Telemedicine and diabetes: Achievements and prospects

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Abstract

Health authorities currently have high expectations for telemedicine (TM), as it addresses several major challenges: to improve access to healthcare (especially for patients in underserved or remote areas); to overcome the scarcity of specialists faced with epidemic disease; and to reduce the costs of healthcare while improving quality. The aims of TM in the field of diabetes differ according to the type of diabetes. In type 1 diabetes (T1DM) associated with complex insulin regimens, the goal of TM is to help patients achieve better control of their blood glucose levels through accurate adjustment of insulin doses. In type 2 diabetes (T2DM), while therapeutic adjustments may be necessary, improvement in blood glucose control is based primarily on behavioural changes (reduced calorie and carbohydrate intakes, increased physical activity). Many TM studies focusing on management of blood glucose levels have been published, but most failed to demonstrate any superiority of TM vs traditional care. While previously published meta-analyses have shown a slight advantage at best for TM, these meta-analyses included a mix of studies of varying durations and different populations (both T1DM and T2DM patients, adults and children), and tested systems of inconsistent quality. Studies published to date on TM suggest two currently promising approaches. First, handheld communicating devices, such as smartphones, loaded with software to apply physicians’ prescriptions, have been shown to improve glycaemic control. These systems provide immediate assistance to the patient (such as insulin-dose calculation and food choice optimization at meals), and all data stored in the smartphone can be transmitted to authorized caregivers, enabling remote monitoring and even teleconsultation. These systems, initially developed for T1DM, appear to offer many possibilities for T2DM, too. Second, systems combining an interactive Internet system (or a mobile phone coupled to a remote server) with a system of communication between the healthcare provider and the patient by e-mail, texting or phone calls have also shown certain benefits for glycaemic control. These systems, primarily aimed at T2DM patients, generally provide motivational support as well. Although the individual benefits of these systems for glycaemic control are fewer than with smartphones, their widespread use should be of particular value for overcoming the relative shortage of doctors and reducing the health costs associated with a disease of such epidemic proportions.

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Keywords: Telemedicine; Type 1 diabetes mellitus; Type 2 diabetes mellitus; Medical device; Smartphone; Education; Review

Résumé

Télémédecine et diabète : état des lieux et perspectives.

Les autorités de santé mettent actuellement beaucoup d’espoir dans la télémédecine (TM) qui devrait répondre à plusieurs défis majeurs : améliorer l’accès aux soins (en particulier pour les patients dans les zones mal desservies ou isolées), pallier à la pénurie de médecins spécialistes face à une maladie qui évolue sur un mode épidémique, et réduire les dépenses de soins tout en améliorant la qualité. Les objectifs de la TM dans le domaine du diabète diffèrent selon le type de diabète en question. Dans le diabète de type 1 (DT1) dans lequel les schémas insulinsiques sont souvent complexes, l’objectif de la TM est d’aider les patients à mieux contrôler leur glycémie par un ajustement précis de leurs doses d’insuline. Dans le diabète de type 2, si des ajustements thérapeutiques peuvent être nécessaires, l’amélioration du contrôle glycémique sera fondée avant tout sur les modifications comportementales (réduction de l’apport en calories et en glucides, augmentation de l’activité physique). De nombreuses expériences de télémédecine centrées sur le contrôle glycémique ont déjà été publiées, mais la plupart ne sont pas parvenues à montrer une supériorité de la TM par rapport à une prise en charge traditionnelle. Quant aux méta-analyses publiées précédemment, si celles-ci ont montré tout au plus un léger avantage en faveur de la TM, elles ont mélangé des études de durée variable, conduites dans des populations différentes (patients diabétiques de type 1 et de type 2, adultes / enfants), et elles ont testé des systèmes de qualité inégale. Deux approches semblent toutefois...
prometteuses : 1) : les appareils communicant de poche, de type smartphone munis d’un logiciel appliquant la prescription du médecin ont permis d’améliorer le contrôle glycémique. Ces systèmes peuvent fournir une aide immédiate au patient (calcul de la dose d’insuline, optimisation des choix alimentaires aux repas, etc.); toutes les données stockées dans le smartphone sont ensuite transmises au soignant autorisé, ce dernier pouvant alors assurer une télésurveillance des données du patient et si besoin des télécotations. Ces systèmes initialement développés dans le DT1 semblent pouvoir ouvrir également de larges perspective dans le DT2 ; 2) : Les systèmes qui combinent un site web interactif (ou un téléphone mobile couplé à un serveur à distance) et un système de communication entre le soignant et le patient par e-mail, sms ou appel téléphonique ont également montré certains bénéfices en termes de contrôle glycémique. Ces systèmes, dédiés avant tout aux patients DT2, assurent également un soutien motivationnel. Même si les bénéfices individuels obtenus avec ces systèmes sont moindres qu’avec les smartphones en termes de contrôle glycémique, leur utilisation à large échelle devrait s’avérer particulièrement intéressante pour pallier à la pénurie relative de médecins et pour réduire les coûts de santé en rapport avec une maladie dont l’expansion est épidémique.

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Mots clés : Télémédecine ; Diabète de type ; Diabète de type 2 ; Dispositif médical ; Smartphone ; Éducation ; Revue générale

Health authorities currently have high expectations of telemedicine (TM), as it could partly solve the problems of shortages of doctors, both specialists and generalists, and the problem of the lack of access of many patients to healthcare centres in the face of limited budgetary resources. It should also successfully improve the quality of care, thanks to the sophisticated electronic tools now available. With diabetes, it is necessary to distinguish between type 1 diabetes (T1DM) or type 2 diabetes (T2DM) treated with multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) and T2DM treated with dietary measures or oral antidiabetic agents (OADs), possibly along with a single injection of basal insulin.

In T1DM, considerable progress has been made with the widespread use of physiological therapeutic basal–bolus regimens with MDI or CSII and educational programmes for functional insulin therapy. However, despite such tools, the results of large-scale clinical studies in T1DM continue to be unsatisfactory: the average HbA1c level was 8.4% at 6 months in the dose adjustment for normal eating (DAFNE) study [1], and 7.9% 6 years after the start of the Treatment and Teaching Program for Intensification of Insulin Therapy (ITTP) involving 538 patients from the German cohort [2]. The average HbA1c level in the T1DM subgroup of diabetic patients in the national sample representative of the French population in the Échantillon National Témoin Réprésentatif des Personnes Diabétiques (ENTRED) study was also 7.9% [3]. Thus, many T1DM patients have an HbA1c value persistently higher than 8%, despite proper follow-up, good education, and compliance with the currently recommended regimen of basal and prandial insulin, preferably with analogues administered through MDI or CSII, with prandial insulin doses titrated according to the carbohydrate content of meals, preprandial blood glucose levels and degree of physical activity, if any [4].

Leaving aside the relatively rare cases of authentic instability, these poor results may be explained at least in part by the difficulties that patients have in coping with the constraints of the disease. One such major constraint on patients is the need to properly apply complex rules for calculation of their prandial insulin dose; another is the need to make time for regular trips to a specialist, as these patients, who are mostly young people, are working and reluctant to give up a work day for their medical visit. An additional difficulty is that of keeping a paper diary. This traditional data-exchange tool that informs doctors of their patients’ daily results is poorly accepted and, so, is often not completed by patients or may indeed be simply missing. In this all-too-common situation, the doctor has little reliable information on which to base any advice regarding an individual patient’s insulin dose adjustments. Undoubtedly, TM could be of great help in overcoming these difficulties.

