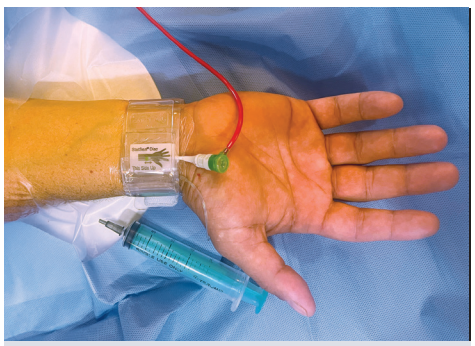
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CLINICAL UPDATE

Independent Investigations of the StatSeal Hemostatic Patch to Aid Same-Day Discharge on Two Continents

CLD talks with:

ARCH Trial Senior Investigator Professor R. H. Stables, MA (Cantab) DM Oxon BM BCh (Oxon) FRCP (London);

STAT2 Trial Principal Investigators Jordan G. Safirstein, MD, and Arnold H. Seto, MD, MPA.

Part I: ARCH Trial Senior Investigator Professor R. H. Stables, MA (Cantab) DM Oxon BM BCh (Oxon) FRCP (London), Liverpool, United Kingdom, describes his experience with same-day discharge and the ARCH trial[1], presented at the 2022 EuroPCR conference. Trial results allowed Liverpool Heart and Chest Hospital to implement a post procedure 2.5-hour minimum observation time for radial access same-day discharge patients.

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In This Issue

Effective Followership: What It is and Why It's Important

Morton J. Kern, MD

In any organization, including the cardiac cath lab, there is a life cycle of success, failure, and optimal/suboptimal performance that waxes and wanes over time. The causes of this cycle are multifactorial. The lab you work in today is not the same as the one you worked in 5 or 10 years ago (and may be better or worse). It is likely the same people are not working in the same place. The composition of the team is continuously evolving, always made up of different personalities. Moreover, changes beyond our control can impact operations, the institution as a whole, and the quality of the leadership.

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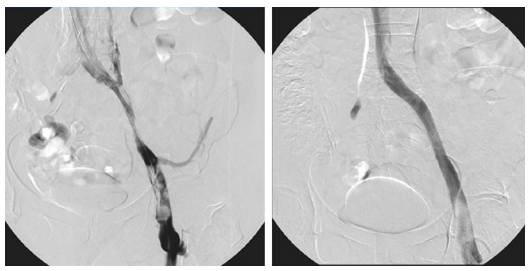
ACUTE VENOUS INTERVENTION

The Use of the Aspirex™ Thrombectomy System for Iliofemoral Deep Vein Thrombosis

CLD talks with Michael Lichtenberg, MD, FESC.

How are you treating iliofemoral deep vein thrombosis?

Our practice for acute iliofemoral deep vein thrombosis (DVT) is to perform mechanical thrombectomy. We are not performing thrombolysis therapy any longer and the reason is simple: we want to be efficient and we want to treat safely. Mechanical thrombectomy is much safer than local thrombolysis and has replaced the use of thrombolysis for many years now.



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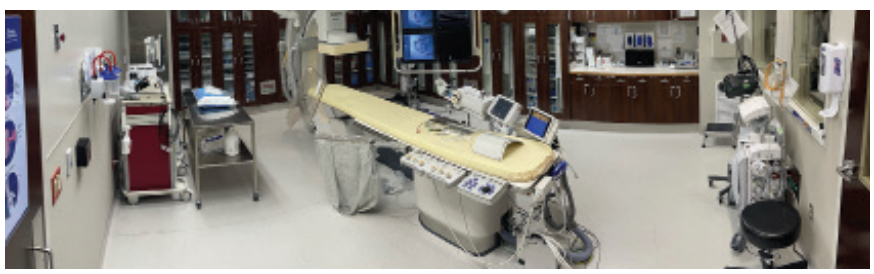
OUT-OF-HOSPITAL CARE

A Hybrid Office-Based Lab (OBL)/Ambulatory Surgical Center (ASC) on the Cutting Edge: HeartPlace

CLD talks with Timothy Dao, MD, FACC, and Rikesh Patel, MD, FACC about their practice and the best-in-class technology they utilize to provide high-quality cardiac care.



