Assessment of Concomitant Use of Herbal and Conventional Medicines among Patients with Diabetes in Public Hospitals of Addis Ababa, Ethiopia

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Addis Ababa, Ethiopia,

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This is to certify that the thesis prepared by Solomon Getnet, entitled "Assessment of Concomitant Use of Herbal and Conventional Medicines among Diabetic Patients in Addis Ababa, Ethiopia" and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Pharmacoepidemiology and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Acronyms and Abbreviations

AACA	Addis Ababa City Administration
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti Retroviral Therapy
CAM	Complementary and Alternative Medicine
DM	Diabetes Mellitus
GDM	Gestational Diabetes Mellitus
HIV	Human Immuno Deficiency Virus
HM	Herbal Medicine
HMP	Herbal Medicinal Plants
IDF	International Diabetic Federation
NCD	Non-Communicable Diseases
SJW	St John's Wort
SPSS	Statistical Package for Social Science
THM	Traditional Herbal Medicine
TM	Traditional Medicine

Abstract

Introduction: Majority of population in developing countries including Ethiopia are dependent on traditional medicines. Patients who have chronic illness like diabetes mellitus were dissatisfied with conventional drugs are more likely to take simultaneously herbal remedies from traditional medicine (TM), with conventional treatment. However, such use could result in potential herb-drug interaction.

Objective: To assess the prevalence of concomitant use of herbal and conventional anti diabetic medicines; and to identify the commonly used herbal medicines among patients with diabetes in public hospitals of Addis Ababa, Ethiopia.

Method: A mixed approach of quantitative and qualitative designs was employed. A health facility based cross sectional study design was employed to determine the magnitude of concomitant use of herbal and conventional medicines among patients with diabetes in Addis Ababa. A qualitative study design with an in-depth interview data collection method was also employed to describe prescribers' history taking practice about TM during their encounter with the patients. Patients with diabetes from four public hospitals in Addis Ababa who were attending outpatient diabetic clinics were the study population for the quantitative study. All prescribers working in the diabetic clinic during an interview were considered as both the source and study population for the qualitative study. Data was collected from April 17 to August 30, 2016. Quantitative results from 791 questionnaires were entered in EPI-INFO version 3.5.1 and analyzed by SPSS Version 20 computer statistical software's. Simple descriptive statistics were used to describe variables and content analysis had been conducted manually for qualitative data.

Result: From a total of 845 questionnaires, 791 were complete; making the response rate 93.6%. Out of 791 respondents, 409 (51.7%) used TM at least once in their life time and 357 (45.1%) used TM in the last six months prior to data collection. Majority 288 (80.7%) of respondents used herb/herbal products after starting the conventional anti diabetic drugs. Leaves of plants were used by most 187 (64.9%) of the patients and oral administration was the major route as cited by 281 (97.6%) of the respondents.. Moringa, thyme, fenugreek, black seed and garlic were among the frequently mentioned herbs used by diabetic patients. Sizable number of respondents 199 (69.1%) also perceived that herbal medicines they took were effective.

None of the prescribers in the qualitative study gathered patients' herbal medicine use history in their history taking practice. They only would like to take any herbal medicine related information when they saw sign of liver toxicity and skin disease. Almost all key informant interviewees revealed that they had no adequate knowledge about drug-herb interactions.

Conclusion: The study revealed that majority of respondents used herb/herbal products concomitantly with conventional antidiabetic drugs. Moringa, thyme, fenugreek, black seed and garlic were identified as the most commonly used herbs by patients with diabetes. This combined use of herbal medicines and conventional antidiabetic medicines could cause potentially serious herb-drug interactions. More studies with scientific methodology are required on dose, frequency, duration and modes of interaction to better healthcare of patients.

Key words: Herb-drug interaction, Diabetes Mellitus, Herbal medicine, Chronic disease

1. Introduction

Traditional medicine (TM) covers a heterogeneous spectrum of ancient to new age approaches to prevent or treat disease. It includes the use of herbs, spiritual healing, and practices such as bone setting. TM is not part of conventional medicine because there is insufficient proof that TM practices are safe and effective (WHO, 2013).

TMs are widely used around the world and are the main source of health care, and sometimes the only source of care (WHO, 2013). 80% of people in the developing world, 360 million people in China and 150 million citizens and 300,000 registered health-care professionals in Europe use traditional medicines (Sarina *et al.*, 2012). They have stood the test of time for their safety, efficacy, cultural acceptability and lesser side effects (Mohamed and Salih, 2014). TMs were used for age related chronic diseases such as hypertension and diabetes for which no modern medicine or only palliative therapy is available (Mollaoğlu and Aciyurt, 2014).

Diabetes is one of the largest global health emergencies of the 21st century. In addition to the 415 million adults who were estimated to have diabetes around the world, there were 318 million adults with impaired glucose tolerance, hence, with high risk of developing the disease. In 2015, 14.2 million people were estimated to be living with diabetes in Africa and this is projected to 34.2 million by 2040 (IDF, 2015).

Patients with diabetes who were dissatisfied with conventional medicine were more likely to use herbal medicines to enhance the effect of conventional treatment with potential for adverse effects (Damnjanovic *et a*l, 2015).

There are herbs which have been used for ages by societies, and hence, are believed to be safe. Users of medicinal herbs are usually suffering from chronic conditions for which they are likely to take prescribed drugs concomitantly. However, the simultaneous use of herbal and conventional drugs may result in potentially serious herb-drug interactions (Sugunabai *et al.*, 2014). Mostly, herbal medicines are complex mixtures of more than one active ingredient. Multitude of active ingredients will increase the possibilities of interactions between herbal medicines and conventional drugs (Chang *et al.*, 2011). These interactions may lead to serious

clinical consequences and both pharmacokinetic and/or pharmacodynamic mechanisms have been considered for these interactions (Al-Ramahi *et al.*, 2015).

The clinical importance of herb-drug interactions depends on many factors associated with the particular herb, drug and patient. As a precaution to consumers, herbs should be appropriately labeled to alert consumers to potential interactions when concomitantly used with drugs and to recommend a consultation with physicians or pharmacists before use (Fasinu *et al.*, 2012).

Many documented interactions are from limited and small case reports. However, they support that some herbal medications or supplements have potentially harmful side effects as well as adverse interactions with conventional drugs (Al-Ramahi *et al.*, 2015).

The extent of use and the commonly used herbal medicines by patients with diabetes are not well documented in Ethiopia. Results on magnitude of the concomitant use of herbal and conventional medicines and identifying the commonly used herbal medicine is important to the decision makers to give attention and preparing standards of safety and efficacy of herbal medicines. This study was, therefore, conducted to determine the extent of concomitant use of herbal medicines with conventional drugs, and also to identify the commonly used herbs among patients with diabetes.

2. Statement of Problem

Herbal medicines are either used on their own, or in addition to conventional medicine which is particularly common in patients suffering from chronic disorders such as cancers, hypertension, HIV/ADIS, diabetes mellitus, psychiatry disorder, cardiovascular problems and their associated physical and psychological problems (Grants *et al.*, 2012). For instance, a study in South Africa indicated that of the 135 participants who reported using traditional herbal medicine, 28 (21%) used herbal medicine (HM) to treat hypertension (Hughes *et al.*, 2013).

A similar study in Ethiopia indicated that medicinal plants were used mainly for the treatment of infectious diseases and for two or more non-infectious diseases (Abera, 2014). Another study done on the use of traditional medicine for the treatment of HIV and opportunistic infections in Dessie Town documented that 25% of 574 had used traditional medicine along with ART. Slightly more than 0.1% of the patients on ART reported to have used herbal formulations (Kloos *et al.*, 2013).

Like other chronic illnesses, TM use among diabetic patients is also prominent. Such combined use of TM with conventional medicine results in various outcomes: for instance, treatment with St John's wort (SJW) significantly increases the apparent clearance of gliclazide (Borrelli and Izzo, 2009). Administration of *Ginkgo biloba* extract increased hepatic clearance of insulin and oral hypoglycemic agents, hence resulting in an increased glucose level (Rai *et al.*, 2012). Adverse effects such as hypoglycemia and lactic acidosis were also detected among diabetic patients who were taking herbal antidiabetic products in China (Ching *et al.*, 2011).

