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## Evaluation of therapeutics management patterns and glycemic control of pediatric type 1 diabetes mellitus patients in Turkey: A nationwide cross-sectional study

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### ABSTRACT

**Aims:** To evaluate the management strategies, glycemic control and complications of pediatric type 1 diabetes mellitus (T1DM) patients in Turkey.

**Methods:** Study included 498 patients with T1DM between the ages 1–18. Data provided from patients' hospital files were recorded on standard case report forms by applicant clinicians within the 3 months of data collection period between October 2012 and July 2013.

**Results:** Mean age of patients was  $11.3 \pm 3.8$  years. Mean duration of DM was determined as  $3.7 \pm 3.1$  years. Majority of patients (85.5%) used basal/bolus injection (BBI), and 6.5% used continuous subcutaneous insulin infusion pump. Assessment of glycemic control based on HbA1c levels showed that 29.1% of patients had an HbA1c value  $<7.5\%$  (58 mmol/mol), 16.1% had a value between 7.5% (58 mmol/mol) and 8% (64 mmol/mol), 19.1% had a value between 8.1% (64 mmol/mol) and 9% (75 mmol/mol) and 35.7% a value  $>9\%$  (75 mmol/mol). Hypoglycemia was reported in 145 (29.1%) patients and the number of severe hypoglycemic attacks in the last 3 months was  $1.0 \pm 2.4$ . Taking into consideration the carbohydrate count and insulin correction dose and parents with high socioeconomic status was related to have better glycemic control. The most common comorbidities were Hashimoto's thyroiditis/hypothyroidism (6.2%) followed by celiac disease (3.8%), epilepsy (1.2%), and asthma (1.0%).

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**Conclusions:** BBI insulin therapy is widely used among pediatric T1DM patients in Turkey. However, despite improvements in treatment facilities and diabetic care, glycemic control is not at a satisfactory level. Therefore, new and comprehensive initiatives require for pediatric T1DM patients with poor glycemic control. Promoting use of carbohydrate count and insulin correction doses may improve the glycemic control of pediatric T1DM in Turkey.

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## 1. Introduction

Type 1 diabetes mellitus (T1DM), one of the most common chronic diseases in childhood, has an increasing trend in the world. The two largest studies, DIAMOND and EURODIAB, evaluating the incidence trends of T1DM, have shown an increase in T1DM incidence throughout the world except Central America [1,2]. The new cases in Europe are expected to be approximately 24,400 in 2020 with a higher rise in the incidence of patients under the age of 5 years. In Turkey, except for limited number of regional reports there is lack of studies on epidemiology of pediatric diabetes [3–6]. Akesen et al. [3] in a regional study conducted on 1,630,751 schoolchildren in Istanbul, reported the prevalence of T1DM in 6–18 year-old schoolchildren as 0.67/1000. Recently, Yeşilkaya et al. reported nationwide prevalence and incidence of T1DM as 0.75/1,000 and 10.8/100,000 respectively [6]. Furthermore, except for a multicenter study reported by Simsek et al. [7], there is no nationwide study conducted on management strategies of T1DM in Turkish children yet. However, collecting a large database could provide valuable data for establishment of national/international strategies in the management of pediatric T1DM patients.

This study, to best of our knowledge, is the first observational study that focuses on the treatment patterns of T1DM in Turkey. The aim of the study is to evaluate the insulin regimen patterns and insulin types, glycemic control, comorbidities and acute and chronic complications of T1DM in a large series of 1–18 year-old pediatric patients who are being followed in different pediatric endocrinology centers throughout Turkey.

## 2. Subjects and methods

### 2.1. Subjects

This national, multi-centered, observational, cross-sectional study included 498 T1DM patients between the ages of 1–18 from 33 tertiary pediatric endocrine centers from 7 different geographical regions throughout the Turkey.

### 2.2. Methods

Data were collected using a standard case report form (Table 1). The centers were selected according to the geographic distribution of pediatric endocrinologists. In addition to the geographic distribution, the distribution of the participant physicians in relation to their institutions such as university hospitals, training and research hospitals, public

hospitals, private hospitals, private offices etc. was also considered. To reach the targeted number of patients, at the beginning of the study each clinic has declared the number of patients they can include. Data collection had started once the number of patients declared reached to the targeted value. The T1DM patients were recorded by an authorized clinician from each center consecutively starting from the first outpatient clinical visit, between the study period of October 2012 and July 2013. Data were collected at a single visit for each patient.

The primary endpoint of the study was to evaluate the therapeutic management patterns including the insulin types and the insulin application regimens for pediatric patients with T1DM in the current medical practice in Turkey. The secondary endpoints were latest HbA1c value available at the visit day or within the last 3 months; latest fasting blood glucose value (according to patients' records within last 24 h); self-monitoring of glucose available at the visit day or within the last 3 months; the percent of pediatric T1DM patients achieved HbA1c  $\leq$  7.5% (58 mmol/mol) and percent of those attained the individual target HbA1c as set by the investigator; complication rate; the dose and routes of administration of insulin and type and number of trainings given for T1DM. In the assessment of glycemic control an HbA1c < 7.5% (58 mmol/mol) was accepted targeted for all age groups [8]. An HbA1c between 7.5 (58 mmol/mol) and 8.0% (64 mmol/mol) was considered as acceptable, between 8.1% (64 mmol/mol) and 9% (75 mmol/mol) as in fair and >9.0% (75 mmol/mol) as in poor glycemic control [9]. The data for comorbidities and complications was provided either from the patients' previous records or from the last follow up visit data recorded to the case report forms (CRF) by clinicians.

Hypoglycemia episodes was recorded as the number of episodes with blood glucose level <70 mg/dl in the last 1 month or number of mild (symptoms of hypoglycemia without confusion and can be resolved without glucagon injection) or severe (hypoglycemia with confusion and/or glucagon requirement) hypoglycemia episodes in the last 3 months according to patients' self-monitoring data.

### 2.3. Sample size justification and statistical analysis

Data about practice patterns in the management of pediatric T1DM patients in Turkey was not available. Moreover, the number of pediatric patients with T1DM was also not well known. According to data provided from the database of National Social Security Institute, the only authorized institution for approval of covering the cost of insulin therapy, it was estimated as more than 10,000 patients. A total of 384

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