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Continued from cover

Independent Investigations of the StatSeal Hemostatic Patch to Aid Same-Day Discharge on Two Continents

CLD talks with:

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Part I *continued*

Why is same-day discharge such a useful concept?

Same-day discharge is popular with patients and it is efficient for hospitals. Ultimately, it reduces healthcare costs. Cardiac units like it, because when they operate day care facilities, other departments cannot co-opt their beds. Particularly in the U.K. environment, if the emergency department receives unprecedented demand overnight, a cardiology department can arrive the following morning to find its beds full of flu or COVID patients, and planned cardiology procedures are then canceled. The day care facility, particularly if it is lounge-based, tends to remain inviolate, which allows you to process predictable work continuously. We were able to continue to offer cardiac services even while facing the COVID pandemic, because our patients didn't occupy traditional beds.

In order to offer day care (same-day discharge), institutions must to determine how late in the day cardiac procedures can still be done while allowing patients to go home the same day. It is a value judgment depending to some extent on the population you serve and the nature of your geography. For example, Liverpool serves a population of 2.4 million people in a densely packed, urban area, where all of that 2.4 million are probably within 90 minutes of home by road travel. If I discharge my patient home at 8 or 9pm, their ability to arrive home at a reasonable hour is credible. If you are located in some wild part of Canada or in certain areas of the U.S., patients might live up to 5 hours away, and so same-day discharge might be less doable. In Liverpool, we wanted to allow people to be leaving the institution at 8 or 9pm at the latest, and to continue performing procedures until perhaps 6pm. In order to do so, we have to be certain that the patient is in a good, safe physical and mental state to venture home after as little as two to three hours. At the end of the procedure, almost every operator, and to a certain extent, almost every patient, will be able to make a very simple decision. Has this procedure gone sufficiently well, in all respects, so that this patient is a candidate for early discharge, or not? There will be patients where the clinical details have not been quite so smooth, you have concerns about the conduct of the procedure or the nature of the hemostasis, or something else. Concerns like these will affect as many as 15% of the clinical population. By retaining these patients in the hospital overnight, you keep an eye on those at potential risk, and the other 85% can then enjoy the tremendous convenience of being managed as a day case, with very little incremental risk.

Figure 1. **The radial recovery lounge at Liverpool Heart and Chest Hospital, Liverpool, U.K.**

Why did you conduct the ARCH trial?

Securing hemostasis at the arterial puncture site was commonly preventing or interfering with our early discharge of patients. As a greater proportion of patients undergo more complex interventions where they are loaded with antiplatelet agents and receive full-dose heparin, then there is a greater risk of difficulties in achieving hemostasis. We would stop performing angioplasty procedures at our center as early as 3:30 or 4pm, when in fact we would have liked to do procedures right up until 6pm. We conducted the 2114-patient, single-center ARCH trial[1] (which, interestingly enough, mirrored almost exactly the results of the STAT2 trial conducted in the United States by Safirstein et al[2]). The Assessment of Radial Artery Complications Whilst Achieving Rapid Hemostasis (ARCH) trial was a classic, open-label randomized trial, done in a single center and was based in our lounge-style care facility (Figure 1), where patients ambulate in their own clothes and there are no beds.

We had approximately 700 patients in each of 3 groups:

- A conventional absorbent dressing with 2-hour compression;
- A conventional absorbent dressing with 1-hour compression;
- A StatSeal (Biolife, LLC) dressing with 1-hour compression (Figure 2).

Compression was provided across all groups by the TR Band (Terumo). Rate of failure (Figure 3) was the proportion of patients who had to go beyond the 1 or 2 hours of compression:

- In the 2-hour compression group with conventional dressing, 50% failed to achieve hemostasis within that time period;
- In the 1-hour compression group with conventional dressing, 60% failed;
- In the StatSeal group, however, only 5% failed to achieve hemostasis within the 1-hour time period.

Not only does StatSeal achieve hemostasis in less time, but it did so in a remarkably consistent manner across the entire population. We can be certain that we will not have hemostasis problems by two hours and confidently use an expedited discharge time.

