

**JENNIFER
CHENNAT:**

Just introduce myself to any students that are in the room, I'm Jennifer Chennat. I'm one of the therapeutic endoscopists here at UPMC, and my talk today is going to be on ERCP indications and complications. It's more of a general overview for people that are starting fellowship and kind of getting a sense of what to look out for if they're evaluating patients, especially on call or after hours if there's any complications related to procedures that we perform here.

So just to review the anatomy for those of you that may have forgotten some of the pancreatic biliary anatomy. The pancreatic duct empties into the major papillae, which converges with the common bile duct. Basically in most normal anatomy, this is the standard anatomy you would see, but there is variation in this, and congenital anomalies can exist, such as pancreas divisum, where the main pancreatic duct predominantly will empty through the minor papillae, which can predispose patients to pancreatitis in certain settings.

Some of the indications for performing ERCP, the well-established indications include common bile cut stone extraction, ascending cholangitis, which is a medical emergency, severe acute biliary pancreatitis, which is also considered a medical emergency. To facilitate biliary stent placement in patients that have biliary obstruction or have an inadequate drainage from prior stone extraction attempts, and treatment of sphincter of Oddi dysfunction, especially type 1 and type 2. Type 3 used to be treated by ERCP, but more recently in very large volume and very randomized type of studies that have been published in the New England Journal of Medicine have actually shown that type 3 sphincter of Oddi dysfunction no longer is an indication for ERCP, because of the grave complication profile existing behind the patient population and the decrease in efficacy profile.

So bio leaks are the last major well established indication for ERCP. This is about performing an ERCP for indications that are related to biliary etiologies. Less evidence-based indications include performing per oral cholangioscopy. You know, in situations where you have an indeterminate biliary stricture, or an inadequately extracted stone, you may need to perform this to facilitate complete evaluation and treatment. Additionally, endoscopic ampullectomy is an indication for performing an ERCP for facilitation of pancreatic stent placement to prophylactic patients against severe pancreatitis when you're performing an ampullectomy.

And then access into the pancreatic duct for endotherapy for chronic pancreatitis and other types of conditions where drainage of the pancreas is required. So getting into more detail about biliary indications, as I talked about, these are the major indications, particularly stricture evaluation and treatment. Strictures can be divided into malignant, indeterminate, and also fibrotic post-op type strictures, such as those we see with post liver transplant patients.

Additionally, these ampullary lesions just to get into more detail about that, ampullary resections are commonly performed here in tertiary referral centers. It's not a standard of practice in more community settings because of the risk profile involved with ampullectomy. There's a higher risk of perforation. There's a higher risk of post procedural bleeding, both immediate and delayed, and additionally pancreatitis is a higher incidence in this population. So we do evaluate ampullary lesions here. We also utilize adjunctive endoscopic ultrasound to further assess the ampullary lesion to see the depth of invasion before determining if the patient is a candidate.

We used to do a lot of ERCP for diagnostic purposes, especially in the 1990s and early 2000s. But with the advent of MRCP, we found that there's no longer really a true indication for diagnostic ERCP in most settings, because our MRCP sensitivities and specificities are so good and so high that most of the time we can rule out major disease processes that way. But in the setting of PSC patients who have chronic inflammatory condition, sometimes in a multi-focal pattern throughout the biliary tree, evaluation by ERCP is indicated if they have abnormal liver enzymes in the setting of a dominant stricture that may be found on a MRCP as part of their routine surveillance.

Pancreatic indications, recurrent acute pancreatitis is probably the more major of the indications that we see. Patients who have pancreas divisum, but also have a presentation of recurrent attacks of pancreatitis, repetitively without any other eliciting factor may benefit from performance of an ERCP with minor papillotomy, where the endoscopist actually goes to the minor papillae and intentionally tries to cut the minor papillary sphincter to try to open it up and facilitate drainage. This may or may not be performed with the placement of a pancreatic stent.

Chronic pancreatitis that we all see on our inpatient service wards, they may benefit from pancreatic drainage if they have a dominant stricture in the pancreatic duct that is causing downstream dilation and obstructive type physiology, and patients that have sustained a pancreatic leak or injury, such as iatrogenics from post-operative resection after, let's say, a distal pancreatectomy, may benefit from pancreatic stent placement, or in the setting of severe acute pancreatitis, where they've actually sustained their pancreatic ductal injury and disruption.

For a stent placement, we do talk about ductal leaks and unremovable stones, but also fistula are another less common indication for biliary stent placement. Strictures can be treated with stents. It used to be done routinely with dilation of a stricture before placing a stent, but that's no longer required, based on large volume studies and experiences at tertiary medical centers. Dilation actually of the bile duct can result in inadvertent perforation of the bile duct. It can also result in inadvertent post procedural pancreatitis if the distal bile duct stricture is very low lying close to the ampullary orifice.

Pancreatic stent placement, again, it's for stricture therapy, sometimes for leaks. It can be for trans papillary pseudo cyst drainage in chronic pancreatitis patients. You don't necessarily have to place the stent directly into the pseudo cyst cavity, but if you're placing it across where the pseudo cyst is communicating, that should wall off that disruption and eventually cause the pseudo cyst to resolve over the course of several weeks or months, and cross-sectional imaging would be used to survey the patient instead of repetitive ERCPs and pancreaticograms.

