Stroke Prevention and Intervention Update

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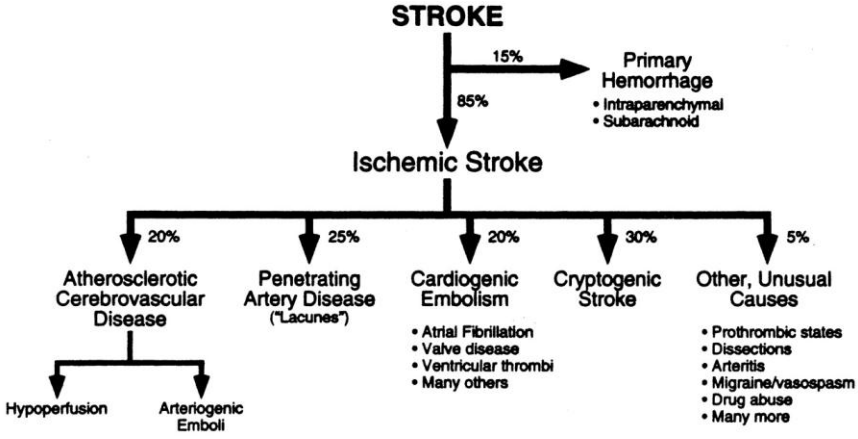
Disclosures

- None
- …But wish I could disclose that I own lots of Apple Stock

Overview

- Introduction
- Stroke Prevention: Optimizing Risk Factors
  - Hypertension
  - Hyperlipidemia
  - Diabetes
  - Antiplatelet Medications
  - Cardioembolic Etiologies
- Stroke Intervention
  - Carotid Stenosis
  - Intracranial Stenosis
  - Acute Stroke Therapies: IV tPA, Stentrievers
- Break Time

Classifications



NINDS Data Bank (1983-1986)

Epidemiology

- Stroke rates in the United States are relatively low compared to other countries
- Currently stroke rate in USA is 42 per 100,000 which is the third lowest in world.
- Worldwide, the median stroke mortality rate is 108 per 100,000 (double the United States)
- 780,000 strokes in USA/year, roughly 180,000/year die
- Total cost of stroke to be approximately $140,000–$200,000 per patient
- The estimated direct & indirect cost of stroke in US is $65.6 Billion

Risk Factor Control: Hypertension

- Hypertension is felt to be the most significant stroke risk factor
  - It is the most prevalent (25–40% of Gen pop)
- Primary Stroke Prevention:
  - British Regional Heart Study
    - SBP 160–180 = RR ~4, compared to SBP <160.
    - SBP >180 = RR ~6

McAllster et. al. New Evidence for Stroke Prevention. JAMA. 2002;288:1388–1395

Risk Factor Control: Hypertension

- After a Stroke:
  - Permissive Hypertension for approximately 1 week
- SCAST Trial:
  - 2029 patients after stroke (<30 hrs) randomized to receive ARB vs. placebo for 7 days
  - ARB group had lower blood pressures during that acute period
  - ARB group had worse functional outcome at 6 months, and had high risk for MI, Stroke or Death
- We typically have goal SBP<160 by discharge

SCAST Study Group, Lancet 2011

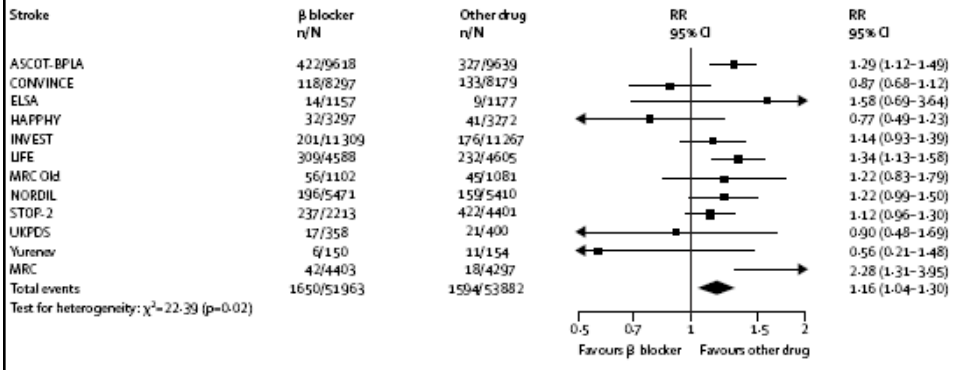
Risk Factor Control: Hypertension

- Secondary Prevention
  - Aggressive Blood Pressure control very important after acute period
- Overall treatment effect of anti-hypertensive medications:
  - Relative RR: 24%
  - Absolute RR 4-5%
  - Dose response: More BP control = decreased risk of recurrent stroke
- Goal SBP <140 except in Diabetics, goal SBP <130

Collns R, Peto R. et al, Lancet, 1990

Stroke Prevention: Hypertension

- Consider avoiding Beta-Blockers (ACE-I?)



