Evidence-based Therapy in Vascular Surgery

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Preface

The topic of this book is evidence-based vascular and endovascular surgery and vascular medicine. Thereby, all prevalent arterial vascular diseases are discussed, from extracranial carotid stenosis to thoracic and abdominal aortic aneurysms, peripheral arterial occlusive disease and the diabetic foot. Furthermore, especially significant for the outpatient field, therapy of varicose veins is included. The objective of this book is to assess surgical procedures and to aid the reader in resolving whether open or endovascular intervention should be preferred in a given situation. This initiates with recommendations from guidelines, which are not necessarily the same in all countries and sometimes may not be of the highest quality. The authors scrutinized which of the most frequently utilized guidelines were identical and which of them differed.

This leads us to the second focus of this book, the treatment results, which serve as a rudiment for an evidence-based therapy decision. Clinical studies are discussed and classified according to their significance; all important meta-analyses and Cochrane-Reviews are presented, and the recent results of randomized and large retrospective cohort studies are explained. Due to their inclusion and exclusion criteria, randomized controlled trials do not always simulate real-life conditions. The results of large registries like the National Surgical Quality Improvement Program (NSQIP) or the Swedvasc and Vascunet, therefore, are indispensable for decision making and are presented and discussed here, as well.

In the end, the reader determines which treatment (e.g., open or endovascular intervention) currently is the best founded. This addresses a wide readership; not only younger doctors in their training but also experienced practitioners can learn the latest developments in our field. The preparation of consultant recommendations is facilitated, which is useful not only for vascular surgeons.

The benefit of such a book depends on its stringent structure and up-to-the-minute data. The authors, therefore, systematically requested all study results from the last 5 years in a Medline (PubMed) search. Previous publications were consulted when only a paucity of new data was accessible. This enables the reader to be certain of encountering the latest study outcomes and guidelines. In view of the rapid developments in our field and the propagation of many cutting-edge endovascular

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techniques, we furnish the readers with a compendium, with the help of which they can implement, in their daily practice, vascular and endovascular procedures, based on state-of-the-art techniques and technologies.

In conclusion, we thank all employees of the Springer publishing house, who participated in this project for their kind assistance, and especially Mr. Andre Tournois, who, from the inception, was convinced of our concepts and buttressed us energetically.

Hamburg, Germany Burghausen, Germany E. Sebastian Debus Reinhart T. Grundmann

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Chapter 1 Extracranial Carotid Stenosis

1.1 Guidelines

1.1.1 European Society of Cardiology (ESC)

Recommendations for management of asymptomatic carotid artery disease (European Stroke Organisation et al. 2011):

- All patients with asymptomatic carotid artery stenosis should be treated with long-term antiplatelet therapy. (Class-I-recommendation/Level of evidence B)
- All patients with asymptomatic carotid artery stenosis should be treated with long-term statin therapy. (Class-I-recommendation/Level of evidence C)
- In asymptomatic patients with carotid artery stenosis ≥60%, CEA should be considered as long as the perioperative stroke and death rate for procedures performed by the surgical team is <3% and the patient's life expectancy exceeds 5 years. (Class-IIa-recommendation/Level of evidence A)
- In asymptomatic patients with an indication for carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centres with documented death or stroke rate <3%. (Class-IIb-recommendation/Level of evidence B)

Recommendations for management of symptomatic carotid artery disease:

- All patients with symptomatic carotid stenosis should receive long-term antiplatelet therapy. (Class-I-recommendation/Level of evidence A)
- All patients with symptomatic carotid stenosis should receive long-term statin therapy. (Class-I-recommendation/Level of evidence B)
- In patients with symptomatic 70–99% stenosis of the internal carotid artery, CEA is recommended for the prevention of recurrent stroke. (Class-I-recommendation/Level of evidence A)

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- In patients with symptomatic 50–69% stenosis of the internal carotid artery, CEA should be considered for recurrent stroke prevention, depending on patient-specific factors. (Class-IIa-recommendation/Level of evidence A)
- In symptomatic patients with indications for revascularization, the procedure should be performed as soon as possible, optimally within 2 weeks of the onset of symptoms. (Class-I-recommendation/Level of evidence B)
- In symptomatic patients at high surgical risk requiring revascularization, CAS should be considered as an alternative to CEA. (Class-IIa-recommendation/Level of evidence B)
- In symptomatic patients requiring carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centres with documented death or stroke rate <6%. (Class-IIb-recommendation/Level of evidence B)

1.1.2 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/ SCAI/SIR/SNIS/VM/SVS

Recommendations for selection of patients for carotid revascularization (Brott et al. 2011):

Class I

- Patients at average or low surgical risk who experience non disabling ischemic stroke or transient cerebral ischemic symptoms, including hemispheric events or amaurosis fugax, within 6 months (symptomatic patients) should undergo CEA if the diameter of the lumen of the ipsilateral internal carotid artery is reduced more than 70% as documented by noninvasive imaging (Level of Evidence: A) or more than 50% as documented by catheter angiography (Level of Evidence: B) and the anticipated rate of perioperative stroke or mortality is less than 6%.
- CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by more than 70% as documented by noninvasive imaging or more than 50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is less than 6% (Level of Evidence: B)
- Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences. (Level of Evidence: C)

Class IIa

• It is reasonable to perform CEA in asymptomatic patients who have more than 70% stenosis of the internal carotid artery if the risk of perioperative stroke, MI, and death is low. (Level of Evidence: A)

1.1 Guidelines 3

• It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention. (Level of Evidence: B)

- It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery. (Level of Evidence: B)
- When revascularization is indicated for patients with TIA or stroke and there are no contraindications to early revascularization, intervention within 2 weeks of the index event is reasonable rather than delaying surgery. (Level of Evidence: B)

Class IIb

- Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established. (Level of Evidence: B)
- In symptomatic or asymptomatic patients at high risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established. (Level of Evidence: B)

Recommendations for periprocedural management of patients undergoing carotid endarterectomy:

Class I

• Aspirin (81–325 mg daily) is recommended before CEA and may be continued indefinitely postoperatively. (Level of Evidence: A)

Class IIa

- Patch angioplasty can be beneficial for closure of the arteriotomy after CEA.
 (Level of Evidence: B)
- Administration of statin lipid-lowering medication for prevention of ischemic events is reasonable for patients who have undergone CEA irrespective of serum lipid levels, although the optimum agent and dose and the efficacy for prevention of restenosis have not been established. (Level of Evidence: B)

Recommendations for management of patients undergoing carotid artery stenting:

Class I

• Before and for a minimum of 30 days after CAS, dual-antiplatelet therapy with aspirin (81–325 mg daily) plus clopidogrel (75 mg daily) is recommended. For patients intolerant of clopidogrel, ticlopidine (250 mg twice daily) may be substituted. (Level of Evidence: C)

Class IIa

• Embolic protection device (EPD) deployment during CAS can be beneficial to reduce the risk of stroke when the risk of vascular injury is low. (Level of Evidence: C)