MOUEN KHASHAB: The goal today is to speak on management of biliary stones. Before we go into the details on management of stones, let's talk first, when is ERCP indicated for suspected stones? And there are some society guidelines, mainly guidelines by the American Society for Gastrointestinal Endoscopy. And there are predictors.

So first, let's talk about the very strong predictors that include CBD stone on imaging, or patients with cholangitis, or patients with very high bilirubin, mainly bilirubin above 4. If you have any one of these criteria, then the patient should go straight for an ERCP, because that means there is a high pretest probability that this patient is going to have a stone. So these patients can go straight for ERCP.

If the patient has strong predictors, like a dilated bile duct on imaging, or a bilirubin between 1.8 and 4. If they have both of these strong predictors, also they go straight to ERCP. If they have either, then we should depend on either MRCP or endoscopic ultrasound, depending on availability and local expertise.

If there are moderate predictors, such as abnormal liver tests, and patients with biliary pancreatitis, these patients should also undergo EUS or MRCP. Remember that if a patient has biliary pancreatitis, that does not mean they should go for an ERCP, because only about 15% of them will have retained stones in the bile duct. So this is about indications for ERCP-- should we go straight to ERCP, or should we do EUS or MRCP first?

So now, we have a patient with stones. How do we manage them? Greater than 85% to 90% of common bile duct stones are effectively removed by what are now considered standard endoscopic techniques, that are mainly endoscopic sphincterotomy, followed by extraction with a retrieval balloon or basket.

So about 90% of your patients that undergo ERCP for management of biliary stones, all what you need to do is perform an adequate biliary sphincterotomy, and then either use a balloon or a basket to retrieve a stone. And then obtain a cholangiogram afterwards to ensure complete clearance of the duct from stones. And this is effective in the vast majority of these patients.

So let's move from stenting to endoscopic papillary balloon dilation. This is a standard procedure where we use a large dilating balloon to open up the biliary sphincter. The main technique is that you want to advance the balloon over a wire. You want to obtain a cholangiogram first to estimate the size of the distal bile duct.

Let's say the duct is 10 millimeter. Then you can only open up the sphincter or dilate the sphincter to 10 millimeter. If the duct is 15 millimeter, then you can perform a large papillary balloon dilation to 15 millimeter. So obtaining a cholangiogram and assessing the size of the distal duct, namely the intrapancreatic portion of the bile duct, then that should dictate the size of the balloon that you're using.

And then the next question is, why and when should we use it? And should we perform a sphincterotomy prior to dilation? Endoscopic papillary balloon dilation without endoscopic sphincterotomy should be reserved for patients with coagulopathy and altered anatomy. There is increased risk of morbidity, including severe pancreatitis and death.

This study that I quoted here at the bottom, published in *Gastroenterology* in 2004, there were a few patients who developed severe pancreatitis from endoscopic papillary balloon dilation without endoscopic sphincterotomy, and that resulted in death in two patients. So we reserve this technique without a sphincterotomy in patients who are coagulopathic-- so they are just bleeding with a sphincterotomy-- or patients with altered anatomy, where performing a sphincterotomy is difficult due to alteration in the direction of the bile duct.

So in standard fashion, we perform the endoscopic papillary balloon dilation after endoscopic sphincterotomy. And that sphincterotomy does not have to be complete. My practice is that I leave few millimeters of sphincter left, and then I perform a endoscopic papillary balloon dilation. I use, typically, a CRE balloon. And the size of the balloon, as I already mentioned, is dictated by the size of the distal bile duct.

There was this meta analysis that I quoted here at the bottom that included six randomized trials and more than 800 patients of endoscopic papillary balloon dilation after sphincterotomy versus sphincterotomy alone for the management of stones 10 millimeter or larger. So now it's standard, if you have a medium-sized stone between, let's say, 10 and 15 millimeter, the standard of practice is to perform a sphincterotomy, then endoscopic papillary balloon dilation, and then remove the stone.

If we compare balloon dilation with sphincterotomy to sphincterotomy alone, there was similar efficacy with the stone clearance. However, there was a reduction in the need for mechanical lithotripsy, lower risk of complications, no difference in risk of post-ERCP pancreatitis or procedure time.

So why there was lower risk of complications if you do papillary dilation with endoscopic sphincterotomy? I think it's for a couple of reasons. One, you don't have to do a full large sphincterotomy. So leaving this couple of millimeter of sphincter saves you a few retroperitoneal perforations. And also, with avoidance of mechanical lithotripsy, that also saves you the complications related to the mechanical lithotripsy itself.

