Discussion of 2021-1734

QUALITY OF LIFE AFTER OPEN VS MINIMALLY INVASIVE PANCREATICODUODENECTOMY: A PROSPECTIVE STUDY

**DR SHISHIR K MAITHEL** (Atlanta, GA): Dr Blazer and his colleagues have conducted a very important study that focuses on patient-reported outcomes, as they relate to either minimally invasive or open pancreaticoduodenectomy. This study goes well beyond the "usual" perioperative outcomes assessed in most studies comparing 2 different techniques. Despite the preconceived notion of patient benefit that leads to a "market demand" of sorts for minimally invasive surgery (MIS) Whipple procedure, the patients included in this study who underwent MIS procedures do not report an improved quality of life across various dimensions. Furthermore, regardless of technique, the qualitative interview portion of this study highlights important information and data we must consider and incorporate into our recommended treatment strategy as we need to balance any potential detriments to quality of life, with a realistic and honest assessment of improvement in quantity of life as we counsel other patients.

 Regarding the patient selection for the study, were the 56 patients consecutively enrolled in both groups? Or do the authors think that there could be some selection bias for the patients who agreed to participate, as it is well‑known that patients who "feel well" are more likely to complete the surveys? Does excluding non‑English speakers introduce any cultural selection bias? And why were only 14 patients selected for the qualitative interview portion of this study?

 In alignment with this study, several other studies have reported similar perioperative outcomes when comparing MIS or open Whipple. However, 1 factor that is not addressed in those studies, including this one, is the incisional hernia rate in both groups over time. Development of a hernia and subsequent treatment for that hernia can affect quality of life in a substantial way. Do the authors have any follow‑up data on incisional hernia rate in both groups?

 The authors mention validating the results of this pilot study on a larger scale, which is very important to do in order to account for individual surgeon outcomes bias, geographic and cultural bias, etc. Have the authors considered collaborating with patient advocacy groups, such as the Pancreatic Cancer Action Network (Pan‑CAN) to include a large geographically diverse, potentially international cohort of patients in the validation study?

 If the results of this study are validated on a grand scale, given the increased cost and resources associated with MIS Whipple, as well as lack of any proven benefit or difference in perioperative outcomes or survival outcomes, how do the authors propose to incorporate these data into clinical practice? Is market demand momentum for robotic surgery too strong to steer away from pancreaticoduodenectomy and focus on other procedures, where there are clear, proven benefits?

**DR ANDREW M CAMERON** (Baltimore, MD): This is an interesting study to an "open‑surgery only" surgeon like me, as it looks for and finds no apparent benefit in quality of life with the move to minimally invasive Whipple. Now, in the minimally invasive pancreaticoduodenectomy group, there was a mix of laparoscopic and robotic Whipples, and we were not given the granularity of whether there was a difference between those 2. That is my first question, were either alone better than the other or the open procedure? Though I understand the numbers might not be large enough to do that comparison, it would be interesting if you had a sense that there was a signal there.

 I think the most interesting aspect of the whole paper was the qualitative data that showed that in either scenario, open or minimally invasive, we are probably not communicating well with our patients about what they are getting into and what they can expect from a Whipple.

 Have you changed practice at Duke considering what you learned from your qualitative interviews? There was some pretty rich material on how we could be doing better, and it was a little bit disconcerting, too.

 What about the blood loss differences? It is not the point of the study, I know. But it i worth noting that there seemed to be a pretty big difference, with less blood loss in the minimally invasive cases. Now, this was not a randomized study. So, were easier cases selected for a minimally invasive approach, perhaps with less blood being the proof?

 Finally, what should we do with these results? Should we abandon minimally invasive pancreaticoduodenectomy based on an inability to show much advantage or difference from the patient perspective? Put these results in perspective for the field, please.

 Maybe we should randomize the next study. Would there be any issues with that? There should not be, if we believe the data.

**DR KEITH LILLEMOE** (Boston, MA): As another “open” pancreatic surgeon, I stand to celebrate your report, but recognize that these results are early in your experience. Your results could certainly be influenced by factors, such as whether patients received neoadjuvant therapy. Was the resection performed for benign vs malignant disease? Quality of life for people who are totally asymptomatic with an incidental islet cell tumor or an asymptomatic intraductal papillary mucinous neoplasm will certainly be different than somebody who has had neoadjuvant therapy or who faces cancer as their diagnosis.

 One of the initial reports from Mayo Clinic looking at MIS vs open Whipple showed enhanced ability to get patients into postoperative adjuvant therapy protocols earlier, which could make a difference in outcomes down the line. Do you have any data on whether patients entered their adjuvant therapy protocols sooner?

**DR SELWYN M VICKERS** (Birmingham, AL): This paper nicely shows the evidence and the power of the qualitative data. Because the data shows that there may not be a great deal of difference in quality of life between open vs minimally invasive, have you taken the time to look at the cost differential? As the driver of doing this may no longer be a faster discharge or fewer complications, what will be the driver to continue doing it if it is 50%, 30%, 40% more costly for our system or our hospital?

**DR MARY BETH HUGHES** (Norfolk, VA): I did not see a difference in length of stay between the minimally invasive and the open group, and that has been shown routinely in some of the published studies. Length of stay in the hospital can certainly impact the quality of life, particularly right at discharge, and preoperative expectations.

