Covered stents for the treatment of renal artery in-stent restenosis (ISR). A viable option for a common problem Case presentation and literature review

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Disclosure

Speaker Name: Ammar Safar, MD

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☑ I do not have any potential conflict of interest

Introduction/Background

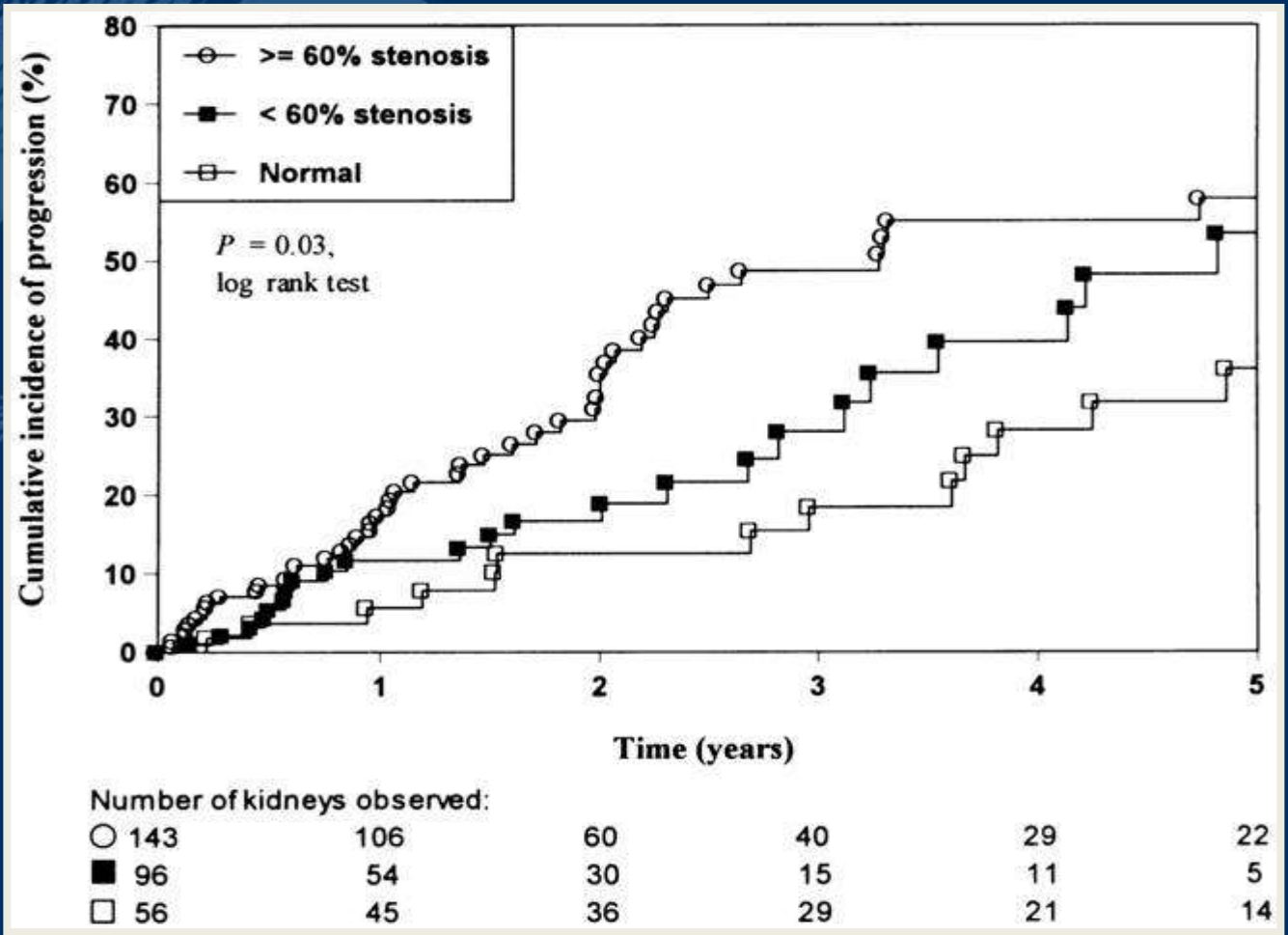
- Atherosclerotic renal artery stenosis (ARAS) is frequent and progressive disease: community-based screening suggest that the prevalence among persons older than 65 years of age may be *as high as 7%*

- Prior studies have suggested that renal artery stenosis may result in hypertension, ischemic nephropathy, and multiple long-term complications

Hansen KJ, et al. J Vasc Surg 2002;36:443-451
Blum U, et al. N Engl J Med 1997;336:459-465
Burket MW, et al. Am Heart J 2000;139:64-71

Natural History of Atherosclerotic Renal Artery Stenosis (ARAS)

Progression to high-grade RAS



Caps et al. Circulation 1998; 98:2866-2872.

