

A COMPARATIVE STUDY ON ASSESSMENT OF TREATMENT SATISFACTION AND QUALITY OF LIFE IN TYPE II DIABETES PATIENTS USING INSULIN AND ORAL HYPOGLYCEMIC AGENTS

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ABSTRACT

Background: Diabetes Mellitus is a chronic metabolic disease that requires continuous therapy and polypharmacy if uncontrolled DM is evident so that the effectiveness and adverse effects can affect the patient's quality of life and treatment satisfaction. Hence, both of them were the primary objectives of our study. **Materials and Methods:** An observational study was conducted in a tertiary care hospital for a period of 6 months. Patients with type II Diabetes mellitus on medication with insulin or oral hypoglycemic were included. The QOL instrument, WHOQOL-BREF questionnaire and the Diabetes Treatment Satisfaction Questionnaire [DTSQ] were administered to all patients at baseline, 3 months and 6 months of treatment. Statistical analysis was performed using SPSS 22 software. Student-t-test was used as a statistical test in the analysis. **Results:** In our study, 100 diabetic patients were enrolled, 50 in each group respectively. The glycemic profile was significantly better in the insulin group than oral hypoglycemic. When QoL is concerned in terms of domain, Insulin is higher in the psychological and social domain and OHA found better in the physical domain. There are no significant differences in the environmental domain. In treatment satisfaction, the Oral hypoglycemic group is significantly higher than the insulin group. **Conclusion:** Overall patients with Type 2 diabetes harm their quality of life with or without complications. It also shows that diabetes affects various domains such as physical functioning, emotional well-being, social functioning, economical status and general health in a patient's life, thereby affecting the QoL. Hence, it is recommended for patients to have adequate and strict glycemic control enabling them to maintain their quality of life, preventing disease progression and diabetic complications.

KEYWORDS: Type II Diabetes, Insulin, Oral Hypoglycemics, WHOQOL BREEF, DTSQ.**INTRODUCTION**

Diabetes Mellitus (type 2) comprise of a array of disorder signaled by hyperglycemia which resulting from the fusion of resistance to insulin action or insufficient insulin secretion and excessive or inappropriate glucagon secretion.^[1] It is a chronic complex disease associated with many severe complications such as blindness (retinopathy), amputation (ulcers), neuropathy, nephropathy and cardiovascular complications which is preventable.^[2] According to WHO, Diabetes Mellitus has been considered a global disease and its prevalence increases year by year. That prevalence is mainly due to population aging as well as changes in lifestyle which leads to decreased physical activity and increased body mass.^[3] In India 40 million people (approx.) have Diabetes in 2017 and it is expected to increase to 70 million by 2025.^[4] Diabetes affects the general health and safety of the patient and it creates a turndown effect in multiple aspects of a person's life including the psychological impression of being chronically ill, dietary

limitations, changes in social life, symptoms of inadequate metabolic control, chronic complexity and ultimately lifelong infirmities.^[5] Well being concerning health status is a complicated concept covering physical, psychological and social performance which is affected by the disease and treatment. Treatment satisfaction is a measure of quality care in the health system.^[3] Thus, Quality of life and treatment satisfaction denote individual perceptions and those play a major role in the effectiveness of the treatment and disease progression.

Quality of life

It has been measured using the WHOQOL-BREF scale. It has a 5-point Likert scale which used to record the responses in the WHOQOL BREF questionnaire. It has 26 questions and measures four domains of the patient well being such as physical, psychological, social and environmental domains.^[3]

Treatment satisfaction

It has been evaluated with the help of the Diabetes

Treatment Satisfaction Questionnaire (DTSQ). It consists of six questions, each with 7 possible answers. It denotes an understanding of diabetes, satisfaction with treatment as well as convenience and flexibility to the treatment, recommending treatment to other diabetic patients.

The main aim of our study to evaluate the differences in QoL and treatment satisfaction, depending upon the treatment given to the patient's condition (insulin vs. OHA). Therefore these evaluations are very much necessary to improve the healthcare of diabetic patients.

MATERIALS AND METHODS

A prospective observational study was directed in a tertiary care center for a period of 6 months. The sample size was about 100 patients (overall), 50 in each group who meet the criteria were included. The inclusion criteria in this study were diabetic patients (type II) over the age of 18 years on either insulin or oral hypoglycemic for more than 3 months on regular follow up and treatment. While the exclusion criteria were

diabetics with serious illness and complications. Informed consent for the study was obtained before each patient was assigned to their respective groups. A structured proforma was used to collect the information on socio-demographic details, history as well as laboratory parameters such as glycemic profile. We assessed the quality of life and treatment satisfaction through questionnaires (WHOQOL-BREF, DTSQ) which were completed by the patient (self) as the baseline, 3 months and 6 months. Statistical analysis was done using SPSS 22 software. Student-t-test was used as a statistical test in the analysis.