Stroke	β blocker n/N	Other drug n/N	RR 95% CI	RR 95% CI
ASCOT-BPLA	422/9618	327/9639		1·29 (1·12–1·49)
CONVINCE	118/8297	133/8179		0·87 (0·68–1·12)
ELSA	14/1157	9/1177		1·58 (0·69–3·64)
HAPPHY	32/3297	41/3272		0·77 (0·49–1·23)
INVEST	201/11 309	176/11 267		1·14 (0·93–1·39)
LIFE	309/4588	232/4605		1·34 (1·13–1·58)
MRC Old	56/1102	45/1081		1·22 (0·83–1·79)
NORDIL	196/5471	159/5410		1·22 (0·99–1·50)
STOP-2	237/2213	422/4401		1·12 (0·96–1·30)
UKPDS	17/358	21/400		0·90 (0·48–1·69)
Yurenev	6/150	11/154		0·56 (0·21–1·48)
MRC	42/4403	18/4297		2·28 (1·31–3·95)
Total events	1650/51963	1594/53882		1·16 (1·04–1·30)
Test for heterogeneity: χ^2=22·39 (p=0·02)				

Stroke Prevention: Hyperlipidemia

- Elevated total Cholesterol (>240mg/dl) seen in approximately 6-40% of people
- Increases relative risk for stroke 1.8-2.6
- Large study known as "SPARCL"
  - RCT of Atorvastatin 80mg/day vs. placebo
  - Patients had a stroke (or TIA) + LDL >100 and no DM or CAD. N= 4731
  - Saw a 16% RRR; 2.4 ARR in recurrent stroke at 5 years
    - (roughly equivalent benefit to ASA)

SPARCL NEJM 2006

Stroke Prevention: Hyperlipidemia

- Unfortunately further analysis showed slight increased risk for ICH
  - Would avoid if amyloid angiopathy demonstrated on MRI or if has previous hemorrhage
- Much debate currently on how to manage statin therapies. Practiced differently in different places
  - Many people give Atorvastatin 80mg to all stroke patients with LDL >100
  - Others treat based on LDL value and with goal of LDL <100 or < 70 in higher risk groups (significant large vessel or intracranial stenosis)

Stroke Prevention: Diabetes

- RR for Stroke 1.5-3.0
- Framingham study found that the increased risk is independent of other co-morbid conditions.
- No study has shown that DM control has not been shown to prevent stroke.
- ACT NOW Trial: Prediabetics followed 3 years taking pioglitazone vs. placebo: DM2 seen in 2% vs. 8%
- Insulin Resistance In Stroke (IRIS) Trial: Prediabetics randomized to pioglitazone vs. placebo, followed for 5 years
  - Endpoints: Stroke, MI, developing DM2

Antiplatelet Medications for Secondary Stroke Prevention

- Aspirin 81mg–325mg PO Daily
  - Not dose dependent
  - 23% RRR versus Placebo
  - Total cost to prevent one stroke: $1,000
- Clopidogrel (Plavix) 75mg PO Daily
  - 10% RRR versus ASA in CAPRIE study (but wasn't statistically significant)
  - CAPRIE did show that it is more effective than ASA in reducing combined risk of stroke, MI or vascular death with similar safety.
- Aspirin+Dipyridamole (Aggrenox) 25mg/200mg PO BID
  - Overall 1% per year absolute risk reduction over ASA in ESPRIT
  - Causes headaches in 30% of patients, temporary

