CAROTID ANGIOPLASTY AND STENTING UNDER PROTECTION IS BECOMING THE GOLD STANDARD TREATMENT IN HIGH AND LOW RISK PATIENTS

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CAROTID STENOSIS

IS C.A.S. BECOMING THE STANDARD OF CARE OR THE GOLD STANDARD TREATMENT ?



C.E.A. ESTABLISHED AS THE GOLD STANDARD TREATMENT

CAROTID STENOSIS

ANGIOPLASTY VS SURGERY



C.A.S CAN BE PROPOSED TO THE MAJORITY OF PATIENTS SUFFERING FROM CAROTID STENOSIS **ALTERNATIVE TO SURGERY SAFE AND EFFICIENT PROCEDURE BUT : SOME LIMITATIONS > RISK OF BRAIN EMBOLIZATION CHALLENGING INDICATIONS CLINICAL**, ANATOMICAL... **>TECHNICAL PROBLEMS : STENT DESIGN**

→ NEW TECHNIQUES



CURRENT ACCEPTABLE STROKE/DEATH RATES
< 3% FOR ASYMPTOMATIC PATIENTS
< 6% FOR SYMPTOMATIC PATIENTS
< 10% FOR RESTENOSIS
NO GUIDELINES FOR HIGH /LOW RISK PATIENTS
Guidelines Ad.Hoc Committee A.H.A.

CAROTID STENOSIS INDICATIONS FOR REVASCULARIZATION

WHICH PATIENT TO TREAT?

SYMPTOMATIC? ASYMPTOMATIC? HIGH RISK? LOW RISK?

C.A.S. HIGH/LOW RISK PATIENTS

HIGH CLINICAL RISK

WHAT CONSTITUTES HIGH RISK?

SOME SURGEONS BELIEVE THAT THERE IS NO ONE WHO COULD NOT BE OPERATED ON, BUT THE DATA SUGGEST THERE ARE MANY PATIENTS WHO SHOULD NOT BE OPERATED ON.

THESE DATA ARE NOT RANDOMIZED, BUT REPORTS ON SEVERAL HIGH-RISK SUBSETS ARE NEVERTHELESS REVEALING

T.C.T. 2005

RISK OF STROKE/DEATH IN HIGH SURGICAL RISK C.E.A.

AGE >75 YEARS :	7%-10%
CONGESTIVE HEART FAILURE :	8%-9%
CO-EXISTENT C.A.D. REQUIRING BYPASS SURGERY :	8%-10%
CONTRALATERAL CAROTID OCCLUSION:	
> ACAS – 2% INCREASE OVER MEDICAL THERAPY	
> NASCET	14,3%
PRIOR AND RECURRENT STENOSIS :	8%-10%
> MAYO CLINIC	
CLIVELAND CLINIC	
RENAL INSUFFICIENCY	
> Cr>1,5mg% :	8.2%
► Cr>2.9mg% :	43%

DAILY PO ET AL J. THOR CARDIOVAS SURG;JUNE 1996:111(6),1185-93 GOLDSTEIN L.B. ET AL STROKE;APRIL 1998:29(4),750-53 WONG J.H.ET AL STROKE;MAY 1997:28(5),891-98



HIGH SURGICAL RISK PATIENTS

NASCET AND ACAS EXCLUSIONS

AGE>79

- PRIOR IPSILATERAL C.E.A.
- UNSTABLE CORONARY
- MYOCARDIAL INFARCT IN PREVIOUS 6 MONTHS
- CARDIAC VALVULAR OR RHYTHM ABNORMALITY LIKELY TO CAUSE EMBOLIC CEREBROVASCULAR SYMPTOMS
- CONTRALATERAL OCCLUSION
- A MORE SEVERE LESION CRANIAL TO THE SURGICAL LESION

- CONTRALATERAL C.E.A. WITHIN PREVIOUS 4 MONTHS
- UNCONTROLLED HYPERTENSION OR DIABETES
- ORGAN FAILURE LIKELY TO CAUSE DEATH WITHIN 5 YEARS
- **TOTAL OCCLUSION**
- MAJOR SURGICAL PROCEDURE IN PREVIOUS 30 DAYS
- **PRIOR SEVERE C.V.A.**
- PROGRESSING NEUROLOGIC SYNDROME

C.A.S. INDICATIONS

HIGH RISK PATIENTS : WELL ACCEPTED

- RANDOMIZED STUDIES :SAPPHIRE STUDY
- <u>REGISTRIES</u>:ARCHER, BEACH, CAPTURE, CASES PMS.....
- LARGE PUBLISHED SERIES

RESULTS NON INFERIEUR TO SURGERY BETTER OUTCOMES THAN SURGERY

F.D.A. APPROVED

LOW RISK PATIENTS : CONTROVERSIAL

LARGE PUBLISHED SERIES

RESULTS NON INFERIEUR TO SURGERY

C.A.S. UNDER CEREBRAL PROTECTION U.S. SAPPHIRE STUDY

RANDOMIZED MULTICENTER TRIAL . HIGH RISK PATIENTS FOR ENDARTERECTOMY C.A.S. WITH ANGIOGUARD[™] XP EMBOLI PROTECTION GUIDEWIRE VS SURGERY