RESULTS

Descriptive Analysis

✓ Gender distribution

The patients who participated in the study were 100 (50 each). Among 50 patients, in the Insulin group, 24 (48%) were male and 26 (52%) were female. Among 50 patients, in the Oral hypoglycemic group, 27 (54%) were male and 23 (46%) were female.

Table 1: Gender distribution of insulin and oral hypoglycemics.

GENDER	INSULIN			ORAL HYPOGLYCEMICS		
	No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
MALE	24	48	33.7-62.6	27	54	39.3-68.2
FEMALE	26	52	37.4-66.3	23	46	31.8-60.7

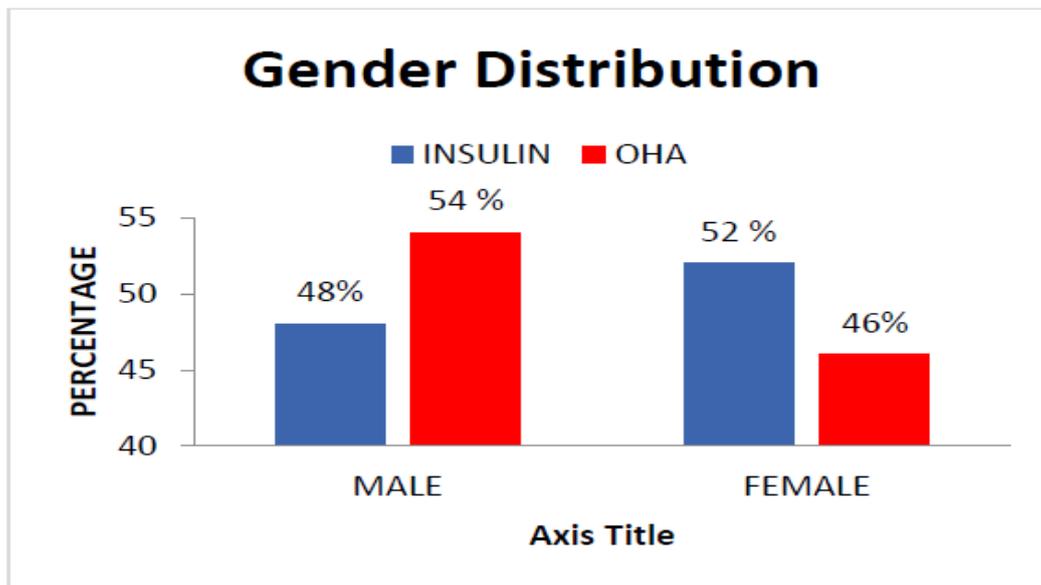


Figure 1: Gender distribution between two groups.

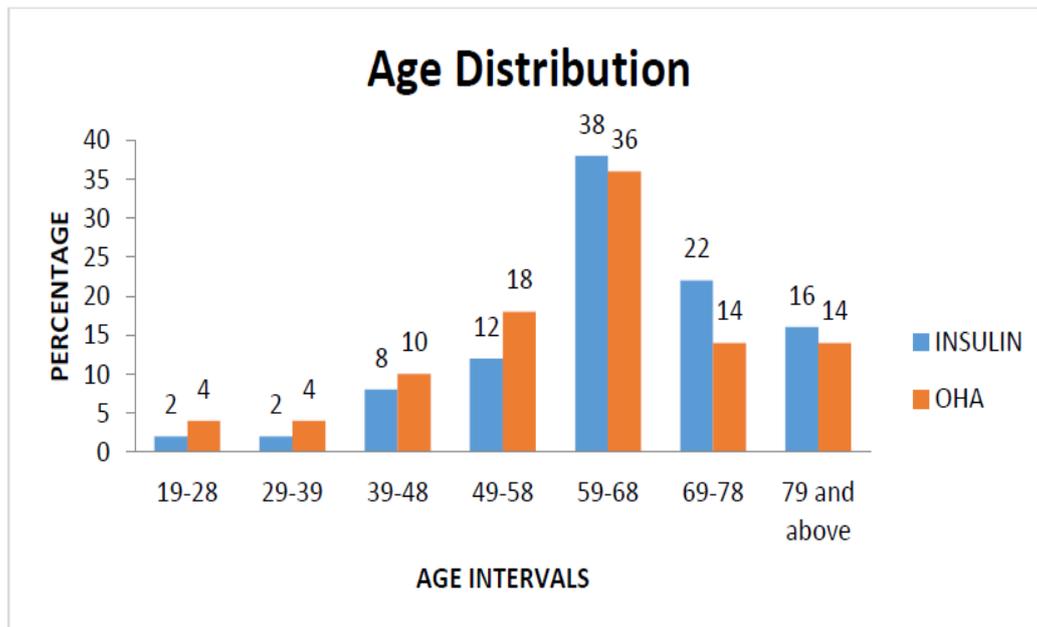
✓ Age Distribution

The patient's age has a significance in insulin resistance which eventually leads to type 2 DM. Patients were categorized into the following age groups with an interval of 10 years as 19-28 years, 29-38 years, 39-48 years, 49-58 years, 59-68 years, 69-78 years, 79 and above. In insulin, the majority of the patients were found within the age group of 59-68 years (38%) and in OHA,

the majority of the patients were found within the age group of 59-68 years (36%).

