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### Health-Related Quality of Life Among Adults with Type 2 Diabetes on Herbal Versus Conventional Antidiabetic Medicines in Nairobi City County, Kenya

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#### **ABSTRACT**

**Background:** Patients with type 2 diabetes often seek care from herbal clinics for glycemic control. Health-related quality of life in patients treated at the herbal clinics has not been established.

**Objective:** To compare health-related quality of life in patients with type 2 diabetes on herbal versus conventional antidiabetic therapies.

**Methods:** A cross-sectional study was conducted among 80 patients with type 2 diabetes attending a conventional clinic and 37 patients receiving care in a herbal clinic in Nairobi City County, Kenya. A general questionnaire was used to collect sociodemographic and clinical information from the study participants. The WHOQOL-BREF was used to assess the health-related quality of life in both group. Descriptive data analysis was performed on all variables. The HRQOL scores were compared by non-parametric Mann-Whitney test. Multiple Linear Regression (MLR) analyses were used to identify the sociodemographic and clinical factors affecting the various domains of HRQOL. P-values equal or less than 0.05 were considered to be statistically significant.

**Results:** The mean overall quality of life scores were 50% and 75% in the herbal and the conventional treatment group respectively (p<0.001). HRQOL scores in all the domains were also higher among the patients treated in the conventional compared to those treated at the herbal clinic. The type of treatment setting was an important determinant of HRQOL across all the domains evaluated in this study.

Domain specific analysis found level of education (P=0.010) and physical activity (P=0.001) as determinants of the physical domain of HRQOL. Microvascular complications negatively affected the psychological domain of the patient's life (p=0.010). Gender affected both the social (p=0.037) and the environment (0.033) domains of the patients' lives. Older age (p=0.004) and alcohol intake(p=0.048) had significant adverse effects on the patient's environment while residing in urban areas (p=0.026) favored this aspect of the patients' health.

**Conclusions:** We reported higher HRQOL scores among patients on conventional therapies compared to those on herbal treatments. We identified factors that can be addressed to enhance the well-being of type 2 diabetes patients in both the conventional and herbal care settings.

**Keywords:** HRQOL; Type 2 Diabetes; Herbal; Conventional.

#### INTRODUCTION

Diabetes is a chronic disease affecting an estimated 537 million adults aged 20-79 worldwide. According vears international Diabetes Federation. this number is projected to increase to 783 million by 2045. The most rapid increase is expected to occur in low and middleincome where 80% of patients with diabetes live (1). The prevalence of diabetes in Kenya has been reported to be 4%. In 2021, diabetes-related complications accounted for 5% of deaths occurring in people under 60 years of age in Kenya (1).

Management of diabetes involves both modifications lifestyle and pharmacotherapy. In addition, selfmanagement practices such as exercise, healthy diet and self-monitoring of blood glucose (SBMG) are recommended to improve diabetes treatment outcomes. The goals of diabetes treatment are to achieve optimal glycemic control, relieve the signs and symptoms of hyperglycemia, prevent progression the occurrence and microvascular and macrovascular complications and improve the patient's quality of life. The impact of these interventions is routinely assessed using objective measures of health such as blood glucose levels and lipid profiles along with morbidity and mortality attributable to diabetes (2).

Diabetes and its treatment have the potential to affect the patient's quality of life in several ways. Diabetes-related complications may lead to decreased mobility, pain and inability to carry out their daily activities. Other comorbid conditions may require additional treatment which further increases the treatment burden. For example, medical therapy, dialysis and renal transplant may be required to treat end-stage renal failure in patients with type 2 diabetes (3). Other factors that may worsen quality of life in patients with type 2 diabetes include the complexities of diabetes treatment regimens, cost of medications, and adverse effects of drugs.

