RENAL ANGIOPLASTY AND STENTING UNDER PROTECTION .LIMITATIONS FIRST HUMAN STUDY WITH A 3D FILTER THE FIBERNET®

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RENAL ARTERY DISEASES ETIOLOGY

- **ATHEROSCLEROTIC STENOSIS:**
 - > 80-90% OF THE CASES OVER 40 YEARS
- FIBROMUSCULAR DYSPLASIA (<10%)
- **ARTERITIS** (takayasu' disease)
- NEUROFIBROMATOSIS
- RENAL ARTERY TRANSPLANT
- RENAL BYPASS GRAFT
- RADIATIONS

RENAL ARTERY STENOSIS MANAGEMENT

RENAL ARTERY STENTING

THE FIRST TREATMENT TO BE PROPOSED

- **TECHNICAL SUCCESS: 98 TO 100%**
- **GOOD ANATOMICAL RESULTS**
- FEW COMPLICATIONS
- **LOW RESTENOSIS RATE**
- **GOOD LONG TERM PATENCY**

RENAL ARTERY STENTING

EFFECTS ON RENAL FUNCTION

RENAL ARTERY STENTING EFFECT ON RENAL FUNCTION

AUTHORS	YEAR	PTS (n)	IMPROVED (%)	STABLE (%)	WORSE (%)
DORROS (21)	1995	69	30	48	22 *
IANNONE (28)	1996	63	36	46	18
TAYLOR (26)	1997	39	33	29	38 *
BLUM (19)	1997	68		100	
HARDEN (27)	1997	32	34	34	28 *
BOISCLAIR (45)	1997	33	41	35	24 *
PAULSEN (37)	1999	135	23	56	21 *
ISLES (44)	1999	379	26	48	26 *
RODRIGUEZ LOPEZ (38)	1999	108	AND DESCRIPTION OF THE PERSON NAMED IN	95,5	4,5
HENRY (17)	1999	235	29	67	4
RUNDBACK (82)	1999	45	25	43	32
GUERRERO (41)	2002	61	19	50	31 *
ALLAQUABAND (83)	2003	22	50	23	27 *
HALLER (84)	2004	261		86	14
ZELLER (34)	2004	340	34	39	27
OVERALL * DATE DATE DE LA CONTROL DE LA CONT		1890	25,3	53,3	21,4

^{*} PATIENTS WITH BASELINE SERUM CREATININE ≥ 1,5 mg/DL

RENAL ANGIOPLASTY STENTING

Categorical Changes in Serum Creatinine Concentrations According to Baseline Renal Function, Degree of Nephrosclerosis, Diabetes Mellitus, and Bilateral Intervention

	Base	line Renal Fun	ction*				,			
		Mild to Moderate	Severely	Resistance Index			Diabetes		Intervention	
	Normal	Impairment	Impaired	<0.7	0.7-0.8	>0.8	No	Yes	Bi	Uni
	(n=176)	(n=130)	(n=24)	(n=112)	(n=168)	(n=50)	(n=208)	(n=122)	(n=85)	(n=245)
Improved	20%	46 %	71%	28%	37%	37%	34%	34%	41%	32%
Unchanged	44%	36 %	21%	45%	36%	35%	33%	42%	36%	40%
Deteriorated	36%	18%	8%	27%	27%	28%	33%	24%	23%	28%

Bi: bilateral, Uni: unilateral.

^{*} Normal: serum creatinine <1.2 mg/dL, mild/moderate impairment: serum creatinine 1.21 to 3 mg/dL, severely impaired: serum creatinine >3.0 mg/dL.

RENAL ARTERY STENTING EFFECT ON RENAL FUNCTION

- 82 PATIENTS
- 96 R.A.S. WITH MODERN LOW PROFILE SYSTEMS
- TECHNICAL SUCCESS: 98%
- RENAL FUNCTION AT 1 YEAR
 - ► IMPROVED: 53%
 - **STABLE: 53%**
 - ➤ WORSE : 24%

