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LAVA Clinical Case Guide

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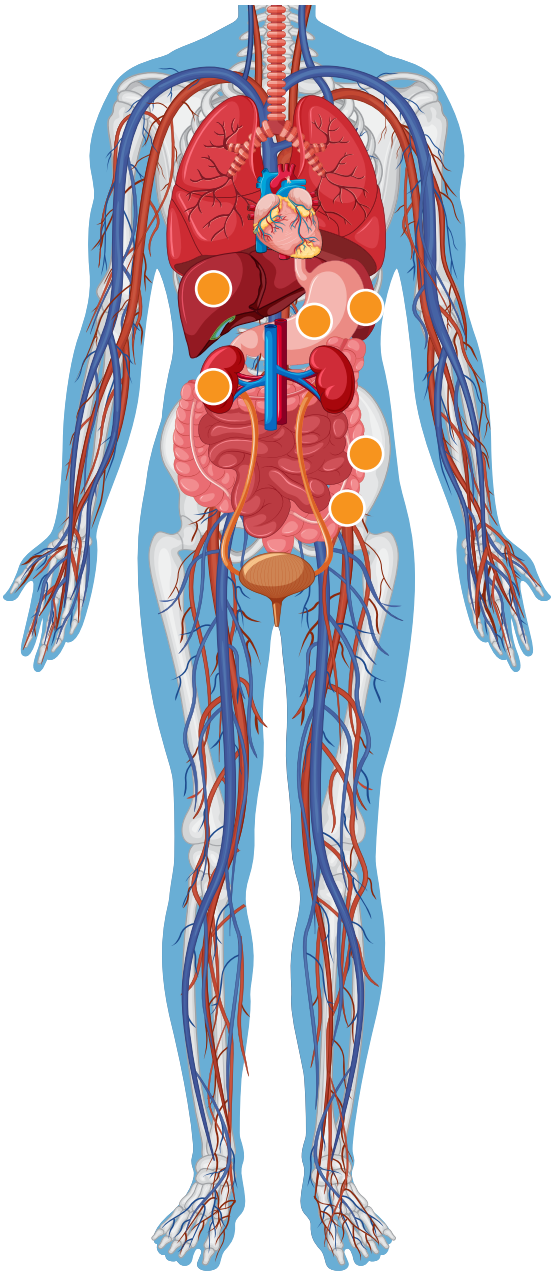
Click on anatomy for related content

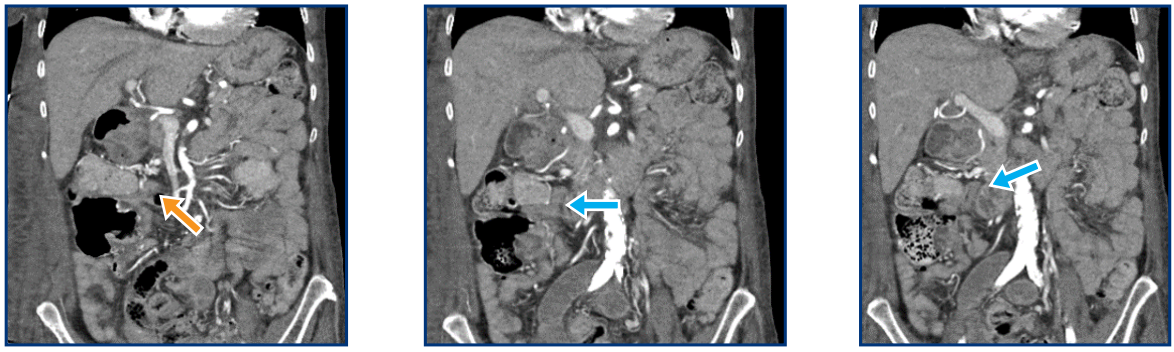


GI Hemorrhage - Upper GI

Chris Stark, MD
Albany Medical Center
Albany, NY

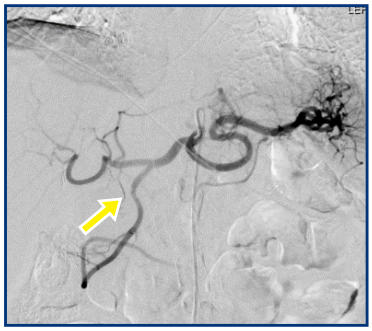
Patient Presentation

72-year-old female patient with ESRD presents with 2-day history of melena and a syncopal episode preceded by central abdominal pain.

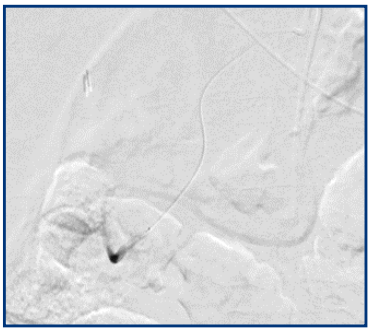


Coronal post-contrast CT images demonstrate a large duodenal ulcer (orange arrow). The gastroduodenal artery courses along the medial aspect of the ulcer (blue arrows).