International surgical guidelines indicate that a surgical wound should be cleaned and dressed

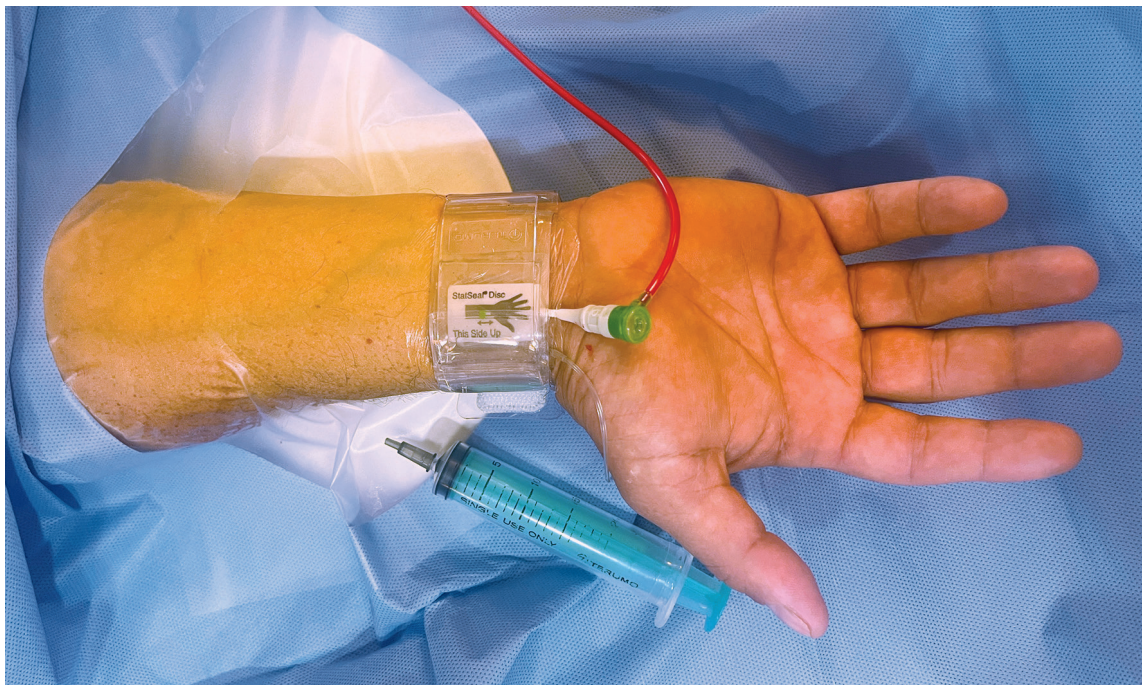

Figure 2. **The StatSeal Advanced RAD Disc (Biolife, LLC) being used in conjunction with a TR Band (Terumo).**

with a bio-occlusive dressing in the environment in which it was created. Ideally that dressing, in the absence of complications or overwhelming bleeding, should not be disturbed until natural endothelialization of the wound occurs, which provides a biological seal against an external infection. We have incorporated this same process for our patients. Immediately after the procedure, we place the StatSeal on the wound, place the TR Band (Terumo) externally on top of the bio-occlusive dressing, and then pull the sheath. It saves nursing time, because the wound is dressed in the cath lab, once, at the time of sheath removal, and the dressing remains in place. The compression band is later removed by simply undoing the velcro patch and the patient goes home with the StatSeal in place. Patients keep it on for a day or two until it falls off, by which time the site has healed over.

More than half of the patients had an angioplasty, percutaneous coronary intervention (PCI), pressure wire, or another intervention done in the coronaries. All were anticoagulated with heparin. Patent hemostasis was attempted in more than 99%. We also measured whether the TR Band was actually taken off at the designated time. For two groups, the target time was 60 minutes, and for the remaining group, the target time was 120 minutes. The people who attempted the TR Band removal were within a median of five minutes, so they did adhere to the timings, and 96%-97% of patients were assessed for radial patency. I am very proud of our clinical team. They are very disciplined, not only in terms of adherence to a trial protocol but also in terms of the quality and consistency of patient care.

