Discussion to: Association of Timing of Percutaneous Left Ventricular Assist Device Insertion with Outcomes in Patients Undergoing Cardiac Surgery

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Dr. Tsuyoshi Kaneko (St. Louis, MO):

I’d like to thank the Association for the invitation. And I’d like to congratulate soon-to-be-doctor Maigrot on this successful and wonderful presentation. And thank you for providing the manuscript well ahead of time.

The Cleveland Clinic team looked at the percutaneous VAD in relationship to the timing of cardiac surgery preoperative, intraoperative and postop. And as you saw, most of these patients were CABG - 85% were CABGs. And the patients who received postop PVADS had the highest mortality and morbidity. I think this PVAD has a lot of implications, especially with the enthusiasm of using Impella intraoperatively in the upcoming IMPACT trial. So, I think this is a very timely presentation in this era.

For my first question: You correctly mentioned that the major limitation of this is the lack of matching. So, I think there is a lot of selection bias. The preoperative PVAD patients probably were on PVAD, and some of them did not survive and did not make it to cardiac surgery. And those patients, of course, were not included in this cohort. On the other hand, the postop group probably had some complications intraoperatively and required PVAD, and therefore were much, much higher risk patients compared to the other two groups. So, are there any efforts to do some sort of matching, whether it’s a propensity match or inverted weight propensity match? I think there are a lot of strategies that you can do to try to minimize that, although the selection bias at the end of the day will not be gone.

Mr. Jean-Luc A. Maigrot (Cleveland, OH):

Thank you very much, Dr. Kaneko. That’s a great question and I think it allows us to highlight a key point of the study in that we know these patient populations are inherently different. And so, we intentionally did not propensity match them because the goal of this study was essentially to show that these different populations had different outcomes, and we also saw that a lot of high-risk patients are in that postoperative group. And so, by doing this, it essentially allows us to demonstrate that we need further risk stratification models to identify these patients who are likely or potentially going to fall in that high-risk population in that postoperative group who are crashing and may benefit from an earlier preoperative or intraoperative plan to control insertion. And so, I do think that there’s a role also for propensity score matching in a further study and something we hope to do with our own institutional data where we have a little bit more clinical granularity of data to match on than we do in the NIS. That is a great question and certainly something that’s the key point of the study.

Dr. Kaneko:
Thank you. The second question is a quick one. Using the codes, can you identify the days that these patients are on PVAD? And that might give us an even further idea whether there is a lot of bias between these three groups.

Mr. Maigrot:

This is a great question, and something we hypothesized would be different, and something we attempted to look at. I think one of the limitations of the NIS in this patient population is that the removal procedure is not always necessarily coded accurately. And so, when we calculated the length of device support for these patients, we were only able to do it for about 38% of the cohort. And so, we did see among these patients that there was no statistically or clinically meaningful difference in the length of time on support between the patients that died and those that survived as well as between the timing groups. That being said, we still speculate and theorize that length of time on support is a critical factor. And with our own institutional data looking at over 200 patients who had peripheral VADs put in, we hoped to be able to kind of characterize this more closely because we do still believe it’s likely contributing to these outcomes.

Dr. Kaneko:

Okay. And the last question is, there’s going to be right-sided PVADs available, and do you think it’s going to have similar implications in the future, as it did in this study?

Mr. Maigrot:

Yeah. The population of patients who require preoperative right ventricular support based on the phenotype of their disease, are not necessarily those we’re going to see become conventional cardiac surgery candidates; rather, they’re ones that might trend more towards the heart failure therapy, VAD, and transplant therapies. And often, these kind of right-sided percutaneous VADs are put in are done in an intraoperative or postoperative setting where that ventricular dysfunction is often a result of the surgery itself, and a little bit hard to predict. So, I don’t necessarily think we’re going to see the prophylactic use of right-sided percutaneous VADs like we see to the level with left ventricular support. That being said, the institutional understanding of how these devices work and the best patient populations indications for them it’s still growing, as they’re fairly new. And so, we’ll continue to evaluate and see these select patient populations where this may be valuable. And so, thank you for that question.

Dr. Kaneko:

Alright, great job answering all the questions. And understanding the limitations of administrative databases, I think this is a great hypothesis-generating study. Congratulations.
Mr. Maigrot:

Thank you.

