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The challenges of the modern cath lab

Over the last decade, the cath lab has transformed. Interventional cardiologists are now not only treating increasingly complex lesions, such as chronic total occlusions, but they are also treating increasingly complex patients (i.e. those that are older with more comorbidities). This article explores the challenges of today's cath lab and how these can be addressed.

Stephan Achenbach

FOR STEPHAN ACHENBACH (Department of Cardiology, University of Erlangen, Erlangen, Germany), today's cath lab has three key challenges. The first is that physicians are increasingly treating lesions that previously would have been treated by coronary artery bypass grafting (CABG). He says: "For example, we more frequently treat patients with chronic total occlusions compared with a few years ago when the likelihood was that those patients would be referred for CABG. So, anatomies that the interventionalist would not have touched a few years ago are now routinely being seen in the cath lab." The second challenge is that patients themselves have become more complex. They are older, which means that they are likely to have more comorbidities that require consideration. For instance, they may have reduced kidney function and, as a result, are less tolerant of contrast.

For both of these challenges, Achenbach says, a good imaging system is vital.

He explains that complex lesions require "excellent image quality" so that the cath lab staff can properly visualise the lesion, and adds that the imaging system also needs to have good flexibility and angulation for the operator to properly access the target vessel. High image quality, Achenbach notes, is important when treating patients with reduced kidney function because it means they do not have to undergo imaging for a prolonged period. Therefore, less contrast is needed and the risk of acute kidney injury is reduced.

The third challenge facing the modern cath lab is that the goalposts have moved. Previously, according to Achenbach, getting the patient "off the table with a nice angiogram" was the only desired outcome. But, now, interventional cardiologists look at the long-term outcomes as well as the short-term outcomes. "These days, we know that we have to produce results that are at least as good as those of bypass surgery. So, we are not looking at the outcomes at one or two days after the procedure but five and 10 years down the line. This is something that is increasingly penetrating the consciousness of both general cardiologists and interventional cardiologists," Achenbach observes.

Furthermore, he says that studies have shown that percutaneous coronary intervention (PCI) can provide equivalent outcomes to surgery, as long as the optimal techniques are used. The SYNTAX II study, for instance, was a multicentre, all-comers, open-label study that compared a contemporary PCI strategy with the strategy used in the original SYNTAX study (SYNTAX I) to manage three-vessel disease.[1] The contemporary strategy consisted of heart team decision-making using the SYNTAX Score II (combining anatomical and clinical factors), coronary physiology guided revascularisation, implantation of new-generation drug-eluting stents, intravascular ultrasound (IVUS)-guided stent implantation, and contemporary chronic total occlusion revascularisation techniques. In contrast, the previous strategy only used the original SYNTAX score (anatomical factors only) and PCI was performed with a first-generation drug-eluting stent.

> **"A connected cath lab, for me, is one in which we can access all of the information we have about the patient. The data just have to be there."**

At one year, the SYNTAX-II strategy was superior to the equipoise-derived SYNTAX I PCI cohort (p=0.006). This difference was driven by a significant reduction in myocardial infarction and revascularisation. Additionally, an exploratory short-term comparison with the equipoise-derived SYNTAX-I CABG cohort suggested that there were no significant differences in the rate of major adverse cardiac or cerebrovascular events at one year.

However, as indicated by SYNTAX II, multiple tools may be required to achieve optimal PCI outcomes: physiological assessment, such as fractional flow reserve (FFR), intravascular ultrasound (IVUS), and/or optical coherence tomography (OCT). Achenbach notes that operators should not lose focus by becoming too wrapped up with these new technologies, stating: "It is important that we concentrate on the coronaries and are not distracted by the technology."

Therefore, he believes that cath labs need a system that can integrate these modalities to make using them as "easy as possible". Integration of information is particularly important because it helps operators make the right decision for patients. "A connected cath lab, for me, is one in which we can access all of the information we have about the patient. The data just have to be there."

