



# Safety and Prescription Trends of *Rasa Aushadhis* (Ayurveda Herbomineral Formulations): A Critical Appraisal of Reported Medical Practices from CCRAS Experience

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## Abstract

**Background:** In *Ayurveda*, metal and mineral-based formulations are popularly practised for their pleasant applicability and first-rate potency. There is no doubt about the safety and potency of *Ayurveda Rasa Aushadhis* if they are prepared and used as per the terms mentioned in the literature. For the globalisation of *Ayurveda*, safety and efficacy with quality control have become important affairs for the scientific presentation of truth/reality. The present study was undertaken to document and analyse the information from clinical records about gross safety and prescription trends of different *Ayurveda Rasa Aushadhis*. **Methodology:** Primary data collection was performed from 24 clinical centres of CCRAS through a prescribed format. Prescription records of patients during the last five years (1<sup>st</sup> April 2012 to 31<sup>st</sup> March 2017); irrespective of age, sex and religion, were analysed. Evaluation of these clinical records confined to prescription trends and consumption of 15 commonly prescribed *Rasa Aushadhis* (herbs-mineral formulations) was done to infer. **Result and Observation:** Overall, 1,09,307 patients were treated with prescribed *Rasa Aushadhis*, and there were no Adverse Drug Reactions (ADR) or Suspected Adverse Reactions (SAR) or any untoward effects associated with the prescribed *Rasa Aushadhis*, during the full course of treatments as well as later/after follow-up. Analysis shows the conditions of clinical application of the *Rasa Aushadhis* were duly based on fundamental concepts of *Ayurveda*. **Conclusion:** Based on retrieved data from reported medical practices of *Rasa Aushadhis* in different clinical research facilities, the present study reveals the safety and rationale of using 15 commonly used *Rasa Aushadhis* across India. The study would certainly disseminate the merits of Ayurvedic *Rasa Aushadhis* in understanding gross safety and potency.

**Keywords:** *Ayurveda*, Herbomineral, Metal and Mineral, Prescription Trends, *Rasa Aushadhis*

## 1. Introduction

The tradition of *Ayurveda* has helped millions of people achieve healthier lives. Owing to its novel healing approaches, this heritage system of medicine has extended its splendour and demand globally<sup>1-4</sup>. The safety of medicines and treatments has always been of high precedence in the practice of *Ayurveda*. It is possibly the primitive system of medicine to have developed the

parameters to assess the safety and efficacy of a drug<sup>5,6</sup>. In *Ayurveda*, a therapy or medicine that alleviates one disease but generates another one is considered to be *Ashuddha* (impure)<sup>7</sup>. Acharya Charaka has mentioned, "Even a strong poison can become a potent medicine if administered properly; on the other hand, even the most useful medicine can act like a poison if handled imperfectly" which is an unwavering verse among all disciplines of medicine<sup>8</sup>. Ancient scholars have warned

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that appropriately used medicine becomes nectar and improperly used medicines act as poisonous<sup>9</sup>. Therefore, to take full advantage of the usage of potential sources of traditional healthcare, there is a need to draw attention to several issues related to policy on safety, efficacy, quality, accessibility, and rational use<sup>10</sup>. Considering this, the present study was undertaken to document and analyse the information from clinical records about gross safety and prescription trends of different *Ayurveda Rasa Aushadhis* among different populations across the country. The study's primary objectives were to critically analyse available data from clinical records of 24 CCRAS clinical research facilities during the last five years, i.e. (1<sup>st</sup> April 2012 to 31<sup>st</sup> March 2017); to document and analyse the information in a structured format to draw the meaningful possible outcomes and conclusions and to develop an Ayurvedic informatics database in a reverse way to substantiate and identify superiority and lacunae in terms of gross safety indicators and prescription trends of 15 commonly practised *Ayurveda Rasa Aushadhis*. Primary data was collected from patients' CCRAS clinics/ hospitals (OPDs) prescription records during the last five years (1<sup>st</sup> April 2012 to 31<sup>st</sup> March 2017), irrespective of age, sex and religion. Evaluation of these clinical OPD records is confined to prescription trends and consumption of 15 common *Rasa Aushadhis* (herbs-mineral formulations) for at least three days. The reason behind selecting the 15 *Rasa Aushadhis* was that Ayurvedic physicians most commonly and most frequently prescribe these. The study has covered 21 States/UTs of India under different geographical locations.

