**Title:** **STRIKE-PE: Safety, Efficacy and Qol in PE Patients Treated with Mechanical Aspiration Thrombectomy**

**Participants: Dr John Moriarty**

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**Dr John Moriarty**

"Hi, I'm John Moriarty. I'm an interventional radiologist and professor and vice-chair at UCLA in Los Angeles, California.

Reasoning Behind The Trial

So this trial, which is a pivotal trial looking at interventional therapy in pulmonary embolism, it's called the Strike PE Trial. This is looking at, I think, one of the most novel areas of interventional vascular therapy. We know that VTE is incredibly common. We know that it's associated with a huge morbidity mortality burden and even a financial burden of up to 8.5 billion within the EU alone. And what the STRIKE PE trial was directed at was to see if a particular therapy of aspirating the thrombus, sucking out the blood clot using the penumbra indigo system, whether this would allow improved patient outcomes with a safe and efficacious procedure and looking not just acutely, but over time, to see how those patients did up to a year out.

Features of the Indigo Aspiration System

So the Indigo Aspiration system has been a product that has gone through evolution over the last few years. And the initial Indigo system, as evidenced by the extract PE trial, was a relatively smaller calibre system, an eight French aspiration system. The systems that we are now more modernly using and looking at in the Strike PE trial are either the Twelve French Lightning or the 16 French flash systems. And what these are, are aspiration catheters that are bespoke for the venous thromboembolism that have various angulations and deliverability optimizations that make it very safe in passage through the right heart to the target areas in the pulmonary arteries. And then they are attached to a bespoke engine which has a vacuum aspiration continuous system, which is controlled by a computer-aided algorithm to both aid in clot removal and mitigate against the downside of blood loss. So it's a system that has gone through, as I said, a lot of evolution to really optimize both the user experience as well as the patient outcomes.

Patient Population and Study Design

So the STRIKE PE study is one that we're very proud of. It's designed to evaluate the real-world long-term functional outcomes, as well as the acute safety and performance of the Indigo Aspiration system for the treatment of PE. It is enrolling at up to 55 global sites and will go for a total of 600 patients. So this is quite a large prospective trial. There are many patient-centric endpoints, including quality of life and functional evaluations, which will go on for a long-term follow-up of up to a year. And so this is an area that we think we're going to give real value in. Determining whether these patients not just survive, but also how they survive and whether the interventions that we are increasingly providing are giving them the benefits to their quality of life in general and as well to PE specific quality of life up to a year.

Key Findings

Fortunately, this study has been enrolling very well. We are now active on three different continents, and we are proud to present here at CIRSE the interim analysis of the first 87 patients who have 90-day follow-up. The key findings are that there is of these patients a very, very low major adverse event range. In other words, the safety of this procedure has been, I think, robustly shown. Again, the device-related clinical deterioration rate was 1%. That is well within expected and in fact lower than expected numbers. We have shown that there is a major bleeding rate of only 2.3% and that most impressively that these patients have had a very marked mortality advantage that so far we have shown an all-cause mortality up to 30 days of 0% with, I think, a very adequate safety profile. So the recurrent PE of 1%, the low extremely low any cause mortality and the low safety profile are all very promising to go into a little bit about who these patients are and do they fit the same patients that are in front of you in your clinic or in your hospital? We see that the majority of these are in the submass of our intermediate risk population as befits most study patients and indeed most patients who we see clinically. So 94% are in the intermediate risk while 5.7% were in the high risk population. We have shown improvements in various metrics including the RV to LV ratio as determined by a CTA or echo, as well as the unstable hemodynamics with the systolic pulmonary artery pressures decreasing from 50 to 41, clinically significant in each case. How these patients have fared according to themselves by both Borg scale perceived [indistinct] at rest as well as different quality of life scales has also been very promising. And we've seen improvements in their Borg scale, we have seen improvements in their EQ visual analogue scale as well as their PEM-QoL, which is a change in their overall quality of life specific to PE. This is also a study which is looking to see longer-term physiologic changes, and I'm proud to say that of the first 87 patients who we have six-minute walk tests, we have shown significant improvement in the six-minute walk test in patients who have this intervention. And so we hope that this is something that we're going to continue to demonstrate as we move through the larger patient cohort.

Take-Home Messages

So my take-home messages are that for the STRIKE PE study in a real-world population that matches what we're seeing in our everyday clinical patient practice with these PE patients, the data from STRIKE PE aligns with the data from the previous single-arm IDE studies and that there are three main things. Number one, there's an acceptable safety profile and a low rate of major adverse events. Number two, we've shown a significant RV to LV ratio reduction so that we believe that we are improving the right heart in these patients. And number three, we've shown a significant improvement in pulmonary artery pressures and hence we believe that the pulmonary hemodynamics and therefore perfusion and all the downstream effects of that are improved in these patients as well. We are beginning to see significant trends towards improved functional outcomes and quality of life in these patients. And as we've demonstrated here, up to 90 days, I really look forward to seeing whether that bears out or is indeed improved once we get the 365, year data.

Opportunities for Further Research

So the opportunities for further research in interventional PE are huge. And the main trend that we're going to see over the next while is higher-level data. And in particular, this is randomized controlled trials to bring us into alignment with cancer, therapies with stroke, with MI. One example would be the STORM PE trial, which is a randomized controlled prospective trial looking at high-risk and intermediate high-risk PE patients for mechanical aspiration, thrombectomy versus conservative management with anticoagulation alone. And I believe the STORM PE trial, which will be at up to 20 sites with 100 patients, a 90-day follow-up of both patient-centric and quality of life and functional outcomes. I think this is the sort of thing that's going to be very exciting to see result into the future.”