Diploma Thesis

Long Term Outcome after Endarterectomy of the Common Femoral Artery

Submitted by

Anna Stockinger

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under the supervision of

Univ. FA Priv.-Doz. Dr.med.univ. Peter Konstantiniuk

Univ. FA Dr.med.univ. Gregor Siegl

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Graz, 18.06.2025 Anna Stockinger m.p.

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Zusammenfassung in Deutsch

Einleitung

Eine Thrombendarteriektomie der Arteria femoralis communis wird typischerweise mit einer Patchplastik geschlossen, um eine Einengung des Gefäßlumens durch die Naht zu verhindern. Bovines Perikard bietet eine Alternative zu autologen Patches aus der Vena saphena magna oder der verschlossenen Arteria femoralis superficialis. Da Patches aus bovinem Perikard sofort verfügbar sind, geht man davon aus, dass ihr Einsatz die Operationsdauer reduziert, den Patienten Erweiterungen des Operationsfeldes oder zusätzliche Inzisionen erspart, und die Venen für zukünftige Revaskularisation erhält. Bis dato haben nur wenige Studien die Langzeitergebnisse der verschiedenen Materialien verglichen. Diese Studie untersucht den Einfluss des Patchmaterials auf Wundkomplikationen und das fünf-Jahres Ergebnis.

Methodik

Alle Patient*innen mit einer isolierten Thrombendarteriektomie der Arteria femoralis communis an der Klinischen Abteilung für Gefäßchirurgie der Medizinischen Universität Graz, im Jahr 2016 und 2017 wurden in die Studie eingeschlossen. Für die Fragestellung der Wundkomplikationen wurden Daten aus den Patient*innenakten extrahiert. Wundkomplikation wurde durch das Auftreten folgender Ereignisse definiert: Drainageliegedauer >7 Tage, Vacuum Assisted Closure–Therapie, Sekundärnaht, Wundheilungsstörung, Lymphfistel, Wundinfektion, Blutungsrevision. Da in den einzelnen Kategorien zu geringen Fallzahlen für statistische Auswertungen auftraten, wurde ein kombinierter Endpunkt definiert. Dieser wurde erreicht, wenn mindestens eines dieser Ereignisse eintraf.

Für die Untersuchung des fünf-Jahres Ergebnisses wurden Patient*innen für eine sonographische Nachuntersuchung der operierten Arteria femoralis communis eingeladen, um den Durchmesser und den Restenosegrad zu ermitteln.

Ergebnisse

Von 159 operierten Arterien haben 129 die Inklusionskriterien erfüllt. Die Wundkomplikationen wurden für alle 129 evaluiert. Akute Blutungsrevisionen

wurden bei1,6% (2/129) durchgeführt, 5,4% (7/129) entwickelten Lymphfisteln, Wundinfektionen wurden in 4,7% (6/129) diagnostiziert, Wundrandnekrosen und Nahtdehiszenzen wurde in 10,9% (14/129) beobachtet, ein Vakuumverband wurde in 1,6% (2/129) verwendet. Es wurde kein signifikanter Zusammenhang zwischen dem kombinierten Endpunkt Wundkomplikation und Patchmaterial gefunden. Eine signifikante Wechselbeziehung wurde zwischen Geschlecht (27,8% der Männer, 9,4% der Frauen hatten Wundkomplikationen, p = 0,03), und der operierten Seite (31,8% der rechtsseitigen Operation, 14,3% der linksseitigen Operation präsentierten Wundkomplikationen, p = 0,02) gefunden.

Achtzehn Patient*innen wurden fünf Jahre nach der Operation sonographisch nachuntersucht. Ein signifikanter Unterschied im Durchmesser der Arteria femoralis communis zwischen den Patches wurde identifiziert: der durchschnittliche Durchmesser war 14mm bei autologen Patches und 10mm bei bovinem Perikard (p = 0,001). Keine signifikante Restenose wurde beobachte.

Diskussion

Kein signifikanter Unterschied zwischen Wundkomplikationen in Zusammenhang mit Patchmaterial wurde entdeckt. Das stellt die Annahme in Frage, dass autologes Material weniger komplikationsbehaftet ist, und könnte die Venenentnahme in Patienten mit eingeschränkter Wundheilung vermeiden. Es ist unklar, ob der größere Durchmesser der Arteriae femorales communes mit autologen Patches unmittelbar nach der Operation auftritt, oder sie erst mit der Zeit dilatieren.

Abstract

Introduction

Endarterectomy of the common femoral artery typically involves patch plasty to prevent lumen narrowing from direct closure. Bovine pericardium provides an alternative to autologous patches won from great saphenous vein or occluded superficial femoral artery. It is expected to reduce operating time, obviate additional incisions, and preserve the great saphenous vein for future revascularization. However, few studies have compared the long-term success of different patch materials. This study investigates the impact of various patch materials on wound complications and the five-year outcome.

Methods

Patients who underwent isolated common femoral artery endarterectomy at the Division of Vascular Surgery, Department of Surgery, Medical University of Graz, in 2016 and 2017 were included. For wound healing complications data from medical records was retrieved. The following events were defined as wound complications: drainage >7 days, vacuum assisted closure-therapy, secondary closure, wound healing disorder, lymphatic fistula, wound infection, revision for acute bleeding. Since there were too few cases in each single category, a combined endpoint was defined. This endpoint was reached when at least one of the mentioned events occurred.

To investigate the five-year-outcome patients were invited for a follow-up where a sonography of the operated common femoral artery was performed to evaluate diameter and grade of restenosis.

Results

Of 159 operated arteries, 129 met the inclusion criteria. Postoperative wound complications were evaluated for all 129 arteries. Acute revision for bleeding was necessary in 1.6% (2/129), 5.4% (7/129) developed lymphatic fistulas, wound infection was diagnosed in 4.7% (6/129), wound edge necrosis or dehiscence was seen in 10.9% (14/129), vacuum assisted closure-therapy was used in 1.6% (2/129). No significant association was found between the combined end point wound complication and patch material. Significant association was observed for

gender (27.8% of men, 9.4% of women had wound complications, p = 0.03), and operated side (31.8% of right groin, 14.3% of left groin operations presented wound complications, p = 0.02).

Eighteen patients underwent a five-year sonographic follow-up. A significant difference in common femoral artery diameter between patch materials was identified: the median diameter was 14 mm with autologous patches and 10 mm with bovine pericardium (p = 0.001). No significant restenosis was observed.

Discussion

No significant difference in wound complications in relation to patch material was found. This challenges the belief that autologous material results in fewer complications and may obviate vein harvesting in patients with impaired wound healing. It is unclear, if the larger diameter of common femoral arteries with autologous patches exists instantly after the operation due to a higher mechanical compliance or if autologous patches enlarge over time.

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Abbreviations

ABI	ankle brachial index
ASA	acetylsalicylic acid
BMI	body mass index
BMS	bare metal stent
CABG	coronary artery bypass graft
CIA	common iliac artery
CFA	common femoral artery
CRP	C-reactive Protein
CTA	computer tomography angiography
DAPT	dual antiplatelet therapy
DES	drug eluting stent
DFA	deep femoral artery
DM	diabetes mellitus
EIA	external iliac artery
ePTFE	expanded polytetrafluoroethylene
EVT	endovascular therapy
HbA1c	glycated hemoglobin
HDL	High-Density Lipoprotein
ICAM-1	intercellular adhesion molecule
IDDM	insulin dependent diabetes mellitus
IIA	internal iliac artery
kg	kilogram
LDL	Low-Density Lipoprotein
LDL-C	Low-Density Lipoprotein-Cholesterol
LMWH	low molecular weight heparin
MRA	magnetic resonance angiography
NIDDM	non-insulin dependent diabetes mellitus
NOAC	new oral anticoagulants
PAD	peripheral artery disease
PET	polyethylene terephthalate

PTA	percutaneous transluminal angioplasty
PTCA	percutaneous transluminal coronary angioplasty
TAVI	transcatheter aortic-valve implantation
TIA	transient ischemic attack
VAC	vacuum assisted closure-therapy
VCAM-1	vascular cell adhesion molecule
SBP	systolic blood pressure
SFA	superficial femoral artery
v_{max}	maximum velocity

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1. Introduction

Endarterectomy of the common femoral artery (CFA) is a standard surgical intervention for treating peripheral artery disease affecting the CFA and its bifurcation. This procedure involves surgical removal of atherosclerotic plaques to restore blood flow and is usually combined with patch angioplasty for vessel closure to prevent arterial narrowing due to sutures. There are different patch materials available. In this study we focus on three patches. An autologous venous patch usually obtained from the great saphenous vein (GSV), a patch harvested from the occluded superficial femoral artery (SFA), and a bovine pericardium patch. The patch is chosen depending on the patient, the circumstances and preference of the operating surgeon. Bovine pericardium serves as an effective alternative to autologous patches. Utilizing the pericardium spares the patient an additional surgical wound and preserves the vein for potential future revascularization procedures. Furthermore, like autologous patches, the pericardium is believed to be resistant to infection, exhibits favorable compliance and rapid endothelialization. Since it is an off-the-shelf product, it is immediately available and might positively influence the duration of surgery.
However, current research on the long-term efficacy of various materials used in the inguinal region remains limited and sample sizes are usually small. Therefore, this study aims to compare the long-term outcomes of these three materials in terms of wound complications and five-year outcome, defined as restenosis.

1.1 Anatomy

1.1.1 Arteries

The arteries of the lower extremity originate from the external iliac artery (EIA). At the level of the fourth lumbar vertebra the abdominal aorta divides itself into two common iliac arteries (CIA). Before the sacroiliac joint the CIA forks into an external and internal branch. The EIA supplies blood flow to the lower extremity, while the internal iliac artery (IIA) perfuses the pelvic organs. The EIA passes between the major and minor pelvis to the lacuna vasorum. When it runs below the inguinal ligament the EIA becomes the common femoral artery (CFA) (1).

Distal of the inguinal ligament the CFA passes lateral beside the femoral vein (2). Lateral to the artery runs the femoral nerve (1). The CFA courses ventral to the femoral head und usually bifurcates distal to its middle into the deep femoral artery (DFA) and the SFA (3). The SFA travels down below the sartorius muscle before it passes through the adductor canal, after which it becomes the popliteal artery. In its course the CFA releases the following branches in descending order: superficial epigastric artery, superficial iliac circumflex artery, superficial, and deep external pudendal artery. Three to six centimeters distal of the inguinal ligament originates the biggest branch of the CFA, the DFA. It runs in a lateral and dorsal direction and supplies the muscles that extend, flex, and adduct the thigh. The DFA releases the following branches in descending order: medial, and lateral circumflex femoral artery, perforating arteries I-IV. The popliteal artery is the continuation of the SFA (1).

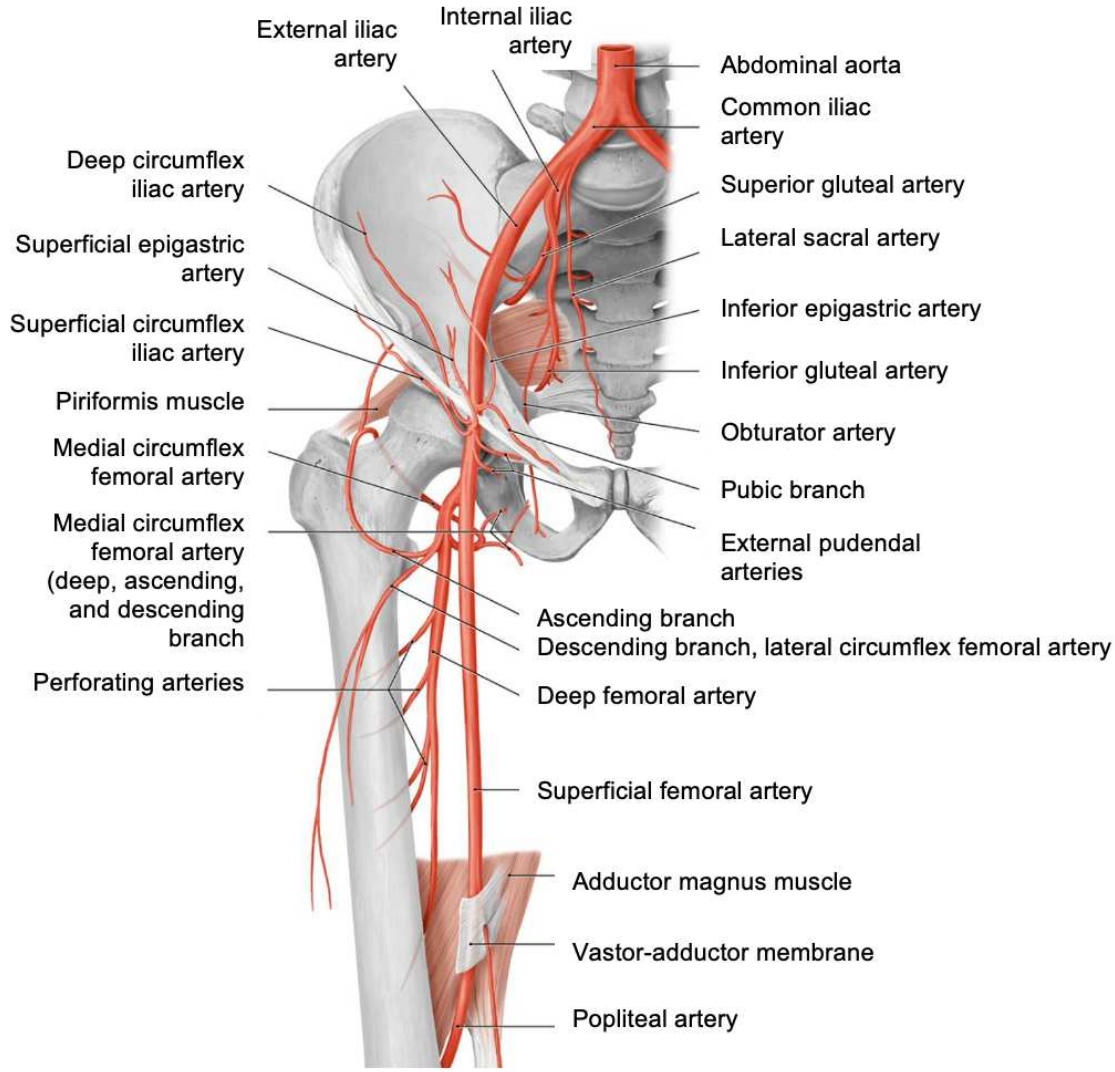


Figure 1: Arteries lower limb (4)

1.1.2 Veins

The great saphenous vein is a preferred choice for harvesting vascular patches due to its accessibility, size, and compatibility for grafting procedures. It originates on the medial foot rim and proceeds anterior to the medial malleolus, extending along the tibial side of the lower leg and thigh. The great saphenous vein contains several venous valves (1).