Accepted Indications for RA Stenting?

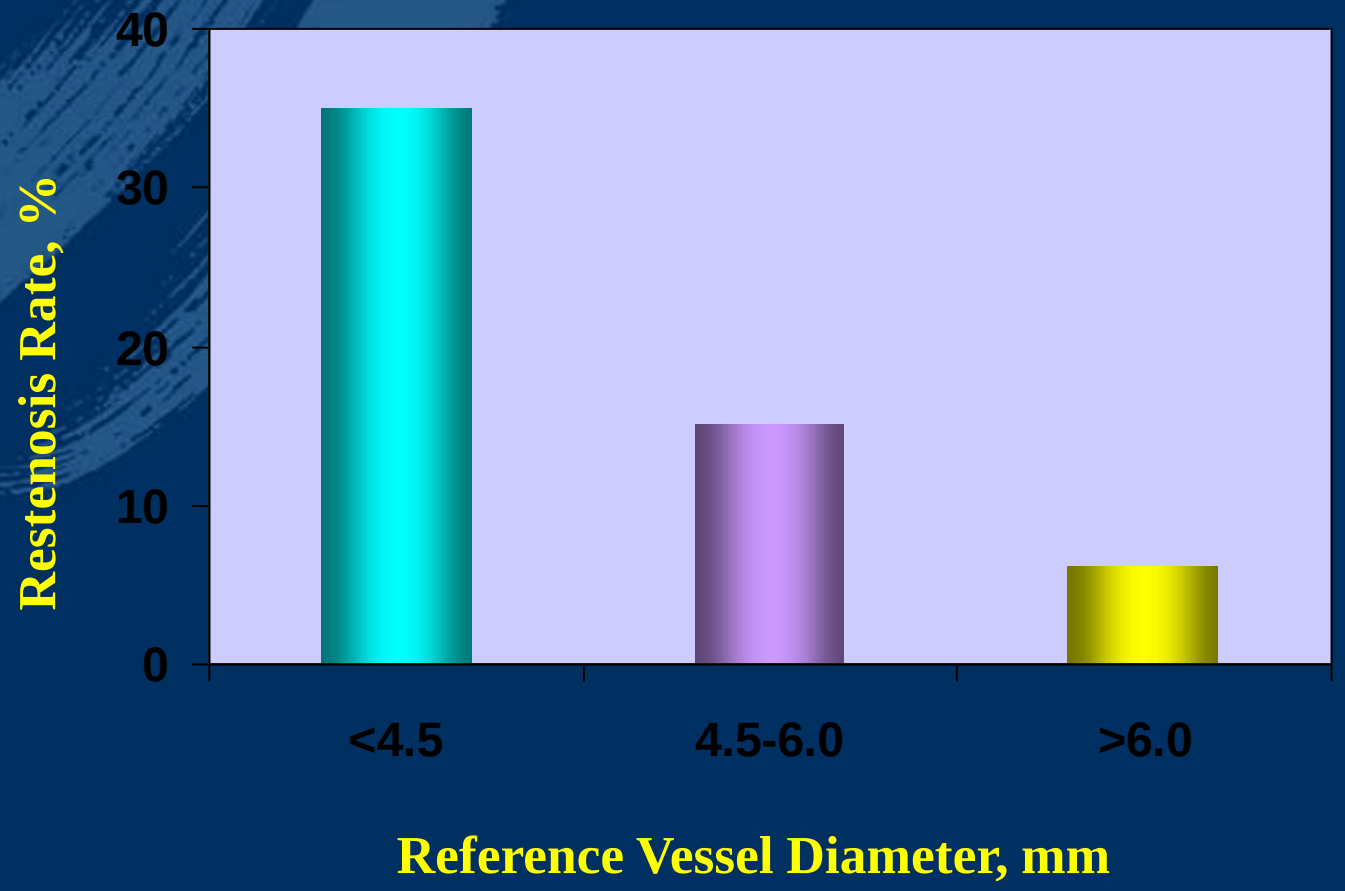
- Significant RAS plus:
  - Acute renal failure (e.g.: patient with solitary kidney and increasing serum creatinine)
  - Flash pulmonary edema
  - Resistant hypertension

