Benefit of Telemedicine for Patients With Diabetes Mellitus

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Abstract-The mean HbA1c difference between Sensor Augmented Pump (SAP) therapy and Multiple Daily Injections (MDI) is 0.3 to 0.6% in favour of SAP, but adolescents, although treated with SAP therapy, show a progressive temporary deterioration of glucose control. Telemedicine in Type 1 Diabetes is thought to facilitate diabetes management and to improve compliance to CSII/SAP treatment especially during adolescence. The aim of the present study was to observe the long term impact on glycometabolic controlled by Telemedicine systems (*Telemedicine Group*) compared with traditional follow-up (*Control Group*) in Type 1 diabetes SAP treated adolescents. The observed HbA1c decrease in the group followed with telemedicine was associated with a better compliance to therapy in terms of frequency of sensor use, number of SMBG tests and number of insulin boluses.

Keywords-Type 1 diabetes; adolescence; telemedicine; telemonitoring; CSII; SAP

I. INTRODUCTION

Diabetes is a hormonal disorder that affects an estimated three hundred million people worldwide [1]. Several treatments have been proposed to guarantee patients a good control of symptoms but, when diabetes is underestimated, it can lead to a poor quality of life. Diabetes is a disease characterized by a group of metabolic disorders, caused by defects of insulin's secretion and/or activity. The first condition is represented by a pancreas inability to produce insulin and the latter is characterized by incorrect use of normal secreted insulin (insulin resistance). Insulin, produced by the Beta cells from the Langerhans islets, has a dual function: transport glucose from the bloodstream to the body's cells, where it is converted into energy and is involved in the anabolic metabolism of glycogen. The previously strong association of low HbA1c with severe hypoglycemia and coma in young individuals with type 1 diabetes has substantially decreased in the last decade, allowing achievement of near-normal glycemic control in these patients [3]. At the same time, high HbA1c value can induce, in the long term, the incurrence of co-morbidity diseases, which is well known from literature.

Several meta-analyses of randomized controlled trials have demonstrated that mean glycated hemoglobin (HbA1c) levels and hypoglycaemic episodes are significantly lower with Continuous Subcutaneous Insulin Infusion (CSII) as compared with multiple daily insulin injections (MDI) in type 1 diabetic patients, children, adolescent and young adults [4]. The mean HbA1c difference between treatments is 0.3 to 0.6%, with a greater reduction (> 0.6%) in patients treated with Sensor Augmented Pump (SAP) therapy [5], especially for very young children [6].

During this age period people with diabetes shows a progressive and temporary deterioration of glucose control and one explanation for deteriorated glycaemic control among adolescents treated with CSII and SAP is omitted bolus doses before meals [7].

Telemedicine in diabetes, defined as the use of telecommunications to deliver healthcare services by interaction between the medical staff and the patients/their families, includes the telemonitoring of the transmission of health data (self monitoring blood glucose data, insulin therapy, pump setting, etc.) from the patient's home to the Diabetic Unit, with a consequent real-time health feedback. An online website on web-based intervention for adolescents with Type 1 Diabetes demonstrated that the tele medical approach seems to be a promising tool for a better disease management [8], but, up to now, poor literature related to Telemedicine in adolescents with Type 1 Diabetes is available. The main aim of this study was to observe the long term (five year) effect of glycometabolic control in patient followed with ambulatory visits and Telemedicine assistance (*Telemedicine Group*), compared with a similar group (*Control Group*) followed with traditional trials (only with periodic ambulatory visit) in Type 1 diabetes adolescents treated with SAP therapy. The paper is structured as follows: Section II discusses the methods used for our approach; Section III presents the results; in Section IV we presents conclusion and ideas for future work.

II. METHODS

This is a case feasibility study on using telemonitoring for diabetes follow-up. This was an analytical observational study, carried out at Bambino Gesù Children's Hospital, in the Unit of Endocrinology and Diabetes in association with Research Unit of Health Technology Assessment, over a period of 60 months. A

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total of 29 consecutive Type 1 diabetes, SAP treated, adolescents (mean age 13), regularly followed at Bambino Gesù Children's Hospital, Unit of Endocrinology and Diabetes, were randomly (randomization 1:1) assigned to a Telemedicine assistance (*Telemedicine Group*), with a frequent (monthly) tele-assistance and tele-interaction between the medical team and patients/families, or to a traditional follow up (*Control Group*): only with ambulatory visit (in-hospital periodic visits at 3 months intervals). Patients with diabetes duration < 1 year were excluded from this study.

For both groups HbA1c values, was compared the mean, at 6 months intervals, of: frequency of sensor use, insulin boluses per day, SMBG tests per day and severe hypoglycemic episodes, by engineers of Research Unit of Health Technology Assessment

The study design conformed to the ethical guidelines of the Declaration of Helsinki (1975), and the Ethics Committee of Bambino Gesù Children's Hospital and Research Institute approved it.

At the beginning and during the study all the enrolled patients received a regular and standardized protocol of education about proper control of diabetes, in which a multidisciplinary team (diabetologist, nurse, dietitian and psychologist) was involved.

To the *Telemedicine Group*, plus the standardization protocol, was asked to store the parameters before mentioned, on each personal profile of online website, day by day, to have telemonitoring of the transmission of health data (Telemedicine protocol) by the team of Unit of Endocrinology and Diabetes, with a consequent real-time health feedback.

