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http://dx.doi.org/10.9734/jocamr/2019/v7i230097

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Comparison and Effectiveness of Complementary and Alternative Medicine as against Conventional Medicine in the Treatment and Management of Type 2 Diabetes

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Authors' contributions

This work was carried out in collaboration among all authors. Authors CB, NW, TG, KC and RK designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors JR and JS managed the analyses of the study. Author CB managed the literature searches. All authors read and approved the final manuscript.

ABSTRACT

Aim: The main objective of the study was to compare, using laboratory data, the efficacy of herbal medicines against conventional drugs in treating and managing diabetes mellitus (DM) among type 2 diabetic (T2DM) patients.

Methodology: The study recruited 80 patients from a private Herbal Clinic and the Georgetown Public Hospital Diabetic and Medical Outpatient Clinic after giving their consent and satisfying the inclusion criteria. Laboratory tests and analysis were done using conventional scientific methods and data analyzed using SPSS version 20 with a p-value of 0.05 being used to determine statistical significance.

Results: The results showed that age, religion, ethnicity, education, marital status and monthly income have significant associations with the use of herbs. Persons using herbal medicine alone had normal lipid profile, renal function and liver function test, in addition to hemoglobin (Hb), white blood cell count (WBC), glycosylated hemoglobin (HBA1c) and fasting blood glucose (FBS). The most common herbs used were Momordica charantia (local name- karela) and Azadirachta indica (local name-neem), which were used in combination or alone. Results showed a positive effect on coronary heart disease risk.

Conclusion: The information generated from the study indicated that a significant number of diabetic patients using herbs alone for their treatment had normal results. However, a more controlled study is required to validate these results.
Keywords: Herbal medicine; complementary medicine; type 2 diabetes; alternative medicine.

1. INTRODUCTION

Diabetes mellitus (DM) is a major metabolic disorder that has become a significant and growing public health problem worldwide. Wanchai and Phrompayak conveyed World Health Organization (WHO) statistics of 1.5 million deaths due to diabetes in 2012 with 80% occurring in low and middle-income countries. Moreover, WHO had also reported that in 2014, 9% of adults aged 18 years and older had been diagnosed with DM. DM had been predicted to become the seventh leading cause of death by 2030 with the International Diabetes Federation envisaging a rise in prevalence of 642 million people by 2040 and a rise in the annual global healthcare spending on DM to $US 802 billion [1].

Currently, DM treatment can be broadly divided into two therapeutic approaches: conventional medicine and alternative medicine [1]. In diabetic patients, significant improvements can be achieved by treatment with hypoglycemic or antihyperglycemic, insulin sensitizing, and insulin secretion enhancing drugs [2]. However, although many drugs improve glycemic control, a number of studies have shown that side effects are still frequently reported when using these therapeutic regimes. Meta-analyses from different studies have showed that intensive glycemic control using metformin, sulfonylurea, and thiazolidinediones increased cardiovascular and mortality risk whilst long-term thiazolidinedione use increased the risk of fracture, lower respiratory tract infection, and bladder cancer among those with diabetes. These reports have prompted the search for complementary and alternative medicine (CAM) for better management of diabetes and its related complications [2,3].

Wanchai and Phrompayak categorized CAM into two categories, namely natural products and practices of the body and mind. Natural products include herbs, vitamins, minerals and probiotics. Practices of the body and mind include a diverse group of procedures or techniques administered or taught by a trained practitioner, such as "yoga, chiropractic and osteopathic manipulation, meditation, massage, acupuncture, relaxation techniques (i.e., breathing exercises, guided imagery, and progressive muscle relaxation), Taichi, Qigong, healing touch, hypnotherapy and movement therapy". In addition, there are other complementary health approaches that may not

neatly fit into either of these two groups such as the practices of healers from the traditions of Ayurvedic medicine, Chinese medicine, homeopathy, and naturopathy [1]. Some studies on CAM use showed inconsistent results. Prevalence of CAM use ranges from 34-38% [4,5,6]. In studies related to CAM use by DM patients, the prevalence of CAM use varies from 17% to 80% [1,7,8]. These studies have also reported that the most commonly used CAM therapies in patients with diabetes are nutritional advice and lifestyle diets, herbal remedies, supplements, spiritual healing, and massage therapy and meditation training.

