OBJECTIVE — Severe hypoglycemia is a major problem for patients with type 1 diabetes and their relatives. The aim of this study was to compare patients’ and relatives’ assessments of rates of severe hypoglycemia and state of awareness and to explore the influence on involvement and concern of relatives.

RESEARCH DESIGN AND METHODS — A cross-sectional paired questionnaire survey on hypoglycemia and the state of awareness was used in our study comprising 284 unselected adult patients with type 1 diabetes and their closest cohabitant. The cohabitant questionnaires also addressed involvement and concern.

RESULTS — The agreement between assessments of rates of severe hypoglycemia and state of awareness made by patients and cohabitants was weak (κ 0.404 and 0.442, respectively; P < 0.001). Cohabitants recalled more episodes of severe hypoglycemia than patients (2.7 vs. 1.6 episodes/patient-year; P < 0.001). Degree of involvement was positively related to the rate of severe hypoglycemia (P = 0.002) and negatively related to the state of awareness (P = 0.007) but not to level of HbA1c, duration of diabetes, or presence of late complications, except for peripheral neuropathy (P = 0.01).

CONCLUSIONS — Cohabitants of patients with type 1 diabetes recall significantly more episodes of severe hypoglycemia than the patients. The rate of severe hypoglycemia and state of hypoglycemic awareness are the principal determinants of degree of cohabitants’ involvement in their partners’ disease.

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R isk of development of late diabetic complications in type 1 diabetes is reduced by tight glycemic control (1) and, consequently, near-normalization of blood glucose is recommended. An inevitable consequence of tight metabolic control is increased frequency of hypoglycemia—in terms of mild hypoglycemia managed by the patients alone and severe hypoglycemia rendering the patients dependent on assistance from others. With increasing duration of diabetes, hypoglycemia becomes a significant problem as many patients experience weakening of hypoglycemic warning symptoms (2,3). Such impairment of hypoglycemic awareness is reported by up to 50% of unselected patients with type 1 diabetes (4) and is associated with up to an eightfold increased risk of severe hypoglycemia (5,6). For the patient, severe hypoglycemia gives rise to as much concern as risk of blindness or kidney failure (2), and the fear of hypoglycemia is a major obstacle to achievement of recommended therapeutic goals in many patients. In recent years, the Steno Diabetes Center has conducted “hypo-courses” for patients with type 1 diabetes prone to severe hypoglycemia to improve their ability to prevent and manage these episodes. As part of the courses, patients’ nearest relatives have been invited to participate in group sessions. These have revealed that relatives may harbor even higher levels of concern and worry than the patients, and that there may be disagreement between patients and relatives in the assessment of problems in relation to hypoglycemia.

The aim of this study was to evaluate agreement between patients with type 1 diabetes and their closest relative in estimating rates of severe hypoglycemia and state of hypoglycemic awareness, and to test the hypothesis that occurrence of severe hypoglycemia and the state of awareness are important determinants of involvement and concern of the relatives.

RESEARCH DESIGN AND METHODS — The study was a cross-sectional questionnaire survey of consecutive adult patients with type 1 diabetes and their closest relative.

Patients and cohabitants

Participants were recruited during a 3-month period in 1999 in the outpatient clinic at the Steno Diabetes Center. Type 1 diabetes was defined clinically by age <40 years at diagnosis and an unbroken record of insulin treatment for ≥2 years. Patients who were pregnant, had end-stage renal disease, or were unable to un-
understand or fill in a questionnaire were excluded. All patients were asked whether they were cohabiting and if so to forward a cohabitants’ questionnaire to their closest relative.

**Questionnaires**
Patients completed their questionnaire in the outpatient clinic. This questionnaire was based on one that was developed by Pramming et al. (2) and was part of a multicenter survey on hypoglycemia (4). Key questions were about 1) the rate of severe hypoglycemia (defined as episodes in which patients needed assistance from other persons) during the preceding year and 2) the state of awareness of hypoglycemia. The latter was assessed according to the answer to the question “Do you recognize symptoms, when you have a hypo?” Subjects giving the answer “always” were classified as having normal awareness, those answering “usually” as having impaired awareness, and those answering “occasionally” or “never” as unaware.

