Peripheral Aneurysm Coiling using Large Volume Ruby Coils: Results from the Multicenter ACE Registry

Jos C van den Berg, MD PhD
Service of Interventional Radiology
Ospedale Regionale di Lugano, Lugano, Switzerland

On behalf of

Parag Patel, MD[2]; Blaise Baxter, MD[3]; J. David Moskovitz, MD[4]; Henry Moyle, MD[5]; Ryan Hagino, MD[6]; Richard Klucznik MD[7], Don Heck MD[8], Philippe Gailloud MD[9] for the Penumbra ACE Study Investigators

[2]Medical College of Wisconsin, Milwaukee, WI; [3]Erlanger Health System, Chattanooga, TN; [4]Florida Hospital, Orlando, FL; [5]Mount Sinai Medical Center, New York, NY; [6]Essenstia Health, Duluth, MN; [7]The Methodist Hospital Research Institute, Houston, TX; [8]Forsyth Medical Center, Winston-Salem, NC; [9]Johns Hopkins University, Baltimore, MD

Disclosure

Penumbra, Inc.

- Consultant

Packing Density: Why is it important?

Packing density promotes complete and stable coil embolization in peripheral aneurysms

Recent publication indicated a packing density **≥ 24%** is optimal[1]

- Protects against compaction or recanalization in long term follow-up (≥ 12 months)

1. Yasumoto T, Osuga K, Yamamoto H, et al. Long-term outcomes of coil packing for visceral aneurysms: Correlation between packing density and incidence of coil compaction or recanalization. *J Vasc Interv Radiol*. 2013;24(12):1798-1807. doi:10.1016/j.jvir.2013.04.030

ACE Trial

The ACE study demonstrated the safety and efficacy of the Ruby™ Coils in achieving high Packing density, leading to complete aneurysm obliteration and stable vessel embolization

ACE Trial

Outcome measures:

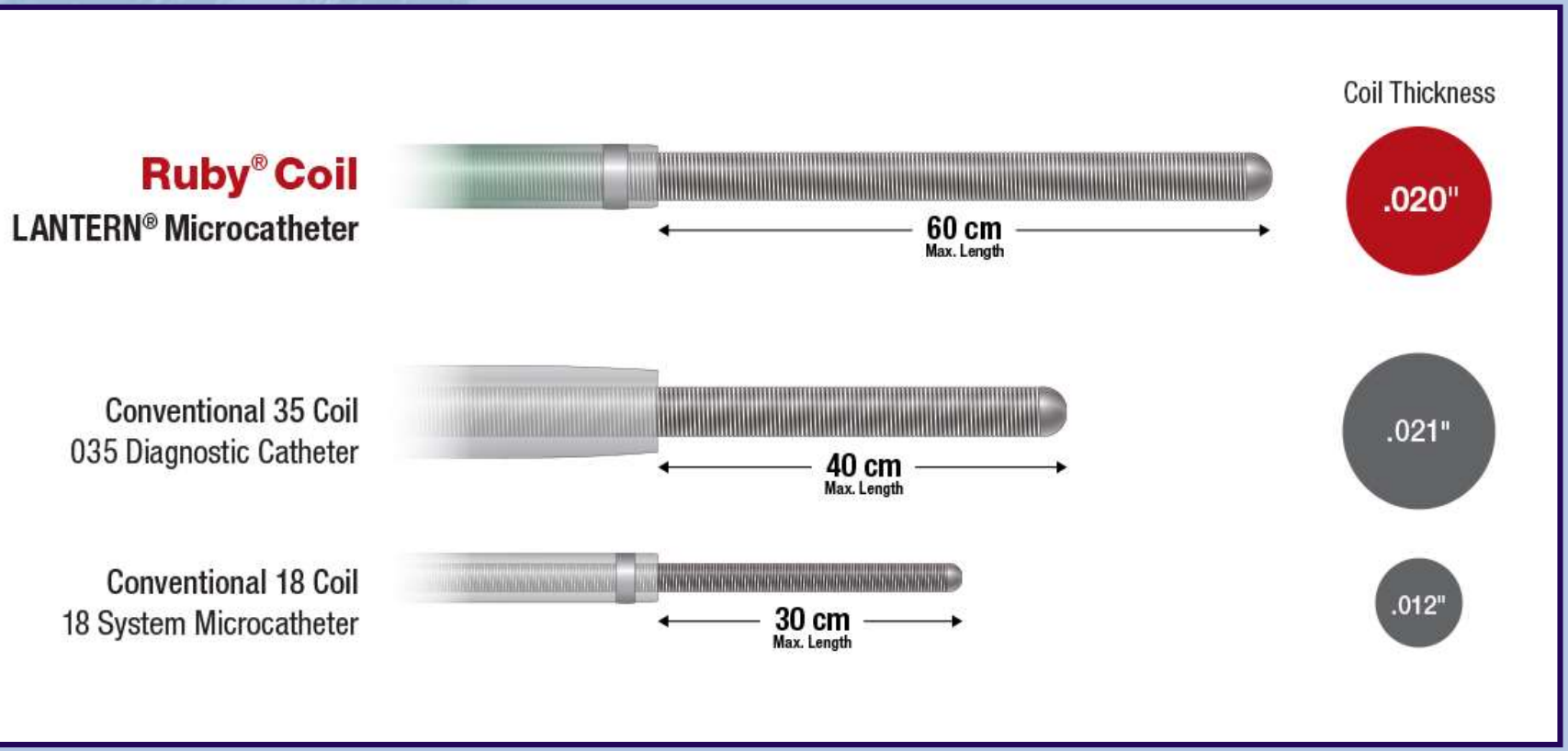
- Packing density with the number of coils deployed
- 6 months occlusion rate (optional 1 year follow-up)
- Time of fluoroscopic exposure
- Device-related serious adverse events (Immediate post-procedure)

