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The V12 RX covered stent as a problem solver for the renal and visceral arteries

Le stent couvert V12 RX comme solution pour les artères rénales et viscérales

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Renal and visceral artery stenting

- Endovascular treatment hampered by restenosis
- Controversy remains

Background

- Randomized studies have not been able to demonstrate a clinical benefit from revascularization in patients with renal artery stenosis
  - ASTRAL
  - STAR
  - CORAL
- High complication rates

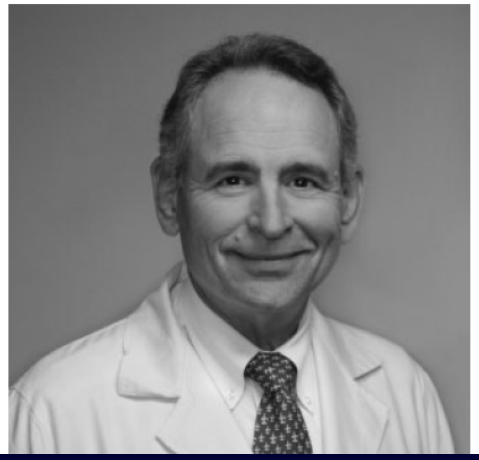
Controversy

Catheterization and Cardiovascular Interventions 75:305–307 (2010)

Editor's Page

Kiss My Astral: One Seriously Flawed Study of Renal Stenting After Another

Christopher J. White,* MD
Editor-in-Chief, Catheterization and Cardiovascular Interventions



This week, the Angioplasty and STenting for Renal Artery Lesions (ASTRAL) trial was published [1]. This study offers students of clinical trials a remarkable opportunity to learn from the mistakes made by the ASTRAL group. The authors are to be congratulated on completing and publishing this study, as it takes a certain amount of courage to publish a trial this poorly conceived. I am sure they took comfort in knowing that they are not alone in reporting data that underestimate the benefits of renal artery stenting [2–4].

If the investigators' goal was to get the most of out of their concluding remarks, sort of the perfect sound bite for the 6 o'clock medical news, they did a really good job. Their findings of ''substantial risks but no evidence of a worthwhile clinical benefit from revascu-

Background

- Complications ASTRAL 9%
  - 38 periprocedural complications in 31 patients
  - 19 serious events (17 patients)
    - Pulmonary edema n=1
    - Myocardial infarction n=1
    - Renal embolization n=5
    - Renal artery occlusion n=4
    - Renal artery perforation n=4
    - Femoral artery false aneurysm n=1
    - Cholesterol embolism n=3

CORAL

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis

Christopher J. Cooper, M.D., Timothy P. Murphy, M.D., Donald E. Cutlip, M.D., Kenneth Jamerson, M.D., William Henrich, M.D., Diane M. Reid, M.D., David J. Cohen, M.D., Alan H. Matsumoto, M.D., Michael Steffes, M.D., Michael R. Jaff, D.O., Martin R. Prince, M.D., Ph.D., Eldrin F. Lewis, M.D., Katherine R. Tuttle, M.D., Joseph I. Shapiro, M.D., M.P.H., John H. Rundback, M.D., Joseph M. Massaro, Ph.D., Ralph B. D'Agostino, Sr., Ph.D., and Lance D. Dworkin, M.D., for the CORAL Investigators*

CORAL

RESULTS

Over a median follow-up period of 43 months (interquartile range, 31 to 55), the rate of the primary composite end point did not differ significantly between participants who underwent stenting in addition to receiving medical therapy and those who received medical therapy alone (35.1% and 35.8%, respectively; hazard ratio with stenting, 0.94; 95% confidence interval [CI], 0.76 to 1.17; P=0.58). There were also no significant differences between the treatment groups in the rates of the individual components of the primary end point or in all-cause mortality. During follow-up, there was a consistent modest difference in systolic blood pressure favoring the stent group (–2.3 mm Hg; 95% CI, –4.4 to –0.2; P=0.03).

CONCLUSIONS

Renal-artery stenting did not confer a significant benefit with respect to the prevention of clinical events when added to comprehensive, multifactorial medical therapy in people with atherosclerotic renal-artery stenosis and hypertension or chronic kidney disease. (Funded by the National Heart, Lung and Blood Institute and others; ClinicalTrials.gov number, NCT00081731.)

CORAL complications

- Dissection 11/495 (2.2)
- Branch vessel occlusion 6/495 (1.2)
- Angiographically evident distal embolization 6/495 (1.2)
- Wire perforation 1/495 (0.2)
- Vessel rupture 1/495 (0.2)
- Pseudoaneurysm formation 1/495 (0.2)

Accepted indications RAS

- Patients with (acute) renal failure (e.g. 99% stenosis in patient with solitary kidney and increasing serum creatinine)
- Patients with flash pulmonary edema

OR vs. ER for CMI

- OR more complications (36% vs. 18%)
- OR longer hospital stay (12 ± 8 vs. 3 ± 5 days)
- ER more restenosis, recurrences and re-interventions
- 5 year primary/secondary patency
  - OR 88%/97%
  - ER 41%/88%
- In subset analysis of ‘first-time’ interventions primary patency at 3 years OR/ER 93% vs. 52%
- ER group consisted of PTA only in 28%, stenting with 0.035” systems and hand-mounted stents (4 dissections and 4 dislodged stents)

Oderich GS et al, JVS 2009;49;1472-1479

Complications ER for CMI

- 156 patients with 173 MAS
- 11 patients (7%) developed 14 complications
  - Distal embolization n=6
  - Branch perforation n=3
  - Dissection n=2
  - Stent dislodgement n=2
- 45% conversion to open repair

Oderich GS et al, JVS 2012;55;1063-1071

Complications ER for CMI

- 6% femoral access site complications
  - False aneurysm/infection/nerve injury
- 10% brachial access site complications
  - False aneurysm/arterial thrombosis/AV fistula
- All procedures done with large profile (7F), 0.035” guide wire devices

Oderich GS et al, JVS 2012;55;1063-1071

Meticulous technique

- Intimal hyperplasia within stent in 43% of cases, 57% proximal or distal from stent edge
- 43% of patients technical imperfections
  - Inadequate stent length
  - Poor stent expansion (calcified and eccentric lesions)
- Patency rates of BMS compare favorable to pooled date from literature, case selection is key

Tallarita T et al, JVS 2011;54;1422-1429

Reinterventions for ISR in CMI

- Restenosis 20%-66%
- Higher restenosis rates in
  - Women
  - Long lesions (>30 mm)
  - Occlusions
  - Severely calcified vessels
  - Small vessels (<6 mm)

Tallarita T et al, JVS 2011;54;1422-1429

Reinterventions for ISR in CMI

- Redo interventions in mesenteric ISR carries high risk (7/30, 27%)
  - Access site complications
  - Distal embolisation
  - Stent thrombosis

Tallarita T et al, JVS 2011;54;1422-1429

High recurrence rate ER for CMI

- 60 mesenteric arteries with PTA and stenting
- Major morbidity 4% (dissection SMA n=1, dissection brachial artery n=1)
- Initial technical success rate was 93%, no 30-day mortality
- Median follow-up 25 months; 2 patients died from intestinal ischemia
- Complete symptom relief 78%
- Primary 1- and 2-year patency rates were 86% ± 5% and 60% ± 9%
- Primary-assisted patency rates were 88% ± 5% and 79% ± 7%
- NB low profile systems

Fioole B et al, JVS 2010;51;386-391

Summary

- High rate of access site complications
- High rate of procedural complications
- High rate of restenosis

How can we solve these issues?

