Transition to Adult Care for Youth with Type 1 Diabetes Mellitus

Structured Support Aids for Adolescents and Young Patients in Morioka Area, Japan

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Abstract-In clinical practice for adolescents and young adults with childhood onset diseases, transitional medicine represents an important element. Type 1 Diabetes Mellitus (T1DM) is a disease that requires patients, their families, and health care professionals involved to face a wide range of problems, including early development of complications, decreased quality of life, socioeconomic problems, and developmental psychological problems. The transition to adult health care is often not smoothly carried out for young patients with this disease. In this paper, first, we discuss problems in this area, including differences between paediatric and adult clinical settings for diabetes care, insufficient preparation for transition, and dissatisfaction of patients and families during transition. Next, we propose a clinical trial, providing a seamless transitional process to the young patients with T1DM at a joint clinic operated by both pediatricians and physicians, trying to ascertain the changes in psychological burden on the patients, quality of life due to transition, self-care behaviors, and blood glucose control during the transition.

Keywords-Type 1 Diabetes Mellitus; Transfer; Transition; Joint Clinic; Bridge Clinc.

I. INTRODUCTION

Progress in medicine over the last decades has given rise to increased survival of children with complicated paediatric diseases who reach adulthood [1]. The transfer of adolescents and young adults from paediatric to adult health care is a complex operation that may generate various difficulties for all participants. The actual operation is called "transition". This process requires young patients to get skills to increase their self-determination and become more responsible and prepared to face self-care, and for their families and health care professionals to be inclined to guide them [2].

Importance of transitional medicine has been recognized throughout the world, but discussion and consensus formation between paediatricians and physicians seem still inadequate. It is an urgent issue to prepare transition systems so that the adolescent and young adult patients can receive appropriate transitional process, considering changes of patients' status, progression of complications, and physical and personality maturity along with age. There are, however, the limited number of researches on the actual condition and problems of the transition of young patients with chronic diseases. Specialised medical facilities bridging transition are globally rare, as well. It is crucial to promote researches on this issue from the socioeconomic or psychological points of view, as well as from a clinical one.

In this article, first, we review and discuss problems in transition, focusing on Type 1 Diabetes Mellitus (T1DM), formerly referred to as juvenile diabetes mellitus, and then present a project to establish a transition system to cohere paediatric and adult health care for adolescent and young adults with T1DM around Morioka area in Iwate, Japan.

II. TYPE 1 DIABETES MELLITUS

Type 1 Diabetes Mellitus arises because of β -cell destruction in the pancreas [3]. It is supposed that 415 million people across the world have diabetes and that T1DM accounts for approximately 7–12% of the subjects [4]. This disease develops most frequently during infancy and adolescence, in people under 30 years. Both genetic and environmental factors may play crucial roles, however, the exact pathogenesis of T1DM remains still unclear.

Beta cells produce a hormone, insulin, which regulates blood glucose levels. Since endogenous production of insulin is generally absent or in very small quantities in the patients with T1DM, lifelong treatment with insulin, either by multiple injections or insulin pump, and with frequent selfmonitoring of blood glucose (SMBG) is required. Self-care is central to successful outcomes for individuals with T1DM and good diabetes management has been shown to minimise the risks of long-term and short-term complications [5].

Type 1 Diabetes Mellitus is a complex and demanding condition, which places a substantial behavioural and psychological burden on young people and their families. Diabetes management imposes considerable requirements, including nutrition guidelines, insulin regimens, glucose fluctuations, and SMBG, that are difficult for the patients to negotiate, specifically for children [6]. The transition into adolescence is often associated with poorer adherence to treatment, deteriorating metabolic control, and increased risk for psychological disorders [5]. In children with T1DM, parents are ultimately responsible for daily management of this disease, which can contribute to parental stress, distress, and diminished quality of life (QOL). Therefore, ensuring quality of life for the patients and their families, while maintaining glycemic control within targets, is an important challenge in diabetes treatment [7]. In addition, medical expenses also represent a large burden to both the patients and their families. Indeed, poor glycemic control in paeditric T1DM is associated with lower socioeconomic status [8].

