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THOMAS KOWALSKI, MD: We are going to be talking about AXIOS, selecting the patient, selecting the timing for intervention, and selecting the appropriate therapeutic plan for intervention. The patients we're going to be talking about today are those patients with acute pancreatitis and acute pancreatic fluid collection with or without necrosis. Now clearly, patients with chronic pancreatitis can develop collections that require AXIOS Stent drainage but today we're going to be talking about the patient after acute pancreatitis.

Now we often think about the indication for drainage of a fluid collection with the AXIOS Stent. But when accessing a pancreatic fluid collection or walled off necrosis we really must not trivialize the procedure and should only perform the procedure when it's absolutely indicated.

The indications for accessing a pancreatic fluid collection or walled off necrosis are an enlarging collection or a symptomatic collection. And the symptoms we talk about are those of the fever, leukocytosis, pain, nausea, vomiting, feeding intolerance, jaundice, and persistent pancreatitis. Now if we look at these symptoms and we think about necrotizing pancreatitis, we understand that essentially all these symptoms and signs can be seen with patients with necrotizing pancreatitis. And the symptoms can be seen two weeks after, four weeks after, or even two months after the onset of necrotizing pancreatitis.

So patients with necrotizing pancreatitis often have low grade fever or low grade leukocytosis or pain. So the challenge for selecting a patient for using an AXIOS Stent is determined when these symptoms are severe enough or persistent enough to undergo a intervention or when we can push through the symptoms to get a patient to a better time period for intervention.

Another thing that we need to do when we're looking at a patient with a pancreatic fluid collection is to exclude a cystic neoplasm, aneurysm, and pseudoaneurysm. And although this seems very straightforward and simple, mistakes are still made not infrequently. And so when you're seeing a patient with a pancreatic fluid collection that does not have a history of acute pancreatitis or chronic pancreatitis, we really need to make a diagnosis of that fluid collection prior to placing an AXIOS Stent.

In addition, if a patient has a fluid collection at presentation of acute pancreatitis, that fluid collection may not be the result of the acute pancreatitis. And again, a diagnosis is necessary prior to considering intervention with an AXIOS Stent. Now regarding the timing of intervention with an AXIOS Stent. We tend to think a four week minimum is necessary to develop the characteristics of a fluid collection that make AXIOS Stent placement successful.

And it is clear that the longer you can wait to intervene on a patient, the better the patient outcome. What we're looking for in a pancreatic fluid collection is organization, consolidation, liquefaction, and wall formation. And these images that I'll show you next week will bring you through those characteristics of pancreatic fluid collections.

So here's a patient who is two weeks out from necrotizing pancreatitis. And you see a very poorly developed fluid collection around where you would think the pancreas should be. Five weeks out from pancreatic necrosis, this is the same patient. Again, you do not see well-developed wall, you see a bit of consolidation and organization of the collection.

But eight weeks out from pancreatic necrosis we see this collection. And this collection clearly shows you a developed wall, organization, consolidation, and liquefaction. And this is the appropriate patient if the patient's symptomatic to undergo a AXIOS Stent drainage.

Now once you've decided upon the timing of placing an AXIOS Stent for intervention, we really need to evaluate that fluid collection to see if it's appropriate for a intervention and to develop a therapeutic plan for intervention. So we talk about the important pancreatic fluid collection characteristics. The first of those characteristics would be apposition to the stomach or duodenum.

And although when we use plastic stents to intervene on pancreatic necrosis we had greater flexibility. The AXIOS Stent is only a centimeter in length and so we really need to keep to that one centimeter length between the gastric wall or duodenum wall and the free aspect of the pancreatic fluid collection.

This image shows a measurement between the muscularis propria of the stomach and the pancreatic fluid collection. And the distance of this spot is only about two millimeters. But this is not the appropriate orientation in which we should be measuring the distance between the stomach and the fluid collection. What we need to be measuring is the trajectory of the deployment apparatus. And that is shown by this next green line, which is still less than a centimeter.

But it's always important to measure the distance between your gastric or duodenal wall and the fluid collection in the trajectory of your needle or your deployment apparatus. This image shows an interesting point where the fluid collection is within one centimeter of the gastric wall but if we look at the endoscopic ultrasound image, the material that is between the gastric wall and the free fluid collection is actually pancreatic parenchyma.

