Comments

This study is based on data from the Swedvasc registry. The registry has a national coverage since 1994 and is validated in core vascular surgery like abdominal aortic aneurysm repair and carotid artery endarterectomises, but vascular surgical repairs of iatrogenic vascular injuries have not previously been specifically validated. There might be a risk of inferior registration of vascular surgery in patients suffering IVI, but there is no obvious reason to believe that complex vascular repair due to IVI should be registered less often than core vascular surgery.

The study misses vascular injuries not requiring repair by a surgeon reporting to the Swedvasc registry or an injury not requiring repair by open surgery or endovascular interventions. For example, most false aneurysms, occurring as a result of femoral artery puncture for endovascular access today, are treated with ultrasound guided compression and/or injection of recombinant thrombin, procedures not always reported to the Swedvasc. For these reasons it is possible to calculate the incidence of IVIs (and non-IVIs) in the Swedvasc registry, but it is uncertain to state the total incidences of vascular injuries in Sweden.

In Swedeheart, the Swedish registry of coronary angiography and interventions, bleedings in the access site (puncture of the femoral or the radial artery) are registered. In 2011 bleeding or vascular complication affected 576 (4.4%) cases of PCI, but only 13 surgical procedures and 47 treatments

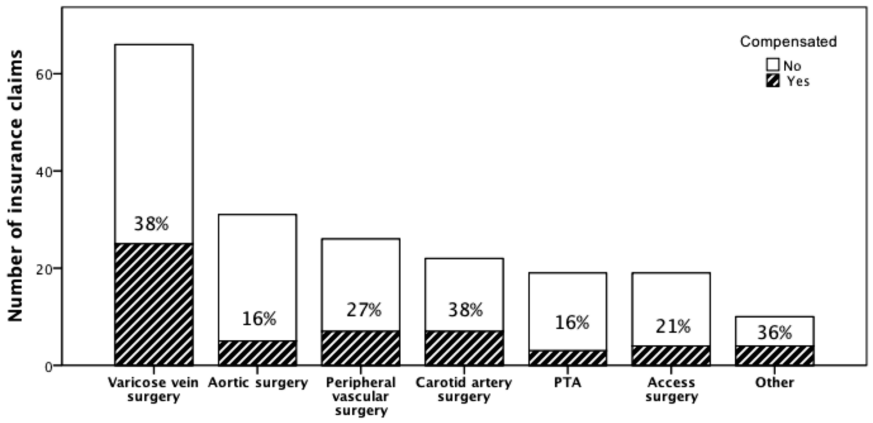
beside compression due to bleeding in puncture site were reported to the registry (Swedeheart annual report 2011). Injections of recombinant thrombin are most likely included among these cases, but there is a risk of under reporting. In 2008, 28 patients needed a surgical procedure due to bleeding. During this time period the puncture of the radial artery increased from 32% (2008) to 67% (2011), which probably decrease the need for surgical repair of the puncture site.

Study III

In study III cases with AEs in association with vascular surgery, resulting in insurance claims were analyzed. A total of 193 cases were identified. There was no time trend in the incidence of claims over the study period. The injuries and AE led to reoperations (23%), prolonged hospital stay (23%), medical treatment (13%), follow-up in outpatient clinic (29%) or no further action (12%).

Type of procedures

Both open and endovascular procedures were involved in the claims. Only six (5%) AEs were secondary to emergent surgery, the remaining were elective procedures during daytime. The types of procedures involved in claims are presented in figure 4.



Figur 4. Number of insurance claims related to type of procedure and proportion receiving economical compensation for damage 2002-2007 (Aortic surgery: open and endovascular surgery, PTA: percutan transluminal angioplasty).

The dominating AEs were 75 (39%) peripheral nerve injuries, 27 (15%) infections (22 wound and 5 graft infections) and 18 (9%) cranial nerve injuries.

Fifty-five (28%) of the claims resulted in economic compensation for injury and suffering, the proportion of patients receiving economic compensation varies between the types surgical procedure. Varicose vein surgery accounted for more than one-third of the insurance costs, followed by aortic surgery of descending thoracic or infra-renal aorta, with open or endovascular technique. Carotid artery surgery had the highest annual incidence of economically compensated claims per number of procedures (Table 7).

The mean time from claim to final notification was 9 months (range 7-49 months, standard deviation 9.4).

Table 7. Annual incidence of claims per type of procedure

Type of procedure	N° of claims/yr	N° of procedures/yr	Claim incidence	Incidence of accepted claims
Varicose vein surgery	11	6145	0.18%	1:1475
Aortic surgery	3.6	983	0.37%	1:1180
PVS*	4.2	3095	0.14%	1:2653
Carotid artery surgery	3.5	866	0.4%	1:650
PTA**	3.2	3158	0.1%	1:6316

Aortic surgery: open and endovascular, *peripheral vascular surgery, **percutaneous transluminal angioplasty

Varicose vein surgery

The largest group of claims (32%) was related to the treatment of varicose-veins. In 15 patients (23%) the indication for surgery was skin changes with active ulcers or healed ulcers (CEAP 4 or more). Operation techniques were high ligation and resection of the great saphenous vein (n = 33), the small saphenous vein (n = 12) and stab phlebectomies (n = 15).

Aortic surgery

Treatment for aortic diseases was the second largest group (31/193, 16%). In 22 of 31 cases the indication for surgery was aneurysm of the abdominal aorta (AAA), eight cases of the thoracic descending aorta (TAA) and one case of aorto-occlusive disease. Endovascular techniques were used in four of the 22 AAA and five of the eight TAA.

Twenty-one (68%) patients suffered permanent injury. Ischemic and neurological complications were the main complaints.

There were five cases of spinal ischaemia with paraparesis of the lower extremities. No one had hypovolemic chock or aneurysm rupture. One received spinal protection prior surgery.

Peripheral vascular surgery

A total of 26 cases had open peripheral vascular surgery. Most frequent complex procedures were femoro-poplitean bypass (n=10) and femoro-distal bypass (n=4). Indications for surgery were critical limb ischaemia (n=13), severe claudication (seven), peripheral aneurysm (three), embolus (two), and one failing graft. The most common AEs in this group were nerve injuries (eight), and infections (seven).

Carotid artery surgery

Twenty-one patients underwent carotid artery surgery. Twenty had carotid endarterectomy and one had carotid artery stenting. Indications for surgery were symptomatic stenosis in 17 (81%) and asymptomatic stenosis in four (19%) of the patients. All patients suffered permanent injuries.
The most common complaint was cranial nerve injuries, 15 patients. Nine of these had dysfunction of the larynx with voice disorders, due to injury to the vagal or the recurrent laryngeal nerve. Three were discharged without diagnosis of the nerve injury.

