Insulin drug study shows significant improvements in more than 52,000 diabetic patients

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A major international diabetes study of more than 52,000 patients from eight countries has shown that using biphasic BIAsp 30 insulin resulted in significant clinical improvements and greater patient satisfaction.

The findings, reported in the March issue of IJCP, the *International Journal of Clinical Practice*, show that 53 per cent achieved a blood glucose (HbA1c) level of less than seven per cent, the target set by the International Diabetes Foundation.

Based on the largest database of Type II Diabetes patients ever compiled, the first phase of the IMPROVE study covered eight countries: Canada, China, Greece, India, Italy, Japan, Poland and Russia.

Data for the Gulf region, Iran and South Korea will be available later this year.

The study looked at the safety and effectiveness of using the biphasic insulin, which contains both fast-acting and intermediate components, prescribed by family doctors and hospital consultants.

"Patients with Type II Diabetes who used the biphasic insulin saw their blood glucose levels drop by up to 31 per cent and episodes of major hypoglycaemia, where the glucose levels become very low, fell by an average of 94 per cent" explains Professor Paul Valensi, head of the

Department of Endocrinology-Diabetology-Nutrition at the Jean Verdier Hospital in France, who led the research.

"They also expressed greater satisfaction in the treatment they received, with the percentage rising from 10 per cent at baseline to 59 per cent at the end of the study."

A total of 52,419 patients were enrolled from three pre-study treatment groups:

• 17 per cent were not receiving any antidiabetic treatment when they joined the study. Time since diagnosis averaged two years and HbA1c levels averaged 9.9 per cent.

65 per cent were on oral antidiabetic drugs. Time since diagnosis averaged 7.4 years and HbA1c levels averaged 9.2 per cent.
• 18 per cent were on injectable insulin, with or without oral antidiabetic drugs. Time since diagnosis averaged 10.4 years and HbA1c levels averaged 9.3 per cent.

"Patients are usually not started on insulin when they are diagnosed with Type II Diabetes" explains Professor Valensi. "Lifestyle changes and oral antidiabetic drugs are usually the first therapeutic steps, but some patients are unable to control their blood glucose levels using this method and insulin is the next step."

Each patient took the biphasic insulin (marketed as NovoMix 30) as directed by their clinician for 26 weeks and data was recorded on each patient at baseline, three months and at the final visit. More than 95 per cent of the patients completed the study.

Reductions in blood glucose levels were significant in all three groups. Patients who had not previously received any diabetes treatment before

they were included in the study achieved the biggest HbA1c reduction, down by an average of 31 per cent.

This took their average HbA1c levels down to 6.8 per cent, 7.1 per cent and 7.3 per cent respectively, with more than half of the patients achieving the seven per cent target set by the International Diabetes Foundation.

The study in IJCP contains detailed results for the 52,419 patients from the first eight countries to complete the study - Canada (1,594 patients), China (21,729), India (17,890), Japan (2,095), Poland (4,117), Russia (4,662), Greece (114) and Italy (218).

Patient demographics and clinical characteristics included:

• Study participants had an average age of 55 and 57 per cent were male. They had an average body mass index of 26. Their average HbA1c (blood glucose level) was 9.3 per cent and average time since diagnosis was seven years.

• Male patients were more likely to be receiving no pharmaceutical therapy at baseline than women (66 per cent versus 34 per cent), with 51 per cent of men and 49 per cent of women receiving insulin, with or without oral anti diabetic drugs.

• Patients receiving no treatment had a lower average BMI (25) and average weight (69.7kg) than those who were on insulin, with or without oral antidiabetic drugs (BMI 27.5 and weight 73.6kg).

Just under a hundred patients (0.19 per cent) reported 110 serious adverse drug problems. The most common was major hypoglycaemia, where glucose levels become very low, with 69 patients reporting 81 incidents. Other less frequent reactions included drug hypersensitivity,

injection site reaction and rash.

"Initiating insulin therapy with BIAsp 30, or switching patients from other medication to the drug, resulted in improved blood glucose control, fewer major incidents of major hypoglycaemia and improved patient satisfaction" concludes Professor Valensi.

"These statistically significant results were observed in the cohort as a whole, across the three subgroups and in the eight individual countries that have so far reported their detailed results."

More information: Initiating insulin therapy with, or switching existing insulin therapy to, biphasic insulin aspart 30/70 (NovoMix ® 30) in routine care: safety and effectiveness in patients with type 2 diabetes in the IMPROVE™ observational study. Valensi et al. IJCP, the International Journal of Clinical Practice. 63.3, pp522-531 (March 2009). The paper can be viewed free at www.ijcp.org/improve

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