And then the major reason to place a pancreatic stent in most of our patients is for post ERCP pancreatitis prophylaxis. For sphincterotomy, performing a sphincterotomy can be done for a variety of reasons. Mainly it's to extract a stone and to facilitate opening up the biliary orifice, so that the stone can be delivered adequately and safely. Sometimes it's also done for biliary stent placement. If a patient is on concomitant anti-coagulation or has underlying coagulopathy for medical reasons, we don't sometimes place a biliary stent because of the complication profile with performing an endoscopic-- I'm sorry. We don't usually perform an endoscopic sphincterotomy in the setting of a placement of a biliary stent because of the complication profile associated with that.

You can place a biliary stent safely without performing a biliary sphincterotomy, but there is an increased risk potentially of causing pancreatitis, because the biliary sphincter is not adequately opened up in that situation. Just to touch on Sump syndrome. This is a less commonly seen condition nowadays. Most patients are not going for resections of the mid to upper bile duct in isolation of the distal bile duct, but in situations where there have been patients, many let's say, 10 to 15 years ago, who have undergone biliary surgeries for indications such as retained stone or iatrogenic injury, they have gone for resection of their mid to upper bile duct and the distal bile duct is left intact, and over sewn, so that there's basically like a reservoir, created in that distal bile duct, and food and debris can sometimes accumulate in there and this can cause a bacterial type of profile syndrome, where the patient has recurrent fever, sometimes elevation of white count, abdominal pain, and such patients can be classified with Sump syndrome, and may benefit from performing an ERCP with biliary sphincterotomy to basically facilitate drainage of that debris.

Just to give you a little bit of historical background, a sphincterotomy was first performed in 1973, back with much more rudimentary instruments than what we have now, but ERCP was performed as early as the 70s, mainly by surgeons in that day and age, but it has you know transformed over that time to more of a predominantly GI-based procedure.

The instruments to perform sphincterotomy can be varied. There are a variety of options, such as single lumen, double lumen, triple lumen instruments that facilitate guidewire simultaneous placement into the bile duct, and that can help anchor the endoscopist, so that the sphincterotome doesn't slip out or you don't lose biliary access while you're trying to perform the splaying of the biliary sphincter. There are a variety of nozzles of the tip that are either blunted or they can be tapered and long, depending on what type of papillae you're encountering. Some patients have a very small punctate type of ampullary orifice, and some have a more gaping orifice, so it just depends on what type of anatomical obstacles you may be encountering.

But the selection is really dependent on the endoscopist. There's no tried and true algorithm, per se, published that everybody necessarily follows universally. So it varies from center to center and based on the endoscopist.

These are just some graphical pictures of various types of sphincterotomes. The needle knife, which is down here in the center is used mainly for pre-cut sphincterotomy. That's an access technique, where we are intentionally trying to cut the ampullary orifice from its external position inside the duodenum, when we are failing to get, you know, free hand cannulation into the bile duct, and this happens in some situations where there is obstruction in the distal bile duct or some aberrancy in their anatomy.

So to perform a sphincterotomy, we have to have an electrosurgical unit. We have these commonly in the GI lab. They're also on our travel carts. They can be modified to have pure cut or blended types of current, and there have been studies that have been published about whether pure cut versus blended type of cut have more beneficial profiles in terms of the post procedural complications. But there's been no statistical difference found between pure cut and blended current for, you know, mitigating the risk of post ERCP pancreatitis. That was the major concern as well. Additionally, the other risk is bleeding.

So some endoscopists would prefer to perform a pure cut during the ERCP, and if bleeding occurs, they can treat it immediately, as opposed to using a blended cut where there's some coagulation involved, but that would then mitigate the immediate bleeding that occurs, but they can have delayed bleeding, up to two weeks later. So patients can present with post ERCP related you know sphincterotomy bleeding in the setting of a blended cut.

So these are just some options available, and it depends on the comfort of the endoscopist, and whether they feel like encountering bleeding then and there or having a nice beautiful picture at the end of their ERCP and walking away from the table and saying, oh you know, patting themselves on the back, saying good job, versus maybe sometimes encountering this patient later on, a couple of days later with a bleed.

In terms of needle knife papillotomy, I just want to go into some of the options available for techniques. Needle knife can be performed freehand, which means almost like painting with a hand, where you're literally just utilizing the instrument, and the anatomic landmarks of the papillae to gauge where to cut. This is a little bit more dangerous, because there is no prophylaxis upfront for pancreatitis. So if you're cutting that ampullary orifice, and you miss, or you cut towards the pancreas, you could induce pancreatitis in this patient.

Most endoscopists feel more comfortable inserting a pancreatic stent first, and then cutting over that stent in the direction of the bile duct if they're intending to get into biliary tree. That's a little bit more safer and graduated approach, and most of us will perform that if at all possible. But it's not always technically feasible if there is difficulty to get into the pancreas to begin with. And then there have been publications from Todd Behrens' group at Mayo Clinic, that have talked about doing a super papillary fistulotomy, where you basically cut directly into the intra duodenal portion of the bile duct, just obviating access through the ampulla.

This is done in situations where the ampulla may just be retracted from really bad cancer. Sometimes it could be because of some anatomic distortion. Sometimes, it could be from ampullary cancer. A small ampullary tumor may prohibit freehand cannulation. So Behrens' group has actually published a successful series of patients where they've actually directly fistulized through the duodenal wall with needle knife instrument, directly into the bile duct, and then placed a guidewire through that tract and been able to access the biliary tree that way.

So in terms of size of sphincterotomy, I know there's a lot of machismo in ERCP, with you know, oh I cut this station so big, and you could drive a truck through there, and all these statements have been said in the ERCP room by various people. But I think, you know, you need to kind of grade the size of your sphincterotomy based on the need. What do you need to do in that case? If it's a small stone, five, six millimeters in size, do what's adequate to remove that size stone, which is usually a comparable size sphincterotomy. There's no need to splay the patient open, stem to sternum, as they would do surgery. I mean, there's no need to get over excited here.

