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RESEARCH

Effects of a Therapeutic Patient Education Network on the Glycated Hemoglobin and Body Mass Index in 59 Patients with Type 2 Diabetes Mellitus: A Retrospective Study from 2013 to 2018

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Introduction: In 2019, there were 4.5 million people with diabetes in France. To assist them, general practitioners can offer therapeutic patient education sessions (TPE). An education network was created for this purpose by healthcare professionals in the south of the Aisne region of France. With hindsight, what has been the impact of a TPE network like this one?
Objectives: The main objective of the study was to assess the effects of unstable type 2 diabetic (T2DM) patients' participation in the activities of an education network on body mass index (BMI) and glycated hemoglobin (HbA1c). These patients were monitored from January 2013 to June 2018. The secondary objective was to determine the impact of adapted physical activity sessions (APA) and of TPE on the two selected clinic-biological parameters.
Methods: A retrospective, quantitative, and monocentric, observational study was performed with analysis of the evolution of HbA1c and BMI of T2DM patients. They were monitored for more than six months in the network between 2013 and 2018, using the Logireso® database. Statistical analysis was performed using SPSS® software. BMI and HbA1c were analyzed by Student›s T test for paired samples. A linear regression test was performed to assess whether there is a correlation between two variables among those measured.
Results: Fifty-nine patients met the inclusion criteria (20.92% of participants in the network). The decreases in BMI (–1.65 kg/m²) and HbA1c (–0.86%) of the patients studied were significant ($p < 0.001$). This change was even more drastic for patients with higher initial values of BMI and HbA1c (result for the highest bracket). However, the study did not link APA or TPE sessions to changes in BMI or HbA1c.
Conclusion: The study showed the overall effectiveness of the proposed program in reducing BMI and HbA1c without highlighting a single factor that could explain it.

Keywords: Patient education as Topic; type 2 Diabetes; General practice; Physical activity; Body mass index; Public Health Practice

Introduction

Chronic illnesses impact the health of more and more people, making it both a national and international public health issue. In 2019, there were 4.5 million people with diabetes in France, including one million who had not yet been diagnosed (European center for the study of diabetes, 2019). Between 2010 and 2017, the prevalence of type 2 diabetes increased annually (French public health agency, 2019). This increase can be attributed to the aging of the population, the improvement in life expectancy of those treated for diabetes, family history, early detection, nutritional imbalances, and a sedentary lifestyle (French public health agency,

2019; French national institute for health and medical research, 2019; Mandereau-Bruno & Fosse-Edorh, 2017). The annual spending by France's national health insurance for this issue amounted to nearly ten billion euros, 2.3 billion of which was for expenses directly attributable to pathology and treatments and 7.7 billion for the management of related complications. On average, the annual cost per patient in 2016 was 6,506 euros (33% represented by hospitalizations, 24% by medications, 14% for paramedical care, and 11% by medical check-ups) (Charbonnel et al., 2016). According to the Entred (National Control Sample Representative of People with Diabetes) study conducted over the years of 2007 to 2010, (French public health agency, 2019) the average age of patients with type 2 diabetes was 65 and a quarter of them were over 75 years old. The majority of the patients were men (54%), and they diagnosed at a younger age than women. Patients' median body mass index (BMI) was estimated to 28.7 kg/m² and had an increasingly frequent level (41%) of obesity (BMI > 30 kg/m²), which is a modifiable risk factor (French national authority for health, 2014; French public health agency, 2019; Mandereau-Bruno & Fosse-Edorh, 2017). In 2012, the Obépi survey found that overweight patients developed type 2 diabetes three times more often than patients with a normal BMI, and seven times more in the event of obesity (Inserm et al., 2012). Patients with type 2 diabetes must therefore benefit from support to change their lifestyle including a balanced diet, the practice of a regularly adapted physical activity, weight loss in the event of obesity, assistance in understanding the disease, and strengthening adherence to the treatment plan (French public health agency, 2019; French society of endocrinology, 2016). Glycated hemoglobin is a marker of diabetes control which reflects the average capillary blood glucose levels over three months (French national authority for health, 2014). The goal is to control capillary blood glucose, obtain glycated hemoglobin (HbA1c) levels within the recommended target range, as well as BMI, in order to limit the short-, medium-, and long-term complications of the disease (French national authority for health, 2014; French society of endocrinology, 2016).

