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Original Article

Complementary and alternative medicine use in children with haematological disorders

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ABSTRACT

Objectives: To study pattern of complementary and alternative medicine(CAM) use in paediatric patients suffering from thalassemia and compare CAM use in patients of thalassemia and sickle cell disease(SCD).
Methodology: This was a prospective, cross sectional study conducted after approval of ethics committee. Patients suffering from thalassemia or SCD, of either gender were included after obtaining informed consent. Parents accompanying patients were interviewed and information obtained was entered in self-developed, semi structured, pretested questionnaire.
Results: Use of CAM as reported by parents was 34.78% and 30.13% in thalassemia and SCD respectively (p = 0.476). Ayurveda (78% and 71%) and homeopathy (22% and 29%) were most common CAM used in both diseases. Most parents didn't disclose CAM use to their doctor (84.37% & 85.50%). Significantly more parents of SCD children reported to have benefitted from CAM (p = 0.0122). Benefits obtained from CAM were: symptomatic improvement, increased haemoglobin, reduced blood transfusion. Reasons for stopping CAM were: no relief with treatment, adverse effects & high cost.
Conclusion: Results of this study indicate that CAM use is similar in SCD and thalassemia. Many patients who used CAM with conventional medicines, didn't disclose CAM use to their doctors, thereby increasing possibility of potential interactions and avoidable problems.

Keywords – CAM, sickle cell disease, SCD, thalassemia

INTRODUCTION

Complementary and alternative medicine (CAM) is defined by the National Centre for CAM (NCCAM), United States as "a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine."[1]

There are number of unconventional therapies which may be used as complementary therapies (in addition to conventional treatments) or as alternative therapies (instead of conventional treatments).[2] Increased side effects, lack of curative treatment for several chronic diseases, high cost of new drugs are some reasons for renewed public interest in CAM.[3] Many methods of CAM having long been established are not considered evidence-based medicine. Because of this physicians often do not ask their patients about CAM usage. CAM includes a wide range of approaches like herbal medicine, traditional therapies, mind-body intervention etc and has gained popularity worldwide in recent years. In India there is a vast diversity of CAM practices, which can be traced back to many centuries. Worldwide the estimated adult general population for CAM use varies from as low as 32% to as high as 80%.[4,5] The use of CAM is common and increasing among children. Rates vary depending on how CAM is defined and how sampling is done.[6] Rates varying between 9-73% have been reported in different studies.[7] The highest international rates (66–73%) are reported in Taiwan , Mexico and Singapore.[8,9,10] In children with chronic illnesses, CAM use has been reported to be 44% in epilepsy, 54% in sickle cell disease, 59.6% in diabetes mellitus and 64% in rheumatoid arthritis. [11,12,13,14] It has been reported that parents use CAM to improve the overall health of their children, provide symptomatic improvement and complement the use of conventional medicine.[15] Although some of the herbal remedies may be beneficial for patients, severe adverse effects like renal failure, veno-occlusive disease, hypertension, convulsions and liver failure have been reported with others.[16]

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Thalassemia is a chronic, life long illness which requires medical treatment almost throughout life and has considerable impact on health care system. It is also a matter of concern due to the high cost of treatment, its increasing prevalence and high morbidity and mortality rates within a few years if left untreated.[17] Though the research on thalassemia is extensive, there is not much literature on concurrent use of CAM in this population. A comprehensive search of the literature yielded only one article specifically related to use of CAM in children with thalassemia. The authors reported that 82.5% of parents used CAM for their children and that majority of the parents (36.1%) stated that they used CAM to ensure their children's health and protect them against disease. [7]

Patients with chronic diseases have been found to use CAM therapies with other medicines. It is very likely that this practice can lead to unnecessary interactions with the prescribed medicines and some of these practices can adversely affect the outcome of some chronic disorders. This is particularly relevant for a disease like thalassemia where the patients need treatment for entire duration of their life. Since this disease is usually diagnosed early in life treatment begins in early childhood. Hence, it is necessary to study use of CAM in children with thalassemia. Use of CAM in the other common haematological disorder, sickle cell disease(SCD) has been reported by various authors.[12,18] With this background, this study was planned with the objectives of studying pattern of CAM use in paediatric patients of thalassemia and to compare CAM use in paediatric patients of thalassemia and SCD.

