Original Research Article

Profile of Complementary and Alternative Medicine Use by Diabetic and Hypertensive Patients Presenting with Angina in North East India

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ABSTRACT

Background: Complementary and alternative medicine (CAM) is quite often used in India in various chronic diseases. Diabetes and hypertension are important causes of coronary artery disease (CAD) all over the world including the Indian subcontinent. We wanted to study the profile of usage of CAM in patients with diabetes and/or hypertension with CAD as regards frequency, reasons and predictors of use, level of satisfaction and perceived toxic effects.
Methods: We conducted a hospital based cohort study by including a total of 155 subjects with diabetes and/or hypertension admitted in coronary care unit of Assam Medical College and Hospital with previous symptoms of angina. A questionnaire on demographics, present cardiac condition and on various aspects of CAM (types, experiences, reasons of use, perceived satisfaction and toxic effects) was administered.
Results: The follow up of 12 months could be completed in 138 patients. 29.7 % patients were found to be using CAM. Male gender, service as occupation and better BMI predicted CAM use. *Terminalia Arjuna* was the most commonly used CAM. The level of satisfaction was significantly high in users of *Terminalia Arjuna* (p=0.008). No perceived toxic effect of CAM was noted by the users.
Conclusion: The use of CAM is common in diabetic and hypertensive patients with angina. There is significantly high level of satisfaction from the use of *Terminalia Arjuna*. Further validation with a larger study is needed to confirm our findings.

Key words: Diabetes, hypertension, complementary and alternative medicine.

INTRODUCTION

The prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. [1] Currently, 4.0-11.6 per cent of India's urban population and three per cent of the rural population above the age of 15 has diabetes. [2] Overall prevalence for hypertension in India was found to be 29.8% in a recent study. [3] Atherosclerotic CAD and other forms of cardiovascular disease (CVD) are the major causes of mortality in type II DM and hypertension. [4,5]

Complementary and alternative medicine (CAM) has been defined as a group of diverse medical and healthcare systems, practices and products that are presently not considered to be a part of conventional medicine. [6] CAM is being increasingly used by people all over the world (9.8-76.0%) even with great advances in conventional medicine (CM). [7] CAM therapies cater to a large proportion of the Indian population. [8] Out

of the recognized Indian systems of medicines Ayurveda is 2000 years old. [9]

A sizeable proportion of the diabetic, hypertensive and CAD patients admitted in different cardiac centers of India are observed to be resorting to CAM besides prescribed CM. There is limited data as regards the usage of CAM along with CM in diabetic and hypertensive CAD patients in India. We wanted to know the prevalence and pattern of use, the level of satisfaction and toxic effects of CAM in these patients.

MATERIALS AND METHODS

155 diabetic and/or hypertensive subjects with history of chronic stable angina admitted to the coronary care unit in Assam Medical College and Hospital were enrolled in the study. The subjects were followed up for 12 months. The assessment of clinical history of chronic stable angina was aided by Rose Questionnaires and 2012 ACCF/AHA guideline for the diagnosis and management of patients with stable ischemic heart disease. [10,11] Hypertension was defined, according to JNC-VII guidelines. [12] The known and self-reported diabetics and those with blood sugar levels consistent with a diagnosis of diabetes mellitus [13] were considered as diabetic. CAM was defined as the use of any medication or non-medication therapy that was different from CM.

The collection of data was done with a questionnaire on demographics, present cardiac condition and on various aspects of CAM usage such as duration before hospitalisation, types, experiences, reasons of use and satisfaction from perceived benefits. 12 questions from Short Form 12 (SF-12) at 7-score Likert scale was incorporated into our questionnaire to get physical and mental component scores (PCS & MCS). [14] Perceived benefits or effects were asked to be described at Likert scale as given below. [15]

1 - Completely dissatisfied, 2 - Mostly dissatisfied, 3 - Somewhat dissatisfied, 4 - neither satisfied or dissatisfied, 5 - Somewhat satisfied, 6 - Mostly satisfied, 7 - Completely satisfied. At score 1-3 we categorised the patients as 'dissatisfied', at score 4 we considered the patients as having 'no definite benefit' and at score 5-7 we considered them as 'satisfied with definite symptomatic relief'. In the 'dissatisfied' category we further asked whether there was aggravation of symptoms needing discontinuation/alteration of drugs. Information about demographic factors, socio economic status (education, income, marital status), lifestyle (smoking and tobacco chewing, physical activity, and dietary patterns) and other associated conditions were obtained. Informed consent forms were obtained from the patients for participation into the study after the study protocol was explained to them.

