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TASC II - spät, aber doch

Minar E, Schillinger M

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ERWO
PHARMA

TASC II – spät, aber doch

E. Minar¹, M. Schillinger²

Kurzfassung: Rezent ist das bereits seit längerem angekündigte TASC-II-Konsensusdokument zur Diagnose und Therapie der peripheren arteriellen Verschlusskrankheit (PAVK) publiziert worden. Die bereits 7 Jahre zurückliegende und somit vielfach nicht mehr ganz aktuelle Erstfassung machte eine Revision dringend notwendig. Dieses neue Konsensusdokument ist in wesentlichen Punkten deutlich gekürzt und somit leichter lesbar. Die Datenlage wird in 43 konkreten Empfehlungen zusammengefaßt. Dieses Dokument zeigt klar, daß auf dem Gebiet der PAVK nur wenige große randomisierte Studien existieren, weswegen nur wenige Empfehlungen einen Grad-A-Status haben.

Kritisch muß angemerkt werden, daß die Klassifikation der Läsionen in Hinblick auf die Differentialtherapie zwischen Chirurgie und endovaskulärer Therapie im Vergleich zur Erstfassung leider geändert wurde. Dies erschwert die Vergleichbarkeit mit bereits publizierten Originalarbeiten.

Abstract: TASC II – Late, but Coming After All.

Recently, the TASC II-Consensus document concerning diagnosis and treatment of patients with peripheral arterial occlusive disease (PAOD) has been published. Since publication of TASC I was already in 2000, revision of the guidelines became urgently necessary. The

new document has been abbreviated in many points, making it more easily readable also for the physician without special expertise in vascular medicine. The available data are summarized in 43 specific recommendations. This document demonstrates that only few large randomized studies have been performed in the field of PAOD. Therefore, only few recommendations are classified as grade A. Unfortunately, the classification of lesions with respect to differential therapy between surgery and endovascular treatment has been changed compared to TASC I, making comparison with already published papers more difficult. **Z Gefäß-med 2007; 4 (1): 11–5.**

■ Einleitung

Ganz rezent ist das bereits seit längerem angekündigte „Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease“ (TASC II) im Jänner 2007 im *Journal of Vascular Surgery* [1] sowie im *European Journal of Vascular and Endovascular Surgery* [2] jeweils als Supplement erschienen. Da das erste TASC-Konsensusdokument bereits im Jahre 2000 erschienen ist, war eine Neufassung dringend erforderlich. TASC II ist im Vergleich zu TASC I deutlich gekürzt und somit insgesamt – insbesondere auch für den Allgemeinmediziner – leichter lesbar. Das Dokument befaßt sich mit Risikofaktoren, Koinkidenzen mit anderen atherosklerotischen Erkrankungen, Diagnose, Prophylaxe und Therapie der PAVK (Claudicatio intermittens, chronisch kritische Beinischämie sowie akute Beinischämie) und faßt die Datenlage in 43 konkreten Empfehlungen zusammen.

Als Kritikpunkt muß hier allerdings auch angeführt werden, daß insbesondere der Therapieteil des TASC-II-Dokumentes doch sehr stark „chirurgenlastig“ erscheint. Es muß auch besonders darauf hingewiesen werden, daß die Klassifikation der Läsionen – und die davon abhängigen Empfehlungen zur chirurgischen bzw. endovaskulären Therapie – im Vergleich zu TASC I doch in wesentlichen Punkten geändert wurden, was leider zu einiger Verwirrung beitragen wird.

In den kommenden Ausgaben der *Zeitschrift für Gefäßmedizin* wollen wir uns mit einigen der angeführten Empfehlungen etwas genauer auseinandersetzen und versuchen, diese für österreichische Verhältnisse zu adaptieren.

Im folgenden werden diese Empfehlungen in der englischen Originalfassung für den eiligen Leser zusammenfassend dargestellt*. Der Grad der Empfehlung ist – in Abhängigkeit von

der Studienlage – als A, B bzw. C klassifiziert (siehe Tab. 1). Es fällt auf, daß insbesondere die Empfehlungen zur Therapie überwiegend als Grad C klassifiziert wurden, da leider immer noch nur sehr wenige große randomisierte Studien zu den verschiedenen Therapiemöglichkeiten bei Patienten mit PAVK durchgeführt wurden.

Recommendation 1.

Smoking cessation in peripheral arterial disease

- All patients who smoke should be strongly and repeatedly advised to stop smoking [B].
- All patients who smoke should receive a program of physician advice, group counselling sessions, and nicotine replacement [A].
- Cessation rates can be enhanced by the addition of antidepressant drug therapy (bupropion) and nicotine replacement [A].

Recommendation 2.

