The Future Role of the Cardiologist in Extracardiac Intervention: Carotid and Renal Arteries

G. Biamino

Clinical and Interventional Angiology

University of Leipzig Heart Center
The Role of the Cardiologist

- Undefined
- Controversial
The Role of the Cardiologist

The Expression "Vascular Interventionalism" does not exist.

Undefined
The Role of the Cardiologist

- **Controversial**
  - Who should decide when the pat. has to be treated?
  - Who should perform the intervention?
  - Who should take care of the pat. during the follow-up?
The Role of the Cardiologist

• Main Question
Do we really need an extension of cardiologist’s interventional activities into the peripheral field?

YES!
Interventional Cardiologists beyond PCI: Multisite Endovascular Therapy

- Renal
- Carotid
- Pelvic
- Subinguinal
The first PTRA, 07.12. 1977

Treatment of Renovascular Hypertension by Transluminal Renal Artery Dilatation

FELIX MAHLER, M.D.; ALEX KRNETA, M.D.; and MICHAEL HAERTHEL, M.D.
Inselhospitai, Bern, Switzerland

A 50-year-old woman was admitted to hospital in 1977 because of hypertension. In July her blood pressure was 240/120 mm Hg, and methyldopa therapy, 750 mg daily, was started. At examination her blood pressure was 140/100 mm Hg, and a high-pitched bruit was heard in the left upper abdominal quadrant. Arteriography revealed severe stenosis in the middle third of the left renal artery and a string-of-beads appearance of the distal right renal artery, suggesting intimal fibroplasia on the left and medial fibroplasia on the right side (4) (Figure 1a). Peripheral renin activity of 8.1 ng/ml-h was clearly higher than our normal standard (5), and the left-to-right ratio of the selective renal vein renin of 1.90 lateralized the excess renin to the left side. On 7 December transluminal dilatation of the left renal artery was done under general anesthesia at the patient's request (Figure 1b). After dilatation, anticoagulation therapy...
The Role of the Cardiologist
Renal Stenosis

Andreas Grünzig 1975
Cosmetic or Clinically Relevant?
Atherosclerotic Renal Artery Stenosis--
What are the Facts?

POOR DATA ON

- Incidence
- Prevalence
- Progression
Incidence of Renal Stenosis in Patients with CHD

15 % of patients undergoing CABG a significant RAS > 50 % can be found (Heart Center Leipzig)

19 % of patients (101/534) referred for coronary angiography with refractory hypertension (> 140/90 on two drugs) had RAS > 70%.

(Khosla et al., Cath. Card. Interv. 2003, 58:400-03)
Incidence of Renal Stenosis in Patients with CHD

- In a cohort of 500 consecutive patients showing a relevant coronary disease
  - 20% had an undetected renal stenosis
  - in half of these cases the stenosis was considered critical

8-10% 

P. Rubino et al., Cardiovascular Clinic, Montevergine Mercogliano (AV)
### Stent-angioplasty of RAS: Results - randomized trial stent vs PTA

<table>
<thead>
<tr>
<th></th>
<th>PTRA</th>
<th>PTRA/ Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td>42</td>
<td>43</td>
</tr>
<tr>
<td><strong>Primary success rate</strong></td>
<td>57%</td>
<td>88%</td>
</tr>
<tr>
<td><strong>Primary patency rate</strong></td>
<td>29%</td>
<td>75%</td>
</tr>
<tr>
<td><strong>Restenosis rate</strong></td>
<td><strong>48%</strong></td>
<td>14%</td>
</tr>
</tbody>
</table>

*Van den Ven et al.: Lancet 1999; 282-286*
Stent-angioplasty of RAS

Kaplan-Meier-curve: n = 364

Th. Zeller, 2002
Renal artery stenting

• Ostial stenosis of right renal artery
Renal artery stenting

• Ostial stenosis of right renal artery
Renal artery stenting

- Ostial stenosis of right renal artery
Renal artery stenting

- Ostial stenosis of right renal artery
What is the Problem Today??