Clinical data were expressed as mean ± SD, and the differences between patients and controls were analysed by t tests for continuous variables and chi square test for categorical concomitants. $p<0.05$ was considered as significant. Chi-squared tests of association between selected sociodemographic and other attribute variables and CAM use was conducted. Odds Ratio (OR) with 95 % confidence interval and p values were calculated while analysing the level of satisfaction with CAM use. All analysis was done using SPSS, version 19 (Chicago, IL, USA) The study was approved by the *Institutional Ethical Committee*, and written informed consent was obtained from all subjects.

RESULTS

A total of 155 patients were enrolled into the study in the enrolment period of 6 months. However we could complete the follow up of only 138 cases as we lost follow up of 17 patients. Mean

age of the study population was 57.12±9.09 years with male preponderance (73.9%). Service was the commonest occupation (42.8%). 9 (6.5 %) patients did not have any formal education. 41 (29.7 %) patients were found to be using CAM in 12 months follow up. The mean age of the CAM users was 59.0 years while that of the non-users was 56.3 years. There were higher male patients among CAM users compared to no users (100.0% vs. 62.9%) which was statistically significant (p=0.001). BMI was found to be inversely associated with CAM use (p=0.001). Occupation had an impact in use of CAM as those in service sector were more likely to use CAM (p=0.02) and the house wives were less likely to use it (p=0.01). Out of the clinical variables, 37.1 diabetic patients and 26.6% hypertensive patients used CAM. 31 % of the patients with dyslipidaemia and 25.6% of the smokers used CAM. Associated clinical factors did not predict use of CAM, but hypertension was a significant negative predictor (p=0.03) for CAM use. (Table 1)

Table 1 Socio-demographic and clinical characteristics of the study subjects

	Subjects, n (%)			
Variable	Total (n=138)	CAM User (n=41) n (%)	CAM non-user(n=97) n (%)	p
Age (years)	57.12±9.09	59.00±8.17	56.33±9.38	0.097
Male	102(73.9)	41(100.0)	61(62.9)	**0.001***
Female	36(26.1)	0 (0)	36(37.1)	
BMI	25.17±3.87	23.55±2.85	25.86±4.05	**0.001***
Education				
Educated	125(90.6)	37(90.2)	88(90.7)	1
Graduate and above	19(13.8)	8(19.5)	11(11.3)	0.28
Higher Secondary	89(64.5)	27(65.9)	62(63.9)	0.84
Primary	17(12.3)	2(4.9)	15(36.6)	0.09
No formal education	13(9.4)	4(9.8)	9(9.3)	1
Marital Status				
Married	137(99.3)	41 (100.0)	96(99.0)	1
Unmarried	1(0)	0 (0)	1(1.03)	1
Occupation				
Service	59(42.8)	24(58.5)	35(36.1)	**0.02***
Cultivation	9(6.5)	4(9.8)	5(5.15)	0.45
Housewife	37(26.8)	1(4.8)	36(37.1)	**0.01***
Daily wage earner	2(1.4)	1(4.8)	1(1.03)	1
Others	31(22.5)	11(26.8)	20(20.9)	0.50
Diabetes	62(44.9)	23(56.1)	39(40.2)	0.09
Hypertension	124(89.9)	33(80.5)	91(93.8)	0.03
Dyslipidemia	116(84.05)	36(87.8)	80(82.5)	0.46
Non smoker	60(43.5)	21(51.2)	39(40.2)	0.26
Smoker	78(61.8)	20 (61.9)	58(61.8)	0.26

p= p value between CAM user vs. non user. * p is significant at ≤0.05.
CAM: Complementary and alternative medicine; CM: Conventional medicine

