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Review Article

A CRITICAL REVIEW OF CTRI REGISTERED TRIALS OF *SHUSHKAKSHIPAKA* AYURVEDIC MANAGEMENT

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ABSTRACT

Acharya Sushruta and *Acharya Vagbhata*, both of them have classified *Shushkakshipaka* under *Sarvagataroga.* Symptoms of *Shushkakshipaka* described by *Sushruta* are *Sudarun Paribodhanam* (dryness of eyelids), *Ruksha Vartma* (dryness of eyes), and *Avil Darshana* (blurred vision) and *Darun Vartma* (stiffness of eyelids). This study scrutinized the trials registered for *Shushkakshipaka* from the database to detect patterns in methodology (study design, sample size) of trials. **Material and Method:** This was an observational study that analysed the CTRI registered trials for *Shushkakshipaka* between March 2012 and July 2024. A trial search was conducted on the CTRI database to include all types of studies registered for *Shushkakshipaka* with keywords like "*Shushkakshipaka*" and studies conducted on conditions other than *Shushkakshipaka* were excluded. **Result:** There were total 51 studies which were analysed from Ayurveda stream. Most of these studies were registered from Maharashtra state [n-19] i.e., 39.75%, most of the study conducted as randomized trial (n-39), parallel group trials (n-39). Conducted as double arm study 76.47%. Most of the study *Shushkakshipaka* related studies registered on CTRI is maximum in year 2024 (n-11). There are 22 studies having age group in between 1 year and 1 year 6 months i.e., 43.13%. Maximum studies conducted in age group between 18- 60 years of age (n-39) i.e., 76.47%. There were 34 studies including *kriyakalpa* as intervention i.e., 66.66%. **Conclusion:** The present review is an attempt to analyse the CTRI-registered *Shushkakshipaka* clinical trials, which show the general characteristics of trials along with study design and setups. Although there is a surge of clinical trials on CTRI regarding Ayurveda for *Shushkakshipaka*, the methodological information is not more elaborative and there is large scope for improvement.

INTRODUCTION

Dry Eye Syndrome is defined as a "multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and subacute inflammation of the ocular surface".[1]

The ocular surface (cornea, conjunctiva, accessory lacrimal glands), meibomian glands (specific sebaceous glands of the eyelid margin, which produce the outer lipid film of the tear film), the main lacrimal gland, and the innervation between them form a functional unit. Any or all of these structures may be affected in dry eye disease.[2] Recent studies have shown that dry eye is an inflammatory disease that has many features in common with autoimmune disease.[3,4] Stress to the ocular surface (environmental factors, infection, endogenous stress, antigens, genetic factors) is postulated as the pathogenetic triggering mechanism. Data from a large US managed care database suggest that the prevalence of clinically diagnosed dry eye disease (DED) is 0.4% to 0.5% overall, and is highest among women and the elderly. The burden of DED to the patient can be substantial, impacting visual function, daily activities, social and physical functioning, workplace productivity, and

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quality of life (QOL).[5,6] The result is a vicious circle of damage to the ocular surface and inflammation.

Classification into "Dry eye with reduced tear production (aqueous-deficient)" and "dry eye with increased evaporation of the tear film (hyper evaporative)" has proved useful on practical ground. *Acharya Sushruta* and *Acharya Vagbhata*, both of them have classified *Shushkakshipaka* under *Sarvagatarog*,[7,8] Symptoms of *Shushkakshipaka* described by *Sushruta* are *Sudarun Paribodhanam* (dryness of eyelids), *Ruksha Vartma* (dryness of eyes), and *Avil Darshana* (blurred vision) and *Darun Vartma* (stiffness of eyelids).[8] These symptoms are similar with the symptoms of dry eyes in modern medicine.[9]

In modern science, therapies like eye drops helps to cure or treat the patients of Dry Eye Syndrome. Ayurvedic treatment of *Shushkakshipaka* can help to lower symptoms and cure the disease. So, there is a need to search for an effective treatment protocol in Ayurveda for the prevention and management of the disease.

The present critical review is conducted to access the features of Ayurveda studies registered in CTRI so that we can analyse the methodology and Ayurveda management in these studies which may be helpful to researchers in the future. These studies were registered in the Clinical Trial Registry– India (CTRI).[10]

MATERIAL AND METHOD

This study adopted a cross-sectional study design, obtaining the data of trials registered on the CTRI website. The CTRI website (www.ctri.nic.in) is administered jointly by the ICMR and the National Institute of Medical Statistics.

