ADDIS ABABA UNIVERSITY

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DEPARTMENT OF PEDIATRICS AND CHILD HEALTH

The Magnitude and Associated Risk factors of Lipodystrophy among Type 1 DM Children and Adolescents on follow up at Black Lion Hospital Pediatric Endocrinology Unit

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Declaration

I Henock Hailu , declare that this study has been de one originally by me and all the materials I used are properly acknowledged

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Contents

Abstract

Background- Type 1 diabetes(T1DM) is chronic autoimmune disease that results from the progressive destruction of pancreatic beta cells, insulin deprivation and therefore, the patients require insulin therapy throughout their lives. Lipodystrophy is a common side effect of insulin use in T1DM patients, characterized by changes in distribution and volume of subcutaneous fat stores. Lipodystrophy therefore can also be lipohypertrophy experienced when fat starts accumulated at the areas where one applies insulin and lipoatrophy which is actually experienced when one loses his or her fat tissue. Severe clinical consequences may include insulin resistance in case of Lipodystrophy, episodes of poor glycemic control and worsened diabetes complications. Research recognizes the lipodystrophy's prevalence among T1DM patients to be 28-66%. Potential risk factors associated with lipodystrophy include duration of the diabetes, insulin use and incorrect method of insulin administration. Nevertheless, lipodystrophy epidemiology and risk factors in T1DM individuals can differ depending on geographical location and some settings.

Objective- The primary objective of this cross-sectional study is to determine the magnitude and risk factor of lipodystrophy, including both lipoatrophy and lipohypertrophy, among T1DM patients under 18 years of age receiving insulin therapy through subcutaneous injections with follow up at Black Lion Specialized Teaching Hospital Pediatric Endocrine clinic.

Methodology- A cross-sectional study will be conducted among Type 1 DM patients visiting pediatrics endocrine unit from Aug 2024 to Sep 2024. The data will be collected by trained interns with face to face interview by using pretested questioner. Data will be entered using Epi data version 3.5.1 and will be analyzed by SPSS version 26.0 and frequencies and percentages will be calculated to all variables. Binary Logistic regression was used to analyze the data.

Results: The study involved 140 participants, including 13 children (9.3%) under 5 years old, 30 (21.4%) aged 6 to 10, and 97 (69.3%) who were older than 11. There were 63 females (45.0%) and 77 males (55.0%), showing a slightly higher number of males in the group. The average BMI of the children was 20.5 ± 6 kg/m². On average, the participants had been living with Type 1 Diabetes for 6.71 years, with 93.6% using a mixed insulin regimen (NPH + Regular Insulin) and 6.4% on a Basal-Bolus regimen (Glargine + Regular Insulin). On the same token , 39 participants (27.9%) selected the thigh and arm as their preferred injection sites, while only 6

(4.3%) selected the abdomen. Of the participants, 43 (30.7%) did not rotate their injection sites on a regular basis, whereas 97 (69.3%) did. Lipodystrophy was more common in children with diabetes for more than five years (53 cases) than in those with less than five years (33 cases), according to the study.

Additionally, older children (11 years and above) also had higher rates of Lipodystrophy, with 55 cases versus 24 in younger children. The condition was more common among those receiving higher insulin doses for their age than among those on moderate doses. Furthermore, lipodystrophy was more prevalent in children who did not regularly rotate their injection sites, with 50 cases compared to 29 who did.

Overall, Our Study found a Prevalence of Lipodystrophy to be 56.4, which included Lipohypertrophy in 37.9% %,(95% CI: 30.0 - 46.0) of patiensts, Lipoatrophy in 12.1% of patients (95% CI: 7.2 -17.5), , and both in 6.4%(95% CI: 2.9 -11.4) . Of the 79 patients with Lipodystrophy, 57 (72.1%) had HbA1c levels above 7%, while 22 (27.9%) were below this threshold: Out of 140 children in the study ,74 children (52.8%) had at least one episode of hypoglycemia in the previous month, and 52 (70.2%) had frequent episodes, with 40 of those (76.9%) are patients with Lipodystrophy. At last , The study found that the thigh was the most common site for Lipodystrophy, and that only 28% of caregivers recognized Lipodystrophy, indicating a significant gap in understanding the complications associated with insulin injections.

IV. Acronyms and Abbreviations

EDHS: Ethiopian Demographic Health Survey

ETB: Ethiopian birr

P: Value Probability Value

PI: Principal Investigator

WHO: World Health Organization

OR: Odd's ratio

T1 DM: Type 1 Diabetes Mellites

LD: Lipodystrophy

LA: Lipoatrophy

LH: Lipohypertrophy

SC: Subcutaneous

IM: Intramuscular

RBS: Random blood sugar

Hgba1c: Hemoglobin A1c

1.Background

1.1. Introduction

Diabetes is a serious and chronic medical condition that stems from either insufficient insulin production by the pancreas or the body's ability to properly utilize the insulin that is produced (1).Uncontrolled elevated blood sugar levels ,a common complication of mismanaged diabetes, can eventually lead to significant damage to vital organs such as the heart ,blood vessels ,kidneys ,eyes and nervous system .Type 1 diabetes mellitus (T1DM) is one of the most wide spread chronic diseases affecting children and adolescents .This form of diabetes poses serious risks to the life and overall health of afflicted young individuals ,which can have detrimental impacts on their physical and mental development.

Globally, It has been estimated that more than 1.2 million children and adolescents worldwide have T1DM. This disease affects an estimated 108,300 children under the age of 15 per year, rising to around 149,500 under the age of 20 and representing a yearly rise of about 3% (7). Worldwide, 227 580 incident cases of pediatric diabetes were reported in 2019. Between 1990 and 2019, the number of cases of pediatric diabetes rose by 39.37%. The global incidence rate increased over three decades, rising from 9.3 to 11.61 per 100,000 people (8).In Ethiopia, the International Diabetes Federation (IDF) 2021 study estimates that 2.4 per 100,000 people annually are anticipated to have T1DM among children and adolescents aged 0-19. One in 76 families are affected today · Ethiopia is experiencing a 10.2% annual growth in Type 1 Diabetes compared to 2.1% for Type 2 Diabetes (7).

The hallmark of type 1 diabetes, formerly known as insulin-dependent, childhood-onset diabetes, is insufficient insulin synthesis in the body. Patients diagnosed with type 1 diabetes mellitus are dependent on exogenous insulin to regulate their blood glucose levels, which can be achieved through repeated daily insulin injections or a continuous subcutaneous insulin infusion (9). Children and adolescents with Type 1 Diabetes face many daily challenges related to managing their disease. These challenges include the need for significant dietary restrictions, frequent exercise, intense therapeutic exogenous insulin regimens, significant lifestyle alterations, and frequent monitoring of biochemical markers. (10).

Insulin therapy for insulin dependent diabetes mellitus can lead to various cutaneous complications stemming from improper injection techniques .Examples of theses complications include lipodystrophy of the skin ,insulin allergy ,edema ,localized induration ,ulceration and scar formation ,as well as cutaneous abscess development and keloid formation .Additionally ,while extremely rare ,some patients may experience idiosyncratic reactions such as pigmentation changes and sporadic keloid development .There have also been reports of skin reactions resembling acanthosis nigricans associated with insulin therapy .

Complete or partial loss of adipose tissue is a medical disorder known as lipodystrophy. One of the main side effects of insulin injection therapy for diabetic patients is the occurrence of lipodystrophy in conjunction with abnormal adipose tissue buildup at specific anatomical regions periodically (11). Insulin-induced lipodystrophy has been classified into two major subtypes – lipohypertrophy and lipoatrophy.