The radial lounge closes at 8pm, and if a patient cannot be discharged because they are not ready, we have to transfer them to a traditional ward. Transfer occurred in about 3.9% of the conventional dressings group, but only two people out of 700 in the StatSeal group had to transfer to the traditional ward. When doing a randomized controlled trial, you cannot enforce a design which deliberately disadvantages one group, so no one was enrolled in the ARCH trial if their procedure took place within three hours of the day ward closure time. If someone was randomized to two hours closure but there was only one hour left until the 8pm lounge closure, I am enshrining (in terms of the trial) their certain failure for the study outcome. Without the 3-hour safety net of the trial, real-world overnight stays could actually be more frequent. Within the context of the trial, about 1.5%-2% of patients ended up staying unnecessarily overnight — just for reasons of radial site care.

Can you describe the concept of patent hemostasis?

Patent hemostasis relates to the desire to reduce subsequent radial artery occlusion. It is vital in a trial of a hemostatic patch to learn about radial artery occlusion rates. We were able to achieve low radial artery occlusion, in keeping with the best values achieved internationally and reported at the moment, and that are in keeping with our institution's current norms. We have charted an institutional improvement in radial artery occlusion over 12 years, from 8% to 0.5%, achieved by systematically introducing measures such as, for example, every patient must get heparin and the smallest possible sheath size must be used. The latest change, which is a critically important measure, is a focus on patent hemostasis. In patent hemostasis, when the compression device is on, there must be no overt bleeding, because that is unacceptable. Ideally, however, it is good to have some flow down the artery to maintain a consistent flow pattern, promote patency, and deliver clotting factors to the puncture site. To achieve this goal, we first put an oxygen saturation probe on the thumb. When the TR Band is placed for maximum compression of the radial artery, there is still blood supply to the thumb due to the ulnar