## 2. Methodology

### 2.1 Design and Method

The study aimed to critical analysis of available data from clinical records of 24 CCRAS clinical research facilities during the last five years i.e. (1<sup>st</sup> April 2012 to 31<sup>st</sup> March 2017). The data was collected through a prescribed format based on various parameters such as age of patients, sex, dose, *Anupana*, dosage form, duration of treatment, drug-related adverse reaction (if any), reaction type, Suspected Adverse Effect (SAE) and number of diseases in which drug was prescribed. The information w.r.t 15 *Rasa Aushadhis* namely *Agnitundi*

*vati*, *Arogyavardhini vati*, *Chandaprabha vati*, *Dhatri lauha*, *Kamadhudha rasa*, *Krimimudgara rasa*, *Laxmivilasa rasa*, *Mahayogaraja guggulu*, *Punarnava mandoora*, *Shirashooladivajra rasa*, *Simhanada guggulu*, *Sutashekhara rasa*, *Shwasakuthars rasa*, *Tribhuvanskirti rasa* and *Vatagajankusha rasa* have been retrieved from the record of overall 1,09,307 OPD patients. The study procedure was limited to review and documentation of existing clinical prescription records for reporting safety and prescription trends, only 15 broad spectrum, most commonly prescribed in OPDs, uniformly procured by all 24 CCRAS's Clinical Institutes Ayurvedic *Rasa Aushadhis*. The total effect of drug or intervention therapy was assessed regarding patients reporting improved signs and symptoms before and after the treatment.

### 2.2 Ethical Declaration

The study was conducted by ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2017) and that are consistent with Indian/ICH Good Clinical Practices (GCP) guidelines. Before the commencement of the trial, the data retrieval proforma and reporting form were submitted to the Institutional Ethics Committees (IECs). The written approval of the same was obtained from the IEC of each participating institute.

## 3. Result and Observation

The study found all 15 classical *Rasa Aushadhis* were prescribed at variant doses with *Anupana* in different geographical areas of the country, as per the conditions of *Roga/vyadhi* (disease) and *Rogi* (patients) based on the assessment/clinical experiences of the physicians. Analysis shows the conditions of clinical application of the *Rasa Aushadhis* were duly based on fundamental concepts of *Ayurveda* (i.e. individualistic approach). Analysing the safety aspects of the prescribed *Rasa Aushadhis* highlights that none of the patients (among overall 1,09,307 patients) treated with the *Rasa Aushadhis* had complained of any kind of Adverse Drug Reactions (ADR) or Adverse Events (AE) and Serious Adverse Event (SAE), during treatments as well as during later/follow-up. The detail of prescribed *Rasa Aushadhis* with their core safety outcome is presented in Table 1.