RENAL ARTERY STENTING

A CONCERN

DETERIORATION OF RENAL FUNCTION AFTER R.A.S.: 20 TO 30 %

PROGRESSIVE RENAL DYSFUNCTION AFTER STENTING ETIOLOGY AND TIME COURSE

ETIOLOGY	TIME COURSE
CONTRAST MEDIA	1 – 2 DAYS
GLOMERULA INJURY HYPERPERFUSION SYNDROM	DAYS TO WEEKS
PROGRESSIVE NEPHROSCLEROSE	MONTHS TO YEARS
RESTENOSIS	3 – 6 MONTHS
ATHERO - EMBOLI	3 – 4 WEEKS

RENAL ARTERY STENTING ROLE OF PROTECTION DEVICES

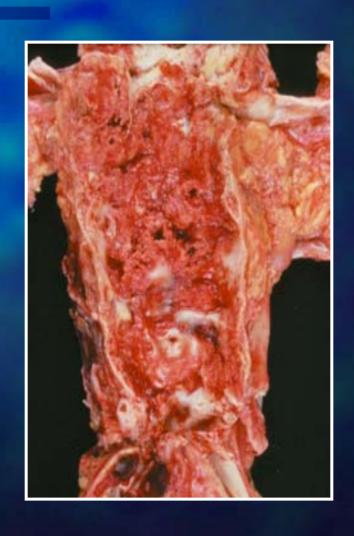
THE RULE IN ANY INTERVENTION IN
ATHEROSCLEROTIC DISEASE AND SEEM THE
ROOT CAUSE OF MANY PROCEDURAL
COMPLICATIONS WHENEVER
ATHEROSCLEROTIC LESIONS ARE TREATED

■IT WAS WELL DEMONSTRATED IN SAPHENOUS BY PASS AND IN CAROTID ANGIOPLASTY

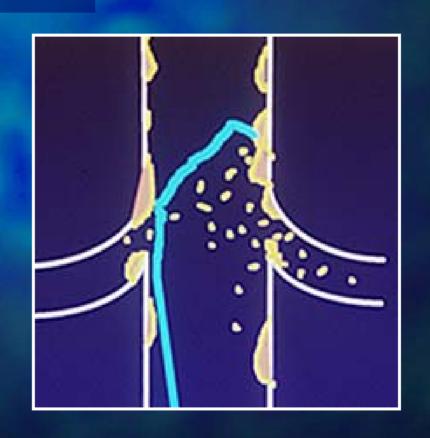
RENAL ARTERY ANGIOPLASTY RENAL ATHEROEMBOLISM

AS IN OTHER TERRITORIES
ATHEROEMBOLI SHOULD PLAY AN
IMPORTANT ROLE IN RENAL
CIRCULATION AND EXPLAIN SOME
COMPLICATIONS (R.F. DETERIORATION)

ATHEROEMBOLISM



ATHEROEMBOLISM



ATHEROEMBOLISM - ETIOLOGY

MOST ATHEROMATOUS OSTIAL STENOSES INVOLVE ATHEROMA OF THE AORTIC WALL

- **ATHEROMATOUS DEBRIS ARE DETACHED DURING:**
 - **>** ANGIOGRAPHY
 - ➤ INSTRUMENTAL MANIPULATIONS IN AORTA -RENAL ARTERIES (CATHETERS, WIRES, GUIDING CATHETERS, BALLONS, STENTS...
- **PROMOTING FACTORS**
 - > LENGTH OF THE PROCEDURE
 - > DIFFICULTIES OF THE PROCEDURE
 - SIZE OF THE DEVICES
 - **ELDERLY PATIENTS**
 - ►ATHEROMATOUS AORTA
 SHOWERS OF CHOLESTEROL CRYSTALS FROM
 ATHEROSCLEROTIC AORTA THAT OCCLUDE SMALL ARTERIES

- 33 EX VIVO RENAL ANGIOPLASTY AND STENTING OF HUMAN RENAL ARTERY ATHEROSCLEROTIC SPECIMENS REMOVED DURING AORTO RENAL ENDARTERECTOMY
- TECHNICAL SUCCESS: 31/33
 - > 0,018 **GUIDE** WIRE
 - > 3 TO 5 mm BALLOONS
 - > 5/6 mm WALLSTENT
- EMBOLIC PARTICLES COLLECTED IN THE EFFLUENT AFTER EACH MANIPULATION