In T2DM, the problems are rather different; the prevalence of T2DM is rapidly increasing, whereas the number of doctors, whether general practitioners (GPs) or diabetologists, is not following the same trend. In France, 90% of T2DM patients are followed-up by their GPs. The scarcity of healthcare in both geographical (areas with sparse medical-care facilities) and temporal (longer periods of time between visits) terms has necessarily led health authorities to turn to TM, which quickly emerged as a potential solution to the problems of caregiver scarcity and of remoteness of patients from healthcare centres.

In addition, T2DM requires not only treatment adjustments, but also behavioural changes (control of calorie intake, especially carbohydrate/lipid intakes, and regular physical activity) that are best established through regular contact with the care team. Such a team should be broad-based and should include not only the doctor, but also other trained paramedical caregivers. TM could be used here to strengthen the national health system and to optimize the available resources, with traditional consultations being replaced by shorter, but more frequent, TM consultations focusing on adjustment of both behaviour and diabetic treatment.

1. Studies of telemedicine in type 1 diabetes

Generally speaking, three types of methods have been tested to improve the management of patients with T1DM:

1) telephone consultations;
2) systems focusing on the transfer of blood glucose values to a care provider, with retrospective feedback and;
3) systems using personal digital assistants (PDAs) that combine automatic immediate feedback and delayed feedback through telephone consultations.

1.1. Telephone consultations

These may be seen as the forerunner of TM, with the founding study in the field of diabetes by Miller and Goldstein [5].
More recently, in Vancouver [6], regular telephone contacts were proposed for poorly controlled insulin-treated diabetic patients (HbA1c > 8.5%). Forty-six patients (52% with T1DM) were recruited and randomized into two groups. In the intervention group (IG), 23 patients had 15 minutes phone contacts three times a week. These phone consultations were performed by a diabetes nurse educator and focused on adjustment of insulin therapy. After 6 months, the mean HbA1c in the IG had decreased from 9.6% to 7.8% while, in the standard-care group, it had decreased from 9.4% to only 8.9%. The difference between the two groups was clinically relevant and statistically significant (P < 0.01); the system was thus considered effective, as would any system allowing close management of diabetic patients. In the Diabetes Control and Complications Trial (DCCT), patients randomized to intensive therapy (n = 711), visiting the study centre every month and having regular phone contact with their study centre, exhibited significant improvement in HbA1c levels compared with the control group (CG: n = 730; HbA1c 7% vs 9%, respectively; P < 0.001) [7]. However, such follow-up proved to be expensive. In the Vancouver study, the nurse spent 17.25 h/week calling patients, the equivalent of a part-time post to cover 23 patients, but most centres currently lack such facilities.

1.2. Teletransmission of glycaemic data to a care provider with feedback

Numerous trials have been published using different systems to transmit blood glucose data. These may be placed broadly into three categories. The first consists of simple teletransmission of blood glucose values from a glucose meter with a memory function. Several studies using such systems have been published, with the majority being conducted by firms that market blood glucose meters. At the Mayo Clinic [8], 31 patients receiving intensive insulin therapy with poorly controlled T1DM (HbA1c > 7.8%) sent their data to the care team regularly over a 6-month period via an ACCU-CHEK Acculink modem. Only half of the patients received telephone “feedback” from a nurse within 24 hours of each transmission; in these patients, HbA1c levels decreased significantly from 9.8% to 7.8% (P = 0.03) whereas, in the CG, the reduction was less (from 8.8% to 8.2%) and was at least partly related to a possible study effect. In another study, 40 patients with T1DM and poor glycaemic control (HbA1c > 8%) transmitted their data regularly from an ACCU-CHEK Spirit glucose meter via the microphone of their telephones (GlucoBeep system) [9]. Those randomized to the IG (n = 20) had nine phone consultations in addition to the three standard face-to-face consultations, whereas the other 20 patients in the CG had 12 face-to-face consultations. At 6 months, the result was similar in both groups (HbA1c 7.6%), but the costs differed considerably between the groups. Thus, while the transmission of blood glucose data facilitates the work of care providers, it does not normalize glycaemic control. In fact, the main noteworthy point is the way these data were used and that, ultimately, the consultation focused on adjustment of insulin treatment regardless of the type of consultation (face-to-face or via telephone).

Nevertheless, more sophisticated systems have been developed. In some cases, patients were provided with desktop computers, allowing them to enter and transmit data other than blood glucose values. With the Telematic Management of Insulin-Dependent Diabetes Mellitus (T-IDDM) project [10], patients were able to transmit not only blood glucose values from a glucose meter, but also other information, such as insulin dose, diet and presence of ketones, to a desktop computer. All these data were then sent to a physician, who could respond to patients via the Internet. However, the preliminary results showed no significant changes in HbA1c. Also, while doctors considered the system useful, the feedback from patients was considerably more mixed.

Several systems involve Web-based TM focused on data transmission. With the DIABTel system, patients can load blood glucose values directly from their glucose meter to a palmtop device, and from that device to their physician’s computer, with feedback provided by text messages. In a 6-month crossover pilot study in 10 T1DM patients, use of the DIABTel system with once-weekly data transmission led to a trend towards a reduction in HbA1c from 8.4% to 7.9% at 6 months during the intervention phase vs 8.10% to 8.15% during the control phase (P = 0.053), although more therapeutic adaptations were performed [11].

The DIABTel system was also tested in a crossover pilot study in 10 patients with T1DM treated by CSII. Although the system was able to transmit data from the pump directly to the palmtop device, the results for HbA1c values were disappointing; the mean HbA1c value was 8.0 ± 0.6% during the active-intervention phase vs 7.8 ± 0.6% during the control phase (P = 0.073). The short study duration and the paucity of feedback to patients (via text messages) may at least partly explain the lack of significant clinical results [12].

In another study, patients using a pump were asked to submit their blood glucose values weekly via a PDA phone loaded with GlucoNet software. Patients randomized to the IG received information back every week via a text message from an experienced diabetologist to optimize adjustment of their insulin dose. However, despite this feedback, HbA1c levels at 6 months did not differ from those in the CG (teletransmission without feedback), although quality-of-life indices did improve [13].

Finally, the Think Positive Diabetes (T+ diabetes) system combines the teletransmission of blood glucose values and telephone feedback from a nurse with a two-stage transmission of blood glucose data: 1) from a glucose meter to a mobile phone with a Bluetooth base, adaptable to the OneTouch glucose meter; and then 2) from the phone to the care provider via general packet radio service (GPRS) and a secure website enabling the caregiver to examine the patient’s data. Feedback is twofold: first, an analysis of the blood glucose values is automatically returned to the patient’s mobile phone screen in the form of histograms and curves; and second, the nurse calls the patient to discuss the blood glucose results. This system was tested in the UK [14] in 80 patients aged 18–60 years with poorly controlled T1DM (HbA1c 8–11%). All participants used the T+ diabetes system. After randomization, half the patients received feedback from a nurse via phone consultations plus graphic analyses (the IG), while the other half (the CG) received only a graphic
reminder of their glycaemic values over the previous 24 h. After 9 months, in the IG, which received graphic analyses and phone calls from a nurse (one 7-minutes consultation every 2.5 weeks), the mean HbA1c had decreased from 9.2% to 8.6%, which was similar to that in the CG (from 9.3% to 8.9%). Thus, in T1DM patients, a graphic depiction of glycaemic results, however perfect, is apparently of little use. The study also showed that even a qualified caregiver would have little effect with access only to blood glucose values and not to the other relevant information, especially insulin and food data, and to accurate adaptation algorithms, necessary to properly advise patients on treatment adjustment.

