



COMPLEMENTARY AND ALTERNATIVE MEDICATION (CAM) USE IN PATIENTS WITH END STAGE RENAL DISEASE ON HEMODIALYSIS: A CROSS SECTIONAL STUDY FROM SOUTHERN INDIA

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KEYWORDS :

Introduction:

The increasing burden of non-communicable diseases (NCD) which account for approximately 60% of all deaths worldwide remains one of the important challenges that face the developed as well as the developing world. Among the NCD's, chronic kidney disease (CKD) now affects more than 500 million people worldwide, with 80% of those affected living in low to middle-income countries. In most of these countries, traditional medications(TM) are used by 75-90% of people and may often form the principal form of health care (1,2). In India, the prevalence of CKD has increased substantially in the past two decades commensurate with the global trend and has currently emerged as a significant cause of mortality and morbidity with a significant decline in the overall patient's quality of life (QOL). Despite several medical advancements, the survival of patients with end stage renal disease (ESRD) remains drastically shorter than the general population (3). In addition due to discrepancies in the availability of renal replacement therapy and the delay in seeking and continuing therapy only about 10% of ESRD patients continue hemodialysis treatment.

It is in this regard that complementary and alternative medication (CAM) fill in to provide therapeutic options for patients with ESRD. While they may mitigate symptoms and improve health-related QOL which conventional therapies such as drugs and dialysis often cannot achieve, the short term side effects as well as possible long term complications attributed to them are presently unknown. CAM as defined by the National Center for Complementary and Alternative Medicine is a 'group of diverse mediated and healthcare systems, practices and products that are not generally considered to be a part of conventional medicine'. The CAM modalities are classified based on the classification of the NCCAM as following. (4)

- 1) Alternative medical systems(acupuncture, Homeopathy, Ayurveda, Siddha and Unani)
- 2) Mind-Body interventions (relaxation techniques, spiritual healing/prayer, hypnosis, meditation, yoga)
- 3) Biologically based therapies(herbal and dietary supplements)
- 4) Manipulative and body based methods(massage therapy, exercise, chiropractic or osteopathy)
- 5) Energy therapies (energy healing, Reiki, magnetic healing)

There is widespread use of herbal and dietary supplements (HDS) particularly in Asian countries. Even in developed countries such as the United States, herbal and supplemental products account for \$100 billion annually (5). India has a long and well documented history of traditional forms of health care such as Ayurveda, Yoga etc all of which are officially recognised by the National Government(6). Among these alternative systems of medicine, Ayurveda which has origins in the Vedic times from 3000 years ago is the most widespread and used by 1 billion people, though it has broad popularity and usage extends well beyond Indian shores(7). CAM use especially Ayurvedic medication use is widespread in most non-communicable chronic diseases such as hypertension, diabetes, asthma etc, though accurate data on prevalence of use in CKD is lacking. These medication being naturally sourced are

believed to be safer and free from undesirable side effects. This may be the reason that most patients do not usually disclose this information to their treating physician unless specifically asked for. There have been some earlier studies on the use of CAM among non-dialysis CKD patients remains insufficient (8-10). Grabe et al in the US found 29% of patients with CKD used HDS, while Spanner et al(12,13) in Canada reported a usage of 45%. Often the varying prevalence in different studies may be due to the fact that CKD patients take them without the knowledge and approval of the health care team. (11). We believe that the usage of these alternative forms of medicine may be far greater in Asian countries particularly in India given that most of them originated here. It has also been known that some traditional medication use may adversely affect renal function and this has led to concerns about the detrimental effect of CAM use in patients with CKD. This effect has been clearly demonstrated for certain Chinese medication containing aristolochic acid. Though traditional Ayurvedic medication uses mainly plant based products, some of them have potent physiological, diuretic and other systemic effects that may effect renal function. Also the contamination with and use of small doses of heavy metals is also part of the Indian system of medicine and heavy metal toxicity with repeated and prolonged use in patients with limited renal function with the potential for long term irreversible damage is of grave concern.

