

# Weekly Telephone Contact by a Diabetes Educator in Adolescents With Type 1 Diabetes

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## A B S T R A C T

### OBJECTIVE

To determine if weekly, semi-structured telephone contact by a diabetes educator improves glycosylated hemoglobin (A1C) over a 6-month period compared to standard care in adolescents with type 1 diabetes.

### METHOD

The authors performed a prospective, randomized trial of 50 patients (age: 11 to 17 years) with A1C  $\geq 8.0$  but  $< 14.0\%$  and duration of diabetes  $> 1$  year. Patients visited the Diabetes Clinic at British Columbia's Children's Hospital, Vancouver, British Columbia, Canada, every 6 months and were randomized to a control group (standard care) or telephone group (weekly reinforcement through telephone contact by the diabetes educator).

### RESULTS

There was no significant difference between the control and telephone groups in mean entry A1C, age, sex or duration of diabetes. After 6 months, A1C (mean  $\pm$  standard deviation [SD]) had decreased significantly from baseline in both the control ( $-0.4 \pm 0.9\%$ ,  $p=0.04$ ) and telephone ( $-0.9 \pm 1.6\%$ ,  $p=0.01$ ) groups, but the magnitude of the change was not significantly different between the 2 groups. Interestingly, in

## R É S U M É

### OBJECTIF

Déterminer si un appel téléphonique hebdomadaire semi-structuré d'un spécialiste de la formation diabétique avait amélioré l'hémoglobine glycosylée (A1C) après 6 mois par rapport aux soins standard chez les adolescents atteints de diabète de type 1.

### MÉTHODE

Les auteurs ont mené une étude prospective avec répartition aléatoire auprès de 50 patients (âgés de 11 à 17 ans) dont l'A1C était  $\geq 8$  mais  $< 14\%$  et qui présentaient un diabète depuis plus d'un an. Les patients se sont rendus à la clinique du diabète du British Columbia's Children's Hospital, à Vancouver (Colombie-Britannique) Canada tous les 6 mois et ont été partagés au hasard en deux groupes : un groupe témoin (recevant les soins standard) et un groupe recevant des appels téléphoniques (renforcement hebdomadaire par un spécialiste de la formation diabétique).

### RÉSULTATS

Il n'y avait pas de différence significative entre le groupe témoin et le groupe recevant des appels téléphoniques pour ce qui est de l'A1C moyenne, de l'âge, du sexe et de l'ancienneté du diabète au départ. Après 6 mois, l'A1C (moyenne  $\pm$  écart-type) avait baissé de façon significative dans les deux groupes ( $-0,4 \pm 0,9\%$ ,  $p = 0,04$ , et  $-0,9 \pm 1,6\%$ ,  $p = 0,01$ , respectivement), mais la différence entre les 2 groupes n'était pas significative. Fait intéressant, dans un sous-groupe de patients recevant des appels téléphoniques et chez qui l'A1C était  $\geq 9,5\%$  au départ, les appels téléphoniques ont produit une baisse de l'A1C chez 13 patients sur 14 (changement moyen par rapport au départ de  $-1,7 \pm 1,4\%$  dans le groupe recevant des appels téléphoniques par rapport à  $-0,5 \pm 1,1\%$  dans le groupe témoin,  $p < 0,05$ ). Par contre, il n'y a pas eu d'amélioration significative de l'A1C dans le sous-groupe de patients dont l'A1C était  $< 9,5\%$ , dans ni l'un ni l'autre des groupes.

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a subset of the telephone group with A1C  $\geq 9.5\%$  at baseline, weekly telephone contact resulted in a decrease in A1C in 13 of 14 patients (mean change from baseline  $-1.7 \pm 1.4\%$  in the telephone group vs.  $-0.5 \pm 1.1\%$  in the control group,  $p < 0.05$ ). In contrast, A1C did not significantly improve in the subset of patients with a baseline A1C  $< 9.5\%$  in either group.

### CONCLUSION

Weekly telephone contact with a diabetes educator is an effective method to improve A1C in adolescents with poorly controlled type 1 diabetes presenting with A1C  $\geq 9.5\%$ . These results may be helpful in determining how to allocate limited clinic resources.

