Early Bleed Detection With the Early Bird® Bleed Monitoring System

CLD talks with Amir Kaki, MD, FACC, FSCAI.

Can you tell us about your practice?

I am an interventional cardiologist and perform approximately 500 coronary procedures a year, as well as transcatheter aortic valve replacement (TAVR), MitraClip (Abbott Vascular), and Watchman (Boston Scientific) procedures. I direct the extracorporeal membrane oxygenation (ECMO) and high-risk percutaneous coronary intervention (PCI) program at St. John Hospital in Detroit. We are involved in innovative research for mechanical circulatory support (MCS), including randomized clinical trials, and early feasibility studies for mechanical support devices. We do a lot of ECMO, both veno-arterial (V-A) and veno-venous (V-V), as well as standard PCI. Large-bore procedures comprise about 20% of my practice and the remaining 80% utilize standard access sites.

What is the current role of femoral access in interventional procedures?

Femoral access is here to stay, particularly for patients who present with cardiogenic shock, or undergo high-risk PCI procedures and need mechanical circulatory support (MCS) devices. Femoral access is also important in the structural arena, particularly for TAVR procedures. The use of ECMO is dependent on sheath and cannula sizing, with big being better. Although it would be ideal if we could do everything through the radial artery, femoral access is critically important and will continue to be, particularly for sicker patients and structural heart patients.

Does a large-bore access procedure always indicate the use of femoral access?

The default access for large-bore arterial procedures is the femoral artery. Sometimes the femoral artery is not adequate due to size, or the presence of prohibitive or hostile peripheral arterial disease (PAD). There are alternative access sites including the axillary artery and the transcaval artery, where we can put in large-bore sheaths and large cannulas. Surgeons can cut down on the carotid artery for TAVR. Still, I'd say over 90% of our large-bore procedures go through the femoral artery.

Why is bleeding an important consideration for patients who undergo femoral access?

Femoral access-related bleeding remains a serious complication. While the rate of occurrence continues to decrease, bleeding is still clinically significant and increases the risk of mortality. As a field, we have improved our ability to mitigate bleeding risk when obtaining access in the femoral artery. However, that risk is not zero and it is not negligible. Patients can have large bleeds that result in transfusions, which we know lead to a worse outcome in our patients. Retroperitoneal bleeding is a problem that is often recognized late and can lead to not only a blood transfusion, but death. To this day, people still die of retroperitoneal hemorrhages from femoral access. Retroperitoneal hemorrhage can occur even with small-bore femoral access, i.e., 5 and 6 French sheaths. Pseudoaneurysms are not infrequent, and fistulas do occur in the common femoral arteries. Despite best practices, including increased utilization of ultrasound, the use of micropuncture, and improvements in technique that have been incorporated by operators, complications still occur at the common femoral site. Bleeding remains a concern.

Figure 1. **The Early Bird Bleed Monitoring System (Saranas) detects bleeds the moment they happen, helping to preserve outcomes and provide an additional level of assurance for the patients most vulnerable to bleeding events.**

If patients experience a bleeding complication, how are they managed?

The severity of the complication, particularly as it relates to bleeding, dictates the course for these patients. For significant bleeding, defined by the need for a blood transfusion, patients prognostically have a worse clinical outcome. Bleeding has been shown to triple mortality risk in large-bore access patients.[1] Hematomas can often be resolved, depending on the size, without the need for a blood transfusion. Patients with large areas of ecchymosis experience discomfort and possibly a prolonged hospital stay, but in the long run, will do fine. As the severity of the bleeding complication increases, we know that those who have hematomas or bleeds that require blood transfusions experience an altered clinical course. They will end up staying in the hospital for significantly longer periods, which from a healthcare economics perspective, is more expensive. Most importantly, the outcome for these patients is much worse once they have a blood transfusion.

What are some of the costs that occur alongside serious bleeding events?

When a patient has a clinically significant bleed, meaning a major bleed based on the high bleeding risk (HBR) criteria, they will often end up in intensive care unit (ICU), which is very costly. These patients can end up with repeat procedures, either percutaneous or surgical, to try to repair the bleed. Cost impacts involve direct clinical costs, meaning the cost and the risk associated with the blood transfusion itself, and where the patient stays (the ICU), but also nonclinical costs, involving things such as potential medical-legal liability. This is particularly the case if the patient has an unrecognized bleed, there was poor technique, and there was the presence of any option that could have mitigated the bleed or avoided it occurring. When there are bad outcomes, mainly if the patient dies, you are exposed to a medical-legal risk and tremendous scrutiny into what happened, how the patient was managed, what the implemented mitigation strategies were, and so forth. Severe bleeding complications trigger a cascade of events, both clinical and economic, but also medical-legal liability concerns.