Access & Treatment

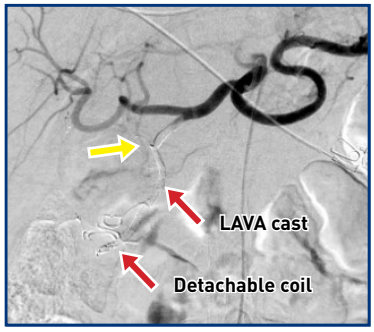


Celiac angiogram demonstrates a focal contour abnormality in the proximal segment of the gastroduodenal artery (yellow arrow), but no active extravasation or pseudoaneurysm. Due to endoscopic findings, prophylactic embolization of the gastroduodenal artery is planned.



A microcatheter is advanced into the proximal right gastroepiploic artery. A single detachable coil is placed as a distal backstop followed by embolization of the gastroduodenal artery with LAVA 34.

Post-Embolization



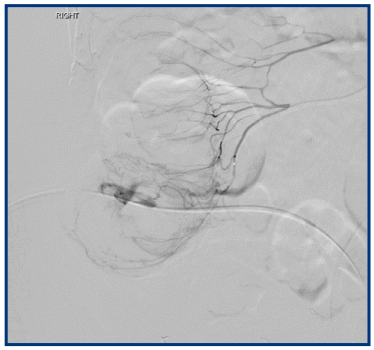
Post-embolization celiac angiogram demonstrates complete occlusion of the gastroduodenal artery. LAVA is seen filling a very small pseudoaneurysm of the proximal gastroduodenal artery, corresponding with the location of contour abnormality identified prior to embolization (yellow arrow). No adverse events observed.

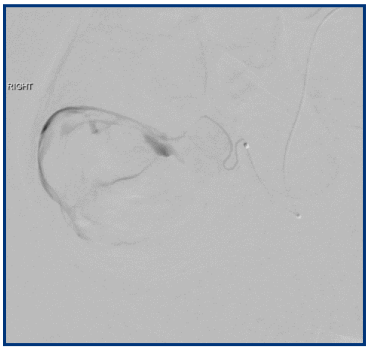
GI Hemorrhage - Lower GI

Bulent Arslan, MD, FSIR
RUSH University Medical Center
Chicago, IL

Patient Presentation

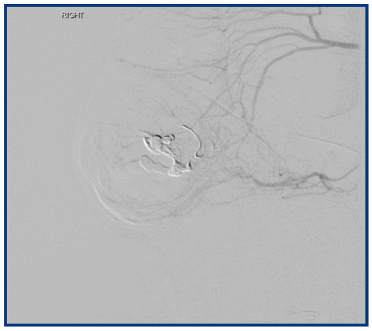
Lower GI Hemorrhage — Cecal



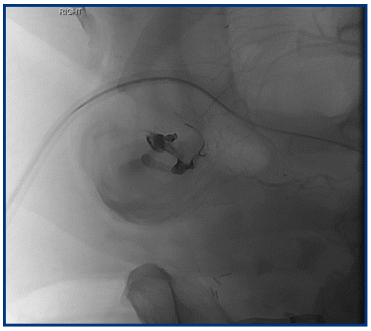


Cecal bleed from small submillimeter marginal branches — opted for LAVA 18 to travel distally to fill these small branches and treat the bleed.

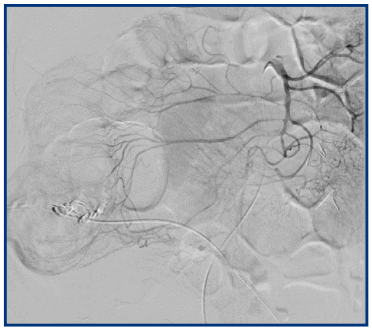
Access & Treatment



Catheterization



Injection of .6 mL of LAVA 18



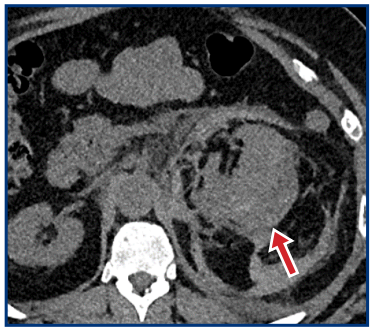
**Post-embolization:
Final angiogram from a more proximal approach does not show any bleeding.
No adverse events.**

Renal Trauma

Ziv Haskal, MD, FSIR
University of Virginia
Charlottesville, VA

Patient Presentation

42-year-old male that underwent CT guided non-focal renal biopsy. Patient developed marked gross hematuria, dropping hemoglobin, low BP and was emergently transferred from an outside hospital.



