BENEDICT DEVEREAUX: I'm going to discuss a few things. Obviously, looking at the aims of cholangioscopy. I mean, why do we pursue it? Why is it all the rage at the moment? Why should it be part of the clinical algorithm?

And then I'm going to present a number of case reports looking at the key indications that you've heard of difficult CBD stones and strictures. And then going to look at issues of developing a SpyGlass service.

I'd like to comment in on the AMEA registry data that I've been pleased to be involved with over the last 18 months. And then at the end, just looking at the expanded indications of intraductal imaging with pancreatoscopy. So why should we take cholangioscopy?

Obviously, it's to assist in the assessment of indeterminate biliary strictures and to help deal with complex or large CBD stones. But we have to ask ourselves, for it to be meaningful, it has to positively impact the patient's management, and it has to confer hopefully a cost-benefit. So in the cases that I present, at the end of each one, I'm going to present this little scoresheet where we'll look at the procedural success. Has it made a positive impact on the patient? And can we conclude that there's been a cost saving?

So in the first case of the 61-year-old male who was referred from a regional center near Brisbane with cholangitis-- a classic presentation. He'd undergone a transabdominal ultrasound, which revealed a dilated common bile duct but no obvious CBD stones and no evidence of cholecystitis. And you can see from the initial ERCP pitches-- the endoscopic pitches, there was pus emanating from the biliary tree. And here is at the initial ERCP in March of last year, a large CBD stone, which couldn't be removed at that time, and the patient was referred internally for our GI service for an ERCP and cholangioscopy. And here is that ERCP.

You can see in the third panel, the large impacted stone. In the fourth panel, the passage of the SpyScope. So initially, the stent was [INAUDIBLE] and removed, of course.

And you can see in the lower left, the EHL probe, which is what we use, to break down the large stones was preloaded and then cannulated. You can see very readily the stone was able to be affected with a central hole right through the middle of it. And within the large duct, you can manipulate the EHL probe with the controls on the SpyScope and actually work along, essentially, the equator of the stone.

And you can see working to the right and just hammering away with the EHL probe. And then it cracks. So that's a positive sign. And then, again, you can manipulate the tip of the scope, then over to the right to essentially bisect the stone. Then with further use with the probe, breaking into smaller fragments-- smaller fragments.

And it was about this time where I thought, well, we've probably done the work. And I'll then troll the duct with an extraction balloon, which is what we did next. And you can see stone and sludge came out, but I wasn't happy that we had all of the fragments.

So with the SpyScope, you can then reintroduce the scope. And of course, there was another fragment. And under direct vision, you can identify that-- further treat that with the EHL probe and clear the duct.

So in that one session, this difficult stone was cleared. So with this case, the patient recovered well and went on to have a cholecystectomy. And that was the end of his gallstone problem. So when we do our assessment, I think we can clearly say that there was procedural success, and it did positively impact on patient management.

And it would be reasonable to conclude that there'd be a cost saving, and that it was all done in one procedure. Perhaps if we had the ability initially, and certainly in regional centers, we could have done that at the index ERCP.

And the second case-- I'll move through quickly-- a similar stone case of a 73-year-old woman. The difference being this woman was referred from a regional center as well, but she had had a total of three ERCPs elsewhere before referral over a two-month period. Large stones, multiple stones, couldn't be cleared fully with baskets, [INAUDIBLE] with balloons couldn't be done unstinted each time. And so I was referred to Albert Hospital at the Royal Brisbane Women's Hospital for treatment.

And you can see in these panels, [INAUDIBLE] here, but there's a stone here with further material above it. Introduction of the SpyScope. The cholangioscopy pictures broken down with EHL-- cleared, cleared, and now clear cholangiogram.

So in a similar case with this patient, it was the definitive procedure, but it took three cases to get to us. The duct is now clear. So I think in our scorecard, we can say that, yes, there was procedural success. Yes, it positively impacted on the patient's management, and she was delighted that she didn't have to have a further procedure. And again, I think we could reasonably conclude that there was a cost saving from this intervention.

