Emerging Drug List
INSULIN ASPART

Generic (Trade Name): Insulin Aspart (NovoLog®)
Manufacturer: Novo Nordisk
Indication: For the control of hyperglycemia, in the treatment of adult patients with diabetes mellitus.

Current Regulatory Status: In Canada, insulin aspart is not currently available; however, its launch is anticipated for the spring of 2002. Currently, this agent is available in the U.S., and was approved by the Food and Drug Administration in June 2000.

Description: Insulin aspart is a rapid and short-acting human insulin analog. It differs from regular insulin by having a negatively charged aspartic acid residue in place of proline at position B28. Like other insulins, it regulates glucose metabolism via its action on insulin receptors on both adipose and muscle cells, facilitating the cellular uptake of glucose and inhibiting the output of glucose of the liver. In healthy volunteer studies, the median time to peak concentration was reached twice as fast with insulin aspart as regular insulin (i.e. 40-50 versus 80-120 minutes, respectively). Insulin aspart is minimally protein bound (0-9%), with an average half-life of 81 minutes. For comparison the average apparent half-life of regular human insulin is 141 minutes.

Current Treatment: Diabetes mellitus is a very prevalent condition, affecting two million Canadians, of whom 10 percent have the insulin-dependant variety. Due to the significant morbidity and mortality associated with this disease, many pharmacologicals have been developed to either delay or prevent disease-associated complications. In Canada there are two prominent manufacturers of insulin products, namely Eli Lilly and Novo Nordisk. Insulins (Humulin® - Lilly, Novolin®ge preparations - Novo Nordisk) come in a variety of formulations depending on the desired onset and duration of action (i.e. as fast, intermediate and long-acting). Also, there are mixtures of insulins available for ease of use (e.g. Novolin 30/70, 40/60, 50/50). The comparable agent in terms of kinetics in Canada is the Humalog® (Eli Lilly) agent; it comes in the fast acting formulation, along with a mixed-action product (i.e. Humalog® Mix25®).

Cost: The cost of this agent in Canada is not currently available as it is not commercialized. Pricing in the U.S. is $47.70 for a 10 mL vial of 100 u/mL or $97.11 for five cartridges of 3 mL each. This is comparable to the American cost of Lilly’s Humalog (insulin lispro). Likely, it will be similarly priced to this agent in Canada as well. According to the PPS® Pharma publication, January 2002, Humalog (100 u/mL) costs $23.00 for a 10 mL vial, and $46.00 for five cartridges of 3 mL each.

Evidence: Insulin aspart has been examined in many open label and double-blind trials (>5), mainly against regular insulin. The largest of these trials (n = 822) was reported by Raskin, which consisted of an initial six-month trial where patients received aspart or regular insulin (along with NPH for basal control), followed by a six-month extension period, which included 714 patients. To surmise the results, mean postprandial blood glucose levels were significantly lower in patients receiving the aspart agent, as compared to the regular insulin group. Also, Hemoglobin A1c values were slightly lower at both six and 12 months in the aspart group (7.78 +0.03 vs. 7.93% +0.05, p = 0.005, 7.78 +0.04 vs. 7.91 +0.06, p = 0.046, respectively). Adverse
events and overall hypoglycemic episodes were similar for both treatment groups. Only one trial to date has looked at insulin lispro versus insulin aspart in type 1 diabetics (n=14). The authors suggested that both insulins had similar profiles, with the exception that insulin lispro had a slightly faster uptake, shorter time to maximum peak concentration and a faster decline. They speculate that this may prove advantageous, but further study is required.

Insulin aspart is a new fast- and short-acting insulin. The premise behind the modifications from regular insulin is that with its different pharmacokinetic profile, it more closely mimics the physiologic action of normal pancreatic insulin, which could lead to better glycemic control with a minimized risk of hypoglycemia. As well, as it is administered sc immediately before meals, it allows for more user-friendly approach to dosing, increasing satisfaction with treatment. At this time, only one other insulin is available in Canada with similar properties, namely insulin lispro. One small scale preliminary trial suggests that there may be pharmacokinetic differences that could be clinically significant between these agents. However, further data would be required to determine this, as it was only a preliminary trial of small scope, and it did not examine long-term effectiveness and diabetes control. To generalize, parameters typically associated with better disease control (i.e. Hb A1c values), have not seen vast improvements with these types of insulins over the regular human insulin counterparts.


This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

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