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Critical limb ischemia (CLI) – role of vascular surgery in endovascular era

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Introduction

During the past decade, dramatic changes have occurred in the field of endovascular management of patients with chronic critical limb ischemia (CLI). Perler and coworkers write that today, we literally have a dozen or so endovascular options for treating CLI. We can dilate it with a balloon, or dilate and cut it with cutting balloon, we can add a stent or primarily stent, with a plain old-fashioned stent, a drug eluting stent, a covered stent or even a biodegradable stent; we can cool it with cryoplasty, or we can heat it with laser, or we can radiate it with brachytherapy; or we can slice it with atherectomy. We can even do a percutaneous bypass. Although this can be seen as a positive development, clinical studies, trying to justify each treatment modality are flawed for many reasons and the lack of evidence means that the same patient may be offered a completely different treatment depending on the clinician and the hospital. And if treatment fails, we try something else at additional cost or we refer patient to amputation surgeon with comment that everything possible was done to prevent major amputation. 

Limb salvage and other outcomes, such as patency, re-intervention, and survival, which have been used to evaluate clinical success, are more and more recognized as inadequate measures because they afford only a snapshot of the vast issues that confront patients with CLI. Patients with CLI, especially patients with tissue loss, require frequent ongoing care of their extremity, are subject to prolonged periods of wound healing and experience a subsequent need for re-intervention. Accordingly, some have suggested that a comprehensive evaluation of success requires contemporaneous evaluation of traditional parameters, along with quality-of-life measures such as symptom relief, wound healing, and functional status. Studies that have incorporated complex evaluation of clinical success measures have reported less-than-optimal outcomes after endovascular intervention for treatment of CLI.

Aorto-iliac segment

From the surgical point of view the golden rule for treatment of CLI is to correct more proximal lesions first. About 50% of all patients needing surgery because of aortoiliac occlusion processes display relevant accompanying atherosclerotic lesions of the infrainguinal region. According to the TASC II recommendations endovascular therapy is recommended for type A lesions and surgery is preferred for type D lesions. Patients with type B and C lesions can be managed by either surgery or endovascular therapy. However the management of aortoiliac occlusive disease has undergone considerable evolution during the past two decades and recent device development to cross chronic total occlusions has increased the utilization of endovascular therapy for type C and D lesions. Primary stent placement for complex iliac artery occlusive disease is without question possible (type C and D lesions), however the procedure takes more time and is associated with a higher frequency of complications than for simple disease. Sometimes multiple endovascular revascularization procedures are required and when failed, surgical vascular procedure may become a very complex treatment modality.

The decision for any type of invasive procedure will depend upon a numerous factors, such as nature of the disease, patient’s fitness, and fully informed preference and success rates. Starting with the nature of the disease there are some patients which are at a present time absolutely not suitable for endovascular procedures, such as patients who have severe calcification. These lesions are difficult to cross, difficult to dilate and have high risk of complications. Separate problem represent patients with renal insufficiency where even small quantities of contrast can lead to severe deterioration of clinical picture and who are unable to undergo endovascular procedures lasting several hours. When talking about anatomical and morphological issues it is important for any invasive procedure to have adequate inflow and outflow. Complete aortic occlusions are best treated by an aortobifemoral bypass. The same is true for bilateral diffuse suprainguinal disease. On the outflow site the repair of deep femoral artery when superficial femoral artery is occluded is extremely important part of procedure. Reconstruction of deep femoral artery is better performed with open procedure. When deep femoral artery is unsuitable as the receptor segment and additional reconstruction of concomitant superficial artery occlusion is needed open surgery has superior primary and secondary patency rates. Prospective evaluation of
endovascular treatment with large number of patients will be required to assess the equality or even superiority of endovascular procedures when serious concomitant common femoral and/or superficial femoral artery disease is present.

**Femoro-distal segment**

The need for subsequent femorodistal vascular reconstruction is estimated at 20-25%. In most cases, revascularization procedures at the proximal end sufficiently improve blood influx. An additional distal reconstruction is needed when there is occlusion of superficial femoral artery in the popliteal segment, occlusion of crural arteries and existence of distal necroses. There are many different types of vascular surgical procedures to achieve distal limb revascularization. In the era of endovascular interventions they are becoming more and more complex, as many patients are referred to vascular surgeon after failed primary procedure. There are increasing numbers of cruro-pedal vascular surgical interventions. Patients with cruro-pedal lesions usually have few developed collateral vessels to compensate for reduced blood flow. These patients display faster progression to stage II and IV of Fontaine classification. Such patients with CLI should be treated as an emergency. However, the majority of patients are still not treated in specialized centers.

