Original Research Article

Comparative glycemic control in adult patients with type 2 diabetes on herbal and conventional glucose-lowering agents in Nairobi County, Kenya.

ABSTRACT

Background: Some diabetic patients seek care exclusively from traditional herbal practitioners. It is not known if the care provided by herbalists is effective in maintaining optimal glycemic control.

Aim: To compare glycemic control in adult patients with type 2 diabetes on treatment with conventional medicines against those on herbal glucose-lowering therapies.

Study design: Descriptive cross-sectional study.

Place and Duration of Study: Patients on conventional treatment were recruited from the Endocrinology and Diabetes Outpatient Centre at Kenyatta National Hospital. The comparative group was enrolled from the New Life Herbal Clinic. The study was carried out between March 2019 and December 2021.

Ethical approval to carry out the study was obtained from KNH/UoN Ethics and Research Committee (Approval number KNH-ERC A/431).

Methodology: We recruited 80 patients on treatment with conventional antidiabetic therapies at Kenyatta National Hospital (KNH)and 37 patients on herbal therapies at New Life Herbal Clinic (NLHC). A structured questionnaire was used to collect sociodemographic and clinical data. Consecutive sampling was used to recruit the study participants. Glycated hemoglobin (HbA1C) levels were measured at the time of the patient visit.

Patients with HbA1c levels $\leq$7% were considered to have achieved adequate glycemic control. Descriptive and inferential data analysis was performed on all the variables and compared across the two study arms. Regression analysis was performed to identify variables associated with glycemic control for each treatment group. Data were entered into and analyzed using SPSS software version 26 (SPSS Inc, Chicago, USA). *P*-values $\leq$0.05 were considered to be statistically significant.

Results: Patients on conventional antidiabetic medications had significantly lower mean HbA1c levels (7.40$\pm$1.92) % compared to (8.34$\pm$1.97) % in the herbal treatment arm (*P*=0.016). Significant differences in mean HbA1c % were reported in patients on a combination of 5-6 herbs (7.06 $\pm$1.54) % compared to those on 3-4 herbs (8.63+1.91) % (*P*= 0.045). Significant predictors of adequate glycemic control (HbA1c$\leq$ 7%) were having a past HbA1c check ((aOR= 3.098 (95% C.I=1.258-7.631) *P*=.014), adherence to medications ((aOR= 6.055 (95% C.I=1.623-22.593) *P*= .007), treatment with *Launaea cornuta* ((aOR= 7.143 (95% C.I=1.462-34.893) P= 0.015) and being married (aOR=2.870 (95% C.I=1.054-7.818) *P*=0.039) .

Conclusion: Patients on treatment with conventional agents reported better glycemic control compared to those on herbal therapies. Regular monitoring of HbA1c, adherence to medications, having a spouse and treatment with launaea cornuta may enhance blood glucose control in patients with type 2 diabetes.

Keywords: Type 2 diabetes, glycemic control, HbA1c, conventional treatment, herbal therapy.

1. INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia. According to the International Diabetes Federation (IDF) 2021 report, the disease affects approximately 537 million people worldwide (1). Type 2 diabetes is the most common form and accounts for 85-95% of the cases (2). The prevalence of diabetes in Kenya is estimated to be 4% (3). This figure is likely to be an underestimate since a large number of people living with diabetes in Sub-Saharan Africa remain undiagnosed (4).
The pathologic hallmark of diabetes involves the vasculature leading to both microvascular and macrovascular complications (5). Optimal glycemic control is associated with reduced risk of onset and progression of diabetes-related complications. This is achieved through a combination of lifestyle interventions, oral glucose-lowering agents and insulin. However, antidiabetic medicines are perceived to be expensive and are sometimes unavailable to patients in developing countries (6). They are also associated with adverse effects leading to poor drug adherence (7). Consequently, patients commonly turn to complementary and alternative medicines to control their blood sugars. Some type 2 diabetes patients use herbal medicines as adjuncts to conventional medicines without informing their healthcare providers (8).

Among the various complementary and alternative therapies, herbal remedies are the most commonly used by both the general population and patients with chronic illnesses such as hypertension and diabetes mellitus (9). Recent studies in Ethiopia and Nigeria have reported the prevalence of herbal medicine use among type 2 diabetes patients. to be 58.5-67.3% (8) (10) (11). The prevalence of use of herbal medicines by patients with type 2 diabetes in Kenya is estimated to be between 12.4% (12) and 40% (13).

