**Title: LINC 22: GPX Embolic Device In Peripheral Applications**

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**Dr Andrew Holden**

- I'm Andrew Holden, an interventional radiologist from Auckland, New Zealand. I'm the director of interventional radiology at Auckland hospital, and I'm going to discuss our experience, our first-in-human experience with a new liquid embolic agent, the GPX agent from Fluidx.

**Device and Study Background**

So GPX is a liquid embolic agent, a new liquid embolic agent. As we know, embolization is rapidly expanding in its applications, and liquid embolic agents have some particular applications. They particularly embolize peripheral vasculature extremely efficiently. This is a new embolic that has some specific advantages compared to the current liquid embolic technologies that we have.

**GPX Embolic Agent**

So GPX is a polymeric embolic agent and it's simply prepared by using two 1 ml syringes, rapidly agitating between the two 1 ml syringes to form a solution that has the tantalum, which makes it very radiopaque, suspended in the solution. And then that 1 ml syringe can be directly connected to your microcatheter of choice. The agent forms a solid by ionic bonding when it gets into the blood system. And so it will form a solid material that penetrates very distally. Some of the key features, I think, of this agent are it's very easily prepared. It can be used with a whole range of microcatheters including small microcatheters 2.0 French. It's very visible because of the tantalum. And because of that, you can inject it very safely and not get non-target embolization. It's non-adhesive, so it doesn't stick to the catheter. So you can withdraw the catheter and reposition. And it penetrates very distally, so you get profound embolization.

**Study Design and Patient Population**

So this first-in-human trial is performed at two centres in New Zealand, Auckland hospital and Christchurch hospital. And we're focused on treating arterial lesions, hypervascular lesions with a tapering distal circulation, but also portal venous anatomy. What we require is vascular anatomy that tapers distally. The common indications that we've used this so far are benign and malignant vascular tumours such as renal angiomyolipomas, renal cell carcinoma, hypervascular metastases, and also portal vein embolization to induce hypertrophy in the contralateral lobe.

**Key Results**

So the key results are safety and efficacy endpoints. If we deal with the efficacy endpoint, the primary endpoint is acute occlusion of the target artery. To date, we've treated 14 patients for the indications I discussed, and we've seen early complete occlusion in 100% of cases. And those that have been followed up, we've seen no evidence of re-canalization and we've seen very profound distal penetration of the embolic agent. In terms of safety, the safety endpoint is at one month, device-related serious adverse events. We've only seen that in one of the 14 patients. Actually, it was because she had such profound embolization of a large angiomyolipoma, she had prolonged hospital admission. That qualified as a serious adverse event, but she fully recovered and had an excellent clinical response.

**Conclusions**

So I think the GPX embolic agent from from Fluidx is really a significant advance in liquid embolic agents. I spoke of the advantages, distal penetration, excellent radio opacity with the ability to avoid non-target embolization. We've only touched on some of the arterial applications. I think there's a lot more work to do with further trials to look at more extensive applications of this product. But it's certainly an exciting addition to the embolic portfolio for interventionalists.

**Next Steps**

So, following this first-in-human trial, the next step is to roll into a much larger US IDE-approval trial. So that'll obviously be a multicenter trial primarily in the US, but perhaps with some OUS centres, such as Auckland, also involved.