RESULTS

- EACH MANIPULATION OF THE SPECIMENS INCLUDING SIMPLY ADVANCING THE GUIDEWIRE THROUGH THE LESION RELEASED THOUSANDS OF FRAGMENTS
- > THE NUMBERS OF FRAGMENTS IN EACH SIZE CATEGORY INCREASED WITH DECREASING PARTICLES SIZE
- ➤ POSITIONING AND DEPLOYING THE STENT RELEASED AN ADDITIONAL BOLUS OF FRAGMENTS SIMILAR TO THAT RELEASED AFTER BALLOON ANGIOPLASTY

CONCLUSIONS

- EX VIVO RENAL ANGIOPLASTY RELEASED THOUSANDS OF ATHEROSCLEROTIC FRAGMENTS OF SUFFICIENT SIZE TO CREATE VASCULAR OCCLUSIONS AND INITIATE SIGNIFICANT RENAL PARENCHYMAL DAMAGE
- > THE RESULTS OF RENAL ANGIOPLASTY PROCEDURES COULD BE IMPROVED BY PLACING DISTAL PROTECTION DEVICES TO PREVENT ATHEROEMBOLIZATION

- **ATHEROEMBOLI TYPICALLY OCCLUDE THE MEDIUM SIZED ARTERIOLES** (150 TO 200 μm IN DIAMETER) AND GLOMERULAR CAPILLARIES. THE INVOLVEMENT USUALLY IS PATCHY
- THE PATHOGENESIS OF RENAL FAILURE MAY BE DUE ENTIRELY TO OCCLUSION OF THESE VESSELS
- BUT REACTIVE INFLAMMATION SURROUNDING THE CHOLESTEROL CRYSTALS MAY PLAY A SIGNIFICANT ROLE IN CAUSING THE LUMINAL OCCLUSION AND SUBSEQUENT RENAL FAILURE

ATHEROEMBOLIC RENAL DISEASE DIAGNOSIS

TRUE INCIDENCE: UNCERTAIN

- PROVEN IN 2-3% (BIOPSY, SEVERE GENERALISED SYSTEMIC CHOLESTEROL EMBOLISATION)
- > REAL INCIDENCE: MUCH HIGHER. DIFFICULT TO PROVE
- ATHEROEMBOLISM REDUCES FUNCTIONAL RENAL MASS
 - SILENT COURSE; LITTLE CHANGE OR NO CHANGE IN RENAL FUNCTION IN SOME PATIENTS DUE TO THE LARGE FUNCTIONAL KIDNEY RESERVE, DESPITE A SIGNIFICANT DECLINE OF TOTAL GLOMERULAR FILTRATION
 - ONLY THE MOST SEVERE CASES CAN BE DETECTED
 - MUCH MORE PROFUND EFFECTS IN PATIENTS WITH PREPROCEDURAL RENAL DYSFUNCTION AND LIMITED FUNCTIONAL RESERVE
 - o ABNORMAL SERUM CREATININE IF 50% OF THE NEPHRON POPULATION IS DESTROYED (→HIGH RISK FOR PATIENT WHO HAS MID RENAL IMPAIRMENT)

RENAL ARTERY STENTING RENAL FUNCTION DETERIORATION

ATHEROEMBOLISM SEEMS TO PLAY AN IMPORTANT ROLE

DIFFICULT DIAGNOSIS

NO SPECIFIC TREATMENT

POOR PROGNOSIS

PREVENTION WITH PROTECTION DEVICES

RENAL ARTERY ANGIOPLASTY RENAL ATHEROEMBOLISM

THE CONCEPT OF DISTAL PROTECTION SHOULD BE APPLIED TO RENAL ANGIOPLASTY AS TO OTHER ANGIOPLASTIES (CAROTID, CORONARY ARTERIES) TO AVOID SOME COMPLICATIONS

RENAL ARTERY STENTING UNDER D.P.D.