Although herbal medicines use among diabetic patients has been reported in Kenya, there are limited studies are comparing glycemic outcomes between patients on herbal and those on conventional therapies. In addition, some patients exclusively seek diabetes care in herbal clinics. It is not known if the care provided by herbalists is effective in maintaining optimal glycemic control. This study was carried out to compare glycemic control and identify its determinants in type 2 diabetes patients at Kenyatta National Hospital and those in a private herbal clinic in Kenya. The study findings will help to identify factors that can be addressed to enhance blood glucose control in both conventional and herbal practice settings.

Methods

Study design
A descriptive cross-sectional study was carried out to compare glycemic control in patients with type 2 diabetes on conventional therapies with those on herbal glucose-lowering therapies between March 2019 and December 2021.

Study setting
The study was carried out at Kenyatta National Hospital and New Life Herbal Clinic in Nairobi County. Kenyatta National Hospital is the largest teaching and referral Hospital in Kenya and is located in Nairobi, the Capital City of Kenya. The Diabetes Outpatient Clinic at Kenyatta National Hospital runs daily except at weekends. The clinic offers outpatient diabetes care services to approximately 400 patients weekly. New Life Herbal Clinic is a

leading provider of herbal medicines with outpatient clinics in Nairobi and the neighbouring Kiambu County.

Study population

The target population for this study were all adult patients with type 2 diabetes attending outpatient diabetes clinics at Kenyatta National Hospital and New Life Herbal Clinic. Participants were included in the study if they were above 18 years of age, had a confirmed diagnosis of type 2 diabetes according to WHO criteria and had been on follow-up and treatment at the study facility for at least 6 months. Informed consent was required to participate in the study. Pregnant women and patients with other types of diabetes were excluded from the study.

Sample size

The following formula was used to calculate the minimum sample size for the study

$$n = \frac{\sigma^2(Z_\beta + Z_{\alpha/2})^2}{(\delta)^2}$$

n is the sample size in each treatment group, ,σ is the standard deviation of the outcome variable, Zβ is the desired study power, Zα/2 is the desired level of statistical significance, δ is the effect size

For a study power of 80% and 0.05 statistical significance, Zβ is 0.8416 and Zα/2 is 1.96 respectively. Using a HbA1c difference of 0.7% between the treatment groups and a standard deviation (σ) of 1 , the calculated sample size for the study was 66 type 2 diabetes patients in each treatment group. To cater for a 10% non-response rate anticipated during the study, the calculated sample size was adjusted to 73 patients in each study group.

An allocation ratio of 1 herbal patient for every 2 patients on conventional treatment was used in this study because the attendance in the herbal clinic was low. This allocation ratio was within the recommended range for studies with unequal allocation of participants to the study arms (14). Consequently, the minimum sample size was 73 patients on the conventional arm and 37 patients on herbal treatments.

Sampling and participant recruitment

Consecutive sampling method was used to recruit the study participants. Patients with type 2 diabetes at Kenyatta National Hospital and New Life Herbal Clinic were recruited during their clinic appointments. The patients were briefed about the study by the researcher. Eligibility to participate in the study was established using the information in the patient files against the inclusion criteria. Patients who met the inclusion criteria and willing to participate in the study were asked to sign the informed consent form.

Data collection

A structured questionnaire was used for data collection in both study groups. Socio-demographic and clinical data were obtained through face-to-face interviews and from patient files. The sociodemographic and lifestyle factors included age, gender, marital status, highest level of education, alcohol and smoking status and BMI.

Clinical data collected included the duration of DM, diabetes treatment regimens, knowledge of previous glycated HbA1c testing and diabetes complications and comorbidities. HbA1c was used as the indicator of glycemic control. Patients with HbA1c levels $\leq$ 7% were considered to have achieved optimal blood glucose control.

Data analysis

Data were entered into and analyzed using IBM Statistical Package for Social Sciences (SPSS) software version 26.0 (SPSS Inc., Chicago, IL). Descriptive data analysis was performed on all variables. The results were expressed as frequencies and percentages.

Pearson's chi-square test was employed to compare the sociodemographic and clinical characteristics of participants from KNH and those from the herbal clinic.
The mean HbA1c in the two groups was compared using the independent samples t-test. The relationship between levels of glycemic control and patient sociodemographic and clinical parameters was examined using Chi square test. A multivariable logistic regression model was constructed to identify independent variables associated with glycemic control . P-values of 0.05 or less were considered to be statistically significant.