METHODS

This was a prospective, cross sectional, questionnaire based study which was initiated after approval from the Institutional Ethics Committee. A total of 321 patients of either gender, upto 12 years of age, suffering from thalassemia or sickle cell anaemia (any variant) who attended the Paediatric OPD or sickle cell clinic of a tertiary care teaching hospital were included. Parents accompanying the children were briefed about the study and informed consent obtained from those willing to participate. Since there is no standard survey instrument for assessing CAM use in children, a self-designed, semi-structured questionnaire composed of 19 questions was developed to record the following information: patient and parents demographic characteristics, use of specific CAM products and therapies (both current and lifetime use), source of information, reasons for use, concurrent use with conventional medicines, benefits obtained, adverse effects, reasons for discontinuation, disclosure about use and expenditure on CAM. CAM was explained to the parents as an intervention, not prescribed by a physician. The questionnaire was subjected to pilot testing in 5 respondents and suitable modifications done. Parents were interviewed by a direct face-to-face interview using the study questionnaire. Parents were approached while they were waiting for doctor's consultation so that they did not need to spent additional time for this purpose.

Statistical analysis: Descriptive statistics were tabulated as counts and percentages for categorical variables. Participant demographics and different aspects of CAM use in the two groups were compared by Fisher's exact test for categorical variables and unpaired t test for numerical variables, e.g. age. P value <0.05 was considered statistically significant. Graph pad prism version 6.0 was used for statistical analysis.

RESULTS

Total of 229 patients of SCD and 92 patients of thalassemia were approached out of which 69(30.13%) and 32(34.78%) reported use of CAM. There was no statistically significant difference in the use of CAM between the two groups ($p = 0.476$). Table 1 shows the demographic characteristics of respondents (parents) and patients who reported use of CAM.

Folic acid was the most commonly prescribed medicine in both the groups. Other commonly prescribed medicines were desferrioxamine in thalassemia and analgesics, hydroxyurea and zinc and vitamin supplements in SCD patients. Ayurveda (78% and 71%) and homeopathy (22% and 29%) were the most common CAM used in both diseases. Table 2 shows respondents' knowledge and practice about CAM. Majority of the respondents in both the groups did not disclose CAM use to their physician (84.37% and 85.5% in thalassemia and SCD respectively). Most common reason for not disclosing CAM use to their physician was that the physician did not ask. Other reasons being: not necessary to tell the doctor about CAM use and fear of negative reaction from the doctor. Significantly more number of SCD patients reported to have benefited from CAM compared to thalassemia ($p = 0.0122$) and more SCD patients opined that CAM is more effective than modern medicine ($p=0.0345$). Figure 1 shows that friends, neighbours and relatives were the most common sources of information about CAM in both the groups. Figure 2 shows that the major reason for stopping CAM in both the groups was no relief obtained from CAM. Table 3 shows that

symptomatic improvement was the major benefit due to CAM in thalassemia patients while in SCD, in addition to symptomatic improvement reduced requirement of blood transfusion was the other major benefit reported. Four and nine patients of thalassemia and SCD respectively stopped CAM use due to adverse effects. Adverse effects reported were nausea, vomiting, bodyache, generalised weakness, blackish discolouration of teeth and were mild to moderate in severity. The average monthly expenditure on CAM in thalassemia and SCD was INR 1035 and INR 1073 respectively.