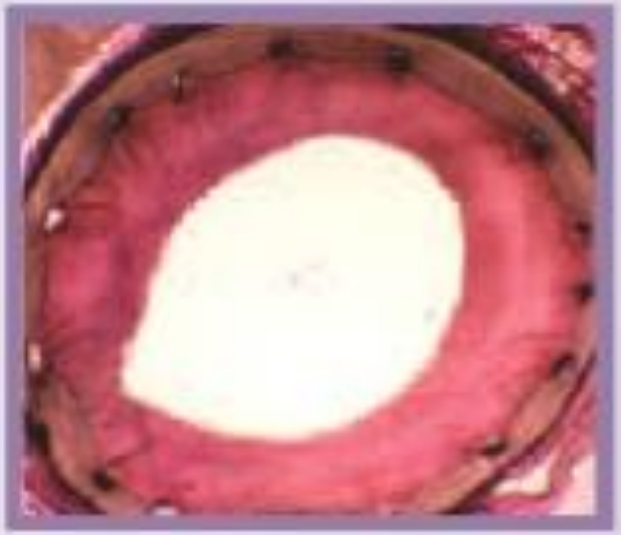
- Preventing access site complications
  - Optimal puncture technique
  - Small sheath size
- Preventing distal embolisation
  - Filter type protection devices
  - Covered stents
- Prevent restenosis

Are covered stents the solution?

Benefits balloon expandable covered stent

- Precise deployment
- Good radial force
- Prevention of embolism by entrapment of debris
- Ability to overexpand the stent
- Less risk of arterial disruption

Animal study



Neointimal growth of a bare metal stent at 28 days

Neointimal growth of V12 at 28 days

Problem of restenosis (CS)

- No published data on RAS
- Data on fenestrated EVAR
- Data on visceral artery stenting

Fenestrated EVAR

- 518 renal arteries treated with bare metal or covered stents (287 patients)
  - BMS: 158 patients with 287 bare 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 stenosis rate: BMS 10% vs 2.5% for CS (p=0.04)

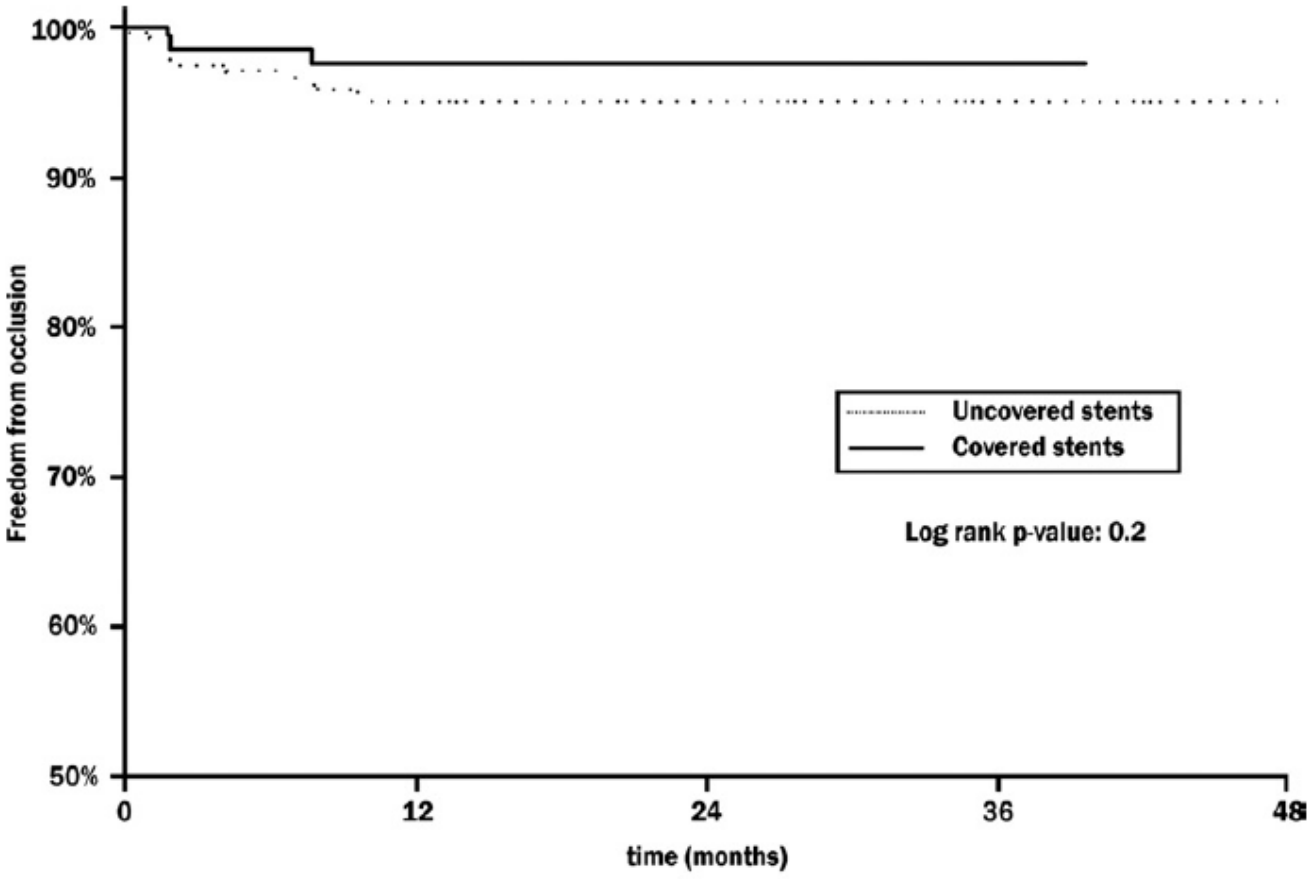
Mohabbat W, et al JVS 2009;49:827-837

Fenestrated EVAR

- Overall in the setting of preserved renal function, renal restenosis rate: BMS 17% vs 5% for CS
- Covered stent stenosis occurred at distal end where BMS stenosis occurred at proximal and distal ends
- Patients treated with bare metal stents were more likely to develop in-stent stenosis 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

Fenestrated EVAR



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

Fenestrated EVAR

- Covered stents are associated with a lower incidence of in-stent stenosis and are thus recommended over bare metal stents for use in fenestrated or branched endografts