Lipid control in patients with peripheral arterial disease (PAD)

- All symptomatic PAD patients should have their low-density lipoprotein (LDL) cholesterol lowered to < 2.59 mmol/L (< 100 mg/dL) [A].
- In patients with PAD and a history of vascular disease in other beds (e.g. coronary artery disease) it is reasonable to lower LDL cholesterol levels to < 1.81 mmol/L (< 70 mg/dL) [B].
- All asymptomatic patients with PAD and no other clinical evidence of cardiovascular disease should also have their

Tabelle 1: Einteilung der Empfehlungen im TASC-II-Dokument in Abhängigkeit von der Datenlage

- | | |
|---|--|
| A | Based on the criterion of at least one randomized, controlled clinical trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation. |
| B | Based on well-conducted clinical studies but no good quality randomized clinical trials on the topic of recommendation. |
| C | Based on evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities (i.e. no applicable studies of good quality). |

*Nachdruck aus [1]. © 2007, mit Genehmigung der „Society for Vascular Surgery“.

Aus der ¹Abteilung Angiologie, Universitätsklinik für Innere Medizin II, Medizinische Universität Wien und der ²3. Medizinischen Abteilung Kardiologie, Wilhelminenspital der Stadt Wien

Korrespondenzadresse: Univ.-Prof. Dr. med. Erich Minar, Abteilung Angiologie, Universitätsklinik für Innere Medizin II, Medizinische Universität Wien, A-1090 Wien, Währinger Gürtel 18–20; E-Mail: erich.minar@meduniwien.ac.at

LDL cholesterol level lowered to < 2.59 mmol/L (< 100 mg/dL) [C].

- In patients with elevated triglyceride levels where the LDL cannot be accurately calculated, the LDL level should be directly measured and treated to values listed above. Alternatively, the non-HDL (high-density lipoprotein) cholesterol level can be calculated with a goal of < 3.36 mmol/L (< 130 mg/dL), and in high-risk patients the level should be < 2.59 mmol/L (< 100 mg/dL).
- Dietary modification should be the initial intervention to control abnormal lipid levels [B].
- In symptomatic PAD patients, statins should be the primary agents to lower LDL cholesterol levels to reduce the risk of cardiovascular events [A].
- Fibrates and/or niacin to raise HDL cholesterol levels and lower triglyceride levels should be considered in patients with PAD who have abnormalities of those lipid fractions [B].

Recommendation 3.

Control of hypertension in peripheral arterial disease (PAD) patients

- All patients with hypertension should have blood pressure controlled to $< 140/90$ mmHg or $< 130/80$ mmHg if they also have diabetes or renal insufficiency [A].
- JNC VII and European guidelines for the management of hypertension in PAD should be followed [A].
- Thiazides and ACE inhibitors should be considered as initial blood-pressure lowering drugs in PAD to reduce the risk of cardiovascular events [B].
- Beta-adrenergic-blocking drugs are not contraindicated in PAD [A].

Recommendation 4.

Control of diabetes in peripheral arterial disease (PAD)

- Patients with diabetes and PAD should have aggressive control of blood glucose levels with a hemoglobin A_{1c} goal of < 7.0 % or as close to 6 % as possible [C].

Recommendation 5.

Use of folate supplementation in peripheral arterial disease (PAD)

- Patients with PAD and other evidence of cardiovascular disease should not be given folate supplements to reduce their risk of cardiovascular events [B].

Recommendation 6.

Antiplatelet therapy in peripheral arterial disease (PAD)

- All symptomatic patients with or without a history of other cardiovascular disease should be prescribed an antiplatelet drug long term to reduce the risk of cardiovascular morbidity and mortality [A].
- Aspirin/ASA is effective in patients with PAD who also have clinical evidence of other forms of cardiovascular disease (coronary or carotid) [A].
- The use of aspirin/ASA in patients with PAD who do not have clinical evidence of other forms of cardiovascular disease can be considered [C].
- Clopidogrel is effective in reducing cardiovascular events in a subgroup of patients with symptomatic PAD, with or without other clinical evidence of cardiovascular disease [B].

Recommendation 7.

Management of coronary artery disease (CAD) in peripheral arterial disease patients

- Patients with clinical evidence of CAD (angina, ischemic congestive heart failure) should be evaluated and managed according to current guidelines [C].
- Patients with PAD considered for vascular surgery may undergo further risk stratification and those found to be at very high risk managed according to current guidelines for coronary revascularization [C].
- Routine coronary revascularization in preparation for vascular surgery is not recommended [A].

Recommendation 8.

Use of beta-blocking agents before vascular surgery

- When there are no contraindications, betaadrenergic blockers should be given perioperatively to patients with peripheral arterial disease undergoing vascular surgery in order to decrease cardiac morbidity and mortality [A].

Recommendation 9.

