

3-dimensional intracardiac echocardiography in transcatheter interventions for the treatment of structural heart disease¹



EXTRACT

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Executive summary²

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method of real-time three-dimensional intracardiac echocardiography (3D-ICE) for intraprocedural use in percutaneous transcatheter interventions for the treatment of structural heart disease in accordance with §137h of the German Social Code (SGB) Book V - Statutory Health Insurance. The assessment documents were submitted to IQWiG on 13 November 2025.

According to the information provided in the submission form, the method is intended to enable improved imaging and procedural optimization of the respective underlying intervention compared with three-dimensional transoesophageal echocardiography (3D-TEE). It is intended to optimize the duration of sedation, reduce the administration of contrast agents and potentially eliminate the need for general anaesthesia and 3D-TEE. In addition, 3D-ICE is intended to enable transcatheter procedures in a population where currently available imaging techniques have not yet been successfully applied.

The present assessment documents relate to an assessment of the method, on the one hand, in patients with structural heart disease for whom 3D-ICE is intended to supplement or replace 3D-TEE (Research Question 1), and, on the other hand, in patients with structural heart disease who require a 3D-TEE-guided transcatheter procedure but for whom this has not yet been feasible due to contraindications (Research Question 2).

Documents relating to 27 studies with results were available for the assessment. Of these, one comparative study on the use of 3D-ICE as a complement to 3D-TEE in the indication of tricuspid valve regurgitation was available for Research Question 1.

For Research Question 1, the comparative data on the use of 3D-ICE as a complementary treatment guidance method to 3D-TEE in tricuspid valve regurgitation did not allow conclusions to be drawn regarding the benefit, ineffectiveness or harm of the method. No further comparative studies were available, either for the use of 3D-ICE as a substitute for 3D-TEE or for other indications or areas of application under assessment. For Research Question 2, no comparative study could be identified. A supplementary review of the results of other submitted studies did not suggest that the method was harmful.

Overall, based on the documentation submitted for 3D-ICE, this §137h assessment does not allow conclusions to be drawn regarding its benefit, harmfulness or ineffectiveness. This

² The executive summary in version 1.1 is the same as the one in version 1.0. Version 1.1 was created after an editorial amendment was made to the reference list in the full report of version 1.0.

applies to all patients with structural heart disease, regardless of whether the planned transcatheter cardiac procedure can be performed using 3D-TEE guidance or is not possible due to a 3D-TEE contraindication.

For a testing study, a multicentre, randomized controlled trial (RCT) involving approximately 1,200 patients could be envisaged for Research Question 1, with the aim of demonstrating that the use of 3D-ICE to supplement or replace 3D-TEE offers advantage in terms of the primary outcome of cardiovascular serious adverse events (SAEs) after 1 year. The randomization of study participants could be stratified according to all areas of application relevant to the assessment, as well as additionally according to the possible uses of 3D-ICE (as a supplement to or replacement for 3D-TEE; i.e. for, say, 6 areas of application considered partly in combination: $2 \times 6 = 12$ strata). Under certain conditions, no separate clinical trials would be necessary to assess the benefit of 3D-ICE for Research Question 2.

The proposal outlined here represents a pragmatic compromise between the feasibility and the validity of a testing study. However, the proposed study's prospects of success depend to a considerable extent on several conditions being met. This also applies to the possibility of being able to dispense with conducting our own testing studies for Research Question 2.

The full report (German version) is published under

<https://www.iqwig.de/projekte/h25-03.html>