Lipohypertrophy is characterized as the formation of a hard, tumor like nodularity of the adipose tissue in the area of injection. Thus, insulin exposure could be the cause for the lipogenic impact for repeated insulin exposure. Lipohypertrophy normally occurs at the thigh and the abdomen which is commonly the areas where injections are administered. The Lipohypertrophy varieties are roughly between the size of a fist and that of a golf ball. They could be lifted up, rubbery/bulging, felt thicker than the skin surrounding the lesion or appeared to be firmer/tougher than the surrounding tissue. In addition, that, the lipohypertrophic lumps are generally associated with decrease or poor sensation or sensibility (12)

Lipoatrophy is localized and circumscribed without changes in epidermis presenting as depressed skin areas. There are four subcategories of localized lipoatrophy and are classified as annular, abdominal, semicircular and post-injection (13). According to occurrence, the most typical drug that leads to lipoatrophy is insulin. The clinical feature of insulin induced lipoatrophy commonly occurs 6 to 24 months after the start of insulin therapy at the insulin injection sites. Based on this concept, a study has shown that lipoatrophy at insulin injection sites is an inflammatory lesion caused by an immune complex (14).

1.2 Statement of the problem

Since the introduction of insulin purification and recombinant insulin, the emergence of lipoatrophy has reduced drastically (15). In a meta-analysis conducted recently, the prevalence of lipohypertrophy is 49 % among insulin-using T2DM patients and 34% among T1DM patients. Lipodystrophy is less reported in T1DM patients than in T2DM patients based on a synthesis of current literature. Significant percentages have also been identified to prevalence of T1DM from 19-49% by various past researches (16). Multiple metabolic abnormalities are observed in lipodystrophic patients, Highlighting the significance of adipose as an active endocrine organ. Adipose tissue depots as well as the total body consumption and a proper distribution between individual depots, are also regulators of the patient's metabolic status. Lipodystrophy patients in some categories had slightly reduced serum adiponectin and leptin hormones that originate from adipose tissues (11)

The lipodystrophic region loses its sensitivity. Even though they are aware that it is necessary to rotate sites, patients often stick to their injection site after they experience pain while doing so anywhere else than the lipohypertrophic area. When insulin is injected into a lipodystrophic location, the insulin may be absorbed erratically, which could result in poor glycemic control leading to Hypoglycemia or hyperglycemia, which requires for a greater insulin dosage to treat diabetes with bad performance on the three-month HgA1c level (17).

Although the exact pathogenicity of LH remains rather obscure, repeated mechanical injury by needles when in combination with the trophic effect of insulin, engorge the tissue with fat and cause an over proliferation of such tissue. The following factors have been associated with LH; Re-use frequency of the needle, Gender, Injection site, High rate of insulin per kilogram, duration at which the insulin therapy is conducted, and frequent tissue insult due to failure to rotate injection site. However, obesity, insufficient patient's knowledge, and ineffectively controlled diabetes are other factors that have been suggested. What is thought to be the cause of LA is an immune reaction to the impurity present in insulin (15).

1.3 Significance of the study

Though, Insulin induced Lipodystrophy has its negative impacts there are comparatively little information available regarding the occurrence of this complication in children and adolescents in the developing countries of which ours is an example. The Study Fills an existing gap in literature regarding the prevalence , Risk factors of Lipodystrophy in a cross-sectional survey of Type 1 DM children and adolescents during follow up one of Ethiopia's largest healthcare facility Tikur Anbessa specialized Teaching Hospital.

1.4 Literature review

A rather uncommon side effect witnessed on children and adolescent using exogenous insulin especially if they are suffering from type 1 diabetes mellitus is insulin induced lipodystrophy. Localized adipose tissue dysfunction over the repeated places of insulin injection addressing either bulking up or wasting, called lipohypertrophy and lipoatrophy, respectively, describe this complication (15). However, especially concerning the large number of children which might be affected by lipodystrophy and its various subtypes, including lipoatrophy and lipohypertrophy, the precise definition of these conditions and the diagnostic criteria are often not definitely set or adhered to. This lack of consensus on definitions may in turn hamper efforts aimed at developing an accurate definition and classification system of the condition in young people.

Currently, it is uncertain what specific pathogenesis result in the insulin-induced lipodystrophy of children. While the exact quantitative effects of these variables might not be known, other variables such as child age, growth and development phase, insulin administration method, type of insulin regimen and individual physiological response to insulin, could play essential functions. Moreover, little is known about the impact lipodystrophy might have on overall child's health, glycemic control, and insulin uptake in the long term.

Nevertheless, theoretical understanding of lipodystrophy in children induced by insulin is somewhat disputable. For instance, whereas some researchers indicated that there is no distinct age distribution, other indicated that the disorder occurs more frequently among younger children. Similarly, the influence of genetic or ethnic factors, as a reason for development of lipodystrophy is not yet fully elucidated and deserves further research. In diabetic children and adolescents, the frequency of insulin-induced lipodystrophy varied depending on the surveys ranging from 5 % to 65 %, differences in research populations, diagnostic criteria, as well as the knowledge of the physicians has contributed to such a wide variation. Cohort research analysis reveals that lipohypertrophy occurs most frequently in children than lipoatrophy, with a prevalence of 50 percent (19).

The prevalence of lipodystrophy remained high in spite of advancements in injection techniques, recombinant human insulin use, and insulin purity increases. Between studies, there are significant differences in the prevalence of LD. There were sixteen research conducted on children and adolescents from eleven different countries (Italy, India, Turkey, United Arab Emirates, Saudi Arabia, Egypt, Canada, The Netherlands, Iran, Austria, and Ethiopia) following 2010. Between 17% and 62% was the wide range of prevalence of LD in these studies, with various risk variables having a major impact. The pooled prevalence of the studies using MDII and CSII (16 studies, n= 3208 children, and adolescents, 1449 had LD) was 45.16 % (20).

Lipodystrophy incidence was observed in 95 children, adolescents, and young adults with TIDM through an observational cross-sectional hospital-based study of patients in West Bengal, India. The participants' glycemic parameters, and dosage and method of insulin administration were documented. Of the participants, 4.2 % of the patients had lipoatrophy exclusively and 45.2 % had lipohypertrophy; 3.1 % of the participants had lipohypertrophy and lipoatrophy at the same time as the illness in the aforementioned study. Compared to patients without lipodystrophy, the patients with lipohypertrophy more frequently used an incorrect injection site rotation method. The age of onset of diabetes, duration of insulin use, and the number of times of needle reuse were not significantly different between the lipohypertrophy and non-lipodystrophy groups.

According to the following study, lipohypertrophy affects up to 50 percent of the young patients with type 1 diabetes and can be attributed to suboptimal glycemic control. Through palpation and inspection, 119 children during their routine follow-up at the Diabetic clinic in El-Chatby University Children's Hospital in Alexandria were assessed for lipohypertrophy. The glycated hemoglobin (HbA1c) of the four preceding scans was retrieved and other variables associated with lipohypertrophy. From 2 months to 21 years of age, the patient's median age was 10 years. undefined Overall 9% of the patient showed lipohypertrophy, it was more common in male (62.7%) than female (48.4). The incidence of lipohypertrophy in Grade 1 was 42 times. 5% and 2 in 12. undefined.

On 176 children and adolescents with diabetes who have been injecting insulin for at least a year, a cross-sectional study was conducted. Prior to utilizing observation and palpation techniques to evaluate lipodystrophy, the patients' anthropometric and clinical features were first documented in a questionnaire.103 individuals (58.5%) out of the 176 total had insulin-induced lipodystrophy, 100 individuals (97.1%) had lipohypertrophy, and 3 individuals (2.9%) had lipoatrophy. According to the study's findings, lipohypertrophy persisted in its high degree even when recombinant human insulin was used. Therefore, a routine workup of insulin-injecting patients for such complication is necessary, especially in the individuals who have a nonoptimal glycemic control(17).

A multitude of factors, including injection site features, patient-related traits, insulin-specific qualities, and lifestyle habits, can increase the chance of developing insulin-induced lipodystrophy in children. Well-established risk factors associated with injection sites include being younger, repeatedly injecting in the same anatomical place, failing to rotate injection sites properly, and reusing insulin needles (21). Lipodystrophy risk can also be increased by patient-specific characteristics such as lengthier diabetes and insulin therapy duration, poor glycemic control, greater insulin dose requirements, and younger age at diabetes onset. The length of diabetes, body mass index, and the amount of insulin units administered per kilogram of body weight were all strongly correlated with liphypertrophy (15).

