General discussion and future perspectives

Part I. Stent placement in endovascular treatment of iliac artery occlusive disease

Open surgical treatment shows excellent long-term outcomes in aortoiliac artery occlusive disease (AIOD). Patency rates up to 90% after 5-years and 80% after 10-years are reported in large meta-analyses.[1,2] These excellent patency rates are however, obtained at a price of morbidity (cardiac arrest during procedure, hematoma, posthemorhagic anemia, infection) and mortality rates around 8% and 3%, respectively. Endovascular treatment of AIOD reduces morbidity and mortality rates, but the main limitation of this treatment strategy is a reduced patency.[3] The Trans-Atlantic Inter-Society Consensus document on management of peripheral arterial disease classification (TASC II 2007 and 2015) defines aortoiliac lesions, potentially involving the distal aorta, common iliac artery (CIA), external iliac artery (EIA) and common femoral artery (CFA). TASC II recommends endovascular treatment for simple, straightforward aortoiliac lesions (TASC A and B) and open surgical treatment for complex lesions (TASC C and D).[4,5] Due to rapid development of endovascular techniques and improved competence, experienced centers advocate an 'endovascular-first' approach in all aortoiliac lesions.[6,7] The optimal endovascular treatment for aortoiliac artery disease has yet to be assessed, as various strategies and devices are available. In particular the use of stents is a much debated subject.

Although a stent is frequently used during endovascular treatment of AIOD, 70% of lesions can be treated with PTA alone.[8] Different stenting strategies exist. Provisional stenting means that a stent is placed after insufficient PTA result (bailout), whereas primary stenting means that a stent is primarily placed. Both regimes are accepted treatment strategies.[9] In chapter 2 the results of a systematic review on primary and provisional stenting in AIOD are described. Only two randomized controlled trials (RCTs) were identified and meta-analysis could not demonstrate a significant difference in patency rates between the two strategies.[10] Only in iliac artery occlusions (instead of stenoses) primary stenting may result in less thrombo-embolic complications. Both trials were initiated 15 to 20 years ago, and since then many improvements have been made in both stents and PTA balloons. For example, stents from the Dutch Iliac Stent Trial [11] were mounted on the balloons by hand, whereas nowadays all stents come premounted on the balloon. Also new devices such as drug-eluting stents and covered stents are introduced. Based on the results of this review, the authors advise to initiate a new review comparing primary stenting and selective stenting for iliac artery stenosis and occlusions.

By using the TASC classification in trials, no distinction is made between the CIA, which is a straight and relatively immobile artery, and the EIA, which is a more tortuous and dynamic artery. It is likely that stents may perform different in the CIA and EIA, but data comparing CIA and EIA stenting is limited. Retrospective series indicate stents perform

worse in the EAI compared to CIA.[12,13] Moreover, various stents with distinctive properties exist. Balloon expandable (BE) stents have high radial force and can be deployed accurately. Self-expandable (SE) stents are made of a memory alloy, which can regain its original shape after deployment, and have high trackability, allowing easier placement in more tortuous vessels. Chapter 3 is a review on the use of SE-stents in AIOD.[14] SE-stents may be the best option for the EIA, but only experimental data and non-randomized data is available on this subject.[15,16]

Literature involving stent placement is mostly observational. As mentioned before 70% of lesions can be treated with PTA alone. However it is suggested that primary stent placement leads to improved patency rates and lower direct complication rates in patients with challenging lesions (TASC C & D).[17–19] Stent placement also has limitations. Neointimal hyperplasia may grow through the struts of the stent and cause in-stent restenosis. Covered stents are basically bare-metal stents covered with ePTFE or Dacron and were originally developed for treating ruptured arteries, arterio-venous fistulas and aneurysms. However, in the treatment of AIOD covered stents may also prevent restenosis by providing a mechanical barrier between the treated vascular wall and the arterial lumen. Moreover, migration of macrophages into the arterial wall is potentially prevented, which limits the macrophages contributing effect on the restenotic process.[20] Data from one RCT is currently available, showing superior patency for covered stents after 5-years.[21,22] However, this study has several limitations.[23] In this study, no distinction is made between CIA en EIA lesions, and subgroups are based on the TASC classification, which is somewhat generic and less useful for research purposes, as mentioned above. In addition uncovered stents were used for the EIA.