**Table 1.** Details of prescribed *Rasa Aushdhis* with their safety analysis in the present study

S. No.	Name of <i>Rasa Aushdhis</i>	Prescribed dose	Prescribed <i>Anupama</i>	ADR Observed	Reaction Type	Adverse Event (SE)
1	<i>Agnitundi Vati</i> [AFI Part-I, 12:1, Pg-181] <i>Bhaisajya Ratnavali (Agni mandyargadhikara)</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
2	<i>Arogyavardhini Vati</i> [AFI Part-I, 20:4, Pg-258] <i>Rasa ratna samucchaya Visarpadi chikitsa 20/106-1080</i>	1-2 tablets (250-500 mg), BD / TDS	Luke warm water/ <i>Maharasnadi Kwatha/ Triushnadi Kwatha, Nimb tvak Kwatha/ Dashamula Bala kashaya</i>	Nil	Nil	Nil
3	<i>Chandraprabha Vati</i> [AFI Part-I, 12:10, Pg-185] <i>Shrangadharasamhita, Madhyama khanda-7/40-44</i>	1-2 tablets (250-500 mg), BD / TDS	Water/Luke warm water/Honey	Nil	Nil	Nil
4	<i>Dhatri Lauha</i> [AFI Part-I, 21:2, Pg-284] <i>Bhaisajya Ratnavali, Shulrogadhikar-142-143½</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
5	<i>Kamdudha Rasa</i> [AFI Part-II, 16:9, Pg-234] <i>Rasatantra sara va siddha prayog sangraha; kharaliya rasayana; 80</i>	1-2 tablets (125-500 mg), BD/TDS	Water/Luke warm water	Nil	Nil	Nil
6	<i>Krimimudgara Rasa</i> [AFI Part-I, 20:10, Pg-260] <i>Rasendra sarsamgraha, Krimi chikitsa-14</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
7	<i>Laxmivilasa Rasa</i> [AFI Part-I, 20:39, Pg-272] <i>Bhaishajya Ratnavali, Rasayanadhikar-55-58</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water/Honey/ Adrakasvarasa	Nil	Nil	Nil
8	<i>Maha Yograj Guggulu</i> [AFI Part-I, 5:6, Pg-68] <i>Shrangadharasamhita, Madhyam khanda-7/56-60</i>	1-4 tablets (250-500 mg), BD/TDS	Water/Luke warm water/Honey	Nil	Nil	Nil
