

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

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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.

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 in lay 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 life style 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 control^{1, 2, 3}, while a few reported a non-significant difference between the two therapies^{4, 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 the 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

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 fatal⁶, 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 MID 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^{7,8}.

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 diabetes⁹. While some studies noted a significant improvement in HbA1C levels^{10, 11}, others have reported non-significant reductions^{12, 13, 14}.

Despite showing no significant differences in glycaemic 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^{3, 5}. But the average cost of CSII treatment, significantly higher than MDI treatment, is a poor choice for the economically handicapped¹⁵.

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 that the participant's degree of literacy might have precipitated this disparity. We suggest further research to explore the efficiency of DTSQ 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.

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REFERENCES

1. Hoogma RP, Hammond PJ and Gomis R. 5-Nations Study Group. Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial. *Diabet Med.* 2006;23:141-147.
2. Jakisch BI, Wagner VM, Heidtmann B, Lepler R, Holterhus PM and Kapellen TM. Comparison of continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI) in paediatric Type 1 diabetes: a multicentre matched-pair cohort analysis over 3 years. *Diabet Med.* 2008;25:80-5.
3. Doyle EA, Weinzimer SA and Steffen AT. A randomized, prospective trial comparing the efficacy of continuous subcutaneous insulin infusion with multiple daily injections using insulin glargine. *Diabetes Care.* 2004; 27:1554-1558.
4. Herman WH, Ilag LL and Johnson SL. A clinical trial of continuous subcutaneous insulin infusion versus multiple daily injections in older adults with type 2 diabetes. *Diabetes Care.* 2005;28(7):1568-1573.
5. Raskin P, Bode BW, Marks JB and Hirsch IB. Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: a randomized, parallel-group, 24-week study. *Diabetes Care.* 2003;26:2598-2603.
6. Adlersberg MA, Fernando S, Spollett GR, APRN and Inzucchi SE. Glargine and Lispro Two cases of mistaken identity. *Diabetes Care.* 2002; 25(2):404-405.
7. Mollema ED, Snoek FJ, Adèr HJ, Heine RJ and van der Ploeg HM. Insulin-treated diabetes patients with fear of self-injecting or fear of self-testing: psychological comorbidity and general well-being. *J Psychosom Res.* 2001;51:665-672.
8. Davies MJ, Gagliardino JJ, Gray LJ, Khunti K, Mohan V and Hughes R. Real-world factors affecting adherence to insulin therapy in patients with Type 1 or Type 2 diabetes mellitus: a systematic review. *Diabet Med.* 2013;30:512-524.
9. Andrea Lukács and LászlóBarkai. Effect of aerobic and anaerobic exercises on glycaemic control in type 1 diabetic youth. *World J Diabetes.* 2015;6(3):534-542.
10. Sideraviciūte S, Gailiūniene A, Visagurskiene K and Vizbaraitė D. The effect of long-term swimming program on glycemia control in 14-19-year aged healthy girls and girls with type 1 diabetes mellitus. *Medicina (Kaunas)* 2006;42:513-518.
11. Salem MA, AboElAsrar MA and Elbarbary NS. Is exercise a therapeutic tool for improvement of cardiovascular risk factors in adolescents with type 1 diabetes

- mellitus. A randomised controlled trial. *DiabetolMetabSyndr.* 2010;2:47.
12. D'hooge R, Hellinckx T, Van Laethem C and Stegen S. Influence of combined aerobic and resistance training on metabolic control, cardiovascular fitness and quality of life in adolescents with type 1 diabetes: a randomized controlled trial. *ClinRehabil.* 2011;25:349-359.
 13. Roberts L, Jones TW and Fournier PA. Exercise training and glycemic control in adolescents with poorly controlled type 1 diabetes mellitus. *J Pediatr Endocrinol Metab.* 2002;15:621-627.
 14. Kennedy A, Nirantharakumar K, Chimen M and Pang T. Does exercise improve glycaemic control in type 1 diabetes? A systematic review and meta-analysis. *Plos One.* 2013;8(3):e58861.
 15. Shobhana R, Rama Rao P and Lavanya A. Expenditure on health care incurred by diabetic subjects in a developing country: a study from southern India. *Diabetes Res Clin. Pract* 2000;48:37-42.