From the anatomical point of view, when constructing distal bypass, there is no objective evidence to preferentially select any of the crural or pedal vessels, although bypass anastomosis to the peroneal artery is rarely performed because of the pathomorphologic characteristics of this vessel. The results of femoral crural bypasses have not been subject to meta-analysis. Five-year assisted patency rates in grafts constructed with vein approach 60% ad those constructed with prosthetic material are usually less than 35%. The greater saphenous vein compares favorably with other materials for bypass grafting to infrapopliteal arteries, but this vein and other autologous veins suitable for grafting may be lacking. Patency rates with prosthetic material can be improved when at least distal anastomosis is constructed with vein patch or cuff.

Despite aggressive therapeutic measures, patients with CLI experience significantly reduced life expectancy. Three years after successful intervention, less than 60% are alive. Additionally impaired wound healing, frequent readmissions and reoperations significantly reduce the quality of life in patients following distal bypass. The ideal therapy should therefore consist of restoration of extremity function, optimization of life expectancy by treatment of underlying disease and its risk factors, and the best possible social reintegration of the patient. Mortality, morbidity and comorbidity, as well as risk factors and life expectancy should be evaluated regarding prognosis and long term results of each intervention technique applied. In many cases best social reintegration can be achieved with primary major amputation and fast rehabilitation. And it must be kept in mind that better long term results (better primary and primary assisted patency rates) can be expected with surgery.

**References**

Selective shunting based on stump pressure measurement during carotid endarterectomy

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Aim
Stroke is the second single most common cause of mortality in Europe accounting for more than one million deaths each year.1 Over 75% of strokes are ischemic in their origin with carotid artery stenosis being responsible for 20% of them.2 Current guidelines suggest that significant carotid stenosis should be evaluated for a possible carotid endarterectomy (CEA) to reduce the risk of stroke and death.3 During carotid endarterectomy blood flow through the ipsilateral internal carotid artery is temporarily interrupted allowing the surgeon to remove the atherosclerotic plaque. To avoid possible cerebral ischemia during carotid clamping routine insertion of a temporary shunt is advocated by some surgeons.4 However, shunting is not without risks and brain embolization, arterial dissection or aneurysm formation due to shunt insertion has been described.5 Some authors therefore suggest the use of a shunt only when cerebral ischemia is predicted or demonstrated by an objective cerebral monitoring method.6 Different methods (EEG, brain oximetry, stump pressure, SSEP) have been evaluated but no one seems to be superior to the others.7 One of the simplest techniques to estimate the need of selective shunt placement during CEA is the intraoperative measurement of ACI stump pressure.8 As we routinely use SP measurements to determine the need for shunt insertion during CEA in general anesthesia (GA) we reviewed the outcomes of 158 consecutive patients treated for carotid stenosis in our institution under GA. Our study sought to determine the difference in morbidity and mortality between the shunted and non-shunted patients according to stump pressure measurements.

Materials and methods
We retrospectively evaluated 158 consecutive CEA performed in our institution. Before surgery, all patients underwent computed tomography angiography of the extracranial carotid arteries. The degree of stenosis was calculated using the North American Symptomatic Carotid Endarterectomy Trial criteria. Patients were referred to surgery according to the guidelines on treating extracranial carotid artery disease released by the European Society of Cardiology.9 Before surgery patients were loaded with 100 mg of Aspirin. All the operations were performed involving general anesthesia. With the patient in a slightly reversed Trendelenburg position the carotid artery stenosis was exposed through a longitudinal incision parallel to the medial border of the sternocleidomastoid muscle. Before carotid clamping, 5000 units of heparin were given to the patient with no reversal used at the end of the procedure. After the common and external carotid arteries were clamped a 22-gauge needle was inserted into the common carotid artery (CCA) proximal to the carotid bifurcation and the mean stump pressure (SP) recorded. The SP was considered accurate if the waveform became flatline during observation, indicating that there is no collateral filling of the carotid artery between the clamps. If the SP exceeded 40 mmHg no shunt was used. When the values were lower than 40 mmHg a Pruitt Inahara type shunt (Le Maitre vascular, Burlington, Mass) was inserted through a longitudinal arteriotomy. After the endarterectomy, the arteriotomy was closed using a 6 mm Dacron patch (Intervascular, La Ciotat, France) and a running 6/0 polypropylene suture. All endarterectomies were evaluated on completion with an 8-MHz handheld Doppler scan. A drain was routinely inserted through a separate small incision opening and removed on postoperative day two.

Our main outcome measure was 30-day stroke and death after CEA across patients with and without shunt insertion based on SP measurements. Chi square and Fisher’s exact test were used to test statistical significance.