Based on the available RCTs only aortailiac occlusion may benefit from primary stenting and in these more complex lesions covered stents may result in improved long-term patency rates compared with bare metal stents. However, in contrast with femoropopliteal occlusive disease the availability of high quality (randomized) trials regarding endovascular treatment of AIOD is very limited. New trials comparing different strategies and different devices are necessary. In future trials a clear distinction must be made between endovascular treatment of the distal aorta, the CIA and the EIA**.**

Part II. Endovascular treatment of femoropopliteal artery occlusive disease

The TASC II consensus document recommends endovascular treatment for simple, straightforward lesions (TASC A) and open bypass surgery for complex lesion (TASC D) in femoropopliteal occlusive disease.[4] Treatment of TASC B and C lesion may depend on local expertise. Reasons for this strategy are the durable results of (venous) bypass surgery and the high rate of restenosis after uncoated balloon (UCB) angioplasty, with patency rates ranging from 40-60% after one year.[4,24,25] The TASC II document is a comprehensive docu-

ment, but has been published in 2007 and many advancements regarding endovascular treatment of femoropopliteal arterial disease have been published since.[5,26]

In quest of more durable results after angioplasty, various stents have demonstrated superior outcomes compared to UCB with regard to patency and target lesion revascularization (TLR) rates, especially in long and calcified lesions.[27–30] Although improved outcomes, stenting is also associated with late complications like stent fracture, in-stent stenosis, stent occlusion and may limit future treatment options.[31–33] Therefore stent placement is usually performed after failed angioplasty, such as recurrent stenosis or flow-limiting dissection (bail-out or provisional stenting).

Focal administration of anti-proliferative drugs at angioplastied or stented regions was introduced to limit neo-intimal hyperplasia after angioplasty. Drug-eluting stents (DES) are coated with antiproliferative drugs and provide a depot, slowly releasing drug to the vessel wall and thus inhibiting neo-intimal hyperplasia.[34] DES demonstrate decreased restenosis and reintervention rates, as well as improved clinical outcomes.[27,35] However, DES may be at increased risk of stent thrombosis while endothelialization is decreased at stented regions, especially in DES with polymer-coatings.[36] These limitations fueled research in treatment modalities to focally deliver antiproliferative drugs without leaving an implant in the vessel. Drug eluting balloons (DEB) were designed to deliver antiproliferative drugs focally, leaving no implant in the vessel. Currently all DEBs use paclitaxel as an antiproliferative drug. Paclitaxel is a cytotoxic taxane compound and inhibits the proliferation of smooth-muscle cells by inhibiting the cell division in the G2/M phase. In preclinical trials with cell cultures and in trials in coronary and peripheral arteries of swine, Paclitaxel demonstrated inhibition of neointimal hyperplasia, even after a short time of balloon inflation.[37–42] When the balloon is inflated, Paclitaxel particles penetrate the vessel wall. Paclitaxel is highly lipophilic, which results in rapid cellular uptake and retention at the site of the delivery, providing prolonged localization of paclitaxel in the vessel wall.[36] On the balloon Paclitaxel is partially hidden in the folds of the wrapped balloon and the coating binds Paclitaxel, controlling the premature loss.[43] The effective drug transfer to the arterial wall results from the coating (loading of the Paclitaxel on the balloon) and the relative solubility of the Paclitaxel between the cell wall and the coating (excipient).

In 2008, the first in-human RCTs comparing DEB and UCB in femoropopliteal artery disease were published with promising results regarding late lumen loss, binary restenosis and TLR.[42,43] In the following years RCTs with larger cohorts up to 476 patients were conducted.[44,45] In these RCTs with highly selected patients groups, small differences existed in types of balloons used, lesion characteristics and stenting strategies. All RCTs reported significant improvement in late lumen loss, patency- and target lesion revascularization (TLR, defined as any repeat intervention of the target lesion for restenosis or other complications involving the target lesion[46]) rates after DEB angioplasty compared to UCB angioplasty. Chapter 5 of this thesis describes the results of a prospective trial conducted in our own

institution of the first 100 interventions with DEB in the femoropopliteal arteries. Chapter 4 describes the results of a systematic review with meta-analysis comparing DEB to UCB angioplasty.[47] This review as well as other recent systematic reviews with meta-analysis confirmed the anti-restenotic features of DEBs compared to UCB.[48,49] However, data regarding clinical outcomes, long-term follow up, long lesions, the role of vessel preparation is only scarcely available. This will be discussed in the following paragraphs.

