- Well hello there, I'm Andrew Holden from Auckland, New Zealand. I'm an interventional radiologist, and lead the interventional radiology team here at Auckland, New Zealand. And I'm going to discuss some interesting work we've been doing with aneurysm sac filling, or active aneurysm sac management, using the shape memory polymer during EVAR procedures.

Study Purpose

We know one of the real Achilles heels of endovascular aneurysm repair has been the failure of the aneurysm sac to regress after treatment. In fact, in a paper by O'Donnell and colleagues published in 2019 in The Journal of Vascular Surgery, we saw that only 40% of aneurysms had regressed at one year, with the remainder remaining stable or 25% actually expanding. But what we learned was that not only were the expanding sacs, but also the stable sacs, associated with a higher long-term all-cause mortality. So really this problem of a lack of aneurysm shrinking and that being a predictor for increased mortality is what we've tried to address with this study.

IMPEDE-FX Technology

So the shape memory polymer is an embolic material with a large surface area designed for space filling, and these large surface areas induce long fluid residence times and low shear rates. And this leads to stasis and thrombus formation without chronic inflammation. We used this polymer in an embolic plug, the IMPEDE embolic plug, and we noticed a very interesting phenomenon, and that was that we saw vessel shrinkage, and progressive healing of the thrombus to mature collagen. And that stimulated some initially animal aneurysm studies, which showed significant sac shrinkage, when we deployed the shape memory polymer with the IMPEDE plug, much more so than aneurysm that was treated with embolic coils, for example. And that really stimulated this trial of using these plugs to fill an aneurysm sac during EVAR, which is what the IMPEDE, I should say, the AAA-SHAPE, early feasibility studies are investigating.

Key Findings

So to date there are two concurrent trials running in New Zealand and in the Netherlands, recruiting, exactly the same trial design, up to 30 patients. And the primary outcomes are technical success and major adverse events, but we're really looking at important secondary outcomes such as the incidence of endoleak. And importantly, the incidence of sac shrinkage, changes in sac diameter and volume. So to date, as of the end of last year, we treated 16 patients, and we do this by having a sheath during the EVAR procedure, within the aneurysm sac, but outside of the endograft. And at the end of the procedure, when we've sealed the aneurysm with the endograft, we fill the blood lumen outside of the endograft with IMPEDE-FX plugs. These are rapid fill plugs, five of them can be delivered at a time. We calculate the number of plugs required based on the pre-operative estimate of volume of the blood lumen, and fill the sac. We've had to date 16 patients treated as of the end of last year. No adverse events that we saw. These patients were treated to date with either the Medtronic Endurant or the Gore Excluder grafts. 100% technical success. The mean additional procedure time to do this was around 25 minutes. And of the patients that have been followed to six months now, we're seeing some very interesting findings, with no endoleaks and very significant sac shrinkage. So we certainly are very encouraged by the preliminary results, but obviously more recruiting to come.

Take-home Messages

So I think one of the key messages we've learned is that intraluminal aneurysm repair is still not the finished product. We've seen this for a number of years, where, in fact, we've seen aneurysm related mortality in the longer term being higher than open repair. And the major driver of this appears to be a failure of aneurysm sac shrinkage. And so really any ancillary procedures we can do to really modify the aneurysm sac response would have significant impact on patient welfare and the outcome of the procedure. What we've seen to date with the AAA-SHAPE study is that we can easily and safely treat the aneurysm sac outside of the endograph with the IMPEDE-FX rapid-fill shape memory plugs. We certainly are seeing no evidence of ongoing endoleak, and to date, we're seeing very pleasing sac responses. But I should add that these are very early findings, and we need to confirm these with ongoing recruitment to this study, and then much larger studies in the future.

Further Research

So I think this is obviously a small study, assessing safety and feasibility. The efficacy signs are really very pleasing, but the trial is not powered for efficacy. And as mentioned previously, I think the next step is a much larger trial. And in the future, potentially a prospective randomised trial, where we randomise patients to treatment with active sac management versus not, and see if this translates into much better outcomes as predicted.