Given the concerns about alternative medication use in CKD patients and the presumed higher prevalence of use in Asian countries, it is important to establish the extent and patterns of use amongst ESRD patients so that health care providers can be better informed and advise patients accordingly.

Materials and Methods:

A cross-sectional study was conducted from January to June 2017 in the hemodialysis units attached to the K.S Hegde Medical Academy in Mangalore, South Western India. The hospital predominantly caters to a semiurban patient population of two adjoining states Kerala and Karnataka. Apart from the main University hospital with a 12 station hemodialysis unit, the hospital also has two peripheral satellite units with 8 additional stations thus totalling 20. Adult patients (>18yrs) with diagnosed ESRD (estimated GFR \leq 15ml/min) on regular hemodialysis for atleast 3 months were considered potentially eligible and approached to participate in the survey. Patients who had undergone kidney transplantation were excluded from the study. Willing patients gave verbal consent to participate and the study was conducted in accordance with the declaration of Helsinki. The study was approved by the Institutional Ethics Committee.

A seventeen semi-structured questionnaire was adapted from the National Health Interview Survey Adult CAM Supplement (NHISAC) was used for the study and administered directly by the principal investigator (LRC). Items were selected based on the prevalence of CAM use during the preceding 6 months, frequency of use, reasons why patients opted for alternative medication use, adverse effects experienced if any and reasons for discontinuation of use if relevant. In addition to the survey, data was available on demographics including age, gender, co-morbid illnesses, religion, marital status, educational

level, employment status and household income/month. Socio-economic status was estimated using the modified Kuppaswamy scale. CAM categories which included

- 1) Herbal supplements
- 2) Ayurvedic medication use
- 3) Other naturopathic ,homeopathic ,Unani ,acupuncture use
- 4) Yoga, meditation
- 5) Others such as spiritual healing ,Reiki, faith healing

Statistical Analysis: Data was analysed using descriptive statistics for CAM use by demographics including age, gender, cause of CKD, employment status and educational level. All CAM therapies were combined as a single category and chi-square test performed to determine factors related to CAM use. Multiple logistic regression analyses undertaken to determine associations between CAM use and demographic characteristics. Tests were two-sided and a p value<0.05 was considered statistically significant. The data was analysed by SPSS version 21. The study was approved by the Institutional Ethics Committee of the University.

Results:

A total of 140 patients (97 males and 43 females) with a mean age of 49.2±12.1 years receiving hemodialysis treatment at the University hospital nephrology clinic were recruited in the study. The socio-demographic data of the study participants is listed in Table 1. The majority of the respondents were unemployed (74.3%) at the time of the interview and married (87.1%). 40.7% of them had completed a primary school education while about 28% had completed a secondary school education. 42.1% of the subjects belonged to the lower middle class category with monthly income of less than Rs.5000(75 USD) and more than 60% lived in a rural setting. Co-morbidities such as hypertension were present in 82% while 44% of the patients were diabetic. CKD was attributable to unknown causes in 3.6% of our patients. The majority of patients (63%) had been on dialysis for <24 months and the mean time on dialysis was 31±2.6 months.

Ninety-seven patients (69. 3%) reported the use of one or more type of CAM therapy in the previous 6 months. The types of CAM used by the patients were as follows and are shown in Table 2. Herbal and dietary supplements in 9(9.21%), Ayurvedic medication in 70(72.1%), naturopathic homeopathic and Unani systems in 14(14.4.3%) while spiritual/faith healing and acupuncture was used by 2(2.06%) and 2(2.06%) of the patients respectively. Out of the 97 patients who reported CAM use, about 19(19.6%) reported using them infrequently (<once/week) while frequent use (> two-three times/week) was seen in 43(44.3%) while 35(36.0%) reported daily usage. 33(34%) of the patients continued to use CAM at the time of the study period while the remaining 64(66%) had discontinued their use. The reasons for CAM use are depicted in Table 3. Most patients (62%) had used CAM based on recommendation from family members and friends. The other reasons for trying CAM were the increasing cost of conventional allopathic medication, social media and advertisements for CAM in newspapers, T.V etc and the fear of side effects with allopathic medication.