Ethical considerations
Ethical approval to carry out this study was obtained from KNH/UON Ethics and Research Committee (Approval number KNH-ERC A/431). The researcher provided comprehensive information on the study to the patients after which they were asked for voluntary consent to participate in the study.

3. RESULTS

3.1 Comparison of The Sociodemographic Traits of Pateints on Allopathic and Traditional Therapy

A total 117 patients on treatment for type 2 diabetes were recruited into the study (Table 1). We recruited 80 patients on conventional antidiabetic therapy at Kenyatta National Hospital Endocrinology Centre and 37 patients from a private herbal clinic (New Life Herbal Clinic, NLHC). The conventional treatment arm had a greater proportion of females (52,65 %) compared to the herbal treatment group (13,35.1%). The mean age of the participants at KNH was higher (62.3$\pm$ 13.91 years) compared to the participants from the herbal treatment arm (55.95$\pm$13.99 years). Notably majority of the participants from both KNH (55, 68.8%) and NLHC (25, 67.6%) had a BMI greater than normal (BMI>24.9kg/m^2).
The median duration of diabetes was longer in patients treated in KNH (10([4-18] years) compared to those treated at the herbal clinic (3[1-7] years). Previous HbA1c testing was reported in 36 (45%) of the participants in KNH. Among patients treated at KNH, 52 (65%) of them owned a glucometer. None of the patients treated at the herbal clinic had a HbA1c measurement six months prior to the study. Only 2 (5.4%) of patients at the herbal clinic had their own glucometers.

Table 1: Sociodemographic and clinical characteristics of the study participants

Characteristic	**Category**	**Conventional therapies (n=80) n (%)**	**Herbal therapies (n=37) n(%)**
Gender	Female	52 (65)	13 (35.1)
Age (years) (mean$\pm$SD)		62.31$\pm$13.91	55.95+13.99
Married	Yes	61 (76.3)	31 (83.8)
Highest education level	No formal education Primary Secondary Tertiary(college/university)	16 (20) 28 (35) 30 (37.5) 6 (7.5)	1 (2.7) 17 45.9) 13(35.1) 6 (16.2)
Body mass index (BMI)	<18.5 (underweight) 18.6-24.9 (normal) >25(overweight/obese)	1 (1.3) 24 (30.0) 55 (68.7)	1 (2.7) 11 (29.7) 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 Macrovascular	55 (68.8) 27 (33.8)	23 (62.2) 2 (5.4)
No. of comorbidities	None 1 >1	0 (0.0) 15 (18.8) 65 (82.1)	3 (8.1) 10 (27) 24 (64.9)

Patterns of allopathic medication and herbal drug use

Half (40, 50%), of the patients at KNH were on a combination of an oral antidiabetic agents and insulin (Figure 1). Metformin was prescribed for 67 (83.8%) of the participants. A total of 27 herbs with known glucose-lowering effects were used at the herbal clinic (Figure 2). The commonly used herbs were *Bidens pilosa* (local name-*mucege*) and *Rubia cordifolia* (local name-*gakaraku*) which were used on 14, (37.8%) each. *Launaea cornuta* (local name-*muthunga*) was used to treat 13, (35.1%) patients while *Sida cuneifolia* (local name-*kamuhinga*) and *Psidium guajava* (local name-*mubera*) were employed in treatment of 11 (29.7%) patients each. Majority, 24 (64.9%), of the patients were on regimens containing 3-4 herbs.