Until recently, herb-drug interaction was often unsuspected by health care providers. Most trained physicians lack adequate knowledge on herbal drugs and their potentials for drug interactions (Fasinu *et al.*, 2012). Patients may also not always inform their doctor of the concomitant use of complementary medicine (Werneke *et al.*, 2004). However, the concurrent use of herbal and drug combinations may raise the potential of herb-drug interactions. Several studies concerning drug-herb interactions with clinical significance pointed that these interactions may lead to serious clinical consequences. Such adverse reactions could involve all systems, age groups and severity (Al-Ramahi *et al.*, 2015).

Therefore, a better understanding of the extent of HM use will help the healthcare system to be more vigilant. In addition, it will also provide information on prevalence and determinants of herbal medicine use among patients with diabetes. This information will help for policy makers and researchers to establish regulatory requirements for manufacturing or safety assessment of traditional medicine and drug development research.

It is also common knowledge that the safety of most herbal products could be compromised by lack of suitable quality controls, inadequate labeling, and the absence of appropriate patient information. It has become essential, therefore, to furnish the general public including healthcare professionals with adequate information to facilitate better understanding of the risks associated with the use of these products (Ekor, 2015).

Ethiopia is not an exception to this worldwide phenomenon, where herbal medicines are the main source of health care for many millions of people in the world (WHO, 2013), and 30% of Ethiopian population is dying from non-communicable diseases where diabetic mellitus is the major component (WHO, 2014). In line with is, this study tried to assess the magnitude of the concomitant use of herb/herbal product and conventional antidiabetic medicines and identify the commonly used herbs so that appropriate education could be given to patients for better treatment outcome.

3. Literature Review

3.1. Epidemiology of traditional medicine use

Interest in the use of traditional medicine has been increasing. The complementary and alternative treatment, especially the herbal medicine, has gained more attention and has also become popular. About 80% of people worldwide rely on herbal medicines for some aspects of their primary health care (Bodeker and Kronenberg, 2011). Herbal medicines and their preparations have been widely used for thousands of years, in developing and developed countries, owing to their natural origin and lesser side effects or dissatisfaction with the results of synthetic drugs (Thillaivanan and Samraj, 2014). Almost half of the population in many industrialized countries now regularly uses some form of TM (United States 42%, Australia 48%, France 49%, and Canada 70%). Considerable use exists in many developing countries (China, 40%; Chile, 71%; Colombia, 40%; up to 80% in African countries) (Bodeker and Kronenberg, 2012).

Individuals with chronic diseases often seek help from sources other than conventional medicine with a reported prevalence rates as high as 83.3% (Buowarib, 2013). A systematic review of 26 surveys in 13 countries showed that the mean prevalence rate of TM use was 31.4%. TMs are used for a wide range of chronic diseases like hypertension, chronic heart failure, diabetes mellitus, chronic obstructive lung disease, chronic renal impairment, migraine, epilepsy and rheumatoid arthritis. Research in Turkey and elsewhere has demonstrated high rates of TM use (25% to 85%) in these diseases (Mollaoğlu and Aciyurt, 2013).

Presently, there is growing interest in herbal remedies due to the side effects associated with the therapeutic agents for the treatment of Diabetes mellitus. The effect of conventional medicine treatment is not satisfactory and problems of the adverse drug reaction are also very prominent. (Bodeker and Kronenberg, 2011).

Hence, the traditional herbal medicines are mainly used playing an important role in the management of diabetes mellitus (Rao *et al.*, 2010).

3.2. Diabetes mellitus and herbal medicine use

Medicinal plants play a prominent role in human health care worldwide. During the last few years the United States alone has recorded an increase of 380% in the use of herbal remedies (Medagim *et al.*, 2014). Plant extracts or different folk plant preparations are being prescribed by the traditional practitioners and also accepted by the users for diabetes like for any other diseases in many countries. Plant materials which are being used as traditional medicine for the treatment of diabetes are considered to be one of the good sources for a new drug or a lead to make a new drug. (Umashanker and Shruti, 2011).

Diabetes mellitus is an illness, where a wide array of HMs has been used with varying success. Around 2–3.6 million people in the United States rely on HM for the treatment of diabetes mellitus (Manya *et al.*, 2012).

Little is known about the prevalence of use of HM therapies in general and among patients with diabetes in particular though the use of HM is widespread and increasingly practiced worldwide (Ali-Shtayeh *et al.*, 2011). When considering the use of HM amongst patients living with diabetes, a North American study has shown the prevalence to be between 31% and 57% (Manya *et al.*, 2012). High rates of HM use, extending from 25% to 85% of individuals with diabetes, were reported in Turkey. In Bahrain, the prevalence rate was also high among patients with diabtes, estimated at 63%, whereas in Jordan it was noted to be 16.6% (Naja *et al.*, 2014).

3.3. Herb-drug interaction

Herbal medicinal plants (HMPs) are by definition complex mixtures of many compounds having different profile of herb-drug interactions. Both the raw herb and the extract contain complicated mixtures of organic chemicals that often make difficult to determine which component, if any, of the herb has biological activity in humans (Zwickey *et al.*, 2014). Adulteration of herbal medicines with synthetic medicines makes the case even more complicated (Filate *et al.*, 2009).

A study in USA revealed that up to 40% of various patient groups take herbal remedies and drugs simultaneously. Another study also found that 40% of pregnant women used herbal remedies and about 85% of these take herbal medicines with conventional drugs. It was also

indicated that 13-47% of elderly patients reported they were using herbal medicines even though the risk of adverse interactions with elderly patients is high (Birhan *et al*., 2011).

A drug may interact with other drug leading to drug-drug interactions. These interactions are more serious with high risk disorders like diabetes, hypertension or high risk drugs like antidiabetic, antihypertensive, and antiarrhythmic drugs (Kumar *et al*., 2012).

Co-use of herbs and drugs might alter the drug's pharmacokinetics and/or pharmacodynamics, hence causing unexpected adverse effects of the drug. Accordingly, both serious and less serious adverse interactions have been reported like between cyclosporine and St. Johns Wort (*Hypericum perforatum*). The drugs such as warfarin interact with a range of herbs like garlic (*Allium sativum*), cranberry (*Vaccinium oxycoccos*), ginkgo *(Ginko Biloba*), ginger (*Zingiber officinale*) and grape fruit (*Citrus paradisi*) (Okoronkwo *et al*., 2014).

Adverse effects associated with herbal medicines may result from contamination of products with adulteration, misidentification or substitution of herbal ingredients, or improperly processed products. Inappropriate use of herbal medicines can also cause negative or dangerous effects. For instance, the herb "Ma Huang" (Ephedra) is traditionally used in China to treat respiratory congestion, while it was marketed as a dietary supplementformulated for weight reduction in US. Over dosage use led to at least a dozen deaths, heart attacks, and strokes (Ching *et al*., 2011).

A retrospective cross-sectional study in China found that the prevalence of concomitant use of herbal medicinal products and antipsychotic treatment was 36.4% (34.2%–38.6%). Herbal medicine regimens containing *Radix* b*upleuri, Fructus gardenia, Fructus schisandrae, Chinensis, Radix rehmanniae, Akebia caulis,* and *Semen plantaginis* in concomitant use with quetiapine, clozapine, and olanzapine were associated with nearly 60% of the risk of adverse outcomes (Zhang *et al*., 2015). *Gymnema sylvestre*, a plant native to the tropical forests of India, has long been used as a treatment for diabetes. In a study of type II diabetes, patients with diabetes given the aqueous leaf extracts of *G. sylvestre* with their oral hypoglycemic drugs, showed improved blood sugar control. *G. sylvestre* enhances the production of endogenous insulin there by lowering blood glucose levels (Baskaran *et al*., 1990).The aqueous extracts of *Bidens pilosa, Erythrina abyssinica, Aspilia pluriseta, Strychnos henningsii* and *Catha edulis*

have also been shown to significantly lower blood glucose as effectively as insulin (Piero *et al.*, 2011).

