Assessment of impact of clinical pharmacist intervention to improve quality of life and medication adherence in pediatric type-1 diabetic patients

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ABSTRACT

Type 1 diabetes in children and adolescents is a challenging management problem for patients and their families. Childhood and adolescence are periods of constant and rapid change, hence adherence to medications and maintaining Quality of life are more difficult than adults. There are only limited studies on medication adherence and Quality of life (QOL) in pediatric type 1 diabetic patients especially from India. Together with adherence and glycemic control, patients can attain a better quality of life. An Interventional study was carried out in endocrinology department and patients were selected based on inclusion and exclusion criteria. The patients were randomized using graph pad method. Control group received standard clinical based care and intervention group received additional input from clinical pharmacist. Medication Adherence and QOL were measured using Morisky (MMAS) and Peds Ql questionnaires respectively. The scores of baseline and follow up visits were compared. The adherence scores for intervention group improved significantly during follow up visit. Statistically significant improvement (p value less than 0.05) in QOL in intervention group of both child and parent report were noted compared to baseline. This study suggests that clinical pharmacist intervention made a significant influence for improvement in medication adherence and quality of life of patients.Due to lack of awareness and motivation among patients and caregivers, health policy makers should consider placing a clinical pharmacist in paediatric diabetes clinics, whose service in association with other health care providers can indeed provide solutions for improving adherence and quality of life of patients.

INTRODUCTION

Type I diabetes mellitus (T1DM) usually occurs in young children, a deficiency of endogenous insulin production caused by the auto immune induced damage to the pancreatic β cells [1]. TIDM contributes to 80% of diabetes that occurs in children. There is a rise in incidence of T1DM all over the world. It is more common in Scandinavian countries .The incidence of T1DM in India is reaching almost similar to the incidence of United States. The main markers are islet cell antibodies, antibodies to glutamic-acid decarboxylase, and antibodies to insulin [2,3].The diagnosis is mainly by the presence of obvious hyperglycaemia, with classic trio of symptoms ie; polydypsia, polyphagia, polyuria[4] .There is an absolute need for exogenous insulin substitution, which lasts life long [5,6]. The long term success of patients suffering from T1DM is achieved by better adherence, drug administration and self monitoring of blood glucose level. The self care by the patient is of utmost importance for better adherence. If the child is empowered as early as possible, and the self care becomes a routine part of the daily life. In order to achieve this, proper encouragement should be given. This can only be attained by better patient education. Clinical Pharmacists can play a very active role in helping patients with Type 1 diabetes, by educating them regarding how to manage with insulin therapy to optimize

health outcomes [7,8]. The Pharmacist can educate the patients about the proper use of insulin syringes and pens, storage of insulin's, how to use a glucometer, how to prick the finger etc. The pharmacist can also counsel the patients regarding the need of insulin administration regularly, dietary and life style modifications so that onset of complications can be postponed by having tight glycemic control [9,10] .So clinical pharmacist can play an important role in helping a diabetic patient in the best possible way to cope with their disease[11].This study was aimed to assess the impact of clinical pharmacist intervention to improve quality of life and medication adherence in paediatric Type1 Diabetic patients.
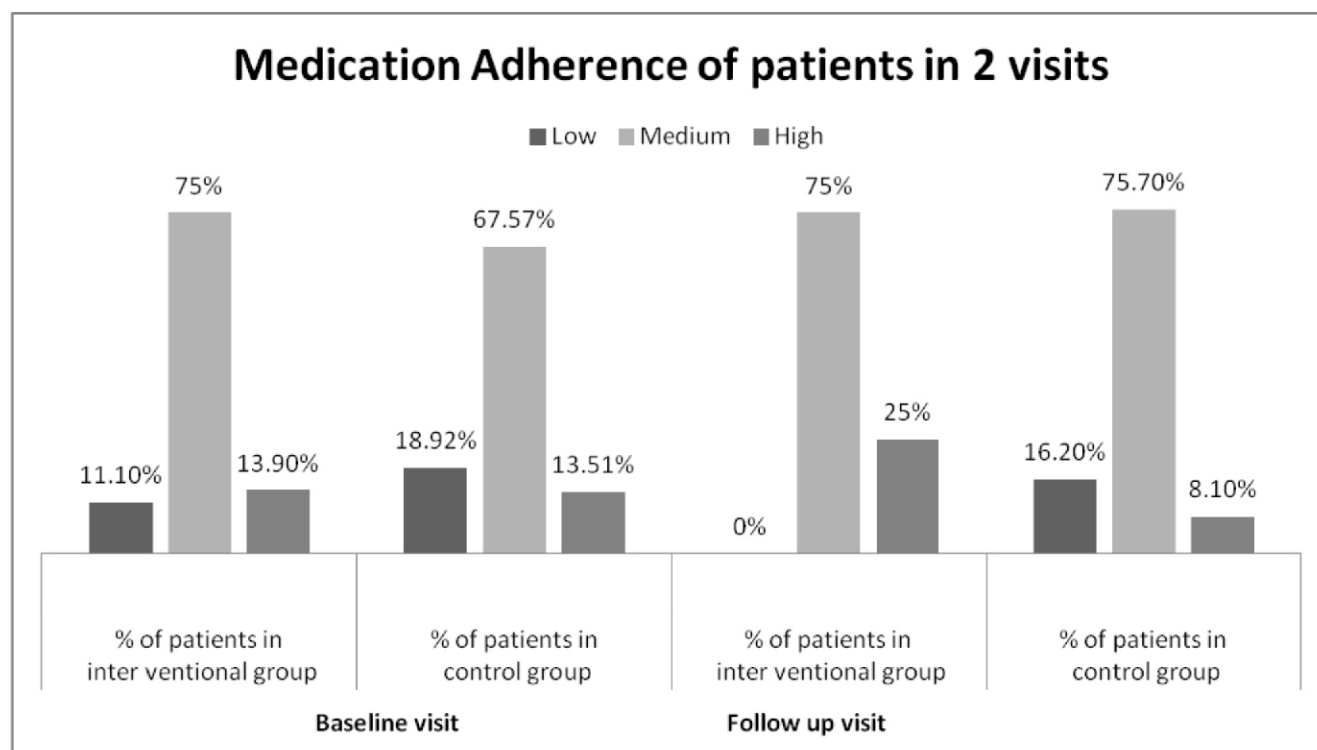
MATERIALS AND METHOD