## INTRODUCTION

Type 1 diabetes mellitus is the most common type of diabetes in the pediatric age group. Standard treatment consists of insulin therapy, self-monitoring of blood glucose (SMBG), an age-appropriate meal plan and a healthy, active lifestyle (1,2). Glycosylated hemoglobin (A1C) reflects mean blood glucose (BG) values over the last 8 to 12 weeks and is regarded as the best marker of diabetes control. Lower A1C is associated with decreased microvascular complications in type 1 diabetes (3-6). A widely accepted standard of care for diabetes consists of visits with a diabetes specialist coupled with an education session with a dietitian and a diabetes educator every 3 months (1,2). However, several studies have shown this method of care to be suboptimal, even though it is more intensive than that received by most patients in the community (7,8). In British Columbia, Canada, where there is only 1 tertiary care pediatric centre and a wide geographic distribution of children with type 1 diabetes, travel is difficult for families and follow-up often occurs only every 6 to 9 months, with more frequent telephone contact.

The Diabetes Control and Complications Trial (DCCT) demonstrated that frequent contact with diabetes educators, dietitians, psychologists, social workers and diabetes specialists is a major factor in the quality of diabetes control (3-5), emphasizing the importance of adherence facilitated through interpersonal support for optimal diabetes management. Adherence is generally recognized as a major obstacle in the management of diabetes, especially in adolescents (9,10). Several studies in adults have shown that case management for insulin adjustment is associated with improved glycemic control (11-16). For example, Thompson and colleagues demonstrated that insulin adjustment by a diabetes educator for a period of 6 months using telephone contact improved absolute A1C levels by  $> 1.0\%$  in adult patients with poorly controlled type 1 and type 2 diabetes (17).

Diabetes control often worsens in adolescence because of rapid physiological changes related to growth and puberty (18),

### CONCLUSION

Les appels téléphoniques hebdomadaires d'un spécialiste de la formation diabétique sont une méthode efficace pour améliorer l'A1C chez les adolescents présentant un diabète de type 1 mal équilibré et chez qui l'A1C est  $\geq 9,5\%$ . Ces résultats pourraient être utiles pour déterminer comment affecter les ressources cliniques, qui sont limitées.

as well as psychosocial factors leading to nonadherence (19). The authors hypothesized that current standard therapy at their clinic does not provide optimal interpersonal support to reinforce optimal diabetes self-management in adolescents with type 1 diabetes, and that the addition of regular telephone contact by a diabetes educator will improve glycemic control. The objective of this study was to determine if weekly, semi-structured telephone contact by a diabetes educator improves A1C over a 6-month period compared to standard care in adolescents with poorly controlled type 1 diabetes.

## METHOD

### Study population

The Diabetes Clinic at British Columbia's Children's Hospital, Vancouver, British Columbia, follows approximately 1100 patients with type 1 diabetes, of which 680 are adolescents. The mean A1C for the entire population, including the adolescent subset, is 8.3%. From October 1999 to April 2000, the authors sequentially invited patients 11 to 17 years of age with type 1 diabetes of  $> 12$  months' duration and with A1C  $\geq 8.0$  but  $< 14.0\%$  at the time of their regular clinic visit to participate in the study. Five patients declined, and a total of 50 patients were recruited. All A1C values were determined using the same DCA<sup>®</sup> 2000 analyzer (Bayer Diagnostics, Tarrytown, New York, United States) with an in-house normal pediatric range of 4.3 to 5.7%. The in-house calculated coefficient of variation for the DCA 2000 ranges from 3.5% (A1C level of 5.5%) to 3.8% (A1C level of 10.7%). Exclusion criteria included the inability to communicate regularly by telephone or to communicate fluently in English, a contraindication to tight glycemic control as deemed by the pediatric endocrinologist, a concomitant serious illness, inability to attend the 6-month follow-up visit, a planned elective surgery date within the next 6 months, or the use of an insulin pump. Patients with A1C  $\geq 14.0\%$  were excluded from the study because the DCA 2000 analyzer

cannot measure values  $>14.0\%$ , so it would have been impossible to quantify any absolute change in this value.

### Study protocol

All enrolled patients were given a 6-month supply of BG test strips to eliminate cost as a factor in the outcome. Each patient was randomized using a computer-generated randomization table to the control or telephone intervention group. The patients randomized to the control group were encouraged to regularly test BG and to continue with their usual telephone contact with the Diabetes Clinic (as needed for emergency management). They were contacted once by the diabetes educator 1 week after the initial clinic visit, as is routine for all clinic patients with  $A1C \geq 8.0\%$ .

