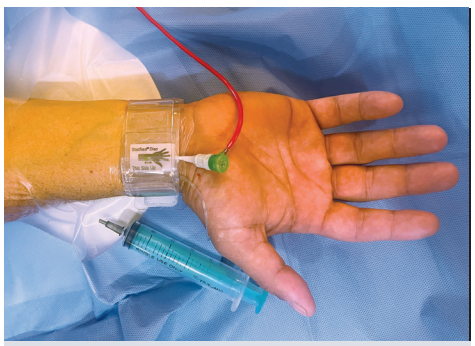
Cath Lab Digest

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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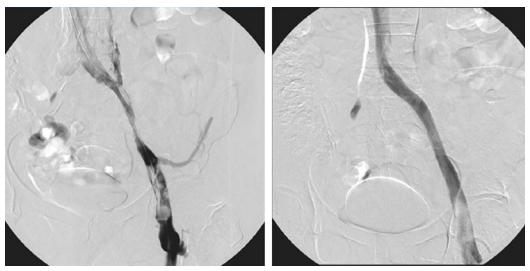
ACUTE VENOUS INTERVENTION

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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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.

Can you tell us about HeartPlace?

Rikesh Patel, MD: HeartPlace is based in North Texas across the Dallas Fort Worth Metroplex, and we are one of the few large independent cardiology practices left in the country. Our group has about 55 doctors and includes advanced practice providers. We have 29 clinics and cover a broad geography. I have been with HeartPlace since 2014.

Tim Dao, MD: I am starting my sixth year with HeartPlace. I joined because I wanted independence. I wanted something where I had a say, where I would be able to help advance the organization, as well as be my own boss and dictate my schedule while still helping patients. HeartPlace is well respected in the community and nationally, so it was a perfect fit.

Dr. Patel: We are a big group, so sometimes change is slow, but if we want to grow something, we can grow it, and if we see an opportunity, we can take it. Sometimes in an employed model, your voice is much smaller, and the ability to change direction on a big ship is harder. I think this idea is reflected in our group having an ambulatory surgical center (ASC) outpatient cath lab. It is unique, particularly in this market, in terms of having functioning high-volume outpatient labs. Having an ASC allows us to deliver care more efficiently, at a lower cost, and offer a better patient experience. We have two outpatient facilities that are hybrid (office-based lab [OBL]/ASC) labs. Originally when the facilities opened, we had more OBL procedure days. We have shifted gradually over time to holding more ASC procedure days, dictated by the types of procedures and the volume required in order to get patients scheduled and taken care of efficiently.

Can you tell us more about the procedures performed in your outpatient facility?

Dr. Dao: We perform a large number of peripheral interventions in addition to coronary and EP (electrophysiology) procedures. I send almost all my peripherals to the outpatient lab because of its ease of scheduling in a timely fashion, patient comfort, and quality care. Patients don't want to go to the hospital if they can avoid it. I think they appreciate being able to go to an outpatient facility and they think very highly of it.

Dr. Patel: We do below-knee work, including tibial interventions, and typical superficial femoral artery (SFA) / popliteal and iliac interventions. There are physicians who do venous stenting, specifically iliac vein stenting. Both of us have done filter placements and filter retrievals in the lab, so we do venous work as well as arterial. Our interventions include peripheral atherectomy, whether it is rotational, orbital, or laser atherectomy. Our coronary work also spans a broad range, including the use of atherectomy. Some selective bypass graft cases have been done there safely. It is a good variety.

Dr. Dao: Any of our pre-transcatheter aortic valve replacement (TAVR) work typically will be done at the ASC, such as the prediagnostic workup and any intervention to revascularize the coronaries prior to TAVR. Then we will either send the images, or some of the TAVR centers have access to our PACS, so they can actually look at the images themselves and incorporate that information into the TAVR evaluation when the time comes.

Dr. Patel: Unless you feel like the patient has too many comorbidities to be safely treated in the ASC setting, which is rare, you can do a diagnostic cath and intervention if needed in an outpatient lab. For some of the complex coronary work, it is probably better to use some judgment and do it in the hospital where there is the ability to observe or admit the patient afterwards if necessary, but it is up to the physicians who come to the lab to make those decisions. If there are questions, it goes under the purview of the medical director of the ASC. Along those lines, I would add that one thing that makes these labs successful is strict attention to safety, efficiency, and cost. If there are fairly complex cases that we know are going to be prolonged, where we are going to need a lot of equipment or need to block off a significant amount of time, those cases are best done in the hospital, because from a time perspective, it doesn't make sense to do that type of case in an ASC setting. It wouldn't follow the ASC model of providing efficient care that gets patients in and out in a timely manner.