Another important factor to consider is the type of insulin used; patients receiving multiple daily injections (MDI) had a lower incidence of hypoglycemia when using insulin analogs as opposed to human insulins. Human insulin and higher insulin concentrations pose a greater risk than insulin analogs. This is explained by the fact that subcutaneous tissue of regular human insulin (e.g., Humulin R) absorbs insulin at a slower rate due to the high percentage of hexamers bound to a zinc molecule. It also takes 60–90 minutes for the hexamers in insulin to dissociate into dimers and monomers for absorption into the blood stream, giving local action more time. In contrast the fast-acting insulin analogs (consisting of monomers with rapid dissociation and absorption) are absorbed within 10–15 min of a subcutaneous injection. This longer stay of insulin in the subcutaneous tissue appears to increase the possibility of developing LH by the proliferating effect of insulin on lipocytes (22)

Lack of appropriate self-monitoring of the injection sites, failure to follow correct techniques of injections and lack of patient information imparted to them on lipodystrophy may worsen the situation. Understanding of these complex risk factors is paramount for the clinician so that they would not let this disabling complication develop in their young patients with diabetes. The type and purity of the insulin-containing preparation has an effect on the development of insulin-induced lipodystrophy; the older animal insulin are more likely to induce fat necrosis and immunological response than the modern human insulin analogs (22)). Another factor is immunogenicity and the individual differences relating to how the person’s immune system will react to the injected insulin; some patients are more susceptible to lipodystrophy. Furthermore,

some characteristics of the injection site, such as a decrease of subcutaneous adipose tissue or an increase of mechanical load, can increase the risk of this pathology (23

Lipodystrophy caused by insulin can further result in various severe complications that affect the quality of life of the patient. The localized loss of fat under the skin may lead to changes in skin contours, such that have a negative impact on the patient's body image and confidence. This disfiguring condition may create feelings of anxiety, depression and social isolation in the patient. Also, the redistribution of fat impacts the body's insulin reception and utilization of injected insulin, causing spikes in blood sugar and frequent hypoglycemia or hyperglycemia episodes. Abnormal skin structure also predisposes them to skin infection such as cellulitis or abscess that may necessitate medical attention (24). Sometimes, it is linked to other metabolic abnormalities such as alterations in lipid profile and cholesterol and increased cardiovascular risk (18).

The best approach to study the prevalence of insulin-induced lipodystrophy is to conduct well-designed cross-sectional studies. These studies involve examining a representative sample of the insulin-treated patient population at a single point in time to determine the proportion of individuals affected by the condition. This approach is advantageous for several reasons.

Firstly, Cross-sectional studies facilitate the assessment of the prevalence of insulin-induced lipodystrophy among the population under investigation at the moment. Developing an Overall index for the total Burden of This disorder in order to come up with a rough estimate of the total amount of this disorder that is inflicted on the society, researchers can assess a huge and diverse population sample. Cross-sectional studies are helpful and inexpensive as types of research as they are not very complex to organize and conduct (25). Some examinations that may be employed while examining the patient, these exams may be done by qualified medical personnel to assess for the specific lipodystrophy signs and symptoms. In this direct manner it is possible to evaluate the state of the patients with higher accuracy. Furthermore, cross-sectional surveys may be done on several occasions to assess the developments and changes in occurrence of insulin - induced lipodystrophy. If investigators choose a cross-sectional design to explore the epidemiology of insulin-induced lipodystrophy, they can collect valid, reproducible and timely data to shape practice at the point of care, policy at the population level and in the long run enhance quality of management of this rare side effect of insulin use. (27)

There is therefore, adequate justification for investigating the epidemiological characteristics and potential correlates of insulin-induced lipodystrophy among children in Ethiopia. Type 1 diabetes is highly prevalent in Ethiopia, and most of the afflicted population are young people.
Recognizing the differences and potential issues of insulin administration like lipodystrophy in this kind of PWDs will play a significant role towards enhancing their health span and quality of life. It has been suggested that the risk factors and the pattern of insulin induced lipodystrophy can vary with the growth and developmental stages of a child or an adolescent when compared to adult patients (15). Researching this population provides an understanding of the condition and its characteristics depending on the age, as well as impacts on insulin absorption and glycemic control. This is particularly important since strict control of glucose levels is crucial for growth and prevention of complications in children suffering from diabetes.

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Additionally, lipodystrophy related complications in children and adolescents significantly affect their social, psychological and physical appearance besides their interpersonal relationships. It is suggested that it is possible to determine the prevalence and risk factors of this condition in order to create the focused interventions that can increase the general wellbeing of affected children (26). In the Ethiopian children, local evidence on insulin induced lipodystrophy, attempts to design age-appropriate insulin delivery guidelines and enhance insulin therapy in this population will be useful.

Furthermore, This research can help in partnering with global experts, develop the human capital for research in Ethiopia, and enhance the country's ability to manage diabetes complications in children. Thus, conducting a comprehensive study on insulin-induced lipodystrophy among children in Ethiopia will enable researchers to gather useful data, which will help in the improvement of clinical guidelines and polices aimed at enhancing the quality of life and health of children with diabetes in the country.

1.5 Conceptual framework

2. Objectives

2.1. General objective;

To assess the magnitude of Lipodystrophy and associated risk factors among Type 1 Diabatic patients under 18 years of age taking insulin injection.

2.2. Specific objectives

2.2.1 Determine the Prevalence:

- Estimate the percentage of children with Type 1 Diabetic patients who develop insulin-induced lipodystrophy.
- Identify the most common types of lipodystrophy (e.g., lipoatrophy, lipohypertrophy) and their relative frequencies.
- Association of Lipodystrophy with poor glycemic control.

2.2.2 Identify the key Risk Factors associated with the development of Insulin induced lipodystrophy among Type 1 DM patients taking Insulin injection.

3. Methods and Materials

3.1 Study design:

An institutional based cross-sectional study will be conducted from Aug to Nov, 2024

3.2 Study area:

This study took place at the Tikur Anbesa Specialized Teaching Hospital in Addis Ababa, the capital of Ethiopia, which also serves as the location of the United Nations World Economic Commission for Africa and the African Union. The capital and largest city of Ethiopia, Addis Ababa, is expected to have about 5 million residents by 2022, based on the most recent data available. With a median age of about 25, Addis Abeba is a youthful and multicultural metropolis that is home to a variety of ethnic groups, including Amhara, Oromo, Gurage, and There are 116 kebeles, or districts, and 11 sub-cities inside the metropolis. Of the 48 hospitals in the city, 13 are public facilities, five of which are managed by the Addis Ababa Regional Health Bureau (AARHB). With over 800 beds in its medical, gynecological and obstetrics, surgical, pediatric, and emergency departments, Tikur Anbesa is a specialized referral hospital. It is also equipped with an outpatient department (OPD), 7 x-ray, 9 surgical, and 2 laboratory diagnostic rooms. Additionally, the hospital has specialized units (referral clinics) for the following conditions: infectious disease, orthopedics, general surgery, gynecologic and obstetrics, diabetic, hematology, renal, neurology, cardiology, dermatology, gastro intestine, and surgical intensive care units. The pediatric department at Tikur Anbesa, specialized and referral hospital, treats between 370,000 and 400,000 patients annually, with six units (a pediatric intensive care unit, pediatric surgical unit, pediatric medical ward, pediatric oncology ward, emergency ward, and neonatal intensive care unit) serving about 8855 in-patient cases annually and an average of 471 pediatric cases per month with a total of 183 beds.

3.3 Source population

All Type 1 DM patients under 18 years of age taking Insulin SC injection on follow up at Tikur Anbessa specialized teaching hospital pediatric endocrine clinic.

3.4 Study population: All Type 1 DM patients with LD taking Insulin SC injection on follow up at Tikur Anbessa specialized teaching hospital endocrine clinic over the study period.

3.5 Inclusion criteria:

Type 1 DM patients under 18 years of age receiving Insulin SC injection for the past 1 year on follow up at Tikur Anbessa Specialized teaching Hospital pediatric endocrine clinic.

