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Ticagrelor after MI: Added benefit called into question by data subsequently submitted

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The drug ticagrelor has been approved since February 2016 for adults who had a myocardial infarction a year or more ago and are at a high risk of a new myocardial infarction or stroke. Ticagrelor is used together with low-dose acetylsalicylic acid (ASA). In its dossier assessment published in early July 2016, the German Institute for Quality and Efficiency in Health Care (IQWiG) determined an indication of a minor added benefit of ticagrelor in comparison with the administration of ASA alone.

On the inclusion of additional analyses that the drug manufacturer provided in the commenting procedure conducted by the Federal Joint Committee (G-BA), the Institute now came to a different conclusion, however: An added benefit is not proven because positive effects are called into question by negative effects.

Non-severe bleeding notably more common

The dossier had only contained data on severe bleeding. There were no data on non-severe bleeding that are clinically relevant. The results of the analyses subsequently submitted by the manufacturer were to the disadvantage of ticagrelor: Since these bleeding events were notably more common than under ASA monotherapy, IQWiG determined proof of greater harm with the extent "considerable".

No data on quality of life

In addition, there were no data on quality of life. Particularly in coronary heart disease (CHD), this is a very important outcome criterion however, which is even more important in view of side effects such as dyspnoea. "Disease-related quality of life" is the first treatment goal listed in the recently published revised version of the National Care Guideline for Coronary Heart Disease.

Since, on the one hand, greater harm was proven for an additional outcome, and, on the other, no data on quality of life were available, the positive effects, including the ones regarding mortality and late complications, were called into question by the negative effects. In the overall consideration, no added benefit of ticagrelor plus ASA in comparison with ASA monotherapy could be derived from the data.

Provided by Institute for Quality and Efficiency in Health Care

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