The World Health Organization (WHO) defines health as "a state of complete physical, mental, and social well-being—not merely the absence of disease, or infirmity" This definition implies measurement of health and the effect of health interventions must not only include biomedical markers of health but also an estimation of the patients' well-being. While laboratory the tests and clinical examinations provide objective information on the effectiveness of health interventions, they do not measure how patients feel or are satisfied with their treatments. effectiveness of health interventions and their effects on the patients' well-being are assessed by combining objective measures of health with patient reported outcomes such as health-related quality of life (HRQOL). Evaluation of HRQOL is important in chronic diseases such as type 2 diabetes low HRQOL may have an impact on adherence to treatment and deterioration of clinical outcomes (Hand, 2016). HRQOL provides insights to the patients' perception regarding the impact of a disease and its treatment on their physical, psychological and social well-being. However, unlike the standard treatment outcomes, HROOL and other patient-reported outcomes are not routinely monitored in care of patients with type 2 diabetes.

In Kenya, some patients with type 2 diabetes turn to herbal therapy for their diabetes control (5). This is driven by factors such as the belief that herbal medicines are totally safe, are more effective than conventional medicines and can cure diabetes. Herbal medicines are also easier to access since they do not require a prescription and are also more culturally acceptable (5). Although several herbs have been reported to have glucose-lowering effects, there are no local guidelines for their use. Despite the widespread use of herbal medicines by type 2 diabetic patients in Kenya, studies on diabetes-related quality of life have focused on patients treated in conventional settings (6). Therefore, there exists a gap on how this patient-reported outcome among patients with type 2 diabetes treated at the herbal clinics. In this study, we estimated and compared the quality of life in patients treated for type 2 diabetes at herbal and conventional diabetes clinics in Nairobi City County in Kenya. The findings from this study will enable providers healthcare in both conventional and herbal care settings to better understand the patient's perception of the effects of both modes of treatment on their daily lives. Additionally, the study will identify factors that can be addressed to enhance quality of life in both herbal and conventional diabetes care settings.

#### **MATERIALS & METHODS**

The methodology for recruitment and data collection on the sociodemographic and clinical characteristics of the patients who participated in this study has been described elsewhere (7).

#### Study design and setting

A facility-based cross-sectional study was conducted at Kenyatta National Hospital (KNH) and New Life Herbal Clinic (NLHC), a private herbal clinic in Nairobi County, Kenya between March 2019 and December 2021. KNH is the largest national referral hospital in Kenya. It provides diabetic services to approximately 400 outpatients weekly. NLHC is a private entity providing herbal antidiabetic therapies in Nairobi and the neighboring counties.

## Study population and sampling procedures

The population for this study were all adult outpatients with type 2 diabetes at the two study sites. Patients were included in the study if they had received treatment and were on follow-up at the study sites for at least 6 months prior to this study. Patients with Type 1 and gestational diabetes were excluded from the study. The minimum sample size required at each study site was calculated as 66 patients. We increased this number to 73 patients per group to cater for

a 10% non-response rate. Since there were few patients at the herbal clinic, we used an allocation ratio of 1 patient in the herbal clinic for every 2 patients recruited at KNH. This ratio was within the recommendations for research with unequal study arms(8). Consequently, we recruited 80 patients at Kenyatta National Hospital and 37 patients at the herbal clinic. Diabetic patients who met the study criteria were recruited consecutively during the clinic visits until the required sample size was achieved.

#### **Data collection on HROOL**

Patients who met the criteria and consented to the study were recruited during their clinic visits. The abbreviated World Health Organization Quality of Life (WHOQOL-BREF) questionnaire was used to collect HROOL data. The questionnaire has a total of 26 questions. Twenty-four questions (items) belong to 4 different domains (dimensions) of health namely; environmental (8 questions), physical (7 questions), psychological (6 questions) and social (3 questions). The remaining two questions assess the patient's general QOL and health. One question asks about the individual's overall perception of HROOL while the other evaluates the individual's general perception of his or her health. Each question has 5 Likert-type response options with scores ranging 1-5. Higher scores represent higher QOL (9). Data on the sociodemographic characteristics, diabetes duration, complications and comorbidities as well as types of antidiabetic treatments was obtained through face to face interviews and from patients files and recorded on a general questionnaire.