Percutan transluminal angioplasty (PTA)

Nineteen cases of claims were associated with PTA during peripheral interventional radiology. This subgroup included all three cases with lethal outcome. Two females (aged 76 and 54 years) and one male (aged 64 years) died after PTA. Indications were critical limb ischemia in two and claudication in one.

Access surgery

Nineteen cases of access surgery were identified in the material. Access surgery is performed by vascular, general and transplantation surgeons. It used to be reported in the Swedvasc, when performed by vascular surgeons, but this practice was changed in 2006.

The dominating insurance claim after access surgery was peripheral nerve injury (n=12) with sensibility dysfunctions, often with an initial neuralgic component. Five (26%) had nerve injury with motion disorder of the hand, thumb or index finger.

Cross-matching with Swedvasc

The vascular surgery patients in the SMII cohort differ in some aspects from Swedvasc. The patients who underwent aortic and carotid surgery in the SMII cohort were younger. There was also a difference in indication for surgery (Table 8).

Table 8. Comparison of the SMII and Swedvasc cohorts

Type of procedure		SMII	Swedvasc	p	OR
AAA surgery	n	22	5898		
(open / endovascular)	mean age (std dev)	68 (8.3)	73 (7.9)	0.002	
	male gender	18 (82%)	4834 (82%)	0.99	1.0 (0.3-3.0)
	rAAA	2 (9%)	1780 (30%)	0.03	4.3 (1.1-16.4)
	EVAR	4 (18%)	1415 (24%)	0.52	0.7 (0.2-2.1)
Carotid artery surgery	n	21	5193		
	mean age (std dev)	62 (9.1)	70 (8.6)	0.001	
	male gender	15 (71%)	3714 (67%)	0.99	1.0
	Symptomatic	17 (81%)	4083 (79%)	0.80	0.9 (0.3-2.6)
	Indication acute	1 (5%)	348 (7.1%)	0.72	1.4 (0.2-10.6)
	Patch	9 (45%)	1950 (39%)	0.62	0.8 (0.3-1.9)
	CAS	1 (4.8%)	250 (4.8%)	0.67	0.7 (0.1-4.8)
Peripheral vascular surgery	n	25	18569		
	mean age (std dev)	69 (10.7)	72 (13.3)	0.16	
	male gender	10 (40%)	10121(54%)	0.15	1.8 (0.8-4.0)
	Claudication	7 (28%)	2240 (12%)	0.015	0.3 (0.1-0.8)
PTA	n	19	18950		
	mean age (std dev)	66.9 (15)	72.0 (11.7)	0.058	
	male gender	4 (21%)	9597 (51%)	0.01	3.9 (1.4-10.7)
	Claudication	7 (37%)	5602 (30%)	0.49	0.72 (0.3-1.8)

SMII: Swedish Medical Injury Insurance, Swedvasc: Swedish national register of vascular and endovascular surgery, OR: odds ratio, AAA: abdominal aortic aneurysm, rAAA: ruptured aortic aneurysm, EVAR: endovascular aortic repair, CAS: carotic artery stenting, PTA: percutaneous transluminal angioplasty.

Thirteen cases of the SMII cohort of core vascular surgery (varicose vein and access surgery excluded) was missing in the Swedvasc, and three cases were registered but the major complication were missing; in total 16 cases of wrongly registered (18%). Patients with insurance claims after PTA had the lowest report rate (74%) to Swedvasc.

No risk factor, such as emergency surgery or procedures performed by a non-vascular surgery specialist, that predicted missing registration in Swedvasc were identified. Fifteen of the 16 missing cases were performed as elective surgery during daytime at a vascular surgery unit: the exception was a patient treated for a ruptured AAA

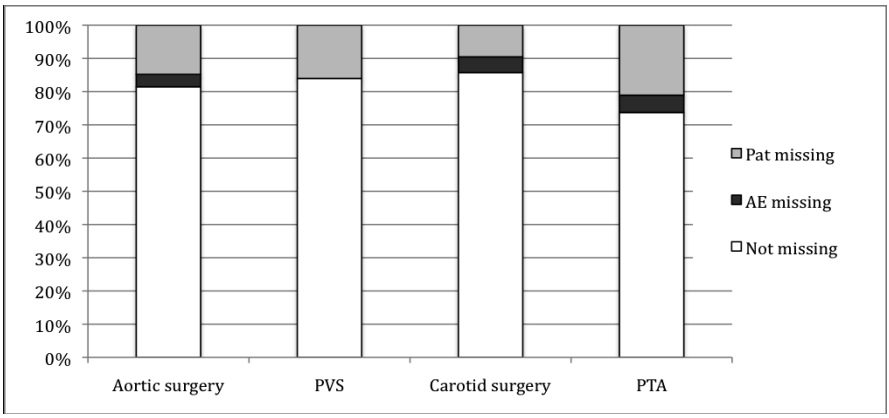


Figure 5. Proportion of patients (Pat) or severe adverse events (AE) not registered in Swedvasc (PVS; peripheral vascular surgery, PTA; percutaneous transluminal angioplasty).

Study IV

In study IV the Iatrogenic vascular injuries (IVIs) registered in Swedvasc with lethal outcome within 30 days were analysed. Study II showed that patients with fatal outcome within 30 days after IVIs were older (median 76 years) compared to survivors (median 67 years) and had more co-morbidities, but were not able to identify the cause of the IVI. Of 1084 patients with IVI as indication for vascular surgery and interventions identified in the Swedvasc registry 1987-2008, 5.2% (n=56) died within 30 days post-operatively. Case-records were retrieved in 52 (93%) of the 56 cases. In four cases, at four different hospitals, the patients records could not been found.

Anatomic distribution of injuries

Of the 52 identified cases 39 were arterial, six graft, five venous, two combined arterial and venous injuries. Anatomic sites of injuries are seen in figure 6. The IVIs in the groin and were bleedings or occlusions of the femoral vessels during or shortly after endovascular procedures.

The anatomic distribution of IVIs between the medical specialities is shown in table 1.

Among the 18 IVIs associated with interventional radiology 13 were (72%) occlusions/thrombosis, five (28%) bleeding complications.

