# Appendix B.2. Comparative studies extraction form.

| | | | | | |
|---|---|---|---|---|---|
| **Author, Year** | | **Study Name** | | **Intervention 1** | |
| **PMID*** | | **RefID** | | **Intervention 2** | |
| **Key Question(s)** | | | | **Intervention 3** | |
| **Design †** | | | | **Control** | |
| **Extractor** | | | | **Comments** | |

* or Cochrane number

† RCT; Randomized; NRCS, prospective; NRCS, retrospective; Cohort, prospective; Cohort, retrospective

**B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Inclusion** | **Exclusion** | **Eligibility criteria same for both arms? (describe differences)** | **Was risk for CEA determined by study? (Y/N/nd/NA)** | **High Risk for CEA? (Y/N/nd/NA)** | **Angiographic/ Medical / Neurologic high risk?** | **Definition of asymptomatic disease*** | **Description of the diagnostic modality#** | **Enrollment Years** | **Multicenter?** | **Country** |
| | | | | | | | | | | |
| | | | | | | | | | | |
| **Funding source** | **Certification of Surgeons** | **Certification of Interventionists** | **High volume center (y/n/nd/NA)** | Comments | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

***** Describe 1) % stenosis 2) how stenosis was diagnosed (imaging modality, measurement method NASCET - ECST) 3) Whether patients were stroke free or not (if not, what was the duration since stroke)

# Describe: ICAVL lab, central reading of imaging, 1 or multiple readers, prevalidated Ultrasound lab, reported diagnostic accuracy, confirmatory imaging technique (CTA, MRA, angiography)

**C. DESCRIPTION OF INTERVENTIONS (per study protocol)**

| CEA | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Selective shunt? | Patch? | Eversion CEA? | Conc Medical Tx before | Conc Medical Tx during | General Anesthesia? | Conc Medical Tx after | Continuation of medical Tx for >30 days? | Any Anti-PLT (Y/N) | Dual Anti-PLT (Y/N) | Comments |
| | | | | | | | | | | |
| **CAS** | | | | | | | | | | |
| Commercial Name | Stent Description (Material, Covered vs noncovered?, Drug-eluting?, Diameter?, Length?) | Embolic-Protection Device Y/N (Commercial Name) | Conc Medical Tx before | Conc Medical Tx during | | Conc Medical Tx after | Continuation of medical Tx for >30 days? | Any Anti-PLT (Y/N) | Dual Anti-PLT (Y/N) | Comments |
| | | | | | | | | | | |
| **Medical Tx** | | | | | | | | | | |
| Anti-PLTs | Dual Anti-PLT | Statins (or other LLT) | Anti-HT | Anti-coagulants | Lifestyle modification | Smoking cessation | Exercise | Diet | Other | Comments |
| | | | | | | | | | | |

**D. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)**

| | Outcome Category* | Specific Outcome | Composite? | Primary outcome? | Definition of outcome (if needed) | FU duration | Baseline screening | FU screening, Timepoints | Assessment by Neurologist (Y/N?) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |
| 4 | | | | | | | | | |

* **peri-procedural** (<30 days from intervention); **efficacy** (>31 days from intervention), **other adverse event or complication** (>31 days from intervention or anytime in medical Tx arm)

Specific outcomes:

Composite outcomes: **(any stroke, MI, death: <30 days; ipsilateral stroke >31 days), (any stroke: <30 days; ipsilateral stroke >31 days), (any stroke, death: <30 days; ipsilateral stroke >31 days), (any adverse event:<30 days), (any stroke, MI, death: <30 days), (any stroke, death: <30 days), (vascular death, stroke, MI)**

Separate outcomes: **Major stroke, Major ipsilateral stroke, Major nonipsilateral stroke, Minor stroke, Minor ipsilateral stroke, Minor nonipsilateral stroke, Death, Cardiac Death, Neurological Death, Other cause of Death, Target vessel revascularization, MI, STEMI, Non-STEMI, Fatal MI, Cranial Nerve Palsy, Complications at the surgical site or the vascular access site, Hyperperfusion syndrome**

**Please add a footnote when an outcome is specifically defined (e.g. MI, major stroke, time-or tissue based TIA definition)**

**E. BASELINE CHARACTERISTICS:**

| Author Year Country PMID | Group | N enrolled (analyzed) | Male, % | Age, y | % age >80 y | HTN, % | AFib/AFlutter, % | % hyper-lipidemia | DM, % | Smokers, % (define) | % CAD | % PVD | % previous TIA | % previous CEA | %≥70% stenosis | % contralateral occlusion | % previous CAS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |

* Mean±SD. If median, SE, range, IQR, or other, specify these.