Overall, the results of the transmission of blood glucose values with retrospective feedback have been disappointing, regardless of the technological improvements introduced. The main findings of these studies are summarized in Table 1. One meta-analysis [8] included seven randomized trials of T1DM adults, with all patients transmitting their blood glucose values (by phone or by Internet) either alone or together with information on insulin doses, diet and physical activity, and with feedback generally provided by phone or e-mail. This meta-analysis showed statistically significant, but limited (0.4%), improvement in HbA1c in the IGs compared with the CGs, and the difference was obtained only after the exclusion of a study conducted in children. These systems generally transmitted data upward from patients, sending a mass of blood glucose values, but did not incorporate truly effective feedback from the caregiver other than an increase in weekly telephone contact, which is neither feasible nor acceptable in routine practice in the long term.

1.2.1. Active electronic diaries on smartphone

More elaborate and attractive systems can provide patients with immediate help in determining their insulin dose, while allowing automatic teletransmission of data (not only blood glucose values, but also insulin doses, dietary data and details of physical activity) in a format readily interpretable by the caregiver, equivalent to the paper diaries in general use. A smartphone coupled with a secure website can achieve this double function: such a tool at the disposal of patients can incorporate an active glycaemic diary proposing an insulin dose, particularly at mealtimes, calculated on the basis of algorithms prescribed by the physician. Such a system is probably more attractive than the traditional paper diary for younger (and certain older) patients with diabetes. All the data are automatically formatted and can be read on the caregiver’s screen, thereby allowing remote monitoring by caregivers and, where necessary, short teleconsultations, either planned or decided by the doctor, during which specific advice focused on diabetes treatment may be given along with the personal contact and support. All data can also be stored in a database readily accessible for statistical analysis. The system itself has no autonomy or responsibility, but merely puts the medical prescription into an electronic format, with the latter remaining the sole responsibility of the physician.

A number of such systems are currently being developed (Table 2). The “Diabetes Interactive Diary” (DID) [15] is a software package loaded onto a mobile phone that enables real-time recording of blood glucose values and doses of insulin injections (diabetes diary). This system can help patients to quantify their carbohydrate intake during meals simply by selecting the specific food and the amount consumed from a set of pictures. It can also help patients determine the most appropriate bolus of insulin based on the carbohydrate-to-insulin ratio and insulin-sensitivity factor previously determined by the healthcare professional (bolus calculator). The system is also able to take into account other information, such as the amount of physical activity requiring adjustment of either insulin dose or diet. In addition, an algorithm has been added for adjustment of basal insulin dose. Data stored in the mobile can be periodically sent as short messages and reviewed by the physician on his personal computer, and any new therapeutic and behavioural prescriptions can be sent from the computer to the mobile phone.

A 3-month pilot study using the DID was conducted in 50 T1DM patients who were fairly well controlled (mean HbA1c 7.2%) and following a basal–bolus regimen. At the end of the study, diabetes remained well controlled, and nine of the 10 patients wished to continue with the system even at their own personal expense. The function considered most useful was carbohydrate-counting, followed by insulin-bolus calculation. However, although communication with the doctor by texting was considered extremely effective or very effective by 85.5% of the patients, it is likely that such a relatively restricted mode of communication contributed to the low and barely positive results of evaluation studies of DID.

An international 6-month open-label, multicentre, parallel-group study was conducted in 130 T1DM patients to validate the value of the DID system. The patients were randomized into IG and CG. However, the results were disappointing. Both groups saw a 0.5% reduction in HbA1c (from 8.2% to 7.8% in the IG and from 8.4% to 7.9% in the CG), with no significant differences in between-group analyses. Also, at the very most, the time devoted to carbohydrate-counting education in the IG was only half that of the CG (6 h vs 12 h, respectively; \( P = 0.07 \)) [16].

A confirmatory multicentre, national, randomized (1:1) parallel-group study involving 13 Italian centres and 130 patients is ongoing at present. This new study aims to compare the impact of DID education vs normal practice on metabolic control, using a previously carefully standardized DID educational intervention. The advantage of the DID system is the electronic illustrated food list: patients simply select the type and quantities of foods they intend to eat, and the device automatically calculates the corresponding amount of carbohydrates [17]. However, poor interaction with the doctor via text messages alone is one of the weaknesses of the system.

The Diabeo system was designed specifically for patients with T1DM using a basal–bolus insulin regimen. The system includes an electronic diary on a smartphone developed thanks to a partnership between French Study and Research Centre for Improvement of Diabetes Therapy (CERITD) and VOLUNTIS, an information-technology and services company (Suresnes, France). The logbook allows automatic calculation of prandial insulin doses in relation to carbohydrate intake levels and preprandial blood glucose values, and takes into account
### Table 1

Systems focusing on the telettransmission of glycemic data feedback by a care provider.

<table>
<thead>
<tr>
<th>References</th>
<th>Population</th>
<th>Methodology</th>
<th>Intervention</th>
<th>Control</th>
<th>Duration of the study</th>
<th>HbA1c at baseline</th>
<th>Metabolic results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montori et al., 2004 [8]</td>
<td>31 T1D patients on intensive insulin therapy with poorly-controlled diabetes (A1c &gt; 7.8%)</td>
<td>RCT / parallel groups</td>
<td>Modern transmission at least every 2 weeks, with telephone feedback from a nurse within 24 h of each transmission. Face-to-face consultation every 3 months</td>
<td>Modern transmission at least every 2 weeks, with feedback on demand. Face-to-face consultation every 3 months</td>
<td>6 months</td>
<td>IG: 9.1 ± 1.3% / CG: 8.8 ± 1.2%</td>
<td>IG: HbA1c decrease from 9.1 to 7.8% / CG: HbA1c decreased from 8.8 to 8.2%. Difference after adjusting for HbA1c at baseline: P = 0.03</td>
</tr>
<tr>
<td>Jansa et al., 2006 [9]</td>
<td>40 T1D patients with poor metabolic control; at least 3 doses of insulin/day, A1c ≥ 8%</td>
<td>RCT / parallel groups</td>
<td>Glucobeep system: modern transmission twice a week, with clinician feedback; IG: 9 Phone consultations + 3 face-to-face consultations</td>
<td>The conventional intensive follow-up (12 face-to-face consultations)</td>
<td>6 months (+ 6 months for the follow-up)</td>
<td>IG: 8.4 ± 1.2% / CG: 8.9 ± 1.3%</td>
<td>IG: HbA1c a 6 months 7.5% and at 12 months: 7.6% / CG: HbA1c a 6 months 7.7% and at 12 months: 7.6%, P = 0.001; no between-group difference</td>
</tr>
<tr>
<td>Gómez et al., 2002 [11]</td>
<td>10 T1D patients</td>
<td>RCT / cross-over design two parallel 6-month phases</td>
<td>DIABTEL system (modern transmission of the data from the glucometer to a palmtop and then to the physician’s computer at least once every 2 weeks. Clinician feedback in the following 24 hours (text message))</td>
<td>Use of a BG meter with memory; conventional logbook</td>
<td>12 months</td>
<td>The median value of HbA1C was 8.15 (5.9, 9.9) at the end of control phase and 7.9 (6.6, 8.9) at the end of the DIABTEL phase (P = 0.053)</td>
<td>The median value of HbA1C was 8.15 (5.9, 9.9) at the end of control phase and 7.9 (6.6, 8.9) at the end of the DIABTEL phase (P = 0.053)</td>
</tr>
<tr>
<td>Rigla et al., 2007 [12]</td>
<td>10 patients, under CSII</td>
<td>RCT / cross-over design two parallel 4-week phases</td>
<td>The DIABTEL system (modern transmission of the data of the glucometer or of the insulin pump, to a PDA and then, from the PDA to the physician’s computer). Clinician feedback in the following 24 hours (text message)</td>
<td>DIABTEL system but no clinician feedback</td>
<td>8 weeks</td>
<td>8.0 ± 0.6%</td>
<td>Active phase: HbA1C tended to decrease from 8.0 ± 0.6 to 7.78 ± 0.6, P = 0.073 whereas no changes were observed during the control phase</td>
</tr>
<tr>
<td>Benhamou et al., 2007 [13]</td>
<td>30 T1D patients, under CSII</td>
<td>RCT / cross-over design two parallel 6-month phases</td>
<td>The GlucoNet system: intensive coaching using the web and the cellular phone network for retrospective data transmission and SMS. Feedback by SMS at weekly intervals</td>
<td>The GlucoNet system with no SMS communication</td>
<td>12 months</td>
<td>8.3 ± 0.7%</td>
<td>Reduction in HbA1C from 8.3 ± 0.7 to 8.2 ± 0.6% with a –0.14% difference during the 6-month period with SMS communication. Increase in HbA1C from 8.2 ± 0.7 to 8.3 ± 0.6% i.e. by 0.12 ± 0.65% during the second 6-month period without SMS transmission (P = 0.097)</td>
</tr>
<tr>
<td>Farmer et al., 2005 [14]</td>
<td>93 T1D patients with poorly controlled diabetes (A1c: 8–11%)</td>
<td>RCT / parallel groups</td>
<td>The T+ system: transmission of BG values from the glucometer to the mobile phone and then to the care provider’s computer via bluetooth. Real-time graphical feedback. Review of the data by a nurse at least every 2 weeks. Telephone feedback from the nurse</td>
<td>The T+ system without the telephone feedback from the nurse</td>
<td>9 months</td>
<td>IG: 9.2 ± 1.1% / CG: 9.3 ± 1.5%</td>
<td>Reduction in the HbA1C value from 9.2 ± 1.1% to 8.6 ± 1.4% in the IG and from 9.3 ± 1.5% to 8.9 ± 1.4% in the CG. The difference in change in HbA1C between groups was not statistically significant (0.2% [–0.2 to 0.7], P = 0.3)</td>
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</table>