General practitioners and primary care providers are responsible for monitoring these patients, prevention, screening, therapeutic education, treatment, and coordination of the care pathway. They support the patient in learning nutritional recommendations and the various follow-up stages (regular blood tests, specialist consultations with cardiologists and ophthalmologists, monitoring of their feet, etc.) in order to develop autonomy. Therapeutic education can help with this development. As specified in Article L. 1161-1 of the Public Health Code, *"therapeutic education is an integral part of the patient's healthcare pathway. It aims to grow the patient's autonomy by facilitating their adherence to prescribed treatments and improving their quality of life"* (French public health code, 2009). Skills for self-care and coping with the disease must be acquired through adherence to the educational pathways approved by the regional healthcare agency (French national authority for health, 2007). This education can be offered at any stage of the disease: from the diagnosis, during life events impacting follow-up (pregnancy, change in pace of work, etc.), during a decrease in motivation that may affect compliance, after onset of complications, etc. (French national authority for health, 2014). The skills aimed for depend on each patient's needs and are adapted to each individual. To carry out therapeutic education of patients, the general practitioner can direct them to a dedicated structure, which they can decide to adhere to or not.

A therapeutic education network as defined by Article L 6321-1 of the Public Health Code was created in 2003 in a southern town of the department of Aisne (French minister for solidarity and health, 2016; Legifrance, 2016). This association was approved for the "Therapeutic Education of Patients suffering from type 2 diabetes" program in 2011. It was made up of various participants, most of them self-employed: general practitioners, nurses, podiatrists, pharmacists, dieticians, sports instructors, biologists, psychologists, art therapists, secretaries, and patient advocates. They worked in partnership with the two hospitals in the area as well as with the municipality in a response to the needs of the inhabitants. They have supported more than a thousand patients over the past fifteen years, with the aim of reducing the BMI and HbA1c of participating patients. With hindsight, what was the impact of this therapeutic patient education network on the region? The main objective of the study was to evaluate the effects of the network on the BMI and HbA1c of patients with type 2 diabetes monitored from January 2013 to June 2018. The secondary objective was to determine the impact the patients' adapted physical activity and therapeutic education sessions played on the two clinic-biological parameters selected.

Method

An observational, quantitative, retrospective, and monocentric study was conducted. The data collection concerned the number of therapeutic patient education sessions and adapted physical activities as well as the evolution of HbA1c and BMI of patients with type 2 diabetes after their monitoring in the network between 2013 and 2018. The geographic area covered by the network is 30 kilometers with a prevalence of diabetes at 4.9% in 2007 (France TV, 2014). A request was made to the network's board of directors to seek

their agreement to carry out the study. Information was provided to patients via the network's newsletter. The data collection period lasted from January 2013 to June 2018, corresponding to the computerization of the network by the Logireso® software. Previous data was not accessible to the researcher. The inclusion criteria in the study were: an unbalanced diabetes (>7%) and a minimum follow-up of six months in the network allowing for three HbA1c measurements with a minimum gap of three months between each analysis. This made it possible to retain clinical and biological measurements of HbA1c and BMI at the start of the treatment course, at mid-term and at the end of the proposed monitoring.

Patients were directed to the network by their general practitioner for unbalanced type 2 diabetes (HbA1c above the target range for the patient's age and comorbidities) and frequent comorbidities associated with sedentary lifestyle or obesity. A variety of informations (age, sex, duration of monitoring, number of therapeutic education sessions and adapted physical activities performed by the patient, and HbA1c and BMI measurements) were collected. The missing information in the network file was completed by contacting either the patient's attending physician or the city's clinical biology laboratories. The entry of anonymized data was done on an Excel® spreadsheet.

Statistical analysis was performed using SPSS® software. The quantitative data was inserted into the Student's t test for paired samples (clinic-biological measurements). A linear regression test, with calculation of the linear regression coefficient R^2 was performed to assess the strength of correlation between the analyzed variables. The range of values was defined to be between zero and one. The closer the result came to one, the more reliable the regression. The significance level was set at 0.05.

Results

The study included 282 patients with an age range from 41 to 84 over a five-year period. Only 59 patients met the inclusion criteria (20.9%). Among the patients not included, 69 did not have sufficient monitoring to be able to analyze an effect on the clinic-biological measures (less six month) or had type 1 diabetes, 32 patients refused monitoring by the network after a first meeting, and 123 had incomplete data in their file in HbA1C or BMI. Among the patients included, 59% of them were women, and the average age was 64 years old. The mean duration of monitoring was 23.8 months [6, 53] with a median of 21 months. The patients had completed an average of ten sessions of adapted physical activities [0, 93] and sixteen therapeutic patient education sessions [0, 73]. In regard to the variation in the BMI of the population studied, the average BMI at the start of the treatment course was 34.1 kg/m², at the middle of the monitoring 33.2 kg/m², and at the end of the monitoring 32.9 kg/m². Throughout the monitoring, the BMI dropped significantly at the mid-term –0.94 kg/m² ($p < 0.001$) and –1.65 kg/m² ($p < 0.001$) at the end of the monitoring period. Likewise, the mean HbA1c at entry was 7.5%, at mid-course 6.9%, and at end of follow-up 6.6%. The decrease in absolute HbA1c at mid-term was –0.61% ($p < 0.001$) and –0.86% ($p < 0.001$) at the end of the monitoring period. The decreases observed in the two analyses were more marked during the first half of the monitoring period. This decrease was greater when the initial values were high. Regarding the tests on the absolute values, no link was found between the decrease in BMI and the number of sessions of adapted physical activities ($p = 0.74$) or with the number of therapeutic patient education sessions ($p = 0.66$), nor between HbA1c and adapted physical activity ($p = 0.63$) or the number of therapeutic patient education sessions ($p = 0.73$). However, the analysis of the impact of the participation of patients in the network on the absolute value of HbA1c found a very marked downward curve ($p < 0.001$) with a regression coefficient, $R^2 = 0.7$, confirmed by the distribution of points very close to the line of regression (**Figure 1**).