Antiplatelet Medications for Secondary Stroke Prevention

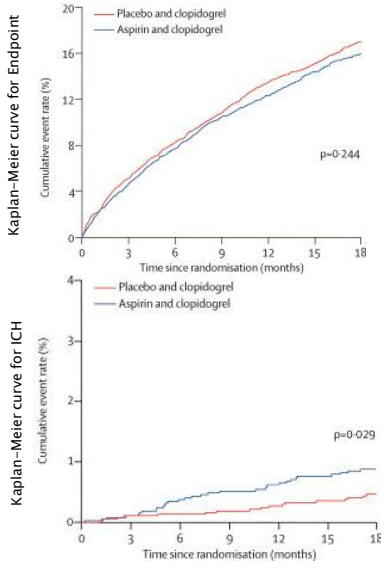
- PROFESS Trial: RCT with 2 x 2 Factorial Design:
  - Clopidogrel versus ASA+Dipyridamole
  - Each antiplatelet arm: Telmesartan +/–
  - All patients either had TIA or Stroke
  - N = 20,333
  - No significant difference in stroke prevention
    - Strokes in 8.8% pts on clopidogrel versus 9% on ASA+Dipyridamole
    - Slight increase in major bleeding in ASA+Dipyridamole group (3.6% vs. 4.1%)
    - No effect of ARB beyond BP control
- Cost to prevent one more stroke than ASA:~$100,000*

PRoFESS Study Group, NEJM 2008
*Hankley GJ, et al. Lancet 1999

Aspirin + Plavix Combo?

- MATCH Trial 2004
  - Plavix+ASA 75mg vs. Plavix+placebo
  - 7,599 Patients (post stroke/TIA) followed 18 mo
  - No significant difference in major vascular events
  - Increased life-threatening bleeding (2.6% vs. 1.3%)

MATCH Trial, Lancet 2004



Aspirin + Plavix Combo?

- SPS3 (2012): Subcortical Stroke Patients (lacunar)
  - ASA 325mg+Plavix vs. ASA 325mg+Placebo
  - Stopped prematurely by DSMB due to:
    - Increased risk of bleeding and death in combo group
    - Small probability of benefit (2.1%/yr vs. 2.4%/yr ischemic strokes, Not significant)

Adverse Events	All Groups	Aspirin	Aspirin + Clopidogrel	P-Value
	3020	1503	1517	
Any Bleeding Event	148 (4.9%)	50 (3.3%)	98 (6.5%)	0.0001
-CNS Hemorrhage	30 (1.0%)	13 (0.9%)	17 (1.1%)	0.58
-Major Non-CNS Hemorrhage	122 (4.0%)	38 (2.5%)	84 (5.5%)	<0.0001

Adverse Events	All Groups	Aspirin	Aspirin + Clopidogrel	P-Value
	3020	1503	1517	
Death	150 (5.0%)	62 (4.1%)	88 (5.8%)	0.036
-Vascular	56 (1.2%)	16 (1.1%)	26 (1.7%)	0.02
-Probable Vascular	20 (0.7%)	6 (0.4%)	14 (0.9%)	0.11
-Non-Vascular	57 (1.9%)	27 (1.8%)	30 (2.0%)	0.79
-Uncertain	37 (1.2%)	13 (0.9%)	24 (1.6%)	0.097

Benavente, et al. ISC 2012, not published yet

Aspirin + Plavix Combo?

- POINT Trial:
  - ASA+Plavix vs. ASA+Placebo within 24 hours of small stroke or TIA
  - 3 months duration of dual therapy
  - Still recruiting
- Based on SAMMPRIS Results, we may also start 3 months of ASA+Plavix for symptomatic intracranial stenosis

Antiplatelet Medications

- Cilostazol 100mg PO BID approved in US for claudication, but has been shown to reduce risk of stroke. Now in guidelines as 4th line medication
- Other alternative antiplatelet medications not studied in stroke
  - Prasugrel: Increased risk of ICH in pivotal trial
  - Ticagrelor: no Increased risk of ICH

Stroke Prevention: Cardioembolic

- Cardioembolic stroke suspected with:
  - Symptoms (chest pain, palpitations, fatigue…)
  - Recent MI
  - Abnormal cardiac history
  - Young age
  - Lapse of consciousness at onset
  - Valsalva then symptoms (suggests PFO)
  - Stroke in multiple vascular territories (often bilateral) on CT or MRI

Stroke Prevention: Cardioembolic

- Diagnosis of atrial fibrillation:
  - Admission EKG: 67–75% of AF
  - Monitor x 48hr (Telemetry or Holter): add'l 4.6%
  - Continuous event recorders for up to 30 days have shown additional screening benefit
- Identification of source of stroke on echo:
  - TTE can't visualize: valves, aortic appendage, ascending aorta
  - Therefore, sensitivity of TTE in stroke is as little as 25% relative to TEE in some studies

Stroke Prevention: Cardioembolic

- AF Risk Stratification:

