IQWiG Reports – Commission No. H21-05

Percutaneously implanted interatrial shunt for the treatment of heart failure

Addendum to commission H20-06[1]

Extract

[1] Translation of the executive summary of the addendum H21-05 *Perkutan-implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz – Addendum zum Auftrag H20-06* (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.

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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 addendum

- Britta Runkel
- Daniel Fleer
- Ulrike Lampert
- Fabian Lotz

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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 H20-06, to examine the conclusions of the assessment according to §137h Social Code Book (SGB) V on the benefit, harmfulness and ineffectiveness of the method "percutaneously implanted interatrial shunt for the treatment of heart failure."

Research question

The aim of the present investigation was to determine whether further relevant studies on the method "percutaneously implanted interatrial shunt for the treatment of heart failure with reduced ejection fraction (HFrEF)" exist besides the documents already used in the §137h assessment H20-06. 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 "percutaneously implanted interatrial shunt for the treatment of heart failure" 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 last search was conducted on 17 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.

Moreover, there is no new information on the currently ongoing study RELIEVE-HF (NCT03499236) and we refer to the §137h assessment H20-06.

Conclusion

After systematic examination, there is still no evidence of a benefit, ineffectiveness or harmfulness of the method "percutaneously implanted interatrial shunt for the treatment of heart failure." 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

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