Reinforced follow-up for children and adolescents with type 1 diabetes and inadequate glycaemic control: a randomized controlled trial intervention via the local pharmacist and telecare

CL Gay1, 2, F Chapuis3, N Bendelac1, F Tixier1, S Treppoz1, M Nicolino1

SUMMARY

Aim: To evaluate the effectiveness and feasibility of reinforced follow-up via telecare mediated by the local pharmacist in contact with the hospital team to improve glycaemic control in children and adolescents with type 1 diabetes (DT1).

Methods: One hundred patients, aged 8 to 17 years, with a history of DT1 of more than 1 year, with HbA1c \( \geq 8\% \), were randomly assigned to either the “reinforced follow-up” group (RFG) or the “usual follow-up” group (UFG). The intervention consisted in downloading and then printing data stored in a glucometer every two weeks, by the local pharmacist. Printouts were faxed to the hospital team which then communicated adapted instructions for better glycemic control directly to the family.

Results: Fifty patients were assigned to each group. The two groups were comparable at the beginning. 71 children had a doctor’s visit at 6 ± 1 months (36 in RFG and 35 in UFG). At this date, there was no significant difference between the average HbA1c levels of the two groups (9.12 ± 1.46 in RFG versus 9.27 ± 1.20 in UFG). We had various difficulties setting up and gaining compliance with the intervention procedure, which explains why only 33 children in the RFG transmitted at least one fax.

Conclusion: At this stage, the reinforced follow-up has not proved to be superior to the usual follow-up. However, it would be possible to make numerous improvements in order to make the former more feasible and probably more efficient.

Key-words: Adolescents/children · Type 1 diabetes · Telecare · Glycaemic control · Pharmacist.

RéSUMÉ

Impact de l’intensification du suivi sur l’équilibre glycémique des enfants diabétiques : essai randomisé d’une intervention de télémédecine par l’intermédiaire du pharmacien de quartier

Objectif: Évaluer la faisabilité et l’efficacité d’une intervention de télémédecine par l’intermédiaire du pharmacien de quartier pour intensifier le suivi des enfants et des adolescents diabétiques et améliorer leur équilibre glycémique.

Méthodes: Cent patients âgés de 8 à 17 ans, ayant un diabète de type 1 plus d’un an, avec une hémoglobine glyquée \( \geq 8\% \) ont été randomisés en deux groupes : « suivi renforcé » (SR) ou « suivi habituel » (SH). Les enfants du groupe « suivi renforcé » se rendaient tous les 15 jours chez leur pharmacien pour y transférer leurs glycémies sur un logiciel. Le pharmacien télétransmettait ces glycémies à l’équipe hospitalière, qui donnait en retour des consignes adaptées à la famille, dans le but d’améliorer l’équilibre glycémique des enfants.

Résultats: Cinquante patients ont été inclus dans chaque groupe. Les deux groupes étaient comparables au début de l’étude. Soixante et onze enfants ont consulté à 6 ± 1 mois (36 du groupe SR et 35 du groupe SH). À cette date, la moyenne d’hémoglobine glyquée n’était pas significativement différente entre les deux groupes (9,12 ± 1,46 pour le groupe SR et 9,27 ± 1,20 pour le groupe SH). Diverses difficultés de mise en place et d’adhésion à l’intervention expliquaient que seuls 33 enfants du groupe SR ont transmis au moins un fax.

Conclusion: Ce suivi renforcé n’a pas fait la preuve de sa supériorité par rapport au suivi habituel dans les conditions utilisées, mais de nombreuses améliorations sont envisageables pour le rendre plus facile à réaliser en pratique et probablement plus efficace.

Mots-clés : Enfants · Adolescents · Diabète de type 1 · Télémédecine · Équilibre glycémique · Pharmacien.