Patients randomized to the telephone group were contacted by the diabetes educator within 2 days of enrollment into the study, and mutually convenient times for telephone contact were arranged. Telephone contact was generally initiated by the diabetes educator and occurred 1 to 2 times per week for 15 to 20 minutes per telephone call. There were a few patients who called the diabetes educator from a cellular telephone or pay phone at a pre-arranged time because of busy after-school schedules. During each telephone call, the diabetes educator recorded the patient's BG values and made insulin adjustments. The educator had extensive experience as a pediatric diabetes educator and adjusted insulin using British Columbia's Children's Hospital's accepted transfer-of-function guidelines for insulin adjustment. Each patient's record was reviewed once per week by his or her clinic physician for the first 4 weeks and, subsequently, as necessary.

The diabetes educator encouraged more frequent SMBG and record-keeping of BG values in logbooks, and reinforced target BG values. She educated the patients on insulin adjustment with practical problems and quizzes that focussed on recognizing patterns of hypoglycemia and hyperglycemia and understanding insulin action. She addressed teen issues such

as autonomy, self-esteem, peer relationships, home and family life, smoking, alcohol and substance use. The diabetes educator encouraged individualized, developmentally appropriate goal-setting. Common goals included lowering A1C to get a driver's license, aiming for BG levels in the target range and understanding more about diabetes to achieve independence from parents. Once goals were established, the diabetes educator would use these goals as a focus point for education, thus avoiding lecturing. Referrals to the dietitian and social worker were made as necessary.

The primary outcome measure was A1C. Patients in both the control and telephone groups visited the Diabetes Clinic for follow-up at 6 months. The secondary outcome measure was the change in prescribed insulin dosage. Each patient's A1C was also evaluated 6 months after completion of the study.

Parents of all participants provided written informed consent, and patients provided written assent. The study protocol was approved by the Clinical Research Ethics Board of the University of British Columbia, Vancouver, British Columbia.

**Table 1. Baseline characteristics**

Characteristics	Control (n=25)	Telephone (n=25)
Sex (female/male)	16/9	14/11
Age (years)	13.8±1.5	14.4±1.7
Duration of diabetes (years)	5.5±3.1	7.0±3.2
BMI-SDS	0.9±0.8	0.9±0.6
A1C (%)	9.6±1.3	9.7±1.2

Data are mean±SD

A1C = glycosylated hemoglobin

BMI-SDS = body mass index standard deviation score

SD = standard deviation

**Table 2. A1C results**

A1C (%)	All study patients		Baseline A1C <9.5%		Baseline A1C ≥9.5%	
	Control (n=25)	Telephone (n=25)	Control (n=13)	Telephone (n=11)	Control (n=12)	Telephone (n=14)
Baseline	9.6±1.3	9.7±1.2	8.6±0.4	8.7±0.4	10.6±1.0	10.5±1.0
6 months	9.1±1.4*	8.8±1.3*	8.2±0.9	8.8±1.6	10.2±1.1	8.8±1.1*†
Change <sub>(0-6 months)</sub>	-0.4±0.9	-0.9±1.6	-0.4±0.8	0.1±1.5	-0.5±1.1	-1.7±1.4†
12 months	9.2±1.7	9.1±0.8	8.2±1.0	8.9±0.7	10.4±1.5	9.3±0.9*†

Data are mean±SD

\*p<0.05 vs. baseline

†p<0.05 vs. control

A1C = glycosylated hemoglobin

SD = standard deviation

### Statistical analysis

Results are presented as mean±standard deviation (SD). Sample size was calculated based on the ability to detect a 1-SD decrease in A1C levels in the intervention group. For a 2-sided t test with  $\alpha=0.05$  and  $\beta=0.90$ , it was estimated that 21 patients would be required in each study arm. To allow for a dropout rate of 20%, 25 patients were recruited to each arm. Since no dropouts occurred, the final power of the study was 0.94. Statistical analysis was performed using the 2-tailed paired and unpaired t tests (Table 1, Table 2), Pearson's correlation coefficient (Figure 1) and analysis of variance (ANOVA) with Bonferroni adjustment as appropriate (Table 3). Body mass index (BMI) was converted to an SD score (BMI-SDS) using the 2000 Centers for Disease Control and Prevention (CDC) Growth Charts (20).

### RESULTS

There was no difference between the telephone and control groups in sex, age, duration of diabetes, BMI-SDS or A1C at baseline (Table 1). The compliance with weekly telephone contact was excellent, and no patients dropped out of the study. The frequency of telephone calls had generally decreased in frequency from twice per week to once per week by study end.

