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Prevalence of the use of traditional complementary and alternative medicine amongst cancer patients in a tertiary care center in Kerala, India

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ABSTRACT

Background: Unmet needs of cancer patients prompt them to seek care from Traditional, Complementary and Alternative Medicine (TCAM) practitioners.**Objective:** To investigate the prevalence of TCAM use in a multi-specialty tertiary cancer center in South India.**Materials and methods:** A cross-sectional survey of cancer patients who used TCAM during the study period. The patients were recruited based on convenience sampling method.**Result:** 320 cancer patients were approached, out of which 279 (87.2%) patients responded, and the prevalence of TCAM use was 34.4%. Home remedies (36%) figure prominently, with family advice (40%) being the primary influence for the TCAM use. The key expectation was an improvement in the quality of life (49%). TCAM use was pronounced during the chemotherapy phase (50%). Most patients (76%) using TCAM reported satisfaction with the treatment. Majority of the patients did not disclose concomitant use of TCAM to their treating physicians (71%).**Conclusion:** TCAM use by cancer patients is prevalent in Kerala. The study results point towards a need for large scale surveys, implementation of pharmacovigilance, patient education and research to identify and integrate TCAM interventions in cancer care that are safe and have beneficial effects.© 2021 The Authors. Published by Elsevier B.V. on behalf of Institute of Transdisciplinary Health Sciences and Technology and World Ayurveda Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Cancer is the second-most cause for mortality globally after cardiovascular disease accounting for approximately 9.6 million cases in 2018 [1]. The main challenges faced are late diagnosis and propensity for metastasis. The standard therapeutic options include surgery, radiation, chemotherapy, targeted therapy, and immunotherapy. Apart from the severity of the disease and side effects from the treatment, most patients undergo a multitude of stress, either emotional, physical, or socioeconomic. Owing to the overwhelming disease burden and unmet needs, many patients and families prefer

to take alternative treatment in the hope of improving outcomes. Previous studies report the usage of Traditional, Complementary and Alternative Medicine (TCAM) either alone or in combination with the standard treatment [2,3].

According to the World Health Organization (WHO), traditional medicine is the total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. The terms “complementary medicine” or “alternative medicine” refer to a broad set of healthcare practices that are not part of that country's tradition or conventional medicine and are not fully integrated into the dominant healthcare system. They are used interchangeably with traditional medicine in some countries [4].

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The extensive global usage of TCAM is evident from the literature. A systematic review reported that the combined prevalence for “current use” of CAM across all studies included for analysis was 40%, which was lower than often claimed. The highest was in the United States and the lowest in Italy and the Netherlands. However, this paper reports an increase in CAM use from an estimated 25% in the 1970s and 1980s to more than 32% in the 1990s and 49% after 2000 [5]. A survey of gynecology cancer patients suggests that the TCAM preferences vary regionally [6] and are also centered on the religious status of the country. The common reasons for TCAM usage were to treat side-effects of chemotherapy and to manage the disease better. TCAM was also used as the last resort treatment option on the recommendation of family or friends [7]. In India, research on the prevalence of concomitant TCAM usage with reference to specific diseases is still in its infancy.

In this study, we investigated the prevalence of TCAM usage by cancer patients in a multispecialty tertiary center in Kerala. The various reasons for its usage, the degree of satisfaction with each TCAM used and the source of information as well as the degree of disclosure were analyzed on the basis of patient interviews.

2. Materials and methods

2.1. Study design and setting

A cross-sectional survey of patients receiving treatment for a cancer diagnosis was conducted at the Medical Oncology Department of Amrita Institute of Medical Sciences and Research Center, Kerala, South India. The institute is 1500 bedded multi-specialty tertiary care hospital. The study was initiated after obtaining prior approval from the Institutional Ethics Committee (IEC-AIMS-2018-ONCO-267).

