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Original Research Article

Morbidity and Drug Utilization Pattern of Integrative Medicine (Siddha medicine and Biomedicine) - A Single Center Retrospective Study of 150 Patients

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ABSTRACT

Integrative Medicine (IM) is a rapidly growing field because of increased demand, which requires further evidence-based research to provide more information on the effectiveness and safety. The aim of the study was to assess morbidity and drug utilization among patients using IM attending Siddha Clinical Research Unit (SCRU), Tirupati, India.The information obtained in the google form, which is the research database of the SCRU, Tirupati, was investigated in this study throughout the time of July to December 2019.The patient demographics, morbidities, commonly used Siddha medications, and biomedicines prescribed at the first visit were studied. Results revealed that most IM users 80 (53.3%) were males, the mean age of IM users was 56.53 years. The most common morbidities were diabetes 95 (63.3%), hypertension 29 (19.3%). Siddha medicines such as *Amukkara chooranam* 98 (65.3%), *Aavarai kudineer* 85 (56.6%), were commonly prescribed along with the biomedicine, metformin 91 (60.6%), amlodipine 62 (41.3%). Thus, the common morbidity of the IM users were diabetes and hypertension, common siddha drugs utilized were *Amukkara chooranam*, *Aavarai kudineer*, and biomedicine were metformin, amlodipine.

***Keywords*:** Biomedicine, Drug-drug interaction, Integrative Medicine, Siddha medicine, Traditional medicine.

Introduction

Integrative Medicine (IM) is healing-oriented medicine that takes account of the whole person, including all aspects of lifestyle. It emphasizes the therapeutic relationship between practitioner and patient, it is informed by evidence, and makes use of all appropriate therapies.[1] The IM approach recently re-emerged with the expectation of providing an affordable practical resolution to the global healthcare crisis. The IM consortium, which includes Arizona, Duke, Harvard, Johns Hopkins, UCLA, and Mayo clinic in the United States, has actively argued for it as a critical component of the new healthcare system in the public interest. Many countries in Asia, Africa, Europe (Norway (Troms), Sweden (Karolinska)), Latin America, Australia and China have IM activities.[2] In general, IM refers to the interaction of multiple medical systems and therapies, such as allopathy and complementary and alternative medicine (CAM).[3,4] In India, it is a common practice, that people unknowingly use one herbal medicine in their day to day life along with the prescribed biomedicine. Such practice can be attributed to their culture.

Siddha system originated in Tamilnadu, the most primordial among the AYUSH (Ayurvedha, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) systems. Siddhars, the forefathers of the Siddha system, transferred their affluent knowledge to the suffering mankind through their disciples.[5] In Siddha medicine, there are 32 types of internal and external medicines, and it has three major subdivisions: plant, inorganic, animal product.

a. Plant products, are used as single herb and as compound formulations. The compound formulations are used in various forms such as *chooranam* (powder), *kudineer* (decoction), *mathirai* (tablet), *charu* (juice), *legium, manappagu* (syrup) etc.

b. Inorganic compounds (IOCs) are divided into 4 subdivisions; they are metals (ulogam)-12, minerals (karasaram)-64, hydrochemicals (uparasam)-24 and toxins (paasanam)-120. IOCs are usually made into preparations such as *parpam, chendhuram, chunnam, padhangam, kattu, kalangu* etc.

c. Animal products (leech, crab, monitor lizard, deer horn, elephant teeth, diary and diary derivatives, and other marine products) and their components such as teeth, bone, and egg are used.

Recently there are 3986 hospitals, 27199 Dispensaries, in AYUSH System, which includes, 291 hospitals, 848 dispensaries, in Siddha system alone. Institutionally qualified practitioners in AYUSH system are 587660, whereas in Siddha it is around 5685 practitioners.[6] In India, doctor–population ratio (1:1,000) as said by the World Health Organization (WHO), is achieved after considering AYUSH doctors.

Thus, the study on drug utilization and disease pattern in IM users serves as an effective tool for identification of combined efficacy and safety of drugs used in both 'systems'. This is the first study in literature to investigate the documentation of Integrative Medicine (Siddha and BioMedicine), as well as the morbidity and drug usage of IM users. The aim of this study is to assess morbidity and drug utilization among patients using IM attending Siddha Clinical Research Unit (SCRU), Tirupati, India.

Materials and Methods

Study design

This was a retrospective study of patients (n=150) who had used both Siddha and Biomedicine herein defined as IM users.