And so although it makes the one centimeter cut off, we still have to be careful of what we're placing the AXIOS Stent through and it would not be appropriate to place an AXIOS Stent through the pancreatic parenchyma. So after we've evaluated the apposition of the fluid collection to the stomach or duodenum, we then evaluate the contents of the fluid collection.

And it's important to remember that the vast majority of patients with fluid collections associated with any acute pancreatitis will contain debris. It's also well known that CT is unreliable to determine the presence of debris and necrosis. And so we look at the images here, the CT image shows a fairly homogeneous collection without much, if any, debris. But if we look at the endoscopic ultrasound image of the same collection we see about a 30% necrosis within the pancreatic fluid collection.

So we always have to plan appropriately. We have to think that this patient's going to have necrosis and is going to need necrosectomy or at least access to the fluid collection to drain some of the debris from the fluid collection. After we look at the contents and the apposition we want to assess the extent of the fluid collection. Large pancreatic fluid collections may extend throughout the abdomen into the pelvis and even into the thorax and often require a multi-disciplinary approach.

And it's always better to attain your dual axis and your dual port rather than waiting for the patient to fail a single port approach. So if you're considering that the patient requires more than one port, you want to do that up front with your intervention radiologist rather than waiting.

Just to show you a couple of images for patients that we would perform AXIOS and dual intervention on, here is a collection in which we think would be appropriate to drain with a single port through the mid-body of the stomach. This collection's a little bit bigger but also a collection which we would think is appropriate to access via the proximal stomach with an AXIOS single port AXIOS Stent.

If we look at this collection however, we might think that multi-gate or multi-port access would be appropriate. And we may access this patient through the duodenum to access the left side of the collection-- or the right side of the collection, sorry. And through the proximal stomach to access the left side of the collection extending inferiorly to perform necrosectomy.

But this patient is a bit different and this patient, from the transverse section looks like it's potentially doable from a single port approach. But if we look at the coronal section here on the right side of the screen, we see that the collection extends down into the pelvic through the colic gutter. And if we take sections more posteriorly in the coronal plane, we see that it's a large left colic gutter collection.

That would be a real mistake for a gastroenterologist to think that we could drain this collection with a single port approach. If we drain this collection through a single port approach, we'd end up with multiple abscesses down in the left colic gutter. Last patient that I wanted to show you is this patient who, again, looks like it's appropriate patient for an AXIOS Stent be placed through the proximal stomach.

Again, when we look at the coronal plane, we see that this collection has these lobules all the way down to the mid-abdomen. That if this patient was drained through an AXIOS Stent, at this point in time we'd end up with multiple, small abscesses throughout the abdomen. So we waited on this patient another month, actually another six weeks before we were able to form an AXIOS Stent drainage.

So we've now looked at apposition, contents, and extent. And the next thing we want to look at is vasculature. And this is done almost exclusively through endoscopic ultrasound. Now we need to understand that the pancreas harbors and is adjacent to numerous blood vessels. And patients with acute and chronic pancreatitis develop vascular changes from those vessels, varices, and aberrant collateral vessels. And that these adverse vessels can exist within the gastric duodenal wall, between the wall and the pancreatic fluid collection, or within the pancreatic fluid collection itself.

And so this scenario is often seen during a time when evaluating a collection for AXIOS Stent placement. And here you see a fairly large vessel that exists between the gastric wall and the pancreatic fluid collection. And what we need to do is avoid this vessel with our electrocautery deployment apparatus. And so by manipulating your endoscopic ultrasound scope and the knobs on your endoscopic ultrasound scope, you can choose a trajectory that will avoid this kind of blood vessel.

Rarely, we will see large vessels within the pancreatic fluid collection itself or within the walled off necrosis itself. And this kind of vessel is almost always a branch of the transverse pancreatic artery, seen in this diagram. And again, most often a caudal or a magnet branch of the transverse pancreatic artery.

And when you see a vessel like this, it mandates a different change in your approach and we would suggest that you prophylactically embolize that vessel before proceeding with any further necrosectomy. The last thing that we look at, the last important pancreatic fluid collection characteristic is whether the fluid collection communicates with the pancreatic duct and whether or not there is downstream obstruction within the pancreatic duct associated with your pancreatic fluid collection.