ARTIS icono

By reducing the complexity of cardiovascular procedures and supporting a smooth workflow, the ARTIS icono (Siemens Healthineers) is designed to address the challenges that Achenbach refers to.

It does this by providing the flexibility to access the patient from any side to support a wide variety of cardiac and vascular procedures, having fully motorised movements of the C-arm, providing automated, precise, and reproducible repositioning, and allowing quick and easy transition between imaging position and emergency case position. In particular, it has "Case Flows" that allow operators to standardise procedures for multiple ARTIS icono labs for more consistent

documentation.

Another feature of the system is it has an ultra-low dose programme to reduce radiation exposure while delivering high-quality images. Achenbach says cath labs rely on systems that are designed to minimise radiation exposure because their procedures can be long and, thus, operators are potentially at risk of receiving high doses of radiation. "It has to be an essential and self-understood issue that radiation exposure is low. We need an intelligent solution to lower radiation exposure even in complex procedures without us even having to think about it," he comments.

The ARTIS icono also has a "Third Party Broker" feature, which enables the next level in connectivity and communication and provides easy set-up for connection of different systems via a single connection, standard protocols, and a unified interface.

Achenbach uses the ARTIS icono at his centre and says he is "very happy" with the speed of the system because it means he has a smooth workflow.

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Angiogram image

ARTIS icono and CorPath GRX

Synchronisation of systems is essential given PCI is becoming increasing complex

ARTIS icono (Siemens Healthineers), an angiography suite that is designed to deliver excellent image-guided therapy, has a feature called "Third Party Broker". The feature enables integration of different systems via a single connection, standard protocols and unified interface. This has benefits for both coronary and structural heart procedures, including multimodality integration for complex procedures and automated therapy guidance. In this interview, **Luise Gaede** (Department of Medicine 2 - Cardiology and Angiology, Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany) talks to *Cardiovascular News* about her use of the system.

At your centre, you use the ARTIS icono angiography suite. What is your experience of the suite?

Its use is very intuitive. The second day of using it, I had my first patient with a ST-segment elevation myocardial infarction (STEMI). A STEMI is a situation in which you have to be quick and the ARTIS icono worked perfectly, like I had been using it for years. I now use the joysticks almost "blind"; I do not have to look at them. I move them and know where they will take me.

The ARTIS icono Third Party Broker feature enables synchronisation with other modalities, such as intravascular ultrasound (IVUS). Why this is a useful feature?

Synchronisation of all the systems you need during a procedure is essential. Percutaneous coronary intervention (PCI) is becoming more and more complex; you have to use multiple modalities. For patients with complex anatomies and lesions, for example, you may need to use both fractional flow reserve (FFR) and optical coherence tomography (OCT) to provide the best therapy. You need to be able to switch between them quickly. You do not want to have to go from one monitor to another; you need them to be on the same monitor and flip between them with just one click. For chronic total occlusions, you may want to use a pre-CT scan of the coronaries to plan your strategy or find the right angulations for ideal treatment. You want to have this pre-acquired information available in the cath lab as well at your hand.

Luise Gaede

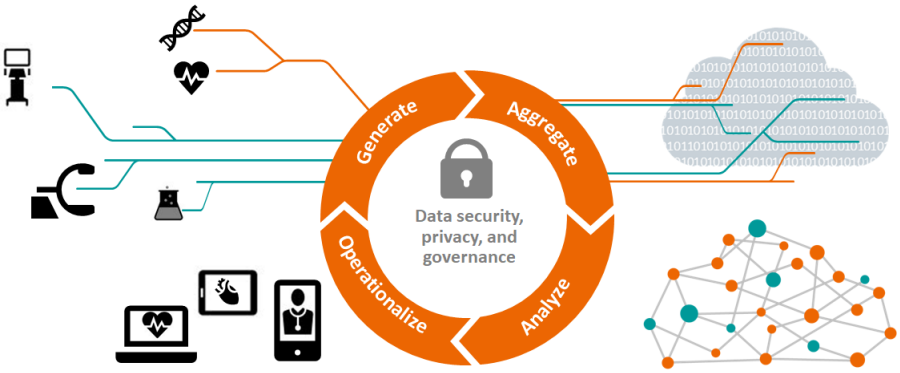
At our centre, we have installed all of the features we need, like IVUS, OCT, FFR, and iFR. The advantage of Third Party Broker is that it allows us to install new features promptly. We do not have to buy any special interfaces, for instance. This helps for potential future combinations as well, and gives a certain investment protection.

