**Title: VIVA 22: 3Y Results of the GORE VIABAHN Stent-Graft in SFA for In-Stent Restenosis**

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**Dr Peter Soukas**

"- Hello, my name is Peter Soukas, I am the Director of the Interventional Vascular Lab here at the Miriam Hospital in Providence, Rhode Island. I'm also the Director of the Brown Vascular and Endovascular Medicine Fellowship Programme, and an Associate Professor of Medicine at Brown Medical School here in Providence, Rhode Island. We're going to be talking today about the REALIGN MAX study. And this was of course a post-market analysis to evaluate the safety and efficacy of covered stents for the treatment of bare metal femoropopliteal in-stent restenosis.

Unmet Needs in PAD

Well, I think one of the greatest unmet needs in the management of femoropopliteal disease is the management of in-stent restenosis. It's an incredibly vexing problem. And we really have very poor data in terms of long-term follow-ups with regards to the various ways that this particular challenge is treated. And so, one of the nice things about the REALIGN MAX trial was that we looked at a three year follow up in a real world population, specifically looking to address the freedom from target lesion revascularization, the risk of stent fracture, and the incidence of acute limb ischemia with stent-graft thrombosis. And then of course, we also looked at other limb outcomes such as major amputation and patients functional improvement post-revascularization with ABI follow-up. And then patients were also evaluated for stent fracture with protocol mandated x-rays of their prosthesis.

Study Device

The device itself is a PTFE covered, self-expanding nitinol stent. It's available in diameters of between four and 13 millimetres and lengths of 2.5, 5, 7.5, 10, 15 and 25 centimetres in length. It has a covalently bonded heparin on the endoluminal surface of the stent-graft, and this obviously helps in terms of thromboresistance. And the proximal end of the device features a contoured edge, and this allows for really optimal conformability of the stent-graft prosthesis, particularly at the origin of the superficial femoral arteries. It is indicated for use in the SFA as well as for iliac lesions, and the treatment of in-stent restenosis or thrombotic occlusion of the venous anastomosis of AV grafts in patients who have the prosthesis in place for treatment of access graft stenosis for their hemodialysis.

Study Design and Patient Population

Well, this study design was really a post-market study to evaluate the safety and effectiveness of the GORE VIABAHN endoprosthesis for the treatment of in-stent restenosis of the SFA. It was a prospective, single arm global study with 20 US sites and three EU sites. And we enrolled patients that had symptomatic Rutherford class two to five disease with underlying in-stent restenosis. A total of 108 patients were enrolled in the study which began in October of 2015 and then wrapped up in April of 2018 with 86 patients that were included in the final analysis through three years. The primary effectiveness endpoint was primary patency at 12 months. The primary safety endpoint was device or procedure related serious adverse events at 30 days. There were a number of secondary endpoints that were included in the study, and these included primary assisted patency, secondary patency, freedom from TLR, as well as freedom from amputation, improvement in ABI, change in Rutherford class, and assessment of stent fracture.

Key Findings

Well, the mean lesion length of the in-stent restenosis segments that were treated was 12.4 centimetres. The average stented length was 19.5 centimetres. 29% of these lesions were CTOs. About a third had moderate to severe calcification. 10% of the patient population were critical limb ischemia patients, and 82% had Tosaka two and three class in-stent restenosis. The 12-month primary patency rate was 74.7%. Freedom from TLR was 65% at three years. Primary assisted patency was 56.4% at three years. And secondary patency was 82.3% at three years. Rutherford class improvement was achieved in over 80% of the patients. And we had 100% freedom for major amputation and zero VIABAHN stent fractures.

Take-Home Messages

Probably the primary take home message is that stent-grafts for the treatment of in-stent restenosis are both very, very safe and efficacious. I mean, these are very long, difficult, complex, challenging femoropopliteal in-stent restenosis lesions, and to have a primary patency of 75% despite all of those adverse characteristics, I think is really quite remarkable. But the study also had important patient-centric outcomes, and that included freedom from TLR of 65% at three years and an 80% improvement in Rutherford class from a patient standpoint, is really a very meaningful statistic. One of the other important findings from the study was that the incidence of acute limb ischemia with stent-graft thrombosis was only 3%. I think there's a myth out there that stent-grafts when they go down, that they go down hard. But it actually turns out that compared to bare metal stent studies, the incidence of ALI is really quite similar. The fact that there were no major amputations and that there were no stent-graft fractures, I think is also very very important, very reassuring data as well.

Further Study Needed

This continues to be a very difficult problem and we have employed a variety of different technologies to try to meet this challenge. We have used in the clinical arena both Paclitaxel, as well as sirolimus drug-coated balloons. We've used atherectomy. We've used atherectomy either alone or with drug-coated balloons. And then there are other stent-grafts which are going to be coming onto the market as well. Most of these previous studies however, have been limited by the fact that these were pretty short lesion lengths that were treated and they had very limited follow up. I think one of the major strengths of this study is the fact that we have three year follow up. So I think it can really help inform physicians and patients about what might be the optimum strategy when they are presented with the challenge of in-stent restenosis. We obviously will need prospective, randomised trials to compare the safety and efficacy of all of these various technologies, either alone or in combination, to help us figure out what's the best way to move forward in this very challenging patient population.”