

Submaximal Angioplasty Prospective Registry: Preliminary Report

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Introduction

Intracranial atherosclerotic disease (ICAD) accounts for approximately 10% of ischemic strokes. A recent prospective study (SAMMPRIS) displayed high perioperative complications (15%) for treatment of ICAD with stenting. Recurrent stroke was found in 12% of patients treated with aggressive medical management, suggesting intervention may remain a viable option if perioperative risk is minimized. Angioplasty without stenting represents an alternative and understudied revascularization treatment for ICAD. A submaximal angioplasty limits the risk of thromboembolism, vessel perforation, and reperfusion hemorrhage frequently reported with stenting in the SAMMPRIS trial.

Preliminary results of an ongoing prospective study are reported.

Methods

A phase 1 prospective study for treatment of symptomatic ICAD with submaximal angioplasty was designed and approved by the local institutional review board. Demographic, and clinical data were prospectively collected. Angioplasty was performed with a balloon undersized to approximately 50-70% of the nondiseased vessel diameter. Neurological status measured by NIHSS and modified Rankin score were collected on days 0, 4, 30, 90, and at one year. The primary outcome measure is incidence of perioperative complications (combined endpoint includes death, stroke, and hemorrhage). Secondary outcome measure is stroke free survival at 90 days and one year.

Angioplasty technique

Results

To date, 16 patients have been enrolled in this registry (81% men; mean age 63 years), with baseline mRS of 0 in 8 patients, 1 in 4 patients, and 2-3 in 2 patients. No intraoperative or perioperative complications were noted (**primary outcome 0% perioperative complications**). In follow-up 15 patients remain stroke-free, with a single mild delayed stroke the only event in follow-up (**secondary outcome 94% stroke free survival at 90 days**). 90-day follow-up was available for 14 patients. Among these patients, NIHSS and mRS was unchanged from baseline or improved in 9 patients and worsened in 3 patients by one point each.

Conclusions

We report interim analysis of a phase 1 prospective study to assess the safety of submaximal angioplasty for ICAD. **This study suggests** submaximal angioplasty for intracranial atherosclerosis is safe.

No perioperative complications have occurred to date in 16 patients. Long-term follow-up data at this point are limited to a single mild stroke in 2,588 person-days of follow-up. Updated material will be presented for the October conference.

Learning Objectives

By the end of this session, participants should be able to

- understand the importance of surgical treatment of intracranial atherosclerotic disease
- understand the difference between submaximal angioplasty and intracranial stenting and the inherent benefits of the latter over the former

References

• Fiorella D, Derdeyn CP, Lynn MJ, et al. Detailed analysis of periprocedural strokes in patients undergoing intracranial stenting in