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Evaluation of Continuous Subcutaneous Insulin Infusion (CSII) as an Alternative Therapy for Type 1 Diabetes in Paediatric Patients: A Focus on HbA1c Levels.

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ABSTRACT

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disorder commonly diagnosed in children or teens. This leads to a complete absence of insulin production due to the immune system's targeted destruction of the pancreatic beta cells responsible for insulin synthesis. Effective management of type 1 diabetes necessitates the maintenance of optimal glycemic control to mitigate the risk of acute complications such as hypoglycemia and hyperglycemia, as well as long-term consequences including macrovascular (e.g., cardiovascular disease) and microvascular (e.g., retinopathy and nephropathy) damage. Hemoglobin A1c (HbA1c) serves as the primary biomarker for assessing average blood glucose levels over the past two to three months, hence monitoring long-term glycemic control. This study examines the impact of continuous subcutaneous insulin infusion (CSII) on glycemic control in diabetes care by comparing patient data from before and after the procedure's implementation. Furthermore, to ascertain whether the use of Continuous Subcutaneous Insulin Infusion (CSII) as opposed to Multiple Daily Injections (MDI) diminishes the incidence of severe hypoglycemic episodes in pediatric patients with type 1 diabetes. Samples from fifteen individuals were analyzed, and blood glucose levels were recorded both during and after the transition to Continuous Subcutaneous Insulin Infusion (CSII) and standard insulin therapy. The average glucose levels and variances were analyzed using statistical methods, including Pearson correlation and t-tests. Following the transition to Continuous Subcutaneous Insulin Infusion (CSII), the outcomes demonstrated a significant enhancement in glycemic regulation, characterized by reduced mean glucose levels and diminished variability. These findings suggest that CSII provides.

KEYWORDS: *CSII; type I diabetes; HbAC1; Accu-Chek Combo.*

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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disorder that usually presents in childhood or adolescence, defined by the destruction of pancreatic beta cells responsible for insulin production, resulting in absolute insulin deficiency. Effective glucose regulation is essential for this illness. The principal biomarker for evaluating long-term glycemic control is hemoglobin A1c (HbA1c), reflecting average blood glucose levels over the preceding two to three months[1].

Multiple daily insulin injections (MDI) constitute the conventional therapy for pediatric patients with type 1 diabetes. This requires meticulous regulation of insulin levels, carbohydrate intake, and physical activity. Nonetheless, the variability in insulin absorption, patient compliance, and the challenge of achieving optimal glucose levels[2] render this method of diabetes management arduous. Nearly 80% of children and adolescents exceed the recommended HbA1c thresholds, as indicated by research, and numerous pediatric patients fail to achieve their target HbA1c levels despite their diligent efforts[3].

Continuous subcutaneous insulin infusion (CSII), commonly referred to as insulin pump therapy, has emerged as a popular alternative to multiple daily injections (MDI). Continuous Subcutaneous Insulin Infusion (CSII) provides enhanced precision in basal insulin administration and bolus dosages for meals or adjustments through a tiny device. CSII aims to improve glycemic management and the patient's quality of life by replicating the pancreas' natural insulin secretion[4]. A substantial cohort study revealed that pediatric patients utilizing Continuous Subcutaneous Insulin Infusion (CSII) exhibited a notable enhancement in long-term glycemic control, with their HbA1c levels being 0.5% lower than those of pediatric patients on Multiple Daily Injections (MDI)[5].

Multiple studies have examined the advantages of Continuous Subcutaneous Insulin Infusion (CSII) versus Multiple Daily Injections (MDI), concentrating on HbA1c levels as an indicator of glycemic regulation. The findings indicate that CSII may assist adolescents with diabetes in managing their disease more efficiently, resulting in fewer hypoglycemia episodes and reduced HbA1c levels[6]. A meta-analysis indicated a 6.5% decrease in severe hypoglycemia incidents among children utilizing Continuous Subcutaneous Insulin Infusion (CSII), hence reinforcing the clinical advantages of this method. Nonetheless, there remains ongoing controversy and study concerning the efficacy of Continuous Subcutaneous Insulin Infusion (CSII) as a substitute for traditional Multiple Daily Injections (MDI) in attaining optimal HbA1c levels, particularly in pediatric and adolescent populations[7].