#### STATISTICAL ANALYSIS

The scores for the physical, psychological, social relationships and environmental domains were derived from the completed questionnaires. The other two items (questions 1 and 2) which assess the overall quality of life and overall satisfaction with health were examined separately. The mean score of items within each domain were

used to calculate the domain score. Mean scores were then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100. Where more than 20% of data was missing from an assessment, the assessment was discarded. Where an item was missing, the mean of other items in the domain was substituted. Where more than two items were missing from the domain, the domain score was not calculated (with the exception of domain 3, where the domain was only calculated if < 1 item is missing).

An SPSS syntax file that automatically checks, recodes data and computes domain scores has been provided by the WHO and was used in the computation of the HRQoL The derived scores were then be entered and analyzed using IBM SPSS 26.0, Chicago, IL). package (SPSS Summary statistics calculated included median scores and interquartile range for the various domains of health. P-values were obtained using the two-sample Mann-Whitney U test. Linear regression analysis was performed to identify the determinants of HRQOL in the two study groups. P-values less or equal to 0.05 were considered to be statistically significant.

#### **RESULTS**

sociodemographic and clinical characteristics of the study participants have been described by Karara et. al. We recruited 80 patients at the **KNH** Endocrinology and Diabetes Outpatient Centre while 37 were enrolled at the herbal clinic (7). A greater proportion of the patients treated for type 2 diabetes at KNH were females compared to those at the herbal clinic. Patients on conventional therapies were also older and had longer duration of diabetes than those at the herbal clinic. Only two patients (5.4%) of the patients treated at the herbal clinic owned a glucometer and none of them had a HbA1c check six months prior to this study. Comorbidities were more prevalent among patients on conventional therapies with 65 (82.1%) of the patients reporting more than one comorbidity (Table 1).

Table 1: Sociodemographic and clinical characteristics of study participants on treatment for type 2 diabetes at KNH and NLHC

Characteristic	Category	KNH (n=80)	NLHC (n=37)		
		n (%)	n (%)		
Gender	Female	52 (65)	13 (35.1)		
Age (years) (mean+SD)		62.31 <u>+</u> 13.91	55.95+13.99		
Married	Yes	61 (76.3)	31 (83.8)		
Highest education level	No formal education	16 (20)	1 (2.7)		
	Primary	28 (35)	17 45.9)		
	Secondary	30 (37.5)	13(35.1)		
	Tertiary(college/university)	6 (7.5)	6 (16.2)		
Body mass index (BMI)	<18.5 (underweight)	1 (1.3)	1 (2.7)		
	18.6-24.9 (normal)	24 (30.0)	11 (29.7)		
	>25(overweight/obese)	55 (68.7)	25 (67.6)		
Alcohol history	Yes	25 (31.3)	28 (75.7)		
Smoking history	Yes	11 (13.8)	21 (56.8)		
Years with DM (median (IQR))		10(4-18)	3 (1-7)		
Own glucometer	Yes	52 (65)	2 (5.4)		
Previous (last 6 months) HbA1c	Yes	36 (45.0)	0 (0.0)		
Complications	Microvascular	55 (68.8)	23 (62.2)		
	Macrovascular	27 (33.8)	2 (5.4)		
No. of comorbidities	None	0 (0.0)	3 (8.1)		
	1	15 (18.8)	10 (27)		
	>1	65 (82.1)	24 (64.9)		

#### **HROOL SCORES**

Since the HRQOL scores in the various domains were not normally distributed, we used the Mann-Whitney test to compare the scores between the two study groups. In this study, patients on conventional therapies for

type 2 diabetes at KNH had significantly better HRQOL scores on all domains compared to their counterparts on herbal therapies (p<0.001). Patients in both groups had the highest scores in the social domain (Table 1). Among patients on herbal

therapies, the lowest scores were on psychological aspect of HRQOL (45.83). With regard to overall quality of life, patients at KNH had significantly higher scores compared to those at the herbal clinic (p< 0.001). Both patient groups had equal scores on general health as evaluated using the WHOOOL-BREF.

