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A STUDY ON DRUG REGIMEN AND LIFE STYLE MODIFICATION OF TYPE 1 DIABETES MELLITUS IN CHILDREN AND ADOLESCENTS

Syeda Lubna Samreen[1], Sandaram Kavitha[1], Rumana Khanam[2], T. Mounika Reddy[1], Kaneez Fathima[2] ,Saniya naaz[1], Paspula Soumya[2*]

[1]Pharm. D Intern, Smt. Sarojini Ramulamma College of Pharmacy, (Palamuru University), Seshadri Nagar, Mahabubnagar District, Telangana State, India.

[2]Assistant Professor, Department of Pharmacy Practice, Smt. Sarojini Ramulamma College of Pharmacy, (Palamuru University), Seshadri Nagar, Mahabubnagar District, Telangana State, India.

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Abstract

Type 1 diabetes mellitus (T1DM) impacts millions of individuals worldwide and necessitates meticulous management to prevent severe long-term complications, such as cardiovascular and renal diseases, stroke, and vision impairment. People with T1DM are very different from one another. They show signs of the disease at different stages and levels of severity, and their genetic backgrounds and disease causes are also very different. This 6-month study focused on patients with T1DM at the paediatrics department of SVS Medical College and Hospital in Mahbubnagar. We collected and evaluated data from one hundred patients. This study underscores the significant impact on individuals aged 11-15 years, and our research findings reveal a higher prevalence of T1DM in males. We also conclude that obesity presents the highest risk of hyperglycaemia. Currently, the standard treatment for T1DM involves exogenous insulin substitution therapy; however, this method does not consistently provide optimal blood glucose control for many individuals. In addition to the appropriate insulin regimen, we also advocate for lifestyle management, which seeks to implement "the right therapy at the right time, for the right patient." As previously stated, innovative strategies are essential for T1DM prevention and management. We also recommend that physical activities provide multiple benefits for individuals with T1DM. Regular physical activity improves overall well-being, aids in obesity prevention, and reduces cardiovascular risk in patients with type 1 diabetes mellitus.

Keywords: Hyperglycaemia, lifestyle modifications, Insulin, Physical Activity, Obesity.

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***Corresponding Author**

Paspula Soumya

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Introduction

Diabetes is a prevalent metabolic disorder worldwide. In 2021, there were approximately 355,900 new cases of type 1 diabetes (T1D) diagnosed among children and adolescents worldwide. Western and Northern Europe, New Zealand and North America reported the highest percentage of new cases, whereas South and East Asia, West Africa, and Melanesia exhibited the lowest percentages, likely attributed to underdiagnosed cases. Forecasts suggest that the trend will persist, with 476,700 new cases predicted by 2050 [5, 6]. Effective management of T1D necessitates an appropriate pharmacological approach, encompassing insulin regimens and a well-structured nutritional plan [7, 8, 9]. Researchers have linked suboptimal glycaemic control, marked by postprandial hyperglycaemic spikes, to decreased adherence to recommendations. The presence of these spikes leads to endothelial damage and inflammation, along with an increase in oxidative stress, which in turn heightens cardiovascular risk in individuals with diabetes [10, 11]. In this context, the effective management of postprandial blood glucose is essential for reducing micro- and macrovascular damage, as evidenced by numerous studies involving diabetic patients [12, 13].

A child's diet plays a critical role in managing their type 1 diabetes. According to the "International Society for Paediatric and Adolescent Diabetes" (ISPAD) guidelines, a child's daily energy intake should consist of 45–50% carbohydrates, 30–35% fat (with saturated fat being less than 10%), and 15–20% protein [14]. These dietary recommendations apply to both diabetic and healthy children. A balanced diet's primary objectives are to

prevent overweight and obesity, guarantee normal development, and help maintain optimal glycaemic control. Eating three major meals and two snacks, combined with a regular mealtime schedule, constitutes a good dietary pattern. They should have dinner at least two hours before bedtime, and their primary meal, breakfast, should make up about thirty percent of your daily calorie intake [15-19].