So the literature on the endoscopic papillary balloon dilation after endoscopic sphincterotomy suggests added value for extracting stones greater than 10 millimeter in size, in terms of need for mechanical lithotripsy, procedure expense, and complications.

So let's talk a little bit about mechanical lithotripsy before we move to cholangioscopy. So factors to consider include the stone size. If the stone is 5 centimeters, you're not going to be able to capture it within the basket. Stone composition-- hard and densely calcified stones may resist mechanical fragmentation. If the stone is impacted, then you're not going to be able to advance the basket around the stone, or are you going to not be able to open the basket fully around the stone. So these are some factors to consider.

What about how safe is mechanical lithotripsy? It's actually pretty safe. A multi-center study reported the rate of complications associated with mechanical lithotripsy to be around 3.6%. So not trivial. Among the spectrum of complications-- basket impaction or fracture of the basket wire are uniquely associated with mechanical lithotripsy. Importantly, residual stones were detected with cholangioscopy in nearly 30% of patients who have undergone stone removal procedures, including mechanical lithotripsy.

So before we move to cholangioscopy, and laser lithotripsy, and electrohydraulic lithotripsy, which are reserved for patients with complex biliary stones, let's define what's considered complex. So there are some factors that are clinical. There are other factors that are related to the stone itself. And other anatomic factors related to the bile duct morphology.

For clinical factors, it's really mainly the anatomy. So if the patient is post Whipple, for example, the patient has altered anatomy. These patients typically have difficult ERCPs, and thus, stone management, stone fragmentation, and stone retrieval will be, obviously, more difficult. Older patients are sicker, and they also present a more challenging group of patients.

For the stone itself, usually 15 millimeter or larger stones are considered difficult stones if you have three or more stones, any stones above biliary strictures, any stones in the intrahepatics or at the hilum or any cystic duct stones. So these are all considered difficult stones. So again, multiple, which means three or more, cystic duct stones, stones at the hilum or above, and stones that are equal or larger than 15 millimeter in size, these are considered difficult biliary stones.

Bile duct morphology-- as I already mentioned, if there is a stricture distal to the stone, that makes it a difficult stone, even if it's sometimes small. If there is concomitant Mirrizi syndrome, these are difficult stones to manage if there is angulation or redundancy of the common bile duct.

So these are some examples of difficult biliary stones. You can see here, this is a giant stone. These are stones above a stricture, these here intrahepatic stones, and this here multiple biliary stones. So multiple, intrahepatic, above a stricture, large size. These are standard examples of difficult biliary stones where our here standard of care at Johns Hopkins is to perform a cholangioscopy with lithotripsy.

So having said that, let's talk a little bit about cholangioscopy. It was first introduced in the 1970s, initially for intraoperative localization of stones during open bile duct exploration. Since then, cholangioscopy has emerged into a technology that can be routinely applied as an adjunct to ERCP or percutaneous transhepatic cholangiography for a variety of indications.

Recently, Boston Scientific introduced SpyGlass DS System, that you can see here with a scope redesign with a tapered tip. There is consistent tip deflection-- the right, and left, and up, and down is pretty consistent. And more importantly, in my opinion, is the image quality. So now we have a digital sensor rather than fiber optic. We have quite a wider field of view. There's automatic light control.

Single use-- with the fiber optic, we used it often, and there was degradation with use and reprocessing. And this one auto white balances. This one here-- plug and play. You can see the image to your right. You just plug it and use it. And in many hospitals right now, this system is stored in the room itself on the beam for quick use. So the way here we teach our fellows and the nurses is that it's just another catheter.

So we don't consider this a new, a completely different system. We should have it in the room. And like you use your balloon and tongs et cetera, you just use a Spy catheter. And we have the ability for water infusion or saline infusion and also suctioning.

This is a good study from Orlando from Shyam Varadarajulu and Rob Hawes' group, along with the Cleveland Clinic colleagues. And they studied the Spy DS in 44 indetermined strictures, and 36 patients with stones. So we're just going to focus on stones in this lecture. And you can see the location. So these are all difficult stones.

And the reason that they were called difficult is per the definition we just talked about. You can see that the majority of the stones were in the bile duct-- 52% somewhere in the common hepatic, cystic duct confluence, intrahepatic, and also, they included some pancreatic duct stones.