A considerable number of patients that are suffering from diabetes turn to self-medication using medicinal plants in the opinion that the use of herbal supplements combined with antidiabetic drugs is absolutely safe and justified. However, a large number of literature data indicates that natural does not always meansafe (Lakshmi *et al.*, 2012).

4. Objective

4.1. General objective

- To assess the prevalence of concomitant use of herbal and conventional medicines and identify the commonly used herbal medicines among diabetic patients in public hospitals, Addis Ababa, Ethiopia.

4.2. Specific objectives

- To estimate the prevalence of the concomitant use of herbal and conventional medicine among diabetic patients in Addis Ababa
- To identify commonly used medicinal plants by diabetic patients in Addis Ababa

5. Method

5.1. Description of the study area

Addis Ababa is the capital city of Ethiopia with an area of 540 km^2 and population of 3.43 million (1.81 million female and 1.62 million male) according to 2017 projection (CSA, 2017). It is administratively divided into 10 sub cities with 117 *Woreda*s During the time of this study, the city had a total of 56 hospitals (14 of which are public), more than 760 clinics, 96 health centers and more than 720 pharmacies (AACAHB, 2016). Out of the 14 public hospitals, five are under the federal Ministry of Health, six are general hospitals under Addis Ababa city, and the rest three are army and police hospitals.

5.2. Study design

A mixed method of both quantitative and qualitative methods was employed in the study. A health facility based cross-sectional study design was carried out to determine the prevalence of concomitant use of herbal and conventional medicines among diabetic patients. A qualitative study design was undertaken to assess prescribers' history taking about patients' use of TM during physical examination. Data was collected from April 17 to August 30, 2016.

5.3. Source population

The source population for the quantitative study constituted all patients with diabetes attending treatment in outpatient clinics of public hospitals of Addis Ababa City Administration (AACA). On the other hand, all prescribers working in the diabetic clinics were considered as the source population for the qualitative study.

5.4. Study population

Patients with diabetes from four public hospitals in Addis Ababa, two hospitals from AACA (Yekatit and Zewditu hospitals) and two hospitals from Federal (St. Paul and Tikur Anebesa Specialized hospitals) were the study population. All prescribers from diabetic clinics of these hospitals were study population for the qualitative study.

5.5. Inclusion and exclusion criteria

For the quantitative study;

- **Inclusion criteria**: Patients with age greater or equal to 18 and taking anti-diabetic agents
- **Exclusion criteria**: diabetic patients who were physically or mentally not capable to be interviewed and those who were health professionals.

For the qualitative study;

- **Inclusion criteria**: Prescribers who were working in diabetic clinics
- **Exclusion criteria**: Prescribers who were diabetic

5.6. Sampling and sample size determination

Sample size determination

The minimum sample size (n) required to conduct an assessment of concomitant use of traditional and conventional medicine among diabetic patients in public hospitals of Addis Ababa was computed using single population proportion formula (Fosgate, 2009),

$$n = \frac{(Z_{\alpha/2})^2 \times P(1-P)}{d^2}$$

Where

n = minimum sample size

P = Expected proportion of concomitant use of traditional and conventional medicine (0.5)

Z = Critical value for a given confidence interval (with 95% CI)

d = Margin of error (5%)

$$n = \frac{(Z_{\alpha/2})^2 \times P(1-P)}{d^2}$$

$$\frac{(1.96)^2 \times 0.5(0.5)}{(0.05)^2} = 384$$

Design effect (of 2) was considered and made up a sample size of 768.

With the assumption of 10% non-and inappropriate response rate, a total of 845 diabetic patients were included in the survey.

Sampling Procedure

For the quantitative study, hospitals were stratified, based on ownership, into AACA and Federal (Fig. 1). Then, two hospitals from AACA, i.e., Zewuditu Memorial Hospital (ZMH) and Yekatit 12 Hospital Medical College were selected based on simple random sampling (lottery method). Similarly, two hospitals namely Tikur Anbessa Specialized Hospital (TASH) and St. Paul Hospital Millennium Medical College (SPHMMC) were selected from federal hospitals. The sample size was proportionately allocated for each of the selected hospitals based on the total diabetic patients in each respective hospital. Recruitment of the respondents was achieved through quota sampling techniques (336 from TASH, 206 from SPHMC, 132 from ZMH and 171 from Yekatit 12 Hospital Medical College).

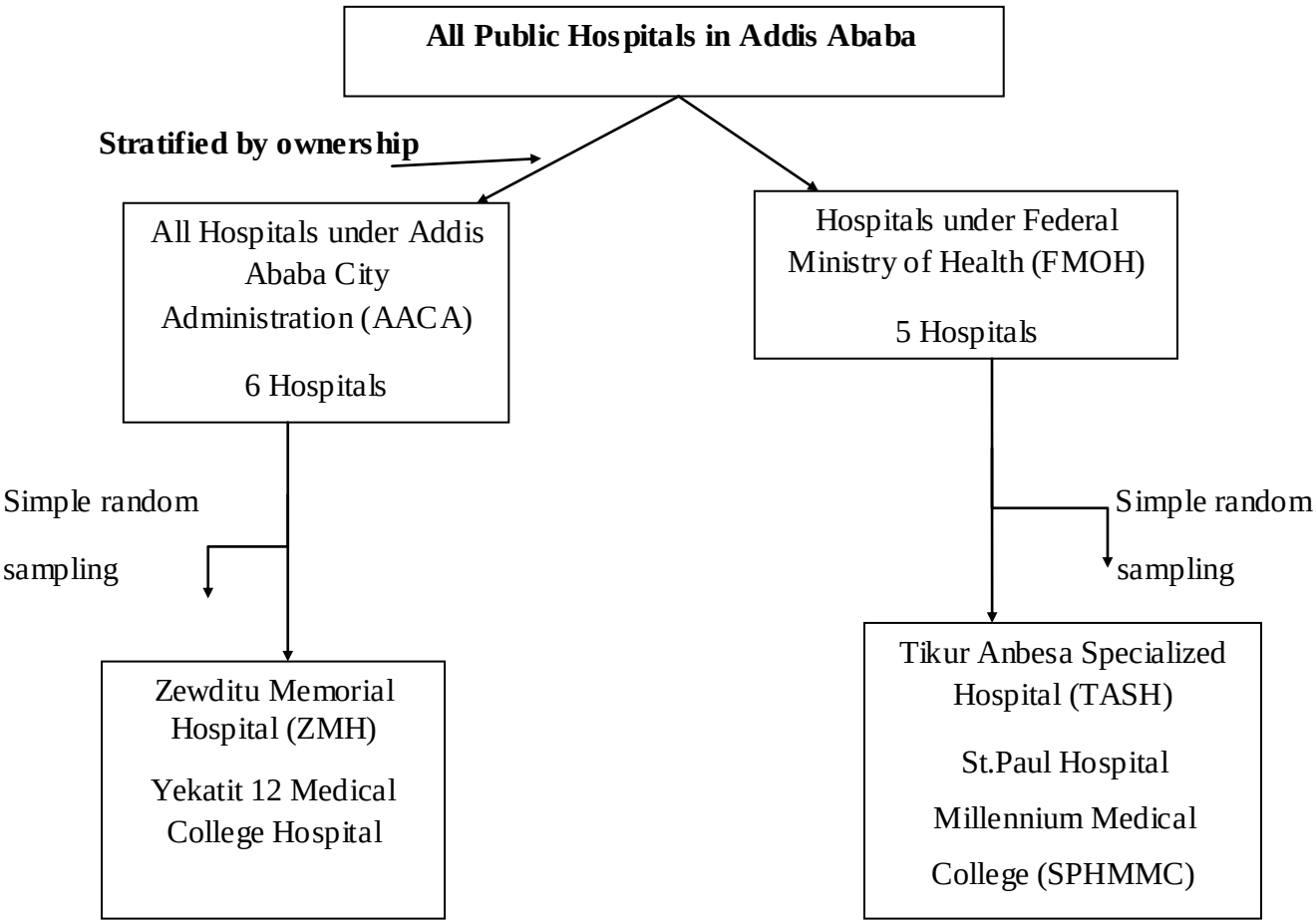

Fig 1: Schematic representation of sampling techniques employed for the selection of hospitals

For the qualitative study, selection of participants was based on purposive sampling. Key informants were recruited purposively on the basis of their professional role and long experience in the diagnosis and treatment of diabetes mellitus. Selection of participants was continued until participants would not raise new concept or ideas. The key informant interview was held with purposively selected internal medicine specialists and general practitioners from each hospital to explore any difference in experience of herbal medicine history taking practice.

