

Patterns of concomitant use of *Ayurveda* and conventional anti-diabetic formulations - Experiences at a tertiary care *Ayurveda* hospital, India

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Abstract

Background: Majority of the population relies on traditional medicines for many of their health related problems. Particularly individuals with chronic illness like diabetes mellitus (DM) are more likely to simultaneously use herbal medicines. Many of such users believe that traditional medicines are natural and therefore safe, but this is a dangerous over simplification. Some herbal medicines may be associated with adverse effects, which include interactions with prescribed drugs. Information on such concomitant use of anti-diabetic drugs along with *Ayurveda* medicines is limited in Indian scenario. **Aims and objectives:** To survey the patterns of concomitant use of Ayurveda and conventional anti-diabetic drugs by diabetic patients attending an out-patient department of a tertiary care teaching hospital in New Delhi, India through a validated questionnaire. **Materials and methods:** This is a questionnaire-based survey, carried out after the approval of the Institutional Ethics Committee, subsequently registered at CTRI. A questionnaire to assess the pattern of concomitant use was developed; content was validated and pre-tested by a pilot study in 40 patients, further refined and used in the survey. The data was analyzed to evaluate the patterns of concomitant use of Ayurvedic and conventional anti-diabetic drugs. **Results:** About 95.9% of diabetic patients were taking herbo-mineral formulations concomitantly with conventional anti-diabetic drugs. Although 45.3% of diabetics were using Ayurveda interventions under the supervision of qualified AYUSH physicians, remaining involved in procuring the drugs over the counter (OTC) or from the local vendors. In majority of these instances, the use of *Ayurveda* formulations was not communicated with their physicians. **Conclusion:** The observations reveal that a majority of the diabetics (95.9%) were taking one or the other form of herbal preparations along with their conventional anti-diabetic drugs and about 44% among them were using these concomitantly. Thus, generating awareness on good practices of drug use seems to be essential.

Keywords: Ayurveda, concomitant use, diabetes, herb-drug interactions

Introduction

Health is the level of metabolic efficiency of a living organism. In human beings, it is the ability of individuals or communities to adapt and self-manage when facing physical, mental, or social challenges. The World Health Organization (WHO) defined health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.^[1] In general, the context in which an individual lives is of great importance for both his/her health status and quality of the life. It is increasingly recognized that health is maintained and improved not only through the advancement and application of health science but also through the efforts and intelligent lifestyle choices of the individual and society.

With drastic changes in lifestyle, dietetic habits, increased industrialization, the global population is getting affected with various kinds of non-communicable diseases (NCDs) that represent a leading threat to human health. In the current scenario, NCDs are posing as the world's biggest killers, causing 63% of total deaths.^[2] Among such NCDs, diabetes mellitus (DM) is an important entity and India heads the

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world with over 32 million diabetic patients and this number is projected to increase to 79.4 million by the year 2030,^[3] earning the dubious distinction of the diabetes capital of the world. Current surveys indicate that diabetes now affects a staggering 10%-16% of the urban population and 5%-8% of the rural population in India.^[4,5] With this increasing incidence worldwide, DM is likely to continue to be a leading cause of morbidity and mortality in the near future.

Since inception, modern medical science is depended on synthetic or isolated extracts for the treatment of various pathologies including DM. However, long-term use of such conventional drugs tends to cause damage and may manifest in drug dependency, adverse effects etc.^[6] Thus, researchers and policy makers are enthusiastically looking towards traditional systems of medicines for remedial measures. *Ayurveda*, Unani, Siddha, and Homoeopathy (ASU and H) systems of medicines are being used in the country since long. Particularly, *Ayurveda* utilizes natural substances in the form of herbs, minerals, metals and other animal byproducts in the treatment. Herbs are predominantly used in this science since the initial days of humanity for medical purposes and form the origin of much of modern pharmacotherapy. Herbal medicinal products have immensely contributed in global health care. In the past one to two decades, they have gained the attraction of researchers and drug-regulating authorities and became popular because of various reasons.^[7]