- *HOWEVER…..*
- RCTs: When compared with OMT, renal artery stenting showed *NO benefit*
  - Preservation of renal function (STAR)
  - Reduction of cardiovascular events (ASTRAL)
  - Reduction in blood pressure (ASTRAL, CORAL)
  - ……. *Studies?? (uncertain indications, high complication rates, etc.*

Bax L et al. STAR trial. Ann Intern Med 2009; 150: 840–848, W150–W151.
Wheatley K et al. N Engl J Med 2009; 361: 1953–1962.
Cooper CJ, et al. N Engl J Med 2014; 370: 13–22

Renal Artery In-stent Restenosis (BMS)

Final stent size



Gray BH. *J Hypertens* 2005;23 Suppl 3:S23–S29.

Why Covered Stent?

- Benefits Balloon Expandable CS
  - Precise deployment
  - Good radial force
  - Prevention of embolism (entrapment of debris)
  - Ability to overexpand the stent to the desired diameter with minimal stent foreshortening
  - Less risk of arterial injury (dissection, perforation)

Any Data on CS for RAS?

- *No published RCTs* on covered stents for de novo RAS or RAS restenosis.
- Most of the data that may relate to renal artery stenting comes from the use of covered stents in:
  - Renal arteries for fenestrated EVAR
  - Mesenteric vessels for CMI

CS vs. BMS in Renal Arteries Fenestrated EVAR

- 518 renal arteries treated with bare metal or covered stents
  - BMS: 158 patients with 287 stents
  - CS: 129 patients with 231 stents
- Mean follow-up 25 months
- Renal stent occlusion rate: BMS 4.5% vs. 2.2% for CS
- *Renal stent restenosis rate:* BMS 10% vs 2.5% for CS (p=0.04)
- They concluded: patients treated with bare metal stents were more likely to develop in-stent restenosis than those treated with covered renal stents (HR 0.4, 95% CI 0.2-0.9, p=0.04).

Mohabbat W, et al JVS 2009;49:827-837

CS vs. BMS stents in Mesenteric Vessels CMI

- 225 patients with CMI treated with bare metal or iCAST covered stents
  - BMS: 164 patients with 197 stents
  - CS: 61 patients with 67 stents

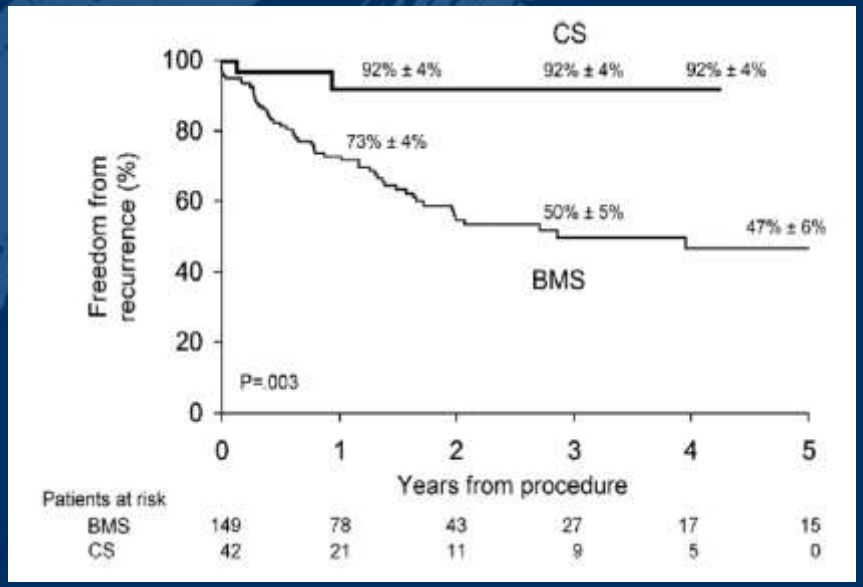
- Mean follow-up 29 months

- CS vs. BMS:
  - Freedom from restenosis (92% ± 6% vs 53% ± 4%; P = .003)
  - Symptom recurrence (92 ± 4% vs 50 ± 5%; P = .003)
  - Re intervention (91% ± 6% vs 56% ± 5%; P = .005)
  - Primary patency at 3 years (92% ± 6% vs 52% ± 5%; P < .003)
  - Secondary patency was the similar in both groups