After DEB angioplasty angiographic parameters (late lumen loss, binary restenosis and patency rates) significantly improved in all meta-analyses, but clinical outcomes such as walking distance, amputation rate and survival, did not improve. In the RCTs, the cohorts predominantly consisted of patients with intermittent claudication. The amputation rate and mortality rates are very low in patients with intermittent claudication and consequently no differences were observed in the RCTs and systematic review. A lack of improvement in walking distance may be explained by the fact that the walking distance maximized after both successful UCB and DEB angioplasty. If patients developed a *symptomatic* binary restenosis during follow-up, they underwent recurrent PTA and again had a maximized walking distance at the next time point in the trial. Not treating patients with recurrent and disabling symptoms as a consequence of recurrent stenosis to show a difference in walking distance or amputation rate is considered unethical. Therefore, the significant decrease of clinically driven TLR, might be considered the most important clinical outcome parameter in the current RCTs.[47–49] Unfortunately, clinically driven TLR is not used as an outcome parameter in the most recent guideline of the Dutch vascular society, omitting possibly the most important benefits of DEBs.[50]

Currently, the price of a DEB far exceeds the price of an UCB, however is decreasing. Repeat intervention for recurrent femoropopliteal artery occlusive disease is costly and inconvenient. Cost-effectiveness analyses in several countries showed that initial costs of DEB angioplasty are higher, but due to the diminished TLR rate, it may be cost saving.[51–53] Endovascular femoropopliteal treatment with DEB has been called "a classic spend now to save later scenario".[53]

Five year patency rates of femoropopliteal vein bypass for intermittent claudication is estimated at 80%.[4] Also long-term follow up data from a single trial of femoropopliteal drug-eluting stent (DES) placement have been published.[27] Follow up evaluation of DEBs in RCTs is currently still relatively short and mostly does not exceed two years.[42,44,45,54–58] Recently, three-year results of the INPACT.SFA trial were published, reporting a sustained significant improvent of primary patency and TLR after DEB angioplasty.[59] The only published long-term data are obtained from the THUNDER-trial. A sustained reduced TLR rate after 5-year has been reported, however TLR was not defined in the study protocol and the numbers of patients completing 5-year follow-up were small.[60] Long-term outcomes of DEB angioplasty have yet to be assessed and compared to other treatment modalities. Especially the results of head-to-head comparisons of the promising new devices like DEB,

DES and covered stents are awaited for. Chapter 6 consists of a study protocol of a RCT comparing DEB vs DES in the femoropopliteal arteries.[61] In this study 254 patients will be randomized to treatment with DEB and provisional stenting or primary DES placement. Inclusion has started in September 2016.

The length of a lesion and the presence of calcium strongly influences the outcomes of endovascular treatment of femoropopliteal lesions.[4,62] In the two largest RCTs comparing DEB and UCB (INPACT.SFA and LEVANT 2 trial), the mean lesion length was 89 mm and 63 mm, respectively.[44,45] In a more recent RCT of 300 patients (ILLUMINATE) the mean length was 80 to 89 mm.[63] Data on treatment of long and complex lesions with DEB is limited, but the available series show promising results. Both Schmidt et al. and Micari et al. have evaluated the effect of DEB in long femoropopliteal lesions. In cohorts with mean lesion lengths exceeding 240 mm, patency rates of 79.2% to 83.2% after one year, and 53.7% to 70.4% after two years were reported. Estimated freedom from TLR was 68.4% to 84.7% after two years. Provisional stenting was 23.5% and 10.5% in these trials.[64–66]

Even more challenging may be the treatment of in-stent restenosis (ISR). Recurrent stenosis rates up to 70% six months after treatment of ISR with UCB angioplasty alone have been described.[67] The value of DEB angioplasty in these lesions has only been assessed in small RCTs, with variable outcomes.[68–71]

