

Assessment of the Impact of Fear of Hypoglycemic Episodes on Glycemic and Hypoglycemia Management

Copied under licence from
access®
 Further reproduction prohibited

Lawrence A. Leiter¹ MD, Jean-François Yale² MD, Jean-Louis Chiasson³ MD, Stewart Harris⁴ MD, Peter Kleinstiver⁵ PhD, Luc Sauriol⁶ MSc

¹St. Michael's Hospital, Toronto, Ontario, Canada

²Centre universitaire de santé McGill, Montreal, Quebec, Canada

³Centre de recherche du CHUM, Hôtel-Dieu du CHUM, Montreal, Quebec, Canada

⁴University of Western Ontario, Department of Family Medicine, London, Ontario, Canada

⁵Katalyst Health Technology Assessments, London, Ontario, Canada

⁶Aventis Pharma Canada, Laval, Quebec, Canada

A B S T R A C T

OBJECTIVE

To assess the impact of mild, moderate and severe hypoglycemia and fear of future hypoglycemic episodes on patients with type 1 or insulin-treated type 2 diabetes.

METHOD

A self-administered questionnaire was used to collect retrospective data on frequency of hypoglycemia and its impact on glycemic management, treatment of hypoglycemia and post-hypoglycemia lifestyle infringements.

RESULTS

Two-hundred-two type 1 and 133 insulin-treated type 2 diabetes patients enrolled. Following a mild or moderate hypoglycemic episode, more type 1 diabetes patients reported increased fear of future hypoglycemia (37.8%) than insulin-treated type 2 diabetes patients (29.9%). However, subsequent to a severe hypoglycemic episode, 84.2% of type 2 vs. 63.6% of type 1 diabetes patients reported greater fear of future hypoglycemia. The most common management strategy for hypoglycemia of any severity was self-treatment.

Address for correspondence:

Lawrence A. Leiter
 St. Michael's Hospital
 61 Queen Street East, Room 6121
 Toronto, Ontario
 M5C 2T2 Canada
 Telephone: (416) 867-7441
 Fax: (416) 867-3696
 E-mail: leiter@smh.toronto.on.ca

Keywords: fear of hypoglycemia, glycemic control, hypoglycemia

R É S U M É

OBJECTIF

Évaluer les répercussions de l'hypoglycémie légère, modérée et grave et la crainte de futurs épisodes d'hypoglycémie chez les patients atteints de diabète de type 1 ou de diabète de type 2 traités par l'insuline.

MÉTHODE

On a utilisé un questionnaire à remplir par le patient pour recueillir des données rétrospectives sur la fréquence des épisodes d'hypoglycémie et leurs répercussions sur la prise en charge de la glycémie, le traitement de l'hypoglycémie et son incidence sur le mode de vie une fois l'épisode passé.

RÉSULTATS

Ont été inscrits à l'étude 202 patients atteints de diabète de type 1 et 133 patients atteints de diabète de type 2 traités par l'insuline. Après un épisode d'hypoglycémie léger ou modéré, un plus grand nombre de patients atteints de diabète de type 1 (37,8 %) que de patients atteints de diabète de type 2 (29,9 %) ont signalé une augmentation de la crainte de futurs épisodes d'hypoglycémie. Cependant, après un épisode d'hypoglycémie grave, 84,2 % des patients atteints de diabète de type 2 par rapport à 63,6 % des patients atteints de diabète de type 1 ont signalé une crainte plus marquée de futurs épisodes. La stratégie la plus courante contre l'hypoglycémie de quelque intensité que ce soit a été l'auto-traitement.

CONCLUSION

La crainte de l'hypoglycémie favorise la surveillance et l'équilibre de la glycémie, les modifications de l'auto-traitement et les modifications du mode de vie après un épisode d'hypoglycémie.

CONCLUSION

Fear of hypoglycemia influences patient health outcomes such as blood glucose management awareness and control, self-treatment modifications and post-episode lifestyle changes.

INTRODUCTION

Hypoglycemia has been reported as the major limiting factor to achieving optimal glycemic control in diabetes (1). The occurrence of hypoglycemia and sensitization to the unpleasant symptoms have been shown to result in fear of future hypoglycemia and avoidance of low blood glucose (BG), particularly among insulin-treated patients (3-6). In these patients, mild or moderate and severe hypoglycemia have been reported as the most common adverse effects associated with intensive insulin therapy and have been estimated to occur annually in 5 to 20% of patients taking oral antihyperglycemic agents (1).

