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ARTICLE

Detection of Hypoglycemia by Children With Type 1 Diabetes 6 to 11 Years of Age and Their Parents: A Field Study

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ABSTRACT

OBJECTIVES. The objectives of this study were to (1) assess accuracy of hypoglycemia detection in children with type 1 diabetes and their parents, using personal digital assistant technology to collect glucose estimates and meter readings, (2) identify demographic, clinical, and psychological predictors of individual differences in accuracy, and (3) test whether poor hypoglycemia detection is a risk factor for severe hypoglycemia in children.

METHODS. Sixty-one children aged 6 to 11 and their parents completed 70 trials, over 1 month, of a survey programmed on a personal digital assistant, which asked them to rate symptoms, estimate current blood glucose level, and then measure blood glucose level. For the subsequent 6 months, parents reported children's severe hypoglycemia episodes bimonthly.

RESULTS. Both parents and children showed poor ability to recognize high or low blood glucose levels, making clinically significant errors as frequently as clinically accurate estimates. Parents failed to recognize >50% of readings <3 mmol/L (<55 mg/dL) and made potentially dangerous errors such as believing the blood glucose level was high when it was low 17% of the time. Children were significantly more accurate at recognizing their hypoglycemia but still failed to detect >40% of episodes. Higher depression scores for children related to lower accuracy. Children who were less accurate at detecting hypoglycemia subsequently experienced more severe hypoglycemia.

CONCLUSIONS. Ability to recognize hypoglycemia is a significant problem for children with type 1 diabetes and their parents. For children, poor ability to detect low blood glucose levels may be a significant and underappreciated risk factor for severe hypoglycemia. More effort is needed to provide education and training designed to improve hypoglycemia detection in this population.

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Key Words
pediatric type 1 diabetes, hypoglycemia detection

Abbreviations
BG— blood glucose
SH—severe hypoglycemia
PDA—personal digital assistant
HbA1c— hemoglobin A1c
DKS—Diabetes Knowledge Scale
BGAT— blood glucose awareness training
EGA— error-grid analysis
AI—accuracy index

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DESPITE TECHNOLOGIC ADVANCES in glucose monitoring, patients with type 1 diabetes must sometimes still rely on the ability to monitor and recognize subjective symptoms and other signs of hypoglycemia for timely treatment. Failure to recognize the early warning signs of low blood glucose (BG) levels and take immediate corrective action is a major contributor to severe hypoglycemia (SH) and its negative sequelae, including mental disorientation, unconsciousness, seizure, accidents, and physical injury. Most published studies have investigated BG detection in terms of overall accuracy across glucose-level ranges.[1–10] For example, studies of adults with type 1 diabetes indicated that overall BG estimates were clinically accurate, on average, 40% to 50% of the time[1–3]; however, when recognition of hypoglycemia was investigated specifically, it was not uncommon for adults to fail to recognize up to 50% of their hypoglycemic episodes.[1,3–5] Adolescents with type 1 diabetes showed even poorer ability than adults in overall accuracy, with clinically accurate estimates ranging from 33% to 37%.[6–10] Little research with pediatric populations has focused specifically on hypoglycemia detection, but 1 inpatient study found that only 28% of adolescents and

young adults accurately recognized mild hypoglycemia, even after being told that their BG levels might be experimentally lowered.[11]

Although problematic for adults and adolescents, hypoglycemia detection may present an even greater challenge in the treatment of young children with type 1 diabetes. Here effective hypoglycemia treatment and SH prevention depend not only on the child's ability to recognize early symptoms but also on parent ability to detect warning signs. Despite its clinical importance, however, hypoglycemia detection in young children with diabetes and their parents has received little scientific attention. One major barrier to research is reluctance to induce hypoglycemia experimentally in young children. An alternative approach is to use outpatient or field methods that take advantage of naturally occurring episodes of hypoglycemia. Using this method, a previous study examined overall accuracy of BG detection of parents of young children with type 1 diabetes (<12 years) and their parents.[12] Parents made clinically accurate estimates of their children's BG level 36% of the time, whereas children accurately estimated their own glucose levels 28.5% of the time. Both parents and children made clinically significant errors as frequently as clinically accurate estimates. Like adolescents and adults, the most common error made by parents and children was failure to detect BG extremes (ie, believing glucose level to be in target range when it was not); however, estimates made by children and parents also included a potentially serious clinical error that rarely occurs in older patients: estimating that BG levels were high when they were actually low.

