

# Clinical Trials and Outcomes in Tricuspid Valve Regeneration Therapy

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## DESCRIPTION

The field of tricuspid valve regeneration therapy has seen significant advancements in recent years, regulated by a growing recognition of the importance of the tricuspid valve in overall cardiac health. Traditionally, tricuspid valve disease, particularly Tricuspid Regurgitation (TR), has been unappreciated by conditions affecting the left-sided heart valves. However, as our understanding of the implications of untreated TR deepens, the focus on developing innovative treatment options has intensified. This article will provide an overview of the current state of clinical trials in tricuspid valve regeneration therapy, highlighting key developments and discussing their potential impact on patient outcomes.

### Understanding tricuspid valve disease

Tricuspid valve disease encompasses a spectrum of conditions, with TR being the most prevalent. This condition occurs when the tricuspid valve fails to close properly, allowing blood to flow backward into the right atrium. The consequences of untreated TR can be severe, leading to right heart failure, arrhythmias, and decreased exercise tolerance. Historically, surgical options for TR were limited, often involving open-heart surgery, which carries significant risks and longer recovery times. As a result, many patients remained untreated or were considered unsuitable for surgery.

### Transcatheter tricuspid valve repair

One of the most promising areas in tricuspid valve regeneration therapy is transcatheter tricuspid valve repair. Several devices have been developed and are currently being evaluated in clinical trials, offering less invasive alternatives to traditional surgical approaches.

**Mitraclip/Triclip:** The triluminate trial is investigating the safety and effectiveness of this device in patients with severe TR. Early results have shown a device success rate exceeding 90%, with significant improvements in symptoms and quality of life reported by patients.

**Pascal (Edwards lifesciences):** The Pascal system has demonstrated an 82%-90% device success rate in clinical reports. The Clasp trial is currently evaluating its effectiveness in a broader patient population.

**Forma (Edwards lifesciences):** This device has shown an 89% success rate in early studies, with notable improvements in TR and overall clinical outcomes.

These transcatheter repair techniques represent a fundamental change in the management of TR, allowing for intervention without the need for open-heart surgery. The minimally invasive nature of these procedures can lead to faster recovery times and reduced complications, making them particularly beneficial for high-risk patients.

### Transcatheter tricuspid valve replacement

In addition to repair techniques, transcatheter tricuspid valve replacement is also an area of active investigation. The TRISCEND (Edwards EVOQUE-Tricuspid valve Replacement: Investigation of Safety and Clinical Efficacy after replacement of tricuspid valve with transcatheter Device) trial, which evaluated the Edwards EVOQUE tricuspid valve replacement system, reported that TR was reduced to mild or less in 98% of patients at one year post-procedure. This suggests that transcatheter replacement may be a feasible option for patients with severe tricuspid valve disease who are not candidates for repair. The ability to replace the tricuspid valve using a transcatheter approach is particularly significant, as it opens up treatment options for patients who previously had limited alternatives. The early results from these trials indicate that transcatheter replacement may provide similar, if not superior, outcomes compared to traditional surgical methods.

### Tissue engineering and regenerative therapies

Beyond transcatheter interventions, researchers are also exploring tissue engineering and regenerative therapies to treat tricuspid valve disease. These approaches aim to restore the function of the valve using biocompatible scaffolds or stem cell

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therapy, without the need for invasive procedures. While still in the early stages of development, these therapies hold promise for the future of tricuspid valve treatment. For instance, tissue-engineered heart valves can be created using a patient's own cells, potentially reducing the risk of rejection and complications associated with synthetic materials. Stem cell therapy may also offer a way to regenerate damaged valve tissue, providing a more natural and durable solution to TR.

### **Impact on patient outcomes**

The advancements in tricuspid valve regeneration therapy have the potential to significantly improve patient outcomes. By providing less invasive treatment options, these therapies may reduce the risk of complications and improve quality of life for patients with tricuspid valve disease. Clinical trials have shown that patients undergoing transcatheter interventions often experience rapid symptom relief and improved functional capacity, leading to enhanced overall well-being. Moreover, the focus on regenerative approaches could lead to more durable and effective treatments, potentially reducing the need for repeat interventions. As these therapies continue to evolve, they may

also help alleviate the increasing prevalence of tricuspid valve disease in an aging population.

### **CONCLUSION**

The field of tricuspid valve regeneration therapy is rapidly evolving, with a growing number of clinical trials exploring innovative approaches to treat this common and often overlooked condition. While challenges remain, the potential impact on patient outcomes is significant. As research continues and these therapies are integrated into clinical practice, patients with tricuspid valve disease may have access to safer, more effective, and less invasive treatment options that can improve their overall cardiac health and quality of life. The ongoing exploration of transcatheter repair and replacement techniques, along with advancements in tissue engineering and regenerative therapies, emphasizes the importance of prioritizing research in this area. By addressing tricuspid valve disease with innovative solutions, the medical community can enhance patient care and outcomes, ultimately transforming the field of cardiac medicine.