9	<i>Punarnava Mandoora</i> [AFI Part-I, 19:1, Pg-251] <i>Charaksamhita, Chikitsasthana-16/93-95</i>	1-2 Tablets (125/250 mg), BD/TDS	Water/Luke warm water	Nil	Nil	Nil
10	<i>Shirahsuladivajra Rasa</i> [AFI Part-II, 16:59, Pg-288] <i>Bhaishajya Ratnavali, Sira roga dhikar, 140-144</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
11	<i>Simhanada Guggulu</i> [AFI Part-I, 5:12, Pg-71] <i>Bhaisajyaratnavali, Amavata dhikara-130-131</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
12	<i>Sutashekhara Rasa</i> [AFI Part-I, 20:52, Pg-278] <i>Yogaratanakar, Amlapitta chikitsa, Pg-705</i>	1-2 tablets (125/250), BD/ TDS	Water/Luke warm water/warm water/ Honey/Haridra Swaras	Nil	Nil	Nil
13	<i>Swasakuthara Rasa</i> [AFI Part-I, 20:49, Pg-277] <i>Yogratnakara, Swasa chikitsa, Pg-373</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil
14	<i>Tribhuvana Kirti Rasa</i> [AFI Part-I, 20:20, Pg-263] <i>Rasamrita, Adhaya-9/80-80½</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water/Honey	Nil	Nil	Nil
15	<i>Vatagajankusha Rasa</i> [AFI Part-II, 16:57, Pg-286] <i>Bhaishajya Ratnavali, Vatavyadhi roga dhikar, 488-492</i>	1-2 tablets (125-250 mg), BD / TDS	Water/Luke warm water	Nil	Nil	Nil

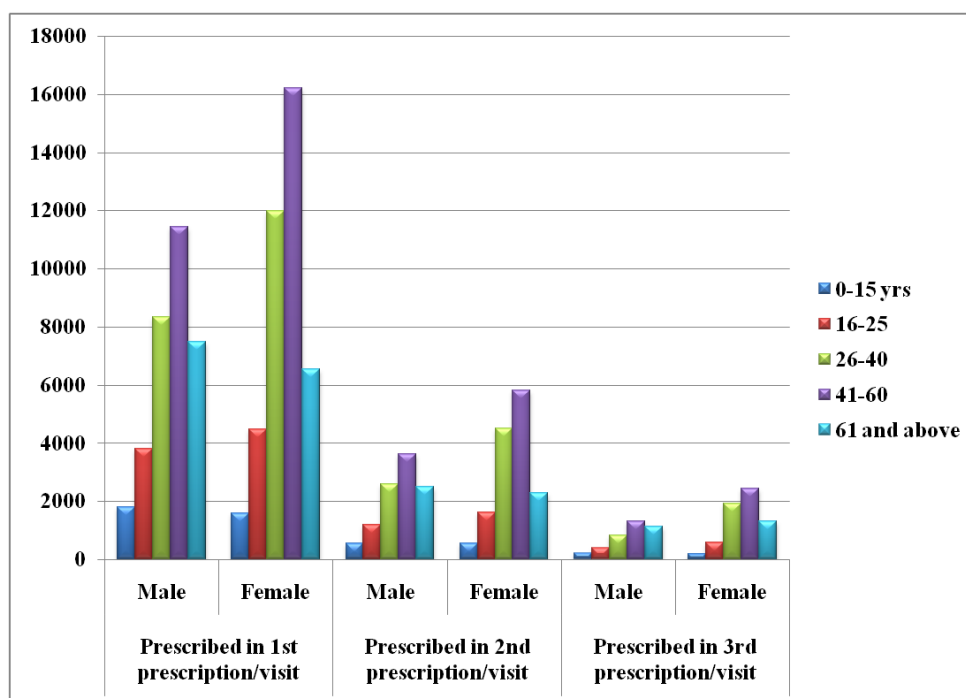
Figure 1 shows age and sex-wise analysis of data/patients attended in the OPDs of all the institutes. Data shows a maximum number of female patients were treated with *Rasa Aushadhis* in OPDs label. The maximum number of patients was in the 41-60 age group, followed by the 26-40 age group.