I think that mainly it's used for facilitation of extraction of a substance, whether it's a stone or sludge debris, to get your instrument out, whether it's a balloon or a basket. These are the decisions you should make intra procedurally, to gauge the size.

Performing the sphincterotomy from a technical perspective, you should remember that there's an intra duodenal portion of the bile duct, but there's also this overlying fold of the duodenum. And this is kind of our barrier or anatomic limit that we should at least keep in mind when we're cutting. Endoscopists have been inadvertently found to have cut through this fold, and that can lead to a duodenal perforation, and that can be seen either immediately or sometimes as a delayed presentation.

As I've talked about with pre-cut, that's another aspect where you sort of have to use it as a last resort. Sometimes you can be using it as an early access technique when you know up front this is going to be a difficult case, such as a failed ERCP that's been referred from another institution. You're not going to try for an hour with the same techniques that the endoscopist did, the community hospital tried to do. So you sort of have to rethink and go back to your toolbox, and maybe pre-cut would be an early option in such a case if you gave it three to five attempts, and then basically you're not able to get freehand cannulation.

It can be utilized also in the situation where a patient has abnormal anatomy, such as a Billroth II anatomy. You could place a stent into the pancreatic duct and then do a pre-cut sphincterotomy into the bile duct in such patients, and in as I said, the minor papillotomy situation.

Contraindications for performing an ERCP. Mainly it's for the vague evaluation of patients with abdominal pain, when you don't really have a clear cut etiology, and you're almost grasping for straws, and they have an obscure origin, where you're not able to clearly delineate that this is biliary related pain. But everything else has been excluded, and their chemical profiles are all normal. This is basically the sphincter of Oddi type of patient that's type 3. So we try to avoid and talk those patients down from urging them to get an ERCP.

Many of those patients will come to us in the outpatient clinic, having read about ERCP. They've gotten themselves all excited and drummed up to get one, and we sort of have to tell them the risk profile and say this isn't in your best interest. Most of those patients don't benefit from performing an ERCP and getting complete relief of their pain profile afterward. And many of them do get post ERCP pancreatitis.

Also for suspected gallbladder disease. If the patient has classic biliary colic in the setting of a normal non-dilated bile duct and normal liver enzymes, there's really no reason to do a pre-operative ERCP or any reason to prophylactically cut their biliary sphincter. That used to be sort of a fashionable thing to do with ERCP as it got more trendy and more sophisticated with its instruments, but it's really not indicated, and there's still a risk presented to the patient with post procedural pancreatitis, which could then delay them from getting the cholecystectomy, that they absolutely would need.

And then for further evaluation of pancreatic malignancy, in the advent of endoscopic ultrasound, which is going to be a separate talk for you guys, EUS is basically the gold standard for biopsying pancreatic tumors and sampling tumors. There's no reason to necessarily do an intentional pancreaticogram and brushing of the pancreatic duct in patients that have a pancreas tumor as the primary presenting issue.

For stone techniques, I just want to touch on this so that it gives you more of a comprehension when you're reading an ERCP report as to what the endoscopist was doing in terms of the instruments described. We do have balloons and baskets available, as various options for us to try to get stones extracted from the bile duct tree. With larger stones, we need to keep in mind that mechanical lithotripsy can be utilized as a backup option.

It's not our first line approach, but in patients that have greater than two-centimeter sized stones, we typically see the little old ladies, who come in, who are 80, 90 years old, and those stones seem like they've been there for literally hundreds of years. But they can be very difficult cases sometimes, two to three hours long if it's very difficult to get into the bile duct and/or try to get the stone to mobilize, or even to fragment in such a way that we can safely extract it. But mechanical lithotripsy can be utilized. It does have a higher risk profile of causing possibly post ERCP pancreatitis, as well as delayed bleeding, and it can inadvertently perforate the bile duct, if the endoscopist is not careful, or the assistant is not careful with opening the lithotripter in a safe way.

The balloons we use are varying in size. They can range from eight to 20 millimeters, depending on the size of the bile duct you're dealing with. So you want to gauge and size your balloon based on the patient's bile duct diameter. So women tend to have a little bit more slender bile duct overall than men, just an anatomic variation. So we keep that in mind sometimes when we're placing stents, sizing stents, and sizing balloons.

Balloons can be used for not only retrieving stones, but also for performing pressure occlusion cholangiograms, and this can be utilized in the setting of things like bile leaks, where it's a very subtle bile leak, such as the duct of Luschka bile leak, that may not always be seen on a standard cholangiogram if you're just injecting through a standard cannula. So occluding the distal bile duct with this balloon and then injecting vigorously may help or pacify the rest of your biliary tree and identify small, subtle findings.

In terms of removing a stone, there are some, you know, steps involved with extraction of a stone that are somewhat standard across the board, and have been taught universally to endoscopists. You typically don't want to start by sweeping at the top of the biliary tree, and if you have several stones stacked on top of each other, you don't want to be sweeping from top, thinking that you can extract all four or five stones in one sweep. That can lead to the balloon getting impacted inside the proximal biliary tree.

So typically, we will try to extract stones in a graduated way, starting with the lowest stone and working our way up. You do want to pull gently. You'll see some people will really pull hard, and that can sometimes evulse the bile duct or torque it in such a way that the patient can actually have anatomic disruption of the bile duct. I've even seen bile duct coming out of the ampulla, which that's not a good day.