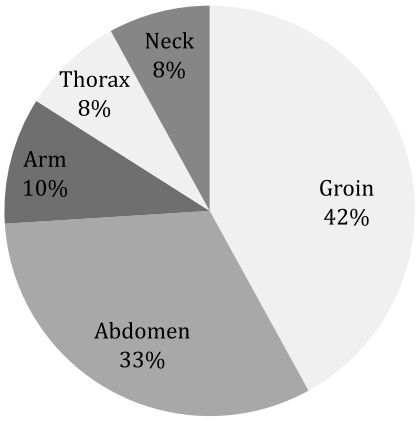


Figure 6.Sites of lethal vascular injuries

Table 9. Speciality involved and anatomic location of injuries

Speciality	Arm	Leg/Groin	Abdomen	Thorax	Neck	total
Interventional radiology	1	12	5	0	0	18
Surgery	0	1	8	0	0	9
Interventional cardiology	1	6	1	0	0	8
Internal medicine	2	0	0	1	2	5
Thoracic surgery	0	2	1	2	1	6
Ortopedic surgery	1	0	1	0	0	2
Other	0	1	1	1	1	4
total	5	22	17	4	4	52

Presentation of injury and diagnostic delay

The presenting symptoms of IVIs were peripheral ischemia (n=20), external bleeding (n=14), and hypovolemic chock without external signs of bleeding (n=10). Eight cases lacked immediate symptoms of IVIs (six cases of puncturing the wrong vessel and two cases of loosing devises intravascularly).

In eight cases (15%) the diagnosis were delayed and affected the outcome negatively. Four cases in interventional cardiology with puncture site complication (three retroperitoneal bleeding, one groin bleeding) and three cases in interventional radiology (two groin bleeding, one limb ischemia) and one patient with retroperitoneal bleeding during spine surgery.

Mechanism of injury

In all 24 cases the primary vascular injury was caused by puncture of the vessel during endovascular procedures. There were 11 cases of penetrating injury during open surgery with massive peroperative bleeding.
In six cases an arteriosclerotic artery or a graft were externally compressed for haemostasis leading to thrombotic occlusion. There were six cases of percutaneous puncturing of an artery instead of an intended vein, and three arterial ruptures during endovascular procedures. In two cases devices were lost intravascularly.

Type of vascular repair

The surgical procedures are seen in table 10. When reconstruction was performed with a by-pass or an interposition graft, prosthetic material was used in 10 cases (85%), vein in two cases and composite in one case.

Table 10. Type of repair

Vascular repair	**number**
Suture	25
By Pass	13
Thromblectomy	7
Endovascular	6
End-to-end	1
no repair	1

Relationship between IVI and the death

The median survival was 8 days (range 1 day to 30 days). Most of the patients died within 2 weeks (n=36, 69%), after 3 weeks 45 (86%) patients were dead.

The IVIs were classified into three categories: fatal IVI, IVI contributory to death or non-fatal IVI. In “fatal IVI” no other causes of death were found. In “contributory IVI” factors other than IVI implicated death within 30 days and in “non-fatal IVI” the IVIs had no relation to death. There was a higher possibility to find cases with non-fatal IVI if death occurred later than 2 weeks after the IVI, figure 7.

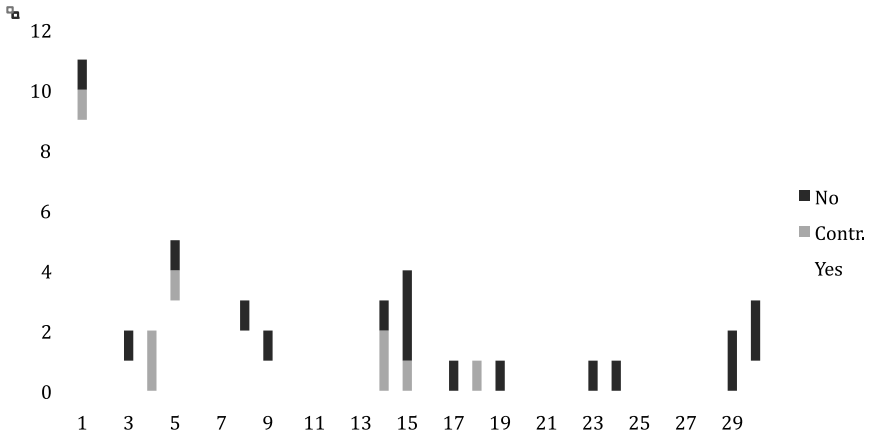


Figure 7. Interval in days from iatrogenic vascular injury IVI to death.

Yes; IVI causing death, Contr.; IVI contributory to death, No; no correlation between IVI and death

There was a difference in correlation between the IVI and death among the medical specialities. The strongest correlation had Interventional Radiology (16 fatal or contributory IVIs out of 18), Interventional Cardiology (seven out of eight) and General surgery (seven out of nine). A weaker correlation between IVIs and death was seen in the groups of Internal medicine (one out of five), and Other (none of the four cases).

None of the five cases with accidental arterial puncture during procedures for central venous line died due to the IVIs.

Avoidable injuries

Twenty-two (41%) IVIs were considered (in retrospective analysis by the authors) to be avoidable, since standard of care was inferior than expected, or if there was failure to adhere to accepted practice.

Autopsy

Thirteen (25%) of the 53 cases of IVIs had the cause of death established by an autopsy. Among the 36 cases of IVIs causing or contributing to postoperative death six (17%) went to autopsy.

Comments studies III and IV

Study III reveals the insurance cost per vascular core surgery procedure for entire Sweden, however, the registry of LÖF has not been validated for the listing of specialities and diagnosis.

The linkage between the Swedvasc and the National population registries, based on the unique Personal Identity Number used in both registries, made it possible to identify all deaths, at any time after discharge or transfer of patients to other health care units. The death certificate together with the case records revealed the cause of death, also when death occurred after discharge.

No matter how simple a procedure may appear, all operations, medical and nursing activities carry inherent risks for the patient. If the standard of care was inferior to that expected, or there was failure to adhere to accepted practice, which resulted in the patient suffering harm, the death was considered to be avoidable. However, there are great difficulties in analysing if the injury was avoidable or not. There is a risk of hindsight bias, i.e. the tendency to impute causation when the outcome is known, and the preventability is judged to legal standard of "more likely than not". In studies with paired expert opinions in retrospective case record review showed good agreement in presence of AE such as wound infections, but lower regarding failure to diagnose and incorrect treatment. Highest disagreement was found in judging preventability (only 58% agreement) (Wilson 1995, Caplan 1991).

