A COMPARATIVE STUDY AND ASSESSMENT OF THE QUALITY OF LIFE OF TYPE 1 DIABETES PATIENTS ON MDI AND CSII THERAPIES IN INDIA

SH. Thakkalapally* and M. Kunta

INTRODUCTION

According to International Diabetes federation, India recorded approximately 66.8 million diabetic cases in year 2014, a number that is expected to rise to 123 million by year 2035. With a cure yet to be found, our primary treatment options lie in prevention and management of diabetes. Diabetes Control and Complications Trial (DCCT) has shown that management of type 1 diabetes should include leading a healthy lifestyle and a structured intensive insulin therapy which could potentially decelerate the onset of diabetic complications. Insulin is administered via pump in continuous subcutaneous insulin infusion (CSII) therapy whereas in multiple daily injections (MDI) therapy, long acting insulin is injected once or twice a day as basal dose followed by rapid acting insulin during meal time.

A majority of studies reported that CSII therapy is more efficient than MDI therapy in glycemic control1, 2, 3, while a few reported a non-significant difference between the two therapies4, 5. However, very few papers studied and compared CSII therapy and MDI therapy in Indian population. PubMed website yielded only 3 results when we used “CSII”, “MDI” and “India” as search words to find relevant research in Indian populations.

The aim of our study was to understand the effect of CSII therapy and MDI therapy on quality of life of Indian population in terms of glycemic control, physical fitness, economical burden and patient’s satisfaction with the treatment.

PATIENTS AND METHODS

All patients enrolled in the study were receiving treatment for Type 1 diabetes at Suraksha Diabetic Hospital, Hyderabad, India. We enlisted 100 outpatients in the hospital, in the age range of 30-70 years, and followed them regularly for a period of 6 months. The study protocol was approved by Independent ethics committee and a written consent was obtained from the patients.

All study participants were diagnosed with Type 1 Diabetes and were enrolled in MDI or CSII therapy for more than a year. Each participant had HbA1c levels in the range of 6.5% - 9.0%, fasting plasma glucose levels greater than 7.0 mmol/L and a body mass index (BMI) of less than or equal to 27 Kg/m². The participants did not experience episodes of severe hypoglycemia or diabetes ketoacidosis with hepatic or renal failure in the

ABSTRACT

We assessed the effect of multiple drug injection (MDI) therapy and continuous subcutaneous insulin infusion (CSII) therapy on 100 type 1 diabetes patients in this 6 month study where we monitored patient's HbA1C levels, exercise frequency and expenses incurred by treatment. While we did not find any significant differences in the regulation of HbA1C levels by the two groups, CSII group reported experiencing a better quality of life compared to the MDI group. The groups also reported significant differences in their physical activity, eating habits and treatment expenses. The CSII group was more active and had better eating habits while the MDI group was more economical.

Keywords: Continuous subcutaneous insulin infusion, multiple drug injections, quality of life, India.
last 6 months from the beginning of the study and did not have a history of incompatibility with either of the therapies. All the 100 study subjects were divided into two groups based on their therapy: Multiple insulin injection group, MID, (n=56) and intensive insulin pump therapy group, CSII, (n=44). The CSII group employed Paradigm 722 pump with Insulin Lispro, and MDI group used Insulin glargine with meal time insulin Lispro. Plasma glucose levels were self monitored using a plasma-calibrated memory glucose meter (Accu-Chek Active Blood Glucose Monitoring System) four times a day, and HbA1c levels were analyzed at a central laboratory. Participants were asked to provide following data during each study visit.

- Periods of hypoglycemia (non-severe hypoglycemia: <4.0 mmol/l blood glucose levels, severe hypoglycemia: <2.0 mmol/l blood glucose levels)
- Daily meal consistency
- Exercise (days/week)
- A weekly evaluation on their quality of life
- Weekly insulin consumption
- Other adverse events, if any

Descriptive statistics were employed to report study group characteristics, and t-test was used to compare groups (a p-value of <0.05 was considered significant). We used IBM SPSS Statistics 21 software to analyze data.