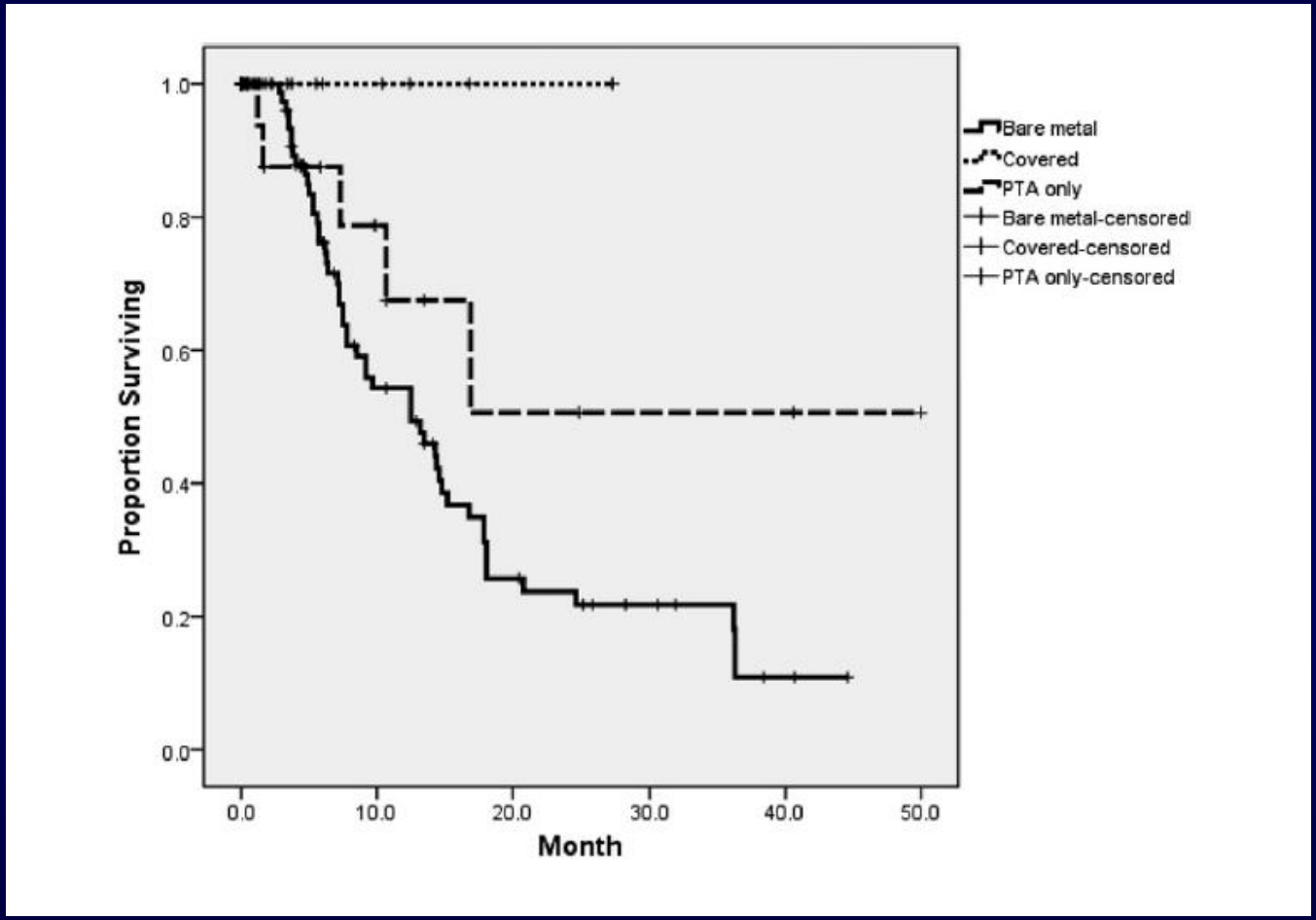
Mohabbat W, et al JVS 2009;49:827-837

Visceral artery stenting

- 107 patients with chronic mesenteric ischemia
- Bare metal stents and covered stents
- Reintervention rate
  - BMS 52%
  - CS 0%
- Primary patency rate @ 1 year
  - BMS 54%
  - CS 100%

Schoch DM, et al J Am Coll Surg 2011;212:668-677

Visceral artery stenting



Schoch DM, et al J Am Coll Surg 2011;212:668-677

CS vs. BMS for CMI

- 225 patients (BMS n=164/197 vessels; iCAST n=61/67 vessels)
- Similar risk profile and extent of disease
- Primary intervention group covered stents
  - Higher freedom from restenosis (92% ± 6% vs 53% ± 4%)
  - Higher freedom from symptom recurrence (92 ± 4% vs 50 ± 5%
  - Higher freedom from reintervention (91% ± 6% vs 56% ± 5%
  - Better primary patency at 3 years (92% 6 6% vs 52% ± 5%)

Oderich et al, JVS 2013;in press

CS vs. BMS for CMI

- Reintervention group covered stents (at 1 yr)
  - Higher freedom from restenosis (89% ± 10% vs. 49% ± 14%)
  - Higher freedom of symptom recurrence (100% vs. 64% ± 9%)
  - Higher freedom of reintervention (100% vs. 72% ± 9%)
  - trend toward improved primary patency (100% vs. 63% 6 9%)
- Secondary patency rates were similar in both groups

