Title: Ultrasound-assisted Thrombolysis Vs Pulmonary Embolectomy for PE
Participants: Dr Stefan Stortecky
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Dr Stefan Stortecky

" My name is Stefan Stortecky. I'm a cardiologist, an interventional cardiologist working at Bern University Hospital. And my main focus is, despite the clinical field of coronary artery disease and the treatment itself, the valvular heart disease is pulmonary embolism. And this is also my research interest, and I'm the director of the pulmonary embolism program at Bern University Hospital, and I'm happy to be here.

Background of this Study

So I think when talking about pulmonary embolism, one might see that pulmonary embolism is still common and it's a potentially life-threatening clinical condition. And the guidelines are pretty clear-cut for patients that approach you with unstable clinical conditions. So with unstable hemodynamics, and there the recommendation of the guideline is pretty clear-cut for the treatment. So systemic thrombolytics should be applied to these patients whenever possible.

So patients that are not unstable, there it's not that clear. So in patients with intermediate high risk, these are patients that approach you with cardiac ischemia and signs of right heart dilation or overload. And for those patients, a wait and see strategy is somehow recommended. So we should not directly treat those patients, but they face a mortality of approximately 11% during the early phase of their event.

Catheter-directed treatment is a novelty. It's a novel treatment approach that is coming, and it's progressively growing. The interest in these techniques and surgical pulmonary embolectomy is a treatment that is established since years but is not widely accepted. And both catheter-directed treatment as well as surgical pulmonary embolectomy are currently considered as alternative reperfusion strategies for patients that are either with a contraindication for systemic thrombolysis or that have failed systemic lysis.

So in this era, both of which can be applied to the patients and there is no head-to-head comparison until now. So we don't have any randomized clinical trials, and this is why we designed the SPECIAL trial.

Study Design and Patient Population

So the SPECIAL trial is a randomized, single-center, clinically non-inferiority trial with the aim to show the effectiveness of catheter-directed thrombolysis to surgical pulmonary embolectomy. And it was executed at Bern University Hospital, single center.

The patient population declusion criteria, they were pretty broad. So patients were considered to be enrolled in case they had or they presented with acute pulmonary embolism, so with symptom onset below 14 days. And furthermore, they had to be at intermediate high or high risk for early mortality.

So when initially planning the trial, we considered a reduction in both of 0.3 to 0.4 of the primary endpoint, which was the RV/LV ratio, and there we set the non-inferiority margin at 0.1 and we had 80% power with a patient population with 28 patients per group, just to come to this power.

Fortunately, we had to prematurely terminate the trial as we had seriously difficulties in recruiting patients due to the progressively ongoing interest in interventional therapies. And patients were mainly denied for surgical pulmonary embolectomy.

Key Findings

So the patient population itself was normal. Patient population with pulmonary embolism, so normal what we would expect in terms of age. So mean age was 62 years of age for both groups we had 26% were females and 15% of patients were in the high-risk patient population in cardiogenic shock and 85% majority was in intermediate to high-risk classification.

Patients were treated with catheter-directed thrombolysis mainly over the femoral access. So in 100% we used the femoral access for the delivering of the catheters and 92% of patients received 20 milligrams of rtPA over the duration of 15 hours.

We had a good reduction in systolic pulmonary artery pressure in this patient population as it was measured through the catheters after the end of the procedure for surgical pulmonary embolectomy, if they were done using median sternotomy and under direct vision, they were just extracting the pulmonary emboli. And they were performed in 57% of patients using beating heart procedures and 43% had a cardioplegic arrest.

What we found, and this was interesting, we found that both procedures were effective in reducing the RV/LV ratio. Meaning? We found a mean change in RV/LV ratio of 0.34 in the patients in the patient population undergoing catheter-directed treatment and 0.53 in patients undergoing surgery when comparing those both non-inferiority was not met for catheter-directed thrombolysis when compared to surgical pulmonary embolectomy. And we had a mean difference of 0.52 which did not reach statistical significance. The p-value was 0.8.

In the post-hoc analysis, we found that a surgical pulmonary embolectomy was even superior to catheter-directed thrombolysis and it reached statistical significance for secondary outcomes. We assessed the obstruction index, the obstruction score, the quanadli obstruction score and there we found the same picture. So both procedures were effectively able just to reduce the obstruction in the pulmonary, in the, vasculature, but on the other side surgically pulmonary embolectomy was even better and had greater reduction in clots as compared to catheter-directed thrombolysis. The same applied also for total and partially occluded segments which was one of our exploratory endpoints.

Take-Home Messages

So the SPECIAL trial is very important just to inform somehow the discussion, particularly with regards to endovascular therapies. Facing our difficulties that we had with recruiting the patients and the discussions we had surrounding this treatment. I

think that surgical pulmonary embolectomy will remain in experienced centers as one of the valid treatment options. But I think as long as patients are able just to discuss their treatment, I think we nowadays have endovascular treatment options. Of embolectomy, which may be as good as the surgical counterparts. And we will see this, I think, in future trials that will approach us pretty soon.

Next Steps

The next steps are we continue to enhance the literature with good studies and we will continue to perform catheter-directed thrombolysis as well as endovascular therapies and for particular for patients who are at increased risk also for death during their clinical situation. Clinically condition there we still consider surgical pulmonary embolectomy because we have a large experience in this area."