III. EMERGING ADULTHOOD

The developmental period from ages 18–25 years has been termed "emerging adulthood" [9]. During this stage, many young adults leave their family homes, become financially independent, start working, and seek intimate relationships with partners [10]. Competing academic, economic, and social priorities often detract from engagement to chronic disease management. Even if young adults face these competing demands, they have not achieved all of the skills necessary to remain independent and accept these responsibilities on their own [9]. In addition, during this relatively healthy time in their lives young adults feel markedly invulnerable, and have a tendency to reject adult control.

The transition to emerging adulthood may give a tall order to those with T1DM. During this stage, on-going family involvement in diabetes management is necessary to reduce the risk of deterioration in glycemic control that often accompanies adolescence [11]. On the contrary, in addition to the new responsibilities and freedoms, those managing T1DM become more and more responsible for their selfcare, with daily requirements including SMBG and insulin dose adjustments, and routine activities such as scheduling physician appointments, ensuring availability of sufficient stocks, and taking care of themselves when sick. It may be unrealistic to expect the person with diabetes in the early phase of emerging adulthood to make major changes in their diabetes management strategies, or even to transition to a new adult diabetes health care provider [12]. The demands of managing the complicated illness like T1DM must be integrated into the standardised changes in occupation, education, relationships, and living situations that accompany emerging adulthood [13].

IV. CULTURAL DIFFERENCE BETWEEN PAEDIATRIC AND ADULT DIABETES CARE

The management of T1DM in paediatric care differs in various ways from adult setting. In general, paediatricians are not accustomed to the needs of young adults, and physicians are trained with different viewpoints of diabetes care. Furthermore, the psychosocial environment and expectations differ markedly between two settings, and paediatric and adult providers have different ideas on transition [14]. Indeed, the adolescents and young adults experienced cultural difference during the transition. While children's care was generally characterized by close, supportive relationships with staff, lower anticipation of patient responsibility, and significant parental involvement, adult care was considered less supportive and less personal, with frequent changes in staff and decreasing involvement by parents [15]. This shift in culture was sometimes experienced as very precipitate [16]. Some felt out of place in adult services, many were less satisfied with adult care than children's care [17].

V. IMPACT OF TRANSITION ON GLYCEAMIC CONTROL, ATTENDANCE AT HEALTHCARE APPOINTMENTS, AND DIABETES-RELATED HOSPITALIZATIONS

A systematic review or meta-analysis by Sheehan et al. [18] tried to examine the impact of transition from child to adult health care on health outcomes and health behaviours for young people with child-onset T1DM.

In nine observational studies that assessed the impact of healthcare transition on glycaemic control either by examining changes in HbA1c following transition, five reported no change in HbA1c, one found an improvement in HbA1c for females, and one reported an increase in HbA1c. The remaining two studies, which compared young adults who had transitioned to adult care with those who remained in children's services, found lower HbA1c levels in those who had not transitioned to adult care. In the 10 studies examining transition programmes or interventions, four reported no change in HbA1c between pre- and posttransition and six reported an improvement. Programmes demonstrating improvements incorporated a range of elements, including joint clinics, letters to patients summarizing medical history and support programmes.

Out of 8 observational studies, which assessed the relationship between healthcare transition and clinic attendance, four studies reported less-frequent attendance post-transfer compared with pre-transfer. Change in the frequency of attendance post-transition, where transition programmes or interventions were in place, was assessed in five studies, and all studies found reduced attendance rates post-transition.

In 4 observational studies that examined the relationship between diabetes-related hospitalizations and healthcare transition, no change in hospitalizations were found in 2 studies, one study found an increase in hospitalization frequency, and the remaining study found fewer diabetesrelated hospitalisations in those who remained in paediatric care.