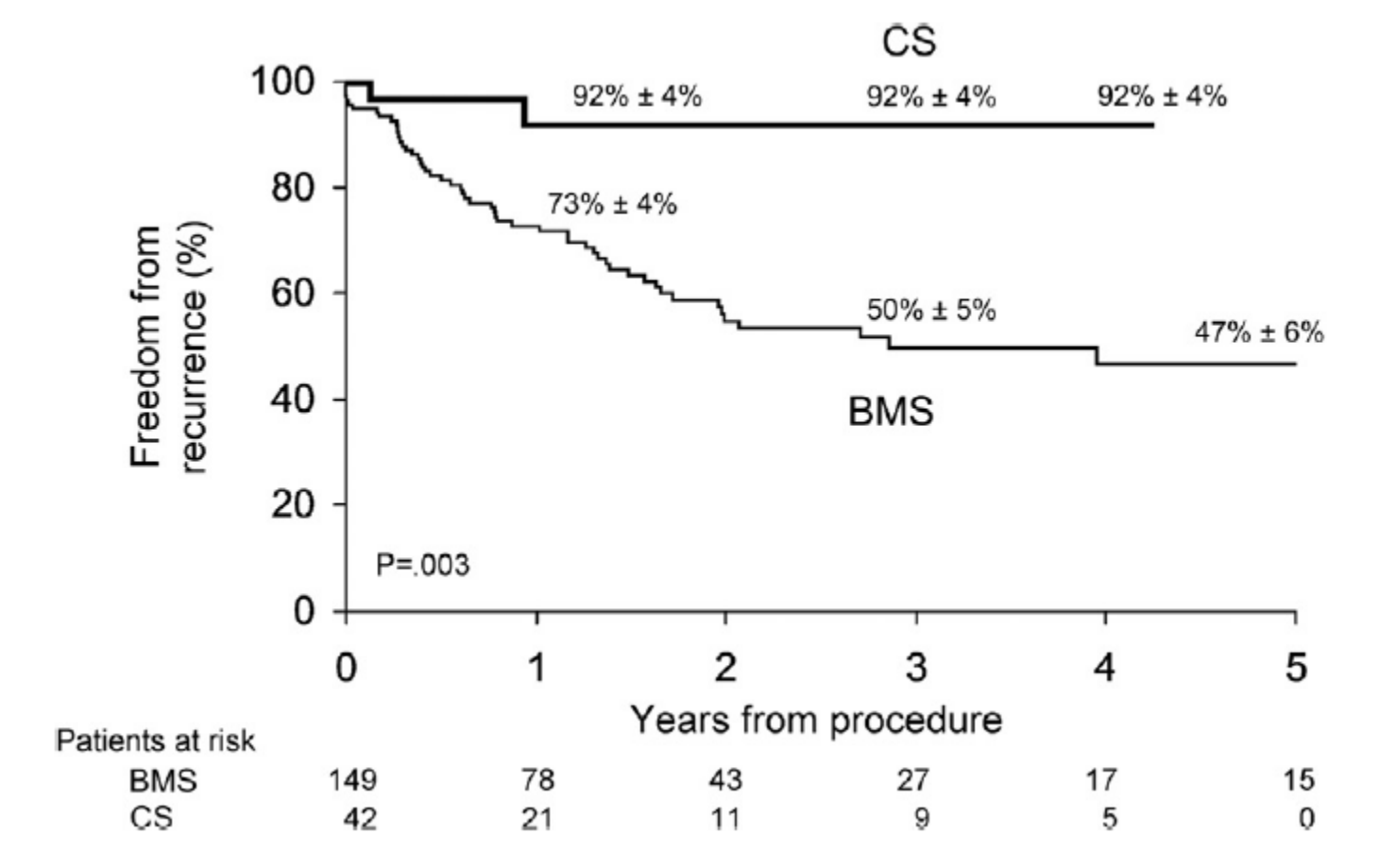
Oderich et al, JVS 2013;in press

CS vs. BMS for CMI

- Morbidity and mortality equally high in BMS and CS

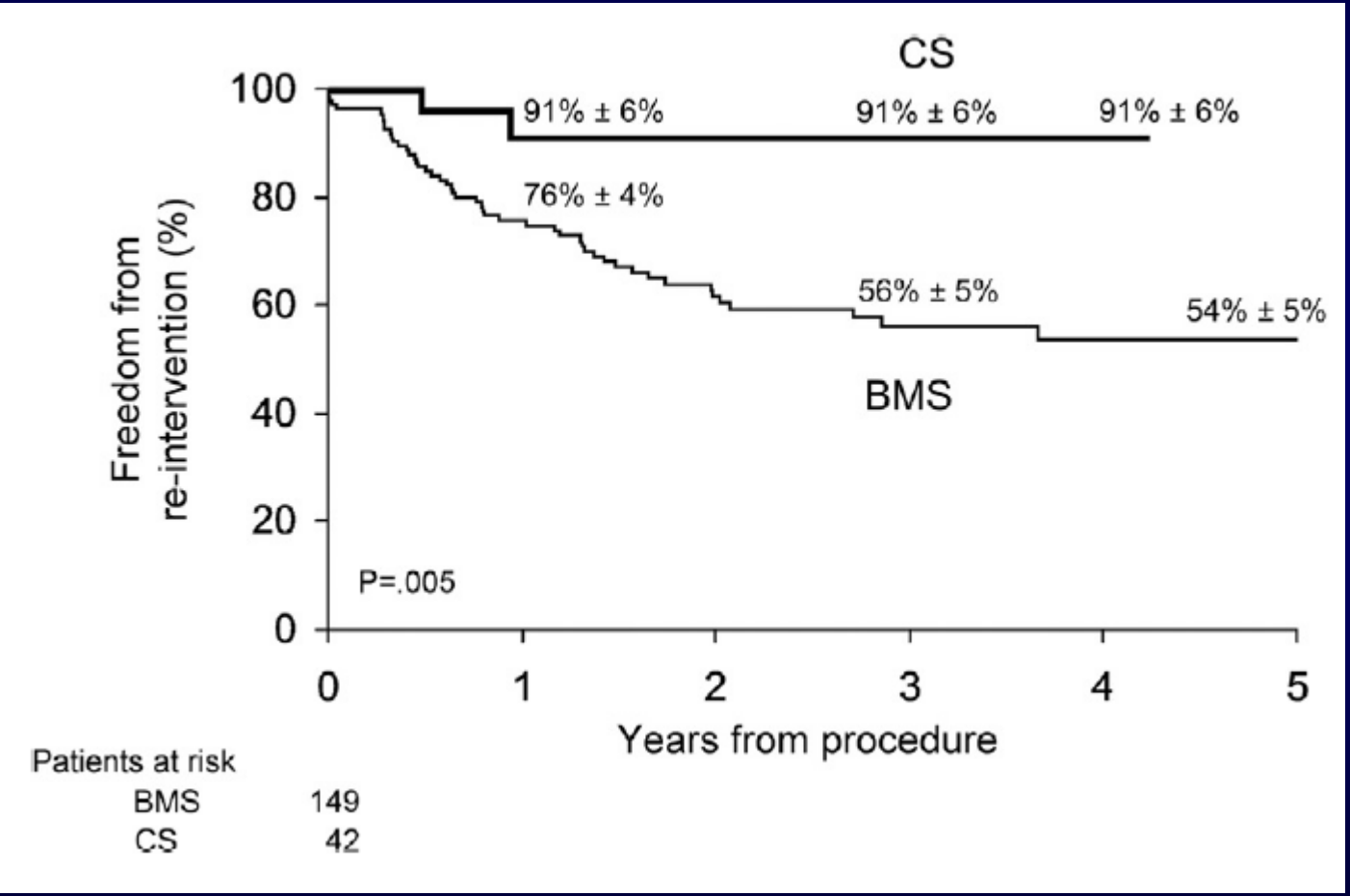
Oderich et al, JVS 2013;in press

Freedom from recurrence



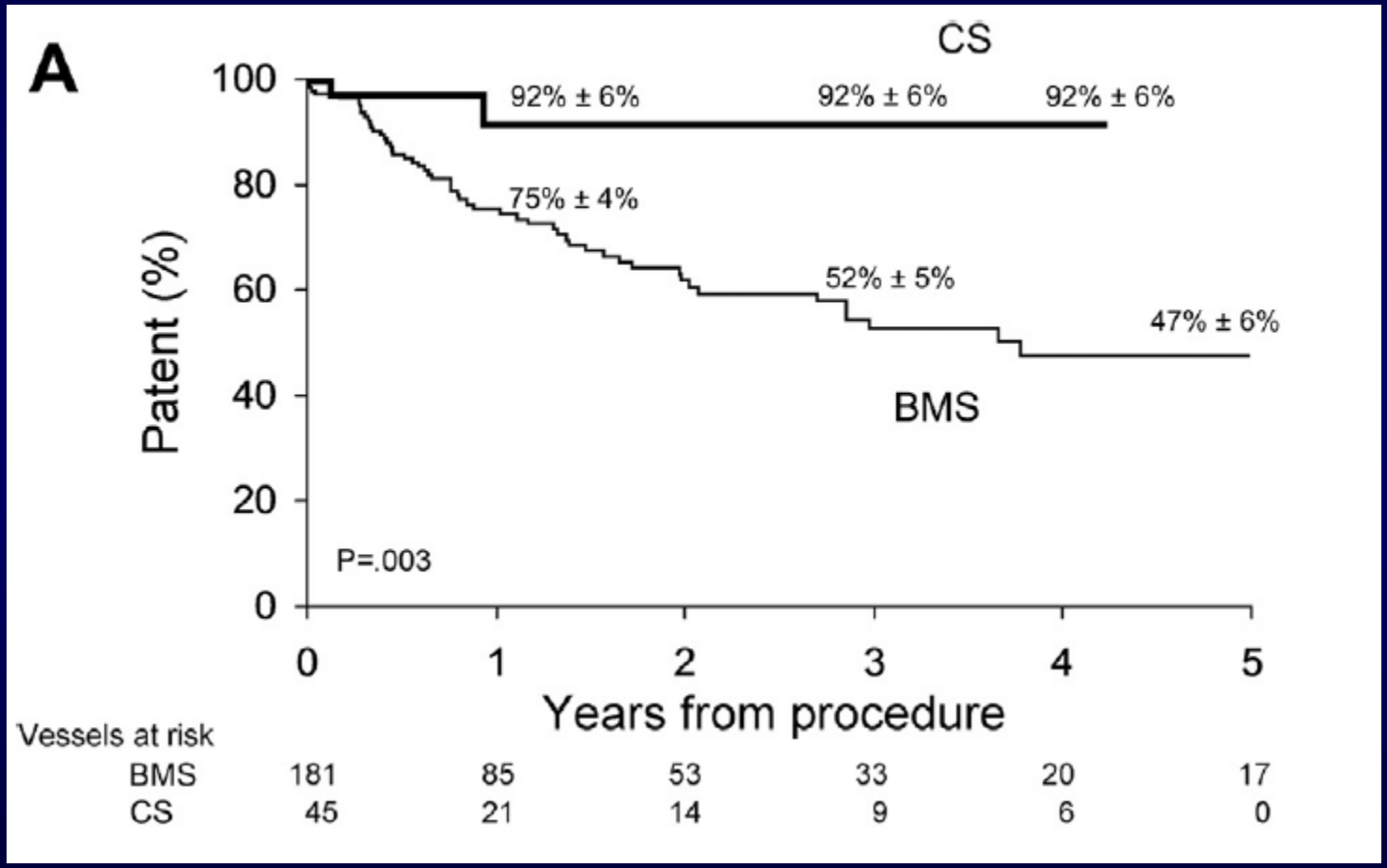
Oderich et al, JVS 2013;in press

Freedom from reintervention



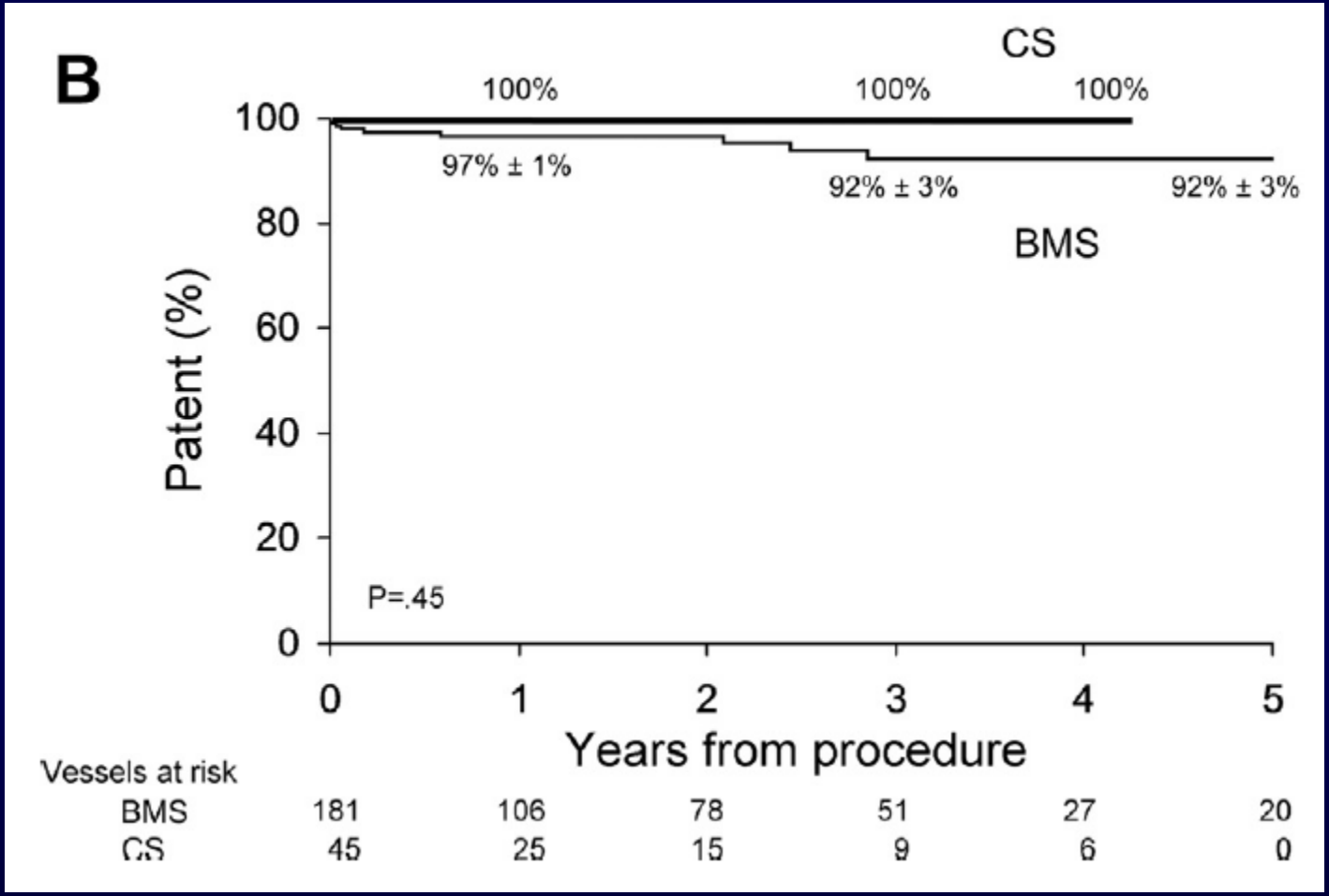
Oderich et al, JVS 2013;in press

Primary patency



Oderich et al, JVS 2013;in press

Secondary patency



Oderich et al, JVS 2013;in press

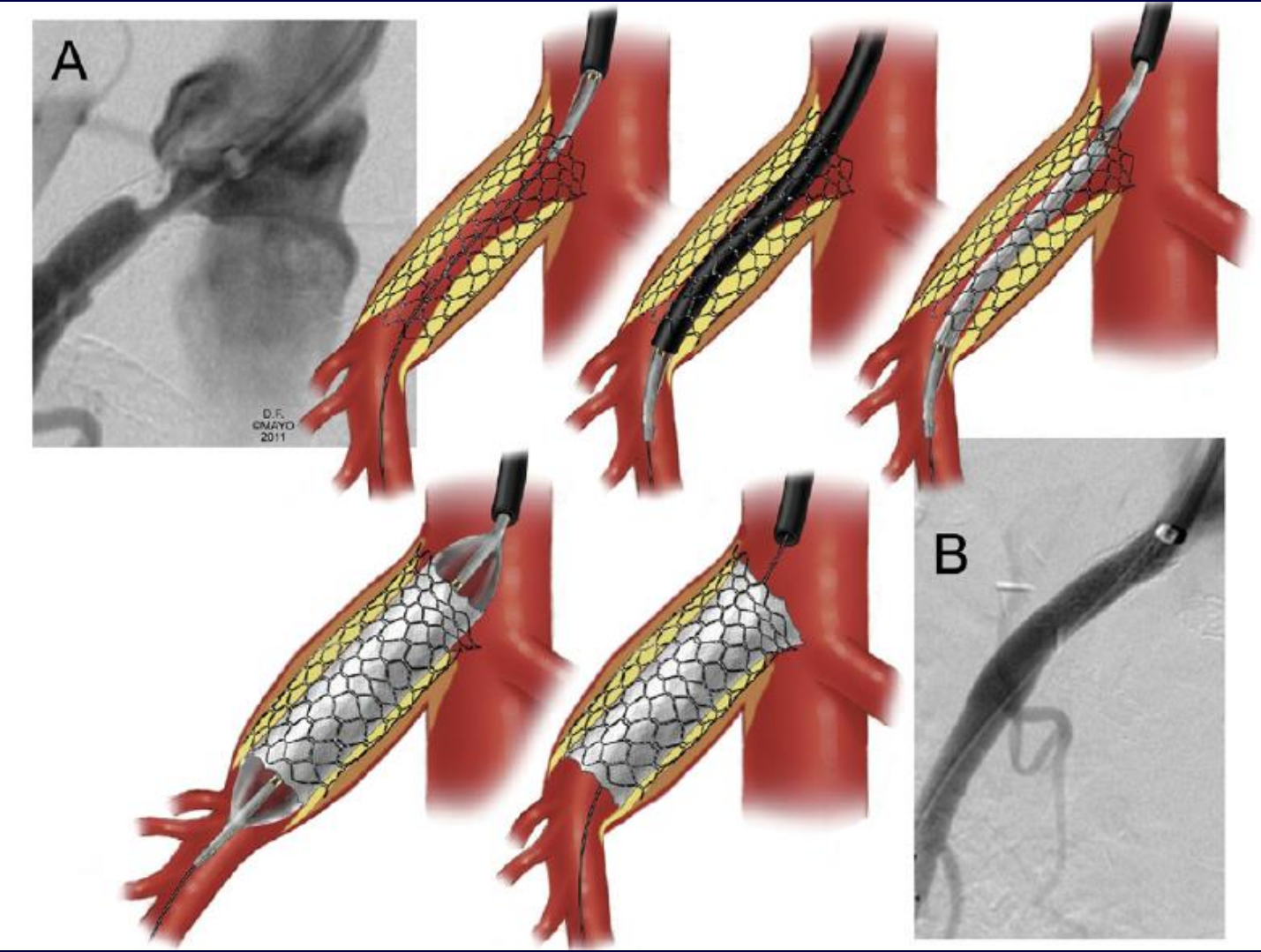
Problem of procedural complications

