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A COMPARITIVE STUDY FOR THE ASSESSMENT OF QUALITY OF LIFE USING MDI CSII FOR TYPE-I DIABETES PATIENTS

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ABSTRACT

Diabetes mellitus (DM), also known as simply diabetes, is a group of metabolic diseases in which there are high blood sugar levels over a prolonged period. Diabetes is due to either the pancreas not producing enough insulin, or the cells of the body not responding properly to the insulin produced. Prevention and treatment involves a healthy diet, physical exercise, not using tobacco and being a normal body weight. Blood pressure control and proper foot care are also important for people with the disease. Type 1 diabetes must be managed with insulin injections. Type 2 diabetes may be treated with medications with or without insulin. The main aim of the current study is to provide a better understanding of the Type 1 diabetes patients quality of life by assessing the difference in glycemic control in patients (Type-1 DM) using MDI (Multiple daily Injection) and CSII (Continuous Subcutaneous Insulin Infusion) by the help of Insulin pump.

KEYWORD

Diabetes mellitus, Insulin, MDI (Multiple daily Injection) and CSII (Continuous Subcutaneous Insulin Infusion).

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INTRODUCTION^{1,2,3}

Diabetes mellitus (or diabetes) is a chronic, lifelong condition that affects your body's ability to use the energy found in food. There are three major types of diabetes: type 1 diabetes, type 2 diabetes, and gestational diabetes.

All types of diabetes mellitus have something in common. Normally, your body breaks down the sugars and carbohydrates you eat into a special sugar called glucose. Glucose fuels the cells in your body.

But the cells need insulin, a hormone, in your bloodstream in order to take in the glucose and use it for energy. With diabetes mellitus, either your body doesn't make enough insulin, it can't use the insulin it does produce, or a combination of both.

Since the cells can't take in the glucose, it builds up in your blood. High levels of blood glucose can damage the tiny blood vessels in your kidneys, heart, eyes, or nervous system. That's why diabetes - especially if left untreated - can eventually cause heart disease, stroke, kidney disease, blindness, and nerve damage to nerves in the feet.

Type 1 Diabetes⁴

Type 1 diabetes is also called insulin-dependent diabetes. It used to be called juvenile-onset diabetes, because it often begins in childhood.

Type 1 diabetes is an autoimmune condition. It's caused by the body attacking its own pancreas with antibodies. In people with type 1 diabetes, the damaged pancreas doesn't make insulin.

This type of diabetes may be caused by a genetic predisposition. It could also be the result of faulty beta cells in the pancreas that normally produce insulin.

A number of medical risks are associated with type 1 diabetes. Many of them stem from damage to the tiny blood vessels in your eyes (called diabetic retinopathy), nerves (diabetic neuropathy), and kidneys (diabetic nephropathy). Even more serious is the increased risk of heart disease and stroke.

Treatment for type 1 diabetes involves taking insulin, which needs to be injected through the skin into the fatty tissue below. The methods of injecting insulin include:

Syringes

- Insulin pens that use pre-filled cartridges and a fine needle.
- Jet injectors that use high pressure air to send a spray of insulin through the skin.
- Insulin pumps that dispense insulin through flexible tubing to a catheter under the skin of the abdomen.
- A periodic test called the A1C blood test estimates glucose levels in your blood over the previous three months. It's used to help identify

overall glucose level control and the risk of complications from diabetes, including organ damage.

Having type 1 diabetes does require significant lifestyle changes that include^{4,5}:

- Frequent testing of your blood sugar levels.
- Careful meal planning.
- Daily exercise.
- Taking insulin and other medications as needed.
- People with type 1 diabetes can lead long, active lives if they carefully monitor their glucose, make the needed lifestyle changes, and adhere to the treatment plan.
- The main aim of the current study is to provide a better understanding of the Type 1 diabetes patients quality of life by assessing the difference in glycemic control in patients (Type-1 DM) using MDI (Multiple daily Injection) and CSII (Continuous Subcutaneous Insulin Infusion) by the help of Insulin pump. It is used to analyze the effects of intensive insulin pump therapy vs multiple insulin injection therapy on the quality of life in adult type 1 insulin dependent diabetes by means of lowering hemoglobin A1 C levels, increasing exercise and injecting consistent meals.