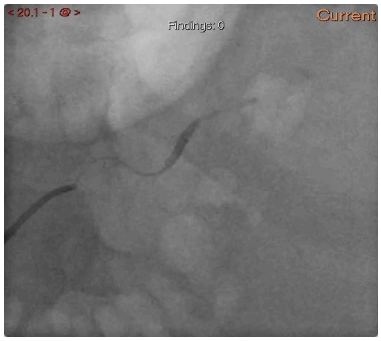
Hemorrhage shown on axial CT (red arrow)

Extravasation seen on angiogram (red arrow)

Access & Treatment

Microcatheter placement (red arrow)

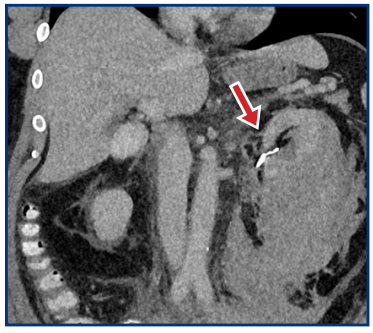
LAVA injection
(click video to watch)



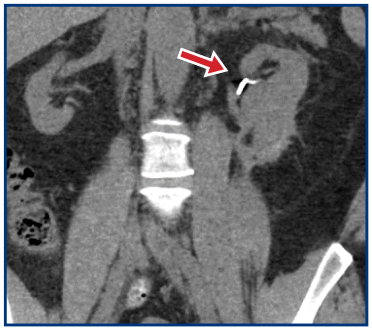
Microcatheter withdrawal
(click video to watch)

Post-Embolization

Post-embolization



2 days post-embolization



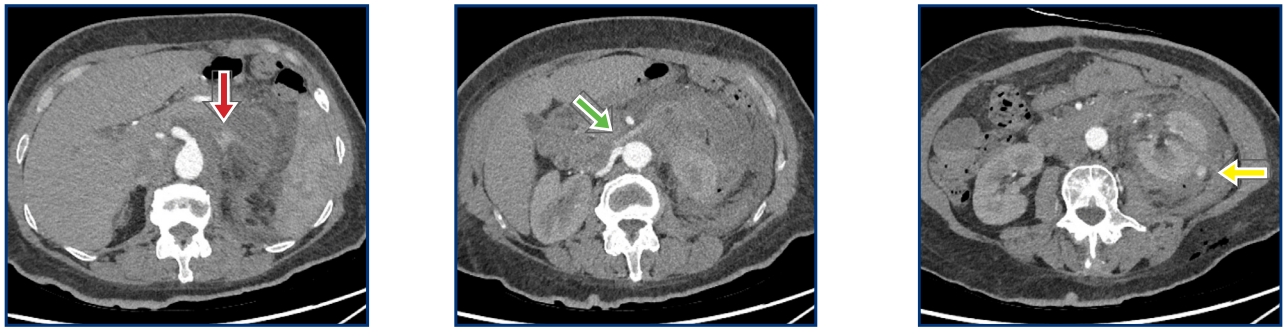
10 months post-embolization
Minimal streak artifact
No adverse events.

Renal Pseudoaneurysm

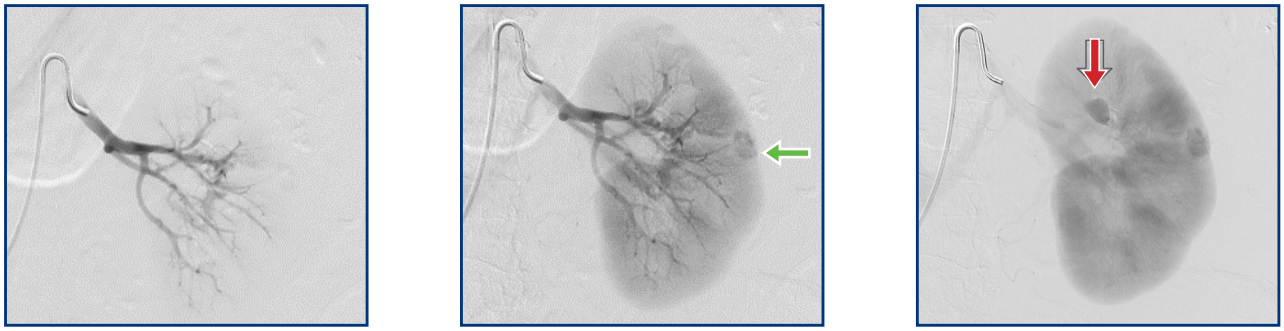
Gary Siskin, MD, FSIR
Albany Medical Center
Albany, NY

Patient Presentation

42-year-old male that underwent CT guided non-focal renal biopsy. Patient developed marked gross hematuria, dropping hemoglobin, low BP and was emergently transferred from an outside hospital.

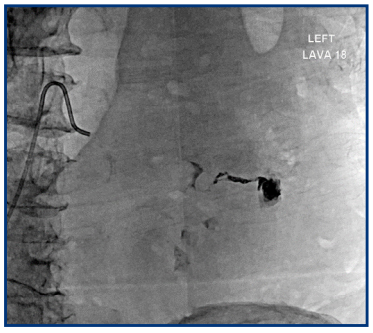


These images from CT scan showed evidence for active bleeding (red arrow), a peripheral pseudoaneurysm (green arrow) and a likely AV fistula (yellow arrow) after the biopsy. No adverse events.



These images from the initial renal angiogram showed evidence for a pseudoaneurysm (source of bleeding) in the periphery of the left kidney (green arrow) with additional abnormal contrast pooling in the more medial aspect of the kidney (red arrow). No adverse events.