5.7. Data collection instrument

For the concomitant use of herbal and conventional medicine assessment, a total of 45 questions were incorporated in the questionnaire (Annex I) (Addis *et al.*, 2002). Questions addressing the

patients' socio-demographic characteristics (age, sex, average income, marital status, educational status) , traditional medicine use, type of traditional medicine chosen, time of use of traditional medicine (before, after or during the conventional drug treatment), reason to use the traditional medicine, perceived effectiveness of the herbal medicine, and adverse effects experienced, were included in the assessment questionnaire.

An in depth interview data collection method for key informants was used with open-ended interview guide (Annex II) with flexible probing techniques for investigating prescribers experience of history taking about herbal medicine use during examination of diabetic patients.

5.8. Recruitment and training of the data collectors

Two data collectors were recruited from each hospital pharmacy department. They were trained for one day to familiarize them on data collection procedures and ethical issues as well as to give standardized instruction and clarify questions up on filling the questionnaire. As part of the training, the data collectors conducted pre-test of the instrument in Ras Desta memorial hospital under the supervision of the principal investigator to check the validity of the instrument. For the qualitative data, the principal investigator administered the key informant interviews.

5.9. Data collection

Prior to interview, data collectors explained the objective and importance of the research was given to study participants. Then each participant was asked to be engaged in the study and the interview continued with volunteer ones.

The principal investigator conducted the key informant interview and notes were taken during interviews to expand later. The interview was started from TASH and continued to ZMH, Yekatit 12 Hospital Medical College and SPHMMC. The interview was done in Amharic and any ambiguities raised from the interviewees were cleared at the time of the interview by the principal investigator.

5.10. Data quality assurance

The questionnaires were prepared in English and the data collectors translated into Amharic. The data collection instrument was pretested to increase the quality of the responses. The pre-test helped to rectify and revise instruments as well as the research procedure in general. Four questions (Annex 2, Question No 12, 19, 24, and 26) were modified to capture possible alternatives of the answer.

Once the data collection began, daily supervision was made by the principal investigator during the whole data collection period and any inconsistencies were amended on time. Regular cross checking, inspection and scrutinizing of the information on the data collection instruments were also done to ensure completeness of the data. Incomplete and inconsistent data were discarded. For the qualitative data, the interview was conducted in Amharic and the Amharic version of the interview transcription was translated into English and complete transcription of all interviews was prepared.

5.11. Data analysis

After the data collection, the principal investigator coded each question and data entry was made using EPI-INFO version 3.5.4 statistical packages and the data was transferred to SPSS version 20 for data analysis. Descriptive statistics such as frequencies and percentages were used to describe and summarize the data.

The qualitative data was analyzed with a view to gain an understanding of prescribers' practice of history taking about herbal medicine during examining patients with diabetic. The qualitative data analysis was involved an intensive reading and rereading through the data and content analysis had been conducted manually, focusing on similarities and differences of perspectives between different informants.

5.12. Variables

- Independent variables
    - Demographic characteristics: age, sex, religion, marital status, and residency
    - Socio economic factors : monthly income, and educational status

- Co-morbidity: hypertension, Heart failure, kidney disease, and cancer
- Length of treatment

- Dependent variables
  - Concomitant use of traditional and conventional medicine

5.13. Researcher's position and reflexivity

A qualitative research is highly affected with relationship between researcher and participants unless a qualitative researcher is aware of openness, closeness and distance, power relations, social class and race. Educational background and ethical dilemmas and given primacy in the qualitative methodology. Therefore, the primary investigator has to be in mind his influence in qualitative inquiry and result due to his position and identities (Heim *et al.*, 2016).

There were three major considerations with regard to the investigator's position. First one is the primary investigator is working in regional health bureau and considered him by the participants as an evaluator of the healthcare system of the region. This has been found to affect the participants to provide the information freely.

Secondly the investigator is a pharmacist considered as drug experts by participants and they may think that the investigator is intended to test their professional competence and place their profession in a bad light in the professional community since the participants most of the time believed that researchers interests and professional identities are threatened during research.

The third consideration was regarding the in-depth interview. The in-depth interview was conducted by the principal investigator who is a pharmacist having an idea on drug-herb interaction. The principal investigator read more on diabetic drug and their interactions with herbal medicines as part of his preparations for the research. As a result the principal investigator might think that he knows more than the participants and this could have impacted on the note taking and he might miss important ideas. The researcher's interest in an interview process is to explore clinically potent challenges in herbal medicines use in their experience of diagnosis and treatment of diabetic patients but a certain inferiority in terms of professional knowledge may existed among participants.

Considering the above assumed considerations that may affect the result and interpretation of the result, the principal investigator approached the participants as researcher with an interest in the objective of the study. He attempted to record their view and perspective being conscious of his identity and position.

5.14. Ethical consideration

Ethical approval was obtained from the Ethics Review Committee of the School of Pharmacy, Addis Ababa University and the study was conducted after obtaining permission from the respective hospitals. Participants of the study were also asked for verbal consent before participating in the study. Participants were assured about confidentiality of the information obtained in the course of the study and not using personal identifiers in data presentation and analyzed in aggregates.

5.15. Operational definitions

- **Diabetes mellitus**: is an endocrinological disorder which is caused by the inability of the pancreas to produce insulin or inability of the body metabolic system to properly use the insulin produced.
- **Traditional medicine**: is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.
- **Herb:** include crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
- **Herbal medicine**: include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants or other plant materials or combinations
- **Herb-drug interaction**: any modification caused by concomitant use of herbal and conventional medicine in the diagnostic, therapeutic, or other action of a drug in or on the body
- **Concomitant use**: Co-use of traditional medicine while they are taking conventional anti diabetic drugs

6. Results

6.1. Quantitative findings

6.1.1. Demographic characteristics of respondents

From the total of 845 semi structured interview guides, 791 were completed; making up a response rate of 93.6%. Male and female accounted almost similar proportion of sample size 402 (50.8%) and 389 (49.2%), respectively. The age of the respondents ranged from 18 to 83 with the mean age of 49.07 years (SD=±14.76 years). Among the respondents, majority 231(29.2%) were house-wives followed by government employees 146(18.5%) and daily laborers 80(10.1%). Majority of the respondents 667(84.3%) were residents of Addis Ababa City Administration. With regard to educational status of the respondents, 524(66.2%) attended at least elementary school (Table 1).

Table 1: Demographic characteristics of respondents in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=791).