Discussion

This observational, retrospective, and monocentric study evaluated made it possible to meet the objective to evaluate the effects of the network on the BMI and HbA1c of patients with type 2 diabetes mellitus monitored from January 2013 to June 2018. This study showed that an improvement in BMI measurements (–1.65 kg/m²) and HbA1c (–0.86%) was found in 59 patients with unbalanced type 2 diabetes at the end of an educational course including patient therapeutic education sessions and adapted physical activities. Only 59 patients were included in the analysis over a period spanning five and a half years, mainly due to a lack of data collected despite the request for supplements from the two laboratories and general practitioners of the city. The number of subjects studied in this research is relatively small compared to the prevalence of diabetes in the general population. It is thus legitimate to wonder whether the presence of insignificant results is a consequence of a possible lack of power in the study. Only the drop in HbA1c could be correlated statistically with participation in the network. This is probably secondary to multiple factors that could not be differentiated in this study (new treatment for exemple). The results obtained were similar to those found in the literature (Deakin et al., 2005; Trento et al., 2004).

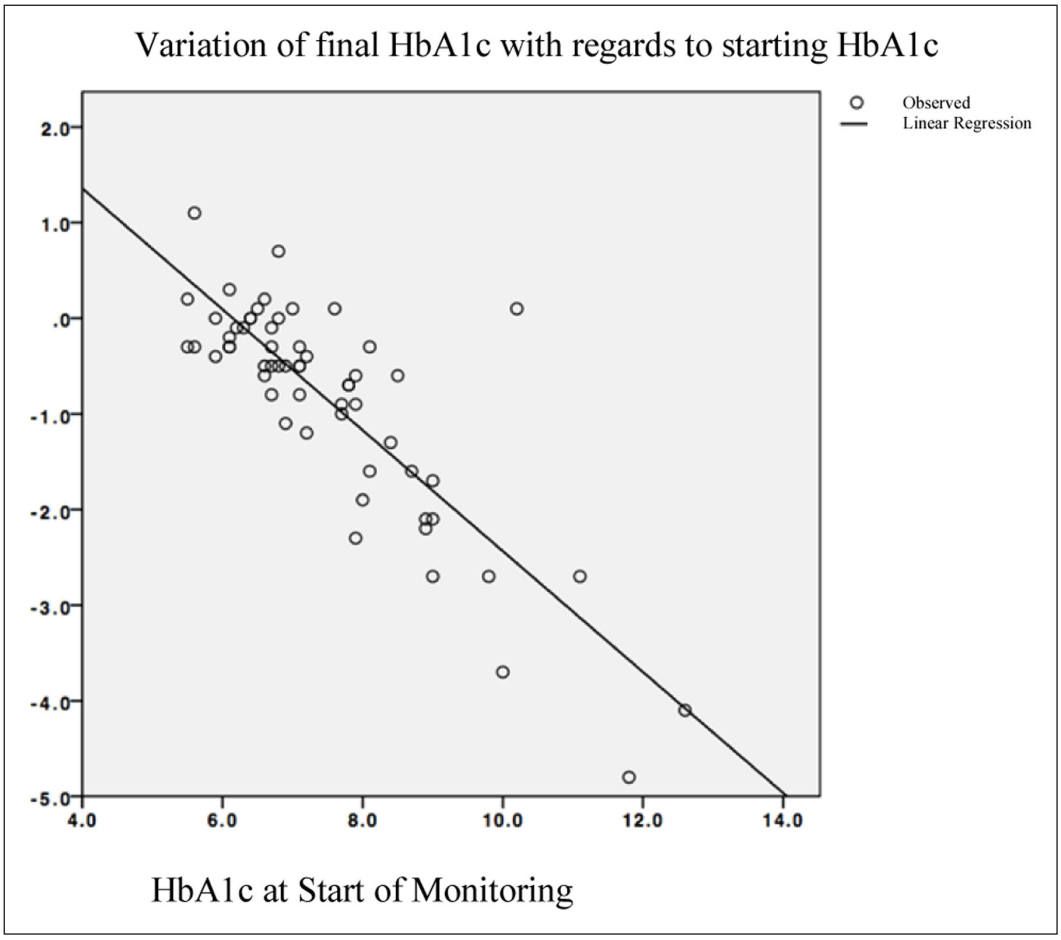

Figure 1: Absolute Change in HbA1c according to Initial HbA1c in 59 Patients included in a Therapeutic Education Program in Aisne.