Table 2: Age distribution between insulin and oral hypoglycemic.

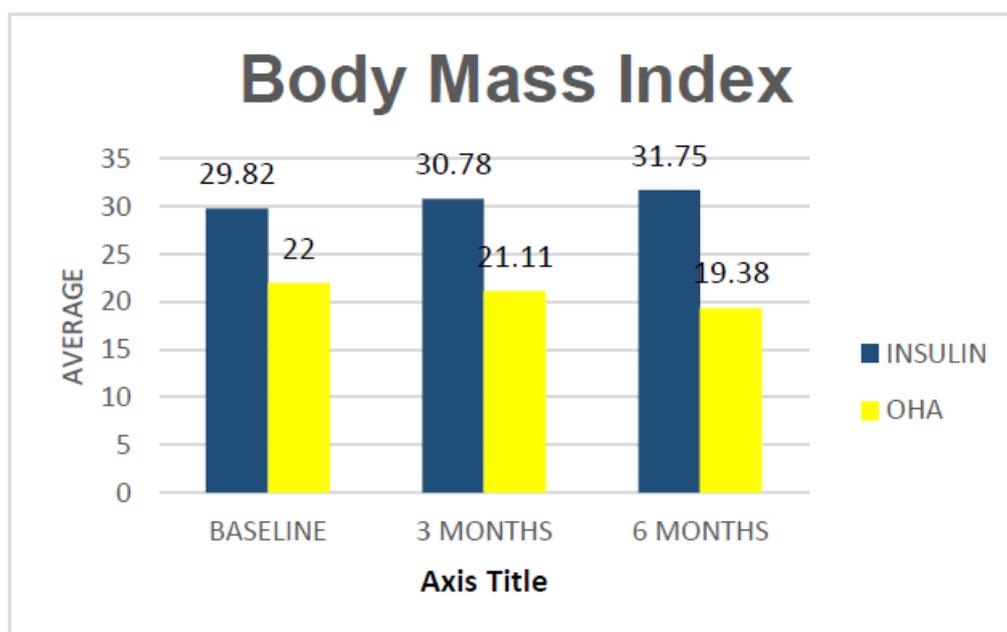
AGE DISTRIBUTION	No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
19-28	1	2	0.1-10.6	2	4	0.5-13.7
29-39	1	2	0.1-10.6	2	4	0.5-13.7
39-48	4	8	2.2-19.2	5	10	3.3-21.5
49-58	6	12	4.5-24.3	9	18	8.6-31.4
59-68	19	38	24.7-52.8	18	36	22.9-50.8
69-78	11	22	11.5-36.0	7	14	5.8-26.7
79 and above	8	16	7.2-29.1	7	14	5.8-26.7

**Figure 2: Age distribution between two groups.**

✓ Body mass index

Body Mass Index (BMI) is a simple index of weight to height that is commonly used to classify underweight,

overweight and obesity in adults. BMI was classified according to Canadian guidelines for body weight classification for adults.

**Figure 3: Comparison of BMI two groups.**

✓ Past medical history

Diabetic patients also have certain co-morbidities such as hypertension, cardiovascular diseases, thyroid disorder, chronic renal disease, CNS defects, respiratory diseases and others such as surgeries. The majority of patients who administered insulin were found to have coronary

artery disease (52%). The majority of patients administered oral hypoglycemic were found to have hypertension (58%).

Table 3: Comparison of comorbidities between insulin and oral hypoglycemics.

PAST MEDICAL HISTORY	INSULIN			ORAL HYPOGLYCEMICS		
	No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
Hypertension	23	46	31.8-60.7	29	58	43.2-71.8
CAD	27	52	39.3-68.2	16	32	19.5-46.7
Thyroid disorders	6	12	4.5-24.3	5	10	3.3-21.8
CKD	8	16	7.2-29.1	0	0	0
CNS defects	11	22	11.5-36.0	6	12	4.5-24.3
Respiratory diseases	9	18	8.6-31.4	4	8	2.2-19.2
Surgeries	12	24	13.1-38.2	6	12	4.5-24.3