32 patients (78%) started CAM due to the perception that CAM promotes general health and well-being. 30 patients (73.2%) believed that CAM was devoid of side effects. 19 patients (46.3%) started CAM because 'it takes care of the complications better'. 36 patients (87.8%) did not communicate to their treating physician about the use of CAM. 14 patients (34.1%) were on alternative medicine for control of hypertension and diabetes before enrolment and they were not getting proper CM before hospitalisation. 4 patients, who discontinued CAM after getting initiated to CAM were from those who were already on alternative medicine before hospitalisation. Amongst the diabetics, 'fear of the side effects of the conventional medicine' was the reason for their initiation to alternative medicine in 3(13.04%) patients. The 'fear of having to continue it lifelong' was the reason for starting alternative medicine in 5(21.7%) patients. However 4 patients (17.4%) stopped taking CAM after they started CM

as they perceived greater benefit of blood sugar control when CM was used. 19(82.6%) of them continued to take CAM. The 'fear of having to continue it lifelong' and the 'fear of side effects was the reason to start CAM in 9(27.3%) and 3(9.1%) of the hypertensive patients who used CAM. All 41 patients (100 %) continued to use CM prescribed to them by the physicians and cardiologist. (Table 2)

Table 2: Reasons of use of CAM /communication to physician/stoppage of drugs/use prior to hospitalisation

Reasons of use /communication to physician/stoppage of drugs/use prior to hospitalisation	Diabetes (n=23) n(%)	Hypertension (n=33) n(%)	All patients using CAM (n=41) n(%)
Inadequacies of CM	0(0)	0(0)	0(0)
High cost of CM	0(0)	0(0)	0(0)
Fear of side effects of CM	3(13.04)	3(9.1)	6(14.6)
CAM promotes general health and wellbeing	16(69.6)	16(48.5)	32(78.04)
CAM has no side effects	14(60.9)	16(48.5)	30(73.2)
CAM relieves the symptoms better	6(26.18)	6(18.2)	12(29.3)
CAM directly treats the complications	8(34.8)	11(33.3)	19(46.3)
Communication to physician	2(8.7)	3(9.1)	5(12.2)
Withdrawal of CAM	4(17.4)	0(0)	4(9.8)
Use prior to hospitalisation	7(30.4)	7(21.2)	14(34.1)

CAM: Complementary and alternative medicine; CM : Conventional medicine

Overall the level of satisfaction was found to be equal in both CAM users and non- users (p=0.13). However, significantly lesser number of CAM users (Table 3) were uncertain about the benefits than the non-users (OR 0.19; CI 0.04-0.88). But if we omit the patients who had to withdraw their drugs (Table 4), the satisfaction regarding control of angina was significantly higher in CAM users (OR 4.93; CI 1.09-22.3).Though 4(9.8%) patients were dissatisfied and discontinued CAM, the dissatisfaction was about control of blood sugar; not about relief from angina. 6(6.2 %) of the conventional treatment users were 'dissatisfied' (Table 3). These patients had to withdraw anti-ischemic drugs temporarily due to issues like gastro intestinal bleeding, headache, and bradycardia and fatigue. 3 of these patients underwent coronary angioplasty and the rest 3 of them continued with a modified regimen but without satisfactory control of angina.

Table3: Satisfaction from the use of CM alone or CAM with CM

Satisfaction status	Subjects n (%)			OR (95%CI)	p
	Total patients n=138	CAM users n=41	CAM Non-users n=97		
Satisfied with definite improvement of symptoms of angina, control of diabetic status and blood pressure	106(76.8)	35 (85.3)	71(73.2)	2.1(0.81-5.67)	0.13
Dissatisfied needing withdrawal/change of medications	10(7.2)	4(9.8)	6 (6.2)	1.6(0.44-6.15)	0.48
Uncertain about benefits	22(15.9)	2(4.8)	20(20.6)	0.19(0.04-0.88)	0.03 *

p= p value between CAM users vs. non users
* p is significant at ≤0.05
CAM: Complementary and alternative medicine; CM : Conventional medicine

Table 4: Satisfaction of angina control in those who continued to take CAM or CM

Satisfaction status	Subjects n (%)			OR (95%CI)	p
	Total patients n=128	CAM users n=37	CAM Non-users n=91		
Satisfied with definite improvement of symptoms of angina	106(82.8)	35 (94.6)	71(78.02)	4.93(1.09-22.3)	0.04*
Uncertain about angina control	22(17.2)	2(5.4)	20(21.97)	0.20(0.04-0.91)	0.04 *

CAM : Complementary and Alternative Medicine , OR : Odds ratio , CI: Confidence Interval
* p is significant at ≤0.05

When we sub-analysed the CAM users, (Table 5) the commonest form of CAM use was found to be herbal medicine *35(85.4 %)* in the form of *Terminalia Arjuna* (56.1%), *Bryophyllum pinnatum* (4.8%), *Syzygium cumini (7.3%)* and Clerondendron colebrookianum (17.1%). Other CAM users used *yoga* (12.2%), homeopathy (12.2%) and meditation (12.2 %). Some of the CAM users used more than one CAM. 4(9.7%) patients used both *Terminalia arjuna* and Clerondendron colebrookianum (*nefafu xaak*), 2(4.9%) patients used both yoga and *Terminalia arjuna*, 2(4.9%) patients used both *Syzygium cumini* and homeopathy and 1(2.4%) patient used both *yoga* and Clerondendron colebrookianum (*nefafu xaak)*.

