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Patient Injuries in Vascular Surgery

Minna Laukkavirta

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To Err Is Human
(A. Pope 1711)

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ABSTRACT

Safe care is a prime priority for all health care professionals. Surgical care is associated with potentially high risks. Patient injuries can cause significant suffering to the patients and major costs to health-care systems.

The aim of this doctoral thesis was to describe patient injuries in vascular surgery in Finland: their causes, consequences, and whether they could have been prevented. The study analyzed all patient injuries compensated by the Patient Insurance Center in vascular surgery in Finland for 1997–2017 inclusive. During that time period, 142 patient injuries were compensated of which the majority were related to the operative care of patients. Patients were mostly elderly with multiple co-morbidities. Typical injuries involved errors in surgical technique, nerve injuries, injuries to adjacent organs or tissues and intraoperative burns. Delays and errors in diagnosis and treatment, and also errors in medication were compensated.

Patient injuries in vascular surgery were rare but their consequences were severe. For 5 patients, death was compensated as a patient injury. Ten patients required either a partial or complete amputation of the upper or lower limb. Twenty-one patients were left with permanent nerve injuries and 3 suffered a major stroke. More than half of the patients required additional surgical operations, the majority of whom were left with permanent impairment.

Injuries in vascular surgery occurred in all stages of care and under the care of several different groups of medical professionals. Almost 90% of the cases were evaluated to have been potentially preventable. Safety procedures already in use such as surgical safety checklists could potentially have prevented more than 10% of the injuries.

Prevention of patient injuries requires continuing efforts in health care and the heightened risks involved with surgery should be recognized. National quality registry in vascular surgery could present possibilities for improving care and help to provide accurate statistics on vascular procedures. The information learned from patient injuries should be used to educate health care staff to prevent injuries from reoccurring.

KEYWORDS: patient injury, patient safety, vascular surgery

TURUN YLIOPISTO
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TIIVISTELMÄ

Turvallinen hoito on kaikkien terveydenhuollon työntekijöiden tärkeä yhteinen tavoite. Kirurgiaan liittyy korostunut potilasturvallisuusriski. Potilasvahingot aiheuttavat potilaille huomattavaa kärsimystä ja terveydenhuollolle merkittäviä kuluja.

Tämän väitöskirjan tavoitteena oli kuvata Suomessa tapahtuneita verisuonikirurgiaan liittyviä potilasvahinkoja ja niihin vaikuttaneita tekijöitä. Tarkoituksena oli myös selvittää vahinkojen seuraukset potilaille ja arvioida, olisivatko potilasvahingot olleet ehkäistävissä.

Tutkimuksessa analysoitiin Potilasvakuutuskeskuksen vuosina 1997–2017 korvaamat verisuonikirurgian erikoisalan potilasvahingot. Kyseisenä ajanjaksona korvattiin 142 potilasvahinkoa, joista valtaosa liittyi potilaan leikkaushoitoon. Potilaat olivat useimmiten iäkkäitä ja monisairaita. Tyypillisimmät potilasvahingot liittyivät leikkaustekniikan virheisiin, hermovammoihin, viereisten kudosten tai elinten vaurioitumiseen ja leikkauksen aikaisiin palovammoihin. Myös diagnoosin tai hoidon viivästymiseen ja lääkitysvirheisiin liittyviä vahinkoja korvattiin.

Verisuonikirurgiaan liittyvät potilasvahingot olivat harvinaisia, mutta niiden seuraukset vakavia. Vahingon kärsineistä potilaista viisi kuoli ja 10:lle tehtiin osittainen tai täydellinen amputaatio ylä- tai alaraajaan. 21 potilasta sai vahingon seurauksena pysyvän hermovamman ja kolme merkittävän aivohalvauksen. Yli puolet potilaista joutui vahingon seurauksena ylimääräiseen leikkaukseen. Valtaosa potilaista sai vahingon seurauksena pysyviä vaurioita.

Potilasvahinkoja tapahtui kaikissa verisuonikirurgisen potilaan hoidon vaiheissa ja useat potilasta hoitaneet ammattiryhmät olivat niihin osallisia. Lähes 90 %:ssä tapauksista arvioitiin, että vamma olisi ollut mahdollista estää. Pelkästään jo tällä hetkellä käytössä olevilla apuvälineillä, kuten leikkaustiimin tarkistuslistan käytöllä, vammoista olisi saatu estettyä yli 10 %.

Potilasvahinkojen ehkäisyyn tulee kiinnittää terveydenhuollossa erityistä huomiota ja kirurgiseen toimintaan liittyvä korostunut riski on tiedostettava. Kansallinen verisuonikirurginen laaturekisteri voisi tarjota mahdollisuuksia potilasturvallisuuden kehittämiseen ja parempiin tilastoihin verisuonitoimenpiteistä. Potilasvahingoista saatavaa tietoa voidaan käyttää hyödyksi terveydenhuollon ammattilaisten koulutuksessa uusien vammojen ehkäisemiseksi.

AVAINSANAT: potilasvahinko, potilasturvallisuus, verisuonikirurgia

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Abbreviations

AAA	Abdominal aortic aneurysm
AE	Adverse event
AV	Arteriovenous
CAS	Carotid artery stenting
CEA	Carotid endarterectomy
CLTI	Critical limb threatening ischemia
EVAR	Endovascular aortic repair
EVLA	Endovenous laser ablation
IAA	Iliac artery aneurysm
ICAS	Internal carotid artery stenosis
M&M	Morbidity and mortality
OR	Open repair
PAD	Peripheral arterial disease
PIC	Patient Insurance Center
PTFE	Polytetrafluoroethylene
RAAA	Ruptured abdominal aortic aneurysm
RCA	Root cause analysis
SMA	Superior mesenteric artery
SSC	Surgical safety checklist
SVI	Superficial venous insufficiency
UK	United Kingdom
US	United States
WHO	World Health Organization

List of Original Publications

This dissertation is based on the following original publications:

I Laukkavirta M., Nikulainen V., Blomgren K., Helmiö P. Patient Injuries in Treatment of Peripheral Arterial Disease in Finland: Review of National Patient Insurance charts. Annals of Vascular Surgery, 2020, Volume 66, pages 225–232.

II Laukkavirta M., Blomgren K., Halmesmäki K., Nikulainen V., Helmiö P. Patient injuries in the treatment of superficial venous insufficiency registered in Finland between 2004 and 2017. Phlebology: The Journal of Venous Disease, 2021, Volume 36, issue 4, pages 260–267.

III Laukkavirta M., Blomgren K., Väärämäki S., Nikulainen V., Helmiö P. Compensated Patient Injuries in Treatment of Abdominal Aortic and Iliac Artery Aneurysms in Finland; A Nationwide Patient Insurance Registry Study. Annals of Vascular Surgery, 2022, Volume 80, pages 283–292.

IV Laukkavirta M., Blomgren K., Rautio R., Nikulainen V., Helmiö P. Compensated and non-compensated patient injury claims in internal carotid artery interventions in Finland, 2004–2017. Vascular: Published online ahead of print Jan 28 2022.

1 Introduction

Primum est non nocere, first do no harm, is an ancient principle in medical care. Although most patients experience safe care, patient harm can have major repercussions for the patient, the family members, the health care professionals and the health care organisation (McCaughan & Kaufman, 2013). Patient harm in Finnish health care can be compensated as a ‘patient injury’ (*Patient insurance Center*, 2021). Patient injuries can lead to increased mortality and morbidity and have devastating effects on the patient (Hakala et al., 2014; Helkamaa et al., 2016; Helmiö et al., 2018; Pitkänen et al., 2013). Such injuries are also a burden to the health care providers and incur disproportionately high costs for health care systems. (Järvelin et al., 2019) Patient harm in ward care has been estimated to incur extra costs of 409 million euros per year in Finland of which more than half may be preventable (Järvelin, 2010). Prevention of errors and adverse events (AEs) that lead to patient injuries should be a high priority for all in health care.

Adverse events occur in approximately 3.8-16.6% of hospital admissions and 7.0% of these AEs lead to permanent disability and 7.4% cause death (de Vries et al., 2008). Between 2007 and 2009 more than 200000 AEs were reported in Finnish health care in HaiPro-system of which 1% led to serious patient harm (Ruuhilehto et al., 2011). It has been estimated that annually 700-1700 deaths are caused by AEs in health care in Finland (Pasternack, 2006).

More than half of recognized AEs in health care are related to surgical care and are common among surgical specialties (de Vries et al., 2008; Gawande et al., 1999; Leape et al., 1991; Thomas et al., 2000). An AE in surgery often results from simple human error (Reason, 1995). The errors that contribute to surgical AEs can be administrative, judgment-based, knowledge dependent, technical or interactive (Andrews et al., 1997; Regenbogen et al., 2007; Rogers et al., 2006). Errors frequently occur in common operations with experienced surgeons (Regenbogen et al., 2007). Errors in surgical care can occur inside or outside of the operating theatre, during, before, or after surgery (Gawande et al., 2003; Greenberg et al., 2007; Griffen et al., 2007). Manual errors in performing surgery can be incidental injuries to anatomical structures, problems in controlling hemorrhage or a misplacement of a graft or prosthesis (Regenbogen et al., 2007). However, these well-recognized complications constitute only one-third to a half of the surgery related errors (Gawande et al., 1999; Regenbogen et al., 2007; Wilson et al., 1999).

Vascular surgery is associated with a high risk for patient harm (Hernandez-Boussard et al., 2012). Malpractice claim data and patient insurance records constitute a detailed source of information on injuries and incidents that contributed to them (de Vries et al., 2011; Greenberg et al., 2007; Regenbogen et al., 2007; Rogers et al., 2006; Studdert et al., 2006; Svider et al., 2014). Linking medical malpractice claims data with clinical data from medical records provide detailed information on error circumstances that lead to an AE (Studdert et al., 2000). Statements by health care personnel can provide additional information that elucidates the causal mechanism of an injury (*Suomen potilas- ja asiakasturvallisuusyhdistys SPTY ry*, 2021). Open and transparent discussion of errors can provide tools for improving patient safety (Hakala et al., 2014).

The aim of this thesis was to examine the patient injuries that occurred in vascular surgery in Finland, their causal and contributing factors, and the consequences of these injuries to the patients. A further objective was to identify potentially avoidable patient harm.

2 Review of the Literature

2.1 Patient safety basics

Over two decades have passed since the Institute of Medicine released its report ‘To Err Is Human’ in 1999, which brought to light the problems in patient safety and the risk of medical errors. The report dramatically raised the awareness of patient safety. It clearly highlighted that errors are common, costly, preventable, and that patient safety can be improved. (IOM, 2000)

2.1.1 Terminology

Patient safety has been greatly hampered by the lack of universal terminology and by inconsistent use of language (Runciman et al., 2009). Various terms such as complication, AE, medical error, medical or patient injury, negligence, and malpractice have been used in studies (Falconer et al., 2019; Hegarty et al., 2020). Several attempts have been made to address the heterogeneity in the terminology of patient safety, but a uniform terminology is still lacking (Pereira-Argenziano & Levy, 2015; Runciman et al., 2009).

A medical error is a failure to complete a planned action as intended or the use of an incorrect plan to achieve an aim (Pereira-Argenziano & Levy, 2015). Medical errors do not always lead to patient harm because they may not directly affect the patient and may not be critical to the process of care (Pereira-Argenziano & Levy, 2015). However, medical errors should be analyzed to prevent patient harm in other patients that are potentially harmed (Pereira-Argenziano & Levy, 2015). A near miss is a medical error that has the potential to cause patient harm but has not done so (Pereira-Argenziano & Levy, 2015). For example, the side of operation was wrongly registered in the patient file, but due to other safety measures the correct side was indeed operated on. Medical errors can be categorized as diagnostic, treatment, or preventive and they can further be classified as preventable or nonpreventable (Pereira-Argenziano & Levy, 2015).

An AE is a medical error that led to patient harm (Pereira-Argenziano & Levy, 2015). It is defined as an unintended injury or complication resulting in prolonged hospital stay, disability at the time of discharge or death, caused by health care management rather than by the patient’s underlying disease (Bosma et al., 2011; Grober & Bohnen, 2005; IOM, 2000).

In Finland, patient injury is defined as a bodily injury that meets the preconditions described in the 'Patient Injuries Act' (*Patient insurance Center*, 2021). Not all AEs that occur in connection with medical treatment and health care are considered patient injuries, but those injuries that fulfil the conditions described in the patient insurance legislation are (*Patient insurance Center*, 2021).

2.1.2 Swiss Cheese Model

The occurrence of medical errors is often multifactorial and requires multiple small deviations to occur in sequence to lead to patient harm (IOM, 2000). The 'Swiss Cheese Model' is used to illustrate a medical error (Figure 1). When the process works well, the 'cheese slices' are arranged so that the holes in the slices, which represent factors contributing to errors do not align. But when the processes of care are flawed the holes align so that opportunities for errors reach the patient and cause harm (Reason, 2000). Process analysis is an important means to understanding errors and their prevention (Pereira-Argenziano & Levy, 2015).

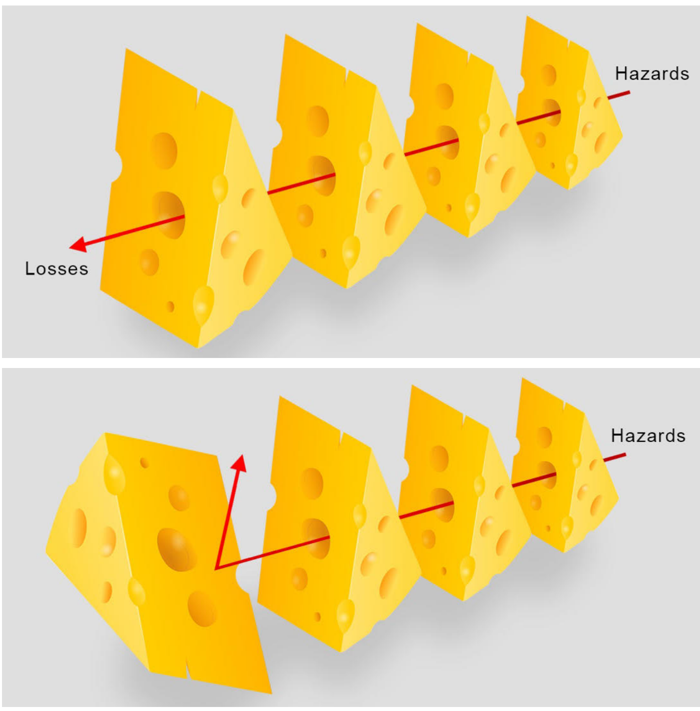

Figure 1. The Swiss cheese model has been used to describe errors in medical care. Hazards are prevented from causing human losses by a series of barriers. Each barrier as depicted by cheese slices with holes representing unintended weaknesses. When by chance all the holes of the slices are aligned, the hazard reaches the patient and causes harm. Safety measures can prevent the holes from aligning and thus prevent harm (Reason, 2000). (Picture copyright Päivi Helmiö)

2.2 Patient safety in surgery

More than 230 million major surgical procedures are undertaken annually worldwide of which over 70 million are performed in Europe (Holmer et al., 2019; Weiser et al., 2008). More than 500000 surgical procedures are annually performed in Finland (*WHO*, 2022). In high-income countries, postoperative complications occur in up to 20% of patients, whereas short-term mortality, which designates mortality occurring less than 90 days after presentation to a hospital, may vary from 1 to 4% (ISOS, 2016; Pearse et al., 2012). Significant progress has been made to address avoidable patient harm before, during and after surgery and other invasive procedures. Nevertheless, patient harm remains a significant challenge at a European and global level (ISOS, 2016; Pearse et al., 2012). Increasing evidence suggests that improved safety culture leads to better patient outcomes in surgery (DiCuccio, 2015; Haynes et al., 2011).

Errors are a common problem in surgery as they occur in 3.9–9.9% of all admissions in surgical specialties (Bosma et al., 2011). Most are of little or no consequence to the patient, but one of every 20 patients experiences significant harm resulting in either death or permanent damage (Bosma et al., 2011). In Finland it has been estimated that roughly 0.4% of all deaths are caused by iatrogenic reasons (Kuvaja et al., 2022). Majority of these deaths involve surgical disciplines (Kuvaja et al., 2022). More than 50% of AEs that lead to death or disability in perioperative period may be preventable (Wacker & Staender, 2014). Operation-related AEs may leave patients with reduced functional independence and lower their long-term survival expectancy (ISOS, 2016; Pearse et al., 2012). For most patients, the risks of surgery are low but studies suggest that 1–4% may die before hospital discharge after surgery (ISOS, 2016; Pearse et al., 2012).

Wrong site/side surgery, wrong performed procedure and retained foreign objects in surgery have been termed as ‘never events’ (Michaels et al., 2007; Thiels et al., 2015). Never events are considered to be wholly preventable, but despite considerable patient safety measures being taken, still continue to occur (Koleva, 2020). Sources of error that may lead to never events in operating theatres comprise human fallibility, miscommunication, lack of collaboration of team activity, human-technology interaction and poor management of the care environment (Koleva, 2020).

The frequency of preventable harm in surgery remains high and more investments must be made to analyze patient harm as such progress could lead to a vast improvement in patient safety (Bates & Singh, 2018). It is evident that patients are frequently injured as a result of the care, and while improvements have been made, never events such as wrong-patient and wrong-site surgery still occur with disturbing frequency (Bates & Singh, 2018).