Several major clinical studies have addressed intensive diabetes management and the resultant risk of hypoglycemia. Patients with type 1 diabetes in the intensive treatment group (≥ 3 insulin injections per day) of the Diabetes Control and Complications Trial (DCCT) maintained glycosylated hemoglobin (A1C) levels almost 2% lower than those in the conventional treatment group (7). This relative A1C reduction was associated not only with a significant reduction in the risk of microvascular complications (7-9), but also with a 3-fold increase in severe hypoglycemia. In fact, in the DCCT, 41% of the conventional treatment group and 73% of the intensive treatment group had ≥ 1 severe hypoglycemia event during the 9-year follow-up (9). In the Stockholm Diabetes Intervention Study (SDIS), 73% of conventionally treated and 86% of intensively treated patients experienced ≥ 1 severe hypoglycemic episodes during the 10-year follow-up (10). The rate of severe episodes has been found to increase exponentially with decreasing A1C (7-11). The fear of hypoglycemia may be so intense that many patients deliberately maintain BG levels above target in order to minimize the frequency and severity of hypoglycemic events (12).

The effectiveness of aggressive glycemic control in preventing diabetes-related microvascular complications was also evaluated in patients with type 2 diabetes. Although the United Kingdom Prospective Diabetes Study (UKPDS) showed significantly lower rates of hypoglycemia than the DCCT, the number of patients with type 2 diabetes experiencing severe hypoglycemia was significantly higher in the intensive therapy group than the conventional group ($p < 0.001$) (13).

Treatment of diabetes and achievement of optimal glycemic control are therefore complicated by the need to balance good glycemic control to prevent future complications against the potential risk of hypoglycemia (9). Fear of hypoglycemia remains a major impediment to implementation of intensive therapy and has historically resulted in difficulty with adherence to the prescribed medication regimen (1,4,6). Although significant research has been conducted on

the relationship between glycemic control, hypoglycemia and diabetes-related long-term complications (7,9), there is a paucity of research on the social and related financial impact of fear of hypoglycemia in patients with type 1 and insulin-treated type 2 diabetes.

METHODS

This survey-based retrospective observational study was designed to quantify the number of hypoglycemic episodes experienced and to assess the effects that hypoglycemia and fear of hypoglycemia have on daily activities, glycemic management and post-episode lifestyle infringements. This study was conducted in 4 Canadian centres with 2 sites in the province of Quebec (Montreal) and 2 in Ontario (Toronto and London), with approval of local ethics committees and in accordance with the Declaration of Helsinki. Male and female patients ≥ 18 years of age, with a diagnosis of type 1 or 2 diabetes, treated with insulin alone or in combination with oral agents for ≥ 1 year, and able to provide informed consent were screened for enrollment. At each site, upon arrival at a scheduled clinic visit, a research assistant provided all patients meeting these inclusion criteria with details about the study. To be included in the study, all participants or their legal guardian provided written informed consent. All study candidates were recruited from July 7 to December 12, 2003. The first 67 to 100 consecutive patients at each site completed the informed consent and the 30-minute questionnaire, in privacy, while waiting for their clinic appointment.

A self-administered questionnaire was used to collect data on frequency of hypoglycemia, impact of hypoglycemia on behaviour and glycemic management, cost of diabetes management and post-hypoglycemia lifestyle infringements. Prior to patient administration, the questionnaire was pretested by a focus group composed of both type 1 and type 2 diabetes patients. The questionnaire was composed of a total of 42 questions with formats including "fill in the value" (a range of choices was not provided), "yes or no" questions and Likert-scale questions with responses that were rated from 1 (never) to 5 (always). The questionnaire also included a validated, 33-item Hypoglycemia Fear Survey (HFS-98) composed of the behavioural or avoidance scale (15 items) and the worry or affect scale (18 items) (2). The HFS-98 and cost of diabetes management results will be reported separately.

The clinical definition of hypoglycemia has been frequently debated and varies between clinical trials. Traditionally, clinical hypoglycemia has been defined as a state in which there is 1) autonomic or neuroglycopenic symptoms, 2) a low plasma glucose (PG) level, and 3) relief with administration of

carbohydrate (1). This study used the Canadian Diabetes Association 2003 Clinical Practice Guidelines definitions of mild or moderate hypoglycemia as a glucose level ≤ 4.0 mmol/L and severe hypoglycemia requiring external assistance and a PG < 2.8 mmol/L (1). On the self-administered questionnaire, patients recorded the frequency of mild or moderate hypoglycemic episodes experienced during the preceding 1 month, and the frequency of severe hypoglycemia experienced during the preceding 12-month period and lifetime.