Table 1: Demographic characteristics of parents and patients

Demographic Characteristics	Thalassemia (n=32)	SCD (n=69)	P value
Parents			
Mothers : Fathers	**18:14**	**40:29**	**0.8707**
Educational level:			
Up to SSC	**14**	**41**	
Higher than SSC	**18**	**28**	**0.1974**
Mean age±SD	**33.5±7.144**	**34.77±7.094**	**0.4063**
Monthly Income (INR):			
<5000	**28**	**55**	
>5000	**4**	**14**	**0.3412**
Number of children:			
≤2	**22**	**57**	
>2	**10**	**12**	**0.1165**
Residential area:			
Urban	**13**	**42**	
Rural	**19**	**27**	**0.0573**
Patients			
Age group:			**0.0586**
≤ 5years	**13**	**15**	
above 5 yrs to 12 years	**19**	**54**	
Duration of illness:			
≤ 2yrs	**2**	**8**	
above 2 to ≤ 5yrs	**13**	**23**	**--**
above 5 to ≤10 yrs	**13**	**34**	
≥10 yrs	**4**	**4**	

SCD - sickle cell disease

Figure 1 : Sources of information about CAM

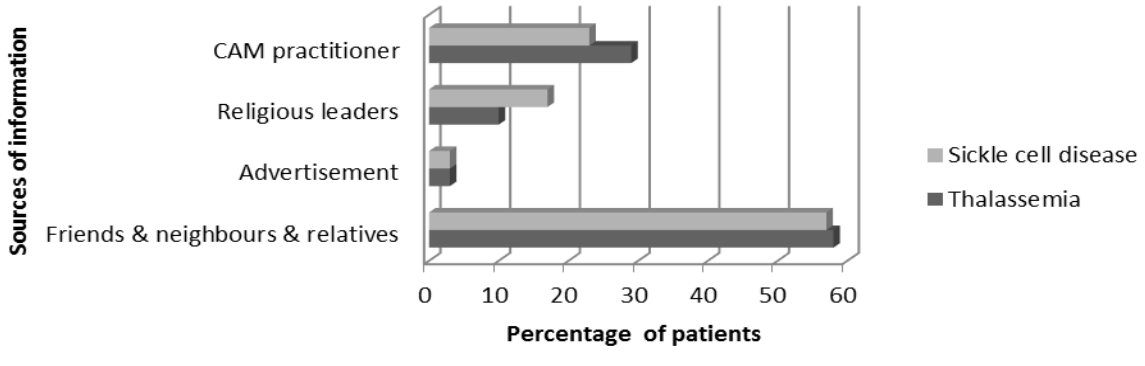
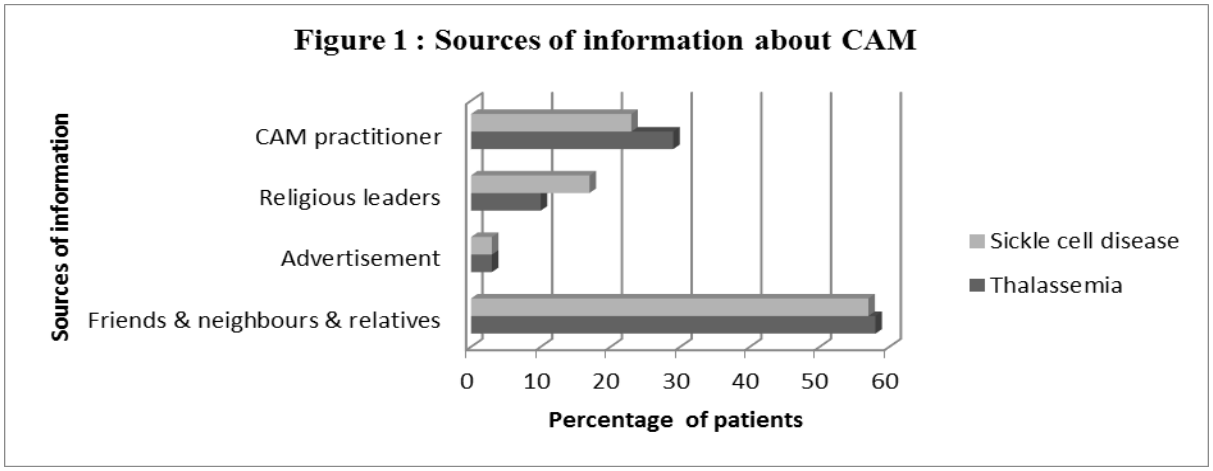