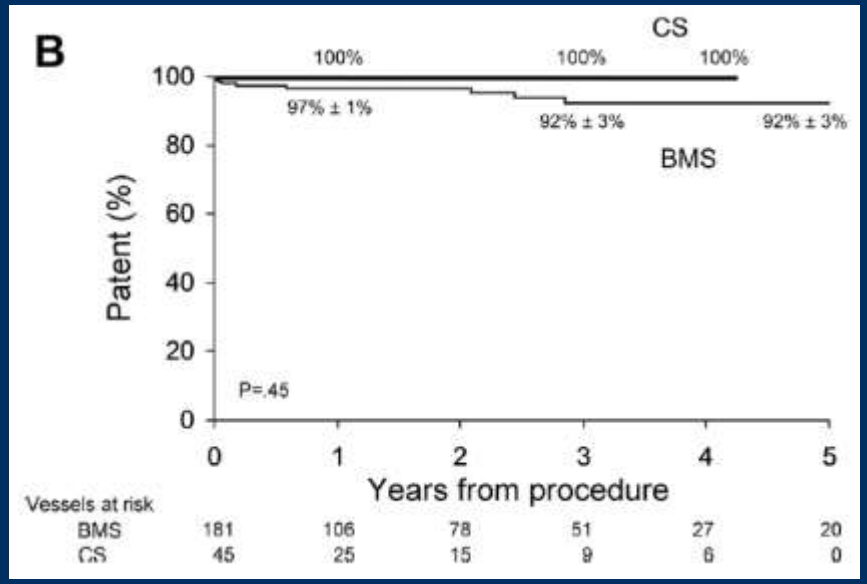
Oderich et al, JVS 2013

CS vs. BMS stents in Mesenteric Vessels

Primary patency



Secondary patency



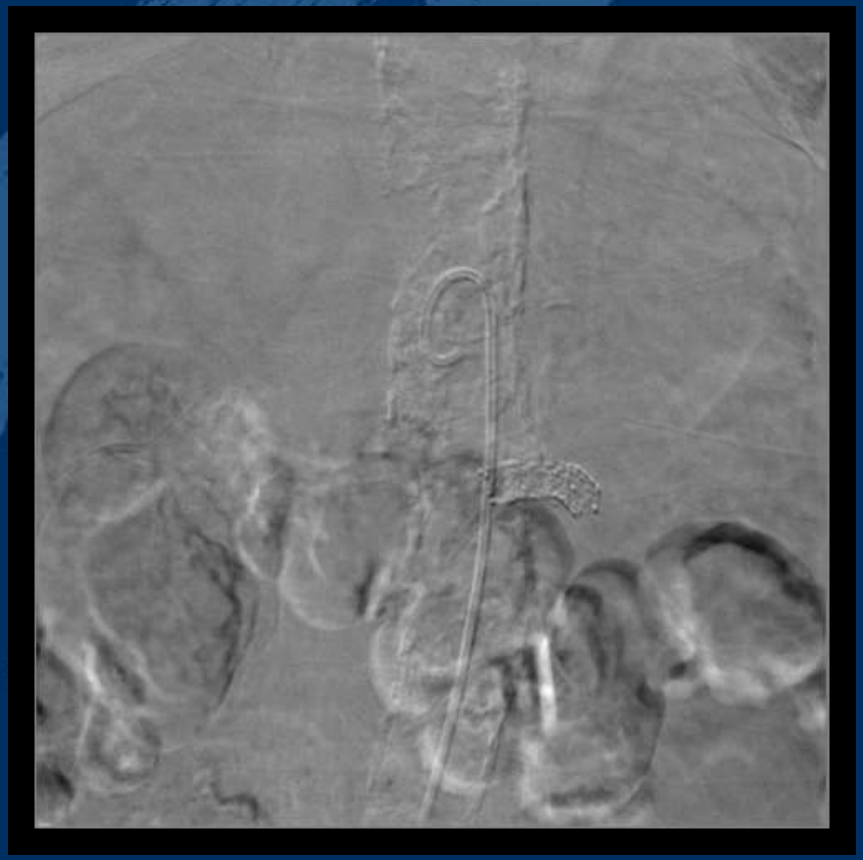
Oderich et al, JVS 2013

Case Presentation

- 72 y/o male
- Medical history significant for:
  - Single functioning left kidney due to remote occlusion of right renal artery, with CKD-baseline Cr 1.7
  - Hypertension
  - Hyperlipidemia
  - CAD s/p CABG
  - Carotid artery disease s/p remote CEA
  - Moderate aortic valve stenosis
  - Had remote stenting of left renal artery in 2010 at an outside facility (no records)