A randomised interventional follow up study was carried out on outpatients at the Endocrinology department of Amrita Institute of Medical Sciences (AIMS), Kochi for a period of 10 months. During the first visit, informed consent was obtained directly from selected patients or their caregivers who satisfied inclusion and exclusion criteria. Inclusion criteria were Patients age ≤ 18 years, diagnosed to have TIDM, patient and/or care givers willing to participate in the study and able to read English or local language Malayalam . If both patient and care givers who were unable to read English or local language Malayalam, were excluded. An appropriate data collection form was designed and pertinent data including the demographic details, medical and medication history, Insulin regimen used with frequency and dose were recorded after interviewing the patient and or patient's caregivers. Patients were asked to fill questionnaires for assessing medication adherence and quality of life.

All the patients included in the study received a standard care of treatment and counselling from the Diabetes care team including Consultant Endocrinologist. Apart from the care of the Diabetes care team, Clinical Pharmacist counselled 50% of randomly selected patients and made them aware about the disease, Insulin and its importance, common adverse drug reactions (ADR) and its management, importance of patient compliance, dietary modifications and exercise. Randomization was done by using software 'Graph pad'. During the time of patient counselling, specially designed patient information booklets in the local language Malayalam or English were explained and given to the patients or caregivers. Diabetes Alert card was also given to patients. In the follow up visit, i.e. after 90 ±10 days the medication adherence and Quality of life [child and Parent proxy] reports were reassessed using the same questionnaires. Follow-up was done either in person and/or via the telephone. Medication adherence was measured using Morisky Medication Adherence Scale (MMAS), an 8-item questionnaire with seven yes/no questions and one question answered on a 5-point Likert scale. The reverse code response to be changed in a positive direction except for item number 5 and standardize the code for item 8 (0-4), resulting in a scale from low adherence to high adherence. Item 8 is divided by 4 when calculating a summated score. This procedure standardizes the 5-point Likert scale. The total scale has a score range of 0 to 8.0.Low Adherence (< 6), Medium Adherence (6 - 8), High Adherence (= 8) [12,13,14].

Child and their parents reported health-related QOL were analyzed using the PedsQL Diabetes Module.. Items were read to the child or given to the child to read, depending on the child's reading skills. In addition, parents completed a parent-proxy version of the measures for all children at the time of their visit. Participants aged above 5 years received two scores for each module (child and parent report), and participants aged younger than 5 years had one score for diabetes module (parent report only). Scores reported by child and parents on each module were analyzed separately. [15, 16]

Medication Adherence of patients in 2 visits

■ Low ■ Medium ■ High

Baseline visit:
- % of patients in inter ventional group: Low 11.10%, Medium 75%, High 13.90%
- % of patients in control group: Low 18.92%, Medium 67.57%, High 13.51%

Follow up visit:
- % of patients in inter ventional group: Low 0%, Medium 75%, High 25%
- % of patients in control group: Low 16.20%, Medium 75.70%, High 8.10%

Table 1 Medication Adherence of patients of control and intervention group in 2 visits.

