



COMPARING VARIOUS KINDS OF STUDY FOR ENHANCING THE QOL IN PATIENTS USING INSULIN PUMP AND DAILY INJECTIONS FOR T1DM.

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ABSTRACT:

In order to control the blood sugar levels, the people with type1 diabetes must have to take insulin. There are currently two methods to control the glucose, such as insulin using an insulin pump or an injection method using a pen or a needle. An insulin pump is a little electronic gadget it disperses the insulin through a tiny tube that is inserted under the patient's skin, it helps to scatter the insulin throughout the body, here daily injections is used as an alternative method to control the glycemic level and which may help to enhance the patients life.

Aim:

To estimate the effectiveness of blood glucose level. The Injectable study using needle was performed in young and adult age patients who are with Type 1 Diabetes. Based on the clinical trial practise data base the participants were recruited from a sizable population. (1)

Methods: Here, I compared a qualitative and quantitative study, Observational study, Study of children along with parents and paediatric children study investigation for T1DM using common guidelines and procedures. The investigations were carried out based on the Quality Of Life measures.

Report: The metabolic control in the young age of children enhances the blood sugar level that is with diabetes. Here the T1DM is controlled by the insulin pump in the young age of the people. This article highlights the Quality Of Life characteristics of the patients involved in the qualitative and quantitative study, Adolescence study, Observational study, Study with children along with parents.as well as the comparison of children or young people in the present scenario.

Conclusion:

When compared with the multiple daily injections, Insulin pump gave good results in promoting and enhancing the Quality of Life in patient who are suffering from high glucose level. Costs were the primary deterrent to utilising or ceasing to use an insulin pump.

Keywords: Insulin dependent diabetes mellitus, Hyperglycaemia, Blood glucose level, Insulin Pump and Insulin Injections.

INTRODUCTION:

Insulin pump:

Some diabetics utilise an insulin pump, which is an insulin-delivery system it is a small battery-operated device that can be worn on a belt or put in a pocket, It is attached to a thin plastic tube that is taped into a place just beneath the skin. The pump is programmed by those who use it to continuously supply insulin throughout the day and to release additional doses of insulin to counter blood sugar increases.

Multiple daily injections:

The people who are treated with Insulin treatment, via through Multiple Daily Injections (MDI) often involve three or more shots per day. This entails injecting rapid- or short-acting insulin before each meal, as well as one injection of long-acting insulin in the evening.(2)

T1DM:

The loss of insulin-producing pancreatic beta cells, which results with insulin insufficiency, is often may causes often referred to as autoimmune diabetes, Type 1 Diabetes Mellitus (T1DM) is a chronic condition which may results in hyperglycaemia. Due to an insulin insufficiency which may cause by pancreatic cell loss.(3) Blood sugar (glucose) levels increase as a result, and in the absence of further insulin, this Diabetes can lead to unconsciousness and death..(4) On the basis of the presence or absence of hyperglycaemia and symptoms associated with hyperglycaemia, the aetiology of T1DM may be divided into three stages. There is now no treatment for these consequences, therefore patients must live with insulin injections for the remainder of their lives. To address these problems, new insulin administration techniques are being developed.To improve the quality of life and prognosis of those afflicted, significant research efforts are necessary to achieve early identification, avoid -cell loss, and find better treatment alternatives.(5) Blood glucose levels that are not properly regulated and altered over time can cause heart disease, kidney illness, eyesight, and permanent nerve damage. Patients with type 1 diabetes (T1DM) must take more insulin, which is administered as injections at particular times of the day (basal) and after meals, in order to reach the conventional treatment objective (glaciated haemoglobin levels of 7%). (bolus or prandial).(6) Some Type 1 diabetics can utilise MDI to keep their blood sugar levels under rigorous control without ever suffering hypoglycaemia. When used for newly

diagnosed diabetes, insulin pumps are well-accepted, safe, and efficient, especially in youngsters where MDI may not be feasible. Insulin control with numerous daily doses or continuous sub mucosal infusions using an insulin pump is the primary treatment for T1DM patients. In order to avoid an unacceptable incidence of hypoglycaemia, patients strive for glaciated haemoglobin (HbA1c) values below 7% .(7)

Three stages of T1DM development were proposed:

- Characterised by the presence of normoglycemia and presymptomatic -cell autoimmunity as shown by two or more islet autoantibodies.
- It is the presymptomatic occurrence of -cell autoimmunity with Dysglycemia.
- It is the beginning of a symptomatic illness.