Are you able to give an example of when the Third Party Broker feature could help in a case?

A patient may present with typical angina and undergoes diagnostic angiography that then identifies three-vessel disease. You might want to quantify, with FFR, the expanse of the disease; to understand whether the disease is functionally significant in just one vessel, two, or all three. You want to know which vessels need to be treated. Alternatively, a patient might have a left main stenosis. In such a situation, you would need imaging; direct visualisation with IVUS or OCT. In cases like these, you need to be able to connect the imaging device and switch easily between different modalities. You would need a lot of tools to help you approach the stenosis.

Another feature of Third Party Broker is that it allows you to use information, wirelessly, for analysis. What is your experience of using this feature?

One example is patient registration. Often you need to type in patient information in the different systems, like angiography, haemodynamic monitoring and recording system, IVUS, OCT, etc. With the ARTIS icono, we are able to get a real integration and single registration of the patient. The ARTIS icono can then send information to the other connected systems if required. This helps to reduce human error in the registration of a patient, and speeds up the workflow.



Features such as Third Party Broker allow the transfer of data between different systems. How does it ensure data protection and patient confidentiality?

Data protection and patient confidentially is our highest priority. The Third Party Broker does mean that extra parties can access the data. However, anyone accessing this information needs to have certification. This does not just apply to users of ARTIS icono. Anyone accessing any system in our hospital would need the proper certification to access the data via the Third Party Broker.

Robotics and advanced imaging provide protection and precision in PCI

The CorPath GRX System is the first robotic platform designed for percutaneous coronary intervention (PCI) that is available in the US market. Coupled with new imaging technologies, such as the advanced imaging provided by the Siemens Healthineers ARTIS icono, cardiologists now have the wherewithal to reform image-guided interventional therapy.

ROBOT-ASSISTED ANGIOPLASTY offers many benefits. For Jean Fajadet (Clinique Pasteur, Toulouse, France), the premier advantage is "the dramatic reduction in X-ray exposure for the operator".

"Even though X-ray imaging has evolved and protection methods in the cath lab have developed, radiation has still been a problem," explains Fajadet, "particularly with more complex procedures, such as chronic total occlusion (CTO) or recanalisation, where a physician might need to spend longer on the same patient, increasing their exposure risk."

He describes the radiation protection offered by CorPath as "a major step forward for interventional practice". This was evaluated by the PRECISE trial, which assessed 164 patients enrolled at nine sites and determined that radiation exposure for the primary operator was 95.2% lower than the levels found at the traditional table position.[1] Additionally, RAPID II showed a significant radiation reduction (>95%) for physicians and staff.[2]

A single-centre retrospective study published in the Journal of Invasive Cardiology compared 40 patients enrolled in PRECISE who had CorPath PCI with 80 consecutive patients who underwent conventional PCI, demonstrating trends toward reduction in fluoroscopy time, radiation dose, and contrast for the patient.[3]

Furthermore, robotic PCI can be used in combination with the ARTIS icono imaging system. This uses the imaging chain software "OPTIQ", which allows operators to choose their imaging quality preference at a low dose. Another tool for reducing radiation exposure while using ARTIS icono is the RaySafe personal dosimetry system. This system provides real-time information to cath lab operators about their levels of radiation exposure, so that they can then use this information to take immediate action to minimise their radiation exposure.