Study V

In study V we analyzed popliteal artery injuries (PAIs) during knee arthroplasty (KA). We identified 32 patients were injured during a knee arthroplasty, of which 26 were primary total KA, 5 revisions KA (rKA) and one unicompartment KA.

The overall proportion of revision total KA during 1987 to 2011 in Sweden was 7.6%, compared to 15.6% (5/32) among those with popliteal artery injury.

Presentation of injury and time to detection

There was a delay in detection and repair of vascular injury. Twelve (38%) cases were detected peroperatiely, before leaving the operation room. Symptoms were bleeding or visualised popliteal artery injury. In this group of patients with early diagnosis, six patients had delay in vascular repair due to need for transportation of patient or vascular surgeon, thus only six patients with PAI had both early detection and repair, figure 8.

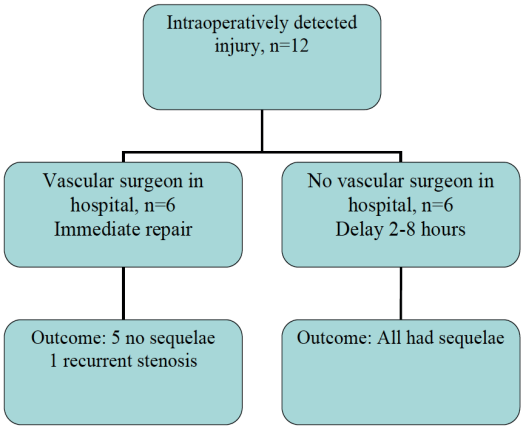


Figure 8. Twelve injuries detected before leaving operation theatre

Eight (25%) patients were detected within 24 hours post-operatively (median 9 hours, range 3-24). Symptoms were bleeding, pain or ischemic signs.

Twelve (38%) patients were detected more than 24 hours after surgery (median 41 days, range 2-90). Eleven were contained bleeding in to a pseudo aneurysm (one communicating to the knee joint) and one case of distal ischemia.

Mechanism of injury and repair

Mechanisms of injury were divided into 25 (78%) penetrating injuries presented with bleeding (n=14) or pseudoaneurysm (n=11) and seven (22%) blunt injuries presented with ischemia.

In total 28 cases (88%) were treated with open surgery and three cases (9%) with endovascular technique and one case with external ultrasound compression.

Outcome

Thirty (97%) of the 31 vascular repairs remained open after 30 days. One patient underwent amputation on day 9.

At one year of follow-up (defined as 10-14 months after primary surgery) 23 of 30 patients (77%) were symptomatic with limb loss, paresthesia, motor dysfunction, pain and/or swelling.

Only seven (22%) patients recovered fully without symptoms or functional impairment. Five of these were detected intraoperatively (Fig. 8) and immediately repaired by a vascular surgeon on call in that hospital.

Comments

This is the largest study in popliteal artery injuries during knee arthroplasty in the literature, and because of the unique personal identity numbers as well as the ethical approval to cross-link, we can now report long-term survival on all patients, and functional outcome in most of them.

Initially one intention was to compare the two registries (Swedvasc and the Swedish Patient Insurance) in order to validate the registration of popliteal artery injuries in the Swedvasc, by using the ICI-10/9 diagnose code of iatrogenic vascular trauma in combination with knee arthroplasty in the Patient Insurance registry. But the ICD coding of injuries were that insufficient, making a comparison impossible. This reveals the difficulties to validate the registration of IVIs, and further, evaluate the incidence.

18 of the 32 identified cases of popliteal artery injuries during knee arthroplasty made an insurance claim for economical compensation, and 17 of these could be found in the Patient Insurance registry.

General discussion

Adverse events (AE) in health care, i.e. complications due to examination, treatment, or care can be devastating for the patient and may lead to prolonged hospital stay, need of rehabilitation, severe morbidity, life-long disability and even death. In addition to personal suffering, AE also increases costs for the patient and the community (health care costs, loss of income and household production, disability).

Learning by mistakes

In two large studies in the US with retrospective chart reviews, AE occurred in 2.9% (Brennan 1991) and 3.7% (Thomas 2000) of all hospitalisations. Of these adverse events, 7-14% resulted in death. In both studies, over half of the AE were the result of medical error. Extrapolation of these results to all admissions to US hospitals implies that 44 000- 98 000 patients a year die due to medical error. Even with the lower estimate, mortality exceeds the number of annual deaths from motor vehicle accidents or breast cancer. In 2000, the Institute of Medicine, Committee on Quality of Health Care in America released the report "To Err is Human: Building a Safer Health System" (Kohn 2000) in an effort to highlight the problem of accidents in health care, and present recommendations for building a safer health care system.
Similar retrospective chart reviews from other countries, such as Australia (Wilson 1995, Kable 2002), Canada (Baker 2004), Denmark (Shioler 2001), and England (Vincent 2001) reveal that AEs are a common reason for illness in hospitalised patients. There is no comparable Swedish study.

Identifying adverse events and sources of data

Vascular surgery patients under treatment and care are not immune to the risk of AEs, either non-avoidable or avoidable, such as medical error. Besides vascular surgery patients AE can strike the vascular system of other patient groups. Due to the importance of the vascular system, injury often leads to severe consequences, demanding urgent treatment by open or endovascular surgery. In order to improve patient safety, it is essential that any

risks present within health care are identified, and undesired events are detected and future events are prevented. One way is to analyse all adverse events and medical errors. There is, however, no absolute way of detecting all undesired events, as this would require prospective observation of all care processes and the registration of all events meeting the definition of AE. Such a system does not exist. In observational studies, an observer is placed at the clinic or at the bedside of randomly selected patients. These methods identify higher numbers of errors and injuries (Donchin 1995, Weingart 2000), and are sensitive to detect medication errors, but they are costly and it cannot be excluded that their presence may influence the outcome.

Prospective methods that use interviews with medical staff in combination with checking medical records generally identify more AE than retrospective medical record reviews (Brennan 1989, Michel 2004). The common standard still is the retrospective scrutiny of randomly selected medical records, as in benchmark studies for estimating medical injuries, such as the Harvard study of medical practice (Brennan 1991) and the Colorado and Utah study (Thomas 2000). Although these types of studies provide an indication of the incidence of AEs, they are resource intensive and time consuming. Furthermore, the reviewing of medical records is limited by the quality of the chart reports and the frequency of the AEs (Vincent 2001). In rare and serious AEs, that are not easily detectable by routine reviews or observations, claims and insurance reviews are more useful (Vincent 2006, Study III). In Study III, five unique cases of spinal ischemic injuries in aortic aneurysm repair were identified: only one case received spinal protection before extensive aortic stenting or open repair. Other more common and dominating AEs, such as peripheral nerve injuries and infections were also identified as potential areas for quality improvement, particularly among varicose vein and access surgery patients (Study III). These results were consistent with claim observations in the UK (Markides 2008) and in a prospective study on varicose vein surgery (Subramonia 2005).