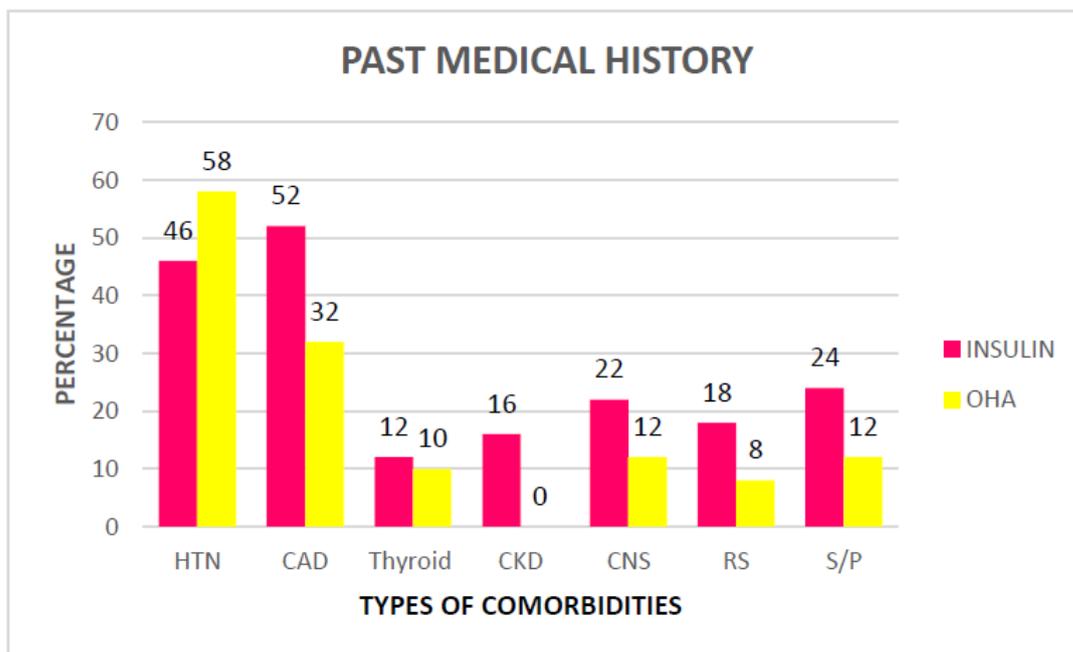


Figure 4: Comparison of comorbidities between insulin and oral hypoglycemic.

✓ Duration of Diabetes

On categorizing the patients based on their duration of diabetes, the following data was obtained. Patients with diabetes were categorized as less than 5 years, 6-10 years, 11-15 years, 16-20 years, more than 20 years. The

majority of the patients in insulin group and oral hypoglycemic group had duration of 6-10 years. In both the groups majority of patient had diabetes around 6-10 years.

Table 4: Comparison of duration of diabetes between insulin and oral hypoglycemics.

DURATION OF DIABETES	INSULIN			ORAL HYPOGLYCEMICS		
	No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
less than 5	3	6	1.3-16.5	13	26	14-40
6-10	25	50	35.5-64.5	23	46	31.8-60.7
11-15	8	16	7.2-29.1	9	18	8.6-31
16-20	9	18	8.6-31	5	10	3-21
more than 20	5	10	3.3-21.8	0	0	0

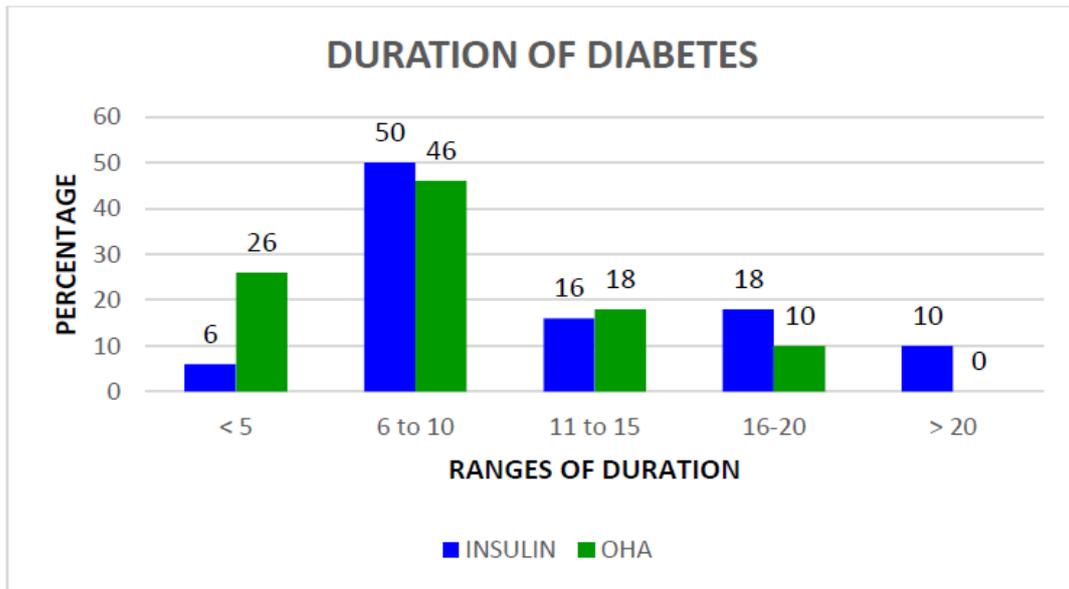


Figure: 5 Comparison of duration of diabetes between two groups.