Many consumers believe that herbal medicines are natural and therefore safe, but this is a dangerous oversimplification. Some herbal medicines are associated with adverse effects, which include interactions with prescribed drugs.^[8] A survey conducted in the UK reported that 15% of patients receiving conventional pharmacotherapy also take herbal products and among these, potential adverse herb-drug interactions were observed in 40% of patients.^[9] Such reports clearly show that all herbs are not safe in all conditions and herb-drug interactions are always possible, of which some are sufficiently serious to endanger the health of the patients. Unfortunately, limited information about patterns of concomitant use of traditional and conventional anti-diabetic drugs is available in the Indian scenario. Hence, it was planned to survey the patterns of concomitant use of Ayurvedic and conventional anti-diabetic drugs by diabetics attending an outpatient department of a tertiary care teaching hospital in New Delhi, India through a validated questionnaire.

Materials and methods

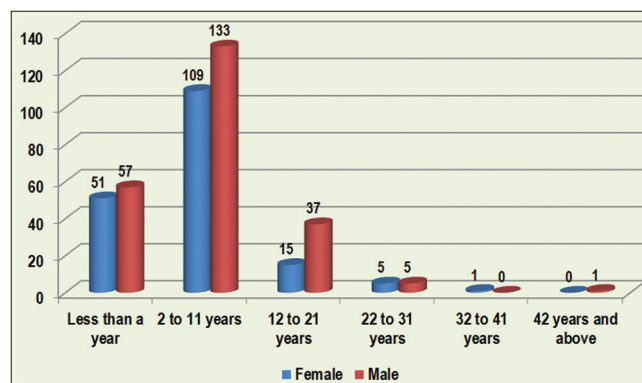
This was a questionnaire-based cross sectional survey that was carried out in an outpatient department of a tertiary care teaching hospital catering to the health needs of the city. The study was approved by the Institutional Ethics Committee (IEC-AIIA/2017/PG-49 dated August 12, 2017), subsequently was registered at CTRI (CTRI/2017/10/010023). The survey was conducted from December 2017 to November 2018. Diabetes of both sexes of all age groups attending the

outpatient department of the hospital during the study period were involved in the survey after having consent to participate. They were informed about the purpose of the survey in the local language (Hindi). A questionnaire involving demographic data and 15 questions consisting about the diabetic history, associated conditions, brief details of drugs being used, modification in diet, life style, source of drugs being procured etc., was used. It was prepared with few close-ended and a few open-ended questions. For content validation, the questionnaire was shared with various stakeholders of *Ayurveda*. Based upon the inputs, the questionnaire was refined. The final version of the questionnaire was used for the survey.

The questionnaire was filled in either by participants or by the investigator by asking questions to the illiterate patients. The questionnaire included information regarding socio-demographic data, present clinical condition, diabetic history, associated conditions, brief details of drugs being used, changes made in lifestyle, conventional anti-diabetic drugs being used, details on concomitant uses of other formulations (particularly *Ayurveda*), their source of procurement, and participant's knowledge about the possibility of drug interactions. Majority of the conventional drugs were prescribed by their brand names. The generic names of such drugs were collected by referring available information on the web.

Results

Total of 414 patients of diabetes were surveyed and included in this study. Out of them, 233 (56.3%) were females. Majority of the diabetes were found to be from the age group of 51-60 years (32.1%), followed by 41-50 years (26.3%) and 61-70 years (21.5%). No positive family history of diabetes was observed in 58.5% of diabetes patients. About 58.5% diabetics (n = 242) had chronicity of 2 to 10 years, while about 12.5% diabetes (n = 52) had chronicity of 12 to 20 years. [Graph 1] The 26% (108) of newly diagnosed (within a year) diabetes are also found to be taking some *Ayurveda* intervention. About 45.41% of the diabetes patients (188 patients) reported using metformin for the diabetes management, while 26.33% (109 patients) were on glipizide. The rest of the diabetes patients were prescribed with drugs such as sitagliptin, glimepiride and insulin by their attending



Graph 1: Chronicity of the surveyed diabetes

physicians. Anti-hypertensive, anti-hyperlipidemic drugs and other combinations were also being used by a few patients.