RESULTS

	POPU	LATION (1)	
RENAL ANGIOPLASTIF	ES AND ST	TENTING:	129
■ PATIENTS:			11
> MALE:			7
> FEMALE:			3
> MEAN AGE :		$64,4 \pm 11,7 \text{ YEARS } (22-6)$	87)
■ BILATERAL PROCEDU	RES:		1
2 ARTERIES AT THE SA	ME SIDE		1
POORLY CONTROLLE	D HYPERT	TENSION:	10/11
RENAL INSUFFICIENC	Y:		43/11
MODERATE	27	(creatinine between 1.5 and 1.9 m	ng/dl)
> SEVERE	16	(creatinine ≥ 2 m	ng/dl)

(1 TRANSPLANT RENAL ARTERY)

■SOLITARY/SINGLE FUNCTIONING KIDNEY:

POPULATION (2)

	CITIZ			a
RI		I A	UK	2

> DIABETES	33/110
> SMOKING	77/110
> DYSLIPIDEMIA	69/110
SSOCIATED DISEASES	

CONONART DISEASES	///110
> P.V.D.	38/110
> SUPRA AORTIC VESSEL DISEASES:	20/110

■ VERY DISEASED AORTA: 61/110

- FEMORAL APPROACH: 128/129
- BRACHIAL ACCESS: 1/129 (TOTAL OCCLUSION ILIAC ARTERIES)
- GUIDING CATHETER: 6F TO 8 F
- PREDILATATION: 28/129
- DIRECT STENTING: 101/129
- 132 STENTS IMPLANTED

AVE: 15 STENTEC: 4

P154 : 6 BIOTRONIK: 1

NIR: 5 EXPRESS: 27

HERCULINK: 14 ABBOTT: 6

CORINTHIAN: 11 CARBOSTENT: 7

GENESIS: 34 CORDIS M3: 2

- MEAN ARTERIAL OCCLUSION TIME: (PERCUSURGE) 6.46 ± 2.42 mm (2.48 13.13 mm)
 - ► DIRECT STENTING: 5.02 ± 1.53 mm
 - \triangleright SECONDARY STENTING: 7.57 ± 2.48 mm

MEAN TIME IN SITU (FILTERS) : $4,22 \pm 1,18$ mm

P < 0.015

PROTECTION DEVICES USED

PERCUSURGE: 46 PROCEDURES

EPI FILTER: 60 PROCEDURES

EMBOSHIELD 6 PROCEDURES

ANGIOGUARD: 11 PROCEDURES

FIBERNET®: 4 PROCEDURES

ACCUNET 2 PROCEDURES

IMMEDIATE RESULTS

TECHNICAL SUCCESS: 100 % (2 PREDILATIONS REQUIRED TO CROSS A SUBOCCLUSIVE CALCIFIED LESION)

PROCEDURAL SUCCESS: 100 %

MAJOR COMPLICATIONS: 0 %

ARTERIAL SPASM: 3/129

FILTER: 2

PERCUSURGE: 1

FOLLOW UP (5)

RENAL FUNCTION

MEAN FOLLOW UP: 29.3 ± 13 MONTHS (2 – 98)

- **ACUTE DETERIORATION: 1**
- **AT 6 MONTHS: 101 PATIENTS**
 - >STABILIZATION: 75

>IMPROVEMENT: 25

99%

- DETERIORATION: 1 (PATIENT WITH MODERATE RENAL INSUFFICIENCY)
- AT 2 YEARS: 84 PATIENTS
 - STABILIZATION: 60

95%

- IMPROVEMENT: 20
- DETERIORATION: 4 (5%)

01 PATIENT: BILATERAL ANGIOPLASTY, 1 WITHOUT PROTECTION

o3 PATIENTS WITH RENAL INSUFFICIENCY (1 MODERATE, 2 SEVERE)

R.A.S. UNDER PROTECTION

- 90 PATIENTS WITH ISCHEMIC NEPHROPATHY
- 106 RENAL ARTERIES
 - MILD RENAL INSUFFICIENCY: 33 (37%)
 - MODERATE RENAL INSUFFICIENCY: 48 (53%)
 - > SEVERE RENAL INSUFFICIENCY: 9 (10%)
- ANGIOGUARD :94 ARTERIES
- FILTERWIRE: 12 ARTERIES

R.A.S. UNDER PROTECTION RESULTS

MEAN FOLLOW UP: 18,2 MONTHS (2-54 MONTHS)

- IMPROVED RENAL FUNCTION: 36%
- STABILIZED: 55%
- PROGRESSIVE DECLINE: 8%
- ACUTE DETERIORATION: 1%

R.A.S. UNDER PROTECTION

32 R.A.S. WITH PERCUSURGE

- ➤ RENAL INSUFFICIENCY: 92%
- 4 6 WEEK FOLLOW UP
 - > R.F. IMPROVEMENT : 50%
 - > R.F. UNCHANGED: 50%
 - > R.F. DETERIORATION: 0%

54% OF PATIENTS WITH R.F. DETERIORATION IMPROVED

CONCLUSION :

- R.A.S. UNDER PROTECTION IS A MARKED IMPROVEMENT IN SHORT TERM R.F. RESPONSE
- RESULTS ARE SIMILAR TO SURGICAL REVASCULARIZATION
- PROTECTION DEVICES MAY PREVENT R.F. HARM DURING R.A.S. AS A RESULT OF ATHEROEMBOLISM

R.A.S. UNDER D.P.D.