To the *Control Group*, plus the standardization protocol, was asked to store, the parameters before mentioned, in a diary (*Traditional protocol*). For the *Telemedicine Group* the data was stored by the patients on each personal profile of online website, day by day.

For each patient, was valued the number of doses of insulin/day (bolus/day) and number of self-monitoring of blood glucose/day (SMBG / day).

So for each patient was reported: the value of glycosylated hemoglobin test (HbA1c) at month: 0,6,12,18,24,30,36,42,48,60 in the years since 2009 to 2014; number of boli/die and SMBG/die.

A. Statistical Analysis:

At the end of the study, the recorded outcomes were analyzed using GrafPad software. Difference between the mean values of HbA1c, bolus/day and SMBG/day in two groups was statistically compared and analyzed by student-t test, standard deviation and When p-value was < 0.05, it was considered as statistically significant. When p-value was<0.01, it was considered as very statistically significant.

III. RESULTS

Results showed that both groups were homogeneous on the socio- demographic characteristics. Mean follow-up duration was more than 60 months.

As reported in Table 1, the observed HbA1c decrease in the *Telemedicine Group* was associated with a better compliance to therapy in terms of frequency of sensor use, number of SMBG tests and number of insulin boluses. Our data showed that there is, for the two groups, in the last year of observation, statistically significant difference ($p< 0.004$) of mean values of HbA1c associated to: significant differences of number boli/die ($p=0.036$) and very significant difference ($p=0.001$) between number of SMBG/die in the five years of observation.

Patients in *Control Group* tendency have values of $8 < HbA1c < 12$, individual patients tend to have higher average of HbA1c equal to 8 even surpassing this threshold.

Patients of *Telemedicine Group* tendency have values of $6 < HbA1c < 10$, individual patients tend to have lower average levels of HbA1c to 8. In Figure 1 is reported the HnA1c trand of two group.

The analysis of the graphs shows a increase of boli/day for patients in *Telemedicine Group* higher than patient in *Control Group*. Patient in *Telemedicine Group*, noncompliance with recommended *Telemedicine protocol* had value of HbA1c comparable of patient in *Control Group*. Again, patient of *Control Group*, more compliance at *Traditional protocol* had vale of HbA1c similar of patient in *Telemedicine Group*.

IV. CONCLUSIONS AND FUTURE WORK

Telemedicine can increase the self-management of disease in pediatric patient with diabetes by increase the number of boli/die and SMBG/die with consequent reduction of HbA1c test value. In our study we compared two groups of SAP treated Type 1 Diabetes adolescents followed for a long period (five years).

The *Telemedicine Group* was followed by standardization protocol of education and storage data on each personal profile means online website, day by day, to have telemonitoring of the transmission of health data (*Telemedicine protocol*) by the team of Unit of Endocrinology and Diabetes, with a consequent real-time health feedback (plus periodic ambulatory visit).

While the *Control Group* was followed by *Traditional protocol* manner with standardization protocol of education and only periodic in-hospital visits consultations and storage data in a diary.

We demonstrated a favorable impact of frequent (monthly) Tele-assistance on compliance to therapy: in fact, patients receiving a frequent feedback by the medical/multidisciplinary team, due to the

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telemonitoring, resulted more compliant to self-management of diabetes then patient in *Control Group* followed with traditional trials, without telemonitoring by the multidisciplinary team. In *Telemedicine Group* frequency of sensor use, as well of SMBG tests, and consequently frequency of insulin boluses, were significantly higher as compared to the *Control Group*. This improved compliance to the therapy and to the global management of the disease, seems to have a direct effect on the glycometabolic control. The results of our study, in fact, demonstrated a better level of HbA1c even after a long period of follow-up in Telemedicine.

In conclusion, our study demonstrated that when remote assistance (Telemedicine) is added to technology (SAP Therapy) we may assist people living with type 1 diabetes to become more compliant to self-management of the disease. More and wider studies are needed in order to confirm this data and better define populations appropriate for the Telemedicine approach.

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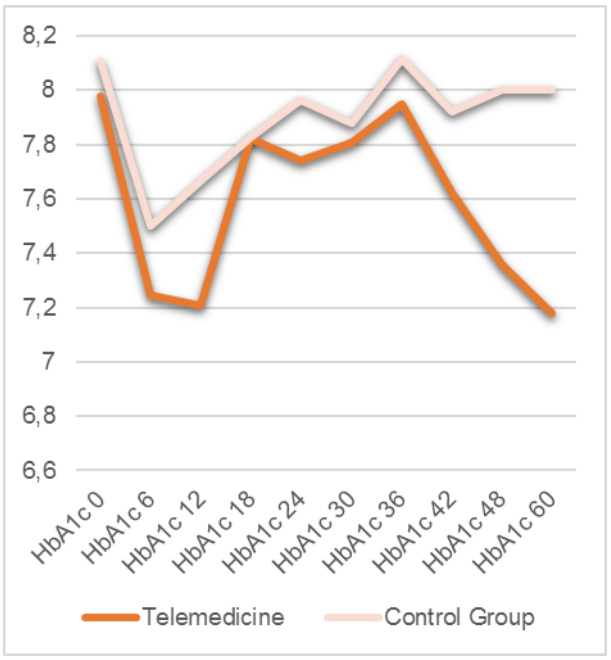

Fig. 1 Trand of HbA1c levels during the follow-up period in *Telemedicine Group* and *Control Group*.