Table 2:HRQOL domain scores in patients with type 2 diabetes on conventional therapies at KNH and herbal therapies at NLHC

HRQOL DOMAIN	NLHC (n=37)	KNH (n=80)	p-value
	Median [IQR]	Median [IQR]	
Physical	50 [37.50, 57.14]	67.86 [60.71, 78.57]	< 0.001
Psychological	45.83 [33.33, 54.17]	66.67 [62.50, 75]	< 0.001
Social	66.67 [33.33, 75]	75.00 [75.00, 97.92]	< 0.001
Environmental	53.13 [46.88, 59.38]	71.88 [65.63, 80.47]	< 0.001
Overall QOL	50[25, 75]	75[75, 100]	< 0.001
General Health	75 [25, 75]	75 [75, 75]	< 0.001

#### **DETERMINANTS OF HROOL**

Due to lack of normal distribution of the scores, we performed a log10 transformation prior to linear regression analysis. The B-coefficients and confidence intervals obtained in the models were then back transformed to the original scale. Study site was found to be a significant predictor of HRQOL across all the domains evaluated in this study (p<0.001). Level of education (P= 0.010) and physical activity (P=0.001) were significant determinants of the physical domain of HROOL. Presence of microvascular complication was reported to negatively affect the psychological domain of the patient's life (p=0.010). Gender was found to influence both the social (p=0.037) and the environment (0.033) domains of the patients evaluated in this study. Although education level was a significant predictor of social domain of HRQOL (p=0.042) on bivariate analysis, this effect was lost when other factors were included in the multivariate regression analysis. While older age (p= 0.004) and alcohol intake(p=0.048) had significant effects adverse on the patient's environment, residing in urban areas (p= 0.026) favored this aspect of the patients' health.

Table 3: Bivariate and multiple linear regression analysis of variables influencing HRQOL among the study participants

Variable	WHO	WHOQOL-BREF Domains														
	Physical				Psychological				Social				Environment			
	Bivariate Multiple regression regression			Bivariate regression		Multiple regression						Bivariate regression		Multivaria te regression		
	Cru de OR (95 % C.I)	P- valu e	Adju sted OR (95 % C.I)	P- valu e	Cru de OR (95 % C.I)	P- val ue	Adju sted OR (95 % C.I)	P- val ue	Crude OR (95% C.I)	P- val ue	Adjust ed OR (95% C.I)	P- val ue	Cru de OR (95 % C.I)	P- val ue	Adj. OR (95 % C.I)	P- val ue
Study site	1.17 (0.7 8- 1.76	0.27	1.48 (1.36 - 1.62)	<0.0	1.44 (0.88 - 2.35)	0.1 05	1.55 (1.41 - 1.70)	<0. 00 1	1.27 (0.71- 2.25)	0.4	1.56 (1.39- 1.75)	<0 .00 1	1.46 (1.11 - 1.92)	0.0 07	1.45 (1.34 - 1.57)	<0 .00 1
Gender	1.11 (0.8 8- 1.41	0.46 9	-	-	1.02 (0.77 - 1.36)	0.9 79	-	-	1.52 (1.06- 2.18)	0.0 23	1.12 (1.01- 1.24)	0.0	0.95 (0.81 - 1.10)	0.4 80	1.08 (1.01 - 1.15)	0.0
Age	0.99 (0.9 2- 1.06	0.69 8	-	-	0.96 (0.88 - 1.04)	0.3 70	-	-	0.92 (0.83- 1.01)	0.0 91	-	-	0.95 (0.91 - 0.99)	0.0 22	0.96 (0.93 - 1.01)	0.0 04
Marital status	0.99 (0.8 4- 1.16	0.83 6	-	-	1.03 (0.84 - 1.25)	0.9 85	-	-	1.01 (0.80- 1.27)	0.9 44	-	-	0.98 (0.88 - 1.09)	0.6 96	-	-