2.3 Patient safety risks in vascular surgery

Vascular surgery is an essential specialty in modern operative hospitals. The speciality uses a multidisciplinary approach to operative intervention and its use is on the increase. A vascular surgeon can offer a reconstruction of vascular structures, vascular control and repair during operative procedures. The vascular surgeon is frequently required in an emergency situation in an intraoperative consultation setting. The need for vascular surgery services are continuously increasing and commonly also in an unplanned manner. (Manzur et al., 2017)

Vascular surgery is a speciality that has a high-risk for patient harm as 5% of patients undergoing a vascular procedure experience an AE (Hernandez-Boussard et al., 2012). Open abdominal aortic aneurysm (AAA) surgery and above knee amputations have higher risk rates than procedures such as femoral endarterectomy and endovascular aneurysm repair, which probably reflects the many co-morbidities and complexity of the disease in these patients (Hernandez-Boussard et al., 2012). Higher volume hospitals seem to have superior outcomes regarding patient safety indicators (Hernandez-Boussard et al., 2012).

The technical development of endovascular devices has enabled more surgical treatments to be used in the care of a growing population of patients (Patel et al., 2016). Indeed such endovascular treatment options have increased greatly and offer a chance for improved care, but also carry unique risks (Patel et al., 2016).

2.3.1 Development of vascular surgery specialty in Finland

Cardio-thoracic surgery and vascular surgery were separated into independent surgical specialties in Finland in 1999, before then they were categorized as a joint specialty (*Finnish Medical Association*, 2021).

During the decades since 1999, the volume of vascular surgery in Finland has increased and methods of treatment have developed (Nikulainen et al., 2019). From 2007 to 2017, a clear increase in vascular procedures, especially endovascular ones, was evident in Finland as open revascularisations increased from 2705 to 3992 and endovascular revascularisations from 791 to 5514 during the time period (Nikulainen et al., 2019).

Vascular surgeons work in conjunction with interventional radiologists in order to provide the best possible patient care. However, as to how the work is distributed between vascular surgeons and interventional radiologists varies greatly among different centres in Finland. Despite this, the vascular surgeon is principally responsible for the treatment of the patient, even though many interventions are carried out by radiologists nowadays. (SVKY, 2019)

Arterial vascular surgery in Finland is mainly practiced in university and central hospitals. Venous procedures are also performed in regional hospitals and also in the private sector. Venous procedures are increasingly performed outside the operating room. Conditions such as varicose veins were traditionally treated mostly by general surgeons but nowadays they are probably mostly handled by vascular surgeons. (SVKY, 2019)

2.3.2 Procedure and disease specific risks

Vascular surgery encompass a wide range of procedures that vary in complexity and periprocedural risks (Hernandez-Boussard et al., 2012). Vascular surgery patients vary significantly in characteristics, although many are elderly with multiple co-morbidities (Sidawy & Perler, 2019). Several patient- and disease related factors must be considered when selecting patients for invasive procedures and the complexity in decision making and timing of the operation provides a challenge of care for the entire specialty (Goodney, 2012). A procedure can be performed for different reasons that reflect different levels of disease severity. For instance, a lower extremity bypass may be performed for limb-threatening gangrene of the foot or because of quality of life reducing claudication (Hernandez-Boussard et al., 2012).

Vascular surgery is a specialty burdened with a high rate of complications as vascular patients often have various co-morbidities and therefore have a high risk of developing postoperative problems (Nowygrod et al., 2006). Not all complications are patient injuries as some risks related to the treatment of the underlying disease must be accepted (*Patient insurance Center*, 2021). When comparing outcomes, the indications for surgery must be taken into account (Hernandez-Boussard et al., 2012). The use of endovascular techniques has reduced the risk of complications in elderly patients but not all patients are eligible for minimally invasive procedures (Nowygrod et al., 2006). Aortic surgery is associated with higher risks than peripheral vascular surgery (Kehlet et al., 2016). Advanced age (older than 80 years), female sex and pre-existing cardiac and renal disease are the most commonly associated risk factors (Kehlet et al., 2016).

Postoperative morbidity of major vascular operations is higher compared to many other surgical specialties (Nowygrod et al., 2006). Complications can often have profound effects on already frail vascular surgical patients (Bennett et al., 2017). They can also have a significant effect on the utilization of health care resources due to prolonged hospital length of stay, increased overall hospital costs and an increased need for readmission (Bennett et al., 2017; Kehlet et al., 2016). The prevention of complications needs to be a major focus in vascular surgery (Bennett et al., 2017).

Peripheral arterial disease

Population growth and the ageing of the population have led to a growing number of people living with atherosclerotic vascular disease worldwide. A global epidemic of obesity and diabetes creates a major concern for global health. In 2015, peripheral arterial disease (PAD) affected almost 155 million people worldwide (Vos et al., 2016).

PAD is a common condition in which atherosclerotic lesions restrict blood flow to the lower extremities (Sidawy & Perler, 2019). Critical limb threatening ischemia (CLTI) is the most severe presentation of PAD and without successful revascularization CLTI is a threat for limb loss (Aboyans et al., 2018).

Patients who require lower extremity revascularization procedures often have atherosclerotic disease in other locations (Aboyans et al., 2018). Complications that follow after peripheral vascular surgery are common, as 30% of patients suffer from at least one major postoperative complication (Kehlet et al., 2016). A significant number of PAD patients may develop postoperative cerebral or myocardial ischemia (Ghansah & Murphy, 2004). Other typical problems include renal insufficiency and pulmonary complications (Ghansah & Murphy, 2004).

The saphenous vein and prosthetic grafts made of polytetrafluoroethylene (PTFE) or polyethylene terephthalate polyester (Dacron) can be used for arterial bypasses in the lower extremities. Other materials such as bovine heterografts, human umbilical vein or cryopreserved vein grafts are rarely used. Hemorrhage, graft failure, pseudoaneurysms, and graft infections are other typical complications after lower extremity revascularization procedures. Graft failure can lead to ischemia of the limb and amputation. (Ghansah & Murphy, 2004)

Early graft failure is typically due to mechanical errors such as graft twisting, errors in suture line construction or graft placement and tunneling. Inadequate inflow and backflow can also result in early graft failure. In vein grafts, poor vein quality or missed valves in in-situ grafts can lead to graft failure. Late failure is often due to kinking of the graft, a clamp injury or a degeneration of a graft or inflow and outflow problems. (Ghansah & Murphy, 2004)

Amputation and mortality rates are high after peripheral revascularisation for claudication or CLTI as 30-day mortality can be as high as 5% (Kehlet et al., 2016). Even with the best possible care, 30% of CLTI patients will require an amputation within 12 months of diagnosis of CLTI and 25% will die (Norgren et al., 2007).

Abdominal aortic aneurysm

AAA is a common disease that especially affects elderly men (Moll et al., 2011). As the size of the aneurysm increases, the risk of rupture increases (Moll et al., 2011). Surgical repair has been practiced since 1952 and minimally invasive vascular repair was first reported in 1986 and has become the chosen method of repair (Patel et al., 2016).

The prognosis of ruptured abdominal aortic aneurysm (RAAA) is poor. In Finland, over half of the patients die from RAAA prior to reaching hospital. Over 30% of patients who are deemed fit for surgery die. Less than 30% of patients survive RAAA. (Laine et al., 2016)

Open repair (OR) of AAA is an acceptable method of treatment and has a mortality rate of 5% (Greenhalgh et al., 2004). Nowadays, endovascular aortic repair (EVAR) has replaced OR to a large extent as it has a lower mortality rate than OR within the first 6 months (Patel et al., 2016). After 6 months the survival benefit is lost and the rate for re-interventions is higher for EVAR than for OR (Patel et al., 2016).

Typical problems with OR include cardiac, pulmonary, and renal complications. Postoperative hemorrhage, gastrointestinal problems such as bowel ischemia and paralytic ileus are also typical in the immediate postoperative period. Graft infections can present immediately or months or even years after successful surgery. Adequate treatment usually requires the removal of the infected graft and prolonged antibiotic treatment. Stroke and spinal cord ischemia are also possible. Acute ischemia of the lower limbs due to emboli can also complicate recovery. (Ghansah & Murphy, 2004)

EVAR is associated with fewer cardiac and respiratory problems. Typical complications associated with EVAR include endoleak and stent-graft migration which might require surgical conversion. (Patel et al., 2016)

Internal carotid artery stenosis

Internal carotid artery stenosis (ICAS) causes about 10 to 15% of ischaemic strokes (Petty et al., 1999). ICAS can be treated with open carotid endarterectomy (CEA) or endovascular carotid artery stenting (CAS) (Lokuge et al., 2018).

Risks and benefits for the patient must be weighed individually in order to correctly choose the most suitable patients for the treatment of ICAS (Bond et al., 2002). As treatment of ICAS carries significant risks, all patients must be comprehensively informed preoperatively about the risks and accept them (Bond et al., 2002; Ferguson et al., 1999).

CEA carries a risk of stroke or death for up to 5% in symptomatic patients and up to 3% in asymptomatic patients (Lokuge et al., 2018). Other typical reported problems in CEA include cranial nerve injury most typically to the recurrent laryngeal nerve or to the hypoglossal nerve. Myocardial infarction and wound hematoma are also common problems (Naylor et al., 2018). Rare complications include vascular patch infection and restenosis (Naylor et al., 2018). Endovascular treatment with CAS has been associated with a slightly higher risk of periprocedural stroke or death (Ederle et al., 2010; Rosenfield et al., 2016). Other potential complications are puncture site hematoma, pseudoaneurysm, and thrombosis of a punctured artery (Müller et al., 2020; Naylor et al., 2018).

Superficial venous insufficiency

The incidence of varicose veins in Finland is 13.5 per 1000 person years (Mäkivaara et al., 2004). The effects of superficial venous insufficiency (SVI) can range from being purely cosmetic to causing venous ulcers (Mäkivaara et al., 2004; Porter & Moneta, 1995).

The treatment aims to improve the quality of life and to prevent disease progression in the patient. Conservative treatment can be carried out with compression therapy. However, surgical treatment has undergone a major shift towards endovenous treatments in the 21st century. The treatment options now include not only traditional open surgery but also foam sclerotherapy and endovenous thermal ablation as well. (Wittens et al., 2015)

Endovenous thermal ablations can be performed as an out-patient procedure under tumescent anaesthesia. The use of ultrasound guided foam sclerotherapy is relatively efficient and safe. The method is simple and costs are low. Foam sclerotherapy is less efficient than thermal ablation or surgery, however. The efficacy of thermal ablation is equal to that of surgery. (Wittens et al., 2015)

Typical complications in open surgery are wound infection and haematomas and deep vein thrombosis (Critchley et al., 1997). More serious complications include vascular injury to the deep veins and arteries and nerve damage (Critchley et al., 1997). Typical complications associated with thermal ablation include thrombophlebitis, thermal skin injury, bruising, hyperpigmentation, and paresthesia (Wittens et al., 2015). Potential problems of foam sclerotherapy include hyperpigmentation, thrombophlebitis, pain at the injection site, and occasionally neurologic events, such as visual disturbances, migraine, and stroke (Wittens et al., 2015).

Arteriovenous access surgery

Patients with acute renal failure or end stage renal disease require renal replacement therapy. Vascular access is essential for patients for hemodialysis. A vascular access can be created by arterialisation of a vein or by joining a prosthetic graft between an artery and a vein. Patients requiring access surgery are often elderly with concurrent comorbidities and poor upper extremity vessels, therefore surgical decision making and risk evaluation are essential for these patients. The risks must be evaluated during the whole care process. Typical complications in arteriovenous (AV) access surgery include the following: hemorrhage, infection, seromas, thrombosis, and limb ischemia. (Schmidli et al., 2018)

Other upper extremity vascular conditions

Other upper extremity vascular conditions include acute ischemia and hemorrhage caused by embolus or trauma or chronic conditions such as PAD or aneurysms (Aboyans et al., 2018; Björck et al., 2020). Complications in the operative treatment of other diseases such as coronary artery disease can lead to iatrogenic pseudoaneurysm formation (Tavakol et al., 2012). Treatment of upper extremity vascular conditions can cause ischemia and hemorrhage and can result in a loss of function in the extremities or even to either the loss of fingers or an entire limb (Aboyans et al., 2018; Björck et al., 2020).

2.4 Existing tools for improving patient safety in surgery

2.4.1 The HaiPro reporting system

A robust reporting system for medical errors and AEs is critical for improving the safety of care (Pereira-Argenziano & Levy, 2015). Error reporting can be voluntary or mandatory but in health care voluntary incident reporting systems are more widely used (IOM, 2000).

HaiPro is a Finnish web-based tool for reporting patient safety-related incidents. It is used by more than 200 health care organizations in Finland. Reports are anonymous, voluntary and no blame is sought in the reports. (*Suomen potilas- ja asiakasturvallisuusyhdistys SPTY ry*, 2021)

The HaiPro system is intended for analysis and improvement of patient safety within organizations (*Suomen potilas- ja asiakasturvallisuusyhdistys SPTY ry*, 2021). HaiPro helps to evaluate the sufficiency of current preventive procedures, and it can also be used to assess the effects of new patient safety measures (Ruuhilehto et al., 2011). HaiPro reports can be generated by all members of the health care staff and reports should be scrutinised regularly with them (Liukka et al., 2019). The HaiPro system can also be used by patients and their next of kin for reporting errors in care (Liukka et al., 2019; Ruuhilehto et al., 2011).

Voluntary error reporting systems have certain limitations: complex reporting systems, inadequate education or training, lack of feedback, concern about legal implications, and fear of punitive actions may lead to underreporting of errors (Pereira-Argenziano & Levy, 2015).

2.4.2 The ISBAR tool

Patient transfer from one unit of care to another is a critical step in the patient's care. Surgical patients undergo several transfers: from the surgical ward or the emergency room to the operating theatre, then to the recovery room and finally back to the surgical ward. Therefore, there are many potential instances of risk. The use of structured, standardised frameworks for handover improves information transfer and patient outcomes (Foster & Manser, 2012).

One of the most widespread and well-studied communication improving tools is ISBAR. The acronym stands for Introduction, Situation, Background, Assessment and Recommendation (Burgess et al., 2020). ISBAR was originally developed by the military for use in nuclear submarines but was later adopted by aviation and then by health care in the 2000s (*WHO, 2021*). The main purpose of ISBAR is to circumvent and ease communication problems between health care professionals. ISBAR can be used in a variety of situations, such as bedside handover and internal or external transfers between health care facilities (Burgess et al., 2020). Moreover, ISBAR provides a standardised approach to communication and it increases transparency and accuracy in inter-professional handovers (Burgess et al., 2020; *WHO, 2021*). The use of ISBAR is recommended by World Health Organization (WHO) and it is in use globally (*WHO*, 2007). ISBAR was found to improve communication in Helsinki University Hospital and its use has spread to other hospitals in Finland as well (Sailavuo, 2021).

2.4.3 Surgical Safety Checklist and team briefings

The WHO Surgical Safety Checklist (SSC) was launched in 2008 (Treadwell et al., 2014). It was adapted from check lists used in aviation to improve patient safety culture in surgery (Birkmeyer, 2010). The SSC is designed to reduce post-operative morbidity and mortality and has been validated in a multicenter study (Haynes et al., 2009). The postoperative mortality decreased from 1.5% to 0.8% and inpatient complications from 11% to 7% after the implementation of SSC (Treadwell et al., 2014). The use of the SSC has been associated with little or no harm and it is also cost effective and time efficient to use (Haynes et al., 2009). Effective implementation of the SSC can, however, be problematic due to confusion how to properly use the checklist, pragmatic challenges to efficient workflow, access to resources, and individual beliefs and attitudes (Treadwell et al., 2014). The SSC was piloted in Finland in 2009 (Takala et al., 2011). It confirms the recognition of the patient, the awareness of team member's names and roles, the identification and confirmation of the operation, and also the operation side (Takala et al., 2011).

Preoperative and postoperative team briefings combined with the use of the SSC can improve the awareness of staff toward patient safety, improve the team work climate, the safety climate, job satisfaction, the perception of management, and also working conditions; but it can also increase staff stress (Hill et al., 2015). The cultural shift in patient safety awareness can be observed after the introduction of such methods but it is important that all staff members have the opportunity to voice their concerns (Hill et al., 2015). The frequent use of briefings is likely to improve team cohesion and safety culture (Lark et al., 2018).

2.4.4 Root cause analysis

When an error or an AE occur, swift analysis is crucial. Root cause analysis (RCA) is a systematic approach aimed at discovering the causes of close calls and AEs in health care and to prevent such events from reoccurring in the future (Charles et al., 2016). In the majority of incidents, a series of events and a wide range of contributory factors occur (McCaughan & Kaufman, 2013). The analysis looks beyond human error to systematic issues that contributed to the event. The goal of RCA is therefore to protect patients by identifying and changing the factors in health care that can potentially lead to harm (Charles et al., 2016). The most common cases for which RCA is used are surgical cases (Kellogg et al., 2017). In Finland, RCA has also been used to analyze patient injuries involving medication errors (Eronen, 2016).

To even begin RCA, honest and open reporting of errors is required. Personnel should be encouraged to report AEs and close calls so that suitable events can then be identified for RCA. The aim of RCA is to answer what happened, how it happened and what can be done to prevent it from happening again. Documentation and interviews are an integral part of the process. After identifying root causes for the event, contributing factors are analyzed. Only then can remedial actions be developed. Measuring the outcome of an intervention is intended to determine the success of the RCA (Charles et al., 2016).

RCA can lead to improvements in health care through safety interventions. Although RCA has become widespread in many countries, the effectiveness of the process has been questioned. Without effective solutions certain types of events repeatedly occur. Critical evaluation of the RCA process is necessary for it to deliver the required benefits (Kellogg et al., 2017).

2.4.5 Morbidity and Mortality meetings

Mortality rates in hospital can be used to monitor the quality of care (Jarman et al., 2010). Hospitals are increasingly beginning to integrate Morbidity and Mortality (M&M) meetings into the evaluation of systemic processes (Higginson et al., 2012). M&M meetings help to achieve and maintain high standards of care (Higginson et al., 2012; Sinitsky et al., 2019).