**RCT:** randomized clinical trial.
Table 2

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population</th>
<th>Methodology</th>
<th>Main validation study</th>
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<tbody>
<tr>
<td>Rossi, 2011 [16]</td>
<td>130 T1D patients</td>
<td>A 6-month open-label international multicentre parallel group study (DIABEO + Phone vs control (G))</td>
<td>Feed-back Main validation study</td>
</tr>
<tr>
<td>Charpentier, 2011 [20]</td>
<td>180 T1D patients, under basal-bolus insulin regimen</td>
<td>A 6-month open-label randomized multi-centre parallel group study (DIABEO + Phone vs control (G))</td>
<td></td>
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</tbody>
</table>

**TM system Functionalities**

- Data can be periodically sent as short messages or via glycemic diary, food exchange, bolus calculator, autoadaptation of prandial and basal insulin parameters, teletransmission of the data to the HCP can review these data on his computer
- Electronic diary, bolus and basal diabetes are recorded in the mobile phone
- Data are transmitted to a secure website via GPRS, and authorized caregivers can consult the data directly via their computer
- Telemedicine, teleconsultations aimed at the initiation or reinforcement of therapeutic follow-up

**HCP: health care provider.**

any physical activity based on the algorithms and glycaemic targets initially set by the physician (Fig. 1). The system also allows adaptation of prandial and basal insulin parameters for patients whose results regularly fall outside the target range. Finally, the system can transmit all data to a secure website via GPRS, and authorized caregivers can consult the data directly in a readable interpretable format (Fig. 2). This allows short, but regular, teleconsultations aimed at the initiation or reinforcement of therapeutic follow-up. Such consultations allow physicians to avoid exceeding their mean allocated time for each patient (approximately 30 min/patient/semester).

The first two evaluations of the Diabeo system [18,19] showed good results for blood glucose profiles, with mean post-prandial blood glucose values at each meal maintained at mean preprandial levels. Patient satisfaction appeared to be excellent, with a large majority wishing to continue using the system even at their own expense, rather than returning to a traditional passive glycaemic diary. The 6-month multicentre randomized TELEDIAB-1 study clearly showed marked metabolic improvement with the Diabeo system [20]. The study included 180 adults with T1DM, using a basal–bolus insulin regimen (for > 6 months and with CSII or MDI), who were chronically poorly controlled (HbA1c > 8% twice consecutively, initial HbA1c 9.1 ± 1.1%). These patients were randomized into the three groups that were regularly and respectively monitored by: 1) quarterly face-to-face consultations (G1 = control group); 2) the Diabeo system with quarterly face-to-face consultations (G2); and 3) the Diabeo system coupled with brief fortnightly telephone consultations (G3). Patients in G2 showed a 0.7% improvement in HbA1c (P < 0.001) at 6 months compared with the G1 controls whereas, in G3 (the Diabeo system plus teleconsultations), HbA1c fell by 0.9% (P < 0.001), with no increase in the incidence of hypoglycaemia. In the latter group, the total time spent on telephone medical consultations was similar to the time spent on face-to-face consultations in the first two groups (1.2 h), but the time “lost” by patients on their consultations was much lower in G3 and, in addition, there was no expenditure related to transport and no workdays lost. This system is now routinely available and accessible to all patients equipped with a smartphone who wish to have it. Compatibility of the system with the main industrial standards is currently being implemented, and discussions are ongoing with the French national health insurance agency regarding reimbursement levels for the system.

2. Studies of telemedicine in type 2 diabetes

Given the number of patients with T2DM, TM in these patients is primarily targeted at larger-scale studies. The three types of system previously described for T1DM are also used for T2DM. However, simpler studies designed to inform and deliver an educational message to patients at a lower cost have also been carried out.

2.1. An educational programme

In a sample population of T2DM patients (n = 56; baseline HbA1c 8.6 ± 1.8%), an educational programme comprising
Fig. 1. The Diabeo system’s main function is the automatic proposal of prandial and basal insulin: (left side of screen) calculated proposed prandial insulin dose, according to the premeal blood glucose value (182 mg/dL) and the amount of carbohydrates (carb.) in the meal (3.5 20 g carb. portions) for a patient planning to exercise; (right side of screen) proposed adjustment of basal insulin.

Fig. 2. The Diabeo system’s second main function is teletransmission: (left) the patient’s data are transmitted to a secure website on the caregiver’s screen (right).

three sessions delivered by educators (nurses and dietitians), focusing on knowledge about diabetes, its management and screening for its complications, showed similar reductions in HbA1c for those receiving either traditional individual consultations or video-conferencing; mean HbA1c was $7.8 \pm 1.5\%$ in both groups immediately after the educational programme and remained at the same level 3 months after the final session [21].

Thus, for general educational messages, TM may be as effective as traditional management.