Highest education level	1.10 (1.0 0- 1.20	0.08	1.07	0.01	1.03 (0.92 - 1.15)	0.4 16	-	-	0.95 (0.83- 1.08)	0.4 16	-	-	1.06 (1.00 - 1.13)	0.0 42	-	-
Employm	0.97 (0.8 1- 1.16	0.71	1.12)	-	1.08 (0.87 - 1.33)	0.4 96	-	-	1.13 (0.88- 1.45)	0.3	-	-	1.04 (0.93 - 1.17)	0.4 90		
Residence	1.03 (0.8 5- 1.25	0.82	-	-	1.04 (0.83 - 1.31)	0.7 95	-	-	1.24 (0.95- 1.63)	0.1	-	-	1.06 (0.98 - 1.15)	0.1 26	1.05 (1.01 - 1.10)	0.0 26
Physical activity	1.13 (0.8 4- 1.53	0.44	1.32 (1.12 - 1.56)	0.00	0.93 (0.65 - 1.34)	0.9	-	-	0.80 (0.52- 1.22)	0.2 89	-	-	1.01 (0.83 - 1.23)	0.9 18	-	-
Cigarette smoking	1.12 (0.8 9- 1.41	0.24	-	-	1.18 (0.89 - 1.56)	0.2 02	-	-	0.88 (0.62- 1.24)	0.4 65	-	-	1.15 (0.99 - 1.34)	0.0 71	-	-
Alcohol intake	0.89 (0.7 5- 1.06	0.17 8	-	-	0.89 (0.72 - 1.09)	0.3 32	-	-	0.81 (0.63- 1.04)	0.0	-	-	0.96 (0.86 - 1.08)	0.5 06	0.93 (0.86 - 1.00)	0.0 48
BMI	1.10 (0.9 6- 1.25	0.15	-	-	0.96 (0.82 - 1.12)	0.6 26	-	-	1.02 (0.85- 1.22)	0.8 61	-	-	1.05 (0.96 - 1.14)	0.2 69	-	-
Duration with diabetes	0.99 (0.8 5- 1.15	0.81	-	-	0.99 (0.83 - 1.19)	0.8 18	-	-	1.09 (0.88- 1.35)	0.4 43	-	-	1.02 (0.92 - 1.13)	0.6 52	-	-
Own glucomet er	1.06 (0.8 6- 1.30	0.44	-	-	1.12 (0.87 - 1.43)	0.4 80	-	-	1.29 (0.97- 1.73)	0.0	-	-	1.05 (0.92 - 1.21)	0.4 46	-	-
Previous hba1c level	1.10 (0.8 6- 1.41	0.45	-	-	1.01 (0.75 - 1.35)	0.9 20	-	-	0.91 (0.65- 1.28)	0.5 70	-	-	0.99 (0.85 - 1.17)	0.9 41	-	-
study hba1c level	0.88 (0.7 4- 1.04	0.14	-	-	0.94 (0.77 - 1.15)	0.4	-	-	1.05 (0.83- 1.33)	0.6 73	-	-	0.99 (0.88 - 1.10)	0.7 89	-	-
Macrovas cular complicat ions	0.95 (0.7 8- 1.15	0.53	-	-	0.96 (0.76 - 1.21)	0.7 46	-	-	1.00 (0.76- 1.32)	0.9 97	-	-	0.96 (0.84 - 1.09)	0.5 15	-	-
Microvas cular complicat ions	0.87 (0.7 5- 1.02	0.06	-	-	0.86 (0.72 - 1.03)	0.1 12	0.89 (0.81 - 1.03)	0.0	0.92 (0.74- 1.13)	0.4 03	-	-	0.97 (0.88 - 1.07)	0.5 67	-	-
No. of comorbidi ties	1.02 (0.9 1- 1.14	0.68	-	-	1.01 (0.88 - 1.16)	0.8 65	-	-	0.95 (0.81- 1.12)	0.5	-	-	1.00 (0.93 - 1.08)	0.9 83	-	-