Although trainees often possess positive attitudes towards safety culture in general, they lack the understanding of organisation's role in error management and error causation (Singh et al., 2019). Encouragement should be made to evaluate systemic errors instead of focusing on individual failures (Higginson et al., 2012).

The evaluation of adverse outcomes is an important part of a surgeon's training and the M&M meeting is a forum where they can be discussed. These meetings provide not only education to clinicians, but also have the potential to improve the quality of care and attitudes toward patient safety and outcomes. The effectiveness of M&M meetings is lessened by poor attendance and the surgeons fear of repercussions following the admittance of errors (Sinitsky et al.,2019). It has been suggested that in order to reach maximum potential in surgery, M&M meetings should be open to all medical professionals, not just surgeons and there should be ample time for discussion (Sinitsky et al., 2019). M&M meetings are not currently a mandatory part of surgical training in Finland but could offer valuable information to clinicians here as well.

2.4.6 Quality registries

Clinical quality registries in surgery are in wide use in several countries now. Such registries have been found to help monitor surgical quality. Clinical registries have advanced the field of surgical quality definition, measurement, and risk modelling and by serving as platforms for quality improvement. The major limitation of clinical registries is the high cost and required rigorous data collection. Auditing and validation of registries requires dedicated and trained personnel. (Stey et al., 2015)

Quality registries in vascular surgery

Quality registries in vascular surgery can be used to provide feedback, initiate professional discourse, improve self-assessment, and develop better decision-making skills. They can be used to study time trends and differences between geographical areas. National vascular registries can have a great impact on the attitudes of vascular surgeons, provided that they are involved in the process. (Salenius et al., 1997)

FinnVasc was one of the first vascular surgical quality registries in the world. It had been developed in 1989, and in 1991 it was implemented into national use in Finland (Lepäntalo et al., 1994). The registry was in use in Finland until in 2000, then it was terminated due to legislative decisions (Lepäntalo et al., 2008). The registry led to the publication of several articles on Finnish vascular surgery and enabled comparisons between different units of vascular surgery (Kantonen et al., 1999; Salenius et al., 1993).

Currently, not all Finnish hospitals are able to maintain a quality registry for vascular surgery. Nevertheless, the numerous hospitals that do have a quality registry communicate poorly with each other (SVKY, 2019). The Finnish Society for Vascular Surgery has called for a cohesive registry to improve patient safety (SVKY, 2019). However, the work with quality registries in Finland has continued with local vascular registries such as HUSVASC (Aro et al., 2019; Lepäntalo et al., 2008).

Interest in vascular registries has been globally high. VASCUNET was established in 1997 to improve the quality, safety and effectiveness of vascular health care in Europe and also in Australasia (Sutzko et al., 2020). It is a collaboration of clinical and administrative vascular registries, administered and partly funded by the European Society of Vascular Surgery (*European Society for Vascular Surgery, 2021*). Currently, 26 different countries work together for research and quality improvements (Sutzko et al., 2020).

Finnish involvement in VASCUNET collaboration has been active despite the lack of a cohesive national registry and it has resulted in multiple publications on practice and outcome of treatment of CLTI, carotid stenosis, aortic disease, amputations, popliteal aneurysms, in addition to rare diseases such as internal iliac aneurysms (Behrendt et al., 2018; Björck et al., 2014; Laine, Björck, et al., 2017; Lees et al., 2012; Mani et al., 2015; Vikatmaa et al., 2012). This body of research has had a significant impact on patient safety. The VASCUNET report on AAAs demonstrated a significantly higher post-operative mortality in the United Kingdom (UK) compared with eight other countries and thus actions in the UK were undertaken that decreased mortality after elective AAA repair from 7.5% to 2.4% (Jongkind & Halliday, 2020; Mani et al., 2011). An integral part of the VASCUNET collaboration has also been international registry validations (Sutzko et al., 2020).

2.4.7 Claim analysis

Insurance records and malpractice claims provide valuable information about factors that contribute to patient injuries and systemic causes behind them (de Vries et al., 2011). Prevention of errors and AEs should be a high priority within every specialty (Roberson et al., 2004). The patient's pathway through the treatment process should be analyzed on a systematic basis and claim analysis offers the opportunities for identifying errors and rare events in patient care in Finland (Hakala et al., 2014; Vincent et al., 2006).

2.5 Patient harm compensation systems

Patient harm is experienced during care all over the world but compensation processes for harmed patients differ greatly between countries.

2.5.1 Compensation systems globally

There are major legislative differences in claim processes among different countries worldwide. In Finland, as in other Nordic countries and also New Zealand, a 'no fault' patient insurance system is in use. In the Finnish system, claims rarely advance to the courts (Mikkonen, 2004). The compensation system is designed to compensate patients for injuries they suffer from avoidable risks and for complications related to medical care (Bal, 2009).

In France, an out-of-court, no-fault system is in use in which patients bring claims before a regional government-appointed review board. The money to compensate injured patients comes from a national fund. (Bal, 2009)

In the United States (US) and the UK a tort insurance system is used and medical malpractice system relies on courts to adjudicate patient complaints. Medical malpractice law in the US is derived from English common law. Medical malpractice lawsuits are a relatively common occurrence in the US. The legal system is designed to encourage extensive negotiations between adversarial parties with the goal of resolving the dispute without going to jury trial. Jury trials are less common in the UK than in the US, but the legal handling of malpractice claims is otherwise similar in both countries. (Bal, 2009)

The Canadian medical malpractice system is similar to that of the US. Most Canadian physicians are insured against medical malpractice by the 'Canadian Medical Protective Association'. Alternative, informal judicial forums are being used increasingly in Canada to address patient concerns. (Bal, 2009)

Australia has a more socialized health system than the US, but similar standards of medical negligence, grounded in English common law, apply to medical malpractice litigation in Australia. (Bal, 2009)

In Germany, medical malpractice claims are referred to mediation boards and expert panels set up by a 'physicians guild'. Patients can reject the outcome of the mediation, and take their case to court where the system of adjudicating medical malpractice claims is similar to that of the US. (Bal, 2009.)

In Japan, doctors are covered for malpractice claims by a collective insurance pool. 'The Professional Liability Program' offers an out-of-court claim review system that is faster and less expensive than court review. The review board's decisions are generally binding, but patients can also sue in court. Unlike the US, injury or death due to medical error in Japan can be treated as a criminal matter with the possibility of physician arrest and prosecutorial investigation. (Bal, 2009)

2.5.2 Patient injury compensation in Finland

Patient Insurance Center

The Patient Insurance Center (PIC) has been handling all personal injuries that occur associated with health care since 1987. It promotes patient safety by encouraging research and by providing statistics. All insurance companies providing patient insurance policies are its members. (*Patient insurance Center*, 2021)

The duties of the PIC include the following: handling compensation procedures in a centralized manner, granting public sector patient insurance policies in the names of the member companies, providing insurance cover when insurance has not been taken out and instructing and promoting cooperation between insurance companies. The function of PIC is to provide fair compensation to the injured patient in patient injuries, and not to determine the party or parties at fault. (*Patient insurance Center*, 2021)

The PIC handles all patient injury claims. It registers claims, obtains necessary documents from the places of treatment and from medical experts, hears individual filing of the claim when necessary, provides a written claim decision and commences the claim handling in favorable claim decisions. (*Patient insurance Center*, 2021)

Claim handling and decisions

Claims must be filed within three years of the suspected patient injury. Currently, the average handling time for a claim in Finland is 7.5 months. More than 90 percent of claims are resolved within a year from the claim registration. The PIC has resolved more than 220 000 cases over its 33 years of operation. Around 73 000 of these cases have been compensated. Almost 600 million euros have been paid in compensation to the injured patients but the costs of these injuries to health care and society are considerably higher. (*Patient insurance Center*, 2021)

Individual compensation sums paid by the PIC are classified but typical compensation sums range from a few hundreds to a few thousands of euros per patient, unlike in some other countries such as the US were compensation sums can be astronomical in scale (Schaffer et al., 2017).

In 2019, 7645 individuals filed a claim with the PIC for a suspected patient injury. This resulted in 9556 separate cases that were registered based on the notices. The high number of separate cases is explained by the fact that one claim may include treatment in several health care units, and all these involved units are registered as separate cases. (*Patient insurance Center*, 2021)

In 2019, 7601 people received 9594 decisions on their cases. Of the cases resolved in 2019, slightly less than half had been reported that year. Moreover, 28.4% of the decisions were in favor of the claimant. In 2017, 8632 reported cases were resolved, which is roughly the same as the number of new notices of injury received that year. Of the resolved cases, 27%, were deemed worthy of compensation. The number of cases has been on a clear rise between 2017 and 2019. (*Patient insurance Center*, 2021)

2.6 Patient safety research in Finland

The importance of patient safety research has been recognized in Finland. Finland's Ministry of Social Affairs and Health issued a Patient and client safety strategy 2017–2021 to improve patient safety (*Ministry of Social Affairs and Health*, 2020). Research is one of the integral parts of the strategy (*Ministry of Social Affairs and Health*, 2020). Surgical quality improvement has been the focal point of several Finnish studies. The effects of the use of the SSC have been studied in otorhinolaryngology and SSC was found to improve verification of patient identity, reduce the side of the operation mistakes and enhance communication between the surgical team members (Helmiö et al., 2015). In neurosurgery, the SSC was found to improve operating room safety culture and to reduce wound complications and unplanned readmissions (Lepänluoma et al., 2014). Simulation training in the treatment of RAAA has been evaluated and proven to improve the treatment process and enhance patient outcomes (Aho et al., 2019). Patient safety studies have also been carried out in nursing and have identified that increased workload per nurse is a risk to patient safety (Fagerström et al., 2018).

In Finland, patient safety falls under the auspices of the Finnish Centre for Client and Patient Safety, in Vaasa. The centre supports patient safety by research, training and networking with patient safety experts. It shares information and distributes good practices and tools for patient safety improvement. The centre is funded by the Ministry of Social Affairs and Health in Finland (*Potilas- ja asiakasturvallisuuden kehittämiskeskus*, 2021).

There is also currently a professor of 'Patient Safety' in Turku University (*Turun yliopisto- University of Turku*, 2021). The Finnish Medical Association also offers a special competence program in 'Health care Quality and Patient Safety' (*Finnish Medical Association*, 2021).

2.6.1 Specialty related patient injury studies in Finland

Several studies of patient injuries involving operative care in Finland have been conducted. Studied specialties include at least orthopedic and pediatric surgery, anaesthesiology, otorhinolaryngology, odontology, thoracic surgery, and gastric surgery (*Patient insurance Center*, 2021). The studies found that procedures related deaths in Finland are rare, but they do occur, and even a minor surgical procedure in a healthy patient can lead to death (Hakala et al., 2014). Post-operative mortality in Finland, at 2.0%, is among the lowest in Europe (Pearse et al., 2012). It is estimated that for every 15000 surgical operations there is one financially compensated death paid by the PIC (Hakala et al., 2014). Of the errors that lead to a patient's death, 45% take place during surgery (Hakala et al., 2014). An error of judgment is the one cause that most commonly leads to death (Hakala et al., 2014).

Anaesthesiology

Administration of spinal and epidural anaesthesia rarely leads to serious complications such as: death, neuraxial haematoma compression of the spinal cord, and severe infections. Risk of fatality was 1 in 233 000 and of a serious complication 1 in 35 000 neuraxial blocks. Even though some major incidents may not have been reported to the PIC, it was assumed that most major complications are. Moreover, 17.1% of the injured patients had undergone a vascular surgery procedure. Patients undergoing vascular surgery have often many co-morbidities and increased anaesthesia risks. Concomitant use of heparin may be associated with higher risk of neuraxial haematoma. The correct use of guidelines in patients with antithrombotic medication was emphasized to avoid unnecessary complications. (Pitkänen et al., 2013)

Cardio-thoracic surgery

After coronary artery bypass, grafting infections formed the majority of compensated claims whereas treatment injuries accounted for the minority of compensated claims in cardio-thoracic surgery. Women seemed to be more inclined to file a claim than men and perhaps sought the opportunity to express their dissatisfaction more actively. Advanced age was associated with a lower likelihood of filing a claim. Aged persons may be unable to file a claim themselves, and require more help in the claim process. (Järvelin et al., 2009)

Gastrointestinal surgery

The incidence of compensated patient injuries for the surgical treatment of ventral and inguinal hernias was found to be much smaller than the previously reported morbidity. Severe visceral and vascular complications were rare, but major complications such as death, major bleeding, or severe infection accounted for 15% of the compensated complications in gastrointestinal operations. On a population level, this is probably an overestimate of major complications as minor complications often do not merit compensation from the PIC. Patient injury claims are considered to give excellent additional information on the subject of gastrointestinal surgery because randomised controlled trials may not easily detect connections between rare complications and different surgical approaches. Surgeons should be aware of possible complications when choosing the surgical technique. (Ahonen-Siirtola et al., 2015; Kouhia et al., 2015)

Orthopedic and pediatric surgery

In primary hip replacement, the most typical reason for compensation was intraoperative technical error such as a malpositioning of the cup. Higher hospital volumes were associated with fewer filed claims. As much as 80% of the patient injuries were caused by avoidable errors, although only 1.2% of total hip replacements led to a compensated patient injury. The injuries were distributed unevenly as a small group of orthopedic surgeons was responsible for 24% of all the technical errors. (Helkamaa et al., 2016)

Patient injuries in the treatment of distal radius fractures involved diagnostic errors and technical errors, errors in decision-making and in follow-up. Over half of the AEs occurred during early follow-up visits. The use of a radial fracture checklist may offer new opportunities for avoiding patient injuries. (Sandelin et al., 2018)

Most patient injuries in pediatric distal humeral fractures were considered avoidable. Problems in diagnosis and the choice of treatment and unsatisfactory operative treatment accounted for the majority of injuries. Nerve injuries were reported in 20% of the patient injuries. In many cases, preoperative neurovascular assessment was cursory and poorly documented. This should be recorded in the patient files with sufficient accuracy. Operative treatment was recommended to be centralized due to the rarity of the fractures. (Vallila et al., 2015)

Otorhinolaryngology

Errors occurred frequently in common operations by fully trained otolaryngologists (Blomgren et al., 2017; Helmiö et al., 2015; Helmiö et al., 2018). Between 0% and 3.2% of the injuries in otorhinolaryngology involved wrong-site surgery (Blomgren et al., 2017; Helmiö et al., 2015; Helmiö et al., 2018). Technical error in performing surgery was identified as the primary incident in 64.4% of the injuries (Helmiö et al., 2015).

In otology, 73% of the injuries were associated with operative care and a typical incident was an error in surgical technique (Helmiö et al., 2018). Injuries in pediatric otorhinolaryngology were strongly related to surgical care and most likely occurred in routine operations, intraoperative burns were the most common surgical error

(Nokso-Koivisto et al., 2019). In rhinology, the injuries occurred in commonplace operations and technical error in performing the surgery was identified in two-thirds of the injuries (Blomgren et al., 2017).

Odontology

Endodontic malpractice claims were evenly distributed among the entire profession and no operator level of experience differences could be found. The majority of injuries would have been avoidable, had the operator followed good clinical practice. Even when the claim led to no compensation, the patient's dissatisfaction with her/his treatment should be noted as they serve as an indicator of a lack of quality and safety. (Vehkalahti & Swanljung, 2017)

In conclusion, it can be said that Finnish patient injuries have been studied to some extent, but a synopsis of the patient injuries is currently lacking. Surgical specialty injuries seem to be strongly related to operative care. The risk of death and serious complications in surgical procedures is clearly demonstrated in the studies, but many studies state that the number of reported patient injuries is lower than would be expected from reported complications in the literature. It seems that not all patients who experienced harm filed a claim with the PIC. As patients are usually well informed of the risks of operations and approve them, they might not consider it necessary to report any problems to the PIC. It is also noteworthy that not all complications fulfil the PIC compensation criteria.

2.7 Patient safety research in vascular surgery

Despite the general interest in research about errors and patient safety, safety research in the vascular surgery specialty has been quite limited so far (Lear et al., 2017). Traditionally, the research by the surgical specialties has focused on the treatment protocols and surgical methods, while lacking the focus on systemic causes of errors and AEs. The patient's pathway through the entire surgical process should be systematically scrutinised and analyzed to identify the root causes of errors (Roberson et al., 2004). Only a few studies of patient harm in vascular surgery exist and they greatly vary in their study approach. Even though some summaries of national patient injuries exist, most studies have been based on the evaluation of a certain disease.