All clinical trials for *Shushkakshipaka* enrolled with CTRI, between March 2012 to July 2024 were recovered utilizing keyword like *Shushkakshipaka*. Those trials that are registered with CTRI are considered as inclusion criteria for the study while those that are not registered with CTRI but registered with other registries are excluded. The gathered information was embedded in book keeping pages according to different things of the CTRI enrolment data set. At first, the investigation was examined by general qualities like study is observational/ interventional. All investigations were dissected regarding sample size, study population, medication, comparators, treatment length, study span. These information qualities are introduced as actual numbers and percentage form.

Trial selection strategy

The trials on *Shushkakshipaka* were identified from the CTRI database (www.ctri.nic.in) and the search was conducted from March 2012 to July 2024. The registered trials were searched in the "trial search" section using keywords such as *"Shushkakshipaka"* to extract all the possible trials registered. For the extraction of terminated trials, the database with filters of recruitment status (Indian) of other (terminated) and terminated trials with the keywords *"Shushkakshipaka"* was searched. Likewise, for the suspended trials, the recruitment status (Indian) for suspended trials with similar keywords was searched.

Inclusion criteria

Any study conducted on *Shushkakshipaka* was included. We included both prospective and retrospective studies. All types of studies, such as interventional, observational during the mentioned time frame were included.

Exclusion criteria

Studies conducted on conditions other than *Shushkakshipaka* were excluded.

General characteristics of the registered studies

All study type should be interventional study [n=51]. Analysing these studies system, it is found that studies from ayurveda are higher in *Shushkakshipaka*. All studies were carried out on a single site. It is found that randomize trial n=39, parallel group trial n=39, Active control trial n=16, Single arm study n=6, placebo control trial n=1, multiple arm trial n=1. As all studies were analysed by different characteristics like sample size, study population, type of intervention, comparator, duration of treatment, age group, duration of study.

Many studies including age group in different manner. But most of the studies having age group in between 30- 100 years of age. This study includes year wise classification including 2012- 1 study, 2013- 1 study, 2017- 1 study, 2019- 7 studies, 2020- 5 studies, 2021- 10 studies, 2023- 9 studies, 2024- 11 studies.

Table 1

Characteristics of studies	Ayurveda (n) [Total -51]	Percentage (%)
Study arm		
Single arm	6	11.76
Double arm	39	76.47
Multi arm	1	1.96
Placebo control trial	1	1.96

Other	5	9.80
Sample size		
<30	4	7.84
30-100	42	82.35
101-200	3	5.88
>200	2	3.92
Type of intervention		
Single drug formulation	10	19.60
Multidrug formulation	20	39.21
Multi formulation regime in group A	16	31.37
Multi formulation regime in group B	2	3.92
Comparison of intervention		
With Ayurvedic drug/ therapy	18	35.29
With allopathic drug including		
1. Carboxymethylcellulose eye drop	14	27.45
2. Hydoxypropylmethylcllulose eye drop	2	3.92
3. Omega 3 fatty acid	1	1.96
Study conducted in single group	13	25.49

State wise distribution of *Shushkakshipaka* in study-

Table 2

S.No	State	Total study done in each state (n)	Percentage (%)
1	Uttar Pradesh	2	3.92
2	Gujrat	6	11.76
3	Rajasthan	3	5.88
4	Uttaranchal	6	11.76
5	Maharashtra	19	37.25
6	Karnataka	11	21.56
7	Himachal Pradesh	2	3.92
8	Bihar	1	1.96
9	Telangana	1	1.96
	Duration of trial	Total	
1.	< 30 days	30	58.82
2.	30-50 days	16	31.37
3.	>50 days	4	7.84
4.	Not particular mentioned	1	1.96
	Duration of Study		
1.	Upto 6 months	10	19.60
2.	6months- 1 year	9	17.64
3.	1 year- 1 year 6 month	22	43.13
4.	>1 year 6 month	9	17.64

