

OBSERVATIONS

Long-Term Effect of an Education Program (HyPOS) on the Incidence of Severe Hypoglycemia in Patients With Type 1 Diabetes

A new education program for treating diabetic patients with hypoglycemia problems, named HyPOS, was developed and evaluated in a randomized controlled trial. The present study investigated the long-term effect of HyPOS on the prospectively assessed incidence of severe hypoglycemia defined as an episode requiring medical assistance by injection of glucose intravenously or glucagon intramuscularly.

HyPOS comprises five lessons of 90 min each over 5 weeks. The program informs about the vicious cycle of frequent hypoglycemia increasing the risk for future hypoglycemia (1,2). Patients were trained in symptom awareness by using diaries and performing blood glucose estimation. The control group consists of four 90-min sessions over 4 weeks. Both interventions were described in more detail previously (3). After 6 months, patients receiving HyPOS improved hypoglycemia awareness compared with control subjects (3).

The incidence of severe hypoglycemia at a 31-month follow-up was compared with the retrospectively assessed prevalence at baseline in the previous 12 months. Patients were asked about the oc-

currence of severe hypoglycemia at each visit in the study center. When an episode of severe hypoglycemia was reported, the patients were contacted by telephone to verify the hypoglycemic episode. The telephone interview was conducted by a person who was not aware of the patient's group assignment.

The sample was recruited at 23 outpatient study centers. Of 164 randomized patients, 140 (85.3%) type 1 diabetic patients (aged 46.0 ± 12.5 years, 50% female, A1C $7.3 \pm 1.0\%$, disease duration 21.4 ± 10.9 years, 41% with continuous subcutaneous insulin infusion therapy, 4.9 ± 1.1 injections/day, BMI 25.4 ± 3.7 kg/m², and insulin dosage 0.54 ± 0.18 IU/kg) were reassessed after a 31-month follow-up period. At baseline the prevalences of severe hypoglycemia were 0.8 ± 1.5 and 0.7 ± 1.05 episodes/patient-year in the control group and HyPOS, respectively. The incidence of severe hypoglycemia was lower in HyPOS than in the control group (0.1 ± 0.2 vs. 0.2 ± 0.4 episodes/patient-year; $P = 0.04$). The reduction of severe hypoglycemia from baseline to follow-up was 0.5 ± 0.3 events per patient-year in the control group and 0.6 ± 0.3 events per patient-year in HyPOS ($P = 0.042$, adjusted for baseline differences). In the control group, 26.5% of the patients experienced at least one severe hypoglycemic episode compared with 12.5% in HyPOS (odds ratio 0.4 [95% CI 0.2–0.9]; $P = 0.04$). There were no significant differences between the control group and HyPOS with regard to glycemic control (A1C 7.3 ± 1.1 vs. $7.1 \pm 0.9\%$; $P = 0.18$) or treatment factors (insulin dosage, number of injections, use of insulin pump, or use of insulin analogs) at the follow-up measurement. The HyPOS program can contribute to better treatment

of diabetic patients who have hypoglycemia problems.

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References

1. Cryer PE. Hypoglycemia: the limiting factor in the glycaemic management of type I and type II Diabetes. *Diabetologia* 2002; 45:937–948
2. Cryer PE, Davis SN, Shamon H. Hypoglycemia in diabetes. *Diabetes Care* 2003; 26:1902–1912
3. Hermanns N, Kulzer B, Kubiak T, Krichbaum M, Haak T. The effect of an education programme (HyPOS) to treat hypoglycaemia problems in patients with type 1 diabetes. *Diabete Metab Res Rev* 2007;23:528–538