LIMITATIONS

R.A.S. UNDER D.P.D. CAPTURE EFFICIENCY

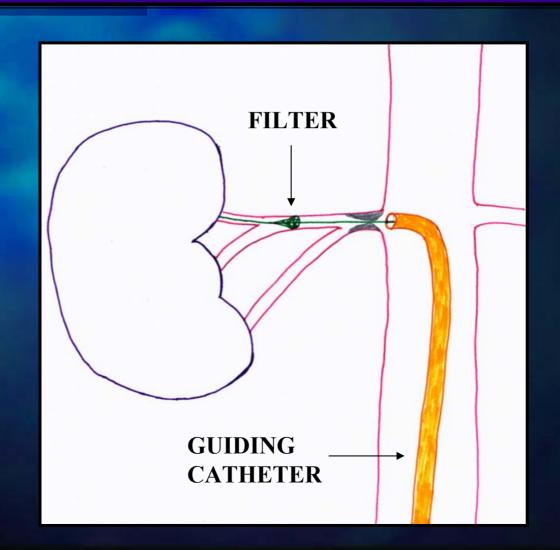
LIMITATIONS OF THE TECHNIQUE

- **EARLY BIFURCATION OF R.A. COLLATERAL BRANCHES**
 - **D.P.D. IN THE MAIN BRANCH?**
 - **▼RISK OF EMBOLISM IN THE NON PROTECTED BRANCH**
 - **▶ 2 D.P.D.?**

10% OF THE CASES

- LARGE VESSELS: SELECT THE D.P.D.
 - ► PERCUSURGE
 Ø 6/7 mm
 - FILTERS •Ø 7/8 mm

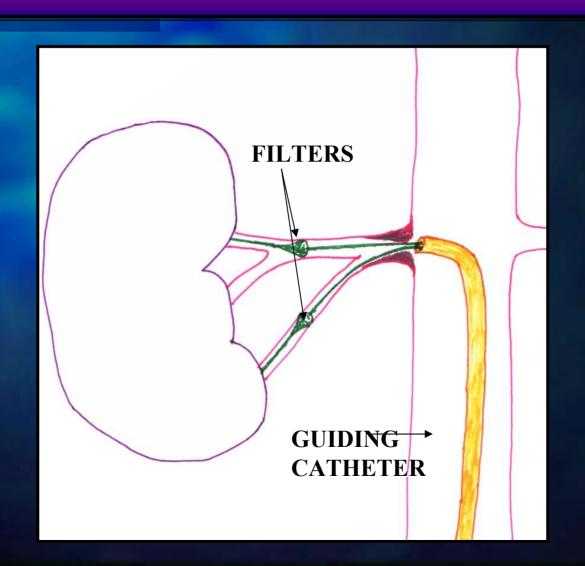
R.A.S. UNDER D.P.D. EARLY BIFURCATION



R.A.S. UNDER D.P.D. EARLY BIFURCATION



R.A.S. UNDER D.P.D. EARLY BIFURCATION



R.A.S. UNDER PROTECTION LIMITATIONS OF CURRENT EPDs

FILTERS

- PORE SIZE >100μ ALLOW SMALLER PARTICLES THROUGH FILTER : OCCLUSION OF SMALL VESSELS / MICROINFARCTS
- NOT WELL APPOSED TO ARTERIAL WALL IN ECCENTRIC OR DISEASED LANDING ZONE
- > RESTRICTIVE LANDING ZONE REQUIREMENTS
- FILTER CLOGGING REDUCES FLOW, MAKES IT DIFFICULT TO WITHDRAW
- POSSIBILITY OF DIFFICULTIES IN RETRIEVING FILTERS CAUGHT ON THE STRUTS OF THE STENT