307 PATIENTS 156 RECEIVED PRECISE[™] NITINOL STENT 151 UNDERWENT C.E.A.

30 DAY FOLLOW UP : MAJOR ADVERSE EVENTS (DEATH, STROKE, MYOCARDIAL INFARCTION)

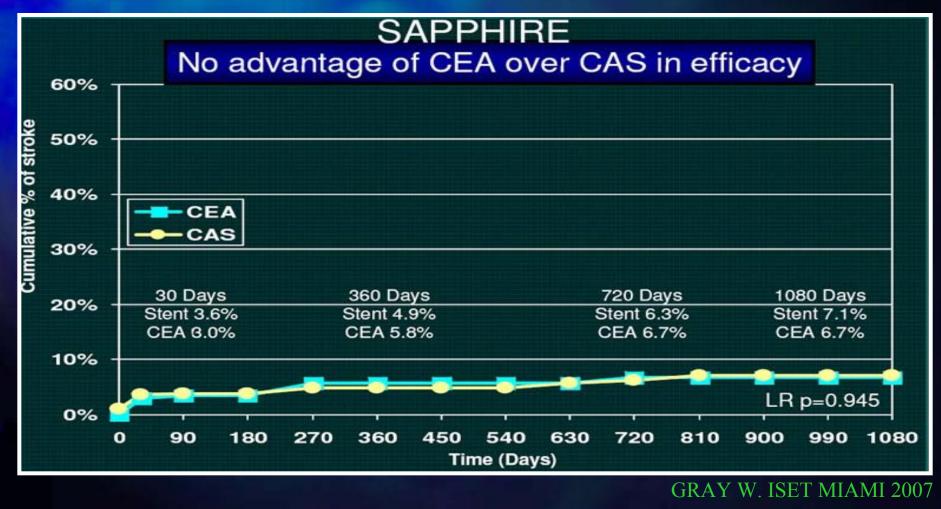
J. YADAV. AHA CHICAGO NOV. 2002

C.A.S. : 5,8%

C.E.A. : 12,6%

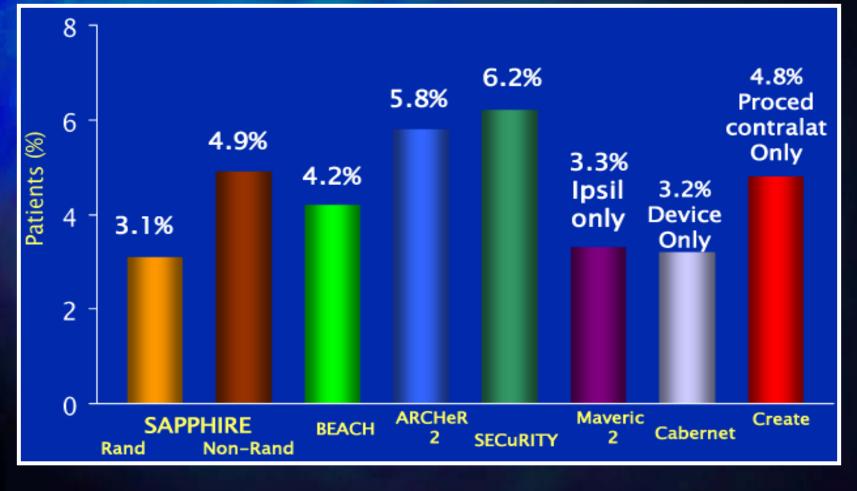
C.A.S. SAPPHIRE STUDY

DURABLE PATENCY AND EFFICACY IN STROKE PREVENTION



C.A.S. UNDER PROTECTION HIGH RISK PATIENT TRIALS 30-DAY RISK OF STROKE

HISTORICAL CONTROLS FROM SURGICAL STUDIES : 11 TO 15%

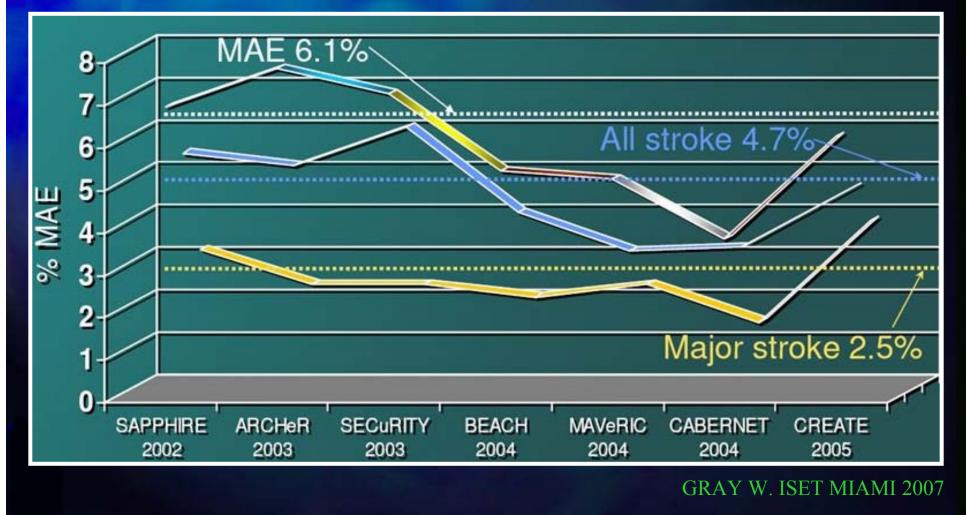


J. YADAV ALL THAT JAZZ NEW ORLEANS MAY 2007

C.A.S.