2.2. Survey instrument

A questionnaire was designed based on the available literature and local use of TCAM. A pilot study on the prevalence of TCAM was previously carried out on 100 cancer patients. Based on the assessment from the pilot study, modifications were made to the initial questionnaire. It was first prepared in English and subsequently translated to the regional language, Malayalam. The questionnaire has been uploaded as [Supplementary file](#). Translational accuracy was validated with the help of back translations. The first section of the questionnaire consisted of patient's demographic details like age, gender, educational status, type of cancer, and type of treatment. The second section consisted of questions about TCAM usage, like consumption of TCAM either in the past or present. If they confirmed the use of TCAM, the patients were asked to select specifically from the list of TCAM, which included Ayurveda, Yoga, Unani, Siddha, Homeopathy, folk medicine, nutraceuticals, and home remedies.

Herbal treatment given by an untrained, unlicensed practitioner were classified under folk medicine. Home remedies included spices and herbs from kitchen and home garden. Products isolated from herbs, dietary supplements (nutrients) and processed foods such as cereals, soups and beverages, which are used as supplements in addition to their nutritional value, were classified under nutraceuticals [8].

The other questions covered in section two were related to the time of initiation and duration of use of TCAM interventions. Study participants were asked whether they took TCAM along with conventional medicine, or during or after the administration of conventional medicine. The third section consisted of questions regarding the reason for use of TCAM. Commonly reported reasons for TCAM usage were listed with an option to specify unlisted

reasons under “Other” category. Level of satisfaction with TCAM usage, source of information prompting TCAM usage, and details regarding the disclosure of TCAM use with treating oncologists were also recorded. We have followed the guidelines recommended by Equator Network for reporting the survey [9].

2.3. Study participants

2.3.1. Inclusion criteria

1. All clinicopathologically confirmed cancer cases that underwent cancer treatment during the study period from January 2019 to December 2019.
2. Patients undergoing chemotherapy, chemoradiation, immunotherapy, hormonal therapy for cancer.
3. Patients who have undergone chemotherapy for cancer and presently are in the follow-up phase.

2.3.2. Exclusion criteria

Palliative care patients who underwent only supportive treatment.

2.3.3. Study sample

Patients were interviewed after obtaining informed written consent. They were included in the study by convenience sampling from the outpatient waiting area, daycare chemotherapy room, and inpatient admission wards. Those patients who fulfilled inclusion criteria, were verbally briefed about the study. The patients or their caregivers who were willing to participate, were asked to sign a written consent and subjected to a questionnaire-based interview. They either personally filled the questionnaire or verbally responded to the questions asked by the interviewer.

2.3.4. Sample size estimation

Based on the prevalence rate of traditional medicine use in cancer patients (38%) observed in an earlier publication [10] with a similar primary objective, and with 95% confidence and 15% relative precision, the minimum sample size required was found to be 279.

2.4. Statistical analysis

Statistical analysis was done using IBM SPSS 20.0 (SPSS Inc, Chicago, USA). For all the continuous variables, the results are given in Mean \pm SD, and for categorical variables as percentage. To compare the mean difference of numerical variables between groups, independent two sample ‘t’ test was applied for parametric data and Mann–Whitney U test for non-parametric data. To obtain the association of categorical variables, Chi-square with Fisher's exact test was applied. A P-value < 0.05 was considered as statistically significant.

3. Results

Between January 2019 to December 2019, around 23,243 patients consulted at the Medical Oncology OPD. Out of these patients, 13,706 consisted of females (59%) and 9,537 were males (41%). From the convenient sample of 320 patients, 279 (87.2%) fulfilled the inclusion/exclusion criteria, all of whom consented to participate. At the point of data collection, patients who underwent chemotherapy were 148, chemoradiation therapy 23, hormonal therapy 21, immunotherapy 9. Seventy-eight patients were in the follow-up phase.

Table 1
Demographic details of the study population.