Carbohydrates are the primary macronutrients in the diet, comprising 45–50% of daily energy intake and yielding 4 Kcal/g. The glycemic index (GI) and glycemic load (GL) denote the qualitative and quantitative attributes of carbohydrates and their impacts on blood glucose. We should place special emphasis on simple sugars, whose consumption should not exceed 8–10% of daily energy needs, as their rapid absorption causes elevated and transient glycaemic spikes (Figure 1). High- and moderate-glycaemic index foods encompass not only processed items and sugary beverages, linked to weight gain and best avoided, but also certain fruits that induce glycaemic spikes, whereas others, like blueberries, raspberries, and blackberries, promote a more gradual increase in blood sugar levels. It is crucial to maintain a sufficient daily consumption of fruit (maximum 300 g/day) to provide a sufficient supply of micronutrients, including vitamins and minerals. We underscore the significance of dietary fibers, which facilitate a gradual intestinal absorption of carbs, leading to a more stable glycemic peak [21]. Fats should constitute 30–35% of daily caloric consumption and provide 9 Kcal/g of energy. Animal products contain saturated fats, while plant items mostly contain unsaturated fats. A nutritious diet should prioritize unsaturated fats, especially polyunsaturated fats (PUFAs) like omega-3 and omega-6, as they are associated with maintaining optimal lipid balance and lowering cardiovascular risk. Furthermore, lipids provide the fat-soluble vitamins A, D, E, and K and contribute to delayed stomach emptying, which aids in preventing glycemic spikes [22].

Proteins, comprising 15–20% of the daily diet, give 4 Kcal/g of energy among the macronutrients. Proteins are present in both animal sources (e.g., eggs, meat, fish) and plant-based meals, such as legumes. They mostly serve a structural role by facilitating development; however, in some instances, such as in untreated Type 1 diabetes, they operate as a metabolic resource [9]. Studies have shown that foods rich in fat and/or protein cause a delayed and sustained increase in blood glucose levels, likely due to the influence of lipids on prolonging stomach emptying time [20, 23]. Therefore, to prevent hyperglycemic spikes, modify the preprandial insulin dose by considering not only carbohydrates but also other macronutrients. Additionally, consider administering a double bolus of ultra-rapid insulin at staggered intervals. Smart et al. examined the individual and synergistic impacts of a high-fat and high-protein meal on blood glucose levels while maintaining a consistent carbohydrate intake in a cohort of 33 children aged 8 to 17 years with Type 1 diabetes on insulin treatment. Protein and fat had a delayed impact on postprandial glycemia: specifically, a high-protein meal elevates glycemia after 3 hours, maintaining its effect for up to 5 hours, whereas a high-fat meal affects glycemia after 3.5 hours. The simultaneous consumption of high-protein and high-fat meals correlated with a more significant elevation in blood glucose levels within a timeframe of 3 to 5 hours [23, 24]. Thus, high-protein meals lead to an extended glycemic elevation lasting up to 5 hours, offering preventive benefits against hypoglycemia episodes [25].

Individuals with T1DM continue to rely on exogenous insulins as the primary therapeutic option. Researchers have developed various innovative formulations, analogs, and delivery systems since the isolation of insulin in 1921. The advancements in glucose monitoring have significantly contributed to the increased survival rates and life expectancy of individuals with T1DM [28]. Still, only a few people with T1DM meet the suggested glycemic and time-in-range goals [29], and high blood sugar is still a major risk factor for both short-term metabolic problems and long-term macro- and microvascular problems. Furthermore, exogenous insulin administration necessitates continuous glycaemic monitoring and dose adjustment to reduce the risk of hypoglycemia. The risk of all-cause mortality is approximately three times greater for individuals with T1DM compared to the general population. Furthermore, T1DM has demonstrated a stronger association with cardiovascular outcomes than any other condition, including type 2 diabetes [30-34].

As previously stated, innovative strategies are essential for T1DM prevention and management. Despite some constraints on progress, the evolving characteristics of T1DM patients suggest that effective disease management should not only ensure precise exogenous insulin titration but also incorporate other fundamental principles. It is critical to take proactive steps to prevent or postpone the loss of functional beta cell mass through immunomodulatory intervention or other disease-modifying strategies. Second, it is important to get the remaining beta cells to release insulin in a balanced way so that blood sugar levels don't change too much while using the lowest dose of exogenous insulin that is needed. Third, reducing the risk of long-term complications, including cardiovascular and renal outcomes, appears to be increasingly important.

Materials And Methods

Study sites, design, and period

This prospective observational research lasted six months and was carried out by the paediatric department of a 300-bed multispecialty teaching hospital. 100 prescriptions were examined in the research. Both inpatients and outpatients from the paediatric departments of SVS hospitals were able to participate once

the study protocol and written informed consent were authorized by the hospital's institutional ethics committee.