For each patient providing consent, data regarding glycemic control, comorbidities, diabetes-related complications and current treatment were collected by the research assistant from the patient's medical chart and recorded on a separate physician data collection form. The physician data collection form was composed of 15 points including patient demographics, laboratory values (fasting PG and A1C), treatment information (diabetes medication and dose), method of administration (injection, oral or pump), frequency of administration, complications and comorbidities. All data were entered into a Microsoft Access® database.

RESULTS

Of the 345 patients screened, 335 enrolled in the study (97.1% (171 male and 164 female). Of these, 202 (60.3%) had type 1 diabetes and 133 (39.7%) had type 2 diabetes. All enrolled patients completed the questionnaire. Mean age for type 1 patients was 43.5 years (male 44.6 ± 12.7 years, female 42.0 ± 13.9 years) and 59.9 years (male 61.6 ± 16.2 years, female 56.2 ± 17.2 years) for type 2 diabetes patients. The mean number of years of university education was 2.21 years for type 1 and 1.15 years for type 2 diabetes patients (all participants did not attend university). Type 1 diabetes participants had a higher average annual income with 54.5% reporting over \$50,000 vs. 30.8% for type 2 diabetes participants. Type 1 diabetes patients had a lower body mass index than participants with type 2 diabetes (26.6 ± 0.7 kg/m² vs. 31.7 ± 2.2 kg/m²).

The mean age at diagnosis for type 1 diabetes patients was 20.6 ± 11.5 years, which was slightly less than the mean age

at initiation of insulin (20.8 ± 11.7 years). The mean age at diagnosis for type 2 diabetes was 43 ± 13.7 years with mean age at initiation of insulin of 48.9 ± 17 years. The mean duration of insulin therapy was 22.5 ± 12.3 years for type 1 diabetes and 10.2 ± 19.3 years for type 2 diabetes patients.

Glycemic control was evaluated by the most recent A1C reported in the patient medical chart. Mean A1C was 7.4% for type 1 and 7.52% for type 2 diabetes patients. With the exception of retinopathy, all comorbidities were more prevalent in type 2 than type 1 diabetes patients. Hypertension, the most common comorbidity, was reported by 33.2% of type 1 and 79.7% of type 2 diabetes patients ($p < 0.05$). Retinopathy was reported by 39.1% of type 1 patients and 34.6% of type 2 patients, while 13% percent of type 1 and 18% of type 2 diabetes patients reported nephropathy. History of cardiovascular problems was reported by 11.4% of type 1 and 36.1% of type 2 diabetes patients ($p < 0.05$).

Table 1 summarizes frequency of mild or moderate and severe hypoglycemia experienced in the preceding month, year and during patients' lifetimes. In the 1 month preceding the study, patients with type 1 diabetes experienced a total of 1642 episodes of mild to moderate hypoglycemia, compared with 531 episodes in patients with type 2.

One patient with type 2 diabetes reported 50 severe hypoglycemic episodes, as did 3 type 1 and 1 type 2 patients. Three type 1 and 1 type 2 diabetes patients reported > 10 episodes for the preceding 12-month period. When the data were reanalyzed excluding these patients, the frequency of severe hypoglycemia dropped to 1.9 and 2.6 episodes per patient per year for type 1 and type 2 diabetes patients respectively. Of those patients who had experienced severe hypoglycemia in the preceding 12 months, 46.5% of type 1 and 58% type 2 diabetes patients reported that these episodes had occurred during sleep. The frequency of severe hypoglycemia reported during sleep was 1.2 and 3.4 episodes per patient per year for type 1 and type 2 diabetes, respectively ($p < 0.05$). One patient with type 2 diabetes reported all 50 severe hypoglycemic episodes in the preceding year had occurred during sleep. When patients reporting

