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Study on quality of life of type 2 diabetes mellitus patients managed with oral hypoglycemic agents vs both insulin and oral hypoglycemic agents in a tertiary care teaching hospital

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Abstract

Diabetes mellitus is a chronic metabolic disorder resulting from the deficiency of insulin secretion or may be excessive insulin secretion. It is one of the major health problems among the worldwide and leads to an increase in the cause of morbidity and mortality rate. As per World Health Organization (WHO), around 31.7 million individuals in India were affected by diabetes during the year 2000 which may further rise to 79.4 million by the year 2030. The Indian Council of Medical Research India Diabetes study (ICMR-INDIAB study) showed that India had 62.4 million people with diabetes in 2011. The study findings showed that female patients were more affected in the age group of 41 to 50 years with 6-10 years duration of disease. The patients under both the regimens had co-morbidities associated with the disease. Metformin is the most commonly prescribed oral hypoglycaemic drug in the monotherapy (Regimen A) whereas in the combination therapy (Regimen B), Metformin + Glimepiride + Insulin was commonly prescribed. Among the Insulin prescribed in combined therapy, Human Insulin was prescribed more. As per the QOL studies based on the WHOQOL-BREF scale, the patients under Regimen A had poor QOL in physical health domain than the Psychological, Social and Environmental domains. The patients under Regimen B had good QOL in all the four domains. The study finding concludes that there was no significant difference in QOL in patients receiving Regimen A and Regimen B.

Keywords: type 2 diabetes, quality of life, WHOQOL- BREF, regimen A. regimen B

Introduction

Diabetes mellitus is a chronic metabolic disorder resulting from the deficiency of insulin secretion or may be excessive insulin secretion. It is one of the major health problems among the worldwide and leads to an increase in the cause of morbidity and mortality rate. Diabetes mellitus (DM) is associated with high health care resource expenditure and incidence of mortality and morbidity. As this indicates a high burden, a drug utilization study was conducted to determine the drug use among diabetic patients attending medical outpatient department of a non-government multispecialty tertiary care hospital. As per World Health Organization (WHO), around 31.7 million individuals in India were affected by diabetes during the year 2000 which may further rise to 79.4 million by the year 2030. The Indian Council of Medical Research India Diabetes study (ICMR-INDIAB study) showed that India had 62.4 million people with diabetes in 2011. These numbers are projected to increase to 101.2 million by 2030 [1-4]. Diabetes mellitus (DM) is the chronic disorder emerging as major health problem which increases the rate of morbidity and mortality Poor management of this disorder leads to several complications [5]. Management of type-2 DM requires both pharmacological and non-pharmacological interventions.

Quality of life

Quality of life (QOL) is described as a multidimensional construct incorporating an individual's subjective perception of physical, emotional, and social well-being, including both a cognitive and an emotional component. The World Health Organization (WHO) has defined "QOL" as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". Health-related QOL (QOL) is increasingly being recognized as an important outcome of health, representing the ultimate goal of all healthcare interventions.

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Conventional outcome assessment for diabetes mellitus (DM) relies on laboratory indicators, primarily glycosylated hemoglobin (HbA1c), and complications [6-7]. However, exclusive reliance on clinical outcomes does not necessarily reflect a patient's perception of his/ her health. Management regimens that require changes in lifestyle and behavior can influence daily functioning and general wellbeing. QOL (health related quality of life) is therefore increasingly being used as an outcome indicator alongside traditional biomarkers. Hence this study was conducted to determine QOL in diabetic patients using WHOQOL-BREF (world health organization quality of life – BREF), a generic tool applicable in any chronic disease. It is increasingly recognized that in diabetes psychosocial factors have an important impact on self-care, acceptance of therapeutic regimens and treatment success and that, metabolic measures like glycemic control are poorly correlated with quality of life necessitating separate assessment. In turn, management models for diabetes that include strategies to identify and enhance patients health-related quality of life issues have the potential to improve compliance and hence their metabolic status. Hence this study was conducted to know the socio-demographic profile and health related quality of life of type 2 DM patients.

Aim

To assess the quality of life in patients with type 2 diabetes mellitus managed with oral hypoglycemic agents Vs combination of insulin and oral hypoglycemic agents.

Objectives

- To observe and document the drug use pattern in type 2 diabetes patients managed with oral hypoglycaemic agents.
- To observe and document the drug use pattern in type 2 diabetes patients managed with both insulin and oral hypoglycaemic agents.
- To assess the quality of life in patients with type 2 diabetes mellitus using oral hypoglycaemic agents.
- To assess the quality of life in patients with type 2 diabetes mellitus using both insulin and oral hypoglycaemic agents.