Risk Scheme	Risk stratification	Stroke Risk	Risk Scheme	Risk Scheme	Stroke Risk
$CHADS_2$ Score 1 point: ▪ **C**HF (recent) ▪ **H**TN ▪ **A**ge >=75 ▪ **D**M Score 2 points: ▪ **S**troke or TIA	Low risk 1 point	1.9%	**NICE**	Low Risk ▪ Age<65 with no history of embolism, hypertension, diabetes, or other clinical risk factors	1%
	Intermediate Risk 2 points 3 points 4 points	2.8% 4.0% 5.9%		Intermediate Risk ▪ Age>=65 with no high risk factors ▪ Age <75 with HTN, DM, or vascular disease	4%
	High Risk 5 points 6 points	8.5% 18.2%		High Risk ▪ Previous stroke, TIA, or thromboembolic event ▪ Age>75 with HTN, DM, or vascular disease ▪ Clinical evidence of valve disease or heart failure ▪ Impaired LV function on echo	8-12%

- CHADS2-VASc adds females aged 65-74 as an additional risk factor

Lip GY et al. Chest 2010

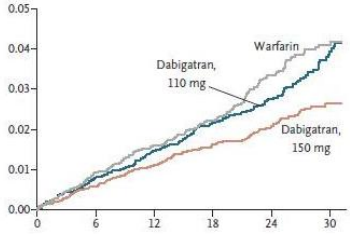
Stroke Prevention: Cardioembolic

- Coumadin for AF: one of the most successful interventions for stroke prevention
  - Overall risk decreased from 4.5%/year to 1.4%/year
  - RRR 68% (similar for all risk categories) versus aspirin which provides RRR ~20%
  - Underused: mainly due to fall risk, perception of increased bleeding risk, and difficulty of achieving therapeutic INR (2-2.5)
  - Fall Risk: One study estimates 295 falls necessary in moderate risk patient to outweigh the benefit of anticoagulation*

*Bond, AJ et al. Thrombosis Journal, 2005

New Anticoagulants

- Direct Thrombin Inhibitors
  - RE-LY Trial: Dabigatran 150mg BID
  - More efficacious than warfarin for prevention of systemic embolism.
  - Stroke rate 1.1% vs. 1.7% per year. (n = 18,113 followed for mean 2 years)
  - Equivalent risk of major hemorrhage
  - No bridging necessary. Therapeutic at 2 hours
  - No blood draws necessary
  - Problems: no way to measure effect or compliance, unclear guidelines in reversing in cases of bleeds, needs renal dosing



RE-LY investigators, NEJM 2009

New Anticoagulants

- Factor Xa Inhibitors:
  - ROCKET AF trial: Rivaroxaban 20mg PO Daily
  - N = 14,264
  - Showed non-inferiority to warfarin for prevention of stroke or systemic embolism (1.7% vs. 2.2%/year)
  - No difference in major bleeding
  - Problems: no way to measure effect or compliance, unclear guidelines in reversing in cases of bleeds
  - Also data suggests possible increased risk of stroke with cessation

Rocket AF Investigators, NEJM 2011

New Anticoagulants

- Factor Xa Inhibitors: Apixaban 5mg PO BID
  - ARISTOTLE Trial: n = 18,201, mean follow up 1.8yrs
  - Met Endpoint 1.27%/yr in apixaban vs. 1.6%/yr in warfarin
  - Major systemic bleeding 2.13%/yr in apixaban vs. 3.1%/yr in warfarin
  - ICH 0.24%/yr in apixaban vs. 0.47%/yr
  - Death from any cause was 3.52% vs. 3.94%
  - Problems: no way to measure effect or compliance, unclear guidelines in reversing in cases of bleeds
- Still awaiting FDA approval for Afib and DVTs

ARISTOTLE Study Group, NEJM 2011

Interventions

Carotid Stenosis

- When to treat carotids??
  - Symptomatic vs. Asymptomatic
  - Degree of stenosis qualifying as "severe"
- Best evidence for symptomatic carotid stenosis
  - Carotid Endarterectomy (CEA) vs. Carotid Artery Stenting (CAS)

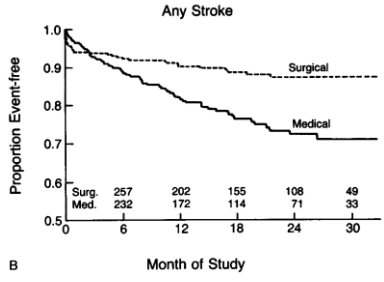
Carotid Stenosis: NASCET 1991

- Randomized controlled trial of symptomatic carotid stenosis (n=659): Aspirin vs. CEA
- Cumulative risk of ipsilateral stroke was 26% in the medical patients vs. 9% in the surgical patients