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Glycaemic control plays a major role in the appearance and development of degenerative complications that occur in people with diabetes generally at adulthood [1−3], but also at adolescence [2,4]. HbA1c level of 8% is generally recognized as being the limit beyond which the risk of contracting microangiopathy increases greatly [1,2,5]. It is also the level at which the American Diabetes Association suggests additional action to improve glycaemic control [5]. During adolescence, physiological and psychological factors combine to make diabetes more difficult to control, resulting in an average HbA1c level at least 1% higher than in adults [2]. Several studies emphasize the advantage of increasing contact with the healthcare team in order to improve glycaemic control [6,7,8].

Strengthening the follow-up provided by a professional team geographically closer to the child’s residence is an alternative that would have the advantage of lightening hospital physicians’ workload while decreasing the number of hospital visits for children.

Among local healthcare professionals, the pharmacist could have a major role, especially in France, because regulations impose monthly contact to obtain insulin and the material for injections and self-care. Furthermore, part of the pharmacist’s mission is to give advice and to survey the health of people with chronic diseases [9,10]. However, a diabetologist’s advice may not be substituted by that of a pharmacist. Moreover, several studies have highlighted the fact that telecare (teletransmission of glucometer data followed by doctor feedback) could become a useful tool in monitoring diabetic patients [11−19]. However, telecare in itself has not been recognized as sufficient [12]. Access to computers and the Internet is not yet universal, and particularly not in the homes of the most disadvantaged families. For these reasons we thought of combining direct contact with the local pharmacist and faxing glycaemic data from his/her pharmacy to intensify the follow-up for diabetic children. We hypothesized that this intervention would be beneficial to diabetic patients’ welfare. Therefore a randomized controlled trial was performed to compare this reinforced follow-up combining telecare and contact with the pharmacist with the usual follow-up for children and adolescents with type 1 diabetes (DT1). The aim of this work was to evaluate the impact on glycaemic control after six months and to describe the conditions under which such a system was set up, the difficulties we met with and how we dealt with them.

**Participants and methods**

**Participants and setting**

Participants were recruited in the outpatient clinic of the Debrousse University Hospital in Lyon. The Medical team included five pediatric endocrinologists who follow about 500 children and adolescents with DT1. Patient eligibility criteria were: DT1 for more than a year, age 8 to 17 years, HbA1c level ≥ 8%, scheduled doctor’s appointment, residence in Lyon or its outskirts and pharmacist’s agreement to participate in the study. Those who refused to participate, who had MODY or secondary diabetes were excluded. The Local Ethics Committee approved protocol. Written informed consent was obtained from all parents and children.

The local pharmacists of children who could potentially be included in the study were contacted a week before the scheduled doctor’s appointment at the hospital, by the study coordinator, who explained the study and asked for their agreement in participating.

**Randomization**

Randomisation was conducted via a computer-generated sequence using block randomization with stratification by age (8-12 and 13-17 years). An independent center assigned patients, who had previously been recognized as eligible by the study coordinator, to either the reinforced follow-up group (RFG) or the usual follow-up group (UFG).

**Description of the intervention**

Within the fifteen days following the children’s inclusion in the RFG, selected pharmacies were equipped with software capable to download, analyze and print blood glucose monitoring data (WinGlucofacts Professional 1.1, Bayer Diagnostics TM). The pharmacists were trained how to use it. An Ascensia Esprit 2 glucometer compatible with the software was given to the children. Each child went to the pharmacist every two weeks to download the data stored in his/her glucometer into the computer. The pharmacist printed out the glycemic record and the average glycemic levels at different moments of the day and faxed it to the hospital. The results were then analyzed by the child’s diabetologist, who provided the child and family with instructions adapted to his situation by mail or over the telephone within five days.

Usual follow-up consisted of a visit to the hospital diabetologist every three months [20]. In each group, the frequency of visits could be increased if the diabetologist deemed it necessary.

**Data collection and measures**

Socio-demographic characteristics including age and sex, diabetes duration, number of annual visits to hospital’s diabetologist, the insulin therapy program, and frequency of self blood glucose monitoring (SBGM) were recorded. These informations were gathered by means of a questionnaire filled out by the parents, the child and the doctor separately during the initial visit. The primary endpoint was HbA1c at 6 months (± 1 month) after randomization.
was measured with the DCA 2000 + method (Bayer Corporation, West Haven, Conn) (normal = 4.3%-6.3%).

