Endovascular implantation of a transcatheter tricuspid valve replacement in tricuspid valve insufficiency

Second addendum to Project H23-03 (§137h assessment)[1]

EXTRACT

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Executive summary

In a letter dated 25 November 2024, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to supplement projects H23-03 and H24-03 by reviewing the conclusions in the assessment in accordance with §137h of the German Social Code, Book V (SGB V) on the benefit, harmfulness or ineffectiveness of endovascular implantation of a transcatheter tricuspid valve replacement in patients with tricuspid valve insufficiency.

Research question

The aim of this investigation was to determine whether, in addition to the documents already referred to in the § 137h assessment H23-03 and in the addendum H24-03, there are any other relevant studies on the endovascular implantation of a transcatheter tricuspid valve replacement in patients with tricuspid valve insufficiency. If this was the case, it was necessary to examine whether, taking these into account, the benefit, harmfulness or ineffectiveness of the examination or treatment method in question were still not apparent. Furthermore, it was necessary to examine whether, in addition to the studies already considered in the §137h assessment, there were any other studies in progress that were fundamentally suitable for providing relevant findings on the benefit, harmfulness or ineffectiveness of the method in the near future.

Methods

Randomized controlled trials (RCTs) were included that examined the method of endovascular implantation of a transcatheter tricuspid valve replacement in tricuspid valve insufficiency with regard to patient-relevant outcomes and that had not already been used in the §137h assessment.

A systematic literature search for studies was conducted in the MEDLINE and the Cochrane Central Register of Controlled Trials. At the same time, a search for relevant systematic reviews was conducted in MEDLINE, the Cochrane Database of Systematic Reviews, and the HTA Database. The search took place on 25 November 2024. In addition, the following sources of information and search techniques were considered: study registries and the review of reference lists. The selection of relevant studies was carried out independently by two reviewers.

The evaluation, synthesis, and analysis of information followed the principles described in the Institute's General Methods.

Results

During the information retrieval process, 3 additional publications were identified on the TRISCEND II RCT, which had already been included in the §137h assessment. This provided

informative results for the first time. The data had moderate certainty of results. No additional relevant completed or ongoing studies were identified.

One advantage of endovascular implantation of a transcatheter tricuspid valve replacement over guideline-based drug therapy alone was found to be health-related quality of life. Although the results of the objective outcome of physical performance were not robust and did not show a clear positive effect of the intervention, they did point in the same direction.

A disadvantage of the intervention was found in particular with regard to severe bleeding, implantation of a pacemaker or other cardiac electronic device, and some serious adverse events (SAEs): atrioventricular block, bradycardia, and thrombosis at the heart valve replacement site. However, patient-based analyses comparing groups in terms of the overall rate of SAEs, procedure- and device-related SAEs, and rates summarized according to the respective system organ classes (SOC) are not included in the published results. It is possible that reporting based solely on individual SAEs underestimates the overall risk of implantation. The available SAE analyses therefore do not provide a complete picture of harm.

The increased risk associated with implantation was also reflected in a temporarily increased mortality risk up to 30 days after the procedure. Over a longer period, however, mortality returned to normal (no statistically significant difference was observed 1 year or 18 months after the procedure) and numerical differences in favour of the intervention were observed. Over the entire observation period, there was neither an advantage nor a disadvantage in terms of mortality.

For the other outcomes (hospitalization due to heart failure, tricuspid valve surgery or percutaneous tricuspid intervention, improvement in physical performance, implantation of a right ventricular assist device [RVAD] or heart transplantation, myocardial infarction and stroke), there was also no discernible advantage or disadvantage of the intervention.

Despite a benefit in terms of health-related quality of life, it is currently not possible to draw an overall conclusion on the benefit, ineffectiveness, or harmfulness due to the incomplete analyses of SAEs. Therefore, the previous assessment result (no proof of the benefit, harmfulness or ineffectiveness of the method) cannot be adequately verified at present.

It is expected that the gaps in knowledge described above can be closed if the complete study documents from the TRISCEND II study are submitted for assessment.

Conclusion

After systematic examination, no overall conclusion can currently be drawn regarding the benefit, harmfulness or ineffectiveness of endovascular implantation of a transcatheter tricuspid valve replacement in patients with tricuspid valve insufficiency due to incomplete

reporting (incomplete analysis of SAEs in the TRISCEND II study). Therefore, the previous assessment result (no proof of the benefit, harmfulness or ineffectiveness of the method) cannot be adequately verified at present.

Beyond the TRISCEND II study already cited in the first addendum H24-03, no other completed or ongoing studies were found that would be fundamentally suitable for providing evidence of the benefit, harmfulness or ineffectiveness of the method in the near future.

The full report (German version) is published under
https://www.iqwig.de/projekte/h24-04.html