RESULTS IN 7 PIVOTAL TRIALS

>3100 PATIENTS



C.A.S.

CAPTURE 3500 STUDY

CAPTURE 3500 VS ARCHER 30 DAY OUTCOMES ACCULINK + ACCUNET VS Xact STENT+EMBOSHEILD

Event	CAPTURE N=3500	ARCHeR N=581	DIFFERENCE 95% CI
Death, Stroke and MI*	6.3%	8.3%	-1.98% [-4.35%, 0.40%]
All Stroke and Death*	5.7%	6.9%	-1.20% [-3.40%, 1.00%]
Major Stroke and Death*	2.9%	2.9%	-0.04% [-1.52%, 1.44%]
Death	1.8%	2.1%	-0.29% [-1.53%, 0.94%]
All Stroke	4.8%	5.5%	-0.71% [-2.69%, 1.28%]
Major Stroke	2.0%	1.5%	0.42% [-0.68%, 1.53%]
Minor Stroke	2.9%	4.0%	-1.07% [-2.75%, 0.61%]
MI §	0.9%	2.4%	-1.50% [-2.78%, -0.21%]

*Hierarchical-includes only the most serious event for each patient and include only each patient's first occurrence of each event

§Denotes statistically significant diffence at the 0.05 level

GRAY W. ISET MIAMI 2007

C.A.S. **PERSONAL SERIES APRIL 1995 JUNE 2007** WITHOUT WITH TOTAL **PROTECTION PROTECTION PATIENTS** 842 172 **670** ARTERIES 902 187 715

BILATERAL ANGIOPLASTIES 60 15 45

► SYMPTOMATIC : 62%

► MEAN AGE : 70,8 ± 9,2 YEARS (22 - 93)

► 118 PATIENTS > 79 YEARS



PERSONAL EXPERIENCE

SYMPTOMATIC LESIONS : 62%
DN: 187
715
ON: 334
: 47
10
277
376
216
58
60
35
7
RS USED IN ONE PROCEDURE)



ARTERIES : 715 PATIENTS : 670
MALE : 507 FEMALE : 163
MEAN AGE : 70,8 ± 9,3 (40 - 93)
RIGHT : 376 LEFT : 339
SYMPTOMATIC : 63 %
HISTORY OF STROKE: 30%
HISTORY OF T.I.A. : 37%

RISK FACTORS

> HISTORY OF HYPERTENSION : 72%
> UNCONTROLLED HYPERTENSION: 23%
> DIABETIS MELITUS : 22%
> DYSLIPIDEMIA : 61%
> SMOKING : 62%
> OBESITY : 15%

ASSOCIATED DISEASES
CORONARY DISEASES: 63%
CARDIAC INSUFFICIENCY: 9%
PERIPHERAL VASC. DISEASES: 27%
RENAL STENOSIS: 10%
RENAL INSUFFICIENCY: 8%
PULMONARY INSUFFICIENCY: 8%

LESION CHARACTERISTICS ► MEAN DEGREE OF STENOSIS (%) : $81,9 \pm 9,4$ MEAN LESION LENGTH (mm) : $14,2\pm 6,2$ MEAN ARTERIAL DIAMETER (mm) : $5 \pm 1,2$ **CALCIFIED LESIONS :** 45% **> ULCERATED LESIONS :** 71% **ECHOLUCENT LESIONS :** 49% HYPERECHOGENIC LESIONS : 51%

C.A.S. UNDER PROTECTION HIGH / LOW SURGICAL RISK PATIENTS

715 ARTERIES

HIGH RISK : 457

SYMPTOMATIC : 297

ASYMPTOMATIC: 160

LOW RISK : 258

SYMPTOMATIC : 153 ASYMPTOMATIC : 105

C.A.S. UNDER PROTECTION HIGH SURGICAL RISK PATIENTS

457 ARTERIES

CONGESTIVE HEART FAILURE (CLASS III/IV) AND/OR KNOWN SEVERE LEFT VENTRICULAR DYSFUNCTION LVEF<30%	141	21%
OPEN HEART SURGERY NEEDED WITHIN 6 WEEKS	161	24%
RECENT M.I. (> 24 Hrs AND < 4 WEEKS	54	8,1%
UNSTABLE ANGINA (CCS CLASS III/IV)	228	34%
SEVERE PULMONARY DISEASE	49	7,3%
CONTRALATERAL CAROTID OCCLUSION	54	8,1%
CONTRALATERAL CAROTID SEVERELY STENOSED (>90%)	127	19%

C.A.S. UNDER PROTECTION HIGH SURGICAL RISK PATIENTS

457 ARTERIES

CONTRALATERAL LARYNGEAL NERVE PALSY	3	0,4%
RADIATION THERAPY TO NECK	11	1,6%
PREVIOUS C.A.S. / C.E.A. WITH RECCURENT STENOSIS	36	5,4%
HIGH CERVICAL I.C.A. LESIONS OR C.C.A. LESIONS BELOW THE CLAVICLE	59	8,8%
SEVERE TANDEM LESIONS	15	2,2%
AGE GREATER THAN 80 YEARS	112	17%
RENAL INSUFFICIENCY (CR > 2,5)	49	7,3%

C.A.S UNDER CEREBRAL PROTECTION 30 DAY OUTCOMES

	_71	5	PR(OCE	DUF	RES
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	HIGH RISK n = 457	LOW RISK n = 258	P value
T.I.A.	4 0,9%	2 0,8%	N.S.
MINOR STROKE	3 0,7%	0	N.S.
MAJOR STROKE	1 0,2%	0	N.S.
RETINAL EMBOLUS	2 0,4%	2 0,8%	N.S.
HYPERPERFUSION SYNDROME	2 0,4%	1 0,4%	N.S.
DEATH	2 0,4%	1 0,4%	N.S.
FATAL STROKE	2 0,4%		N.S.
NON STROKE DEATH	at the second	1 0,4%	N.S.
DEATH AND STROKE	6 1,3%	1 0,4%	N.S.
M.I.	1 0,2%	0	N.S.
EMBOLIC EVENTS	10 2,2%	4 1,6%	N.S.