Although that study suggested that recognizing hypoglycemia may be a significant problem for younger children with type 1 diabetes and their parents, there were also several methodologic limitations. Only a small number of families participated (19 parents/12 children), each completing only 50 BG estimates and concurrent glucose readings. Only 10% of these readings were <3.9 mmol/L, making it difficult to investigate hypoglycemia detection in depth. In addition, families used paper diaries to record data, which provided no validity checks. The purpose of this study was to assess hypoglycemia detection in school-aged children and their parents, using a more reliable data collection procedure in which glucose-level estimates were entered into a handheld computer (personal digital assistant [PDA]) connected to a BG meter that stored and time-stamped readings. In addition, a larger number of families were assessed across a longer time period to capture more hypoglycemic episodes. This larger data set was also used to explore demographic, clinical, and psychological factors relating to individual differences in accuracy for children and parents. Previous studies across all age groups have consistently found large individual differences in ability to estimate BG level[1–12] and attempted to identify predictors of individual accuracy. Variables such as gender, age, diabetes duration, metabolic control, and trait anxiety (chronic personality-based predisposition toward anxiety) have been examined but with mixed results.[6–13] Finally, this study also examined the clinical implications of hypoglycemia detection in this population by testing whether risk for SH is higher when children with type 1 diabetes and their parents show poorer ability to recognize hypoglycemia.

METHODS

Participants

Families were recruited through pediatric endocrine clinics at the University of Virginia and the Joslin Diabetes Center, advertisements, and parent support groups. Inclusion criteria for children were age 6 to 11 years, at least 1 year since diagnosis, ability to read and complete questionnaires, and ability to use the PDA. Exclusion criteria were developmental disabilities and comorbid illnesses that would interfere with study completion or symptom perception (eg, mental retardation, poorly controlled asthma). When 2 parents lived in the home, the 1 primarily responsible for the child's diabetes management was asked to participate.

Eligible families attended orientation meetings during which institutional review board–approved informed consent/assent was obtained. A total of 77 families entered the study, and 66 completed, with 11 families withdrawing because of relocation, family stressors, and unwillingness to continue. For 2 families, PDA data were lost as a result of computer malfunction, and 3 families had missing data that excluded them from data analysis. The final sample of families with complete data were 61 (University of Virginia: $n = 31$; Joslin: $n = 30$). Parents were paid $70, and children received a $35 toy store gift card for participation.

There were 31 girls and 30 boys; 25 children were 6 to 8 years of age, and 36 were 9 to 11, with average age of 8.83 (SD: 1.6). Average duration of diabetes was 4.7 years (SD: 2.6 years), and 18 of the children used an insulin pump. Hemoglobin A1c (HbA1c) values ranged from 6.7% to 10.4% (mean: 7.9%; SD: 0.68%). A total of 48 mothers and 13 fathers participated. Almost all families were white (95%), and most parents had some college education (mean years of school: 15.8; SD: 2.6). Although not an inclusion criterion, all of the families had access to e-mail, which was used for prospective data collection. Parents had the option to receive computerized telephone calls for the prospective data collection, but none selected to do so.

Assessment Measures

Questionnaires

Children completed a Diabetes Knowledge Scale (DKS), the State-Trait Anxiety Scale,[14] and the Children's Depression Inventory.[15] Parents completed a DKS, the Beck Depression Inventory,[16] and the State-Trait Personality Inventory.[17] The 40-item parent DKS was developed at the University of Virginia for use in previous studies of adults with type 1 diabetes and shows sensitivity to changes in knowledge as a result of behavioral interventions such as blood glucose awareness training (BGAT).[4,5] The children's DKS was developed for clinical use at the Center for Diabetes, Endocrinology and Metabolism at the Childrens Hospital Los Angeles.