Feasibility and acceptance of the intervention

To evaluate the pharmacists’ involvement, different parameters were studied: frequency of refusal to participate and the motives for refusal, number of faxes transmitted to the hospital and responses to a questionnaire during the course of the study, defining the pharmacy’s characteristics (number of employees, computer equipment, satisfaction with the study). To evaluate the families’ involvement, we studied the frequency of refusal to participate and the motives for refusal, the number of faxes transmitted to the hospital and the reasons why some were not. Concerning the doctors’ compliance, we noted the number of responses given to the faxes received and the number of responses given within five days after reception.

Sample size and statistical analysis

To detect a reduction in HbA1c of 1%, with $\alpha = 0.05$, $\beta = 0.05$ and SD = 1.5, 98 children had to be included. Analyses were done using the SAS System version 8.2 (SAS Institute Inc., Cary, NC, USA). The normal distribution of the quantitative variables was tested with the Shapiro-Wilk test. Differences between groups were analyzed with parametric (t-tests) or non-parametric tests (Wilcoxon) for quantitative variables, and with chi-square tests or Fischer exact tests for qualitative variables. To compare HbA1c levels at the beginning and end of the study, paired Student t-tests were performed.

Results

One hundred children and adolescents were included in the study (figure 1). Sixteen families (11.8%) refused to participate; among them three refused to change glucometers in order to participate in the study.

Patients’ characteristics

At inclusion, the two groups were comparable with respect to age, sex distribution, HbA1c level, number of annual visits, frequency of SBGM, type of insulin therapy program (table I).

Other socio-demographic characteristics did not differ between groups: 72% of the parents were married or living together, 57% of the families were from Europe and 41% from North Africa, 65% of the children were in normal schooling (35% in late), 25% of the parents had primary level, 34% GCSE level, 20% A level level and 21% graduate level education. Patients who refused to participate had lower HbA1c levels than the participants of the study ($8.6 \pm 0.5\%$ versus $9.2 \pm 1.1\%$, $P = 0.02$), but did not differ from them in the other variables.

Pharmacists’ characteristics

Ninety-nine pharmacists were ready to participate. Six refused, two of whom, at the second request, because they felt it would be too time consuming. Finally, 12 did not participate because the children were excluded (HbA1c <8%). Therefore 87 pharmacists were included in the study: 44 ensured “usual follow-up” without intervention (two of whom had two children in this group), 39 ensured “reinforced follow-up” (three of whom had two children in this group) and four pharmacies had children in both groups, one of whom had two children from the RFG and one in the UFG (figure 1). The characteristics of pharmacies for the UFG did not differ from those for the RFG. Among the children who usually went to the six pharmacies who refused to participate, three also went to an other pharmacy that agreed to participate in the study and two installed the

![Diagram of the study design.](image)
Installation of the software and data transmission

The software was installed without difficulty in 26 pharmacies in the RFG (60.4%). It was impossible to install it in ten pharmacies (22.7%) because none of their computers had Windows OS. One pharmacy could not print the results and two others did not succeed in downloading the data from the glucometer. Another was already equipped with different software and had a client whose glucometer corresponded; the data were transmitted to the hospital using different software. Two pharmacies were not equipped because the corresponding children had stopped using the study’s glucometer before installation of the software, and one for unknown reasons.

Faced with the impossibility of making the software work in some pharmacies, we decided to install the software in their patient’s homes whenever possible. These patients faxed their results from home or from the pharmacy. This was the case for nine children. Five others did not have a computer. One patient’s glycaemic data could not be downloaded with WinGlucofacts Professional. Two children were not equipped with the software for technical reasons. So eight children did not have the opportunity to use the software, neither in their local pharmacy nor at home. Four children did not use their study glucometers, and five did not bring their glucometers to their pharmacy. For these reasons, seventeen children sent no fax at all.