Methods and Materials

The study was conducted in the Department of medicine, Rajah Muthiah Medical College Hospital (RMMCH), a 1450 bedded multispecialty tertiary care teaching hospital, Annamalai University, Chidambaram. The outpatients affected with type 2 diabetes mellitus of both genders with all age groups in the Department of Medicine between November 2017 to April 2018 were enrolled in the study, while the inpatients and patients with intellectual disability, pregnancy and lactation were excluded. The patients (or care takers) were explained about the study and their consent was obtained along with the signature (of the patients or the care takers) and recorded.

Tools used

The WHOQOL-BREF – English version is used. It is a self-report questionnaire. For those who could not read, the questionnaire was filled by interview method. It consists of 26

items, of which the first 2 items measure the perceived QOL and general health satisfaction whereas the remaining 24 items are grouped into four domains of QOL (physical health, psychological health, social relationships and environment). Subjects would rate all items on a 5-point Likert scale.

Results

Table 1: Gender wise distribution

S. No.	Gender	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	Male	43	28 (56%)	15 (30%)
2	Female	57	22 (44%)	35 (70%)

Table 2: Age wise distribution

S. No.	Age	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	30-40	3	2(4%)	1(2%)
2	41-50	37	15(30%)	22(44%)
3	51-60	33	14(28%)	19(38%)
4	61-70	17	13(26%)	4(8%)
5	>70	10	6(12%)	4(8%)

Table 3: Duration wise distribution

S. No.	Duration of Disease (years)	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	1-5	11	6(12%)	5(10%)
2	6-10	43	25(50%)	18(36%)
3	11-20	26	12(24%)	14(28%)
4	>20	20	7(14%)	13(26%)

Table 4: History wise distribution

S. No.	History	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	Known case	64	43(86%)	21(42%)
2	Recently diagnosed	36	7(14%)	29(58%)

Table 5: Socioeconomic status wise distribution

S. No.	Social History	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	Smokers	17	10 (20%)	7 (14%)
2	Alcoholic	28	18 (36%)	10 (20%)
3	Both smoker and alcoholic	32	22 (44%)	10 (20%)

Table 6: Comorbid wise distribution

S. No.	Co-morbidities	Total (No's)	Regimen A No's (%)	Regimen B No's (%)
1	CAD	18	11(22%)	7(14%)
2	Dyslipidaemia	6	2(4%)	4(8%)
3	Diabetic foot	28	13(26%)	15(30%)
4	UTI	14	10(20%)	4(8%)
5	Anaemia	8	3(6%)	5(10%)
6	CVA	14	6(12%)	8(16%)
7	Hypokalaemia	12	5(10%)	7(14%)

Table 7: Drug use pattern based on two different regimens

S.no.	Regimen Type	Oral hypoglycemic drugs	No's	%
1.	Regimen A (n=50)	Metformin	21	42%
		Glimepiride	14	28%
		Glibenclamide	06	12%
		Voglibose	09	18%
2.	Regimen B (n=50)	OHA+Insulin	No's	%
		Metformin +glimepiride +Insulin	31	62%
		Glimepiride + Insulin	09	18%
		Metformin + insulin	10	20%

Table 8: Quality of life assessment among two different regimen users

Domain characteristics		Regimen A		Regimen B	
		Raw score (Mean± SD)	Transformed score* (Mean±SD)	Raw score (Mean±SD)	Transformed score* (Mean± SD)
Physical Health: (Raw score out of 35)	Q3- Pain	21.34 ± 1.96	50.4 ± 16.79	23.78± 5.80	56.88± 19.24
	Q10- Energy				
	Q16- Sleep				
	Q15- Mobility				
	Q17- Activities				
	Q4-Medication				
	Q18-Work				
Psychological Health (Raw score out of 30)	Q5-Positive feelings	21.29 ± 2.40	58.92± 17.01	22.71± 4.94	57.78± 16.68
	Q7-Thinking				
	Q19-Self esteem				
	Q11-Body image				
	Q26-Negative feelings				
Q6-Spiruality					
Social relationship (Raw score out of 15)	Q20-Personal relations	10.56 ± 2.56	58.74± 21.79	6.84± 1.54	69.14 ± 18.7
	Q22-Social support				
	Q21-Sex				
Environmental health (Raw score out of 50)	Q8-Safety & security	23.14 ± 4.61	62.46± 16.90	24.24± 6.44	61.96± 16.51
	Q9- Home situation				
	Q12-Finance				
	Q24-Health/social care				
	Q13-Information				
	Q14-Leisure				
	Q23-Physical				
	Q25-Transport				
	Q1-General QOL				
Q2-General health					

*Transformed scored out of 100

Results and Discussion

During the study period, a total of 100 cases of type 2 diabetes were collected and reviewed. Among that the demographic status of the patients were categorized into two regimens. They were shown given below,

Regimen A (Oral Hypoglycemic Drug Agents)