 Secondly, most people with minimally invasive pancreaticoduodenectomy have reported a much lower delayed gastric emptying compared with the open cohort. I was wondering if you saw this. Again, that would impact the quality of life. I would like to get clarification on those two points.

**DR J BART ROSE, III** (Birmingham, AL): Obviously not everyone in your practice is doing a minimally invasive Whipple, so could it be that some of what you are seeing is variability in postoperative practice? For example, are some people adhering to a robust enhanced recovery after surgery program? How much of a contribution could practice variation between surgeons be making to your findings?

**DR DAN G BLAZER, III** (Durham, NC): To Dr Maithel's questions, number one, regarding selection bias–are people who feel more well more likely to participate? There is absolutely selection bias, and you can see it in our fallout. You can see it in the number of patients who participated in the more extensive qualitative portion of the project. When patients do not feel well, asking them to participate in an hour or 2 interview by phone is challenging. Out of all patients who were approached, only 14 or so ended up participating in the postoperative extended interview. So, there is no question that there is bias there. You asked about cultural selection bias for non‑English speakers. That was merely a limitation of our research core in terms of what they were able to do. But there is no doubt if we were to expand this, that we need to incorporate Spanish-speaking and other non‑English speakers in this sort of work You asked about incisional hernia rate–we did not measure that. I will comment that the LEOPARD trial update recently published for distal pancreatectomy showed no difference in incisional hernia rate between the 2 groups. Again, I do not have the data for us. You asked a how we would conduct this in a larger, more geographically diverse cohort, and I
love your suggestion about Pan‑CAN, because I think if I approached a cooperative group with this sort of study, there would be complete and utter disinterest. I think approaching groups like Pan‑CAN is a great idea and that will be on the to‑do list. How do we propose to incorporate these data into clinical practice? I am, by no means, advocating that robotics is not legitimate and safe. It is at our institution. I think the usual response is that you must perform the operation that you think you perform do safely; we have to have our patient safety at the forefront.

 Regarding Dr Cameron's comments as an open surgeon, as to the mix of laparoscopic and robotic, this shift really took place when Dr Perez started us on the laparoscopic train. When he left, our primary MIS surgeon was Dr Zani, who is all about doing this robotically, so we have essentially abandoned laparoscopy. Everything that we are doing in terms of MIS Whipple now is from a robotic approach, so there has not been much enthusiasm to compare these 2, because I think we have really evolved to the robotic platform.

You asked about communication with our patients–that is a great question. It is pretty shocking, if you read a lot of that narrative. It is shocking how badly we explain this operation. I think some of this has to do with how much we have patted ourselves on the back about multidisciplinary care, and how these patients come in and see medical oncology teams, radiation oncology teams, surgery teams, nutritionists, this, that, and the other, and they leave, and they do not even know that they have pancreas cancer sometimes, and they do not understand that they are about to have a really significant operation. So, I think one result of the pandemic is the increased use of telehealth, and we have pivoted to doing a second teaching in a separate setting where we cover the complexities of this operation and the potential outcomes from it. So, I think it is not necessarily the result of my study as much as a result of what the pandemic has done to us. There are some things I think we have learned from the pandemic that may help these patients in terms of understanding what they are going through.

 The blood loss difference is definitely selection bias, and that has been shown in multiple studies; we had several vein resections in our open group, no vein resections yet in our robotic practice at Duke thus far. And as I reviewed all cases with blood loss over 1 L, they were all open cases with significant vein resection and/or pancreatitis. That certainly drove that difference. Should we keep performing MIS? Again, every oncologic operation that I am aware of has been able to show ultimately equivalent outcomes, and by no means am I going to advocate that we should go back to open surgery. There is just no precedent that that is where we are going. I just think that we must be honest, and we need to assess these issues in a scientific way rather than just saying, “I know it is better.”

 To Dr Lillemoe’s questions about chemotheraply, we have looked at our data for years and we have done a really good job. Nationally, 50% of patients are shown to receive adjuvant chemotherapy. Our results at Duke have been about 80% or better. So, we are proud of that, and we have published that. I would also mention that those differences are much the same regardless of approach. So, I do not think the secret is in MIS, in terms of getting people to adjuvant chemotherapy.

 Dr Vickers asked a question about cost. We had a recent presentation at the Americas Hepato-Pancreato-Biliary Association on that very subject, and Dr Zani is working hard on decreasing our cost. I think robotic cost is coming down in general, so to just make a blanket statement that robotics is too expensive would also be shortsighted, because I think that technology continues to evolve.

 Dr Hughes, you asked about length of stay. Length of stay was equivalent in our groups. Delayed gastric emptying was higher in our MIS group. I think that is because Dr Zani does not like nasogastric tubes, and he ends up only putting some in, whereas the rest of us put a nasogastric tube in people routinely, which is a good transition to the last question about differences in the way we manage patients postoperatively. Everybody is on a care map. The care map is the same regardless, other than our occasional different practice in terms of leaving the intraoperative nasogastric tube in place. But every patient is on an enhanced recovery after surgery program and is managed the same regardless of the approach. So, I think that probably plays into our equivalent length of stay outcomes a little bit.