Three joysticks for precision guiding

The physician sits at a radiation-shielded workstation, either within the procedure room or the control room, where three joysticks and touchscreen controls translate their movements into device control. One joystick moves the guiding catheter, one the guidewire, and a third the RX catheter, allowing remote delivery and manipulation during PCI. It permits precise measurement of patient anatomy to the submillimetre, and 1mm device, and stent positioning; a top priority during interventional procedures. Fajadet clarifies: "You can move both your guiding catheter and the guidewire forwards or backwards, and rotate them clockwise or counter clockwise, and the third joystick allows back and forth movement of the RX catheter. With these three joysticks," he notes, "we can mimic what we have been doing manually for many years."

Jean Fajadet

Robotic precision in complex lesions was assessed in the CORA-PCI trial, a comparison of consecutive robotic or manual PCI procedures over an 18-month period. This trial demonstrated 99.1% clinical success in complex cases and comparable procedures times with manual PCI.[4]

Measurement of lesion length is also facilitated. "In long lesions, robotic assistance allows exact measurement of the length of the lesion and allows selection of the correct length of stent. If we are able to select a shorter stent, it may lead to better results," Fajadet points out.

Measurement of lesions with robotic PCI may reduce measurement errors, need for extra stents, and longitudinal geographic miss (LGM) and stent length selection with those provided by CorPath in 60 consecutive patients undergoing robotic PCI.[6] The researchers noted that visual estimates were highly variable, and concluded robotic PCI may reduce measurement errors, the need for extra stents, and LGM.

CorPath GRX's workstation

Procedural automation

Rotate on Retract (RoR) is a feature that automatically rotates the guidewire upon joystick retraction, providing consistent and predictable movement and aiding manipulation. The company is working on adding additional features mimicking the manual techniques of highly-skilled physicians in an effort to standardise interventional medicine. Pace can also be altered: "With the press of a button, you can increase the speed of advance of the wire or the device," says Fajadet. "This is helpful when removing the device. And when crossing a lesion, by turning the wire clockwise or anticlockwise."

And, an extended reach arm enables radial access, and allows operators to work from a seated position without the need to wear lead, a factor, he says, that reduces fatigue, particularly in high-volume operators and at the end of a full day performing PCI.

Seeing is believing

The benefits of robotic angioplasty have been married to the image-guided developments of ARTIS icono. ARTIS icono provides excellent images of the moving heart and of challenging cardiac anatomies in any angulation, and at low dose, even during complex procedures. The completely new image chain of ARTIS icono uses algorithms to optimise the image quality. This is a great value addition to the robotic system.

Fajadet urges those who are hesitant of robotic technology not to be wary, but to embrace it. As with all novel techniques, he says, there is a learning curve: "It is true

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that with robotic-assisted angioplasty we use images on the screen instead. But after 10 to 20 cases, the manual instinct in your fingers transfers into a visual instinct. With manual PCI experience, it is very easy to move to robotic procedures."

Case Flows

Of note, ARTIS icono has a feature called "Case Flows" that is designed to help to standardise workflows. Case Flows, for example, provides a sequence of system settings that match the diagnostic steps and treatment path—these settings can then be adjusted to match the needs of the situation.

Fajadet has had "really good results" using robotic PCI. "In our centre, we have treated more than 150 patients with a very high rate of success. Initially, the rate of conversion from robotic to manual was <3%; among the last 30 or 40 patients, none have required conversion." His experience is borne out by a study last year reporting six- and 12-month outcomes following robotic PCI that showed no difference in clinical outcomes or safety measures as compared to manual PCI.[6]

The next step, according to Fajadet, is a large multicentre registry of >1,000 patients looking at success rates, complications, and risk factors. He predicts a wide range of future applications. A preclinical study established the feasibility of robotic telestenting over long geographic distances.[7] The development of tele PCI may help to address barriers to access, although, for now, Fajadet remains cautious: "It is nice to be able to share experience in difficult complex anatomies between high-volume operators and those who have performed fewer procedures. But what is the volume of procedures that could be performed with this strategy? There is also the issue of responsibility if there are complications."