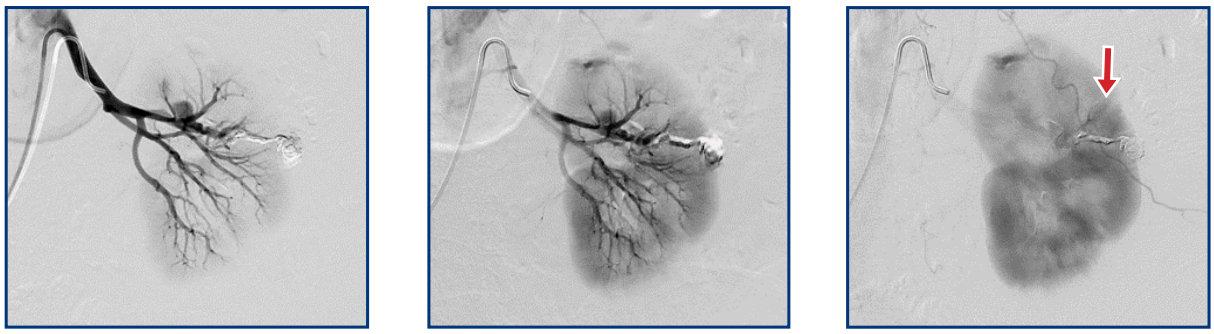
Treatment- Initial Bleed



This is an image following the administration of LAVA 18 into the mid-pole branch supplying a pseudoaneurysm where contrast extravasation was seen. No adverse events.

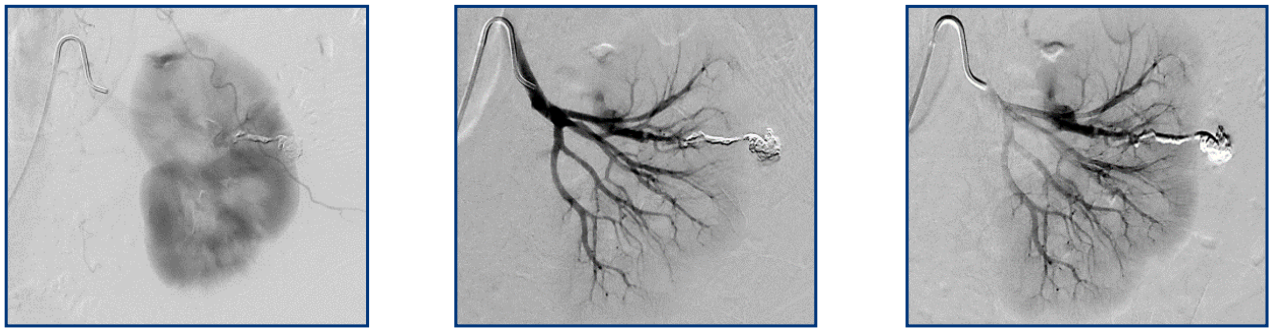
Renal Pseudoaneurysm (cont')

Gary Siskin, MD, FSIR
Albany Medical Center
Albany, NY

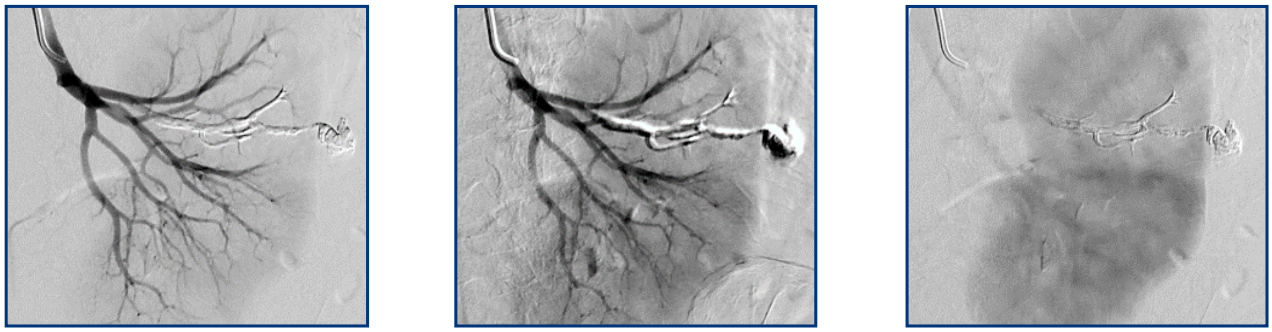


An angiogram after LAVA 18 administration showed good control of the peripheral bleeding, but additional bleeding was seen in the medial aspect of the upper pole (red arrow). This corresponded to the area of bleeding seen on CT.

Second LAVA Administration



Additional angiographic images showed that there was additional bleeding in the medial aspect of the upper pole of kidney that was likely arising from a more proximal position of the same artery supplying the original area of bleeding.



LAVA 18 was administered more proximally into the injured artery with good control of the bleeding at both sites. The target vessels was embolized in its entirety which impacted only a small percentage of the left kidney.