But all stone cases aren't the same. Now, this is a 70-year-old man who underwent a cholecystectomy 30 years ago, and he was diagnosed with prostate cancer as a result of an elevated PSA. And as part of his work, he had a staging CT scan. And this revealed a grossly dilated common bile duct with a six centimeter stone. And despite that he was asymptomatic, and he had normal liver function tests, but it was decided by the oncologist that he should have his duct cleaned before he underwent chemotherapy and the associated immunosuppression.

So he was referred from our oncology department. And due to the size of the stone, and our desire to clear it, he went straight to ERCP with SpyGlass as his initial procedure. Now, here's the cholangiogram.

Now, in my experience, this is the biggest stone I've seen and here it is. So into the duct with the SpyScope EHL probe. Now, this is the second ERCP. This is the second time I did this.

The first time, I spent about 40, 50 minutes with the EHL probe fragments everywhere. Cleared it, cleared it, cleared it but there was still residual stone there. So I stinted him and brought him back about a month later. And that's this ERCP, and that was the picture you saw throughout the cholangiogram.

But again, within that large duct, you can manipulate the probe. You can move from one fragment to the other. You can clear that section lavage and go to the next section.

So I did this for another 40 or 50 minutes. And then I thought, well, I'll do a check cholangiogram to see where I'm at. And there was no longer a six centimeter stone. There was a 5 and 1/2 centimeter stone with a little nibbled bit at the bottom of the stone, and that's all I had done in two procedures in an hour and a half or more of dedicated treatment.

So in this case, I felt that I was never going to win, or I may over multiple procedures. But I thought the appropriate step was to refer him to our surgical colleagues who were very expert for a laparoscopic clearance. So this is it.

So they've opened the duct, and they're removing the stone. And there's a bigger one. So I didn't feel quite as bad when I saw this video. They said it actually popped when that came out.

So this gentleman went on to have clearance. I saw him two weeks ago. I spent a further half an hour clearing stones from his bile duct.

So clearly, I didn't enjoy procedural success. But I think we made a positive impact because it actually defined his treatment. And I think we could argue whether it was cost saving or not but possibly rather than multiple ERCPs.

So some stones are more difficult. Difficult stones-- there are a number of reasons. There are anatomical reasons, then there's large stones, multiple stones. I think importantly strictures, particularly stones proximal to a tight structure. And then there are patient factors as you can see.

As general guidelines, if the stone's less than 10 millimeters, it can be removed after sphincterotomy Less than 20 millimeters, it can be removed by crushing in with a basket as you can see here. But greater than 30 millimeters, lithotripsy is completely reasonable. And the two main modalities are the EHL and lithotripsy. And looking at the electrohydraulic lithotripsy, it's a bipolar probe.

There's a charge across the bottom. And then that transmits a shockwave to the stone. And there are varying power sources with the laser. It forms the yttrium aluminum garnet laser.

It's a focus light, and it forms a plasma. And results in this tensile force with which breaks up the stone. And recently, Takao, Itoi, and colleagues from Japan reviewed this. And you can see in the table that the success rate in clearing the stones and the complication rate is comparable between the two procedures.

We use EHL. Of course, many units use laser. And that's what Takao and colleagues concluded that, indeed, they were comparable, but laser tends to be more expensive. And certainly, we have to attend to a special setup of our rooms and training of our staff. So we move into strictures.

In this 57-year-old female-- she had undergone a cholecystectomy in 2010, and she presented to a Regional Hospital earlier this year. She was generally feeling unwell. She had abnormal liver function tests. And MRCP revealed dilated intrahepatic ducts and the suggestion of a mass at the hilar. And she underwent an ERCP at the Regional Hospital again.

And they defined the stricture. They didn't inject contrast above it. They selectively placed a wire and then placed a 10 centimeters stent.