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Data source
The information obtained in the google form, SCRU, Tirupati, was investigated for this study, which included patients' age, sex, registration number, date of medical visits, drugs, diagnosis, management and treatment from July 2019 to December 2019.
Since it is a retrospective study, Institutional review board approval was not required because all personal data were kept confidential. All data analyzed were collected as part of routine diagnosis and treatment, they were not reported separately.

Statistical analysis
Data analysis included the prevalence of IM user segregated by the patient's demographic characteristics, morbidity, proportion of the first prescribed Siddha drugs and biomedicine drugs.

Results and Discussion

Demographic characters and morbidity of IM users
The IM usage differed depending on age and sex; males were high users of IM 80 (53.3%), females were fewer 70 (46.7%). The mean age of IM users was 56.53 years. No patient was reported between the ages of 0-10. Number of patients with IM in age groups of 50-60 > 60-70 > 40-50 > 70-80 > 30-40 > 20-30 = 10-20 were reported (Table 1). Male female ratio 1.14: 1. The utilization of IM increases with age; maximum users were reported in the age group of 50-60 years [45 (30%)] and 60-70 years [44 (29.3%)]. The top ranked morbidity in IM users were diabetes mellitus, hypertension, dyslipidemia and hypothyroidism (Table 2). The increase in the prevalence of non-communicable diseases, drug resistance and biomedicine complications; dissatisfaction with the outcomes of certain biomedical treatments; have intended for much attention to traditional medical systems. This has led the public to conceive the idea of integration of biomedicine with traditional Medicine. According to WHO 2021 statistics, non-communicable diseases (NCDs) claim the lives of 41 million people each year, accounting for 71% of deaths worldwide. The most common NCD is cardiovascular disease, which kills 17.9 million people each year, preceded by cancer (9.3 million), respiratory diseases (4.1 million), and diabetes (1.5 million). This indicates that NCDs needs to be controlled and prevented.[7] In this study cancer was reported in three (2%) patients, this showed the demand of taking Siddha medicine along with the standard chemotherapy and in post-operative stage of cancer.
A single case study of 53-year male patient of squamous cell carcinoma- tongue, who underwent Siddha treatment, after 7 months of radiation therapy, showed an increased survival rate of about 5 years.[8] The study on Yagya Therapy as supportive care in cancer patients for two months showed an increase in their Quality of life (QOL).[9] The study on herbal use among cancer patients during palliative and curative chemotherapy treatment in Norway, revealed that curative patients used herbal remedies more often to counteract adverse reactions and the palliative patients used to improve their immune system.[10] These findings showed that the results facilitate the use of integrative medicine in cancer palliative care.

Commonly used Siddha medicines and Biomedicines
The most prescribed Siddha medicines in IM users were *amukkarachooranam* 98 (65.3%), followed by *aavaraikudineer* 85 (56.6%), *nilavaagaichooranam* 63 (42%), *thiripalakudineer* 62 (41.3%) and the biomedicines were metformin (60.6%), amlodipine (41.3%), aspirin (15.3%), telmisartan (14.6%). (Table 3)
In India both traditional medicine and Biomedicine are regulated and supported by the Indian government. Traditional medicine is actively practiced in all AYUSH medical hospitals and in some allopathy hospital. There are two forms of IM,

- Referral between the Biomedicine practitioner and AYUSH practitioners.
- AYUSH practitioners working directly within the allopathy hospital.

In this study the first commonly prescribed Siddha medicine is *Amukkara chooranam* for pain management (Table 4) it has anti-inflammatory, anti-arthritic, immune-modulatory, anti-microbial activity. According to the annual report of SCRU Tirupati 2019-2020[11], the first common diseases reported was osteoarthritis and it is also evident that the peoples of Andhra pradesh was the first leading state affected by osteoarthritis in India.
Aavarai kudineer is the second commonly prescribed Siddha medicine, has anti-diabetic, anti-microbial activity. According to the Siddha classical text it can be used for both diabetes mellitus and renal dysfunction. Third most prescribed Siddha medicine is *Nilavaagai chooranam* (NVC) used as a laxative. A study reported the inadequate glycemic control increases the frequency of constipation in diabetes mellitus patients.[32] Hence NVC was prescribed in addition with either *thiripala kudineer or aavarai kudineer*, commonly prescribed medicines for diabetes.
Thiripala kudineer the fourth most prescribed Siddha medicine along with Biomedicine, has several therapeutic activities (Table 4). Since it has anti-diabetic activity, was prescribed for diabetes and to treat complications caused by diabetes such as cardiovascular diseases, obesity, dyslipidemia etc.
In this study not only, herbal drugs some of the Herbo-mineral drugs were also prescribed, they were *silasathu parpam, kalnar parpam, arumuga chendhuram, ayabringa raja karpam, rasagandhi mezhugu*.