MATERIALS AND METHODS

The effectiveness of continuous subcutaneous insulin infusion (CSII) was assessed through glycemic control, determined by the HbA1c level in pediatric patients with type 1 diabetes. This research used a quantitative, retrospective methodology. The CSII technique was employed with the Accu-Chek Combo insulin pump. All data originated from the patient records of the Zliten Center for Diabetes and Endocrinology in 2022.

SAMPLES

Samples from children were gathered for 15 instances of Type 1 Diabetes. Data was obtained from patient records at Zliten Medical Center. Prior to and following the transition from multiple daily injections (MDI), a conventional insulin management technique, to the contemporary continuous subcutaneous insulin infusion (CSII) method utilizing the Accu-Chek Combo insulin pump, patients were mandated to document HbA1c levels in accordance with the inclusion criteria. The data for this study was obtained by a standardized questionnaire specifically designed to collect pertinent patient information and features.

DATA ANALYSIS

The average HbA1c levels in pediatric patients prior to and following continuous subcutaneous insulin infusion (CSII) were evaluated using a paired two-sample T-test. The T-test was employed to ascertain if the application of Continuous Subcutaneous Insulin Infusion (CSII) yielded a statistically significant difference in glycemic control compared to the prior approach of Multiple Daily Injections (MDI). The calculated statistical parameters were the mean and variation of HbA1c levels for the two treatment periods. The two datasets (pre- and post-CSII) were analyzed using the paired sample T-test to ascertain the statistical significance of the observed increases in HbA1c. A significance threshold (P-value) of 0.05 was employed to evaluate the null hypothesis. The computed P-value was juxtaposed with the significance level to ascertain the acceptance or rejection of the null hypothesis. Supplementary statistical metrics, such as the T-statistic and the critical values for one-tailed and two-tailed tests, were employed to assess the data. Microsoft Excel was employed for these experiments to guarantee precise data computation and interpretation.

RESULTS

The gender distribution chart (refer to Figure 1) indicates that the samples comprised 15 pediatric patients, with 8 males and 7 females. This representation reveals a slight predominance of males among the participants. The distribution is sufficiently balanced to assess the impact of the CSII approach on both genders. The majority of participants were younger, as illustrated in Figure 1. Specifically, seven patients were aged between 11 and 20, while eight patients were aged between 5 and 10. This highlights the study's emphasis on younger children and adolescents, which is crucial for understanding the efficacy of the CSII approach during these significant developmental

stages.

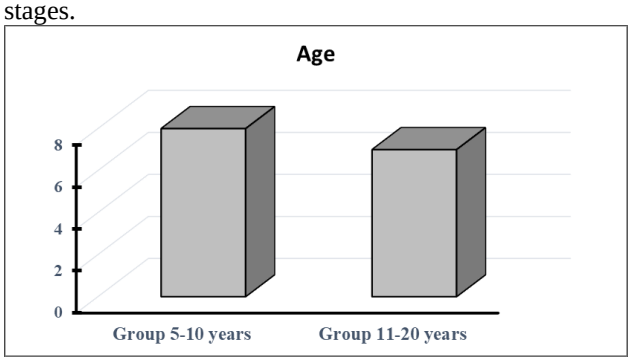

Figure 1. Age Distribution

The HbA1c level chart starkly contrasts the HbA1c levels prior to and after to the implementation of the CSII technology. Prior to the intervention, HbA1c values varied between 7.5 and 10, signifying inadequate blood glucose regulation. Following the implementation of the CSII, the values, which ranged from 5.5 to 8.7, significantly diminished. This drop illustrates the efficacy of the CSII method in enhancing patients' glycemic regulation.