- Access
- Dissection
- Branch perforation

RX system

- Low profile system will reduce access site complications and allows for safe brachial access
- 0.014” guide wire reduces risk of branch perforation
- 5F RDC sheath allows for optimal stability and back-loading

‘Back-loading’ technique



Tallarita T et al, JVS 2011;54;1422-1429

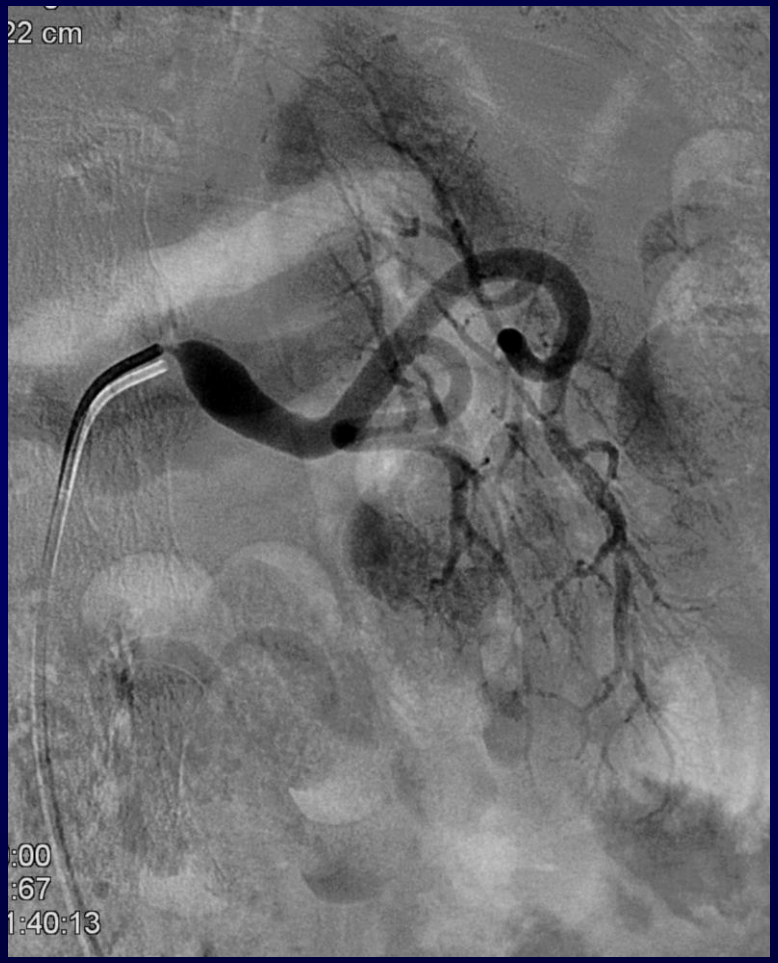
V12 PTFE covered stent

- 316L stainless steel PTFE covered stent
- RX-system
- Crossing profile 5F (5-6 mm diameter), 6 F (7 mm diameter)
- Working length 140 cm
- 0.014” guide wire compatible
- Dilatation to 8 mm feasible