Management of carotid artery disease in peripheral arterial disease (PAD) patients

- The management of symptomatic carotid artery disease in patients with PAD should be based on current guidelines [C].

Recommendation 10.

Management of renal artery disease in peripheral arterial disease (PAD) patients

- When renal artery disease is suspected in PAD patients, as evidenced by poorly controlled hypertension or renal insufficiency, patients should be treated according to current guidelines and consider referral to a cardiovascular physician [C].

Recommendation 11.

History and physical examination in suspected peripheral arterial disease (PAD)

- Individuals with risk factors for PAD, limb symptoms on exertion or reduced limb function should undergo a vascular history to evaluate for symptoms of claudication or other limb symptoms that limit walking ability [B].
- Patients at risk for PAD or patients with reduced limb function should also have a vascular examination evaluating peripheral pulses [B].
- Patients with a history or examination suggestive of PAD should proceed to objective testing including an ankle-brachial index [B].

Recommendation 12.

Recommendations for ankle-brachial index (ABI) screening to detect peripheral arterial disease in the individual patient

An ABI should be measured in:

- All patients who have exertional leg symptoms [B].
- All patients between the age of 50–69 and who have a cardiovascular risk factor (particularly diabetes or smoking) [B].
- All patients age ≥ 70 years regardless of risk factor status [B].
- All patients with a Framingham risk score 10–20 % [C].

Recommendation 13.**Determining success of treatment for intermittent claudication**

Patient-based outcome assessment (including a focused history of change in symptoms) is the most important measure; however, if quantitative measurements are required the following may be used:

1. Objective measures include an increase in peak exercise performance on a treadmill [B].
2. Patient-based measures would include an improvement on a validated, disease-specific health status questionnaire; or the physical functioning domain on a validated generic health status questionnaire [B].

Recommendation 14.**Exercise therapy in intermittent claudication**

- Supervised exercise should be made available as part of the initial treatment for all patients with peripheral arterial disease [A].
- The most effective programs employ treadmill or track walking that is of sufficient intensity to bring on claudication, followed by rest, over the course of a 30–60 minute session. Exercise sessions are typically conducted three times a week for 3 months [A].

Recommendation 15.**Pharmacotherapy for symptoms of intermittent claudication**

- A 3- to 6-month course of cilostazol should be first-line pharmacotherapy for the relief of claudication symptoms, as evidence shows both an improvement in treadmill exercise performance and in quality of life [A].
- Naftidrofuryl can also be considered for treatment of claudication symptoms [A].

Recommendation 16.**Clinical definition of critical limb ischemia (CLI)**

- The term critical limb ischemia should be used for all patients with chronic ischemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease. The term CLI implies chronicity and is to be distinguished from acute limb ischemia [C].

Recommendation 17.**Cardiovascular risk modification in critical limb ischemia (CLI)**

- CLI patients should have aggressive modification of their cardiovascular risk factors [A].

Recommendation 18.**Evaluation of peripheral arterial disease (PAD) in patients with diabetes**

- All diabetic patients with an ulceration should be evaluated for PAD using objective testing [C].

Recommendation 19.**Diagnosis of critical limb ischemia (CLI)**

- CLI is a clinical diagnosis but should be supported by objective tests [C].

Recommendation 20.**Indications for evaluation of critical limb ischemia**

- All patients with ischemic rest pain symptoms or pedal ulcers should be evaluated for CLI [B].

Recommendation 21.**Importance of early identification of peripheral arterial disease (PAD)**

- Early identification of patients with PAD at risk of developing foot problems is essential for limb preservation [C]. This can be achieved by daily visual examination by the patients or their family and, at every visit, referral to the foot specialist.

Recommendation 22.**Early referral in critical limb ischemia (CLI)**

- Patients with CLI should be referred to a vascular specialist early in the course of their disease to plan for revascularization options [C].

Recommendation 23.**Multidisciplinary approach to treatment of critical limb ischemia**

- A multidisciplinary approach is optimal to control pain, cardiovascular risk factors and other co-morbid disease [C].

Recommendation 24.**Optimal treatment for patients with critical limb ischemia (CLI)**

- Revascularization is the optimal treatment for patients with CLI [B].

Recommendation 25.**Treatment for infections in critical limb ischemia (CLI)**

- Systemic antibiotic therapy is required in CLI patients who develop cellulitis or spreading infection [B].

Recommendation 26.**Multidisciplinary care in critical limb ischemia (CLI)**

- Patients with CLI who develop foot ulceration require multidisciplinary care to avoid limb loss [C].

Recommendation 27.**Amputation decisions in critical limb ischemia (CLI)**

- The decision to amputate and the choice of the level should take into consideration the potential for healing, rehabilitation and return of quality of life [C].