C.A.S. UNDER CEREBRAL PROTECTION 30 DAY OUTCOMES

	PERCUSURGE				FILTER	S	
652 ARTERIES	H.R. N=178	L.R. N=99	TOTAL N=277	H.R. N=241	L.R. N=135	TOTAL N=376	
T.I.A.	2	1	3 (1%)	1	1	2 (0,5%)	
MINOR STROKE	0	0	0	2	0	2 (0,5%)	
MAJOR STROKE	0	0	0	0	0	0	
RETINAL EMBOLUS	0	1	1 (0,3%)	2(0,8%)	1(0,7%)	3 (0,8%)	
HYPERPERFUSION SYNDROME	1	0	1 (0,3%)	1	1	2 (0,5%)	
DEATH	0	1	1 (0,3%)	1	0	1 (0,3%)	
FATAL STROKE	0	0	0	1	0	1 (0,3%)	
NON FATAL STROKE	0	1	1 (0,3%)	0	0	0	
DEATH AND STROKE	0	1	1 (0,3%)	3	0	3 (0,8%)	
M.I.	0	0	0	1	0	1 (0,3%)	
EMBOLIC EVENTS	2	2	4 (1,4%)	5(2,1%)	2	7 (1,9%)	
P = N.S. FOR H.R./L.R./ALL PATIENTS							

C.A.S.UNDER CEREBRAL PROTECTION 30 DAY OUTCOMES

P=NS

DEATH AND STROK	E RAT	E	
> SYMPTOMATIC PATIE	NTS :	5 /450	1,1%
	H.R.	4/297	1,3%
	L.R.	1/153	0,7%
> ASYMPTOMATIC PATE	ENTS :	2 /265	0,8 %
	H.R.	1/160	0,6%
	L.R.	1/105	0,9%
EMBOLIC COMPLIC	ATION	RATE	
> SYMPTOMATIC PATIEN	TS:	10 /450	2,3 %
	H.R	7 /297	2,4%
	L.R.	3 /153	2%
> ASYMPTOMATIC PATIE	ENTS :	4 /265	1,6 %
	H.R.	2 /160	1,3%
	L.R.	2 /105	1,9%

C.A.S UNDER PROTECTION HIGH AND LOW RISK PATIENTS

588 ARTERIES

	HIGH RISK n = 326	LOW RISK n = 262	P value
MINOR STROKE	4 1,2%	3 1,1%	N.S.
MAJOR STROKE	1 0,3%	1 0,4%	N.S.
FATAL STROKE	2 0,6%	0	N.S.
ALL STROKES	7 2,1%	4 1,5%	N.S.
ALL DEATH	4 1,2%	1 0,4%	N.S.
DEATH + STROKE	9 2,8%	5 1,9%	N.S.

G.WEISZ JACC 2004;43:101A

C.A.S UNDER PROTECTION HIGH AND LOW RISK PATIENTS

30 DAY OUTCOME

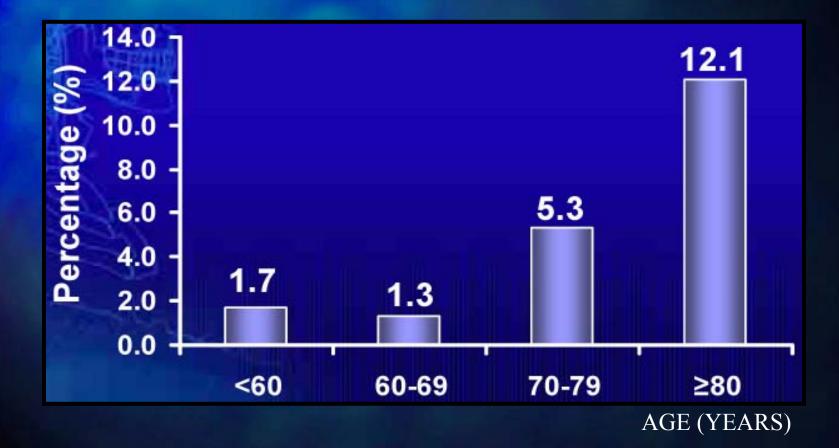
287 ARTERIES 133 WITH E.P.D. 154 WITHOUT E.P.D.

and the second	H.R.	L.R.
NBR.	144	143
MINOR STROKE	0	2
MAJOR STROKE	4	1
M.I.	0	0
DEATH	1	0
TOTAL EVENT RATE	5 (3,5%)	3 (2,1%)

SIMILARLY GOOD OUTCOME CAS SHOULD BE OFFERED TO L.R.

H.ARJOMAND AM. J.CARDIOL. 2004;94:61E

C.A.S. CREST STUDY STROKE AND DEATH



M. WHOLEY ALL THAT JAZZ NEW ORLEANS MAY 2007

C.A.S.