A multiple regression analysis between CAM users and non-users revealed that older age (p value=0.02), educational status (p= 0.05) and marital status (p=0.011) correlated strongly with CAM use. CAM users were more likely to be in the age category of 40-60 yrs and were largely primary school educated or illiterate. Gender, income and occupational status as well as CKD stage did not have any statistical impact on CAM usage. About 12(12.3%) of CAM users had experienced side effects of therapy. Out of the patients who has previously used and later on discontinued use of CAM , 41(42.2%) said that they stopped using due to the perceived lack of benefits of their kidney disease while 19(19.5%) had been advised to stop them by the treating physician.

Discussion:

The present cross-sectional study included 140 patients diagnosed with end stage kidney disease undergoing hemodialysis in a University based teaching hospital and associated satellite centres . Participants were considered representative of patients with ESRD in Southern India. Of the 140 patients included, the prevalence of CAM use was fairly high at 69%. Of these about 34.0% of patients were ongoing CAM users. The use of CAM has been reported among HD patients at a global level (9,10,14-16) , however the use of CAM amongst ESRD patients on hemodialysis is limited(17) and to the best of our

knowledge , this is only the second study to be reported from Southern India. More than 2/3rd of patients in our study reported to the usage of herbal and alternative medication use. This number is far greater than other studies which have reported prevalence of use ranging from 26-45% (16,17). In the previous Indian study done by Arjuna Rao et al(16) , the prevalence of CAM use in hemodialysis patients was 26%. The majority of patients identified as CAM users were in the age group of 40-60 yrs and this finding is similar to other reports by Birdee et al(14) and Rao et al(16) which showed that usage of CAM was more among middle-aged (50-64 yrs) patients compared to other age groups. This correlates with the prevalence of CKD being higher in this age group due to higher incidence of chronic diseases like diabetes and hypertension. The use of CAM also varies by gender, geographic region , socioeconomic status etc. In our study, we analyzed the usage of CAM according to age, gender ,educational status ,occupation ,place of living ,marital status and stage of CKD. We found that income , occupational status and age were found to significantly influence CAM usage while educational and marital status were not relevant. Our study identified Ayurveda as the most commonly used CAM therapy (72.1%) followed by other traditional systems of medicine practised in India such as naturopathy, Unani and homeopathic medicine (14.4%). We postulate that most of this group turn to alternative medication use along with the hemodialysis therapy which they found inaccessible or unaffordable as a desperate attempt at a possible cure or reprieve from the routine of hemodialysis and that they perceived them to be safe.

In India, there is a paucity of data on the use of CAM among CKD patients. As many as 200 million people may be living with CKD, the majority of whom live in rural settings (18,19) and have limited access to conventional health care. It is in this context that the traditional systems of medicine function as the principal form of health care. Individuals not only take CAM specifically for the treatment of their kidney disease, but also for treatment of co-morbid conditions such as diabetes and hypertension. Ayurveda is a complex system of medicine using various potent herbs and plant products, sometimes also using miniscule amounts of amalgamation of certain heavy metals and in the context of biomedicine , these treatments promote diuresis , erythropoiesis , cause glucose-lowering and anti-inflammation. Some traditional medicines have also been proven to reduce proteinuria in patients with diabetic nephropathy (20). Despite the widespread use of Ayurvedic medication amongst patients with CKD, evidence of their safety and efficacy remains limited. In our study, 12(12.3%) of patients had experienced side effects of CAM therapy, while 3(3.1%) had stopped therapy due to toxicity. Since the study patients were not followed up over a longer period, long term toxicities association with CAM usage could not be assessed. Renal failure affects the pharmacokinetics of various medications including traditional medication. In addition, regular and prolonged consumption of TM can increase the potential risks of heavy metal toxicity with rapid decline in kidney function. Hemodynamic, hypoglycemic, electrolyte and coagulation abnormalities and unpredictable effects on blood pressure have been seen (21). The risk of undesirable side effects of CAM use could also be due to the fact that most patients do not inform health care professionals of their use of CAM. It has been reported in one study that 72% of respondents (17) did not inform their doctor about herbal and dietary supplement use(HDS) . This study also found a significant association between HDS use and poor adherence to conventional medication. Treating physicians should be well informed about the possible side-effects of herbal treatments. Our study subjects were also highly influenced about CAM use by family and close friends. This influence has also been supported by other studies in Asian population (19, 22, 23) in patients with chronic illnesses.