Table 2: Respondents' knowledge and practice about complementary and alternative medicine

Statement	No. of respondents				P value
	Thalassemia(n=32)		SCD(n=69)		
	Yes	No	Yes	No	
Currently using CAM	1(3.13)	31(96.87)	16(23.19)	53(75.36)	0.0107
Used CAM but currently not using it	31(96.87)	1(3.13)	53(76.81)	16(23.19)	0.0107
Used conventional treatment with CAM	30(93.75)	2(6.25)	54(78.26)	15(21.74)	0.0839
Disclosed using CAM to doctor	5(15.63)	27(84.37)	10(14.50)	59(85.50)	1.0000
Benefited from the CAM used	5(15.63)	27(84.37)	29(42.03)	40(57.97)	0.0122
CAM is safer than modern medicines	2(6.25)	30(93.75)	13(18.84)	56(81.16)	0.1353
CAM is more effective than modern medicine	1(3.13)	31(96.87)	13(18.84)	56(81.16)	0.0345
CAM use can cause any harm	8(25)	24(75)	6(8.70)	63(91.30)	0.0591
Experienced any adverse effects after using CAM	7(21.88)	25(78.12)	5(7.25)	64(92.75)	0.0481
Would recommend CAM to other patients	2(6.25)	30(93.75)	30(43.48)	39(56.52)	0.0002
Ever used CAM for yourself for any illness	6(18.75)	26(81.25)	20(28.99)	49(71.01)	0.3338

CAM- complementary and alternative medicine. Figures in parentheses indicate percentage.



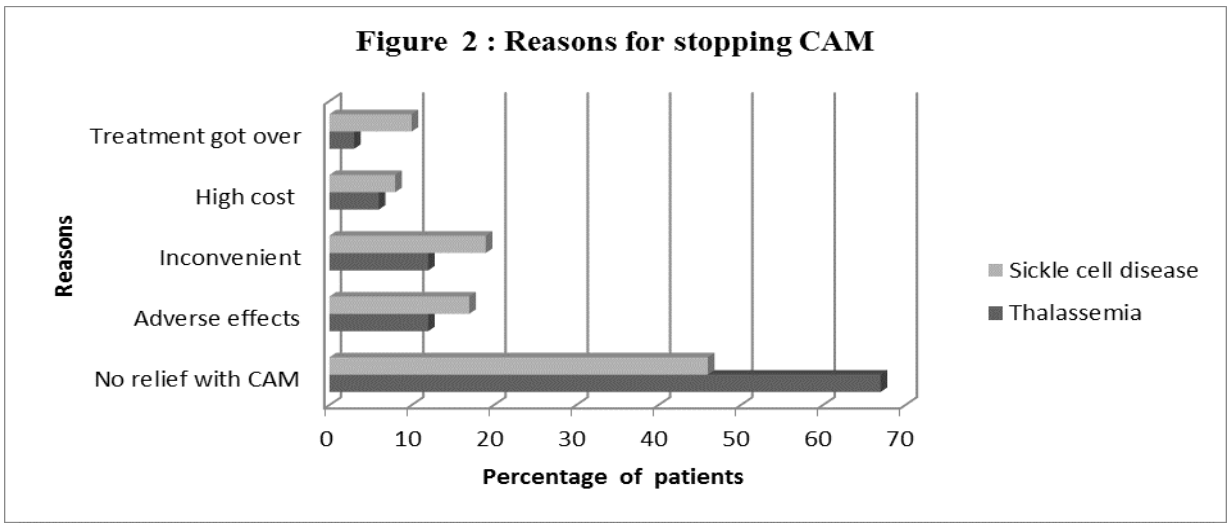


Table 3: Benefits obtained from CAM

Benefits	Number of Patients	
	Thalassemia(n=5)	Sickle cell disease(n=38)
Symptomatic improvement	5(100)	19(50)
↑ Haemoglobin	0	4(11)
↓/ No requirement blood transfusion	0	13(34)
Improved sense of well-being	0	2(5)