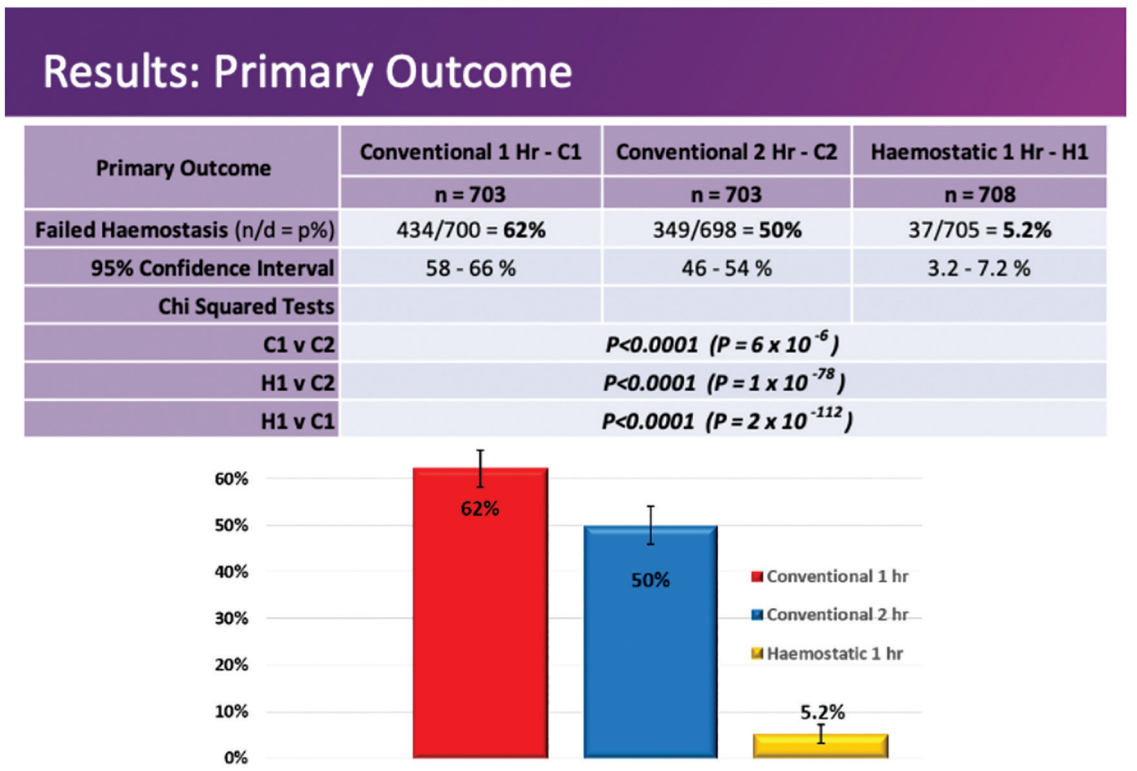

Figure 3. **The primary outcome showed a substantial advantage for the hemostatic dressing with only a 5.2% rate of failure after 1 hour of compression. In the other groups, 50% and 62% of patients required re-application of radial compression because of failure to achieve hemostasis during the planned compression time. Unsurprisingly, the differences between the groups have a high level of statistical significance.**

artery and palmar arch. We manually compress the ulnar artery, get a flat line, and maintain that manual compression while gradually reducing pressure at the radial artery until just there is just the beginning of a blood flow return. At that point, we have the maximum pressure on the radial puncture site, yet compatible with some flow down the radial artery. That is patent hemostasis. I was actually a big opponent of patent hemostasis for a while and I used to put on the compression device, and let air out of it gradually, in tiny, tiny increments, observing the puncture site until I saw it just begin to bleed. Then I would put a little bit more air compression in and leave it at that. When people said, "No, you need to use a sat probe. You need to do patent hemostasis," I would respond, "I want to promote flow in the radial artery. I currently have the minimum pressure that it is possible to exert without actually bleeding. You can't do better than that." But I was wrong. While I left the patients with the minimum pressure compatible with not overtly bleeding, these patients would then get off the cath lab table, walk back to the lounge, have a cup of coffee, laugh with their friends, and their blood pressure would go up a little bit and then potentially they could start to bleed. I had the minimum pressure compatible with not bleeding when I put the device on, but as their blood pressure became higher, the patient would bleed.

You want to achieve the maximum pressure compatible with tiniest amount of flow, because then you are going to withstand blood pressure increases later and can minimize rebleeding. The concept of patent hemostasis forms part of European Society of Cardiology international guidelines, and has a very strong biological plausibility and evidence base. You have to train people to do it and at our center, it has to become the norm. Once people realize that they are preventing occlusion of the radial artery, there is a very strong incentive.

Did you analyze cost in the ARCH trial?

We have worked out that we would be able to save money by using StatSeal. It is starkly cost effective mainly via its ability to avoid ward transfers and overnight stays.

There are other spin-off benefits, including patient certainty, because bleeding at the puncture site is upsetting and distressing. Nobody likes to see their own blood or feel that something isn't going well. Also, the management of these events, quite apart from the emotion, consumes quite a lot of nursing time. If you simply just remove the velcro band and say, "Thank you, that's brilliant, let's crack on," that saves so much time so that you can then invest the time and energy in other things.

Have you expanded use of StatSeal beyond patients planned for same-day discharge?

We are focusing just on the day ward arena at the moment, because everything is cost-based in the U.K. If a patient will be in hospital for a week anyway, it is harder to show a cost advantage by saving a couple of hours in one evening. You could restrict StatSeal use to the latter half of the working day if you wanted to emphasize cost-effectiveness, but, actually, that idea ignores other critical benefits from StatSeal use, such as in order to keep your lounge-based facility attractive, you do not wish it to be overcrowded. We stagger admissions throughout the day, but it gets crowded as the day goes on unless you are discharging the earlier patients, so there are spinoff benefits to StatSeal use that you need to consider.

Any final thoughts?

The ARCH trial took place from June 2020 to Jan 2022. We were able to randomize 2000+ people over 19 months while dealing with COVID limitations. The ARCH trial is the largest randomized, controlled trial to date that tests hemostatic dressings. Many trials report some marginal gain or benefit, but in the ARCH trial, we have shown the ability to achieve gains that are overwhelming.