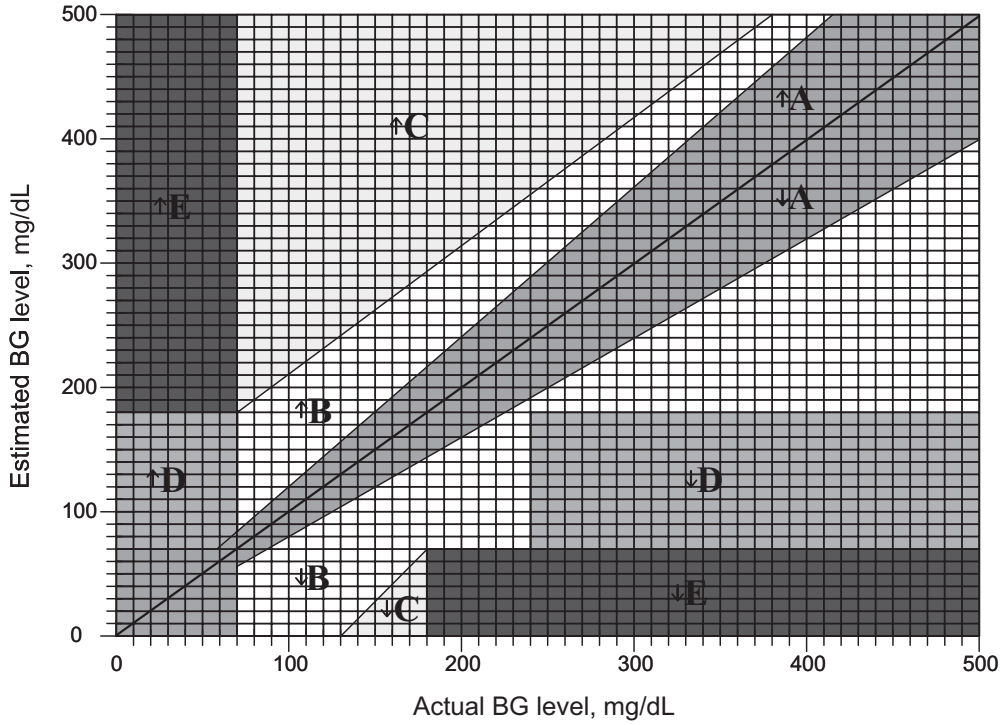

FIGURE 1
The error grid.

PDA Survey

Families were provided with a Visor PDA, which was linked to a Freestyle Tracker BG monitoring system to collect, time-stamp, and store glucose readings (Abbot Diabetes Care, Abbott Labs, Alameda, CA) and programmed with a brief survey. Families were asked to complete 3 to 5 PDA survey trials each day until completing 70 trials during a 1-month period. At the beginning of each trial, parents rated the degree to which their child was experiencing 14 symptoms on a scale from 0 to 6 (0 = not at all, 6 = extremely). Only symptoms that could be observed by the parent, including changes in behavior and mood, were included. Parents then estimated their child's current BG level and rated their degree of confidence about their estimate on the scale from 0 to 6. Parents were instructed not to divulge their estimate to their child or to ask their children about symptoms. Then, children rated the extent to which they were experiencing 14 symptoms on a visual analog scale from 0 to 6, estimated their current BG level, and rated their confidence in this estimate (ie, "How sure are you?"). After the parent and the child completed each survey, the child's BG level was measured.

Procedure

After orientation and informed consent/assent, parents and children were given Visor computers and the Freestyle BG meters and instructed on their use. Families were also given questionnaires, which were completed at home, and a stamped envelope for mailing. Parents were asked not to help their children complete the questionnaires, with the exception of providing assistance when children could not read or understand a question. After 70 PDA trials were completed, a blood sample kit was mailed to parents, who obtained blood from their children and returned the sample to the University of Virginia Clinical Laboratories for HbA1c analysis. Parents then entered the prospective SH follow-up phase of the study. Every 2 weeks for the next 6 months, parents received a brief e-mailed questionnaire that included the question, "Over the last 2 weeks, how many times did your child's blood glucose go so low that s/he could not self-treat because s/he was stuporous or unconscious or having a seizure?" When the parent answered yes to this item, other questions were asked regarding the time and the date of the SH episode. Of the 61 parents, 53 completed the 6-month protocol.

Data Analysis

Error-grid analysis (EGA) was used to measure the accuracy of BG estimates. The error grid shown in Fig 1 was originally designed to measure accuracy of BG estimates made by patients, but it is also a widely used and standard technique for assessing the accuracy of BG estimates generated by glucose meters and other glucose-measurement devices, including continuous glucose sensors. In this study, separate EGA was performed (1) across all glucose ranges and (2) for hypoglycemic readings.[1,2] For each parent and child, the percentage of estimates that fell into the error grid's A zone, or "clinically" accurate estimates, were computed. Clinically accurate estimates fall within 20% of the actual BG reading or occur when both actual and estimated BG levels are <3.9 mmol/L. The percentage of estimates that fell into the error grid's C, D, and E zones, indicating clinically significant errors, were also computed. C zone estimates occur when the BG level is perceived to be in need of correction (ie, too low or too high) when it is

not. D zone estimates are failures to detect hypo- or hyperglycemia. E zone estimates occur when the actual BG level is low but estimated BG level is high, and vice versa.