These findings indicate that not only severe AE are identified in insurance claim analysis, but also less severe and more common injuries can be identified in claim analysis, as well as in prospective studies (Subramonia 2005).

In varicose vein surgery, major vessel injuries do occur, and since these AE are rare complications, they are difficult to identify prospectively and are mainly documented as case reports. Frings et al. (2001) performed one of the largest prospective studies on varicose vein surgery, where deep vascular injuries were identified: there was no arterial injury, but four major venous injuries in 31 838 high ligations at the saphenofemoral junction (0.013%), and three venous injuries in 6 152 ligations at the saphenopopliteal junction (0.049%). This category of injury was neither found among insurance claims (Study III), nor could it be identified in the Swedvasc based studies (Studies II and IV). It is likely that vascular surgeons will encounter this situation at some stage during their career. Although the use of case reports have been

questioned from a scientific point of view, because of the risk of publication bias, they have a value in identifying uncommon or rare events and alternative therapeutic solutions. We used the methodology of a systematic literature review to obtain available information on deep vascular injuries during varicose vein surgery for analysis, when other sources of data were unavailable (Study I). There is the risk of reporting bias, however. For example, arterial injuries were as common as venous injuries in Study I. It cannot be concluded that they have the same incidence on the basis of these case reports, as we do not have the denominators. Frings et al (2001) have only identified venous injuries, and it is likely that venous injuries predominate, but that the arterial injuries are more likely to be published.

Swedvasc, a speciality register with national coverage, is a potential tool to identify AE (Study II). In combination with other registries and sources of information, such as the Swedish Patient Insurance (LÖF) databases (Studies III and V), the Swedish Population Register, and the Swedish Cause of Death register (Study IV), the availability of data increased, thereby improving analysis to obtain the study objectives. In addition, access to medical records (Studies III, IV, and V) further expanded the possibilities of drawing conclusions.

Registries have their strengths but also their limitations (Bergqvist 2007). In a self-reporting system, such as Swedvasc, underreporting is a risk, and since raising an insurance claim is sometimes complex, claim registries present only a minor part of total AE. Thomas and Petersen (2003) classified and reviewed different methods of studying AE and errors in health care, and conclude that there is no perfect way of estimating the incidence or prevalence of AE. All methods have their strengths and limitations. Estimates of AE rates and incidence are based on reviewing medical records, but there is no reference method for identifying AE (Murff 2003), no gold standard to compare against. Thus, for improving quality of care and safety (freedom from accidental injury), more than one method is needed for identifying adverse events and errors.

Validation

Swedvasc is extensively validated with excellent external validity, above 90% for core vascular surgery, such as carotid artery endarterectomises, abdominal aneurysm repairs, and peripheral artery by-passes (Kragsterman 2006, Ravn 2007, Troeng 2008). There is no previous validation on iatrogenic vascular injuries as an indication for surgery. The external validation of Swedvasc registration of vascular surgery leading to insurance claims was good (above 80%) (Study III). In Study V Swedvasc was the main source for identifying popliteal artery injuries during knee arthroplasty, and in the County Councils' Mutual Insurance Company (LÖF) database, four iatro-

genic popliteal artery injuries were identified. Three (75%) of these popliteal artery injuries were registered in Swedvasc, but the cases were too few for a validation in the statistical sense. For further validation of IVI in Swedvasc, an extensive review of randomly selected case records is needed for all medical specialties.

Symptoms and diagnosis

IVI can present as bleeding or ischemia. In cases with external bleeding, diagnosis is often obvious; however, with internal bleeding, diagnosis may not be as evident. Although access site complications, mostly bleeding in the groin, are common and reoccurring AE (Studies II and IV), they appear difficult to diagnose if there is no overt bleeding or obvious swelling in the groin. One explanation might be the risk of normalisation of deviance, i.e. it is normal with access site problems, and there is no need to worry. Internal bleeding in a cavity (retroperitoneal) is difficult to diagnose, however, as there are no apparent external signs, except pain, and hypovolemia with subsequent drop in blood pressure.

There are diagnostic difficulties with contained bleeding from the popliteal artery forming a pseudoaneurysm (Study V), instead of hypovolemia and/or apparent bleeding. The symptoms are local pain and neurologic symptoms of peripheral nerve compression, such as anaesthesia, paresthesias, or paralysis.

In injuries manifesting through impaired circulation in the limbs there can be a delayed diagnosis as well. Both mild and severe ischemia can escape diagnosis (Studies I, III, IV, and V). Ischemia can even escape in-hospital detection, and diagnosis being delayed until follow-up at the outpatient clinic (Study I).

AE in vascular surgery leading to insurance claims seldom involve bleedings. Closed claim analyses in medicolegal cases are biased by severity (Vincent 2006, Thomas 2003). However, this did not appear to be the case for Swedish insurance claims, as they are handled outside of the legal system (Study III). The majority of diagnoses leading to insurance claims were less severe wound infections (11%, 22/193) and peripheral nerve injuries (39%, 75/193). There were few major bleedings (6%, 11/193) and only three deaths (1.6%). Even so, more than half of the patients suffered from permanent injury and functional loss, and the AE led to reoperations and prolonged hospital stay in half of all insurance cases in vascular surgery. Thus, there are areas for potential quality improvement.

The first step for correct diagnosis is awareness of the possibility of the risk of an IVI or AE. A postoperative physical examination with careful investigation of signs of vascular injury is essential and preoperative assess-

ment would be beneficial for comparison. The assessment should include palpation of pulses and measurement of ankle-brachial index to evaluate circulation in the extremities and exclude ischemic signs.

IVI with bleeding into a cavity or with a retroperitoneal bleeding is more difficult to diagnose, especially if there are no signs of hypovolemia and in some cases, even after such deterioration. Awareness of the possibility of this AE, although rare, must be in the mind of every physician responsible for a patient. If there are any doubts or difficulties with the assessment, a vascular surgeon should be involved at the bedside (Studies IV and V).