Results
Our study group consisted of 158 primary CEAs performed in general anesthesia at our institution between the year 2006 and 2014. Patients who underwent CEA in locoregional anesthesia were excluded from further analysis. Of the 158 patients included 72.2% were men and 27.8% women. Their mean age was 68.2 years. CEA was performed for asymptomatic carotid artery stenosis in 112 patients (70.9%). The patient- and procedure-related characteristics are shown in table 1. Prior to endarterectomy, SP pressure was measured in all patients. A threshold value of 40 mmHg was used to guide shunt insertion and according to this 19% of the patients were shunted. The perioperative stroke and neurologic event rate was 0.63% (1 of 158). The combined 30-day stroke and death rate was 1.28% (2 of
Table I. – Patient- and procedure-related characteristics.

<table>
<thead>
<tr>
<th></th>
<th>No shunt (128)</th>
<th>Shunt (30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (y)</td>
<td>68 ± 8.5</td>
<td>69 ± 8.5</td>
</tr>
<tr>
<td>Females</td>
<td>34 (26.6%)</td>
<td>10 (33.3%)</td>
</tr>
<tr>
<td>Males</td>
<td>94 (73.4%)</td>
<td>20 (66.7%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>29 (22.7%)</td>
<td>9 (30.0%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>82 (64.0%)</td>
<td>23 (76.7%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>54 (42.15)</td>
<td>15 (50.0%)</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>100 (78.1%)</td>
<td>12 (40.0%)</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>28 (21.9%)</td>
<td>18 (60.0%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>20 (15.6%)</td>
<td>3 (10.0%)</td>
</tr>
<tr>
<td>TIA</td>
<td>8 (6.3%)</td>
<td>15 (50.0%)</td>
</tr>
<tr>
<td>Operation time</td>
<td>83 min (65-112)</td>
<td>93 min (72-118)</td>
</tr>
<tr>
<td>Patch</td>
<td>50 (39.1%)</td>
<td>19 (63.3%)</td>
</tr>
</tbody>
</table>

Table II. – Procedure-related complications.

<table>
<thead>
<tr>
<th></th>
<th>Total (158)</th>
<th>No shunt (128)</th>
<th>Shunt (30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative death</td>
<td>1 (0.63%)</td>
<td>0</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>PND</td>
<td>1 (0.63%)</td>
<td>0</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>TND</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nonfatal cardiac</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nerve injury</td>
<td>4 (2.5%)</td>
<td>3 (2.3%)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3 (1.9%)</td>
<td>2 (1.6%)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>1 (0.63%)</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
</tbody>
</table>

PND: Permanent neurologic deficit; TND: temporary neurologic deficit.

158). Both events occurred in the shunt group. The only death in this series occurred 10 days after the procedure due to a pneumonia followed by ARDS. Surgical outcome data are provided in table II.

Discussion

Various trials have shown that CEA is an effective treatment for selected patients with symptomatic or asymptomatic carotid artery stenosis.10,11 Because a temporary interruption of blood flow through the carotid arteries is needed during CEA some authors advocate routine shunt placement during endarterectomy thus avoiding cerebral ischemia. They reported low complication rate with 0.1% mortality and 0.7% stroke events in a 30-days postoperative period.14 On the other hand some authors have reported low neurological complications rate (<3%) in patients undergoing CEA without the use of an intraluminal shunt even in the presence of a contralateral carotid artery occlusion.12 Not using a shunt could eliminate the risk of plaque dislodgement or vessel injury during shunt placement and allow better visualization of the endarterectomy end point. Other authorities suggest that selective shunting with routine monitoring of brain perfusion or function could avoid unnecessary shunt insertion while eliminating cerebral ischemia in patients who do not tolerate transient carotid clamping.6

Our study sought to determine the difference in morbidity and mortality in 158 patients undergoing CEA in general anesthesia and in whom SP was used to determine the need of shunt insertion. In our series patients who need shunt insertion were more frequently hyperlipidemic, symptomatic and have a history of transitory ischemic attack compared to patients who didn’t need shunt insertion. The overall shunt insertion rate of 19% was somewhat lower compared to Aburahma who also used routine intraoperative SP measurement to direct selective shunt placement and reported a 28% shunt insertion rate.13

Perioperative morbidity and mortality in our series was comparable with other series of CEA.14 Both serious complications in our series (one stroke and one death ten days after the procedure due to pneumonia) occurred in the shunted group. The patient with ipsilateral stroke manifested hemiplegia and aphasia immediately after awakening from anesthesia suggesting that the stroke evolved intraoperatively. Although the numbers of complications in our series are small one should keep in mind that shunting is no without risks and could be itself the cause for embolic stroke if performed inappropriately.9 No conclusion could be done regarding the possible differences in complication rate between the two groups. The Cochrane collaborative group recently also concluded that available data are too limited to either support or refute the use of routine or selective shunting in carotid endarterectomy.7

Conclusion

Our study showed good patient outcomes by using a selective shunt policy during CEA based on intraoperative SP measurement. Since there is no scientific consensus regarding the routine, selective or no use of shunt to prevent cerebral ischemia during CEA surgeons should select the method with which they are more comfortable. However, personal and institutional outcomes after CEA as should be systematically recorded and compared with published data. Any aberration from expected results should be analyzed and treatment strategies thoroughly reevaluated.

