



IQWiG Reports – Commission No. H21-07

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

Addendum to commission H20-08¹

Extract

¹ Translation of the executive summary of the addendum H21-07 *Endovaskuläre Implantation eines Stentgrafts mit Klappenelement bei Trikuspidalklappeninsuffizienz – Addendum zum Auftrag H20-08* (Version 1.0; Status: 14 June 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
– Addendum to commission H20-08

Commissioning agency

Federal Joint Committee

Commission awarded on

7 May 2021

Internal Commission No.

H21-07

Address of publisher

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Im Mediapark 8
50670 Köln
Germany

Phone: +49 221 35685-0

Fax: +49 221 35685-1

E-mail: berichte@iqwig.de

Internet: www.iqwig.de

IQWiG employees involved in the §137h addendum

- Heike Kölsch
- Daniel Fleer
- Wolfgang Groß
- Tatjana Hermanns
- Christoph Schürmann

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

Executive summary

In a letter dated 7 May 2021, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission H20-08, to examine the conclusions of the assessment according to §137h Social Code Book (SGB) V on the benefit, harmfulness and ineffectiveness of the method “endovascular implantation of a stent graft with a valve component for tricuspid regurgitation.”

Research question

The aim of the present investigation was to determine whether further relevant studies on the method “endovascular implantation of a stent graft with a valve component for tricuspid regurgitation” exist besides the documents already used in the §137h assessment H20-08. If this was the case, it was to be examined whether, taking these into account, still neither a benefit, harmfulness nor ineffectiveness could be identified for the examination or treatment method in question. Furthermore, it was to be examined whether, besides the studies already used in the §137h assessment, ongoing studies exist that are in principle suitable to provide relevant findings on the benefit, harmfulness or ineffectiveness of the method in the near future.

Methods

Randomized controlled trials (RCTs) were to be included that investigated the method “endovascular implantation of a stent graft with a valve component for tricuspid regurgitation” with regard to patient-relevant outcomes and had not already been used in the assessment according to §137h.

A systematic literature search for studies was conducted in MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was conducted in MEDLINE, Embase, the Cochrane Database of Systematic Reviews, and the HTA Database. In expectation of the commission, the search was conducted on 18 March 2021. In addition, the following information sources and search techniques were considered: study registries and screening of reference lists. The selection of relevant studies was performed by 2 reviewers independently of one another.

Results

Information retrieval did not identify additional relevant completed or ongoing studies that related to the present research question.

Conclusion

After systematic examination, there is still no evidence of a benefit, ineffectiveness or harmfulness of the method “endovascular implantation of a stent graft with a valve component for tricuspid regurgitation.” Beyond the studies already considered in the §137h assessment, no additional completed or ongoing studies were found that would in principle be suitable to provide evidence of a benefit, ineffectiveness or harmfulness in the near future.

The full report (German version) is published under
<https://www.iqwig.de/en/projects/h21-07.html>