OCTOGENARIANS



HIGH RISK OF BRAIN EMBOLISM WITH TYPE 3AORTIC ARCH ATHEROMATOUS ARCH TORTUOSITIES

AORTIC ARCH IS A SUBSTANTIAL SOURCE OF EMBOLI

AORTIC ARCH HAS ITS OWN SET OF EMBOLIC POTENTIAL

AVOID EXCESSIVE CATHETER MANIPULATION IN ARCH

MORE THAN 20 mn : BETTER TO QUIT

M. WHOLEY ALL THAT JAZZ NEW ORLEANS MAY 2007

C.A.S. IN OCTOGENARIANS 30 DAY OUTCOMES

		> 80 Y.			< 80 Y.		
902 PROCEDURES	TOTAL	WITHOUT EPD	WITH EPD	TOTAL	WITHOUT EPD	WITH EPD	
NBR	118	6	112	784	181	603	
T.I.A.	2 (1,7%)	1 (17%)	1 (0,9%)	8 (1%)	3 (1,7%)	5 (0,8%)	
MINOR STROKE	1 (0,8%)	1 (17%)	0	5 (0,6%)	2 (1,1%)	3 (0,5%)	
MAJOR STROKE	0	0	0	3 (0,4%)	2 (1,1%)	1 (0,2%)	
RETINAL EMBOLUS	0	0	0	4 (0,5%)	0	4 (0,6%)	
HYPERPERFUSION SYNDROME	0	0	0	3 (0,4%)	0	3 (0,5%)	
DEATH FATAL STROKE NON FATAL STROKE	0	0	0	5 (0,6%) 4 (0,5%) 1 (0,1%)	2 (1,1%) 2 (1,1%) 0	3 (0,5%) 2 (0,3%) 1 (0,2%)	
M.I.	0	0	0	1 (0,1%)	0	1 (0,2%)	
DEATH / STROKE	1 (0,8%)	1 (17%)	0	13 (1,7%)	6 (3,3%)	7 (1,2%)	
DEATH / STROKE / M.I.	1 (0,8%)	1 (17%)	0	14 (1,8%)	6 (3,3%)	8 (1,3%)	

E.P.D. : EMBOLIC PROTECTION DEVICES

C.A.S. IN OCTAGENARIONS

- 1053 PATIENTS 1222 C.A.S.
- < 80 YEARS : 1078</p>
- > 80 YEARS : 144
- **30 DAY OUTCOME**

	> 80 YEARS	< 80 YEARS
DEATH STROKE RATE	2,12%	1,11%
FATAL STROKE	2	
MINOR STROKE	1	6
MAJOR STROKE		3
DEATH	2	3

C.A.S IS SAFE AND EFFECTIVE IN EDERLY PATIENTS

SETACCI C. ET AL J. ENDOVASC THER.: 2006;13:302-309

C.A.S. IN HIGH VOLUME CENTERS OCTOGENARIANS

STROKE / DEATH / M.I. : 0 - 30 DAYS

	ALL PTS	< 80Y.O.	≥ 80Y.O.
ROUBIN et al n : 312	1,3%	1,3%	1,2%
MYLA et al n : 724	3,5%	3,1%	1,7%
WHOLEY et al n:814	1%	0,8%	1,7%
REIMERS et al n : 815	3,4%	3,5%	2,3%
HENRY et al n:842	1,5%	0,8%	1,8%

PATIENTS WITH CONTRALATERAL CAROTID OCCLUSION

PERSONAL EXPERIENCE -30 DAY OUTCOMES

54 C.A.S. UNDER PROTECTION

30 DAY COMPLICATIONS

DEATH: $\mathbf{0}$ **MAJOR STROKE :** $\mathbf{0}$ **MINOR STROKE :** ▶ M.I. $\mathbf{0}$ ► T.I.A. : 1/54 (1,9%) > AMAUROSIS : 1/54 (1,9%) **DEATH / STROKE /MI INTOLERANCE DURING PROCEDURE : 4/54 (7,4%) PERCUSURGE** : 1 FILTERS : 3

C.A.S. OCTOGENARIANS

HOW TO REDUCE THE RISKS ?

CAROTID ANGIOPLASTY AND STENTING HOW TO REDUCE THE RISKS

1 - GOOD INDICATIONS (PATIENT AND LESION SELECTION)

2 CORRECT TECHNIQUE OF C.A.S.

3 - BRAIN PROTECTION DEVICES (B.P.Ds) CONSENSUS AMONG SPECIALISTS THAT B.P.D.s NEED TO BE USED IN EACH C.A.S. PROCEDURE

4 - GOOD CHOICE OF THE STENT AND CORRECT IMPLANTATION

5 – PHARMACOLOGICAL ADJUNCTS

6 - GOOD TEAM

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CAROTID STENOSIS INDICATIONS FOR REVASCULARIZATION

SYMPTOMATIC PATIENT WITH A **STENOSIS > 50%**

ASYMPTOMATIC PATIENT WITH A STENOSIS > 80%



ASYMPTOMATIC PATIENTS

WHICH PATIENTS TO TREAT ? PATIENTS WITH HIGHER RISK OF IPSILATERAL STROKE

ULTRASONIC PLAQUE MORPHOLOGY : HETEROGENOUS HYPOECHOLUCENT PLAQUES

PATIENTS WITH SILENT BRAIN INFARCTS

PATIENTS WITH IMPAIRED CEREBROVASCULAR RESERVE

PATIENT WITH ASYMPTOMATIC EMBOLIZATION IN M.C.D. BY T.C.D.