• Primary Success Rate
  ~100%
• Restenosis Rate < 10%
• Complications rare

LET'S DO IT!!

INDICATION ???
Potential Indication for Renal Artery Revascularization

- Refractory/Resistant Hypertension
- Chronic Renal Insufficiency
- Recurrent Flash Pulmonary Edema
- Need for Use of ACEI
- Unilateral Renal Artery Stenosis

FEW DATA
NO DATA
Results of Renal Artery Angioplasty/ Stenting in Hypertensives

- Accumulate data from 8 authors
  349 patients with mean follow up 11 months

Hypertension:

- Unchanged: 44%
- Improved: 56%
- Cure: 10%

Palmaz JVIR 1998;9:539-430
Endovascular Treatment of RAS in Ischaemic Nephropathy

- CURED
- IMPROVED
- UNCHANGED
- DETERIORATED ??
Acute Deterioration in Renal Function after Angioplasty/ Stenting

- Incidence of 10-20% in patients with ischemic nephropathy
- Possible aetiologies:
  - iodinated contrast nephropathy
  - procedure related arterial trauma (e.g., dissection)
  - cholesterol atheroembolization

Sos, ISET 2004

NO DATA
## GREAT Study 6-Month QCA Data

<table>
<thead>
<tr>
<th></th>
<th>Bare Mean ± SD</th>
<th>SES Mean ± SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=41 (79%)</td>
<td></td>
<td>N=45 (85%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Bare</th>
<th>SES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference vessel diameter</td>
<td>$5.58 \pm 0.81\text{ mm}$</td>
<td>$5.52 \pm 0.73\text{ mm}$</td>
<td>0.74</td>
</tr>
<tr>
<td>Diameter stenosis (%DS)</td>
<td>$23.9 \pm 22.89\text{ (0.2 - 6.8)}$</td>
<td>$18.7 \pm 15.58\text{ (0.2 - 6.8)}$</td>
<td>0.39</td>
</tr>
<tr>
<td>Minimum lumen diameter (MLD)</td>
<td>$(0.2 - 6.8)$</td>
<td>$(1.6 - 6.1)$</td>
<td></td>
</tr>
<tr>
<td>In-stent restenosis (&gt; 50%)</td>
<td><strong>6 (14.3%)</strong></td>
<td><strong>3 (6.7%)</strong></td>
<td>0.30</td>
</tr>
<tr>
<td>Late Loss</td>
<td>0.92</td>
<td>0.62</td>
<td>0.21</td>
</tr>
</tbody>
</table>

**My conclusion:**

**NO differences, waste of time and money**
Renal Artery Angioplasty

• No reliable noninvasive test to assess the functional severity of the renal stenosis

• 1/3 improves, 1/3 unchanged, 1/3 further deterioration (BP + Renal function)

• No reliable noninvasive testing to predict which patient might benefit from renal artery revascularisation.

99,000 procedures, in 2003 (WW)

• US : 60,000
• EU : 30,000
• ROW: 10,000

With permission of Bernard De Bruyne
How can we prevent an excess of

OCULO-STENOTIC REFLEXES IN RAS??

!!! WE NEED EVIDENCE BASED DATA !!!
The Role of the Cardiologist in Carotid Artery Stenting (CAS)

First FDA Approval
Sept. 10th 2004
Current principles of neuroprotection

Flow Blockage by distal ICA Occlusion
- PercuSurge GuardWire

Distal ICA Filtering
- AngioGuard
- EmboShield
- EPI FilterWire
- Spider CV3
- Accunet
- Antegrade Flow

Endovascular Clamping by CCA and ECA Balloon Occlusion
- ArteriA System Mo.Ma

Flow reversal or blockage
Filter Wire - Animation
Filter Embolic Protection Devices

BSC FilterWire EZ™

Guidant ACCUNET™ Filter

EMBOSHIELD (Abbott)