CT scanning is useful for diagnosing retroperitoneal haematoma (Illescas 1986), and should be performed if there is any doubt. Colour-coded Doppler is considered appropriate to identify vascular injuries in the extremities (Fry 1994; Meissner 1991). MR- and CT-angiography are other non-invasive useful methods. Percutaneous angiography is sensitive to detect vascular injuries, but is invasive and involves the risk of complications, both puncture and contrast media related. However, one advantage of invasive angiography is the potential of simultaneous endovascular therapy (Goltz 2011, Risberg 2000). The choice of diagnostic method depends on the availability, which may differ between office and emergency hours.

Treatment and Outcome

The outcome of IVI and AE in vascular surgery can be associated with severe morbidity, such as pareses, limb loss, and death. Mortality rates between 1.9 to 7.1% were reported (Bains 2009; Giswold 2004; Hatakeyama 2000; Lazarides 1998, Study II). Mortality from iatrogenic vascular injuries is higher than from non-iatrogenic vascular injuries (Giswold 2004, Study II). IVI affect an older group of people with more co-morbidities and a higher risk of fatal outcome.

IVI affecting larger and more central (such as abdominal) vessels are more often fatal and usually need treatment with more complex methods, such as by-passes and interposition grafts, but with less favourable results (graft occlusions and reoperations due to bleeding)(Study II). Vascular injuries of percutaneous endovascular or cardiovascular interventions and intra-abdominal surgery account for the majority of fatal IVIs, but death within 30 days is more often related with the conditions and diseases of which the patients suffered from, rather than the IVI itself (Study IV). Registry data indicated iatrogenic carotid artery injuries often to be fatal (Study II). However, complementary case record analyse revealed that patients with IVI of the carotid artery often died from the disease from which the patient suffered before the injury, rather than the IVI (Study IV).

Patients with IVIs, and treated with by-pass or interposition graft, had a reasonably good outcome of the reconstruction, but one-tenth had an occlud-

ed reconstruction and 7% had major limb amputation within 30 days (Study II). There were no differences in occlusion or graft infection rates related to the graft material used (vein or synthetic). Although reconstruction results were acceptable, there were often sequelae, including functional disability, pain and/or paresis (Studies I, III, and V). Outcome was correlated with both the severity of injury, and the delay in diagnosis and treatment (Studies I and V). Although complications are infrequent, it is appropriate to have a strategy for caring for vascular injuries, since when they occur, there is little time before irreversible damage to the nerves and muscles occur.

When a serious IVI occurs, rapid diagnosis is fundamental for early treatment and good outcome. Early diagnosis is crucial to avoid delay of vascular repair and to reduce the risk of permanent disability (Waller 1993, Studies I and V).

Good risk management is essential for limiting patient harm and there should be prevention strategies for minimising iatrogenic vascular injuries and injuries during vascular surgery, which require knowledge about the areas of highest risk and potential adverse events. Knowledge about AE and IVI is therefore essential and the care providers within the different surgical specialities must have a plan of action. Safety in this context is defined as freedom from accidental injuries and errors (Kohn 2000). Learning from errors and mistakes is possible and an important component in making health care safer. One good example is to highlight the AEs and injuries at "Morbidity and Mortality" conferences. Questions to discuss are for instance (Studies I and IV):

> "Was there a failure in communication, e.g. at handovers of patient or change of care units?"
> "Was there an unclear responsibility between different care providers and physicians?"
> "Was there insufficient anatomic knowledge or no reaction to an anatomic anomaly?"

Not all errors result in harm and it usually takes more than one error or failure for an AE to occur; however, approximately three errors per AE according to Morris et al (2003). Errors not leading to AE, in other words 'close calls' or 'near mishaps', are also potential sources of knowledge and opportunity for learning as well as the AE itself. The reporting and documentation of such 'close calls' would benefit improvement strategies (Barach 2000).

All procedures carry inherent risks. AE does happen and will occur and there is no single solution to this complex problem. The goal of an action plan is to establish ways of preventing the repetition of errors and minimising non-preventable adverse events. Safety strategies include increasing

knowledge and awareness of near mishaps, errors, as well as AE. Therefore, it is fundamental to have an effective way of detecting errors and AE, including 'close calls'. There is no perfect system, all methods have strengths and limitations, and different methods should be used together for the optimal identification of AEs. It is important to create an environment that encourages the organisation of safety management and identification of errors, and shift the focus from blaiming individuals towards preventing future errors. This means that a systematic process for evaluating all AEs is needed to determine if there is a root cause for the AE (i.e., the most fundamental reason explaining that an event occurred), and the contributing factors or if there is a system-induced error. In this stage, implicit judgement is often a requirement because of the difficulty of establishing causality (Hayward 2001). Ultimately, all measurements should contribute to create a safer system that protects patients from medical error and accidental injury, and treats adverse events quickly and adequately to minimise sequelae.

Conclusions

In case reports deep venous are as common as arterial injuries. Laceration or division of the femoral vein in the groin and arterial stripping were the most common injuries. Bleeding was common and major arterial injuries resulted in ischemia, often with a diagnostic delay and high morbidity. All reported deaths were secondary to venous injuries.

Iatrogenic vascular injuries constitute half of all vascular injuries registered in Swedvasc. Both the proportion and crude numbers are increasing over time. IVIs have a different anatomic distribution than non-IVIs.

The 30-day mortality rate was higher in the group of IVIs compare with non-IVIs. In addition, iatrogenic vascular injuries affect an older, more vulnerable group of patients with more co-morbidities. Risk factors for early post-operative death among iatrogenic vascular injuries were renal impairment, diabetes, age over 68 and obstructive lung disease.

Varicose vein surgery dominates claims for economic compensation. In core vascular surgery, carotid artery surgery and abdominal aortic aneurysm surgery (open or endovascular) have the highest frequency of annual insurance claim (0.4% and 0.37%). Carotid artery surgery has the highest frequency of economically compensated claims per number of procedures performed (1:650). The most common causes of insurance claims in vascular surgery were peripheral nerve injuries and infections.

The registration in Swedvasc of vascular surgery cases with insurance claims (due to complications) was over 80%, the lowest registration rate was after percutaneous endovascular procedures for peripheral arterial disease (PTA).

General abdominal surgery, interventional cardiology and endo-vascular procedures on peripheral arteries are the main procedures involved in lethal IVIs. All postoperative deaths within 30 days after surgery for IVI are not attributable to the injury itself but the disease from which the patient suffered before the injury. The majority died within the first two weeks (68%) and after that the association between the injury itself and death was week.