Looking to the future, one wonders what we can expect from the synergy of using robotic PCI (providing a new-generation of treatment delivery) in combination with ARTIS icono (providing a new generation of image guidance). According to Siemens Healthineers, the value of using the two systems together is protection from the risk of radiation exposure, greater precision of procedures, and standardisation for better results.

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A variety of tools are now available for physiological assessment

Multiple studies have shown that fractional flow reserve (FFR) is a valuable modality for assessing the functional significance of coronary lesions. However, it does have limitations—such as the need for a hyperaemic agent. Therefore, other modalities for physiological assessment have been developed to address this. This article explores the evidence behind these emerging cath lab tools.

SINCE IT WAS FIRST INTRODUCED in the cath lab in the 1990s, FFR has been established as a key tool for physiological assessment, and studies have shown that FFR-guided percutaneous coronary intervention (PCI) improves outcomes. Zimmermann *et al*, for example, performed an individual patient data meta-analysis of three randomised controlled trials of FFR.[1] They found that "FFR-guided PCI [compared with medical therapy] resulted in a reduction of the composite of cardiac death or myocardial infarction compared with medical therapy, which was driven by a decreased risk of myocardial infarction."

Furthermore, European guidelines give a Class I, Level of Evidence A recommendation (the strongest) for FFR, or an instantaneous wave-free ratio (iFR), to be used to assess the haemodynamic relevance of an intermediate-grade stenosis "when evidence of ischaemia is not available".[2]

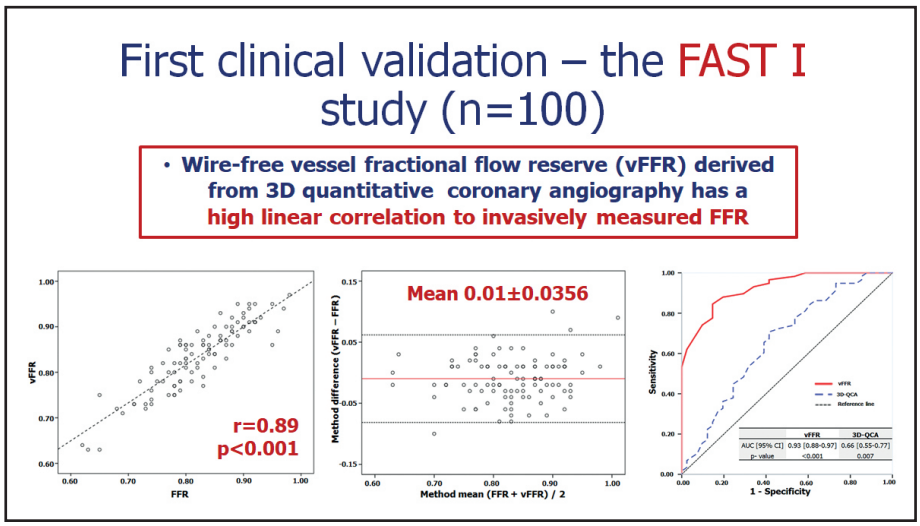
However, there are some challenges associated with using FFR and it may not always be the right tool. Joost Daemen (Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands) points out that using a hyperaemic agent to "create an artificial stress test" in FFR can cause "some challenges".

Joost Daemen

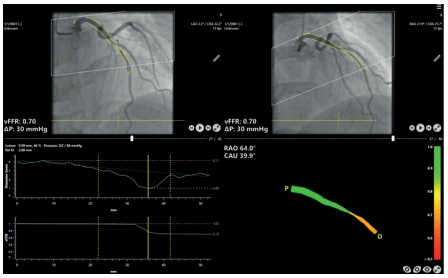
"Particularly in patients presenting with an acute coronary syndrome or in those with severe left ventricular hypertrophy, aortic stenosis, elevated left ventricular end diastolic pressures or mircovascular disease in which the interpretation of the obtained FFR value might not be straightforward. These patients may not respond predictably compared to those who do not have these issues," he explains. He adds that the agent can also "cause symptoms that are quite uncomfortable for the patient at the point at which you administer it during your test … you might induce side-effects like dyspnoea or atrioventricular block. Also, the use of a hyperaemic agent adds time to the assessment, especially if you administer it through an intravenous catheter as that takes several minutes to deliver the agent."