As a matter of fact, concerning the decrease in BMI, the study by Trento et al. conducted in 2004 on 112 patients followed for five years found a decrease in BMI of –1.4 kg/m² in the group who received care with systemic training (Trento et al., 2004). In addition, after nine months of monitoring, Sanguignol et al. found an average loss of BMI of –3.7 kg/m² in 49 patients. The improvement is more substantial compared to our study. This may be due to the initial hospitalization of patients for five days, multidisciplinary care, and an average patient age of 45 years with 85% of participants being women (Sanguignol et al., 2009). Moreover, BMI does not reflect the transformation of body fat mass into lean body mass and abdominal circumference measurement.

Additionally, concerning the decrease in HbA1c, Ricci-Cabello et al. indicated in 2014 an average decrease of –0.31% in a meta-analysis of twenty randomized controlled trials (Ricci-Cabello et al., 2014). Likewise, a 2005 Cochrane Collaboration meta-analysis showed a significant drop in HbA1c level of –1.4% after four to six months of educational monitoring and follow-up, from –0.8% at 12–14 months and –1% at two years ($p < 0.00001$) (Deakin et al., 2005). Another study by Boule et al, in 2001, focusing on the review of nine studies (including a total of 310 patients), showed a decrease in the average HbA1c level of –0.66% (95% CI: –0.98, –0.34, $p < 0.01$) with the practice of more than eight weeks of physical activity. The review also analyzed two studies (142 patients) which noted that physical exercise combined with a balanced diet significantly lowered HbA1c compared to patients who did not exercise and diet (–0.76% [CI at 95%: –1.32, –0.20, $p = 0.008$]) (Boule et al., 2001).

In addition, physical activity has other proven benefits. In fact, the National Health Interview Survey study in 2003 indicated that people with diabetes, who walked more than two hours per week, had an all-cause/cardiovascular disease cause mortality rate decreased by 39% and 34% respectfully when compared to inactive patients (Gregg et al., 2003). This study made it possible to highlight the work carried out by the network and the educational pathway of the patients monitored during these years.

The main bias of this study is the lack of power, and that the protocol for collecting the data was not able to be defined beforehand. Despite the support of general practitioners and medical biology laboratories, many incomplete files remained, and were therefore excluded. A selection bias was also present. The

patients included in the educational program were referred by their general practitioner, had compliance difficulties, and suffered from unbalanced diabetes and obesity. Even if this bias can be seen as a strong point in a pragmatic design method, this falls within the framework of secondary or even tertiary prevention, depending on the co-morbidities of the patients. These were patients who were motivated to change their lifestyle, with educational monitoring for more than six months. A measurement bias, with the risk of over or underestimating the results, could also be found, in particular in the calculation of the BMI with different scales for measuring weight. Likewise, since each patient journey is different, the measurements of HbA1C and BMI were not taken within the same time frame, rather they were taken halfway through the educational process. Finally, this study did not analyze a change in drug treatment or an improvement in therapeutic compliance; this may inflate the decrease in patients' HbA1c in parallel with the educational actions carried out.

Further research with larger sample sizes would improve the power of the analysis. It would also be interesting to investigate the long-term effects of monitoring through further analysis of the clinic-biological measures in order to verify their effectiveness in the long term. The recommendations of the National Institute for Health and Care Excellence offer patients with type 2 diabetes a structured education with several approaches including individualized care, therapeutic patient education adapted to each patient's needs, regular dietary monitoring, regular monitoring of the patient's HbA1c, control of arterial hypertension, training in self-measurement of blood sugar, and overall management of therapy (National institute for health and care excellence, 2015). Other studies could prove useful in investigating the impact of TPE programs and adapted physical activity on other criteria such as quality of life or the development of self-care skills, for example.

Conclusion

This study made it possible to highlight the positive impact of the educational program offered by a health network with a decrease in the values of BMI and HbA1c in patients with type 2 diabetes. On the other hand, this could not be correlated with the number of therapeutic patient education sessions and physical activity performed, probably due to the low power of the study. Patient education and adapted physical activity are a priority in the French national recommendations for support of patients with type 2 diabetes, in addition to nutritional balance and medication adaptation (Mandereau-Bruno & Fosse-Edorh, 2017). This has an impact on the risks of short-, medium- and long-term complications of diabetes and it is therefore a public health issue to put it into practice in general practice (French national authority for health, 2021).

Competing Interests

The authors have no competing interests to declare.

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