

**SERGEY**

Thank you very much for this nice introduction, Chris. But it's not my title. That's what Stavros assigned me. And I

**KANTSEVOY:**

was thinking for a long time, how do I put it into the play? So I will let you judge what happened. And I hope that after this talk, he will still invite me every time, entirely grateful that he is doing it for so many years.

So this is my list of disclosures. Now the real question is, so there is no question that when we see premalignant or early malignant lesion, they have to be removed. The real question is how to remove it, whether to do it EMR and remove it in piecemeal fashion or to do it ESD.

If you do it with EMR, it's really easy. It's very, very fast. It can be done anywhere. So you don't need to look for a special doctor. Practically it can be done within driving distance from your house. And it is inexpensive equipment which is readily available everywhere.

With ESD, it's very different story. It's difficult and time-consuming procedure. The number of people who do it is limited. And there is a real possibility that if you want to have it removed in one piece, then you will have to travel, sometimes a significant distance. And it requires expensive equipment. And you need to know how to use it.

But there was already several presentations today. And I am not going to spend that much time on the literature. But even individual studies and large meta-analyses, they all demonstrated that whether you are talking about stomach, esophagus, or colon, ESD has multiple, multiple advantages.

And for example, this is one of the meta-analyses. And it says that ESD can achieve a much higher rate of en bloc resection. And it's very clear. If the lesion is more than 20 millimeters, there is no Snare which can be big enough to get it in one piece. So obviously, everything which is bigger than 20 millimeters, if you do an EMR, it will come in multiple pieces.

And the rate of R0 and curative resection is significantly higher with ESD than with EMR. And because of that, the rate of recurrence with ESD is significantly lower than with EMR. The only problem with ESD, or probably one of the biggest problems with ESD is the length of the procedure.

So if it takes only 29 minutes to do EMR, for all these studies, it takes 10 times longer to remove the lesion in one piece comparing to the multiple pieces. Especially, ESD is difficult in the colon, because first of all, colon is not a straight line. And to deliver endoscope to the place where you want to remove the polyp can be difficult. An endoscope create multiple loops. And then when you are doing ESD, it will not be one-on-one movement. And the lengths of the knife protrusion out of the channel will also vary.

It's difficult to access lesion located behind colonic folds and lesions located right behind colonic turns.

Colonoscope is unstable in the colon because of peristalsis, and especially because of the patient's breathing. And colonic wall is much thinner than upper GI tract wall. And that is why the chance of perforation is much higher with ESD.

Last year, I was talking about my initial experience with the device, DiLumen, which is a new interventional platform for colonic intervention. It is not a device for ESD. It is actually a device for any intervention inside the colon, including EMR or [INAUDIBLE]. But for ESD, it's especially a good fit.

So I started to use DiLumen in November 2017. Last year, when I was talking here, my experience was 122 procedures. And since that time, I did about 270 more procedures by now.

So location of my lesion is mostly on the right side. It's sustained in colon cecum, hepatic flexion, so forth. So last year, I listed those advantages of DiLumen. And I'm not going to spend time on this. It's still on the website. So when you go to the last year presentations, on the same course, you will see all that.

But I want to talk about something which I learned for since the last presentation. So first of all, DiLumen is a universal platform. It covers the entire colon, from rectum to cecum. And we just had two publications. One of them demonstrated a large polyp which I did as a live demonstration in Germany. They told me that the polyp is 5 centimeter big, so I agreed to do it. The final size of the polyp was 17 centimeters. It start from the dentate line. And it was going into sigmoid colon. So it took a really long period of time.

But here, how the DiLumen is helpful-- after initial dissection, we put the suture on the DiLumen. And then we connect that suture to the margin of the polyp. And from that point forward, you have full control of the lesion. So you can see that I am pushing the slide there on the handle of the DiLumen. And it completely opens up the submucosal space.

And this is not a static retraction which you will achieve with, let's say, clip and, clip and flows technique or clip with OREM technique. That is dynamic retraction. I can move it forward, or I can pull it back. And I can change the direction of this traction. So this is really dynamic retraction. And it significantly facilitated my procedure, even with this lesion.

This patient was a 51-year-old gentleman. And previously, the biopsy already demonstrated that was a superficial cancer right above the dentate line. So I needed to remove it in one piece. Without DiLumen, it would be extremely difficult. With DiLumen, you can see that we were able to achieve it. The whole lesion was removed in one piece.

But removal left a huge defect. I try to avoid doing circumferential lesions. But this was one of the cases where you had to do it, because otherwise, the only option that this gentleman had was a colostomy for the rest of his life. So here you can see the entire mucosa of the rectum is gone. So this patient would have 100% chance of post-procedure structure formation. And it will be tight stricture and require dilation. And life would be miserable.

So what I do, I do endoscopic rectal reconstruction in cases like this. And here you can see that using Overstitch, it took me only 20 minutes to close the entire defect. And it took only two sutures.

So I will just speed it up. I don't think that you want to watch for all 20 minutes. But this is the end of the procedure. And here you can see, dentate line is restored. We enter into the rectum. We look back, and everything is completely closed. You do not see the muscularis layer like it was right after procedure.