Table 1 : Baseline scores of medication adherence of control group and intervention group.

Adherence	Mean	P value
Baseline (Control)	6.42	0.400
Baseline (intervention)	6.65	

Table 2 : Baseline scores of Quality of life of control and intervention groups in child and parent report.

Problems related	Group	Child Report		Parent Report	
		Mean	P values	Mean	P values
Diabetes	control	75.63	0.570	75.52	0.652
	intervention	77.57		77.02	
Treatment1	control	82.26	0.771	76.28	0.617
	intervention	83.27		73.96	
Treatment2	control	84.52	0.782	84.25	0.665
	intervention	85.51		82.59	
worry	control	76.57	0.765	66.88	0.462
	intervention	75.47		63.42	
communications	control	94.14	0.597	98.08	0.128
	intervention	91.90		95.14	

Table 3 : Quality of life in control group - child report

Problems related	visits	Mean	SD	Mean Difference	p - value
Diabetes	Baseline	76.58	14.528	1.064	0.295
	Follow up	77.64	13.255		
Treatment 1	Baseline	83.39	15.529	0.536	0.324
	Follow up	83.93	15.331		
Treatment ll	Baseline	86.50	13.859	0.527	0.476
	Follow up	87.02	14.103		
Worry	Baseline	76.19	16.928	0.714	0.324
	Follow up	75.47	17.845		
Communication	Baseline	93.81	19.211	0.238	0.324
	Follow up	93.57	20.220		

Table 4 : Quality of life in intervention group - child report

Quality of life in intervention group - child report					
Problems related	Visits	Mean	SD	Mean Difference	p - value
Diabetes	Baseline	77.57	14.054	8.194	0.000
	Follow up	85.76	12.311		
Treatment I	Baseline	83.27	13.277	5.000	0.000
	Follow up	88.27	12.992		
Treatment II	Baseline	85.51	14.106	4.966	0.000
	Follow up	90.48	12.276		
Worry	Baseline	75.47	14.424	7.857	0.000
	Follow up	83.33	13.558		
Communication	Baseline	91.90	16.969	3.333	0.037
	Follow up	95.24	10.939		

Table 5 : Quality of life in control group - parent report

Quality of life in control group - parent report					
Problems related	visits	Mean	SD	Mean Difference	p - value
Diabetes	Baseline	76.41	13.448	0.129	0.881
	Follow up	76.28	12.873		
Treatment I	Baseline	77.03	20.309	0.338	0.600
	Follow up	77.36	20.271		
Treatment II	Baseline	86.10	14.233	16.171	0.276
	Follow up	102.27	85.381		
Worry	Baseline	66.44	18.889	2.252	0.067
	Follow up	64.19	19.231		
Communication	Baseline	97.97	6.336	0.225	0.324
	Follow up	97.75	6.704		

Table 6 : Quality of life in intervention group - parent report

Quality of life in intervention group- parent report					
Problems related	Visits	Mean	SD	Mean Difference	p - value
Diabetes	Baseline	77.02	15.005	8.461	0.000
	Follow up	85.48	12.030		
Treatment I	Baseline	73.96	19.961	8.854	0.002
	Follow up	82.81	16.729		
Treatment II	Baseline	82.59	16.966	6.753	0.001
	Follow up	89.34	13.813		
Worry	Baseline	63.42	21.937	14.119	0.000
	Follow up	77.54	18.773		
Communication	Baseline	95.14	10.036	2.315	0.048
	Follow up	97.45	6.555		

RESULTS

In this study, 75 patients satisfying the inclusion and exclusion criteria were enrolled. Out of 75 patients, 73 patients successfully completed the study (97.33%) and 2 patients were drop outs (2.67%) . There was a female preponderance with 58.9%. Majority of patients (46.58%) were in 13-18 years age group followed by 8-12years (35.62%), then 5-7 years (13.7%) and the least number of patients in 2-4 years (4.10%) group. The mean onset age for male was found to be 8.80 ± 3.752 and 7.76 ± 3.848 in females. Baseline scores for control and intervention groups' medication adherence were quite similar. (Refer table 1)In baseline visit, for intervention group of patients, 11.1% had low adherence, 75% had medium adherence and 13.9 % had high adherence. In follow up visit, for intervention group of patients, there was none having low adherence, instead 75 % had medium adherence and 25 % had high adherence. In baseline visit, for control group, 18.92 % of patients had low adherence, 67.57% of patients had medium adherence and 13.51% had high adherence. But in visit 2, 16.2 % of patients had low adherence 75.7 % had medium adherence and the percentage of patients in the high adherence shown a decline from 13.51% to 8.1%. (Refer Figure 1)The scores for intervention group have statistically significant improvement in adherence (p-value is 0.001) in the follow up visit. The scores for control group were similar in follow up visit.