In Sweden, the largest group of compensated patient injury claims involved varicose vein surgery. The most common causes for compensation were peripheral nerve injuries and infections. More than half of the patients suffered a permanent injury and 1.6% of the injured patients died. (Rudström et al., 2011)

In Spain, 1.3% of the registered claims were related to the practice of vascular surgery, 53.8% were related to venous pathology and 46.1% to arterial pathology. Nerve injury was the main reason for claims. Vascular surgery did not seem to be a specialty with a high risk for claims, but complications did occur and deserve special attention so that improvements could be made to enhance patient safety. (Roche et al., 2014)

In the UK, a majority of compensated ligation claims in vascular surgery involved varicose vein surgery. The most common reason for the complaint was intraoperative problems such as nerve or vessel damage. Delays in treatment and diagnosis were also common. (Markides et al., 2008)

2.7.1 Disease specific studies

Arterial surgery

Lear et al. published a systematic review in 2017 about system factors and quality and safety in arterial surgery. They found only a small number of studies on the subject and these were of varying quality. There was some evidence of an association between system factors and patient outcomes, but they stated that more work needed to be done to fully understand this relationship. They concluded that future research would benefit from consistency in definitions, the use of validated assessment tools, measurement of clinically relevant endpoints and an adherence to national reporting guidelines. (Lear et al., 2017)

Abdominal aortic aneurysm

Systemic failures concerning aortic procedures and their effect on patient outcomes were analyzed by Lear et al. in a multicenter observational study of English hospitals. They found that failure in aortic procedures is frequently caused by issues with team-working and with equipment and stated that patient harm is frequently caused by systemic failures. (Lear et al., 2016)

Malpractice lawsuits in the treatment of aortic aneurysms and dissections in the US, involved mostly failures to diagnose and treat. Delays occurred primarily in hospital emergency departments or outpatient clinics. Postoperative complications after open repair also contributed to the lawsuits. A majority of the injuries had grave consequences. (Choinski et al., 2021)

Carotid artery stenosis

Factors raised in carotid endarterectomy litigation in the US vary. Of all the reported complications stroke was involved in 51.3% and hypoglossal nerve injury in 27.0%. Other reported complications were airway compromise, vocal cord injury, and death. There were no reported myocardial infarctions. Of the 37 verdicts and settlements analyzed, defendants were not liable in 25 (67.5%) of the cases. (Svider et al., 2014)

Superficial venous insufficiency

In the Netherlands, nerve damage and deep vein injury during varicose vein operations were the most typical reasons for a compensated claim. A majority of claims involved open surgery. Communication issues and errors in medical record keeping were also noted. The number of claims was not related to the experience of the surgeon performing the procedure but was evenly distributed between registrars and surgeons in training. (Dickhoff et al., 2014)

Arteriovenous access

The malpractice litigation in US for AV access procedures was most likely to be for haemorrhage, loss of limb function or ischemia due to steal syndrome. A majority of cases involved the death of the patient due to bleeding. It is important to prevent, diagnose and treat bleeding in a timely manner, avoid nerve injury, and avoid steal syndrome. (Phair et al., 2020)

2.7.2 Lack of evidence

Despite the importance of the topic, a paucity of research exists concerning patient injuries in vascular surgery. More research is needed to identify and analyze the errors that cause the patient injuries in modern vascular surgery, and to assess how these errors can be prevented. It can also provide means to analyze the influence of minimally invasive techniques on AEs and to identify the errors associated with these novel treatment modalities.

3 Aims

The present study has the following aims:

1. Identify errors and incidents that contributed to patient injuries in the vascular surgery specialty in Finland over the 1997-2017 period.
2. Identify patient or disease specific characteristics of injuries.
3. Identify surgeon type, experience, hospital or procedure specific characteristics of injuries.
4. Analyze the consequences of the patient injuries.
5. Identify errors in care process that could have been preventable by systemic tools.
6. Study patient injuries with special reference to the development of endovascular treatment modalities.
7. Identify ways to improve patient safety in vascular surgery in Finland.
8. Evaluate usefulness of patient injury information in improving patient safety.

4 Materials and Methods

The study design is a retrospective analysis of national patient insurance charts obtained from the PIC of Finland.

4.1 Study material

All closed compensated patient injury claims concerning the patients within the vascular surgery specialty between 1st January 1997 and 31st of December 2017 filed in the PIC were searched and analyzed. The search was conducted by the PIC.

A list with a summary of the cases was provided by the PIC. Cases that were clearly not related to vascular surgery were excluded. The included cases were analyzed and all the material, which was partly electronic and partly printed on paper, was reviewed. Information was stored in Microsoft Excel files.

Data provided by the PIC included all the documents that had been used in the insurance claim process. This included the patient's written petition, applicable medical records provided by the treatment facility including information not recorded directly in the patient's medical charts during treatment such as laboratory values and anesthesia information. Experts' assessments and claim decisions were also provided.

The PIC also provided a summary of annual non-compensated cases in vascular surgery, which was used to calculate the number of non-compensated claims. Using the summary of cases provided by the PIC those injuries that were not related to vascular surgery were excluded.

4.1.1 The Patient Injuries Act

The Patient Injuries Act mandates that all official health care providers in Finland must have patient insurance to cover for possible patient injuries. On 1st of January 2021, new patient insurance legislation (Potilasvakuutuslaki 948/2021) replaced the old patient injury law (Potilasvahinkolaki 585/1986). Patient injury is a bodily injury that fulfils compensation criteria prescribed in patient insurance legislation. Not all complications that occur in connection with medical treatment and health care are compensated; only those that fulfil the conditions described in the Patient Injuries Act. (*Patient insurance Center*, 2021)

The Act states *inter alia* that following preconditions have to be met: A patient has sustained a bodily injury, such as an illness, disability or other temporary or permanent weakening of health, or loss of life in connection with medical treatment or health care. The injured party must be a patient, i.e. a person being examined or treated. The injury must have occurred while the Patient Injuries Act was in force, in other words, on 1 May 1987 or after and the injury occurred within the geographical area of Finland. From the beginning of 2021, the Act can also be apply to treatment received abroad when certain preconditions are met. (*Patient insurance Center*, 2021)

When these abovementioned preconditions are met, the PIC will assess whether the injury is compensable and on what grounds the injury may be compensated. Not all injuries fulfil compensation criteria and most negative claims decisions are due to the fact that the injury sustained could not be avoided. Due to the severity of an illness or injury, it is not always possible to achieve satisfactory treatment results. Even if the competence of medical professional has not reached the expected standard, no compensation will be paid when the injury such as delay in treatment had no effect on the content, prognosis or outcome of the treatment. (*Patient insurance Center*, 2021)

In the Act, no presumption of blame of a health care personnel is required; rather the act allows compensation for deficiencies in organization and management of treatment processes. Monetary compensation can be paid for income losses, health care user charges, and immaterial costs. (Järvelin et al., 2019)

4.1.2 Patient injury types

The injuries were classified by using PIC patient injury compensation criteria. There are eight patient injury types currently in existence (*Patient insurance Center*, 2021).

Treatment injury

The most common compensable injury is treatment injury. It is a bodily injury caused by an examination, treatment or similar action performed or non-action on the patient. A prerequisite for compensation is that an experienced medical professional could have acted different thereby avoiding the injury. Not all health care professionals are required to reach the same standard. A different level of expertise is required from a specialist in a hospital than a general practitioner. Example of the injury could be nerve damage during operation or a delay in treatment. (*Patient insurance Center*, 2021)

Infection injury

Infection injuries must have been contracted in connection with an examination, treatment or similar action for compensation purposes. Infection injuries can be compensated without determining whether they could have been avoided by acting differently. An evaluation of infection tolerance that is carried out, comprises an assessment of the risks related to the procedure and also of the risks related to the patient such as underlying conditions and medications. Infection injuries related to operations are usually only compensated when the likelihood of infection preoperatively is considered low (usually under 2%). The severity of infection is assessed and minor infections are not usually compensated. When the patient receives treatment for severe illnesses, the patient is expected to tolerate more serious consequences of infections as well. If an infection is considered rare and sudden, it might be compensable even when the risk of infection was already considered elevated. (*Patient insurance Center*, 2021)

Accidental injury

Accidental injury refers to any injury that was related to medical examination or treatment and is a sudden, unexpected and external event without the will of the injured party. An example of the injury could be a patient's sudden fall from the operating table during a procedure. (*Patient insurance Center*, 2021)

Equipment-related injury

An equipment-related bodily injury is an injury that was caused to the patient by a defect in the equipment or device that was used for the examination, treatment, or other similar action and that the defect was not caused by the actions of the medical staff. Such equipment or devices include surgical instruments, patient monitoring equipment and examination tables but exclude permanently installed devices such as joint endoprostheses or pacemakers. (*Patient insurance Center*, 2021)

Accidents relating to permanently installed medical devices

This is the newest category of patient injuries, which came into effect from 1st of January 2021. It covers personal injuries caused by a permanently installed medical devices within the patient that had been assessed safe at the time the device was released into the market. Such injury could be related to malfunctioning total hip arthroplasty. (*Patient insurance Center*, 2021)

Injury arising from damage to premises or treating equipment

This injury arising from damage to a premises must be sudden by nature and cause bodily injury. For example, his kind of injury could be caused by fire in the hospital. (*Patient insurance Center*, 2021)

Injury due to incorrect delivery of pharmaceuticals

Incorrect delivery of prescription drugs by a pharmacist that led to bodily injury is covered under this injury category. It does not cover incorrect administration of pharmaceuticals by other medical professionals. (*Patient insurance Center*, 2021)

Unreasonable injury

Injury that is materially disproportionate with the initial situation can be compensated as an unreasonable injury regardless of whether it could have been prevented by acting differently. The compensability is based on the unreasonableness assessment. It comes into question only when the patient has suffered a permanent severe illness, injury or loss of life. An illness or injury is considered to be severe, if it falls into at least into classes 7 or 8 in the Ministry of Social Affairs and Health's classification of injuries. An example of such an injury could be a patient dying of unforeseen complications after routine surgery. (*Patient insurance Center*, 2021)

4.2 Study data

For all compensated patient injury cases, patient characteristics such as age, sex, medications, information regarding smoking, and co-morbidities were recorded. Cases were categorized by using the International Classification of diseases (ICD-10) codes for diseases and also by the procedure codes of the Nordic Classification of Surgical Procedures when applicable.

Information on health care providers and institutions were also recorded. Indication for treatment and whether a treatment was elective or urgent was registered. Types of surgery or other performed procedures and required re-operations were listed. Procedure length and antibiotic prophylaxis provided were listed. Patient injury date and compensation date, injury type, injury characteristics, and injury consequences were recorded. Grounds for compensation decision were recorded.

For non-compensated cases the number of cases was recorded but no other data were collected. For cases involving carotid artery stenosis, the reason for the claim was recorded.

4.3 Background information

Background information concerning annual numbers of performed vascular surgery procedures in Finland was collected from the open database on the Finnish Institute of Health and Welfare’s web page. The earliest available data were obtained from 2008 and the latest from 2017. Similar data were not available from earlier years without a surcharge. Applicable procedures were searched from the database by using procedure codes of the Nordic Classification of Surgical Procedures. Diagnosis was not used as it was not possible to conduct a search based on that criterion.

4.4 Data analysis

First, all data were collected into a joint archive and analyzed as one group. Data were then separated into subgroups according to different conditions and the subgroups were analyzed separately. The subgroups selected were as follows: PAD, AAA, popliteal aneurysm, ICAS, SVI, AV access, arterial embolus and other vascular problems.

Treatment facilities and personnel provision of the treatment were assessed. The number of different treatment facilities was compared to the number of injuries and the association between fully trained vascular surgeons and surgeons in training were compared as well. Treatment indications and chosen treatment method were evaluated for their link to the injury or injuries. Open surgery and endovascular repair were assessed. Patient characteristics were evaluated. Injury types and consequences were separated into different subgroups for easier analysis.

Evaluation was made whether the use of the SSC or another similar systematic prevention tool could have prevented the injury. When the SSC covered the injury and the correct use of SSC could have prevented the injury, it was classified as preventable.

The number of patient injuries was compared to available background data on the numbers for each specific procedure in vascular surgery. The numbers of compensated and non-compensated patient injuries were compared to each other.

4.5 Injury classification

Incidents and errors contributing to the injury were identified and classified by using a care-flow based classification chart. Up to three significant incidents were identified and classified in each patient injury. The structure of the classification had been based on the classification originally presented by Shah et al., and has subsequently been modified by others (Helmiö et al., 2015; Shah et al., 2004).

Table 1. Modified care-flow based classification chart for errors and incidents (Helmiö et al., 2015).

A	OUTPATIENT CARE/SURGICAL ASSESSMENT	**Inc 1**	**Inc 2**	**Inc 3**
A1	Delay or error in diagnosis			
A2	Delay or error in treatment			
A3	Error in medication			
BCD	OPERATIVE CARE			
B	***Preoperative judgement and planning***			
B1	Incorrect/unnecessary procedure or technique			
B2	Insufficient preoperative imaging			
B3	Other error in preoperative care			
C	***Operative unit***			
	Preoperative errors			
C1	No prophylactic antibiotic			
C2	Problems in anaesthesia procedures			
C3	Catheterization problems			
C4	Other problems in preoperative preparation			
	Intraoperative errors			
C6	Wrong site surgery			
C7	Nerve lesion			
C8	Other injury to adjacent anatomical structure			
C9	Incomplete surgery			
C10	Other error in surgical technique			
C11	Intraoperative major haemorrhage			
C12	Retained instrument in body			
C13	Retained gauze in body			
C14	Unregistered gauze in wound			
C15	Burn injury			
C16	Equipment related errors			
C17	Other error in operative room			
D	***Postoperative period***			
D1	Burn injury			
D2	Wrong/insufficient medication			
D3	Infection			
D4	Haemorrhage			
D5	Postoperative follow up insufficient			
D6	Postoperative treatment insufficient			
D7	Lost biopsy sample			
D	***Postoperative period in ward***			
D8	Error in postoperative ward care			
D9	Wrong/insufficient medication			
D10	Delay in fasciotomies			
D11	Other error in postoperative care			
	Total			

Inc=Incident

4.6 Statistics

The research data were stored and calculated using Microsoft Excel. As the study data were given as categorical variables, frequencies, and percentages, no hypotheses were formulated and no statistical testing were carried out. Descriptive statistics were used. Numbers and percentages were calculated and presented.

4.7 Ethics

The study protocol and data search were approved and the research permit was granted by the PIC and also by the University of Turku. All claim documents and recorded data were handled with confidentiality.

As the PIC is an insurance company, it is legally obligated to provide researchers data from its archives. This obligation requires no separate patient consent by law. The risk of identifying individual patients or hospitals is low as the study period is long and geographical range is vast.

Information regarding the identity of patients and health care providers was excluded from the research data registry. Research data did not form a patient registry.

No separate statement from the ethics committee was necessary for this study as the study was retrospective and did not influence the treatment of the patients or the decisions about the claims. All information concerning patient and health care workers identity was excluded from the gathered material. There was no contact with any of the patients by any member of the research team.

5 Results

5.1 Claims and decisions

During the 21-year study period, 142 patient injury claims out of a total of 855 claims made, were compensated in vascular surgery in Finland. Over the same time period, 713 patient injury claims were left uncompensated. Thus 16.6% of claims in vascular surgery led to compensation. The numbers of claims and compensations for each study year are presented in Figure 2.

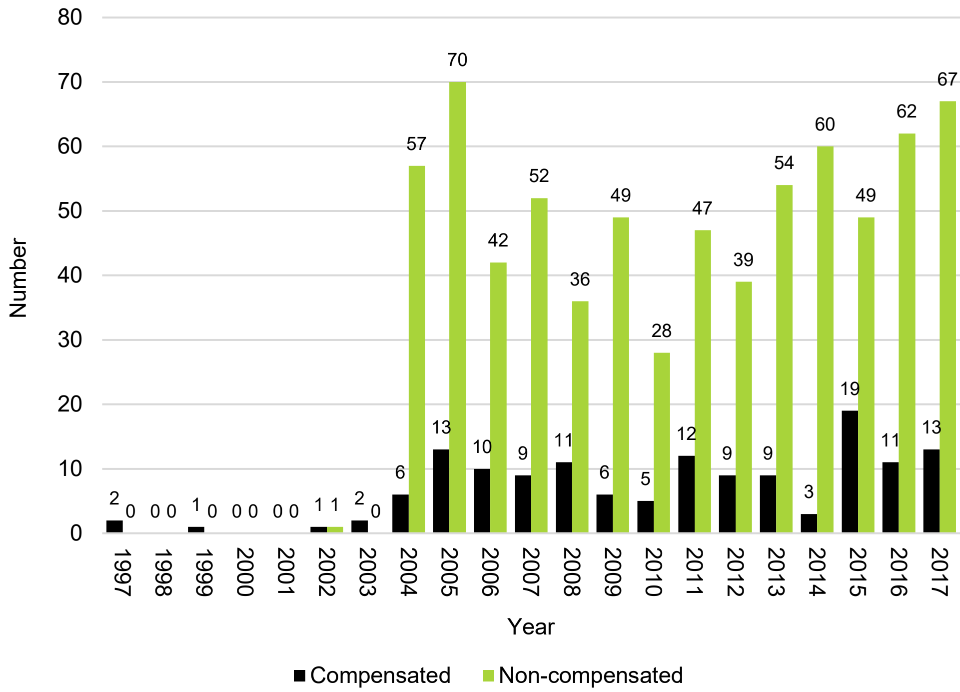

Figure 2. The distribution of compensated and non-compensated patient injuries in vascular surgery 1997–2017 in Finland. The total number of claims was 855 of which 142 were compensated. Vascular surgery became a specialty of its own in Finland in 1999 but was not listed separately in the PIC statistics until 2004.

The PIC classified the majority of the injuries as treatment injuries. Infection injuries and unreasonable injuries were the next commonly reported injuries. The distribution of injuries is presented in Figure 3.

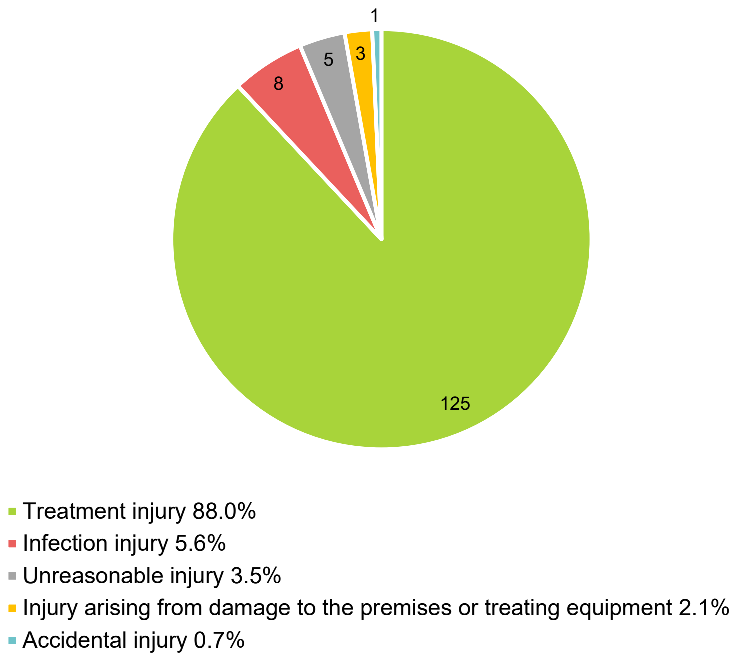

Figure 3. Distribution of the 142 compensated patient injuries in vascular surgery in Finland 1997-2017 by PIC's injury classification.