Table 1: Basic demographic character of IM user

Characteristics age Years	Male n (%)	Female n (%)	Total n (%)
0-10	Nil	Nil	Nil
10-20	Nil	2 (1.3)	2 (1.3)
20-30	1	1 (0.6)	2 (1.3)
30-40	7 (4.6)	3 (2)	10 (6.7)
40-50	8 (5.3)	19 (12.6)	27 (18)
50-60	24 (16)	21 (14)	45 (30)
60-70	25 (16.6)	19 (12.6)	44 (29.3)
> 70	15 (10)	5 (3.3)	20 (13.3)
Total	80 (53.3)	70 (46.7)	150 (100)
Ratio Male: Female	1.14:1		
Mean Age	56.53 years		

Table 2: Morbidity of IM users

S. No	Diseases	No. of patients n (%)
1.	Diabetes	95 (63.3)
2.	Hypertension	29 (19.3)
3.	Hypothyroidism	5 (3.3)
4.	Psychiatric disorder	6 (4)
5.	Cardiovascular disorder	5 (3.3)
6.	Rheumatoid arthritis	3 (2)
7.	Cancer	3 (2)
8.	Epilepsy	2 (1.4)
9.	Urticaria	2 (1.4)

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Table 3: List of Biomedicines and Siddha medicines used in IM

S/N	Biomedicine	No. of patients n (%)	Siddha medicines	No. of patients n (%)
1.	Metformin	91 (60.6)	*Amukkarachooranam*	98 (65.3)
2.	Amlodipine	62 (41.3)	*Aavaraikudineer*	85 (56.6)
3.	Asprin	32 (15.3)	*Nilavaagaichooranam*	63 (42)
4.	Telmisartan	22 (14.6)	*Thiripalakudineer*	62 (41.3)
5.	Glimipride	21 (14)	*Thalisaathichooranam*	46 (30.6)
6.	Atorvastatin	20 (13.3)	*Parangipattaimathirai*	34 (22.6)
7.	Levothyroxine	19 (12.6)	*Silasathuparpam*	41 (27.3)
8.	Calcium	12 (8)	*Kalnarparpam*	44 (29.3)
9.	Copidogrel	8 (5.3)	*NerunjilKudineer*	4 (2.6)
10.	Vit-D12	8 (5.3)	*Elathychooranam*	4 (2.6)
11.	Hydrochlorothiazide	5 (3.3)	*Arumugachendhuram*	2 (1.3)
12.	Atenolol	4 (2.6)	*Ayabringarajakarpam*	2 (1.3)
13.	Insulin	10 (6.6)	*Capsule Rasagandhimezhugu*	2 (1.3)

Table 4: Siddha medicine, ingredients, their activities used in IM

S/N	Siddha medicines	Ingredients	Pharmacological activity
1	*Thiripalakudineerchooranam* (Decoction powder)	Terminalia chebula, Emblica officinalis, Terminalia belerica	Stress-reducing potential[12], Anti-obesogenic[13] Anti-diabetic[14], Anti-microbial[15], Anti-neoplastic [16], Antioxidant[17], Anti-inflammatory, Anti-aging[18]
2	*Amukkarachooranam* (Powder)	Withania somnifera, Zingiber officinale, Piper nigrum Piper longum, Elettaria cardamomum Cinnamomum verum, Syzygium aromaticum Saccharum officinarum	Anti-Inflammatory, Arthralgia[19] Immuo-modulatory, Anti-microbial[20]
3	*Aavaraikudineer* (Decoction powder)	Cassia auriculata, Cassia fistula, Syzygium cumini Cyperus rotundus, Saussurea lappa, Terminalia arjuna Salacia reticulata	Anti-diabetic[21], Anti-microbial[22]
4	*Nilavaagaichooranam* (Powder)	Cassia angustifolia, Zingiber officinale, Piper nigrum Embelia ribes	Eczema[23]
5	*Thalisaathichooranam* (Powder)	Saussurea lappa, Piper longum, Cumimum cyminum Anethum sowa, Nigella sativa, Piper longum, Syzygium aromaticum, Myristica fragrans, Piper nigrum, Nardostachys jatamansi, Cinnamomum verum Michel champaca, Embelia ribes, Trachyspermum ammi Coriandrum sativum	Anti-oxidant[24]
6	*Parangipattaimathirai* (Tablet)	Smilax china Saccharum officinarum	Anti-inflammatory, Immuno-modulatory Anti-psoriatic [25], Anti-microbial [26] Anti-vitiligo[27]
7	*Silasathuparpam*	Calcium sulphate dehydrate, Coldenia procumbens	Anti-urolithiatic Activity[28]
8	*Kalnarparpam*	Asbestos, Aristolochia bracteolata	
9	*NerunjilKudineer* (Decoction powder)	Tribulus terrestris, Embilica officinalis, Terminalia chebula Terminalia belerica, Asteracantha longifolia, Smilax china Solanum nigrum, Cassia fistula, Foeniculam vulgare,	Nephroprotective[29] Lithotriptic effect[30]

