Calcification in Carotid Artery Stenting

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Disclosures

- **Consultant/Scientific Advisory Board:** Access Vascular; Angiodynamics; Contego; Philips; Boston Scientific; Surmodics; Janssen; Neptune Medical; Magneto; Mayo Clinic; BMS-Pfizer; Summa Therapeutics; Thrombolex

- **Grants:** NIH; Boston Scientific; Intact Vascular

- **Equity:** Accolade; Access Vascular; Capture Vascular; Contego; Cruzar Systems; Embolitech; Endospan; Eximo; JanaCare; Magneto; Micell; Orchestra; PQ Bypass; Shockwave Medical; Summa Therapeutics; Thrombolex; Valcare

- **Board Member:**
  - National PERT Consortium™, a not for profit 501c3 organization dedicated to advancing treatment and improving outcomes in Pulmonary Embolism
Keys to successful CAS

• Proper training and experience
• Proper case selection
  • Good patient substrate and favorable carotid anatomy
  • Avoid questionable cases
• Complete preparation (pre-load DAPT/Statin; procedural meds/equipment ready; pre-hydration)
• Meticulous technique
• Avoid overdilation/high pressure
• Anticipate potential complications (access issues, vasodepressor response)
• Follow protocols and “Leave ego at the door”
Clinical factors that Potentially Increase Risk for CAS

- Patient substrate
  - Symptomatic
  - Older age
  - Frail/poor reserve
- Co-Morbidities
  - Cardiac (Active ischemia or CHF)
  - Chronic kidney disease
Anatomical Factors that can Increase Risk for CAS

• Complex aortic arch
• Friable plaque
• Visible thrombus
• Ulceration
• Ostial disease
• Tandem/long lesions
• Vessel tortuosity/severe angulation
• Intracranial disease

• Extreme Calcification
  • Exophytic
  • Concentric
Heavy calcification
Early reports: “CAS is feasible in Calcified Lesions...even with near-total circumferential calcification”

Carotid Artery Stenting for Calcified Lesions

**BACKGROUND AND PURPOSE:** Our aim was to assess the feasibility of carotid artery stent placement (CAS) for calcified lesions.

**MATERIALS AND METHODS:** Using embolic protection devices (EPDs), we performed 51 CAS procedures in 43 patients with severe carotid artery stenosis accompanied by plaque calcification. Before intervention, all lesions were subjected to multidetector-row CT. The arc of the circumferential plaque calcification was measured on axial source images at the site of maximal luminal stenosis, and the total volume of the plaque calcification was determined. The angiographic outcome immediately after CAS, and intra- and postoperative complications were recorded.

**RESULTS:** The mean arc of calcification was 201.1 ± 72.3° (range, 76–352°), and the mean of the total calcification volume was 154.9 ± 35.4 mm³ (range, 92–2680 mm³). Balloon rupture occurred in 1 procedure (2.0%) at predilation angioplasty; all 51 CAS procedures were successful without clinical adverse effects. Although there was a correlation between the arc of plaque calcification and residual stenosis ($r = 0.6, P < .001$), excellent dilation with residual stenosis $\leq 30\%$ was achieved in all lesions. There was no correlation between the total volume of calcification and residual stenosis. None of the patients developed stroke or death within 30 days of the CAS procedure.

**CONCLUSION:** CAS by using EPDs to treat lesions with plaque calcification is feasible even in patients with near-total circumferential plaque calcification.

1590 Tsutsumi | AJNR 29 | Sep 2008 | www.ajnr.org
Early reports:
"Excellent stent expansion possible through disruption and fragmentation of Ca++ plaque"
Proximal calcification - associated with higher stroke rate...just below mobile plaque ("jellyfish sign")
Conclusion:
Ca++ plaque (both concentric and eccentric) → more prolonged hemodynamic instability (vasodepressor response)
“Carotid stenosis with high calcium score → less stent expansion compared to those with low calcium score, suggesting that CEA may be recommended...”
Challenges and Pitfalls of CAS with Severe Carotid Calcification

- Lesion assessment $\rightarrow$ more challenging
- Resistance to dilation $\rightarrow$ Requirement for higher pressure
- “Non-dilatable”
- Underexpansion / Non-uniform stent apposition / Recoil $\rightarrow$ all more likely
- Eccentric plaque protrusion between struts
- Embolization potential greater $\rightarrow$ shearing off calcific fragments
- Accentuated Carotid vaso-depressor response
- Marker for Arch pathology/complexity and calcification $\rightarrow$ more challenging vessel canulation and higher embolization risk

EXTREME CALCIFICATION (esp. thick concentric) $\rightarrow$ HIGHER COMPLICATION RATE!!!

CEA is currently the preferred for these patients!
What is best for the patient?