Amongst the CAM users (Table 5), 30(85.7%) of the herbal medicine users were satisfied. However there was no significantly greater satisfaction from herbal medicine compared to other forms of CAM use. But all the users of *Terminalia Arjuna*, an ayurvedic medication, were highly satisfied with its use (p=0.008) for control of angina. *Nefafu xaak* (Clerondendron colebrookianum) was principally used to control hypertension. 6(85.7%) of the users of *Nefafu xaak* were satisfied about both blood pressure control and angina relief. But the overall satisfaction was not significantly higher compared to other CAM users (p=0.66). However significantly less satisfaction was seen in users of *Jamu* (p=0.03) and homeopathy (p=0.03). None of the patients revealed any perceived aggravation of the symptoms with use of CAM. None of the patients discontinued conventional medicine.

Table 5: Different types of CAM amongst the users and satisfaction

	Total no patients n= 138 CAM users n(%) 41(29.7%)			p
Type of CAM	Total patients n(% out of all CAM users)	Patients satisfied with perceived improvement of symptoms n (% out of total number of particular CAM)	Patients with no definite relief of symptoms n (%)	
Herbal medicine				
(a) *Nefafu xaak* (Clerodendrum colebrookianum)	7(17.1)	6(85.71)	1(14.29)	0.66
(b) *Jamu (Syzygium cumini)* ††	3(7.3)	0(0.0)	3(100)	0.03**
(c) *Terminalia Arjuna)* †	23(56.1)	23(100)	0(0.0)	0.008*
(d) *Dupor tenga* (Bryophyllum pinnatum)	2(4.87)	1(50)	1(50)	0.99
Total no of herbal medicine users	35(85.4)	30(85.71)	5(14.29)	0.18
Meditation	5(12.2)	2(40)	3(60)	0.30
Homeopathy	5(12.2)	1(20)	4(80)	0.03**
Yoga #	5 (12.2)	3(60)	2(40)	0.62

† 4 patients used both *Terminalia Arjuna* and *Nefafu xaak* (Clerodendrum colebrookianum) ; 2 patients who did *Yoga* , also used *Terminalia Arjuna.*

†† 2 patients used both *Jamu* (Syzygium cumini) and homeopathy.

#; 1 patient used both *Yoga* and *Nefafu xaak* .

 * p<0.05 is significant.

** Significantly poor satisfaction.

DISCUSSION

Use of CAM was found to be 29.7 % in the present study. The prevalence of CAM use among patients with coronary artery disease is found to be 4–61%. [16] In the present study, use of CAM was seen in 37.1 % of diabetic and 26.6 % of hypertensive CAD patients. The prevalence of CAM use in diabetes was estimated to be 34% in USA. [17] The prevalence of CAM use in hypertension is 69.5% in USA and 43.1 in UK. [18,19] In Indian context, 63.9% of patients with hypertension were found to be using CAM. [20] The prevalence of CAM use was found to be less in the hypertensive

patients in the present study. Moreover, hypertension was found to be a negative predictor for the use of CAM. As CM for hypertension is commonly available, the hypertensive patients could be resorting less to CAM. Moreover, in the previously mentioned Indian study, though 63.9 % of the patients resorted to CAM initially, more than half of them eventually stopped taking CAM as they became dissatisfied. [20] Interestingly in a Chinese study, although 74.2% of the hypertensive patients reported using CAM, only 13.1% of these CAM users used it to control blood pressure. [21] So there may be an undercurrent of dissatisfaction regarding CAM use for control of blood pressure. That explains the relatively lesser use of CAM by hypertensives in the present study.