	Age group		
1.	<18 years	0	0
2.	18- 60 years	39	76.47
3.	>60 years	12	23.52

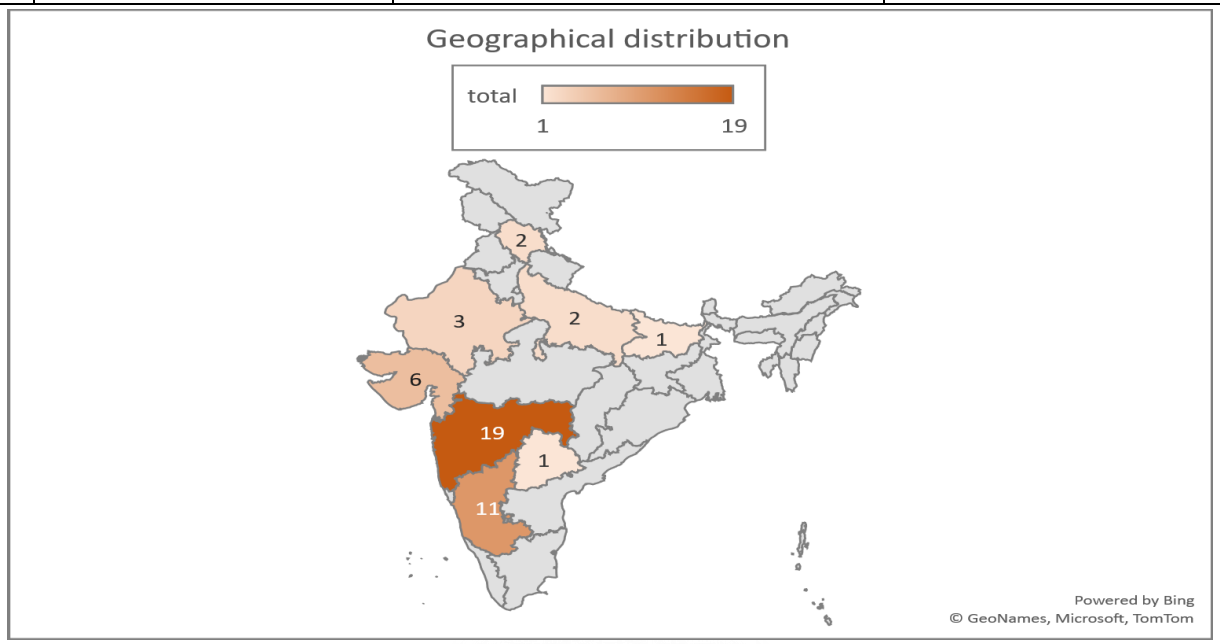

Figure 4.1 Geographical distribution of *Shushkakshipaka*

Details of Ayurveda studies

Table 3

Details of Intervention	**(n)**	**Percentage (%)**
Tarpan	7	13.72
Aschotan	16	31.37
Anjana	11+ 1 (ointment form)	23.52
Seka	9	17.64
Nasya	8	15.68
Basti	1	1.96
Intervention used		
1. Kriyakalpa	34	66.66
2. Kriyakalpa with *Abhyantar Pana*	12	23.52
3. Abhyantar pana only	3	5.88

Table 4

***Shushkakshipaka* comparison in study**	**Total**	**Percentage (%)**
Meibomian gland dysfunction	3	5.88
Dry Eye Syndrome	28	54.90
Computer Vision Syndrome	6	11.76
Evaporative Dry Eye	2	3.92
Computer and visual display terminal vision syndrome	2	3.92
Dry Eye	6	11.76
Dry Eye Disease	3	5.88
Digital Eye Strain	1	1.96