✓ **Diabetic complications**

Diabetes Mellitus leads to complications that involve the retinal system, nervous system, renal system, cardiovascular system and foot ulcers when the blood glyceimic values are uncontrolled. Diabetic complications reduce the patient's Health-Related Quality of Life

(HRQoL) by developing gradually and are also life-threatening. The majority of insulin and oral hypoglycemic patient were found to have cardiovascular disease. In the study population majority of them (64%) in insulin group and (46%) in oral hypoglycemic groups had cardiovascular disease as diabetic complication.

Table 5: Comparison of diabetic complications between insulin and oral Hypoglycemics.

COMPLICATIONS	INSULIN			ORAL HYPOGLYCEMICS		
	No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
Retinopathy	5	10	3.3-21.8	3	6	1.3-16.5
Neuropathy	16	32	19.5-46.7	10	20	10-33.7
Nephropathy	10	20	10.0-33.7	6	12	4.5-24.3
CVD	32	64	49.2-77.1	23	46	31.8-60.7
Foot ulcer	3	6	1.3-16.5	2	4	0.5-13
Hearing problem	1	2	0.1-10.6	1	2	0.5-10

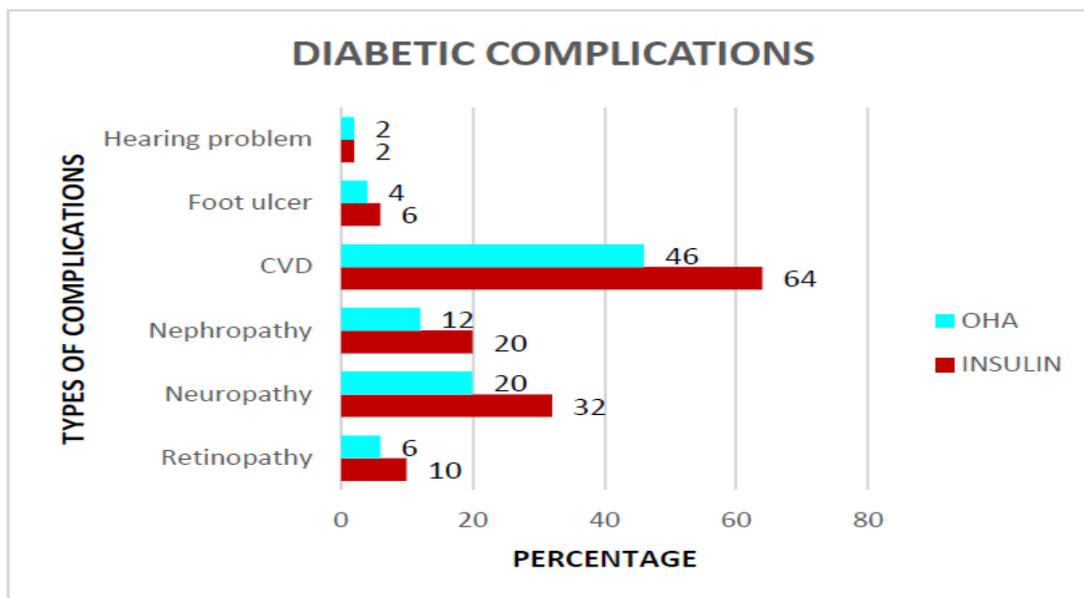


Figure 6: Diabetic complications between the two groups.

❖ Drug treatment

Out of 50 patients receiving Insulin, 23 patients are suggested Monotherapy and 27 patients with combination therapy.

Out of 50 patients receiving OHA, 14 patients have suggested monotherapy and 36 patients with combination therapy.

Table 6: Comparison of drug therapy between insulin and oral hypoglycemics.