But they weren't confident that they got across the stricture. So a few days later, they removed that stent, and she was sent to us for a cholangioscopic assessment-- no stint in. And she wasn't jaundiced.

And here you can see in these plaques, particularly down here, the intrahepatic ducts are not dilated. But there is a slender duct and the suggestion of a stricture in the common hepatic duct. And so we proceeded to cholangioscopic assessment. You can see the air coming down from the intrahepatic ducts and just moving the SpyGlass through the tighter part of the structure.

And as you heard from Isaac, it's important to image the proximal extent of the stricture, but this was very tight. And it took body movement actually moving the scope and the catheter and controls of the tip of the SpyGlass to try and angle the tip through that proximately extent. And then in a moment, you'll see prominent intrahepatic ducts with a normal mucosa.

As you can see here, as we just can tip up through that area. I then went on and performed biopsies similar to what you've seen-- targeted biopsies. And those biopsies returned benign histology. They revealed inflammation and fibrosis. There was no evidence of malignancy.

I similarly did salvage cytology OptiLavage and we sent that for cytologic assessment and no malignant cells were seen. We're at a three-month mark follow-up, and the patient is clinically well. Her LFTS remain abnormal. But she's not jaundiced, and there's no evidence of a development of a mass. So we continue to watch.

So in this case, again, I think there's been procedural success. I think it's had a positive impact in reassuring her. And her referring doctors as to the nature of her pathology, and it's likely cost saving.

So when we look at intermediate biliary strictures, there are a number of challenges. Are we able to confidently assess the nature of the stricture by its appearance alone? And I think that our biopsy and our sampling algorithms are indeed evolving. And I think, as in elsewhere in the gastrointestinal tract, targeted biopsies are becoming more important. I'm going to quickly move through just a few papers and series, which reveal this.

This is a series from Phil Craig's in the audience from Sydney. Now, this is directly cholangioscopy, but it's asking the question, can we tell by looking at a lesion, looking at a stricture-- can we predict whether it's malignant or not? And you can see that in expert hands of the patients with a benign appearance, they were all confirmed to be benign out of the 12 patients where it appeared malignant, nine were confirmed to be benign with a specificity of 88%. So in expert hands, there's clearly a learning curve. We can obtain good results, but it's not perfect.

In this series presented by Rob Hawes in the Florida group, looking at the targeted SpyGlass biopsies. In summary, the overall sensitivity and specificity of the SpyBite biopsies was moderate. Again, it's not perfect.

There are challenges with the site-- with selecting the right target site and with the sample specimen. And then from Peter Draganov from Florida as well. And presented this series and compared the conventional brushings and intraductal biopsies with SpyBite biopsies.

And interestingly, now before I go on, I'll acknowledge that whereas brushings are disappointing, this is certainly very low. But there was a significant difference between the accuracy and sensitivity of the brushings with the targeted biopsies. And similarly, with the intraductal biopsies, which many people consider standard of care in the SpyBite biopsies. So perhaps it's the targeting that affords us this benefit.

So how do we develop a SpyGlass service? Obviously, it needs to be promoted within our area. And we need to develop a referral axes with gastroenterologists, and surgeons, and oncologists.

And within our hospital, certainly, we found that the multi-disciplinary clinics with hepatobill surgeons has been very productive. And from the Regional Hospital point of view, I think directing patients, who are referred to SpyGlass early on a case by case basis, is helpful. And also educational sessions.

But it's certainly helpful when discussing SpyGlass and cholangioscopy that you can reflect on what is the current breadth of indications and procedural success and complications? And that's where I think the registries have been very helpful. This was the first registry published in 2011.

And as I said, I've been very pleased to be involved in the current registry and AMEA. Now, I always thought one of these As was Australia, but it's not. AMEA is actually Africa, Middle East, and Asia, and Australia comes into the Asian subset.