5.2 Patients

Eighty-six (60.6%) of the injured compensated patients were male and 56 (39.4%) female. The mean age was 61.8 years (SD ±13.8 range 17 to 86 years). Most of the injured patients were in the age group 60–79 years. Patient distribution by age groups is presented in Figure 4.

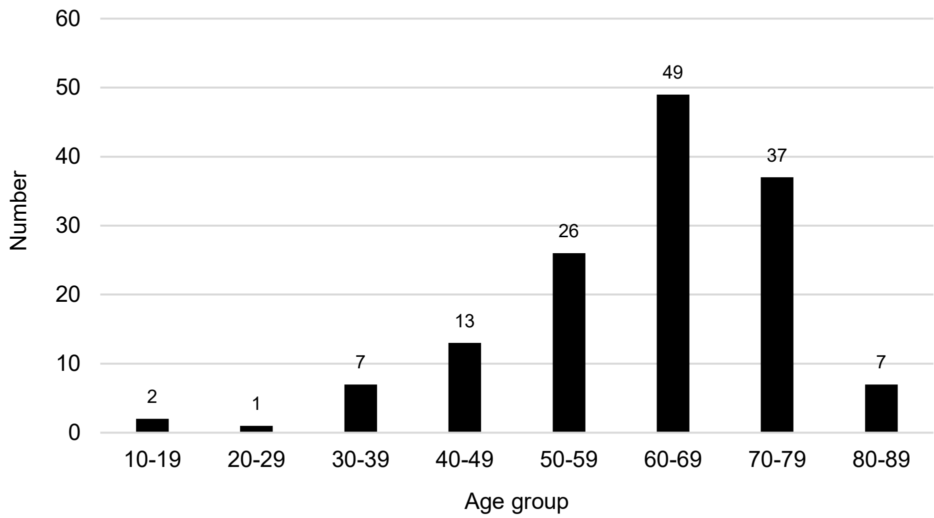

Figure 4. Distribution by age group of the 142 patients who suffered patient injuries in vascular surgery in Finland in 1997–2017.

A majority of patients had multiple co-morbidities. Hypertension, hypercholestherolemia and coronary artery disease were the most common diagnoses. The patients' co-morbidities are presented in Table 2.

Table 2. Co-morbidities of the 142 compensated patients injured in vascular surgery in Finland 1997–2017.

Patients' co-morbidities	N	%
Hypertension	81	57.0
Current smoker	56	39.4
Hypercholesterolemia	52	36.6
MCC	38	26.8
Type 2 diabetes	33	23.2
Asthma/COPD	22	15.5
Renal insufficiency	14	9.9
Atrial fibrillation	14	9.9
Hypothyreosis	10	7.0
Type 1 diabetes	7	4.9
Rheumatoid arthritis	6	4.2
Heart insufficiency	4	2.8
None	21	14.8

N = number, MCC = coronary artery disease, COPD = chronic obstructive pulmonary disease

5.3 Treated diseases involved in the patient injury

The treatment of PAD accounted for 45.1% (n=64), AAA or iliac artery aneurysm (IAA) for 16.2% (n=23), SVI for 15.5% (n=22) and ICAS for 6.3% (n=9) of the injuries.

Treatment of emboli, AV access problems, popliteal aneurysms, and other upper extremity vascular problems accounted for 9.9% of the injuries. Ten (7.0%) patients were compensated for treatment of various other vascular conditions including trauma, dissection, splanchnic aneurysms, and congenital AV malformation. The distribution of diseases is presented in Table 3.

Table 3. The primary diagnosis during the treatment period that led to patient injury in 142 patients compensated for patient injury in vascular surgery in Finland over the 1997–2017 period.

Disease	N	%
Peripheral arterial disease	64	45.1
AAA and iliac aneurysms	23	16.2
Superficial venous insufficiency	22	15.5
Internal carotid artery stenosis	9	6.3
Embolus	4	2.8
Arteriovenous access	4	2.8
Popliteal artery aneurysm	3	2.1
Upper extremity	3	2.1
Other	10	7.0
Total	142	100

AAA=abdominal aortic aneurysm

5.3.1 Peripheral arterial disease

The treatment of PAD was the most common category of patient injuries. A majority of the patients were treated for claudication. Most of the injuries involved open arterial surgery but injuries incurred in endovascular procedures and amputations were also recorded. Errors in surgical technique and delays in diagnosis or treatment were the most common reasons for injury. Retained foreign material, hemorrhage, and infections also contributed to the injuries.

Delays resulted in 4 major amputations. One patient died due to post-operative bleeding after femoral endarterectomy. A majority of injuries required re-operation. Three patients had to undergo deep vein reconstruction and removal of the Y-prosthesis due to infection. One Y-prosthesis infection was treated with life-long antibiotics.

5.3.2 Abdominal aortic and iliac artery aneurysms

Twenty-three patients suffered a patient injury in conjunction with the treatment of AAA or IAA. Typical injuries were delays in diagnosis or treatment, errors in surgical technique or injuries to adjacent anatomical organs.

Three patients died due to patient injury. Two deaths were caused by delays in the diagnosis of RAAA and the third death was due to missed diagnosis of post-operative myocardial infarction. Two patients had an above-the-knee amputation due to patient injury: one being a bilateral amputation and the other a unilateral amputation. Retained foreign material caused injuries to two patients and required re-surgery. Compensation for infection injury was given to one patient due to severe Y-prosthesis infection, which required the removal of the prosthesis and deep vein reconstruction.

5.3.3 Popliteal artery aneurysm

Three injuries occurred during the treatment of popliteal aneurysm. Two of the patients were operated electively and one urgently for acute ischemia. One patient had a burn injury to the buttocks during surgery that required additional surgery and skin graft but eventually healed. The other patient received a burn injury to the knee during recovery room care from heat blanket. It healed without surgical intervention. The third patient was injured due to an error in surgical technique that resulted from the creation of a bypass distal anastomosis to the anterior tibial artery instead of to the distal popliteal artery. This caused poor blood flow that required re-surgery.

5.3.4 Superficial venous insufficiency

Twenty-two patient injuries were related to the treatment of superficial venous insufficiency. All operations were elective. A majority involved open surgery (n=19), 2 EVLA (endovenous laser ablation) and 1 foam sclerotherapy.

Two patients suffered necrotising fasciitis, which required intensive unit care, hyperbaric oxygen treatment and several re-surgeries. Four deep vein injuries were reported, three to the femoral vein and one to the popliteal vein. Four patients had a permanent nerve injury (2 femoral, 1 peroneal, 1 sural). Two patients had retained endovenous material that required surgical removal after EVLA. There were no deaths but 4 of the injuries could have been life-threatening.

5.3.5 Carotid artery stenosis

Nine of the patient injuries were associated with the treatment of internal carotid artery stenosis. Six of the patients were symptomatic prior to their operations. Seven of the injuries involved an operation. All operations were CEA. In two cases, no operation was performed. Injuries were related to errors in decision-making and patient selection.

Typical injuries were nerve injury and stroke. One patient had a permanent injury to the accessory nerve. Three patients suffered permanent vocal cord paralysis. Three patients were left with permanent impairments due to stroke. One patient required lifelong antibiotics due to carotid patch infection. No deaths were compensated as patient injuries.

5.3.6 Arterial embolus

Four of the injuries involved treatment of emboli. Three emboli occurred in the lower limb and one in the superior mesenteric artery (SMA). In three cases, the embolectomy was delayed. In two of those cases the result was permanent nerve damage of the lower limb, and in the third case death was due to a delay in SMA embolectomy. In one patient an embolus in the lower limb was diagnosed upon angiography but no thrombolysis or operation was carried out. Non-operative treatment eventually led to a crural amputation.

5.3.7 Arteriovenous access

Four injuries were reported in conjunction with the creation or closure of AV fistulae. One injury involved problems in perioperative preparation that led to the skin of the hand being torn apart during scrubbing for surgery. This resulted in pain and cosmetic defect. Two injuries involved errors in surgical technique. In one, the access was incorrectly created between superficial and deep vein. It thrombosed and the patient required re-operation. In the other case, the closure of access was performed poorly and led to severe postoperative bleeding that required re-surgery. For the fourth patient, there were delays in the treatment of arterial steal syndrome that led to amputation of three fingers.

5.3.8 Other upper extremity vascular conditions

Other upper extremity vascular conditions accounted for 2.1% of the injuries. These injuries involved a diverse range of causes. One was related to posttraumatic problems and other to radiation therapy issues. One patient had an injury was attributed to sclerotherapy of a vascular malformation. Consequences of all injuries were severe as all patients required partial or complete amputations to the upper extremity due to insufficient blood flow.

5.4 Background data

The number of performed vascular surgical and endovascular procedures in Finland ranged annually between 18372 and 29577. Diagnostic angiographies to the aorta, upper and lower extremity artery and veins varied between 1059 and 4119. Figure 5 displays the numbers of annual procedures and angiographies between 2008 and 2017. When the compensated patient injuries were compared to the procedure numbers the incidence of patient injuries varied between 1:1766 and 1:10068. During the time period the average incidence of patient injuries was 1:2806.

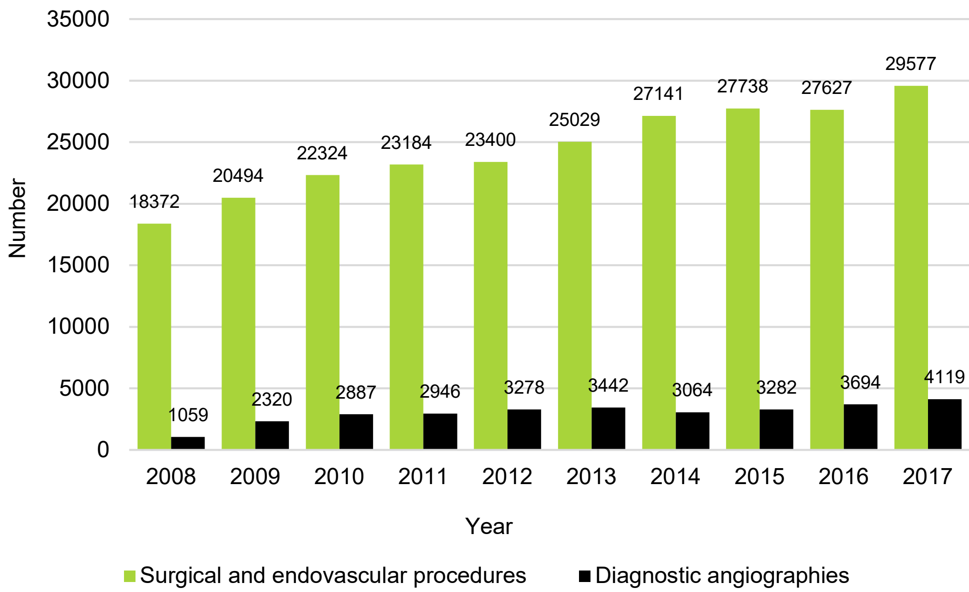

Figure 5. Annually performed vascular surgery procedures and diagnostic angiographies in Finland over the 2008–2017 period published by the Finnish Institute of Health and Welfare (*National institute of Health and Welfare*, 2019).

5.5 Circumstances of treatment

5.5.1 Treatment facility

A majority of patients were treated either in a university or central hospital. Figure 6 shows how the injuries were divided between the treatment facilities.

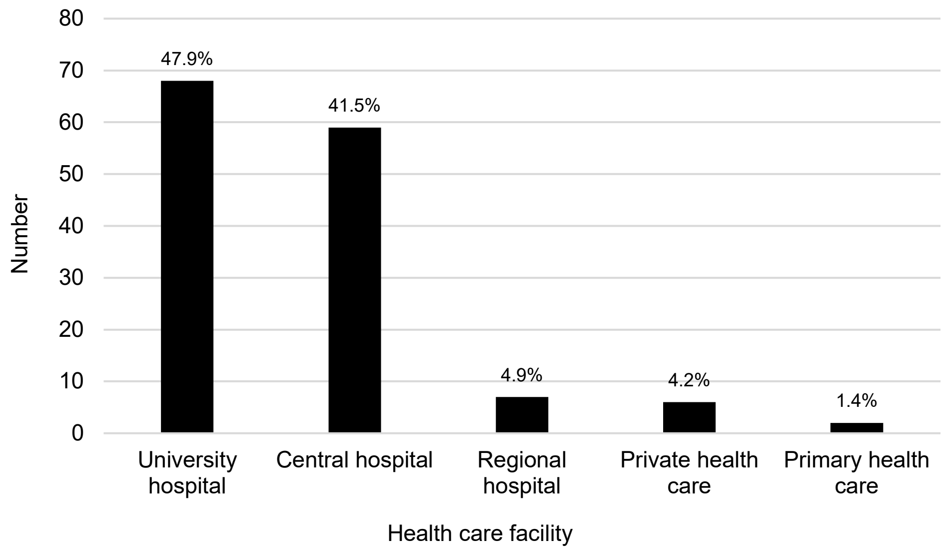

Figure 6. Characteristics of health care providers of the 142 patients compensated for injuries in vascular surgery 1997 to 2017 inclusive.

5.5.2 Professional specialization

One-hundred-one (74.3%) of the patients were operated either by a fully trained vascular surgeon or a fully trained surgeon of another specialty. In only one case, the specialization had been clearly recorded to have been other than a vascular surgeon. In that particular case an embolectomy procedure had been performed by a urologist. For 6 patients, the information about whether a procedure was performed by a surgeon in training or a fully trained surgeon was not available.

In varicose vein treatment, none of the operations were recorded to have been performed by general surgeons but it is possible as in 27.3% (n=6) of the operations, the surgeon had been marked as a ‘specialist’ but the actual specialization *per se* was not recorded.

Nineteen (14.0%) of the injured patients were operated by surgeons-in-training. The patient injury was related to errors in surgical technique in 9 cases. Three of the 9 cases were related to arterial surgery. One involved a postoperative hemorrhage due to technical errors in AV-access closure. Another patient for resection of the duodenum in an open AAA operation. The third patient had a forgotten gauze in the femoral amputation wound. Six of the 9 cases involved varicose vein surgery. The remaining errors included the incomplete removal of varicosities or greater/smaller saphenous vein, ligation of the femoral vein and failure to close one operating wound. The cases were distributed evenly over the years.

5.5.3 Provided treatment

As much as 136 (95.8%) of the 142 patients compensated underwent an operation. Of the 136 treated patients, 41(30.1%) were operated urgently and 94 (69.1%) electively. The information was not available for 1 operated patient.

For 6 (4.2%) patients, no procedure was performed during the treatment period and this led to injury. One patient had been admitted only for imaging, whereas for the remaining 5, the injury was due to delays or errors in diagnosis or treatment.

A majority, 116 (85.3%), of the 136 patient injuries were related to traditional open surgery and 5 involved an endovascular procedure performed by a surgeon (1 sclerotherapy to varicose veins, 2 EVAR, 2 EVLA). For 15 patients, the treatment period that led to injury involved an endovascular procedure performed by interventional radiologist. The annual distribution of injuries related to endovascular treatment is displayed in Figure 7.

Thirteen of the endovascular patient injuries involved an angiography. Of angiography related injuries, 7 involved an error in procedural technique that led to injury, 4 were related to error in operation timing, 1 to error in preprocedural diagnosis and 1 to error in preprocedural preparation. 2 of the angiographies were diagnostic without therapeutic intervention. All others involved an intervention such as percutaneous transluminal angioplasty or thrombolysis.

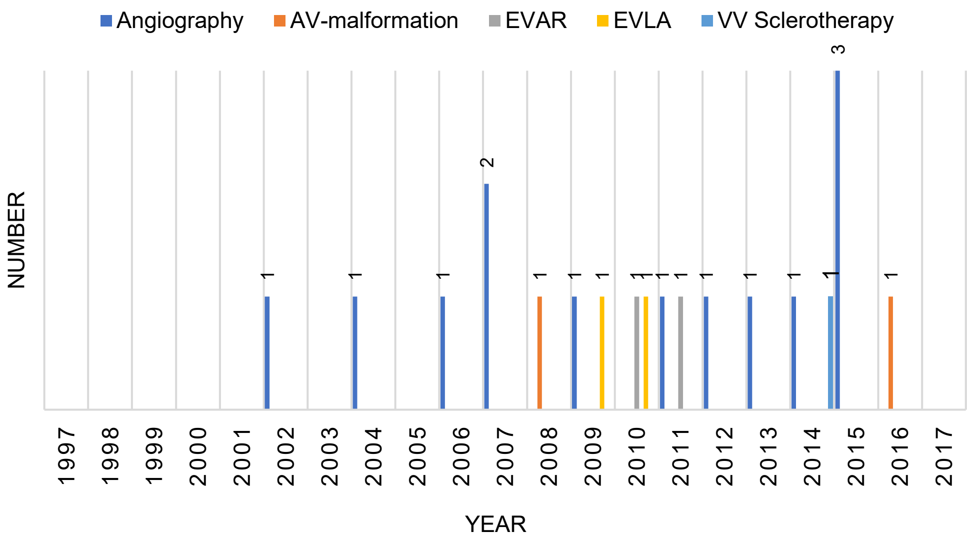

Figure 7. The annual distribution of patient injuries that involved endovascular treatment between 1997-2017 in vascular surgery in Finland. AV=arteriovenous, EVAR= endovascular aortic repair, EVLA = endovenous laser ablation, VV = varicose vein.