Recommendation 28.**Use of prostanoids in critical limb ischemia (CLI)**

- Previous studies with prostanoids in CLI suggested improved healing of ischemic ulcers and reduction in amputations [A].
- However, recent trials do not support the benefit of prostanoids in promoting amputation-free survival [A].
- There are no other pharmacotherapies that can be recommended for the treatment of CLI [B].

Recommendation 29.**Assessment of acute limb ischemia (ALI)**

- Due to inaccuracy of pulse palpation and the physical examination, all patients with suspected ALI should have

Doppler assessment of peripheral pulses immediately at presentation to determine if a flow signal is present [C].

Recommendation 30.

Cases of suspected acute limb ischemia (ALI)

- All patients with suspected ALI should be evaluated immediately by a vascular specialist who should direct immediate decision making and perform revascularization because irreversible nerve and muscle damage may occur within hours [C].

Recommendation 31.

Anticoagulant therapy in acute limb ischemia (ALI)

- Immediate parenteral anticoagulant therapy is indicated in all patients with ALI. In patients expected to undergo imminent imaging/therapy on arrival, heparin should be given [C].

Recommendation 32.

Completion arteriography

- Unless there is good evidence that adequate circulation has been restored, intraoperative angiography should be performed to identify any residual occlusion or critical arterial lesions requiring further treatment [C].

Recommendation 33.

Treatment of choice for compartment syndrome

- In case of clinical suspicion of compartment syndrome, the treatment of choice is a four-compartment fasciotomy [C].

Recommendation 34.

Intra-arterial pressure measurements for assessment of stenosis

- If there is doubt about the hemodynamic significance of partially occlusive aortoiliac disease, it should be assessed by intra-arterial pressure measurements across the stenosis at rest and with induced hyperemia [C].

Recommendation 35.

Choosing between techniques with equivalent short- and long-term clinical outcomes

- In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first [B].

Recommendation 36.

Treatment of aortoiliac lesions

- TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions [C].
- TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions and surgery is the preferred treatment for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions [C].

Recommendation 37.

Treatment of femoral popliteal lesions

- TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions [C].
- TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions and surgery is the preferred treatment for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions [C].

Recommendation 38.

In-flow artery for femorodistal bypass

- Any artery, regardless of level (i.e. not only the common femoral artery), may serve as an in-flow artery for a distal bypass provided flow to that artery and the origin of the graft is not compromised [C].

Recommendation 39.

Femoral distal bypass out-flow vessel

- In a femoral tibial bypass, the least diseased distal artery with the best continuous run-off to the ankle/foot should be used for outflow regardless of location, provided there is adequate length of suitable vein [C].

Recommendation 40.

Femoral below-knee popliteal and distal bypass

- An adequate long (greater) saphenous vein is the optimal conduit in femoral below-knee popliteal and distal bypass [C]. In its absence, another good-quality vein should be used [C].

Recommendation 41.

Antiplatelet drugs as adjuvant pharmacotherapy after revascularization

- Antiplatelet therapy should be started preoperatively and continued as adjuvant pharmacotherapy after an endovascular or surgical procedure [A]. Unless subsequently contraindicated, this should be continued indefinitely [A].

Recommendation 42.

Clinical surveillance program for bypass grafts

- Patients undergoing bypass graft placement in the lower extremity for the treatment of claudication or limb-threatening ischemia should be entered into a clinical surveillance program.

This program should consist of:

- Interval history (new symptoms)
- Vascular examination of the leg with palpation of proximal, graft and outflow vessel pulses
- Periodic measurement of resting and, if possible, post-exercise ankle-brachial indices
- Clinical surveillance programs should be performed in the immediate postoperative period and at regular intervals (usually every 6 months) for at least 2 years [C].

Recommendation 43.

Indications and methods to localize arterial lesions

- Patients with intermittent claudication who continue to experience limitations to their quality of life after appro-

priate medical therapy (exercise rehabilitation and/or pharmacotherapy) or patients with critical limb ischemia, may be considered candidates for revascularization if they meet the following additional criteria:

- (a) a suitable lesion for revascularization is identified;
 - (b) the patient does not have any systemic contraindications for the procedure; and
 - (c) the patient desires additional therapy [B].
- Initial disease localization can be obtained with hemodynamic measures including segmental limb pressures or pulse volume recording [B].

- When anatomic localization of arterial occlusive lesions is necessary for decision making, the following imaging techniques are recommended:

- duplex ultrasonography
- magnetic resonance angiography and
- computed tomography angiography (depending on local availability, experience, and cost) [B].

Literatur:

1. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; on behalf of the TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg* 2007; 45 (Suppl 1): S5–S67.

2. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; on behalf of the TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg* 2007; 33 (Suppl 1): S1–S75.

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