Angio confirmed; % ipsilateral CVA

	ASA	CEA	NNT	P Value
70–99%	24%	7%	8	0.0005
50–70%	22%	16%	15	0.045

- **< 50% CEA not better than ASA**
- **Major complication rate for CEA 6.7%**
- **> 50% TX indicated Urgently**

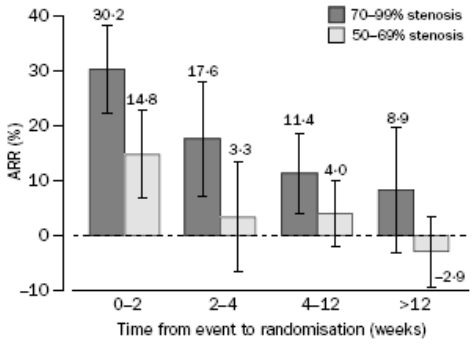


NEJM 325: 445–453

Stroke Intervention: Large Vessel

- Early Intervention is more beneficial:

Pooled data from the symptomatic European and American CEA trials



ARR: combined endpoint of 5 yr ipsilateral stroke risk + 30 day operative complications (any stroke + death)

Asymptomatic Carotid Stenosis

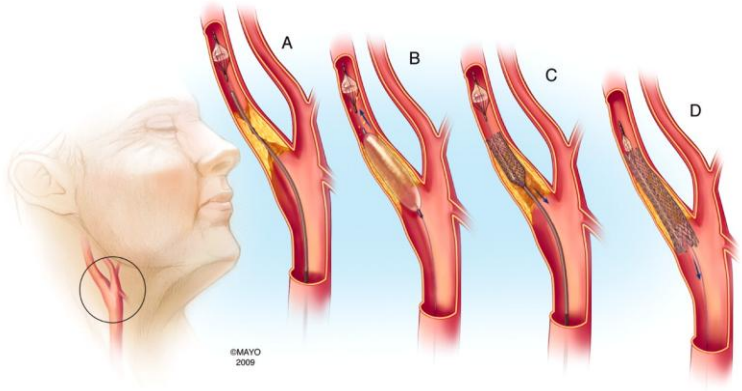
- ACAS: 1662 pts with asymptomatic carotid stenosis of 60% or greater enrolled
- CEA versus Aspirin
- Risk over 5 years for stroke or death was 5% in CEA group versus 10% in medical treatment
- **Only "1% year difference" vs. "surgery twice as good"**
- Caveat: This study was done when other stroke risk factors weren't addressed

Asymptomatic Carotid Stenosis

- Tend to treat medically in older patients
- Consider CEA/CAS in younger patients with >70% stenosis

- Will be starting new study "CREST 2"
  - Aggressive Medical Management versus Procedure

Carotid Artery Stenting



Carotid Artery Stenting

- At least 13 randomized trials: CEA vs. CAS
- Each with its limitations

Trial	*No. of patients*	*Cerebral protective devices, %*	*Mean age (year)*	*% asymptomatic*	*Degree of stenosis, %*
Naylor, 1998[13]	23	0	67.2	0	>70
Alberts, 2001[14]	219	0	68.3	0	>60
Brooks, 2001[15]	104	0	68.0	0	>70
CAVATAS, 2001[3]	504	0	67.0	3	NR
Brooks, 2004[16]	85	0	68.2	100	>80
Yadav, 2004[21]	334	96	72.6	71	>50; >80[a]
Mas, 2004[19]	527	92	69.7	0	>60
The SPACE Group, 2006[20]	1200	NR (mixed)	67.9	0	>70
Ling, 2006[18]	166	100	63	Mixed, % unclear	>50; >70[b]
Hoffman, 2006[17]	20	NR	NR	0	>70
Steinbauer et al[12]	87	0	69	0	>70
CREST, 2010[6]	2502	96	69	47	>50 (angio) >70 (US) >70 (CTA/MRI)
ICSS, 2010[7]	1713	72	70	0	>50

angio, Angiography; *CTA,* computed tomography angiography; *MRI,* magnetic resonance imaging; *NR,* not reported; *US,* ultrasound.
All angioplasties were performed with stenting except in Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS; only 26%).
[a]Stenosis in symptomatic patients was >50% and in asymptomatic patients was >80%.
[b]Stenosis in symptomatic patients was >50% and in asymptomatic patients was >70%.