MATERIALS AND METHODS

Study group and procedures

- 100 patients with type-1 diabetes were participated.
- All patients were treated and followed up at the Department of Diabetes at site under the Syncorp Clincare Technologies, Hyderabad.
- Number of subjects- 100
- Duration of study- 24 week (6 Months)
- Run in period (Baseline) = One week
- Active dose titration = 4 weeks (0, 2, 8, 16 and 24)
- Place of study- Sites under the Syncorp Clincare Technologies, Hyderabad.
- Types of subjects- Patients.

Criteria for Patient Participation

- Inclusion Criteria

- Exclusion criteria

Inclusion criteria

- Type 1 DM patients aged from 30-70 years old adult
- Patient those are taking insulin pump and insulin injection therapy
- Willing to give Consent
- BMI = $\leq 27.0 \text{ kg/m}^2$
- HbA1 C = 6.5- 9.0 %
- Fasting plasma Glucose = $> 7.0 \text{ mmol/l}$ (126 mg/dl)
- Duration of diabetes = $> 1 \text{ yr.}$

Exclusion criteria

- Type 2 DM patients
- Insulin dependent type 2 was eliminated from the study due to the fact that most are on oral diabetic agents to control their glycemic levels.
- If they are prior user of CSII or MDI unable to use MDI or CSII
- Had more severe hypoglycemic event within 6 months.
- With recent diabetes ketoacidosis with hepatic/ renal function.

Procedure

- The subjects ranged in age from 20-70 yrs
- The subjects were categorized in to two groups

- Multiple Insulin Injection Therapy (N = 56)
- Intensive Insulin Pump Therapy (N= 44)
- Participant subject were given signature in the consent form.

Treatment

MDI - Multiple daily injection = Insulin Glargine/ meal time insulin lispro (Humalog- tis- Eli Lilly).

CSII- Continuous Subcutaneous Insulin Lispro (Paradigm 722 pump).

Insulin dose titration was to the same glucose targets on both treatments FPG 4.4- 6.6 mmol/l (80-120 mg/dl), other pre-prandial blood glucose 5.0-7.7 mmol/l (90-140 mg/dl), 2-h postprandial blood glucose $< 7.7 \text{ mmol}$ ($< 140 \text{ mg/dl}$), and bed time blood glucose 6.1- 8.3 mmol/l (110-150 mg/dl).

Study measurements

- Analysts of A1C were performed at a central laboratory at screening and weeks 8, 16 and 24.
- Participants were asked to perform self monitored plasma glucose measurements four times daily using a plasma calibrated memory glucose meter.

RESULTS

All results are showed in the Table No.1 and Figure No.1-4.

Table No.1: Effect of MDI and CSII on T-2 DM patients by means of average weekly exercise, meal consistency and quality of life

S.No	Parameters	MDI (%)	CSII (%)	P Value
1	HbA1C	6.8	7.9	0.05
2	Weekly average exercise	0.42	2.1	
3	Meal consistency	42.7	53.9	
4	QOL result	71	92	