Having an ASC allows us to deliver care more efficiently, at a lower cost, and offer a better patient experience.

Figure 1. The Cath Lab at HeartPlace Plano, Plano, Texas.

Can you talk about your use of physiologic measurement and coronary intravascular ultrasound at your ASC?

Dr. Dao: We follow guideline-based therapy and do evaluations from that standpoint. The use of

Figure 2. HeartPlace staff.

invasive imaging and physiologic testing as a way to help decide whether to stent a particular lesion or leave it alone is better for patient care and quality. It is our standard, irrespective of reimbursement changes that may be upcoming. Rather than just stenting only based on a visual assessment, we use technology to our advantage. I've had cases where looking only at the angiogram, I did not think I would need to stent, but have been fooled, and vice versa. We trust the technology for a reason; it has been validated time and time again. It also allows us to do cases in the outpatient setting that would typically occur in the hospital.

Dr. Patel: Since the lab opened, we have been using Philips OmniWire Pressure Guide Wires and Philips Verrata Plus Pressure Guide Wires for assessments, as well as the Philips Eagle Eye Platinum RX Digital IVUS catheter with intravascular ultrasound (IVUS). I use pressure wire assessments where lesions are indeterminate in terms of functional ischemia. Once I have made a decision to stent, I don't do any percutaneous coronary interventions (PCIs) without IVUS. There are two reasons. One is good data showing that using IVUS to guide your lesion assessment and sizing for your stent implant offers a better outcome long term. The second is that I sleep better at night. I know that I placed the right size stent, that it was expanded well, and I didn't see any concerning dissection or anything else surprising like angiographic miss that is going to potentially set the patient up to have target vessel failure in the near future. In peripheral interventions, I also use IVUS routinely for sizing. Cardiologists in particular like to think that they know the size just by looking at something, but until you measure it, you don't know. You get a small person on the table and there is a tendency to say, the SFA must be a 4.0 millimeter (mm) vessel or maybe it is a 6.0 mm visually, but you do the IVUS to get the right size for the patient. The stent will not be oversized, causing the patient to have in-stent restenosis, and it won't be undersized, setting them up for thrombosis or a worse outcome.

Dr. Dao: IVUS allows me to determine how aggressive I should be without being detrimental to the patient and helps in my device selection, if needed. Or it helps me decide if I should choose laser as opposed to another atherectomy device in order to avoid any potential complications like burrs getting stuck in dissections and having to stent when I wasn't planning to do so. All those things matter. We have been fooled in post dilatation, especially down the smaller tibial arteries in diabetic patients. Those vessels look small angiographically, but once you are in there, IVUS measurement can show us, "Wow, this vessel is actually bigger than we thought. We can easily increase the device size and maximize flow." IVUS sizing also helps limit restenosis, so we can avoid having the patient come back, and for chronic limb-threatening ischemia (CLTI) patients, limits any redevelopment of their ulcers, because we do a lot of limb salvage and our intent is to get that wound closed as quickly as possible, and get the patient out of wound care and back to ambulatory status, reducing morbidity and mortality.

Dr. Patel: Additionally, you might think something is plaque, but sometimes it is actually subacute thrombus, and if you don't use IVUS, you could make a wrong decision, risking embolization or other issues. Many of our patients have diabetes, and may also have chronic kidney disease. In these patients, it is especially important to limit your contrast. We will use pedal access and once I put a wire up, I can take limited pictures and use IVUS. I will run it all the way up through the iliac into the aorta, then pull it all the way back. I can see basically every level of that patient's flow to their leg with IVUS and then decide what I need to treat without using more than 5 ccs of contrast. We often finish the procedure and have only used 20 ccs of contrast. It makes things better for the patient in terms of risk to their kidneys, and we obtain the necessary information more efficiently. There are a lot of advantages to using these technologies, whether in a hospital or in an outpatient lab. It makes your cases go more smoothly and gives you a better outcome.

Dr. Dao: Absolutely, I do IVUS-based PCI. Using IVUS for your chronic kidney disease patients who are on the verge of dialysis, you can get by with 30 ccs or less, and feel good about it. Patients can be concerned that they have had other prior interventions and say, "My kidneys were wrecked once before." They don't want to go through that experience again. We tell these patients there is an alternative. IVUS imaging allows us to do their procedure safely, if not better. I can see everything that I need to see with a third of the contrast.

Are there specific aspects of Philips technologies that you appreciate?

Dr. Patel: There is a reason that our physicians chose the Philips Azurion image-guided therapy platform collectively. The picture quality is better than any of the other systems we have used and it offers decreased radiation. We have

Figure 3. Recovery.