In T1DM patients previously treated with several daily injections, insulin delivery by pump improves glycaemic control with fewer hypoglycaemia episodes., resulting in a significant decrease in HbA1c. In comparison to injectable patients, insulin pump users, especially children, had reduced Hb1A1c and reported insulin needs.(8)

QoL [Quality of Life]:

The patient's quality of life is poorer than that of their healthy peers due to problems and the worry of complications. Using an insulin pump reduces worry about severe hyperglycemia and diabetic coma.(9)

This mixed-method cross-sectional study's objective was to investigate the factors that affect patients' quality of life and T1DM-related self-management in two patient groups: those who use insulin pumps and those who use frequent daily insulin injections. Our main hypotheses were as follows:

1. Insulin pump users had a greater quality of life than insulin injection users, and pump users found it easier to control their T1DM than injection users.
2. Better Quality Of Life is related to easier T1DM-related self-management.

METHODS AND STUDY DESIGN:

Generally two types of methods were involved in comparison studies for T1DM:

1. Qualitative and Quantitative study.
2. Observational study.
3. Study with children along with parents.
4. Adolescence study.

Methods:

1. Quantitative study: The quantitative portion of a mixed-method cross-sectional investigation on adult T1DM patients included both pump users and injection users. This study includes with most of the patients who are treated with the diabetes. The study include the quantitative results for the patients who are involved in the study (11).

Qualitative study: Here the minimum number of patients with pump users are involved in the treatment of qualitative study for diabetes and also injection users are also participated in the qualitative part. Through the digital platform the patients are involved in the study so that the study can be easily performed. In addition, qualitative analysis the answers were performed well though the patient's results are good in the qualitative part (11). In proportional ratio of 1:2 the patients were involved for the study part, the study cases were more than 80% of diabetic patient were involved in this type of study.

2. Observational study: In this type of study more than 15000 of people with type were involved with Type 1 Diabetes, using, more than 2000 Insulin pump patients were involved in therapy part and more than 16000 patients using multiple daily injections were involved in this study. (12).

3. Study with children along with parents:

In this method of study the children's at below the age of 12 were considered and the they were interviewed. The parents of children under the age of 12 were interviewed in-depth by the researchers. The patients data base were collected based on the different portions such as insulin pump and multiple injections. The study methods shows that the pump user are more flexible than the injection.(13)

4. Adolescence study.

A comparative study had been conducted at the paediatrics clinic of the National Diabetic Centre. The patients who are above the age of 18 were considered as adult and the study has been carried out. Patients with type 1 diabetes had been included, were the ratio of 2:1 of the people were involved in the study. Patients were assessed by HbA1c, hypoglycaemic and ketoacidosis [14].

STUDY DESIGN FOR EACH GROUP:

Population:

The mixed-method cross-sectional study, featuring both a quantitative and a qualitative component, was performed out during April and May 2021. Participants in the study proportion of 1:2 were required to be T1DM patients who were at least 18 years of age and then had to sign the informed consent forms.

1. QUANTITATIVE STUDY DESIGN:

- The study's quantitative part contains self-reported demographical data.
- Disease-related parameters include Body Mass Index (BMI) calculations based on height and weight as well as years of T1DM occurrence, number of hypoglycaemia episodes per week, number of episodes per half-year, HbA1c interpretations taken at the most recent check-up, frequency of HbA1c readings throughout the year, and T1DM ends up costing.