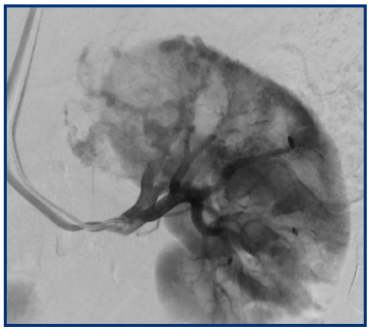
Renal Hemorrhage

Jeremy I. Kim, MD
Charlotte Radiology
Charlotte, NC

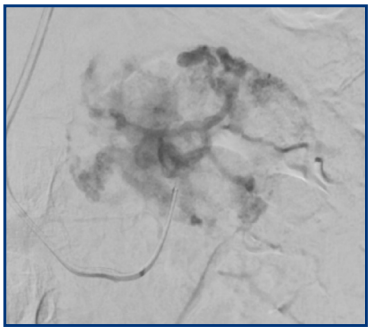
Patient Presentation

59-year-old male with no significant past medical history presenting with acute hemorrhage from ruptured 6.4 cm AML of the left kidney.

Pre-embolization coronal CT image

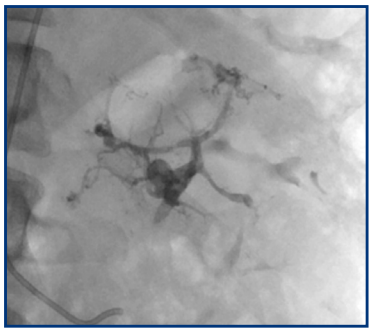


Pre-embolization angiogram of left kidney demonstrates hypervascular mass in the upper pole consistent with known AML.

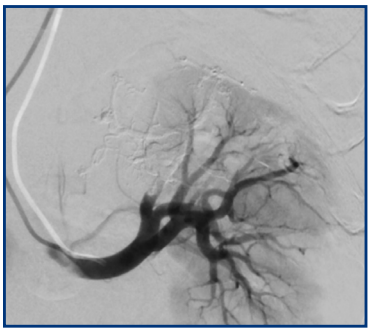


Selective angiogram of AML

Post- Embolization



Post-embolization spot image demonstrates excellent casting of the AML vasculature.

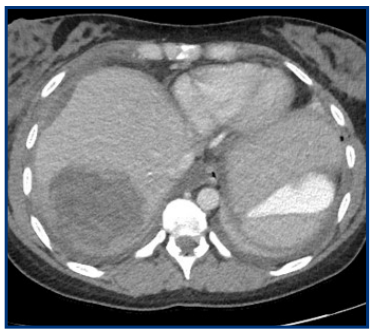


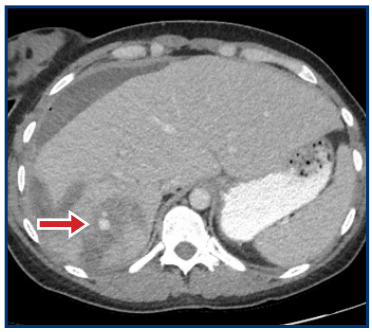
Post-embolization renal artery angiogram demonstrates no vascular flow to the AML and preserved vasculature to normal renal parenchyma.

1-Month Follow Up shows no complications post-embolization. Coronal CT image demonstrating near-complete necrosis with smaller 5.3 cm size.

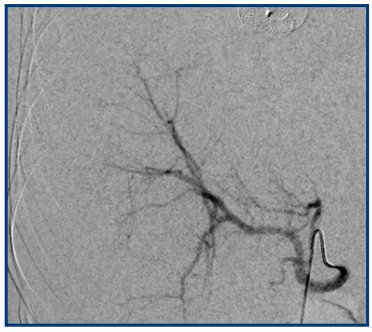
Liver Trauma - Hepatic Pseudoaneurysm

Chris Stark, MD
Albany Medical Center
Albany, NY



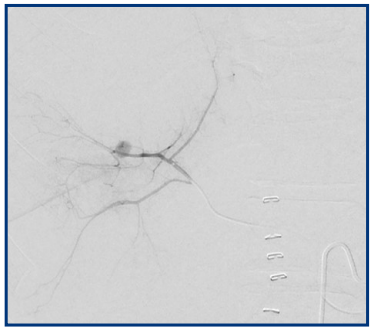
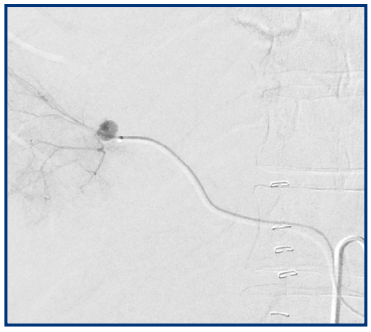



CT images through the liver demonstrate subcapsular and intrahepatic hematomas. Focus of enhancement centered within the right hepatic hematoma is suggestive of a pseudoaneurysm (red arrow).




Hepatic angiogram demonstrates a pseudoaneurysm arising from a branch of the right hepatic artery (red arrow).

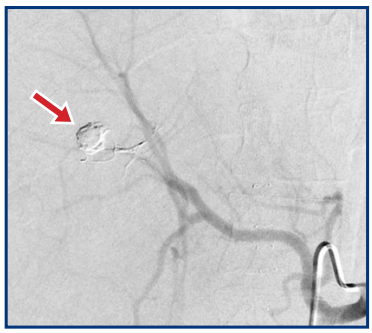
Access & Treatment

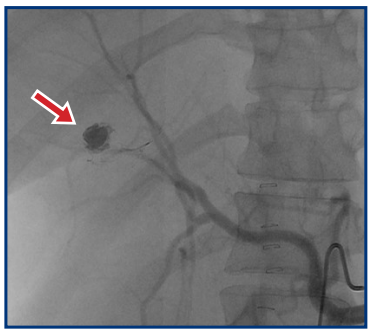



A microcatheter is advanced distally into the hepatic vasculature to the site of the pseudoaneurysm.