Hospital physicians received at least one glyemic record from 33 children in the RFG (66%): the data from 23 of them was processed using WinGlucofacts Professional 1.1 at their local pharmacy, nine children’s data using the same software at home and one using different software at the pharmacy.

The hospital should have received 550 faxes from the 50 children in the RFG: 406 from pharmacists and 144 from families. Only 167 faxes (30.4%) were actually received, 135 (33.3%) from pharmacists and 32 (22.2%) from families. If we only consider those 33 children who sent at least one fax, we noted that out of 366 expected faxes, only 167 were received (45.6%). 135 (50.8%) of the 266 faxes expected from pharmacies were received. Only 32 (32%) faxes out of the 100 expected from families’ homes were received. Some factors explain the failure to send faxes: the study’s period included the summer vacation, and the software was sometimes tardily installed, which account for 20% and 16.6% of lacking faxes respectively.

Diabetologists’ replies

Physicians replied to at least 113 (67.7%) faxes, 81 (71.7%) of which were within five days after reception. The percentage of responses given to faxes was maximal (81.3%) at the third month of the study, and then decreased regularly to 50% by the last month.

HbA1c at 6 months

Out of the 100 children included in the study, only 71 went to a doctor’s appointment at 6 ± 1 months: 36 in the RFG and 35 in the UFG. The 29 others came earlier or later and could not be analyzed for this reason, but their characteristics did not differ from those of the 71 children analyzed. There was no significant difference between the two groups’ 6-month HbA1c levels (RFG 9.12 ± 1.46 vs. UFG 9.27 ± 1.20, P = 0.41). Nor were there any significant within-group differences between initiation and completion of the study: the average difference in HbA1c levels was -0.10 ± 1.10 in the RFG vs. 0.10 ± 0.95 in UFG (P = 0.59 and P = 0.58 respectively).

Table I

Characteristics of the children included.

<table>
<thead>
<tr>
<th></th>
<th>Usual Follow-up (n = 50)</th>
<th>Reinforced Follow-up (n = 50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex n (%)</td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>Male</td>
<td>32 (64%)</td>
<td>29 (58%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>18 (36%)</td>
<td>21 (42%)</td>
<td></td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>13.5 ± 2.5</td>
<td>13.2 ± 2.7</td>
<td>0.45</td>
</tr>
<tr>
<td>HbA1c (mean ± SD)</td>
<td>9.2 ± 0.9</td>
<td>9.3 ± 1.3</td>
<td>0.96</td>
</tr>
<tr>
<td>Duration of diabetes</td>
<td>6.1 ± 3.2</td>
<td>6.3 ± 3.4</td>
<td>0.71</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin dose per kg</td>
<td>1.0 ± 0.2</td>
<td>1.0 ± 0.3</td>
<td>0.49</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Number of visits to Debrousse</td>
<td></td>
<td></td>
<td>0.76</td>
</tr>
<tr>
<td>Hospital n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 2/yr</td>
<td>19 (38%)</td>
<td>22 (44%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 2 and ≤ 4/yr</td>
<td>15 (30%)</td>
<td>12 (24%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 4/yr</td>
<td>9 (18%)</td>
<td>9 (18%)</td>
<td></td>
</tr>
<tr>
<td>unknown</td>
<td>7 (14%)</td>
<td>7 (14%)</td>
<td></td>
</tr>
<tr>
<td>Number of SBGM/day n (%)</td>
<td></td>
<td></td>
<td>0.88</td>
</tr>
<tr>
<td>≤ 2</td>
<td>17 (34%)</td>
<td>15 (30%)</td>
<td></td>
</tr>
<tr>
<td>2 to 3</td>
<td>15 (30%)</td>
<td>17 (34%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 3</td>
<td>18 (36%)</td>
<td>18 (36%)</td>
<td></td>
</tr>
<tr>
<td>Insulin therapy program n (%)</td>
<td></td>
<td></td>
<td>0.41</td>
</tr>
<tr>
<td>Basal-bolus*</td>
<td>16 (32%)</td>
<td>20 (40%)</td>
<td></td>
</tr>
<tr>
<td>Classic</td>
<td>34 (68%)</td>
<td>30 (60%)</td>
<td></td>
</tr>
</tbody>
</table>