Thai diabetic patients relied mostly on a modified version of Taichi, Daode Xinxi technique, whereas, nutritional supplements were common among T2DM patients in Taiwan, China, whilst Iranians with DM used herbal remedies [1]. The possible reasons for these differences may be due to the differences in culture, socioeconomic status and geographic contexts. Herbal remedies in particular are quite popular in the management of diabetes as from the patient perspective, it may be considered very acceptable to include plants as part of their medical intervention based on the recognition that herbal intervention is considered to be natural and have been part of culture and practices for many generations [9]. Diabetics are 1.6 times more likely, compared to non-diabetics, to use a CAM for several reasons [10].

Australia and the United Kingdom record a prevalence of 46% among diabetics [11,12]. India, a country that is steeped in tradition and boasting a rich history of healing practices records a very high use of 67% among its diabetic population. The majority of these patients (97%) used naturoapathy, which often included herbalism [13].

Several Randomized controlled trials demonstrating a benefit on lipid parameters in diabetes include Ayurvedic polyherbal formulation [14], Hintonia latiflora [15] and magnesium [16]. In postmenopausal women with type 2 diabetes, vitamin D supplementation for 6 months reduced serum triglycerides (TG) without effect on other lipid parameters [17], while a meta-analysis with high heterogeneity showed benefit on lowering total cholesterol and TG [18]. A meta-analysis of Berberine (a quaternary ammonium salt from the protoberberine group of benzylisoquinoline alkaloids found in some plants) showed it to reduce TG and increase high-density lipoprotein cholesterol (HDL-C) more than traditional lipid-lowering drugs, with no difference on total or low-density lipoprotein cholesterol (LDL-C) [19]. Berberine was also shown to reduce total and LDL-C and increase

HDL-C combined with traditional lipid-lowering drugs compared with those drugs

alone.

Several studies have also investigated the effects of cinnamon, garlic preparations, bitter melon and fenugreek and multi-vitamins which are some of the popular over the counter CAMs used among diabetics for its anti-diabetic effects [20].

Khan et al. in 2003 studied a total of 60 patients, who were randomized to receive 1, 3, or 6 g of cinnamon daily or a placebo. The background medication consisted of sulphonyureas only. At the end of 40 days at all 3 doses, cinnamon caused a significant decrease in Fasting plasma glucose (18-29%), total cholesterol (12-26%), triglycerides (23-30%) and LDL cholesterol (7- 27%) [21]. This study did not evaluate the effect of the intervention on HbA1c. Fuangchan et al. in 2007 compared 3 incremental doses (500 mg, 1000 mg and 2000 mg a day) of Momordica charantia (MC) against a standard dose of 1 g of Metformin in newly diagnosed, treatment naïve type 2 diabetics over a period of 4 weeks. They utilized capsules of MC containing 500 mg of dried fruit pulp. There was a significant decrease in the fructosamine levels of patients receiving metformin and those on MC 2000 mg per day.

However, there was no significant lowering of the FPG or the 2-h PPG in the MC group, in spite of the lowering of the fructosamine [22]. In 2008, Lu et al. randomized 69 type 2 diabetic patients on background oral hypoglycaemic therapy to receive Fenugreek 6 capsules 3 times a day (46 patients) or a matching placebo (23 patients) for a 12-week duration. In the treatment group, the FPG was reduced from $155 + \_31$ mf/dl at baseline to $122\_ + 25$ mg/dl, PPBG from $240 + -72$ mg/dl to $170 + -39$ mg/dl and the HbA1C from 8.02% to 6.56%. All values were statistically significant [23].

Guyana is a country steeped in culture and folklore due to its multiracial beginning. Consequently, the use of herbal remedies for ailments has been passed down from generation to generation and it is therefore not surprising that with the upsurge of diabetes, Guyanese may take to herbs to combat this disease. This study was done using laboratory studies, to compare the efficacy of herbal medicine used against prescribed medicine among diabetic patients. It is stated that a high level of knowledge or awareness will affect the outcome of the disease, regardless of race or the geographic location of the various sample populations. Therefore, by providing knowledge on how effective herbal medicine is in managing diabetes in Guyana, there can be better patient outcomes.