3.6 Exclusion criteria:

Parents using insulin Pump.

3.7 Sample size determination

The sample size was determined by the from the previous study show that 46.9 % of the patients had Lipodystrophy with 5% marginal error, 95% confidence interval (CI) and a Based on this assumption, the actual sample size for the study was determined using the formula for single population proportion.

$$\text{Sample Size for infinite population} = Z^2 \times P \times \frac{(1-P)}{M2}$$

Therefore, based on using the above single formula the sample size can be calculated as:

- 95% CI and 5% margin of error
- P= 0.5
- n=384.16

The study was conducted from October 2024 to February 2025 during this period Type 1 DM patients taking insulin injection for atleast one year duration available for questioning were 140 ,The above formula will be modified by the following sample correction method.

nadj=n/(1+(n/N) = 384/ (1+(384-1/140)) = 102

Where n adj = adjusted population n: calculated sample size

N: number of Type 1 DM patients taking insulin injection for atleast one year duration available for questioning during the study period

3.8 Sampling procedure

Interns will be trained to collect data (using a pre-tested well-structured questionnaire). Face to face interview the parents and fill the Questioner properly

3.9 Variables of the study

3.9.1 Dependent variable

- **Presence of Insulin-Induced Lipodystrophy**:

It would be a binary variable, categorized as either "present" or "absent" based on clinical diagnosis.

- **Type of Lipodystrophy**:

If insulin-induced lipodystrophy is present, the specific type could be further categorized:
Lipohypertrophy (localized fat accumulation)
Lipoatrophy (localized fat loss)

3.9.2 Independent variables

- Demographic Factors
- Diabetes -related Factors
- Injection Site-related Factors
- Anthropometric Factors
- Genetic and Familial Factors
- Lifestyle and Behavioral Factors
- Medication -related Factors

3.10 Operational definitions

The following operational definitions will used **Insulin-Induced Lipodystrophy, Lipohypertrophy, Lipoatrophy, Severity of Lipodystrophy, Quality of Life**

Insulin-Induced Lipodystrophy: Abnormal changes in the subcutaneous fat distribution at insulin injection sites, characterized by either localized fat accumulation (lipohypertrophy) or localized fat loss (lipoatrophy), as diagnosed by a healthcare provider through physical examination and/or imaging techniques.:

Lipohypertrophy: Localized increase in subcutaneous fat at the insulin injection site, appearing as a palpable, soft, doughy, or irregular nodule or thickening of the skin.

Lipoatrophy: Localized loss of subcutaneous fat at the insulin injection site, appearing as a visible, sunken, or concave depression in the skin.

Longer Duration of Diabetes : More than 5 years of insulin Subcutaneous Injection use

Higher dosage of Insulin Per age : Below 6 years : > 0.7 iu /kg /day
Between 6 – 10 years : > 1 iu /kg/day
Above 10 years : > 1.2 iu/kg/day

Frequent episode of hypoglycemia : 3 or more episodes of hypoglycemia over the last month

Regular rotation of injection site : Rotate injection site with each injection

3.11 Measuring instruments

The first draft of English version of a questionnaire was taken from previous study result section and it was adapted in to this study with slight modification and the questionnaire has been translated in to Amharic version by language experts and it was re-translated back to English to check for its consistency.

3.12 Data collection procedure

Two data collectors' interns were recruited for administering the questionnaire. One supervisor resident were also recruited. The data was collected by using a pre-tested, and culturally accepted structured questionnaire.

3.13 Data quality control

Through the following, the data quality was guaranteed:

The data collection instrument (PSS) was carefully modified to reflect the circumstances in

Ethiopia. A pretest involving 5% of the sample size was done to evaluate the data collection tool's coherence, length, consistency, and amount of time needed to conduct the interview. Data cleaning (cross-tabulating and verifying frequencies for every item) and coding was taught to data collectors and supervisors.

3.14 Data processing and analysis

After collection, the data was coded, cleaned, processed, and imported into SPSS version 26 and Epi Info. To describe the degree of lipodystrophy and other features, a descriptive analysis was carried out. Tables, charts, graphs, and text were used to display the findings. For multivariable logistic regression, variables with crude odds ratios and p-values below 0.25 from pairwise binary logistic regression were chosen. The relationship between predictors and the dependent variable (lipodystrophy) was shown by the adjusted odds ratios, their 95% CIs, and their significance. In the multivariable analysis, variables were considered significant if their p-values were less than 0.05. The Hosmer-Lemeshow test was used to evaluate model fit, and a model was deemed well-fitting if the test result was not significant (p-value) greater than or equal to 0.05). The final multivariable model demonstrated a good fit for the data.

3.15 Ethical consideration

The Research ethics committee (REC) of Addis Ababa University, the College of Health Sciences, the Department of Pediatrics, and the Publication Committee on Child Health granted ethical clearance. The study was conducted with written and verbal consent obtained from the Pediatric department at Tikur Anbessa Hospital. Before any data is collected, all study participants were told about the purpose and significance of the research, and their informed consent will be sought. Additionally, they were made aware of their freedom to withdraw from the study at any moment. Information privacy and confidentiality was guaranteed, and data collection was in an anonymous manner.

3.16 Dissemination and utilization of result

The study's findings will be submitted to the pediatrics and child health department at Addis Abeba University's College of Health Sciences. Additionally, attempts will be made to present the findings at scientific conferences, and publishing in peer-reviewed journals will be taken into consideration.

4. Result

4.1 Results

Socio-Demographic Characteristics

In this out of 140 participants, 13 (9.3%) were under 5 years , 30 (21.4%) aged 6 to 10 years, 97 (69.3%) older than 11 years, In terms of sex, 63 (45.0%) were female and 77 (55.0%) were male, reflecting a slightly higher number of males in the sample. Regarding the BMI of children the mean BMI level was 20.5 ±6 kg/m2. The mean duration of Illness with type I DM was 6.71 years ±6.

Table 1. Socio-demographic characteristics among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024

Variables	**Frequency(n=140)**	**Percentage (%)**
Age group		
6 to 10	30	21.4
Greater than 11	97	69.3
Less than 5	13	9.3
Sex		
Female	63	45.0
Male	77	55.0

4.2 Insulin Injection Practices

Regarding the type of insulin regimen that they are taking, 131(93.6%) were using Mixed split (NPH + RI). While, 132 (94.3%) inject 2 times per day. Also, thigh arm was the most preferred site for injection among 39(27.9%). In contrast hip was the least preferred site for injection and

was reported among 48 (34.3%). Apparently , 133(95%) have been using insulin syringe as a device. Likewise, 108 (77.1%) used 4 mm length syringes. Regarding rotating the injection site, 97(69.3%) responded yes we rotate the injection site. One hundred (71.4%), reuse the insulin needles less than five times. Moreover, 75(53.6%) perform self-monitoring of presence of lipodystrophy every 3 months. Thirty seven (26.4%) change their insulin needle every three day. Also, 51(36.4%) of the parents check their children injection site checked by health professional every 3 months. (See table below).

Table 2. Insulin Injection Practice related characteristics among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024

Variables	**Frequency(n=140)**	**Percentage (%)**
Type of Insulin Regimen		
Basal Bolus (Glargine + RI)	9	6.4
Mixed split (NPH + RI)	131	93.6
Frequency of Insulin intake/day		
2	132	94.3
3	7	5.0
4	1	.7
Insulin Device		
Insulin Pen	7	5.0
Insulin Syringe	133	95.0
Insulin Length		
4mm	108	77.1
5mm	30	21.4
6mm	2	1.4
Rotate the child insulin injection site?		
No, I tend to use the same sites	43	30.7
Yes, I rotate sites regularly	97	69.3
Frequency of Re-Using insulin needle		
Less than 5 times	100	71.4

More than 5 times	40	28.6
How often you get your child injection site Checked by health professional?		
Every 1 year	15	10.7
Every 3 months	51	36.4
Every 6 months	41	29.3

4.3 Magnitude of Lipodystrophy

The prevalence of Lipodystrophy identified in this study is 56.4%, comprising Lipohypertrophy at 37.9% (95% CI: 30.0 - 46.0), Lipoatrophy at 12.1% (95% CI: 7.2 -17.5), and both at 6.4% (95% CI: 2.9 -11.4). (See the figure below).