Dr. Muhammad Faraz Masood (St. Louis, MO):

Excellent job for the presentation at your level, and this is really promising. My question is specifically about NIS use. Our center presented the data about two years ago that there’s 2,200% increase in the use of PVAD. But we had to truncate our analysis in 2015 because it was easier in the cohort of NIS before 2015 because there were only two codes to apply, VA-ECMO and VV-ECMO. There were not all of these devices that you could enter through every vessel in the body. So now coming into 2023, we noticed that 2016 and onwards, the PVAD got split into seven, eight different categories. Did you take that into your analysis as you’re analyzing that? Which category are we looking at?

Mr. Maigrot:

That’s a great question. To devise the analysis in the codes, we used the industry-published codes for billing for their devices in order to capture the use of these devices across the multiple different codes that can be used for them. I don’t know if that answers your question fully. But we did take into account that there are now multiple codes that can be used in specific combinations that are used based on our clinical experience and what the surgeons at our center are using to make sure that we’re accurately capturing these devices.

Dr. Masood:

Because the mortality will be different for somebody who is going for an ECMO to CABG as opposed to a balloon pump to CABG. So those codes have to be identified separately.

Mr. Maigrot:

Yes. I think to add to that further, we did look at patients and actually figure out who was on ECMO and who was on a balloon pump, and at what stage of their perioperative management they were on. So, were they escalated from balloon pump to PVAD? Were they de-escalated from ECMO to more ventricular support with percutaneous VAD? And this is something that will be available in the upcoming manuscript associated with this presentation, but also certainly something that we need to characterize and pay attention to.
Dr. Masood:

Another thing you can do is look at how your own institution codes these things. And if let’s say the code for a balloon pump was 11252.2 and code for ECMO was 11252.3, you could easily identify and apply those to your NIS sample.

Mr. Maigrot:

Exactly. And we have a group that does many studies like this and so we do have some experience making sure to use the correct codes and we’ve developed standardized code sets that we can use it across projects to make sure we accurately capture these patients.

Dr. Craig H. Selzman (Salt Lake City, UT):

Don’t let anybody keep telling you “at your level.” Hey, you’re here. You’re doing an awesome job; you’re one of us.

Mr. Maigrot:

Thank you.

Dr. Selzman:

I might have missed it in this last comment, but none of us wants to put these things in afterward. Nobody wants to put a device in. You think you’ve done a routine CABG, and it isn’t going so well, and you have to do something. And obviously, if you’re having to do something three or four days later, you’re asking yourself, “Should I have done something at the time?” So, can you just clarify the balloon pump issue? Because the balloon pump is kind of the sad guy in the corner that nobody really wants to use. But most of us use it because we don’t want to believe that we did anything that was that bad that you need to put the Impella in in the first place. So, it seems like you should be able to clarify that post- to intraoperative group by trying to figure out: Did they have a balloon pump in before the PVAD went in? Did you have that?

Mr. Maigrot:

So, we didn’t present that here, and it will be in the manuscript, but we did look at the use of balloon pump escalation to percutaneous VAD. This most commonly occurred in the postoperative group who had escalation balloon pump—so they had cardiac surgery, balloon pump, percutaneous VAD, escalation. Which kind of goes right along the lines of what you’re saying. You don’t want to put the device in. The balloon pump goes in, and then you realize it
actually still has to be escalated. And so one of the questions we hope to answer with further studies is how do we avoid that and how do we move those postoperative patients who had to escalate support and crashed into an earlier group where they’re more optimized, more controlled, and can have a higher level of support before that postcardiotomy shock that you’ve seen in needing escalation.

Dr. Selzman:
So, do you have a ballpark number of how many of the folks that got a PVAD postop actually had a balloon pump on the way?

Mr. Maigrot:
I believe it was 30, 40 percent.

Dr. Selzman:
A lot.

Mr. Maigrot:
Yeah.

Dr. Selzman:
Ok. Thanks.

Dr. Edward Soltesz (Cleveland, OH):
Great job. I think what we’re beginning to see with a lot of this work-- and this NIS work was a follow-up to a study we did with the STS Adult Cardiac Surgery Database looking at 44,000 patients who had low EF CABG or CABG mitral-- and we found the exact same phenomenon which is, if you look across no support, preop support, intraop support, or postop support, despite the fact that they all had the same predictive risks of mortality, there was a significantly lower rate of postcardiotomy cardiogenic shock in the preoperative patient group then intraop or postop. So, I think this is all, of course, hypothesis-generating because there’s a lot of granularity of the data that we don’t even have even in the STS database. But I think this study and a number of others that were not even mentioned here lead us to say, “We need to do a randomized trial in this area.”
Moderator:

Thank you very much. A wonderful presentation.