TREATMENT		INSULIN			ORAL HYPOGLYCEMICS		
		No of Patients	Percentage (%)	CI (%)	No of Patients	Percentage (%)	CI (%)
Monotherapy		23	36	31.8-60.7	14	28	16.2-42.5
Combination Therapy	Fixed	17	34	21.2-48.8	12	24	13.1-38.2
	Free	7	14	5.8-26.7	10	20	8.9-31.1
	Fixed+free	3	6	1.3-16.5	14	28	16.2-42.5

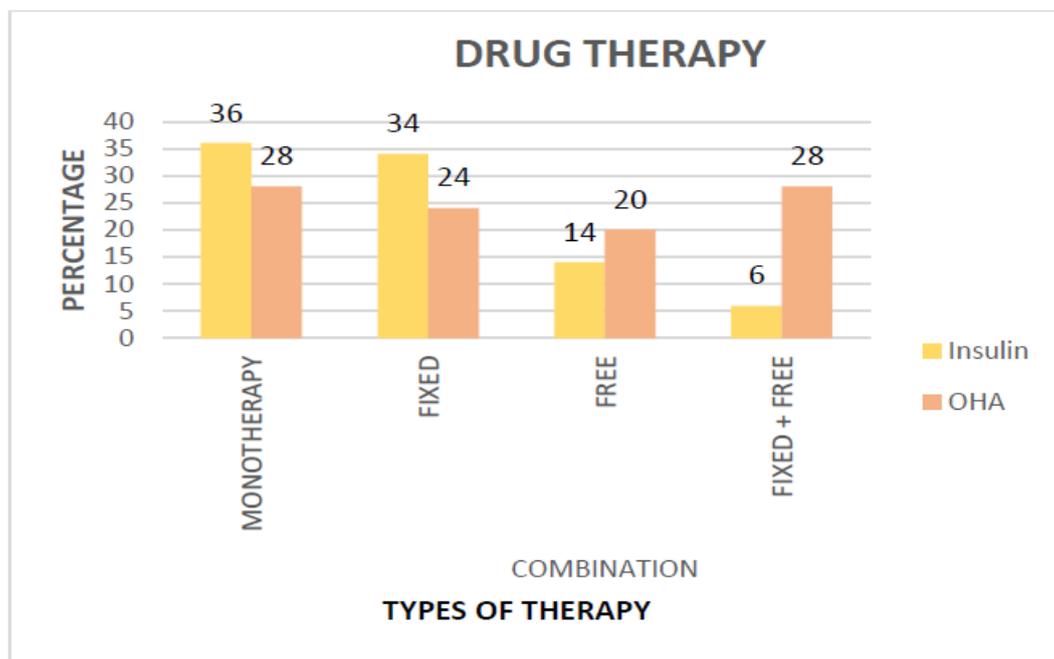


Figure 7: Drug treatment between two groups. Comparison of Mean Value.

Statistical analysis was done using SPSS 22 software. The student t-test was performed and p value (<0.05) considered as statistically significant.

In this study, 50 patients treated with oral hypoglycemic agents and 50 patients with insulin were included to observe the difference in the quality of life and treatment satisfaction using WHOQOL-BREF and DTSQ questionnaire at the baseline, 3 months and 6 months. Age and gender were matched. The mean age of oral hypoglycemic was 61.20 ± 14.86 years and insulin group were 64.16 ± 13.58 years. In the oral group majority were

males and in the insulin group majority were females. There was no significant difference in mean age and gender between the two groups as shown in below table. There are significant differences found in the duration of diabetes as well as the glucose profile shown in the below Table 1. The glucose profile such as FBS, PPBS and HbA1c shows better control in the insulin group than OHA group.

Table 7: Significance differences of age, gender and duration between two groups.

	Insulin (n=50)		OHA (n=50)		P VALUE
	Mean	SD	Mean	SD	
Age	64.16	13.38	61.20	14.86	0.2787
Gender	0.5014	0.504	1.440	1.520	0.3992
Duration of Diabetes	2.760	1.135	2.120	0.9179	0.0049**

* denotes level of significance

Significant changes found in the body mass index were observed in two groups. BMI shows a slight variation for a period of every 3 months. BMI increased in the insulin

group it means that patients taking insulin causes weight gain and vice versa in the OHA group in table 2.

Table 8: Significance differences of BMI at various intervals between two groups.

BMI	Insulin (n=50)		OHA (n=50)		P VALUE
	Mean	SD	Mean	SD	
Baseline	29.82	1.662	22.00	1.906	<0.0001****
3 Months	30.78	1.565	21.11	1.588	<0.0001****
6 Months	31.75	0.9626	19.38	2.906	<0.0001****

*denotes the level of significance

The glucose profile such as FBS, PPBS and HbA1c shows significantly better control in the insulin group than the OHA group.

Table 9: Significance differences of Glucose profile at various intervals between two groups.

Glucose Profile		Insulin (n=50)		OHA (n=50)		P VALUE
		Mean	SD	Mean	SD	
FBS	Baseline	123.0	25.13	139.8	39.62	0.0128*
	3 Months	117.5	25.13	137.4	44.41	0.0048**
	6 Months	108.6	13.89	142.0	43.92	<0.0001****
PPBS	Baseline	163.7	33.94	203.4	82.03	0.0021**
	3 Months	160.5	35.30	206.4	82.08	0.0004***
	6 Months	153.1	38.11	222.4	88.54	<0.0001****
HbA1C	Baseline	7.014	0.7091	9.091	2.170	<0.0001****
	3 Months	6.709	0.66	8.849	2.008	<0.0001****
	6 Months	6.343	0.53	10.05	1.505	<0.0001****

*denotes the level of significance

Quality of life

The physical domain was significantly higher in the oral hypoglycemic group than in the insulin group irrespective of the presence or absence of metabolic syndrome. The psychological domain and social domain

were significantly higher in the insulin group than in the oral hypoglycemic group irrespective of the presence or absence of metabolic syndrome. No significant difference was observed in environmental domain.

