## Title:

## Residual Stenosis and Restenosis Following Carotid Endarterectomy with Primary Closure, A Prospective Tracking Study (RECEPT)

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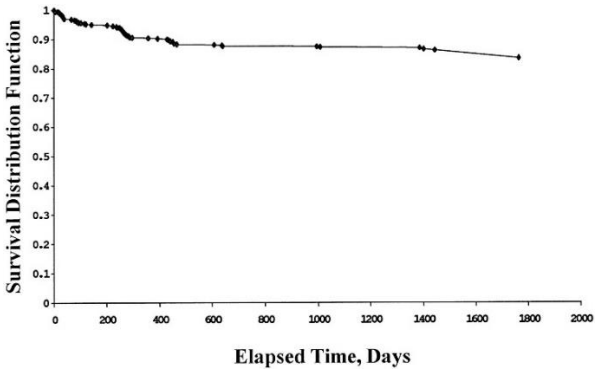
## Introduction:

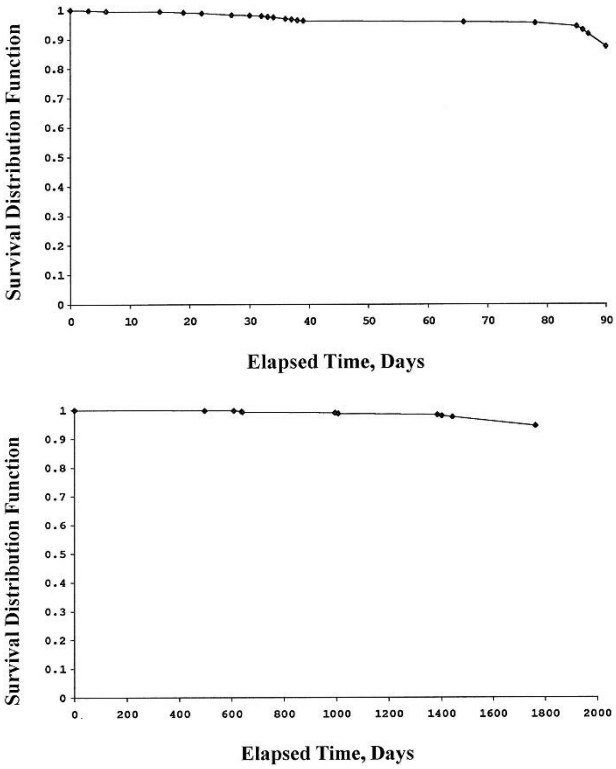
According to current guidelines, carotid endarterectomy (CEA) with primary closure is associated with a higher incidence of residual stenosis and restenosis compared to the eversion technique (eCEA) and patch angioplasty (pCEA). A Cochrane database analysis reported restenosis (defined as ≥50% stenosis) in 26% of patients after CEA, 18% after eCEA, and 19% after pCEA. However, no significant difference was observed in the incidence of high-grade restenosis (≥70%). (Cheng, 2021)

Nevertheless, the reported incidence of restenosis following CEA varies significantly across studies, ranging from 2% to 34%. These discrepancies are attributable to variations in surgical technique, study methodologies, and diagnostic protocols.

Given the considerable body of literature on carotid restenosis, several terms have emerged to describe it based on timing and histological features. Most authors agree that stenosis occurring within 6 weeks (or 30 days) after surgery is classified as **residual stenosis**, representing a technical failure rather than a true recurrence. **Early restenosis** (typically within 3–18 months) is generally attributed to neointimal hyperplasia, while **late restenosis** (18–60 months post-op) is usually due to progressive atherosclerosis.

As illustrated in the Kaplan–Meier curves below, the highest risk period for restenosis is during the early phase. Residual stenosis is observed in 4–6% of cases, early restenosis in 7–11%, and late restenosis in 2–5%. (Moore, 1998)






## Figures 1–3:

Kaplan–Meier curves showing the proportion of patients free from new stenosis over time. Y-axis = number of days.

## Study Objective:

The objective of this study is to assess the true incidence of restenosis following CEA in the Czech Republic. A major advantage of this study is the use of standardized surgical procedures across participating centers, along with unified data collection methods and diagnostic algorithms.

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## Methodology:

### *Patient Cohort:*

All patients meeting the current guideline indications for CEA will be enrolled.
**Exclusion criteria** include:

- Age ≤18 or ≥90 years
- Previous endarterectomy or stenting
- Unsuitable vascular anatomy
- High perioperative risk
- Contralateral cranial nerve X or XII palsy
- History of neck irradiation
- Tandem carotid stenosis or intracranial vascular pathology (e.g., aneurysm or AVM)

- Absence of signed informed consent

**Collected data will include:**

- Epidemiologic risk factors: age, sex, diabetes, hypertension, dyslipidemia, metabolic syndrome, renal insufficiency, smoking, physical activity, weight, comorbidities
- Laboratory markers: LDL, HDL, cholesterol, lipoprotein A, triglycerides, CKD-EPI, sedimentation rate, fibrinogen, INR (Quick test), APTT

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## Diagnostics:

All patients will undergo non-contrast brain CT. Carotid stenosis will be assessed by CT angiography performed within 3 months prior to surgery. In addition to stenosis severity, the degree of calcification will be classified as:

- No calcification
- Minimal
- Partially calcified
- Pronounced
- Severe/unable to evaluate

Other vascular pathology will also be recorded. Follow-up imaging will be performed at 1 month, 1 year, and 3 years postoperatively. CT findings will be assessed by two independent reviewers.

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## Surgical Technique:

All patients will receive mono- or dual antiplatelet therapy, and 5,000 IU of heparin will be administered intraoperatively. Surgery may be performed under general anesthesia with electrophysiological monitoring or under local anesthesia, based on the surgeon’s preference.

A longitudinal incision will be made anterior to the sternocleidomastoid muscle. The common carotid artery and its branches will be dissected and clamped. The internal carotid artery will be clamped distal to the most significant stenosis, as identified on preoperative CTA. The surgeon will incise through the tunica adventitia and media to expose and excise the atherosclerotic plaque. Any residual fragments will be removed, and the arterial wall will be closed using 6/0 suture.

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## Follow-Up:

Patients will continue on mono- or dual antiplatelet therapy. Mandatory follow-up CT angiography will be performed at 30 days, 1 year, and 3 years. During follow-up, the following will be evaluated:

- CTA findings
- Overall patient condition
- Incidence of ischemic stroke (iCMP), TIA, myocardial infarction, and death

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## Outcomes:

**Primary Outcome:**

- Restenosis ≥50% at 12 months

**Secondary Outcomes:**

- Residual stenosis ≥50% at 30 days
- iCMP/TIA/death/MI
- Change in modified Rankin Scale (mRS)

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## Timeline:

All participating centers (ÚVN, ČB, ÚNL, Poruba, Plzeň, Liberec, Vinohrady, Zlín, Olomouc, Hradec Králové, Fifejdy) together treat approximately 600–700 patients annually.
An estimated 350 patients will be enrolled within 6 months.
By the end of 2025, 300 patients will be included (expected dropout: 50).
This will allow evaluation of:

- Secondary outcomes in all 300 patients
- Primary outcome in approximately 8 out of 26 centers (those with complete 12-month data)

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## Ethical Approval:

All participating centers have received approval from their respective institutional ethics committees.

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## Funding:

This study is conducted **without external financial support**.