The current study provides information about the prevalence and use of different types of CAM used by ESRD patients in a single centre in Southern India and reasons for their use. The study population is reflective of the general trend of hemodialysis population over the sub-continent. Though our results cannot be generalised to other heterogenous HD patients, it does bring to attention the high prevalence of use of alternative medication use amongst these patients, though they have diagnosed irreversible kidney injury and are on long term renal replacement therapy. Usage of CAM may be due to the fact that alternative medications are used and accepted commonly as well as reflect patient's hopes of a possible cure for the kidney disease even if slim. The study has some limitations which include its cross-sectional design and the results being subject to recall bias regarding CAM use. Another limitation was that the study only assessed patients' responses and not those of the treating physicians towards CAM use.

We were also not able to systematically go into the details and exact nature of the herbs the patients were taking and this information will need a chemical analysis of the drug specimen which was beyond the scope of this study.

Conclusions:

The present study highlights the high prevalence (69.2%) of use of alternative medication use in patients with chronic kidney disease on hemodialysis. Ayurveda therapies was the most commonly used mode of therapy with higher prevalence of use in middle aged and lower socioeconomic status patients. The health care team should play an active role in enquiring about the use of such alternative therapy in all patients and be aware of possible drug interactions and complications that may arise. Better communication and education by health care providers on the potential risks and benefits of CAM use in this vulnerable group of patients is needed to provide more holistic care.

Conflict of interest: None

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Table 1: Demographics of study population

Demographics	Frequency (n=140)	Percentage
Age category		
<20 yrs	4	2.9
21-40 yrs	33	23.6
41-60 ys	80	57.1
>60 yrs	23	16.4
Gender		
male	97	69.3
Female	43	30.7
Residence		
Rural	84	60.0
Urban	56	40.0
Religion		
Hindu	96	68.6
Christian	15	10.7
Muslim	29	20.7
Occupational Status		
Professional	3	2.1
Skilled Work	9	6.4
Unskilled work	24	17.1
Unemployed	104	74.3
Marital Status		
Single	18	12.9
Married	122	87.1
Education Status		
Illiterate	34	24.3
Elementary (primary) school	57	40.7
Secondary (high) school	39	27.9
Graduate	7	5.0
Postgraduate	3	2.1
Income category		
Low	23	16.4
Lower middle class	59	42.1
Upper middle class	28	20.0
Comorbidity: Diabetes mellitus		
	58	41.4
Hypertension		
	72	51.4

Table 2: Types of CAM used in the study (n=97)

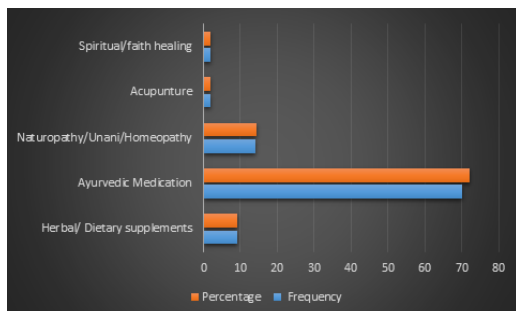
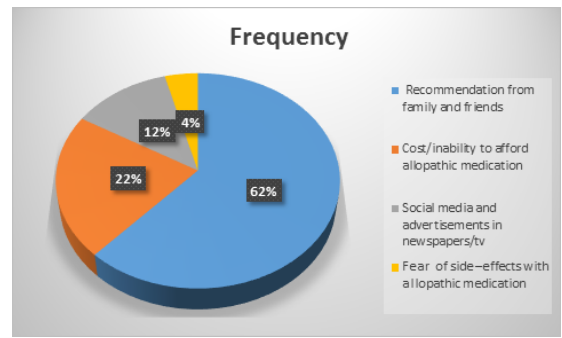


Table 3: Reasons for CAM use



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