SBGM: self blood glucose monitoring.
*including patients with pump: 2 in UFG and 3 in RFG.
When comparing HbA1c levels in relation to compliance with the intervention, the difference in average HbA1c levels between the groups was not significant at inclusion (P = 0.51), but became significant at six months (P = 0.02) (table II). The average difference in HbA1c levels between the initiation and the completion of the study was not statistically significant in either of the groups. Furthermore, HbA1c of children with home installed software didn’t differ between initiation and completion of the study (8.83 ± 0.54 at inclusion versus 8.87 ± 0.88 at 6 months).

Number of SBGM per day did not differ between groups at the end of the study (P = 0.53).

**Conclusions**

In this randomized trial we found that our intervention had little impact on glycaemic control. There is a trend towards better glycaemic control in RFG opposed to a trend towards lesser glycaemic control in UFG, but we failed to demonstrate a significant difference. When analyzing results between subgroups, we noted that the more faxes children sent, the better their HbA1c levels were at six months. However, within-group differences were not significant. The main reason for this failure was that we did not have optimum participation and setup for the intervention, in spite of initial acceptance of our study by families and pharmacists as there was a low refusal rate. The first problem encountered was installing the software in the pharmacies. We got around this obstacle by installing it in the homes of some patients, who were then deprived of the closer contact with their pharmacist. However, even when the software was correctly installed and transmission of the results was technically possible, we counted only 45.6% of the expected faxes coming to the hospital. In 36.6% of cases, failure was due to tardy installation of the software or to families’ or the pharmacist’s absence for summer vacation; thus we could reasonably suppose that the system would operate better during the school period. In the remaining cases, children and families did not go to the pharmacies or did not fax the data for unknown reasons. This is one limit to our study: children’s, pharmacists’ and doctors’ compliance with our intervention was not high. Although we may hope that in the long-term, some of the appointments with the doctor will be replaced with telecare [19], this was not attempted during our study. Thus, replying to faxes was additional work to the usual daily hospital’s load. Another difficulty came from the fact that doctors received only the information concerning dated glycaemic data and not about insulin doses, diet or physical activity, which are fundamental factors in correctly adapting treatment and correcting possible errors. Furthermore, telecare implies changes in patients’ and doctors' habits, and 6 months may be too short to judge the real impact of the study.

Our results support published data concerning diabetes and telecare. A meta-analysis of this subject concluded that glycaemic control did not differ between telecare and control groups [12]. Few studies are still available in pediatrics [17-19]. Marrero also studied the impact of transmitting glycaemic values every two weeks with a modem and having medical feedback in relation to usual follow-up among 106 randomized children [12]. The difference in HbA1c levels between the two groups was not significant after six and twelve months, with a slight decrease in both groups. Chase compared classic follow-up and transmission by modem of glycaemic values every two weeks with response by telephone from a healthcare professional (a nurse in 94% of cases) among 70 adolescents [19]. The HbA1c of the intervention group went from 8.9 ± 1.1 to 8.6 ± 1.2% at 6 months, while that of the control group went from 9.0 ± 1.2 to 8.6 ± 1.7% (P = 0.96). Only one randomized controlled study showed a significant difference in HbA1c levels between the intervention group and the control group at the end of the study [12]. This intervention also consisted of transmission of glycaemic values by modem every two weeks with feedback from a nurse who was supervised by an endocrinologist. Only 31 patients with inadequate glycaemic control were included and followed for six months. Both groups improved, with HbA1c levels decreasing from 9.1% to 7.8% in the intervention group, and from 8.8% to 8.2% in the control group (P = 0.03). Perhaps the explanation for difference with the other studies is in patient recruitment: 115 patients refused to participate, which allows us to presume the existence of a selection bias: those who accepted were probably the most motivated (to participate they had to make four SBGMs per day).