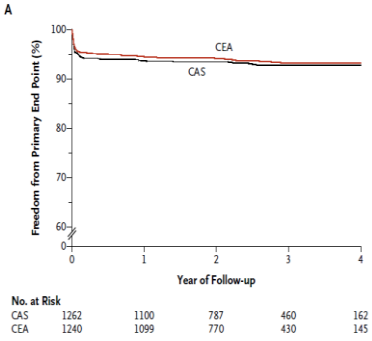
Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST)

- Prospective, multicenter RCT comparing CEA and CAS in participants with symptomatic and asymptomatic stenosis
  - n =2502 patients
  - Endpoints: MI, Stroke, or Death
  - Eligibility criteria
    - Symptomatic: Stenosis >50% on angiography, or >70% on Carotid Doppler. If US was 50-69%, then need CTA/MRA >70%
    - Asymptomatic: Stenosis >60% on angiography, or >70% on Carotid Doppler. If US was 50-69%, need 80% on CTA/MRA

CREST NEJM 2010

CREST Results

- Primary Endpoint <4 years (Stroke, MI, Death)
  - 7.2% in CAS vs. 6.8% in CEA, P=0.51 (NS)
- Ipsilateral Stroke after Periprocedural Period
  - 2.0% in CAS vs. 2.4% CEA, P=0.85 (NS)
- When looking at symptomatic patients periprocedurally:
  - Patients with CEA had slightly higher rate of MI (2.3% vs. 1%)
  - Patients with CAS had slightly higher rate of CVA (5.5% vs. 3.2%)



CREST NEJM 2010

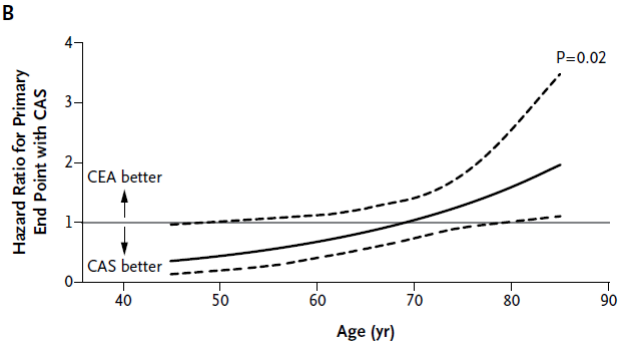
CREST Results

- Minor stroke 4% CAS vs. 2% CEA
- Overall, no difference major strokes (1.9% in CAS vs. 3% in CEA [NS]) and they occur early
- No difference in restenosis rates (>70%) at 2 years
- Angio predictors of CAS strokes: distal tortuosity, sequential lesions, length > 20mm

CREST NEJM 2010

CREST Results

- Subgroup analysis suggests stenting favored in younger patients while endarterectomy favored in older patients

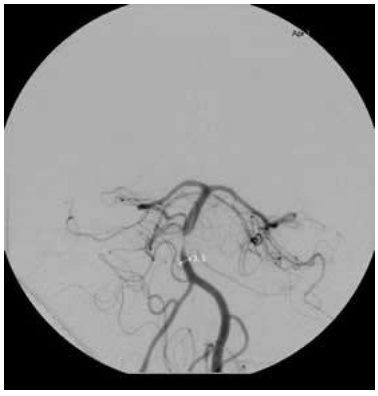


CREST NEJM 2010

CREST Conclusions

- At experienced centers both CEA and CAS appear to have low perioperative complications and excellent longer-term results
- Both CEA and CAS appear to be useful tools for preventing stroke.
- 1/26/11 FDA approved Acculink/CAS for low risk patients to prevent stroke: 50% stenosis in symptomatic & 60% in asymptomatic

Intracranial Stenosis



Intracranial Stenosis

- SAMMPRIS Trial
  - Intracranial Stenting vs. Aggressive Medical Management
  - Med Tx.= SBP <140, LDL <70, ASA/Plavix x 3 mo
  - Stopped after 451 patients enrolled by DSMB
  - 30 Day stroke/Death: 14% in stented group versus 6% in Medical group (P <0.002)
  - 30% of strokes in stent group were ICH
  - Long term follow up in progress

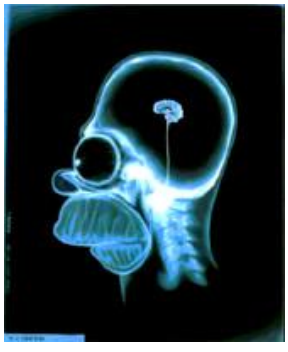
SAMMPRIS NEJM 2011

Intracranial Stenosis

- Looked at patients who failed antithrombotic therapy at time of enrollment
  - 63% of all SAMMPRIS patients had their qualifying event on antithrombotic therapy
  - Most of these were on antiplatelet (95%)
  - Of these patients who were randomized: 12.1% of patients on med therapy had events vs. 21.5% in stented group
  - Conclusion: Similar results even if failed antithrombotic before enrolling in trial
- Will still consider stenting in select cases