So you know you want to align your scope with the access of your bile duct. So as you're pulling this balloon out of the patient's bile duct, you want to anchor the balloon catheter with your left hand as you're controlling the dials of your endoscope, and you're torquing with your right hand in such a way that the balloon is literally pulling in the access of the bile duct and not in some tangential plane, because that could lead to, again, the same issues with anatomic disruption.

Less aggressive traction is generally recommended. Sometimes if you put too much traction on, you could actually rupture your balloon. So then you've wasted an instrument, and cost is something that we also try to keep in the back of our mind. Of course, we do what's best for the patient, and if it means we have to use 10 different instruments, so be it. But if we can mitigate and lessen the number of instruments and the expense involved with utilizing those instruments, we try to keep that in mind during ERCP, because it is a pretty costly procedure overall.

Patient discomfort is another aspect of overinflating the balloon. We have seen patients that literally will rise off of a prone position off the ERCP table if the balloon is inflated too maximally, and even under deep anesthesia sedation, they can sense that visceral type of pain.

So baskets, these are another type of instrument we can use for extractions. And these can be medium to larger sized balloons that you would use a basket for. Some of them have injection capacity, so we can inject contrast through the basket so that simultaneously we can opacify the bile duct and see whether or not we've extracted the stone or whether there's any residual stones left over.

These baskets, though, do have a danger of getting impacted. Sometimes they can capture the stone, and you're getting ready to do the extraction, and suddenly you're stuck. You're stuck in the distal bile duct, or you're stuck up above a stricture. Sometimes these patients with chronic stone disease develop biliary strictures as part of a post inflammatory process. And that can be a conundrum in some situations because if it's stuck, if you don't have a rescue mechanism, the patient has to go to the operating room to have the basket extracted.

And we've had a series of probably less than five patients over the last 20 years that have been sent for the operation to actually have a common bile duct exploration. The surgeon would literally banana split open the bile duct and try to extract out the basket and the wires and the catheter and the scope, everything is left in the patient, as they're wheeled to the operating room. So that's not exactly a cosmetically good situation for the patient. They're not feeling good. They're obviously anxious. The family will be more heightenedly anxious in that situation. So these are circumstances you want to explain to the patient as you're consenting them for ERCP, if you know upfront that there's stones, and that they're going to be difficult. Keep in mind, less than five percent of these patients may have a failed situation and may need emergency operation.

And variety of baskets also exist, just like for stone extraction. Balloons, some are wire guided, and some are non wire guided. It just depends on the preference of your endoscopist. The technique for basket extraction is similar to a balloon. You want to capture the target stone, and then try to extract it and working from distal, working your way upward through the biliary tree.

So moving on to complications of ERCP, especially in the setting of basket or stone extraction, as I mentioned to trapped basket is one of the more grave situations. There is a rescue device available that is manufactured by one of our leading endoscopy companies. They can actually screw onto the back end of this basket device, this crank, which will then enable either your assistant or the endoscopist to under fluoroscopic guidance, advance this portion, the catheter portion, up to the office of the bile duct, and it literally, through a cranking mechanism, will ratchet its way up to the basket and break the cages of the basket inside the bile duct. Then it releases that tension on the stone, and the endoscopist can remove both this device, as well as the basket safely from the bile duct, and that rescues the patient from having to have an emergency operation.

This can be a little bit tricky, because we don't use it so much so our assistants and nurses, and even the endoscopists who have sometimes forgotten how to assemble this, and it can be utilized sometimes accidentally in a wrong way, and sometimes this can lead to breakage of the basket at a point of less tension. And in that situation, the catheter breaks, but the basket is still stuck inside the patient. So then, you're really in sort of a pickle, because you have to get that out by surgical methods.

So again, all of these things are complications that can occur. They don't routinely occur. But we should be prepared to state this to the patient and deal with it. And luckily, in a tertiary medical center, we have the backup of sophisticated surgeons. So we have the option to rescue such patients in most instances.

So just to get into the stone extraction a little bit more. The techniques of fragmentation and stone extraction, we want to reserve this for using balloons and baskets in standard stones. If you know that you're dealing with like a more difficult case, such as a failed case, you also want to talk to the patient about electrohydraulic lithotripsy, because that may be utilized upfront, if you know this is a larger than two-centimeter stone, if it has been mechanically lithotripsyed in the past, and this has failed. These are techniques that we can then use adjunctive cholangioscopy as well as EHL to try to blast the stone inside the bile duct and fragment it even further.

So moving on to pancreatic sphincterotomy, this is mainly done in specialized centers. We don't routinely do this in community practice with ERCP. Most community ERCP is done for biliary stone or stricture, basic treatments. Hilar strictures are pancreatic endo therapy is usually reserved for tertiary level centers. It's similar in terms of the performance of sphincterotomy, the technique involved, except that the endoscopist would be cutting in a one or 2:00 position on the ampulla, which is directed towards the pancreas, as opposed to the 11:00 position, which is directed towards the bile duct. So that the position of your cutting wire on your sphincterotome has to be directed, according to whichever duct you're intending to access.

But the indications, as I've touched upon before, are mainly for end of therapy of pancreatitis, whether it's recurrent acute or chronic pancreatitis, pancreas divisum or drainage of pseudo cysts. Stone extractions in the setting of pancreatic stone disease can be done successfully with balloons. These stones, though, tend to be calcified. They can be very rock hard and jagged. They can be sharp on the edges, and they have been known to cut the balloon and perforate our balloons. So sometimes as a backup option, we have to utilize a basket to try to get these stones out.

They tend to be smaller than our biliary stones, so you don't usually see something that's above 1.5 or two centimeters in size inside the pancreas duct, because the pancreas duct in general, its morphology isn't that wide. But in chronic obstructive pancreatitis, you may see larger stones.