Most of the surveyed diabetes patients (76.6%) were aware about the importance of diet and diabetes restrictions. About 61.1% of diabetes patients made some modifications in their lifestyle and added walking, while a section of patients (7.4%) added *Yoga* and *Pranayama* into their lifestyle. However, around 31.4% of the population was unable to modify their lifestyle considering reasons related with occupation, lacking of information. The survey also revealed that 95.9% of diabetes patients were taking one or the other form of herb or herbal formulations or other AYUSH preparations or self-made home remedies along with their conventional anti-diabetes drugs.

The 60.6% diabetes patients (n = 251) have heard about the usefulness of traditional practices. About 129 diabetes patients (31.1%) approached traditional physicians as the symptoms of diabetes were not managed with conventional management. [Graph 2] It is observed that only one patient was referred by their attending conventional physicians to traditional practitioners for the possibility of traditional interventions.

Although 45.3% of diabetics were using traditional interventions under the supervision of qualified AYUSH physicians; it is alarming to observe that 47% of the surveyed diabetics were procuring the herbal material from the local vendors without consulting or informing to their physicians. About 4.2% diabetics were purchasing the Ayurvedic formulations over the counter (OTC). Importantly, the addition of Ayurvedic formulations in the diabetes management was not communicated by the diabetes patients with their health-care providers that may put the consumers at risk.

A large number of medicinal plants are believed to possess anti-diabetic properties and are being utilized to manage diabetes. A list of herbs or herbal formulations being used by the surveyed diabetics is placed in Table 1. After adding Ayurvedic interventions into the management, 85 diabetes patients (20.5%) mentioned that the dose of conventional antidiabetic drugs was reduced by their physician. Around 54.3% of the surveyed

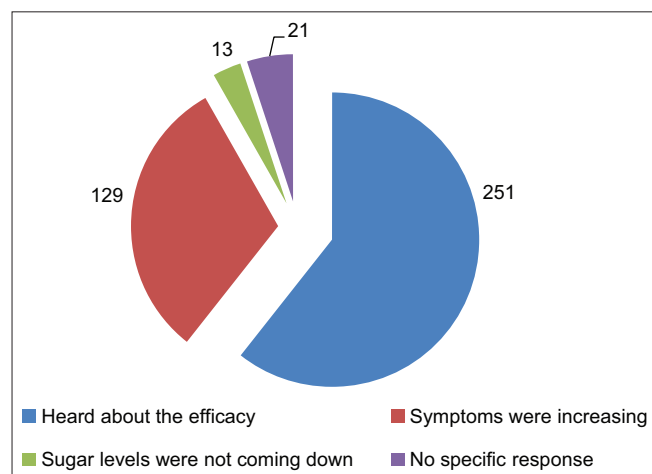
diabetics (225) reported a feeling of betterment in their routine activities after the addition of *Ayurveda* interventions, 47.3% (196) reported reduction in levels of fatigue, reduction in polyuria by 140 diabetes patients (33.8%), polydipsia by 115 diabetes patients (27.8%), reduced neuritis associated symptoms by 57 (13.8%), reduced symptoms associated with urinary tract infection by 36 (8.7%), blurred vision by 10 chronic diabetics (2.4%) and reduced gingivitis by three (0.7%) diabetes patients. Improved quality of sleep was reported by 117 (28.3%) diabetes patients, while improved sexual health by 18 (4.3%) diabetes patients [Graph 3].

Around 44% of diabetes patients were concomitantly using Ayurvedic formulations with prescribed conventional anti-diabetic drugs, while 22.5% of diabetes patients never observed about the timings of the drug consumption. Although the reason is unknown, 33.6% of diabetes patients were observing a gap in between the use of conventional and traditional formulations. About 83% (n = 345) of the surveyed diabetes patients were unaware about the possibility of herb-drug interactions [Graph 4].