There was no significant difference between baseline scores of quality of life for both parent and child report in the control and intervention group.(Refer table 2) In the control group, the scores obtained for QOL of child report shows a mean difference for problems related to Diabetes symptoms, barriers, adherence, worry and communication were 1.064,0.536,0.527,0.714 and 0.238 respectively. (Refer table 3)But the calculated P value

failed to show the significance (>0.05). In the control group of parent proxy report scores too there was no statistically significant difference in follow up visit. (Refer table 5)

In the intervention group, the mean scores obtained for Qol of Child reports related to Diabetes symptoms, barriers, adherence, worry and communication were 8.194,5.0,4.966,7.857 and 3.333 respectively in the follow up visit. There was a statistically significant difference in scores after intervention. (Refer table 4) Parent proxy report also showed improvement in scores for Diabetes symptoms, barriers, adherence, worry and communication with values 8.461, 8.854, 6.753, 14.119 and 2.315 respectively with P value less than level of significance. (< 0.05).(Refer table 6)

Out of 73 patients 9 patients suffered from visual disturbances. Among these 9 patients, 4 had HbA1c value above 9 with poor glycemic control and 4 with HbA1c value below 8 showing fair glycemic control. Patients received twice daily and basal bolus regimens. Majority of patients (78.08%) were receiving basal bolus therapy. Patients were prescribed Human insulins (80.82%), followed by analogues and pump therapy respectively. Hypoglycaemia related problems were more in patients receiving human insulin as basal bolus regimen.

DISCUSSION

Adherence to medication is linked with glycemic control. According to the meta-analysis conducted by Korey K. Hood et al there exist an association between adherence and glycemic control in pediatric type 1 patients [17]. In our study, the baseline scores of control and intervention groups showed no significant difference between the groups. However counsellng and motivation was given by the clinical pharmacist for patients and

caregivers for the proper administration of insulin and education regarding the disease made a   statistically significant improvement in the intervention group in the follow up visit .In a study conducted by Deak D et al   in children and adolscents with type 1 diabetes , it was found that one of the main reasons for non-compliance was lack of education [18]. . Non compliance to the medication leads to poorer glycemic control which invites diabetic complications and ultimately affects the quality of life of patients. The importance of measuring adherence helps the health care providers to consider the best possible approach to overcome some of the barriers to adherence. For the Patients with T1DM, hypoglycaemia is the most acute side effect of insulin therapy which remains one of the major barriers to optimal glycemic control and elicits multiple negative physiologic outcomes. This study gave importance for educating children and their care givers to motivate them for compliance. As a part of this, telephonic follow-ups were also done. Patients and care givers were given chances to interact with each other and share their experiences. There was a decline in the no: of patients in the high adherence level in control group .But there was a statistically significant improvement in the medication adherence in the intervention group

There are limited no: of studies assessing Quality of Life (QOL) in paediatric patients with T1DM [19,20,21].   In a study conducted by Maartje W et al concluded that periodic monitoring and discussion of HRQoL in adolescents with type 1 diabetes have positive effects on their psychosocial well-being [22].In the present study after the intervention by clinical pharmacist ,there was statistically significant improvement (p value less than 0.05) in the child as well as parent report compared to the control group. Children with T1DM are dependent on parents and need special care from their parents or care givers. So it is very important that parents also need to know important issues related to the disease and administration of insulin. So in order to achieve better diabetic control both patients and care givers should be motivated.

CONCLUSION

The present study was aimed to assess the impact of clinical pharmacist intervention to improve quality of life and medication adherence in pediatric Type1 Diabetic patients. There was a statistically significant improvement in the medication adherence scores as well as Quality of life assessment in both parent proxy and child proxy reports while compared with baseline using paired t test at a significance level (α=0.05), even though the base line scores for both control and intervention groups were quite similar. Majority of patients followed Basal bolus schedule and hypoglycaemia was found in patients treated with human insulin in basal bolus regime compared to analogues. The present study proves the intervention of clinical pharmacist can bring changes in the adherence related thoughts of the patients and caregivers which in due course achieve improved   wellbeing of the patients. Hence the service of clinical pharmacist in all paediatric diabetic clinics plays an important role.