Inclusion Criteria

- Patients visiting department of Paediatrics and who are diagnosed with T1DM.
- Patients with age group of ≤18 years.
- Patients willing to give their consent for the study.
- Patients with familial history [parents/ siblings] of T1DM.

Exclusion Criteria

- Patients with a history of blood transfusion
- Patients with Type 2 diabetes mellitus.
- Patients having any malignancy/chronic systemic disease.

Method of data collection

- Patient consent form.
- Patient Data Entry Form.
- Questionnaire Form.

Study Procedure

This research design is prospective observation. We included eligible participants in this trial after obtaining their informed permission. We will design and implement the data collection form. The main components of this form are the patient's demographic information, the results of the laboratory tests, and a complete inventory of drugs. The research was carried out at the SVS Medical College and Hospital Paediatrics department. We used appropriate statistical methods to evaluate the necessary data from inpatient and outpatient patients for the research.

RESULTS

AGE AND GENDER WISE PREVALENCE OF TYPE 1 DIABETES MELLITUS

This study encompasses a total of 100 cases. Our research shows that most people with T1DM are between the ages of 11 and 15, with 55 cases (55%). The next age group is 6 to 10 years, with 32 cases (32%), then 16 to 20 years, with 8 cases (0.8%), and finally 01–05 years, with 5 cases (0.05%) (Table 1). The data clearly indicates that out of 100 patients, a higher proportion are male, with 74 patients (74%) more likely to develop T1DM compared to female patients, who account for 26 patients (26%) (Table 2).

Table 1: Table showing Age wise prevalence of T1DM

AGE	NO. OF PATIENTS	PERCENTAGE
01-05 Years	05	05%
06-10 Years	32	32%
11-15 Years	55	55%
16-20 years	08	08%
Total	100	100%

Table 2: Table showing Gender wise prevalence of T1DM

GENDER	NUMBER OF PATIENTS	PERCENTAGE
MALE	74	74%
FEMALE	26	26%
Total	100	100%

Body Mass Index In Type 1 Diabetes Mellitus

The data analysis shows that 48 patients, or 48% of the total, are overweight. 25 patients, representing 25% of the total, are of normal weight. Additionally, the BMI categorizes 18 patients, or 18%, as underweight, and 9 patients, or 9%, as severely underweight. Table 3 presents the information.

BMI	NUMBER OF PATIENTS	PERCENTAGE
Severely Underweight (<12.7)	9	09%
Underweight (12.8 – 16.5)	18	18%
Normal weight (16.6 – 25.9)	25	25%
Overweight (>26)	48	48%

Treatment Regimen for Type 1 Diabetes Mellitus:

The ideal insulin dose is one that effectively maintains glycaemic control while minimizing the occurrence of hypoglycaemic episodes. With the correct dosage, a child can achieve optimal growth and development. This study reveals that the obtained data indicates the use of short-acting or regular insulin in conjunction with intermediate-acting neutral protamine hagedorn insulin (NPH). To achieve the best results, administer regular insulin 20-30 minutes prior to meals, as its peak effect occurs within 3-4 hours and its overall duration of action lasts about 6-8 hours. Intermediate-acting insulin serves as basal insulin in split-mix or pre-mix (twice daily insulin) regimens, as well as in basal-bolus regimens. This type of insulin does not exhibit a uniform action; it has a notable peak effect occurring after 6-8 hours, with its impact diminishing over 12-14 hours.

We adjusted the insulin doses based on the units per kilogram of the individual's body weight. We determined the insulin dose using the established formula. The

formula for calculating total daily insulin requirements is as follows: TDI = 0.55 multiplied by the total weight in kilograms. Vials containing 40 units/ml and 100 units/ml of human regular and NPH insulin are available in India. Given this, we implemented a split-mix regimen. Utilizing a regimen of two insulin injections daily has demonstrated effectiveness in managing blood glucose levels. This regimen involves administering both short-acting (regular) insulin and intermediate-acting (NPH) insulin in the morning prior to breakfast and again before dinner. We administered about 50% of the total daily dose as basal insulin and the rest as primary insulin. Duals following this regimen need about two-thirds of the total daily dose in the morning, with the rest administered at night.

