AN INTERVIEW WITH...

Simon R. Redwood, MD

Professor Redwood shares thoughts on public reporting and outcomes data, insight on the ACTIVATION and ARREST trials, areas of growth in percutaneous mitral valve interventions, keys to a successful live case, and more.

Under your term as President of the British Cardiovascular Intervention Society (BCIS), the society and the National Institute of Cardiovascular Outcomes Research started an initiative to publicly report individual percutaneous coronary intervention (PCI) operators' outcomes. Now that we're a few years from the study's publication,[1] how would you summarize what we know about the relationship between public reporting and outcomes data in the interventional cardiology world?

This was one of the major tasks we had to deal with during my time as president. In fact, we were the first medical specialty to do so. The cardiac surgeons had been publishing their outcomes for some time, and there was a real concern that it led to risk-averse behavior. With individual operator outcomes published, the public may tend to favor operators with the best outcome, but those operators may be the ones that avoid intervening on any patients perceived as higher than normal risk, which could of course be counterproductive.

We were very concerned that the same would happen in interventional cardiology, and we addressed that by publishing risk-stratified outcomes according to a published model and benchmarking them against the predicted model. In addition, we removed the highest risk subsets, namely, patients with cardiogenic shock, as we were concerned that operators may prefer to treat those patients conservatively.

This outcomes information is now in the public domain (eg, anyone can look up my outcomes on the BCIS website [www.bcis.org.uk]); however, the press and the public don't seem to have focused on it, and there has been little in the way of impact. It may be because, overall, the outcomes in interventional cardiology are excellent, and separating good from bad operators is extremely hard, and we actually didn't find any outliers using the risk-stratified outcomes.

The ACTIVATION trial, which you presented at the 2020 PCR Valves course, demonstrated that PCI prior to transcatheter aortic valve implantation (TAVI) in patients with significant coronary artery disease does not improve rates of death or rehospitalization at 1-year follow-up. How will these results change practice, if they haven't already?

What's odd is that as the trial progressed, it became increasingly difficult to enroll patients to the trial. As TAVI simplified, it became more common not to admit patients for a prior angiogram. Increasingly, patients would have their angiogram immediately before the TAVI procedure. The only patients who tended to have an angiogram before were those whose main or predominant symptom was angina, and these patients were excluded from the trial. In addition, many felt comfortable that in the absence of significant angina, prior PCI had little role. So, in a way, practice had already started to change prior to the trial results even being presented!

As a result of difficulties in recruitment, we were unable to reach our intended enrollment target. Despite that, the trial showed no signal of benefit (in terms of death or rehospitalization) of previous PCI, and, if anything, a signal of harm with higher bleeding; we must remember that committing elderly patients to dual antiplatelets is not without risk.

At present, this is the only randomized trial in this group of patients and by the time you read this, it will have been published online in *JACC: Cardiovascular Interventions*, so we will have to see if it changes published guidelines. However, it certainly seems fairly well accepted by the interventional community that patients without significant angina can safely have their TAVI procedure and, if necessary, have PCI at a later sitting. In addition, there have been advances in coronary access post-TAVI facilitating that approach. What remains to be seen is whether that approach is valid as we move to younger (and lower-risk) patients. That's the next potential trial, but it will inevitably involve larger numbers and a longer period of follow-up.

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You are also involved in ARREST, which is looking at expedited transfer to a cardiac arrest center for non–ST-segment elevation out-of-hospital arrest. As Principal Investigator, can you share the current status? What led to your interest in studying this?

Soon after setting up a primary angioplasty service, we began to treat patients with out-of-hospital cardiac arrest who had clear ST-segment elevation on their electrocardiogram (ECG), and the benefits were undoubted. What seemed less clear was how best to treat the cohort who did not have ST-segment elevation on their ECG—was it a primary cardiac event leading to their cardiac arrest or not? In addition, several centers set up dedicated cardiac arrest centers without any firm evidence of benefit.

We decided to address both of these issues by taking patients without ST-segment elevation on their initial postreturn of spontaneous rhythm ECG and randomizing them to an expedited protocol of transfer direct to a center with the ability to perform primary angioplasty on arrival (if deemed appropriate) versus transfer to the nearest emergency department, which may or may not have been colocated with the ability to perform primary angioplasty.

We have a target of 860 patients. Prior to COVID, this was one of the few trials that remained on target, with approximately one patient enrolled per day. This has been largely due to the fantastic support we've had from the London Ambulance Service (LAS) and the British Heart Foundation. However, COVID put a stop to that. We had to pause recruitment due to the pandemic, as both LAS and the receiving hospitals were overwhelmed with COVID patients. In addition, they saw an increase in mortality in these patients and we were concerned that the trial results may be diluted as a result. The good news is that the pandemic is largely over, and we have just restarted recruitment with just over 600 patients. We should complete recruitment within a year or so, with a goal to present and publish the results within the next 2 years. Regardless of the outcome, this trial will inform us on how best to treat this difficult cohort of patients who have an unacceptably high mortality.