In statistical experiment of this study, we examined pump users about how long they had been using the pump and also their intention and also they examined injection users about their reasons for not using a pump, as well as their justifications for stopping if they had previously used a pump.

ADDITIONAL ANALYSES OF QUANTITATIVE STUDY:

They asked pump users about their reasons for using the equipment, how long they had been using it, and other details to understand more . They queried injection users why they didn't use pumps , as well as why they had stopped using pumps in the past . We created several logistical regression models for the two QoL blocks such as Therapy and Concerns significantly changed between the different users for the evaluation, categorising the results for each block into "worst" and "good" categories based on the data.

(b) QUALITATIVE STUDY DESIGN:

The test's qualitative design involved the analysis of semi-structured interviews conducted in person, over the telephone, either through videoconference. Using Conventional technology, conversations were captured, transcribed, edited, and reviewed for their main topics. Consumers of pumps and users of injections did not vary in this factor. 90% of pump users cited improved quality of life (12) as the primary motivation for using a pump. Injection users had been injecting insulin for an average of eight years, and nearly half of them cited the pricing of a pump as the significant barrier for purchasing. The respondents were between the ages of 18 and 50, and their durations of T1DM ranged from 1 to 35Eight individuals seemed to have no T1DM records, and some had one just when they started therapy, two used them solely for doctor appointments, and six frequently recoded their activity logs. The quality of life was one of the key justifications for using an insulin pump. (16)

ADDITIONAL ANALYSIS OF QUALITATIVE STUDY:

We asked pump users on how long people had been utilizing the device and their goals in order to learn more. We questioned injection users reasons why they didn't use a pump and why they had stopped using one, if they had already used one. The results for each block were divided into "worse" and "better" categories based on the average price for the analyses. This was done for the two Quality Of Life blocks for the Treatment and Concerns that they significantly differed between the user groups. According to primary study, lower T1DM expenses, years, and male sex were connected to better Treatment and Conversation blocks, and years living with T1DM.

2. OBSERVATIONAL STUDY DESIGN

As compared to both quantitative and qualitative analyses, observational studies stand out as being very distinct from them. More than 18000 T1DM patients have been incorporated into this study's design (17). Here, they contrasted the three distinct study design types, including T1DM, MDI, and CVI. The participants in this scenario are under the age of 30. The right documentation and maintenance of the insulin pump meds and the therapy both are done. Here, they used several procedures to do five imputations using the Markov chain Monte Carlo method for missing data in the sample. But, the outcomes were not quite clear. Mistakes might happen. Over this research period, no differences were noticed. The death rates for T1DM and MDI are identical. (18)

BY OTHER STUDY DESIGN:

However, when the exploratory approach is contrasted with other study designs, the mortality rate for the Insulin pump technique is displaying decent findings while that of the many daily injections were slightly deceptive. Contrary to several daily injections of insulin, continuous insulin Infusion treatment have been shown to lessen the incidence of severe hypoglycaemia. Type 1 diabetes research demonstrates a significant decrease in the risk of deadly heart attacks, fatal heart disease, and cause death while using an insulin pump. (18)

STATISTICAL ANALYSIS:

We used the SAS MI and MIANALYSE routines to perform five Markov chain Monte Carlo imputations for missing data in the sample of people. The procedures were recorded based on clinical characteristics in two treatment groups: insulin pump therapy and Multiple Daily Injections. The mean or frequencies of each multiple imputed variable were noted, and we used Student's t - test to evaluate significance for raw variations between the two groups. We compared the outcomes of the two different groups using incorrect Kaplan-Meier curves and reported hypoglycaemia episodes during study follow-up. Using logistic regression, we constructed a propensity score for pump therapy, which shows the conditional risk of obtaining pump therapy given baseline data. The results for variations among the two treatment groups were calculated after accounting for all 36 parameters. These inclusion criteria were age, gender, diabetes duration, cardiovascular illness, heart failure, fibrillation, HbA1c, systolic and diastolic blood Pressure, high density lipid cholesterol, fats, and cumulative micro albumin. Estimation using generalised linear models. Moreover, standardised distinctions among the two groups were assessed; a discrepancy of less than 10% was considered acceptable. The confirmatory factor stratification by fifths and the number of outcomes by fifth of the score were computed for the two treatment groups. To evaluate the efficacy of insulin pump therapy to many daily injections, we generated hazard ratios with 95% confidence intervals using the Logistic statistical approach. Covariates were controlled for using propensity score stratification. In the Cox regression analysis, the proportional hazard assumption was tested by including an interaction effect between the predictor and log time. Estimating using generalised linear models, computed with generalised linear models Maximum likelihood estimation was used to examine interactions