But the same potentials for complications can happen, such as rupture of a balloon or a trapped basket can happen, and these mechanical options, like lithotripsy or EHL or even ESWL can be utilized. ESWL is extracorporeal shock wave lithotripsy. We use it here in our center. It's not utilized in all tertiary centers. There's probably less than 20 centers across the world that are well known in ESWL. And ours is one of them in the United States. Most of ESWL as performed in Europe, as sort of a standard option there, but here in our country, because of the expense involved and some of the logistics of getting this machine in, we actually have to rent it on a per diem basis. So we stack up patients that we know need this treatment for pancreatic stone disease and then schedule them on a given day and utilize the machine in a more cost effective fashion.

But it delivers shock waves under fluoroscopic guidance to patients that have recalcitrant stones inside the pancreatic duct. The endoscopist would perform an ERCP first, placing a pancreatic stent into the pancreas. That would help as a landmark identifier, so that when you're shining the fluoroscopy on the patient, you have an idea of where exactly the stone might be. Then this target crosshairs type of marker would be placed on top of the patient, and then you would deliver a sequence of shocks to the patient.

There have been reports of increased abdominal pain after such procedures. Some patients will have transient hypotension, fever, nausea, and vomiting. So they have to be carefully monitored in the post-procedural area for usually one to two hours after procedure. So it's a lengthy day for the patient. They're usually there all day. They have to go to the ERCP room first, get the ERCP with the stent. Then come over to another room where this machine is parked, and they get the treatment usually in room five, which is our GI procedure room.

So overall complications of ERCP, just to kind of give you a broad based overview. Bleeding can happen in about one to two percent of cases. Infection, usually less than one percent. But in cases where you have hilar obstruction, such as a bismuth tumor, in cholangiocarcinoma, or even in some post liver transplant patients that have very extensive fibrotic disease, that's extending into the biliary hilum, because of you know prior hepatic artery stenosis or whatnot.

Those patients have a higher predisposition to getting infection after ERCP, because of the dye that can be retained into the bile duct, especially in the inter hepatics, and they can be more predisposed to developing post-procedure abscesses, especially if they're immuno compromised or transplanted patients. We want to prophylax them with antibiotics. We also want to prophylax them in cases of hilar obstruction, even if they don't have cholangitis on presentation, because we can anticipate that they may have substandard or sub adequate drainage from the bile duct tree.

PSC patients also fall into this profile, because they can in situations where they have inadequate drainage because of beading and rarefaction of their inter hepatics, they can have inadequate drainage of their biliary tree. And also pseudo cyst drainage patients. If you know you are going to be doing an intentional pseudo cyst drainage, these are the patients who want a prophylax upfront.

Perforation, thankfully, it's pretty small in terms of the risk profile. It's 0.1 to 0.6%. But perforation can happen in a variety of ways in an ERCP. You can perforate a patient in their esophagus, especially as people are learning how to intubate with a duodenal scope, which is a specialized scope that looks to the side as it's passing through the GI tract. First and second year fellows often don't have a lot of experience with that, and as they get into their third year, and they do more ERCP based rotations, they will get more expertise with this, but it can be difficult to intubate, especially if the patient has a very prominent cricopharyngeal bar.

I encourage all of you in training to get experience with passing a side viewer, because as you become a gastroenterologist, whether you choose to do pancreas biliary or not, you will be faced at some point with a very bad torrential GI bleed, or maybe a lesion in the duodenum that is in a position where utilizing a side viewing scope would be beneficial to see the lesion or the target or the suspected area and to provide proper endotherapy, whether it's hemostasis or clip placement.

So if you can be involved in those situations, or we can work out a system with the fellows where fellows get opportunity to intubate these patients during an ERCP and then hand over the scope if they don't have an interest to do the ERCP component, maybe there can be a system worked out amongst fellows that way,

Cardiopulmonary and sedation events can happen in the setting of ERCP. The patients are typically on their bellies in a prone position, so they don't have as much respiratory motion or respiratory reserve. An air embolism is a major complication in this setting with ERCP. This is mainly reported in the setting of cholangioscopy. There were some trials going on about six to seven years ago of cholangioscopy devices that were being trialed and basically developed through R&D by a variety of endoscopy companies. And they were being tried here in the US, Canada, and Europe. And multiple centers through these different nations we're finding out that patients were getting air embolisms on the table.

The reason for that is they were designing a balloon to be anchored inside the bile duct up in the hilum of the liver, and then over that balloon, the endoscopist was feeding a small intranasal type of scope, the type of scope that we use for placement of nasoduodenal tubes, and the thought process was that this anchor could then be deflated, you could pull out that anchor, and then keep this intranasal type of scope inside the bile duct and have great, high definition pictures of the biliary tree, which is much better than the standard cholangioscopy pictures that we get with spyglass type of pictures that we do with standard mother-daughter type of cholangioscopy.

So there was a great idea behind it. But the problem is the air embolization was happening because during the procedure, endoscopists were insufflating CO2 or sometimes regular air at the rate of a intranasal endoscopy, which is meant for a luminal view. So the pressure applied with insufflation was too great, and then some of these patients had sometimes circulatory anomalies where their biliary tract and their portal tract were sometimes in communication, and they were getting embolized that way.

So it's a rare complication, rare settings, but it's something you need to be aware of, and patients had, you know, obviously fatality from this. And then pancreatitis, obviously, is the main waste bucket. You know, pancreatitis is in the main waste bucket complication of ERCP. This is probably the most common of everything that we see, and it happens in about five to eight percent of cases that we do. But it can be as high as 15% in cases that are more high risk.