C.A.S. HIGH/LOW RISK PATIENTS

CLINICAL RISK

ANATOMICAL RISK

CAROTID STENOSIS INDICATIONS FOR REVASCULARIZATION

PREASSESSMENT

- CLINICAL BIOLOGICAL ASSESSMENT
- NEUROLOGICAL ASSESSMENT
- CARDIOLOGICAL ASSESSMENT
- DUPPLEX SCAN
 - **PLAQUE CHARACTERIZATION**
 - **EVALUATION OF RISK OF EMBOLISATION ?**
- **C.T. SCAN / M.R.I.**
- ANGIOGRAPHIC EVALUATION

RECOGNIZE HIGH RISK PATIENT

C.A.S. ANGIOGRAPHIC EVALUATION

 ANGIOGRAPHY OF AORTIC ARCH
 4 VESSEL ANGIOGRAPHY
 I.C.A. LESIONS CHARACTERISTICS HIGH RISK PLAQUES CALCIFICATIONS TORTUOSITIES

INTRACRANIAL CIRCULATION AND CONTRALATERAL LESIONS

WHICH PATIENT TO AVOID

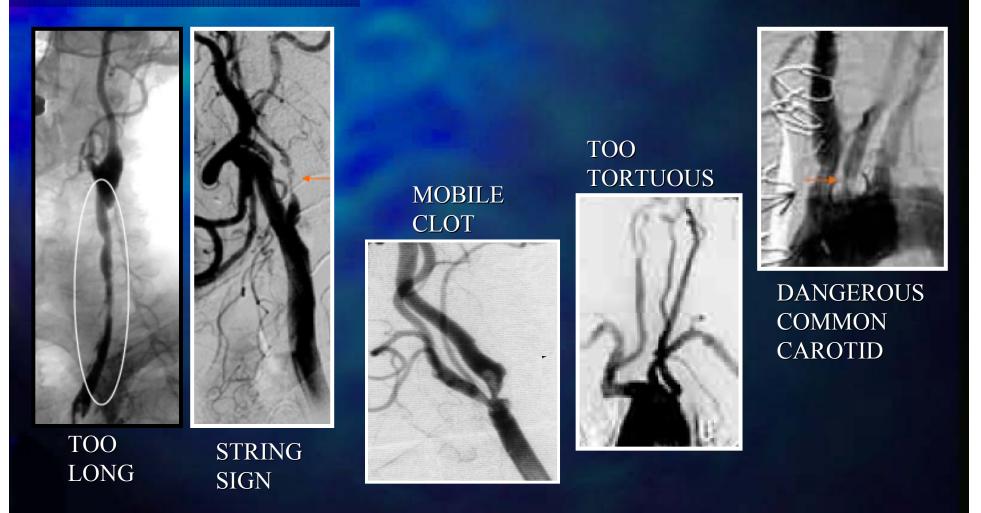


HIGH ANATOMICAL RISKS

COMPLEX AORTIC ARCH

- **> TYPE 3**
- **> TORTUOUS ARTERIES**
- LENGTH OF LESION
- PLAQUE MORPHOLOGY: ECHOLUCENT PLAQUE (GSM < 25) .VULNERABLE PLAQUE. IMPORTANT ROLE OF DUPLEX-SCAN, IVUS IN THE FUTURE
- **TYPE C LESION**
- INTRACRANIAL CIRCULATION