VI. RESISTANCE TO NEW PHYSICIANS

Young people with T1DM generally experienced greater difficulties in accessing and keeping their own heath care after transition [19]. They felt that adult clinics were less reachable because of less-frequent appointments and less multi-dimensional support, and had difficulties in building consistent relationship with their new health caretakers. Clinic cancellation rates were higher in adult services [20]. Engagement may have been disturbed by various reasons, for example, the location and opening hours of adult clinics, capacity to travel, other appointments such as work or education, parking difficulties or transport costs and latency time [21]. Patients in adult services were reportedly less likely to be followed up if they did not attend their appointments and were not automatically rebooked [22]. Within adult diabetes clinics, young adults preferred consultations with familiar health care staff [22]. Health care staffs in adult health providers tend to make generalisations and judgements in relation to young adults, which undermined relationship development within the clinic [22]. Fear or perception of being told off or judged by health care professionals for unsatisfactory glycaemic control was a barrier to clinic attendance studies [22]. Young adults felt health care staff did not take the time to understand the struggle they experienced to achieve glycaemic control [23]. Some felt out of place in adult services and that the care was inappropriate for the needs of their age group [21], many were less satisfied with adult care than children's care [22].

VII. PSYCHOLOGICAL AND SOCIOECONOMIC ISSUES

Mental health is a more common concern among young adults with T1DM than those without it, which is usually a miscalculated problem [25]. A recent study found much higher prevalence of psychosocial illness among adolescents with T1DM than those without it [55.95% vs. 20%; P<0.0001] [25]. Major depressive disorder was the most common, while conduct disorder and generalized anxiety disorder were less. Depression and anxiety have been identified as a risk factor for impaired adherence to diabetes care and higher HbA1c [26]. It is important to monitor and refer older adolescents and young adults with T1DM to appropriate mental health resources [12].

Substance use was common among adolescents and young adults with T1DM, as well as those without diabetes. High-risk alcohol use has been reported in 12.9% of 14–19-year old patients with T1DM [27]. The effects of alcohol on glucose and a risk for hypoglycaemia unawareness should be made well known to the young people with T1DM [27]. Among patients with diabetes, tobacco use is an independent modifiable risk factor for development of cardiovascular diseases, diabetic neuropathy, and nephropathy [28]. Illicit drug use has been found to be a risk factor for non-adherence and diabetic ketoacidosis (DKA) [29].

Eating disorders and eating disordered behaviour also are of concern in adolescents with T1DM. Rates of eating disorders among adolescents with T1DM are estimated at 10%; it is twice as high as in girls without diabetes and e the incidence of eating disorders increases into young adulthood [30]. Insulin restriction is the most concerned eating disordered behaviour for adolescents with T1DM, which results in hyperglycaemia creating glucosuria leading to weight loss. This behaviour is very common and could occur in patients who do not meet criteria for an eating disorder [30].

Pregnancy planning is an important topic to be young woman with T1DM. The American Diabetes Association (ADA) recommends preconception planning should be discussed with all women with T1DM starting at puberty [12]

Lack of access to adequate health care coverage remains to be one of the most significant issues to transition for the emerging adult population with T1DM. They may have increased pressure to secure full-time employment to maintain health insurance for on-going medical care for their chronic illness because of changes in legal status and living situation that occur in early adulthood. Due to high co-pays, some may be pushed to switch to less optimal insulin use or become less adhered to diabetes care [31].

VIII. STRUCTURED SUPPORT AIDS FOR THE ADOLESCENT AND YOUNG PATIENTS IN MORIOKA AREA, JAPAN

A. Transition Trial

1) The aims of this study

The first aim of the present study is to provide a seamless transitional process to the young patients with T1DM, considering changes of patients' status, progression of complications, and physical and personality maturity along with age, at a joint clinic operated by both paediatricians and physicians. We also endeavour to ascertain the changes in psychological burden on the patients, quality of life due to transition, self-care behaviours, and blood glucose control during the transition.