In terms of number of stones, the majority had more than or equal to 3. The mean size was 15 millimeter. Stone impaction 36%. And after stone fragmentation, you can see, a retrieval basket or balloon were used in the majority of patients. And look at these amazing results-- complete duct clearance where the stone removal was achieved in 35 out of 36 patients-- so 97%.

This is a summary of the literature on cholangioscopy-guided intraductal lithotripsy for biliary stones-- some old and some newer studies. And if you look at the clearance, here you can see, on average, it's between 80 and 100%, depending on the study and depending on what kind of patients they are including.

You see when we have extrahepatic stones, it's close to 100%. So extrahepatic stones are much easier to manage than intrahepatic stones. But this is just to show you that using EHL or laser lithotripsy, you can achieve success in the majority of patients.

This is a study that Trad mentioned initially that we presented at Digestive Disease Week this year, and we will be presenting at UEGW in Barcelona in October. This was about the role of digital SpyGlass in the treatment of difficult biliary stones using electrohydraulic lithotripsy or laser lithotripsy. This was an international multi-center study at 22 tertiary centers that included 407 patients undergoing digital Spy for difficult bile duct stones. This is, by far, the largest study that exists on bile duct stones.

So our definition of difficult bile duct stones-- we keep repeating that, because that's important-- is again, per our discussion before, either large, multiple, impacted, intrahepatic or cystic duct location, above a stricture, difficult anatomic access, or Mirizzi syndrome.

So 306 patients were treated with EHL-- electrohydraulic lithotripsy-- and 101 with laser lithotripsy. The mean procedure time was 66 minutes. A technical success, which means complete clearance of the duct from bile duct stones in 95% of patients. Again, 407 patients, so amazing result with 95% clearance of these difficult bile duct stones. Mean number of lithotripsy sessions was 1, which also tells us how effective this strategy is.

And you can see here, if you want to stratify by the type of lithotripsy-- is it electrohydraulic or laser-- you see 94% versus 99%. And there was really no statistical difference between both arms. The number of lithotripsy sessions to clear the bile duct-- 80.6% of patients underwent one session, and 18.7% needed 2 to 3.

So what you need to tell your patients is that the majority-- about 80%-- will require one session. So although it's difficult bile duct stones, in an average of 66 minutes, one session will suffice. But in about 20% of patients, more than one session will be necessary. What we do if we don't achieve ductal clearance during the first session, we place stent to avoid post-procedure cholangitis and ensure patency of the bile duct and biliary drainage. And then we bring the patient back a couple of weeks later for continued lithotripsy.

So we had 19 patients, or a little less than 5%, of patients who failed. So if you have patients who fail this strategy, what do you do? So most of these patients will undergo biliary surgery, sometimes some type of biliary exploration with reconstruction. Some will undergo, as well, extracorporeal shock wave lithotripsy. And some will undergo both. But this is, again, in the minority of patients.

So I get a lot of questions on which is better-- EHL or laser lithotripsy. So this study that I just mentioned was the first to compare both, and showed basically equivalent or equal results between both arms. However, in my opinion, there's increased complexity with operating a laser system. Operating a laser system dictates a large time commitment for formal training of the physicians and staff.

Personal protection equipment and careful device calibration before each session are necessary. And a substantial upfront cost-- usually if you want to buy it, it's more than $50,000. All of these have limited the wide dissemination of this technique, especially in the setting of less complex alternatives such as EHL, which offer similar rates of efficacy. So laser is very safe. It's extremely effective. But I just detailed some of the difficulties, basically in logistics rather than safety and efficacy.

So if we are using electrohydraulic lithotripsy, you want to use saline instead of water for irrigation of the bile duct. Position the tip of the probe about 5 millimeter outside the Spy scope and about 2 millimeters from the surface of the stone for optimal fragmentation pressure. So you don't want to be touching the stone. It's not dangerous, but you want to be about 1 to 2 millimeters away to be able to create the shock wave. And that shock wave will be transmitted to the stone that results in fragmentation.

The power settings are very easy-- basically low, medium, and high. Usually we start at low, and if you have adequate fragmentation, you continue. If not, you go higher on the power and the frequency. Since the EHL process is destructive to the probe tip, low power will extend the probe life.

Stone composition determines how many probes will be needed for successful fragmentation. And we frequently get these large, hard stones, and you're going to need to have more than one probe stored, because some of these stones are going to require more than one probe.

So I'm going to show you some videos on how we use this system. And then we'll end up with a simplified algorithm. And then we'll open the session for questions. So this is a large stone that's impacted in the mid bile duct. This is here. We see that the EHL probe is outside despite the Spy DS scope about 5 millimeter. It's about 2 millimeter from the stone with direct visualization, avoidance of targeting the bile ducts.