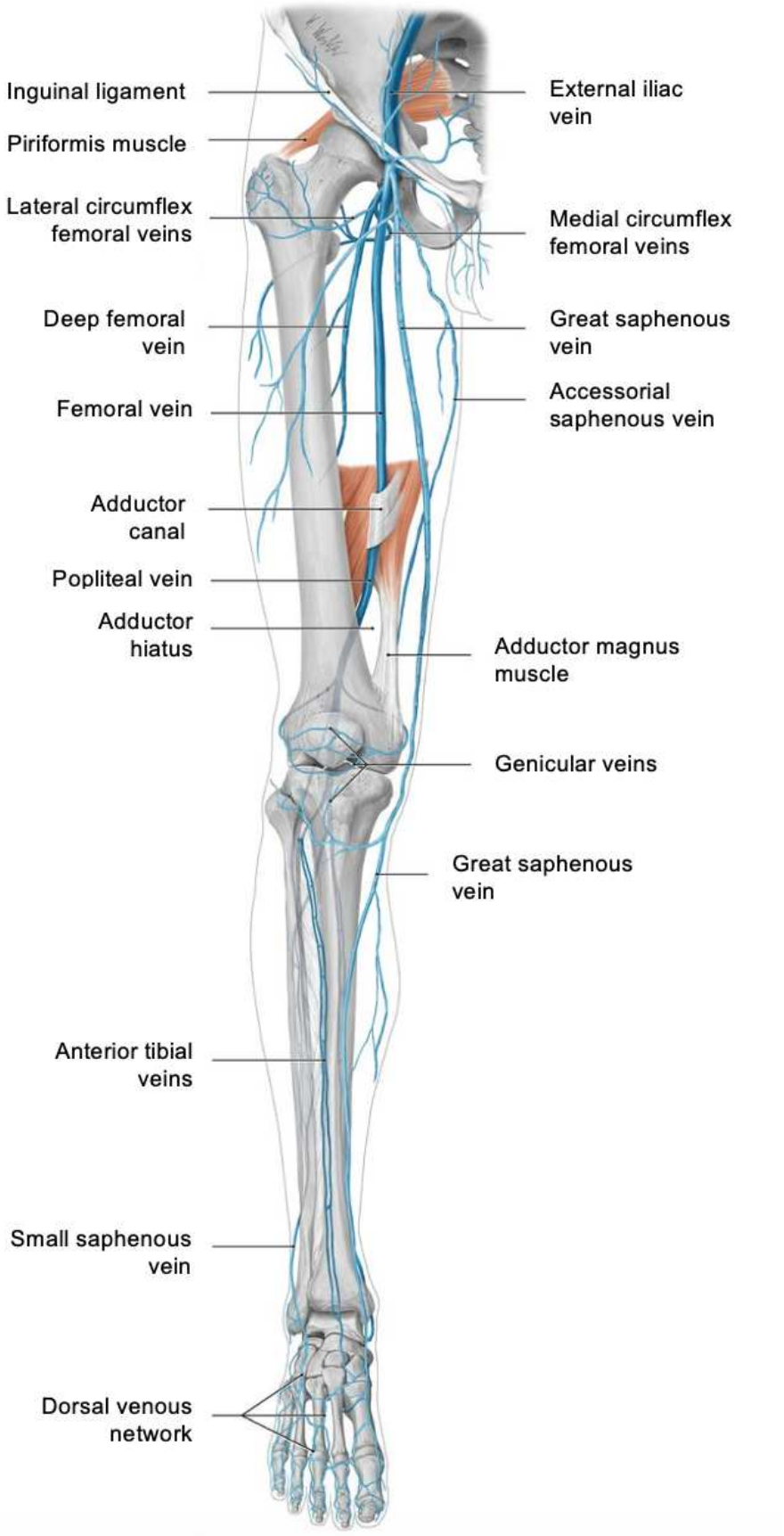


Figure 2: Veins lower limb (4)

1.2 Physiology

All blood vessels except capillaries consist of three layers:

- Inside, the Tunica intima which is composed of single layer endothelium
- In the middle, the Tunica media with smooth muscle cells, elastin, and collagen
- Outside, the Tunica adventitia consisting of connective tissue

While the endothelium is always single layered, the thickness of the muscle layer and the amount of connective tissue varies. We distinguish between a high-pressure system and a low-pressure system. The high-pressure system includes the left ventricle, the big arteries which fulfill the Windkessel effect, and the smaller arteries and arterioles, also called resistance vessels. The Windkessel effect is based on the elasticity of the aorta. While blood is ejected from the left ventricle during systole, pressure increases inside the aorta and causes it to expand. After the aortic valve closes the aorta contracts and the blood is transported into the periphery. Due to the higher pressure in the arterial system, the walls of the arterial vessels are thicker (5).
The endothelium partakes in various physiological reactions of the circulation. It has an antithrombogenic quality. Due to the formation and release of substances that inhibit the adhesion and aggregation of platelets as well as coagulation, the endothelium can prevent the formation of blood clots (5).

The smooth muscle cells of the tunica media regulate the diameter of the vascular lumen. Smooth muscles are under a certain tonus. The intensity of the basic tone determines the maximum possible increase in blood flow, also called perfusion reserve. The higher the basic tone, the higher the perfusion reserve (5).

The adventitia is essential for the mechanical properties and the perfusion of the vascular wall. The big arteries feature their own vascular system, called vasa vasorum. The walls of smaller arteries are supplied by diffusion (5).
All vessels are innervated by fibers of the autonomic nervous system. The efferent innervation regulates the tone of the smooth muscle cells in the vascular wall. The

nervous fibers are therefore called vasomotor. Those fibers are mostly part of the sympathetic nervous system and induce vasoconstriction (5).

1.3 Atherosclerosis

Arteriosclerosis is a general term for three vascular pathologies:

- Atherosclerosis
- Mönckeberg medial sclerosis
- Arteriolosclerosis

Atherosclerosis is by far the most frequent of these three diseases and therefore often used synonymously for arteriosclerosis. It is a disease of civilization which accounts for more than half of all deaths in western industrialized nations (6). Furthermore it causes more than 90% of all arterial perfusion disorders (7). Atherosclerosis mostly affects cerebral, coronary, and peripheral vessels. It can also obstruct the visceral blood vessels and cause intestinal ischemia (7).

Mönckeberg medial sclerosis provokes calcification of the media of muscular arteries. The calcifications do not compromise the diameter of the artery and therefore are usually not clinically significant (8). Even though Mönckeberg medial sclerosis does not compromise the arterial blood flow, it can coexist with atherosclerotic plaques and cause intraoperative complications (9).

Arteriolosclerosis affects the small arteries and arterioles and refers to the thickening of their walls. It is associated with arterial hypertension and can result in ischemic injury. Arteriolosclerosis often affects the kidneys and brain. There are two types of arteriole thickening, hyaline arteriolosclerosis, which is associated with subarachnoid hemorrhage, and hyperplastic arteriolosclerosis (9).

1.3.1 Risk factors

The risk factors which increase the manifestation of atherosclerosis can be divided into three groups, constitutional risk factors, modifiable major risk factors, and additional risk factors (8). The constitutional risk factors include family history of arteriosclerotic diseases, age, and gender. Atherosclerosis is a progressive pathology, which usually becomes clinically relevant between 40-60 years of age (8). Premenopausal women in comparison with age-matched men are relatively protected against atherosclerosis. However, after menopause the incidence in atherosclerosis increases (8).

Among the modifiable major risk factors, we find dyslipidemia, hypertension, diabetes mellitus and smoking (6, 8, 10).

The additional risk factors include inflammation, elevated C-reactive protein (CRP), and hyperhomocysteinemia (6-8, 10).

1.3.2 Pathogenesis

Atherosclerosis is not an acute but progressive disease, which can take decades until clinical manifestation (7).

The “response to injury” hypothesis is the main mechanism postulated to drive the pathogenesis of atherosclerosis. It assumes that an injury of the endothelium caused by the earlier mentioned risk factors initially triggers a response leading to atherosclerosis (8). Frequent predilection sites are those with a high mechanical stress, i.e. vessel bifurcations (6). Through the injured endothelium low density lipoprotein (LDL) can enter the intima and accumulate. The LDL particles underlie an enzymatic and oxidative modification, which is the most important factor for the migration of leucocytes (7). An endothelial expression of adhesion molecules (i.e. vascular cell adhesion molecule (VCAM), intercellular adhesion molecule (ICAM)) lead to the attachment of monocytes and T-lymphocytes (7). Chemokines enable the endothelial penetration and migrations of those immune cells into the subendothelial space (7). There the monocytes develop into macrophages and release oxygen radicals further injuring the endothelium due to their cytotoxicity (6). The macrophages express scavenger-receptors, which unlike normal LDL-receptors, do not underlie a negative feedback mechanism. They thus are

massively overloaded with lipids and turn into so called foam cells. The development of foam cells is the earliest and potentially reversible stage of atheromatous plaques (7).

The next phase is the migration of smooth muscle cells from the media into the intima, where growth factors stimulate them to proliferation and increase production of extracellular matrix (7). An atherosclerotic plaque consists of a nucleus rich in lipids embedded in extracellular matrix and smooth muscle cells. A fibrous cap stabilizes the plaque and separates it from the vascular lumen (7). The continuous growth of the plaque coincides with a progressive stenosis of the vascular lumen and is often the basis of stress-induced ischemic syndromes such as angina pectoris or intermittent claudication (7).

The macrophages and T-Lymphocytes keep up a chronic inflammatory reaction in atherosclerotic vessels and hence weaken the fibrous cap. This produces an unstable plaque with a risk of rupture. If a plaque ruptures, the thrombogenic material inside the plaque gets in contact with blood. This can lead to thrombotic total occlusion at the site of the lesion or thromboembolic occlusion further downstream. Consequences of such sudden complete occlusions can be myocardial infarction, stroke, transient ischemic attack (TIA), sudden cardiac death, and acute limb ischemia (7).

Other effects of plaque development in arterial walls are luminal narrowing, stiffening of the vascular wall, formation of thrombus, hemorrhage inside the plaque and increased diffusion distance from the vessel lumen to the tunica media. These effects lead to ischemic injury and weakening of the vessel wall, which can further lead to aneurysm formation (6).

If the stenosis reduces the lumen of a blood vessel by more than 50% it can cause changes in the peripheral circulation (7). These changes in the peripheral circulation depend on various factors, which will be further described as compensation mechanisms. A very important compensation mechanism is the development of collateral vessels. Depending on the tissue, arteries feature a dense system of anastomoses. These anastomoses can grow into collateral circulation pathways if a stenosis causes too little blood flow to the distal segments. Depending on their quality, such collateral vessels can bridge the obstructed section and enable sufficient blood supply to the distal segments (7).

When supplying arteries to peripheral areas are narrowed or obstructed by atherosclerotic plaques, this is referred to as peripheral artery disease (PAD).

2. Peripheral Artery Disease

Peripheral artery disease is a stenosing and occluding disease which affects the distal aorta and arteries of the extremities. Atherosclerosis is the most common arterial vascular disease and the leading cause of PAD accounting for 90% of cases. Other possible causes are thrombosis, embolism, vasculitis, or trauma. Patients in their 60's or 70's are particularly at risk to suffer from atherosclerotic PAD with multiple sites of vessel damage distributed throughout the body. Due to uneven distribution of obstructive lesions PAD of the lower extremities accounts for 90% cases while only 10% affect the upper extremities (11). The most frequently affected arteries are the femoral and popliteal arteries with 80-90%, the tibial and peroneal arteries with 40-50%, and the abdominal aorta and iliac arteries with 30% (12). Even though PAD manifests in these anatomic sites, it is usually accompanied by systemic atherosclerosis. One in two PAD Patients also suffers from coronary artery disease (11).

The leading symptom is usually intermittent claudication, which the patients experience as pain, cramps, or numbness in the affected limb occurring during exercise, which improves upon resting. Symptom manifestation lies distal to the occlusive lesion (12). With progression of disease severity, some patients develop rest pain primarily when lying down, due to the elevated position of the limbs. Symptoms decrease when lowering the limbs, which slightly improves circulation. Persisting rest pain indicates severe ischemia (12).