B. Method/Design

1) Design

A prospective, uncontrolled trial is conducted in Morioka Children's Hospital [paediatric and joint clinics], and Iwate Medical University (an adult clinic). The structured transition program is a multidisciplinary intervention designed to provide additional support in the transition period, which include age-specific education and counselling on basic knowledge on diabetes, sick days, family planning, pregnancy and childbirth, drinking and smoking, and carbohydrate counting, by paediatricians, physicians, nurses, registered dieticians, and clinical psychologists. A web site provides information on the joint clinic by a newsletter, and downloadable forms of useful knowledge for diabetes selfmanagement. Central to the program is use of the flash glucose monitoring system FreeStyle Libre (Abbott Diabetes Care Ltd., Witney, UK) to acquire flexible insulin therapy corresponding to dietary modification, including the carbohydrate counting. Subjects are seen in the paediatric care setting, the joint clinic at the Children's Hospital, for 12 months and then transferred to the adult care setting where they are seen for one year. There will then be a one-year follow-up period for outcome assessment. This study is going to be approved by the Institutional Review Board of Iwate Prefectural University, Iwate Medical University, and Morioka Children's Hospital, respectively. All participants must complete an informed consent at study enrolment. The competitive research funding by Iwate Prefectural University is financially supporting this project.

2) Participants

a) Inclusion criteria

- Established T1DM diagnosis for a minimum of one year
- Older than 15 years of age
- At least 1 visit during the previous year with the paediatric endocrinologist at Morioka Children's Hospital

- Ability to participate in all aspects of this clinical trial
- Written informed consent/assent must be obtained and documented
- Willingness to participate in the joint clinic and to be transferred to the adult clinic
- Resident of Iwate Prefecture
- b) Exclusion criteria
- Pregnant or lactating females or intent to become pregnant during the next 3 years
- Condition(s) which in the opinion of the investigator may interfere with the subject's ability to participate in the study
- Prior enrolment in the current study
- Prior enrolment of a sibling in the current study
- Current participation in another clinical trial or participation in another clinical trial in the 6 months prior to enrolment
- *3) Study procedures*

a) Recruitment

Eligible patients are identified in Morioka Children's Hospital. The investigators introduce the study and provide a document on information to all eligible patients. If the prospective participant agrees to be approached, the investigators make contact during the clinic to answer any questions or concerns regarding the study. If the subject agrees to participate, informed consent is obtained at the time or at the next routine paediatric clinic visit. The researchers make contact during the clinic to answer any questions or concerns regarding the study.

b) Baseline assessment

Once consent has been obtained, the baseline assessment is completed as part of the initial visit. Baseline characteristics collected are: age, gender, level of education, family structure, distance from the treatment centre, smoking and alcohol use, comorbid conditions, concomitant medications, and family history of diabetes. In addition, baseline assessment includes detailed initial medical history, measurement of weight and height, blood pressure, centralized venous A1C, insulin use, clinic attendance, and completion of baseline patient satisfaction questionnaires.

- c) Hisotorical measures
- Sociodemographic: age, sex, level of education, persons living with participants/ family structure, and distance from the treating centre
- Medical history: detailed initial medical history; family history of diabetes-related complications, social habits (smoking, alcohol, illicit drug use), follow-up interim history with focus on hospital visits for hypoglycaemia and diabetic ketoacidosis
- Insulin dosage and method of delivery
- Frequency of medical care (retinal, monofilament, lipid profile testing and microalbumin to creatinine ratio)
- Concomitant medications: all longstanding therapies, with the emphasis placed on insulin therapy