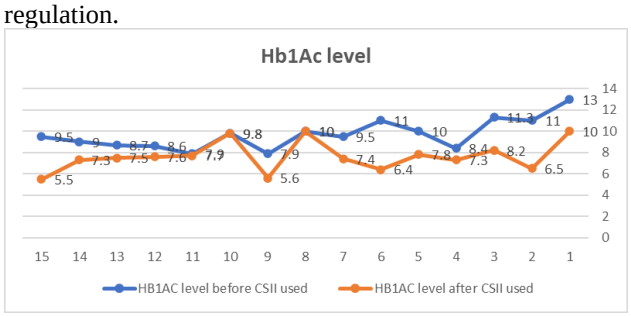

Figure 2. HbA1c levels before and after the use of the CSII approach.

Table 1. HbA1c values in individuals were statistically evaluated prior to and following the continuous subcutaneous insulin infusion (CSII) technique.

Data analysis		
Statistical Measures	**Variable 1**	**Variable 2**
Mean	9.706666667	7.64
Variance	1.997809524	2.002571429
Observations	15	15
Pearson Correlation	0.409461294	
Hypothesized Mean Difference	0	
Df	14	
t Stat	5.207641727	
P(T<=t) one-tail	6.63593E-05	
t Critical one-tail	1.761310136	
P(T<=t) two-tail	0.000132719	
t Critical two-tail	2.144786688	

Variable 1 means patient's Hb1Ac level before use CSII technique (i.e. patients on traditional treatment).
Variable 2 means patients' Hb1Ac level after use CSII technique.

The HbA1c levels of patients before and after employing the continuous subcutaneous insulin infusion (CSII) method are statistically compared in the table above. This analysis indicates significant changes. The average HbA1c prior to CSII was 9.71, significantly exceeding the average post-CSII of 7.64. The variation for the CSII phase is 2.003, whereas the variance for the normal therapy phase is 1.998, indicating they are nearly equivalent. The Pearson correlation coefficient of 0.409 signifies a moderately strong association between the two measurement sets, implying consistency throughout the two timeframes. The p-value of 6.64E-05 and the t-statistic of 5.21 indicate that the observed difference in HbA1c means is statistically significant. Moreover, substantial data suggests that the CSII method can reduce patients' HbA1c levels, as demonstrated by significant outcomes for the one-tailed test (1.761) and the two-tailed test (2.145).

DISCUSSION:

The researchers determined that continuous subcutaneous insulin infusion (CSII) technology surpassed conventional insulin injection therapy in glycemic management. The average HbA1c level declined from 9.71 before CSII to 7.64 after the intervention, demonstrating that the current approach enhances blood glucose control. The variance before and after employing CSII is 1.998 and 2.003, respectively, indicating minimal volatility and implying stability in the results' variability. This corroborates the documented rise in average values.

The Pearson correlation coefficient of 0.409 between the pre- and post-CSII assessments indicates that the implementation of CSII leads to a notable enhancement in glycemic control. The exceedingly low p-value (6.64E-05) and the markedly significant t-statistic (5.21) reinforce this enhancement and indicate that the observed drop in HbA1c is improbable to be attributable to chance.

Continuous subcutaneous insulin infusion (CSII) markedly enhances glycemic control relative to many daily injections, as indicated by prior studies[8]. Nonetheless, a prior finding indicates that the CSII technique yields a more uniform decrease in HbA1c for this group, despite other studies highlighting the diversity in patient responses to CSII[9]. Basic alterations in contrast indicate that the results are consistent, illustrating the dependability of CSII performance.

The statistical findings align with prior research, demonstrating that the strategy is superior to conventional diabetes management methods. These findings indicate that further study is necessary to examine these benefits through larger and more diverse patient trials to assess their potential for broader applicability.

CONCLUSION:

The investigation indicated that the Continuous Subcutaneous Insulin Infusion (CSII) method offers

superior glycemic control compared to conventional insulin therapy. The statistically significant difference, along with the CSII group's lower mean blood glucose levels, indicates that CSII may be a more effective diabetes treatment strategy.

The consistent variance and moderate correlation between the two methodologies indicate that CSII is a more stable and dependable strategy that enhances outcomes. Considering that CSII may enhance the health of individuals on insulin therapy, our findings endorse the notion that it should be utilized more extensively in clinical environments.

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