

tration in a large population of IDDM children, the previous attainment of the mean adult values, and the lack of correlation of these levels with the duration of the disease and metabolic control indicate that the aberrant immune response may have a substantial pathogenetic link with IDDM. Furthermore, quantitative and qualitative longitudinal studies are required to clarify the potential mechanism involved, because neither the cause of this phenomenon nor its implications for monitoring diabetes are known.

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Table 1

Type of treatment	Cumulative follow-up (patient-year)	HbA _{1c} (%)	Severe hypoglycemia (mean per patient-year)	n
Group 1	51	8.1 ± 0.1	0.69	35
Multiple injections	20	8.2 ± 0.2	0.99	
External pump	28	7.9 ± 0.1	0.29	
Group 2	214	7.7 ± 0.1*	0.11*	23

HbA_{1c} is mean ± SE. *P < 0.001 vs. subcutaneous administration.

Decreased Severe Hypoglycemia Frequency During Intraperitoneal Insulin Infusion Using Programmable Implantable Pumps

The Diabetes Control and Complications Trial (DCCT) study (1) has shown that subcutaneous intensive insulin therapy minimizes microvascular complications by lowering HbA_{1c} levels but dramatically increases severe hypoglycemia frequency. A previous Evadiac group report (2) showed that intraperitoneal insulin infusion significantly decreased both HbA_{1c} levels and severe hypoglycemia frequency when comparing retrospectively preimplant subcutaneous therapy data to postimplant data in a longitudinal study.

In this prospective trial, the frequency of severe hypoglycemia has been determined in 240 type I C-peptide-negative patients. All patients were treated with an implantable pump before the study. Group 1 (n = 120) was switched to subcutaneous therapy using an external pump (n = 55) or multiple injections (n = 59) because of technical pump or catheter dysfunction mainly due to insulin aggregate formation in the device. Group 2 (n = 120) remained under intraperitoneal implantable pump therapy. Metabolic results are summarized in Table 1.

Statistical tests used were the Student's t test for HbA_{1c} comparison and comparison of two frequency test for hypoglycemia data. Despite a statistically better metabolic control in group 2, the severe hypoglycemia frequency is significantly lower than in group 1. Severe hypoglycemia frequency in group 1 is higher than previously described (2) but remains

comparable to the DCCT data. Part of this increase may be explained by the recent change in therapy. The same difference is observed in group 2, the patients have now been treated with an implantable pump for a long time and may be less careful regarding their diabetes control than in the first study.

Continuous subcutaneous insulin infusion tends to induce hypoglycemia less than multiple injections.

Although hypoglycemia frequency was higher than in our previous report and our study was not randomized, the results confirm that intraperitoneal therapy decreases the risk of severe hypoglycemia in spite of HbA_{1c} improvement. However, insulin aggregate formation needs to be solved before considering intraperitoneal therapy as an alternative to subcutaneous therapy. Improved insulin formulations are currently under evaluation.

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