Title: FiH Experience with Shockwave M5+ Intravascular Lithotripsy Catheter
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- I'm Andrew Holden from Auckland New Zealand I'm Director of the Northern Region Interventional Radiology Service in New Zealand. And I've also been an investigator for a number of Shockwave trials, including the first- in-human trials and the Disrupt series of trials. And today we're going to discuss the results of the Disruptor PAD+ Trial evaluating a new Shockwave Catheter called the M5+ catheter.

The Shockwave M5+ Catheter

So, the Shockwave M5+ Catheter has a lot of similarities to the currently available M5 catheter. That is, it is a catheter that's 60 millimetres long it's delivered over an 0.14-inch guide wire, and it delivers a total of 300 pulses in its treatment capacity.
But there are some key differences. The diameter of the angioplasty balloon has been increased from 7 millimetres to 8 millimetres. And this really increases our ability to treat lesions in the iliac and common femoral arteries. The delivery catheter is actually a little longer. It's now 135 centimetre in length which allows us to treat more extensively from a contralateral groin approach and possibly even an upper limb pro approach.
But the key difference is the frequency of the pulses. So the traditional M5 catheter delivers a pulse at one pulse per second. The M5+ catheter delivers a pulse at a frequency of two pulses per second or two hertz and of course this means that the treatment cycles are considerably shorter. And this enables us to increase our procedural efficiency in patient throughput.

Comparison to Other Lithotripsy Catheters

Well, in many ways, it's, it's very similar to other catheters, except as I mentioned it does have increased our ability to treat larger diameter lesions which is something we previously have not been able to do. It's really designed in our trial to evaluate the, from the common iliac artery to the distal popliteal artery. Whereas the previous M5 catheter was presumed previously designed to treat essentially the superficial popliteal arteries.

Recommended Use

Well, I think there are, you know, obviously this is a system designed for vascular calcification and it was interesting when I very first got asked to get involved in the first-in-human trial. I can remember, well, the conversation saying, look the more calcified a lesion is the better, this works and that's completely different to any other endovascular device we currently have.

Which all perform more poorly and heavy calcification. The real sweet spot for the catheter is concentric arterial calcification but we do have a lot of experience with the eccentric calcification as well. And we often have to treat those lesions a little more with the shockwave catheter system, but we can get an excellent result with both concentric and eccentric calcified disease.

Supporting Data

Yes. So, the Disrupt M5+ or PAD+ trial is really designed to assess safety and early effectiveness of the M5+ catheter. This was a trial performed in New Zealand and Australia and in the United States. It was a 37-patient trial using the M5+ catheter in patients who had stenotic disease.
As I mentioned previously from the common iliac artery down to the popliteal artery, and the lesion length could, could be less than 200 millimetres in length. So, a long lesion length. A chronic total occlusion length would need to be less than 100 millimetres in length. And we assess safety as well as technical and procedural success in this study. So, in this trial, we had a range of clinical presentations from claudication to critical limb ischemia, but the majority of the patients were Rutherford 3 claudicants. The majority of patients were treated in the iliac artery. 58% of the lesions were in the iliac arterial system as well as a further significant percentage in the common femoral artery.
So, this patient cohort was really quite different to those that have been previously treated in the Disrupter PAD and observational registry study. The average lesion length was 58 millimetres and the reference vessel diameter was 7.2 millimetres, really which indicates a much larger calibre vessel reflecting the fact that we were treating iliac and common femoral arteries. Now the overall procedural success, which was a per patient assessment defined as a residual stenosis of less than 30% diameter loss and freedom from a significant dissection that's grade D or worse.
The procedural success was a very pleasing 86%. And when we look at that kind of procedural success and compare it to the much more controlled Disrupt PAD3 series and also the observational registry we can see very similar outcomes. So, we see very pleasing and very reproducible outcomes with this new M5+ catheter when compared to the previous M5 catheter. I would say just from my own experience with this catheter that it really does have a positive impact on patient throughput and patient turnover. And we seem to have just as an effective tool in terms of intravascular lithotripsy.

Further Research Required & Next Steps

Well, the M5+ catheter is now available. And in our institution, it's being replacing our current M5 system. There's no downside. There were no safety concerns with this system. So, there's no real reason to not be using the M5+ catheter when it becomes available. Availability is, is being progressively rolled out across different countries and territories. And I think the next step will really be just to continue to capture performance data with the M5+ catheter. I think that system is fairly mature, but I think there's still some exciting applications for intravascular lithotripsy. And, and I'm aware that the company is working on some other projects that will further increase our toolbox for managing calcified arterial disease.