Although more than 50% of patients with PAD are asymptomatic, they have an elevated cardiovascular risk, while not experiencing any complaints (11, 12).

2.1. Diagnosis

Ninety-five percent of PAD cases can be diagnosed by means of patient history and physical examination. Physical findings of PAD include decreased or absent pulses distal to the stenosis, muscle atrophy, hair loss, reduced skin temperature, pallor or cyanosis (12).

With the help of the ancle brachial index (ABI) PAD can be reliably detected or ruled out (11). The ABI is a noninvasive method to diagnose and monitor lower extremity artery disease. Furthermore, it is a marker for generalized atherosclerosis and cardiovascular risk. To determine the ABI the highest systolic blood pressure (SBP) in the ankle is divided by the highest SBP in the arms (13). Physiological ABI values lie between 1.00 and 1.40. Ranges between 0.91 and 0.99 are considered borderline, and values below 0.90 are abnormal and diagnose PAD. A value above 1.40 can be an indication for non-compressible arteries due to vascular calcification (12). Another diagnostic measure is duplex sonography, which is used to detect and image atherosclerotic lesions. Imaging such as magnetic resonance angiography (MRA), computer tomography angiography (CTA) and catheter-based angiography are not indicated for routine diagnostic testing but are performed before potential revascularizing procedures (11, 12). Stress testing on a tread mill assesses functional limitations and enables a classification of the severity of the PAD (12). This thesis relies on the classification of Fontaine, which divides PAD into the following stages:

Table 1: Fontaine Classification (14)

Grade	**Symptoms**
Stage I	Asymptomatic, incomplete blood vessel obstruction
Stage II	Mild claudication pain in limb
Stage IIA	Claudication at distance of >200m
Stage IIB	Claudication at distance of <200m
Stage III	Rest pain, mostly in feet
Stage IV	Necrosis and/ or gangrene of the limb

Stage III and IV indicate critical limb ischemia with potential loss of the extremity and therefore require rapid action (11).

2.2. Treatment

Treatment of PAD consists of secondary prevention, revascularization, and pharmacological therapy.

The purpose of secondary prevention is to slow down the progression of the disease. Its primary aim is to minimize the cardiovascular risk factors through nicotine abstinence, weight loss, and glycated hemoglobin (HbA1c) <7%. Especially quitting smoking can have the most noticeable effect on patients walking distance (13).

The most effective treatment for reducing cardiovascular risk is statins. Statins inhibit the HMG-CoA-Reductase and therefore the synthesis of cholesterol (15). They are indicated in all patients with PAD, even when the initial value of LDL-cholesterol (LDL-C) is in the normal range. The LDL-C in high-risk patients should be lowered to <55mg/dl or reduced by 50% of the baseline. If statins do not provide the desired effect, ezetimibe can be added. Ezetimibe inhibits the intestinal cholesterol absorption by blocking their transport protein in the small intestine. Ezetimibe can be combined with statins (15, 16). In hypertensive patients the blood pressure should be lowered to <140/90. To slow down the atherosclerotic progression a long-term therapy with acetylsalicylic acid (ASA) or clopidogrel is recommended. ASA and clopidogrel are antiplatelet drugs. For patients with stage II PAD structured exercise therapy can increase the painless walking distance and the quality of life. It serves for the formation and strengthening of the collateral circulation (11). Even though structured exercise therapy increases the walking distance, it does not improve the ABI score. Therefore, it is still unclear if structured exercise therapy effects cardiovascular events and mortality (13).

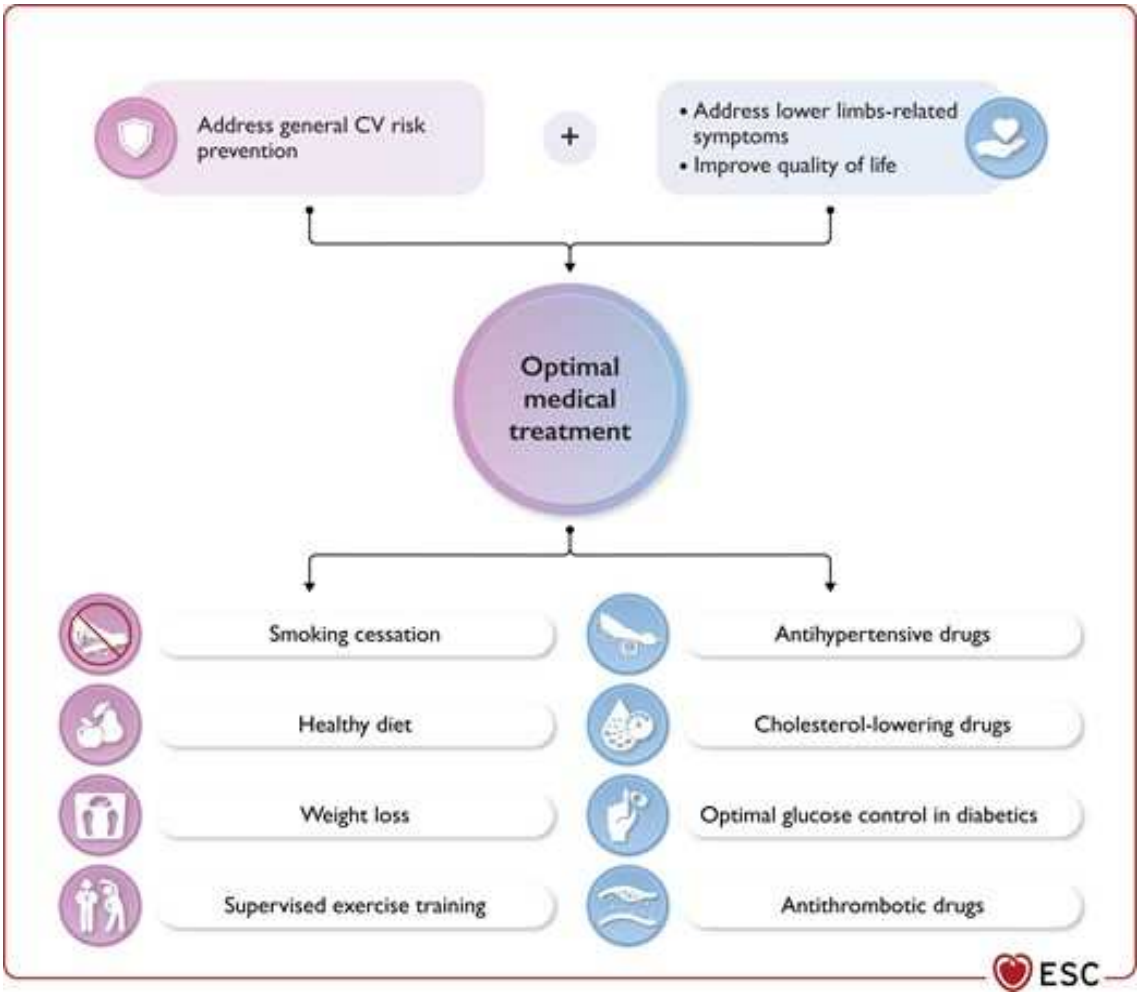


Figure 3: Conservative management of PAD (16)

Revascularizing therapy is indicated for stage III or IV to preserve the extremity. Depending on the patient, revascularizing therapy may already be considered in stage IIb or lower (11, 12).

In general, there are two different approaches to revascularize an obstructed vessel, an endovascular catheter procedure, or an open surgical procedure (11, 12). Catheter methods include percutaneous transluminal angioplasty (PTA) with or without stenting, regional thrombolysis where the catheter is placed directly into the thrombus and releases a thrombolytic drug, and catheter-based atherectomy. Surgical therapy includes endarterectomy and bypass surgery. During an endarterectomy the atherosclerotic plaque, thrombus and intima are removed from the vessel through an incision, which is then closed with a patch or direct suture. A

bypass bridges the occluded segment with either a vein from the patient or a plastic prothesis (11).

The different revascularizing therapies are discussed in more detail in separate chapters.

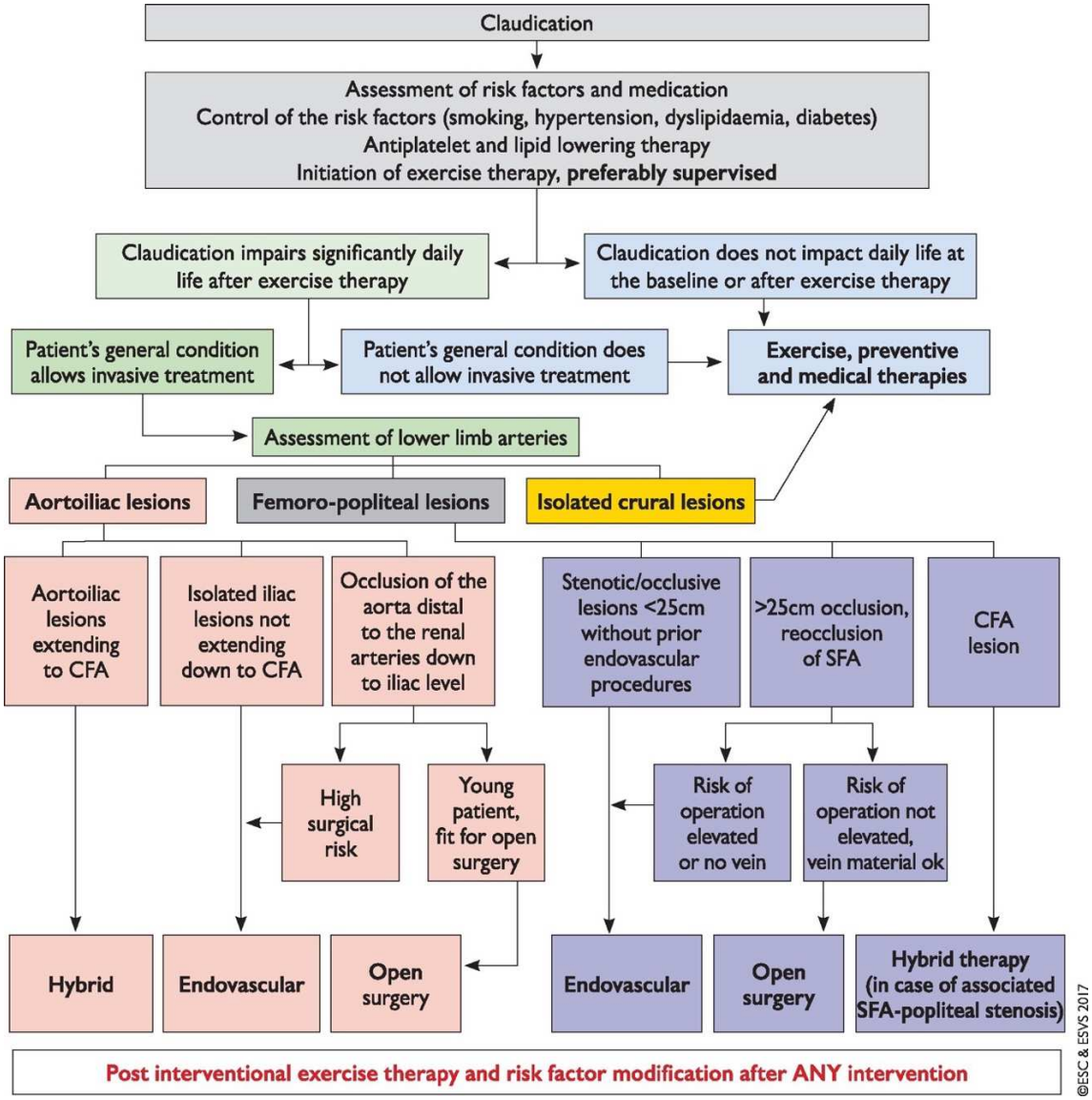


Figure 4: Revascularization (13)

2.2.1. Endovascular Therapy

Endovascular therapy (EVT) has become more and more popular in the last years, since it is associated with lower morbidity and mortality, making it a suitable alternative for older and multimorbid patients. The arterial access is normally established via Seldinger technique. The Seldinger technique is up until today the foundation of percutaneous access. The procedure begins with the insertion of a needle into the vessel, providing access for the introduction of a guidewire through its lumen. Once the guidewire is securely in place, the needle is carefully withdrawn, leaving the guidewire positioned intraluminal. Subsequently, a catheter is advanced over the guidewire into the vessel, ensuring precise placement. The final step involves removing the guidewire, leaving the catheter positioned within the vessel, ready for further intervention (17). The most used access is the retrograde transfemoral access. Meaning the needle is inserted into the CFA pointing in the direction of the iliac arteries. This access can also be used for a cross over procedure, which enables a simultaneous treatment of the pelvic arteries as well as the femoral and crural arteries (17). Another option is the antegrade access, in which the needle is inserted in the direction of the blood flow towards the crural arteries. Before balloon angioplasty or stenting is performed, an angiography of the targeted lesion is performed to obtain a precise overview of the pathology. After imaging the catheter is put through the obstruction (17).
During balloon angioplasty a balloon catheter is placed into the lesion and expanded. The extension causes a localized and controlled trauma to the arterial wall, provoking a tear in the intimal layer, an irreversible overextension of the media and an increase in the inner and outer diameter of the vessel (17). The balloon must be precisely adapted and should ideally exceed the vessel diameter by 10-15%. If the balloon is too big it can cause a rupture. For this procedure regular balloons or drug-coated balloons (DCB) can be used (17). DCBs contain drugs that inhibit intimal hyperplasia, such as Paclitaxel and Rapamycin. Both drugs interfere with the cell cycle of smooth muscle cells, inhibiting their proliferation (18).
After the desired result is achieved the catheter is retrieved and no foreign material remains in the vessel, in contrast to stenting.