So in summary, the signs and symptoms of necrotizing pancreatitis overlap with the indications for intervention. So it's important when we access pancreatic fluid collections and walled off necrosis that we only do so when it's absolutely necessary and the signs and symptoms push us to intervene.

It is clear that the longer you can wait for intervention, the better the patient outcome. And we want to carefully evaluate the collection after we've decided to intervene so that we can formulate an appropriate therapeutic plan. And we carefully evaluate the collection by looking at the distance of the collection between the stomach or the duodenal wall, the contents of the collection, the extent of the collection, the presence or absence of vasculature, and the presence or absence of communication with the main pancreatic duct.

SPEAKER: Our first question is what are the possible adverse events associated with placing electrocautery enhanced AXIOS through the pancreatic parenchyma?

THOMAS KOWALSKI, MD: Well, the two biggest adverse events would be pancreatitis, making the necrotizing pancreatitis that you're treating worse or a pancreatic fluid leak from the pancreatic duct. But mainly it would be injury to the pancreatic parenchyma, which is intact. And you're already treating a patient with pancreatitis.

In the pancreatic parenchyma I showed there was healthy parenchyma. And placing an AXIOS Stent, which would be a 50 millimeter stent through pancreatic parenchyma would be very likely to cause damage to the pancreatic parenchyma and induce pancreatitis.

SPEAKER: The next question we received is if the patient is symptomatic but the collection is not mature, how do you recommend managing them?

THOMAS KOWALSKI, MD: That is an excellent question because it's a question that we wrestle with every single time we place an AXIOS Stent. Patients with acute necrotizing pancreatitis are symptomatic and we're often asked by our surgical colleagues and colleagues in the intensive care unit to drain immature fluid collections.

But most of these patients can be managed conservatively with good supportive care, antibiotics if necessary, and again, excellent supportive intensive care unit care. And that we push through leukocytosis, fever, pain, and feeding intolerance with a variety of different supportive management strategies until the patient develops a collection that is a organized, consolidated collection with a wall.

It is difficult and if the patient develops a high fever or a complete feeding intolerance that can't be treated in other fashions then we do intervene on a potentially immature collection or we intervene with the assistance of our intervention radiology colleagues.

SPEAKER: Thank you. Our next question is how do you navigate vasculature during necrosectomy that is not visible when accessing the collection under Doppler?

THOMAS KOWALSKI, MD: Also an extremely good question. The large vessel that I showed you in the presentation today, we did not see under Doppler ultrasound. So of course, we want to be very meticulous with Doppler ultrasound into Dopplering the wall and the collection and the area in between the wall and the collection in the trajectory of your deployment apparatus. So it's very important to use Doppler. But all the vessels are not always seen under Doppler, particularly those within the walled off necrosis.

So when we get into a walled off necrosis, we actually dissect the necrosis carefully so that we can detect vessels that may not be seen by Doppler ultrasound. So it's basically blunt dissection before we remove necrosis so we can find those vessels.

SPEAKER: Great, thank you. This next question has a couple of different parts to it. So in a dual port approach what do you flush in the percutaneous drain? What size of perc drain do you prefer? And at what rate do you flush, for how many days?

THOMAS OK, if we're doing dual access with our intervention radiologist, we are flushing relatively aggressively. We're
KOWALSKI, MD: using normal saline and at first when we're trying to mobilize debris, we are flushing 100 CC's every four hours to mobilize, to create a turbulence and mobilize debris within the walled off necrosis.

After that, after the initial flushing period we then switch to a bit of a lower volume flush that is done more chronically by the patient. And we'll be using 50 CC's every six hours and that is, again, done at home by the patient.

SPEAKER: Excellent, thanks. And this is our last question. Do you consult your IR doctor when reviewing CT scans or do you review them yourself?

THOMAS We always review our CT scans ourselves and with our radiologist. And if we think that a collection is
KOWALSKI, MD: manageable by gastroenterology alone, we don't generally consult our intervention radiology colleagues. However, for many of the larger collections, some of which I showed you today, we do have a multi-disciplinary conference and a multi-disciplinary approach where we develop a well thought out plan before we intervene.