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		Cucumis sativus, Lagenaris vulgaria	
10	*Elathychooranam* (powder)	Elettaria cardamomum, Cuminum cyminum	
		Syzygium aromaticum, Glycyrrhiza glabra	
		Emblica officinalis, Cinnamomum tamala	
		Cinnamomum verum, Murraya koenigii	
		Santalum album, Nardostachys jatamansi	
		Foeniculam vulgare, Saccharum officinarum	
11	*Arumugachendhuram*	Mercuric sulphide, Magnetic oxide of iron Sulphur,	
		Sodium biborate, Sodium chloride impure, Ferrum – Iron	
		Aloe vera	
12	*Ayabringarajakarpam*	Iron, Citrus limon, Eclipta prostrata	
13	*Rasagandhimezhugu*	Elemental Mercury, Elementary Sulphur	Anti-Cancer[31]
		Mercurous chloride, Arsenic trisulphide	
		Magnetite ore of Iron, Copper sulphate	
		Zinc carbonate with traces of Zinc sulphate	
		Lead monoxide and 40 other herbs	

These medicines are also called as higher order medicines (Peru marunthugal). The uniqueness of higher order medicine is,

a) effective even in minimal dose,
b) it challenges incurable diseases,
c) it has increased bioavailability,
d) shelf life is higher compared to plant products,
e) therapeutic efficacy is high,
f) Gives quick remedy.

Arumuga chendhuram is also one of the herbo-mineral drugs prescribed in this study has anti-arthritic activity (Table 4) treated by incineration process. *Chendhuram (Red oxide)* is a red-colored powder generated by burning, frying, or incineration of metallic or arsenical compounds. *Ayabrinaraja Karpam* is one of the herbo-mineral karpam (Rejuvanator) prescribed in this study indicated for anemia, dropsy etc. Karpam means rejuvenator, it is one of the distinctive therapeutic divisions in Siddha system of medicine advocated specially for rejuvenation, decreasing morbidity and increasing the life span. Nearly 108 herbs and herbo-mineral combinations are recommended for prevention of diseases and restoration of health from specific diseases. *Rasagandhi mezhugu* (RGM) is also one of the higher order medicines prescribed in this study; contains 40 herbal drugs, 8 metallic and mineral drugs, indicated for a variety of diseases. It was also tested for anti-cancer activity, HPV-positive cervical cancer cells, ME-180 and SiHa and it affected the viability of both the cells. *Silasathu parpam* has anti urolithiatic activity. In the classical text, black asphaltum is indicated for dysuria, urinary tract infection. *Kalnar parpam*, is used in all types of epilepsy, mental retardation, schizophrenia, burning micturition, dysuria, spermatorrhoea.

Prospects for future studies

1. This study focus on the disease identification of IM users, which yet to be revealed. The use of IM in non-communicable diseases such as diabetes mellitus, hypertension, dyslipidemia, hypothyroidism and malignancy were more. This gives an insight into the research focus on integrative medicines utilization in major non-communicable diseases.

2. This study exploring the Siddha medicine and biomedicine utilization for diseases, will open a new path for drug-drug interaction studies. The studies on drug utilization and prescribing patterns can serve as an effective tool for investigating the clinical pharmacology to offer suggestive information to identify the effective Integrative medicine[33].

Conclusion

This study found out that the males were high users of IM, females were fewer. The mean age of IM users was 56.53 years. Maximum users were reported in the age of 50-60 years and 60-70 years. The top ranked morbidity was diabetes mellitus, hypertension, dyslipidemia and hypothyroidism. The most prescribed Siddha medicines in IM users were *amukkara chooranam*, followed by *aavarai kudineer*, *nilavaagai chooranam*, *thiripala kudineer* and the biomedicines were metformin, amlodipine, aspirin, telmisartan. These findings facilitate further research into IM, specific to disease.

Conflict of Interest

The authors declare no conflict of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

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