Angioguard Cordis

NO COMPARATIVE DATA
Restenosis post TEA
Restenosis post TEA
Operational Steps

1. Device introduction, positioning, balloons inflation
2. Lesion pre-dilatation
3. Debris removal by blood aspiration
4. Stent deployment
5. Stent post-dilatation
6. Debris removal by blood aspiration
7. Device removal
Step by Step Carotid Stenting using the Mo.Ma Protection Device I
Step by Step Carotid Stenting using the Mo.Ma Protection Device II
Step by Step Carotid Stenting using the Mo.Ma Protection Device III
Step by Step Carotid Stenting using the Mo.Ma Protection Device V
Debris Following Carotid Stenting
(MoMa-Device)
### In-Hospital Outcome

<table>
<thead>
<tr>
<th></th>
<th>during procedure</th>
<th>in-hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Major Stroke</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Minor Stroke</strong></td>
<td>2 (1.25%)</td>
<td>2 (1.25%)</td>
</tr>
<tr>
<td></td>
<td>1 (intracr. bleeding)</td>
<td></td>
</tr>
<tr>
<td><strong>TIA</strong></td>
<td>5 (3.2%)</td>
<td>3 (1.9%)</td>
</tr>
</tbody>
</table>

**Primary Endpoint**

(Death, Stroke at discharge)

**2.5%**
# SAPHIRE STUDY

## Randomized Patients (n : 307)

### 30-Day Event

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEATH;STROKE;AMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>5.8 %</td>
<td>12.6 %</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>4.2 %</td>
<td>15.4 %</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>6.7 %</td>
<td>11.2 %</td>
</tr>
</tbody>
</table>
Personal Summary of CAS-Studies at EuroPCR 2003

- European Carotid High-Risk Study
- Mo.Ma. Registry,
- ARCHefR,
- SAPPfHIRE,
- Beach

SECURITY

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEATH</td>
<td>&lt; 0.2%</td>
</tr>
<tr>
<td>MAJOR STROKE</td>
<td>&lt; 0.5%</td>
</tr>
<tr>
<td>MINOR STROKE</td>
<td>3.5 – 4.0%</td>
</tr>
</tbody>
</table>
World Wide Carotid Procedures
Morgan Stanley, BSC, estimates

CEA
CAS

72%
Carotid Artery Stenting (CAS)

Different sources of data indicate > 60% of CAS are performed by cardiologists.
Carotid Artery Stenting (CAS)

• Prescriptions for a Disaster
  – Just do it
  – Learn by doing
  – Treatment of angiographic pictures
• The new nightmare of renal stenting
“Nonsense” of filter-wires

Non-dedicated renal filter-wires

Which segmental branch?

23 mm

Courtesy of A. Cremonesi
Open Questions

- Which amount of embolic material may provoke a relevant deterioration of the renal function in pts. with creatinine:
  - <1.1 mg/dl
  - 1.1-1.8 mg/dl
  - > 2.0 mg/dl

NO DATA
Open Questions

• Within which time frame should we expect a deterioration of the renal function after embolization
  – Hours?
  – Days?
  – Months?

NO ANSWER

NO DATA
Open Questions

• We do not have any data indicating that using the new low profile systems and direct stenting-technique the amount of collected debris remains constant ????
Technical Improvement: The Coronary Technique
ENDOVASCULAR CLAMPING

Case Example

V.P. 010518_10
ENDOVASCULAR CLAMPING

Case Example

V.P. 010518_7
ENDOVASCULAR CLAMPING

Case Example
ENDOVASCULAR CLAMPING

Case Example

V.P. 010518_8
ENDOVASCULAR CLAMPING

Case Example

V.P. 010518_9
ENDOVASCULAR CLAMPING

Case Example

V.P. 010518_10
1977

First Peripheral PTA in Zürich 1971

At this time in 1977 he had already performed nearly 200 peripheral interventions before he abandoned the field starting the coronary adventure.
Preface:

"I am convinced that percutaneous transluminal angioplasty represents a real expansion of our therapeutic possibilities.....The advantage of this easy, safe, and cost reducing technique is evident....we have to evidentiate its value on the basis of credible scientific data, analyzing indication, acute and long term results."

Walter Siegenthaler, Zürich 1977