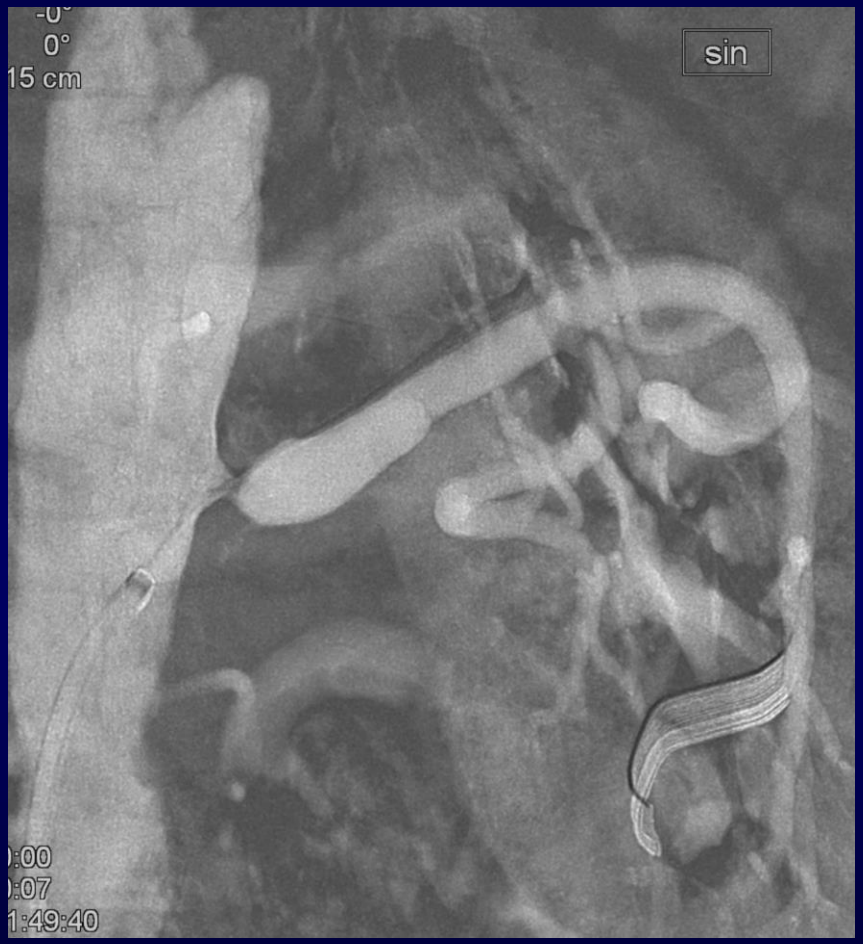
Representative case

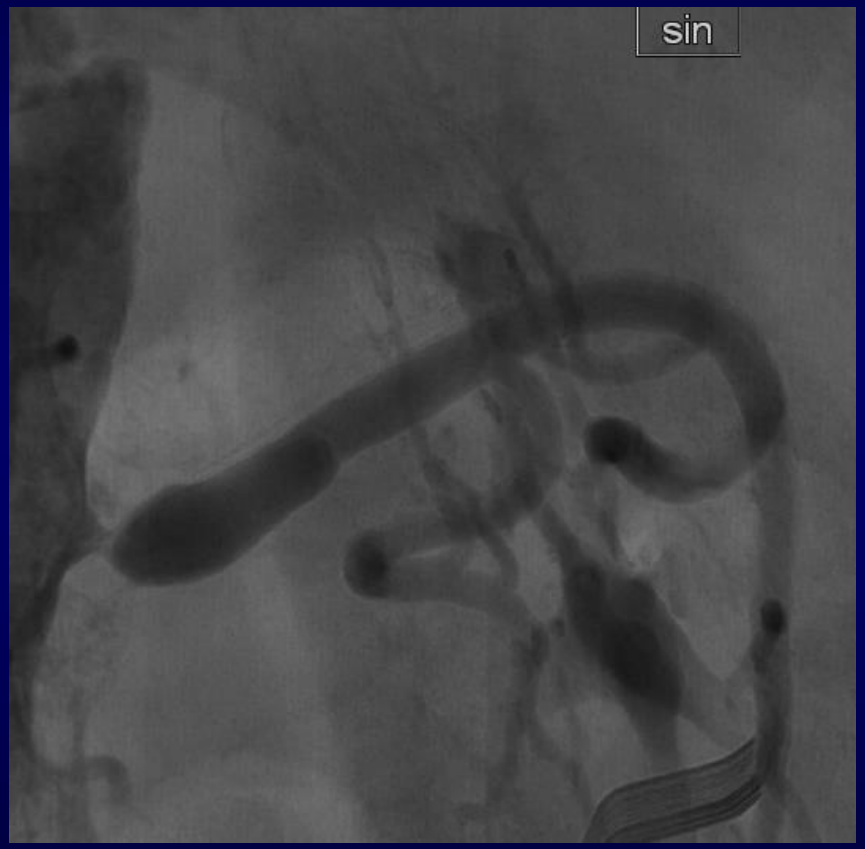
- 78 year old female
- Progressive renal insufficiency
- Right kidney atrophic (renal artery occlusion)