Cohabitants’ questionnaires were completed at home and mailed to the clinic. This questionnaire was developed with inspiration from a previously published questionnaire (7) and with items from the patients’ questionnaire. The key questions were congruent with those posed to the patients concerning the rate of severe hypoglycemia and state of awareness. In addition, cohabitants were asked questions on involvement (“How involved are you in the management of your partner’s diabetes?”) and concern (“Are you worried about hypoglycemia when your partner is late for an appointment?” and “Do you have disturbed sleep due to fear of hypoglycemia during nighttime?”). Answers were given on 5-point scales. Other questions further explored types of involvement and concern. Questions were phrased to get answers that were exhaustive and mutually exclusive.

The study was approved by the regional ethics committee. Written informed consent was obtained from all patients.

**Clinical and laboratory data**
Background data were extracted from the patients’ medical records. Late diabetic complications were graded as previously described (6). HbA1c was measured by Bio-Rad Variant (Bio-Rad Diagnostics Group, Hercules, CA) and was standardized against the Diabetes Control and Complications Trial standards (normal range 4.1–6.4%).

**Statistical methods**
Data analysis was performed using the SPSS software package (Version 10.0). Comparisons of independent samples were performed by *t* test or Mann-Whitney’s *U* test where appropriate. Agreement between ratings made by patients and cohabitants was assessed using the *κ* statistic. Relationships between the rate of severe hypoglycemia, state of awareness, and involvement and concern were evaluated by *F* test. The level of statistical significance was chosen as *P* < 0.05 (two-sided).

**RESULTS**

**Patients’ characteristics**
Baseline characteristics of the 284 participating and 146 nonparticipating patients are given in Table 1.

The nonparticipating patients were slightly younger and younger when diagnosed, but duration of diabetes was not different in the two groups. HbA1c was slightly higher among nonparticipants. No statistical significant differences were recorded with respect to late diabetic complications, treatment modality, insulin dose, use of insulin analogs, and self-perceived awareness. However, the self-reported rate of severe hypoglycemia was lower among nonparticipants (0.8 vs. 2.0 episodes/patient-year, *P* = 0.001).

**Cohabitants’ characteristics**
Of 430 patients, 335 agreed to participate in the survey and bring the cohabitants’ questionnaire to their closest cohabitant. From these, 284 (85%) completed forms were returned: 55% were women; 73% were spouses; 24% were unmarried partners; and 3% were parents or near friends. The mean duration of cohabitation was 18 years, and 20% had lived together for 30 years or more (3% had diabetes themselves). Of the cohabitants, 76% had assisted at least once during episodes of hypoglycemia and 13% had assisted in >50 episodes each. Of those having attended one or more episodes of severe hypoglycemia, 52% had called an ambu-

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**Table 1—Characteristics of participating and nonparticipating patients**