In clinical settings, we administered insulin subcutaneously. We implemented precautions to prevent intradermal injections, as they can cause discomfort and lead to suboptimal insulin absorption. Moreover, we generally avoid intramuscular injections due to their faster absorption rate compared to subcutaneous injections, which increases the risk of hypoglycemia. Optimal locations for injection include the abdomen (at least four finger breadths from the umbilicus), the anterolateral aspect of the thigh, the deltoid region, and the upper-outer quadrant of the buttock. Administering injections in the deltoid region and buttocks typically necessitates assistance from another individual, whereas a patient can independently perform injections in the abdomen and thigh.

Adverse Drug Reactions (Adr's) In Type 1 Diabetes Mellitus Treatment Regimen

The data indicates that a small subset of patients experienced adverse drug reactions associated with the insulin regimen. Hypoglycemia is a common side effect of insulin treatment that significantly impedes tight glycaemic control. The patient received a comprehensive overview of hypoglycemia symptoms, management strategies, and potential contributing factors, including exercise and the impact of delayed or skipped meals, during the insulin prescription process. Individuals experiencing hypoglycemia receive an oral glucose dose of 0.3 g/kg body weight, or approximately 5 g for a child weighing 15 kg. When glucose powder or tablets are not available, we used a solution of simple sugar (sucrose).

We noted weight gain in certain patients, which we linked to improved glycaemic control, as repeated hypoglycaemia may lead to heightened hunger and the direct lipogenic effects of insulin on adipose tissue. We proposed that the repeated use of a blunt needle and insulin administration at the same injection site resulted in lipohypertrophy in a small number of patients. Given the minimal discomfort experienced, the patient opted to persist with insulin injections in the lipohypertrophic area, which led to further hypertrophy and variability in insulin absorption. To resolve this matter, our physicians performed regular assessments of injection sites, especially in instances of unexplained blood glucose fluctuations. To effectively address this condition, we meticulously adhered to the rotation of sites and replaced the needle at consistent intervals, ideally after each injection.

Lifestyle Modifications for Management Of In Type 1 Diabetes Mellitus.

Effective lifestyle management is critical in managing T1DM. Understanding the impact of diet and physical activity on glycemia is critical for effective T1DM management.

- Maintaining glycemia within the normal to near-normal range while minimizing or eliminating hypoglycemia.
- Ensuring maintenance of optimal blood pressure, weight, and lipid levels.
- Ensuring sufficient nutrition to support healthy growth and development in children and adolescents.
- Prevent the onset or progression of diabetes-related complications, both microvascular and macrovascular in nature.
- Considering individual nutrition requirements, integrating personal, social, and cultural preferences. Enhancing overall health by making informed food selections.

Each diabetes patient received a tailored diet plan that accounted for their socio-cultural context, dietary habits, preferences, and work commitments to ensure effective adherence. The energy requirements for children are aligned with those of the general population. We evaluated the decrease in caloric consumption for individuals who are obese and overweight. We recommend maintaining a carbohydrate content of 50–55% and limiting the intake of sucrose to less than 10%. • Fat content: 25–35% Saturated fat and trans fatty acids should be less than 10%. Trans fatty acids are less than 1%. Polyunsaturated fat: less than 10% Monounsaturated fat: 10-20 percent • Protein content should be between 15% and 20%.

We also recommended incorporating exercise due to its numerous benefits for people with T1DM. Engaging in regular physical activity improves overall well-being and aids in obesity prevention, while also mitigating the heightened cardiovascular risk associated with T1DM patients. Also, while the results of different studies are mixed, regular physical activity may help control blood sugar levels a little better and lower the risk of microvascular complications. Therefore, we encouraged individuals with T1DM to engage in regular physical activity.

Additionally, a significant number of individuals with T1DM expressed an interest in sports; however, only a limited few may consider pursuing sports as a career. Therefore, T1DM should not hinder the capacity to achieve excellence in a selected sport. We achieved effective glycaemic control by counselling patients and caregivers on the significance of lifestyle management in T1DM control. The results indicate that, out of 100 patients, 82

are successfully managed their glucose levels through lifestyle modifications. This helped patients effectively manage their T1DM.While rest of them did not achieve positive results because of inadequate diet and lack of physical activity.

Discussion:

Type 1 diabetes mellitus impacts around 1.2 million children and adolescents globally within the 0 to 19 age range, with 149,500 new cases diagnosed annually. According to the International Diabetes Federation (IDF) Diabetes Atlas 2021, India reports the highest prevalence of Type 1 diabetes mellitus among children and adolescents globally. Our findings confirm the highest prevalence of T1DM in the 11–15 age group, in line with Yasmin, Masuma et al.'s study [31]. The results of an additional study prompted us to determine that males exhibit a higher susceptibility to T1DM compared to females, aligning with our findings [32].

