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# **Study Methods and Procedures for Diabetics Patients**

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## Description

Insulin is the primary treatment for patients with Type 1 Diabetes Mellitus (T1DM). It is often used as a supplement to oral hypo-glycemic agents for patients with type 2 Diabetes Mellitus (T2DM) who have failed to achieve the glycemic target. Insulin has been the most effective treatment in controlling hyper glycemia among patients with diabetes for over the past 90 years. It is given subcutaneously, either through an insulin pump or via multiple daily insulin injection devices. All proper insulin administration techniques should be applied to achieve the desired outcomes from insulin therapy. Several studies showed that the greatest benefit from insulin treatment is achieved by correcting insulin injection techniques.

#### **Diabetes Mellitus**

Previous studies have shown that healthcare professionals rarely instruct patients about proper insulin injection techniques. The injection techniques, including the appropriate needle length, rotating insulin injection sites, changing needles between injections, and checking injection sites for the presence of lipo-hypertrophy are all crucial factors in the glycemic control. Lipo-hypertrophy is defined as the development of lumps, raised areas, firmness, or hardness in the fatty tissue under the skin caused by the repeated injection or infusion of insulin. There is a strong inverse association between lipo-hypertrophy and rotation of insulin injection sites. Patients frequently rotating their injection sites had lower lipo-hypertrophy prevalence.

Studies about the effect of insulin injection technique on glycemic control are scarce, especially in the Middle East Region. The current literature available in Jordan includes only one published study that assesses the association between lipohypertrophy and some factors of insulin injection technique in type 2 diabetic patients. This may indicate the need for more research on this subject.

This study aimed to assess the practices of insulin injection techniques among patients with diabetes treated at the National Center for Diabetes Endocrinology and Genetics (NCDEG) in Amman, Jordan, and assess the effect of these practices on glycemic control.

At our center, patients are routinely referred to education clinics, where specialized diabetes nurses provide them with extensive theoretical and practical training on insulin injection techniques according to ADA recommendations. These education sessions are provided at the initiation of insulin therapy and are regularly repeated every three to six months. However, the current study and previous studies in Jordan have revealed some serious gaps in DM patients' education. This emphasizes the need for additional creative DM educational resources and methods. Also, there is a need to involve additional health workers in the educational process, such as pharmacists, laboratory technicians, and community health workers.

## **Endocrinology**

This cross-sectional study was conducted between November 2020 and February 2021 at the outpatient clinics of the National Center for Diabetes, Endocrinology, and Genetics (NCDEG) in Amman, Jordan. The study methods and procedures are similar to those that had been used in an earlier study in 2015.11 A systematic sampling technique was used to recruit study subjects by choosing every fifth patient who attended the diabetes specialist outpatient clinics for regular follow-up during the study period. At NCDEG, patients are routinely referred to the educational clinic for comprehensive training on insulin administration techniques at the beginning of insulin implementation and regularly during their follow-ups every three to six months.

The prevalence of lipo-hypertrophy varies widely across countries. The current study shows that almost half of Jordanian Diabetes Mellitus (DM) subjects had lipo-hypertrophy. A systematic review and meta-analysis of 26 studies reported an overall estimated prevalence of lipo-hypertrophy of 49% among T2DM subjects and 34% among T1DM subjects. Insufficient health education about injection techniques in Jordan might explain the high prevalence of lipo-hypertrophy among current study subjects.

Patients with type 1 diabetes mellitus or type 2 diabetes mellitus that had been using insulin injections for at least a year were eligible for inclusion in the study. Women with gestational diabetes and infants were excluded from this study. The total sample was 851 subjects which translate to a margin of error of about 3.2%, given a prevalence of 37% and a 95% confidence level.

At enrolment, trained researchers administered a comprehensive structured questionnaire prepared explicitly for

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the purpose of the research based on similar previous studies. The main data obtained included socio demographic variables, diabetes history, co-morbidities, current medications, practices of insulin injection techniques, and other variables. Insulin injection techniques were assessed by asking the subjects or their caregivers to demonstrate how they take insulin, checking the correct dose, angle degree of insulin injection, injection site, rotation of injection site, and time of needle lift after injection.

The researchers examined the site of insulin injection for the presence of LH. Also, the researchers checked the needle length with the support of a catalog that contains pictures of insulin type and type of needle length picture to help the subjects to identify the type of insulin and needle they were using. Glycosylated hemoglobin level and anthropometric measurements were extracted from the medical records.

Grade 1 lipo-hypertrophy was defined as visible hypertrophy of fat tissue but palpably normal, while grade 2 as a massive

thickening of fat tissue with firm consistency and grade 3 as lipoatrophy. Glycemic control was classified, according to the American Diabetes Association (ADA) criteria, as controlled if HbA1c is <7% and uncontrolled if HbA1c ≥7%.

The study was approved by the ethical committee at the national center for diabetes, endocrinology, and genetics in Amman, Jordan. All procedures performed in this study were in accordance with the 1964 Helsinki declaration and its later amendments. A written informed consent was obtained from each adult subject. Caregiver written informed consent was taken for younger subjects. Also, the ascent was taken from children aged seven to 17 years. Data were treated with rigorous confidentiality and used strictly and exclusively for scientific study purposes. Interviews with the subjects were conducted with proper social distancing measures to avoid Coronavirus Disease 2019 (COVID-19) hazards.