C.A.S. BETTER PATIENT SELECTION



M. WHOLEY ALL THAT JAZZ NEW ORLEANS MAY 2007

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CLOSED CELL STENTS

LASER CUT

BRAIDED



CLOSED-CELL PATTERN ONE-TO-ONE CELL RELATION e.g ABBOTT-XACT BOSTON-NEXSTENT



WOVEN TUBE ONE-TO-ONE CELL RELATION e.g WALLSTENT

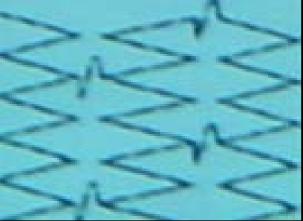
OPEN CELL STENTS



PERIODIC PEAK-PEAK FLEX CONNECTORS E.G.OPTIMED SINUS

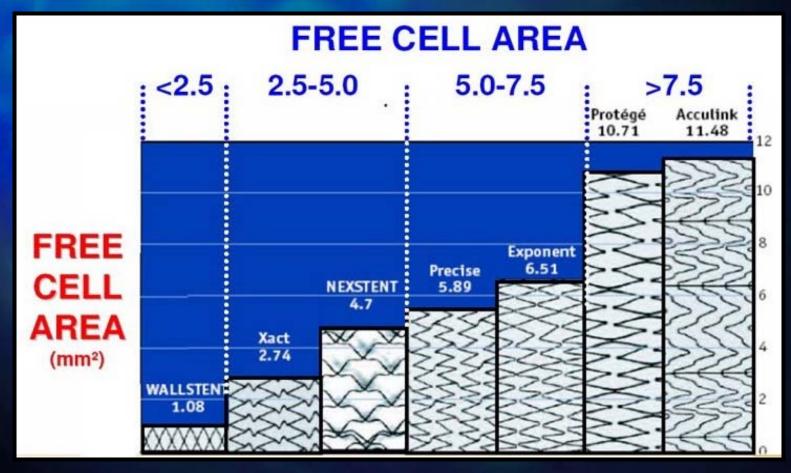


PERIODIC PEAK-PEAK NONFLEX CONNECTORS E.G. CORDIS - PRECISE

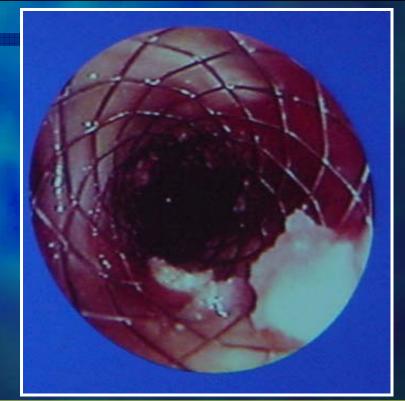


PERIODIC PEAK-VALLEY NONFLEX CONNECTORS E.G. COOK - ZILVER

RINGS CONNECTED BY "BRIDGES"

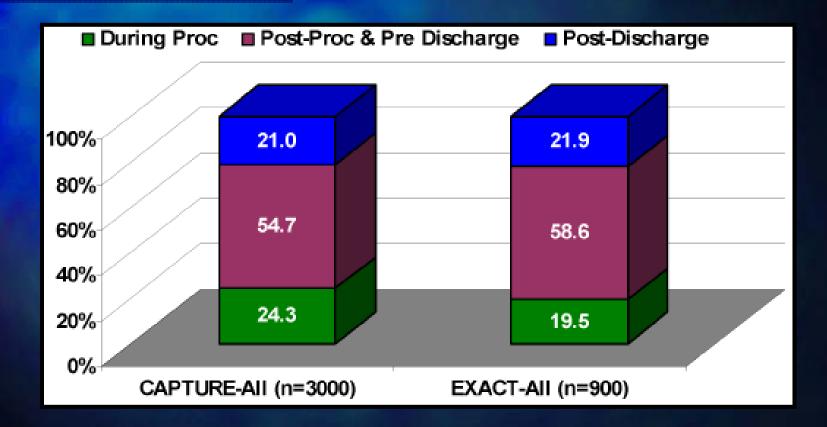


DELOOSE ISET MIAMI 2007



ROLE OF PLAQUES PROLAPSE INCREASE EMBOLIC RISK →DELAYED EMBOLIC EVENTS

CAPTURE 3000 VS EXACT 900: TIMING OF STROKE



THE MAJORITY OF STROKE OCCUR POST PROCEDURE AND BEFORE DISCHARGE

C.A.S. ROLE OF STENT DESIGN

BOSIERS'S SERIES – 30 DAY OUTCOME

	OPEN CELL	CLOSED CELL		
	N=63	N=235		
STROKE/DEATH	1,6%	0,9%		
DEATH	0%	0,4		
T.I.A., STROKE, DEATH	11,1%	3%		

HIGHER RISK OF T.I.A. WITH OPEN CELL STENT

BOSIER M. ET AL EURO J.ENDOVASC. SURG. 2007;33:135-141



S. E. STENT EFFECTS HIGH EMBOLIC RISK PLAQUES

NEED FOR DIFFERENT STENTS AND TECHNIQUES

USE CLOSED CELL STENTS EXCEPT IN TORTUOUS VESSELS

METICULOUS CLEANING OF THE DILATED AREA (ASPIRATION WITH ASPIRATION CATHETER OR GUIDING) TO AVOID DELAYED EMBOLIC EVENTS

ROLE OF NEW PROTECTION DEVICES

CAROTID ANGIOPLASTY AND STENTING HOW TO REDUCE THE RISKS

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3 - BRAIN PROTECTION DEVICES (B.P.Ds) CONSENSUS AMONG SPECIALISTS THAT B.P.D.s NEED TO BE USED IN EACH C.A.S. PROCEDURE

4 - GOOD CHOICE OF THE STENT AND CORRECT IMPLANTATION

5 – PHARMACOLOGICAL ADJUNCTS

6 - GOOD TEAM



UNDER CEREBRAL PROTECTION

 E.P.D. CAN NOT PREVENT FROM ALL NEUROLOGICAL COMPLICATIONS
 ALL E.P.D. ARE NOT EQUIVALENT
 CURRENT E.P.D. HAVE LIMITATIONS

IMPROVEMENTS IN E.P.D. ARE INDISPENSABLE

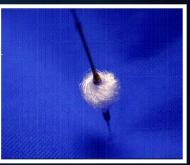
CHOOSE CAREFULLY YOUR E.P.D.