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Professor R. H. Stables, MA (Cantab) DM Oxon BM BCh (Oxon) FRCP (London)

Consultant Cardiologist, Liverpool Heart and Chest Hospital; Hon Professor of Interventional Cardiology, University of Liverpool; Clinical Lead, British Heart Foundation Clinical Research Collaborative

Professor R.H. Stables can be contacted at rod.stables@lhch.nhs.uk

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Part II: *CLD* talks with Drs. Safirstein and Seto about their plans to follow up on the success of the STAT2 trial[1,2] with the Hemostasis, Educate, Ambulate, and Medicate (HEAM) trial, along with a review of 10-year American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) data around timing of post procedure radial access complications.

Tell us about starting up the HEAM trial and your plan to evaluate timing of radial access complications by looking at 10 years of NCDR data.

Jordan G. Safirstein, MD: We hope the HEAM trial will confirm that discharging patients based on a metric-based protocol as opposed to a defined time point is actually very safe and a preferred methodology. We plan to start collecting data in the first quarter of 2023.

Research has shown almost no radial complications occur between 6 and 24 hours post procedure. Since most complications occur before 6 hours, it has become a defining time point for discharging patients the same day. In evaluating 10 years of NCDR data, we similarly expect to find that radial access patients who experienced significant complications had those complications take place within 4-6 hours of their procedure. The goal is to define the time points when those complications occurred within that window.

Arnold H. Seto, MD, MPA: The EASY trial[3] from Olivier Bertrand and colleagues used a 4-hour protocol for discharge and other trials have used 6 hours. It has been proven that 6 hours is a safe window and our goal is to make it even shorter, ideally 2 to 2.5 hours, which is what the ARCH trial[4] from Dr. Stables demonstrated recently with use of the StatSeal (Biolife, LLC). In Olivier Bertrand's editorial[5] accompanying publication of the STAT2 trial, he noted that after percutaneous coronary intervention (PCI), we normally hold patients for 4 hours, because of an ischemic risk. But that hold is actually not evidence-based. No one actually knows if there is an ischemic risk to discharging at 2 hours versus 4 hours, so that will be the subject of the NCDR study: when are these complications actually happening? We know it is within 6 hours. Most likely, it is actually in the first hour, because bleeding from the access site typically happens in the first hour. Bleeding is the most common access site complication. The gray zone is at around two hours after the procedure, when people are coming off heparin and often being loaded on a P2Y12 inhibitor. There is a gap where someone might be coming off their heparin and not yet be fully inhibited on their P2Y12, so that is where we want to see if complications happen and if so, is the timing at 2.5 hours? 2 hours? 1.5 hours? I think that Dr. Safirstein's large NCDR database review is essentially the only way we can resolve that question. You can't randomize people because the complication rate is so low.

Jordan G. Safirstein, MD; Arnold H. Seto, MD, MPA

[1]Medical Director, Cardiac Catheterization Laboratories, Morristown Medical Center, Morristown, New Jersey; [2]Section Chief, Cardiology, Long Beach VA Medical Center, Long Beach, California; Director of Interventional Cardiology Research, University of California, Irvine, School of Medicine, Irvine, California

It is much better to take the actual people who have had complications and to see at what time those complications occurred.

Dr. Safirstein: We do about 3000 PCIs at Morristown Medical Center a year. We will be screening 10 years of patients; maybe there are 1% with significant enough complications to merit inclusion.

Dr. Seto: Multiply that by 10 years and then you have 30,000 patients to draw from, and if you have a 1% chance of a complication of a serious nature, then it is about 300 people. Even with radial access, you might have a 2% to 3% chance of a hematoma. You are still talking about good numbers and it will probably be one of the largest studies done on radial complications to date.

Can you talk more about the planned evaluation of a metrics-based versus time-based protocol to discharge in the HEAM trial?

Dr. Safirstein: HEAM is an acronym for hemostasis, education, ambulation, and medication. Patients will complete all four of those aspects. There is a protocol explaining what is going to be done at what time for each of the 4 metrics. When we were discussing the protocol at our institution, people kept saying, "We're looking to accelerate discharge," but I want to stay away from that term because it implies we are trying to push people to discharge, and that is not the case. We are not trying to accelerate anything. What we want to do is discharge patients safely, at the right time, and if they are staying in the hospital unnecessarily because of the lack of data to support safe discharge, then we want to show that, but by no means are we trying to accelerate discharge beyond what is safe. We are trying to demonstrate that it is safe to discharge via a metric-based protocol rather than saying, "Six hours is what the data says, so everyone stays for 6 hours."