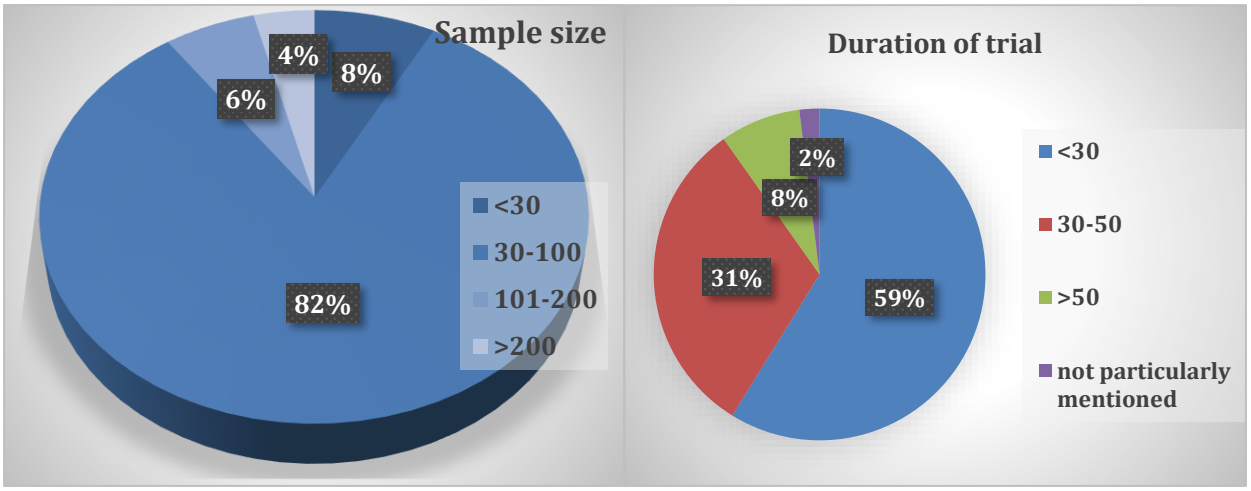

Fig 4.2 Sample size distribution fig 4.3-Distribution according to Duration of Trial

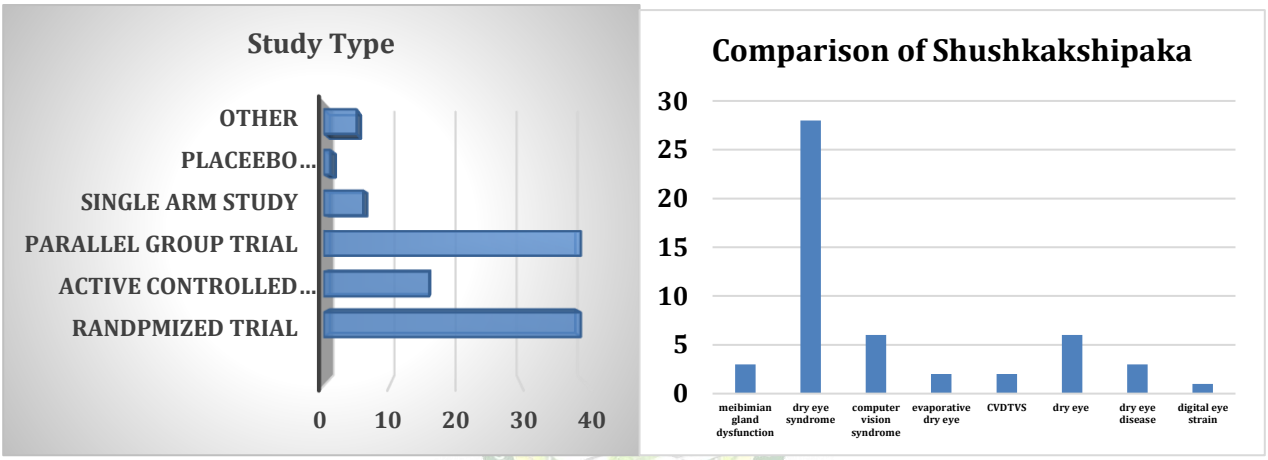

Fig 4.4 Distribution according to Study type Fig 4.5- Comparison of *Shushkakshipaka*