Figure 2 shows the total number of patients treated with different *Rasa Aushadhis* in OPDs of the selected institutes. Here, data shows that 17,196 patients were treated with *Arogyavardhini Vati*, 14,974 were treated with *Punarnava Mandoor*, and 12,427 were treated with *Sutashekhar Rasa*. Meanwhile, 11,807 patients were treated with *Chandraprabha Vati*, and 10,175 patients were treated with *Dhatri Lauha* in OPDs.

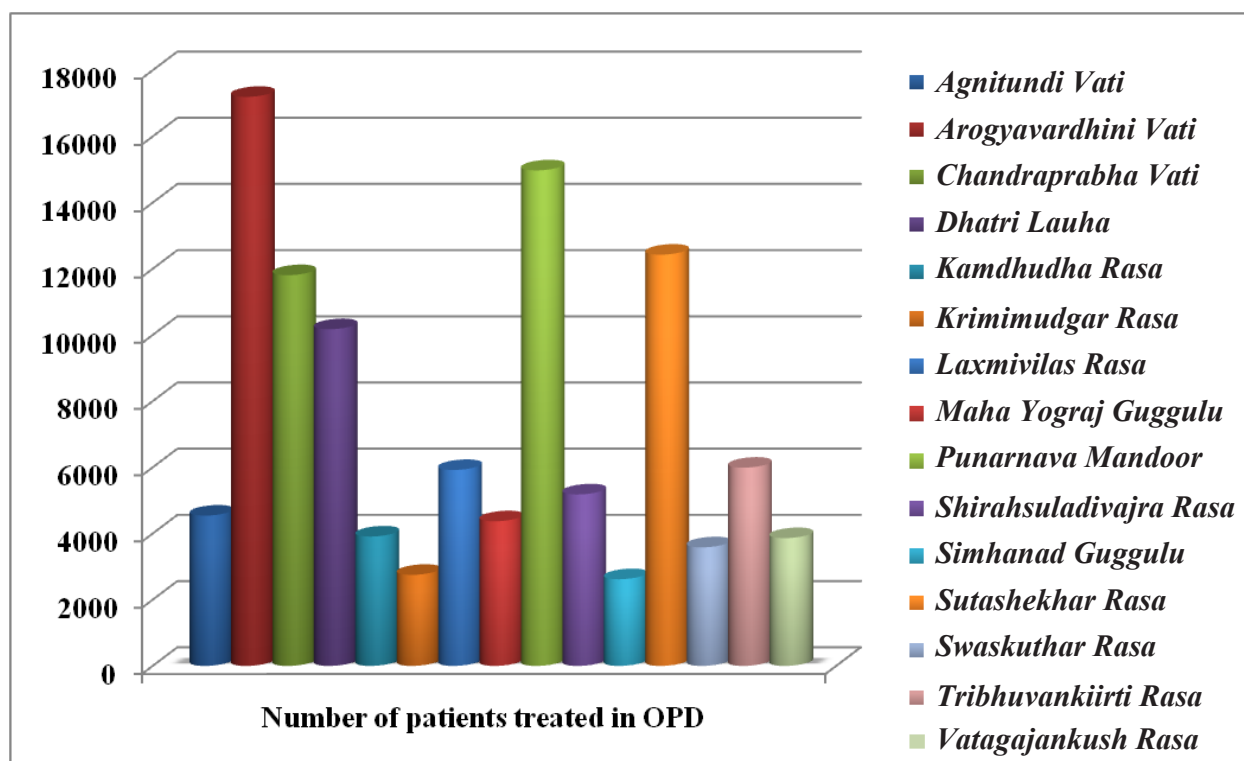
The study shows a maximum of 35,967 patients continued the prescribed *Rasa Aushadhis* for up to 2 weeks whereas 9,412 patients followed the *Rasa Aushadhis* treatment for more than 12 weeks (Table 2). Data shows that 4,456 patients consumed *Arogyavardhini Vati* for up to 1 week, followed by 2874 patients who consumed *Punarnava Mandoor*. A maximum of 5827 patients consumed *Arogyavardhini Vati* for up to 2 weeks, followed by 5749 patients who consumed *Punarnava Mandoor* for up to 2 weeks. Data analysis for up to 4 weeks shows a maximum of 2752 patients consuming *Arogyavardhini Vati*,

