- My name is Stephan Baldus, I'm head of the department of cardiology at the University Heart Centre in Cologne. And I'm focusing on catheter treatment of structural heart disease.

Unmet Needs of Patients With TR

So the unmet needs of patients with tricuspid valve disease are, as following. We foresee a large cohort of patients. The prevalence of tricuspid regurgitation is as high as aortic stenosis. However, most of these patients with severe tricuspid regurgitation are those patients who cannot be offered an operative treatment strategy because they are simply too sick. And in the past we have in way neglected this large cohort of patients because we were not able to address an equivalent and adequate treatment option for these patients. And this is the challenge we are facing as of today. So patients with tricuspid regurgitation, with tricuspid valve disease are probably one of the most challenging patient cohorts we face in, in our daily practice. On the one hand, tricuspid regurgitation is very prevalent is it- it is as prevalent as aortic stenosis, but it has been for a long time overseen because we didn't have a, a good treatment option for these patients. The problem is that these patients are typically in an very advanced stage of their disease, so that surgical treatment is most often not a potential treatment strategy, given the high surgical risk for these patients. Mortality per procedural mortality of most of these patients is above 10%. If you have a singular, if you have an isolated treatment of tricuspid regurgitation, and on the other hand the simple treatment with medical therapy is not efficient enough. So we are facing a very prevalent disease with worse prognosis. We know that patients who have tricuspid regurgitation have a twofold increase in mortality irrespective of other cardiac diseases. And we have a patient collective which is so severely diseased that surgical therapy for most of these patients is not an option.

Study Design, Patient Cohort and Outcome Measures

So in this study, which investigated a transcatheter approach to treat tricuspid regurgitation using the PASCAL transcatheter system, we designed a prospective multicenter single arm study to evaluate safety and the efficacy of the tricuspid PASCAL system in patients with severe tricuspid regurgitation. This study was a multicenter study as I just said, it was adjudicated, and we had a clinical events committee as well as a core valve for assessment of severity of tricuspid regurgitation as well as follow up assessment of the efficacy of the treatment.

Key Findings and Considerations

So the patients we treated were typical cohort of patients with tricuspid disease, with tricuspid valvular disease. These patients had an average age of 80. They had a high risk score for operative surgery, and were considered very high risk cohort of patients. Had atrial fibrillation, had renal disease, diabetes, very high percentage. And these patients were treated with the PASCAL device and the major clinical findings we have so far for the first 74 patients, consecutive patients treated, is that we had an exceptionally low mortality. 30 day mortality of below 2% and a very high efficacy rate. Almost 90% of these patients had moderate or less residual tricuspid regurgitation. And 50% of these patients were in New York heart association class two after the intervention. So we consider this therapy very, very efficient, very safe given the low mortality rates, which is far below what, what we see with respect to surgical therapy and significantly lower than what we've seen in in early trials, evaluating reconstructive therapy for tricuspid regurgitation. So we are very optimistic that this therapy has an indication in the future for the treatment of this particular patients.

Characteristics of Studied Technology

So the key characteristics of this transcatheter system the PASCAL transcatheter system is that this system is an, a leaflet based reconstructive therapy system. So what you're doing is you're basically coacting two of the three leaflets of the tricuspid valve. And you're doing this with a mechanism of pedals which engage the two of leaflets. And then you have grippers, which we call clasps in this case, which secure the leaflets, and then you can close it and thereby you directly reduce the the regurgitant orifice as well as reduce the circumference of the tricuspid annulus. So you have an annuloplasty effect as well as a direct TR-reducing effect by the device.

Take-Home Messages for Clinicians

I guess the key take home message from this trial are first tricuspid regurgitation is a malignant disease. It's very prevalent, and it imposes increased risk of mortality. Second, most of the patients with this disease are no candidates for conventional surgical therapy. So the transcatheter device we tested, we evaluated in this study, this device is of, of high importance for the future treatment of patients with this prevalent disease. And what we've seen is that the system is very safe with respect to mortality and morbidity, and we have seen that this system also is very efficient in reducing the extent of tricuspid regurgitation. Whether this system has the impact in reducing mortality is something we will evaluate in further, in upcoming randomised trials. What we know for now is that it's a safe and efficient tool to treat this cohort of patients.