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Carbon Dioxide Stent Flushing To Prevent Cerebral Air Microembolism During Carotid Artery Stenting: Protocol for a Randomised Study.

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Objective: Carotid artery stenting (CAS) has been shown to protect patients from future stroke with long term efficacy comparable with that of carotid endarterectomy (CEA). However, differences in outcome following CAS and CEA still exist, consisting primarily of a higher rate of neurological events occurring in the peri-procedural period after CAS, caused by embolisation from aortic arch manipulation, plaque debris, and probably air embolism, the latter reported in literature after thoracic endovascular aortic repair, due to air trap in the thoracic endograft flushed only by saline solution. The present authors suppose that the same mechanism could be responsible for air microembolisation during CAS, and micro-embolisation has been documented as a cause of neurocognitive decline. New generations of dual layer mesh covered carotid stent systems increase plaque coverage with a reduction of debris, but their design also increases the risk of more air being trapped in the stent shaft because of multiple components, thus increasing the risk of air brain embolism. The present authors present the protocol for a study assessing effectiveness of a new technique for reducing air microembolism during CAS. After an *in vitro* pipeline test of a c-guard stent, saline solution washing and deployment demonstrating little bubble air release, the effectiveness of CO_2 flushing of the stent to prevent air microembolism after CAS will be investigated. Diagnostic and clinical outcomes will be analysed.
Methods: In two university referral teaching hospitals, consecutive patients (divided into two groups) affected by asymptomatic carotid stenosis $\geq$ 70% and enrolled for CAS will be submitted to pre-operative diffusion-weighted magnetic resonance imaging (DW-MRI) scan, to exclude the presence of pre-operative silent cerebral lesions. Patients will be randomised to CAS using c-guard stent with or without CO_2 flushing using a computer generated random allocation sequence with a blocked randomisation by an allocation ratio 1:1. A transfemoral approach through an 8 fr. arterial sheath will be established, and an initial intravenous heparin bolus will be administered, followed by a continuous intra-arterial infusion of heparinised saline solution through the guiding catheter/re-inforced sheath in a closed flushing system to avoid external air bubble introduction. A distal cerebral protection by filter wire will be used in all patients. The c-guard stent flushing will be done according to the instructions for use with saline solution for the control group, preceded by medical CO_2 flushing for the study group. DW-MRI will be performed within 24 hours after the intervention. Moreover, pre- and post-operative Mini-Mental-State-Examination Tests (MMSE) will be conducted, as well as serum S100β neurobiomarker assessment.
Results: The primary endpoint of the study will be the evaluation of technical and clinical success of CAS with or without CO_2 stent flushing peri-operatively, at 24 hours, 30 days, and at one and two years. The following secondary endpoints will also be assessed: operative time, radiation exposure and contrast medium use, post-operative DW-MRI new lesions, neurobiomarkers, and MMSE variation within 24 hours. After that at 30 days, one and two years, an MMSE test will be evaluated. Sample size estimation is 80 patients (40 patients per each group). The study will start in June 2022 and the final patient is expected to be treated by June 2023. The estimated study completion date should be June 2025.
Conclusion: This study will aim to show, in real world practice, the effectiveness of CO_2 stent flushing to prevent cerebral embolism during CAS, and its effectiveness in neurocognitive decline prevention.

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Abstract O-109

Lower Limb Angioplasty Training Using a Virtual Reality Simulator: Experience at the Largest School Hospital in Latin America

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Objective: Vascular surgery is a low volume/high complexity specialty, where rigorous training and assessment of technical skills is vital. Therefore, the traditional apprenticeship model may not be valid in modern practice. During the COVID-19 pandemic, there was concern among surgical educators that residents are not prepared to practice independently the full spectrum of vascular surgery; as an important reduction in the number of surgeries was expected. This study aimed to assess skill acquisition and operative competency of the vascular surgery residents analysing their performance on iliac and infra-inguinal angioplasties on a virtual reality simulator.
Methods: This was a prospective, controlled, single centred study. During three consecutive years (2018 — 2020), residents in their final year of vascular residency at Hospital das Clínicas FMUSP were enrolled. The residents of 2018 (Control Group) performed their residency according to the routine of the present authors' institution, which is mainly the traditional apprenticeship model, and their surgical performance on iliac and infra-inguinal angioplasty was evaluated at the end of their residency using