Vessel preparation prior to the use of DEB, but also prior to DES or even covered stent placement, is gaining popularity. Predilatation and prolonged inflation reduces the risk of major dissection and the need of additional intervention directly after angioplasty. [72,73] In more complex lesions, like severely calcified lesions and in-stent restenosis (ISR), vessel preparation with an atherectomy device may be of benefit.[74,75] In a series of 135 patients with symptomatic femoropopliteal ISR lesions, the use of an atherectomy device before uncoated balloon angioplasty did not lead to differences in restenosis or occlusions rate, however lead to a significant decrease of TLR after 2 years, compared to uncoated balloon angioplasty alone. Also, few retrospective series on the use of a cutting balloon (or sculpting device) for vessel preparation exist.[76]

The femoropopliteal trajectory is the longest in PAD and knows a broad variety of lesion characteristics en treatments. Lesions may range from short focal stenosis to long and heavily calcified lesions. Treatment of each these lesions may require different strategies. The past decade treatments options for femoropopliteal lesions have been extended. DEB angioplasty as well as various stenting options show improved and more durable outcomes compared to UCB alone. Also complimentary devices such as atherectomy and sculpting devices may contribute in the treatment of complex, heavily calcified lesions.[72,76]

Several head-to-head trials randomizing promising new devices like DEB, DES, atherectomy devices and covered stents are currently recruiting patients.[61,72,77–79] These trials will clarify the role of each of these devices, facilitating easier and more focused decision

making in endovascular treatment of femoropopliteal disease, enabling tailor-made endovascular treatment for all types of lesions in every segment of the femoropopliteal artery.

Part III. Endovascular treatment of autologous bypass grafts

One third of patients treated with infrainguinal autologous bypass grafts develop stenosis, usually occurring at the anastomoses of the graft, putting the bypass at risk for occlusion. Surveillance leads to an increase of detection of these stenoses and early re-intervention, improving assisted- and secondary patency rates of the bypass grafts.[80,81] However, it is still unclear if early re-intervention of a bypass at risk also leads to increased limb-salvage rates.[82] Nevertheless, the Dutch vascular society recommends duplex surveillance at 1 year after infrainguinal autologous bypass surgery.[83] Although patch plasty of a bypass at risk has excellent results, the less invasive endovascular techniques have become an established treatment modality.[84–86] Freedom from recurrent stenosis after PTA is disappointing, repeat intervention however leads to patent bypasses. The antirestenotic features of new technologies such as DEB, DES or cutting balloons may decrease the number of reinterventions needed, however have only been researched scarcely in this vascular territory.

In chapter 7 the results from a retrospective series of 69 failing autologous bypass grafts treated with UCB angioplasty are presented. The most important finding was that freedom from binary restenosis or bypass occlusion after PTA of a bypass at risk was rather poor. However, repeated interventions of these lesions improved patency rates substantially, and assisted patency rates up to 80% were observed.[87] These results suggest that endovascular treatment of an autologous bypass graft at risk with only UCB angioplasty is insufficient and alternatives have been explored.

Cutting balloons have also been used for the treatment of stenoses in infrainguinal venous grafts. However, in small single arm and retrospective comparative studies the results of this technique in autologous bypasses at risk were inconsistent.[88,89] Engelke et al. and Schneider et al. published promising results, but others were not able to show an advantage of cutting balloon angioplasty over UCB.[88–92] A well-designed and sufficiently powered RCT has yet to be performed to determine the true value of cutting balloons in these patients.

We hypothesized that DEBs, with established anti-restenotic features, may also improve patency rates after endovascular treatment of autologous bypasses at risk. In chapter 8 the results from a non-randomized comparison of patients treated for an infrainguinal autologous bypass at risk with either DEB angioplasty or UCB angioplasty were evaluated. In total 39 patients (21 DEB, 18 UCB) were included in the analysis and we observed no differences in primary-, primary-assisted and secondary patency rates between the two groups. Despite the limitations of this small cohort, these findings are in accordance with other published data on this subject, where also no significant differences were found in primary, primary-assisted and secondary patency rates between treatment with DEB or

