Endovascular implantation of a transcatheter tricuspid valve replacement for tricuspid valve insufficiency[1]

EXTRACT

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[1] Translation of the executive summary of the §137h assessment H23-03 *Endovaskuläre Implantation eines Transkatheter-Trikuspidalklappenersatzes bei Trikuspidalklappeninsuffizienz* (Version 1.0; Status: 8 May 2024). 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.

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Medical and technical advice

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IQWiG would like to thank the medical expert for his contribution to the §137h assessment. However, he was not involved in the preparation of the §137h assessment. IQWiG alone is responsible for the content of the §137h assessment.

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Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method of endovascular implantation of a transcatheter tricuspid valve replacement for tricuspid valve insufficiency in accordance with §137h of the German Social Code (SGB) Book V - Statutory Health Insurance. The assessment documents were submitted to IQWiG on 28 March 2024.

Endovascular implantation of a transcatheter tricuspid valve replacement is intended for the treatment of patients with severe tricuspid valve insufficiency who are not suitable for surgical intervention (repair or replacement) based on the cardiac team's decision or the surgical risk, and/or for whom transcatheter tricuspid valve repair is not suitable for anatomical reasons (e.g. coaptation gap too large or significant leaflet tethering).

Six case series were available for the assessment. In addition, one ongoing randomized controlled trial (RCT) was identified.

No conclusions about the benefit or ineffectiveness of the method could be drawn from the data presented, as no comparative data were available. The supplementary review of the case series to identify harms revealed relevant discrepancies between the published study data and the submitted highly confidential study data. However, these highly confidential data could not be used for this report. Due to these discrepancies, the usable sources did not provide a sufficiently reliable source for the assessment of the harmfulness of the method; it is therefore not possible to make an adequate assessment in this regard. For this reason, the key points of a testing study are not discussed.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h23-03.html