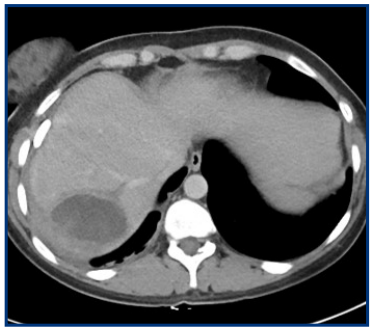
Liver Trauma - Hepatic Pseudoaneurysm (cont')

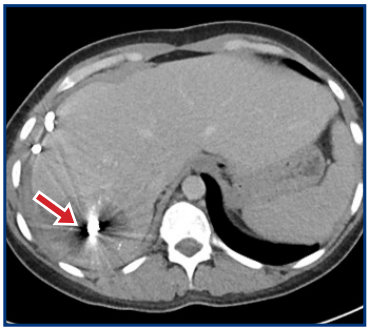
Chris Stark, MD
Albany Medical Center
Albany, NY

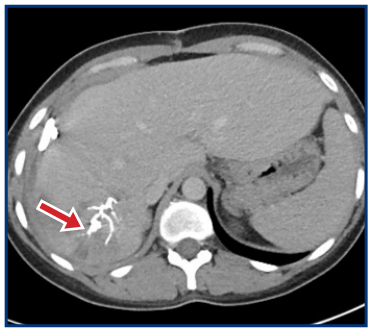


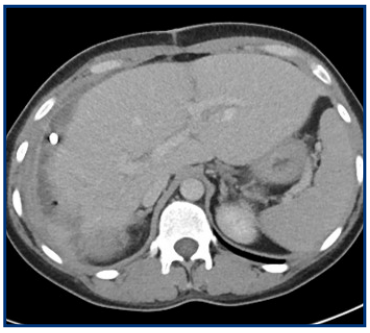


Embolization of the feeding vessel and pseudoaneurysm is performed with LAVA 18. Post-embolization angiogram with and without digital subtraction demonstrates the LAVA cast with complete occlusion of the pseudoaneurysm (red arrows). No adverse events.









Post-embolization CT scan performed two weeks later demonstrates the LAVA cast filling the pseudoaneurysm and adjacent vessels (red arrows). The intrahepatic hematoma has decreased in size. No adverse events.

Splenic Trauma

Parag Patel, MD, FSIR
Froedtert Medical College of Wisconsin
Milwaukee, WI

Patient Presentation

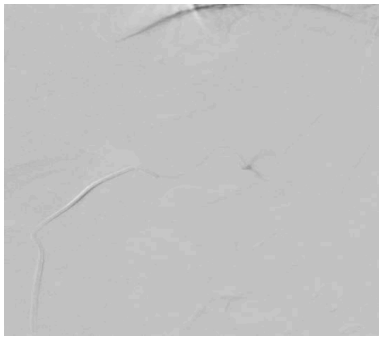
33-year-old male presented post motor vehicle collision. Multiple traumatic fractures and a grade 5 splenic laceration with extension into the splenic hilum, s/p massive transfusion protocol.

Imaging showed fractures of left acetabulum, left acromion and left open patella fracture.

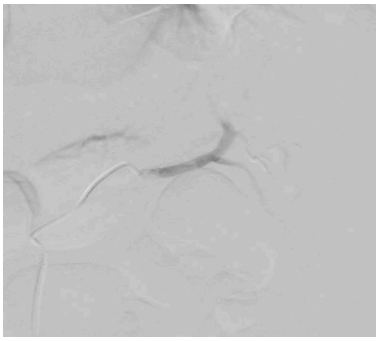
Grade 5 splenic laceration with findings suggestive of multiple splenic pseudoaneurysms. There has been an increase in amount of blood in the paracolic gutters and perihepatic space.

Selective splenic angiogram displaying psuedoaneurysms and extravasations.
(click each video to watch)

Access & First Administration



Selective placement for access to pseudoaneurysm.
(click video to watch)

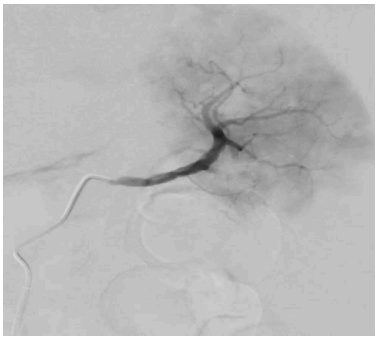


Post Embolization imaging following administration of .2 mL LAVA showcases embolic cast mimicking bleeding site.
(click video to watch)

Splenic Trauma (cont')