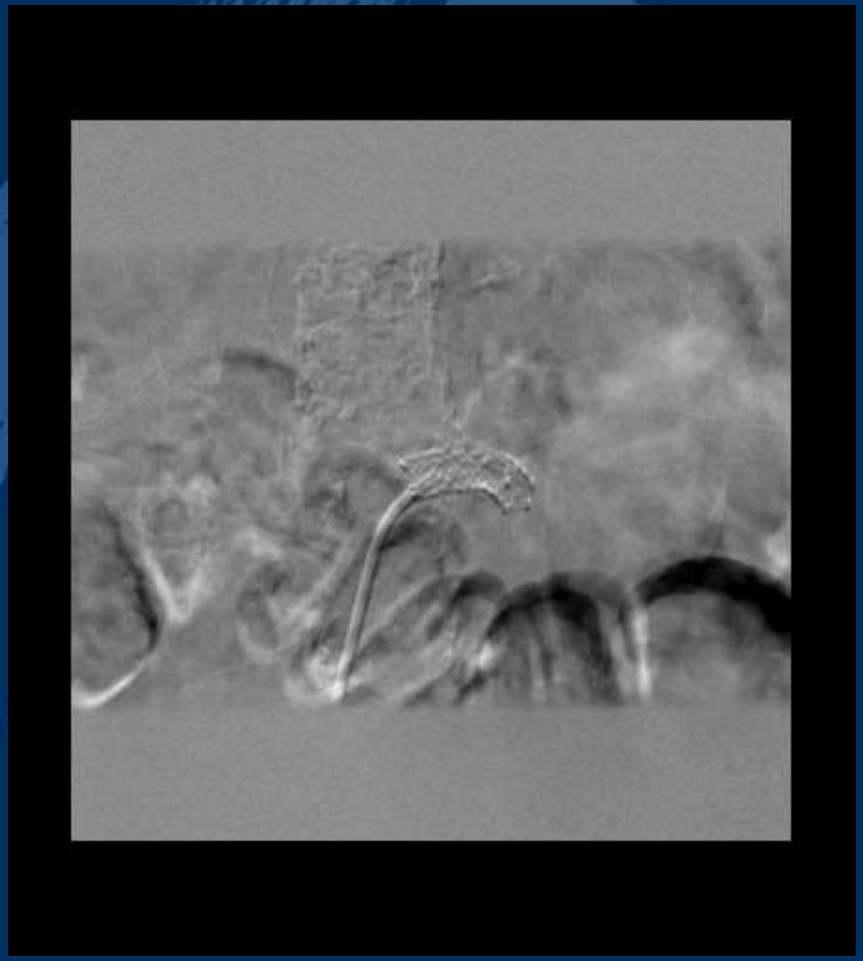
- Presented in 09/2015 to the hospital with uncontrolled/severe hypertension, acute decompensated diastolic HF and worsening renal dysfunction with creatinine of 2.9
- Elevated velocities by renal artery duplex US

Angio 09/2015



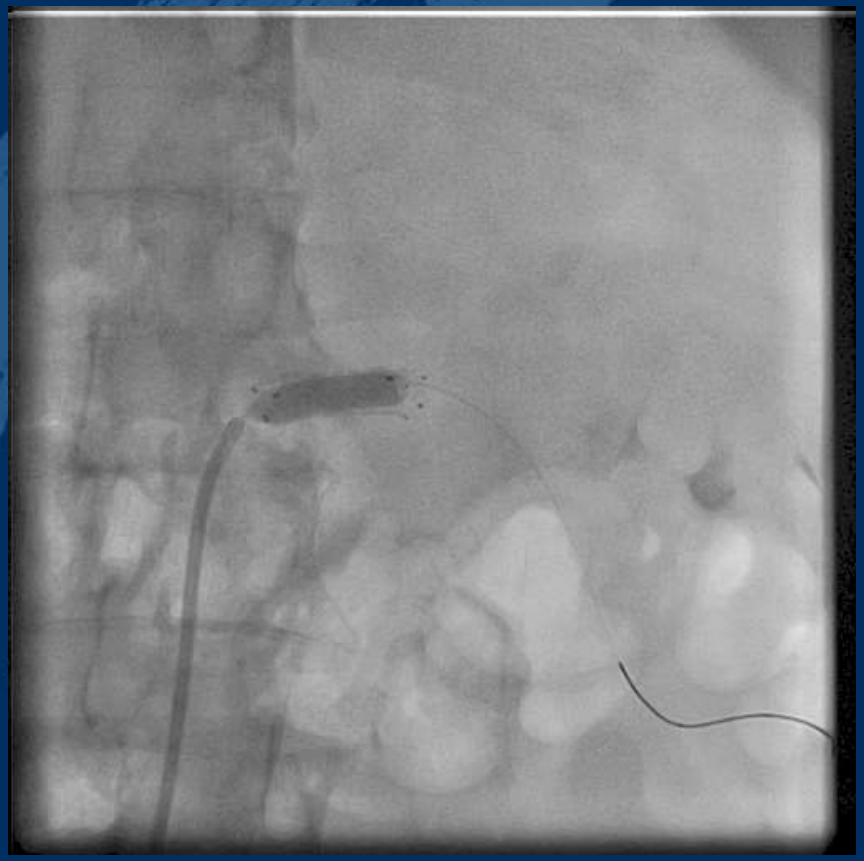
- 5 F Pigtail catheter
- Aortic angio
  - Aorta: Calcified
  - Right renal artery: flush occlusion (old)
  - Left renal artery: stent is hazy and protrude into the aorta