Variable		Frequency (n)	Percent (%)
Sex	Male	402	50.8
	Female	389	49.2
Age	18-40	290	36.7
	41-64	368	46.5
	>64	133	16.8
Marital Status	Single	159	20.1
	Married	526	66.5
	Divorced	43	5.4
	Widowed	63	8.0
Residency	Addis Ababa	667	84.3
	Oromia	111	14.0
	Others*	13	1.6
Religion	Orthodox Christian	590	74.6
	Muslim	97	12.3
	Protestant Christian	89	11.3
	Others**	15	1.9
Educational Level	Unable to read and Write	187	23.6
	Non Formal Education	80	10.1
	Elementary School	166	21.0
	High School	190	24.0
	TVET and above	168	21.2
Occupation	House wife	231	29.2
	Government employee	146	18.5
	Merchant	70	8.8
	Daily Laborer	80	10.1
	Student	45	5.7
	Jobless	75	9.5
	Others***	144	18.2

* Tigray, SNNP and Amhara regions, ** Jehova's Witness and pagan

***Retired, contract employee, and handicraft

6.1.2. Clinical conditions of patients interviewed

At the time of the study, 210 (26.5%) of patients were on insulin, 499(63.1%) were on oral hypoglycemic and 82(10.4%) were on both insulin and oral hypoglycemic medicines respectively. More than half of them 459(58%) had another disease. Hypertension was the major co-morbid disease for 313(39.5%) of patients with diabetes. Sizeable number of the patients, 333 (42.1%) were diagnosed as diabetic before 5 to 10 years (Table 2).

Table 2: Clinical conditions of diabetic patients in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=791).

Variable		Frequency (n)	Percent (%)
Current treatment	Insulin	210	26.5
	Oral hypoglycemic	499	63.1
	Both	82	10.4
Co-morbidity	Yes	459	58
	No	332	42
Co-morbidity type *	HTN	313	68.2
	Asthma	49	10.7
	Kidney Disease	65	14.2
	Heart Problem	53	11.5
	Eye disease	47	10.2
	Others**	126	27.5
Duration of the diabetic disease	<5	174	22.0
in years	5-10	333	42.1
	>10	284	35.9

HTN; Hypertension

*= percentages will not add up to 100% as some DM patients had more than one type of co-morbidity

**= Atherosclerosis, GI problem, hemorrhoid, HIV/AIDS, neurological problem, mental problem, etc

6.1.3. Traditional medicine use practice of diabetic patients

From the 791 respondents, 409 (51.7%) of them used TM at least once in their life time and 357(45.1%) used in the last six months. Majority of them 218(61.1%) used to treat diabetes mellitus. From the total herbal medicine users, 101(30.4%) used herb/herbal products before and 231(69.6%) used after starting conventional antidiabetic medicines in this study.

Diabetic patients mentioned various reasons for using TM. The most common one was a belief that TM is more potent than conventional antidiabetic medicines, as mentioned by 240 (58.7%) of respondents. Sizable number of respondents 96(23.5%) also believed conventional medicine is expensive and reported to use TM (Table 3).

Table 3: Traditional medicine use practices of diabetic patients in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=791).

Variable		Frequency (n)	Percent (%)
Ever use of TM	Yes	409	51.7
	No	382	48.3
TM use in the last six months	Yes	357	45.1
	No	434	54.6
Use of TM for	Diabetic mellitus	218	61.1
	Other diseases	25	7.0
	Both	114	31.9
Time for TM use	Before starting antidiabetic drugs	101	30.4
	After starting antidiabetic drugs	231	69.6
Type of TM	Herb/Herb product	288	80.7
	Holy water	69	19.3
Reason to use TM	TM are more potent and curable	240	58.7
	Cost of conventional drug	96	23.5
	Toxicity/side effect of the conventional drugs	33	8.1
	Inaccessibility of the health facilities	29	7.1
	Others*	11	2.7

*= Unsatisfactory service in health facilities, to augment treatment, no reason

6.1.4. Source, duration and part of the herb used

The majority of patients with diabetes 260 (90.3%) remember the name of the herb/herb product they used and also reported using the leaf of the plant. Majority of the herbal medicine users, 211(73.3%) used the leaf of the plant. Market 217 (75.3%), garden 44(15.3) and traditional healers 31(10.8%) were the major sources for obtaining herbal medicine. From the total (288) concomitant users of herbs and antidiabetic conventional drugs, 111 (38.5%) respondents used herbal medicine once and 40 (13.9%) used for more than 30 days (Table 4).

Table 4: Source, duration and part of the herb used by respondents in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=288).

Variable		**Frequency (n)**	**Percent (%)**
Remember the name	Yes	260	90.3
	No	28	9.7
Part of the herb used*	Leaf	211	73.3
	Seed	37	12.8
	Oil	19	6.3
	Root	5	1.7
	Stem	4	1.4
	Other**	65	22.6
Source of the herb*	Traditional healer	31	10.8
	Market	217	75.3
	Garden	49	17
	Other***	24	8.3
Duration of use	Used once	111	38.5
	2-7 days	57	19.8
	8-30 days	80	27.8
	more than 30 days	40	13.9

*= Multiple responses were possible

**= Don't know the part, fruit, flower,

***= Neighbor, Family, another user,

6.1.5. Commonly used herbal medicines

Moringa is used by 144 (50%) of patients with diabetes who have started using herbs after they started using conventional antidiabetic drugs. Similarly, thyme, fenugreek, black seed and garlic were reported by 50 (17.4%), 21 (7.3%), 19 (6.6%), and 16 (5.5%) of patients with diabetes, respectively. A considerable amount of herbal medicines were prepared in crushed form as cited by 194 (67.4%) of patients with diabetes and 243 (84.4%) of them expressed that the herb was available in dried form. Oral administration was the major route herbal medicine use among patients with diabetes (Table 5).

Table 5: Commonly used herbal medicines by patients with diabetes in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=288)

Local Name	Common name	Scientific name	Part used	Frequency * n=288	Percent	Formulation
Shiferaw	Moringa	*Moringa stenopetala*	Leaf	144	50	Dried leaves of Moringa are crushed and taken as a tea on daily basis.
Tosign	Thyme	*Thymus vulgaris*	Leaf	50	17.4	Tea of dried, crushed leaves is taken daily
Abish	Fenugreek	*Trigonella foenum-graecum*	Seed	21	7.3	Dried seeds are powdered. The powder is mixed with water and taken in the morning with an empty stomach.
Tikur Azimud	Black seed	*Nigella sativa*	Oil	19	6.6	An oil obtained from squeezed seeds of the dried black seed is taken after food at any time
Nech Shinkurit	Garlic	*Allium sativum*	Knob/clove	16	5.6	Fresh knob or clove of garlic cooked with food
Teliba	Linseed	*Linum usitatissimum*	Seed	9	3.1	Dried seeds of Linseed are powdered. The powder of linseed seed is mixed with water and taken with food.
Zingible	Ginger	*Zingiber officinale*	Rhizome	9	3.1	The dried and crushed rhizomes of ginger are cooked with food.
Dama Kese	Dama kese	*Ocimum lamiifolium*	Leaf	9	3.1	Fumigation of the fresh leaf
Senafich	Mustard	*Brassica nigra.*	Seed	7	2.4	Dried seeds are powdered. The powder is then mixed with water and taken with food.
Tena'dam	Rue	*Ruta chalepensis*	Leaf	5	1.7	Fresh leaves are socked in a tea for some time and drunk
Arenguade Shay kitel	Green tea	*Camellia sinensis*	Leaf	3	1	The dried leaves of green tea are socked in hot water for some time and drunk as a tea.
Others**				28	9.7	

*= Multiple responses were possible

**= Don't know the name and part of the herb

6.1.6. Source of information and decision on herbal medicines used

Of 288 herbal medicine users, 263 (91.3%) respondents tried to get more information about the herbal medicine related to its effectiveness and toxicity they used (Table 6). Of those 164 (62.4%) of them got the information from the community and 55 (20.9%) respondents got the information from healthcare providers. Only 3 (1.2%) respondents got the information about herbal medicine from the pharmacist. Of the total concomitant users of herbs and antidiabetic conventional drugs (N=288), only 103 (35.8%) of them informed their healthcare providers that they were using herbal medicine. Being afraid of the doctor and feeling that the herb has no problem were the frequently mentioned reasons for not informing the health care providers (Table 6). Among those who informed their use of HM to their healthcare providers, 74 (71.8%) and 28 (27.2%) were advised by healthcare providers to continue and discontinue the herbal medicine, respectively (Table 6).

Table 6: Source of information for decision on herbal medicine use of diabetic patients interviewed in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=288).