Penetrating injury with bleeding and pseudoaneurysm formation dominates popliteal artery injury in knee arthroplasty. Use of tourniquet does not seem to play a role in the mechanism of injury. Immediate detection and repair is crucial for long term results, avoiding permanent functional impairment.
Pseudoaneurysms are often diagnosed and treated with delay and resulted in functional loss, despite vascular repair. Greater knowledge about this complication among orthopaedic surgeons could improve outcome in the rare event of popliteal artery injury in knee arthroplasty.

Future perspectives

Detecting adverse events for safety research

In studying iatrogenic injuries a central issue is detecting the events. All existing sources are underestimating the true incidence of adverse events and injuries. It would be useful in safety research and safety management, to construct a continuous reporting system for adverse events and injuries. It would be beneficial to include medical near misses in order to gain more material for analysis, like in non-medical high safety industries reporting systems for near misses (aviation, nuclear power technology and petrochemical processing). The reporting system should be voluntary and non-punitive. It cannot be anonymous, but confidential, making it possible for quick feedback and to collect complementary information if needed. It would be of great interest to apply this reporting system on selected departments of general surgery and cardiac interventions (coronary angiography and percutaneous coronary interventions).

Comparison of two independent registries of same variable

In order to evaluate registration of iatrogenic vascular injuries, we need to compare Swedvasc with a different independent register of the same studied variable (IVIs or a selected type of IVI). Each register is an access to a population of cases, but no one includes the total true population (A), which is unknown, figure 9.

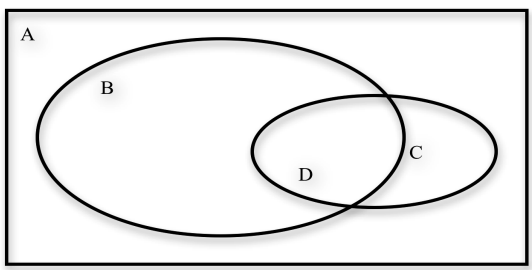


Figure 9. Theory underlying comparison between registries (Bergqvist 1998).
Swedvasc collects B+D, but misses those in C. Registry 2 collects D+C.

Non-iatrogenic vascuar injuries with lethal outcome

Further analysis of the group of non-iatrogenic vascular injuries with lethal outcome (Study II) is needed. A study of non-IVIs with lethal outcome during the last decade, complemented with case records, would reveal the types of non-iatrogenic traumas causing these injuries. This investigation would doubtless lead to additional queries and studies, perhaps in co-operation with other registries or authorities, such as the Swedish transport administration (Trafikverket).

Sammanfattning på svenska, Summary in Swedish

Det övergripande målet med min avhandling har varit att undersöka och belysa iatrogena kärlskador, skador orsakade av vården, som kräver öppen eller endovaskulär kärlkirurgisk åtgärd, samt resultaten av dessa åtgärder. Vidare har jag beskrivit komplikationer och oönskade effekter inom öppen och endovaskulär kärlkirurgi som lett till försäkringsärenden.

Bakgrund

Iatrogena skador innebär för patienten onödigt lidande, förlängd sjukhusvård och ibland död. För samhället resulterar det i ökade kostnader för sjukvård, rehabilitering, förlorad arbetsinsats samt ekonomisk ersättning i försäkringsärenden. En rapport (To Err is Human) publicerad vid millenniumskiftet i USA, baserad på två stora nordamerikanska studier, visade att iatrogena skador är ett hot mot patientsäkerheten. Man påvisade, efter extrapolering av studiernas resultat på all given sjukhusbunden vård i hela nationen, att vårdskador utgör en av de tio vanligaste dödsorsakerna. Trots skadornas stora betydelse för patienter och sjukvård, är de förvånansvärt lite utforskade.

Genom kärlsystemets betydelse kan skador på detta få allvarliga konsekvenser. Iatrogena kärlskador är komplikationer som drabbar kärlsystemet i samband med öppna eller endovaskulära kirurgiska ingrepp. Endovaskulär teknik är korrektion eller diagnostik av ett sjukt kärlsegment med kateterteknik, under genomlysning via en punktion av pulsåder eller ven. Oftast sker detta via ljumskens kärl. Avhandlingen syftar till att utforska kärlskadors orsaker (etiologi), hur det går att identifiera fall av iatrogena kärlskador (IKS), beskriva skadepanorama och utfall samt försäkringsärenden inom kärlkirurgi. Avhandlingen är framförallt en beskrivande studie av ovanliga men allvarliga komplikationer med hög efterföljande sjuklighet och stort lidande.

Delarbeten

I avhandlingens första delarbete, **delarbete I**, studeras djupa kärlskador i samband med öppen åderbråckskirurgi. En allvarlig komplikation i samband med rutinmässig kirurgi, för en godartad åkomma. Dessa iatrogena kärlskador är svåra att finna, på grund av att de är sällsynta och att åderbråckskirurgi inte registreras i något nationellt kvalitetsregister. Det går inte att identifiera dessa skador i det nationellt täckande svenska kärlregistret (Swedvasc) eller Patientskaderegleringens register (Landstingens Ömsesidiga Försäkringsbolag, LÖF). Studien är en genomgång och en sammanställning av samtliga publicerade fallbeskrivningar av djupa kärlskador vid åderbråckskirurgi i internationella medicinska tidskrifter.

Vi fann att skador på djupa vener oftast sker i ljumsken, med stora blödningar och snabb diagnos som resultat, vilket kunde åtgärdas kärlkirurgiskt. En tredjedel av alla venösa rekonstruktioner fick kvarstående avflödesproblem, med kroniska besvär (så kallat post-trombotiskt syndrom). Artärskador skedde både i ljumsken och genom s.k. stripping längre distalt (kirurgisk metod där man drar ut kärlet över en ledare/vajer). Ofta ställs diagnosen för sent. Bara 1/3 upptäcktes peroperativt, med dåliga rekonstruktiva resultat och hög sjuklighet som följd. Alla fall med dödlig utgång var dock venösa skador.

Delarbete II baseras på data från det rikstäckande Svenska kärlregistret, Swedvasc. Under åren 1987 - 2005 registrerades 1793 fall med kärlskada som indikation för kärlkirurgisk åtgärd, varav 888 var p.g.a. en iatrogen kärlskada. Studien visar att kärlskador ökar över tid som indikation för kärlkirurgi, och merparten av ökningen beror på en ökning av iatrogena kärlskador, som utgör hälften av alla kärlskador. Iatrogena kärlskador (IKS) skiljer sig från icke-iatrogena skador. De drabbar oftare kärl i ben, ljumskar och buken, jämfört med icke-IKS som oftare drabbar armar. Dödligheten är högre bland IKS (4.9%) jämfört med icke iatrogena kärlskador (2.5%), och drabbar äldre patienter med identifierade riskfaktorer för dödlig utgång såsom ålder, diabetes, obstruktiv lungsjukdom, nedsatt njurfunktion samt stopp i en tidigare genomförd kärlrekonstruktion.