Figure 4. Waiting room.

used everything at different hospitals. Philips is definitely preferred.

Dr. Dao: We also request the Azurion in the hospital, too, because for our longer 3- or 4-hour cases, we want to limit radiation both to us and the patient. We have found it worth the investment. It allows us to work more efficiently and safely while dramatically reducing radiation exposure. Not all the other imaging companies out there offer that option. The user interface is great. I play with IVUS all the time and it has gotten better and smoother. It is easier to annotate to show the location of plaque, thrombus, and any dissections. I can use Philips ChromaFlo imaging to further define what I am seeing and then offer these images as a way to show resolution of the problem(s) once we conclude the case. I make sure to re-image and can redo an instant wave-free ratio (iFR) post intervention, because while it looks good on angiography, I want to know the ischemic burden is actually reduced. iFR allows me to objectively prove it in a straightforward fashion.

Dr. Patel: I don't do a lot of post intervention iFR, but I do post intervention IVUS to make sure I didn't miss the lesion and the stent is appropriately expanded. What if your iFR is still abnormal afterwards and you don't feel like the distal target is great? I can use IVUS to decide if the distal target is worth pursuing. I have yet to put a 2.0 mm stent in anyone in over 10 years. I will put 2.25 mm stents in on occasion, but infrequently, because most proximal and mid coronaries are not 2.25 mm. These arteries are usually larger, which is what we are using IVUS to help ascertain. Distally, IVUS will tell us if our stent is well expanded, well opposed, and if there is a significant angiographic miss in a lesion that we might consider treating.

Dr. Dao: If it is a short focal lesion and I put in a 4.0 mm stent, the likelihood of a residual ischemic burden is very low. It is those long, small, diffused tubular lesions, where it is not one focal spot, but is all the way throughout, where IVUS helps me. How far down do I go? How many branches do I compromise and what is the minimal length of metal that I need to put in? With the pullback technology, I try to localize it. Where is the big step up and was it covered? There will be some small-vessel poor distal runoff, potentially, so am I going to make all the ischemic burden go away? Ideally, yes, that is the intent, but at least I covered that main lesion and then we can use medical therapy post. I also use IVUS to see if we need to re-expand the distal portion of the stent to maximize flow, avoiding restenosis or stent occlusion. IVUS lets me know if I have at least adequate runoff.

Do you think there is benefit in having your iFR, IVUS, and imaging system all from Philips?

Dr. Dao: It makes it easier. We have been in institutions where you are subject to whatever is available, and it just eats into the time and probably the cost, too, because you have to switch modalities. You wait to transition to a different imaging or move to a different iFR platform. Then you are opening more equipment from that standpoint. Since we have all Philips equipment, the ease of use of toggling with one click from iFR to IVUS on the same patient case, where all we need to do is swap out the catheter for the wire, makes it so much more convenient. You can also trust there is no variability.

Dr. Patel: I don't see how co-registration will happen between different vendors and I think that is where we will see the benefit in everything being from the same vendor. You will get your angiogram, get an overlay with integrated measurements in real time, and then you can put your IVUS catheter on your overlay. You can use a Philips OmniWire or Verrata Plus Pressure Guide Wire, it will show you on the screen where your gradient is, and then you can line that up with where the plaque is located. This scenario is where a single vendor will have a real advantage. On a simpler level, the ease of use of having all Philips equipment is nice. You can flip things up and down when it's integrated on your screens and that makes it easy. Another note is that for most labs I have worked in, Philips equipment tends to be the most reliable.

How does Philips help you currently?

Dr. Dao: During cases, Philips clinical and support staff are always welcome to attend. They continue to update us about emerging updated technologies and modalities that are available to us. Philips is very accommodating and their equipment is easily upgradable. We may see it in the hospital first and then bring it to the outpatient center, such as with technologies like Philips StentBoost. In the old days of fractional flow reserve (FFR), we saw how slow it was for people to adopt it. Accommodating the need for these technologies has gotten easier with iFR and then IVUS.

We gain a lot of efficiency, and both the patients and providers benefit. We get patients who don't know much about the outpatient lab, have their procedure done there, and come back raving about it because of the staff and the experience.

Dr. Patel: As our outpatient lab has evolved, when we need to upgrade equipment, they are able to help us decide whether we want to upgrade our overlay, IVUS, or one of the pressure guide wires. In the hospital, we have the overlay from the angiogram, but we did not have that upgrade done for the outpatient lab yet. It will come. When things get co-registered with the overlay, then I think it will be something valuable to invest in, because it will reduce contrast and speed up your procedure.