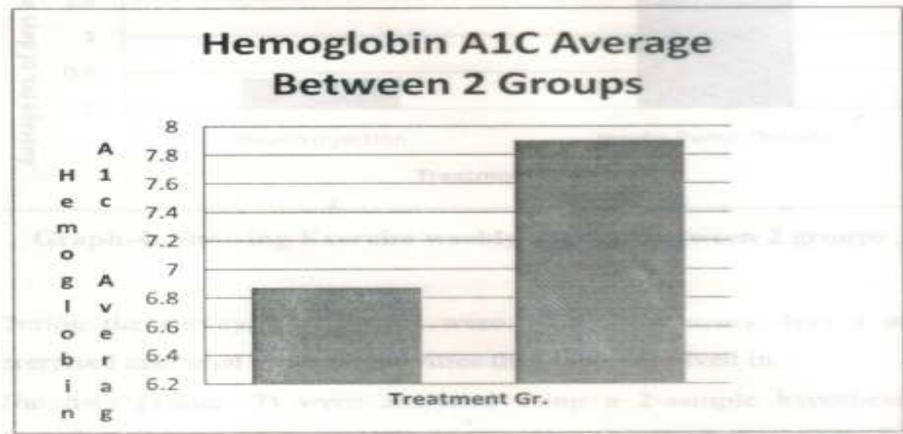


Figure No.1: Showing hemoglobin A1C Average between 2 Groups

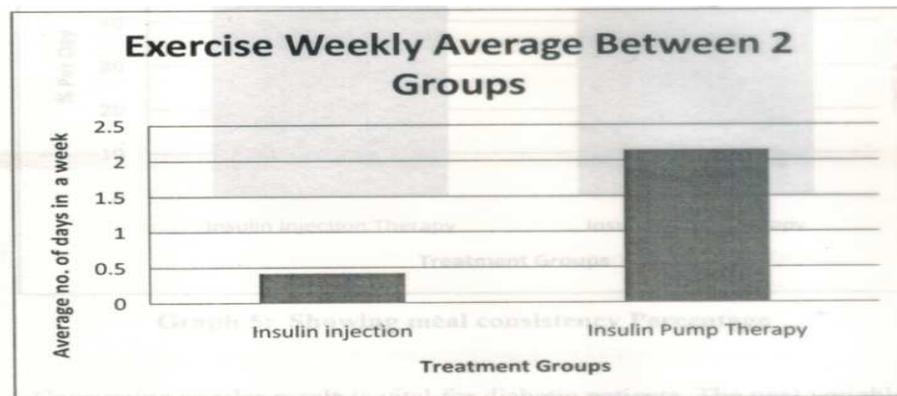


Figure No.2: Showing exercise weekly average between 2 groups

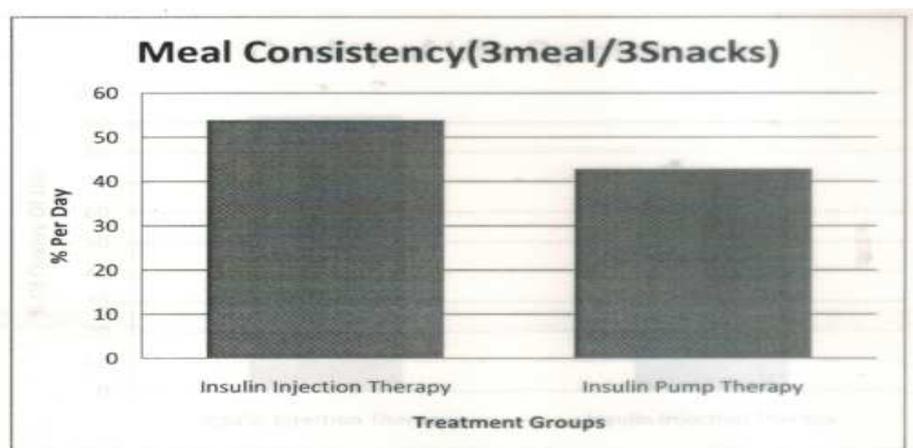


Figure No.3: Showing meal consistency percentage

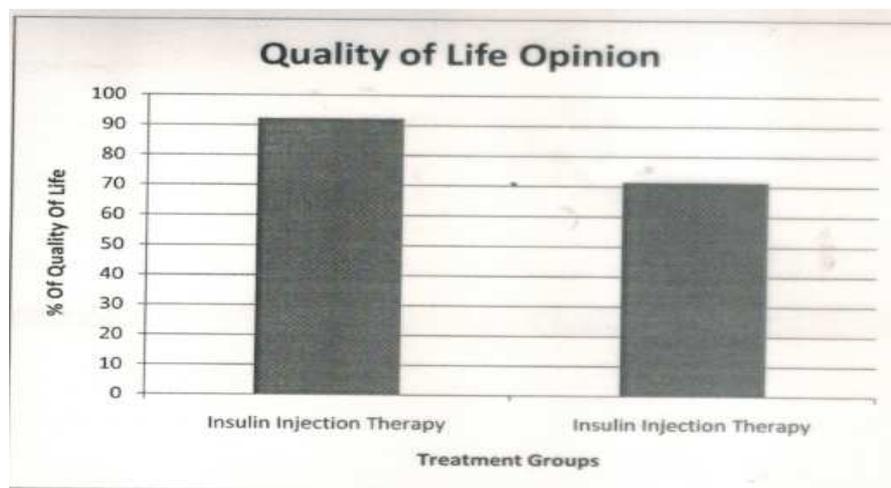


Figure No.4: Showing Quality of life opinion

CONCLUSION

In the present study, glucose variability and DTSQ assessment with CSII and Insulin Glargine based MDI was not showing statistical significance. The costs of CSII are higher than those of MDI are perhaps obvious given the costs of pump and infusion sets. The overall conclusion of this study was that the hypothesis that “there is a significant improvement in adult diabetes” overall health and quality of life when using intensive pump therapy compared to multiple insulin injections.

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