In addition to the percentage of estimates that fell into each EGA zone, a summary statistic, the accuracy index (AI), was computed by subtracting the percentage of clinically significant errors from the percentage of clinically accurate estimates.[1] Thus, higher positive scores indicate relatively more clinically accurate estimates, whereas higher negative scores indicate relatively more clinically significant errors. For each parent and child, separate AI scores were computed across all BG readings (overall AI) and for BG readings of <3 mmol/L (hypoglycemia AI). The hypoglycemia AI included only readings of <3 mmol/L (<55 mg/dL) to ensure that this measure reflected detection of moderate hypoglycemia, which would be expected to be more symptomatic than mild hypoglycemia. Thus, hypoglycemia AI scores were computed only for children with BG readings of <3 mmol/L across the 70 trials ($n = 35$). As noted, symptom ratings were analyzed to compute the number of symptom items significantly related to low BG levels for each parent and child, a variable used in subsequent regressions. The statistical technique for identifying significant symptoms from PDA data were described in detail in a previous publication.[18]

Exploratory hierarchical regressions were performed to test several possible predictors of individual differences in accuracy. Predictor variables were chosen on the basis of previous findings (eg, age, BG-level variability, trait anxiety) and theoretical considerations (eg, number of hypoglycemic symptoms, diabetes knowledge, depression). Sets of variables were entered in 3 steps: demographic and clinical variables in the first step (age, diabetes duration, BG-level variability, and HbA1c), diabetes-specific cognitive variables in the second step (diabetes knowledge and number of significant symptoms), and psychological status variables in the third step (trait anxiety and depression scores). Separate regressions were performed for parents and children to predict overall and hypoglycemia AI scores. To test the hypothesis that parents and children with poorer accuracy would experience more episodes of SH during the 6-month follow-up, *t* tests compared hypoglycemia AI scores in families who did and did not experience SH during this period.

RESULTS

EGA Results

Table 1 presents the EGA results for overall accuracy across all BG levels, as well as hypoglycemia accuracy when the BG level was <3 mmol/L. Both parents and children made clinically accurate (A zone) estimates less than one third of the time and clinically significant errors 23% and 27% of the time, respectively. AI scores were computed for overall and hypoglycemia accuracy for parents and for children. Average overall AI score was 0.7 (SD: 1.6) for parents and 0.1 (SD: 1.7) for children, indicating that parents and children made clinically significant errors as often as clinically accurate estimates. A total of 35 children experienced BG readings of <3.0 mmol/L (55 mg/dL) during the study, with an average of 2.8 readings (SD: 2.2). Average hypoglycemia AI score was −3.9 (SD: 7.9) for parents and −0.6 (SD: 8.5) for children. Both overall and hypoglycemia AI scores correlated for parents and children ($r = 0.41$, $P = .001$; $r = 0.59$, $P = .0001$, respectively); however, overall AI scores for parents were significantly higher ($t = 3.79$, $P = .0004$) than for children, whereas hypoglycemia AI scores were higher for children ($t = 3.0$, $P = .007$). Parents failed to detect 54% of BG levels of <3 mmol/L, whereas children failed to detect 41% (zone D errors). Parents and children also made E zone errors, believing the BG level to be too high when it was low 17% and 11% of the time, respectively.

TABLE 1 EGA Results

Zone	All BG Levels (Overall Accuracy; $n = 61$)		<3 mmol/L (<55 mg/dL; Hypoglycemia Accuracy; $n = 35$)	
	Parent	Child	Parent	Child
A	30	27	29	48
B	47	46	[a]	[a]
C	03	04	[a]	[a]
D	18	19	54	41
E	02	04	17	11

Data are mean percentage of BG estimates that fell into the zone.
[a] B and C zones are not relevant for BG values of <3 mmol/L.