Since most of the studies concerning herbal remedies affects and use were done in other countries, the results might not be applied for Guyanese patients appropriately

due to differences in culture, behaviors, socioeconomics and other factors. Using herbs that have no proven clinical benefit to patients, may lead to delays in seeking appropriate treatment, leading to severe diabetes-related complications and associated disability and mortality. Therefore, this research was conducted to determine factors associated with the use of herbal medicine and quality of life effects for Guyanese diabetic patients. The aim of this study was to compare, using laboratory analyses, the efficacy of herbal medicine used against prescribed medicine among diabetic patients in Guyana.

2. METHODS

Eighty participants (T2DM and age-matched healthy controls) attending the Georgetown Public Hospital Diabetic Clinic, Georgetown Public Hospital outpatient department and a private herbal clinic were enrolled in the study after giving informed consent. In order to be included in the study, participants had to be diagnosed with diabetes for more than six (6) months, using herbal remedies or conventional medication for more than six (6) months and cleared by their physician as fit to enroll in the study. The 80 participants were divided into four groups: Group A (20 Diabetic participants using alternative medicine), Group B (20 Diabetic participants using conventional medicines and alternative medicine), Group C (20 Diabetic patients using conventional medicine) and Group

D (Control group- 20 participants without diabetes). All the participants were advised to maintain a balance diet while using their medications as prescribed by their physician for four weeks. At the end of the four (4) weeks, blood samples were drawn from each participant and tested using the ChemWell Chemistry analyzer to determine biochemical parameters and the Beckman Coulter to analyze hematological parameters.

A semi-structured questionnaire was employed to collect demographic, socioeconomic and cultural details of participants. Biochemistry and hematology reports of each participant were also collected for analyses. The study was a prospective convenience based study with mixed method approach. Data were analyzed using Chi Square with Statistical Package for Social Science (SPSS) version 20.0.

3. RESULTS AND DISCUSSION

3.1 Socio-demographic Status

The results showed that the study had a higher percentage of females (62.5%) than males (37.5%). The Majority (31.5%) of the participants fell within the >60 age group, while 27.5% and 18.8% of the subjects were found in the 50-59 and 40-49 age group, respectively. The data also revealed that 37.5% of the study participants were Christian, while 21.3% Hindu, 13.8% Muslim and 2.5% Buddhist. Significantly, 48.8% of participants were of East Indian descent while only 22.5% represented those of African descent. In relation to education, 1.3% was considered illiterate, 27.5% had a primary education, 43.8% participants had secondary education and 2.5% had a tertiary education and 47.5% were married. The majority of the participants were unemployed (42.5%) with only 20% having annual income between $2500-5000 USAD. Significantly, ($p<0.05$) a higher percentage (47.5%) of patients were ≤45 years when diagnosed with DM.

Age ($p \leq 0.05$), religion ($p \leq 0.05$), ethnicity ($p \leq 0.05$), education ($p \leq 0.05$), marital status ($p \leq 0.05$) and monthly income ($p=0.000$) were all found to have significant associations with the use of herbs according to chi square analysis.

Fig. 1 shows the type of prescribed medications used by the diabetic participants. The results showed that most participants (45%) used a combination of insulin and OHA (either Metformin, Daonil or both) for control of DM, while 28% used insulin alone, 7% used metformin and 20% used a combination of different anti-diabetic pills. Fig. 2 shows the different types of herbal medicine used by the participants. A combination of Karela (Momordica charantia) and neem (Azadirachta indica) was used by 28% of the participants, while 27% used Karela alone, followed by Karela and Cinnamon combination (22%).

3.2 Laboratory Analysis

Table 1 shows the percentage of values falling within normal range for each group for each parameter tested. For HbA1c, significantly higher percentage (85%) of

participants taking AM had normal value. Similarly, significantly higher percentage of normal values were also observed among AM participants for FBS, Lipid Profile (Cholesterol, TGL, HDL, LDL, VLDL and CHD), Renal Function (BUN, Creatinine) and liver function (AST,ALT, GGT).