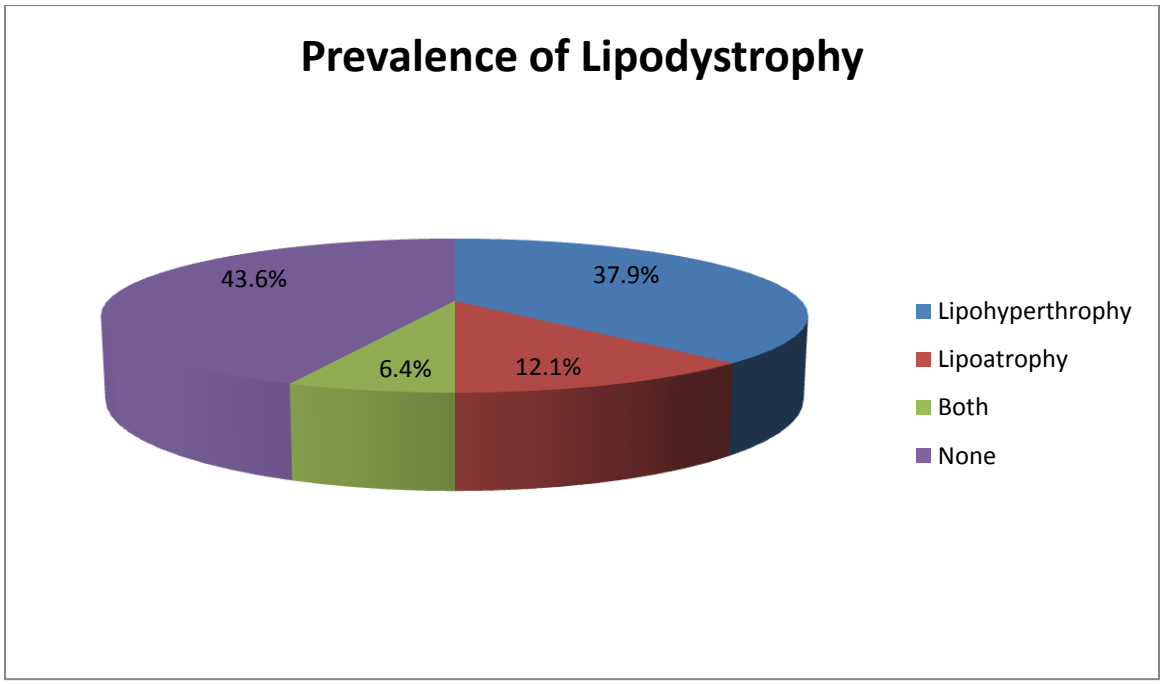

Figure 1. Prevalence of Lypodystrophy among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

4.4 Risk factors of Lipodystrophy

Cross tabulation with Chi square test was performed to assess the higher occurrence of Lypodystrophy across the potential risk factors.

The study accordingly revealed, those children with prolonged duration (5 years) with the DM have higher level of lipodystrophy i.e. 53 vs 33 for <5 years respectively. Also, those children with higher age (11 years) as compared to their counter parts (6-10 and <5 years) have higher level of lipodystrophy i.e. 55 vs 16 respectively. Likewise, Lipodystrophy was more apparent among children receiving higher doses of insulin for their age compared to those receiving moderate doses for their age. Moreover, lipodystrophy was high among those who didn't rotate their injection site. i.e. 50 vs 29 respectively. *See the tables below).

Table 4. Duration With TYPE DM with Lypodystrophy Cross tabulation among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

Count

		300.2 Please show the interrogator the site of insulin injections				
		Lipohyperthrophy	Lipoatrophy	Both	None	Total
Duration With TYPE DM category	<=5 years	19	10	2	28	59
	>5 years	34	7	7	33	81
Total		53	17	9	61	140

Table 5. Age with Lypodystrophy Cross tabulation among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

Count

Table 6. Current Daily Dosage with Lypodystrophy Cross tabulation among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024. (for less than dose)

		300.2 Please show the interrogator the site of insulin injections				
		Lipohyperthrophy	Lipoatrophy	Both	None	Total
100.2 Age	6 to 10	11	3	2	14	30
	Greater than 11	38	11	6	42	97
	Less than 5	4	3	1	5	13
Total		53	17	9	61	140

		300.2 Please show the interrogator the site of insulin injections				
		Lipohyperthrophy	Lipoatrophy	Both	None	Total
Current daily dosage	<0.7 iu /kg/day for 0-6 years	3	2	0	10	15
	<1 iu/kg/day for 6-10 years	13	1	2	10	26
	<1.2 iu/kg/day for greater than than 10	3	1	0	15	19
Total		19	4	2	35	60

Table 7. Current Daily Dosage with Lypodystrophy Cross tabulation among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024. (for greater than dose).

		300.2 Please show the interrogator the site of insulin injections				
		Lipohyperthrophy	Lipoatrophy	Both	None	Total
Current Daily Dosagecat	>0.7units/ke/day for 0-6 years	7	6	1	7	21
	>1 units/kg/day for 6-10 years	20	4	5	8	37
	>1.2 units/kg/day for .10 years	7	3	1	11	22
Total		34	13	7	26	80

Table 8. Rotation of Injection site with Lypodystrophy Cross tabulation among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

Count

		300.2 Please show the interrogator the site of insulin injections				
		Lipohyperthrophy	Lipoatrophy	Both	None	Total
Do you rotate your child's insulin injection sites?	No, I tend to use the same sites	40	4	6	1	51
	Yes, I rotate sites regularly	13	13	3	60	89
Total		53	17	9	61	140

4.5 Glycemic Control

In this study, 131(93.6%) had poor diabetic control as suggested from their most recent Hga1c. Out of 79 patients with Lipodystrophy 57 (72.1%) had higher HbA1c (>7 %) , only 22(27.9%) had HbA1c level of (<7 %) Additionally, Out of total of 140 patients , 74 children (52.8%) experienced at least one episode of hypoglycemia in the past month. From 140 patients , 52 (70.2%) experienced frequent episode of hypoglycemia over the past one month ,Of those 40(76.9 %) were patients with Lipodystophy .Also, Likewise, other medical conditions were apparent among, 8 (5.7%). Whereas, 3 (2.7%) were taking medications other than insulin. Also, 62(44.3%) have been engaging in regular physical exercise. Of those who have been doing regular physical exercise, 28(20.0%) were doing two times per week. (See table below).