- Questionnaires (Diabetes therapy Related QOL; Problem Areas in Diabetes; Summary of Diabetes Self-Care Activities)
- d) Physical examination measures
- Anthropometric measurements: height, weight, and BMI
- Blood Pressure
- Systems physical examination: general survey, skin, head, neck, chest, heart, abdomen, musculoskeletal/ extremities, and neurologic (including lower extremity monofilament testing)
- Laboratory measures A1C, lipid profile, creatinine

e) Transition interventions

The structured transition program is a multidisciplinary intervention aiming to provide additional support during the transition period, which include age-specific education and counselling on basic knowledge on diabetes, the differences in the structure of adult and paediatric diabetes care, sick days, family planning, pregnancy and childbirth, drinking and smoking, and carbohydrate counting by paediatricians, physicians, nurses, registered dieticians, and clinical psychologists. Written information is provided. The intervention lasts 24 months, 12 months at a joint clinic in paediatric care and 12 months in adult care. Recommended revisits interval ranges 4-8 weeks. At every visit, laboratory tests are performed. The participants complete the questionnaires at the beginning and the end of the joint clinic, and the end of the adult clinic.

f) Primary outcomes

The primary objectives of the study are:

- To compare the mean A1C levels before and after the transition clinic, or before and after the adult clinic
- To compare the rates of diabetes related emergency room visits and hospitalizations for DKA and hypoglycaemia before and after the transition clinic, or before and after the adult clinic
- To compare the patient satisfaction and perception of the care before and after the transition clinic, or before and after the adult clinic, using selfadministered questionnaires
- g) Adverse events and safety

Due to the nature of the intervention, it is not expected that serious adverse events related to the intervention will occur. However, adverse events will be collected from the time of signing the Informed Consent. The following adverse events will be recorded in the subject's medical records and on the case report form:

- Any medical occurrences requiring medical intervention
- Any action or outcome (e.g., hospitalization, discontinuation of therapy, etc.) will also be recorded for each adverse event

IX. DISCUSSION

Mental health is a more common concern among young our knowledge, this study is the first project to perform a prospective evaluation of a structured transition program in Japan. This study incorporates the recent recommendation of the American Diabetes Association (ADA) [32], for transition from paediatric to adult care, emphasizing that "Both paediatric and adult diabetes care providers should provide support and links to resources for transitioning young adults."

To date, there are no studies that have directly compared various transition interventions, and there is a limited number of clinical trials on transitional medicine in the T1DM field. In our present project, we follow the transition procedure of randomised controlled trial by Sequeira PA, et al [33], the Let's Empower and Prepare (LEAP) study, which included 51 young patients with T1DM, and successfully facilitated their transition to adult care without a decrease in clinical follow-up. The LEAP program provided had four major components that we inherit in our study, diabetes education tailored to patients' developmental stage, a joint clinic operated by both a paediatrician and a physician, carbohydrate counting education, and a private social networking website to facilitate social support. Indeed, the LEAP study first proved the efficacy of tailored diabetes education and joint clinic in the transition [33]. Carbohydrate counting is a popular method of calculating grams of carbohydrate consumed at meals and snacks, allowing patients with T1DM to adjust the mealtime insulin dose considering the amount of carbohydrates to eat. There is significant evidence that this method improves blood glucose controls and quality of life of the patients [34]. We introduce a modification to this meal planning method with novel a novel flash glucose monitoring system for interstitial glucose measures, which significantly reduced time in hypoglycaemia without deterioration of HbA1c, and improved treatment satisfaction [35]. Internet-based selfmanagement among young patients has found some success [36]. Recent trends indicate a major shift to incorporate mobile telecommunication technologies into health behaviour interventions. These technologies offer several advantages for health behavioural interventions, including information and messages tailored to the participant, quick access, increased cultural sensitivity, and anonymity, which may be attractive regarding sensitive health issues [37].

X. CONCLUSION

Psychological and socioeconomic issues characteristic of young adults with T1DM similar to those reported in the Caucasian population were found in our study, as well. Continuous and developmentally tailored diabetes medical care by health care providers trying to integrate the patient's life circumstances is central to resolution of these issues. The findings of the current project are expected to support the routine implementation of standardized intervention during the transition period not only in T1DM, but also all other areas of care for emerging adults with chronic medical conditions.

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