We start at low power, and then go to medium and high as needed until the stone is fragmented. Here in the middle, you can see there's beginning of fragmentation. So you continue at the same spot to result in complete fragmentation. You're using your paddle for continued irrigation with saline to clear the bile duct, and to ensure adequate visualization, and also to ensure there is continued saline medium for conduction.

And here, a repeat cholangiogram at the end ensures complete clearance. And again, with a full sphincterotomy and a sphincteroplasty. If you leave any of those 1 to 2 millimeter stones, they should pass adequately.

So one thing I didn't mention is that I do not perform a sphincteroplasty before I place the Spy DS, because you want to retain the fluid in the bile duct. If the orifice is completely open, then retention of the fluid is more difficult. So we'll perform a sphincterotomy, which you need to perform before you advance the Spy into the bile duct. And then, if you have a lot of fragments, then you can perform sphincteroplasty, and then you can retrieve the fragments easily after the sphincteroplasty.

This is a extensive 5 centimeter stone that starts in the bile duct, and goes into the intrahepatics. And again, similar method-- saline injection, direct visualization, continued irrigation, and continue the stone fragmentation. You do not need to break these stones into 2 and 3 millimeter fragments. These are the fragments that may travel up through the proximal duct. And actually, they're harder to retrieve.

There's no reason for that. You just need the fragments to be about 10 millimeter or a little smaller than that for easy retrieval. If you are removing stones above the hilum, then usually we're more aggressive in fragmenting them, because it's hard to pass a 10 millimeter stone through the hilum. And then, once you are done with your fragmentation, you can use a balloon, a basket, or a combination of both, depending on the success.

I typically start with a balloon. It's easier. And then, if there is a piece that I can't get, then we can go ahead and use the basket. And typically with fragmentation, there's typically these extensive small pieces that you're going to see in the duodenum that sometimes you have to flush away to clear your view. And you saw there a repeat cholangiogram showed complete clearance of the duct.

This is the last video I want to show you-- a patient who presented with a bile duct stone and actually Mirizzi Syndrome. These are more difficult patients to treat. And of course, some of these patients need to go to surgery, depending on the type of Mirizzi's. So this here is not playing. So let me just go further, see if the other one plays. If it doesn't play, we're just going to move.

Anyway, so this patient had Mirizzi's syndrome. So it was a cystic duct stone that was compressing the bile duct. And patient presented with cholangitis. And again, same technique. You advance your Spy and you do EHL of that cystic duct stone with-- and this can be treated effectively with this method.

So let's talk about now the finish with the algorithm before the Q&A session. If you have stones that are less than 10 millimeter, for the most part, we just use conventional techniques-- endoscopic sphincterotomy and retrieval with a balloon or a basket. Sometimes if you have multiple fragments, you may need to perform endoscopic papillary balloon dilation. This is not necessarily a complete ablation of the sphincter with a 15 millimeter balloon. It can be just a smaller balloon that facilitates removal of the stones.

If it's a stone that's 10 to 14 millimeter, or if there are multiple stones, then typically what we do, again, is a sphincterotomy and endoscopic papillary balloon dilation. That's pretty standard these days. So get comfortable with this technique and then you'll be successful most of the time.

Now if we move to what we just talked about-- the difficult stones, which means stones larger or equal to 15 millimeter in size, multiple stones, distal stricture, bile duct angulation, cystic duct stone, intrahepatic stones-- there are two ways to look at this. The conventional way is to do a large endoscopic papillary balloon dilation or mechanical lithotripsy. And then if that fails, then you go for EHL or laser lithotripsy.

And you can see here, refer for EHL or laser lithotripsy. So if you are at a center that doesn't have EHL or laser lithotripsy with cholangioscopy, then obviously mechanical lithotripsy should be tried first. The question now is, if you have both, what should be done first? It has to do, of course, with efficacy, the need for repeated procedures, safety, and cost.

Here, due to our experience with cholangioscopy and EHL, we go straight to cholangioscopy with EHL for these difficult stones. We have proven efficacy and safety in a large cohort of patients. And this has been our go-to procedure.

Of course, mechanical lithotripsy can always be on the side, and you can use it as part of your algorithm. But this is how we're moving. It's still a little controversial. Nobody will say you're doing the wrong thing by trying mechanical lithotripsy first, especially if you don't have a cholangioscopy with EHL or laser lithotripsy.