

**Title: TRILUMINATE Pivotal: TEER for Tricuspid Regurgitation**

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## **Dr Paul Sorajja**

"So I'm Paul Sorajja. I'm an interventional cardiologist at the Minneapolis Heart Institute in the United States. I do a lot of work focused on valvular interventions and structural heart disease.

### **What are some of the unmet needs in patients with TR?**

So when we think about tricuspid regurgitation, we know that historically it's been defined or described as a relatively forgotten disease. And that's because the vast majority of these patients have been treated without medicines. And it's historically been kind of left on its own because there's been so much historical focus on aortic and mitral disease instead of TR. But I think in terms of the unmet needs, what we realize in recent studies is that TR is actually associated with a lot of morbidity. It's associated with an impaired quality of life, and for some patients, it's also associated with impaired survival.

### **What was the study design, patient population and outcome measures?**

So in TRILUMINATE, We did a randomized trial of TriClip versus medical therapy alone. And what we found in that trial was that TriClip associated with a high degree of relief of TR and an improvement in quality of life.

### **What are the key findings to date?**

So the key findings for TRILUMINATE was a pretty marked reduction in TR for the device compared to the control group. There was no difference in survival at one year and no difference in hospitalization for heart failure. But we did see marked improvements in quality of life with the device over medical therapy alone. And importantly, it was a very safe procedure as well.

**Were there any specific aspects of quality of life that showed the most notable improvement?**

So we didn't look at specific physical or mental or different measures of quality-of-life. It was more that the quality-of-life as an instrument as a whole was markedly improved with the device. And I think that's also important because most of the quality-of-life measures that we have been for left sided disease. They haven't necessarily been specific to right sided disease. And so we do need to look at that in more detail.

**What are the take-home messages for clinicians?**

I think the most important part about TRILUMINATE and the results that we presented here at EuroPCR is that, first of all, the TriClip is highly effective in reducing TR. It's a very safe procedure. It is associated with marked improvement of quality-of-life. And when we look at these patients in TRILUMINATE, these are patients who had TR without untreated left-sided valve disease. And the prognosis of these patients, while there's certainly a significant degree of impairment at baseline, the survival is not the same as left-sided disease. These patients had RV enlargement, they had RV dysfunction, they had moderate degrees of pulmonary hypertension and the TR was causing hemodynamic congestion. But overall, they actually did quite well with medical therapy. It's just that the quality-of-life was not improved.

**What are the next steps? How do you see the future of TEER?**

Well, I think that when we think about TEER, it's important that this trial picked patients who were eligible for the trial based on anatomic suitability. So there will be patients who are not anatomically suitable that would require other methods such as replacement or cardiac surgery. And I think when we follow these TRILUMINATE patients, it's going to be important that we see what the long-term effects of TR would be in the control arm, because it's actually quite torrential in the control arm compared to the patients in the device arm, where it was importantly quite relieved. And it's also important to see how close those differences in quality-of-life that we saw, which were

much better with TriClip, how those continue to be sustained in the long-term follow-up.”