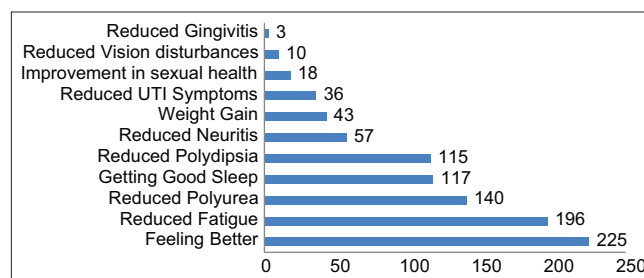
Discussion

Out of 414 surveyed diabetes patients, 233 (56.3%) were females. There is no considerable difference by gender in the prevalence of DM. The prevalence of DM among men was not significantly different from that among women.^[10] Majority of the diabetics were found to be in between 41 and 60 years. This data supports the fact that the individuals aged between 45 and 64 years were the most diagnosed age group for diabetes.^[11] Although majority (58.5%) of the diabetes patients under the survey were with negative history, diabetes in the families is not only a risk factor for the disease but is also positively associated with risk awareness and risk-reducing behaviors. It may provide a useful screening tool for the detection and prevention of diabetes.^[12] Family history can be used not only to assess disease risk but also to examine the awareness of the risk and motivation to engage in risk-reducing behaviors.

The role of diet in the etiology and management of diabetes is well established. Majority of the surveyed diabetes patients (76.6%) were aware about the importance of diet and lifestyle in diabetes management. These diabetes patients modified their diet avoiding rice, potatoes, sugars, sweets, bananas, mangoes, milk, milk derivatives, curd, fruit juices, junk food, street food and all other fruits that are sweet and rich



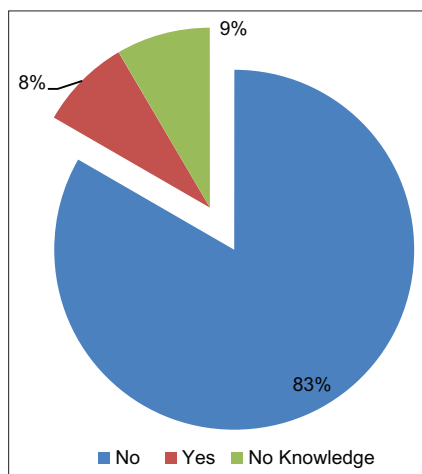
Graph 2: Reasons to start traditional interventions (n=414)



Graph 3: Positive changes noticed in number of diabetes after using traditional formulations

Table 1: Medicinal herbs/formulations being used by surveyed diabetes patients

Single herbs	
<i>Amalaki (Phyllanthus emblica Linn.)</i>	<i>Karavellaka (Momordica charantia Linn.)</i>
<i>Arjuna (Terminalia arjuna [Roxb.] Wight and Arn.)</i>	<i>Katuki (Picrorhiza kurroa Royle ex Benth.)</i>
<i>Ashwagandha (Withania somnifera Linn.)</i>	<i>Methika (Trigonella foenum graecum Linn.)</i>
<i>Bilva (Aegle marmelos Linn.)</i>	<i>Musta (Cyperus rotundus Linn.)</i>
<i>Guduchi (Tinospora cordifolia (Thunb.) Miers.)</i>	<i>Nimba (Azadirachta indica Linn.)</i>
<i>Haridra (Curcuma longa Linn.)</i>	<i>Vijayasara (Pterocarpus marsupium Roxburgh.)</i>
<i>Indrayava (Holarrhena antidysenterica Linn.)</i>	<i>Yashtimadhu (Glycyrrhiza glabra Linn.)</i>
<i>Jambu Beeja (Syzygium cumini [L.] Skeels.)</i>	
Polyherbal compound formulations	Herbomineral/metallic formulations
<i>Nishakatakadi Kwatha</i>	<i>Shilajatu (Asphaltum punjabianum)</i>
<i>Vijayasaradi Kwatha</i>	<i>Chandraprabha Vati</i>
<i>Phalatrikadi Kwatha</i>	<i>Arogyavardhini Vati</i>
<i>Dashamula Kwatha</i>	<i>Prabhakara Vati</i>
<i>Sarpagandha Ghana Vati</i>	<i>Shilajatvadi Lauha</i>
<i>Gokshuradi Guggulu</i>	<i>Swarnamakshika Bhasma</i>
<i>Triphala Guggulu</i>	<i>Abhraka Bhasma</i>
<i>Triphala Churna</i>	<i>Vanga Bhasma</i>
<i>Sudarshana Churna</i>	<i>Trivanga Bhasma</i>
<i>Nishamalaki Churna</i>	<i>Naga Bhasma</i>
<i>Bilwadi Churna</i>	<i>Vasanta Kusumakara Rasa</i>
<i>Amritarishta</i>	
<i>Mustakarishtha</i>	
<i>Arjunarishtha</i>	