Gary Roubin’s first randomized case in CREST 2 Trial … recruited into the CEA vs CAS arm because of excessive calcification.
A tale of two carotids…making the right decision
Potential Opportunities to Mitigate Severe Carotid Artery Calcification

- Better cerebral protection
  - TCAR and TFCAS (e.g. Paladin)
- Calcium modification
  - IntraVascular Lithotripsy (IVL)
- Plaque trapping
  - Novel covered stents (e.g. C-Guard)
First device that combines an embolic protection filter and balloon/stent

- 40 micron pore size allows micro-embolic capture
- Filter size can be adjusted to suit patient’s unique anatomy
• 77 year old female with right sided amaurosis fugax
• PMH: HTN, HL, CAD (prior CABG), CHF (HFPEF), COPD, extensive PAD
• Carotid DUS: severe bilateral CAS
• CTA: Severe Ca++
Non-Dilatable lesion!

- Baseline
- 3.5 x 20 NC Balloon Waist @20 ATM
- Residual stenosis at non-dilatable segment of ICA
S4 4.0 x 40mm IVL Balloon
IVL (4 x 20 pulses)

Waist relieved/better appearance after IVL

Post-stent

• Nav 6 “empty”
• Clinical course unremarkable
  • No neuro sx’s
  • No hemodynamic instability

Final post IVL and stent
Intravascular Lithotripsy for Treatment of Calcified Lesions During Carotid Artery Stenting

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Abstract

Purpose: To report the use of intravascular lithotripsy (IVL) in the treatment of calcified carotid artery lesions. Materials and Methods: The records of 21 high-surgical-risk patients (mean age 75.1 ± 8.1 years; 17 men) who were treated at 8 centers for carotid artery stenosis ≥ 70% were retrospectively reviewed. Twelve patients had a history of cerebrovascular disease. All patients had heavily calcified carotid artery lesions: 19 de novo and 2 in-stent restenoses (ISR). The mean baseline stenosis was 82.3% ± 9.7%. IVL was utilized at the discretion of the operator, followed by balloon angioplasty. Embolic protection devices were used in all cases. Results: In 19 patients, IVL was followed by stent implantation; the 2 ISR lesions were dilated only. The mean IVL balloon diameter was 4.64 ± 1.13 mm, and the mean number of IVL pulses applied was 67.2 ± 61.4 (range 10–180). All procedures were technically successful (1 ≤ 30% residual stenosis). No patients developed symptomatic bradycardia or hypertension due to IVL, and there were no adverse events associated with IVL delivery. All patients were discharged on dual antiplatelet therapy. Seventeen days after the procedure, 1 patient experienced an ischemic stroke that was deemed due to arterial manipulation during transcranial access. Carotid duplex ultrasound examination identified significant restenosis (>70%) in 1 asymptomatic patient at 12 months after the index procedure. No patients required reintervention during a median follow-up of 6 months (range 1–12). Conclusion: This preliminary experience demonstrates that IVL can be a safe and effective approach for the management of severely calcified carotid lesions. Further research is warranted to determine the longer-term safety and efficacy of IVL for dilation of calcified carotid artery lesions as an adjunct to carotid artery stenting.

Keywords

arterial calcification, balloon angioplasty, carotid artery disease, carotid artery stenting, endovascular treatment/therapy, in-stent restenosis, intravascular lithotripsy

Introduction

Despite advances in balloon angioplasty technique, calcified lesions remain a challenge for endovascular procedures and are associated with increased overall morbidity and mortality. Experience in several vascular areas has shown that calcification of the target lesion is one of the most widely encountered predictors of technical failure and restenosis. The technology of intravascular lithotripsy (IVL) provides selective fracturing of intimal and medial calcium deposits in the arterial wall of affected arteries without harming surrounding normal soft tissues. As such, IVL has a minimal risk of dissection or embolization and improved compliance and improves acute lumen gain after balloon angioplasty with/without stent implantation. To date, peripheral IVL has been used for the treatment of lesions in the iliac, femoropopliteal, and infrapopliteal arteries, while experience in the carotid arteries is relatively new, although the risk for distal embolization has been considered minimal.

Ballon angioplasty with stenting for the treatment of calcified carotid artery stenosis has been associated with several procedural complications, including not limited to stent mispositioning, stent underexpansion, increased risk for dissection, and higher risk for residual stenosis/recall, which eventually may lead to suboptimal angioplasty created from ultrasonic energy. Calcium disruption increases vessel compliance and improves acute lumen gain after balloon angioplasty with/without stent implantation. To date, peripheral IVL has been used for the treatment of lesions in the iliac, femoropopliteal, and infrapopliteal arteries, while experience in the carotid arteries is relatively new, although the risk for distal embolization has been considered minimal.

Adverse Events

None

1 ischemic stroke at 17d*, 1 asymptomatic restenosis (>70%) at 12 months
Mesh Covered Stent with MicroNet™ Technology

INSPIRE MD
Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

DW-MRI analysis @ 48 hours

new ipsilateral lesions (mL)

0.6

0.5

0.4

0.3

0.2

0.1

CGuard

p < 0.005

0.04

n=27

Conventional Carotid stent (hybrid)

0.59

n=31

see patient fluxogram
J. Schofer, P. Musialek et al. JACC Intv. 2015; 8:1229-34
Bijuklic et al. (manuscript in preparation)
Conclusions

- Extreme/concentric Calcification increases risk for CAS
- These patients should generally be sent for traditional open CEA
- New technologies (Paladin double protection; IVL plaque modification; coverage with C-Guard stent) have the potential to enable more safe and effective CAS for severely calcified lesions