2.2. Telephone consultations

Early studies [22,23] showed that remote follow-up of diabetic patients involving phone calls by a nurse improved
glycaemic control. However, such programmes are expensive and time-consuming. Interventions in large populations have necessarily led to attempts to focus the activity of nurses to those patients identified as the most distressed. In a randomized study by Piette et al. [24] involving 248 veterans with diabetes, the IG (n = 124) received a series of automated telephone assessments to identify the most distressed patients likely to benefit the most from targeted intervention by a nurse (telephone monitoring). The average length of contact with the nurse was 6 min/month/patient. The nurse was not in the clinic and had no direct physical contact with patients or access to their medical records. The intervention focused on blood glucose results and also provided general educational information. The CG (n = 124) was followed-up as usual (traditional care). HbA1c values at baseline were similar between the two groups (IG vs CG: 8.8 ± 1.8% vs 8.6 ± 1.8%), and the 12-month assessment also showed no differences (ΔA1c [IG vs CG] = –0.3%; P = 0.1). The number of IG patients achieving an HbA1c level < 7% was twice that of the CG patients (17% vs 8%, respectively; P = 0.04). Several explanations may be proposed for the disappointing results in terms of HbA1c, including the nurses’ lack of knowledge of the patients’ history, the brief contact with patients, the general nature of the intervention and the inefficient method of identifying the most distressed patients.

In France, there has been renewed interest in the system of telephone consultations (the Sophia programme) launched in early 2008 by the French health insurance fund for employees (Caisse nationale d’assurance maladie des travailleurs salariés [CNAMTS]). The programme is based on dealing with patients according to their individual risk level, as assessed by the severity of their diabetes complications. Patients considered at low risk were sent information about their disease. Patients at intermediate or high risk, in whom the aim is to reduce the severity of complications and prevent the occurrence of new complications, were offered telephone calls by trained nurses. The evaluation results of the pilot programme, which involved a target population of 136,000 diabetic patients in 10 metropolitan departments, are not yet known, but the programme has been extended to other departments in France.

Telephone interventions using a call centre manned by non-medical staff have also been developed to limit healthcare costs. One such study was conducted in Salford (Manchester, UK) using a call centre to monitor a large population of T2DM patients with limited resources [25]. The call centre employed two part-time professionals with an “excellent voice” that was “calm, reassuring and professional” (according to the published report) who had been trained for 3 months in advance to screen for educational gaps in diabetic patients, and to assess their desire to change their behaviour, their compliance to treatment and their self-monitoring of blood glucose (SMBG). The intervention was conducted under the supervision of a diabetes educator. Of 2894 T2DM patients (80% of all identified patients in Salford), 508 agreed to participate in the study and were randomized into two groups: 176 patients were included in the “usual care” (CG) and 332 in the IG. The latter patients were contacted by the call centre for a 20-minute phone consultation, according to their baseline HbA1c, either every 3 months (baseline HbA1c < 7%), every 7 weeks (baseline HbA1c 7.1–9%) or every month (baseline HbA1c > 9%). Overall, after 12 months and more than 4000 telephone consultations, a 0.31% reduction in HbA1c was observed in the IG compared with the CG (95% CI: 0.11–0.52; P = 0.003). More interesting was the differential analysis based on glycaemic control at baseline: patients who were initially well controlled (HbA1c < 7%) remained well controlled whereas, for patients with an HbA1c of 7–9%, this significantly improved in the IG compared with the CG (–0.49%; P < 0.001). For patients with poorly controlled diabetes (HbA1c > 9%), the difference was modest and not significant (–0.37%; P = 0.33).

Another study conducted in a low-income insured minority population with T2DM and poor glycaemic control (baseline HbA1c 8.6%) showed modest results favouring a telephone intervention (one phone call at 4-to-6-week intervals from their health educator under the supervision of a diabetes nurse educator) vs a printed intervention, with a 0.40% difference in HbA1c between the two groups at 1 year [26]. There was also an improvement in medication adherence with the telephone intervention for patients treated with OADs, but not for those using insulin therapy (24% of participants).

Taken altogether, these results suggest that a simple and inexpensive intervention by non-clinical health educators can be useful in cases of gaps in basic education or omissions, or where there is a need to rekindle patients’ motivation. However, it is also clear that this approach is not sufficient for those using complex treatments or with greater barriers to treatment, such as attitudes of denial or rejection usually associated with severe blood glucose imbalance.

2.3. Teletransmission of glycaemic data to a care provider with feedback

As with T1DM, findings have been published from numerous trials using systems focused on data transfer. In addition to blood glucose values, these systems allow patients to transmit a variety of useful data for the management of diabetes and of potential associated risk factors.

2.3.1. Internet-based glucose-control systems

Widespread Internet access makes this medium a viable and logical way of delivering healthcare interventions, and some clinical trials have attempted to use the Internet as a novel healthcare delivery tool. In Korea [27], 110 patients with T2DM were randomized into two groups, both of which received the same initial recommendation: 1–3 capillary blood glucose readings per day on at least 3 days per week. In the IG, patients were asked to enter their blood glucose values on the website before and after meals, and to also provide information on their treatment (insulin, OAD type and dose); they could also record any changes in weight or blood pressure and ask the healthcare team questions via the Internet. These data were viewed by the medical team (three diabetologists, a dietitian and a nurse), which then advised patients via the Internet in accordance with the Korean national recommendations. Patients in the CG had two to three traditional consultations during the 12-week study. HbA1c decreased from 7.6% to 6.9% (Δ –0.5%; P < 0.001) in the IG,
but increased from 7.2% to 7.6%, ($\Delta + 0.3\%$; $P < 0.001$) in the CG, with a significant difference at 12 weeks between the two groups ($P < 0.001$). The average number of questions per patient (14 in the IG throughout the study) underscores the high interactivity of the system. The metabolic results were also maintained over time.

Of the 80 patients with T2DM taking part in the long-term study [28], the benefit in terms of HbA1c reduction was maintained at 30 months in the IG compared with the CG (6.9 ± 0.9% vs 7.5 ± 1%; $P = 0.023$). The differential analysis based on HbA1c levels at baseline showed significantly greater reductions in HbA1c in the IG than CG, regardless of baseline HbA1c level (whether <7% or >7%).

Other systems aimed at indirect control of blood glucose levels (through increased physical activity or weight reduction) have also been developed. The Diabetes Network (D-Net), an Internet-based supplement to the usual care, was designed to increase physical activity through the remote intervention of a coach. This system was evaluated in 78 sedentary T2DM patients over a period of 3 months. A moderate increase in physical activity was observed in the IG compared with the CG, but the lack of metabolic evaluation limits the impact of such a system [29]. As for diet, Tate et al. [30] showed that Internet-based behavioural counseling significantly improved weight loss in overweight and obese adults at risk of T2DM. The study involved submission of calorie intake data and information on exercise by the patients, who received weekly behavioural counseling and feedback by e-mail from a counselor.

### 2.3.2. Systems using a cell phone connected to a remote server

The widespread distribution of cellular phones coupled with their ability to communicate data in real time makes them an ideal new healthcare delivery tool for patients with chronic disease. Indeed, cell phones have also been combined with the Internet to take advantage of both approaches.

Recently, Quinn et al. [31] reported the results of a US pilot study using the WellDoc™ system: blood glucose values were transmitted via Bluetooth from a blood glucose meter to a mobile phone, and from the mobile to a remote server; automated messages were then immediately generated according to the value compared with patient-specific target levels, and these messages would appear on the patients’ mobile phone screen. Patients were also prompted to enter other information (such as medication dosages and carbohydrate intake at meals). When patients’ blood glucose levels were either above or below their target levels, they were given real-time feedback on how to correct it. All suggested changes to patients’ therapy regimens were communicated to their healthcare provider (HCP). Also, each patient’s logbook was sent electronically to the HCP every 4 weeks, or more frequently if necessary. Patients’ data were analyzed by automated algorithms and by the research team.