5.6 Required re-operations

Eighty-two (60.3%) of the operated patients had to undergo additional surgery for patient injury. For 32 patients, the re-operation took place immediately after the original surgery and was mostly caused by problems in the original procedure. Figure 8 presents the reasons for immediate re-surgery. For the remaining 50 patients, the re-operation usually took place within weeks or months after the original operation but in some patients as long as years had elapsed from the original operation.

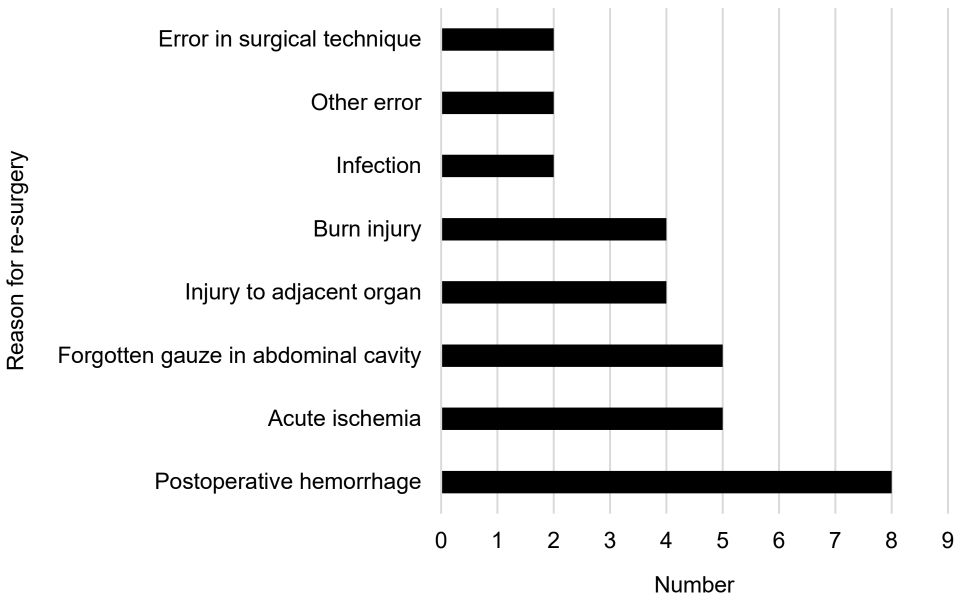

Figure 8. The reasons for immediate re-surgery after original procedure in 32 patients.

5.7 Patient injuries by the care-flow

Altogether 173 patient injury incidents were identified. For 29 patients, two separate injury incidents were identified, and for 2 patients there were three separate incidents. The incidents were classified by the patients' care flows. Injuries were divided into subgroups for further analysis by the care flow of the patient. A primary patient injury incident was the decisive incident for subgroup placement. Please see Table 4 for details.

Table 4. 173 patient injury incidents of 142 compensated patients injured in vascular surgery in Finland over the 1997–2017 period classified by patient care-flow.

A	OUTPATIENT CARE/SURGICAL ASSESSMENT	**Inc 1**	**Inc 2**	**Inc 3**
A1	Delay or error in diagnosis	13	0	0
A2	Delay or error in treatment	15	0	0
A3	Error in medication	1	0	0
BCD	OPERATIVE CARE			
B	***Preoperative judgement and planning***			
B1	Incorrect/unnecessary procedure or technique	5	3	0
B2	Insufficient preoperative imaging	4	0	0
B3	Other error in preoperative care	1	0	0
C	***Operative unit***			
	Preoperative errors			
C1	No prophylactic antibiotic	0	0	0
C2	Problems in anaesthesia procedures	1	0	0
C3	Catheterization problems	3	0	0
C4	Other problems in preoperative preparation	1	0	0
	Intraoperative errors			
C6	Wrong site surgery	0	0	0
C7	Nerve lesion	15	2	0
C8	Other injury to adjacent anatomical structure	8	1	0
C9	Incomplete surgery	5	1	0
C10	Other error in surgical technique	14	2	0
C11	Intraoperative major haemorrhage	1	0	0
C12	Retained instrument in body	3	0	0
C13	Retained gauze in body	5	0	0
C14	Unregistered gauze in wound	1	0	0
C15	Burn injury	7	0	0
C16	Equipment related errors	2	0	0
C17	Other error in operative room	1	0	0
D	***Postoperative period***			
D1	Burn injury	2	0	0
D2	Wrong/insufficient medication	5	0	0
D3	Infection	12	9	1
D4	Haemorrhage	1	7	1
D5	Postoperative follow up insufficient	2	1	0
D6	Postoperative treatment insufficient	5	0	0
D7	Lost biopsy sample	1	0	0
D	***Postoperative period in ward***			
D8	Error in postoperative ward care	2	0	0
D9	Wrong/insufficient medication	2	0	0
D10	Delay in fasciotomies	3	3	0
D11	Other error in postoperative care	1	0	0
	Total	142	29	2

Inc=Incident

5.7.1 Outpatient care and surgical assessment

Twenty-nine of the primary patient injuries involved errors in outpatient care or in surgical assessment. No secondary or tertiary incidents were recorded in this subgroup. Outpatient care involved treatment both in primary health care or in hospital before referral to vascular surgery. Surgical assessment was determined to have occurred after the referral to the vascular surgeon but before any performed procedures.

Thirteen primary incident patients had a delay or error in their diagnosis. For 15 patients, the diagnosis had been made correctly but the treatment was either delayed or conservative treatment was incorrectly chosen by the vascular surgeon even though operative care should have been carried out. One injury involved incorrect administration of medication. Peripheral arterial disease was the most commonly involved condition as it accounted for 48.3% of injuries. Moreover, 17.2% of the injuries involved the treatment of AAA, whereas 10.3% of injuries involved emboli or upper extremity vascular problems. Please see Table 5 for details.

Consequences

Patient injuries in outpatient or preoperative care led to the death of 3 patients. The deaths involved a missed diagnosis of RAAA in two patients, and the delayed treatment of SMA embolus and bowel ischemia in the third patient. Six patients suffered a major lower or upper limb amputation due to injury, whereas 2 patients had a minor amputation to the upper limb. Five patients suffered from permanent nerve damage. One patient developed a major stroke after conservative treatment was incorrectly chosen for symptomatic inner carotid stenosis. For 9 patients, the major consequence was prolonged pain and suffering.

Table 5. The 29 primary patient injury incidents and their consequences in outpatient care and surgical assessment.

Incident number	Disease	Type of incident	Consequence
1	EMB	Error in the treatment of lower limb embolus	Amputation (crural)
2	PAD	Delay in the diagnosis of CLTI	Amputation (crural)
3	PAD	Delay in the treatment of CLTI	Amputation (crural)
4	PAD	Delay in the treatment of CLTI	Amputation (crural)
5	UPP	Delay in the diagnosis of axillary stent thrombosis in the upper arm	Amputation of all fingers in the hand
6	UPP	Delay in treatment of axillary bypass occlusion and upper extremity acute ischemia	Amputation of an arm
7	PAD	Delay in the treatment of CLTI	Amputation of complete lower limb
8	UPP	Delay in the treatment of finger ischemia after sclerotherapy	Amputation of one finger
9	AAA	EIM, Administration of incorrect medication prior to aortic CT-scan	Anaphylactic shock
10	AAA	Delay in the diagnosis of RAAA	Death
11	AAA	Delay in the diagnosis of RAAA	Death
12	EMB	Delay in the treatment of SMA embolus. No operation was performed.	Death
13	PAD	Lung cancer missed in preoperative chest x-ray	Delay in cancer treatments. No effect to final result.
14	ICAS	Error in the treatment of symptomatic inner carotid stenosis	Major stroke
15	EMB	Delay in the treatment of lower limb embolus	Permanent nerve damage
16	OTH	Delay in the diagnosis of spontaneous femoral haemorrhage	Permanent nerve damage
17	PAD	Delay in the treatment of occluded Y-prothesis limb	Permanent nerve damage
18	PAD	Delay in the treatment of Y-prothesis limb occlusion	Permanent nerve damage
19	TRAU	Delay in the treatment of lower limb vascular trauma	Permanent nerve damage
20	AAA	Delay in the diagnosis of RAAA	Prolonged pain and suffering
21	AAA	Delay in the diagnosis of TAAA and bowel ischemia.	Prolonged pain and suffering
22	PAD	Delay in the diagnosis of CLTI	Prolonged pain and suffering
23	PAD	Delay in the diagnosis of CLTI. Treated as sciatic nerve pain.	Prolonged pain and suffering

Incident number	Disease	Type of incident	Consequence
24	PAD	Delay in the diagnosis of CLTI. Treated as sciatic nerve pain.	Prolonged pain and suffering
25	PAD	Delay in the diagnosis of CLTI. Treated as sciatic nerve pain.	Prolonged pain and suffering
26	PAD	Delay in the treatment of CLTI	Prolonged pain and suffering
27	PAD	Delay in the treatments of bypass graft occlusion	Prolonged pain and suffering
28	TRAU	Delay in the diagnosis of lower limb vascular trauma	Prolonged pain and suffering
29	PAD	Delay in the diagnosis of bypass graft occlusion	Re-operation

AAA = abdominal aortic or iliac aneurysm, CLTI = critical limb threatening ischemia, CT = computer tomography, EIM = error in medication, EMB = embolus, ICAS=inner carotid artery stenosis, OTH = other, PAD= peripheral arterial disease, RAAA= ruptured abdominal aortic aneurysm, SMA = superior mesenteric artery, TAAA = thoraco-abdominal aortic aneurysm, TRAU = trauma, UPP = upper extremity vascular condition

5.7.2 Preoperative care

Preoperative care involved the preparations for procedure in the policlinic, surgical ward or operating theatre. 15 of the patient injuries that occurred related to preoperative care.

Preoperative judgment and planning

Ten primary and 3 secondary patient injury incidents occurred during preoperative planning. In 8 cases, the performed procedure was judged to be poorly planned or completely unnecessary. For 4 patients, preoperative imaging had been insufficient and therefore the operation was unsuccessful. For 1 patient, preoperative instructions for medication cessation were incorrect. Primary patient injury incident details are presented in Table 6.

Consequences

Seven of the injured patients required re-operation later due to either poor planning or insufficient pre-operative imaging. Three of these patients also suffered from infection related problems after surgery. One patient suffered a major stroke due to cessation of all antithrombotic medication before the planned carotid artery endarterectomy. The preoperative instructions had been delivered incorrectly before hospital transfer and eventually the operation was never carried out. In other patient postoperative hemorrhage led to a worsening of an already poor heart condition. The cardiologists had recommended postponing angiography and percutaneous transluminal angioplasty but for unknown reasons the procedure was carried out as originally planned. In another patient’s case the procedure should not have been attempted at all and the operation caused unnecessary pain and suffering.

Table 6. The 10 primary patient injury incidents and their consequences involved in preoperative judgment and surgical planning. Indication and type of surgery for the injured patients.

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequence
1	ICAS	Symptomatic stenosis	No procedure performed	EIM, Incorrect cessation of medication	Major stroke
2	PAD	Claudication	Femoral artery exploration	Insufficient preoperative imaging	Pain and suffering, unnecessary operation
3	PAD	CLTI	Angiography	Incorrect procedure timing	Postoperative hemorrhage, heart problems
4	PAD	Claudication	Angiography	Unnecessary procedure	Re-operation
5	SVI	Skin changes	Sclerotherapy	Preoperative imaging insufficient	Re-sclerotherapy
6	SVI	Pain and swelling	Phlebectomy	Preoperative imaging insufficient	Re-surgery
7	SVI	Skin changes	Phlebectomy	Unnecessary procedure	Re-surgery, infection
8	PAD	Claudication	Femoro-popliteal bypass	Incorrect planning, unnecessary bypass	Re-surgery, infection
9	PAD	Claudication	Femoral endarterectomy	Unnecessary procedure	Re-surgery, infection
10	AAA	Stomach pain	Explorative laparotomy	Preoperative imaging insufficient	Re-surgery, unnecessary operation

AAA = abdominal aortic or iliac aneurysm, CLTI = critical limb threatening ischemia, EIM = error in medication, ICAS = inner carotid artery stenosis, PAD = peripheral arterial disease, SVI = superficial venous insufficiency

Problems in preoperative preparations

Five of the injuries occurred during preoperative preparations for procedure in the operating theatre or at the surgical ward. The most typical incident involved problems with urinary catheterization, which led to injury in 3 patients. The preoperative problems are presented in Table 7.

Consequences

Consequences of the injuries involved pain and suffering, permanent cosmetic handicap, infection, and damage to the urethra.

Table 7. The 5 primary patient injury incidents and their consequences involved in preoperative care. Indication and type of surgery for the injured patients.

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequence
1	PAD	Claudication	Femoro-popliteal bypass	Problems in urinary catheterization	Damage to the urethra
2	PAD	Claudication	Femoro-popliteal bypass	Problems in urinary catheterization	Damage to the urethra, penile fistula
3	PAD	CLTI	Angiography	Problems in urinary catheterization	Infection, urosepsis
4	ICAS	Symptomatic stenosis	Carotid endarterectomy	EIM, Incorrect medication in anaesthesia preparation	Momentary inability to breathe
5	ACC	Kidney failure	AV-access creation	Skin of the hand was torn during scrubbing	Pain and suffering, scarring

ACC= arteriovenous access, CLTI = Critical limb threatening ischemia, EIM = error in medication, ICAS = inner carotid artery stenosis, PAD = peripheral arterial disease

5.7.3 Intraoperative care

Sixty-two of the primary patient injury incidents involved intraoperative care. There were also 6 secondary incidents. The primary incidents are presented in Table 8.

Fifteen of the primary injuries were related to nerve injury. Five injuries involved the femoral nerve and four injuries of the sural nerve. Fourteen incidents involved an error in surgical technique. The errors were of a mixed variety including incorrect placement of a bypass distal anastomosis to the vein instead or the artery, a twist in the bypass and stent migration to the aorta.

Seven injuries involved intraoperative skin burns. These were usually caused by incorrectly positioned patient return electrodes. Six involved an injury to an adjacent anatomic structure. The small bowel was the organ most commonly injured. In 9 injuries, either a gauze or an instrument was retained in the body after closure. For 4 patients, the injury was caused by incomplete surgery. The majority of these injuries occurred in operation for SVI. There were three major hemorrhages, one in an EVAR operation and two in SVI operations.

Consequences

For 33 patients, the injury led to a re-operation. All re-interventions were surgical. Four of the original operations in which injury occurred had been endovascular operations performed by an interventional radiologist. Six patients required re-surgery to remove a retained gauze in body and 3 patients for a retained part of an instrument in body.

Fifteen patients had permanent nerve damage. The consequences involved permanent pain, loss of function and in three cases of dysphonia caused by vocal cord paralysis.

One patient had to have a bilateral femoral amputation after major intraoperative hemorrhage led to arterial thrombosis in both lower limbs. In 2 others hemorrhage was corrected successfully during the same operation.

For 10 patients injuries caused prolonged pain and suffering but left no permanent injuries.

Table 8. The 62 primary patient injury incidents and their consequences involved in intraoperative care. Indication and type of surgery for the injured patients.

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequences
1	AAA	Aneurysm size	EVAR	Major intraoperative hemorrhage	Amputation (bilateral femoral)
2	SVI	Unknown	Femoral exploration	ITAO, femoral vein	Hemorrhage, intraoperative correction
3	SVI	Pain and swelling	HL+S GSV, phlebectomy	ITAO, femoral vein	Hemorrhage, re-surgery
4	ACC	Kidney failure	AV access occlusion	EIST, incorrectly closed access	Hemorrhage, re-surgery
5	ICAS	Symptomatic stenosis	Carotid endarterectomy	ND	Nerve lesion, vocal cord paralysis, dysphonia
6	ICAS	Asymptomatic stenosis	Carotid endarterectomy	ND	Nerve lesion, vocalcord paralysis, dysphonia
7	ICAS	Asymptomatic stenosis	Carotid endarterectomy	ND	Nerve lesion, vocalcord paralysis, dysphonia
8	SVI	Skin changes	HL+S GSV, phlebectomy	ND, branch of peroneal nerve	Nerve pain
9	SVI	Pain	HL+S GSV, phlebectomy	ND, branch of peroneal nerve	Nerve pain
10	OTH	Aneurysm size (renal artery)	Angiography and stenting	ND, femoral nerve	Nerve pain
11	PAD	Claudication	Femoral endarterectomy	ND, femoral nerve	Nerve pain
12	PAD	CLTI	Femoro-popliteal bypass	ND, femoral nerve	Nerve pain
13	PAD	Claudication	Iliaco-femoral bypass	ND, femoral nerve	Nerve pain
14	SVI	Skin changes	HL+S GSV, phlebectomy	ND, femoral nerve	Nerve pain
15	PAD	CLTI	Femoro-tibial bypass	ND, peroneal nerve	Nerve pain
16	SVI	Pain and swelling	Phlebectomy	ND, sural nerve	Nerve pain
17	OTH	Hypersedimentation	Temporal artery biopsy	ND, facial nerve	Nerve pain, loss of function
18	PAD	CLTI	Femoro-tibial bypass	ND, peroneal nerve	Nerve pain, loss of function
19	ICAS	Asymptomatic stenosis	Carotid endarterectomy	ND, accessory nerve	Nerve pain, loss of function
20	PAD	Claudication	Femoral endarterectomy	Burn injury to buttock	Prolonged pain and suffering
21	PAD	CLTI	Femoro-tibial bypass	Burn injury to buttocks	Prolonged pain and suffering
22	PAD	Claudication	Femoro-popliteal bypass	Burn injury to groin	Prolonged pain and suffering
23	SVI	Skin changes	Femoral exploration	EIST, deep femoral vein ligation	Prolonged pain and suffering