OCCLUSION BALLOON

- POSSIBILITY OF DEFLATION
- PROBLEM OF WALL APPOSITION
- PROBLEM OF THE SHADOW ZONE
- **KIDNEY ISCHEMIA IF OCCLUSION IS GREATER THAN 10 mn?**

NEED FOR NEW PROTECTION DEVICE THAT OFFERS SIMPLICITY OF DELIVERY AND REMOVAL AND MORE EFFECTIVE EMBOLI ENTRAPMENT WHILE STILL PERMITTING DISTAL BLOOD FLOW

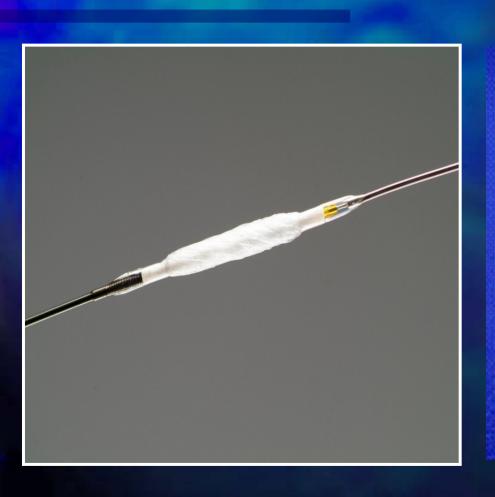
FIBERNET®

■ 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



- FIBER BASED FILTER
- UTILIZES A MESH OF 150 600 PET FIBERS TO CAPTURE EMBOLIC PARTICLES IN A "3DIMENSIONAL FILTER"
- FIBERS INCORPORATED ON A HIGH PERFORMANCE .014"CORONARY GUIDEWIRE (190cm) WITH A SHAPEABLE TIP
- DOES NOT REQUIRE A DELIVERY SHEATH FOR DELIVERY DEPLOYMENT

FIBERNET®





AVAILABLE IN 5 SIZES FOR VESSELS 1,75 - 7.0 mm IN DIAMETER

■ LOW CROSSING PROFILE (1.7 -3.1F)

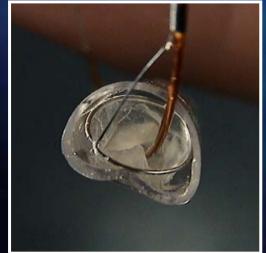
GOOD VESSEL WALL APPOSITION

VESSEL WALL APPOSITION



FIBERNET®





FILTERWIRE EZTM



FIBERNET®



EMBOLIC PROTECTION PARTICLE ENTRAPMENT





FIBERNET® RETRIEVAL CATHETER



- RETRIEVAL CATHETER ALLOWS FOCAL SUCTION DURING DEVICE REMOVAL
- ASPIRATION IS ACHIEVED THROUGH THE RETRIEVAL CATHETER USING VACUUM SYRINGES TO PROVIDE SUCTION
- CONTAINED AND CAPTURED EMBOLI ARE RECOVERED/REMOVED PRIMARELY BY ASPIRATION THROUGH THE RETRIEVAL CATHETER BUT ALSO BY RETENTION WITHIN THE FILTER FIBERS WHEN THE FILTER IS CLOSED AND RETRACTED INTO THE RETRIEVAL CATHETER
- ABILITY TO USE THE RETRIEVAL CATHETER TO ASPIRATE WITHIN THE STENT PRIOR TO FILTER RETRIEVAL

RETRIEVAL CATHETER ALLOWS CAPTURE OF EMBOLI AS LOW AS 30/40 MICRONS WHILE MAINTAINING BLOOD FLOW DURING PROCEDURE.

3 ASPIRATIONS ARE DONE:

- > INSIDE THE STENT
- **BETWEEN STENT AND FILTER**
- WHEN FILTER IS COLLASPED AND RETRACTED INTO THE RETRIEVAL CATHETER

RENAL ARTERY STENTING ATHEROEMBOLISM

POSITIVE BIO-TEST FOR EMBOLISM

- PORCINE MODEL
- **2x SAFER QUANTITY AND SIZE OF P.V.A. PARTICLES INJECTED**
- LEFT KIDNEY UNPROTECTED; RIGHT KIDNEY PROTECTED WITH FIBERNET
- 4 HOUR PERFUSION