**Table II**

Comparison between HbA1c levels at initiation and completion of the study, in relation to number of faxes received (concerning the children who went to a doctor’s appointment at 6 ± 1 months).

<table>
<thead>
<tr>
<th></th>
<th>HbA1c at inclusion</th>
<th>HbA1c at 6 months</th>
<th>Average of the differences in HbA1c*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“Usual follow-up”</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 35)</td>
<td>9.17 ± 0.97</td>
<td>9.27 ± 1.20</td>
<td>0.10 ± 1.05</td>
</tr>
<tr>
<td><strong>“Reinforced follow-up”</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all (n = 36)</td>
<td>9.22 ± 1.18</td>
<td>9.12 ± 1.46</td>
<td>-0.10 ± 1.10</td>
</tr>
<tr>
<td>≤ 2 faxes transmitted (n = 17)</td>
<td>9.57 ± 1.50</td>
<td>9.77 ± 1.70</td>
<td>0.20 ± 1.19</td>
</tr>
<tr>
<td>3 to 6 faxes transmitted (n = 11)</td>
<td>9.02 ± 0.75</td>
<td>8.49 ± 0.98</td>
<td>-0.53 ± 1.06</td>
</tr>
<tr>
<td>&gt; 6 faxes transmitted (n = 8)</td>
<td>8.74 ± 0.59</td>
<td>8.58 ± 0.81</td>
<td>-0.15 ± 0.82</td>
</tr>
</tbody>
</table>

*Between initiation and completion of the study. Results expressed in mean ± standard deviation.
A limitation of most of those studies (as in our study) is a follow-up period limited to 6 months, which is short to observe a significant improvement in glycemic control.

The originality of our study is its similarity to telecare, with the advantage of direct contact with the local pharmacist. He is the healthcare provider patients see the most because his position makes him most accessible. Paradoxically, local pharmacists have been an underused resource. Their efficiency in monitoring diverse chronic illnesses has been studied [21,22]. Making use of pharmacists’ competencies in managing diabetes has been cited by several authors [23-26]. Hirsch notes that current systems of diabetes care are not optimal, and suggests resorting to other healthcare professionals, particularly to pharmacists [26]. Campbell describes pharmacists’ possible roles in this domain [23] and the American Society of Health-System Pharmacists confirms they could indeed advise diabetic patients [25].

Our program calls for several improvements.

1. Simplifying transmission of the data. We should enable children to keep their habitual glucometer. It would be ideal to have universal software which could easily download readings from all glucometers, and then easily transmit the results. This software would have to be compatible with any computer. We are beginning to find such software on the market.

2. Providing doctors with richer data, including meal-times, insulin doses injected, physical activity and any other recurrent events.

3. Concentrating on installing software on pharmacists’ computers. 1) because the average number of faxes sent per child was greater when the pharmacist had the software, even though the difference was not statistically significant, and 2) because the local pharmacist could play an important role in monitoring diabetic children.

4. Considering the financial aspects: doctors were not paid for their replies, and pharmacists were not paid for the visits from the children. In fact this extra workload, which would increase if the system became more widespread and if there were greater participation from pharmacists, could justify charging fees [19,23].

5. Creating and developing a formal pharmacist-hospital network, with pharmacist training for those who wish to learn more about diabetes in children. Pharmacists could then be more involved in monitoring these children.

Because children with diabetes are particularly exposed to poor glycaemic control during adolescence, healthcare providers have to make joined efforts in order to improve self-management. Even if we failed to demonstrate that our intervention was better than usual care to improve glycaemic control in children and adolescents with inadequate glycaemic control, our study has opened new paths for research which we are going to explore. Local pharmacists and telecare can help in monitoring diabetes in children, and this operation must be optimized.

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