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequences
24	AAA	Aneurysm size	Open repair	ITAO, ileocutaneus fistula	Prolonged pain and suffering
25	AAA	Aneurysm size	Open repair	ITAO, small bowel	Prolonged pain and suffering
26	SVI	Skin changes	HL+S GSV, phlebectomy	Pressure ulcer from wound dressings	Prolonged pain and suffering
27	OTH	AV-malformation	Sclerotherapy	Sclerotherapy catether broke	Prolonged pain and suffering
28	PAD	CLTI	Toe amputation	Unregistered gauze in wound	Prolonged pain and suffering
29	SVI	Unknown	HL+S GSV, phlebectomy	EIST, failure to close all wounds	Prolonged pain and suffering, infection
30	PAD	Claudication	Angiopraphy + PTA	Retained part of a PTA balloon in body	Re-operation
31	PAD	Claudication	Angiography and PTA	EIST, stent placement incorrect	Re-operation
32	PAD	Claudication	Angiopraphy + PTA	EIST, stents migrated to aorta	Re-operation, prolonged recovery
33	PAD	Claudication	Angiopraphy + PTA	Stenting equipment got stuck to artery	Re-operation, prolonged recovery
34	SVI	Unknown	HL+S GSV, phlebectomy	Burn injury to both legs	Re-surgery
35	PAD	Claudication	Femoro-popliteal bypass	Burn injury to buttock	Re-surgery
36	AAA	Aneurysm size	Iliaco-femoral bypass	Burn injury to buttocks	Re-surgery
37	POP	Acute ischemia	Femoro-popliteal bypass	Burn injury to buttocks	Re-surgery
38	ACC	Kidney failure	AV-access creation	EIST, access created between deep and superficial vein	Re-surgery
39	PAD	CLTI	Femoral amputation	EIST, bone left too long, broke the skin	Re-surgery
40	AAA	RAAA	Open repair	EIST, bowel trapped in wound	Re-surgery
41	POP	Aneurysm size	Femoro-popliteal bypass	EIST, distal anastomosis created to ATA instead of popliteal artery	Re-surgery
42	PAD	CLTI	Femoro-tibial bypass	EIST, distal anastomosis created to vein instead of artery	Re-surgery
43	PAD	CLTI	Femoro-popliteal bypass	EIST, graft occlusion due to technical problems	Re-surgery

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequences
44	AAA	Aneurysm size	EVAR	EIST, occlusion of superficial femoral artery	Re-surgery
45	PAD	CLTI	Femoro-tibial bypass	EIST, twist in bypass	Re-surgery
46	AAA	Claudication	Aorto-femoral bypass	EIST, Y-prothesis branch twisted	Re-surgery
47	SVI	Not known	HL+S GSV, phlebectomy	Incomplete surgery	Re-surgery
48	SVI	Pain and swelling	HL+S GSV, phlebectomy	Incomplete surgery	Re-surgery
49	SVI	Skin changes	HL+S GSV, phlebectomy	Incomplete surgery	Re-surgery
50	SVI	Skin changes	Phlebectomy	Incomplete surgery	Re-surgery
51	AAA	Aneurysm size	Open repair	ITAO, bladder	Re-surgery
52	PAD	Claudication	Aorto-bifemoral bypass	ITAO, small bowel	Re-surgery
53	AAA	Infection aneurysm	EVAR, laparotomy	Retained gauze in body	Re-surgery
54	AAA	Symptomatic aneurysm	Open repair	Retained gauze in body	Re-surgery
55	PAD	CLTI	Aorto-bifemoral bypass	Retained gauze in body	Re-surgery
56	PAD	CLTI	Aorto-bifemoral bypass	Retained gauze in body	Re-surgery
57	PAD	CLTI	Femoral amputation	Retained gauze in body	Re-surgery
58	SVI	Pain	EVLA	Retained instrument in body	Re-surgery
59	SVI	Pain	EVLA	Retained instrument in body	Re-surgery
60	OTH	Aneurysm size (IMA)	Open repair	Retained gauze in body	Re-surgery
61	EMB	Acute ischemia	Embolectomy	Incomplete surgery	Re-surgery, permanent nerve damage
62	AAA	Aneurysm size	Laparotomy	ITAO, small bowel	Re-surgery. AAA repair postponed

AAA = abdominal aortic or iliac aneurysm, ACC = arteriovenous access, ATA = anterior tibial artery, CLTI = critical limb threatening ischemia, EIM = error in medication, EIST = error in surgical technique, EMB = embolus, EVAR= endovascular aneurysm repair, EVLA = endovenous laser ablation, HL+S GSV = high ligation and stripping of greater saphenous vein, ICAS=inner carotid artery stenosis, ITAO = injury to adjacent organ, ND = nerve damage, OTH = other, PAD= peripheral arterial disease, POP= popliteal artery aneurysm, PTA = percutaneous transluminal angioplasty, RAAA= ruptured abdominal aortic aneurysm, SMA = superior mesenteric artery, SVI= superficial venous insufficiency, TAAA = thoraco-abdominal aortic aneurysm

5.7.4 Postoperative care

Thirty-six primary patient injuries occurred in the postoperative period. Twenty secondary and 2 tertiary incidents occurred in this group as well. Errors occurred during the immediate postoperative care in the recovery room and during the postoperative ward care. Twelve postoperative infections were identified as primary incidents, 9 as secondary and 1 as tertiary. Infections occurred after arterial and venous operations. Delays in treatment affected 9 patients. Delay in fasciotomies (n=4) and delay in hematoma evacuation (n=2) being the most common ones. Errors in medication affected 7 patients. Burn injuries due to heat blankets injured 2 patients. All incidents are presented in Table 9.

Consequences

Two patients died due to injuries. One death involved a major hemorrhage after discharge from hospital after CEA in patient. The other death was due to missed diagnosis of postoperative myocardial infarction after open surgery for AAA in patient. One patient had to have amputation of 3 fingers due to delay of treatment of arterial steal syndrome that developed after AV access creation. Delays in fasciotomies led to permanent loss of function in the lower limb in 3 patients and to femoral amputation in 1 patient. Two of the infection patients were treated with lifelong antibiotics. For 9 patients, the infection required re-surgery.

Table 9. The 36 primary patient injury incidents and their consequences involved in post-operative care. Indication and type of surgery for the injured patients.

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequences
1	AAA	RAAA	Aorto-bifemoral bypass	Delay in fasciotomies	Amputation (femoral)
2	ACC	Kidney failure	Arteriovenous access creation	Delay in treatment of stealsyndrome	Amputation of 3 fingers
3	AAA	Symptomatic aneurysm	Aorto-bi-iliac bypass	Missed postoperative myocardial infarctation	Death
4	PAD	Claudication	Femoral endarterectomy	Postoperative hemorrhage	Death
5	PAD	Claudication	Femoro-popliteal bypass	EIM, insufficient antithrombotics	Deep vein thrombosis
6	PAD	CLTI	Angiography, thrombolysis	EIM, incorrect medication in thrombolysis	Hemorrhage
7	OTH	No operation	No operation	Fall from an examination table	Hip fracture, surgery
8	PAD	Claudication	Femoro-popliteal bypass	EIM, insufficient antithrombotics	Major stroke
9	ICAS	Symptomatic stenosis	Carotid endarterectomy	Infection, vascular patch	Permanent antibiotic treatment
10	PAD	Claudication	Aorto-bifemoral bypass	Infection, Y-prothesis	Permanent antibiotic treatment
11	AAA	Aneurysm size	Aorto-bifemoral bypass	Delay in fasciotomies	Permanent loss of function
12	PAD	Claudication	Femoro-popliteal bypass	Delay in fasciotomies	Permanent loss of function
13	PAD	Claudication	Aorto-bifemoral bypass	Delay in fasciotomies	Permanent loss of function
14	PAD	Claudication	Femoro-popliteal bypass	Delay in hematoma evacuation	Permanent loss of function
15	AAA	Aneurysm size	Aorto-bi-iliac bypass	Delay in postoperative treatment of aortic dissection	Permanent loss of function in legs
16	AAA	Infection aneurysm	Resection	Infection, delay in treatment	Prolonged and more severe infection
17	PAD	CLTI	Toe amputation	EIM, insufficient antibiotics	Prolonged and more severe infection
18	PAD	CLTI	Femoro-popliteal bypass	Hematoma to leg from faulty geriatric chair	Prolonged pain and suffering

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Consequences
19	POP	Aneurysm size	Femoro-popliteal bypass	Burn injury to knee	Prolonged pain and suffering
20	AAA	Aneurysm size	Aorto-bifemoral bypass	Infection, Y-prothesis	Re-surgery
21	OTH	Unknown	Temporal artery biopsy	Biopsy was lost	Re-surgery
22	PAD	CLTI	Femoral amputation	Burn injury to lower stomach	Re-surgery
23	PAD	CLTI	Crural amputation	Fell from a faulty hospital bed after surgery	Re-surgery
24	PAD	Claudication	Femoral endarterectomy	Infection, vascular patch	Re-surgery
25	PAD	Claudication	Femoro-popliteal bypass	Infection, vascular prosthesis	Re-surgery
26	PAD	Claudication	Femoro-popliteal bypass	Infection, vascular prosthesis	Re-surgery
27	PAD	Claudication	Aorto-bifemoral bypass	Infection, Y-prothesis	Re-surgery
28	PAD	CLTI	Aorto-bifemoral bypass	Infection, Y-prothesis	Re-surgery
29	PAD	Claudication	Aorto-bifemoral bypass	Infection, Y-prothesis	Re-surgery
30	SVI	Skin changes	HL+S GSV, phlebectomy	Infection, necrotizing fascitis	Re-surgery
31	SVI	Pain	HL+S GSV, phlebectomy	Infection, necrotizing fascitis	Re-surgery
32	AAA	Aneurysm size	Aorto-bi-iliac bypass	EIM, incorrect administration of noradrenalin	Re-surgery, hemorrhage
33	PAD	Claudication	Femoro-popliteal bypass	Delay in treatment of postoperative hemorrhage	Re-surgery, prolonged pain and suffering
34	ICAS	Symptomatic stenosis	Carotid endarterectomy	Delay in hematoma evacuation	Re-surgery, stroke
35	SVI	Skin changes	HL+S GSV, phlebectomy	EIM, incorrect antibiotics	Severe allergic reaction
36	PAD	CLTI	Toe amputation	EIM, incorrect administration of antibiotics	Temporary renal insufficiency

AAA = abdominal aortic or iliac aneurysm, ACC = arteriovenous access, CLTI = critical limb threatening ischemia, EIM = error in medication , EMB = embolus, EVAR= endovascular aneurysm repair, EVLA = endovenous laser ablation, HL+S GSV = high ligation and stripping of greater saphenous vein, ICAS=inner carotid artery stenosis, OTH = other, PAD= peripheral arterial disease, POP= popliteal artery aneurysm, PTA = percutaneous transluminal angioplasty, RAAA= ruptured abdominal aortic aneurysm, SVI= superficial venous insufficiency

5.8 Systemic tools for error prevention

Correct use of the WHO SSC *(WHO*, 2009) or other similar systemic checklist was evaluated to have potentially prevented 18 injuries. These are presented in Table 10. Nine injuries involved either a retained gauze or an instrument in body. Five gauzes were left in the abdominal cavity and 1 in a femoral amputation wound. All patients had to be re-operated to remove the gauzes. Two retained instruments were left inside a patient who had an EVLA procedure and 1 in percutaneous transluminal angioplasty. They required re-surgery to remove the instruments. Six patient suffered burn injuries. They were mostly due to incorrectly positioned patient return electrodes. Four patients had to be re-operated due to burn injuries. Two healed with non-surgical treatment.

Table 10. The 18 patient injuries that could have been prevented by correct use of the SSC.

Incident number	Disease	Indication for surgery	Type of surgery	Type of incident	Preventability
1	OTH	Unknown	Temporal artery biopsy	Biopsy was lost	Yes
2	SVI	Unknown	HL +S GSV, phlebectomy	Burn injury to both legs	Possibly
3	PAD	Claudication	Femoro-popliteal bypass	Burn injury to buttock	Possibly
4	PAD	Claudication	Femoral endarterectomy	Burn injury to buttock	Possibly
5	POP	Acute ischemia	Femoro-popliteal bypass	Burn injury to buttocks	Possibly
6	AAA	Aneurysm size	Iliaco-femoral bypass	Burn injury to buttocks	Possibly
7	PAD	CLTI	Femoro-tibial bypass	Burn injury to buttocks	Possibly
8	ICAS	Symptomatic ICAS	Carotid endarterectomy	Incorrect medication in anesthesia preparation	Yes
9	AAA	Aneurysm size	Open repair	Retained gauze in body	Yes
10	AAA	Infection aneurysm	EVAR, laparotomy	Retained gauze in body	Yes
11	AAA	Symptomatic aneurysm	Open repair	Retained gauze in body	Yes
12	PAD	CLTI	Aorto-bifemoral bypass	Retained gauze in body	Yes
13	PAD	CLTI	Femoral amputation	Retained gauze in body	Yes
14	PAD	CLTI	Aorto-bifemoral bypass	Retained gauze in body	Yes
15	SVI	Pain	EVLA	Retained instrument in body	Yes
16	SVI	Pain	EVLA	Retained instrument in body	Yes
17	PAD	Claudication	Angioprahy + PTA	Retained part of a PTA balloon in body	Yes
18	PAD	CLTI	Toe amputation	Unregistered gauze in wound	Yes

AAA = abdominal aortic or iliac aneurysm, CLTI = critical limb threatening ischemia, EVAR= endovascular aneurysm repair, EVLA = endovenous laser ablation, HL+S GSV= high ligation and stripping of greater saphenous vein, ICAS=inner carotid artery stenosis, OTH = other, PAD= peripheral arterial disease, POP= popliteal artery aneurysm, PTA = percutaneous transluminal angioplasty, SVI= superficial venous insufficiency

6 Discussion

6.1 Claims and decisions

Compensated patient injuries in vascular surgery in Finland are rare. The incidence of a compensated patient injury in vascular surgical and endovascular procedures between 2008 and 2017 was 1:2806 in Finland. In Sweden, patient injury incidence in vascular surgery varied between 1:650 and 1:6316 depending on the type of vascular procedure (Rudström et al., 2011).

According to Finnish Institute of Health and Welfare 2.4% of procedures in 2017 involved vascular or lymphatic system (*National institute of Health and Welfare*, 2019). However, in PIC statistics only 1.6% of all compensated patient injuries occurred in procedures of the same category (*Patient insurance Center*, 2021). The likelihood of a compensated patient injury in vascular surgery seems low also in this aspect.

During the study period, the proportion of compensated claims of all patient injury claims in vascular surgery in Finland was 16.6%. The percentage of compensated claims varied between 4.8 and 27.9% annually. The claim frequency for all patient insurance claims in Finland has been on a steady rise over the years (*Patient insurance Center*, 2021). In contrast, a similar trend could not be seen in vascular surgery claims. The claim frequency for vascular surgery varied significantly over the years but no clear increasing trend was evident. The reason for this difference is unclear.

The proportion of compensated claims in vascular surgery is significantly lower than the general compensation percentage in PIC data, which was 27.1% in 2017 and during the previous years has varied around 25–30% (*Patient insurance Center*, 2021). The majority of negative claim decisions were due to expert opinion that the injury could not have been avoided by acting differently. In other Finnish patient injury studies, compensation percentage has varied between 36–69.9% (Helkamaa et al., 2016; Sandelin et al., 2018; Vallila et al., 2015). Sample sizes in Finnish studies vary greatly. Some studies have not even reported the number of non-compensated injuries at all. A thorough analysis of the non-compensated claims would be necessary in order to ascertain how so few of the vascular surgery related claims merited compensation.

In other European patient injury studies in vascular surgery, compensation percentages have varied between 28.5 and 48.5% (Markides et al., 2008; Roche et al., 2014; Rudström et al., 2011). This difference might be partly explained by the fact that PIC pays no compensation for treatment injuries with minor consequences. Moreover, not all complications are considered patient injuries, only the bodily injuries that fulfil the conditions described in the Finnish Patient Injuries Act (*Patient insurance Center*, 2021). Even so, an unreasonable injury category is in use in Finland, which is not the case for all other countries. In this injury category, the treatment itself had been correct but the consequences of the injuries were severe enough to justify compensation (*Patient insurance Center*, 2021). Five of the injuries in our study were compensated as unreasonable.

The number of filed and compensated claims was much higher after 2004 than prior to it. This is explained by the fact in the statistics provided by PIC, vascular surgery became a specialty and listed as such in 2004. Prior to 2004, all surgical specialties were classified under 'surgery' (*Patient insurance Center*, 2021). This renders a computerised search for only vascular surgery prior to 2004 impossible. The search from those years would have to have been conducted manually, which could have drastically affected the number of found cases.

Not all the compensated and non-compensated cases that were labelled under vascular surgery in the PIC data involved vascular surgery related patient injuries. A majority of the cases were labelled correctly, but there were also errors in specialty determination. The cases that were not vascular surgery were excluded from the analysis of claims in this study. It should be noted for future patient injury studies, that the specialty recorded patient injury claim numbers should not be used alone without also familiarizing oneself with the case summaries.

We had hoped to demonstrate how the progress of the vascular surgery specialty to become its own independent specialty affected the claim frequency. However, as the claim frequency prior to 2004 in PIC is uncertain, no thorough comparison or analysis was therefore possible. Moreover, the change in background information concerning annual vascular surgical and endovascular procedures and diagnostic angiographies was also difficult to ascertain. As the Ministry of Health and Welfare does not provide procedure numbers crosslinked with diagnosis without a surcharge, it is difficult to evaluate the data for which indication the procedure was performed. The procedure numbers are therefore a best possible estimate of performed vascular procedures. Numbers prior to 2008 were not available free of charge, and the reliability and coverage of the information from earlier years is poorer and did not necessarily cover all of Finland (*National institute of Health and Welfare*, 2019).