Table 1. Mild or moderate and severe hypoglycemic episodes experienced		
Hypoglycemic episodes	Type 1 diabetes n=202	Type 2 diabetes n=133
Patients who reported mild or moderate hypoglycemic episodes in the preceding month	n=193 (95.5%) 8.5 events/patient/month	n=97 (72.9%)* 5.5 events/patient/month
Patients who reported severe hypoglycemic episodes per lifetime	n=144 (71.3%) 12.7 events/patient/lifetime	n=34 (25.6%)* 8.1 events/patient/lifetime
Patients who reported severe hypoglycemic episodes in preceding 12-month period	n=55 (27.2%) 2.6 events/patient/12 months	n=19 (14.3%)* 5.9 events/patient/12 months*
% patients who experienced severe hypoglycemic episodes during sleep in the preceding 12-month period	46.5% 1.2 events/patient/12 months	58.0% 3.4 events/patient/12 months*

* $p < 0.05$

>10 severe episodes were excluded from the analyses, the number of episodes during sleep per patient per year was 0.5 for type 1 and 0.2 for type 2 diabetes patients.

Table 2 summarizes the self-monitoring of blood glucose (SMBG) and use of insulin following a hypoglycemic event.

More type 1 diabetes than type 2 diabetes patients were following an intensive treatment regimen (93.2 vs. 37.4% routinely injecting insulin 3 or 4 times per day). For both type 1 and type 2 diabetes patients, there was no significant difference in frequency of severe hypoglycemia between those on conventional or intensive treatment. The frequency of mild or moderate hypoglycemia events reported for type 2 diabetes patients was comparable for those on conventional or intensive treatment. In patients with type 1 diabetes, the frequency of mild or moderate hypoglycemic events in the preceding month was 3.4 for those on conventional treatment and 8.5 for those on intensive treatment ($p < 0.05$).

Forty-eight percent of patients with type 2 diabetes were treated with oral antihyperglycemic agents in combination with insulin and 2 patients with type 1 diabetes were treated with insulin in combination with an oral antihyperglycemic agent (metformin). For those patients with type 2 diabetes treated with oral agents plus insulin, the frequency of mild or moderate hypoglycemia was 2.5 episodes per month, which was significantly less than the 5.4 episodes reported by type 2 diabetes patients treated with insulin alone ($p = 0.018$). For patients with type 2 diabetes, there was no statistical difference in the frequency of severe hypoglycemia for those on combination therapy vs. those on insulin alone (0.6 vs. 1.1 episodes during preceding 12 months).

Table 3 presents changes in the average daily insulin dose following a hypoglycemic episode. Patients were asked to

indicate if they modified their insulin dose following a hypoglycemic event. Patients with type 1 diabetes “sometimes” or “always” modified their insulin dose 78.5% of the time following severe and 74% of the time following mild or moderate hypoglycemia. Patients with type 2 diabetes reported “sometimes” or “always” modifying their insulin dose 57.5% of the time following severe and 43% of the time following mild or moderate hypoglycemia episodes.

Both type 1 and type 2 diabetes patients reported a variety of indicators of hypoglycemia. For those patients who experienced mild or moderate hypoglycemia, 75.1% of type 1 and 86.2% of type 2 diabetes patients felt the symptoms coming on; 19.5% of type 1 and 10.3% of type 2 diabetes patients detected hypoglycemia when performing SMBG; and 4.9% of type 1 and 1.7% of type 2 diabetes patients were told by others that the episode was occurring. In the case of severe hypoglycemia, the major indicators were, in order of frequency; found confused (type 1 diabetes 38.4%, type 2 diabetes 35.3%), told by others (type 1 diabetes 21%, type 2 diabetes 23.3%), found unconscious (type 1 diabetes 15%, type 2 diabetes 21.1%), and other indicators (type 1 diabetes 24.9%, type 2 diabetes 20.4%).

Patients who had experienced hypoglycemic episodes were asked to quantify actions taken after suffering a mild or moderate and/or a severe hypoglycemic event. Following a mild or moderate event, 90.8% of type 1 and 84.5% of type 2 diabetes patients self-treated. Only 1 patient reported requiring an ambulance on 1 occasion for a mild or moderate episode. Eight percent of type 1 and 15% of type 2 diabetes patients mentioned the occurrence of the mild or moderate hypoglycemic episode to their doctor at their next visit. For those who had experienced severe hypoglycemia in