AUDIENCE: On the topic of [INAUDIBLE], could you talk about PTCs?

JENNIFER CHENNAT: Oh yes, so PTCs. At our institution, we've had some anecdotal experience of patients receiving PTCs and then going for an ERCP or some type of an endoscopy procedure, whether it's maybe placement of an enteral stent or a biopsy of a tumor in patients that have an obstruction in their GI lumen and such as their duodenum. In those situations, if they had concomitant biliary obstruction, and they receive a PTC, and then, you're asked as an endoscopist to go down and sample or treat something in the GI lumen.

You're dealing with a closed loop, where this tumor or this obstruction is basically causing all of the gas that you're insufflating to be lingering inside the GI lumen. This can track up the PTC catheter and actually lead to an air embolization situation for patients. This has been reported because the PTC tract is initially very immature for the first week or two, sometimes longer than that. And this is a situation where there can be iatrogenic injury to the bile duct during the PTC. There can be accidental communication with the circulation during that time, and patients have been found to demise from this.

And so we had sort of a moratorium placed on doing endoscopy in the first one to two weeks after a PTC. Now it's case-based. So if somebody is really sick and needs to have these other interventions done, because let's say they have very bad duodenal and gastric outlet obstruction, and they need to have enteral access established, we can tweak the timing based on the need. But if at all possible, we try to push out the endoscopy after PTC, usually til about three to four weeks would be ideal. But not all places and not all situations can wait that long. So I've had to morph that, you know, decision based on the patient and the immediate need.

I don't know if you guys have been given any kind of instruction about that, when you're doing consults, or if you see a patient that has a fresh PTC, whether you've come up with any kind of policy from an inpatient, you know, rounding perspective.

AUDIENCE: [INAUDIBLE]

JENNIFER CHENNAT: Right, so it's sort of like a catch all type of consult that's placed at all these services, and then IR might place the PTC, but then we have to wait. So if we can talk to IR and sort of coordinate things, sometimes placing the enteral stent first, and then sending the patient for PTC would be more beneficial in terms of timing. Any other questions?

AUDIENCE: [INAUDIBLE]

JENNIFER CHENNAT: Oh OK.

AUDIENCE: [INAUDIBLE]

JENNIFER CHENNAT: You noticed it on fluoroscopy?

AUDIENCE: [INAUDIBLE]

JENNIFER CHENNAT: So then they aborted the procedure. OK. Yeah, that's probably the safest method. And you know, of course there's decompression pegs, and other things that can be placed in patients. So there are other options besides enteral stenting, so we should advise the inpatient teams that there are as ancillary options available.

Just to get into the complications from an incidence perspective. I just mentioned the overall incidence. That was quoted from the ASGE guidelines, and this is a more older study from the '90s, published by Marty Friedman, but it's still a pretty landmark study, and it's utilized and quoted quite a bit in the literature in terms of the incidence of pancreatitis and hemorrhage that are the major complications.

The issue really is case selection, and you know, Friedman tried to spearhead selecting the proper patient that was the purpose of why these studies were published in the 90s and early 2000s, because initially diagnostic ERCP was almost done universally, and they started seeing more and more of these complications, and they were able to break apart the risk factors involved for developing pancreatitis. And I'm going to get into that in a little bit.

So technical complications I talked about, as I mentioned, the impaction of a stone, a rupture of a balloon, also migration of stents. Biliary and pancreatic stents can migrate either inward into the ducts, to the point where you can't see them on endoscopy anymore, and you can only find them on fluoro. And that would require stent retrieval. So in those instances, we can actually use a crank similar to what I showed you for the rescue mechanism of a stone, and that crank can be utilized over a guidewire to Roto Rooter into the stent and pull it out of the duct.

And guidewires can actually perforate the ducts, so that's something to keep in mind, if you're trying to get through a very difficult stricture, if you push very hard, the guidewire can perforate through a bile duct or through a pancreas duct. Most of the time, those perforations close on their own. We're not required to necessarily stent them, but if it's a larger leak, and you're seeing it under fluoroscopy with cholangiogram performance, you may want to place a prophylactic stent, because you want to mitigate the chance for a post-procedural leak.

So risk factors for hemorrhage. The definite risk factors that I should touch upon are obviously underlying coagulopathy, cholangitis, a patient that has underlying cholangitis, and they're presenting for ERCP. Keep in mind those patients are at higher risk for bleeding. So they may bleed when you're performing an ERCP to do the sphincterotomy and stone extraction, or even during placement of a stent.

If the patient bleeds during performance of an endoscopic sphincterotomy, they're at a higher risk of developing post-procedural sphincterotomy related bleeding. And if the endoscopist has a lower case volume, so that's why we urge community practices to send their more complicated cases our way, because they don't, by sheer necessity, they just don't have the volume needed, because of the construct of private practice or community based practice. Most of their bread and butter is endoscopy and colonoscopy, and there's just not enough patient population for them to get adequate technical proficiency and to maintain it.

And then anti-coagulation. If they've been anti-coagulated medically in less than three days prior to the performance of an endoscopic sphincterotomy, those are absolute reasons why patients can have hemorrhage. So keep that in mind.

Aspirin and NSAID usage is no longer really considered a high risk reason for someone to bleed. So if they're on concomitant aspirin therapy from cardiovascular perspective, you want to keep that going. You don't need to discontinue aspirin before doing an ERCP. And usually, patients that have an ampullary tumor, they don't tend to bleed to the point where they have a very torrential type of bleed. They can have friability of the tumor, but it's not to the point where they typically bleed extensively for days or have a delayed bleed in a week or so after the ERCP.