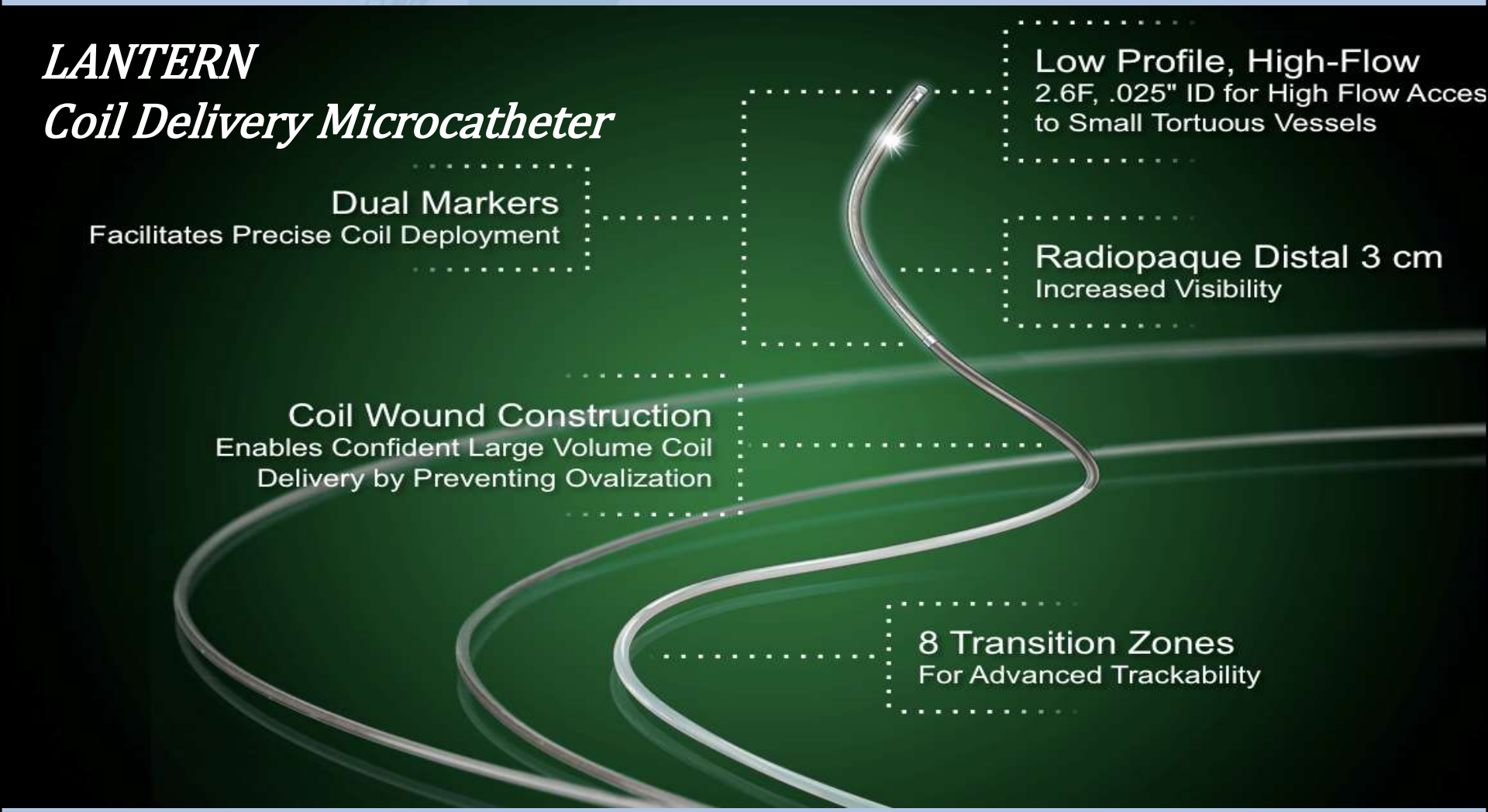
Ruby Coil
Large Volume Detachable Coil

- Long and ***Soft*** embolization coil
- Similar in size to .035" coils
- 1-click mechanical detachment
- Multiple softness levels
  - **Standard coils –** to "Frame"
  - **Soft coils –** to "Fill" aneurysms and pack vessels

Delivery

Designed to be delivered through high flow Microcatheters




LANTERN
Coil Delivery Microcatheter
Low Profile, High-Flow
2.6F, .025" ID for High Flow Acces
to Small Tortuous Vessels
Dual Markers
Facilitates Precise Coil Deployment
Radiopaque Distal 3 cm
Increased Visibility
Coil Wound Construction
Enables Confident Large Volume Coil
Delivery by Preventing Ovalization
8 Transition Zones
For Advanced Trackability

Ruby Volume Advantage

One 30 cm Ruby Coil
28% Packing

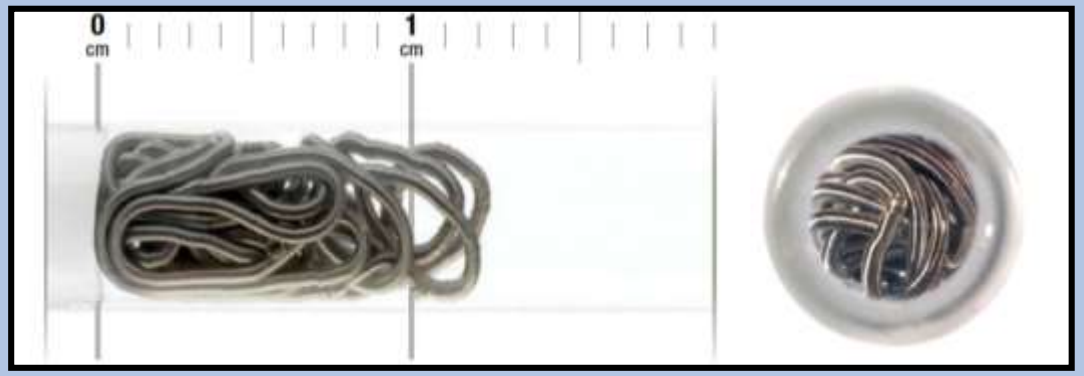
One 30 cm 18 system coil
7% Packing

7.5 mm glass aneurysm

Ruby Softness Advantage

Conventional Detachable Coil

Large Volume ***Soft*** Coil



SOFT COILS TIGHTLY PACK FORMING DENSE METAL OCCLUSION

Methods

- ACE was a prospective registry with patients enrolled from March 2012 to April 2016

- 78 peripheral lesions were treated in 67 patients across 15 centers

Procedure Characteristics

Baseline Characteristics	
Total Patients, N (Lesions)	67 (78)
Age, Median [IQR]	59 Years [IQR 48 – 71]
Female, % (n/N)	44.8% (30/67)

Safety Results	
Device Related SAEs	0
Procedural SAEs	3/67 (4.4%)*

*Splenic infarction documented in one patient post embolization. One patient developed a splenic rupture, treated by splenectomy. The remaining patient had 2 embolizations; expired due to polytrauma complications (after family made decision to begin comfort care).