Glucose monitoring and control	Type 1 diabetes n=202	Type 2 diabetes n=133
Routine SMBG (mean number of tests/day)	4.4	2.8*
Patients who performed more frequent SMBG following mild or moderate hypoglycemia	136 (70.5%)	78 (80.4%)
Mean number of additional tests/patient/24 hours	2.1	1.9
Patients who performed more frequent SMBG following severe hypoglycemia	50 (90.9%)	16 (84.2%)
Mean number of additional tests/patient/24 hours	3	2.2
Patients who “sometimes” modified insulin dose following mild or moderate hypoglycemia	98 (51%)	30 (31%)*
Patients who “sometimes” modified insulin dose following severe hypoglycemia	24 (44%)	9 (47%)
Patients who “always” modified insulin dose following mild or moderate hypoglycemia	45 (23%)	12 (12%)**
Patients who “always” modified insulin dose following severe hypoglycemia	19 (34.5%)	2 (10.5%)

* $p < 0.001$

** $p < 0.05$

BG = blood glucose

SMBG = self-monitoring of blood glucose

the preceding 12 months, self-treatment involved consuming fruit juice (with external assistance) in 48.8% of type 1 and 83.1% of type 2 diabetes patients. Other self-treatment interventions (with external assistance) included the application of oral glucose gel (6.7% of type 1 and 1.3% of type 2 diabetes patients) and the injection of glucagon (7.2% of type 1 and 2.1% of type 2 diabetes patients). An ambulance was requested by 11.5% of type 1 and 3.4% of patients with type 2 diabetes, and emergency room/hospital visits were required by 10.5% of type 1 and 5.5% of type 2 diabetes patients. Subsequent to an episode of severe hypoglycemia, additional visits to the family physician and/or the diabetes specialist were reported by 4.8% of type 1 patients and 2.5% of type 2 diabetes patients. Consultations to a physician or nurse including telephone, fax and email consultations accounted for 1% of actions taken for type 1 and 0.4% for type 2 diabetes patients.

Following hypoglycemia, the most frequent lifestyle changes (Table 4) reported by patients with type 1 diabetes were modification of insulin dose (74.1% for mild or moderate and 78.2% for severe), followed by consumption of additional food (66.8% for mild or moderate and 70.9% for severe). Type 2 diabetes patients reported consumption of additional food (62.9% for mild or moderate and 63.2% for severe) followed by modification of insulin dose (43.3% for mild or moderate and 57.9% for severe). Fear of future hypoglycemia was greater for type 1 (37.8%) than type 2 (29.9%) diabetes patients following a mild or moderate event. However, 84.2% of type 2 diabetes patients indicated that they "sometimes" or "always" had a greater fear of future severe hypoglycemia episodes vs. 63.6% of type 1 diabetes patients.

Fear of driving following a hypoglycemic episode was reported by more type 1 diabetes patients than type 2 diabetes patients; 29.2 vs. 9.4%, respectively, for mild or moderate and 36.4 vs. 15.8%, respectively, for severe.

DISCUSSION

These data suggest that hypoglycemia and a fear of future hypoglycemia have an impact upon both type 1 and type 2 diabetes patients. We have shown in this retrospective study that patients not only manage their BG to prevent hypoglycemia, but also self-treat mild or moderate hypoglycemia, require

assistance for self-treatment of severe hypoglycemia, and fear future hypoglycemia. Additionally, we noted a remarkable variation in attitude towards treatment and responses to a mild or moderate vs. a severe episode, especially with respect to significant changes in lifestyle following the event.

It has been well documented in trials such as the DCCT (7-9), the SDIS (10), and the UKPDS (13) that hypoglycemia is 1 of the most prevalent and serious treatment-related complications of type 1 and type 2 diabetes. As found in these and the Kumamoto (14) trials, our study patients were faced with weighing the benefits of intensive diabetes therapy against the frequency of hypoglycemia. Our finding of severe hypoglycemia of 71.3% in patients with type 1 diabetes is comparable to the DCCT 9-year follow-up data in which 73% of type 1 diabetes patients experienced ≥ 1 severe hypoglycemic event. In our patients with type 2 diabetes, of whom 37.4% were on intensive treatment, we found 25.6% had experienced severe hypoglycemia during their lifetime. This finding is lower than that noted in the UKPDS trial, in which 86% of intensively treated and 73% of conventionally treated patients had ≥ 1 severe hypoglycemia episodes over 10 years (13). We noted that 27% of type 1 and only 14% of type 2 diabetes patients had ≥ 1 severe hypoglycemia episodes in the preceding year. Type 1 diabetes patients reported a frequency of severe hypoglycemia of 0.69 and 0.71 episodes per patient per year for conventional and intensive treatment, respectively. In the last 2.5 years of the UKPDS study, intensively treated patients reported 0.9 severe episodes per patient per year and conventionally treated patients reported 0.66 severe episodes per patient per year (13). In our study, the high frequency of severe episodes reported per year may have been skewed by the 5 patients who reported >10 severe episodes in the preceding year. These patients may not have correctly classified severe hypoglycemia, thereby inflating the number of severe hypoglycemia episodes reported, particularly for patients with type 2 diabetes. When data from these 5 patients were excluded, the frequency of severe hypoglycemia in both type 1 and type 2 diabetes patients fell to levels similar to those reported in the DCCT and UKPDS. The frequency of severe hypoglycemic episodes that occurred during sleep were similar to that found in the DCCT (7) for both type 1 and type 2 diabetes patients. Our

