Submaximal Angioplasty for Symptomatic Intracranial Atherosclerosis – A Prospective, Phase I Study

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Introduction

Intracranial-atherosclerotic-disease(ICAD) accounts for approximately 10% of ischemic-strokes. The recent SAMMPRIS study displayed a high incidence of perioperative complications(15%) for treatment of ICAD with stenting. Although the incidence of stroke was lower in the medical arm, recurrent-stroke was found in 12% of patients despite aggressive medical management, suggesting intervention may remain a viable option for ICAD if perioperative risk is minimized. Angioplasty without stenting represents an alternative and understudied revascularization treatment for ICAD. Submaximal-angioplasty limits the thromboembolism risk, vessel perforation, and reperfusion hemorrhage.We conducted a prospective phase-I-trial designed to assess the safety of submaximal-angioplasty in patients with symptomatic ICAD

Methods

This study was approved by the local-institutional-review-board. Demographic and clinical data were prospectively collected. Angioplasty was performed for patients with symptomatic-ICAD(significant-stenosis =70%) with a balloon undersized to approximately 50-70% of the nondiseased vessel-diameter. The primary outcome measure was the incidence of periprocedural complications(combined rate of death, stroke, and hemorrhage occurring within 30 days and at 1 year).

Learning Objectives

By the conclusion of this session, participants should be able to: 1) Describe the importance of treating symptomatic intracranial stenosis 2) Discuss, in small groups the efficacy and safety of the treatment 3) Identify an effective treatment of intracranial stenosis

Results

Among 65 patients screened with symptomatic-ICAD, 24 had significant angiographic-stenosis that met the inclusion criteria of this study. Mean-age was 64.08years(median 65 years;standard-deviation+11.24), most were men(62.5%),and most were white(66.67%). Many patients had vascular-disease concomitants, including hypertension(95.8%),hyperlipidemia(70.83%),smoking history(54.1%),and diabetes-mellitus(45.8%).Coronary artery-disease(37.33%) and previous-stroke or TIA(45.83%) were present frequently. Most patients(75%) had anterior-circulation-stenosis. The mean preprocedure stenosis was 80.16%(median 80%, range 70–95%). Successful angioplasty was performed in all patients, with a mean postangioplasty stenosis of 54.62%(median55.5%,range31–78%). Rates of ischemic-stroke in the territory of the treated artery were 0% within 30-days and 5.55%(in the only patient who presented with restenosis)at 1 year. The mortality and hemorrhage rate was 0%.

Conclusions

Submaximal-angioplasty for symptomatic intracranial-atherosclerotic-disease is a safe and effective technique. None of the patients had ischemic stroke in the first 30 days, and only 1 patient presented with symptomatic restenosis leading to ischemic stroke during 1 year of follow-up.

Table 1

TABLE 1. Demographics for Smoking, instead of Yes, please use current or former for consistency

CASE	AGE (Y), SEX	RACE	HTN	DM	HLD	SMOKING	CAD	PREVIOUS STROKE/TIA	PRESENTATION (CVA/TIA)
1	77, M	WHITE	YES	YES	YES	NEVER	YES	NO	TIA
2	70, M	WHITE	YES	NO	YES	NEVER	YES	NO	TIA
3	48, F	WHITE	NO	NO	NO	CURRENT	NO	NO	TIA
4	69, M	WHITE	YES	YES	NO	NEVER	NO	NO	CVA
5	64, M	BLACK	YES	NO	YES	CURRENT	YES	CVA	CVA
6	60, M	WHITE	YES	NO	NO	CURRENT	YES	NO	TIA
7	73, M	WHITE	YES	NO	NO	CURRENT	NO	NO	CVA
8	77, F	WHITE	YES	YES	YES	NEVER	YES	CVA	CVA
9	48, F	WHITE	YES	NO	YES	CURRENT	NO	TIA	TIA
10	59, M	BLACK	YES	YES	NO	NEVER	NO	TIA	CVA
11	44, M	WHITE	YES	YES	YES	CURRENT	NO	TIA	TIA
12	60, M	WHITE	YES	YES	YES	NEVER	NO	CVA	CVA
13	66, M	WHITE	YES	NO	YES	CURRENT	YES	NO	TIA
14	68, F	BLACK	YES	NO	YES	FORMER	NO	NO	CVA
15	76, F	OTHER	YES	NO	YES	NEVER	YES	NO	TIA
16	80, M	BLACK	YES	NO	YES	NEVER	NO	NO	CVA
17	77, F	WHITE	YES	YES	NO	CURRENT	NO	NO	TIA
18	74, M	WHITE	YES	YES	YES	FORMER	NO	CVA	CVA
19	53, M	WHITE	YES	NO	YES	CURRENT	NO	NO	CVA
20	55, M	BLACK	YES	YES	YES	NEVER	NO	NO	CVA
21	48, F	WHITE	YES	YES	NO	NEVER	NO	TIA	CVA
22	54, M	BLACK	YES	YES	YES	YES	YES	CVA	CVA
23	60, F	BLACK	YES	YES	YES	YES	YES	CVA	CVA
24	78,F	WHITE	YES	NO	YES	NEVER	YES	CVA	CVA

