



IQWiG Reports – Commission No. H20-08

Endovascular implantation of a stent graft with a valve component for tricuspid regurgitation¹

Extract

¹ Translation of the executive summary of the §137h assessment: H20-08 *Endovaskuläre Implantation eines Stentgrafts mit Klappenelement bei Trikuspidalklappeninsuffizienz* (Version 1.0; Status: 25 February 2021). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher

Institute for Quality and Efficiency in Health Care

Topic

Endovascular implantation of a stent graft with a valve component for tricuspid regurgitation

Commissioning agency

Federal Joint Committee

Commission awarded on

14 January 2021

Internal Commission No.

H20-08

Address of publisher

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IQWiG thanks the medical expert advisor for his contribution to the §137h assessment. However, the advisor was not involved in the preparation of the §137h assessment. IQWiG is solely responsible for the content of the §137h assessment.

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Keywords: Tricuspid Valve Insufficiency, Heart Valve Prosthesis, Device Approval, Risk Assessment, Benefit Assessment

Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method “endovascular implantation of a stent graft with a valve component for tricuspid regurgitation” according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were submitted to IQWiG on 14 January 2021.

According to the submission form, endovascular implantation of a stent graft with a valve component is intended for the treatment of patients with severe tricuspid regurgitation who show corresponding symptoms, whose general condition (physical performance, state of decompensation) is gradually deteriorating, and for whom no surgical intervention is possible due to a high risk of surgery. Endovascular implantation of a stent graft with a valve component aims to compensate for the leakage of the diseased native tricuspid valve in such a way that backflow and thus excess pressure in the venous circulation no longer occur. The insertion of an additional valve on the right side of the heart aims to correct the unphysiological pressure changes in the venous system, which lead to considerable symptoms.

Only 9 case reports and 2 case series were available to assess endovascular implantation of a stent graft with a valve component for patients with tricuspid regurgitation.

Findings on a benefit, ineffectiveness or harmfulness of endovascular implantation of a stent graft with a valve component for patients with tricuspid regurgitation could not be derived from the data submitted, as no comparative data were available. Likewise, the supplemental examination of the results of the case series did not suggest that the method is harmful.

Overall, in this assessment according to §137h, based on the documents submitted neither a benefit, harmfulness nor ineffectiveness of endovascular implantation of a stent graft with a valve component for patients with tricuspid regurgitation can be identified.

A testing study suitable to provide the necessary findings to assess the benefit of the method is possible in principle. To demonstrate a difference in health-related quality of life, a medium-sized randomized controlled trial comparing endovascular implantation of a stent graft with sham treatment would be required.

The full report (German version) is published under

<https://www.iqwig.de/en/projects/h20-08.html>