Characteristics	Category	TCAM Users n = 96 (%)	TCAM Non-users n = 183 (%)	P-value
Age (Mean ^a ±SD)		55.99 ± 11.529	55.53 ± 11.881	0.757
Gender ^b	Male	26 (27.1%)	55 (30.1%)	0.603
	Female	70 (72.9%)	128 (69.9%)	
Education level ^b - all patients	Primary	13 (13.5%)	13 (7.1%)	0.187
	Secondary/post-primary	46 (47.9%)	100 (54.9%)	
	University/college level	37 (38.5%)	69 (37.9%)	

^a Independent two sample 't' test.

^b Chi square.

3.1. Demographics

Among 279 respondents, 198 were women, which constituted 71% of the study population. The age among TCAM and non-TCAM users was 55.99 ± 11.52 years and 55.53 ± 11.88 years (represented as Mean ± SD). Of the 279 study participants, 26 (9.4%) had primary level education, 146 (52.5%) had a secondary or post-primary level, and 106 (38.1%) had college or university level education. The demographic details of the patients are shown in Table 1. The type of cancers and the distribution of survey participants based on their cancer types is shown in Fig. 1. Breast cancer was found to be the most common cancer among the survey population. Table 2 depicts the gender-based distribution of TCAMs within users. Home-remedies were found to be the most frequently preferred TCAM.

3.2. TCAM users

Among 279 patients, 96 (34.4%) patients used TCAM either before, after, or during chemotherapy. Interestingly, the percentage of female users who underwent Ayurveda treatment was less than that of males (p value = 0.008). The majority of TCAM users (47.9%) possessed a secondary education level; 38.5% of patients had a University or college level of education, and 13.5% had only primary education (p value = 0.187).

3.3. Types of TCAM used

Among the 96 patients who reported using TCAM, 35 patients (36%) used home remedies. Examples included consumption of *Amla* (*Phyllanthus emblica*) with pepper powder and turmeric

Table 2
Gender-based distribution of TCAMs within users.

TCAMs used	Male n = 26	Female n = 70	Total	P-value ^a
Home remedy	7 (20%)	28 (80%)	35 (100%)	0.738
Folk medicine	5 (15%)	29 (85%)	34 (100%)	0.050
Nutraceuticals	8 (36%)	14 (64%)	22 (100%)	0.430
Ayurveda	11 (55%)	9 (45%)	20 (100%)	0.008
Homeopathy	4 (31%)	9 (69%)	13 (100%)	1.000
Yoga	1 (20%)	4 (80%)	5 (100%)	0.410

^a Chi square test.

powder; lemon juice in warm water; powdered turmeric in warm milk; mixing *Aloe vera* gel, turmeric and honey; incorporating amla, ginger lemon and salt; honey and aloe vera gel added in whiskey or brandy; a decoction of hibiscus petals; adding aloe vera, lemon and honey and a few others. In total, thirty-four patients (35%) of the TCAM users followed folk medicine such as *Lakshmi Taru* (Paradise tree, *Simarouba glauca*), *mullatha* (Soursop, *Annona muricata*), and Karnataka tree bark. A total of 22 patients (22%) consumed nutraceuticals, which constituted of various nutritional supplements and protein powders. This was followed by Ayurvedic medicines, which comprised 20 patients (20%), including *Drakshadikashayam*, *Ashwagandha choornam*, *Chyavanaprasha*, *Rasagandhi* capsule, *Varanadi* capsule and *kvatham*, herbomineral medicine made out of mercury. Thirteen patients (13%) administered homeopathy medicines and a very small fraction, i.e., five patients (5%), favored Yoga. None of the cancer patients chose Siddha or Unani.

3.4. Pattern of TCAM usage

Half of the 96 patients consumed TCAM along with conventional cancer treatment. Six patients (6%) administered TCAM before initiating traditional cancer treatment and 26 patients (27%) started using TCAM during follow up. Other 13 patients (13%) started using traditional therapy during conventional treatment and continued even after completing conventional treatment. Only three patients (3%) started before initiating conventional treatment and continued throughout the conventional treatment.