The study was undertaken to compare hematological and biochemical values of diabetic patients using alternative medicine and conventional medicine. Graphical representation (Fig. 1) shows the different types of conventional medications used by participants in the study, which indicated that combination use of Insulin and OHAs was the treatment choice. Martins claim that dissatisfaction with results from orthodox pharmaceuticals was the main reason among DM patients to use herbs [24]. Frequency among DM patients to use herbs [24]. Frequency of the different types of herbal medicines used by the participants showed that the majority used either *Momordica charantia* (Karela) alone or combination of Karela and *Azadirachta indica* (Neem). Studies have reported several herbs to have lowering effects on HbA1c and FBG, including Fenugreek, Gymnema and Karela which was found to lower both HbA1c and FBG and Green tea and Cinnamon which were found to lower FBG but have no effect on HbA1c [3, 25, 26]. However, even though these herbs among others were reported by various studies, no study was found that analyzed the comparison of their effectiveness against the effectiveness of conventional medications.

Gupta et al indicated that several of these herbs, when used in concordance with conventional medications, had better glucose lowering results than when either was used alone [27]; contrarily to the present results which showed that almost all the patients in the combination group had elevated HbA1c and FBG. One possible reason for this could have been non-compliance to therapy as was reported by Shams et al who conducted a study on predictors for non-adherence to therapy in T2DM patients. In their study, they found that there was 73.7% non-compliance to therapy when drugs were being used with other modes of therapy [28]. It was reported that most persons stopped therapy when they felt healthy. Non-adherence could also be the reason for the drastically large number of persons with elevated HbA1c and FBG in the conventional medicine alone group. According to WHO, the recommended glycemic levels are achieved by less than 50% of patients, which is usually associated with decreased adherence to long-term therapies [29].
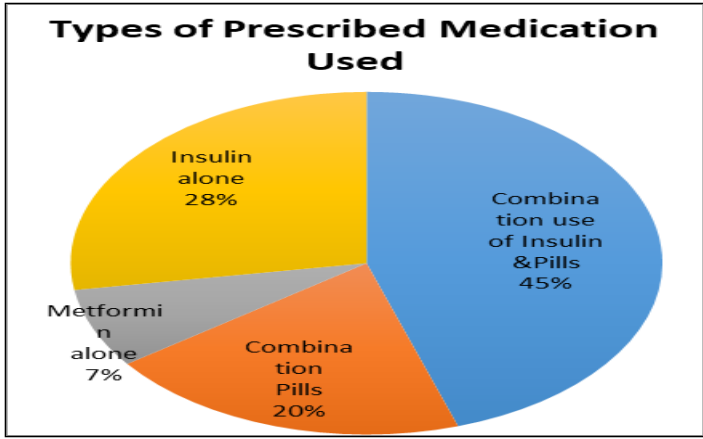
Fig. 1. Pie Chart showing the types of prescribed medications used by diabetic participants
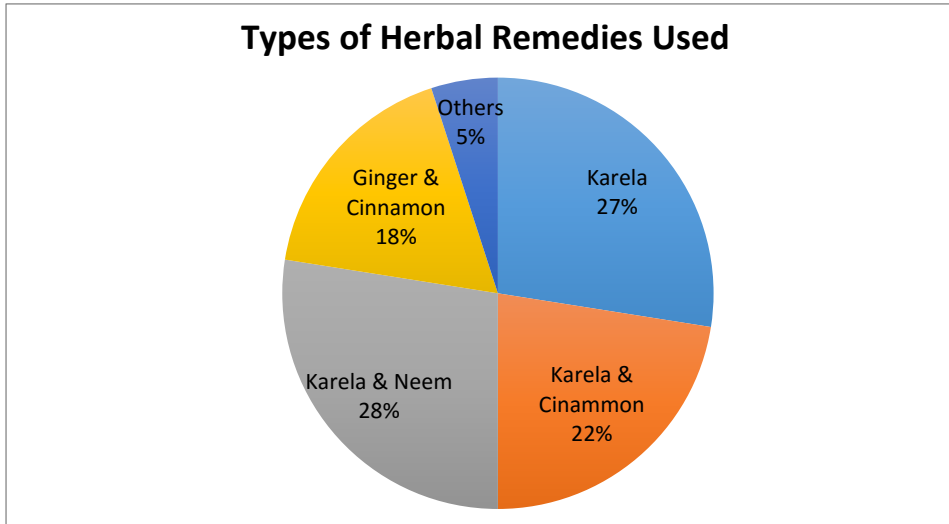

Fig. 2. Pie chart showing the types of herbal remedies used by diabetic participants

Table 1. Data showing comparison of normal laboratory values of participants among the four groups. Data are presented as the actual number of participants and percentages