Angio 09/2015



- 5F JR-4 catheter
- Selective left renal angio:
  - Significant restenosis in the proximal portion
  - Stent seems to sticks out in the aorta
  - Old stent: ?self-expanding stent (markers on both ends)

Angio 09/2015



- 6F JR4 guide
  - 014 Grand Slam wire (good supportive body)
  - PTA: 4x15, 5x15, 6x15 mm

Angio 09/2015

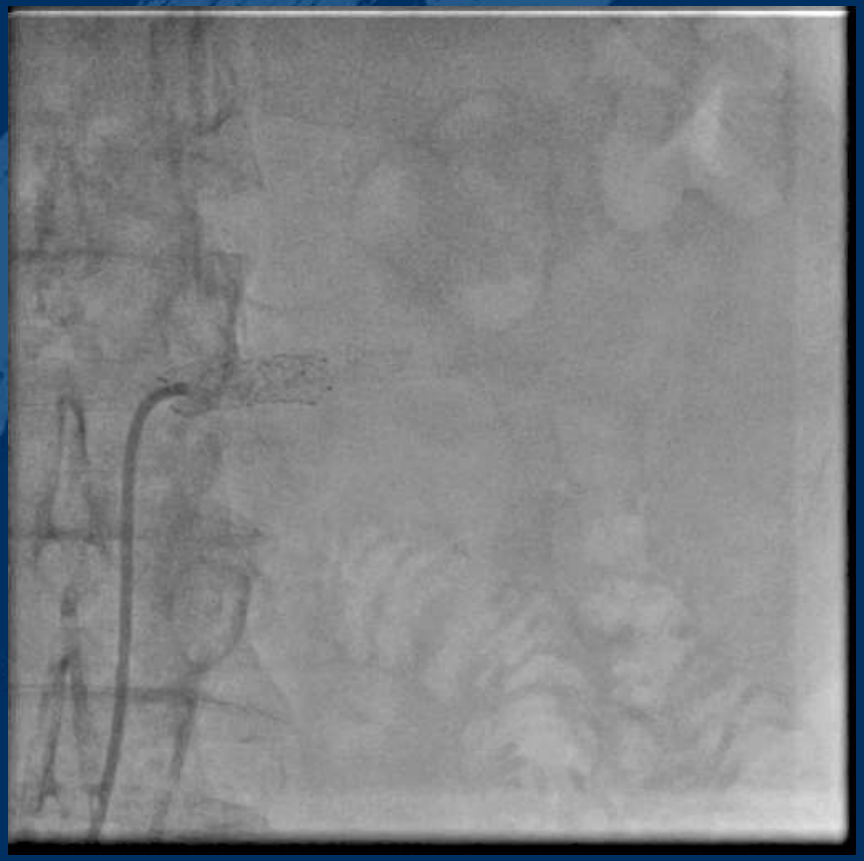
- Final results:
  - Significant improvement
  - Only mild focal residual proximally

Clinical Course

- Clinically: Did real well
- Hemodynamically: BP improved, HF resolved
- Renal function: Cr improved and by day 6, Cr down to 1.5 (was 2.8 on presentation, and has been 1.7 at baseline)

- **HOWEVER…..**
- Less than 4 months after: (01/2016)
  - Severe, uncontrolled hypertension
  - Renal artery duplex US: elevated velocities
  - Repeat angio

Angio 1/2016



- 6F JR-4 guide
- Selective left renal angio:
  - Recurrent restenosis in the proximal portion