So the specimen confirmed that my margins were clean. And this is the total size of the specimen. And then the patient had a follow-up colonoscopy in three months. You can see that rectal mucosa is completely restored. There is very little of the scar tissue. And besides that, there is no structure formation, wide open rectum. So it's complete restoration of the rectal mucosa. So this is the case where DiLumen was used in the beginning of the colon, or actually, at the end of the colon, right at the dentate line.

The next case, which I want to show you, is appendicular problem. Dr. Stravopoulos demonstrated how they did a full-thickness resection for the polyp originating from the appendix. He has demonstrated it today on the talk. And they used a [INAUDIBLE] modified [INAUDIBLE] clip to do a full-thickness resection.

And I agree with his concern, because if you try to-- for this example, this is the polyp, which is growing somewhere from inside the appendix. So if you put a Snare around this polyp, then part of the polyp will stay there. And then you did not really remove everything.

So here, I am using DiLumen. I am using a pulley loop on the top of the polyp. And I connect that pulley loop with DiLumen. And then when I pull DiLumen back, that invert appendix into the cecum.

And then I have access to the place of the attachment. I can remove it easily. So this is the actual case. You can see that preparation leaves much to be desired. But that's what I get.

And here you can see that we are putting the pulley loop on the base of the polyp. And I know that it's not at the site of the attachment. But another end of the pulley loop, I am connecting with the suture loop, which is coming from there for a balloon of the DiLumen. And now you don't need to put those sutures. The company is now modifying the device. And it is FDA-approved approved modification. So the devices which you will be getting from DiLumen will be coming with that suture already mounted.

And there will be two lengths of the sutures. One is really long for traction, and one is short. So here you can see that appendix inverted. You clearly can see the difference between normal tissue and the attachment of the polyp. And then dissection is very, very easy.

So the first case demonstrated you the DiLumen in the rectum. And this case demonstrated your use of the DiLumen in the appendix. So this is a device for the entire colon. So you can see that polyp is cut. And this is the healthy part of the appendiceal mucosa. Everything is removed in one piece.

And just to speed it up, this is the specimen. So this is my loop somewhere in the middle of the polyp. But all the margins were clean. And pathological examination confirmed that.

So the second thing which we learned over this year is that DiLumen allows you multidimensional traction. And it is dynamic traction. I showed on the rectal case where I was pushing it. So it is pushed. And this is another example. Appendix, it was pull technique. And this is another example of the pull technique.

So you can see by scope guide that this is a large, flat polyp located in the cecum. And after submucosal injection, you can see that the polyp is very difficult to remove with the Snare. It's clearly a case for endoscopic submucosal dissection. Here you can see, we started 10:51. I'm doing circumferential incision around the polyp, obviously, a big blood vessel right next to the mucosa.

So the circumferential incision is completed. Now I am deploying DiLumen. But the polyp is located in the cecum. So there is no place to do a push technique. There is no space there. So the only possibility is the pull technique in this case. So I am grasping the long suture. In the new modification of the DiLumen, it will be a different color. So you can easily see which one is long and which one is short.

And now after that long suture is attached, then I am pulling DiLumen back, and look at all this. So we started 10:50. It's now 15 minutes, and the dissection itself started at 11:04. And look how quickly it is progressing. And it is difficult place, cecum. It is difficult polyp. But with the help of the DiLumen, it is just very easy, very manageable technique.

Dynamic retraction is very important, because at some point, I want to make sure that my margins are still clean. So at this point, I am releasing traction to look into the opposite side of the polyp to make sure that I am not cutting beyond where I should be.

So this is the end of the procedure. And the polyp is removed. And after the polyp is completely removed, then I'm using DiLumen as a conduit to direct the suturing device into cecum. And it takes, really, seconds. And here it is. Everything is completed and sutured. And the polyp is removed in one piece with the clean margins.

So by doing all this, DiLumen really simplifies and facilitates colonic ESD and saves time needed for ESD. This is another example. So ESD in the ascending colon, a flat polyp. And you see 12:51. We're starting procedure. Polyp is about 3 centimeter big. And this time, I am doing it without DiLumen. I am doing just regular ESD. Believe you or not, from time to time, I do regular ESD without any assistive devices.

So anyway, to cut the story short, it takes a long time. Yes, we removed the lesion in one piece. But ESD itself takes a-- and then directing the suturing device through the colon also take time. So eventually, we finish procedure. We finish everything in one piece. But it takes about almost three hours to remove that large polyp in the ascending colon.

The same day, May 22nd, and this procedure was finished by 3:30 PM. The same day, I have another polyp located in the ascending colon. The polyp is little bigger. Previous polyp was granular type. This is non-granular type, very, very flat. But this time, I am using DiLumen.

And by the way, this is Kurt from Lumendi. You see him outside. He is watching to make sure that I am not overstating my numbers, that he is accounting for every DiLumen case that I am doing.

So here you can see that I am doing circumferential incision. And this procedure started almost at 7:00 PM. So circumferential incision is finished. Now we are clipping the DiLumen. This time, I am using short loop, because I will be using traction to push it away, to open the anal side of the lesion. Previous, in the cecum, I needed to access the oral side of the lesion.