Table 10: Significance differences of Quality Of Life at various intervals between two groups.

QoL Domains		Insulin (n=50)		OHA (n=50)		P Value
		Mean	SD	Mean	SD	
Physical	Baseline	51.86	14.38	62.54	1.36	0.0001****
	3 Months	44.80	2.250	64.00	5.385	0.0001****
	6 Months	37.40	3.209	70.60	3.507	<0.0001****
Psychological	Baseline	85.80	7.43	41.22	3.85	0.0021**
	3 Months	60.80	5.891	33.00	1.581	0.0001****
	6 Months	67.00	7.00	27.60	3.912	<0.0001****
Social	Baseline	71.48	2.38	45.62	2.96	<0.049**
	3 Months	73.60	1.949	34.00	3.91	<0.0001****
	6 Months	79.60	3.286	28.60	3.50	<0.0001****
Environmental	Baseline	69.60	9.78	65.82	11.88	0.3091
	3 Months	50.80	3.033	59.60	10.45	0.291
	6 Months	44.60	7.021	45.40	8.905	0.225

*denotes the level of significance

Treatment satisfaction

When treatment satisfaction was compared between the two groups using Diabetes Treatment Satisfaction Questionaries oral hypoglycemic group had better

treatment satisfaction and statistically significant results than patients in the insulin group.

Table 11: Significance differences of Glucose DTSQ at various intervals between two groups.

DTSQ	Insulin (n=50)		OHA (n=50)		P value
	Mean	SD	Mean	SD	
Baseline	12.88	5.049	26.76	7.258	<0.0001****
3 Months	17.48	5.853	29.92	6.037	<0.0001****
6 Months	20.04	2.857	35.44	7.183	<0.0001****

*denotes the level of significance

DISCUSSION

WHO issued an action on diabetes on World Health Day 2016, which stressed the need for hastening the treatment and prevention of Diabetes Mellitus. This study describes HRQOL in Type 2 diabetic patients treated with insulin and OHA, using a diabetic specific instrument as WHOQOL- BREF. This study found that better glycemic control associated with better HRQOL and complications were the most important disease-specific determinant of HRQOL.^[5]

Men and women differ substantially concerning degrees of insulin resistance, body composition and energy balance. In the insulin group, the majority were females because females have higher insulin sensitivity than males. These similar results were shown by Eliza B. Geer *et al.*^[6]

The number of diabetic patients was found to be greater in the age group of 59-68 years, it tends to have an increase in the incidence of diabetes. These may be due to the deterioration in the metabolic activity in the body as a result of aging. There is also a greater increase in diabetic complications due to poor glycemic control owing to poor medication adherence and polypharmacy as a result of co-morbidities. Impaired glucose intolerance is associated with aging and postprandial hyperglycemia is a prominent characteristic of type 2 diabetes in older adults.^[7]

The current study states that in both groups majority of the patients had diabetes for the duration of 6-10 years. Due to the increase in the duration of diabetes, patient compliance found to be better that had an impact in the glycated hemoglobin. Thus, insulin resistance increases with the duration of diabetes.^[8] Our result was consistent with a previous study by Franch Nadal *et al.*^[9] showed that the prevalence of oral hypoglycemic therapy or insulin therapy increased as the duration of diabetes increased.

In our study, the majority of the patients in both insulin and OHAs have coronary artery disease followed by hypertension. The pathophysiology of the link between diabetes and cardiovascular disease (CVD) is complex and multifactorial. DM is associated with a 2 to 4-fold increased mortality risk from heart disease.^[10] The implications of a diagnosis of DM are as severe as a diagnosis of coronary artery disease (CAD). Amongst adults with DM, there is a prevalence of 75% to 85% of hypertension, 70% to 80% of elevated LDL and 60% to 70% of obesity.^[11]

The Glycemic profile such as FBS, PPBS and HbA1c was significantly higher in oral hypoglycemic group than in the insulin group. This shows that better glycemic control was observed in the insulin group than in oral hypoglycemic group. According to Sehgal S *et al.*^[12] states that all insulin types can significantly reduce HbA1c levels, but very few can achieve HbA1c targets. If HbA1c levels fall then the risk of long-term complications decreases so that the patient's quality of life will be better maintained.^[13] Similar results were found by Spoelstra *et al.* Says that patients also taking OHA had significantly higher HbA_{1c} levels than patients on insulin.^[14]