LESION INFORMATION

RENAL PATIENTS

N: 4 SUBJECTS

- LESION CHARACTERISTICS 25 % CALCIFIED
- LESION LENGTH
- > PERCENT STENOSIS

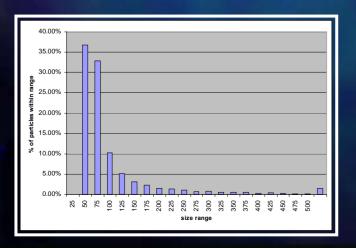
0% ULCERATED

MEAN 10.5mm (8-12mm)

MEAN 79% (75-80%)

RENAL RESULTS

- RENAL PATIENTS: 4 SUBJECTS
 - > PROCEDURE SUCCESS 100% (4/4)
 - %VISIBLE DEBRIS CAUGHT 100% (4/4)
 AVERAGE SURFACE AREA FOR DEBRIS: 117.1 mm2
 - **DEBRIS ANALYSIS: PARTICULES OF LESS THAN 40 MICRONS CAN BE REMOVED**
 - **ATHEROMATOUS MATERIAL FOUND IN BOTH ASPIRATE AND FILTER SAMPLES (65 % IN ASPIRATE SAMPLES)**



DEATH: 0 %

> SERIOUS ADVERSE

EVENTS: 0 %



CLINICAL STYDY DEBRIS ANALYSIS (UNIVERSITY OF MINNESOTA)

	FIBERNET®	OTHER EPD*
Nbr	34	14
VISIBLE DEBRIS	100 %	43 %
MEAN PARTICLE SIZE	28 TO 6839µ	28 ΤΟ 5302μ
NUMBER OF PARTICLES<100µ	4976	2752
MEAN SURFACE AREA	63,8 mm ²	12,2 mm ²

^{*}FILTERWIRE EZ:6, ACCUNET:6, EMBOSHEALD:1, ANGIOGUARD:1

CLINICAL STYDY DEBRIS ANALYSIS (UNIVERSITY OF MINNESOTA)

■ DEBRIS REMOVED WITH FIBERNET®: 5 TIMES MORE

■ 30% OF EMBOLI WAS ASPIRATED WITHIN THE STENT WITH THE FIRST SYRINGE

ADVANTAGES

- EASY TO USE AND TO PLACE EVEN IN ANGULATED RENAL ARTERY
- NO PREDILATATION REQUIRED AS IN C.A.S.
- > SHORT LANDING ZONE REQUIRED

DISTAL PROTECTION DURING RENAL ARTERY STENTING

INDICATIONS ALL ATHEROMATOUS PATIENTS? MAYBE THE FUTURE

- SELECTIVE INDICATIONS AT LEAST
 - **ELDERLY PATIENTS**
 - > PATIENTS WITH RENAL INSUFFICIENCY: CREATININE > 1.4 mg %
 - ISCHAEMIC NEPHROPATHY PATIENT GROUP
 - BILATERAL RENAL STENOSIS
 - SOLITARY OR SINGLE FUNCTIONING KIDNEY
 - DISEASED AORTA AND RENAL OSTIA
 - DIABETICS?

RENAL ARTERY STENTING CONCLUSIONS

- R.A.S. IS WIDELY PERFORMED, GIVING EXCELLENT IMMEDIATE TECHNICAL SUCCESS, GOOD LONG TERM PATENCY, <u>BUT</u> DETERIORATION OF RENAL FUNCTION AFTER R.A.S. IS A CONCERN (20 30 % OF THE CASES) AND LIMITS THE IMMEDIATE BENEFITS OF THE PROCEDURE
- ATHEROEMBOLISM SEEMS TO PLAY AN IMPORTANT ROLE
- RENAL PROTECTION IS A NEW APPROACH TO IMPROVE THE RESULTS OF R.A.S. AND IS NOT MERELY PARTICULATE RETRIEVAL.
- OUR RESULTS SHOW THE SAFETY AND EFFICIENCY OF THIS PROCEDURE
- BUT THIS TECHNIQUE HAS SOME LIMITATIONS (TECHNICAL PROBLEMS, COST....) AND HAS TO BE IMPROVED
- THE NEW FILTER FIBERNET® SEEMS PROMISING
- INDICATIONS SHOULD BE DEFINED
- RANDOMIZED STUDIES ARE AWAITED