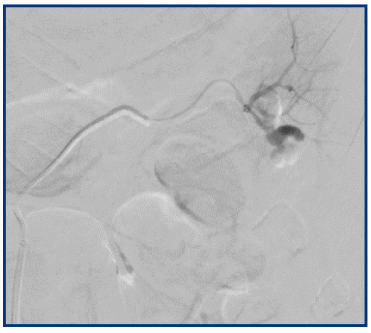
Parag Patel, MD, FSIR
Froedtert Medical College of Wisconsin
Milwaukee, WI

Additional Bleeding Source

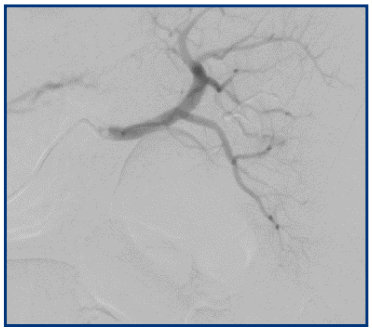


An additional lower pole branch that is also supplying the pseudoaneurysm is identified andselectively catheterized for subsequent LAVA administration.
(click each video to watch)

Nonselective general splenic angiogram



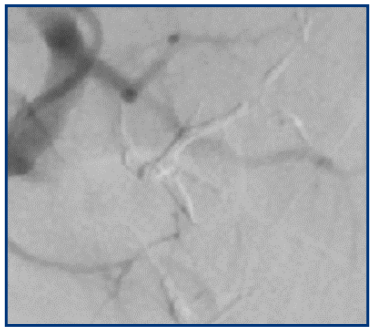
Sub-selective catheterization



Post-embolization image displaying the LAVA cast in the target vessel confirming the resolution of the pseudoaneurysm and extravasation. No adverse events.

2nd branch, lower pole further down subsequently selected

Confirmation of 2nd branch occlusion, and both LAVA casts



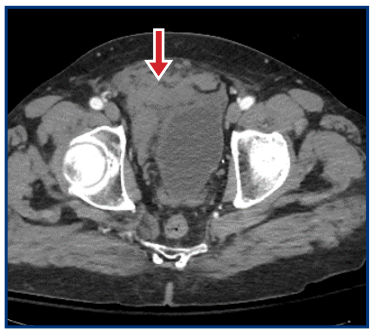
Magnified view of both LAVA casts

Pelvic Trauma

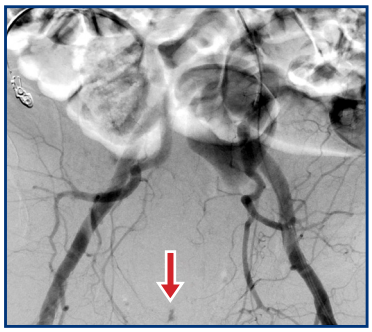
Gary Siskin, MD, FSIR
Albany Medical Center
Albany, NY

Patient Presentation

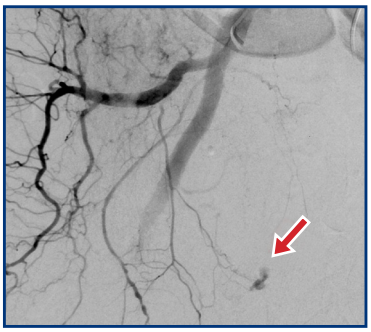
54-year-old male patient who was run over by a tractor. A CT scan was performed upon his presentation to the ER.



These images from the CT scan show a hematoma on the right side of the bleeding (red arrow), deviating the bladder to the left. In addition, there is active bleeding inferior to the bladder (green arrow).

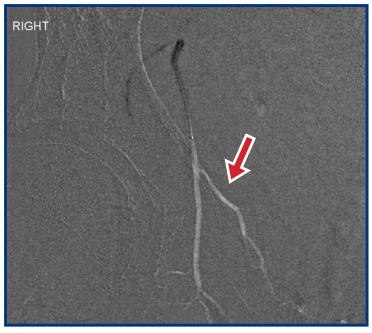


This image from the initial angiogram shows an area of active bleeding in the central portion of the pelvis (red arrow) which corresponded to the area on the CT scan.

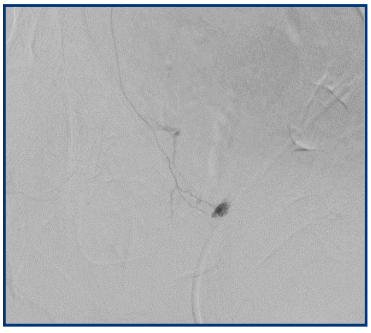


Angiography performed in an oblique projection shows the bleeding more clearly (red arrow) and also demonstrates the vessel where the bleeding is originating.

Access



This image shows the source vessel and the target for catheterizing the labelled vessel.



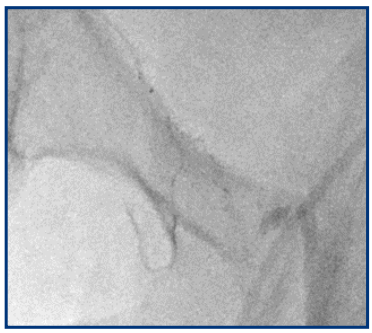
This image was taken after the catheter was in the vessel, showing the bleeding.

These images show the change in catheter position as it was moved closer to the site of bleeding.