**Graph 4:** Knowledge about herb-drug interactions in the surveyed diabetes patients

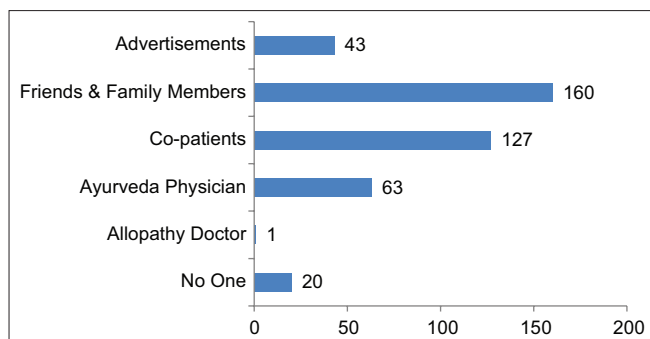
in carbohydrates to suit the management of diabetes. This data is matching with earlier surveys.^[13] Reinforcement of education including dietary management through health-care providers becomes essential in understanding about the importance of disease management for appropriate self-care and better quality of life.^[14]

Significant association between physical inactivity and diabetes is well established.^[15] Evidences suggest that lifestyle changes such as exercise, diet, and other non-pharmacological interventions can delay and even prevent the development of type 2-diabetes.^[16] About 61.1% of diabetics attempted on modifying the lifestyle and added walking in their daily

life. A section of diabetes patients (7.4%) added *Yoga* and *Pranayama* into their lifestyle. *Yoga* practice is useful in the management of diabetes. Psycho-neuro-endocrine and immune mechanisms are involved in the beneficial effects of *Yoga* on diabetes. Incorporation of *Yoga* practice in daily life helps to attain glycemic control and reduces the risk of complications in people with diabetes.^[17] The remaining diabetics (31.4%) were unable to modify their lifestyle because of various reasons.

The observations reveal that a maximum (95.9%) of the surveyed diabetes patients were taking one or the other form of herb or herbal formulation or other Ayurveda preparations or self-made home remedies along with their conventional anti-diabetic drugs. Earlier studies report that up-to 72.8% of people with diabetes use herbal medicine, involve dietary supplements besides the routine management.^[18] The global use of complementary and alternative medicine (CAM) for the management of diseases such as diabetes has reported to be rapidly increased over the last decade.^[18] The observations of the current survey also in lines of this finding. Furthermore, researches also indicate that most people who use traditional therapies do so in addition to, rather than in place of conventional medicine. Friends and family members are the main source of information on the usefulness of traditional medicines in diabetic management. Co-patients and advertisements also played a role in this [Graph 5].

Maximum of the diabetes patients (60.6%) in the current survey have heard about the usefulness of traditional practices in the management of diabetes. Friends, family members (38.6%), and co-patients (30.6%) are the major sources of information



Graph 5: Source of knowledge in number of surveyed diabetes patients on Ayurveda formulations

toward knowing the usefulness of traditional practices in diabetes management. *Ayurveda* physicians (15.2%) and advertisements (10.3%) were the other sources of information. Around 31.1% of diabetics started approaching traditional physicians as the symptoms were unable to be managed with conventional management.

Around 45.3% of the diabetics under the survey were procuring *Ayurveda* preparations through their physicians, while 47% were purchasing required herbal material from local vendors without the knowledge or supervision of qualified physicians and about 4.2% of the diabetes patients were purchasing the formulations over the counter (OTC) or involved in online purchases. It reflects that majority of the diabetes patients are involved in self-prescribing patterns, which may present both a benefit and a potential risk to the effective management of their disease.^[19] At times, these products might be of poor quality, consumers might not be aware of their correct usage, which may associate with various health-related issues, eventually bringing a bad repute to the traditional systems.^[20] Around 83.3% of the surveyed diabetics of the current study were unaware about the possibility of herb-drug interactions. Thus, the use of any medicine should mandatorily be under the information/supervision of their respective physicians. Drug-regulating authorities should exercise on generating awareness on good practices of drug use and frame stringent procedures to curb self-prescribing practices.