<table>
<thead>
<tr>
<th></th>
<th>Participants</th>
<th>Nonparticipants</th>
<th><em>P</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>284</td>
<td>146</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>44 ± 12</td>
<td>42 ± 13</td>
<td>0.033*</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>46</td>
<td>46</td>
<td>0.98</td>
</tr>
<tr>
<td>Age at diagnosis (years)</td>
<td>22 ± 10</td>
<td>20 ± 10</td>
<td>0.044*</td>
</tr>
<tr>
<td>Duration of diabetes (years)</td>
<td>24 ± 12</td>
<td>23 ± 13</td>
<td>0.67*</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8.4 ± 1.1</td>
<td>8.7 ± 1.1</td>
<td>0.005*</td>
</tr>
<tr>
<td>Retinopathy (%)</td>
<td>59</td>
<td>55</td>
<td>0.28</td>
</tr>
<tr>
<td>Nephropathy (%)</td>
<td>19</td>
<td>22</td>
<td>0.62</td>
</tr>
<tr>
<td>Peripheral neuropathy (%)</td>
<td>25</td>
<td>27</td>
<td>0.96</td>
</tr>
<tr>
<td>Autonomic neuropathy (%)</td>
<td>14</td>
<td>12</td>
<td>0.98</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>14</td>
<td>14</td>
<td>0.88</td>
</tr>
<tr>
<td>Macrovascular complications (%)</td>
<td>4</td>
<td>3</td>
<td>0.69</td>
</tr>
<tr>
<td>Treatment modality, insulin doses/24 h (%)</td>
<td>47</td>
<td>50</td>
<td>0.054*</td>
</tr>
<tr>
<td>1 dose</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2 doses</td>
<td>16</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>3 doses</td>
<td>8</td>
<td>9</td>
<td>0.37</td>
</tr>
<tr>
<td>4 doses</td>
<td>70</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>5 or 6 doses</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Insulin pump</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment with insulin analogs (%)</td>
<td>3</td>
<td>2</td>
<td>0.81</td>
</tr>
<tr>
<td>Insulin (units/24 h)</td>
<td>5.1</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td>Self-reported rate of severe hypoglycemia (episodes within the past year)</td>
<td>2.0 ± 5.1</td>
<td>0.8 ± 1.6</td>
<td>0.001*</td>
</tr>
<tr>
<td>Self-estimated awareness (% normal%/impaired/unaware)</td>
<td>37/52/11</td>
<td>42/49/9</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Data are mean ± SD or %. *t*-test, other analyses used the Mann-Whitney *U* test.
Impact of severe hypoglycemia on relatives

Fifty-one percent of cohabitants and 58% of the corresponding patients were familiar with use of glucagon. Thirty-four percent kept glucagon at home, and 21% of the cohabitants had given an injection of glucagon at least once.

**Agreement in ratings between patients and cohabitants**
The patients reported a significantly lower rate of severe hypoglycemia compared with cohabitants (1.6 vs. 2.7 episodes/patient-year; t test, P < 0.001). The proportion of patients reporting at least one episode of severe hypoglycemia was also lower than that of the cohabitants (χ²: 53 vs. 65%, P = 0.020). The agreement between ratings of severe hypoglycemia made by patients and cohabitants was weak (κ 0.404, P < 0.001), with disagreement in 28% of the couples on whether there had been episodes of severe hypoglycemia in the preceding year.

Normal awareness, impaired awareness, and unawareness was reported by 37, 52, and 11%, respectively, of patients and by 35, 56, and 9%, respectively, of cohabitants. The agreement between ratings of "state of awareness" made by patients and cohabitants was better (κ 0.442, P < 0.001) than agreement on rate of severe hypoglycemia.

**Cohabitants’ concerns due to fear of hypoglycemia**
Fifty-nine percent of the cohabitants (more women than men) (F test, P = 0.029) worry about hypoglycemia when the patient is late for an appointment. No significant correlations were found between concern of hypoglycemia during daytime and duration of diabetes, duration of the couple living together, or HbA₁c. A high rate of severe hypoglycemia and poor awareness of hypoglycemia reported by patients was associated with higher frequencies of concern (F test, P < 0.001 for both). Multivariate analyses including both the rate of severe hypoglycemia and state of awareness showed no interaction between the variables, which both remained significantly associated with concern in the model (F test, P < 0.001 for both). Forty-four percent of the cohabitants reported disturbed sleep due to fear of their partner getting an episode of severe hypoglycemia during nighttime. Sleep disturbance was more commonly reported by female than by male cohabitants (F test, P = 0.016). There was no association between occurrence of sleep disturbance and duration of diabetes, duration of the couple living together, or HbA₁c. Cohabitants of patients with high rates of severe hypoglycemia reported more frequent sleep disturbances compared with cohabitants of patients with low rates, as did cohabitants of patients with impaired awareness compared with cohabitants of patients with normal awareness (F test, P < 0.001 for both). Assessment in a multivariate analysis, including the rate of severe hypoglycemia as well as the state of awareness, did not reveal interactions between the variables, both of which remained significantly related with disturbed sleep (F test, P < 0.001 for both).