So high risk ERCP, this is a population that we try to either not do an ERCP in, or we try to really counsel the patient up front in clinic. And these other patients you typically want to meet in clinic before you're embarking on an ERCP. Sphincter of Oddi population, like I talked about, the type 1 and type 2 who have abnormal liver enzymes or dilated bile duct, at least they have some objective criteria to justify doing an ERCP. Type 3's, as I said, they don't really have any objective criteria that are abnormal.

PSC patients, Billroth II anatomy. Billroth II isn't really a surgery that's performed as much anymore, but when ulcer disease was rampant before the advent of PPIs, many patients did go on and have Billroths performed, and those patients sometimes later in life require ERCP for an unrelated reason, such as stone disease. And they then become a high risk case, and they often refer to tertiary centers because of this aberrancy.

Non-dilated duct patients, so patients that have maybe a stone, but the duct is not dilated, they can be at higher risk of post procedural related complications, because the duct doesn't have any type dilation to accommodate the stone, and you're trying to drag these instruments through a non-dilated duct. That can lead to iatrogenic induced bleeding or even pancreatitis. Females and younger age people tend to have a higher risk profile. So we try to counsel younger women with abdominal pain to work on medical management of abdominal pain if at all possible and exhaust that work up before we embark on any type of ERCP intervention. And anybody that's had post ERCP pancreatitis before has a higher risk of developing it again.

Just to touch on the Billroth II anatomy, just to refresh your memory, this creates an antrectomy with the creation of a gastrojejunostomy. That's what the surgery actually does. It can be evaluated in terms of the Billroth II anatomy, using either side viewing or a forward viewing endoscope. So you could go down with a forward viewer first, if you're intending to do an ERCP and just study the patient's anatomy, so that you know which limb actually has the biliary and pancreatic orifice, the ampulla in it.

They do have an intact ampulla, so thankfully it's not a ductal anastomosis to the bowel, but still that ampulla is oriented in such a way that everything is almost upside down. So the bile duct is closer to about 6:00. And so you can cannulate in a downward position with your instruments as opposed to an 11:00 position, which can make it difficult. And oftentimes, because of longer limbs that were produced by surgeons in the past, the side viewing endoscope can't reach this ampulla, so we sometimes have to do this procedure using a pediatric colonoscope.

And in that case, there's no elevator. There's no way to lock your instruments as you would have with a side viewer, and some of our instruments are too short to accommodate through the pediatric colonoscope. So these are all technical limitations and why this procedure can be more difficult.

As I mentioned, the bile that would be in this position at 6:00. So you want to position your endoscope in such a way that you can access your instruments and direct them in a downward fashion, and you may have to place a stent into the pancreas and then do a needle knife access before getting into the bile duct. So these are even more higher risk if you're performing a needle knife in the setting of a Billroth. So you're sort of compounding your risk even more.

This is just another graphical table with the same types of complications I touched upon. I just want to mention that the number of pancreatic injections is another independent risk factor. So if you're having cannulation difficulty, and you're injecting once, and you're getting the pancreas, and you're injecting twice, and you've gotten pancreas, well, each time you're doing that you're causing more chance for the patient to get pancreatitis. So we try not to do high pressure injection as we're doing our initial cannulation.

Some centers will actually do wire guided cannulation, but wire guided cannulation means you're basically tickling with a guidewire inside your catheter and trying to feed it up the selected duct of choice. Sometimes you can inadvertently cause a perforation or sub mucosal tract where this guidewire will inadvertently go into the duodenal sub mucosa, and that can lead to a false lumen, and then you may pass your catheter into that and inject, and that creates a big bleb. So then you have even more difficulty sometimes getting into the bile duct.

So our center tends not to do wire guided in most cases. You'll see most of our endoscopists will do contrast based cannulation. So to touch on post ERCP pancreatitis, one of the landmark studies that was published in 2012 was a randomized control trial of rectal indomethacin versus placebo for prevention of post ERCP pancreatitis, and this was published by Al Munser who is based in, well he was based in Michigan at one point, but he moved. Yeah, he's now in South Carolina.

So this was a multi-center trial, and basically it sort of shows us that patients that received indomethacin had an overall lower incidence of post ERCP pancreatitis, and especially those who developed moderate or severe post ERCP pancreatitis. Interestingly, they also had less chance for gastrointestinal bleeding, which is sort of counter intuitive. You would think that indomethacin would have really caused more GI related bleeding.

That could have been due to other systemic inflammatory related effects of having less pancreatitis as well. We don't know, and then renal failure as well was less. But the most important take home point is that post ERCP pancreatitis, the risk profile was mitigated using rectal indomethacin. And so we've been able to institute this as a quality change in our practice here for the last three to four years where we've been actually routinely placing this in more difficult cases, cannulation difficulty, such as several attempts to get into the bile duct, and you're not successfully getting in, but you've injected the pancreas several times. Those are the patients that would be considered high risk or female patients that are high risk if you're doing it for sphincter of Oddi indication. These are the patients that we typically will place rectal indomethacin, and we have it available readily in the GI lab, and all of our ERCP nurses are trained on placement of this. Mainly it's either through the nurse or sometimes the fellows have to place it.

Our SVI trial, as you know Dr. Papacristou is heading that up here in our center. This is a nine-center, multi-center trial, including UPMC. It's a randomized and double blind controlled trial. It's actually comparing the effectiveness of whether rectal indomethacin alone is non inferior by a pre-specified amount to the combination of rectal indomethacin and pancreatic stent placement. So these patients are getting rectal indomethacin across the board if they're having certain criteria met during the case, such as a difficult cannulation. But then they're getting randomized as to whether they're also receiving a prophylactic pancreatic stent.