And here you can see, from that point forward, it's 9:13. It is just no effort. The removal is very quick, very fast. And you cannot even compare. Similar lesion, actually, this one a little more difficult, than the previous one. Similar location, previous one without DiLumen, almost three hours. And this one, with DiLumen, took only 45 minutes. And out of these 45 minutes, dissection itself was about 15 minutes all total.

So you can see that everything is very stable. DiLumen was deployed after balloon allows me to pull the scope in and out, if necessary. And you can see that my right hand, from time to time, goes down. And that's when I am pushing forward the balloon and create more traction and open up more of the submucosal space.

So here at the end of the dissection, and it's only 19:17. So 17 minutes into dissection, and it's all done. This is final. The suturing is completed itself as well. And this is the end of the procedure. You can see the lesion is removed in one piece. And it's 19:45, so less than an hour to remove the polyp in the location which previously took almost three hours. That's how much time it's cost-saving with DiLumen.

So for this DDW, we submitted that abstract. When we look into the large polyp, every polyp was bigger than 5 centimeters, removed with DiLumen. And we did a propensity match study with our historical control-- similar size, similar location of the DiLumen. So this demonstrated that DiLumen saved me approximately 25% time on the ESD itself and approximately 20% of the time on dissection of the lesion itself.

Finally, the final example, why I want my colon polyp removed with ESD, not with EMR. So this is the patient who came to my office on January 2018. She is a 43-year-old. And in September 2015, she was found to have a large, flat polyp in the rectum. So the polyp was 40 millimeter and was removed by EMR.

After that, she had four more, so a total of five EMR, because she still had residual polypoid tissue at the site of the removal of the polyp. And once again, this is rectum. So this is her sixth procedure. And when I started this procedure, you can see that that polyp is fixed in the scar tissue. So I don't do really marking if I am doing EDS in the rectum or in the colon. I do marking if I do ESD in the esophagus and stomach. But here, it was very important for me to remove everything.

You can see how extensive the scar tissue is. So it is 17:55. We're starting dissection itself, and definitely, a lot of scar tissue, definitely only ESD. And once again, this is her procedure number six. And if we are not able to remove that polyp, then this 43-year-old woman will have to live with colostomy for the rest of her life, because that's the only option for her location of the rectal polyp, too close to the anal verge to create anastomosis.

So you can see extensive scar tissue. I am not using any assistive devices. It's just a typical ESD. And this is practically the end of the procedure. So we started at 17:50. It is now 18:19. And we removed the entire lesion in one piece after multiple, multiple unsuccessful EMR. So this is the end of the procedure, everything removed. But it's left a large defect. And I don't leave any defects post-ESD without closure. I don't use clips for closure. I always close with the suturing device. So that's how it look at the end, when the suturing is completed, as if there was no procedure. And this is the specimen. And you can see that the entire procedure took less than an hour, after five previous attempts of endoscopic removal in piecemeal fashion.

So this is pathology report of that lady, tubulovillous adenoma. Margins of resections are negative. Luckily, there was no high-grade dysplasia or carcinoma. And she was fighting with that polyp for three years. This is the same patient in three months, obviously, nothing left. And the biopsy confirmed that there was no polypoid tissue left.

So in conclusion, for my own colonic polyp, I would like to have EDS. And I would like to have that ESD performed by somebody who are using DiLumen, because DiLumen facilitate advancement of the colonoscope, stabilize the lesion inside the therapeutic zone, helps with multidirectional traction and retraction, and significantly facilitate not only ESD, but EMR and full-thickness resection of the colonic lesion. And it significantly simplifies and shortens ESD and total procedure time. Thank you very much.

[APPLAUSE]

**SPEAKER 1:** Great, Sergey. Do we have any questions for Sergey? Sorry?

**SPEAKER 2:** How do you pay for that?

**SERGEY** So when I was doing like 100 ESD a year, the billing was horrible. And I always bill for unlisted code, and plus

**KANTSEVOY:** Modifier 22 for difficulties of procedure. Practically it was unreimbursed procedure. I was getting \$300 or something of that sort. Since I'm doing close to 500 ESD a year, insurance company now very well paying for all this. We have no problem.

**SPEAKER 3:** Dr. Kantsevov, impressive as always. For the rest of us that encounter difficult scar tissue, I was just wondering what do you change your generator settings to to improve cutting?

**SERGEY** I know that many people, I thought, will criticize me. But I don't pay much attention to the generator. I think it's

**KANTSEVOY:** all in your technique, rather than generator. What I am using, I always use for the cut of the mucosa. I use endo-cut or pure-cut.

And for submucosal dissection, I always use spray. If I use Coagrasper, then I use a soft coag. I do not play with generators setting. And I don't think that that is the answer. The answer is modify your technique. Adjust your technique. If something is not working, then maybe you are not in good contact or maybe the knife needs to be clean or maybe you need to add some normal saline to increase the conduction of the electricity. But other than that, I don't play with generator settings.