For stenting procedure there are a variety of different stents. They vary in their characteristics, length, and diameter. As a general rule the stent should exceed the vessel diameter by one millimeter (17). For the iliac and femoropopliteal arteries the following four types of stents are used.
Balloon expandable stents can be deployed very precisely, they come with high radial force and only minimal shortening after deployment. They have poor flexibility and if subjected to external force are permanently deformed which makes them unsuitable for periarticular and superficial vessel sections (17).
Self-expandable stents are very flexible but shorten up to 15% after deployment. Their radial force is lower than that of balloon expandable stents. Since self-expandable stents are resistant against external force they are indicated in superficial vessel sections (17).
Stent grafts are usually not the first choice for treatment of PAD but for complications during EVT and aneurysms (17).
Stents can either be bare metal stents (BMS) or coated with an antiproliferative agent, called drug-eluting stents. Drug-eluting stents (DES) are rather novel and release antibiotics or cytotoxic drugs. A recent prospective, randomized, multicenter study shows superior one-year primary patency for DES treatment over BMS (19).

An **advantage** of EVT is, that it can be performed under local anesthesia. Contrary to open surgery, the mortality and morbidity is lower. Recovery is faster than in open surgery and the patients can usually return to their daily life a few days after the procedure (20). Depending on the Intervention site and severity, EVT can also be performed at an outpatient clinic. A follow up period of eight hours is recommended after which the patient can be discharged (17, 20).

But there are also **disadvantages** to consider. Stenting in high movement areas like the inguinal region has been controversial and the CFA considered a ‘stent-forbidden zone’ since the mechanical stress was believed to compromise the stent and access site for future interventions (21). A meta-analysis of 28 studies questions the inhibition to perform stenting in the CFA. The result shows that endarterectomy of the CFA has comparable one-year primary patency to

endovascular therapy. However, endarterectomy remains the gold standard for CFA stenosis due to its higher long term primary patency rate but shows a significantly higher local complication rate of 22% compared to stenting with 5-7% (16, 22). Suggesting that, endovascular treatment may have become a viable alternative, especially in patients with higher surgical risk (21).

EVT related **complications** can be differentiated by the area in which they occur. Access site complications include arterial bleeding, hematoma, aneurysm, arterial occlusion, infection, and venous thrombosis. Dissection, Perforation, arteriovenous fistula, and stent misplacement are possible intervention site complications. Additionally, a stent can potentially cover and obstruct collateral vessels that are crucial for limb preservation (23). Systemic complications include myocardial infarction, stroke, and infection.
Arterial bleeding is a common peri- and postinterventional complication. Due to their underlying disease, PAD-patients are often on dual anti platelet therapy, which increases the risk of bleeding. Arterial bleeding may result from insufficient closure of the puncture site or perforation caused by the guide wire. However, modern vascular closure devices have significantly reduced post-interventional bleeding, and advanced imaging techniques have minimized the risk of perforation (17).

2.2.2. Open Surgery

Open surgical endarterectomy remains the gold standard to treat an obliterated common femoral artery due to the superficial and easily accessible location of the CFA as well as the favorable primary patency.
Surgical endarterectomy describes the direct removal of an obstructive plaque. It is performed under general or local anesthesia. To perform an endarterectomy a longitudinal groin incision is made. The CFA is carefully dissected while preserving the surrounding tissues (24). Typically, the arteriotomy is performed longitudinally and under systemic heparinization and exceeds the obstructive lesion by one to two centimeters (17, 24). After establishing an adequate access, a suitable dissection layer is sought out with a dissector and the plaque, including the tunica

intima, is removed. After removing the pathologic material, the remaining intima distal of the lesion poses a risk for further dissection caused by the blood flow. To avoid dissection, a tacking suture is applied. After cleaning out the vessel of all debris the arteriotomy can be closed with a patch angioplasty or direct suture. A patch angioplasty is performed to prevent narrowing of the vascular lumen due to a longitudinal suture. The most frequently used patches are autologous vein patches (i.e. GSV), allogenic patches made from polyethylenterephthalat (PET) or expanded polytetrafluoroethylene (ePTFE) and xenogeneic patches from bovine pericardium. The different patch materials are further discussed in a separate chapter (17).

The **advantage** of endarterectomy is its very high short- and long-term patency of nearly 100% (23). It is a benign and straightforward procedure. The superficial location of the CFA allows easy access, and the procedure can be performed under general anesthesia as well as local anesthesia (24, 25).

Even though the procedure has a very high success rate, it also poses several **disadvantages** like significant morbidity rate of up to 20% due to wound complications, hematoma, and hemorrhage. The 30-day postoperative mortality rate lies between 1-2% (23).

The superficial location of the CFA makes it easily accessible for surgeons. However recent studies have shown that surgery might have a higher risk of **complications** than previously thought. In a retrospective cohort study including 1843 patients undergoing CFA endarterectomies Nguyen et al. (25) state a mortality rate of 3,4% with the combined postoperative mortality and morbidity rate reaching 15%. Predictors for mortality are age, non-independent functional status, preoperative dialysis, preoperative sepsis, emergency surgery, and ASA classification >3 (25). To date there are only a handful of retrospective studies completed regarding this procedure. Most published research consist of only 100 or less patients from single centers (25).

Systemic complications usually affect the cardiovascular, respiratory, and renal system (17). They include myocardial infarction, cardiac arrest, deep vein thrombosis, pulmonary embolism, pneumonia, prolonged intubation, genitourinary tract infection, acute kidney injury, dialysis, sepsis, and septic shock (25).

Hemorrhage is a common early postoperative complication after vascular surgery. A distinction is made between bleeding from the sutures, which occur because of insufficient clotting activity, and bleeding from the anastomosis due to inadequate suture technique. Furthermore, bleeding can originate from the surgical site. Beside the iatrogenic causes, coagulopathies, such as hemophilia, thrombopenia or platelet disfunction must be ruled out. Postoperative hemorrhages of the femoropopliteal vessels are often easy to assess due to their superficial location. They present themselves through swelling, skin discoloration, and or high drainage flow rate (17). Hematomas occur in about 9% of patients (25).

Arterial occlusions after vascular surgery are divided into immediate and early occlusion. Immediate occlusions occur within the first 24 hours post-surgery and are caused by technical errors, wrong indication, embolism, or dissection due to tampering with distal, often atherosclerotic, vessel sections.
Early occlusions appear within one-year post-surgery and usually have the same underlying mechanisms as immediate occlusions. However, due to intensified antiplatelet therapy the occlusion occurs later (17).

A study from Yamamoto et al. showed no aneurysms or rupture after endarterectomy and venous patch plasty at a median follow-up of 22 months (26).

Vascular surgery with groin incision can result in lymphatic complications, such as lymphatic fistulas and lymphorrhea. Lymphatic complications pose an increased risk for wound infections and have a reported incidence of 2-15% after vascular surgery (27). So far there is no standardized definition of lymphatic fistulas. Uhl et al. defines a lymphatic fistula in his study as secretion of at least 50ml per day for more than seven days after surgery and lymphorrhea as one or more compresses drenched by lymphatic liquid within 24 hours (28). Lymphoceles are lymphatic

secretions from the wound after the drainage is removed. Therefore, a measurement of the secretion is not possible. Nevertheless, they count among lymphatic complications and should be recorded (28). Eighty years of age or older is considered a risk factor for lymphatic complications (28). Conservative treatment consists of limited bedrest and compression. If the wound is infected, surgical therapy is indicated. Surgical therapy includes vacuum assisted closure therapy (VAC), muscle flap coverage and patch replacement (28).

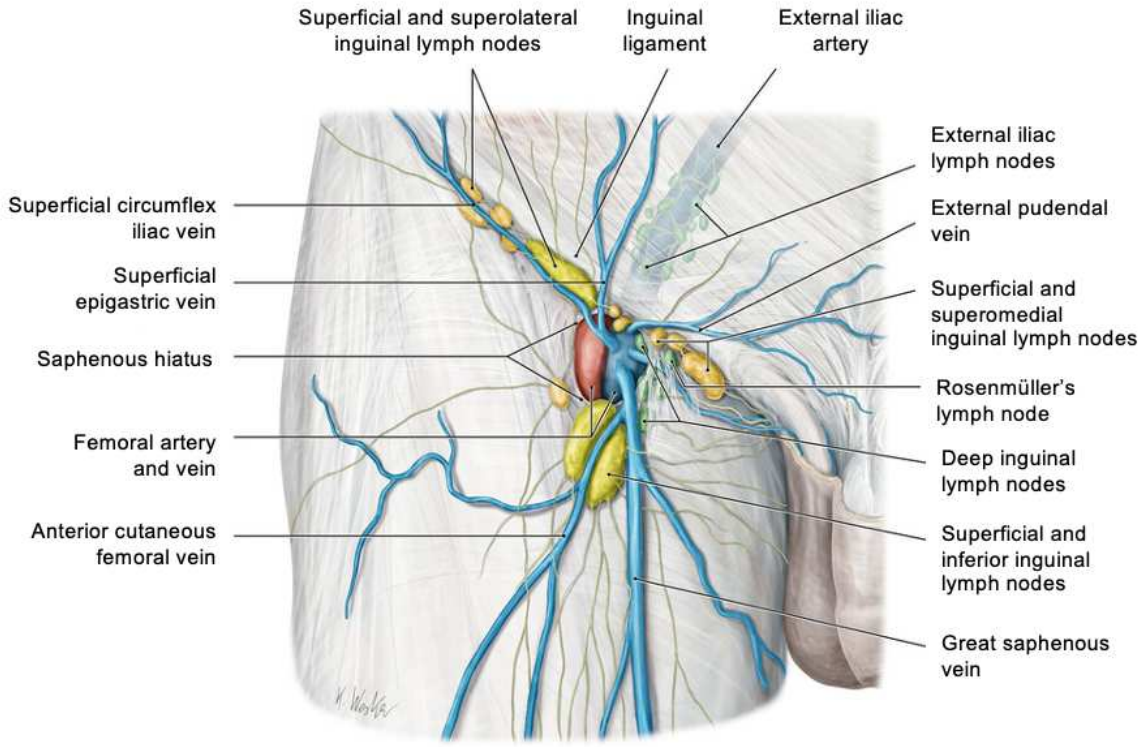


Figure 5: Inguinal lymph nodes

Wound infection is categorized according to the Szilagyi classification. Grade I describes a superficial infection. Grade II includes the subcutis. Grade III wound infection represents a deep subfascial infection, involving the transplant. The grade of infection determines the therapy. While Grade I and II infections (epifascial) may be treated conservatively, Grade III infections (subfascial) require surgical revision, such as debridement, muscle flap coverage, or patch replacement (17, 25). Potential complications of Grade III wound infections can be

acute arterial hemorrhage, local abscess formation, thrombosis, and sepsis (17). Independent risk factors for wound infection are previous groin incision and postoperative drainage (25). With 17% infections, 9% hematomas, and 5% seromas CFA endarterectomy poses a significant risk for wound complications. Since most complications occur after hospital discharge a strict follow-up is recommended (25).

Wound dehiscence, a partial or complete separation of previously approximated wound edges due to insufficient healing, is another postoperative local complication. It typically occurs five to eight days after surgery and is associated with ischemia, infection, diabetes, malnutrition, smoking, obesity and increased pressure in the wound (29).

3. Patch material

An ideal patch material should demonstrate durability and long-term stability, ease of handling, immediate availability, anticoagulant properties with a low risk of restenosis, resistance to infection, and compliance similar to native artery (30).

3.1. Autologous

A popular option for patch plasty is an autologous vein patch usually harvested from the distal GSV or small saphenous vein. Autologous material is known for its excellent healing tendencies, absence of foreign body reaction, patency rate, and its low susceptibility to infections (17, 31). As a result of the endothelial lining, vein patches are resistant to thrombosis and restenosis (30). However, autologous resources are limited and using the great saphenous vein as a patch can affect future revascularization procedures (17). Furthermore, vein harvesting may prolong surgery duration, and the additional incision increases the risk of wound complications, especially in patients with impaired wound healing, which is the case in PAD patients. It was also found that the compliance of the vein is reduced compared to the native artery (31).

In patients with an occluded SFA, said artery provides a good alternative for vein patches. It can be harvested without additional incision, has the same advantages than a venous patch, and preserves the veins for future revascularization procedures. Surgery time might still be affected as an endarterectomy must first be performed on the occluded SFA (32).

3.2. Allogenic

For the sake of completeness this material is mentioned, even though it was not applied in the conducted study. Commonly used allogenic materials are ePTFE and PET. ePTFE has anticoagulant properties and supports reendothelialization. Due to its high tensile strength PET patches are resistant to stretching. Allogenic patches are off-the-shelf and therefore do not extend surgery duration (30). Nevertheless, their increased susceptibility to infections makes them particularly unsuitable in the groin region, where the surgical procedures involve numerous lymphatic vessels and the infection risk is inherently higher compared to other areas like the carotid artery (17). Allogenic materials also trigger a foreign body response which can cause further complications such as chronic inflammation, limited compliance, and poor resistance to infection (31).

