Long-acting insulin analogues in type 1 diabetes: No proof of additional benefit

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It has so far not been proven that the long-acting insulin analogues (LAIAs) insulin detemir (trade name: Levemir) and insulin glargine (trade name: Lantus), which are approved for the treatment of type 1 diabetes, offer patients an additional benefit versus long-acting human insulin. This applies to adults as well as to children and adolescents. This is the result of the final report published by the Institute for Quality and Efficiency in Health Care (IQWiG) on 19 April 2010.

The final report is the last part of a comprehensive commission package awarded by the Federal Joint Committee (G-BA), by which key therapy options for people with diabetes were to be assessed. The reports on rapid-acting insulin analogues in type 1 and 2 diabetes, as well as on LAIAs in type 2 diabetes had already been completed beforehand.

Only one 24-month study available

For the assessment of the LAIAs, IQWiG searched for studies that either compared one of the two currently approved LAIAs for the treatment of type 1 diabetes (insulin glargine and insulin detemir) with human insulin, or compared the benefit of the two LAIAs with each other.

A total of 12 studies were found that were suitable for consideration in the benefit assessment of adult patients; 2 of these studies were previously unpublished. Five further studies in children and adolescents were identified, of which 2 were also unpublished. However, the

manufacturers (Sanofi-Aventis, Novo Nordisk) provided IQWiG with the required information. All studies were open label, i.e. patients and treating staff knew who was receiving which agent. Sixteen studies only monitored patients over a period of 24 to 54 weeks. Only one study, which compared insulin detemir and human insulin in adults, lasted 2 years.

Human insulin often not used in the best possible way

In addition, IQWiG found that the treatment schemes differed in the individual studies. In particular, the frequency of the insulin injections varied. It was notable that patients were given specifications particularly on the use of long-acting human insulin, which prevented them from injecting this type of insulin in a way that is customary and recommended in Germany. Studies were therefore primarily considered in the benefit assessment where patients were allowed to individually optimize their treatment with human insulin. No advantage of insulin analogues was shown in these studies.

No conclusions on late complications and mortality possible

Due to the mainly short duration and small patient numbers in the present studies, no conclusions are possible regarding the effects of LAIAs on late diabetic complications, mortality and long-term safety.

For insulin glargine (Lantus) controversy exists at an international level as to whether this drug could promote the growth of cancer cells. Cell experiments and several epidemiological studies have given rise to this suspicion. However, this association is not proven. Moreover, the epidemiological studies mainly analysed data on patients with type 2 diabetes. In the present benefit assessment of type 1 diabetes, IQWiG

and its external experts did not identify studies allowing conclusions to be drawn regarding any cancer-promoting effect of insulin glargine or insulin detemir compared to human insulin or to each other. Patients have the option of avoiding the uncertainty surrounding glargine by choosing not to use this agent.

No advantage regarding severe hypoglycaemia

No superiority of insulin glargine or insulin detemir versus human insulin can be inferred from the data for the outcomes quality of life and treatment satisfaction. Some of the clinical comparisons showed no relevant differences. Differences were shown in others; however, due to methodological deficits in the studies, they could not be interpreted with sufficient certainty. In particular, it was again problematical that patients using human insulin were seldom treated with individually optimized treatment schemes.

The same conclusion applies to the outcome hypoglycaemia, with consideration of long-term blood-glucose lowering (HbA1c value). Although one study in adults showed a lower rate of severe hypoglycaemia under insulin detemir than under human insulin, in this study too, the latter insulin was not injected as is customary for optimized therapy in Germany. Therefore the difference observed in the study could also have been caused by a disadvantage of patients treated with human insulin, which is why this finding cannot be regarded as proof of an additional benefit of insulin detemir.

Procedure of report production

The preliminary results (preliminary report) were published by IQWiG at the beginning of July 2009 and interested parties were invited to submit comments. Following the commenting procedure, the preliminary

report was revised and the final report sent to the contracting agency, the Federal Joint Committee, at the end of February 2010. The documentation of the written comments, as well as the meeting minutes of the oral scientific debate, will be published in a separate document simultaneously with the final report, which was prepared together with external experts.

Provided by Institute for Quality and Efficiency in Health Care

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