Overall AI scores were significantly higher for older than for younger children, but both age groups showed poor overall accuracy, with mean scores of 0.4 and −0.5, respectively ($t = 2.14$, $P = .04$). There was no difference in the number of clinically significant errors made by older (22%) and younger children (25%). There were no significant gender differences in overall AI (0.0 for girls and 0.1 for boys) or hypoglycemia AI. Parent anxiety did not correlate with either AI score, but children's anxiety showed a positive trend toward a relationship with overall AI ($r = 0.31$, $P < .06$). Neither parent nor child confidence correlated with AI scores. For determination of whether accuracy improved over time, reflecting a learning effect, overall AI scores for the first 35 trials were compared with the last 35 trials. For parents, there was no difference in accuracy across time, whereas children showed a lower AI during the second half ($t = 2.1$, $P = .044$).

Predictors of Accuracy

Table 2 summarizes the results of exploratory regressions to identify significant predictors of accuracy for both overall AI scores ($n = 61$) and hypoglycemia AI scores ($n = 35$). For parents, only 1 variable, higher BG-level variability, was negatively related to overall AI scores ($P < .01$), accounting for 19% of the variance. For children, higher BG-level variability was negatively related to overall AI scores ($P < .01$), whereas age was positively related to accuracy ($P < .01$). Higher levels of depression for children were also negatively related to

TABLE 2 **Significant Predictors of AI Scores**

Parameter	Predictor Variable	β	R^2	F
Overall AI scores				
Parents ($n = 61$)	BG variability	−0.40[a]	19.3	11.47[a]
Children ($n = 61$)	BG variability	−0.59[a]	31.7	
	Age	3.47[a]	9.1	
	Depression	−2.68[b]	4.8	12.57[a]
Hypoglycemia AI scores	Diabetes duration	9.95[b]	17.8	
Parents ($n = 35$)	No. of low symptoms	11.53[b]	12.0	6.16[a]
Children ($n = 35$)	None	ns	<2.0	ns

ns indicates not significant.
[a] $P < .01$.
[b] $P < .05$.

accuracy ($P < .05$). Together, these variables accounted for 46% of the variance in children's overall AI scores. For parents' hypoglycemia AI scores, duration of diabetes and number of significant low symptoms ($P < .05$) both related positively to accuracy, together accounting for 30% of variance. For children, none of the tested variables predicted hypoglycemia AI.

Hypoglycemia Detection and Future SH

At least 1 episode of SH was reported in 13 of the 53 children whose parents completed the 6-month prospective protocol. A t test showed that hypoglycemia AI scores for children who experienced SH (mean: −0.79; SD: −0.39) was significantly lower than for children who did not (mean: 0.20; SD: 0.81), indicating poorer accuracy ($t = 4.4$, $P < .0001$). Hypoglycemia AI scores did not differ for parents whose children did or did not experience SH.

DISCUSSION

This study supports earlier findings showing that younger children with type 1 diabetes and their parents are less accurate than adults or adolescents with type 1 diabetes at overall BG detection.[12] Although parents were statistically more accurate than children across BG levels, both had average AI scores of <1.0, indicating no clinically meaningful difference in accuracy. In terms of hypoglycemia, parents failed to detect >50% of their children's hypoglycemia, suggesting that they may frequently "miss" symptoms and other cues indicating that glucose level is low. Although children were significantly more accurate at recognizing their own hypoglycemia, they still failed to detect 41% of episodes. Parents and children also made E zone errors in recognizing hypoglycemia, which rarely occur for adults or adolescents with type 1 diabetes and have potentially serious clinical implications. For example, if low the BG level is mistakenly believed to be hyperglycemia, then treatment mistakes such as failing to eat when the BG level needs to be raised could occur. Of note, these failures to recognize hypoglycemia occurred under conditions that might be expected to enhance accuracy; that is, when parents and children were preparing to check BG levels, focused on symptoms and other signs of glucose extremes, and presumably motivated to be accurate.