C.A.S. UNDER PROTECTION A NEW 3D FILTER: FIBERNET® (LUMEN BIOMEDICAL)



FIBERNET[®] IS A NOVEL E.P.D. THAT INCORPORATES THE ABILITY TO ALLOW FLOW DURING THE PROCEDURE (FILTER), CAPABILITY TO CAPTURE SMALL PARTICLES (OCCLUSION BALLOON) AND IS DELIVERABLE AS A STANDARD CORONARY GUIDEWIRE

UTILIZES A MESH OF 150 - 600 PET FIBERS TO CAPTURE EMBOLIC PARTICLES IN A "3DIMENSIONAL FILTER" FIBERS INCORPORATED ON A 0,014"CORONARY GUIDEWIRE (190cm) WITH A SHAPEABLE TIP DOES NOT REQUIRE A DELIVERY SHEATH FOR DELIVERY DEPLOYMENT AVAILABLE IN 5 SIZES FOR VESSELS 1,75 -7.0 MM IN DIAMETER BETTER WALL APPOSITION THAN WITH OTHER FILTERS EXCELLENT PARTICULE ENTRAPMENT RETRIEVAL SHEATH WHICH IS A N ASPIRATION CATHETER



C.A.S. UNDER PROTECTION LIMITATIONS

LEARNING CURVE OPERATOR EXPERIENCE



EXPERIENCE – LEARNING CURVE

	GROUP 1	GROUP 2	GROUP 3	GROUP 3	GROUP 3
and the second	CASES nº1	CASES n°51	CASES nº101	CASES n°151	CASES n°2011
	TO 50 N = 50	TO 100 N = 50	TO 150 $N = 50$	TO 200 $N = 50$	TO 246 N = 46
TECHNICAL SUCCESS	47 (94%)	49 (98%)	50 (100%)*	50 (100%)*	46 (100%)*
HOPITAL LENGTH OF STAY (D)	1.6±1.2	1.3±1.1	1.4±0.7	1.5±0.6	1.4±0.8
PROCEDURAL VARIABLES					
a) PROCEDURAL TIME (min)	58±10	43±11*	39±8 †	36±10†	38±12†
b) CONTRAST USED (ml)	98±24	79±19*	55±15†	53±12†	50±15†
COMPLICATIONS					
a) CARDIOPULMONARY	2 (4%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)
b) HEMORRHAGIC	3 (6%)	1 (2%)	0*	0*	0*
c) STROKE (T.I.A.)	1 (2%)	0	0		0
d) STROKE (MINOR)	1 (2%)	1 (2%)	0	0	0
e) STROKE (MAJOR)	1 (2%)	0	0	0	0
30 DAY DEATH	1 (2%)	0	0	0	0
30 DAY STROKE/DEATH	4 (8%)	1 (2%)*	0†	0†	0†
OVERALL COMPLICATION RATE	9 (18%)	4 (8%)†	1 (2%)‡	1 (2%)‡	1 (2%)‡
*P <.05 WHEN COMPARED TO GROUP 1					
[★] P <.03 WHEN COMPARED TO GROUP 1					

‡P < .01 WHEN COMPARED TO GROUP 1

LIN P. ET AL ENDOVASC. TODAY 2006

C.A.S. CREST STUDY

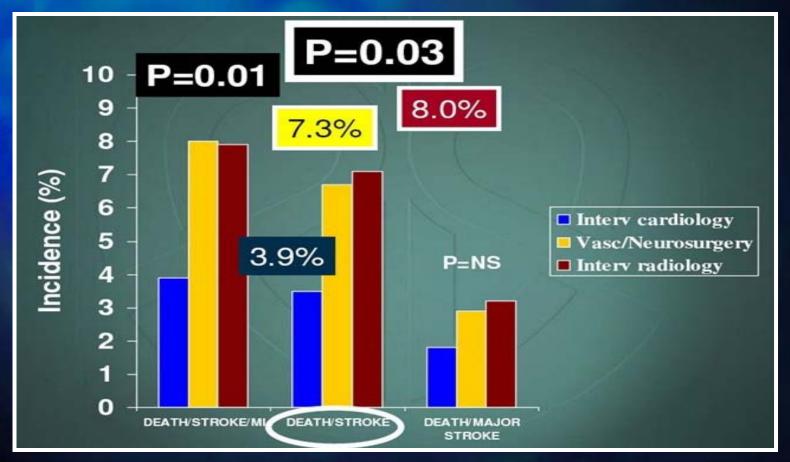
LEAD - IN N= 1479

- Cardiology
- Surgery
- Radiology
- Neuro-Radiology
- Neurology
- Unclassified

567(38%) 450(30%) 251(17%) 136(9%) 11 60

C.A.S. CREST STUDY

TOTAL POPULATION 30 DAY EVENTS BY SPECIALITY



ROUBIN G. ISET MIAMI 2007

C.A.S. UNDER PROTECTION IN HIGH AND LOW RISK PATIENTS CONCLUSIONS

- C.A.S. WITH DISTAL EMBOLIC PROTECTION DEVICES HAS FAVORABLE LOW EVENT RATE
 C.A.S. HAS SIMILARLY GOOD OUTCOME IN H.R. AND L.R. PATIENTS
- A METICULOUS TECHNIQUE IS NEEDED AS WELL AS GOOD INDICATIONS, GOOD PATIENT AND LESION SELECTION

COMPARED TO H.R. PATIENTS, L.R. PATIENTS HAVE A TREND TOWARDS LOWER SHORT TERM MAJOR EVENT RATE, BUT THE DIFFERENCES DID NOT REACH STATISTICAL SIGNIFICANT

C.A.S. UNDER PROTECTION IN HIGH AND LOW RISK PATIENTS CONCLUSIONS

 PROTECTION DEVICES ENLARGED THE INDICATIONS FOR C.A.S. AND SHOULD NOT BE LIMITED TO H.R. PATIENTS
 C.A.S. SHOULD BE OFFERED TO L.R. PATIENTS

BETTER PROTECTION DEVICES WILL BE SOON ON THE MARKET

C.A.S. UNDER PROTECTION IS BECOMING THE GOLD STANDARD TREATMENT