Although the past decade has seen a rise in transcatheter mitral valve replacement for treatment of severe mitral regurgitation, questions and challenges still remain for this technique. What is the number one issue that needs to be addressed in this area in the next decade?

You're correct in saying that percutaneous mitral valve (and tricuspid valve) interventions are a major growth area in transcatheter interventions. There's no single issue that needs to be addressed, but I suppose a main one is that compared to the aortic valve, the mitral valve is incredibly complex. The annulus is not round (or nearly round), is "D" shaped, isn't in one plane, changes size and shape with the cardiac cycle, changes size when the heart fails, is a high-pressure closing valve rather than a high-pressure opening valve like the aortic valve, and is more prone to develop thrombus. I could go on. In addition, mitral regurgitation has many etiologies. Finally, depending on the treatment, it can be relatively easy to block the left ventricular outflow tract (LVOT).

As a result, many treatments have been proposed and investigated. Some have survived and are quite commonplace, like edge-to-edge repair. In addition, valve-in-valve and valve-in-ring procedures using the Sapien valve (Edwards Lifesciences) are relatively straightforward, provided that careful, detailed, preprocedure CT analysis and modeling ensures a low risk of LVOT obstruction. In certain patients, valve-in-mitral annular calcification is feasible but more challenging technically.

However, many proposed treatments have failed in clinical testing. I think that edge-to-edge repair is here to stay; it effectively treats a cohort of patients with mitral regurgitation. What is likely to emerge is a range of treatments that are tailored to the individual patient depending on the cause of the mitral valve disease and the individual anatomy of each patient.

The issue of percutaneous mitral valve replacements is also a massive research area. It is likely that several will survive clinical testing, but we still need to address and resolve the issues of long-term durability and thrombosis risk.

If you were to publish a third edition of the *Oxford Textbook of Interventional Cardiology*, after serving as lead editor for the first two editions, what new techniques or innovations would you like to cover?

It has been a great privilege to be able to be the lead editor of two editions of a major textbook, but I had no idea how much work would be involved! With the massive growth in material obtained online, I fear that the appetite for major textbooks has waned.

If I were invited to organize a third edition, in addition to building on the last two editions, I think I would focus on percutaneous treatments of valve disease as a major growth area, as discussed previously, and the core disciplines of interventional cardiology. In addition, there would be a main section on management of out-of-hospital cardiac arrest. Finally, there would be a large online educational section with links to numerous case examples, talks, and other educational materials that complement the written text, for example.

Your team at St Thomas' Hospital can be frequently seen at meetings presenting live cases. What do you consider the keys to a successful live case demonstration?

The most important aspect to remember is that at the core of the live case is the patient—nothing must be done that may compromise that. Never try to demonstrate procedures that you wouldn't be comfortable doing otherwise.

Second, the case and techniques presented should be educational and be able to clearly teach viewers techniques and/or procedures they otherwise may have been uncertain about.

Third, you will likely have moderators and a panel commenting on the case. It's very important to remember that you are doing the case, not them, and it's very rare to need to be deviated from your intended course by them. I often find that some members of the panel will quite forcefully suggest interventions or procedures you hadn't planned, but don't be persuaded to do things you wouldn't otherwise be comfortable with. As I mentioned earlier, it is the patient who is at the core of the case!

Finally, remain calm and do what you do best—treating patients—and forget about the panel/moderators/audience. All that matters is that you do a safe and appropriate intervention for the patient.

With an active research team, clinical work, leadership roles, and involvement in scientific symposia, you seem to always have several projects in the works at one time. What aspect of your career are you most excited about right now?

I think you've summarized the best aspects of my career in one sentence! Being able to have a mix of clinical work and supervising very driven research fellows who are helping to drive forward projects that we see as important is a fantastic mix that really excites me. We're doing some great work on futility and trying to ascertain which patients really benefit from aortic valve intervention, as well as developing specific risk scores for TAVI and looking into the issue of TAVI valve thrombosis and long-term durability, which are some of potential limitations of rolling out TAVI to younger and lower-risk patients.

What are your interests outside of work?

I enjoy touring Europe on my motorbike, a BMW R1200GSA, and I'm also a keen private pilot. On days off, when the weather holds up, I enjoy flying around Southern England. I fly a Piper PA-161, a single-engine, four-seat plane. I'm in the middle of doing my instrument rating at the moment. As doctors doing procedures, we've learned so much from the airline industry—we now incorporate similar checklists, which undoubtedly makes the procedures safer and more predictable. ■

1. Jones DA, Rathod KS, Koganti S, et al. The association between the public reporting of individual operator outcomes with patient profiles, procedural management, and mortality after percutaneous coronary intervention: an observational study from the Pan-London PCI (BCIS) registry using an interrupted time series analysis. Eur Heart J. 2019;40:2620–2629. doi: 10.1093/eurheartj/ehz152

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