Results: Aneurysm

Clinical Results	
Mean Aneurysm Diameter	2.1 ± 1.4 cm*
Packing Density, Median [IQR]	26.8% [IQR 18.6 – 33]
Number of Coils Deployed, Median [IQR]	6.5 [IQR 4 – 14]
Fluoroscopy Time, Median [IQR]	29.0 Minutes [IQR 21 – 36]

*Aneurysm locations included splenic, renal, mesenteric, iliac, and vertebral arteries.

Long-term Outcomes of Coil for Visceral Aneurysms

Correlation between Packing Density and Incidence of Coil Compaction or Recanalization

Taku Yasumoto, MD, PhD, Keigo Osuga, MD, PhD, Hiroshi Yamamoto, MD, Yusuke Ono, MD, Maki Masada, MD, Koji Mikami, MD, Daigo Kanamori, MD, Masahisa Nakamura, MD, Kaisyu Tanaka, MD, Tetsuro Nakazawa, MD, PhD, Hiroki Higashihara MD, PhD, Noboru Maeda, MD, PhD, and Noriyuki Tomiyama, MD, PhD

ABSTRACT

Purpose: To evaluate the correlation between packing density and the incidence of coil compaction or recanalization of visceral artery aneurysms (VAAs) after coil packing.

Materials and Methods: Between July 2004 and April 2012, coil packing was performed for 46 true visceral aneurysms (16 splenic, 11 pancreaticoduodenal, eight renal, six hepatic, three superior mesenteric, one right gastric, and one gastroepiploic) in 42 patients. The size and volume of the aneurysm, packing density, and the incidences of compaction and recanalization were evaluated retrospectively.

Results: The mean follow-up period was 37 months ± 8 (range, 11–80mo). The mean packing density was 19% ± 8 (range, 5%–42%), mean aneurysm size was 19mm ± 8 (range, 5–40mm), and mean volume was 4,108mm^3 ± 5,435 (range, 72–26,235 mm^3). Compaction and recanalization occurred in two (4%) and 12 aneurysms (26%) respectively. The mean packing density was significantly lower in aneurysms with compaction or recanalization than in unaffected aneurysms (12% vs 22%; $P = .00014$). There was a significant difference in mean packing density between small (< 20 mm; 22%) and large (≥ 20 mm) aneurysms (15%; $P = .0045$). The mean size and volume were significantly larger for coil-compacted or recanalized aneurysms than for unaffected aneurysms ($P < .05$). In aneurysms with a packing density of at least 24%, no compaction or recanalization occurred.

Conclusions: Coil compaction or recanalization after coil packing for VAAs more often occurs after insufficient embolization with low packing density and in patients with large aneurysms.

Yasumoto, Taku et al. Long-term outcomes of coil packing for visceral aneurysms: correlation between packing density and incidence of coil compaction or recanalization. *J Vasc and Interv Radiol.* 2013;24(12):1798 – 1807.