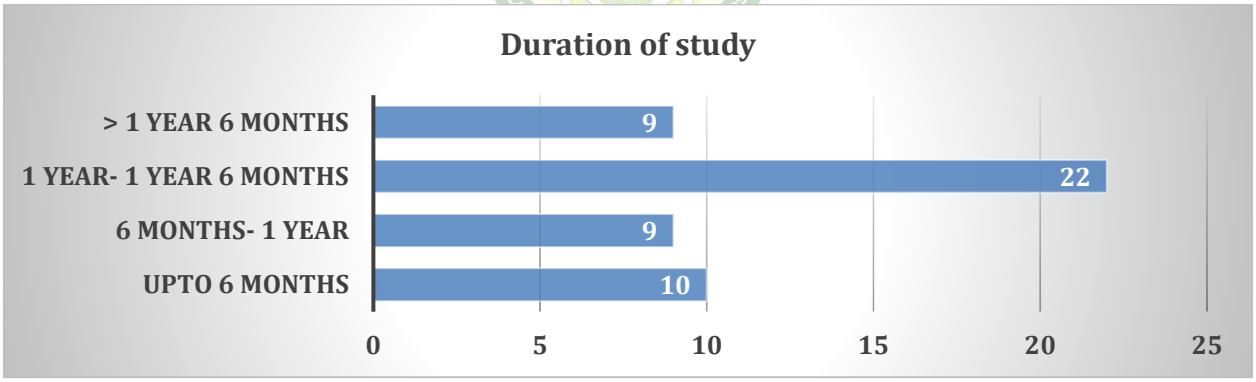

Fig 4.6 Classification according to Duration of Study

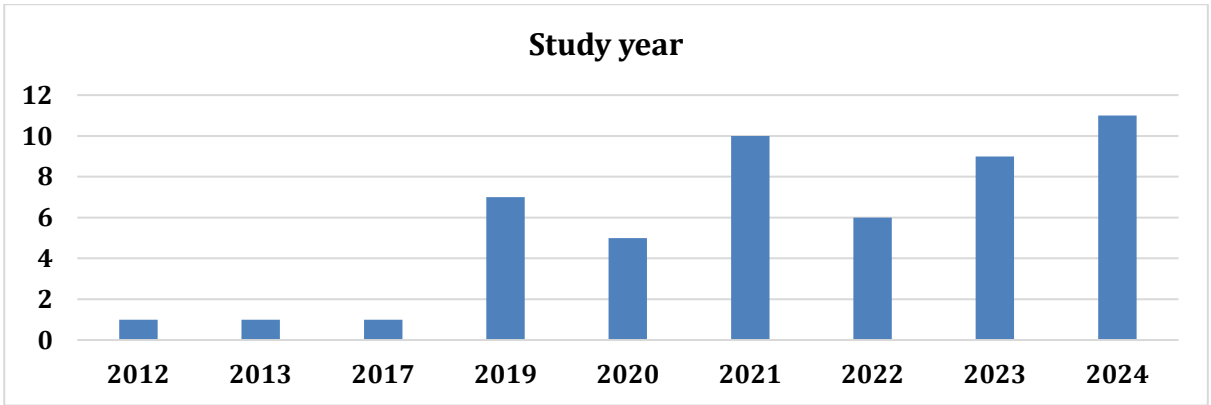

Fig 4.7 Distribution according to study year

Table 5

S.no.	Details of Intervention	Frequency of Intervention
1	*Ghrutpana*	5
2	*Shadang guggul*	3
3	*Guduchyadi ghanvati*	1
4	*Nasya- anu tail*	5
5	*Anjan -vasanjan* *Keshanjan* *Saindhavadi* *Haridradi siddha ghrita* *Yashtivara ghrita* *Haridradi* *Shushkakshipakahar* *Haridradarvyadi*	2 2 2 1 1 1 1 1
6	*Bidalaka*	2
7	*Aschotan - Manjisthadi siddha ghrita* *Rajanyadi* *Punarnava ghrita* *Draksha ghrita* *Shusnthyadi* *Ghrutkumaryadi* *Guduchi kheerpaka* *Lakshadi* *Goghrita* *Jivaniya ghrita* *Drakshadi ghrita* *Rajani daru* *Shigru arka*	1 1 2 1 1 1 1 1 1 1 2 1 1
8	*Seka - Bilwadi* *Triphaladi kwath* *Haridradi* *Rajanyadi ksheerpaka* *Yashtimadhu Ksheerpaka*	1 1 1 1 2
9	*Tarpan - yashtimadhu ghrita* *Mudgaparni ghrita* *Jivaniya panchamul ghrita* *Chakshushya ghrita* *Jivantyadi ghrita* *Yashtimadhu Ksheerpaka*	2 1 1 1 1 1
10	*Matra basti - yashtimadhu ghrita*	1
11	*Bibhitakadi* eye ointment	1

RESULT

We studied 51 trials from Ayurveda stream related to *Shushkakshipaka* that were registered with CTRI during the review. All studies are interventional type. The records said that these studies were conducted at 51 sites. As per geographical distribution, the maximum number of sites are in Maharashtra [n–19]. 39.75%, most of the study conducted as randomized trial (n-39), parallel group trials (n-39). Conducted as double arm study 76.47%. Most of the study *Shushkakshipaka* related studies registered on CTRI is maximum in year 2024 (n-11). There are 22 studies having age group in between 1 year and 1 year 6

months i.e. 43.13%. Maximum studies conducted in age group between 18-60 years of age (n-39) i.e., 76.47%. There were 34 studies including *Kriyakalpa* as intervention i.e., 66.66%.