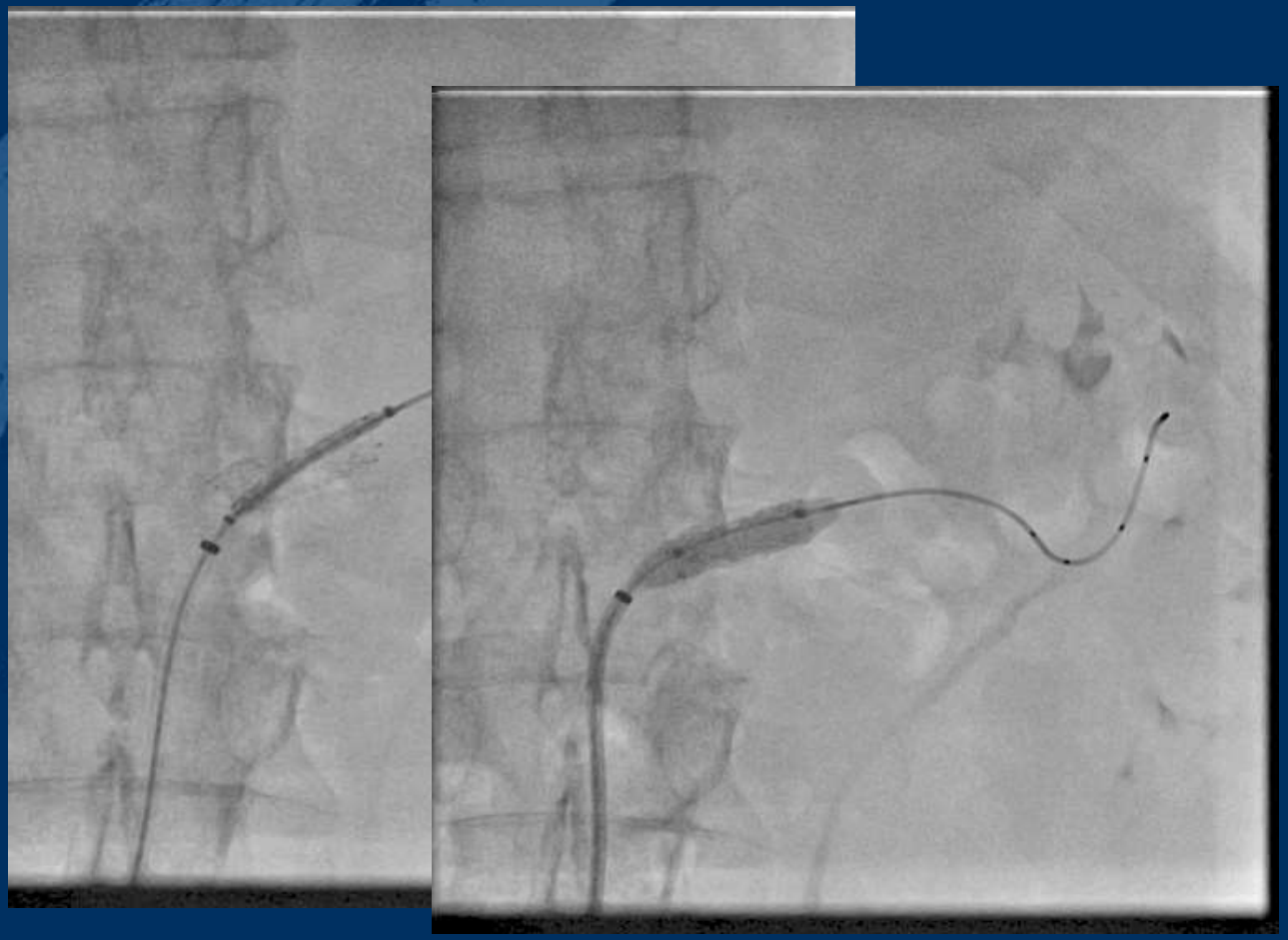
Angio 1/2016

- 6F JR4 guide
  - 035 magic torque wire (very soft tip)
  - PTA: 5 x 20 mm balloon