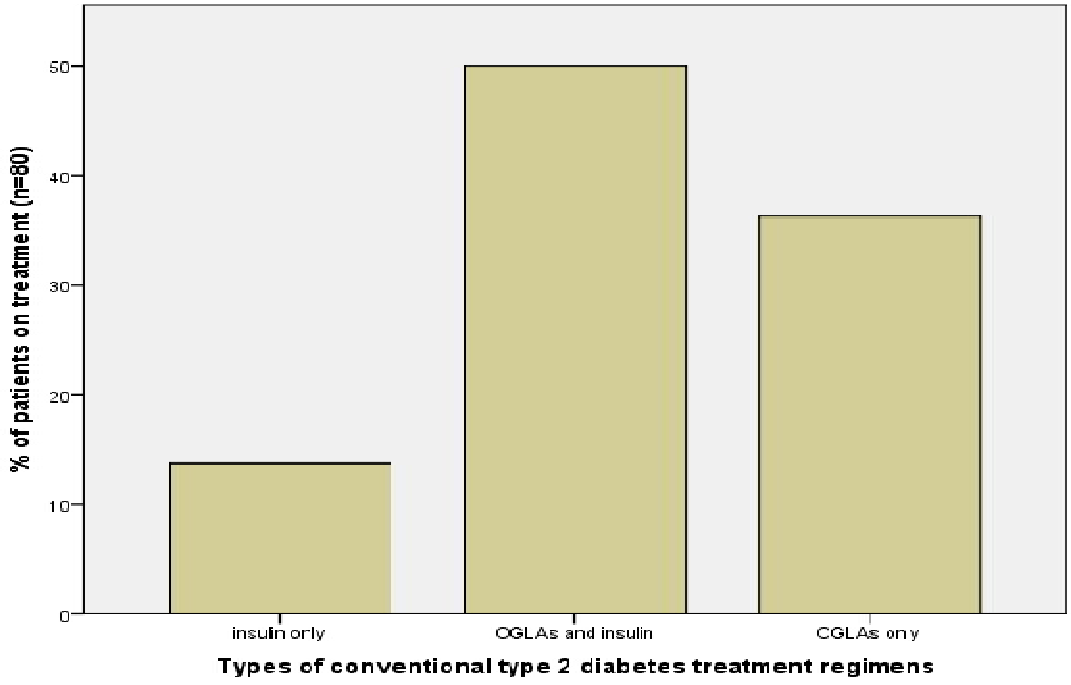

Figure 1: Types of conventional antidiabetic regimens

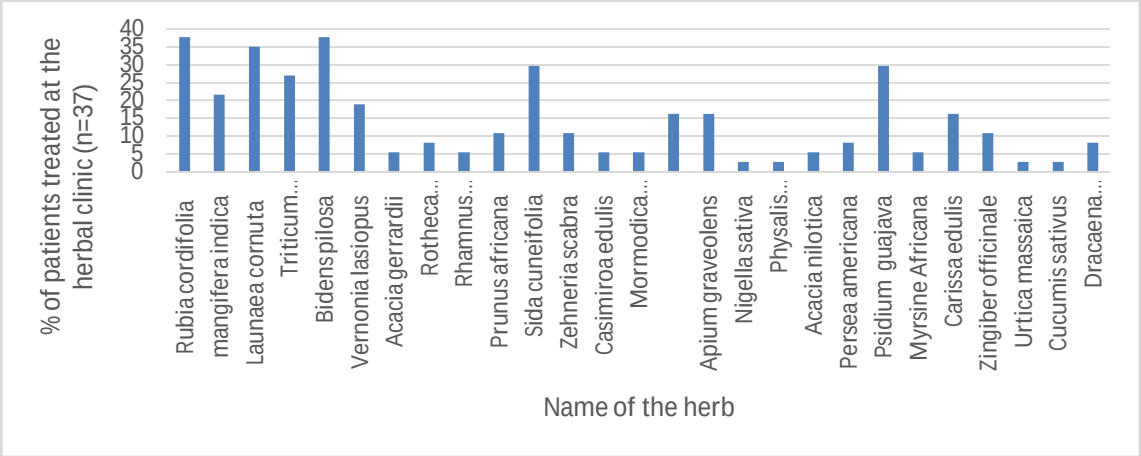

Figure 2: Types of herbs used for management of type 2 diabetes at the herbal clinic

Glycemic control

The mean HbA1c for patients on conventional antidiabetic regimens was 7.40%±1.92%. This was significantly lower compared to 8.34±1.97% for participants on herbal therapy (*P*=0.016). Among the patients on conventional treatment, the mean HbA1c for patients who had a HbA1c test six months prior to the study was 6.72±1.82% compared to 7.95±1.83% among participants who had not had a previous HbA1c check (p=0.004). Lower HbA1c levels (7.14±1.36%) were noted for patients on a combination of oral and insulin therapy compared to those on either oral antidiabetics (7.58±2.30%, p=0.733) or insulin (7.86±2.52%, p=0.206) only therapy. Patients on regimens containing 5-6 herbs had significantly lower HbA1c levels (7.06 ±1.54%) compared to those on 3-4 herbs (8.63±1.91)% (p= 0.045).

