Percutaneously implanted interatrial shunt for the treatment of heart failure with reduced left ventricular ejection fraction (LVEF < 40%)[1]

EXTRACT

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[1] Translation of the key statement of the rapid report N24-04 *Perkutan implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz mit reduzierter linksventrikulärer Ejektionsfraktion (LVEF < 40 %)* (Version 1.0; Status: 1 July 2025). 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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This report was prepared in collaboration with external experts.

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Key statement

Research question

The aim of this investigation is

- to assess the benefit of treatment with a percutaneously implanted interatrial shunt in addition to guideline-based drug therapy, compared with guideline-based drug therapy alone

in patients with heart failure and reduced left ventricular ejection fraction (LVEF < 40 %) (HFrEF) and elevated left atrial pressure, who remain symptomatic despite guideline-based drug therapy.

Conclusion

This assessment included one randomized controlled trial (RELIEVE-HF) comparing interatrial shunts with standard drug therapy alone, with data from a total of 206 patients with heart failure and reduced LVEF (≤ 40 %).

With regard to heart failure-related hospitalizations, the data suggest a possible advantage. Although data on the total number of hospitalizations were collected, they were not available. Due to the lack of such data, the results concerning heart failure-related hospitalizations cannot be interpreted with sufficient certainty as indicating an advantage.

Furthermore, data on adverse events are only partially available: despite planned data collection, results are notably missing on the overall rate of serious adverse events (SAEs), on SAEs by System Organ Class and Preferred Terms according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, and on all device- and procedure-related SAEs.

Due to the only partial availability of study data on hospitalizations and SAEs, the benefit and harm of an interatrial shunt compared with standard drug therapy alone remain unclear until a comprehensive assessment can be made on the basis of the complete study results.

The full report (German version) is published under

https://www.iqwig.de/projekte/n24-04.html