Table 3. Changes in the mean total daily dose of insulin following a hypoglycemic event

Patient population	Type 1 diabetes n=202	Type 2 diabetes n=133
All patients	0.701	0.705
Patients not reporting any severe hypoglycemic episodes	0.735	0.638
Patients who reported 1 severe hypoglycemic episode	0.585	0.659
Patients who reported >2 severe hypoglycemic episodes	0.630	0.734
Patients who reported 0-2 mild or moderate hypoglycemic episodes	0.759	0.732
Patients who reported >11 mild or moderate hypoglycemic episodes	0.704	0.563

results also suggest that severe hypoglycemia was more common during sleep for type 2 diabetes patients. However, when the patients with >10 severe episodes per year were removed from the analysis, the frequency during sleep for type 1 diabetes patients was slightly greater than for type 2 diabetes patients.

We were surprised to observe that in the preceding 12 months, type 2 diabetes patients had a greater frequency of severe hypoglycemia than type 1 diabetes patients. We hypothesize that the difference was due to the fact that type 2 diabetes patients had been treated with insulin for as long as type 1 diabetes patients, thereby limiting their experience in managing BG and hypoglycemia. Additionally, type 2 diabetes patients were older and not as well educated with regard to diabetes as type 1 diabetes patients perhaps rendering them less confident in their ability to adapt their insulin doses according to their needs (BG, diet and hypoglycemia events). Finally, type 2 diabetes patients may have misclassified moderate events as severe hypoglycemia, thereby overestimating the number of severe events experienced. We believe that our findings are accurate as our study population consisted of patients attending diabetes clinics and therefore may have been refractory to standard treatment found in the general diabetes population.

Our study demonstrated that self-treatment was the predominate means of coping with mild or moderate and severe hypoglycemia, and that related costs were borne by the patient and/or their insurance company. Following a mild or moderate event, neither type 1 or type 2 diabetes patients utilized healthcare resources and did little more than

mention the episode to their physician at their next scheduled visit. Remarkably, healthcare resources utilized following a severe hypoglycemia event were limited. Healthcare resources utilized included ambulance, emergency room and hospital services, non-scheduled visit to family physician, and visits to diabetes specialists, with all related costs borne by the healthcare system.

Severe hypoglycemia was shown to have a considerable impact upon patient lifestyle. Both type 1 and type 2 diabetes patients were burdened with the inconvenience and cost of monitoring their BG until they had regained glycemic control. Patients also reported frequent modification of BG levels through manipulation of their insulin dose to prevent future hypoglycemia. This strategy was most prevalent in the type 1 diabetes population. Although we captured modifications in treatment patterns, we did not ask the participants to report modifications in frequency of injections, the change in their insulin dose or a combination of these techniques used to manage glycemic control.

Type 1 diabetes patients demonstrated an ability to cope with mild or moderate hypoglycemia, however, severe hypoglycemia did provoke lifestyle changes with a social impact. Type 2 patients also reacted with more frequent lifestyle changes following severe hypoglycemia. In the early 1990s, Polonsky and colleagues correlated frequency of hypoglycemic episodes to fear of hypoglycemia and documented that patients with type 2 diabetes experienced significantly less fear than those with type 1 diabetes (4,12). Our results confirm this finding for mild or moderate hypoglycemia. However, more patients with type 2 reported greater fear of

Table 4. Percentage of patients who “sometimes” or “always” made lifestyle changes following a hypoglycemic episode*