Representative case



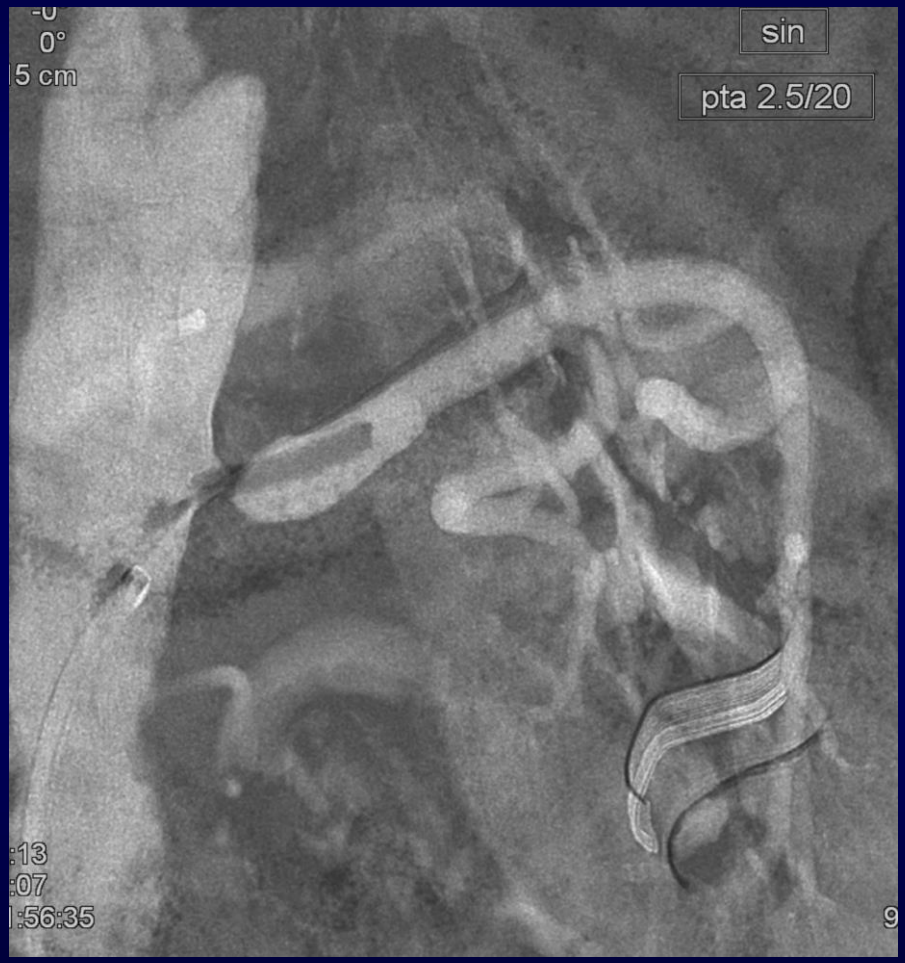
Representative case





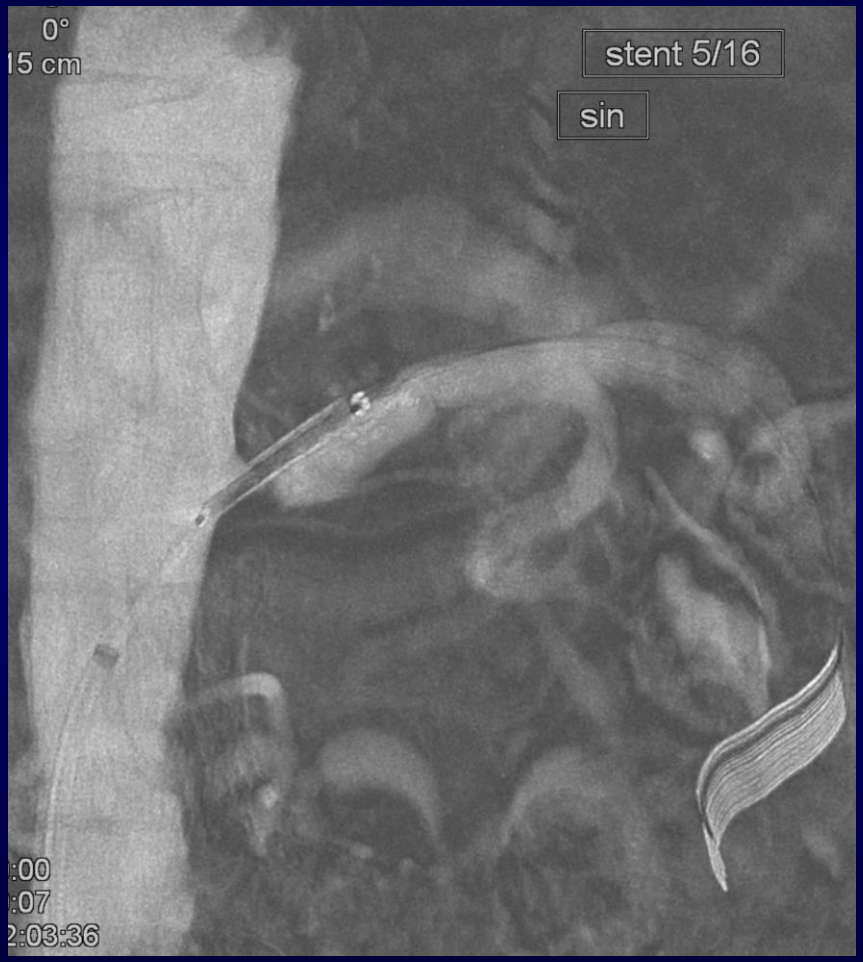
Change of angle

Representative case



Predilation

Representative case



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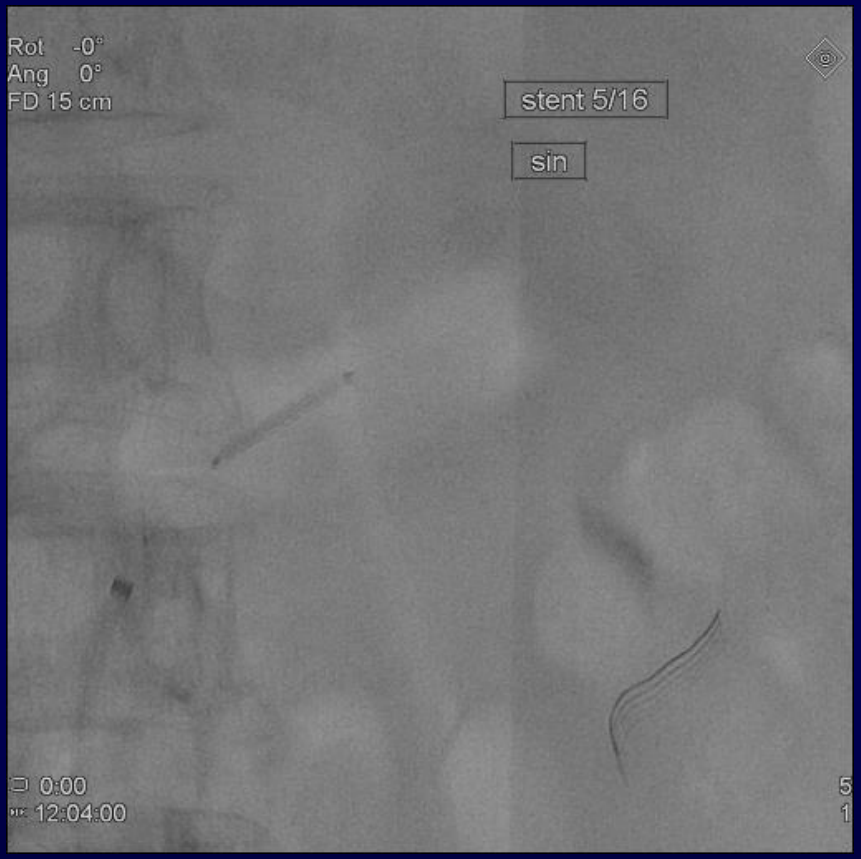