Pelvic Trauma (cont')

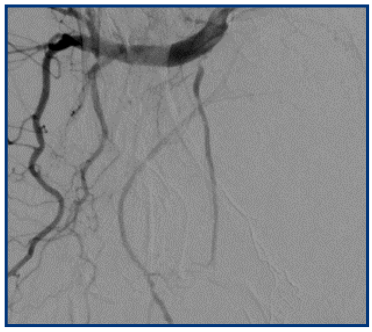
Gary Siskin, MD, FSIR
Albany Medical Center
Albany, NY

Administration

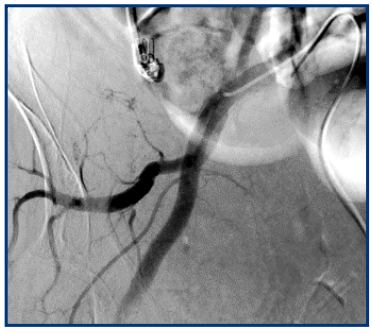


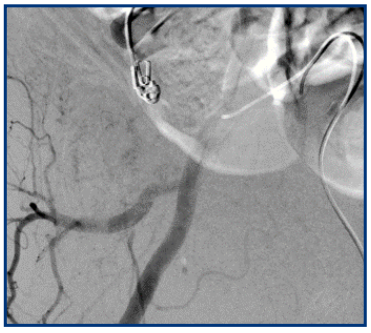
These images demonstrate how the LAVA occupies all branches of the target vessel.

Post- Embolization



Post-embolization image shows occlusion of the target branch. The LAVA is visualized on the subtraction images.





These images confirm occlusion of the target vessel with the LAVA. No bleeding is seen. No adverse events.

Click or scan here to watch a LAVA webinar with case reviews

CAUTION
U.S. federal law restricts the sale, distribution, and use of this product to physicians or as prescribed by a physician.
This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures.

INDICATIONS FOR USE
LAVA LES is indicated for embolization of arterial hemorrhage in the peripheral vasculature.

CONTRAINDICATIONS
LAVA LES is not indicated for use in pregnant women, neonates or individuals with significant liver or kidney function impairment. Safety for these patient groups has not been evaluated.

WARNINGS
DO NOT use monopolar electrocautery devices for surgical resection of tissue embolized with LAVA due to a possibility of electrical arcing with tantalum metal in the embolic cast. Bipolar devices should be used with caution. Use only DMSO compatible microcatheters. LAVA LES has been tested for compatibility with Terumo Medical Progreat®, Boston Scientific Renegade®, and Merit Medical Maestro® microcatheters. Also, use only the DMSO compatible syringes supplied with the LAVA LES Kit. Use of non DMSO compatible microcatheters and syringes may result in degradation that can potentially result in unexpected complications such as thromboembolic events. The LAVA LES should be used only by physicians with peripheral vascular training and a thorough knowledge of the pathology to be treated, angiographic techniques, and super-selective embolization. Performing embolization to occlude blood vessels in the peripheral vasculature is a high-risk procedure. If the vessel wall is compromised, LAVA could escape outside the vascular space. It may result in a subacute inflammatory response to the material and tissue damage. Dimethyl sulfoxide (DMSO) can initiate the liberation of histamine that may result in an occasional hypersensitivity reaction. If anaphylactoid symptoms develop, appropriate therapy should be instituted. DO NOT perform a therapeutic embolization when high blood flow precludes safe injection of LAVA. Special attention must be taken to the positioning of the microcatheter tip. The microcatheter tip should be placed to minimize the potential of embolization of non- target vessels or tissues. Mix LAVA per the "LAVA Mixing and Preparation" section of this IFU and inject LAVA immediately after mixing. Failure to prepare and mix LAVA per the "LAVA Mixing and Preparation" section of this IFU may result in inadequate suspension of the tantalum, resulting in inadequate fluoroscopic visualization during delivery. If LAVA injection is delayed, tantalum settling can occur within the syringe resulting in poor visualization during injection. Adequate fluoroscopic visualization must be maintained during LAVA delivery or non- target vessel embolization may result. If visualization is lost at any time during the embolization procedure, halt LAVA delivery until adequate visualization is re- established. Premature solidification of LAVA may occur if the microcatheter luer contacts any amount of saline, blood, or contrast. DO NOT exceed an injection rate of 0.3 mL/min of DMSO or LAVA into the vasculature as this may result in vasospasm and/or angionecrosis. DO NOT use palm of hand to advance plunger during injection of DMSO or LAVA as this may result in microcatheter rupture due to over pressurization in the event of microcatheter occlusion. DO NOT allow more than 1 cm of LAVA to reflux back over the microcatheter tip. Angioarchitecture, vasospasm, excessive LAVA reflux, or prolonged injection time may result in difficult microcatheter removal and potential entrapment. Excessive force to remove an entrapped microcatheter may cause serious hemorrhage. The long-term effects of an entrapped microcatheter that is left in a patient are unknown, but potentially could include clot formation, infection, or microcatheter migration.

BlackSwan Vascular, Inc. 709 Sandoval Way, Hayward, CA 94544 USA Customer Service: +1 888 474 7839

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