3.3. Xenogeneic

Xenogeneic, further also described as biologic, patch materials combine the advantages of autologous and allogenic patches. They are immediately available, meaning surgery time is not prolonged, and patients are spared an additional incision and its associated complications. Biological patches show reduced risk for infection, good compliance, biocompatibility, and excellent patency rate. They can be remodeled into native vascular tissues (31). The biologic patch used in this study is treated with glutaraldehyde to chemically crosslink collagen fibers and decrease antigenicity. The crosslinking of collagen fibers increases mechanical stability and inhibits degradation of the patch (31, 33). The patch has two different surfaces, a serous and fibrous side. Cilia are found on the fibrous side, whereas the serous side is hairless and glistening and demonstrates less thrombogenicity. Therefore, the serous side is placed towards the blood flow (33). It is possible that

the chemical crosslinking may compromise the natural remodeling process, and lead to calcification and structural impairment (31).

4. Methods

4.1. Study design

This study is a retrospective analysis of patient data as well as prospective sonographic follow up on selected patients. Two issues are addressed. The influence of patch material on five-year outcome, defined as level of restenosis, and postoperative wound complications depending on patch material.

4.2. Ethics

Before extracting the data from the local vascular database and regional hospital information management system an application was submitted to the Ethics Committee of the Medical University of Graz. Approval was granted on September 23, 2022, with the number 34-465 ex 21/22 1265-2022.

4.3. Inclusion and exclusion criteria

All patients who underwent isolated endarterectomy with patch plasty of the CFA in 2016 and 2017 are included in this study.
Absolute exclusion criteria are emergency procedure, non-isolated endarterectomy, and direct suture. Patients who fulfill those exclusion criteria are neither considered for the five-year result nor for wound complications. For the 5-year result stricter exclusion criteria where defined: deceased, additional surgery, additional endovascular intervention, previously operated CFA, radiation therapy of the pelvic region, ongoing chemotherapy, lack of consent, incapable of consenting.

4.4. Data collection

The necessary characteristics are determined in an excel sheet. The required data is then extracted from the regional hospital information management system as well as the local vascular data base of the Department of Surgery, Division of Vascular Surgery, Medical University of Graz. To obtain the data each patient is

researched in those data bases. The required information is manually extracted from the medical records of each patient and recorded in the excel sheet. To simplify the statistical analysis the results are only recorded with numerical values. Where no numerical data is collected, numerical codes are used.
Since some patients had endarterectomies performed on both sides, within the defined time span, we refer to operated arteries instead of patients.

4.5. Data characteristics

To identify potential associations, data on patient demographics, cardiovascular risk factors, medical history (current and past), prior and additional endovascular or surgical procedures, laboratory parameters, details of the performed endarterectomy, as well as mortality and amputation outcomes, were collected and analyzed.

4.5.1. Demographic and baseline characteristics

The demographic characteristics are crucial for understanding the general profile of the study population. These variables provide context for assessing potential influences on outcomes.

- Gender
- Age
- Height
- Weight
- Body mass index (BMI)
- Smoking status
    - Active smoker
    - Former smoker
    - Non-smoker

Table 2: BMI Classification (34)

Category	BMI (kg/m^2)
Underweight	<18.5
Normal weight	≥18.5-24.9
Overweight	≥25.0-29.9
Obesity	≥30

4.5.2. Clinical history and pre-existing conditions

The following relevant medical histories and pre-existing conditions are obtained to evaluate risk profiles and potential impacts on the study results.

- Prior surgery
- Prior endovascular intervention
- Percutaneous transluminal coronary angioplasty (PTCA)
- Coronary artery bypass craft (CABG)
- Myocardial infarction
- Status post radiation therapy of the pelvis
- Ongoing chemotherapy
- Immunosuppression
- Diabetes mellitus (DM)
    - Insulin dependent diabetes mellitus (IDDM)
    - Non-insulin dependent diabetes mellitus (NIDDM)

4.5.3. Current clinical and functional status

Following characteristics are evaluated prior to surgery to provide a basis for assessing patient health status and disease progression.

- Blood pressure
    - No hypertension
    - Hypertension without treatment
    - Normotension with treatment
    - Hypertension despite treatment
- eGFR
- LDL Levels
- Creatinine
- ASA Classification (American Society of Anesthesiologists)
- Cardiac rhythm
- Limitation in walking distance
- Fontaine stage

4.5.4. Perioperative and intraoperative details

To identify potential associations between different variables and applied patch material these characteristics are collected.

- Operating surgeon
- Operation duration
- Days with drainage
- VAC
- Secondary closure
- Split-thickness skin graft

4.5.5. Complications and postoperative outcomes

Postoperative complications and outcomes are evaluated to determine whether an association between them and the applied patch exists.

- Wound healing disorder
    - Wound dehiscence
    - Wound edge necrosis
- Lymphatic fistula
- Wound infection
- Bleeding revision
- Restenosis
- Amputation

4.5.6. Medication and treatment protocol

- Antiplatelet agents
    - ASA (acetylsalicylic acid)
    - Clopidogrel
    - Other antiplatelet agents
- Lipid-lowering drugs
    - Rosuvastatin
    - Atorvastatin
    - Simvastatin
    - Fluvastatin
    - Pravastatin
    - Ezetimibe
- Low molecular weight heparin (LMWH)
- Coumarin derivative
- New oral anticoagulants (NOAC)

4.5.7. Mortality

- Days of hospital stay
- Deceased
- Date of death
- Cause of death

4.6. Data analysis

The collected data is analyzed with the statistics program IBM SPSS® Statistics Version 29.0.0.0 (241). A p-value of <0.05 is determined statistically significant and the confidence interval (CI) is selected at 95%.

4.6.1. Wound complication

In this study wound complication is defined with the following features: drainage >7 days, VAC, secondary closure, wound healing disorder (wound dehiscence, wound edge necrosis), wound infection, lymphatic fistula, bleeding revision.
Since there are too few cases in the individual categories a combined endpoint is defined. This endpoint is reached when one of the above-mentioned features has occurred.

The focus here is to show whether an association between wound complication and the different patch materials exists.
A cross tab is used to analyze the relationship between the three different patches (SFA, vein, bovine pericardium) and the wound complications. To determine if a statistically significant relationship exists a Pearson Chi-Square-Test is performed. To discover other significant relations, other characteristics, and their impact on wound complications are statistically analyzed.
Categorical variables are explored with Chi-Square-Tests. When comparing 2x2 tables like gender, operated side, smoker, or non-smoker, prior endovascular or surgical intervention and surgery duration (>120 or <120 minutes) a Fisher´s Exact Test is applied.

To determine the significant association for larger contingency tables like blood pressure (no hypertension, hypertension without treatment, hypertension with treatment), diabetes mellitus (no diabetes, IDDM, NIDDM), smoking status (never smoked, former smoker, current smoker), patch material (SFA, vein, bovine pericardium) a Pearson Chi-Square Test is implemented.

The significance of continuous values like age, weight, height, BMI, eGFR, and surgery duration are analyzed with logistic regression variables.
The occurrence of wound complications is obtained via frequencies variables.

4.6.2. Hospitalization

The median duration of hospitalization is calculated for each patch material to assess whether it influences the length of stay. To minimize confounding, patients who underwent additional procedures or treatments not related to the CFA endarterectomy are excluded from the analysis. A Kruskal-Wallis Test is then performed to identify any significant differences in their median values and either accept or reject the null hypothesis, which states that "The distribution of length of stay is identical across the categories of patch material." The results are illustrated using a boxplot diagram.

4.6.3. Mortality

The one-year mortality post-surgery is investigated with the help of frequencies variables and listed in a table.
Average survival is estimated using Kaplan-Meier-Method, which is displayed.

4.6.4. Five-year result

Using descriptive statistics, the mean diameter of the CFA is calculated. To compare the means of the CFAs with the three different patches an ANOVA test is performed.

4.7. Sonographic follow up

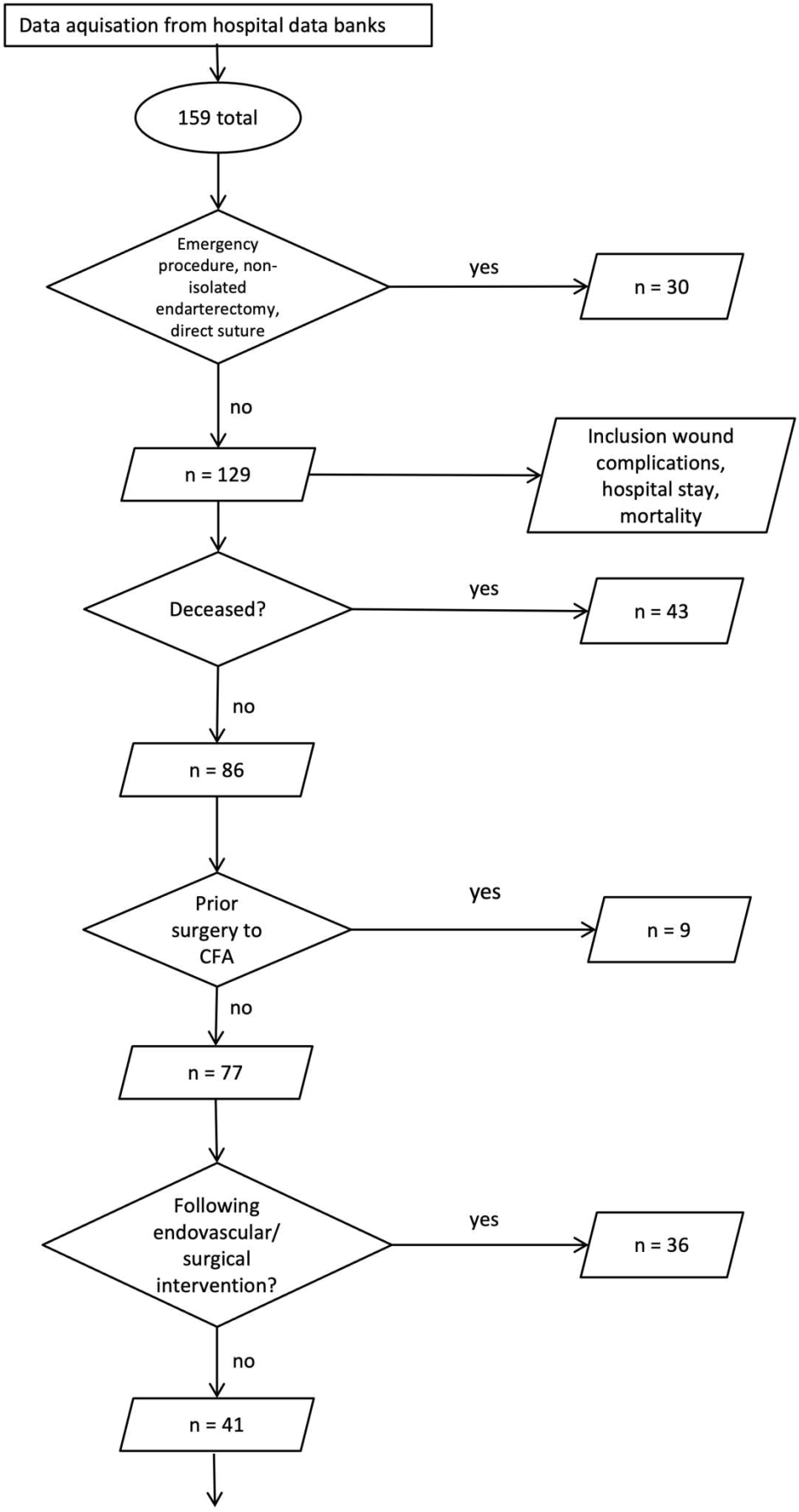
Patients who fulfill the inclusion criteria are invited for a sonographic follow up investigation. Suitable patients are contacted via telephone. When accepting the invitation, a letter is sent with the date, time, and place of the appointment. During the appointment the patients are educated about the study and requested to sign an informed consent document to allow the use of the examination findings for research. An ultrasound examination is then performed on the operated CFA to determine the diameter, level of restenosis, and the maximum velocity (v_{max}) measured in centimeters per second. The results are documented in the excel sheet.

5. Results

5.1. Selection process

The flowchart in table 6 demonstrates the patient selection process applying the previously discussed inclusion and exclusion criteria.

Of initially 159 cases 30 were excluded due to emergency procedure, non-isolated endarterectomy, and direct suture. Those 30 cases were neither considered for the wound complication nor for the 5-year result. For the sonographic follow-up investigation another 109 cases were excluded, so that 20 patients were invited and examined.