between the two treatment groups and all factors in the propensity score; no interactions were observed between any covariates. If unmeasured factors are irrelevant or not properly accounted for by measured factors, or if they impact the decision to utilise an insulin pump instead of several daily injections, the results may be altered. Using Lin and colleagues' technique, we created a sensitivity analysis by quantifying the effects of a hypothetical unmeasured confounder. All statistical evaluations performed using SAS version. A two-sided P value was regarded as significant.

3. STUDY DESIGN WITH CHILDREN ALONG WITH PARENTS:

QUALITATIVE STUDY:

Only qualitative methods were used in this study design. While attempting to quantify it, qualitative techniques seek to explore new lines of inquiry by employing flexible and open-ended data gathering procedures that allow participants to raise and debate topics. In this strategy, the qualitative component approaches a powerful and successful way for unearthing people with superior understanding and experiences as compared to the quantitative component. [19]

Data design:

Children with T1DM between the ages of 3 and 12 were included in the trial, along with their 19 parents, and the younger participants received insulin pump therapy. Due to a rise in high blood pressure, the parents have decided against using many daily injections [20]. They advised parents to monitor the pump for at least 6 months. Diabetic patients should be questioned to learn about their pump experience. A total of 14 home interviews were done with the assistance of literature studies, unique study questions, clinic observations made prior to data collection, and feedback from advisory group members, including parents of Type 1 diabetic children [21]. Two experienced qualitative researchers conducted a theme analysis using the constant comparison approach. To maintain analytical rigour, each researcher separately read and reread each interview before cross-referencing them all to identify issues and themes that pervade parents' perspectives. Meetings were organised on a regular basis to discuss interpretations, gain consensus on recurring themes, and create a coding structure to capture the original research questions and newly uncovered information. D.R. coded the entire set of data, and J.L. confirmed that the segments were right. The use of NVIVO, a qualitative software tool, facilitated data coding and retrieval, and coded datasets were subsequently submitted for more in-depth research. Members of the Advisory Committee, clinical colleagues, and article co-authors also assessed, confirmed, and offered advice on data interpretation to ensure that the study's results and recommendations were applicable in clinical practise.

SAMPLE AND DATA COLLECTION:

We recruited parents of 14 children who used insulin pumps as part of a larger study that examined parents' experiences caring for a child with Type 1 diabetes aged 3 to 12 years. These mothers were chosen from four paediatric diabetes clinics in Scotland, where about

30% of children under the age of 12 currently use insulin pumps and where extensive training and information on how to operate these devices is offered as standard. Health experts gave recruiting packets to clinic-going parents who fit the criteria. Purposive sampling was utilised to guarantee variance in the final sample in terms of parental demographics and child demographics/disease characteristics. Using an opt-in approach, parents were recruited. At the beginning of the study, an Advisory Committee was established to give extra advice on sampling. This group was made up of medical experts, lay representatives, parents of children with Type 1 diabetes, legislators, and representatives from charity organisations. To ensure that parents could share their thoughts on the apparatus, group members suggested that our larger sample match the proportion of parents whose kids use pumps in the four clinics. Parents who had been using a pump for at least six months were also to be interviewed, according to their suggestion. In keeping with grounded theory research principles, recruitment and interviewing were spaced out to allow for the collection and analysis of data in real time. [26]. Since no new themes or conclusions were uncovered in the newly available data, the recruiting process was discontinued. D.R., an experienced qualitative researcher, performed 14 home interviews between November 2012 and August 2013, five with both parents and nine with only one. Topic criteria derived from literature research, original study questions, clinic observations made before to data collection, and recommendations from advisory group members, including parents of children with Type 1 diabetes, led the interviews. To accommodate new information acquired from early interview analysis, we changed the subject guide using our inductive method.

