**WSA Discussion of 2022-339**

**Predictability of Endoscopic Success for Foregut and Bariatric Leak in an Experienced Quaternary Center**

**DR JULIANE BINGENER-CASEY** (Rochester, MN): This is a large study: 7 years, 81 leaks. I am not quite sure from the manuscript and the presnetation whether everyone who had a leak underwent endoscopy and possibly operation, or some just underwent operation and never endoscopy, and how they were included in the study. I am presuming most of them underwent endoscopy with about 70% chance of success, which is great. Endoscopy has changed a little bit over time. It would be nice to learn from your experience whether we have improved since 2013. Do we have a higher chance now with vacuum therapy, which you have beautifully delineated?

What were the index surgical procedures? There may be a difference between a radiated esophageal cancer and a staple line leak from a gastric sleeve, and the reader would certainly like some help understanding how the data applies to their patients. In which clinical situations did you make the decision to go to operation, and was it different for bariatric and non-bariatric operation? Does the risk factor “previous bariatric operation” mean any reoperative surgery? Were there other reoperative situations involved, eg failed Nissen converted to Roux-en Y gastric bypass? And lastly, what are your plans for external validation?

**DR STEVEN LEEDS** (Dallas, TX): We did not include a slide with all the index operations. A total of 64% were sleeve gastrectomy. The rest were kind of all over the place: total gastrectomy, subtotal gastrectomy, endoscopic complication, some were dilations, 1 was from a bronchoscopy, Roux-en-Y gastric bypass, 6 were paraesophageal hernia and fundoplication. There is a category for “spontaneous,” which is basically not iatrogenic: 1 patient swallowed a bone that perforated his esophagus, 1 was traumatic. We had a couple from lung and liver transplant and then esophagectomy and non-radiated fields. It was a very heterogeneous group of people, so, that was the idea of the nomogram: to take that earlier operation out of it and just look at factors that promote healing.

As far as the situations that prompted us to go to operation, that is what we are trying to figure out. Should we just go straight to operation, or should we try endoscopy? Those endpoints started to shake out early in the experience, and there was a learning curve associated. Those patients were eliminated because of that learning curve. We would perform prolonged endoluminal vacuum therapy (EVAC) trials on patients when we did not really know what was going on. EVAC is in its infancy. It has been around in Germany and overseas for a few years, but we did not start doing it until 2014, so we are still learning a lot about it. You must go patient by patient, which is why age and BMI come into it. But ultimately, endoscopic therapy was instituted on almost every patient. There was only 1 who went straight to operation. We would always judge it based on failure to progress. Usually, I would make it about a 2-week duration. After 2 weeks, we would reassess. If we were not making any headway, then we will bail and go to operation. In some cases, with stents, we would go a little bit longer. We would trial them for 4–6 weeks and then we would go to operation.

At this point these were chronic leaks, and the patients were weighing in. They do not want their stomach out. That is what focused us on the nomogram itself. I want to be able to go in the room and say, “Listen, I can do this for a month, 2 months, 3 months, putting the VAC in you, but you only have about a 25% chance of success.” So, it is a tool to help us discuss that with the patients.

Regarding the plan for validation, as you can tell, the data range stopped on January 1, 2021. Since January, we have been collecting the patients who we have managed with leaks, and all we are doing is what we normally had done, and just running the nomogram on them. We will validate that internally, and we probably need to solicit externally, to figure out if it can be done on other platforms outside of our hospital. That may be difficult because some places do not offer these endoscopic therapies that we offer. Most patients will get a stent right off the bat. So, this can be a difficult thing to validate, but we will try our best based on what I discussed.

**DR MICHAEL UJIKI** (Chicago, IL): Most of us hopefully do not have 84 leaks that we can present our outcomes for treating. You get a lot of referrals from outside of your system because you have been so successful at treating these endoscopically. This is applicable to everybody in this room, because if you operate on the colon, the pancreas, the gastrointestinal tract in any way. and you have a leak, Dr Leeds’ group is showing us how to manage these in a noninvasive way. We all know that taking the patient back for a second operation a week or 2 later, or even a month later, can be a disaster, and here Dr Leeds is teaching people around the country how to use the EVAC therapy successfully. Now we are going even further, and you are helping us understand when we can use it.

I think that your paper will help us if you even just describe your experience. The nomogram is great, but there is also a lot missing from it in my opinion, not just other factors that might affect success, but also which therapy is best to use. Is it a stent? If somebody has an esophageal leak, should we be doing a stent? Should we be doing an EVAC? Should we do internal drainage? Should we just close it primarily if it shows up the next day? And I still do not think we really know that yet, but I think you can help us. I think in your manuscript, if you could elaborate more on that and not get so caught up in the nomogram alone, because your experience is one of the highest in the world really. If you could just comment on the different options available, and then what we should all be thinking about doing when our patients have a leak.

**DR STEVEN LEEDS** (Dallas, TX): The point of the nomogram is the basis of guiding the therapy. What we want is for the surgeons or whoever gets the leak to be able to use this and say, “Let’s not keep you here or let’s not go to operation. Let’s get you to a center that has the experience.” I think that’s the most important part. Your point is valid that we are a regional center, and we get a lot of referrals from outside, so if we can just guide people who do not have the ability to do EVAC, stent, endoscopic therapy, they can get the patient somewhere that can, and we can spare this organ.

As far as which therapy to use, that is the next thing. We need to look at the duration. We need to look at what therapy they received and then look at the demographics within each patient and try to tease that out. That is coming. I think that is part of not validating this area of the science but going the other way and trying to figure out how we can help the endoscopic surgeons and the savvy endoscopists spare organs.

**DR J CRAIG COLLINS** (Los Angeles, CA): I want to call out the beauty of your nomogram approach and using continuous variables. So much of the data we see is presented as binary, BMI less than 30 kg/m2, BMI greater than 30 kg/m2. Is it 32 kg/m2? Is it 62 kg/m2? I would request that you take some time in the manuscript or perhaps even a second accompanying manuscript to describe your statistical methods so that the rest of us can benefit from this.

**DR STEVEN LEEDS** (Dallas, TX): Our statistician is a wizard. We put it on the table, and he tells us exactly what we can and cannot do. Trying to understand this in the linear values, if you notice our BMI, it circles around. We noticed that the patients with a chronic leak and a lower BMI are falling into malnourishment, and that is why they do not heal well. The patients with high BMI, especially if they have a leak in the belly, we are starting to see the trend toward the adiposity or some inflammatory inhibition with obese patients that is preventing this. So, we are starting to find trends by using the real linear numerics.

**DR JAMES DEBORD** (Peoria, IL): It was not clear to me from your presentation on your nomogram, did “history of bariatric operation” refer to any remote bariatric operation or that bariatric operation was the cause of the index leak?

**DR STEVEN LEEDS** (Dallas, TX): That is something we probably should tweak; it should be any gastric operation. Most of our patients are bariatric patients. But any gastric operation, previous fundoplication, anything where you are compromising blood flow or creating scar tissue, has absolutely been shown in our data to increase leak rate. We found that as probably the biggest difference, especially in the bariatric sleeve, band to sleeve vs sleeve alone, we see a lot more leaks. I can almost tell you right off the bat when the patient shows up at the hospital, “This patient had a band because of the way they leaked.” I think any previous gastric operation would influence this.