Variable		**Frequency (n)**	**Percent (%)**
Sought for more information	Yes	263	91.3
	No	25	8.7
Recommendation obtained from	Community	164	62.4
	Doctor	24	9.1
	Herbalist	28	10.6
	Pharmacist	3	1.1
	Others	44	16.7
Patients who informed the doctor	Yes	103	35.8
	No	185	64.2
Reason not to inform the healthcare provider	Afraid the doctor	74	25.8
	There is no problem	72	25.0
	the doctor didn't ask	14	4.9
	Considered as food	25	8.7
Has information about drug herb interaction	Yes	44	15.3
	No	244	84.7
Doctors' advice	Discontinue	28	27.2
	Continue	74	71.8
	Neither continue nor discontinue	1	1.0

6.1.7. Perception of effectiveness and method of side effect aversion

From 288 respondents, 40 (13.9%) perceived that they experienced side effects due to herbal medicine use. Constipation 14(24.6%), vomiting 8(20%) and headache 8(20%) were some of the reported side effects. Of those having side effects, 24 (60%) discontinued herbal medicine use and 10 (25%) consult the health professionals to avert the side effects (Table 7).

Table 7: Herbal medicines effectiveness perception and method of side effect aversion of respondents in selected public hospitals of Addis Ababa, Ethiopia, (2016) (n=288).

Variable		**Frequency (n)**	**Percent (%)**
Effectiveness perception	Yes	199	69.1
	No	89	30.9
Side effect experience	Yes	40	13.9
	No	248	86.1
Type of side effects*	GI problem	5	12.5
	Vomiting	8	20.0
	Head ache	8	20.0
	Diarrhea	5	12.5
	Tiredness	5	12.5
	Constipation	14	35.0
	Abdominal pain	5	12.5
	Others	8	20.0
Actions to avert side effect	Consulted the health professional	10	25.0
	Discontinued using herbal medicine	24	60.0
	Consulted the herbalist	3	7.5
	No action	3	7.5

*= Multiple responses were possible

6.2. Qualitative findings

The qualitative study was conducted to elicit information on prescribers' history taking practice about herbal medicine during diagnosis of diabetic patients. Interview was done with eight health professionals (3 were females and 5 were males). Four of the participants were specialist medical doctors while the rest were general practitioners. Their age ranged from 29 -54 years. In terms of work experience, participants had worked in diagnosis of diabetic patients for a range of from 2-12 years. Four major themes were defined in qualitative data analysis: herbal medicine history taking practice, commonly used herbal medicines, prescriber's perceived knowledge about drug-herb interactions and challenge in herbal medicine use.

Herbal medicine history taking practice

All (n=8) the key informants mentioned that they took patient history information but they didn't gather information about herbal medicine. High patient load was ascribed as a reason for this. An internal medicine specialist from one hospital reported the reason behind for not asking herbal use history of diabetic patients as follows:

" Since there were a lot of patients I had to see every day, I had no time to ask my clients about their herbal medicine use practice"

However majority of them (n=5) reported that they asked patients with diabetes about their herbal medicine experience when they saw sign of liver toxicity. This was strengthened by one of the participants as follows,

"When I found liver toxicity or increased enzyme level in the patients, I would ask whether they took herbal medicine or not. However, I would not record the herbal medicine he /she was taking on the patients chart."

In addition to liver toxicity some key informants (n=2) also mentioned herbal medicine use experience was mainly observed among patients with diabetes with skin diseases. This was substantiated by one of the participants as;

"I had an experience that when patients had dermatological problem, they would mostly use herbal medicine and I would ask these patients with diabetes for their herbal medicine use practice".

Commonly used herbal medicines

Most of the key informants (n=7) agreed that Moringa as the most commonly used herb by patients with diabetes as it was believed to have hypoglycemic effect. One of the specialists had encountered patients with diabetes who were using coffee extract for diabetic treatment.

One general practitioner also explained there were patients who told him as they were using herbal medicines for the treatment of diabetes mellitus. He expressed his experience as follows;

''There were plants used by patients with diabetes that I didn't remember the name and type of the herbs since I did nothing with that. I only advised them to discontinue using herbal medicine".

Prescribers perceived knowledge about drug-herb interaction

The majority (n=6) of key informants agreed that it was important to know most commonly used herbal medicines so that appropriate information about concomitant use of herbal and conventional medicine to patients with diabetes could be delivered. Almost all (n=8) key informants revealed that they had no adequate knowledge about drug-herb interaction. They also reported that much emphasis was not given to drug-herb interaction course in medical schools as drug-drug interaction. As a result, low attention was given to taking history of herbal medicine use. One general practitioner strengthened this as,

"If I ask the patient whether he/she has been using herbal medicine and found that he/she was using any herb, I wouldn't take any decision towards using herb because I don't have any knowledge about a specific herb and the conventional antidiabetic drug interactions."

Majority of key informants cited (n=7) that many patients go to traditional healers for treatment but they explained that they didn't come across with magnitude of concomitants use of herbal medicine and conventional anti diabetic drugs.

Challenge in herbal medicine use

Identifying the herbs taken, standardizing dose, safety, frequency and route of administration and herb-drug interaction were challenges related to herbal medicine use. The challenge was substantiated by one of an internal medicine specialty participant as

"Even though the patients with diabetes told me that they had been using herbs and they were benefited from the herb, it was difficult to give right advice. Because I didn't have adequate knowledge about the safety of herbal medicines and I advised not to continue taking the herbal medicine."

Taking of herbal medicine related information was also cited as a challenge. One key informant explained as;

"It was also a big challenge to take herbal medicine related information from each patients with diabetes since I saw a number of diabetic patients every day. In addition to little knowledge we had about drug-herb interaction, it was also another challenge to know what kind of herb the patients were taking."

All of the key informants mentioned that a great attention was not given to drug-herb interaction in medical school training and the curriculum should include a course about traditional medicine; especially herbal medicines and their interaction with conventional drugs. Most of them also explained that absence of comprehensive and standardized materials to refer was also cited as a challenge.

7. Discussion

Diabetes mellitus has a significant impact on the health, quality of life and life expectancy of patients as well as healthcare expenditure. With increasing incidence and mortality from its complications, prompt and adequate glycemic control in diabetes is crucial (Arika *et al.*, 2016). In this regard, herbal medicines have been recognized as one of the oldest form of remedies used by humans (Kumar and Mandapaka, 2013).

This study has been carried out with the purpose of determining the preference of herbal medicine use and identified the commonly used herbs by patients with diabetes. The current study revealed that more than half of the respondents had co-morbidity where hypertension was the major disease occurred in 68.2% of patients with diabetes. This finding is similar to 65% in Oriental Morocco that at least one cardiovascular disease was observed in with patients with diabetes (Alami, 2015). This study also showed that 45% of diabetic patients used TM within the last six months. The finding was lower than that of another study Malaysia which indicated 62.5% of patients with diabetes used TM (Kew *et al.*, 2015). The difference may be due to sample size and recall period difference between the two studies.

The study also estimated that 36.4% of patients with diabetes took herbal medicine which was higher than from a study in black South African communities where 28 (21%) used HM to treat hypertension (Hughes *et al.*, 2013). This difference could be due to difference patients with NCD might use HM in different level. This finding was also lower than 68.9% and 80% of HM use prevalence among patients with diabetes in Gucha district, Kenya (Ondich *et al.*, 2015) and South East Region of Morocco (Eddouks *et al.*, 2012), respectively. The difference in magnitude may be due to difference in study design where study population in Kenya's and South East Morocco were those who visited the traditional healers. But it was higher than 25.9% prevalence of HM use among population of cardiovascular disease in Pahang, Malaysia (Kew *et al.*, 2015). The difference may be due to sample size and recall period difference between the two studies.