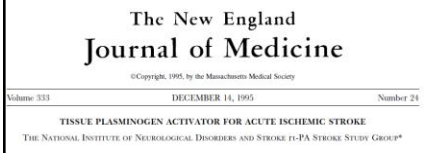
SAMMPRIS NEJM 2011

Acute Stroke Therapies

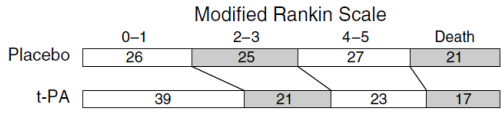


IV Thrombolysis (IV tPA)

- NINDS tPA Study, NEJM 1995
  - IV tPA within 3 hours of symptom onset
  - Dose: 0.9mg/kg (max dose 90mg) 10% given over 1-2min with remaining dose infused over 1 hr.
  - Ages 18-79, BP <185/110
  - CT Head without e/o Hemorrhage


The New England
Journal of Medicine

Volume 333 DECEMBER 14, 1995 Number 24
TISSUE PLASMINOGEN ACTIVATOR FOR ACUTE ISCHEMIC STROKE
THE NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE rt-PA STROKE STUDY GROUP*

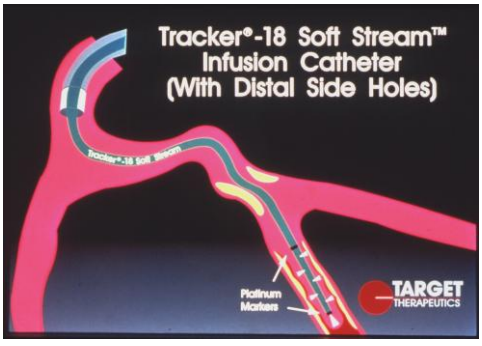


NINDS Trial: IV tPA

- Improved the odds of a good outcome (complete recovery or minimal deficit but able to fully resume all prior activities) from 25% to 45% at 3 months.
- Risk of ICH ~6%, with severe results in 3%
- Overall, IV tPA does not change risk for death after stroke

Intra-Arterial Thrombolysis

- PROACT II, JAMA Dec 1999
  - 6 Hour Window: Angio confirmed MCA Occlusion
  - N =180
  - IA ProUrokinase 9mg over 2 hours



PROACT II Results

	ProUrokinase	Placebo	P-Value
mRS 0, 1, 2	40%	25%	<0.05
SICH	10.2%	1.8%	<0.01
Death	24%	27%	0.80

Figure 4. Intracranial Hemorrhage With Neurological Deterioration in Patients Treated as Randomized

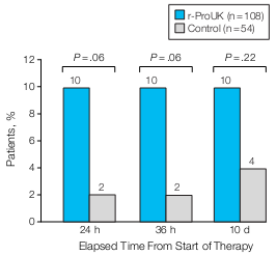
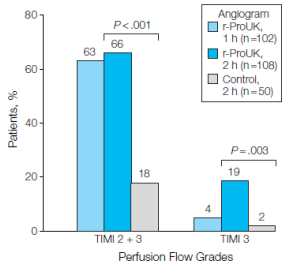
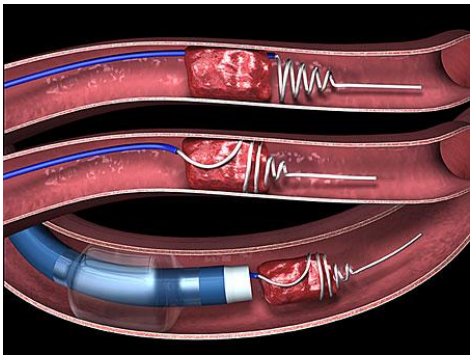


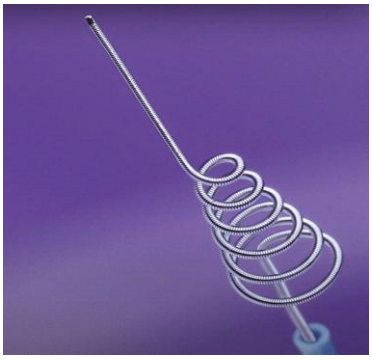
Figure 5. Recanalization of Occluded Middle Cerebral Artery in Patients Treated as Randomized