3.5. Source of advice for TCAM usage

Family members were the most common source (39 patients, 40%) of advice for initiating TCAMs, followed by friends (22 patients, 22%), neighbors (12 patients, 12%), self-prescribed (11

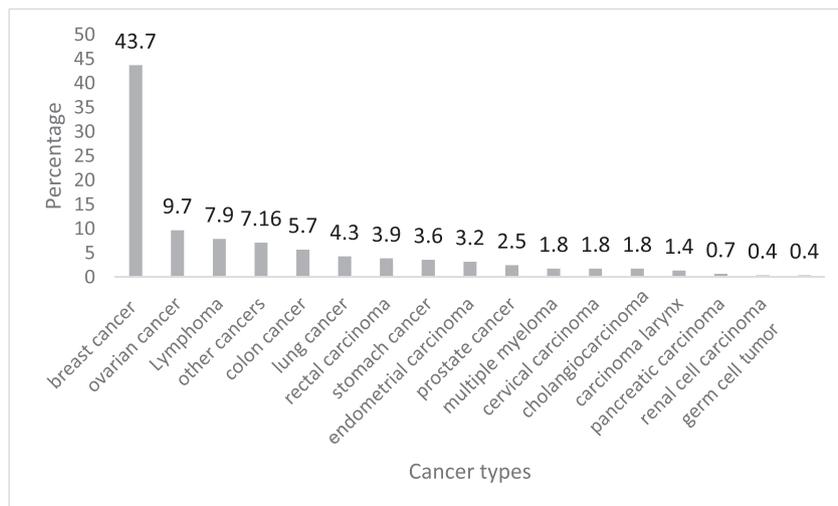


Fig. 1. Types of cancer in the study population.

patients, 11%), social media (9 patients, 9%), other practitioners (6 patients, 6%) and treating doctor (3 patients, 3%). Various reasons for which patients were using TCAM included improving the quality of life or enhancing the overall health condition (47 patients, 49%), improving blood counts (26 patients, 27%), anything to fight cancer (19 patients, 19%), as immunity boosting agent (13 patients, 13%), avoiding the recurrence of the disease (11 patients, 11. %) and for reducing side-effects of chemotherapy (7 patients, 7%).

3.6. Satisfaction with TCAM usage and rate of non-disclosure

The majority (76%) of the users of TCAMs were satisfied. As shown in Table 3, the exception was homeopathy where 9 of the 13 patients stated they were dissatisfied. Only 29% of patients disclosed the TCAM usage with their treating oncologists, whereas 71% failed to discuss their TCAM usage with their treating doctor.

4. Discussion

This study was undertaken in order to explore the prevalence and usage pattern of TCAM by cancer patients undergoing conventional treatment at a multispecialty tertiary care facility in Kerala. The other objectives were to explore the various reasons for its usage, the degree of satisfaction with each TCAM used and the source of advice prompting TCAM use along with degree of disclosure to the treating oncologist. The study revealed that there is 34.4% prevalence in TCAM use in the study sample. Home remedies (36%) were the most commonly used TCAM with family contributing to be the main source of influence (40%). The expected benefit was to improve the overall quality of life (49%) and it was found that most patients were satisfied (76%) with its usage. The degree of non-disclosure to the treating oncologist was high (71%).

4.1. Prevalence or usage of TCAM

The findings from our study are consistent with previous surveys suggesting that TCAM usage was widespread among cancer patients in India. The prevalence rate (34.4%) observed in our study was almost similar to an Indian study conducted in North India (38.7%) but higher than that reported in a study from South India (23.5%) [9,10].

Another review focused on research papers published on TCAM usage in gynecologic cancer patients determined a prevalence rate of 40.3%–94.7% [6]. In the meta-analysis of research conducted in 18 countries, the prevalence rate was found to be 40% [7].

4.2. Characteristics of TCAM users

In our study, like other surveys conducted in India [11], significantly more females used TCAM. This is due to more female cancer patients visiting OPD and their willingness to participate in the study and this trend is consistent with many parts of the world, including Europe, Chile, Saudi Arabia and India [12–14]. The mean

Table 3
Levels of satisfaction with TCAMs.