DISCUSSION

The present review was taken out to assess the features of Ayurveda clinical trials registered with CTRI for *Shushkakshipaka* of 12 years. Our reviews considered Ayurveda studies, Interventional and observational, registered till July 2024. For registering any study with CTRI, approval from the Ethics Committee is a precondition. So, it is assumed that the ethics related to these age groups must have been adequately taken care of by respective committees.

Study types and designs

All 51 Ayurveda studies were of interventional type. It is a very positive signal that Ayurveda systems are being propagated for the treatment of *Shushkakshipaka*. The important characteristics of studies revealed maximum double-arm studies (n-39). Ayurveda interventions compared with conventional care (n-18), sample size ranging from 30-100 (n-42) including multidrug formulation and multi-formulation regimen.

In maximum studies (n-42), sample size is somewhere in the range of 30-100. In 22 studies the study duration was 1 year-1 year 6 months while in 33 studies treatment span was below 30 days. This period has been found good considering the clinical recovery time of the illness.

In these studies, the population was involved (n-39) between the age group 18 to 60 years. While no population is under 18 years and the population above 60 years is 12. But the majority affects the younger population.

Interventions

If there should arise an occurrence of interventions, more inclinations are given to multi-drug plans and formulation regimes presumably, as it is mentioned in the AYUSH protocol. The therapeutic procedure used in many cases is *Tarpan/Aschotan/ Seka/Anjan/Nasya/Basti* as it is a very useful procedure in *Shushkakshipaka*. Of the medications utilized in Ayurveda, *Jivantyadi Ghrita* and *Triphala Ghrita* combined and *Daruharidradi* drugs stay the most often as possible utilized medications.

CONCLUSION

The present review is an attempt to analyze the CTRI-registered *Shushkakshipaka* clinical trials, which show the general characteristics of trials along with study design and setups. There were 66.66% studies including *Kriyakalpa* as intervention than oral medicines. 39.75% studies conducted in Maharashtra. 54.90% studies compared with dry eye syndrome in which interventional studies were more than observational studies. Research findings indicate that *Aschotan*, a specific *Kriyakalpa* procedure, is more frequently employed than other *Kriyakalpa* methods, highlighting its potential therapeutic value in the management of ocular disorders. One study done on *Matra Basti* with *Yashtimadhu Taila*. Although there is a surge of clinical trials on CTRI regarding Ayurveda for *Shushkakshipaka*, the methodological information is not more elaborative and there is large scope for improvement. The CTRI database does not provide the outcome of trial but this article could be used as baseline reference for further futural research in *Shushkakshipaka.*

Limitations

The present study highlighted the CTRI registered trials only and their evaluation as general characteristics. The Dry Eye Syndrome is highly prevalent in developing countries with the habit of screen work. Many countries have their trial registry affiliated to WHO and these registries should also be taken into consideration in terms of Ayurveda clinical trials. The current review was completed based on information accessible on CTRI. CTRI does not include a SPIRIT checklist so drawing conclusions based on incomplete datasets or trials that are open is difficult. Bias assessment can be done in completed published studies. This study involves only CTRI registered study hence bias assessment was not possible. It is one of the limitations of the study.

Implications

Over the time of nearly 12 years, the information and proof regarding management of *Shushkakshipaka* remains restricted. Our reviews have compactly summed up all potential qualities of *Ayurveda* trials on utilizing the information accessible on CTRI. We can look hopefully some of these characteristics will work with the planning of future studies. As the duration of these studies is long, their outcomes will be accessible. It would be imperative to realize the number of and how effectively these studies were or will be executed. Further, the results of these investigations will state more about their effects and commitment to the Ayurveda framework towards *Shushkakshipaka*. Lastly, the quantity of Ayurveda studies enlisted with CTRI shows an ever-evolving change towards proof-based medication.

Declaration of generative AI in scientific writing

We hereby declare that the manuscript is entirely the original work. I affirm that no generative AI tools or artificial intelligence applications were used in any part of the manuscript preparation, including drafting, editing, or data analysis. All scientific content, conclusions, and language within the manuscript have been developed through our expertise and efforts and by our mentor's guidance as per JAIM requirement.

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