Figures in parentheses indicate percentage

DISCUSSION

Most of the questionnaire-based studies use self-administered questionnaires which have some limitations such as inability of the respondents to understand certain terminologies or misinterpretation of some questions in spite of translating the questionnaire in vernacular language. The same factors may be responsible for incomplete filling of the questionnaire which is the other commonly encountered problem in such studies.[11,12,18,19] In this study the investigators themselves interviewed the respondents thereby overcoming these limitations.

This study evaluated the extent of CAM use in thalassemia and SCD in children. CAM use was found to be similar in the two disorders (34.78% and 30.13%). In another study from Turkey which is the only other reported study on the extent of CAM use in thalassemia patients, the proportion of parents who reported using one or more of the CAM methods was 82.5% while use of CAM in SCD was reported to be 36% in yet another study.[7,18] This large difference in the extent of CAM use may be due to various reasons the major being variation in the definition of CAM.[6] Vitamins, minerals, nutritional supplements, biological products have been the commonly used CAM in other studies while in this study Ayurveda and Homeopathy were the most commonly used CAM.[7,18] There has been some debate over whether vitamins, minerals and nutritional supplements should be considered as CAM.[20] In this study the respondents were not specifically asked about use of vitamins, minerals and nutritional supplements but none of them mentioned about use of these products on their own. Hence, it is likely that patients may have been using other forms of CAM not specifically addressed by the study questionnaire. This might have resulted in underreporting of CAM use. The reason for Ayurveda and Homeopathy being the common CAM used may be the widespread belief in the Indian population that these medicines do not produce any adverse effects and are effective in various chronic disorders for which modern medicine has no definitive cure.[3] This fact is further confirmed by this study wherein majority of the respondents believe that CAM is safer than modern medicine and it cannot cause any harm. Though a preliminary study has shown beneficial effects of Homeopathic treatment in patients of thalassemia on hydroxyurea therapy there is no definitive evidence to confirm the same.[21] Further, there is no evidence available to prove the safety and efficacy of Ayurvedic or Homeopathic medicines administered concurrently with conventional medicines.

The common reasons for CAM use as reported by respondents in both the groups were: symptomatic improvement, reduced need of blood transfusions, cure of disease or slowing its progression, increase haemoglobin level. Similar reasons have been reported in another study in thalassemia.[7] A significantly higher number of sickle cell anaemia patients used CAM to improve their body immunity in another study.[18] This suggests that parents who opt for CAM use are aware about the limitations of modern medicine in their child's illness and want to try other options.

The percentage of patients who reported to have benefited from CAM use were significantly more in SCD group compared to thalassemia. There is no obvious reason for this difference. The respondents could only tell that they used Ayurvedic and Homeopathic treatment for their children. Ayurveda and Homeopathy are different pathies which include large number of medicines. The nature of these medicines taken by the patients in both the groups is not known. Hence, it is difficult to predict the reasons for difference in beneficial effects of CAM observed in the two groups. Among patients who stopped using CAM the major reason was no relief obtained with CAM in both the groups. It is difficult to comment on the efficacy of these treatments in these conditions due to nonavailability of adequate evidence. It is also known that some conventional biomedical therapies do not have enough proof of effectiveness, and some unproven and alternative therapies may at times prove effective. Also, some alternative therapies believably may have placebo effects, which impart more therapeutic benefit and improved quality of life. [22] This may to a certain extent explain the differences reported in the two

groups. In this study symptomatic improvement was the major benefit reported in both the groups while reduced need of blood transfusions was the other beneficial effect in SCD patients. In another study in children with asthma, epilepsy and sickle cell anemia 46% of the patients reported to have benefited from CAM which included improvement in general wellbeing, symptomatic relief and complete cure of the illness. [18] Relief of pain in sickle cell anemia following CAM use has been reported.[23] Most of the benefits reported with CAM in this study are subjective in nature, hence, it is difficult to draw any conclusive fact regarding the benefits produced by CAM. Further, need of blood transfusions was reported to be reduced in SCD patients in whom even otherwise need of blood transfusions is less compared to thalassemia. Patients of thalassemia who need more frequent blood transfusions did not report any such benefit.