Abbreviations: CAD, coronary artery disease; CVA, cerebrovascular accident; DM, diabetes mellitus; HLD, hyperlipidemia; HTN, hypertension; TIA, transient ischemic attack; y, years

Demographics

TABLE 2. Procedures and Outcomes

Case	Time from presentation event to plasty (d)	Vessel	Pre-stenosis (%)	Post-stenosis (%)	Baseline NIHSS	30-day NIHSS	Baseline Barthel	30-day Barthel	Baseline mRS	30-day mRS	1 Yr. NIHSS or at last follow-up	1 Yr. BARTHEL or at last follow up	1 Yr. mRS or at last follow-up
1	1	L VA	74	47	0	0	100	100	0	0	0	100	0
2	2	basilar	70	60	0	0	100	100	0	1	0	100	0
3	8	R MCA	83	50	1	0	100	100	0	0	N/A	N/A	N/A
4	4	basilar	73	52	2	1	100	100	0	1	0	100	0
5	2	L MCA	76	42	1	0	100	100	1	0	0	100	0
6	2	R ICA	76	43	1	N/A	100	N/A	0	N/A	N/A	N/A	N/A
7	12	basilar	76	66	1	1	100	100	2	2	0	100	0
8	6	R ICA	86	60	1	1	95	95	3	3	0	100	0
9	1	L MCA	77	46	2	1	65	65	3	3	1	90	2
10	21	L MCA	84	69	1	1	80	80	3	3	0	100	0
11	1	R ICA	86	62	2	0	90	100	1	0	0	100	0
12	5	R MCA	83	43	3	4	85	70	2	3	3	80	2
13	1	L ICA	76	32	0	0	100	100	0	0	0	100	0
14	2	R ICA	81	61	4	2	80	95	3	3	0	100	1
15	5	R ICA	80	50	0	0	100	100	1	1	0	100	1
16	14	basilar	75	51	1	0	100	100	1	1	0	100	0
17	3	L VA	85	50	0	1	100	100	1	1	0	100	1
18	29	L ICA	73	59	0	0	100	100	0	0	0	100	0
19	1	L MCA	85	65	0	0	100	100	0	0	1	90	1
20	7	L MCA	91	78	5	4	70	95	2	3	2	100	1
21	3	L MCA	95	70	1	0	100	100	1	0	0 (90 d.)	100 (90 d)	0 (90 d)
22	2.0	R MCA	75	31	1	N/A	100	N/A	1	N/A	N/A(30 d)	N/A(30 d)	N/A(30 d)
23	7.0	R ICA	84	64	0	0	100	100	0	0	0 (30 d)	100(30 d)	0 (30 d)
24	13.0	L MCA	80	60	1	1	85	100	1	1	1 (30 d)	100 (30 d)	1 (30 d)

Abbreviations: d, day(s); ICA, internal carotid artery; L, left; mRS, modified Rankin Scale; MCA, middle cerebral artery; N/A, not available; NIHSS, National Institutes of Health Stroke Scale; R, right; VA, vertebral artery