Lab values	AM	AM+CM	CM	C	p-value
HbA1c	17 (85.0)	0	3 (15.0)	20	0.00*
Hb	12 (60.0)	17 (85.0%)	10 (50.0)	20	0.01*
WBC	20	16 (80.0)	18 (90.0)	20	0.10
Platelets	20	19 (95.0)	18 (90.0)	20	0.53
FBS	17 (85.0)	1 (5.0)	1 (5.0)	20	0.00*
Cholesterol	19 (95.0)	8 (40.0)	8 (40.0)	20	0.00*
TGL	20	10 (50.0)	11 (55.0)	20	0.00*
HDL	20	17 (85.0)	16 (80.0)	20	0.06
LDL	20	15 (75.0)	11 (55.0)	20	0.00*
VLDL	20	19 (95.0)	19 (95.0)	20	0.56
CHD	20	12 (60.0)	9 (45.0)	20	0.00*
BUN	17 (85.0)	13 (65.0)	11 (55.0)	20	0.00*
Creatinine	18 (90.0)	15 (75.0)	11 (55.0)	20	0.00*
Na	19 (95.0)	18 (90.0)	19 (90.0)	20	0.34
CHL	19 (95.0)	17 (85.0)	16 (80.0)	20	0.00*
GGT	18 (90.0)	1 (95.0)	16 (80.0)	20	0.00*
AST	19 (95.0)	18 (90.0)	19 (95.0)	20	0.00*
ALP	19 (95.0)	19 (95.0)	18 (90.0)	20	0.00*
ALT	20	16 (80.0)	19 (90.0)	20	0.00*

AM: Alternative Medicine; CM: Conventional Medicine; C: Control

**<0.01 and *p<0.001

Similarly, other studies have reported that some herbs used to treat diabetes may also have anti-lipid effects, namely Cinnamon, Karela, Fenugreek, Green Tea, Ginseng and Ginger [30, 31]. Even though there were significant number of persons with elevated LDL and TRIG values in the conventional medicine alone and combination groups, most had either low or normal CHOL values. All three groups had mostly normal HDL. However so, there were notable findings with regards to the coronary heart disease (CHD) Risk. All patients in the AM group had normal CHD risk values

whilst almost half in the CM group had elevated values. Only 5 out of 20 persons in the AM+CM group (half of that in the PM group) had elevated values, which can suggest that alternative remedies used did have a positive effect on CHD risk.

Like cardiovascular disease (CVDs), diabetes is a precursor for renal damage, also called Diabetic Nephropathy, which usually occurs due to uncontrolled diabetes, and results in raised kidney function values [32]. From current analysis in the present study, considerable relationships were found with the Kidney Function Tests and herbal medicine with BUN, CREAT and electrolytes (with the exception of Na) having highly significant p-values. There were very few persons (3) in the AM group with elevated BUN levels whilst there were 7 and 9 with high values in the AM+CM and CM groups, respectively. Similar results were obtained with CREAT. As there is a link between uncontrolled glycaemia and raised BUN and CREAT, it is possible to suggest that since the herbs were better at controlling glucose levels, they were indirectly responsible for positively affecting BUN and CREAT levels. However, even when diabetes is controlled, the disease can lead to chronic kidney disease and kidney failure with prolonged existence [32].

Although there may be relationships between elevated liver enzymes and diabetes, theses are multi-factorial in origin and are mostly associated with features of metabolic syndrome rather than glycemic control [33]. The results from the present study indicate that all the tests in the Liver Function Panel (GGT, ALP, AST, ALT) had highly significant associations. However, most of the patients in all three groups had normal liver enzymes with very few being elevated and therefore, these associations remain inconclusive. However, many other physiological and biochemical factors have to be taken into consideration in future controlled studies.

4. CONCLUSION

It can be concluded from the results that, persons using alternative medicines were found to have better glycemic control and exhibited better lipid profile, renal function and liver function as well as Hb and WBC values. However, a more rigorous and controlled study is needed to validate these results as several interfering factors may have played a role such as type of alternative medicine, dosage and adherence.

CONSENT

Informed consent was also obtained from the respondents before questionnaire was issued.

ETHICAL APPROVAL

 Ethical approval was sought from the Institutional Review Board (IRB) before commencement of research.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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