In our study, most of the patients were treated with Monotherapy in both groups then, followed by fixed-dose combinations. Initial treatment of patients with type 2 diabetes mellitus includes lifestyle changes focusing on diet, increased physical activity and exercise and weight reduction, reinforced by consultation with a registered dietitian and diabetes self-management education, when possible. Monotherapy with metformin is indicated for most patients and insulin may be indicated as initial treatment for those who present with catabolic features (polyuria, polydipsia and weight loss).^[15] An analysis from the United Kingdom Prospective Diabetes Study (UKPDS) found that 50 percent of "newly diagnosed" patients, identified clinically and originally controlled with a single drug, required the addition of a second drug after three years; by nine years, 75 percent of patients needed additional medications to achieve the target fasting plasma glucose level <108 mg/dL (6 mmol/L) and a mean A1C value of 7 percent.^[16]

Descriptive analysis

The mean age of oral hypoglycemic was 61.2±14.8 years and the insulin group was 64.1±13.5. Previous study by Ali *et al.*^[16] also gave away an observation showing that the prevalence of diabetes is higher in the age group of 59.65±12.3 years. The majority of the patients (n=100) were in the age group between 40-65 years as observed in a study of global prevalence in diabetes by Wild *et al.*^[17] King *et al.*^[18] also made a similar observation to our study that the age increases, there is a significant decrease in the QoL score (p= 0.27). Ali *et al.* and Glasgow *et al.*^[19] made a similar observation in a study, where an increase in age decreased the QoL in diabetes patients. In the OHA group, the majority were male and in the insulin group majority were females.

There are no significant differences in mean age and gender between the two groups in our study and this is

similarly proven in the study conducted by Chaveepojnkamjorn *et al.*^[20]

There is a significant difference in the mean duration of diabetes. We observed that as the duration of history increased there was a significant decrease in the QoL ($p=0.004$). With an increase in the duration of diabetes eventually switches over from OHA to insulin.

Overweight and obesity (BMI >25 and >30, respectively) have important negative factors in determining the QOL³. Patients with BMI of <18.4 Kg/m² had a better QoL than the patients with a BMI >25 kg/m², but there is no statistically significant difference in the QoL scores, previously the studies independently looking at the association between obesity and QoL have indicated that the obesity impairs the QoL Kolotkin *et al.*^[21] A study by Hlatky *et al.*^[21] from Stanford also showed that among diabetics, the presence of obesity significantly impaired QoL.^[22]

Quality of life

Quality of life (QOL) was assessed in 100 diabetic patients on oral hypoglycemic agents and on insulin respectively. Our QoL-WHOQOL-BREF-based survey revealed a higher QoL assessment in the psychological domain for insulin treatment. Similar results were observed by Nadeau *et al.*^[23] and Andrezej M Fal *et al.*^[3] higher QoL found in the psychological domain for the patient receiving insulin.

The physical domain was significantly higher among oral hypoglycemic than in the insulin group. This can be due to the pain of insulin injections and frequent change in injection sites. According to Sepulveda *et al.* in 2015^[24] and Johnson *et al.* in 2013^[25] who use insulin have a lower quality of life in the domains of physical functioning, limitations due to physical problems, social functioning and general health perceptions. This may be because patients taking insulin treatment that affects the scheduling and regulations of their daily activities, the fear of weight gain and the impact of insulin treatment on social environment.^[26]

The social domain was found to be significantly higher in the insulin group than in the oral group. This can be due to better glycemic control by insulin than oral agents.

The environmental domain harms both groups. They are not statistically significant.^[27]

Treatment satisfaction

It was also observed that treatment satisfaction in patients receiving OHAs was significantly better than patients receiving insulin. A multicentric study in type 2 DM using DTSQ showed that patients receiving insulin had lesser treatment satisfaction compared to patients receiving OHAs.^[28]

Patients receiving more drugs (combination therapy) are

those who suffered from uncontrolled DM or complications. However, a lesser number of drugs (monotherapy) mean lesser side effects and better compliance.^[29] Patients receiving insulin have lesser treatment satisfaction because of the self-administration of insulin. Treatment satisfaction improved in patients receiving only metformin.

CONCLUSION

Diabetes continues to be a major contemporary epidemic. In addressing the challenges of confronting the epidemic a primary therapeutic goal is QoL. Diabetes affects major components of QoL although differences in terms of ethnicity, environment, gender, socioeconomic status, culture, dietary and lifestyle habits do exist. The presence of complication and comorbidity had an adverse effect on the QoL of diabetic patients, as the number of complications increased the QoL decreased. Hence, it is recommended for patients to have an adequate and strict glycemic control enabling them to maintain their quality of life, preventing disease progression and diabetic complication.

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Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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