After 6 months (Table 2), A1C (mean±SD) had significantly decreased from baseline in both the control ( $-0.4\pm 0.9\%$ ,  $p=0.04$ ) and telephone ( $-0.9\pm 1.6\%$ ,  $p=0.01$ ) groups. The magnitude of the change in A1C was not significantly different between the 2 groups.

Linear regression analysis of the change in A1C over 6 months relative to the baseline A1C was performed in both groups to determine if telephone contact had a greater impact in those patients whose diabetes was less well controlled. Figure 1 shows the significant inverse correlation between A1C at baseline and the change in A1C after

6 months in the telephone group ( $r=-0.60$ ,  $p<0.01$ ). This relationship was not present in the control group (not significant, data not shown).

After observation of this correlation, the authors subdivided the control and telephone groups into 2 subgroups using  $A1C \geq 9.5\%$  as the discriminant of poorly controlled diabetes. A1C did not significantly improve in either subset of patients (control or telephone) with a baseline  $A1C < 9.5\%$  (Table 2). In contrast, in the subset of patients with  $A1C \geq 9.5\%$  at baseline, A1C significantly decreased in the telephone group (from  $10.5\pm 1.0$  to  $8.8\pm 1.1\%$ ,  $p<0.05$ ), but not in controls ( $10.6\pm 1.0$  to  $10.2\pm 1.1\%$ ). The magnitude of the change in A1C in this subset ( $A1C \geq 9.5\%$ ) of the telephone group was also significantly greater than that in the same subset of the control group ( $-1.7\pm 1.4$  vs.  $-0.5\pm 1.1\%$ , respectively;  $p<0.05$ ). Six months after study completion, the patients in this subset of the telephone group continued to have an improved A1C compared to the same subset of control patients ( $9.3\pm 0.9$  vs.  $10.4\pm 1.5\%$ , respectively;  $p<0.05$ ). The A1C within this subset of the telephone group also remained improved compared to baseline ( $p<0.05$ ).

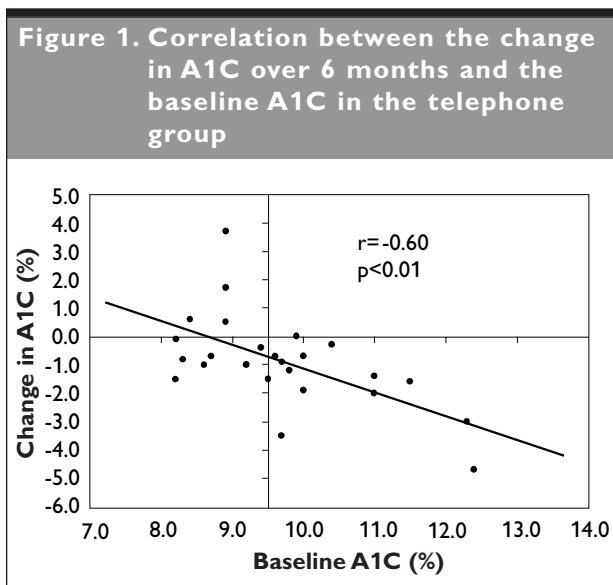
At baseline, there was no difference in insulin dosage between the telephone and control groups (Table 3). At 6-month follow-up, the dose of insulin in the subset of the telephone group with a baseline  $A1C \geq 9.5\%$  had significantly increased compared to baseline ( $p<0.05$ ). There was also a trend suggesting that this dose was increased compared to the dose in the same subset ( $A1C \geq 9.5\%$ ) of the control group, but this was not significant ( $p=0.06$ ).

BMI-SDS significantly increased in both the control ( $0.2\pm 0.2$ ,  $p=0.0003$ ) and telephone groups ( $0.1\pm 0.3$ ,  $p=0.02$ ) after 6 months, but the magnitude of the change was not significantly different between the 2 groups. In the telephone group, there was a significant inverse correlation between the change in A1C and the change in BMI-SDS at 6 months ( $r=-0.58$ ,  $p<0.01$ ); this correlation was not observed in the control group. In the subset of the telephone group with  $A1C \geq 9.5\%$  at baseline, there was also a significant inverse relationship between the change in A1C and change in BMI-SDS ( $r=-0.70$ ,  $p<0.01$ ) at 6-month follow-up.