In this survey, conducted among patients suffering from diabetic mellitus, 36.4% of the respondents used herbal medicines along with prescribed therapy for the treatment of diabetes in the last six months. This finding was lower than 58% similar prevalence study in South Sudan (Badreldin and Mohamed, 2014). The lower prevalence of the concomitant use in this study

might be due to difference in socio-demographic characteristics of the study populations between the two studies. But a study in Turkish showed approximately similar finding (33%). A different results were obtained from India, where 71% of patients with diabetes used herbal medicines along with the conventional therapy (Balamurugan and Ganesh, 2015). The higher in prevalence of using herbal medicines in India might be due to better integration of herbal medicines with modern healthcare system in India (Umashanker and Shruti, 2011).

Even though the quantitative study indicated that high proportion of patients with diabetes used herbal medicines concomitantly with conventional antidiabetic medicines, finding on exploration of herbal medicine history taking practice of prescribers during physical examination of patients with diabetes showed low. The contradictory results from the quantitative and qualitative studies could be due prescriber's low knowledge on drug-herb interaction and work load.

Moringa, thyme, fenugreek, black seed and garlic were the most frequently used herbal medicines in this study. A similar study in Oriental Morocco also indicated that the most five medicinal plants used by Morocco population were *Salvia officinalis*, *Trigonella feoenum-graceum*, *Olea europea*, *Artemisia herbaalba* and *Origanum vulgare* (Alami, *et al.*, 2015). Another similar study in Turkey revealed that the most frequently used herbal products by the patients are green tea, garlic and ginger (Culha *et al*., 2016). Different herbal medicines might be used in different areas with different level as a result of difference in accessibility of the herb and information dissemination among patients with diabetes. Moringa and coffee extract were also identified as the commonly used herbal medicines by diabetic patients in the qualitative study.

Majority of the diabetic patients (58.4%) in this study used HM. Believing that TM was more potent and affordable than conventional antidiabetic medicine were the major reason to use HM. Similarly, a study in North Sudan indicated patients' belief in herbal medicine efficacy, easy accessibility and lower cost have encouraged patients with diabetes to seek herbal medicine (Mohamed and Mahfouz, 2014). Another study in Kenya revealed unaffordability, unwanted side effects and unavailability of conventional antidiabetic drugs have given herbal medicine considerable attention to use them (Arika *et al*., 2016).

This study also reveled that, 69.1% of the herbal medicine users perceived herbal medicines they used were effective. A qualitative study also indicated that patients with diabetes were benefited from moringa. A similar study in Beirut found that 48% of herbal medicine users reported that they were benefited from herbs (Alaaeddine *et al.*, 2012).

A systematic review in Ethiopia indicated that the aqueous extracts of *Moringa stenopetala* leaves significantly reduced blood glucose level (Meresa *et al.*, 2017) and another study in Guinea indicated *Allium sativum* has a real therapeutic effect in patients with diabetes (Balde *et al.*, 2016). In addition to this, a study in Nigeria showed administration of the aqueous extract of *Thyme vulgaris* led to significant decrease in blood glucose level (Akubugwo *et al.*, 2014). Another similar study in Nigeria revealed ginger extracts reduced fasting blood glucose to normal as effectively as the antidiabetic drug, glibenclamide, (Oludoyin and Adegoke, 2014). A review of clinical studies done in Iran indicated *Trigonella foenum-graecum* had clinical evidence for their antidiabetic effects (Ghorbani, 2013). Nigella sativa was also found to lower the blood glucose level significantly in a study conducted Aligarh (Ahmad *et al.*, 2012). An experimental study in UK indicated that garlic was found to reduce fasting blood glucose significantly as compared to metformin (Ashraf *et al.*, 2011).

Herbs identified by this study, Moringa, Thyme, Fenugreek, Black seed and Garlik, which were the most frequently concomitantly used with the conventional antidiabetic medicines have got literature support of having hypoglycemic effects. But qualitative study explored prescribers lack adequate information of herbal medicine hypoglycemic effect which will compromise treatment outcome of the diabetic patients.

This study also revealed that 13.9% of herbal medicine users reported they experienced side effects. This might be due a result from an additive and/or synergetic effect of the concomitant use of these herbs with conventional antidiabetic medicines. Like hypoglycemic effect, an experimental study identified chronically treated male animals with fenugreek were analyzed for spermatogenic dysfunction and administering in high dosages may adversely influence the bone marrow cell proliferation (Al-Ashban *et al.*, 2010, Araee *et al.*, 2009). Nigella sativa treatment also has proved its hepatoprotective effect (Saheb et al., 2016). Similarly, use of *Moringa stenopetala* leaves increases body weight (Yohannes et al., 2014).

This study revealed that the very common method of remedy preparation was in dried and crushed form. Mostly the dried and crushed form of the herbs was taken by mixing with water. But a study in central Ethiopia indicated more than half of the medicinal plants were used in fresh form (Getaneh and Girma, 2014). Another similar study in Ethiopia showed that decoction was the most common method of preparations (Ayele *et al.*, 2012).

Oral administration was the major route herbs that patients with diabetes used and leaf of the herb was the most frequently used (73.3%) part of the herb in this study. It was also observed that some patients with diabetes used herbal medicines mixing with tea. Different route of administration and different part of the herbs were also used. This study identified that measurements of the dosages and frequency of administration were not standardized. But using different route of administration, preparation and part of the herb may yield different active ingredients of a herb which might result different effect (Ajibola *et al.*, 2014).

This study found that market and community were the major source and source of information for the herbal medicines respectively. Having information on a certain herb having antidiabetic effect from the community and obtaining the herb easily the market might affect the patients with diabetic adherence to the conventional medicine. Small proportion of respondents got information about the herbal medicines from healthcare providers. This might be due to lack of free communication between prescribers and patients as a result of patient load and prescribers' low knowledge of herb-drug interactions. A similar study in Thailand showed most of the patients with diabetes used TM concomitant with conventional therapy. Similarly, small proportion of patients with diabetes informed their physicians (Moolasarn *et al.*, 2005).

8. Strength and Limitation of the study

8.1. Strength of the study

The study adopted (Addis *et al.*, 2002) instruments and triangulation was made through employing both quantitative and qualitative methods. Necessary data quality assurance measures were employed before, during and after data collection.

8.2. Limitation of the study

The study may be subjected to health facilities and social desirability bias since it was conducted in health facilities. It might be also subjected to recall bias as cross sectional surveys. Generalization to all Addis Ababa diabetic patients might be affected due to inclusion of only public health facilities.

9. Conclusion

According to findings of this study, herbal medicines are used concomitantly with conventional drugs for the treatment and management of diabetic diseases by patients attending treatment in four selected hospitals of Addis Ababa. Half of diabetic patients used at least once in their life time and 80% of them used herb/herbal products. Combined use of herbal medicines and conventional antidiabetic drugs could potentially lead to serious toxic effects and major drug to herb and herb to disease interactions. Knowledge gap among prescribers on herbal medicine was found to be the major reason for not taking herbal medicine related information during physical examination of diabetic patients. Moringa, thyme, fenugreek, black seed and garlic, linseed, ginger, Dama kese, mustard, rue and green tea were the most commonly used herbs by diabetic patients.

10. Recommendations

Policy

- ✓ Developed national policies and regulations to promote the safe and effective use of herbal medicines

Education

- ✓ Emphasis about the drug herb interaction in the health science curriculum should be given.
- ✓ In-service training on herbal medicine should also be designed and offered to healthcare providers

Practice

- ✓ Herbal medicine use experience should be included in patient history information sheet
- ✓ Strong regulation and control of herbal medicines in the market
- ✓ The hospital should ensure patient's herbal medicine use experience was included in patient chart
- ✓ The hospital should avail the necessary herbal medicine reference material
- ✓ Herbal medicine related issues should be an agenda in morning session
- ✓ Patient should be advised on risk of drug-herb, herb-herb and herb-disease interaction
- ✓ There should be free communication between the prescribers and diabetic patients about herbal medicine use.