6.2 Patients and diseases

The majority of patient injuries happened to be found in elderly men. This is probably explained by the fact that arterial diseases such as PAD and AAA affect men more commonly than women and the incidence increases with age (Criqui & Aboyans, 2015). Injured patients suffered from typical cardiovascular co-morbidities, with hypertension and hypercholesterolemia being the most common. Almost 40% of injured patients were current smokers. Smoking causes problems in wound healing and it increases the likelihood of infection postoperatively (Sørensen, 2012).

A majority of Finnish patient injuries occurred in arterial surgery. PAD was most often involved and accounted for 45.1% of the injuries. The numbers of both open and endovascular revascularization procedures have increased in Finland since 2000 but the number of major lower extremity amputations has remained relatively constant (Nikulainen et al., 2019).

A surprisingly small proportion of injuries involved the treatment of venous disease, in contrast to other European studies in which varicose vein related injuries were the most commonly compensated category (Markides et al., 2008; Roche et al., 2014; Rudström et al., 2011). As procedures performed for venous conditions are the most common of vascular procedures in Finland, it seems odd that only 15.5% of the injuries are associated with them (*National institute of Health and Welfare*, 2019). This might be explained by the fact that no compensation is paid by the PIC for minor injuries.

Even though aortic procedures are considered high risk surgery, only 25.8% of the intraoperative injuries involved aortic procedures. The PIC compensation criteria stipulate that patients are expected to tolerate more complications in high risk procedures and this might be one explaining factor. Four of the aortic procedures were EVAR and there were 12 bypasses of the aortic region. Five of the bypasses were performed because of PAD and the remaining 7 were for aneurysmatic disease. Only a small proportion of injuries involved EVAR even though the number of EVAR procedures has been on a steady rise in Finland (Laine et al., 2017). This might reflect the fact that EVAR is generally linked to less mortality and morbidity than for the OR (Greenhalgh et al., 2004).

Upper extremity vascular patient injuries were rare, as were injuries related to popliteal artery and other aneurysms. These diseases constitute a minor occurrence in vascular surgery (Aboyans et al., 2018; Björck et al., 2020).

6.3 Circumstances

Almost 90% of compensated injuries occurred in either university or central hospitals. This reflects the fact that these larger units perform more procedures and arterial surgery is mostly centralized to them, whereas smaller units mainly perform procedures related to superficial venous insufficiency (SVKY, 2019). There was no clear indication that higher volume hospitals would have better patient safety outcomes.

Patient injuries occurred mainly in routine vascular surgery procedures. As 69.1% of the procedures involved in the injuries were elective, only a small portion of the injuries can be explained by the situational constraints of urgent surgery.

The majority of the procedures were carried out by fully trained surgeons, so a lack of expertise does not explain the injuries incurred. Surgeons in training were the main operators in 13.3% of the procedures. In other studies, 3.0–10.3% of the injuries were caused by surgeons in training (Helmiö et al., 2015; Regenbogen et al., 2007). This might be explained by the fact that surgeons in training generally have a very active role in their departments in Finland early on. It has been estimated that the ratio of vascular surgeons in training compared to fully trained vascular surgeons in Finland should be roughly 1:6 to meet the needs of the service system (Rellman, 2016). This ratio corresponds approximately to the injury distribution between fully trained vascular surgeons and trainees.

Errors related to surgical care also occur for other health care professionals than surgeons (Reason, 2005). In our study, injuries were recorded during preoperative preparations by nursing staff both in surgical ward care and in the operating theatre. One case injury was related to medication error during anaesthesia preparation and the other occurred during transfer to intensive care unit by an anaesthesia team. Burn injuries occurred under recovery room care and there were shortcomings in patients follow up in surgical wards postoperatively. Thus, the heterogeneous nature of injuries highlights the importance of teamwork and communication in the whole surgical care process.

6.4 Types of injuries

Injuries were identifiable at all stages of care. Injuries that were related directly to intraoperative care constituted 43.7% of all injuries. Typical injuries included the following: errors in surgical technique, nerve injuries, injuries to adjacent organs or tissues and intraoperative burns. Delays, and errors in diagnosis, errors in treatment and also errors in medication were compensated. Infections and hemorrhage also contributed to injuries.

Nowadays, endovascular revascularisation procedures constitute almost 60% of all revascularisations in Finland (Nikulainen et al., 2019). This distribution is not reflected in the compensated patient injury claims. A majority of injuries involved open surgery, which was evident for all treated vascular diseases. Risks in endovascular treatment also exist, but the likelihood of injury in these modalities seems to be smaller. Endovascular treatment injuries were sporadic and no clear trends could be seen. Endovascular treatment does, however, carry its own unique risks but endovascular operations seem to lead to patient injury only rarely. Similar results were reported in Sweden where an increasing number of endovascular procedures did not seem to influence the pattern of claims (Bergqvist et al., 2019).

New endovascular treatment modalities such as EVLA reported unique complications. This is probably due to the learning curve in the beginning of mastering a new treatment technique.

6.5 Consequences of the injuries

Five (3.5%) of the injured patients died. In three of these cases delay in diagnosis or treatment led to the patient's death. Two of these cases involved a delayed diagnosis of RAAA and one delayed treatment of a SMA embolus. The two other deaths occurred post-operatively. Both patients had undergone open surgery. One patient died due to a missed myocardial infarction after aorto-bi-iliac bypass to treat AAA. The second patient's death was caused by post-operative haemorrhage after femoral artery endarterectomy to treat claudication. It occurred after discharge from hospital. The second patient's death was compensated as an unreasonable injury. There was no fault found in the patient's treatment.

Four of the 5 deaths were evaluated to have been preventable, if the medical professionals had acted differently. The RAAA cases highlight the importance of constant education of health care professionals to recognize critical medical conditions better. Failure to recognise a deterioration of a patient's condition postoperatively in hospital can lead to a failure to rescue that patient (Staender & Smith, 2017). A significant proportion of patients who experience cardiac arrest in hospital, have had recognizable changes during the 24 previous hours (Vincent et al., 2018). In hindsight, it is clear that the deteriorating condition of the patient with heart infarction was missed. Rapid response teams or medical emergency teams improve outcomes of patients deteriorating outside of intensive care units and could have helped to rescue this patient as well (Solomon et al., 2016).

There were also other life-threatening injuries. Three of the injured patients suffered a major stroke, 1 had anaphylactic shock that required intensive care unit treatment, 1 suffered a worsening of a heart condition due to a poorly timed operation and 1 had a severe postoperative hemorrhage due to an overdose of noradrenalin. Infection also caused life-threatening consequences for 6 patients. Two of these patients had necrotizing fasciitis after varicose vein surgery that required multiple re-surgeries, hyperbaric oxygen treatment, and intensive care unit treatment. The four remaining patients had Y-prothesis infections that required the removal of the prosthesis and deep vein reconstruction. Some infections required lifelong antibiotic treatment. All the infections involving lower limb prosthetic bypasses required the removal of all prosthetic material.

Seven patients suffered a major amputation and 3 a minor amputation due to patient injury. Eight of the amputation injuries were related to a delay in diagnosis or treatment, which underlines the importance of correct timing of operations in vascular surgery. Although some patients can wait for treatment for their CLTI it is crucial to recognise those patients that cannot.

6.6 Economics

Vascular surgery is considered to be a high-risk specialty for patient harm (Hernandez-Boussard et al., 2012). Patient injuries incur a high cost to the welfare system. In 2020, the PIC paid 45.1 million euros in compensation for patient injuries in all specialities Finland (*Patient insurance Center*, 2021). The precise compensation sums are confidential. Compensations paid by the PIC are only a small proportion of the total costs the patient injury has caused to health care and the exact amount can only be guessed. However, patient injuries are known to cause major extra costs in health care (Järvelin et al., 2019). Even though vascular surgery patient injuries have contributed only to a fraction of the costs, it is clear that by reducing the number of patient injuries in vascular surgery it would be possible to radically reduce these extra costs for these patients. For example, as much as 57.7% of the injured patients in vascular surgery in Finland had to undergo additional surgery due to injury, an event that drastically increases the monetary burden to health care.

Patient injury claim analysis has shown that all claimants treatments has been more costly than those for non-claimants, which should be a strong motivation to reduce AEs (Järvelin et al., 2019). Uncompensated claims can provide additional information about patient safety and analysis should not focus solely on compensated claims (Järvelin et al., 2019).

6.7 Prevention of harm in the future

6.7.1 The human factor

It is unrealistic to believe that human error could be eliminated completely but it is plausible that serious AEs could be prevented by better education. The training of surgeons should reflect the need for constant feedback between experienced surgeons and trainees and the discussion about errors and hazards should not be limited to only among peers but should also address systematic problems as well (Hakala et al., 2014). Complications and errors should be openly analyzed and their evaluation should be a mandatory part of the training process (Hakala et al., 2014).

Of the injuries in procedures, 15.4% involved either a nerve injury or an injury to other adjacent anatomical structure and 10.3% to an error in surgical technique. This highlights the importance of adequate training in anatomy and surgical technique to vascular surgeons in training. A modern way to teach anatomy involves combining multiple pedagogical resources such as anatomic dissections, medical imaging and multimedia resources (Estai & Bunt, 2016). The time in the operating room for the acquisition of complex surgical skills for trainees is often limited. Modern technology such as online surgical videos, simulations, including virtual reality, and gaming can offer opportunities for improving education of trainees (Evans & Schenarts, 2016).

6.7.2 Communication

Good teamwork can improve patient safety culture. The importance of team work in health care and especially in surgery cannot be emphasized enough. Outdated hierarchical structures should not be allowed to inhibit collaboration and learning.

One of the most common interventions in health care is the use of medications. Medication errors often involve errors in communication. Medication harm results in lengthened hospital stays and considerable morbidity and mortality (Lazarou et al., 1998; Miguel et al., 2012). In our study, 7.0% (n=10) of the patient injuries were related to errors in medication. The consequences of these mistakes ranged from brief discomfort to anaphylactic shock and major stroke. Even though patient harm in surgical patients is mostly thought to be associated with the surgery itself, medication errors cause a significant risk to patient as well.

Communication tools such as ISBAR can prevent errors in patient transfer (Burgess et al., 2020). Risk associated with communication errors in transfer were evident in our study because one patient suffered a major stroke due to communication errors in patient transfer to another facility. Systemic tools can help to avoid recurrence of such errors.

6.7.3 Organizations

Even the simplest of procedures carries inherent risks to the patient. Good risk management is essential to keep patient injuries to a minimum. Without understanding the areas of risk, accurate information cannot be passed onto the patient and the medical staff. Robust reporting of errors and AEs is crucial to understanding the areas of risk for patient safety. In Finland, the HaiPro reporting system is in use and facilitates the recognition of errors in health care (Ruuhilehto et al., 2011).

Organizational culture with patient safety focus is essential to improve perioperative care. Perioperative hazards include insufficient preoperative assessment, wrong site surgery, equipment malfunction, infections, medication error, venous thromboembolism, and other complications (*Patient Safety Policy Summit: Consensus Statement 2020*; Staender & Smith, 2017). Organizational tools for improving patient safety include the following: the spread of known good practices, the use of learning-from-errors systems, checklists, other cognitive aids, interprofessional teamwork training, patient safety education, application of patient management tools, and other innovative data collection and analysis systems (*Patient Safety Policy Summit: Consensus Statement 2020*; Staender & Smith, 2017). Data collection tools are crucial to help avoid undesirable outcomes because they measure and monitor mortality, and morbidity and they also evaluate the effectiveness of patient safety improvement measures (*Patient Safety Policy Summit: Consensus Statement 2020*; Staender & Smith, 2017). Information sharing between different organizations should be transparent and easy, so that we can learn from each other's mistakes (Leape et al., 2009).

6.7.4 Patient safety tools

The SSC that was formulated by the WHO has been found to be a valuable tool in improving patient safety in surgery (Haynes et al., 2009). Its usefulness was also demonstrated in our study as many as 18 (12.7%) of the injuries could have been prevented by the correct use of the checklist. The use of the SSC is now mandatory in Finland in all surgical specialties and its use is routinely evaluated in surgical patient injuries. It might, however, be beneficial that all surgical units should monitor the compliance of SSC use in their units as it is possible that over time, people will become prone to forget safety measures, if they are not continually reminded of them.

Never events caused injuries to 9 (6.3%) patients in our study. In previous surgical malpractice claim studies, 3% of the injuries involved retained foreign material (Regenbogen et al., 2007). No cases of wrong patient, site or wrong side surgery were among the compensated injuries. Six of the cases involved open surgery, 2 EVLA, and 1 angiography and percutaneous transluminal angioplasty. It is unclear whether the SSC was in use in all open surgeries but if it were, it could have potentially prevented all never events. One of the injuries occurred before the SSC was piloted in Finland.

Many EVLA and angiography procedures are performed outside the operating theatre where the SSC is not usually in routine use in these sites. Similar vigilance should also be used in these procedures in these locations to prevent never events.

Six patients suffered burn injuries. These injuries were mostly due to incorrectly positioned patient return electrodes. A return electrode check is not part of the original WHO SSC but has been added to the surgical check lists used in a number of countries and from the findings of this study it should be a standard part of the checklist in all operations.

Currently no national quality registry for vascular surgery procedures exists in Finland and the methods how different vascular surgery units register and monitor complications vary considerably. A uniform registry could provide more information on the number of performed procedures and would be valuable in identifying complications that might fulfil patient injury criteria even though no claim was filed. Such a registry would also enable comparisons with other countries and could potentially reveal hidden problems in care. In order to have a consistent and reliable way to measure harm in vascular surgery in the future, a national vascular registry is therefore essential.

It should be kept in mind though that, despite their usefulness, quality registries do not directly measure the safety of care. Even though the patient reports health improvement, it is not possible to deduce if the care was indeed safely delivered. Systemic causes behind patient injuries are not easily captured by these registries and require other approaches of analysis.

The use of RCA can be an effective way of learning from patient harm. Analysis of patient injuries should not be confused with RCA. Instead the use of the RCA is intended to find answers to experienced harm as soon as it has happened. Patient injury claims can also be used to recognize harm that became evident only after a long time period. These two methods i.e. RCA and patient injury claims, can complement each other in patient safety improvements.

Patient injury data should be utilized in all operative units in Finland. Globally M&M meetings are in frequent use and similar meetings should be a part of Finnish health care as well. Patient injury claim decisions should be used for education of all surgical staff to prevent errors from happening in the future. The continual education of safety science to surgeons and anesthetists is essential to improve safety and efficiency of surgical systems. A lack of knowledge and lack of experience are, *inter alia,* substantial barriers to redesigning patient safety (Marshall & Touzell, 2020).

6.8 Study strengths

Our data were directly obtained from the PIC insurance chart registry. The PIC handles all patient injury claims in Finland for both the public and private sectors, therefore the registry is highly representative. It contains all necessary information about care of the claimant. Thus the claim process and consequently data collection, handling and recording were optimal. All health care facilities are required to have an ombudsman to assist patients in filing a claim to the PIC and the claim handling is always free of charge to the patient. This makes claim filing after injury more likely to occur. The study period was long and it enabled a reliable description of the situation in Finland.

6.9 Study limitations

Not all patients file a claim to the PIC after injury, thus closed claim analysis has its limitations. Inadequate knowledge about the insurance system among patients and medical professionals might influence the frequency of claims made.

Accepted patient injury claims represent only a portion of all errors and AEs in health care. According to some estimates only 1–3% of all patients with severe, compensable AEs ever file a claim to PIC for a patient injury (Mikkonen, 2004). This implies that the PIC registry represents only a small proportion of all AEs. Currently there is no national quality registry in vascular surgery which could be used for identifying possibly missing cases.

Vascular surgery patients are often elderly, which might influence their likelihood of filing a claim. Some patients may also fear that filing a claim will have a negative effect on their treatment in the future.

The PIC registry of patient injuries is not a registry of all complications in Finland but only of those cases that were filed by the patient for an injury claim. As such it cannot be used for determining the rate of complications in vascular procedures in this study.

6.10 In conclusion

Patient injuries can seriously undermine patients' trust in health care organizations and they can have profound effects on the patient and the patient's next of kin. Patients should be encouraged to file patient injury claims after suffering harm in health care in order to advance patient safety.

It is the moral duty of all medical professionals to be aware of patient injuries that have already taken place and work actively against their recurrence. All patients should be able to come to health care with confidence in receiving safe care. Human memory is short, and we tend to repeat our errors, therefore we should use patient injuries as a tool to remind ourselves of failures that have already occurred. Patient injuries should not be repeated and it is the responsibility of all health care staff to ensure that they do not reoccur.

7 Conclusions

1. Injuries in vascular surgery were rare. Most patient injury incidents in vascular surgery occurred in operative care, intraoperative errors being the most common. Nerve damage was the single most common injury. Errors were identified in diagnostic processes as well.

2. Patient injuries occurred most commonly in patients suffering from PAD. A majority of the patients were male and more than 65% of the injured patients were over 60 years old which is comparable to typical patient sex and age distribution in vascular surgery.

3. A majority of the patient injuries occurred in either central or university hospitals at the hands of experienced surgeons. Most of the injuries involved open surgery.

4. The consequences of the injuries were severe. Five of the injured patients died, 7 suffered a major amputation, 3 had a minor amputation, 21 permanent nerve damage, and 3 a major stroke. More than 50% of the patients required additional surgery due to the injuries.

5. Correct use of the WHO SSC or other similar systemic checklist was evaluated to have potentially prevented more than 10% of the injuries.

6. Endovascular treatment modalities only rarely led to injury. Unique injury types were recognized in new endovascular treatment techniques during learning phase.

7. National quality registry in vascular surgery could present possibilities for improving safety of care and help to provide accurate statistics on vascular procedures.

8. Patient injury information provides detailed information on patient safety hazards. Analysis of patient injuries should be part of education in all surgical departments in order to prevent injuries from reoccurring.

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