UCB.[93–95] These results may be explained by differences in lesion characteristics between atherosclerotic stenoses and stenoses developing in venous bypass grafts. Lesions in venous bypasses may develop for technical reasons such as improper suturing, instrument trauma and intrinsic tissue changes (ie venous valves, intima hyperplasia at the anastomoses), resulting in predominant fibrotic stenoses.[96] DEB angioplasty does not seem to effectuate a significant improvement in patients with autologous bypasses at risk and, for now, we suggest using a (cheaper) UCB angioplasty for the endovascular treatment of an autologous bypass at risk. However, similar to cutting balloons, a well-designed and sufficiently powered RCT has yet to be performed to determine the true value of DEB in these patients.

To improve the primary patency after endovascular treatment of patients with an autologous bypass at risk alternative strategies may be explored. In a small single arm series of only ten patients DES showed promising results in patients with a failing bypass graft.[97] This treatment strategy needs further investigation. Treatment with covered stents has not been described in these patients.

Part IV. Angiosome concept theory in critical limb ischemia

In contrast with patients treated for intermittent claudication, treatment of patients with critical limb ischemia (CLI) is aimed at wound healing, limb salvage and prolonged survival.[98] Compromised vascularization to the foot can be compensated by direct arterial connections, such as collaterals and the pedal arch, and indirect connections such as choke vessels. Choke vessels are small, reduced-caliber connecting branches that are usually closed between the angiosomes.[98] Angiosomes are three-dimensional units of tissue that are fed by a source artery, and were first described by Taylor and Palmer nearly thirty years ago.[98] When a particular angiosome becomes compromised, the choke vessels open to allow a neighboring angiosome to support the compromised area. Plastic surgeons use choke vessels are an important concept in free-flap surgery to determine the location of the incision and maximize postoperative outcomes. The clinical applicability of the angiosome theory in patients with CLI is different from the applicability in patients undergoing plastic reconstructive surgery. Tissues in patients undergoing free-flap surgery are mostly healthy, with patent vascularization. The compromised macroangiopathy of the ischemic foot is associated with microcirculatory changes like neuropathy, thrombosis, local sepsis, arterio-venous shunting and hypercoagulability.[99] Of note, choke vessels are diseased in patients with diabetes en atherosclerosis.[100]

According to the angiosome concept, it is likely that direct revascularization (DR) of the target artery of the affected angiosome improves perfusion of that angiosome, providing better wound healing and reduction of amputations.

The applicability of DR in all clinical situations is however debatable while patients with CLI have developed compensation mechanisms such as collaterals. Since the endovascular treatment of the infrapopliteal arteries may be challenging, technical considerations often

determine whether a treating physician performs DR or decides to treat the best available tibial artery with collaterals to the affected angiosome (indirect revascularization (IR).

In chapter 9 the results of our systematic review with meta-analysis comparing DR and IR, consisting of almost 4000 patients are described. An overall significant improvement in wound healing, major amputation and amputation free survival after DR was observed.[101] This is in line with results found in systematic reviews performed earlier.[102,103] Sensitivity analysis of the cohort shows that the significant improvement after DR is lost in some subgroups. For instance, in studies including bypass surgery, no improvement in major amputation was found after DR. In bypass surgery, the quality of the outflow artery seems a more important determinant for limb-salvage than DR the affected angiosome.[4] Therefore bypasses are generally anastomosed distally to the least affected tibial artery with run-off passing the ankle, whatever the affected angiosome.

In the systematic review a distinction between patients with, and patients without collateral circulation was made. When collaterals to the affected angiosome were present on angiography, no significant difference in wound healing and amputation rates were found between DR and IR. On the other hand, in patients without collateral vascularization, DR significantly improved outcomes compared to IR. It must be taken into account that all the data is derived from retrospective series. To date no prospective studies or RCTs are conducted comparing DR and IR.

Although only patients without collateral vascularization to the affected angiosome benefit from DR compared to IR, knowledge of the vascular anatomy and angiosomes is indispensable for a successful endovascular infrapopliteal revascularization. Prospective and randomized studies, with subgroup analyses of patients with and without developed compensatory mechanisms, are needed to fully determine the value of the angiosome concept in patients with CLI.

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