Data aquisation from hospital data banks
159 total
Emergency procedure, non-isolated endarterectomy, direct suture
yes
n = 30
no
n = 129
Inclusion wound complications, hospital stay, mortality
Deceased?
yes
n = 43
no
n = 86
Prior surgery to CFA
yes
n = 9
no
n = 77
Following endovascular/ surgical intervention?
yes
n = 36
no
n = 41

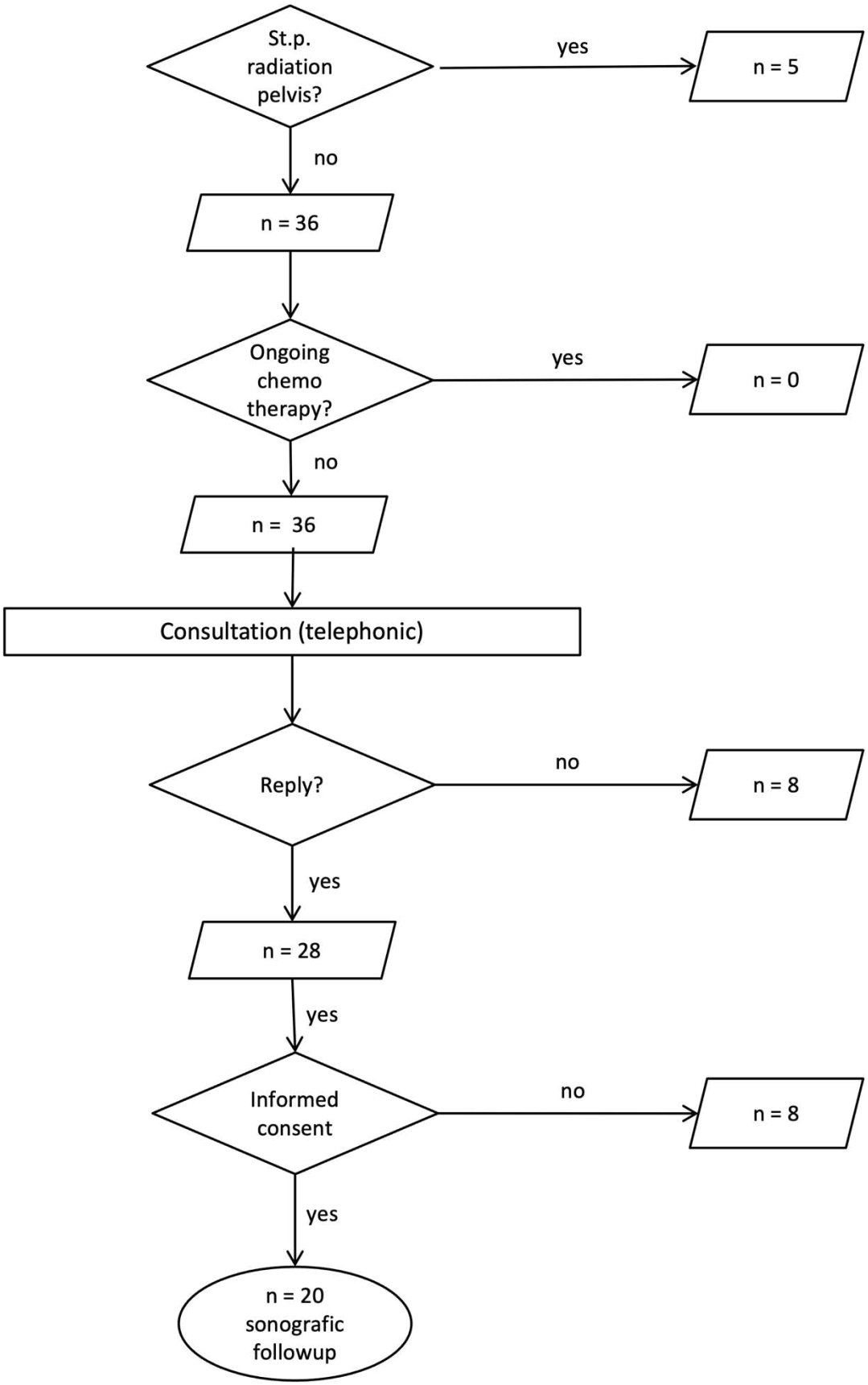


Figure 6: Flow chart selection process

5.2. Patient characteristics

A total of 159 groins that received endarterectomy in 2016 and 2017 were identified in the local vascular data base. Of these, 30 cases (18.9%) were excluded from the study due to being emergency procedures, non-isolated endarterectomies, or closures performed with direct sutures. Therefore 129 groins fulfilled the inclusion requirements and could be considered for the data analysis.

Table 3: Exclusion criteria

Exclusion criteria	Occurrence	Percentage
Emergency procedure	6	20.0
Non-isolated endarterectomy	19	63.3
Direct suture	5	16.7
Total	**30**	**100.0**

From 129 included groins 32 (24.8%) were female. The average age of the study population was 68 $\pm$ 10.2 years. The mean weight of the patients was 76.9 kg, the mean height 170.7 centimeters (cm) and the median BMI 26kg/m2. This indicates that the average in this study population was overweight according to the BMI-based classification shown in Table 2.

The blood pressure of every patient was measured repeatedly during their stay. Table 4 shows that 45% suffered from hypertension despite taking antihypertensive medication. 11% were normotensive without treatment.
114 Patients were eighter actively smoking or former smokers. The average had 37.7 pack years. Only 15 patients (11.6%) had never smoked. Table 5 shows the gender distribution of smokers. Of the female patients 28.1% were non-smokers whereas 6.2% of the male patients were non-smokers. A p-value of 0,003 indicates a significant association between smoking and gender.

Table 4: Clinical history and pre-existing conditions

	Total (n=129)
Blood pressure	
No hypertension	14 (10.9)
Hypertension without treatment	8 (6.2)
Normotensive with treatment	49 (38)
Hypertensive with treatment	58 (45)
Diabetes mellitus	
No diabetes mellitus	91(70.5)
Non-insulin dependent diabetes mellitus	23 (17.8)
Insulin dependent diabetes mellitus	15 (11.6)
Smoking	
Non-smoker	15 (11.6)
Smoker	32 (24.8)
Former smoker	82 (63.6)
Pack years (smoker & former smoker)	37.7
Prior surgery ipsilateral	19 (14.7)
Prior puncture ipsilateral	55 (42.6)
PTA ipsilateral	56 (43.3)
Myocardial infarction	31 (24)
PTCA	37 (28.7)
Coronary stenting	22 (17.1)
CABG	13 (10.1)
St. p. radiation therapy of the pelvis	9 (7)
Ongoing chemotherapy	2 (1.6)
Immunosuppression	3 (3.2)

Data are presented as absolute number (%) for categorical variables.

Table 5: Smoking and Gender

Gender	Non-smoker	Smoker	Former smoker	Total
Female	9 (28.1)	7 (21.9)	16 (50)	32 (100)
Male	6 (6.2)	25 (25.8)	66 (68)	97 (100)
Total	**15 (11.6)**	**32 (24.8)**	**82 (63.6)**	**129 (100)**

Data are presented as absolute number (%) for categorical variables.

To determine the health status of all included patients the characteristics shown in Table 6 were evaluated. As stated prior usually endarterectomy is only indicated in stage III PAD or higher, in stage IIb when quality of life is significantly impaired. One patient underwent endarterectomy with stage I PAD because he suffered an intimal injury while receiving transcatheter aortic-valve implantation (TAVI).

Table 6: Current clinical and functional status

Characteristics	Total n = 129
eGFR	71.1 ± 25.0
LDL levels	89.8 ± 43.1
Creatinine	1.2 ± 0.9
ASA classification	
ASA 2	10 (7.8)
ASA 3	72 (55.8)
ASA 4	47 (36.4)
Cardiac rhythm	
Sinus rhythm	109 (85.8)
Atrial fibrillation	10 (7.9)
Intermittent atrial fibrillation	1 (0.8)
Pacemaker rhythm	4 (3.1)
Other rhythm	3 (2.4)
Fontaine Stage at time of surgery	
Stage I	1 (0.8)
Stage IIa	7 (5.4)
Stage IIb	60 (46.5)
Stage III	30 (23.3)
Stage IV	31 (24)

Data are presented as mean ± standard deviation for continuous variables or number (%) for categorical variables.

To review a possible influence of patch material on surgery duration an ANOVA-Test was performed. The mean surgery duration using a venous patch was 120.4 minutes, with a SFA patch 116.8, and with a bovine pericardium patch 113.7. Thus, the average operation duration was shortest with a patch made of bovine pericardium. Though, with a p-value of 0.73 the association is not significant.

Table 7: Perioperative and intraoperative details

Characteristics	Total n = 129
Patch material	
Vein	59 (45.7)
Occluded SFA	25 (19.2)
Bovine pericardium	45 (34.9)
Surgery duration in minutes	117.4 ± 43.2
Vein	120.4 ± 44
SFA	116.8 ± 37.9
Bovine pericardium	113.7 ± 45.5
Operated side	
Right	66 (51.2)
Left	63 (48.4)

Data are presented as mean ± standard deviation for continuous variables or number (%) for categorical variables.

Another aim was to assess whether the stage of disease influences the choice of patch material. Because there were too few cases in the individual Fontaine stages, Fontaine stages I-IIb were merged into one group. With a p-value of 0.011 venous patches were significantly lesser used in patients with stage IV PAD.

Table 8: Fontain stages and patch materials

	Patch material		
Fontaine stage	**Bovine pericardium or SFA**	**Vein**	**Total**
I, IIa, IIb	31 (45.6)	37 (54.4)	68 (100)
III	15 (50)	15 (50)	30 (100)
IV	24 (77.4)	7 (22.6)	31 (100)
Total	**70 (54.3)**	**59 (45.7)**	**129 (100)**

Data are presented as absolute number (%) for categorical variables.

With a Chi-Square-Test a potential association between patch material and duration of drainage was investigated. The p-value of 0.63 proves that the relation is not significant.

No patient needed a split-thickness skin graft.

Table 9: Complications and postoperative outcomes

Characteristics	Total n = 129
Days of drainage	
1 day	50 (39.7)
2 days	47 (37.3)
3-7 days	22 (17.5)
> 7 days	7 (5.6)
VAC	2 (1.6)
Secondary closure	6 (4.7)
Split-thickness skin graft	0
Wound healing disorder	
Wound dehiscence	2 (1.6)
Wound edge necrosis	11 (8.5)
Both	1 (0.8)
Lymphatic fistula	7 (5.4)
Wound infection	6 (4.7)
Bleeding revision	2 (1.6)
Repeated hospitalization within 30 days	5 (3.9)
30-day mortality	
Amputation ipsilateral	4 (3.1)

Data are presented as absolute number (%) for categorical variables.

Prior to discharge each patient received an individual therapy recommendation. To lower the LDL-C to the recommended level of ≤55mg/dl or reduce it by 50% from baseline, statins were prescribed (16). In some patients the targeted LDL-C level was not met with the use of statins alone, therefore ezetimibe was additionally prescribed. For antithrombotic therapy most patients received ASA or clopidogrel. Five patients received coumarin derivatives due to their comorbidities and clinical history (atrial fibrillation, myocardial infarction, PTCA, coronary stenting, CABG). Five patients received NOAC (atrial fibrillation, myocardial infarction, PTCA, CABG), one was under dual antiplatelet therapy (DAPT) with a NOAC and ASA.

Ten patients were discharged with LMWH alone or combined with either ASA, clopidogrel, coumarin derivative or NOAC.
Even though pharmacological treatment is recommended in all PAD patients, two patients were discharged without antithrombotic therapy and 30 patients without lipid lowering therapy.

Table 10: Treatment protocol

Drugs	**Total n = 128**
Antiplatelet agents	
ASA	92 (71.9)
Clopidogrel	44 (34.4)
Coumarin derivative	5 (3.9)
NOAC	5 (3.9)
LMWH	10 (7.8)
Statin	93 (72.7)
Ezetimibe	5 (3.9)
Ezetimibe + Simvastatin	3 (2.3)

Data are presented as absolute number (%) for categorical variables.

The total (n) in table 10 is 128 due to loss of data in one case.

Twenty-two (17.1%) arteries were subject to subsequent surgery performed on the ipsilateral CFA after discharge. Of which 16 (12.4%) were bypasses (iliofemoral, crossover, femoropopliteal, femorocrural), two (1.6%) were isolated CFA endarterectomies, another two were embolectomies, and two subsequent surgeries were performed due to wound complications (hematoma, abscess).

Forty (31.1%) arteries were punctured for various catheter supported vascular procedures, including PTCA and PTA, during the five-year follow-up interval after discharge.

Two (1.6%) above knee amputations and two below knee amputations were necessary after discharge.

5.3. Wound complications

One goal was to determine whether the operating surgeon had an influence on the wound complications. Due to the relatively high number of surgeons and the resulting low personal case numbers (<5), it was not possible to perform statistically meaningful tests. Therefore, no conclusions can be drawn about the influence of the surgeon on the postoperative course.
As mentioned in chapter 2.6.1 the case numbers in the individual categories were too low for a statistical analysis, hence a combined endpoint was defined. Thirty cases (23.3%) reached that combined endpoint, meaning one or more of the mentioned criteria was fulfilled.

Table 11: Wound complications

Complication	Total n = 129
Wound healing disorder	14
Wound dehiscence	2
Wound edge necrosis	11
Both	1
Drainage >7 days	7
VAC	2
Secondary closure	6
Bleeding revision	2
Wound infection	6
Lymphatic fistula	7

The primary objective was to evaluate whether an association exists between the type of patch material used and the occurrence of wound complications. Among the patient groups, those receiving a bovine pericardium patch had a complication rate of 15.6%, compared to 28.8% for those with a venous patch and 24% for those with a SFA patch. However, the observed differences were not statistically significant, indicated by a p-value of 0.283.

Even though the results show that the influence of patch material on operation time was statistically not significant, the operation time had a significant impact (p = 0.001) on wound complications. In surgeries lasting 120 minutes or less, 13.1% complications occurred whereas in surgeries lasting more than 120 minutes the complication rate was 42.2% and therefore more than three times higher.

Table 12: Surgery time and wound complications

Surgery duration	No complication	Complication	Total (n=129)
≤ 120 minutes	73 (86.9)	11 (13.1)	84 (65.1)
> 120 minutes	26 (57.8)	19 (42.2)	45 (34.9)
Total	**99**	**30**	**129 (100)**

Data are presented as absolute number (%) for categorical variables.

