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CEA Cool, Cooling during Carotid EndArterectomy: a pilot study

Candela S¹, Casolla B¹, Dito R², Persiani F², Citoni G², Silvestri E³, Battocchio C², Brancadoro D³, Taurino M², Orzi F¹

- 1. NESMOS (Neurosciences Mental Health and Sensory Organs) Department, School of Medicine and Psychology, "Sapienza" University, Neurology Unit, "Sant'Andrea" Hospital, Via di Grottarossa 1035-1039, 00189, Rome, Italy
- 2. Surgical anesthetic sciences Department, School of Medicine and Psychology, "Sapienza" University, "Sant'Andrea" Hospital, Via di Grottarossa 1035-1039, 00189, Rome, Italy
- 3. Cardiothoracic vascular sciences Department, School of Medicine and Psychology, "Sapienza" University, "Sant'Andrea" Hospital, Via di Grottarossa 1035-1039, 00189, Rome, Italy

BACKGROUND

Carotid Endarterectomy (CEA) is of proven benefit in stroke prevention, but the procedure carries a perioperative risk of stroke. Mild hypothermia (34-35°C) is probably the most effective approach to protect the brain from ischemic insult (1). It is therefore a substantial hypothesis that the hypothermia lowers the risk of ischemic brain damage potentially associated with CEA.

OBJECTIVE

Purpose of our study is to test whether systemic cooling, to a target of 34,5-35°C, initiated before and maintained during CEA, is feasible and safe.



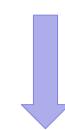
Fig. 1
QUATTRO®
Intravascular Heat
Exchange Catheter
Kit with central
venous infusion
capabilities, 3
lumens. Femoral
vein insertion only.

METHODS

Inclusion criteria: patients referred to the Vascular Surgery Unit and judged eligible for CEA



<u>Before and within 30 days from CEA</u>: brain Magnetic Resonance Imaging (MRI), with Diffusion Weighted (DWI) and Gradient Echo (GRE) sequences; general cognitive function (Montreal Cognitive Assessment), neurological assessment (NIHSS score, mRS)

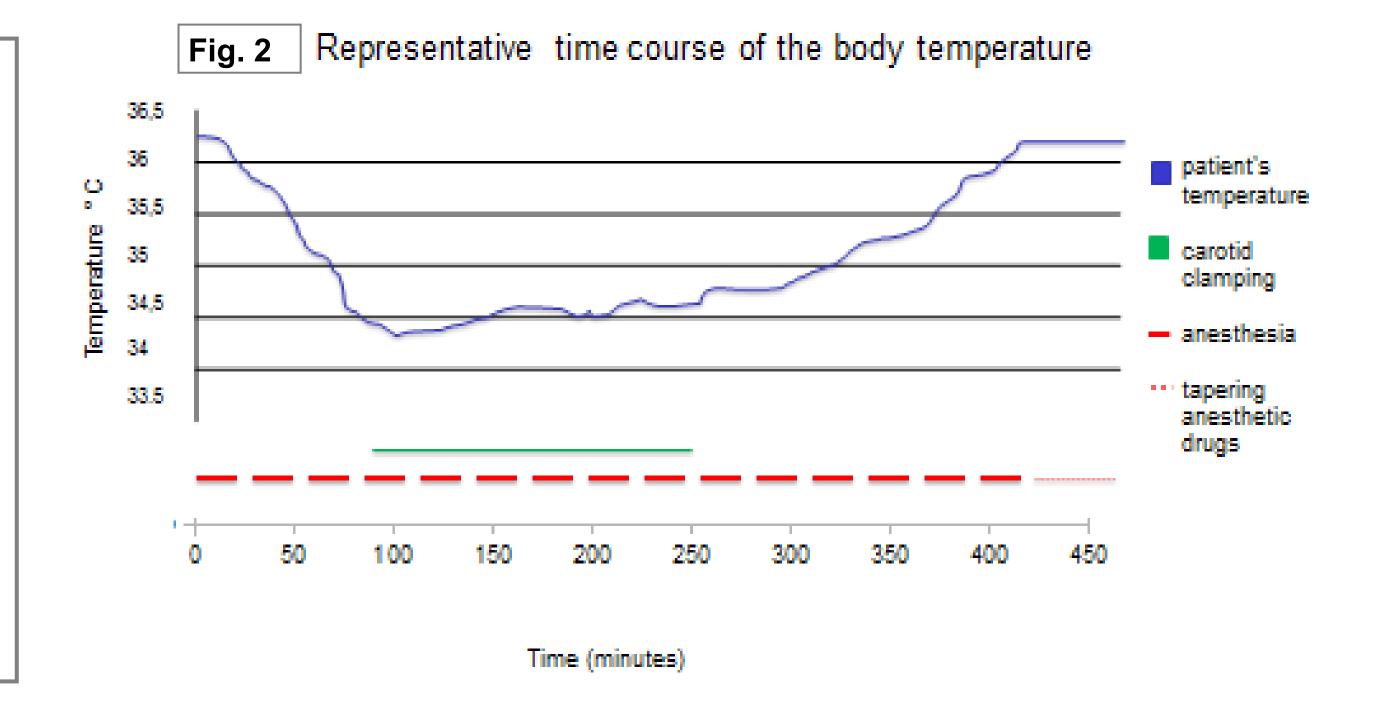


<u>Treatment</u>: Hypothermia was initiated just before the beginning of CEA, by endovascular cooling (Zoll system, Fig. 1), to the target 34,5-35°C (assessed by urinary bladder temperature). The target temperature was maintained until the release of clamping, followed by passive, controlled rewarming (0.4 °C/h) (Fig. 2 shows a representative graphic). The cooling procedure was carried out under general anesthesia, as required by the surgical intervention

OUTCOME

Primary safety outcome was the incidence of severe adverse events at 1 month. Severe adverse events were defined as any life-threatening event, including pneumonia, myocardial infarction and parenchymal hemorrhage.

Secondary safety outcomes of interest included the incidence of bradycardia (<40 beats per minute), cardiac arrhytmia, hypertension, hypotension and any coagulation disorders.



RESULTS AND CONCLUSIONS

All the 7 patients enrolled had **no adverse events**, **except for two cases of bradycardia** during hypothermia, successfully treated with atropine and dopamine. Pre- and post-CEA MRI showed no difference in terms of new areas of altered signal. Neurological status assessment remained unchanged before and after CEA. Our results show that systemic cooling to a target temperature of 34-35°C, initiated before, and maintained during CEA, is feasible and safe. Mild hypothermia could be an effective and widely available method for prevention of perioperative risk of stroke during CEA.