Physiological assessment without a hyperaemic agent

Given the issues associated with hyperaemic agents, several methods of performing



Key findings from the FAST study



FFR result

physiological assessment without such agents have been developed. The most widely used of these is iFR, which, Daemen explains, is "based on a specific algorithm measuring the pressure gradient during diastole; a so-called wave-free period". Thus, the need for a hyperaemic agent is negated. However, while iFR has been the "most widely tested" of the FFR alternatives, according to Daemen, it uses a patented algorithm of a single vendor. Several generic diastolic algorithms are now available, with Daemen noting "when assessed by multiple groups of researchers, these appear to correlate near perfectly to iFR".

Another option is to remove the need for a pressure wire as well as for a hyperaemic agent. Angio-derived FFR measurement (3D angio-based FFR) uses angiogram data to compute FFR values. Daemen reports that it is a "relatively novel modality that is based on the fact that you can also model blood flow using computational fluid dynamics; that is a concept that has been applied to angio-based FFR." As with wave-free period algorithms, several different modalities, such as CAAS vFFR (Pie Medical) sold by Siemens Healthineers, are available. He notes that vFFR has a "particular feature making it perhaps a bit easier to apply and faster because it uses the aortic blood pressure at the time of angio as an advanced condition to compute the flow". Of note, Masdjed *et al* (including Daemen) evaluated vFFR in the FAST trial and found that "3D-QCA derived vFFR has a high linear correlation to invasively measured FFR, high diagnostic accuracy to detect FFR ≤0.80, and a low inter-observer variability".[3]

Daemen does not believe that angio-based FFR modalities "will ever completely replace FFR". But, he does think that they can potentially "drive the adoption of the physiological assessment". "The total cases that use FFR [in some form] could significantly increase because performing physiological assessment—at potentially very low cost—will become a lot easier," he adds.

Computed tomography (CT) can also be used to calculate FFR values (FFR_{CT}). The PLATFORM study showed that FFR_{CT} can be used to determine which patients with coronary artery disease require coronary angiography (and possibly revascularisation).[4] Additionally, Hlatky *et al* report: "An evaluation strategy based on FFR_{CT} was associated with less resource use and lower costs within 90 days than evaluation with invasive coronary angiography. Evaluation with FFR_{CT} was associated with greater improvement in the quality of life than evaluation with usual non-invasive testing."

Based on these findings, the main role of FFR_{CT} in clinical practice is to rule out disease (and the need for invasive diagnostic tests); it is not a direct alternative to FFR as a patient may go on to have invasive testing (with angiography/FFR) if the modality indicates they have significant disease.

However, the SYNTAX REVOLUTION trial suggested that FFR_{CT} could also be used to determine the optimal management approach for patients with coronary artery disease.[5] Investigators Andreini *et al* state: "In patients with three-vessel coronary artery disease, a non-invasive physiology assessment using FFR_{CT} changed the heart team's treatment decision-making and procedural planning in one-fifth of the patients."

Even if further trials support the findings of SYNTAX REVOLUTION, Daemen does not believe that this will signal the "end of the wire" (that is, invasive testing with angiography). "I do not think CT will replace angiograms. It has been shown to be perfect at ruling out disease. However, challenges with CT still remain in older patients with more calcified disease, previous stenting, bypass grafts, or those with kidney disease in which CT is less efficient. For these patients, who already have coronary artery disease, I am not so sure that non-invasive technologies will replace angiograms," he says. For these patients, then, coming to the cath lab imaging-based assessment of physiological stenosis is the way of the future with the potential to be faster and reduce costs.

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