With regard to the study sites, adequate glycemic control was reported in 13 (35.1%) patients receiving treatment at the herbal clinic and 39 (48.8%) of the patients treated at KNH (P= 0.168) (Figure 3).

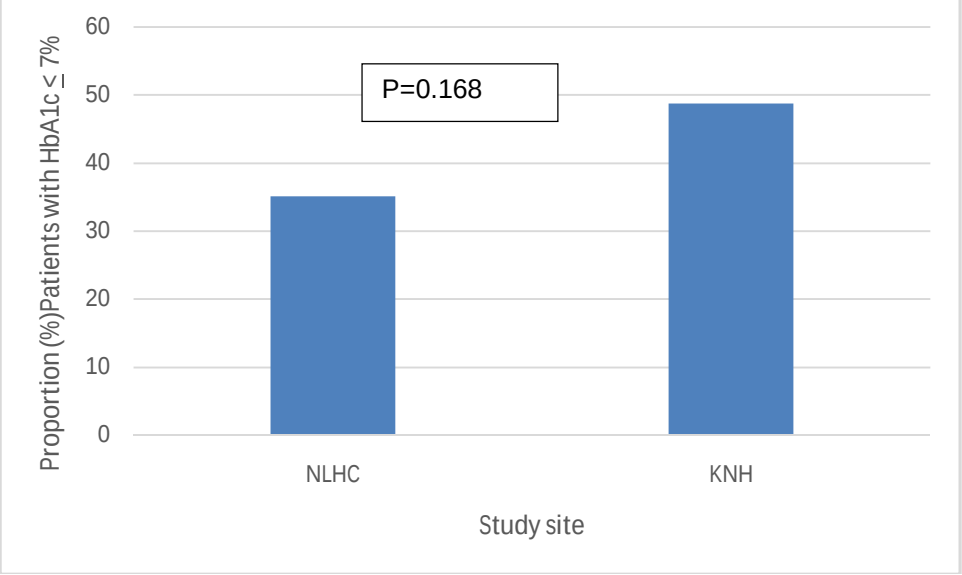

Figure 3: Proportion of patients with HbA1c ≤7% per study site

Bivariate and multivariate logistic regression analyses were performed to identify factors associated with glycemic control (Table 2). Significant predictors of adequate glycemic control (HbA1c≤ 7%) were having a past HbA1c check ((aOR= 3.098 (95% C.I=1.258-7.631) *P*=.014), adherence to medications ((aOR= 6.055 (95% C.I=1.623-22.593) *P*= .007 and treatment with *Launaea cornuta* ((aOR= 7.143 (95% C.I=1.462-34.893) P= 0.015). Patients who were married were also likely to achieve HbA1c ≤7% (aOR=2.870 (95% C.I=1.054-7.818) *P*=0.039) .

Table 2: Bivariate and multivariate analysis of patient characteristics with study HbA1c levels

Variable	**Bivariate regression (n=117)**		**Multivariate regression (n=117)**	
	Crude OR (95% C.I.)	**P-Value**	**aOR (95% C.I)**	**P-Value**
Site	0.531 (0.235-1.200)	0.128	-	
Sociodemographic factors				
Gender	0.405 (0.189-0.470)	**0.020**		
Age (years)	0.993 (0.967-1.019)	0.588	-	
Married	2.443 (0.989-6.033)	**0.053**	2.870 1.054-7.818)	**0.039**
Physical activity:				
Heavy manual work	1.939 (0.795-4.726)	0.145	-	
Household chores	2.573 (1.211-5.465)	**0.014**	-	
Smoking history	1.619 (0.695-3.768)	0.264		
Alcohol history	2.621 (1.220-5.631)	**0.014**	-	
Residence	1.830 (0.852-3.928)	0.121		
Disease and Treatment-related factors				
Medication adherence	0.311 (0.121-0.801)	**0.016**	6.055 (1.623-22.593)	**0.007**
Metformin	1.007 (0.427-2.375)	0.988	-	
sulfonylureas	0.390(0.157-0.970)	**0.043**	-	
Insulin	0.390 (0.338-1.470)	0.351	-	
Herbal treatments				
Rubia cordifolia	0.191(0.41-0.896)	**0.036**	-	
Launaea cornuta	1.169 (0.367-3.720)	0.792	7.143 (1.462-34.893)	**0.015**
Bidens pilosa	0.325(0.086-1.234)	0.099	-	
Diabetes duration (years)	0.981 (0.940-1.024)	0.374	-	
Glycemic control and monitoring				
Own glucometer	0.663 (0.317-1.385)	0.274	-	
Previous HbA1c (6 months) test	0.236 (0.103-0.545)	**0.001**	3.098 (1.258-7.631)	**0.014**
Complications and comorbidities				
Macrovascular complications	1.583 (0.661-3.791)	0.302	-	
Microvascular complications	1.971 (0.904-4.297)	0.088	-	
No. of comorbidities	0.679 (0.325-1.420)	0.303	-	