Long-Term Follow Up

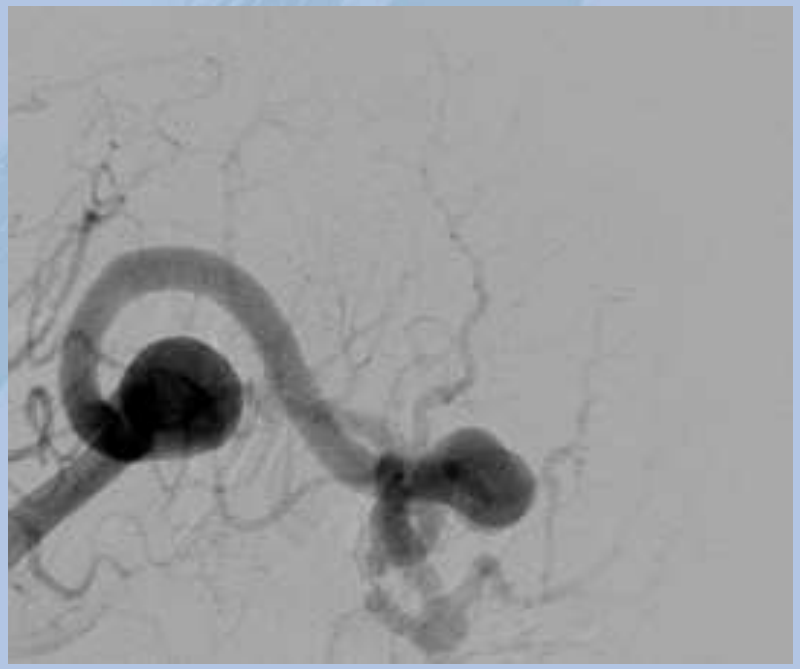
Follow Up from Index Procedure	Stable Occlusion
6 months	90.9% (20/22)
1 year	100% (15/15)

2 Aneurysms Recanalized:

- Splenic Artery Aneurysm – **Packing Density only 9.5%**
- Type II endoleak initially treated with coils and Onyx®[1]. Recanalization likely observed as a result of recruitment of new feeding artery

[1]Onyx is comprised of EVOH (ethylene vinyl alcohol) copolymer dissolved in DMSO

19 mm Splenic Artery Aneurysm



Corey Teigen MD, Sanford Health, ND

- 8 **Ruby®** **Coils** deployed
- 33.8% packing density achieved
- Stable Occlusion at 6-month and 1-year follow up

Results: Vessel Sacrifice and Malformations

Clinical Outcomes	
Number of Vessels, N	52
Number of Coils Deployed, Median [IQR]	3 [IQR 2 – 5]
Fluoroscopy Time, Median [IQR]	21.5 Minutes [15 – 29]

Results: Vessel Sacrifice

Patients completing 6-month follow up	Stable Occlusion
19	94.7% (18/19)

One recanalization occurred in a pregnant patient treated for a Pulmonary AVM. The embolization was stopped prior to complete occlusion to **limit contrast and radiation dose due to pregnancy.**

Conventional Fibered Coils: 20.4% Recanalization

Gastroduodenal artery recanalization after transcatheter fibered coil embolization for prevention of hepaticoenteric flow: incidence and predisposing technical factors in 142 patients

Jose Enriquez[1], Sanaz Javadi[1], Ravi Murthy[1], Joe EnsorJr[2], Armeen Mahvash[1], Mohamed E Abdelsalam[1], David C Madoff[3], Michael J Wallace[1] and Rony Avritscher[1]

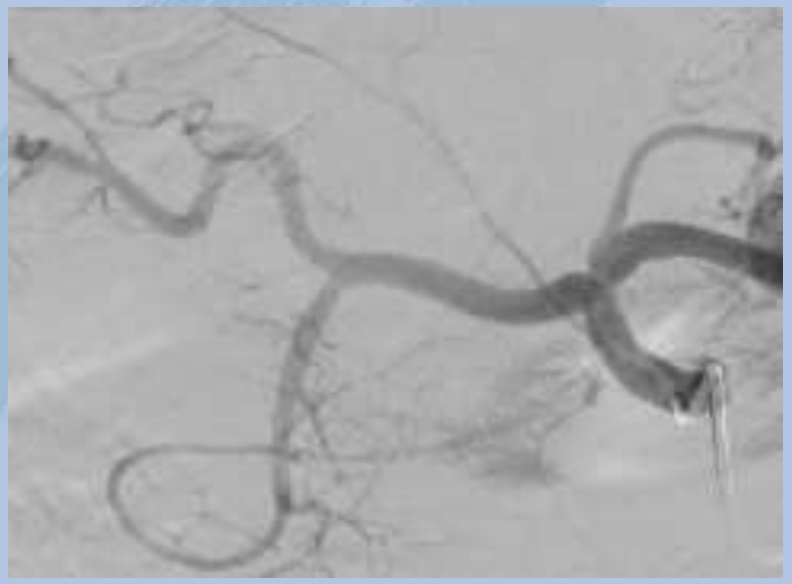
[1]Department of Diagnostic Radiology, The University of Texas MD Anderson Cancer Center, Houston, TX; [2]Department of Biostatistics, The University of Texas MD Anderson Cancer Center, Houston, TX; [3]Division of Diagnostic Imaging, Interventional Radiology, New York, Presbyterian Hospital/Weill Cornell Medical Center, New York, NY, USA