Dr. Seto: In the Society for Cardiovascular Angiography and Interventions (SCAI) guidelines[6], we talk about length of stay in a milestones-based approach. Has the patient received their P2Y12 inhibitor? Is it in effect? Is their access site stabilized? Are they at their baseline? Did they get education on their medication compliance afterwards? If you are able to achieve all those milestones, then instead of saying that everyone stays for at least 4 hours or 6 hours, then you can conceivably discharge patients earlier if they are stable. Finding that safe time limit is really the question, and I venture to think that it is somewhere around 2.5 hours, which is what the ARCH trial suggested. Dr. Stables has said that their new protocol is to go to 2.5 hours after every PCI, if procedure was uncomplicated and the post procedural care in all its aspects was completed. Here we have someone implementing not a milestones approach but rather a shorter time approach, and we believe our research will probably end up showing around the same time, around 2 to 2.5 hours. For every patient, it is going to be different. I have a patient who was preloaded a week before on clopidogrel and was therapeutic. As soon as hemostasis occurred, one of my nurses followed my protocol and actually discharged him at 1 hour, so that was maybe unexpected, but perfectly acceptable according to the SCAI guidelines. Another patient who might have come in and only received clopidogrel after their procedure, where we know that it can take up to 6 hours to be therapeutic, might take longer for a safe discharge. If someone uses prasugrel or ticagrelor on an elective patient, that time again might be shortened. We have to think pharmacologically and physiologically about what makes for a safe discharge. These are the parameters, along with hemostasis, education, and ambulation, that are in my mind when evaluating my patients for discharge.

"In the Society for Cardiovascular Angiography and Interventions (SCAI) guidelines[6], we talk about length of stay in a milestones-based approach.... If you are able to achieve all those milestones, then instead of saying that everyone stays for at least 4 hours or 6 hours, then you can conceivably discharge patients earlier if they are stable."

— Arnold H. Seto, MD, MPA

Are your protocols similar between both your institutions in terms of use of the StatSeal post intervention with TR Band (Terumo) compression?

Dr. Safirstein: The protocols are probably technically similar in the device realm, as in how we apply the device and when we take it off. Probably where the protocols differ is in our institutional policies. We have some institutional policies in place that make it challenging for us to move to milestone-based discharge. One easy way for us to overcome that is to explore it in the setting of a trial. The other way is to try to change those protocols. I am not sure if you have ever tried to change protocols at a large institution. It can be like banging your head against a wall sometimes, but other times it is like chiseling through a wall where you make slow progress and eventually get to the other side. We are doing that, but also, we are doing a trial. It was the same situation with the implementation of StatSeal. If I came to our lab that does 3000 PCIs and 5500 caths in a year and just said, "I want to use this new device. What do you think? It's FDA-approved. Everybody's using it," no one would use it. Literally, I would be the only person that would use it, but with the help of Dr. Seto, we did the STAT2 trial. Not only did we enroll the most patients at Morristown, but in that process, we educated a lot of the physicians and staff, and the trial demonstrated success. Our same-day discharge patients were leaving earlier. They were having their TR Band taken off at an hour after PCI, which was unheard of. When people saw that, it gave them the confidence to go ahead and use the StatSeal outside of trials. A trial, although hard work and involving a lot of planning, can also be a good way to introduce successful techniques into an institution that has been doing the same thing for a long time. Our people had a vested interest and took ownership. It was awesome and by the way, 99% of our PCIs now use StatSeal, and it is the same for our diagnostic caths. This is true for almost every one of our patients, not just at Morristown Medical Center, but at almost every Atlantic Health Institution across the board. StatSeal has become the dominant hemostasis strategy because we demonstrated its effectiveness.

Dr. Seto: I second that. At my institution, all of our outpatients are getting StatSeal. The cath lab staff give the StatSeal to us on the table right away, and that is a change in our practice.