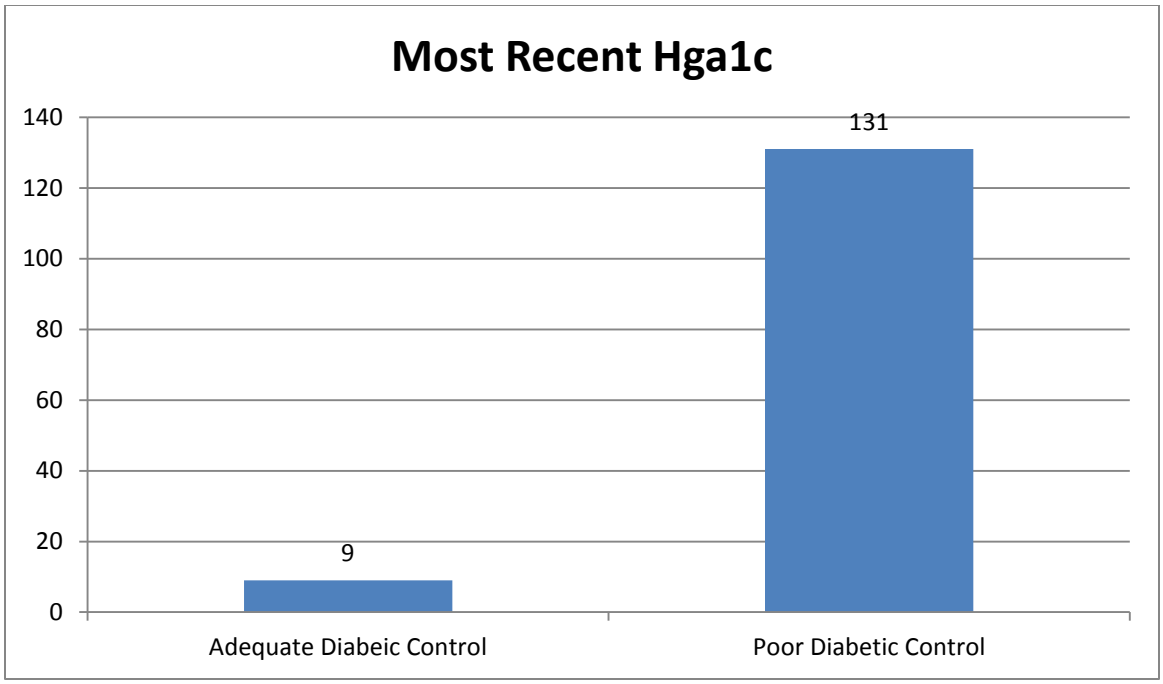

Figure 2. Glycemic Control among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

Table 3. Glycemic Control related characteristics among Type 1 Diabetic patients under 18 years of age taking insulin injection TASH, Addis Ababa, Ethiopia, 2024.

Variables	**Frequency(n= 140)**	**Percentage (%)**
Experienced frequent episodes of hypoglycaemia		
Yes	74	52.8
No	66	47.2
Other medical conditions besides type 1 DM?		
No	132	94.3
Yes	8	5.7
Taking medications other than Insulin?		
No	137	97.9
Yes	3	2.1

Does the child engage in doing regular Physical Exercise?		
No	78	55.7
Yes	62	44.3
If yes, how frequent/times/week? n=62		
1	7	11.3
2	28	45.2
3	17	27.4
4	8	12.9
5	2	3.2

5. Discussion

In this study the prevalence of Lipodystrophy was (56.4%) i.e. Lipohyerthrophy, Lipoatrophy, and both were 37.9%, 95% CI (30.0, 46.0), 12.1%, 95% CI (7.2, 17.5), 6.4%, 95% CI, (2.9, 11.4), respectively. Also, the higher occurrence of Lipodystrophy was observed among children with age of >11 years, taking higher current daily dosage of insulin injection for age , not rotating the insulin injection site regularly and prolonged duration with DM.

The prevalence of Lipodystrophy revealed from this study is inline as compared to the pooled prevalence from sixteen researches conducted on children and adolescents from eleven different countries (Italy, India, Turkey, United Arab Emirates, Saudi Arabia, Egypt, Canada, The Netherlands, Iran, Austria, and Ethiopia) following 2010. Between 17% and 62% was the wide range of prevalence of LD in these studies, with various risk variables having a major impact. The pooled prevalence of the studies using MDII and CSII (16 studies, n= 3208 children, and adolescents, 1449 had LD) was **45.16 %** (20).

Also, the finding about the prevalence of Lipodystrophy (All types) from the current study is, concordant from a study on Lipodystrophy incidence which was observed in 95 children, adolescents, and young adults with TIDM through an observational cross-sectional hospital-based study of patients in West Bengal, India. The participants' glycemic parameters, and dosage and method of insulin administration were documented. Of the participants, 4.2 % of the patients had Lipoatrophy exclusively and 45.2 % had Llipohypertrophy; 3.1 % of the participants had Lipohypertrophy and Llipoatrophy simultaneously.

In contrast, the finding about the prevalence of Lipodystrophy from this study is lower as compared to a study conducted on 176 children and adolescents with diabetes who have been injecting insulin for at least a year, a cross-sectional study was conducted. Prior to utilizing observation and palpation techniques to evaluate Lipodystrophy, the patients' anthropometric and clinical features were first documented in a questionnaire.103 individuals (58.5%) out of the 176 total had insulin-induced Lipodystrophy.

According to the study done in the Diabetic clinic in El-Chatby University Children's Hospital in Alexandria ,Lipohypertrophy affects up to 50 percent of the young patients with type 1 diabetes and can be attributed to suboptimal glycemic control. Through palpation and inspection, 119 children during their routine follow-up at were assessed for lipohypertrophy. From 2 months to 21 years of age, the patient's median age was 10 years. , it was more common in male (62.7%) than female (48.4) Which more or less inlines with the finding in our study .

Moreover, Our study showed, patients with Lipodystrophy had significantly higher mean levels of HbA1c (Out of 79 patients with Lipodystrophy 57 (72.1%) had higher HbA1c (>7 %) , only 22(27.9%) had HbA1c level of (<7 %). Lipodystrophy is also associated with an increased incidence of hypoglycemia (From 140 patients , 52 (70.2%) experienced frequent episode of hypoglycemia over the past one month ,Of those 40(76.9 %) were patients with Lipodystophy These results are consistent with a study conducted in Iran, Underlining the importance of early detection of Lipodystrophy an proper management and education for the parents and patients to achieve a good glycemic control .

6. Limitation

The First Limitation of the study is that , the result can not be generalized to the generalized population as the research was conducted solely in a Single center .Additionally the data collectioned relied on Physical examination for identifying Lipodystrophy leading to gaps in identifying the correct Prevalence as sub clinical Lipodystrophy specially Lipohypertrophy may be missed by clinical diagnosis. Furthermore the Questionner relied on the parents memory for various questions regarding insulin injection practices which may lead to Recall Bias .

7. Conclusion

In Summary , The result showed that , There is higher ocuurence of Lipodystrophy (Lipohypertrophy and Lipoatrophy) was observed among children with prolonged duration of Diabetes (>5 years) , Older age of diagnosis , among those taking higher dosage of insulin per kilogram for age and those who do not rotate injection sites regularly . Furthermore The current study found that patients with Lipodystrophy had significantly higher mean levels of HbA1c and an increased incidence of hypoglycemia.

8. Recommendation

The present study demonstrated that, there is significant knowledge Gap regarding appropriate insulin injection techniques and complications of insulin injection .Patient education is paramount regarding proper Rotation of Injection Sites, Use of Different Injection Techniques and self monitoring for complication over injection sites .Additionally Training healthcare providers on the importance of regular monitoring of injection sites by documenting Lipodystrophy as a diagnosis in patients' medical records. Moreover, future research should focus on developing effective prevention strategies and management techniques for Lipodystrophy to better support patients and caregivers.

Reference

1. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2014;37(Suppl 1): S81-S90.

2. Vardar B, Kizilci S. Incidence of lipohypertrophy in diabetic patients and a study of influencing factors. Diabetes Res Clin Pract. 2007;77(2):231-236.

3.Johansson UB, Amberg R, Aspegren A, et al. Impaired absorption of insulin aspart from lipohypertrophic injection sites. Diabetes Care. 2005;28(8):2025-2027.

4.Al Hayek AA, Robert AA, Braham RB, Al Dawish MA. Frequency of lipohypertrophy and associated risk factors in young patients with type 1 diabetes: A cross-sectional study. Diabetes Ther. 2016;7(2):259-267.

5, Frid A, Hirsch L, Gaspar R, et al. New injection recommendations for patients with diabetes. Diabetes Metab. 2010;36 Suppl 2: S3-S18.

6, Saez-de Ibarra L, Gallego F. Factors related to lipohypertrophy in insulin-treated diabetic patients: role of educational intervention. Pract Diabetes Int. 1998;15(1):9-11.

7. Bekele BT, Demie TG, Worku F. Health-Related Quality-of-Life and Associated Factors Among Children and Adolescents with Type 1 Diabetes Mellitus: A Cross-Sectional Study. Pediatric Health Med Ther. 2022 Jun 22; 13:243-256.