A total of 50 out of 100 patients were on Oral Hypoglycaemic Agents to control their blood glucose levels. The study shows that the oral hypoglycaemic drug was used mostly in males with (56%) and females with (44%). The most affected age group were 41-50 years with (30%) cases. The patients with duration of the disease 6-10 years were found to be more with (50%) followed by 11-20 years with (24%). The study shows that the number of patients consuming alcohol (36%) was higher than the smokers with (20%). The patients with both smoking and alcohol habits were found to be (44%).The known case of Type 2 Diabetes Mellitus was found to be more with (86%) in patients managed with OHA. The study shows that all the patients using Oral Hypoglycemic Agents (50 out of 100) were identified with co-morbidities. The major co-morbidities associated with patients using OHA were diabetic foot ulcer with (26%) followed by coronary

artery disease (22%), Urinary tract infection (20%), Cerebrovascular accident (12%), Hypokalaemia (10%), Anaemia (6%) and Dyslipidaemia (4%). Metformin was used as the first line oral hypoglycaemic agents for type 2 Diabetes mellitus in the study. Next, to Metformin (42%), Glimepiride (28%), voglibose (18%) and Glibenclamide (12%) were used as monotherapy. Metformin+ Glimepiride (15.4%) were prescribed commonly in combination among the oral hypoglycemic agents.

Regimen B (Both oral hypoglycaemic agents and insulin)

A total of 50 out of 100 patients were using a combination of both Oral Hypoglycemic agents and Insulin to control their blood glucose levels. The study shows that combination of both Oral hypoglycaemic agents and Insulin were used mostly in females with (70%) than males with (30%). In this study, the most affected age group were 41-50 years with (44%) followed by age group between 51-60 years with (38%). The patients with duration of the disease more than 6-10 years were found to be more with (36%) followed by 11-20 years with (28%). Only a few patients had a social history of smoking and alcohol, in which smokers were found to be less in number (14%) than alcoholics with (20%). In this group

recently diagnosed type 2 Diabetes Mellitus patients were more with (58%). All the patients using combined therapy of both Oral Hypoglycemic agents and Insulin (50 out of 100) were identified with co-morbidities. The major co-morbidities associated with the patients in this regimen were diabetic foot ulcer with (30%) followed by cerebrovascular accident (16%), Coronary artery disease (14%), Hypokalaemia (14%), Anaemia (10%), Dyslipidaemia (4%) and Urinary tract infection (4%). The commonly prescribed combination of OHA and Insulin therapy was Metformin+Glimepride+Insulin with (62%), Metformin+ insulin with (20%), Glimepiride + Insulin (18%).

Quality of life

The WHOQOL-BREF score was used to determine the quality of life in both the regimens. All the four domain characteristics (Physical health, Psychological health, Social relationship and Environmental health) were assessed in both the regimens. The WHOQOL was significantly lower for diabetic patients managed with OHA and both OHA and Insulin. The study shows significant differences in the physical health domain and psychological domain between the two regimens. Both groups had particularly low scores in the physical health and social relationship compared to other domains. This indicates poor physical conditions and social relationship affecting QOL of patients using OHA and combined therapy in a similar way. There were considerably fewer differences in Psychological and Environmental domains between the two regimen groups. Diabetes and its complications affected negatively all of the domains of the WHOQOL-BREF. However, the effects were strongest for the physical health and psychological domains and weaker for the social relationships and environment domains. We found a strong effect of interactions between gender and disease status. Whereas this finding could be partly explained by no significant difference among both the groups with respect to the QOL in this study. Regimen B affected the QOL of diabetic patients in physical health and psychological domains [7-10]. Most patients had a longer duration of disease which indicates that these patients are at higher risk of developing complications. On the other hand, only a few patients were newly diagnosed with the disease [11]. The longer duration of the disease also affects the QOL in the patients under both the regimen.

Conclusion

The study findings showed that female patients were more affected in the age group of 41 to 50 years with 6-10 years duration of disease. The patients under both the regimens had co-morbidities associated with the disease. Metformin is the most commonly prescribed oral hypoglycaemic drug in the monotherapy (Regimen A) whereas in the combination therapy (Regimen B), Metformin + Glimepiride + Insulin were commonly prescribed. Among the Insulin prescribed in combined therapy, Human Insulin was prescribed more. As per the QOL studies based on the WHOQOL-BREF scale, the patients under Regimen A had poor QOL in physical health domain than the Psychological, Social and Environmental domains. The patients under Regimen B had good QOL in all the four domains. The study finding concludes that there was no significant difference in QOL in patients receiving Regimen A and Regimen B.

Limitations of the study

- Inpatients were excluded due to fewer numbers of admissions.
- Complete follow up for all the patients was not possible throughout the study due to lack of response.
- Small group of population.

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