An increasing number of medicinal plants are being used to treat diabetes and its related conditions. Many of these plants have been used ethnopharmacologically in traditional medicine as anti-diabetics, particularly for type 2-diabetes.^[21] The frequently using drugs were enlisted. About 32% of diabetes patients were using *Jambu Beeja* (seeds of *Syzygium cumini* [L.] Skeels.), while 28% *Guduchi* (*Tinospora cordifolia* (Thunb.) Miers.) and 24% *Amalaki* (*Phyllanthus emblica* Linn.). Remaining diabetes patients were using *Arjuna* (*Terminalia arjuna* Roxb.) Wight and Arn.), *Ashwagandha* (*Withania somnifera* Linn.), *Bilva* (*Aegle marmelos* Linn.), *Haridra* (*Curcuma longa* Linn.), *Indrayava* (*Holarrhena antidysenterica* Linn.), *Karavellaka* (*Momordica charantia* Linn.), *Katuki* (*Picrorhiza kurroa* Royle ex Benth.), *Methika* (*Trigonella foenum graecum* Linn.), *Musta* (*Cyperus rotundus* Linn.), *Nimba* (*Azadirachta*

indica Linn.), *Vijayasara* (*Pterocarpus marsupium* Roxburgh.) and *Yashtimadhu* (*Glycyrrhiza glabra* Linn.). The classical literature of *Ayurveda* credited anti-diabetic values to these drugs and recent researches substantiated the role of herbal drugs in the management of different phases of diabetes.^[22-37] A few mineral/metal-based formulations including *Shilajatu* (*Asphaltum punjabianum*), *Chandraprabha Vati*, *Shilajativadi Lauha* and some patented formulations were also being used by the diabetes patients.^[38-41] The underlying anti-diabetic effects of these herbs may be because of one or the other types of the mechanism involving a direct effect on insulin secretion, activation of glycogenesis and hepatic glycolysis, adreno-mimeticism, pancreatic beta-cell potassium channel blocker activity, cAMP activation, and/or modulation of glucose absorption from the intestine, etc.

Around 44% of diabetes patients in the present survey were reported using traditional formulations with prescribed conventional antidiabetic drugs concomitantly, while 22.5% of diabetes patients never noticed about the pattern of usage of these medicines and unaware about the possible interactions. Concomitantly used medications possibly elevate the risk of experiencing adverse drug effects or drug interactions. However, none of the diabetes patients surveyed in the present study reported adverse effects.

After adding traditional interventions, 20.5% of diabetes patients mentioned that the dose of conventional antidiabetic drugs was reduced by their physician. A feeling of betterment, improved alertness, reduced levels of fatigue, reduction in other diabetes symptoms including polyuria, polydipsia, neuritis, vision disturbances, improved sleep quality and sexual health infers that the traditional formulations are possibly interfering some of the pathways of diabetes pathology and helping in diabetes management. Formulations with antioxidant properties will be beneficial in diabetes management to counter free radical-induced diabetes and its complications. Various forms of alkaloids and other functional groups present in the herbs and herbal formulations can exert antioxidant activity and thus help in the diabetes management.

Conclusion

It is well accepted that there is a global increase in the use of traditional medicinal products. Unlike conventional medicines, where the ingredients are well-defined and characterized; traditional medicinal products contain multiple bio-active components for which there is a lack of understanding of how these components interact with each other and with pharmaceutical medicines when they are used in combination. Although many studies regarding herb-drug interactions emphasize on the potential harmful effects of such interactions, the possibility of herbal components beneficially enhancing anti-diabetic action may also exist. The survey revealed that a majority of the diabetics (95.9%) were taking one or the other form of herbal preparations along with their conventional anti-diabetic drugs and about 44% among them using these concomitantly that may lead to interactions at times. This

pattern infers that the use of any medicine should mandatorily be under the supervision of their respective physicians. Though, no significant interactions were noticed in the current survey; generating awareness on good practices of drug use seems to be an essential component. All stakeholders of the country including drug regulating authorities can play a crucial role in this direction to frame regulations to curb self-prescribing practices and generate awareness on good practices of drug use.

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Conflicts of interest

There are no conflicts of interest.

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