You have been using the Early Bird Bleed Monitoring System (Saranas). Can you describe the system and how it works?

The Early Bird is a very elegantly designed sheath, placed in the femoral vein, with sensors that allow for the detection of bleeding in a radius that is in close proximity to the femoral artery. Using

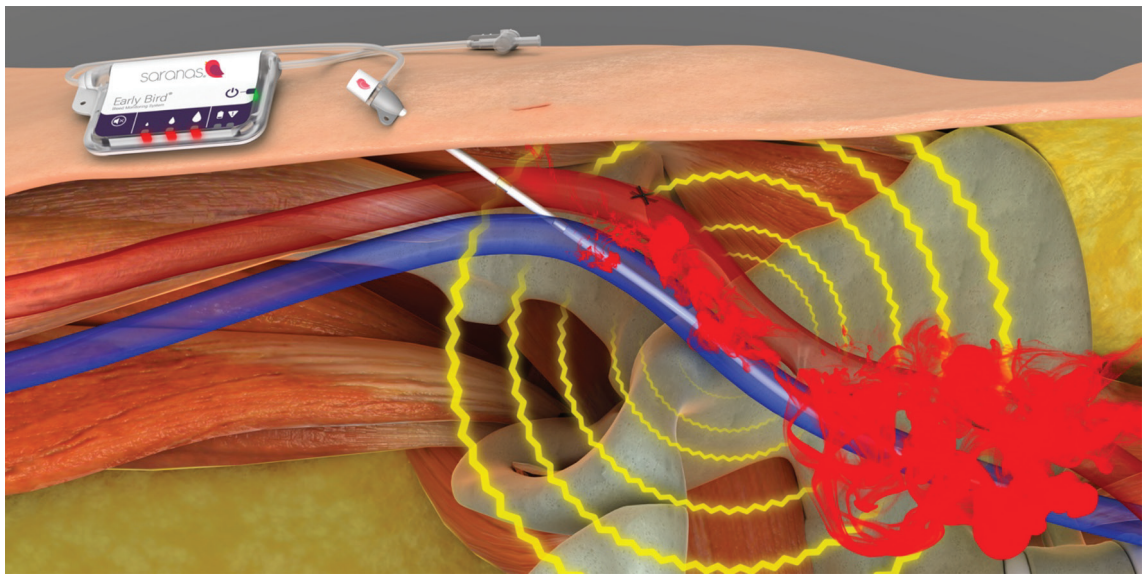

Figure 2. The Early Bird easily integrates into standard workflow. In the femoral vein, Early Bird detects bleeding during both large-bore and standard access procedures and can remain in place for sustained monitoring in the hours following closure.

bioimpedance, the Early Bird lets us know if the patient is bleeding before that bleed is clinically evident to us. It is very sensitive. The system is also very functional, because we often use the femoral vein as an access point for sheaths in a high-risk procedure or TAVR. Since all these patients have a venous access sheath, use of the Early Bird doesn't add any incremental risk, because these patients already are having a sheath inserted, either for the transvenous pacer or right heart catheterization. If we are doing a large-bore access procedure in the right femoral artery, for example, we would use the Early Bird in the right common femoral vein to do the right heart cath or transvenous pacing.

How does the Early Bird alert you to the presence of a bleed?

The Early Bird is designed to detect the onset and progression of bleeds across three levels displayed on the system's user interface display. There is an auditory function on the device as well as a visual one. It will chirp, so to speak, and will illuminate LED lights on the system's user interface display. The duration of the audible tone and number of LED lights also tell us the state or level of the bleed. The information we receive is actionable and offers a clinical advantage. If the Early Bird is chirping at a level 1, for example, then we will examine the groin and probably hold pressure. If the device triggers to levels 2 or 3, we may take a more aggressive approach, such as taking the patient to the cath lab for angiography or further advanced imaging.

How do you decide whether Early Bird use is appropriate in a particular patient?

At present, we are using the Early Bird in the majority of our high-risk PCI procedures. We used to take large-bore access patients to the ICU post procedure for monitoring of their access site. However, ICU beds, particularly considering the impact of the COVID-19 pandemic, come at a premium. Our protocol involves activating the Early Bird post procedure after obtaining hemostasis. The Early Bird stays in four hours post procedure, while the patient is in our post procedure unit. If the Early Bird does not detect a bleed, then the patient is sent to a non-ICU environment. In high-risk PCI patients, using the Early Bird post procedure to ensure safe hemostasis has helped us triage where the patient needs to go and has freed up ICU beds. In our practice, we now send select patients home the same day after a high-risk PCI procedure. If the patient wants to go home, if we had good access, good hemostasis, and the Early Bird didn't identify any bleeding, we send them home. These are patients we would not have sent home the same day historically, but are now comfortable doing so.

