

For immediate release

European Association for the Study of Diabetes: Press Release

POSSIBLE LINK BETWEEN INSULIN GLARGINE AND CANCER PROMPTS URGENT CALL FOR MORE RESEARCH

But experts stress patients should not stop using insulin and consult their doctor if concerned

The European Association for the Study of Diabetes (EASD) today makes an urgent call for more research into a possible link between use of insulin glargine (an insulin analogue, brand name Lantus) and increased risk of cancer, following evidence from studies in Germany, Sweden and Scotland. However, until this further research becomes available, these experts are stressing that patients with diabetes taking Lantus should continue to do so, although some might wish to consider alternative types of insulin. The studies are reported in *Diabetologia* (the journal of EASD).

Worldwide, there are over 200 million people with diabetes. About 10% of these develop diabetes in early life, and most of them have what is known as type 1 diabetes. People with type 1 diabetes have an absolute reliance upon insulin treatment for their continued health and well-being. Type 2 diabetes, which affects the remaining 90%, typically develops later in life and may be associated with excess weight. People with type 2 diabetes are able to make some of their own insulin, which means that they can usually be treated with diet and tablets in its early stages. At a later stage, however, many patients with type 2 diabetes lose the ability to produce their own insulin, and will then need insulin injections to maintain their health.

Human insulin has been widely used for decades and its safety is beyond doubt; this new information relates to an artificial form of insulin, or insulin analogue, called insulin glargine (or Lantus insulin) which has been widely used since 2000. The concerns about a possible link between use of Lantus insulin and increased cancer risk were raised by a German study of around 127,000 insulin-treated patients in an insurance database. The research identified a statistically significant link between patients who had used Lantus insulin and those who had been diagnosed with cancer. Compared with people using similar doses of human insulin, out of every 100 people who used Lantus insulin over an average of about one-and-a-half years, one additional person was diagnosed with cancer. Of particular note in this study was the finding that the increased risk of cancer was dose-dependent. Thus for patients given a dose of 10U, Lantus insulin alone increased the risk of cancer by 9% compared with human insulin; but for a dose of 50U, the increased risk was 31%. The study did not consider insulin detemir (Levemir), an insulin analogue whose action is prolonged by a different mechanism.

Professor Edwin Gale, Editor of *Diabetologia*, and Professor Ulf Smith, President of EASD, realised the significance of these findings but wanted them replicated in other studies from other European countries before announcing them formally. Studies were thus carried out using databases from Sweden, Scotland, and the UK. The Swedish study found that compared with patients on insulins other than Lantus insulin, patients on Lantus insulin alone had double the risk of breast cancer. The

Scottish study found a non-significant increased risk for breast cancer specifically. The UK study found no link between insulin glargine and cancer.

Prof Gale and Prof Smith emphasise the limitations to the studies. The main one is that, although the data were adjusted for a number of variables, the characteristics of the groups of patients taking Lantus insulin alone (generally older, higher blood pressure, more overweight) were different to those on other forms of insulin. Thus any difference in cancer risk could be attributed to the pre-treatment characteristics of the groups, rather than the treatment itself. Also, the numbers of cases of breast cancer in the Swedish and Scottish studies were very small, meaning the findings could have occurred due to chance. They state categorically that Lantus and other insulins do not cause cancer, but these studies expose the possibility that Lantus insulin could cause existing cancer cells to grow and divide more rapidly—which might explain why more cancers came to be diagnosed over 1-3 years of observation. They say: “We believe people are entitled to know that use of Lantus insulin might be associated with greater risk, but this must also be balanced against the possibility that we might be causing unnecessary alarm by raising these concerns.”

To establish whether these concerns are warranted or can be set aside, EASD have communicated their findings to EMEA, the European regulatory authorities, and are in contact with sanofi-aventis, the manufacturers of Lantus insulin. While a prospective clinical trial would be the most scientifically sound manner to proceed, Profs Gale and Smith say such a trial would be slow, unfeasible and unethical. They say: “A large combined analysis of the best available databases worldwide is the best way forward, and EASD and sanofi-aventis are pledged to carry this investigation forward until we have either confirmed these preliminary observations or, more hopefully, finally put them to rest.”

While this research is awaited, EASD advises that patients do not stop taking Lantus insulin on the basis of the findings reported here. However, since Lantus does not offer better overall glucose control than human insulin in type 2 diabetes, patients can consider alternatives. In an advice leaflet published with the studies, Profs Gale and Smith say: “People with diabetes do however have the option of using long acting human insulin or a mixture of long- and short-acting human insulin twice a day instead of the once-daily analogue. You may wish to consider this option if you already have a cancer, or, for women, if there is a family history of breast cancer. You should not make any change in your insulin treatment without consulting your own doctor, and you should on no account stop taking your insulin.”

ENDS

The papers can be accessed at

<http://www.diabetologia-journal.org/>

<http://www.easd.org/>

The video statement by Profs Smith and Gale and relevant information can be accessed here:

<http://webcast.easd.org/press/glargine/glargine.htm>

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