TCAM types	Very satisfied	Satisfied	Dissatisfied	Total
Home Remedy	10 (29%)	21 (60.00%)	4 (11%)	35 (100%)
Folk Medicine	4 (12%)	28 (82%)	2 (6%)	34 (100%)
Nutraceuticals	7 (32%)	12 (54%)	3 (14%)	22 (100%)
Ayurveda	6 (30%)	8 (40%)	6 (30%)	20 (100%)
Homeopathy	3 (23%)	1 (8%)	9 (69%)	13 (100%)
Yoga	2 (40%)	3 (60%)	0	5 (100%)

age of TCAM users was similar to the survey conducted in South India, but there was a difference in the educational status of TCAM users. The majority of our TCAM users had post-primary or secondary education levels, and no one was uneducated [11]. Elderly patients were major users of TCAMs in our study and the North Indian study [10]. Patient demographics like educational status have not been reported uniformly across the studies; hence, comparison was difficult. For example, in our study, we classified education levels as illiterate, primary, secondary or post-primary, University, or college. In contrast, other studies classified participants as illiterate, primary, upper primary, secondary, tertiary, bachelors, and masters.

4.3. Significance of types of TCAM used

The types of TCAM used differed markedly from country to country. In India, the AYUSH system of medicine, which consists of Ayurveda, Yoga, Unani, Siddha, and Homeopathy, is well-recognized. The official Ministry of AYUSH classification of the healthcare system and a few other TCAM practices in vogue in India were listed in our study questionnaire for data collection. Our study's usage patterns differed from what was found in the North Indian study, where Ayurvedic treatment was used mostly. Home remedies were more common in our patient population, not listed in the earlier Indian studies [10]. Home remedies are the wide range of kitchen items extending from spices, herbs, dry fruits, and vegetables consumed with a notion of having a therapeutic value. In most of the cases, if not all, its therapeutic effectiveness is not proven. Many of these are easily accessible, cheap, and grown in the home garden. The TCAMs listed in research studies conducted in other parts of the world were according to their local context and different from our research. For example, Quran recitation, Zamzam water, olive oil, black seed, garlic, camel milk, honey, camel urine, known herbal and unknown herbal mixtures, multivitamins were the TCAMs used in Saudi Arabia [12]. On the contrary, herbals, vitamins and minerals, prayer or meditation, special diet, Homeopathy, yoga, acupuncture, chiropractic, and hypnosis were the TCAMs that the Chilean population used [14]. Although there is a disparity in the TCAMs being listed in various reports, the prevalence rates are higher in the studies conducted in Europe, Saudi Arabia, and Malaysia [12,13,15].

4.4. Source of advice prompting the use of TCAM

Patients with advanced malignancies who are not offered any curative therapy seek TCAMs with hope of a cure, and reliability of the source is often overlooked. A study on cancer patients was conducted in the United States to determine the relationship between the influence of the family in prompting TCAM usage and the patient's expectation of its benefits. It was found that the patients who were influenced by the family were more likely to use alternative or complementary treatments, expecting the TCAMs to cure cancer and to increase their survival than those who were not influenced by family members [16]. Our study found that family members were the most common information source, similar to two previously published Indian studies and a Chilean study [10,11,14]. The main reason for using TCAM in the South Indian study was to improve the overall quality of life or tolerance to chemotherapy [11].

4.5. Non-disclosure of TCAM usage with consulting oncologist

The rate of non-disclosure in our study was found to be 71%. A systematic review consisting of an extensive search of the literature in databases Medline, PubMed, Proquest 5000, ScienceDirect, and

Cochrane Library during the period from 1990 to 2011 to explore the rate of non-disclosure of TCAM usage by cancer patients with the treating oncologist was conducted. The TCAM prevalence rate ranged from 11% to 95%, and the rate of non-disclosure ranged from 20% to 77% [17].