DISCUSSION

Our primary objective was to determine if there was a difference in glycemic control among patients receiving treatment at the herbal clinic and those in KNH. In this study patients on conventional treatment had better glycemic control compared to those on herbal therapies.

The effectiveness of conventional therapies in control of blood sugars is well documented in many studies and guidelines exist for their use (15) . However, studies evaluating the effectiveness of herbal therapy on glycemic control have yielded conflicting results. In Pakistan, use of herbal therapy for type 2 diabetes did not result in significant reductions in HbA1c levels (16).Use of complementary and alternative medicine in patients with type 2 diabetes has also been associated with poor cardiometabolic control (17) and severe diabetes (18). On the other hand, beneficial effects of herbal medicines have been reported previously. In Guyana, patients on herbal medicines reported normal HbA1c and lipid profiles (19) . The effectiveness of various herbal medicines on glycemic control as well as cardiovascular complications has also been demonstrated in a systematic review(20).

Previous history of HbA1c testing was a significant predictor of glycemic control among the study participants. Research has demonstrated the importance of regular HbA1c monitoring in diabetes management. In The Global Discover Study, it was noted that lack of a baseline HbA1c was associated with increased likelihood of inadequate glycemic control (21). In addition to being an indicator of long-term blood glucose control, HbA1c levels monitoring has prognostic potential in type 2 diabetes with poor control being predictive of dyslipidaemia(22).Therefore HbA1c monitoring may help in identifying patients at increased risk of cardiovascular complications.

Despite its well established importance in diabetes management, most patients on the conventional management did not have a HbA1c check prior to this study and the test was non-existent among the patients treated at the herbal clinic. This points to a major gap in diabetes care at the two care settings. Measures to ensure awareness and availability of HbA1c testing should be employed. This may include patient health education, baseline assessment of the knowledge and skills regarding HbA1c testing among care providers at both the conventional and herbal settings. Other measures may include training programs to address the identified information and skills gaps and improved availability of the test. Adherence to medications was predictive of good glycemic control among the study participants. There exists a direct relationship between adherence and diabetes control (23). Therefore interventions to improve this aspect of self-management of diabetes should be employed for better treatment outcomes. In our study, patients who were married were more likely to achieve their glycemic targets compared to those who were not. The positive impact of marital relationships on glycemic control and has been reported previously (24). This highlights the importance of spousal support in management of type 2 diabetes.

We reported better glycemic control with regimens containing 5-6 herbs compared to those with fewer components. Polyherbal formulations have been reported to exert superior antihyperglycemic effect compared to metformin and placebo (25) . This effect has been attributed to the action of the various phytochemicals in different herbs in reducing the blood sugars (26) . Among the various herbs used for type 2 diabetes in this study, treatment with *Launaea cornuta* had significant association with glycemic control. Extracts from this herb have been reported to be safe and efficacious in management of diabetes in animal studies (27). However, the antidiabetic efficacy of this plant has not been evaluated in clinical studies.

4. CONCLUSION

Patients on conventional medicines for type 2 diabetes had better glycemic control compared to those on herbal remedies. Regular HbA1c monitoring, medication adherence and having a spouse are potential factors that should be addressed to enhance glycemic control in patients with type 2 diabetes. *Launaea cornuta* has potential to improve glycemic control and should be evaluated in clinical settings.

CONSENT

All authors declare that written informed consent was obtained from the patients who participated in this study. A copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal.

ETHICAL APPROVAL

All authors hereby declare that this study was approved by the KNH/UoN Ethics and Research Committee (Approval No. KNH-ERC A/431) and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki." The researcher provided comprehensive information on the study to the patients after which they were asked for voluntary consent to participate in the study.

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