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The Role of The Carotid Database in Prospective Survey of Patients With Carotid Atherosclerosis Unsuitable For Surgical or Endovascular Treatment

Uloga postojanja baze podataka u istraživanju pacijenata obolelih od karotidne ateroskleroze na koje se ne može primeniti hirurško i endovaskularno lečenje

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Abstract

Randomized Controlled Trials (RCT) comparing carotid endarterectomy (CEA) and carotid angioplasty and stenting (CAS) provide the key data in appropriate treatment of carotid atherosclerosis. Still further survey of patients' not meeting inclusion criteria or patients' unsuitable for randomization is not mentioned during the follow up and thus seriously impairing the message these trials are sending to the world medical community. The answer to this question can be obtained from specially created carotid databases (CDB) that include all patients diagnosed and treated for carotid atherosclerosis. Besides preoperative characteristics, CDB includes all the details regarding diagnostic (ultrasound, CT angiography) and interventional (CEA or CAS) procedures in each included patient. In addition to this valuable material, CDB provides very important information about the patients during the follow-up and especially the patients who were not treated by any interventional procedure (CEA or CAS). The results of further treatment and follow up of patients' unsuitable for the CEA or CAS are needed to give 'real-world' answer which of the two procedures is superior to another in the treatment of carotid atherosclerosis. Specially created carotid databases could give the answers to this specific question.

Carotid atherosclerosis treatment

Carotid atherosclerosis represents one of the leading causes of cerebral ischemia and stroke with share up to 70-90%. Timely diagnosis and appropriate treatment of the patients with carotid atherosclerosis significantly influence decreased stroke rate. Several treatment options are recommended for patients with severe carotid atherosclerotic disease: surgical (carotid endarterectomy), endovascular (carotid angioplasty and stenting) and the best medical therapy.

Since its first introduction by De Bakey et al [1], carotid endarterectomy (CEA) experienced a precipitous success in world public community with constant improvement of surgical technique. Later on, prospective randomized studies [2,3] confirmed the benefit of CEA in stroke prevention in symptomatic patients when compared to medical treatment showing that CEA is the gold standard in carotid atherosclerosis

treatment. Cochrane Database systematic review clearly indicated that CEA reduces the incidence of stroke and death in patients with symptomatic and asymptomatic carotid stenosis. [4,5] It is still controversial as to which surgical technique should be preferred ('standard' of eversion endarterectomy), still eversion CEA has been identified as an independent factor contributing to a better outcome after the surgery. [6,7] At our institution, eversion CEA was firstly performed in 1991, and over the years it has completely replaced standard longitudinal arteriotomy for primary treatment of atherosclerotic carotid disease. Till 2010 at our Institute nearly 10.000 eversion CEAs were performed [8] and just over 12.000 so far, with excellent neurological and overall outcome.

In the last decade carotid angioplasty and stenting (CAS) raised as less invasive alternative to CEA for carotid

atherosclerosis treatment. To evaluate the most appropriate treatment option for carotid atherosclerosis numerous randomized controlled trials (RCT) compared CEA and CAS in the terms of early and long-term results. [9-14] These studies included several hundreds of symptomatic and asymptomatic patients randomized to CEA and CAS with International Carotid Stenting Study (ICSS) Trial and The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) including the largest number of patients (1713 and 2502). [13,14] All of aforementioned studies indicated that CAS is not inferior to CEA in primary carotid atherosclerosis treatment except for Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) Trial and ICSS Trial [12,13] showing that CAS is associated with statistically significant increased post-procedural risk when compared to CEA.

Randomized Controlled Trials (RCT) for carotid atherosclerosis –The role of Carotid Database (CDB)

There is no doubt that RCTs provide the key data in appropriate treatment of carotid atherosclerosis that greatly contribute to designing of official guidelines published by the world's leading associations. Still, in none of the largest trials [9-14] further survey of patients' not meeting inclusion criteria or patients' unsuitable for randomization is mentioned during the follow up that could provide valuable information.

A large number of patients is not considered at all for the randomization since CAS is not possible or might be performed with high-risk in patients >80 years of age, highly symptomatic lesions, severe atherosclerosis and calcifications of the aortic arch, severe calcifications or tortuosity of the common carotid artery, internal carotid artery (ICA) pathological

elongations or tortuosity, aortic arch anomalies, poor femoral access, long near to occlusion ICA lesion or severe renal insufficiency. In most of such patients CEA could be performed with a favorable outcome, still further survey of such patients are not presented in RCTs and thus decreasing applicability of the CEA on one side making unrealistic compare of CAS and CEA on the other. The authors of recently published paper [15] have analyzed 48035 CEAs from a large international vascular registry and concluded that RCTs for carotid atherosclerosis treatment provide useful information by also that further longitudinal follow up of non-operated patients is needed as well.

The answer to this question can be obtained from specially created databases. Three years ago at our Insti-

tute specially designed carotid database (CDB) was created that enrolls all patients diagnosed and treated for carotid atherosclerosis. CDB includes all preoperative characteristics of the patient: demographic data, risk factors, laboratory findings, previous medications, diagnostic procedures performed prior to admission or any past medical history. Following admission appropriate diagnostic procedures are performed (color duplex ultrasonography, CT angiography, brain CT) and fulfilled within the CDB as well. If the patient is referred to surgical or endovascular treatment all the details regarding the procedure itself are fulfilled within the separate sheet in the CDB as well as all the details on the discharge including post-procedural or other intra-hospital complications, laboratory findings and medications.

Analysis of the data from the CDB provides us the answers to numerous questions of appropriate treatment modalities of carotid atherosclerosis, association with other diseases and the prevention of possible complications. In addition to this valuable

material, CDB gives us very important information about the patients during the follow-up and especially the patients who were not treated by any interventional procedure (CEA or CAS). In this way we obtain information about the natural course of

carotid disease, symptoms and ischemic events that appear during the follow up that helps us to promptly react by the means of interventional procedures.

Conclusion and perspectives

The results of further treatment and follow up of patients unsuitable for randomization in large RCTs are needed to give 'real-world' answer which of the procedures (CEA or CAS) is superior to another in the treatment of carotid atherosclerosis. By analyzing the CDB important information of

further survey of patients not referred to any interventional procedure could be obtained, natural course of the disease and the answer to the most optimal treatment modality of carotid atherosclerosis that should be performed.

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