

# Transcatheter mitral valve replacement with the NaviGate stent in a preclinical model

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### Abstract

**Aims:** The aim of this study was to test the feasibility of transcatheter mitral valve implantation of the NaviGate device in acute and chronic preclinical models.

**Methods and results:** We evaluated NaviGate valved stent implantation in the mitral position in an acute swine model (n = 24, <= 5 days) through three different approaches - transatrial, transapical, and transseptal - and in a chronic swine model (n = 12, > 10 days) through a transatrial approach. The NaviGate implantation procedures were successful in 83% of the acute model studies (n = 20) and 83% of the chronic model studies (n = 10).

Echocardiographic assessment showed low gradient across the valved stent (mean gradient < 3 mmHg) and the left ventricular outflow tract (mean gradient < 6 mmHg). Post implantation, there was no mitral regurgitation (MR) in 75% (n = 15) of the acute studies and mild MR in 25% (n = 5). In the chronic model, there was no MR in 60% (n = 6) and mild MR in 40% (n = 4). The implantation procedure was aborted in four acute studies due to inferior vena cava injury and in two chronic studies due to prosthesis-annulus mismatch.

**Conclusions:** In preparation for clinical application, transcatheter mitral implantation of the NaviGate valved stent was proved feasible in acute and chronic preclinical models. The three featured delivery approaches are of particular value for high-risk patients with functional MR and challenging vascular access.

**Palabras clave**

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