followed by 2268 patients consuming *Chandraprabha Vati*. Likewise, *Sutashekhar Rasa* was the maximum consumed (4176 patients) *Rasaushadhi* upto 8 weeks. Three *Rasa Aushadhis*, namely *Punarnava Mandoor* (2078 patients), *Arogyavardhini Vati* (1414 patients) and *Dhatri Lauha* (1187 patients) were consumed more than 12 weeks in comparison to other *Rasa Aushadhis*, and a large number of patients (9412) were prescribed *Rasa Aushadhis* more than 12 weeks (Table 3).

Data on prescription trends of *Rasa Aushadhis* shows that out of 1,09,307 patients treated in OPDs, 73,677 (67.40%) patients were prescribed *Rasa Aushadhis* on their first visit, 25269 (23.12%) on the second visit and only 10361 (9.47%) patients in the third visit. While analysing the individual *Rasaushadhi* data shows *Arogyavardhini Vati* (prescribed to 12,565 patients out of a total of 73,677 patients prescribed overall *Rasa Aushadhis* in their first prescription/visit) was the maximum choice of prescribed *Rasaushadhi* at first visit/first prescription of the patients. At the same time, *Punarnava Mandoor* was the most prescribed *Rasaushadhi* (prescribed to 3,710 patients out of a total of 25,269 patients) on the second as well as third time (prescribed for 1776 patients out of a total of 10,361 patients) visit/prescription of the patients (Table 4).



**Figure 1.** Age and sex-wise distribution of patients attended in OPDs.



**Figure 2.** Total number of patients treated with different *Rasa Aushadhis*.

**Table 2.** Distribution of patients according to duration of treatment in OPDs

Duration	Number of patients			Total
	Prescribed in 1 <sup>st</sup> prescription/visit	Prescribed in 2 <sup>nd</sup> prescription/visit	Prescribed in 3 <sup>rd</sup> prescription/visit	
Up to one week (7 Days)	15623	5144	2200	22967
Up to 2 weeks (14 Days)	23742	8576	3649	35967
Up to 4 weeks (28 Days)	11602	3706	1543	16851
Up to 8 weeks (56 Days)	14438	4646	1595	20679
Up to 12 weeks (84 Days)	2177	862	392	3431
More than 12 weeks (more than 84 Days)	6095	2335	982	9412
<b>Total</b>	<b>73677</b>	<b>25269</b>	<b>10361</b>	<b>109307</b>

## 4. Discussion

The ancient scholars of *Ayurveda* were most innovative and dynamic in their healing practices. They discovered newer medicines by mingling philosophical principles and clinical trials<sup>11</sup>. From the beginning, *Ayurveda* has concentrated on the area of toxicity and safety with all-encompassing clinical judgment. The untoward effects of treatments are also thoroughly described in

the texts, and iatrogenic diseases caused by improper treatment are described incredibly well in the early hours of the evolutionary history of *Ayurveda*<sup>12,13</sup>. Numbers of listed antidotes are available in classics for many commonly known poisons from both the animal and plant kingdom. Various rationale methods were developed to reduce the toxic effects of *Ayurveda* metal and mineral-based formulations as well as to enhance their therapeutic potential<sup>14-16</sup>. The core analyses of the