**CONCLUSIONS** — Our study population demonstrates that severe hypoglycemia is a conspicuous topic in the minds of cohabitants of patients with type 1 diabetes. In accordance with the study of Heller et al. (8), we found that spouses/cohabitants recalled more episodes of severe hypoglycemia and that agreement between patients’ and cohabitants’ ratings was weak. The discrepancy may be due to different perceptions of hypoglycemic episodes among patients and spouses. Thus, an episode in which a relative is worried about impending hypoglycemia and therefore serves a snack to a person with diabetes may be recorded as severe, whereas the patient may regard it as a mild “hypo” because he is convinced that he would have been able to manage the situation without interference. Furthermore, the temporary mental impairment of the patients during episodes of hypoglycemia may lead to underestimation by the patients, and some persons with diabetes may deliberately “forget” episodes due to embarrassment or fear of losing their driving license. Also, in terms of state of awareness, there was a poor agreement between patients and cohabitants. This is likewise in accordance with the study of Heller et al. (8). The degree of involvement of cohabitants was positively related to the rate of severe hypoglycemia and negatively related to state of hypoglycemic awareness. Other clinical variables, e.g., duration of diabetes, level of metabolic control, and presence of all late diabetic complications except for peripheral neuropathy, were not associated with cohabitants’ involvement. Thus, in the present study, frequency of severe hypoglycemia and the state of awareness of hypoglycemia are the principal determinants of degree of cohabitants’ involvement in their partners’ disease. This is not surprising since the vast majority of episodes of severe hypoglycemia are witnessed and treated by spouses. Cohabitants to patients at high risk of severe hypoglycemia face the risk every day and have to be prepared to furnish assistance.

Concern about severe hypoglycemia was reported by a high proportion of cohabitants during both daytime, which is in accordance with the study of Stahl et al. (9), and nighttime, which is in accordance with the study of Gonder-Frederick et al. (10). As expected, concern of hypoglycemia was strongly related to previous rate of severe hypoglycemia,
and in addition, concern was independently related to the state of awareness. Similar correlations have been reported previously for sleep disturbance due to fear of hypoglycemia (10). In contrast to Gonder-Frederick et al. (10), we found sleep disturbances to be more prevalent in women. Our study population was similar to the nonparticipants in many ways but different in one important aspect—the rate of severe hypoglycemia that was lower in nonparticipants. This is probably due to the fact that some patients refused to participate in the survey, stating that “I have no problems with hypoglycemia.” This may have resulted in higher overall ratings of involvement and concern. However, the material includes a broad spectrum of patients, ranging from a large group without severe hypoglycemia and with normal awareness to patients prone to repetitive episodes of severe hypoglycemia due to unawareness; thus, correlations across this spectrum should not be affected by selection.

A number of studies have reported that severe hypoglycemic episodes bear a considerable negative psychosocial impact on spouses of diabetic patients (9–12). Hypoglycemia in patients with long-standing type 1 diabetes is usually an unexpected event. Often the cohabitants, including the dog of the family (13), are able to recognize impending hypoglycemia before the patient becomes aware of the problem. The resulting involvement of relatives may be perceived in a negative way by the person with diabetes and may give rise to marital conflicts (12). The Diabetes Attitudes Wishes and Needs (DAWN) study (14) showed that family or social networks that put too much pressure on diabetic patients through well-meant but constant interference have a marked negative effect on how patients deal with their condition.

In conclusion, our study supports the view that the psychosocial impact of hypoglycemia on family members should receive more attention. Cohabitants of patients with type 1 diabetes who are prone to severe hypoglycemia inevitably get involved in their partners’ disease and should be offered support and education to cope with episodes of severe hypoglycemia. Furthermore, attention should be paid to possible negative consequences of severe hypoglycemia on relations between patients and cohabitants. As a first step, the diabetes team should encourage patients who are prone to severe hypoglycemia to invite their cohabitants to participate in the consultations to disclose individual problems and needs.

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References