#### **DISCUSSION**

The main objective of this study was to evaluate and compare health-related quality of life among patients treated for type 2 diabetes in a conventional setting with those receiving care in a herbal clinic. We reported significantly higher HRQOL scores in all the domains among patients treated at KNH compared to those recruited at the herbal clinic. Similar findings have been reported in previous studies comparing HRQOL in patients on conventional versus those on complementary and alternative medicine (CAM). In Japan, patients with type 2 diabetes on CAM were found (10) to have lower HRQOL compared to those who did not use these forms of therapy (11). This trend has also been reported among CAM users with bronchial asthma ((12) and inflammatory bowel disease (13).

In this study, higher levels of education and regular physical activity had significant effects on the physical domain of HRQOL. Previous studies have revealed that level of education has significant effects on HRQOL with higher scores among the educated and poorer scores among illiterate. The educated diabetics may be more knowledgeable and therefore able to seek appropriate healthcare services. The less educated diabetics more likely to be engaged in heavy labour which may lead to physical pain and discomfort (10). In Iran, physical activity among patients with type 2 diabetes was associated with better overall QOL with the greatest improvements observed in the physical domain. Physical activity on prescription (PAP) was also reported to improve physical domain scores among Swedish patients (14). Physical activity plays a critical role in the management of type 2 diabetes. Regular exercise has been shown to be helpful in control of weight, blood sugars, blood pressure as well as in reducing the incidence of cardiovascular diseases. Moderate exercise can improve the body's immunity and insulin resistance resulting in better glycemic control, reduced risk of diabetes-related complications and improved QoL (15).

**Participants** with microvascular complications were less likely to achieve high scores on the psychological domain. Diabetes complications are known adversely affect HRQOL. In Taiwan, moderately low HROOL scores on mental health perspectives were reported among patients with diabetic complications (16). In the multinational DISCOVER prospective development of neuropathy, microvascular complication, was associated with reduction in the physical and mental aspects of life (17). The presence of microvascular complications also increases the risk of depression (18).

Male participants in our study were more likely to experience better HRQOL compared to their female counterparts. Generally, women play the role of care providers in their families and therefore may be not receive the necessary support from other family members in managing and coping with diabetes (19). Similarly, the male participants had better scores on the environment domain. This may be a reflection of better means of transportation, security and access to health information among the male participants compared to the female participants.

Older age and alcohol intake had adverse effects on the environment domain. Alcohol consumption may have a negative economic impact and also increases the risk of comorbidities leading to poor HRQOL (20). Elderly diabetic patients have increased risk factor for development of diabetes complications and other comorbidities which may negatively impact their selfrated wellbeing (21). Urban residence was associated with increased odds of having better scores in the environment domain in this study. This is supported by similar findings among type 2 diabetes patients in Ethiopia (22). Although there are limited studies comparing diabetes HRQOL in rural versus urban residents, findings from studies in healthy populations have reported better HROOL scores from urban dwellers compared to rural residents. Urban residents are likely to better access to transport, health services and health information leading to better HRQOL compared to rural residents (23).

#### **CONCLUSION**

Patients on conventional therapies for type 2 diabetes had significantly better HRQOL compared to those on herbal therapies. The study identified the different factors affecting the physical, psychological, social and environment domains of quality of life in patients with type 2 diabetes. Patients-centered interventions to address these factors should be incorporated in diabetes management to improve the quality of lives in patients with type 2 diabetes in both the conventional and herbal care settings.

#### **Declaration by Authors**

**Ethical Approval:** The KNH/UON Ethics and Research Committee granted ethical approval for this research (Approval number KNH-ERC A/431). Participants were asked for voluntary consent to be recruited into the study.

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