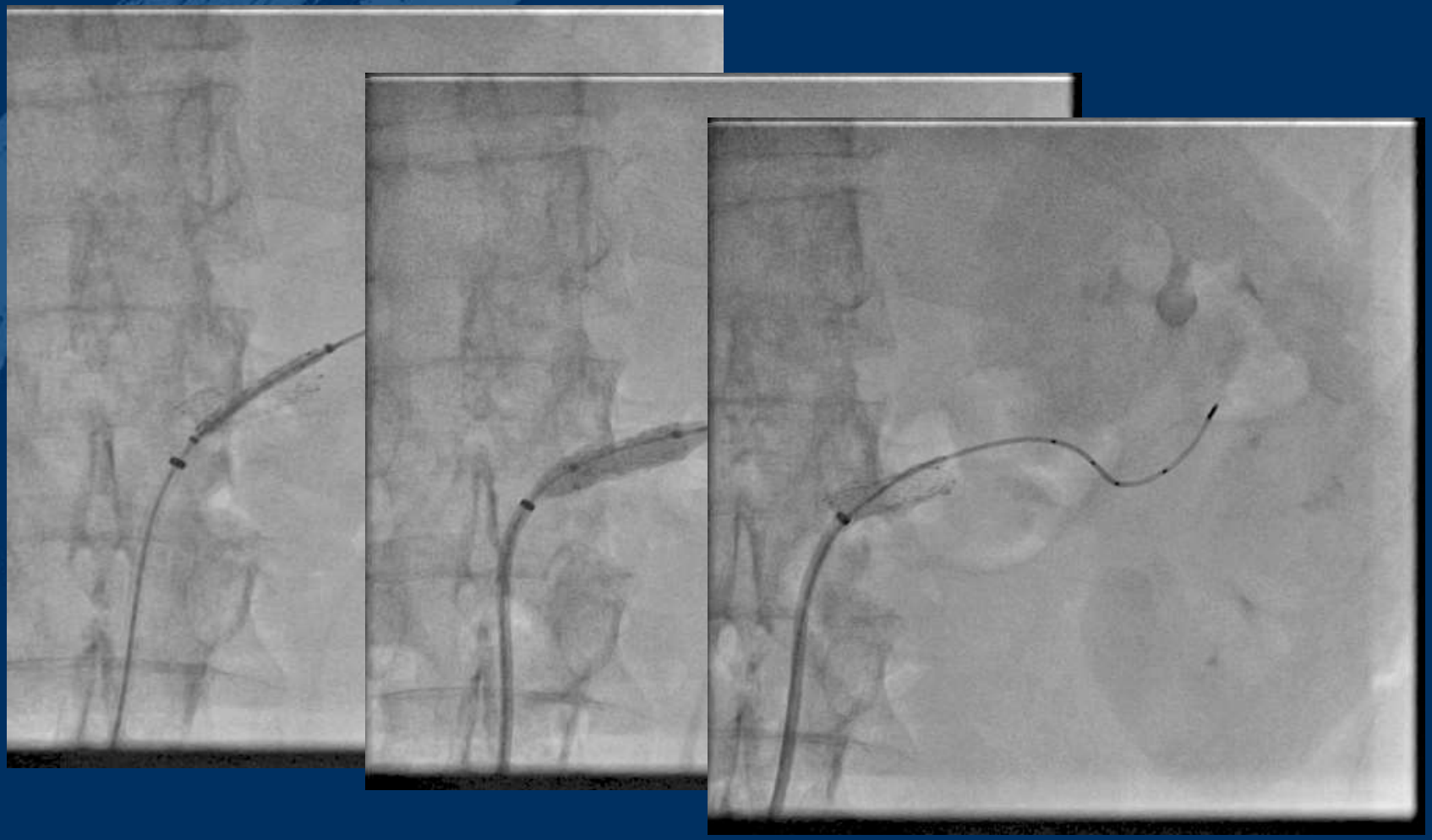
Angio 1/2016

- iCAST covered stent 6 x 22 mm
- Post-dilated with 6 x 20 mm balloon at high pressure

Angio 1/2016



Angio 1/2016



Clinical Course

- Clinically: Did real well
- Hemodynamically: BP improved
- Renal function: improved, Cr down to 1.3 in March 2016
- Latest Cr was 1.6 last month on 12/2018
- Long term DAPT

- 12/2017 (almost 2 years after the covered stent): Pre TAVR CTA

Clinical Course

- Clinically:
- Hemodyna
- Renal func
- Latest Cr v
- Long term

- 12/2017 ha rocedure CTA

Conclusions

- Renal artery in-stent restenosis (ISR) is common and depends largely on the final stent diameter (greater than 6 mm, had the lowest rates of restenosis)
- ISR remains a difficult to treat clinical problem. Innovative techniques to maintain an “endovascular- first approach” have included balloon angioplasty with cutting or cryoplasty balloons, redo stenting with bare metal, drug-eluting stents, and individual reports of using DCB. All with various results
- Observational, non-randomized data does show that balloon expandable covered stents (CS) are associated with significantly less restenosis, recurrences, and re-interventions than BMS in patients undergoing primary interventions or re-interventions
- The key is to size appropriately, and post dilate with high pressure balloon.

Thank You!

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