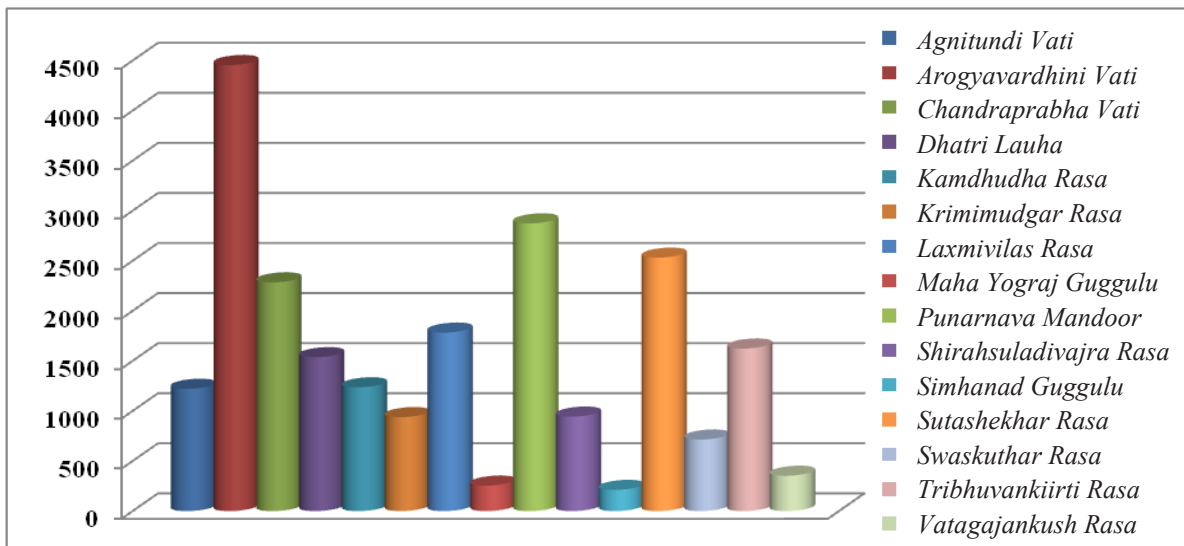


**Table 3.** Distribution of patients according to the duration of treatment with respective *Rasa Aushadhis*

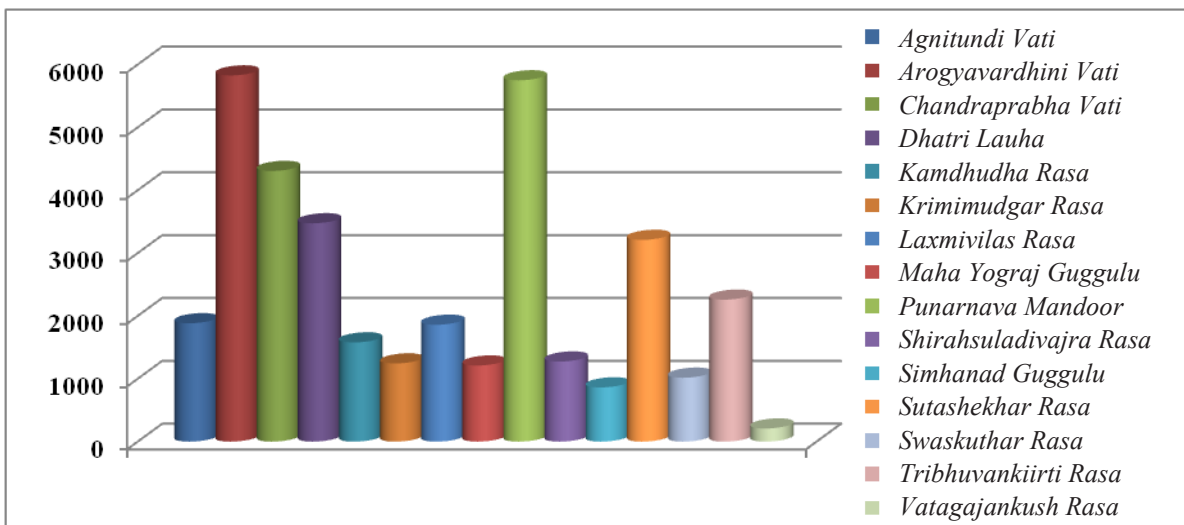
S. No.	Name of <i>Rasa Aushadhis</i>	Duration of Treatment						Total
		Up to 1 week (7 Days)	Up to 2 weeks (14 Days)	Up to 4 weeks (28 Days)	Up to 8 weeks (56 Days)	Up to 12 weeks (84 Days)	More than 12 weeks	
1.	<i>Agnitundi Vati</i>	1222	1884	559	357	172	347	<b>4541</b>
2.	<i>Arogyavardhini Vati</i>	4456	5827	2752	2253	494	1414	<b>17196</b>
3.	<i>Chandraprabha Vati</i>	2285	4307	2268	1620	354	973	<b>11807</b>
4.	<i>Dhatri Lauha</i>	1537	3474	1957	1638	382	1187	<b>10175</b>
5.	<i>Kamdudha Rasa</i>	1237	1579	522	265	100	207	<b>3910</b>
6.	<i>Krimimudgar Rasa</i>	939	1244	204	149	40	175	<b>2751</b>
7.	<i>Laxmivilas Rasa</i>	1783	1860	758	802	145	572	<b>5920</b>
8.	<i>Maha Yograj Guggulu</i>	255	1211	656	2037	103	108	<b>4370</b>
9.	<i>Punarnava Mandoor</i>	2874	5749	1962	1537	774	2078	<b>14974</b>
10.	<i>Shirahsuladivajra Rasa</i>	944	1274	680	1456	189	639	<b>5182</b>
11.	<i>Simhanad Guggulu</i>	212	863	550	737	82	176	<b>2620</b>
12.	<i>Sutashekhar Rasa</i>	2531	3210	1630	4176	253	627	<b>12427</b>
13.	<i>Swaskuthar Rasa</i>	715	1017	611	880	100	260	<b>3583</b>
14.	<i>Tribhuvankiirti Rasa</i>	1624	2259	849	509	177	572	<b>5990</b>
15.	<i>Vatagajankush Rasa</i>	353	209	893	2263	66	77	<b>3861</b>
	<b>Total</b>	<b>22967</b>	<b>35967</b>	<b>16851</b>	<b>20679</b>	<b>3431</b>	<b>9412</b>	<b>109307</b>