And you can see that there are 10 countries have been involved, 20 centers, and we've accrued data on 500 patients or so. And I won't dwell on this, but the primary aim is just to see about what role a cholangioscopy has in the management of patients and how it's being used. And then to drill down and look at different endpoints for indeterminate strictures for biliary stones and for other indications. And then it was further importantly looking at the clinical impact of the procedure on diagnosis and patient management.

So between November 2014 and March of this year, we've recruited these patients, and the follow-up is six months. Now, we're not at the six-month mark yet. So these are preliminary data, and the final data set will be presented later in the year. It was split 50/50 male/female, really. But as you can expect, the commonest indications with stones and strictures and then there were an array of other indications.

Procedural success was comparable amongst both the legacy and the DS systems. What was significant about this registry was that it was commenced with the legacy system. But the DS came to availability earlier than we thought, and so it became incorporated into the data set. So that's all we have. We have data on both the legacy system and the DS system with comparable impact on management.

But what one would expect is that the image interpretation and the image quality was better with the digital platform. I'll just have one point, which was when looking at the visual interpretation of a stricture as being malignant, how did that correlate with malignant histopathology? And that was significantly better for the DS system versus the legacy system. Obviously, because you can interpret the image better with-- that was the positive predictive value-- better with the digital platform.

Adverse events-- were very low at 1.4%, and they're the normal array that you would expect from cholangitis. There was one limited perforation, and all complications were mild. So that's all cholangioscopy.

And I've just finished with one case, which is using the cholangioscope in the pancreas. This is a 42-year-old woman who was referred within the last six months. She had diabetes mellitus. She'd had one episode of acute pancreatitis 15 years ago.

She was really clinically quite well, but she presented with abdominal pain on this occasion with nausea, had a normal lipase. And then imaging revealed a grossly dilated pancreatic duct. So you can clearly see a grossly dilated pancreatic duct. And on MRCP, there was the suggestion that of a filling defect.

Now, she did undergo an endoscopic ultrasound by a colleague in a group community practice. And we showed no evidence of chronic pancreatitis, a dilated duct, a filling defect in the duct but seemingly no posterior shadowing. So it wasn't obviously to him a stone, and he thought it may well have been mucin. So we've got a young woman of Vietnamese descent with diabetes, with maybe main duct IPMN, which lots of things didn't quite really ring true.

So she was presented at the multi-disciplinary meeting, and we were asked to perform a SpyScope examination really because she was being plain for total pancreatectomy. So this was the pancreatogram. And you can see that there's a tight stricture in the head, a grossly dilated upstream pancreatic duct, and on the lower frame, you can see a filling defect. So cannulation of the pancreatic duct was not complex and see with the SpyScope, with that distal stricture, I just cannot cannulate the pancreatic duct, so I exchanged that sphincters time again guidewire. And with that, use the wire as a guide to railroad the SpyScope through the distal stricture. And you can see the wire there.

We're in the pancreatic duct. We're proximal to the stricture. And then you can see that beautiful image there of the pancreatic ductal stones. So normal looking mucosa, a dilated duct, dilated side branches, and these stones floating around. That thick fluid, of course, is the contrast and not mucin.

And then with the instrument just inside the propeller, we can examine the distal stricture. So as one pre-procedure may have predicted, a main duct type IPMN was unlikely, and this young woman had chronic pancreatitis. So in this case, she remained clinically well and is being observed.

So procedurally, I think this was successful. It clearly impacted the patient's management. She avoided a total pancreatectomy. And certainly, in that regard, it's cost effective.

So to conclude on intraductal imaging, it has a key role in management of biliary disorders, as we've seen--stones and strictures. There's an evolving role in pancreatoscopy as we gain experience. It positively impacts patient management in defining and in providing definitive treatment or defining the management plan. It's likely cost-effective, but there are limited data on this.

And the opinions in those assessments that I've given are really opinions and could be discussed. There's likely a cost-benefit and in-service development requires a multi-disciplinary approach and promotion within your own hospital and within your referring region. Thank you.

[APPLAUSE]