Randomized Control Study of the IntraVascular UltraSound vs. catheter angiography for the evaluation and treatment of carotid artery stenoses.

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Primary endpoint was to evaluate the real time ability of IVUS to identify any technical difficulties or complications during stenting and improve outcomes and patency rates.
Methods and Materials

Patients
A randomized prospective evaluation was performed on 60 Patients who underwent CAS during a 14-month period. The institutional review board at our institution gave full approval and waiver of informed consent for our study and approved our treatment protocol. Written informed consent was obtained from each Patient prior to intervention.

Patient population
We performed IVUS-assisted CAS in 30 Patients (50%) and only-angiography assisted CAS in 30 Patient (50%).

The patient cohort was predominately male (N=42) with mean age of 68±1.4 years old (range from 56 to 82 y.o.). Thirty-eight patients were diabetic (63%), 51 had hypertension (85%) and 27 presented dyslipidemia (45%). Twenty-three patients (38%) presented two or more risks factors. Symptomatic ICA stenosis were present in 15 Patients (25%) (2 amaurosis fugax, 12 transient ischemic attack, and 1 controlateral stroke).

All patients were selected using Duplex Ultrasound evaluation as primary diagnostic tool. Fifty-four patients (90 %) were evaluated by pre-procedural Magnetic Resonance Angiography (MRA) integrated with HR-MR for plaque characterization; 6 (10 %) Patients underwent Computed Tomography Angiography (CTA) for MR contraindications.

Patients presenting stenoses higher than 85% were excluded from the study, to avoid significant blood flow reduction to the brain during the IVUS catheter passage, particularly in bilateral carotid pathology.

Data about total procedure time, fluoroscopy time and success rate have been collected for all the 60 patients treated.

All Patients underwent a 5-day anti-aggregation therapy with ASA (100 mg / day) and clopidogrel (75 mg / day) or Ticlopidin (500 mg/die) before the procedure.

CAS procedure
All procedures were carried out in an angiographic suite and performed by the same interventional radiologist. Procedural and fluoroscopy times have been measured starting from the first successful arterial puncture to the sheath removal moment. Common femoral artery access was obtained using Seldinger technique and guide catheter access into the common carotid artery was obtained using a 7-Fr 10 cm-long introducer sheath (Terumo, Tokyo, Japan). A diagnostic angiography was performed in order to confirm the carotid plaque location, stenosis degree and to evaluate intracranial vessels anatomy and patency.

5000 IU of heparin were administered intravenously to maintain the Active Coagulation Time (ACT) between 200 and 250 seconds. Distal embolism prevention was carried out using a cerebral protection device during both IVUS guided and angio-alone procedures. The Gray-Scale IVUS and VH-IVUS evaluations were performed using a 20-MHz IVUS probe (Eagle Eye, Volcano Therapeutics, Rancho Cordova, CA). The IVUS catheter
was washed with saline solution prior to its use and, once catheterized the internal carotid artery with the guide catheter, was introduced. After optimization of the gain, the IVUS catheter was retrieved from the distal segment of the internal carotid artery at a speed of 1.0 mm/sec using a motorized pull-back device. A 360° rotational and two dimensional longitudinal ultrasound was performed to assess plaque composition and stenosis degree, and the examination was recorded on a DVD. This evaluation was also performed after stent deployment to assess wall integrity, stent-wall apposition and stent expansion.

Stent type and size were chosen in all cases on the basis of pre-procedural MRA or CTA findings. IVUS findings were evaluated in order to confirm or disprove the pre-procedural stent choice.

The analysis of the histological composition of the atherosclerotic plaque, Virtual Histology (VH-IVUS) was used for the assessment of the plaque ultrastructure, and for an appropriate stent type choice.

After stent deployment and retrieval of the cerebral protection device, a diagnostic angiography was performed to evaluate extra and intra-cranial vessels patency and blood flow.

Patients underwent post-procedural neurological evaluation and were discharged one day after the treatment, with 6 weeks double anti-aggregation therapy.

Technical success was defined as residual stenosis degree lower than 30%.

**Follow up**

Neurological status and blood pressure of every patient were monitored for at least 24 hours, with a Duplex US examination before the discharge.

Follow-up was performed at 1, 3, 6 months and each year after the procedure by Duplex US evaluation.

Mean follow up period was 23 month (minimum 15 - maximum 28). A lifelong antiplatelet therapy was administered to each patient while clopidogrel or ticlopidin were administered for 6 weeks.
Fig. 1: (A) Post procedural IVUS Grey Scale showed a suboptimal stent expansion (B) A stent further dilatation was performed, with good final result in IVUS scan.

Fig. 2: IVUS imaging shows (A) an high lipid plaque at the origin of the internal carotid artery and (B) the following stent deployment. (B) An intraluminal lesion was identified at
the distal end of the stent with a substantially hypoechoic ultrasound pattern at IVUS Grey Scale, corresponding to ruptured plaque material protrusion through stent cells caused by plaque squeezing.

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**Fig. 3:** Carotid plaque debris showed in figure 2, removed by local manual aspiration using a 6 Fr 90 cm long guide catheter.

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Results

Technical success was achieved in all patients. In 2 patients (3 %) an angioplasty to improve stent wall apposition was required; in this group we didn't observe significant differences in terms of patency rate. A peri-procedural self-resolving transient ischemic attack was observed in one patient (1.6%), which underwent VH-IVUS assisted procedure.

At 14 months follow up, 3 (5%) significant restenoses, which required a secondary angioplasty, were observed; two cases (3%) were observed in the angiography-guided-only group and one case in the IVUS-assisted group.

The VH-IVUS evaluation led to a stent type change in 3 cases (5 %): 2 close-to-open cell, 1 open-to-hybrid cell. However no stent size and/or length changes were required after VH-IVUS plaque evaluation.

An incomplete vessel wall-stent apposition, which was not evident with fluoroscopy, was identified in IVUS group, and treated by angioplasty (Fig. 1).

In one Patient, during after stenting VH-IVUS evaluation, intraluminal lesion at the distal third of the stent was observed. This lesion presented ultrasonographic characteristics suggestive for ruptured plaque material protrusion through stent cells, caused by plaque squeezing, such as a substantially hypoechoic ultrasound pattern at Grey Scale (Fig. 2). It was decided to perform a thrombo-aspiration with a 6 Fr 90 cm long guide catheter (Mach 1™ Guide Catheter, Boston Scientific Corporation, Natick, United States).

A subsequent Grey-scale IVUS scan was performed and showed absence of the lesion. The distal protection device was retrieved, demonstrating fragments of embolic plaque material (Fig. 3). The patient was transferred to the Stroke Unit, remaining in stable neurological condition after the procedure and was subsequently discharged to home after three days after the procedure.

Mean procedure time was longer in VH-IVUS guided procedures (IVUS group procedure lengthened of 7 ± 2.1 minutes).
Conclusion

In summary, this study confirmed the usefulness of IVUS evaluation in "real time" examination of the carotid plaque during endovascular treatment for the choice of the appropriate stent type, reduction of contrast media amount injection and reduction of embolic and restenosis complication rate. Though not recommendable as a routine evaluation, we believe that IVUS may result more useful for challenging plaques such as "soft" or inflamed ones, or whenever an intra-procedural morphologic evaluation is required.
References