What about Early Bird use in structural heart procedures?

In our structural heart procedures, we are using it more selectively, particularly in patients who have high bleeding risk, female patients, those with a low body mass index, patients who are morbidly obese, and the patient population with a predefined high bleeding risk. We have been using the Early Bird in the same fashion as in our high-risk PCI patients. Historically, if TAVR patients had a high bleeding risk, we would send them to the ICU after their procedure, but now, if the Early Bird alert us to any signs of bleeding post procedure, we are sending these patients to the floor.

Is insertion of the Early Bird any different than inserting a standard sheath?

Insertion is no different than for any standard sheath. At present, the Early Bird comes in 6 and 8 French iterations. We predominantly are using the 8 French, because we use pulmonary wedge pressure and Swan-Ganz catheters, which typically need a 7 or 8 French compatible sheath. For our transcatheter aortic valve patients, when we have 5 French transvenous pacing, we will use a 6 French Early Bird.

What about Early Bird use for periprocedural bleeding?

We are still trying to determine the highest value use of the Early Bird. Right now, we find it to be most valuable when activated post procedure. The device is designed to be sensitive to blood loss. Peri procedurally, blood loss sometimes occurs during exchanges. We found that the Early Bird would alert us while we had direct visualization, a right heart cath, and had lots of information that could help us evaluate for the presence of bleeding. As a result, we now insert the Early Bird, use it as a standard sheath, and activate the system after hemostasis has been achieved. I like to think of it as a watchdog, watching over our access site.

It sounds like the Early Bird can bring some peace of mind.

It helps us with peace of mind, but new products in the cath lab must also add clinical value. We act on the information that is given to us from the Early Bird and make decisions based on that information. It offers real clinical value for us. If the Early Bird is not chirping, then I feel comfortable sending the patient to telemetry. If the Early Bird is chirping or we have had problems with the groin access site, then I send that patient to the ICU environment. Prior to our use of the Early Bird, we would send all these patients to the ICU. That was our practice, because having a bleed from a large-bore access site that was unrecognized or potentially happened on the floor could be catastrophic, if not fatal. The Early Bird has changed our practice. We have leveraged this technology to help us evaluate and triage where patients go.

Can you share an example of a patient where the Early Bird alerted?

The good thing about our protocol is we are alerted early on, when patients are in an environment where staff understand and know how to deal with bleeding. The last time the Early Bird alerted us was in a patient who had undergone a high-risk PCI. The Early Bird chirped at level 1, indicating mild bleeding. A fellow then came over and held pressure. We have been fortunate that we have not had a catastrophic bleed alert by the device. There have been low levels of bleeding, where a fellow, experienced nurse, or physician would then hold pressure on the groin. The intent of the technology is to notify us early, before these bleeds become clinically significant.

How has use of the Early Bird affected clinician and patient satisfaction?

I have been very satisfied, because I am able to perform cases in an environment where resources were scarce, staffing was scarce, and with relatively

high assurances that these patients would not go to the ICU. The Early Bird has allowed me to take care of patients that I might not have otherwise been able to take care of because of a lack of ICU beds. Patients are also skeptical about staying in the hospital any longer than necessary. If we feel it is safe for them to go home the same day after their high-risk PCI, they are happy. I haven't met any patient who has resisted going home early when we decided to discharge them. From a patient satisfaction perspective, from a staffing perspective, from a resource utilization perspective, the Early Bird has been very helpful.

When you first introduced the system, how did you do it?

The Early Bird system is intuitive, so it is not a hard device to learn. We in-serviced all our cath lab and post-op holding staff, which did not take much time and we signed off everyone successfully. We found that staff appreciates and embraces the use of the Early Bird as an extra layer of safety. They know if something bad happens at the access site, they will be alerted. Our ICU staff is also happy that our patients are no longer automatically directed there, because they, particularly coming out of the pandemic, are under-resourced and understaffed.

Do you have any suggestions for labs interested in adopting the Early Bird?

Try it out and see how the Early Bird fits in your program. High-risk PCI cases and transcatheter aortic valve patients are great ways to start, as these are both very controlled procedures. We actually learned about the Early Bird protocol of monitoring these patients post hemostasis from Dr. Philippe Généreux, who led the initial clinical trial of the Early Bird. The Early Bird has added value and efficiency to our program and improved our cost effectiveness in caring for these patients. I encourage operators that do high-risk PCI and TAVR to see how the Early Bird helps throughput and improves safety for their patients. The Early Bird has been a good addition to our toolbox for large-bore arterial patients. ■

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Reference

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