8.Zhang K, Kan C, Han F, Zhang J, Ding C, Guo Z, Huang N, Zhang Y, Hou N, Sun X. Global, Regional, and National Epidemiology of Diabetes in Children From 1990 to 2019. JAMA Pediatr. 2023 Aug 1;177(8):837-846.

9.Subramanian S, Baidal D. The Management of Type 1 Diabetes. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000. [Updated 2021 May 22].

10.Chiang JL, Maahs DM, Garvey KC, Hood KK, Laffel LM, Weinzimer SA, Wolfsdorf JI, Schatz D. Type 1 Diabetes in Children and Adolescents: A Position Statement by the American Diabetes Association. Diabetes Care. 2018 Sep;41(9):2026-2044.

11.Fiorenza CG, Chou SH, Mantzoros CS. Lipodystrophy: pathophysiology and advances in treatment. Nat Rev Endocrinol. 2011 Mar;7(3):137-50.

12. Xu XH, Carvalho V, Wang XH, Qiu SH, Sun ZL. Lipohypertrophy: prevalence, clinical consequence, and pathogenesis. Chin Med J (Engl). 2020 Aug 17;134(1):47-49.

13. Alhusain AM, Alrodiman OA, Alfaqeeh FA, Alissa SI. Isolated Congenital Lower Limb Lipoatrophy: A Case Report and Literature Review. Plast Reconstr Surg Glob Open. 2023 Aug 29;11(8): e5222.

14. Radermecker RP, Piérard GE, Scheen AJ. Lipodystrophy reactions to insulin: effects of continuous insulin infusion and new insulin analogs. Am J Clin Dermatol. 2007;8(1):21-8.

15. Elsayed S, Soliman AT, De Sanctis V, Fawzy D, Ahmed S, Alaaraj N. Insulin-induced lipodystrophy and predisposing factors in children and adolescents with type 1 diabetes mellitus (T1DM) in a tertiary care Egyptian center. Acta Biomed. 2023 Jun 14;94(3):e2023078.

16. Deng N, Zhang X, Zhao F, Wang Y, He H. Prevalence of lipohypertrophy in insulin-treated diabetes patients: A systematic review and meta-analysis. J Diabetes Investig. 2017 Sep 1;9(3):536–43.

17. Tsadik AG, Atey TM, Nedi T, Fantahun B, Feyissa M. Effect of Insulin-Induced Lipodystrophy on Glycemic Control among Children and Adolescents with Diabetes in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. J Diabetes Res. 2018 Jul 4; 2018:4910962.

18. Fourman LT, Grinspoon SK. Approach to the Patient with Lipodystrophy. J Clin Endocrinol Metab. 2022 May 17;107(6):1714-1726.

19.Gentile S, Strollo F, Ceriello A; AMD-OSDI Injection Technique Study Group. Lipodystrophy in Insulin-Treated Subjects and Other Injection-Site Skin Reactions: Are We Sure Everything is Clear? Diabetes Ther. 2016 Sep;7(3):401-9.

20. Soliman A, Hamed N, Alyafei F, Ahmed S, Alaaraj N, Fawzy D, Elsayed S. Insulin-induced Lipohypertrophy and factors affecting it in children and adolescents with type 1 diabetes mellitus: Review of Literature in the past 12 years. World J Adv Res Rev. 2022;16(3):977-987.

21. Blanco, Marta & Hernández, Mª & Strauss, Kenneth & Amaya, Marisa. (2013). Prevalence and risk factors of lipohypertrophy in insulin-injecting patients with diabetes. Diabetes & metabolism. 39. 10.1016/j.diabet.2013.05.006.

22. Umpierrez GE, Jones S, Smiley D, Mulligan P, Keyler T, Temponi A, Semakula C, Umpierrez D, Peng L, Cerón M, Robalino G. Insulin analogs versus human insulin in the treatment of patients with diabetic ketoacidosis: a randomized controlled trial. Diabetes Care. 2009 Jul;32(7):1164-9.

23. Petersen MC, Shulman GI. Mechanisms of Insulin Action and Insulin Resistance. Physiol Rev. 2018 Oct 1;98(4):2133-2223.

24. Donnor T, Sarkar S. Insulin- Pharmacology, Therapeutic Regimens and Principles of Intensive Insulin Therapy. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000- [updated 2023 Feb 15].

25.Setia MS. Methodology Series Module 3: Cross-sectional Studies. Indian J Dermatol. 2016 May-Jun;61(3):261-4.

26. Adams, Claire & Stears, Anna & Savage, David & Deaton, Christi. (2018). "We're stuck with what we've got": The impact of lipodystrophy on body image. Journal of Clinical Nursing. 27. 10.1111/jocn.14342.

27. Thewjitcharoen Y, Prasartkaew H, Tongsumrit P, Wongjom S, Boonchoo C, Butadej S, Nakasatien S, Karndumri K, Veerasomboonsin V, Krittiyawong S, Himathongkam T. Prevalence, Risk Factors, and Clinical Characteristics of Lipodystrophy in Insulin-Treated Patients with Diabetes: An Old Problem in a New Era of Modern Insulin. Diabetes Metab Syndr Obes. 2020 Nov 26; 13:4609-4620.

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ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Faculty of Public Health in effect at the time of grant is forwarded as the result of this application.

Name of the student: __ _____Henock Hailu

Date. August, 2024_____ Signature _____

APPROVAL OF THE FIRST ADVISOR

Name of the first advisor:_____

Date._____ Signature _____

Appendix I: Participant Information Sheet

1. Name of the study area (Black lion specialized hospital)
2. Name of the pediatric specialty_____
3. Questionnaire identification no. _____

INTRODUCTION: Good morning/afternoon? My name is _____. In this Study which is undertaken by Addis Ababa University, College of Health sciences school of allied Health sciences department . you and me would have a short discussion of about 15-20 minutes only and I am asking you to help us. Before we go to our discussion, I will request you to listen carefully to what I am going to read to you about the purpose and general condition of the study and you will tell me whether you agree or disagree to participate in this study at the end.

The purpose of this study is to assess the Prevalence and Associated Risk factors of Lipodystrophy among Type 1 DM Children and Adolescents on follow up at Black lion specialized hospital, Addis Ababa, 2015. The study will be conducted through interviews. The results of the study will enable to improve the quality of life of children and adolescents with Type 1 DM . I would like to assure you that confidentiality will be maintained strictly throughout. A code number will identify every participant and no name will be used. Your responses to any of the questions will not be given to anyone else and no reports of the study will ever identify you. If a report of results is published, only information about the total group will appear.

Your participation in the study is strictly voluntarily, and your decision to complete the study will not affect the care and/or treatment of your child. You will not be paid for your willingness to complete the survey.

Are you willing to participate in this study?

1. [ ] Yes. 2. [ ] No

Thank you!!!

የተሳታፊዎች መረጃ መስጫ ቅጽ-በአማርኛ

1. ጥናቱ የሚካሄድበት ቦታ ስም (ጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል)
2. የህክምና ክፊሉ ልዩ ስም_____የህጻናት ድንገተኛ ክፍል_____
3. የመጠይቅ መለያ ቁጥር_____

መግቢያ ፡ እንደምን አደሩ/ዋሉ? ስሜ_____ ይባላል፡፡ በአዲስ አበባ ዩንቨርስቲ ህጻናት ስፔሻሊቲ ክፍል አስተባባሪነት በሚከናወነው ጥናት እኔ እና እርስዎ አጠር ያለ እና ከ 15_20 ደቂቃ የሚወስድ ውይይት ይኖረናል፡፡ ለዚህም ውይይት እንዲተባበሩኝ በትህትና እጠይቃለሁ፡፡ ወደ ውይይቱ ከመግባታችን በፊት ስለጥናቱ አላማ እና ጠቅላላ ሁኔታ ስለማነብለዎት በጥሞና እንዲያዳምጡኝ በትህትና እጠይቃለሁ፡፡ በመጨረሻም በጥናቱ ለመሳተፍ መስማማትዎን ወይም አለመስማማተዎን ይነግሩኛል፡፡