RESULTS

Both MDI and CSII groups experienced a decrease in mean blood glucose and fasting blood glucose levels. There was no statistically significant difference (p <0.05) between the average HbA1C levels in the two therapies. The average HbA1C levels in MDI and CSII groups were 6.3% and 7.2% respectively. The MDI group however reported higher hypoglycemic episodes compared to CSII group (8 compared to CSII group’s 3).

The MDI group reported a lower frequency of physical exercise than the CSII group, an average of 6 days in one month compared to an average of 14 days per month. The difference in these groups was statistically significant at p = 0.05, showing that CSII group was relatively more active than the MDI group. The CSII group also had better eating habits. 64.3% of the CSII group had at least 3 meals a day whereas only 47.7% of the MDI group had 3 meals a day (the difference was statistically significant, p = 0.05). No significant BMI changes were noticed in either group.

According to the information provided by the participants, the average cost of insulin dispensed per subject was comparable to the MDI group. But the average cost of treatment, inclusive all items of equipment and dispensed insulin, was significantly higher for CSII group (at least by 2 times).

Overall quality of life of the participants in the two groups was compared by asking each subject a YES/NO question (YES for better QOL and NO for poor QOL) regarding his/her opinion of the overall quality of life with diabetes. 51 out of 56 (91%) in the CSII group said YES while only 26 out of 44 (59%) in the MDI group said YES. Two sample t-test, at p=0.05 significance level, proved that CSII group indeed experienced a better quality of life than MDI group. But the DTSQ values between MDI and CSII groups showed no statistical difference.

DISCUSSION AND CONCLUSION

In this study, the CSII group was administered insulin lispro and the MDI group was administered insulin glargine with meal time insulin lispro. The regimens did not produce any significant difference in glycemic control. Though our study did not precipitate any causality from mistaken dosage in MDI group, substituting glargine with lispro can lead to severe hypoglycemia that might prove fatal, as such patients need to be informed and advised.

Both groups had comparable HbA1C levels suggesting that both MDI and CSII therapies contributed equally in glycemic control. But the pump users did report that they exercised better consumed meals frequently and generally felt that they had a better quality of life than MDI group. When participants were questioned about their daily meal planning, we found that insulin pump users were more likely to consume 3 meals a day than the MDI group. Since both the groups come from comparable economical backgrounds, we speculate that the decreased meal consumption could be attributed to the difficulty and fear of administering insulin by MDI shots compared to pump. When questioned about dietary planning, only 16 out of 56 (28.6%) in group CSII reported counting carbohydrates and calories before meal consumption. While only 12 out of 44 (27.2%) in MDI group did the same. These small percentages show that a majority of the patients do not plan their diet. But, CSII group subjects’ perceptions of their lives were superior to those on multiple injection therapies and were more conscious of their health and fitness in general. This better
quality of life of CSII group could be a result of better education and awareness about the disease, but we lack sufficient data to back this hypothesis. Although the data indicates that CSII group is physically more active than MDI group, HbA1C levels were not significantly different in these two groups. Research studies present ambiguous results on the effect of exercise on Type 1 diabetes. While some studies noted a significant improvement in HbA1C levels, others have reported non-significant reductions. Despite showing no significant differences in glycemic control in comparison with MDI, CSII therapy elicited comparatively higher satisfaction in the patients' quality of life and reported an overall better life style. This satisfaction with CSII therapy is in accordance with other studies. But the average cost of CSII treatment, significantly higher than MDI treatment, is a poor choice for the economically handicapped.

Interestingly, while the participants in CSII group reported enjoying a satisfactory life, the study groups did not display a significant difference in their DTSQ scores. We suspect further research to explore the efficiency of CSII in populations with varying levels of literacy.

In conclusion, CSII group boasts a better quality of life compared to MDI group, but CSII therapy is also more expensive which makes it difficult for the lower to middle class populace to adapt it.

ACKNOWLEDGEMENTS
We thank Suraksha Diabetic Hospital's cooperation and help with the study.

REFERENCES