Parents were less accurate at recognizing hypoglycemia than their children. This finding highlights that parents face a daunting task: monitoring their child for warning signals when they have no direct access to subjective symptoms and must depend on signs such as changes in skin tone or behavior or their child's report. In addition, confidence in estimations was unrelated to actual accuracy for both parents and children, indicating that perceived ability to detect hypoglycemia may not always be reliable.[1,12] There was also no evidence of learning or improvement in ability to detect BG over time for parents or children. This replicates previous findings demonstrating that accuracy does not increase merely with repeated estimations but requires systematic feedback and specific training.[1,19]

Taken together, the regression results suggest that ability to estimate BG levels is complex and multifactorial, potentially influenced by a number of different variables. For overall accuracy, BG-level variability was the only variable that predicted AI scores for both parents and children, replicating previous findings that wider and more frequent fluctuations in glucose levels contribute to poorer detection.[7,12,13] For children, increased age was also associated with higher overall accuracy, but duration of diabetes was not, suggesting that advances in cognitive development have more influence on BG detection than length of time the child has lived with diabetes; however, average overall AI scores for both younger and older children were close to 0, and there was no age difference in hypoglycemia AI scores, so the clinical significance of age in preadolescent children may be minimal. Surprising, depression predicted poorer overall accuracy for children, but anxiety did not.[10,11] The impact of depression on BG detection has not been investigated in previous research. Depression may lead to decreased attention to somatic cues or cause other physical symptoms that interfere with children's ability to detect glycemic changes or may interfere with the cognitive processes involved in recognizing and interpreting symptoms.

For parents, ability to recognize hypoglycemia was predicted by the number of significant low BG level symptoms that they observed, as well as duration of their child's diabetes. Thus, not surprising, parents who were more aware of signs of low BG levels in their children or whose children were more symptomatic showed better ability to recognize hypoglycemia, as well as those who had more experience with diabetes and perhaps with hypoglycemic episodes. For children, none of the tested variables predicted hypoglycemia detection, including the number of significant low BG level symptoms; however, this finding does not necessarily suggest that symptoms do not play a critical role in children's hypoglycemia awareness. This study was the first attempt that we are aware of to measure perceived BG symptoms in young children using a visual analog scale. More research is needed to understand young children's ability to recognize symptoms of low BG levels accurately, as well as the best methods for assessing symptom perception in pediatric populations.

This study also explored the question of whether ability to recognize hypoglycemia, as measured in field studies, has any real-world implications as a risk factor for the occurrence of SH in pediatric populations. Parents whose children experienced SH during the 6-month prospective period did not differ in accuracy from those whose children did not; however, children who experienced SH during the next 6 months had significantly lower hypoglycemia AI scores than children who did not experience any episodes. Although this finding suggests that problems in ability to recognize hypoglycemia may have important clinical implications for children, more research is obviously needed.

Several methodologic limitations to this study should be considered when interpreting the results. Although more families as well as more BG estimates during a longer period than in previous studies were included,[12] the sample size for both participants and glucose readings is still an issue. Only 58% of the children experienced BG levels of <3.0 mmol/L during the study, and approximately one third of these children had only 1 episode. Future studies should include observation for an even more extended time to capture more low BG level episodes and obtain a more reliable assessment of hypoglycemia detection. In addition, only a small number of children in this study experienced SH during the 6 months, not surprising given the relatively low base frequency of these episodes. Because of sample size, the regression analyses to predict accuracy of BG detection are also underpowered and should be considered exploratory. Finally, a disadvantage to any field procedure is the inability to measure critical biological variables, such as epinephrine response to falling glucose levels, which likely contribute to individual differences in accuracy. Another disadvantage is the inability to control the extent to which parents and children influenced each other's symptom reports and BG estimates.

Even with these limitations, this study confirms what many clinicians already believe: that hypoglycemia detection is a significant problem for young children with type 1 diabetes and their parents. It also provides preliminary evidence that, for children, poor hypoglycemia detection may be an underappreciated risk factor for SH. The obvious clinical implication is that more effort needs to be directed at educating and training parents and children to recognize early warning signs of hypoglycemia. Knowledge did not predict accuracy for either children or parents, showing that general diabetes education is not adequate. Instead, interventions focused on improving awareness and interpretation of symptoms, and other cues relevant to hypoglycemia is needed. For adults, this type of targeted intervention, BGAT, has been shown to improve accuracy of hypoglycemia detection, reduce extremes in glucose-level fluctuations, and improve psychosocial status.[1,3–5] A recent review summarized the results of 15 studies in the United States and Europe.[20] Our research group is translating BGAT into a training program for parents of young children with type 1 diabetes. Parents play a critical role in teaching their children diabetes management skills, including recognition of hypoglycemia. Providing parents with more training in recognizing and predicting hypoglycemia may not only improve their accuracy but also help them better teach their children this important skill.

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