Lifestyle changes	Mild or moderate hypoglycemic episodes		Severe hypoglycemic episodes	
	Type 1 diabetes n=193	Type 2 diabetes n=97	Type 1 diabetes n=55	Type 2 diabetes n=19
Modified insulin dose to avoid future hypoglycemia	74.1%	43.3%*	78.2%	57.9%
Ate extra food	66.8%	62.9%	70.9%	63.2%
Had greater fear of future hypoglycemia	37.8%	29.9%	63.6%	84.2%
Had additional concerns about driving	29.2%	9.4%*	36.4%	15.8%
Asked someone to check on them	9.3%	14.4%	45.5%	57.9%
Went home from school, work, activities	6.7%	10.3%	25.5%	32.0%
Stayed home the next day	1.6%	9.3%**	20.0%	26.3%

*Reported within the 24 hours following the event

*p<0.001

**p<0.01

future hypoglycemia following a severe episode. A major alteration to daily activities was noted with respect to fear of driving, which was a prominent concern reported, particularly in the type 1 diabetes population.

There are potential limitations to the study that may affect the generalizability of the findings. We may have inadvertently excluded participants who were not able to speak either English or French, potentially introducing biases related to cultural diversity, isolation, age and inability to access health-care. Additionally, the majority of the patients were recruited from diabetes specialist clinics and were likely aware of the value of regular visits to their physician. Furthermore, a participation bias may exist as those who volunteered to participate may have been more concerned and knowledgeable about their disease and its management than the general population.

This study has shown that fear of hypoglycemia significantly affects patient health outcomes such as glycemic control and management, self-treatment modifications and post-episode lifestyle infringements, all resulting in the utilization of considerable personal and healthcare resources. There is a need for accessible and better programs to educate patients about avoidance of hypoglycemia in order to alleviate fear of hypoglycemia during activities of daily living. In addition, treatments that do not increase the risk of hypoglycemia would be a welcome addition to diabetes management options.

ACKNOWLEDGEMENTS

The authors thank Sandra Kleinstiver for her assistance in preparing this manuscript and Nathalie Cayer for her administrative assistance. This work was supported by Aventis Pharma Canada.

REFERENCES

1. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 clinical practice guidelines for the prevention and management of diabetes in Canada. *Can J Diabetes*. 2003;27(suppl 2):S1-S152.
2. Yale, J-F, Begg I, Gerstein H, et al. 2001 Canadian Diabetes Association clinical practice guidelines for the prevention and management of hypoglycemia in diabetes. *Can J Diabetes*. 2002;26:22-35.
3. Cox DJ, Irvine A, Gonder-Frederick L, et al. Fear of hypoglycemia: Quantification, validation and utilization. *Diabetes Care*. 1987;10:617-621.
4. Polonsky WH, Davis CL, Jacobson AM, et al. Correlates of hypoglycemic fear in type I and type II diabetes mellitus. *Health Psychology*. 1992;11:199-202.
5. Gonder-Frederick L, Cox D, Kovatchev B, et al. The psychosocial impact of severe hypoglycemic episodes on spouses of patients with IDDM. *Diabetes Care*. 1997;20:1543-1546.
6. Cryer PE. Hypoglycemia: The limiting factor in the management of IDDM. *Diabetes*. 1994;43:1378-1389.
7. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977-986.
8. Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (A1C) to the risk of development and progression of retinopathy in the diabetes control and complications trial. *Diabetes*. 1995;44:968-983.
9. Diabetes Control and Complications Trial Research Group. Hypoglycemia in the diabetes control and complications trial. *Diabetes*. 1997;46:271-286.
10. Reichard P, Pihl M, Rosenqvist U, et al. Complications in IDDM are caused by elevated blood glucose level: the Stockholm Diabetes Intervention Study (SDIS) at 10-year follow-up. *Diabetologia*. 1996;39:1483-1488.
11. Egger M, Davey Smith G, et al. Risk of adverse effects of intensified treatment in insulin-dependent diabetes mellitus: a meta-analysis. *Diabet Med*. 1997;14:919-928.
12. Polonsky W, Davis A, Jacobson B, et al. Hyperglycemia, hypoglycemia, and blood glucose control in diabetes: Symptom perceptions and treatment strategies. *Diabet Med*. 1992;9:120-125.
13. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352:837-853.
14. Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: A randomised prospective 6-year study. *Diabetes Res Clin Pract*. 1995;28:103-117.