References

Endovascular management of patients with CLI

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Aim
CLI is defined by rest pain and/or ulcerations, often on distal foot, lasting more than 2 weeks. Excruciating and constant pain requires analgesics, even opiates; ulcers are often present on toes or heel, mostly dry with pale base. About 20% of patients with CLI will die in the next six months and about 40% will lose their leg. Approximately 50% of the patients that are not candidate for revascularization will be alive after a year, 25% will have a major amputation and about 25% will die. Patients are often in stage III and IV of Fontaine classification and in Rutherford category 4-6. In patients with CLI, distal arteries are often diffusely affected; multilevel disease is common. Angiographic evaluation reveals diffuse changes in peripheral arteries, often below the knee, lesions are often diffuse. Diagnostics should be minimally invasive, since CLI patients are often elderly and have different co-morbidities. Arterial ultrasound examination and CTA should be performed if feasible. Angiography is used often only as introduction into endovascular therapy. The treatment is based on revascularization, resulting in ulcers healing and pain reduction. Since the beginnings of the millennium, technological evolution led to significant improvement of endovascular techniques. Hydrophilic and steerable and weighted low-profile guide wires revolutionized recanalization, low-profile balloon catheters increased the recanalization rates, especially in BTK arteries. Transfemoral, transfemoral and subintimal access raised hope for those in whom classical recanalization was not feasible. Calcified lesions are challenged with plaque – removal techniques etc. Drug coated balloons (DCB) showed promising results for SFA and popliteal pathology, their role in BTK arteries should be evaluated, potentially influencing management of the patients with CLI. The follow-up of these patients is difficult, since morbidity and mortality is high; any treatment is extremely complex due to the fragility of the patients due to co-morbidities. Since 2012, hospitalization of the patients is feasible on our Institute. Majority of the patients is referred from smaller hospitals, lacking interventional radiology. The aim of our study was to evaluate the results of endovascular treatment in CLI patients, admitted in our Institute in 2015.

Materials and methods
The data of patients, admitted to Institute between January 1st and November 30th 2015 were evaluated retrospectively, focusing on PAOD (peripheral arterial occlusive disease) patients. The frequency of CLI was assessed; primary technical success was determined as angiographic and clinical improvement immediately after the revascularization. Major and minor complications were analysed.

Results
In the first eleven months of 2015, 148 patients were treated in our day hospital department. 83 were referred as PAOD; 61 (73,5%) of these patients had CLI. In four patients endovascular therapy was not performed—three only diagnostic angiography was performed due to extensive disease and in one, coagulation parameters were not matching required values. Endovascular treatment was performed successfully in 52 patients with CLI (91% primary technical success), in others recanalization was not feasible. The revascularization was performed with POBA in only three patients (5,7%) stenting of SFA was necessary for acceptable hemodynamic. Single major complication was detected—limb ischemia after arterial occlusion by vascular closure device that was resolved surgically, while minor haematoma was present in five patients, requiring no treatment.

Discussion
Majority of patients with PAOB, admitted to our Institute in 2015, had CLI. The clinical and non-invasive diagnostics, performed prior to admission, was adequate, since the large majority of patients (91%) could be treated successfully by endovascular approach. The primary technical success in our study was comparable to results, reported in the recent literature. Plain old balloon angioplasty (POBA), dedicated guide wires and hydrophilic catheters were used additionally to improve results (Figures 1-4). No stents in arteries below the knee were necessary and in only less than 6% of patients, bailout stenting was used in SFA to achieve feasible hemodynamic results. The need for the use of BTK stents in CLI patients is therefore questionable and limited in SFA. Based on
results of our study, the wide use of additional expensive tools in treatment of CLI should be evaluated individually, since the complexity and the duration of the procedure may lead to additional complications, compromising fragile CLI patients. Endovascular management of patients with CLI proved safe, since the number of serious complications was low and patients’ conditions were not aggravated by the procedure itself. Long-term results of endovascular treatment are encouraging.\cite{3}

The selection of the patients is crucial to avoid unnecessary invasive procedures. It should be based on non-invasive diagnostics; patients should be optimally prepared for the procedure, including normal coagulation parameters, adequate hydration, hypertension management etc.

**Conclusion**

The treatment goal in CLI patients is recanalization and consequent pain relief, ulcers healing, amputation
avoidance. Life-saving recanalization can be achieved in majority of patients with simple, not expensive endovascular tools. Multidisciplinary approach – refer, treat, support – is of utmost importance for successful treatment in these patients and patients should be adequately prepared for the procedure. New endovascular approaches and tools might further improve results.

References