You mentioned Philips StentBoost. What benefits do you see with its use?

Figure 5A-B. The exterior of HeartPlace Plano. Medfinity Health is a group partner.

Dr. Dao: Phillips StentBoost is specific and selective integrative imaging I use to enhance the target lesion of interest, reducing fluoroscopy times. StentBoost allows me to visualize the stent, particularly when there is patient interference, without the need for higher magnification and subsequent radiation. It is a unique technology that I haven't seen on any other systems. I typically use it for post dilation to make sure that I am within the stent margins and am not going to propagate or worsen a dissection outside of the stent. StentBoost makes it easier to see. I don't have to magnify so much and increase the radiation to absurd levels, so it is a nice technology to have that I haven't seen on any other systems.

Dr. Patel: StentBoost is helpful. It makes it easier to post dilate within the stent edge and allows you to be more confident that you are within the stent edge as opposed to being a little outside.

CMS has released a ruling about adding complexity adjusted payments for physiology and coronary IVUS in ASCs. What do you think about this ruling?

Dr. Dao: Would it help improve the adoption of that physiological-based technology? 100%. People will adopt it a lot sooner and you'll see an uptake as a result.

Dr. Patel: It should have been something that was supported by CMS all along. If you are doing something in a coronary artery, whether putting a pressure wire or an IVUS catheter, you are assuming additional risk for yourself and for the patient. You are doing additional work beyond a plain diagnostic angiogram and gaining more information to manage your patient. If you are doing the work, it should be reimbursed appropriately. With regard to adoption, it should help encourage people to spend the time to do what is right for the patient. It's bad that it was disincentivized in the first place. Not paying somebody for doing something that is good for patients doesn't seem like a good idea, and I think encouraged people to skip a step that may result in work that is suboptimal or unnecessary. The big picture they are missing is that CMS may get cost savings as a result. Say you don't use the Philips OmniWire or Verrata Plus Pressure Guide Wire and just stent. It might be an unnecessary stent, which costs a lot more than it would have to use the wire and find out the functional significance. Or had you done IVUS, you may have put in a single longer stent instead of putting in one that was too short and having an angiographic miss, and finding out that you need to add a second short stent. There are real benefits from a cost perspective that are underappreciated. CMS, and therefore, the system and patients have been missing out, I think, on opportunities to reduce overall cost, because if you also do a good job with your stent size and expansion the first time, 3 years or 5 years later, you are not going to have in-stent restenosis. There are opportunities to avoid downstream events that are being overlooked, in a shortsighted attempt to save money rather than investing in what was right for the patient long-term, which itself will ultimately save money. If you are not encouraging physicians or people who are invested in owning their outpatient labs to save on costs — and this is a cost and not adding any revenue — then you are discouraging its use, basically. You are saying it is not of value, especially in a setting where you are trying to bring value. Part of the problem historically is that hospitals have been inappropriately reimbursed at higher rates versus ASCs for the same amount of work. Even without the reimbursements, it is about doing the right thing for the patient.

Any final thoughts?

Dr. Patel: Something we didn't spend a lot of time talking about is how incredibly safe the ASC is for the procedures being done there. Procedures can be done safely if you have operators that are attentive to detail and a good team is in place. The staff we have in our lab is essential to our success. We have very good staff in our lab.

Dr. Dao: We hand-select the best staff we can find. A lot of staff wants to get out of the inpatient setting, particularly in recent years with the changing healthcare landscape post-pandemic. ASCs have become an attractive option for staff members and patients alike, from a quality of life and a quality-of-care perspective. They are happier and we are happier as well. We feel confident that we have the best staff around to safely triage our valued patients, in a superior, cost-effective ASC platform.

Dr. Patel: The other point to emphasize is the patient experience in an ASC. The lab is well-designed from a patient flow perspective. Patients check in, and the nurse gets their IV, point-of-care labs, and EKG. They are prepped and on the table to get their procedure. After the procedure, they go out a second door located on the other side of the lab and are in recovery. At the hospital, we may spend from 8am to 4pm doing five cases; it is a whole-day process. At our ASC, we are doing five cases from 8am to 12pm, including interventions. It also is nice parking and walking directly into the lab from 20 feet away. Patient time spent at the outpatient lab versus the hospital is shorter. Their recoveries are shorter. We gain a lot of efficiency, and both the patients and providers benefit. We get patients who don't know much about the outpatient lab, have their procedure done there, and come back raving about it because of the staff and the experience. It has been very successful and we have no regrets. Our lab has been a good venture for the group and it has been successful for patients. ■

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