Now it's somewhat technically challenging in some instances, because we may not get into the pancreas, and if the patient is randomized to get a stent, you know, these are some of the confounding issues in the study design. But they're trying to capture it in such a way where the patient is blinded to whether or not they received a stent, so it's not reported in the procedural report, and then, of course, the endoscopist knows that they placed a stent. But the people who are reviewing the data are also blinded.

So in terms of the evaluation and the patient's subjective post procedural reporting, those aspects are all blinded at this point. So we're still awaiting the final results of this trial. It's still going through enrollment right now. But it was registered in 2015, and we're still in the active enrollment phase. But it will be interesting to see what the data shows and whether this will change the paradigm of practice, if every patient that has a difficult cannulation or a quote unquote difficult case, should receive post ERCP pancreatitis prophylaxis with stent placement. That's sort of the decision making crux or dilemma that we right now have. It's not a standard of practice.

Lawsuits have been rendered over this or issued over this in patients that have presented with very fulminant severe acute necrotizing pancreatitis after ERCP. If the legal review finds that there was no attempt made to place a pancreatic stent, that could be a position to find fault in the physician who performed the procedure, and that could you know sway the results of the case. So it's something to keep in mind, and again, we don't have enough data yet to uniformly advocate for it, but it is something we should at least keep in the back of our minds.

So some last minute special considerations in ERCP. I talked about Billroth patients, but gastric bypass is another emerging and dynamically growing population in the United States. These patients obviously have altered anatomy, often with a roux-en-y type of anatomy, which makes it difficult to reach either in native ampulla, or sometimes they also have creation of a hepatic jejunostomy in some situations, such as liver transplant patients.

These patients may benefit from either balloon interoscopy guided ERCP, using either double balloon or single balloon, or sometimes we try laparoscopic guided ERCP in the operating room. There have been studies that have published the overall efficacy and utility of performing either type of modality, and lap assisted ERCP tends to be more successful in getting to the ampulla and successfully performing the maneuvers that we intended to do, whether it's to get a stone out or perform a sphincterotomy or evaluate a stricture.

So we tend to err on the side of doing this in the operating room, because there's a higher failure rate for endoscopists who are trying to get up these longer roux-en-y of limbs, and if we can't get to the ampulla, then obviously the whole purpose of performing an ERCP is defunct.

Performing it in pregnant patients, ERCP. We do have McGee Hospital down the road, so obviously our population is skewed. We do get a lot of pregnant patients that get referred up here with intra pregnancy related biliary complications. Overall, it's a relatively safe procedure to perform in pregnant patients, but there's a choice in terms of the trimester you want to advocate for the patient to get an ERCP. Typically, we try to do it in the second trimester because of the risks involved in the first trimester towards fetal complications related to the anesthetic and the drugs given and even the fluoroscopy, as the fetus is initially developing in the first trimester.

In the second trimester, the woman's uterus is beginning to become more gravid, but it isn't to the point where it's as likely to cause respiratory compromise, as it would in the third trimester of a pregnancy. So from a cardiopulmonary perspective for the woman, the second trimester is sort of the best option in terms of the medical safety window.

If you can at all postpone the ERCP till after the pregnancy is finished, and the delivery is accomplished, that would be the best case scenario. But if a person has presented with multiple attacks of biliary colic and/or pancreatitis or recurrent attacks of you know stone disease related presentations, like jaundice or abnormal liver enzymes, you may not be able to last all the way through the third trimester and get the woman to safely deliver and then treat the stone disease.

It has to be done with the blessing of maternal fetal medicine or an obstetric specialist. We want to send the patient up here to our GI lab ideally, so that we have a controlled setting to do the ERCP. They should have a fetal monitor and usually an OB nurse accompanies the patient. We have to have a multi-disciplinary review of the patient's case, usually an anesthesiologist who is well well-versed in obstetric related anesthesia may need to be sent up from McGee, depending on the complexity of the case.

And then prone positioning is generally not feasible for such patients, so we try to accomplish these cases in a supine position, and typically we'll do it with a general anesthesia for airway protection if they're in a supine position, especially with a more gravid type of uterus that may inhibit their respiratory reserve.

So in conclusion, ERCP overall is the highest risk endoscopic procedure that we perform. I mean, there are other endoscopy type procedures that do have high risk profiles, such as endoscopic resections or even EUS guided therapeutics, you know, where we're placing stents through EUS guidance, or even sometimes very difficult luminal strictural diseases. But overall, ERCP still has a very high risk profile. So it should be performed by people that have high proficiency and high case volume, ideally.

And the lesser the indication, if it's a soft indication, the higher chance of causing some type of complication in the patient. So properly informing the patient, which doesn't mean just having them sign the consent. It's actually having that dialogue and quoting these risks and these percentages of the incidents is important to them. And I often will ask for the family to be present if at all possible in the pre-procedural area or up on the ward, and we can talk about the risks involved and what we're about to embark on, so that they're fully prepared.

If it's an outpatient, sometimes I tell them to pack a small bag of belongings, and come in with that so that they're prepared to be admitted afterward for observation if I know that it's going to be a more difficult case. So these are just things if you do upfront, if you put a little bit of effort up front, it has a huge reward on the downside, the downstream side of things, because the patient and the family are more well informed, and there's less chance for surprise and maybe potential for disappointment, or even discontentment with the course or the outcome of their procedure. Thank you very much for your time.