- Good morning. I'm professor Alun Davies. I'm the Professor of Vascular Surgery at Imperial College and a consultant at Imperial College NHS Trust, and I'm a Senior Investigator for the National Institute of Healthcare Research. I am going to talk to you today about the role of neuromuscular stimulation in patients with claudication.

Aim of This Study

One of the issues with patients who have claudication is that it's been shown that one of the best ways that they can actually improve their outcomes is by using supervised exercise programmes. Unfortunately, worldwide supervised exercise programmes are not widely available. So we had shown in a pilot study that patients with claudication who used neuromuscular stimulation were able to walk further and have an improved quality of life. This was obviously in a cohort study. So the basis of this study was to use neuromuscular stimulation to see if it could improve the outcomes for patients with claudication. In view of the fact that centres either could or could not offer supervised exercise therapy, we recruited patients from both groups, and within those groups, they were randomised to receive adjuvant neuromuscular stimulation or not. So all in all, there were four groups. There was a supervised exercise programme group that just also had best medical therapy and advice plus neuromuscular stimulation, compared to a group that just had supervised exercise and no neuromuscular stimulation. And then the other group was recruitment where the centres did not offer any supervised exercise and patients were randomised between best medical therapy and the use of neuromuscular stimulation. And the key outcome that we were looking for in the trial was the improvement in the absolute walking distance. We also looked at quality of life measures and also looked at the severity of the claudication.

Study Design, Patient Population and Endpoints

The key study population were patients who had intermittent claudication that was confirmed on ABPI and by also using the Edinburgh Claudication Questionnaire. The primary outcome measure was to look at an improvement in the absolute walking distance. Then there were subsequent other secondary outcome measures such as quality of life, cost effectiveness, and the distance at which the claudication came on. We also looked at the effect on APBI and on laser Doppler flow measurements.

Key Findings

The key findings that were the fact that supervised exercise was undoubtedly the best at improving people's walking distance. If we then looked at the compliance of people looking at supervised exercise and for those who used neuromuscular stimulation, in supervised exercise it was defined as 50% of the classes attended. Neuromuscular stimulation compliance was defined as 75% of the time they used the device. The answer is that in both groups there was over 70% compliance, which overall is good. When we then looked at the outcome with respect to the distance walked, those that were short distance claudicants really didn't get any benefits from supervised exercise or from neuromuscular stimulation. If you were a middle distance or moderate claudicant, then you did get some benefit from supervised exercise. And then for those patients who were what we would call mild claudicants, or who could initially at the time of entry walk in to the study longer, they were the cohort who benefited the most from supervised exercise and/or neuromuscular stimulation.

Take-Home Messages

I think the biggest take home message for clinicians is one, that we need to reinforce the benefits of supervised exercise programmes for moderate to mild claudicants. Two, we need to reconsider the use of supervised exercise in severe claudicants. Three, we need further larger studies, 'cause this really was a pilot study looking at mechanism. We need larger studies to look at the benefits that neuromuscular stimulation can offer, but it does offer, obviously offer some benefit into those patients who are milder claudicants.

Further Research Required and Next Steps

Well, I think there are two major steps. One is to look at factors affecting implementation of supervised exercise programmes and reinforcement for patients. The second is to, in a larger study, look at neuromuscular stimulation as a comparator, again to supervised exercise, but also to no exercise at all. And also just to look at where various apps and self-motivation programmes will play their part, but I think we need larger studies with more data.