Mechanical Clot Retrieval

- The MERCI Device (Concentric)





The MERCI Trial

- Prospective, open-label trial
- Can use on vertebral artery, basilar artery, ICA, MCA (M1 & M2) within 8 hours
- 27% with 90-day MRS <= 2
  - 46% in recanalized group vs. 10% in failed recanalization group
- Revascularization significantly associated with good outcome
- Became FDA approved to recanalize vessels

The Penumbra System

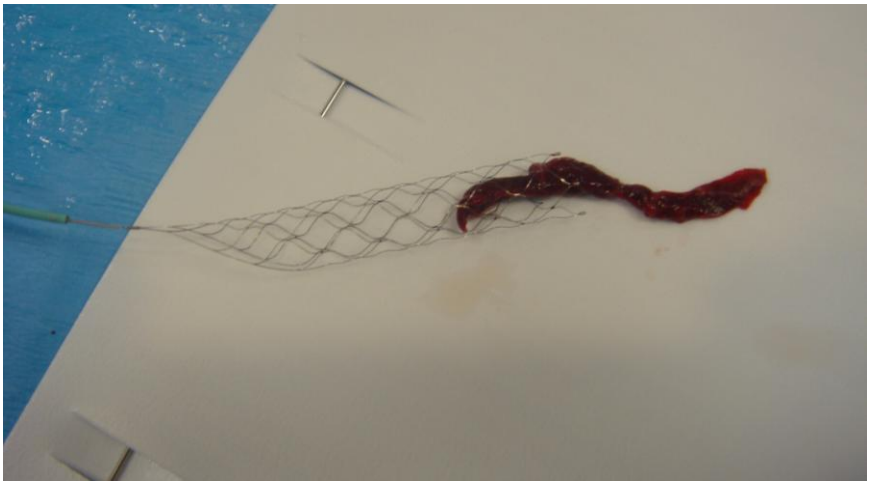
Penumbra Trial Results N=125

	% Recanalized	ICH	mRS 2 or less
Control	18%	2%	25%
Penumbra	82%	11%*	23%

* 29% (4/14) were Subarachnoid Hemorrhages

Stentreivers: The Next Generation

Stentreivers: The Next Generation



Solitaire Device (EV3)

- SWIFT Trial: Randomized between Solitaire vs. MERCI within 8 hours of onset (N=113)
  - Overall successful recanalization without ICH seen in 60% in Solitaire versus 24% in MERCI (P <0.0001)
  - Good outcome (mRS 0-2) seen in 58% vs. 38% (P=0.017)
  - 90-Day Mortality 17% vs. 38% (P=0.02)
  - ICH seen in 2% vs. 11% (P=0.05)

Solitaire Device (EV3)

- FDA approved March 3, 2012

Future Devices

- Concentric: TREVO Device (Completed Enrollment)
- Reverse Medical: RESTORE (Currently Enrolling)
- Codman: ReVive (Will Enroll Soon)

Stroke Prevention Summary

- Work-up:
  - Fasting lipids, fasting glucose, HgbA1C
  - Imaging of vessels from arch to brain
  - EKG, consider Holter or event monitor to eval AFib
  - Echocardiogram, consider TEE
- Treatment:
  - Antiplatelet for non-cardioembolic
  - Anticoagulation for AF and mechanical valves
  - Antihypertensive:
    - Permissive HTN (1 week)
    - (SBP<120 in most patients, but at least SBP<140)
  - Hyperlipidemia
    - Goal LDL <100 in most patients, Goal <70 in intracranial stenosis, significant large vessel stenosis or high-risk patients

Stroke Prevention Summary

- Large vessel Stenosis
  - Symptomatic Carotid Stenosis >50%: Early CEA/CAS
  - Asymptomatic Carotid Stenosis >~70%: Consider CEA/CAS
- Intracranial Stenosis:
  - Vast majority: dual antiplatelet (ASA+Plavix x 3 months), LDL<70, SBP<140 unless has DM2 then SBP<130
  - If continues to fail maximum medical therapy or disabling orthostatic symptoms: consider angioplasty and/or stenting

Acute Stroke Therapy Summary

- IV tPA
  - Effective when given within 3 hours of last normal
  - Can be used within 4.5 hours in select groups
  - Need labs, CT Head, EKG
  - Review exclusion criteria
- Intra-Arterial Therapies (tPA & Mechanical)
  - Can benefit from treatment after 3 hours
  - Highly specialized therapies often requiring transfers
  - Can be very effective in the appropriate population

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Thank You

Remember "Time is Brain"

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