4. STUDY DESIGN FOR ADOLESCENCE:

Sampled comparative study had been conducted at the paediatrics clinic of the National Diabetic Centre for a period of 6 months [22]. When a research variable was not normally distributed, the Mann-Whitney test was performed to compare two groups. To determine the relationship between variables, Pearson's chi square (X^2) and the Fisher-Exact test were utilised. [28]. Most of the patients were involved in the eligibility criteria for the study test design [23]. For this kind of study the eligibility criteria was above age of 2 -18. DM diagnosed within first year of life, DM associated with other disease that might affect metabolic control of the patients. [23-27] as there is no diabetes nurse educator, bolus doses were achieved by fixed doses (dividing 50% of the total insulin daily dose into 3 equal fractions (pre-breakfast, pre-lunch, pre-dinner) plus ISF, also patients was advised to take extra insulin dose before snacks (broadly 1 unit for each 10 g carbohydrate). No patient use insulin pump [27]. In this kind of study only MDI is used for controlling the diabetic patients. [30]

STRENGTH OF THESE STUDIES:

The main strength of the studies is to determine the QoL Quality of Life with the patients who are suffering with the T1DM. A mixed cross –sessional study also followed in all of these studies such as qualitative and quantitative analysis has been carried out with T1DM

patients. These helped in throughout the process for the QoL in diabetic patients. The study states that the pump user and the MDI are mostly involved in these kind of studies.

When compared to the strength of these users the insulin pump users have more advantages when compared to the MDI users. Because the insulin pump helps in the hypoglycemic control and also helps to control the blood glucose level.

LIMITATIONS OF THIS STUDY:

ADVANTAGES:

The main advantages are:

1. Mostly insulin pump helps to increase the flexibility
2. It helps to deliver smaller amount of insulin.
3. The variations of blood sugar will be controlled easily.
4. Helps to manage the overnight and early morning blood variations.
5. It helps to prevent/treat the hypoglycaemia.

DISADVANTAGES:

The major disadvantages are

1. The cost of insulin pump is very high when compared to the multiple daily injections.
2. In order to control the blood glucose level injection should be taken multiple times.
3. The ratio of the study is about 1:3 where most of the people use MDI in place of insulin pump.

REPORT:

By comparison of all these studies I came to know that the insulin pump is the main reason to determine the quality of life. Here in many cases the insulin pump is majorly used in all study areas and also gives good effect to control the hypoglycaemic conditions and it helps to reduce and maintain the blood glucose level. By comparing all these 4 studies the quality of life will be well enhanced in the pump user compared to the MDI users.

Here, the state explain that the insulin pump helps to control all the glycaemic activities. But foremost main reason to avoid the insulin pump is because they are cost is very high. Because of the cost the people and the patients prefer MDI. But in some cases the most of the foreign countries prefer the insulin pump rather than the multiple daily injections.

CONCLUSION:

In this study by comparing all the study design the insulin pump helps to determine the Quality Of Life of patients and it helps to control the blood sugar level. Here the cost of insulin pump is very high compared to the MDI, So most people prefer the MDI.

Insulin pumps could help:

1. To decrease consequences associated to poor treatment adherence,

2. To avoid increasing extra morbidity, and
3. To prevent a health-care system overburden.

By comparing all four studies, it states that the insulin pump leads to control the blood variations. In the study cases mostly they have compared with the qualitative and quantitative analysis with various patients such people with young stages, adolescence, diabetic patients, children etc. In all these stages of analysis insulin pump plays a major role in the control of blood glucose level and helps to reduce the glycaemic control activities.

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