**F. RESULTS (dichotomized or categorical outcomes)** **If a value is calculated by us (not reported), highlight yellow**

***Leave an empty row between outcomes data***

| Author, Year Country PMID | Outcome | Tx | Cx | N_Tx | N_Cx | Follow-up (y) | n Event_Tx | n Event_Cx | Unadjusted (reported) | | | | | | Adjusted (reported) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Metric* | Result | LCL | UCL | SE | P btw | Result | LCL | UCL | SE | P btw | Adjusted for: |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |

* RR, OR, HR, RD

**G. RESULTS (other reporting)**

| Author, Year Country PMID | Outcome | | Intervention | Follow-up | Results |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**H. RESULTS FOR ANNUAL RATE OF EVENTS IN MEDICAL ARMS ONLY**

| Author, Year Country PMID | Outcome | Intervention | Follow-up in person-years (raw data) | Events (raw data) | Annual Rate as per Raw Data * | Follow-up in person-years (Kaplan Meier estimates) | Events (Kaplan Meier estimates) | Annual Rate as per Kaplan Meier estimates | Quality | Quality issues |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |

| Comments on Results | |
|---|---|

**I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE**

| Intervention | % Dropout | Reasons |
|---|---|---|
| | | |
| | | |

**SUBGROUPS:** Eg, Subgroups = male/female; age group (<50, 50-70, >70); ….

**J. SUBGROUP RESULTS (dichotomized or categorical outcomes)**

| Author, Year Country PMID | Subgroup | Outcome | Tx | Cx | N_Tx | N_Cx | Follow-up (y) | n Event_Tx | n Event_Cx | Unadjusted (reported) | | | | | | Adjusted (reported) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | Metric* | Result | LCL | UCL | SE | P btw | Result | LCL | UCL | SE | P btw | Adjusted for: |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |

* RR, OR, HR, RD

**K. ADVERSE EVENTS (Any)**

| Author, Year Country UI | Adverse Event | Follow-up | Intervention | Intervention | Intervention | Intervention |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |

**L. QUALITY (y/n/nd/NA)**

| RCT (y/n) | Appropriate Randomization Technique (y/n/nd/NA) By symptoms? | Allocation Concealment (y/n/nd/NA) | Dropout Rate <20% (y/n) | Blinded Patient (y/n/nd) | Blinded Outcome Assessment (y/n/nd) | Intention to Treat Analysis (y/n/nd) | Appropriate Statistical Analysis (y/n) | If Multicenter, Was this accounted for in analysis? (y/n/NA) | Were Potential Confounders Properly Accounted For? (y/n/nd/NA) | Clear Reporting with No Discrepancies (y/n) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |

| | Were Eligibility Criteria Clear? (y/n) | Was Selection Bias Likely (if yes, explain below)? (y/n) | Were Interventions Adequately Described? (y/n) | Were the Outcomes Fully Defined? (y/n) | Did the Analyses Account for Compliance? (y/n/NA) | Any cross-over before start of intervention? | Any cross-over during intervention? | Training/certification well outlined | Baseline imbalance between groups | Device/surgical modifications? |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |

| | |
|---|---|
| **Reasons for drop-outs:** | |
| **Other Issues:** | |
| **Overall Quality (A, B, C)** | ? |

*nonrandomized cannot be A, retrospective study is always C

**M. SPECIFIC COMMENTS CONCERNING THE STUDY**

| Comments |
|---|
| |

**N. Summary Table (Intervention _____ vs. Control ____)**

| Author, Year Country PMID | Total (n) | Intervention (n) | Control (n) | Age (y) | male (%) | CAD (%) | DM (%) | %≥70% stenosis | Followup (y) | Outcome | Metric* | Result | 95% CI | P btw | Study quality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

**Table O. Conditions potentially associated with increased risk for periprocedural adverse events from CEA**

| Condition | Type of Condition |
|---|---|
| Contralateral occlusion | Angiographic |
| Contralateral stenosis >50percent | Angiographic |
| Stenosis of ipsilateral internal carotid siphon | Angiographic |
| Previous CEA with recurrent stenosis | Angiographic |
| Prior radiation treatment to the neck | Angiographic |
| Bifurcation of carotid artery at the level of C2 in conjunction with short neck | Angiographic |
| Atrial fibrillation | Medical |
| Age >80 years old | Medical |
| Left ventricular ejection fraction<30 percent | Medical |
| Unstable angina | Medical |
| Recent MI | Medical |
| Severe obesity | Medical |
| Emergency CEA | Neurologic |
| Preoperative ipsilateral stroke | Neurologic |
| Stroke as an indication for CEA | Neurologic |
| Crescendo transient ischemic attack /stroke | Neurologic |
| Cerebral events *versus* ocular events | Neurologic |
| History of transient ischemic attack /stroke in the prior 6 months (contralaterally) | Neurologic |