Thirty T2DM patients were recruited into this 3-month study, and randomized into an IG ($n = 15$), in which each patient received a cell-phone system coupled to the Internet, and a CG ($n = 15$), in which each patient received the standard care. The average decrease in HbA1c for IG patients was $-2.03\%$ vs $-0.68\%$ in the CG ($P < 0.02$), although their baseline HbA1c levels were both high (9.51% and 9.05%, respectively). In the IG, physicians were four times more likely to titrate/add drugs than in the CG. From the patient’s point of view, immediate feedback and the ability to receive advice from a nurse regarding treatment adjustments based on blood glucose results was greatly appreciated. The HCPs, meanwhile, reported that the system facilitated treatment decisions, provided organized data and reduced logbook-review time.

A randomized control study including three treatment groups—a tiered IG and a CG—has also been conducted with the WellDoc system, and the results are expected to be published soon [32].

In Korea, several studies have been conducted combining the use of a mobile device and a Web-based monitoring system. After transmitting glucose measurements via a cell phone, patients immediately received messages with recommendations based on a preset algorithm developed by the healthcare team (endocrinologists, dietitians and nurses). Using an Internet website, physicians were able to follow the patients’ trends in terms of blood glucose levels, blood pressure and physical changes, and to send them personalized recommendations when necessary. This system showed favourable effects on multiple metabolic factors in overweight patients with T2DM and hypertension.

In another study, 51 obese T2DM patients with hypertension were randomized into two groups for 12 weeks [33]. In the IG ($n = 25$), patients were required to connect to a website regularly via cell phone (or Internet) and to enter their blood glucose values weekly. These patients received recommendations from the healthcare team (nurses, doctors) via their cell phone (by texting) and via the Internet each week, while patients in the CG ($n = 26$) visited their specialist regularly for face-to-face consultations. An improvement in HbA1c was observed in the IG compared with the CG at all evaluation times (0, +3, +6, +9, +12 months; $P < 0.05$); in particular, the 12-month change in HbA1c from baseline in the IG was $-1.32\%$ vs $+0.81\%$ in the CG.

Yet another study involved the combined use of a mobile device and a Web-based monitoring system, and showed improvements in various metabolic indicators in 123 obese patients with T2DM and hypertension randomized into IG and CG [34]. After 12 weeks, there were significant improvements in HbA1c levels in the IG (from 7.6 ± 0.9% to 7.1 ± 0.8%; $P < 0.001$) compared with the CG (from 7.4 ± 0.9% to 7.6 ± 1.0%; $P = 0.03$). Other clinical and laboratory parameters also improved in the IG (lowered systolic and diastolic blood pressure, and improvements in total cholesterol, low-density lipoprotein cholesterol and triglyceride levels). Compliance with the system was high, and patients were satisfied with the approach. The system also improved the use of medical resources, as it used an automated algorithm for notification, confirmation and feedback recommendations based on measurements of metabolic parameters. However, because of the short duration of the study (3 months), it is not clear whether these effects persist over a longer period of time. Moreover, no medical analysis was performed to assess the cost–benefit ratio of the system for diabetes management.
Recently, the results of a study based on a more sophisticated tool—an automated clinical-decision support system (CDSS) for T2DM patients—were reported. This system was assessed with no direct involvement of healthcare professionals [35]. Glucometer data were transmitted by landline through a public switched telephone network (PSTN). The CDSS engine automatically generated instructions individualized to each patient in response to their glucose results, and regularly generated evaluation messages based on each patient’s average glucose level. Other data such as anthropometric data, blood pressure, HbA1c and current medication were simultaneously uploaded from the hospital’s electronic medical-records server to the so-called “u-healthcare” server. Messages and instructions were sent to patients via their mobile phone. The system was tested in 144 patients aged > 60 years in a 6-month randomized study. Patients were randomly assigned to a routine-care group (controls, \( n = 48 \)), a self-monitored blood glucose group (SMBG, \( n = 47 \)) or a u-healthcare group \(( n = 49 \)). After 6 months of follow-up, mean HbA1c had decreased significantly from 7.8% \( \pm \) 7.4% \(( P < 0.001)\) in the u-healthcare group and from 7.9% \( \pm \) 7.7% \(( P = 0.02)\) in the SMBG group, compared with 7.9% \( \pm \) 7.8% \(( P < 0.05)\) in the controls. To a certain extent, this system allows patients to make self-adjustments to their treatment based on automatic algorithms, thereby favouring patient empowerment in diabetes care.

In addition, other more sophisticated systems have been developed using dedicated computers that allow patients to transmit whole series of data from their homes. Such systems have been developed to overcome time and location barriers (remoteness from healthcare centres, underserved geographical areas, poor social conditions/limited resources, elderly patients). Indeed, some large-scale trials of such systems have been conducted.

The Informatics for Diabetes Education and Telemedicine (IDEATel) study was a randomized trial comparing TM case management with the usual care in older, ethnically diverse, medically underserved, Medicare beneficiaries with diabetes residing in medically underserved areas of New York State. The study included 1665 Medicare beneficiaries with T2DM considered to have the greatest need for intervention using TM. These patients (mean age: 71 years; HbA1c around 7.4%) were randomized to receive either TM intervention \(( n = 844)\) or the usual care \(( n = 821)\). TM patients received a home TM unit to allow video-conferencing with a diabetes educator every 4–6 weeks mainly for self-management education, and for review of blood glucose and blood pressure measurements. However, in spite of the complex and expensive equipment \( (\$3425/\text{unit in 2006)}\), the metabolic results were disappointing: HbA1c only decreased from 7.35% \( \pm \) 6.97% over 1 year in the TM group, and from 7.42% to 7.17% in the controls, with a mean between-group difference of 0.18% which, while statistically significant \(( P < 0.006)\), was not clinically relevant. Furthermore, although TM patients said they were very satisfied with the system, only 41% completed the satisfaction questionnaire. Also, after 5 years of follow-up, the difference between the two groups was still small \(( \Delta: 0.29\% [0.12–0.46\%])\) [36]. Subgroup analyses revealed racial/ethnic disparities among the participants in glycaemic control: HbA1c was higher at baseline in Hispanics \((7.79 \pm 1.68\% ; n = 585)\) than in non-Hispanic whites \((7.02 \pm 2.15\% ; n = 821)\) and in blacks \((7.58 \pm 1.78\% ; n = 248)\). However, Hispanic patients in the TM group showed greater improvement in HbA1c compared with the usual-care group at the end of 5 years \((7.32\% \text{ and } 7.82\%, \text{ respectively})\), although the baseline HbA1c levels were not the same \((7.69\% \text{ and } 7.94\%, \text{ respectively})\). The treatment effect was thus 0.50 \((95\% \text{ CI: } 0.22–0.78)\) for Hispanics compared with 0.29 \((0.12–0.46)\) overall, as reported above. This population, which had the worst glycaemic control, also had the lowest levels of income, educational attainment and computer experience, as well as fewer glucose uploads, suggesting less self-monitoring of blood glucose levels. This suggests that TM may have potential in reducing racial/ethnic health disparities in diabetes management [37].