I don't necessarily use StatSeal on inpatients because they are going to be discharged hours later and the floor nurses can't always be on top of it. No one has done a head-to-head trial of a 2-hour or a 4-hour TR Band deflation compared with a 1-hour StatSeal plus TR Band deflation. There is a risk that with a shortened deflation that you might have a few more complications compared with a 2-hour deflation. The ARCH trial did find a slight difference between these 2 groups. I think that the prudent and maybe the more cost-effective thing to do is leave the TR Band on for 2 hours if it is an inpatient. My nurses are at a 1:8 ratio on the floor. They are not necessarily going to be able to check

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— Jordan G. Safirstein, MD

the site should they deflate the TR Band early, and then a hematoma might form 30 minutes later.

Dr. Safirstein: There were a lot of people that said, "Why do we need it? We're already doing a great job. We don't have a lot of complications." There is a difference between an accepted number of complications and "not a lot" of complications. For a long time in the femoral space, people said, "Yes, 5% is the accepted rate of femoral access complications. You get a hematoma. That's what's expected. Sorry. You're one of the 5%." But then, people realized, we don't really have to accept that. We can use ultrasound guidance and best techniques to reduce that number. Then we realized we can go radial and reduce complications almost completely. That was hard to get people to do, but data started coming out showing that you can do the same PCI and have 0% access site complications. Then people started to say, "Maybe I should consider radial access," because having a certain amount of femoral access complications was no longer accepted; it is not the standard anymore. A similar paradigm has developed now, where people became comfortable doing what they are doing and saying, "Yes, but the standard is 4 hours after diagnostic and 6 hours after PCI." Why change? They're not having complications. Their patients aren't complaining. The nurses aren't saying anything. But I do believe there is room for improvement.

Dr. Seto: There is definitely room for improvement, which is what we are all aiming for. It is just a matter of people taking up the mantle, with all the advantages we are pointing to, and trying it out. The practicality is a huge advantage for same-day discharge, and once people try it, once their nurses try it, I think people will like where they end up. We are excited for the future.

Dr. Safirstein: Staff will now inform me when someone is not willing to use StatSeal because it is such a major benefit to our lab for throughput and flow. There is a small learning curve, just as there was a learning curve to applying the TR Band initially, but once that quick and easy learning curve is completed, it brings a wonderful amount of buy-in and support. We have been able to replicate this protocol across all the hospitals in our system. When the patient comes out to our holding area, the first person that greets them usually takes that first 3.0 cc out of the TR Band because it usually has already been 15-20 minutes since it was placed. Then the patient is ready to go to cardiac access and eventually have the remainder of that compression removed. Whenever that protocol doesn't happen, we now get pushback, which is lovely because we were getting so much pushback when we tried to do it initially. We have staff buy-in. Staff members are happy because using StatSeal means predictability. They know they won't have to go back in and fuss around with the TR Band or reinflate it, and deal with a radial artery issue or complication. ■

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In the Literature: *CLD* Editor's Picks

JOURNAL OF Invasive Cardiology

A Visual Depiction of Left Ventricular Unloading in Veno-Arterial ExtraCorporeal Membrane Oxygenation With Impella

Lina Ya'Qoub, MD; Alejandro Lemor, MD; Mir Babar Basir, DO; Mohammad Alqarqaz, MD; Pedro Villablanca, MD

Left ventricular (LV) unloading has been associated with improved survival in patients treated with venoarterial extracorporeal membrane oxygenation (VA-ECMO).[1] This case visually demonstrates the effect of LV unloading in a 30-year-old male with a history of COVID-19 myocarditis.

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Value of Outpatient-Based Labs for Endovascular Therapy of Peripheral Artery Disease: The Cardiovascular Institute of the South Experience

Sarah Melvin, MSPH; Pradeep Nair, MD

The purpose of this review from the Cardiovascular Institute of the South's office-based lab experience is to investigate the safety, efficacy, and patient outcomes of lower-extremity endovascular intervention in patients with symptomatic peripheral arterial disease. Subjects that underwent a peripheral arterial intervention in the OBL setting from 2018 through 2020 were included in the study.

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