4.6. Possible benefits and safety concerns related to TCAM usage

The majority of the patients in our study initiated and continued the TCAM usage mainly while undergoing chemotherapy, and only a few have continued after chemotherapy. However, evidence supporting safety of concomitant use of TCAM along with chemotherapy or to treat the side-effects caused due to chemotherapy is inadequate and limited to few preclinical studies. For example, preclinical studies show that *Brahmarasayana* and *Chyavanaprash* can prevent acute kidney injury caused due to cisplatin and prevent doxorubicin-induced acute cardiotoxicity [18,19]. A trial on 36 cancer patients undergoing radiation therapy and chemotherapy to evaluate the efficacy of *Rasayana Avaleha* as an adjuvant treatment in reducing adverse effects showed that the combination of radiation therapy plus chemotherapy plus *Rasayana Avaleha* which was the treatment arm reduced the adverse events such as nausea and vomiting, mucositis, fatigue, xerostomia, alopecia and tastelessness than the control arm which was treated with radiation therapy and chemotherapy alone [20].

Safety concerns include the presence of heavy metals such as mercury, cadmium, arsenic and lead, pesticides like aflatoxins and other harmful substances. The interactions between TCAMs and chemotherapeutic agents also raise concerns about safety. A review article describing the herb-drug interactions of herbs which are commonly used by cancer patients like turmeric, green tea, ginger, *ashwagandha* and a medicinal mushroom discusses various examples elaborating both beneficial as well as harmful effects when combined, one among which was the interaction between curcumin and chemotherapeutic agents, doxorubicin and cyclophosphamide through its antioxidant property [21]. From the level of satisfaction data collected in this study, it is evident that the patients are satisfied with their TCAMs. When feedback regarding satisfaction was enquired, the patients discussed that the TCAMs did not cause any side-effects or disease progression. This could be due to the inability to distinguish between side-effects of chemotherapy and those caused by herb-drug interactions.

5. Limitations of the study

This study is a single institutional study inviting participation of cancer patients from an oncology department. We would miss cancer patients who have gone directly to the TCAM practitioners. Hence, it would be difficult to extrapolate the findings from this study to the general population. The exact percentage of patients who quoted the various reasons for non-disclosure could have been documented. The actual duration of treatment in terms of days, months, or years could not be found. From the interaction with the patients, no event of herb-drug interaction was noticed or documented, but we cannot rule out the risk of such interactions leading to undesirable outcomes. Another limitation of the study was the retrospective nature of data and difficulties in addressing recall bias in data collection. On the other hand, the use of a pre-piloted questionnaire is a strength of this study.

6. Conclusion

A prevalence rate of 34.4% was found in the sample we studied. Home remedies were found to be the most commonly used TCAM, and the family was found to be the most reliable and encouraging

source of advice prompting TCAM use. The main reason for TCAM use is expected improvement in the general quality of life, and most patients preferred consuming such medications during active chemotherapy. The degree of non-disclosure to the treating oncologist remained high. This is the first study done so far in Kerala on small sample of patients. There is a need to do studies on larger samples. Prevalence of TCAM medications' concurrent use calls for implementing pharmacovigilance, patient education, and research to identify and integrate TCAM interventions in cancer care that have beneficial effects. Preclinical studies to understand interactions between TCAM medications and chemotherapeutic agents need to be initiated urgently.

Statement of ethics

The study was conducted after getting prior approval from the Institutional Ethics Committee of Amrita Institute of Medical Sciences (IEC-AIMS-2018-ONCO-267).

Author's contributions

SK was involved in data collection and drafting the manuscript, RP was involved in conceptualization, supervision, reviewing and suggesting modifications in the manuscript, AP helped with data collection, reviewing and suggesting the modification to be made in the manuscript, GCR was involved with statistical analysis of data collected, KP was involved in conceptualization, supervision, reviewing and suggesting changes in the manuscript. All the authors have approved the final version of the document.

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Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jaim.2021.04.011>.

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