Another Web-based system for the management of glycaemia and blood pressure in patients with poorly controlled T2DM showed more favourable results. In this case, 104 diabetic patients with HbA1c > 9% attending the Department of Care for Veterans in Boston, MA, USA, were included in a 12-month feasibility study [38]. All patients attended a half-day educational meeting on diabetes and met with a team of “educators” (a nurse, a nutritionist and a pharmacist). The patients were then randomized into one group receiving the usual care \((CG, n = 52)\) and another group receiving the usual care plus additional support through the website \((IG, n = 52)\). In the latter, patients received an electronic notebook, and a system for monitoring their blood glucose and blood pressure at home; they also had access to the website. Data from the monitoring systems (glucose and blood pressure) were uploaded to the website, and could be recovered by both patients and caregivers for further analysis. The website provided educational modules, and patients could communicate with caregivers by internal messages via the website.

The baseline characteristics of the two study groups were comparable \((\text{IG: HbA1c 10%}; \text{CG: HbA1c 9.9%})\). A significant reduction in HbA1c was achieved in both groups \(( P < 0.001)\) at 3, 6, 9 and 12 months from baseline, and was greater over time \((12 \text{ months})\) in the IG compared with the CG \(( P < 0.05)\). Over 12 months, the HbA1c reduction from baseline was \(-1.6 \pm 1.4\%\) in the IG and \(-1.2 \pm 1.4\%\) in the CG. More interesting was the correlation between level of use of the system and blood glucose control: subjects who continuously used the website had a greater reduction in HbA1c than those who used it intermittently \((-1.9 \pm 1.2\% \text{ vs } -1.2 \pm 1.2\%, \text{ respectively}; \text{ } P = 0.051)\) and those in the CG \((P < 0.05)\). A greater number of data downloads was associated with a larger reduction in HbA1c (highest tertile of downloaded data: \(-2.1 \pm 1.1\%\); lowest tertile: \(-1.1 \pm 1.7\%\); \text{ } P < 0.05). This correlation between HbA1c and patient/system interactivity once again underscores the need for frequent contact to ensure good system efficiency. The main results of these studies are summarized in Table 3.

2.3.3. Active electronic diaries on smartphone

TM systems involving smartphones have also been developed for T2DM. These systems have several functions, including data collection and decision support systems for insulin-dose
Table 3
Systems involving a cellular phone connected to a remote server.

<table>
<thead>
<tr>
<th>References</th>
<th>Population</th>
<th>Methodology</th>
<th>TM system</th>
<th>Control</th>
<th>Duration of the study</th>
<th>HbA1c at baseline</th>
<th>Results on A1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinn et al., 2008 [31]</td>
<td>30 T2D patients with poorly-controlled diabetes (A1c &gt; 7.8%). Treatment with oral agents, insulin or both</td>
<td>RCT/parallel groups</td>
<td>The WellDoc™ system: connexion from a glucometer to a cellular phone (via bluetooth) and then to a remote server. Feedback by text messages</td>
<td>Transmission of the BG values of the logbook (fax or phone call) every 2 weeks to the HCP until BG levels were in the target ranges or until the HCP changed testing frequency</td>
<td>3 months</td>
<td>IG: 9.51% / CG: 9.05%</td>
<td>The average decrease in HbA1c for patients in the IG was 2.03% vs. 0.68% in the CG (P &lt; 0.02). No between group comparison</td>
</tr>
<tr>
<td>Yoon et al., 2008 [33]</td>
<td>51 obese T2D patients with hypertension</td>
<td>RCT/parallel groups</td>
<td>A nurse short message service by cellular phone; transmission of BG values and information on treatment to a website via a cellular phone or wired internet; feedback by a nurse (SMS) by cellular phone and wire Internet weekly</td>
<td>Face-to-face consultations</td>
<td>12 months</td>
<td>IG: 7.6 ± 0.9% / CG: 7.4 ± 0.9%</td>
<td>The change in HbA1c from baseline was –1.32% in the IG vs +0.81% in the CG</td>
</tr>
<tr>
<td>Yoo et al., 2009 [34]</td>
<td>123 DT2 overweight patients with both T2 diabetes and hypertension</td>
<td>RCT/parallel groups</td>
<td>The Ubiquitous Chronic Disease Care (UCDC) system composed of a patient-based cellular phone and a web-based physician system. Feedback by sms</td>
<td>Routine schedule for appointments</td>
<td>12 weeks</td>
<td>IG: from 7.6 to 7.1% (P &lt; 0.001) / CG: from 7.4 to 7.6% (P = 0.03) with a significant change between groups (P = 0.001)</td>
<td></td>
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<tr>
<td>Lim et al., 2011 [35]</td>
<td>144 T2D patients, aged ≥ 60 years</td>
<td>RCT / parallel groups / three groups: CG (n = 48), SMBG group (n = 47) and U-healthcare group (n = 49)</td>
<td>An automated clinical decision support system (CDSS): data from the glucometer are transmitted to a data collection server. Instructions specific to the patient are generated by an automated system and specific messages are sent on the mobile phone of the patient (sms). SMBG Group (BG controls at least 8 times a week)</td>
<td>Follow-up according to current medical care</td>
<td>6 months</td>
<td>IG: 7.8 ± 1.0% / SMBG G: 7.9 ± 0.9% / CG: 7.9 ± 0.8%</td>
<td>U-healthcare group: from 7.8% to 7.4% (P &lt; 0.001); SMBG group: from 7.9% to 7.7% (P = 0.02); Control group: from 7.9 to 7.8% (P &lt; 0.05). No between group comparison</td>
</tr>
<tr>
<td>Shea et al., 2009</td>
<td>1665 Medicare beneficiaries with T2D</td>
<td>A 1-year randomised controlled study</td>
<td>IDEATEL system: a home TM unit to interact and video conference with the diabetes educator</td>
<td>Follow-up according to current guidelines by primary care providers</td>
<td>12 months</td>
<td>7.4%</td>
<td>HbA1c decreased from 7.35 to 6.97% over 1 year in the IG and from 7.42% to 7.17% in the CG, with a mean difference between the 2 groups of 0.18% (P = 0.006)</td>
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<tr>
<td>Shea et al., 2009 [36]</td>
<td>A 5-year randomised controlled study</td>
<td></td>
<td></td>
<td></td>
<td>5 years</td>
<td>7.4%</td>
<td>HbA1c decreased from 7.35 to 7.05% over 5 years in the IG and from 7.42% to 7.34% in the CG, with an intergroup difference of 0.29% (0.12–0.46%)</td>
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<tr>
<td>McMahon et al., 2005 [38]</td>
<td>104 p with HbA1c ≥ 9%</td>
<td>RCT / parallel groups</td>
<td>An electronic logbook and a system to monitor BG and BP at home + additional support through the website. Communication between the patient and the care giver by internal messaging via the website</td>
<td>Ongoing care by the primary care provider, as needed</td>
<td>12 months</td>
<td>IG: 10 ± 0.8% / CG: 9.9 ± 0.8%</td>
<td>A significant reduction in HbA1c was achieved in the 2 groups (P &lt; 0.001) at 3, 6, 9 and 12 months from baseline and this reduction was greater over time (12 months) in the IG compared to the CG: –1.6 ± 1.4% in the IG vs –1.2 ± 1.4% in the CG (P &lt; 0.05)</td>
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determination. Data can also be sent via the Internet to a secure website, and a message may be sent back to the patient from the caregiver. These small and handy tools are designed to enhance patients’ empowerment in their own diabetes care. Some published studies in T2DM patients have focused on adjustment of basal insulin, while others have emphasized dietary management or increased physical activity. However, where performed, the evaluation of such studies is usually based on changes in HbA1c.