የዚህ ጥናት አላማ በዚህ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል በህጻናት ህክምና ክፍል ውስጥ ተኝተው ስለሚታከሙ ህጻናት ወላጆች ልጆቻቸው እያገኙት ባለው ህክምና ምን ያክል እንደረኩ እና ተግዳሮቶቹ ምን እንደሆኑ ለማወቅ የተዘጋጀ ሲሆን ጥናቱ የሚካሄድበት መንገድ በመረጃ ሰብሳቢው በሚቀርብ መጠይቅ ይሆናል፡፡ መጠይቁ ልጆዎ እያገኘ ስላለው ህክምና የእርስዎን ሀሳብ ወይም አስተያየት ወይም እይታ በተመለከተ ይሆናል፡፡ እርስዎ የሚሰጡት መረጃ ደረጃውን የጠበቀ የህጻናት ህክምና አገልግሎት ለማስፋፋት ይረዳል፡፡

በቆይታዎ ሁሉ ስለሚሰጡን መረጃ ሚስጥር እንደሚጠበቅ እያረጋገጥኩኝ ለእያንዳንዱ ተሳታፊ የተለየ መለያ ቁጥር የሚኖረው ሲሆን ስምም አይጻፍም ::

ለማንኛውም ጥያቄ የሚሰጡት ምላሽ ለሌላ ሰው ተላልፎ የማይሠጥ ሲሆን የጥናቱም ሪፖርት ስለእርስዎ
አይገልጽም፡፡ በተጨማሪም የጥናቱ ሪፖርትም ቢታተም የሚወጣው ስለ አጠቃላይ ተሳታፊ ሰዎች መረጃ ብቻ
ይሆናል፡፡ ተሳትፎዎ
በፍጹም ፍካደኝነት ላይ የተመሰረተ ነው፡፡ በጥናቱ ላይ ለመሳተፍ መወሰነዎ አሁን ለልጀዎ እተሰጠ
ባለው የህክምና አገልግሎት ላይ ምንም አይነት ለውጥ ወይም ጉዳት አያመጣም ፤ ጥናቱ ላይ
በመሳተፈዎ የሚያገኙት ክፍያም የለም፡፡
::ጥናቱ እንደተጠናቀቀ ውጤቱ ለጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ተሰጥቶ ሆስፒታሉም
ለታካሚዎቹ የተሻለ የህክምና አገልግሎት ለመስጠት እንደመረጃ ይተቀምበታል፡፡
በጥናቱ ለመሳተፍ ፍቃደኛ ነዎት?
1. ( ) አዎ 2.( ) አይደለሁም
አመሰግናለሁ!!!
ማስታወሻ፡
1. የጥናቱ ተሳታፊ በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ወደ ፈቃደኛነት ማረጋገጫ ቅጽ ይለፉ
2. የአገልግሎቱ ተጠቃሚዎች በጥናቱ እንዲሳተፉ ማስገደድ አያስፈልግም

Appendix II: Informed consent

I the undersigned have been informed about the purpose of this particular research project. I have been informed that I am going to respond to this question by answering what I feel and experienced concerning the issue. I have been informed that the information I give will be used only for the purpose of this study and my identity as well as the information I give will be kept confidential. I have also been informed that I can refuse to participate in the study or not to respond to questions if I am not interested. Furthermore I have been informed that I can stop responding to the questions at any time in the process. Based on the above information I agree to participate in this research voluntarily.
Signature: _____
Date: _____
NB: 1.If the study subject is voluntary to participate in the study, start the interview.
2. Interviewer signature certifying that informed consent has been given verbally by the respondent.
Name _____
Signature _____

Appendix V: የስምምነት መግለጫ ፎርም - በአማርኛ

ከታች ፊርማዬን ያኖርኩት እኔ የጥናቱ አላማ የተነገረኝ ሲሆን ለምጠይው ጥያቄ የማውቀውን
መመለስ እንደምችል ፤ እኔ የምሰጠው መረጃ ለዚህ ጥናት አገልግሎት ብቻ የሚውል ሲሆን ስሜን እና
የምሰጠው መረጃ በሚስጥር እንደሚጠበቅ ተነግሮኛል፡፡ ፍላጎት ከሌለኝ በጥናቱ ያለመሳተፍ ፤ጥያቄ
ያለመመለስ እና በጥያቄው ወቅት ምላሽ መስጠት ማቋረጥ እንደምችል ተነግሮኛል፡፡
በዚህ መሰረት በጥናቱ ለመሳተፍ ፈቃደኛ መሆኔን በፊርማዬ አረጋግጣለሁ፡፡
ፊርማ_____
ቀን_____
ማስታወሻ፡
1. የጥናቱ ተሳታፊ በጥናቱ ለመሳተፍ ፍቃደኛ ከሆኑ መጠይቁን ይጀምሩ
2. የፍቃደኝነት መግለጫ በመልስ ሰጪው በቃል መሰጠቱን የሚያረጋግጥ የመረጃ
ሰብሳቢው ስም እና ፊርማ
ስም_____

ፊርማ_____ ቀን_____

ማንኛውም ገለጻ የሚያስፈልጋቸው ነገሮች ካሉ መረጃ ሰብሳቢውን ሆነ ዋና ተመራማሪውን በአካልም ሆነ በአድራሻቸው ይጠይቁ፡፡
የዋናው ተመራማሪ አድራሻ

አዲስ አበባ ዩንቨርሲቲ
ህጻናት ስፔሻሊቲ ክፍል
ስልክ ቁጥር፡ 0912369644
አ.አ
ስለ ትብብርዎት አሁንም በድጋሜ እናመሰግናለን፡፡_

Questionnaire

Participant Information

1.Age: ___ years Code _____

2.Sex: M / F Wt.=_____ Ht=_____

3. BMI:

4.Duration of type 1 DM: ___ years

Insulin Injection Practices

5. Current daily dosage of insulin per kg ----------

6.What is the Type of Insulin regimen

A. Mixed split (NPH + RI) B.Basal Bolus (Glargine + RI)

7.How many times per day do you take insulin injections? ___ times

8.What is Commonest or Preferred site of injection site you /your child use?

A. Abdomen B. Thigh C. Arm D. Mixed E. Hip

9.What is the least preferred injection site you/your child use? _____

10.What Type of insulin device does your child use?

A. Insulin pen B. Insulin Syringe

11.What is the insulin Needle length

A.4mm B. 5mm C. 6mm D. 8mm

12.What type of insulin does your child use?

A. NPH + RI B. Glargine + RI C. Other _____

13.Do you rotate your child's insulin injection sites?

A. Yes, I rotate sites regularly B. No, I tend to use the same sites

If no, why_____

14.How often do you reuse insulin needles

A. Less than 5 times B. More than 5 times

15.How often do you change the insulin needle _____

16. How often do you perform self-monitoring for presence of lipodystrophy in your child's injection site

A. every 6 months B. Every year C. Every two years D. Never

17.How often do you get your child's injection site checked by health care professional

A. every 6 months B. Every year C. Every two years D. Never

18. How do you prepare the injection site?

A. Clean with alcohol swab B. Do not clean the site C. Clean with Water

Lipodystrophy Assessment

19.Have you noticed any changes in the appearance of the skin and/or subcutaneous tissue at your child's insulin injection sites?

A. Yes B. No

20.If yes, please show the interrogator the site … (to be filled after physical examination)

A. Lipohypertrophy B. Lipoatrophy C. Both

21.Where did you first notice these changes?

A. Abdomen B. Thigh C. Arm D. Other

22.When did you first notice these changes? ___ months / years ago

Glycemic Control

23.What was your child's most recent HbA1c value? ___ %

24.Have your child experienced frequent episodes of hypoglycemia (<70 mg/dl) in the past 3 months?

A. Yes B. No

25. If yes, please specify the number of hypoglycemic episodes ------

Other Factors

26.Do your child have any other medical conditions besides type 1 DM?

A. Yes, please specify: _____

B. No

27. Is Your child currently taking any medications other than insulin?

A. Yes, please specify: _____

B. No

28.Does your child engage in regular physical activity?

A. Yes, ___ times per week

No

Thank you for your participation in this study