Further research

- ✓ Studies to determine the effectiveness of each herb Studies to assess any potential drug-herb and herb-herb interaction
- ✓ Studies to determine the toxicity of each herb

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Annex I

Structured questionnaires for an interview to assess the extent of traditional medicine use and identify the potential drug-herb interactions among diabetic patients

Addis Ababa University, School of Pharmacy

Department of Pharmaceutics and social pharmacy

Hospital code No _____

Participant code no. _____

Verbal consent form before conducting interview

Greeting, my name is _____. I am working with the research team of the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy, Addis Ababa University. I would like to ask you a few questions concerning your experience regarding traditional medicine use. The interview would take 10-15 minutes of your time. The purpose of this study is to assess the extent of traditional medicine use and identify the potential drug-herb interactions among diabetic patients in Addis Ababa. This will help the decision makers to prepare standards of safety, efficacy and the quality of traditional medicine. It also provides necessary information to healthcare providers in herb-drug interactions among the co-users in diabetic patients. Your participation is voluntary. You can refuse to answer any questions if you are not interested. You can also withdraw from the study at any time. All your responses will remain strictly confidential. I will not ask your name and it will not appear on the interview guide. The information you will provide is analyzed in aggregate form with the other participants.

If you have/will have any questions or problems, you can contact

1. Solomon Getnet (Principal Investigator) : +251937440518
2. Dr. Teferi Gedif (the research project Advisor): +251911684854
3. Dr. Mariamawit Yonathan (the research project Advisor): +251911506609

Do you understand all the information I gave you? A. yes B. No

If yes, do I have your permission to continue? A. yes B. No

If Yes, Continue to the Next Page (encircle or write the response accordingly)

If No, Skip to the next Respondent

Date of Interview_____

Time Started _____

Date _____

S.No	Question	Response option	Skip to
1	Sex	1. Male 2. Female	
2	Age	_____ years	
3	Marital Status	1. Single 2. Married 3. Divorced 4. Widowed	
4	Residency	Region _____ Zone _____ Woreda _____ Name of the specific area _____	
5	Religion	1. Orthodox 2. Muslim 3. Protestant 4. Catholic 5. Other (Please, specify_____)	
6.	Level of Education	1. Unable to read and write 2. Non-formal education (can read and write) 3. Elementary school (Grade 1-8) 4. Secondary school (Grade 9-12)5. TVET and above	

7	Occupation	1. House wife 2. Government employee 3. Merchant 4. Daily laborer 5. Student 6. Jobless 7. Other (please, specify _____)	
8	Average income (Monthly)	_____ Birr	
9	When were you diagnosed as diabetic?	year _____ If possible, Month _____	
10	Type of diabetes	1. Type 1 2. Type 2	
11	When did you start your anti diabetic medication?	Year _____ If possible Month _____	
12	What was your treatment when you started antidiabetic drugs?	1. insulin 2. oral hypoglycemic 3. both	
13	What is your current treatment?	1. insulin 2. oral hypoglycemic 3. both	
14	Did you have any other disease other than Diabetes Mellitus?	1. Yes _____ 2. No _____	If the answer is No for Q No 14, Skip to Q No 16.
15	Which type of disease?	Please specify the type of disease _____	
16	Have you ever tried TM?	1. Yes 2. No. Please specify the reason _____	If the answer is NO for Q No 16, Stop the interview.

17	For what disease condition you used the TM?	1. For diabetic mellitus. 2. For other diseases. 3. For both	
18	Did you take any TM in the last six months?	1. Yes 2. No	If the answer for Q No 18, Skip to Q.No 23.
19	For what disease condition was you use the TM?	1. I used the TM for diabetic mellitus. 2. I used the TM not for diabetic mellitus 3. I used the TM for diabetic and other disease conditions	If the answer is No 2 for Q No 19, Skip to Q.No 22.
20	When did you use TM ?	1. I used before I started taking anti-diabetic agents 2. I used after I started taking anti-diabetic agents	If the answer is No 1 for Q No 20, Skip to Q.No 23.
21	In what time interval you took your TM after you took your antidiabetic agents?	1. I was taking TM sometime before antidiabetic drugs 2. I was taking TM with antidiabetic drugs 3. I was taking TM medicine some time later than antidiabetic drugs	
22	What was your reason for using TM?	1. Conventional drug is more expensive 2. Service in health facilities is unsatisfactory facilities 3.Health facilities are inaccessible 4. Conventional drug are toxic or have serious side effects 5. TM are More potent and curable 6. Other (Please specify _____)	
23	How frequent you	1 _____/day 2 _____/week	

	use TM?	3 _____/month Other_____	
24	What was the TM you used?	1. Herb/ herb product 2. Minerals 3. Holy water 4. Other (Please specify _____)	If your answer is not No 1 for Q No 24, Stop the interview
25	Do you remember the name of the plant/s you used?	1. Yes Please specify _____ 2. No	
26	Which part of the plant you used?	1. Leaves 2. Stem 3. Fruit 4. Root 5. Seed 5. Other (Please specify _____)	
27	From where did you get the herb?	1. From traditional healer 2. From market 3. From garden 4. From another, Please specify _____	
28	Where the location where you get your herbal medicine?	Please specify the area _____ _____	
29	Method of preparation	Preparation form 1. Crushed 2. Powder	

		3. Chewed 4. Other _____	
30	In what form used?	1. Alone 2. Mixed with water 3. other _____	
31	The condition of the herb?	1. Dried 2. Fresh 3. Both	
32	How did you take your herbal medicine (Route of administration)?	1. Oral 2. Nasal 3. Dermal 4. Other _____	
33	How did you measure the medicine to be taken at once?	Please clarify the dose as much as possible _____	
34	Are you taking the herbal medicine currently?	1. yes 2. No, why _____	
35	For how long have you used the herbal medicine?	3. I used once 4. 2-7 days 5. 8 – 30 days 6. More than 30 days	
36	In your perspective, Was there any improvement with the use of herbs?	1. Yes 2. No	If the answer is no for Q No 36, Skip to Q.No 38.
37	How did you grade the effectiveness of the plant?	1. Highly effective 2. Effective 3. Moderately effective 4. Little effective 5. Not at all effective	

38	Have you experienced side (unfavorable) effects during the concomitant use of drug and herb?	1. Yes If yes, please specify _____ 2. No	If the answer is no for Q No 38, Skip to Q.No 40.
39	How did you overcome the side effect?	1. Consulting your doctor 2. Discontinue the herbal medicine 3. Consulting the herbalist 4. Let it to subside by itself 5. If other, please specify _____	
40	Are there any conditions which restrict taking of the herbal medicine?	1. Taking anti diabetic drugs 2. Co morbidity 3. pregnancy 4. Age 5. No restriction 6. If other, please specify _____	
41	Did you desire to receive more information on the therapies with herbal drugs?	1. Yes 2. No	If the answer is no for Q No 41, Skip to Q.No 43.
42	From where you want to get the information?	1. The community 2. The doctor 3. Herbalists 4. pharmacists 5. If other, please specify, _____	
43	Do you have any information about drug-herb interaction	1. Yes 2. No	
44	Did you inform the health professional that you were using TM?	1. Yes, 2. No, (Please specify) _____	If the answer is no for Q No 44, Stop the interview
45	What was the advice from the health professional?	1. To discontinue using the herbal medicine 2. To continue using the herbal medicine 3. Left the patient to decide by him/her self	

Annex II

Questionnaire for key informant interview

I. General Information

1. Hospital Code _____

2. Interviewee Code _____

3. Age _____ years

4. Sex ☐ Male

☐ Female

6. Educational status ☐ Health Officer (HO)

☐ General practitioner (GP)

☐ Specialist (please specify the specialty) _____

☐ If other, Please specify _____

7. Year of experience in diagnosis and treatment of diabetic patients? _____

II Interview Questions

1. What information have you gathered while you are taking patient history?

2. Have you taken TM related information especially herbal medicine and why?

3. What are the commonly used TM for diabetic patient, specially herbal medicines?

4. Did you have any experience in D-H interactions in diabetic patients?

5. What do you say about the knowledge of medical practitioners about traditional medicine?

6. What have you advised for patients using traditional especially herbal medicine?

7. What are the challenges in drug- herb interaction in diabetic patients?

8. If you have anything to add, please describe.