2.3.3.1. Interventions focused on adjustment of basal insulin. In patients with T2DM inadequately controlled by OADs and for whom the introduction of a basal insulin injection at bedtime was considered, it has been shown that insulin doses were usually insufficient to achieve good control of fasting glucose levels despite recommendations by caregivers. The T+ diabetes system described previously [14] has been adapted and modified to automatically provide a recommendation to increase insulin dose in accordance to the physician’s prescription in cases where fasting plasma glucose (FPG) remained above target levels. A feasibility study showed that patients reduced their FPG to target levels (<110 mg/dL) within an average of 22 days, with a concomitant decrease in HbA1c from 8.5% to 7.1% over a period of 3 months [39].

2.3.3.2. Interventions focused on diet. In the US, a preliminary study evaluated the outcome of intervention by a nutritionist coupled with the use of a PDA incorporating a food database to determine the glycaemic index (GI) of foods and to guide food choices in T2DM patients [40]. In the study population, which had a baseline HbA1c of 8%, the reduction in HbA1c at 6 months was only –0.5% (P=0.02). This modest result, the small number of patients (n=13), the lack of a control group and the limited level of satisfaction with the system suggests that such an intervention will not go beyond the experimental stage. The main criticisms were the difficulties in finding certain foods in the food database, the need to continuously record food consumption and the small size of the PDA screen.

Of greater interest is the study conducted in Hong Kong by Tsang et al. [41], the aim of which was to evaluate a computerized system for monitoring diabetes and involving the transmission of food data. A prospective interventional crossover study was conducted for 6 months (12-week intervention and 12-week usual treatment) in 20 diabetic patients (type of diabetes not specified). An electronic pocket book connected to a telephone line was used to monitor diet and blood glucose values. These data were then sent via a modem twice weekly to a healthcare team at the medical centre. Patients received immediate automatic feedback on the contents of their diet (G, P, L, calories). They could also ask the caregiver questions and receive suggestions back via e-mail. When the system was used, the average reduction in HbA1c was –0.825% (P<0.019) compared with control periods. Patients were satisfied with the system, with 95% finding it easy to use and 63% considering it useful. These positive results suggest that interventions focused on diet may be beneficial for the management of T2DM patients especially when they receive automatic feedback immediately. However, it is uncertain whether these results can be replicated in other T2DM populations.

2.4. Towards a more comprehensive system incorporating all functions

A version of the Diabeo system has been customized specifically for T2DM patients. The system, the result of collaboration between CERITD and VOLUNTIS, is geared towards patients inadequately controlled by OADs and in whom the introduction of a basal insulin injection at bedtime is warranted. To overcome inadequate titration of basal insulin, the Diabeo system was adapted to provide automated proposals for insulin dose based on an algorithm preset by the physician. However, its chief value remains the educational coaching to provide patients with advice on diet and physical activity by way of automatic messages if the results of postprandial blood glucose values or blood glucose values at the end of the afternoon fall outside of the target range; advice can also be given to patients in the event of hypoglycaemia. This system is currently being evaluated in the multicentre TELEDIAB-2 study.

3. Conclusion

For years, there have been an increasing number of studies of TM in diabetes care, although most have failed to demonstrate any superiority over traditional care. This accounts for the negative—or, at best, modest—results of TM when applied to diabetes. TM has been globally evaluated by means of meta-analyses that lumped together all studies in the literature, regardless of methodology, type of diabetes and study populations. In a meta-analysis [42] of nine randomized trials involving 636 patients published in 2005, the decrease in HbA1c compared with controls was 0.11%—in other words, neither clinically nor statistically significant. Another meta-analysis of the pooled results of six randomized clinical trials showed similar results [43]. Recently, however, a meta-analysis incorporating some additional new studies reached the threshold of statistical significance in favour of TM, although the HbA1c reduction was low (–0.21%) and not truly clinically relevant [44]. In all these meta-analyses, the individual studies were of variable quality, and the efficacy of the systems tested was also mixed.

Indeed, what are the prerequisites of a successful TM system focused on blood glucose control? Comparative analyses of previously reported studies underline the critical importance of the quality of interaction between patients and caregivers. In T2DM patients, this interaction is a prerequisite for any effective and sustainable action in the management of large patient populations. Web- or cell-phone-based interventions are an effective method for continuing the educational, motivational and monitoring activities of patients with diabetes.

As regards the more technological interventions (especially in T1DM), the most common patient expectations may be summarized into three concepts. First, the system should be easy to use, with readily available, pocket-sized electronic devices. In contrast, good compliance and satisfactory results are difficult to obtain with systems involving desktop computers. Second,
programmes that fail to respond immediately to patients’ questions account for the poor performance of the many systems that transmit blood glucose data with delayed feedback on adaptation of insulin doses, and explain the genuine success of systems incorporating algorithms that allow automatic dose adjustment. Similar observations can be made for dietary interventions, with success for systems that provide automatic assessment of carbohydrate contents using a food database. Finally, easy interactivity with a known caregiver explains both the good results achieved with TM systems using teleconsultations and the poorer results where human contact consists merely of texting or e-mail, or where the care provider does not know the patient.

Technical improvements to smartphones, and more secure data transmission via GPRS and the Internet, are now allowing the implementation of new easy-to-use tools. These active electronic diaries appear set to replace traditional paper diaries in the near future, and will allow insulin doses to be proposed based on the automatic application of algorithms previously prescribed by the physician. Also, glucose readings could be entered via microglucometers plugged into smartphones, pending direct connection with the glucose sensor and the return to control of the insulin pump, forming a closed loop.

These devices should also guide food choices through an extensive onboard database and encourage increased physical activity, taking into account blood glucose levels. Automatic remote transmission of results will also lead to better monitoring. Both physicians and patients alike will waste less time on urban transport and in hospital waiting rooms, and fewer working days will also be lost. Also, such systems will need to be adapted to younger patients who need complex treatment regimens and to elderly patients who require simpler treatments, and could even focus on solving problems concerning diet and physical activity.

The widespread use of such systems will depend on the readiness of patients and their caregivers to embrace change. It will also depend on the cost to health insurance-paying bodies and to patients, and on the perceived value of TM consultations. TM also requires reorganization of the healthcare system, with the involvement of new “actors” and the emergence of new professionals into the diabetes field.

To face the epidemic spread of diabetes and to overcome the scarcity of physicians, it is now essential to involve nurses specialized in diabetes who are able to ensure the education and regional management of patients (through call centres if necessary), thanks to efficient TM devices. Such devices should be equipped with an automated alarm system that would inform the specialized diabetes nurse in real time of any issues (such as a lost connection to the patient or blood glucose values outside of target levels), thereby allowing a quick response to the problem. Local intervention by a local nurse (or even the physician in charge of the patient) may then be considered at a later stage, if necessary.

An organization that allows monitoring of a large amount of data from patients should be particularly beneficial from a medical-economics point of view. Such an organization will soon be tested in a large study across the French territory using the Diabeo system, which is currently undergoing procedures to obtain reimbursement by the national health insurance system. In addition to metabolic control, the aim of this multicentre study will also be to assess whether such an organization can prefigure the new care organization imposed by issues of medical demographics and the need to control health costs.

Disclosure of interest

S. Franc (and some of the authors of the manuscript) works for CERITD, which developed the Diabeo system in collaboration with VOLUNTIS S.A.

References

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