Most of the adverse effects reported by respondents in both the groups were mild to moderate in severity. Though no serious adverse effects were reported, four and nine patients from thalassemia and SCD groups respectively stopped CAM due to adverse effects. All the adverse effects reported are non-specific and it is difficult to attribute these either to conventional medicines or CAM. Relatives, friends and neighbours were the main source of information about CAM in both the groups. Similar factors influencing CAM use have been reported in earlier studies wherein 60-80% of parents were influenced by relatives, friends and neighbours for CAM use in their children. [24,25] Approximately one-third of parents from both the groups identified their CAM practitioner as their information source about CAM which is also similar to that reported earlier.[6,26]

In this study, 93.75% of thalassemia and 78.26% of SCD patients reported CAM use along with prescription medicines. Other studies have reported approximately 50% of patients using CAM with prescription medicines. [6,26] The alarmingly high number of patients who used CAM with prescription medicines in this study is a matter of concern since patients who are totally unaware of the potential for drug interactions are exposed to such risk. Though data on drug interactions between conventional medicines and CAM in children is sparse, some combinations of conventional medicines and CAM likely to be involved in serious interaction are reported. [27]

Number of parents not disclosing CAM use to their child's physician was 84.37% and 85.5% respectively in thalassemia and SCD. Earlier studies have also reported that a high proportion of patients, ranging from 41% to 92%, do not disclose CAM use to their physicians.[28,29] Reasons for not disclosing CAM use were: did not feel the need to tell and doctor did not ask which are similar to that reported in earlier studies.[30] A less common reason reported in this study was concern about a negative response by the physician which is also reported in another study.[30,31] Considering widespread use of CAM along with conventional medicines and not disclosing this to the treating physician creates an additional potential hazard for patients which they may be totally unaware of. Hence, it can be suggested that health professionals routinely inquire about CAM use as part of their history taking at each follow-up visit.[26] But even this may not be of much benefit most of the times since conventional health care providers may not always be able to advice the patient about CAM use due to lack of knowledge or education about CAM during their training. The average monthly expenditure on CAM in thalassemia and SCD was more than 1000 INR. Only a few other studies have looked at the cost of CAM and reported expenditure ranging between US $ 31.7 to US $70.1 per month.[11,18] Though the expenditure on CAM cannot be compared between different studies, in this study since most of the parents were from low socio-economic background, the amount spent on CAM is significant and may be economically exhausting for the family. This appears to be pitiable as a major portion of the already meagre income is spent on therapy of which the safety and efficacy in these disorders is not established. It has been suggested that though there is uncertainty about the safety, efficacy, and cost-effectiveness of CAM, increasing their use, where sufficient proof of their efficacy and safety is available, may provide health, social as well as economic benefits. [32] The limitation of our study is that we depended on recall of past events by the respondents who acted as proxy for the patients. But then parents are usually much concerned about their child's health particularly in case of chronic illnesses and usually tend to remember all major health issues concerned with their child.

CONCLUSION

Use of CAM is similar in thalassemia and SCD with Ayurveda and Homeopathy medicines being the most commonly used CAM. More patients of SCD reported to have benefited from CAM. The matter of concern is that many patients who used CAM along with conventional medicines, didn't disclose CAM use to their doctors, thereby increasing possibility of potential drug interactions. Hence, it is necessary that concurrent use of CAM and conventional medicines should be monitored for safety and efficacy, especially in children with chronic illnesses who are considered vulnerable population.

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