One patient in the telephone group reported 1 severe hypoglycemic reaction during the study. Three patients in the control group reported severe hypoglycemic reactions, but this information was gathered retrospectively.

### DISCUSSION

This randomized, controlled study examined the effect of regular telephone contact by a diabetes educator on glycemic control in adolescent patients with type 1 diabetes. Although a significant difference in A1C was not observed between control and telephone groups in the entire study population, the results suggest that telephone contact by a diabetes educator is an effective method of improving A1C in adolescents with poorly controlled type 1 diabetes presenting with  $A1C \geq 9.5\%$ .



A1C = glycosylated hemoglobin

Data from the DCCT indicated that a 10% reduction in A1C resulted in a 43% risk reduction of retinopathy progression (3-5). Therefore, the 16% mean decrease in A1C in the present study suggests that telephone contact can result in clinically relevant improvement in glycemic control in adolescents with poorly controlled diabetes.

This study differed from studies in adults (12,17) in that A1C in the control group, as a whole, improved significantly from baseline. This improvement was probably related to a study effect. The ability to fax BG records on a weekly basis for review by a diabetes educator or physician is a routine service provided by the Diabetes Clinic at British Columbia's Children's Hospital. Although not specifically recorded, the authors observed that the parents of patients in the control group faxed BG records to the clinic more frequently than they had done previously. Eliminating the high cost of BG test strips may also have been a factor in the improvement observed in the control patients. The overall improvement in A1C in the entire control group may have contributed to the lack of significant difference observed between A1C in the control group and telephone group in the entire study population at 6-month follow-up.

The improvement in A1C observed in the telephone group was associated with an increase in prescribed insulin dosage. There was also a positive correlation between the degree of improvement in A1C and the change in BMI. However, a similar increase in BMI-SDS was observed in both the control and telephone groups, suggesting that the change in BMI may not be related to increased insulin administration or reduction in A1C. This observation differs from the findings of the DCCT where the risk of becoming overweight was almost 2-fold greater in the intensively treated group compared to the conventionally treated group (3,4).

It should be noted that this study was conducted in the diabetes clinic of a teaching hospital, which is also the only children's hospital in the province. It is possible that the positive results observed in this study are at least partly related to the diabetes educator's extensive experience with the

pediatric/adolescent population and her access to unique resources. Whether or not similar results would be obtained in different settings will require further study.

Finally, the results of this study are limited by the relatively short duration of follow-up. Although this study found a positive benefit of telephone contact only in the subset of patients with initial A1C  $\geq 9.5\%$ , it is promising that 6 months after study completion, there continued to be improvement in A1C compared to baseline in this subset of the telephone group. Because of the varied lifestyle of each adolescent, the diabetes educator had to be very flexible in her schedule. The cost-benefit analysis of implementation of such a program on a continued basis was beyond the scope of this study. However, there is evidence that using diabetes educators or other healthcare professionals instead of physicians for certain aspects of diabetes care can reduce costs as well as improve BG control (21). Furthermore, higher A1C values are directly associated with higher costs to the healthcare system (22). Wagner suggested that the case manager system should be limited to high-risk patients, as this system is probably not affordable for all patients with diabetes (13). The results of the present study would support this recommendation by targeting such a program to adolescents with A1C  $\geq 9.5\%$ .

In summary, the authors have demonstrated that telephone contact by a diabetes educator is an effective method of improving A1C over a 6-month period in adolescents with poorly controlled type 1 diabetes. Future studies with a longer duration of follow-up are required to determine whether the results observed in this study can be sustained in the long term.

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**Table 3. Insulin requirements of the control and telephone groups subdivided by baseline A1C**

Insulin dosage (units/kg/day)	Baseline A1C <9.5%		Baseline A1C $\geq 9.5\%$	
	Control (n=13)	Telephone (n=11)	Control (n=12)	Telephone (n=14)
Baseline	1.3 $\pm$ 0.5	1.1 $\pm$ 0.3	1.0 $\pm$ 0.2	1.2 $\pm$ 0.3
6 months	1.3 $\pm$ 0.7	1.2 $\pm$ 0.3	1.1 $\pm$ 0.3	1.6 $\pm$ 0.4*
Change <sub>(0-6 months)</sub>	0.1 $\pm$ 0.3	0.2 $\pm$ 0.3	0.1 $\pm$ 0.2	0.3 $\pm$ 0.3

Data are mean $\pm$ SD

\*p<0.05 vs. baseline

A1C = glycosylated hemoglobin

SD = standard deviation

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