With 130.7 minutes, surgeries performed in patients with PAD stage IV lasted the longest, surgeries in stage III patients lasted 115.1 minutes and surgeries in patients with PAD stage I to IIb were the shortest with 112.3 minutes. The stages I, IIa and IIb were summarized due to too few numbers of cases in each category. The differences concerning operation time were statistically not significant (p = 0.14).

An analysis was conducted to assess the impact of various characteristics on wound complications.
A significant association (p = 0.032) between wound complications and gender was discovered with a complication rate of only 9.4% in female arteries compared to 27.8% in male groins. Further, a significant difference (p = 0.022) between the operated sides was found. Operations on the left CFA showed a 14.3% complication rate whereas 31.8% of right sided operations presented with wound complications. The exact distribution is shown in tables 12 and 13.
All other factors were not significant (see table 14).

Table 13: Gender and wound complication

Gender	No wound complication	Wound complication	Total
Female	29 (90.6)	3 (9.4)	32 (100)
Male	70 (72.2)	27 (27.8)	97 (100)
Total	**99 (76.7)**	**30 (23.3)**	**129 (100)**

Data are presented as absolute number (%) for categorical variables.

Table 14: Surgery side and wound complication

Surgery side	No wound complication	Wound complication	Total
right	45 (68.2)	21 (31.8)	66 (100)
left	54 (85.7)	9 (14.3)	63 (100)
Total	**99 (76.7)**	**30 (23.3)**	**129 (100)**

Data are presented as absolute number (%) for categorical variables.

Table 15: Characteristics and wound complication

Factor	Statistical test	p-value
Age	Logistic regression variables	0.60
Weight	Logistic regression variables	>0.99
Height	Logistic regression variables	0.27
BMI	Logistic regression variables	0.59
Blood pressure	Pearson Chi-Square Test	0.92
Diabetes mellitus	Pearson Chi-Square Test	0.75
Smoking status	Pearson Chi-Square Test	0.27
Prior surgery	Fisher´s Exact Test	0.24
Prior puncture	Fisher´s Exact Test	>0.99
eGFR	Logistic regression variables	0.68

5.4. Hospitalization duration

The duration of hospital stay was investigated for every operated groin. Nineteen (14.7%) cases were excluded from this analysis due to additional treatment not related to the CFA endarterectomy. Thus 110 (85.3%) cases were included. Overall, the average hospital stay after CFA endarterectomy was 7.7 ± 5.1 days.

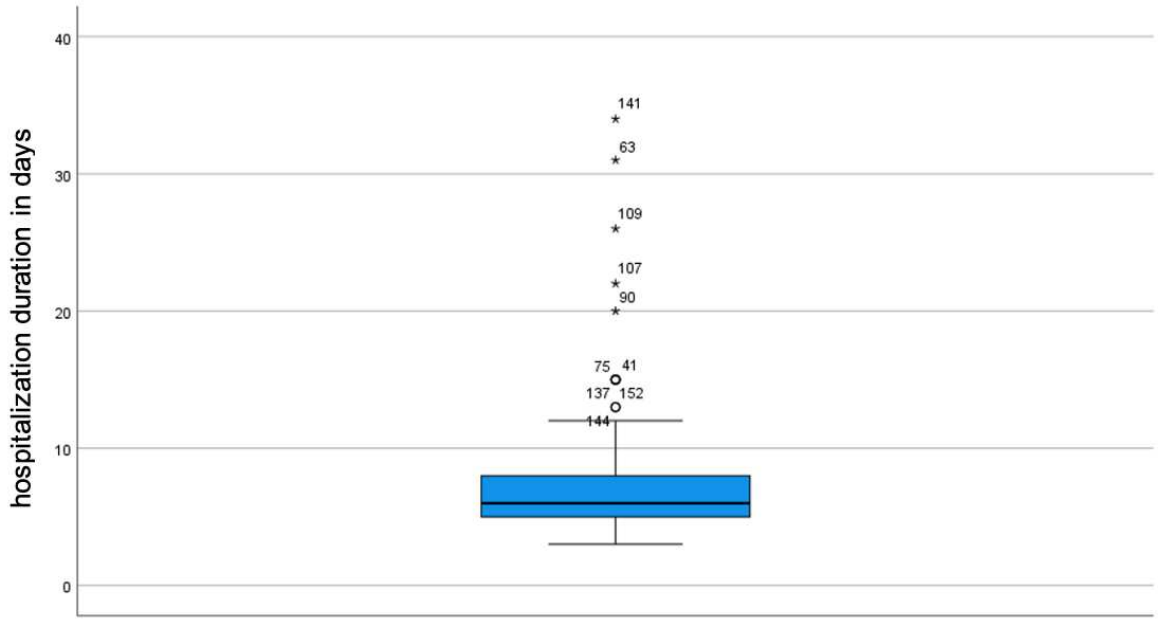


Figure 7: Hospitalization duration

Patients receiving a bovine pericardium patch had an average hospitalization duration of 8.8 ± 7.2 days, while those with a venous patch had an average stay of 6.7 ± 3.5 days, and those with an occluded SFA patch were hospitalized for 8.2 ± 3.3 days. The p-value of 0.069 does not reach statistical significance.

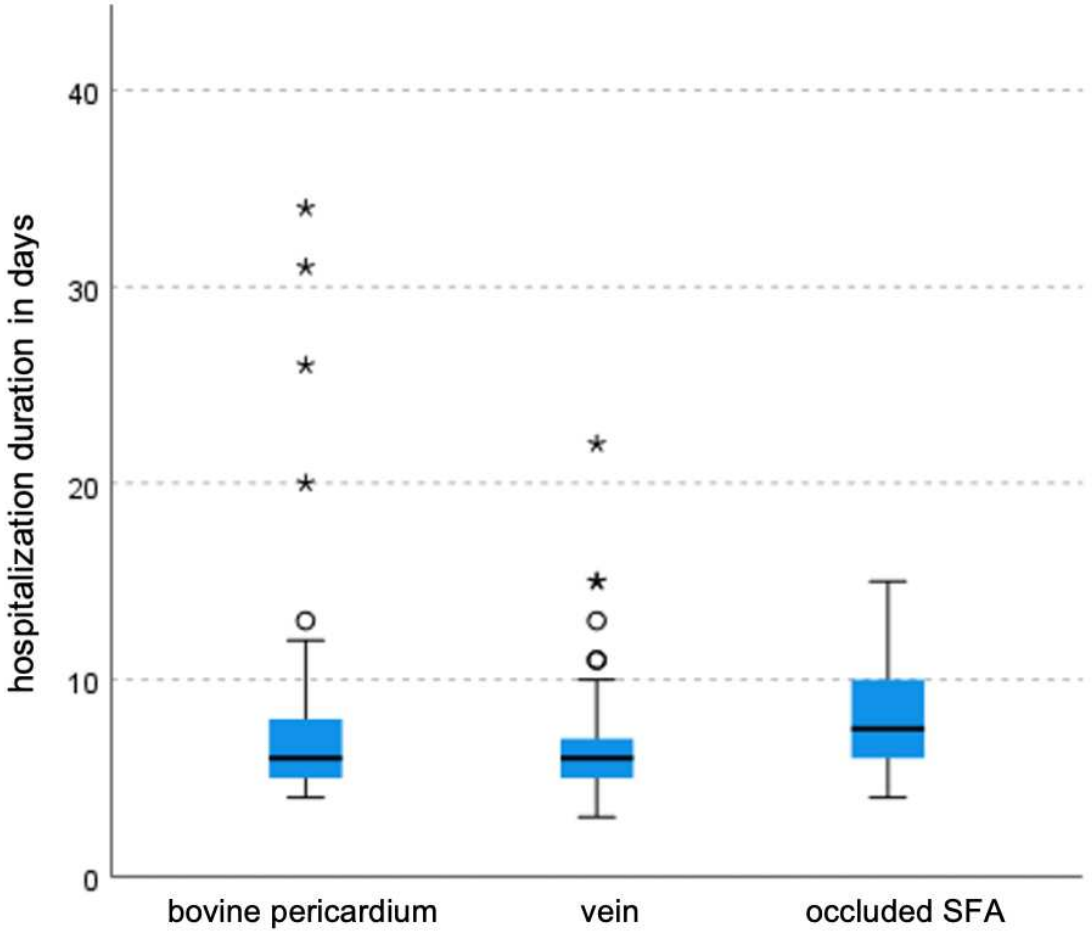


Figure 8: Hospitalization duration depending on patch

5.5. Five-year result

Based on primary 129 patients, 109 (87.4%) were excluded due to the strict defined exclusion criteria (see figure 6). The most common reason for exclusion was death. Twenty (12.6%) patients underwent sonographic follow-up investigation.

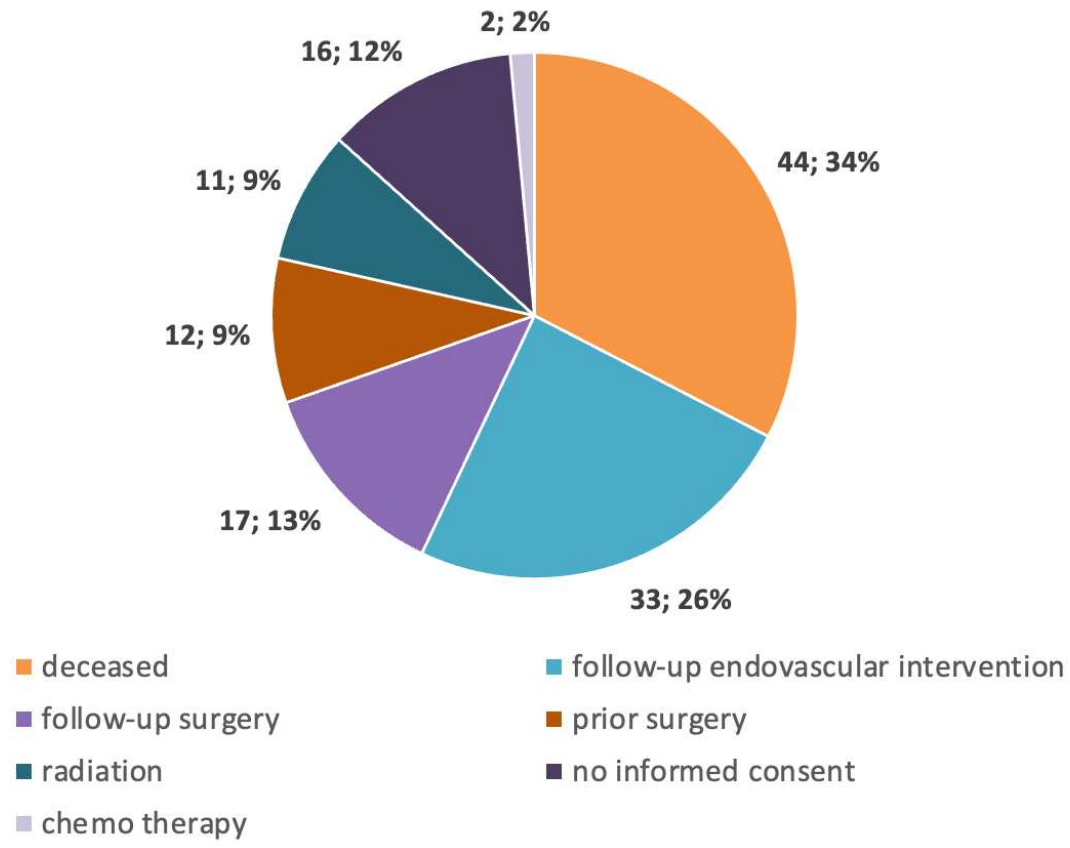


Figure 9: Diagram exclusion five-year result

Due to documentation errors, only 18 (14%) groins were considered for the statistical analysis of the CFA diameter. The average maximum diameter of the CFA after endarterectomy with patch plasty was 12,9 mm ± 2.7 mm. The table shows how the maximum diameter varies between the different patch materials.

Table 16: Max. CFA diameter

Patch material	Total n = 18	Average max. diameter in mm
Bovine pericardium	7 (39.9)	10.4 ± 2.6
Vein	6 (33.3)	14.8 ± 0.8
Occluded SFA	5 (28.8)	13.3 ± 0.8

Data are presented as mean ± standard deviation for continuous variables or number (%) for categorical variables.