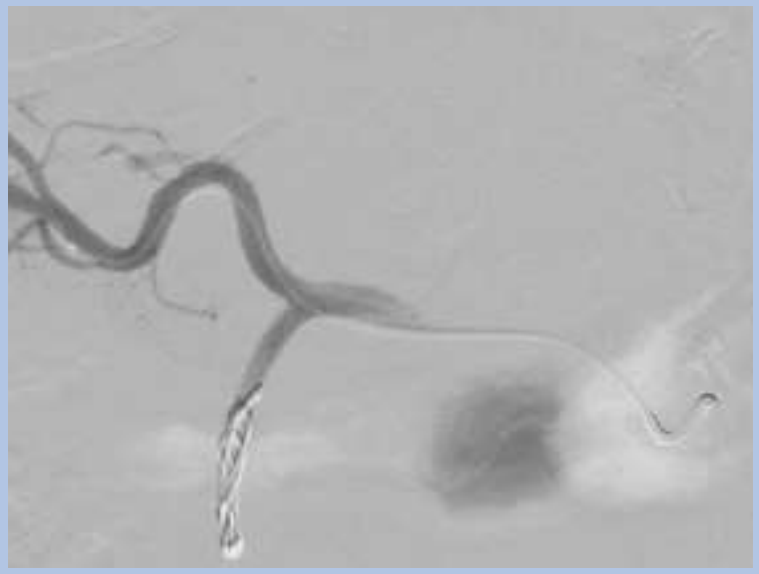
Correspondence to: Rony Avritscher. Email: rony.avritscher@mdanderson.org

Results: Twenty-nine of 142 patients (20.4%) experienced GDA recanalization. The distance between the GDA origin and most cephalad coil was significantly greater in the recanalization group than in the non-recanalization group (9.6 mm *vs.* 12.6 mm, $P = 0.01$). A prospective multivariate analysis established that the further the coil was from the origin the more likely the GDA was to recanalize. The two groups did not differ on the basis of any other factors examined.

Enriquez, J. et al. Gastroduodenal artery recanalization after transcatheter fibered coil embolization for prevention of hepaticoenteric flow: incidence and predisposing technical factors in 142 patients. *Acta Radiol.* 2013;54:790–794.

Gastroduodenal Artery Sacrifice





Rahul Patel MD, Mount Sinai, NY

- Pre Y90 mapping
- Complete cross sectional mechanical occlusion

Conclusion

Dense packing with **Ruby® Coil** enables stable long-term occlusion

Aneurysm exclusion and vessel sacrifice procedures were associated with:

1. short procedure times
2. low fluoroscopy exposure
3. few devices per case

Peripheral Aneurysm Coiling using Large Volume Ruby Coils: Results from the Multicenter ACE Registry

Jos C van den Berg, MD PhD
Service of Interventional Radiology
Ospedale Regionale di Lugano, Lugano, Switzerland

On behalf of

Parag Patel, MD[2]; Blaise Baxter, MD[3]; J. David Moskovitz, MD[4]; Henry Moyle, MD[5]; Ryan Hagino, MD[6]; Richard Klucznik MD[7], Don Heck MD[8], Philippe Gailloud MD[9] for the Penumbra ACE Study Investigators

[2]Medical College of Wisconsin, Milwaukee, WI; [3]Erlanger Health System, Chattanooga, TN; [4]Florida Hospital, Orlando, FL; [5]Mount Sinai Medical Center, New York, NY; [6]Essenstia Health, Duluth, MN; [7]The Methodist Hospital Research Institute, Houston, TX; [8]Forsyth Medical Center, Winston-Salem, NC; [9]Johns Hopkins University, Baltimore, MD