We found that sociodemographic variables like male sex, and occupation predicted the use of CAM as significantly higher number of male patients (p=0.001) and service holders (p=0.02) were found to be using CAM. Moreover, CAM users had a better BMI profile (23.5 vs. 25.9; p=0.001). In some previous studies, CAM use was found to be more common in females; those studies were not specific to coronary artery disease (CAD) patients with diabetes and hypertension. [22,23] The fact that the males get more treatment and attention in angina pectoris compared to females might be operative in the differential use of CAM here. [24] BMI was found to be inversely associated with CAM use in a previous study. [25] Service holders generally have a better family income. In a previous survey, higher income was found to be a predictor of use of CAM. [26]

In our study, all of the 41 patients, who used CAM, continued to use CM prescribed to them. In A previous meta-analysis it was noted that the use of biological-based CAM did not affect compliance to prescribed conventional medications most of the time. [16] Majority of the patients (85.3%) did not have any negative perception about conventional treatment. Fear of side effects of CM was seen in only 6(14.7%) patients. None of the patients cited high cost of CM and inadequacies of CM as reasons for using CAM. However positive perceptions about CAM like that it can promote general health and wellbeing (78.1%), that it is devoid of side effects(73.2%) and that CAM can take care of the complications better (46.3%) were the primary reasons to use CAM. It has been suggested that disenchantment with allopathic medicine is not necessarily the only reason why patients turn to CAM. [27] The support for this observation also comes from an American study that reported that users of alternative healthcare were no more dissatisfied with or distrustful of conventional western care than non-users. [28]

Significantly higher number of CAM users were certain about the benefits than the non-users (OR 0.19; CI 0.04-0.88). Moreover, the satisfaction regarding control of angina was found to be significantly higher in CAM users (OR 4.93; CI 1.09-22.3) after omitting the 4 CAM-users and 6 CM-users, who had to withdraw their drugs. Specifically, satisfaction was greater in those who used *Ayurvedic* herbal medications in the form of *Terminalia Arjuna*. All 23 patients (100%) were satisfied *(p=0.008)* without any toxic effect. The users of all forms of herbal medications including *Terminalia arjuna* did not experience any new symptom or toxic effect. Withdrawal of these drugs due to toxicity was not noted. The satisfaction was particularly due to better control of ischemic symptoms. The anti-ischemic effects of *Terminalia arjuna* may be due to bradycardia and blood pressure reduction which was reported in one study. [29] In isoprenaline induced myocardial ischemia, *Arjuna* has been found to possess prostaglandin E2 like activity with coronary vasodilatation and

hypotension. [30] Anginal frequency was found to be reduced with *Arjuna* in stable angina. [31,32] A high number of users of *Nefafu xaak* were satisfied too. Clerodendrum colebrookianum (*Nefafu xaak*), commonly known as East Indian Glory Bower, is a perennial shrub belonging to the family. The natives of several states of NE use the leaves of this plant as a popular folk remedy for hypertension. [33]

87.8 % patients in our study did not communicate to their treating physician about the use of CAM. Earlier Indian studies reported lower reporting of CAM usage by patients to their physicians (3.8-13%). [34,35] It was also observed in a previous meta-analysis that a large proportion of medical practitioners (35-92%) were unaware of the CAM use by their patients. [16] This is a matter of concern since all the patients continued to use CM along with CAM and the treating physicians were not aware of it. Concurrent use of CM may have drug interactions with some of the biological therapies.

Our sample size was adequate with 80 % power. Moreover we have followed the patients for a long period of 12 months. As to the *limitations* our questionnaire did not include certain types of CAM like food supplements and vitamins, which some of the patients might have been using. We had to exclude 17 (10.9%) of the subjects from our initial enrolment, as we could not complete the follow up. There is also some possibility of under estimation of CAM use due to non-disclosure.

Though there have been various studies in the past as to the use of CAM in chronic diseases in India, there is no reported study of diabetic and hypertensive patients with chronic stable angina. Our study can provide vital information in this aspect.

CONCLUSIONS

The use of CAM is quite common in diabetic and hypertensive subjects with chronic stable angina. Positive perceptions about CAM prompted the patients to use it. In North east India herbal medications have been the most common CAM used by diabetic and hypertensive patients with chronic stable angina. All the patients who used CAM continued to use CM. However the communication with the physician regarding use of CAM use found to be low. Ayurvedic herbal medication (*Terminalia arjuna)* has been the commonest pattern. There is significantly high level of satisfaction from the use of *Terminalia Arjuna* in terms of relief of angina in both diabetic and hypertensive patients. No obvious toxic effect has been seen with use of CAM with CM. The satisfaction with use of herbal medications like *Terminalia Arjuna and Clerodendrum colebrookianum* needs further validation in a larger study with more objective parameters.

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