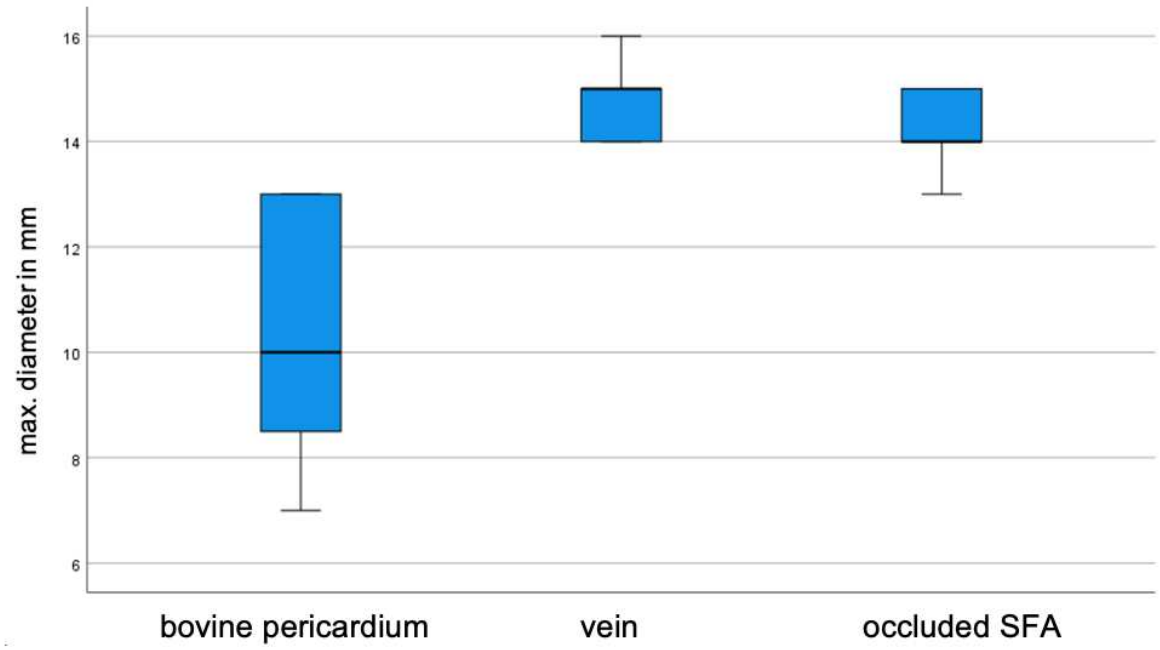


Figure 10: Boxplot max. diameter depending on patch

A highly statistically significant difference of the average maximum diameters was identified between the three different patch materials, with a p-value of 0.001. None of the operated CFAs showed significant stenosis in the ultrasound examination. However, it should be noted that 50 (38.8%) of the operated CFAs required a subsequent surgical or endovascular intervention.

5.6. Survival

To determine the one-year survival after endarterectomy all 129 patients were included. Four patients (3,1%) were deceased within one year.
The average overall survival was determined with a Kaplan Meier Graph and is 5.8 years. With a loss of data in 13 cases, the five-year survival rate is 62.9% (73/116).

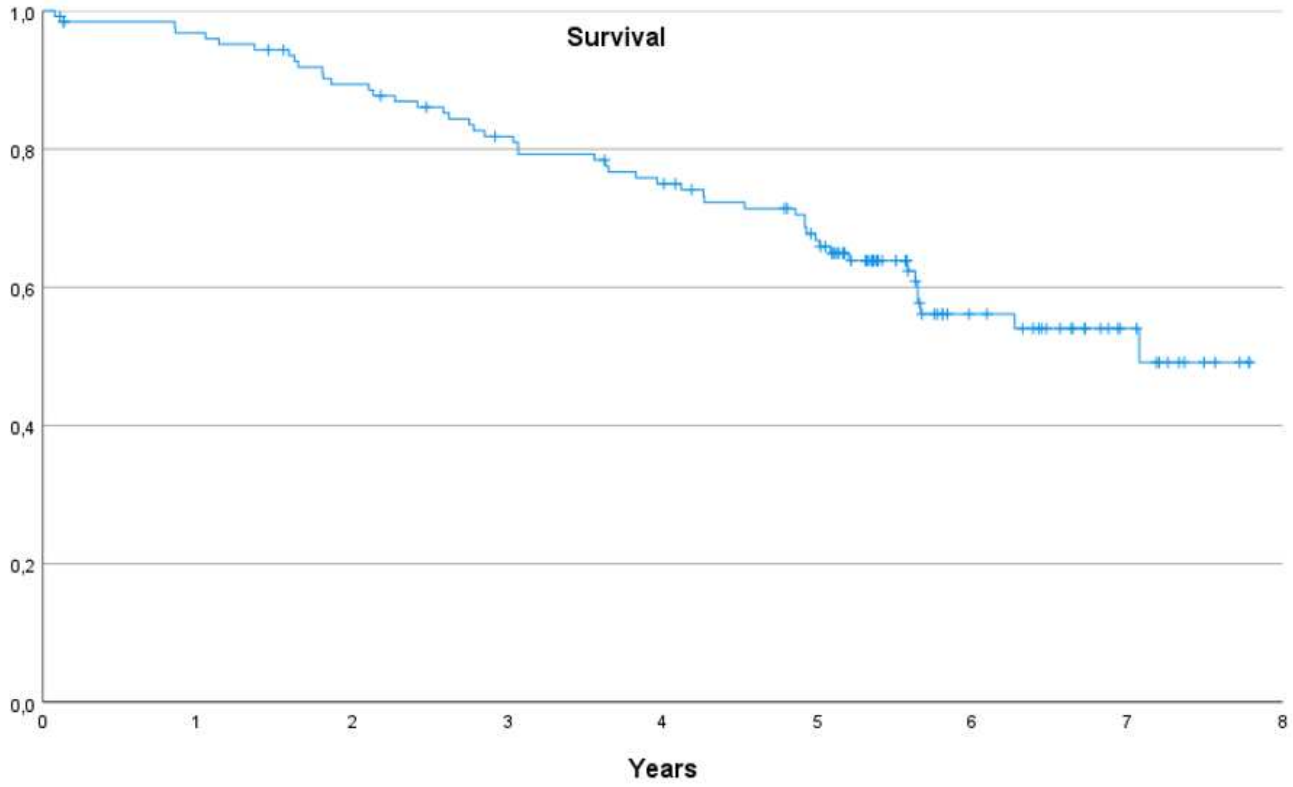


Figure 11: Overall survival (Kaplan Meier survival curve)

6. Discussion

6.1. Summary of key findings

The main aim of this study was to determine if different patch materials have an influence on postoperative wound complications and the five-year result. Even though arteries who received bovine pericardium patches showed a considerably lower complication rate in the analysis than venous and SFA patches, the difference was not statistically significant. Contrary to the assumption that the chosen patch material makes a difference regarding wound complications, no such association could be confirmed in this study. Autologous patches, especially obtained from the GSV, are the most popular choice due to their great biocompatibility and low thrombogenicity (30). Nevertheless, vein harvesting prolongs surgery and requires additional incision in patients with already impaired wound healing (17).

Interestingly, no significant impact of risk factors like smoking, hypertension, dyslipidemia, on wound complications was discovered. However, a significant influence of gender concerning wound complications was discovered, with men being more prone to complications, experiencing nearly four times more complications than women. Surprisingly, also the operated side seems to have an influence on wound healing. Left operated CFAs showed significantly less wound healing complications than right CFAs.

No significant restenosis could be found in the sonographic follow-up.

An unexpected result was the significant difference in CFA diameter of almost half a centimeter between autologous and xenogeneic patches.

6.2. Comparison with existing literature

The determined wound complication rate of this study is 23.3%. This is consistent with results from existing literature. Park et al. observed a complication rate of 22% in their retrospective study with 45 CFA lesions (35). A meta-analysis conducted by Hoffmann-Wieker et al. obtained a wound complication prevalence of 20.8% after CFA endarterectomy (23).

In the follow-up sonography a significant difference in CFA diameter was found between autologous and xenogeneic material. These observations may be clinically relevant, as a larger diameter might potentially be associated with improved long-term patency. However, in current literature there is no evidence for such association. Further investigation is necessary to evaluate the influence of patch material on arterial diameter and its clinical significance.

Disregarding the loss of data in 13 cases, the five-year survival rate was 62.9% (73/116). This result is consistent with findings from current studies for surgical treatment of PAD, especially in the femoral segment. For example, Hashimoto et al. report in their single-center retrospective study a three-year survival of 85% and an eight-year survival of 77% at a mean observation period of 39 months (36). The study did not mention, how many patients were lost to follow up at three and at eight years, but a mean observation period of 39 months indicates a substantial loss of data, which limits the reliability of these findings and demands cautious interpretation. Similarly, Hoffmann-Wieker et al. document an overall survival of 70% after five years, without mentioning an exact follow-up rate but stating that the follow-up rate was not perfect (23). In contrast, Uhl et al. found a lower overall survival of 52% at seven years in a single-center retrospective analysis, comparing the outcome of non-octogenarians and octogenarians after CFA endarterectomy, with survival rates of 59.1% and 15.7%, respectively and with a follow-up rate of 91.3% (37).
Ballota et al. showed a 89 ± 6% five-year survival rate, disregarding loss of data in six patients (38).
These variations in overall survival likely reflect differences in patient populations, comorbidities, and surgical techniques across the studies.

6.3. Interpretation of findings

Since no significant connection was found between patch material and wound complications, no procedural changes can be derived from the results. Furthermore, significantly fewer venous patches were used in patients with PAD stage IV, that might indicate a certain hesitancy to create additional skin incisions for vein harvesting in this group to prevent distal wound healing disorders.

The significant differences in wound complications based on gender and operated side raise important questions.
A study on the influence of gender on colonic anastomotic wound healing in rats found a significant lower collagen concentration in male rats than in female rats. However, no differences in mechanical properties of the anastomosis could be measured. The initial collagen concentration in the rat's colons did not differ between genders, indicating a gender difference in early stages of wound healing (39). The amount of collagen in granulation tissue impacts the tenacity (40). Jorgensen et al. conducted a post-hoc analysis of 37 volunteers and a prospective study of 47 smoking individuals (40). They found that female gender and non-smoking benefit higher collagen concentrations, but even the study with smoking volunteers showed a significant higher collagen concentration in female individuals, despite the inhibiting influence of smoking (40). Age is suspected to influence collagen levels of the skin, but these observations are limited to premenopausal women, therefore they have little impact on our findings since the mean age of our patients was 68.3 years (40).
However, another study found nearly identical collagen levels in women younger than 45 years and women older than 45 years, though collagen levels in men decreased significantly with age (41), which could explain our gender differences. It should be noted that none of these studies are recent, some conducted in the 2000s.

Another hypothesis regarding the gender difference is, that the male groin might be more difficult to disinfect properly before surgery.
We hypothesized, that the difference between sides could occur because most PTCA and PTA procedures are being performed in the right groin. However, no

significant association between postoperative wound complications and prior puncture to the CFA was found.

No significant stenosis was found in the examined CFAs. Though, many patients required subsequent surgery, in form of bypasses or embolectomies, or endovascular treatment due to their primary disease PAD.

Although the hospitalization duration was not significantly depending on the patch material, the observed difference remains noteworthy. Nevertheless, it is essential to consider potential confounding factors. Patients with advanced PAD (stage IV) may be less suitable for vein harvesting due to significantly impaired distal wound healing (42). Additionally, patients with an occluded SFA exhibit a more advanced stage of disease, which may contribute to a longer postoperative hospital stay due to the increased complexity of management and recovery.
Noronen et al. compared endarterectomy closures with pericardial patch and venous patch, and found that significantly more urgent surgeries were closed with pericardial patches, underlining our suspicion of confounders (43).

6.4. Limitations

Due to too few case numbers the influence of surgeons on outcomes could not be investigated. Furthermore, there are other factors besides the patch material that may influence the operating time like comorbidities, scarring, and extent of disease.
The relatively small sample size for the five-year result may limit the statistical significance. It was necessary to define a combined endpoint for wound complications since the individual subgroups lacked a sufficient number of cases to produce statistically significant results.

The retrospective study design introduces potential bias due to missing or incomplete documentation of patient history. The regional hospital information management system is a collection of medical reports and doctors' notes, which

are not standardized but written by each doctor individually. This is a hazard for documentation errors.
Selection bias may be an issue due to only inviting patients who did not need subsequent surgery or endovascular treatment for sonographic follow-up. Those patients are not representative of the studied population. Furthermore, patients who were not able to give informed consent due to cognitive impairment or were not able to come into the clinic for the sonographic examination were not included. Comorbidities, medication or individual surgical techniques and decisions are possible confounders. The choice of applied patch material was not randomized but was based on the personal judgment of the surgeon, which may also cause confounding. A single center design limits the applicability of results for other hospitals with different surgical techniques or patient population.

The focus of this study is the five-year result and wound complication, though improvement of walking distance and life quality was not investigated.

6.5. Suggestions for further research

A larger multicenter cohort study could improve the applicability of the results and achieve more substantial findings. Prospective data acquisition could decrease bias due to retrospective documentation errors.
Additional functional tests, like walking distance assessment or quality of life surveys could provide further results.
A randomized application of patch material could help minimize the influence of confounders and enable more objective comparison.

It is unclear, whether the larger diameter of CFAs with autologous patches occurs right after surgery due to higher compliance, or if the patches enlarge over time. This provides the basis for future research.
To determine why left sided CFA endarterectomies experience so much less wound complications than right sided, larger multicenter studies can be conducted to reinvestigate the influence of prior endovascular treatment and puncture on wound complication.

The remarkable difference in wound complication rates between male and female patients should be subject to further research. Microbiological investigation of the surgery site could provide answers to that subject. Taking microbiological samples via swabs from the disinfected groin of male and female patients could prove or refute this theory. To follow-up on the superior collagen deposition in women a prospective investigation comparing i.e. a group of male and female groin wounds in regard of their collagen levels could provide more clinically relevant data.

6.6. Conclusion

This study evaluated the long-term outcomes and wound complications following CFA endarterectomy, with a particular focus on the influence of different patch materials. No significant difference in wound complication rates was observed among bovine pericardium, vein, and SFA patches. This questions the assumption that autologous material leads to fewer complications and suggests that vein harvesting may be unnecessary for patients with compromised wound healing. Interestingly, female patients demonstrated a significantly lower rate of wound complications.

Another key observation was the significant difference in postoperative CFA diameter between autologous and xenogeneic patch materials. The larger diameters observed in autologous patches raise the question whether this dilation occurs perioperatively or gradually over time due to different compliance.

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