Vid analys av alla skador inom kärlkirurgi som leder till försäkringsärenden hos Patientskaderegleringen, LÖF, Landstingens Ömsesidiga Försäkringsbolag (**delarbete III**) framkom det att nervskador och infektioner dominerade. Kärlkirurgi på halspulsådern orsakade flest ekonomiskt ersatta försäkringsärenden per utförda operationer och år (1:650), men i absoluta tal dominerade skador efter åderbråckskirurgi. Mer än hälften av samtliga försäkringsärenden får varaktiga symtom efter skadan. En viktig slutsats vid jämförelse med kvalitetsregistret Swedvasc, är att skador och komplikationer inom kärlkirurgi registreras bra. Drygt 80 procent av kärlkirurgisk kärnverksamhet som leder till försäkringsärenden inom LÖF registreras i Swedvasc.

Störst bortfall noterades inom radiologisk kärlintervention (endovaskulär teknik), där drygt 70 procent registrerades. Det gick inte att identifiera någon förklaring till att vissa fall inte blev registrerade, såsom operation på jourtid eller akut operation.

I **delarbete IV** analyserades journalhandlingar och dödsorsaksregistret för alla fall i Swedvasc med kärlkirurgisk åtgärd (öppen eller endovaskulär teknik) av iatrogena kärlskador, med dödlig utgång inom 30 dagar enligt data från Svenska befolkningsregistret. Specialiteter som bukkirurgi (oftast för malignitet), kardiologisk intervention och radiologisk kärlintervention dominerade som orsak till dödlig kärlskada. Av de som avled skedde dödsfallet inom två veckor hos 70%. En viktig slutsats var att enbart dödlighet inom 30 dagar inte är ett bra självständigt kvalitetsmått på kirurgi av iatrogena kärlskador då en del av fallen (17/53) ej dog av sin kärlskada, men pga sin grundåkomma (malignitet eller hjärtsjukdom). Det gäller särskilt de patienter som avled senare än två veckor efter operationen för kärlskadan.

I **delarbete V** är fokus på ett kärlsegment, arteria poplitea (knäpulsådern) som kan skadas vid knäledsartroplastik (operation med knäledsprotes). Efter att i Swedvasc ha identifierat patienter med iatrogen skada på kärlsegmentet kontrollerades i ortopedjournalerna om en knäprotesoperation hade utförts och 32 sådana patienter identifierades. Studien visar (liksom studie I) att IKS som inte orsakar stor peroperativ blödning ofta missas, bara 12 (38%) identifierades på operationssalen. Rekonstruktionen av den skadade artären blir därmed fördröjd vilket påverkar resultaten negativt. Ett oväntat fynd var att många utvecklade falska knäpulsåder-bråck (pseudoaneurysm) som ett sent symptom på artärskada, oftast med sen diagnos och långvariga besvär i form av värk och funktionsnedsättning.

Den kirurgiska åtgärden av kärlskadan blev bra, nästan alla (97%) av rekonstruktionerna fungerade vid 30-dagars uppföljning. Däremot var enbart 7 (22%) av patienterna utan kvarstående restsymtom vid ett-års kontroll. De med mest gynnsamma resultat utan restsymtom hade tidig rekonstruktion genom tidig diagnos av den iatrogena kärlskadan och där en kärlkirurg fanns lättillgänglig.

När allvarliga iatrogena kärlskador uppstår är det viktigt att behandlaren har en kunskapsbas och en plan att agera utifrån. Att kartlägga iatrogena kärlskador är det första steget i prevention, i syfte att öka medvetenheten hos alla grupper av opererande specialister, samt att belysa problemet med oönskade kärlkomplikationer. Ökad medvetenhet om risker och identifiering av kärlskador är därför viktig eftersom kärlskada inte alltid presenteras med yttre blödning utan i stället kan presenteras som nedsatt cirkulation av en kroppsdel, eller ett pulsåderbråck som trycker på nerver. Prognosen i dessa fall avgörs av tidig diagnos och behandling.

Acknowledgements

I am grateful to many people who in various ways have contributed to this thesis project. I would like to extent my gratitude especially to:

Professor **Martin Björck**, my tutor and the head of the vascular surgical research team at Uppsala University. Thank you for excellent tutoring and generous support, and for your patience in trying to improve my academic writing. You are a great source of inspiring for all vascular surgeons, in Uppsala and surrounding counties, in the field of clinical science. You introduced me to the field of clinical research, but also to exotic food like old herring and African barbeque sauces.

Professor emeritus **David Bergqvist**, my co-tutor, for generously sharing your outstanding knowledge about vascular surgery and science. I am proud to have been working together with you, both in clinic and science.

Karin Bernhoff, orthopaedic surgeon and my co-writer in Study V, for excellent collaboration and making science fun while writing paper together.

Christer Ljungman, the head of the Section of Vascular Surgery, at Uppsala University Hospital, for your leader ship, flexibility and caring, both for colleagues and patients. Thank you for sharing your enormous skills in vascular surgery. Your generous Christmas parties together with your knowledge in Swedish cultural songs are greatly appreciated.

Jon Ahlberg, Head doctor and **Kai Essinger**, CEO at The Swedish Patient Insurance, LÖF (Swedish County Councils' Mutual Insurance Company) for supporting my scientific paper III.

Mats Öberg for your excellent help in epidemiology and statistics and for challenging me intellectually.

Björn Kragsterman, for your never fading enthusiasm in vascular surgery and high working capacity. Don't forget your love in sailing and endless skylines. **Anders Wanhainen** for your insightful feedback during my

presentations of research results, and for being an inspiring and always pleasant colleague and researcher.

My hard working colleagues at the section of vascular surgery: **Annika Boström-Ardin, Gustaf Tegler, Nakisa Esfahani, Johnny Steuer** and **Elisabeth Skagius**, for your high motivation in daily clinical practice and your competence in care and treatment of the vascular surgical patient. There are days I really miss you. Keep up the good spirit.

All Colleagues, at various Swedish hospitals for your generosity in providing me case reports asked for. Without your willingness this project would have been very hard.

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