The incidence of obesity among children and adolescents with T1DM is increasing, in conjunction with trends observed in the general population. Previous research from various regions of the world revealed that 25%–38.5% of children with T1DM had overweight and obesity. Our study also indicated that a significant proportion of T1DM patients are overweight, which presents an additional risk factor in managing T1DM [33]. Patients with T1DM receive the combination therapy. The combination therapy consists of Humulin R, which is a short-acting insulin, and Humulin N, an intermediate-acting insulin. Humulin R was administered before meals and Humulin N twice daily. The Humulin R begins to take effect approximately 30 minutes following injection. Humulin N begins to take effect within approximately 1 to 3 hours. Individuals have established the adjustment of insulin doses according to units per kg of body weight as a standard treatment for Type 1 Diabetes Mellitus [34]. Numerous studies indicate that engaging in physical activity, along with a healthy diet and a low-glycemic diet, can effectively reduce hyperglycemia. These lifestyle modifications have positive impact in 82% of patients, while 18% experiencing hyperglycemia because of inadequate diet and lack of physical activity [35].

Recommendations and Limitations

This study's main limitation from the use of a single fingerstick random blood glucose measurement for diabetes diagnosis, which may not align with the gold standard of HbA1c testing. Secondly, while there is some potential for bias, it is unlikely to significantly affect our estimates due to the presence of a very small proportion of non-respondents or individuals whose blood glucose samples were not collectable. This paper offers thorough estimates regarding the prevalence, awareness, treatment, and control of diabetes in Telangana, India, despite certain limitations. The results of this study could have a significant impact on the oversight and formulation of national protocols for diabetes regulation and management within the country.

conclusion

In recent years, individuals with T1DM and their healthcare professionals have experienced both hope and subsequent disillusionment over the elusive prospect of a treatment. Type 1 diabetes mellitus in adolescents and young adults is an escalating worldwide health issue, particularly in nations with low socioeconomic development indices and underdeveloped economies. The worldwide burden of Type 1 Diabetes Mellitus (T1DM) in teenagers is significant, but the death rate has decreased over the last three decades owing to advancements in healthcare. The increasing prevalence and severity of T1DM in children and adolescents necessitates the urgent introduction of lifestyle modification programs throughout childhood. Type 1 Diabetes Mellitus (T1DM) is a complex condition marked by fluctuating insulin requirements during various life stages, seasonal variations, and daily circumstances. Before, during, and after physical activity and meal consumption, variations in insulin requirements occur. Achieving stringent glycaemic control to avoid late diabetic complications while also preventing hypoglycaemia may be very challenging with various life demands. As a result, several people with T1DM have diabetic discomfort, significantly diminishing their quality of life. Avoiding sedentary behaviour is essential for glycaemic benefits. This shows how important it is to be physically active, especially at high frequency and intensity, to lower the risk of developing diabetic nephropathy, cardiovascular disease (CVD), CVD mortality, and all-cause mortality. Our study consistently demonstrates that, even in chronic T1DM, making favourable dietary choices and administering precise prandial insulin doses continues to pose difficulties. Furthermore, our findings indicate that increasing fiber consumption and substituting lipids and carbs with protein may improve glucose regulation and reduce arterial stiffness. Our study indicates that changes in diet, physical activity participation along with right insulin therapy reach good diabetes outcomes.

Abbreviations

T1DM: Type 1 Diabetes Mellitus
T1D: Type 1 Diabetes
ISPAD: International Society for Paediatric and Adolescent Diabetes
GI: Glycaemic index
GL: GlycaemicLoad
PUFAs: Polyunsaturated Fats
BMI: Body Mass Index
NPH: Neutral Protamine Hagedorn insulin
TDI: Total Daily Insulin
TDD: Total Daily Dose
IDF: International Diabetes Federation
CVD: Cardiovascular Disease
SVS: Sri Venkata Sai

Conflict of Interest

Authors confirm they have no conflicts of interest.

Author’s contributions

All authors contributed equally to the study as well as the analysis and interpretation of the data. All authors read the final manuscript and gave their approval.

Consent for publications

The final manuscript has been read and approved by all authors.

Ethics approval and consent to participate

The ethical committee clearance was obtained from the Institutional Ethical Committee of SVS MEDICAL COLLEGE HOSPITAL before initiating the study. Reference number: - IEC/DHR-005/2023/1512.

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