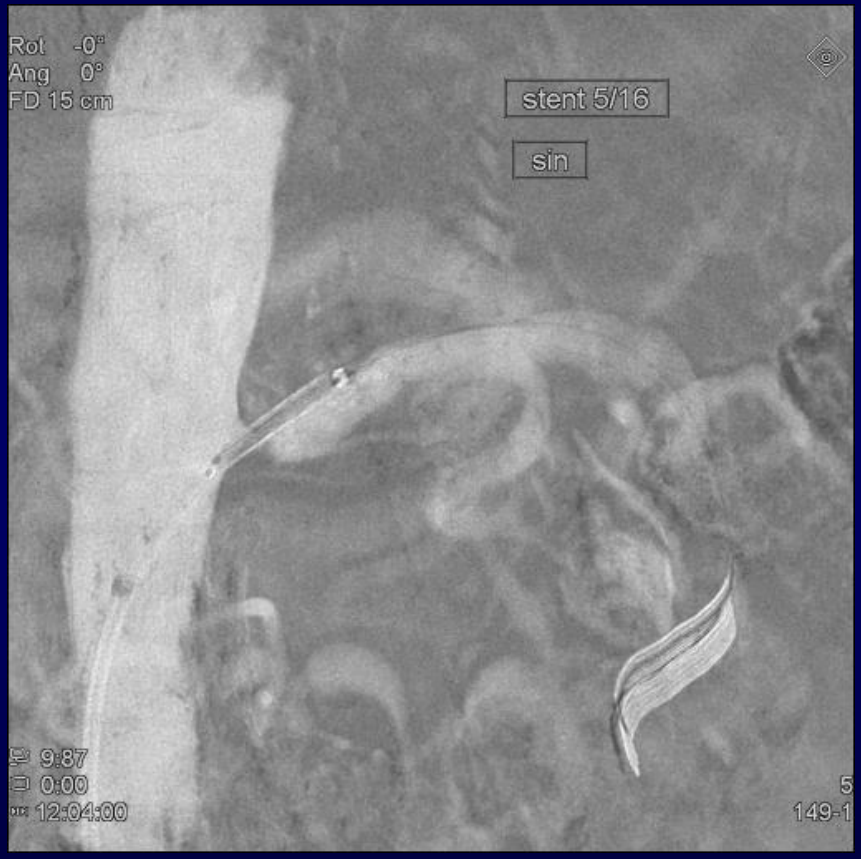

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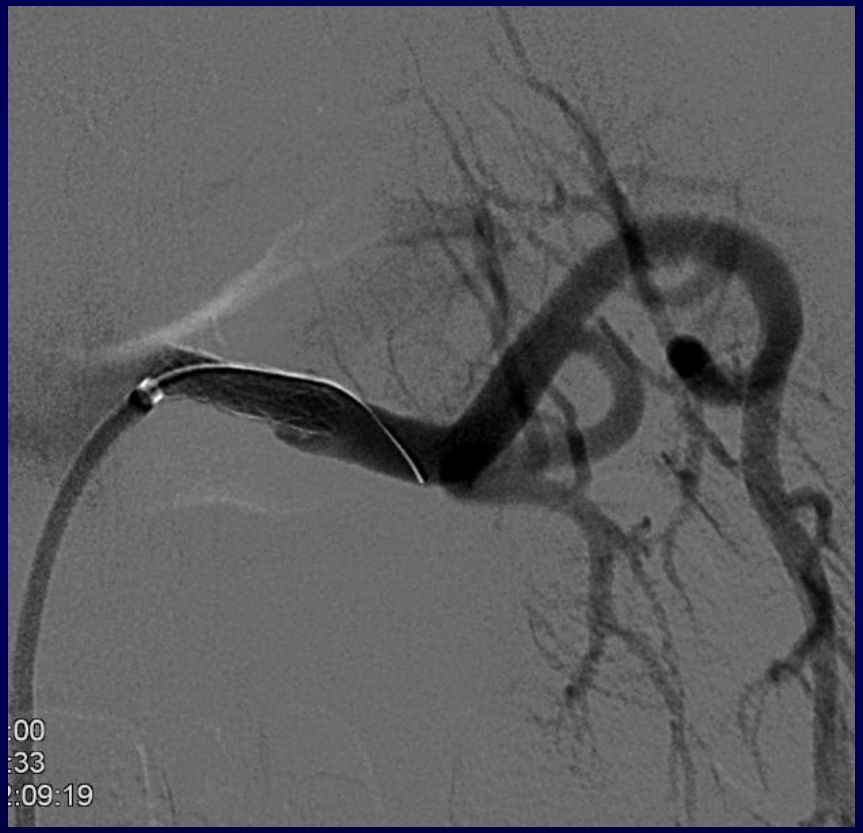
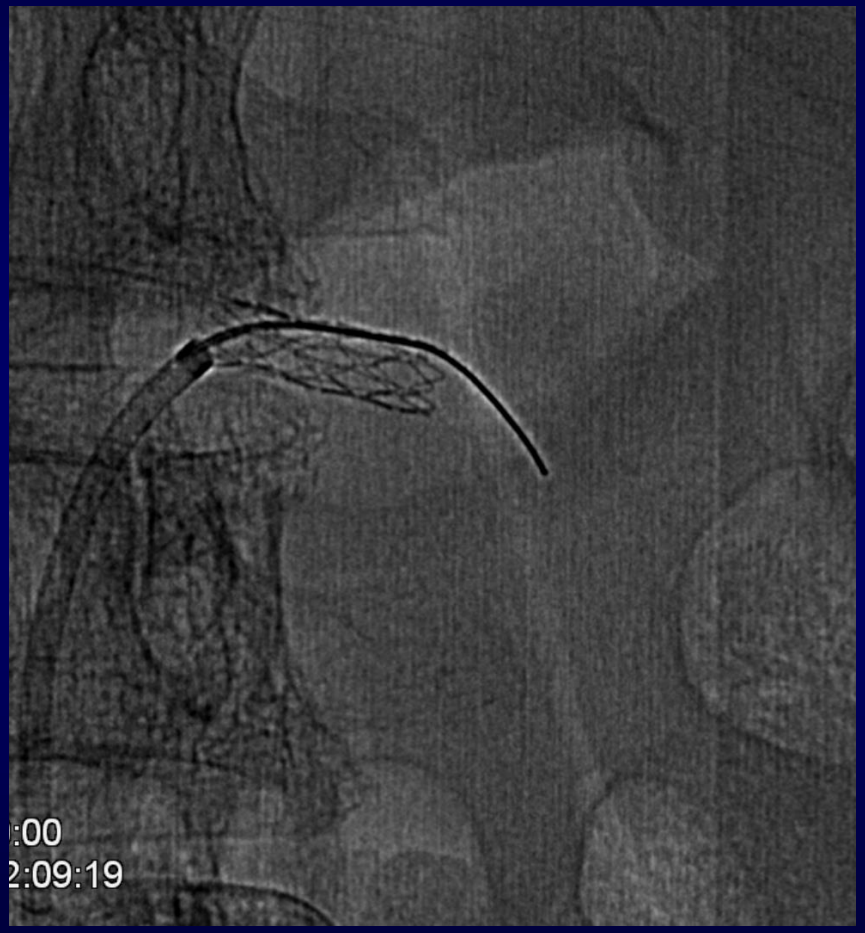
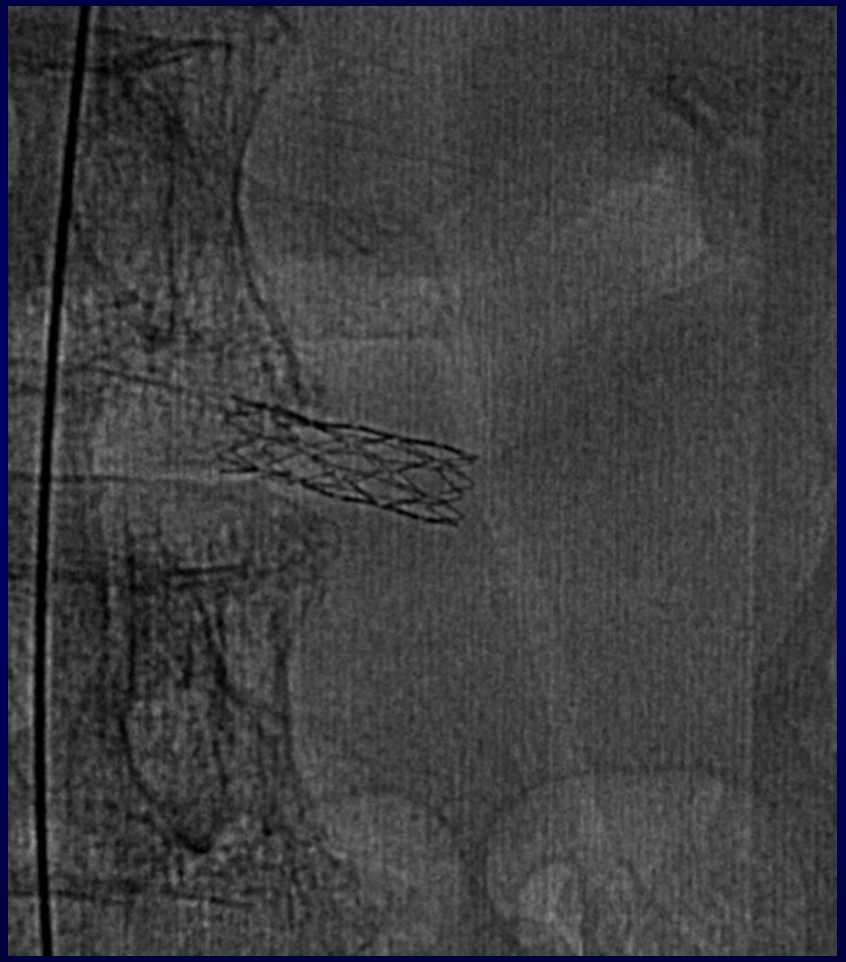




Post-stenotic dilatation

Representative case



Caveats

- Price (but significantly lower re-intervention rate)
- Beware of critical branches

Conclusion

- The use of covered stents improves long-term patency in fenestrated EVAR and visceral artery stenting
- The use of a low-profile Rx system can further reduce procedural complications
- The V12 RX can therefore be considered a problem solver