REFERENCES

1. Curtis L. Diabetes Mellitus. In: Dipiro TJ, Talbert R, Yee GC, Matzke GR, Wells BG, Posey M, editors. Pharmacotherapy- A Pathophysiologic Approach, 6 th edition, Mc Graw Hill Medical Publishers, 2008: 1333 -67.

2. Denman D. Type 1 diabetes. Lancet .2006; 367:847-58.

3. American Diabetes Association. Diagnosis and classification of Diabetes Mellitus. Diabetes Care 2012; 35:64-71.

4.   The pathogenesis and Natural History of Type 1 diabetes. Cold spring Harb Perspect Med 2012 (Accessed May 4,2012 at http:// perspectives in medicine. cshlp. Org/)

5. Bluestone JA, Herold K, Eisenbarth G. Genetics, pathogenesis and clinical intervention of type 1 diabetes. 2010; 464:1293-300.

6. Delli JA . Type 1 Diabetes. In: R. Holt, C. Cockram, A. Flybjerg and B. Goldstein, editors. Textbook of Diabetes, 4th edition, Blackwell Publishing, 2010:141-50.

7. Hutton JC . The insulin secretory granule. *Diabetologia* 1989 ; 32 : 271 81.

8. Peter MJ. Islet Function and Insulin Secretion. In: R. Holt, C. Cockram, A. Flybjerg and B. Goldstein .Textbook of Diabetes, 4th edition, Blackwell Publishing ,2010:91-03.

9. Eesh B, Ajay A et al. Insulin Therapy for patients with Type 1 Diabetes. Supplement of JAPI.2007;55:29-40.

10. Hirsch IB. Intensive treatment of type 1 diabetes. Med Clin North Am 1998;82:689-719.

11. Role of pharmacist in counselling diabetes ,2012. (Accessed on August 2012, at http://www.ispub.com/ journal/theinternet journal of pharmacology/2005 :volume-4)

12. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self   reported measure of medication adherence. Med Care 1986; 24: 6774.

13. Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. *Journal of Clinical Hypertension* 2008; 10:348-54.

14. Harith Kh, Al-Qazaz, Mohamed AH, Asrul AS, Syed AS, Shameni S, Morisky ED. The eight-item Morisky Medication Adherence Scale MMAS: Translation and validation of the Malaysian version, Diabetes Res Clin Pract 2010 November; 90(2): 21621.

15. Sand, Kljajić, Schaller, Forsander .The reliability of the health related quality of life questionnaire Peds QL 3.0 Diabetes Module for Swedish children with Type 1 diabetes. Acta Paediatrica 2012; 101:34449.

16. Varni JW,Burwinkle TM,Jacobs JR,Gottschalk M, Kaufman F,Jones KL.The pedsQL intype 1 and 2 diabetes: reliability and validity of the pediatric Quality of life Inventory generic core scales and type 1 diabetes module.Diabetes Care 2003;26:631-37.

17. Korey K, Hood Phd ,Clair M , Peterson MA, Jennifer M ,Rohan MA, Dennis D . Association Between Adherence and Glycemic Control in Pediatric Type 1 Diabetes: A Meta-analysis. Pediatrics 2009:124; e1171-79.

18. Deak D, Baumann U. Compliance of children and adolescents with type 1 diabetes (juvenile diabetes mellitus) Psychother Psychosom Med Psychol 1989 ;39:404-10

19. Mostafa A A, Mofida M K, Mohammad D E .et al. Quality of life and glycemic control in adolescents with type 1

diabetes and the impact of an education intervention nt J Gen Med 2011; 4: 14152.

20. Rasoul A,F Al Otaibi, Al Mahdi M, Al Kandari H. Quality of life in children with type 1 diabetes in Kuwait. BMC Proceedings 2012; 6:P7.

21. Krishnavathana H, Robert L, Barbara JA, Rubina A H . The role of socioeconomic status, depression, quality of life, and glycemic control in type 1 diabetes mellitus (Accessed on May 2013 at http://dx.doi.org/10.1016/j.jpeds.2006.o5.039)

22. Maartje W, Henriette A D, Jan Alle B . Monitoring and Discussing Health-Related Quality of Life in Adolescents With Type 1 Diabetes Improve Psychosocial Well-Being *Diabetes Care 2008;* 1:152126.