**Table 4.** Overall trends of prescription of *Rasa Aushadhis*

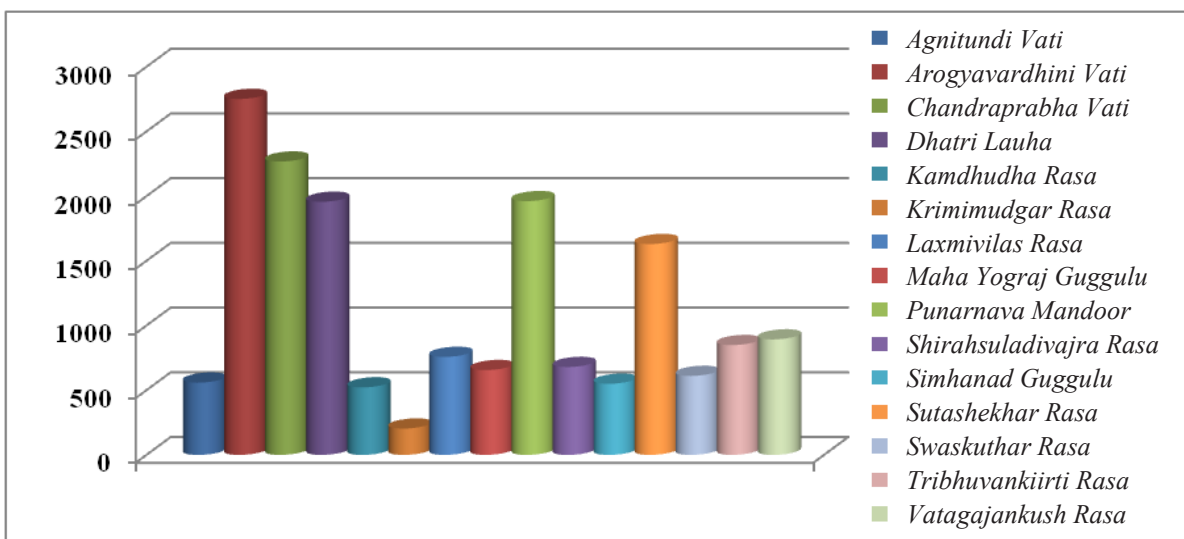
Sr. no.	Name of <i>Rasa Aushadhis</i>	Prescribed in 1 <sup>st</sup> prescription/visit	Prescribed in 2 <sup>nd</sup> prescription/visit	Prescribed in 3 <sup>rd</sup> prescription/visit	Total
1.	<i>Agnitundi Vati</i>	2603	1189	749	4541
2.	<i>Arogyavardhini Vati</i>	12565	3197	1434	17196
3.	<i>Chandraprabha Vati</i>	8907	2193	707	11807
4.	<i>Dhatri Lauha</i>	6082	2883	1210	10175
5.	<i>Kamdudha Rasa</i>	2186	1107	617	3910
6.	<i>Krimimudgar Rasa</i>	1463	821	567	2751
7.	<i>Laxmivilas Rasa</i>	3723	1617	580	5920
8.	<i>Maha Yograj Guggulu</i>	3040	920	410	4370
9.	<i>Punarnava Mandoor</i>	9488	3710	1776	14974
10.	<i>Shirahsuladivajra Rasa</i>	3744	1003	435	5182
11.	<i>SimhanadGuggulu</i>	2056	462	102	2620
12.	<i>Sutashekhar Rasa</i>	8437	3136	854	12427
13.	<i>Swaskuthar Rasa</i>	2648	659	276	3583
14.	<i>Tribhuvankiirti Rasa</i>	3922	1447	621	5990
15.	<i>Vatagajankush Rasa</i>	2813	925	123	3861
	<b>Total</b>	<b>73677</b>	<b>25269</b>	<b>10361</b>	<b>109307</b>



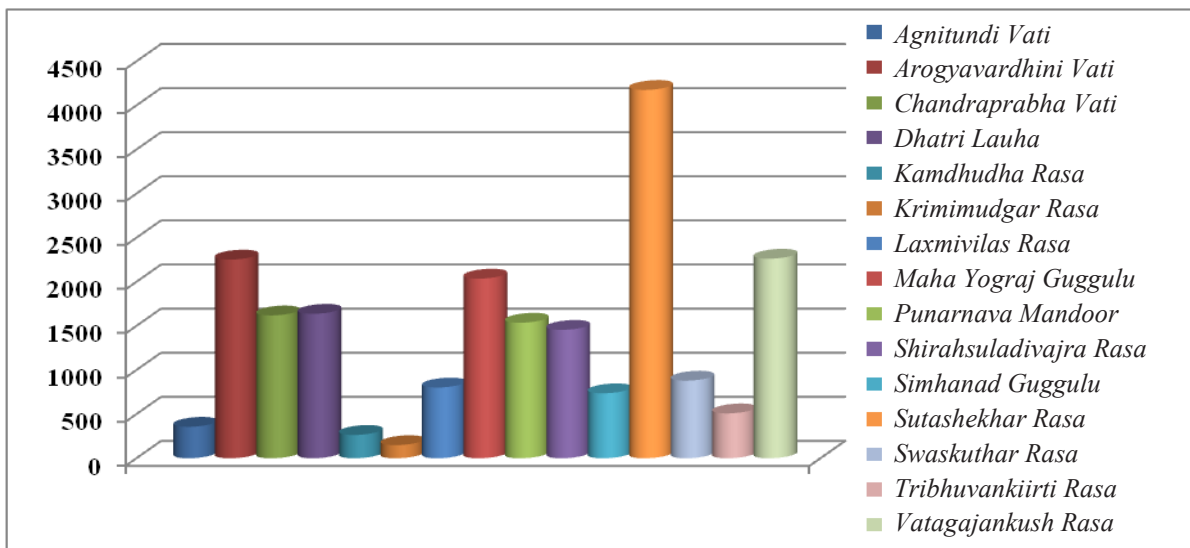
**Figure 3.** Total patients consumed respective *Rasa Aushadhis* for up to one week.



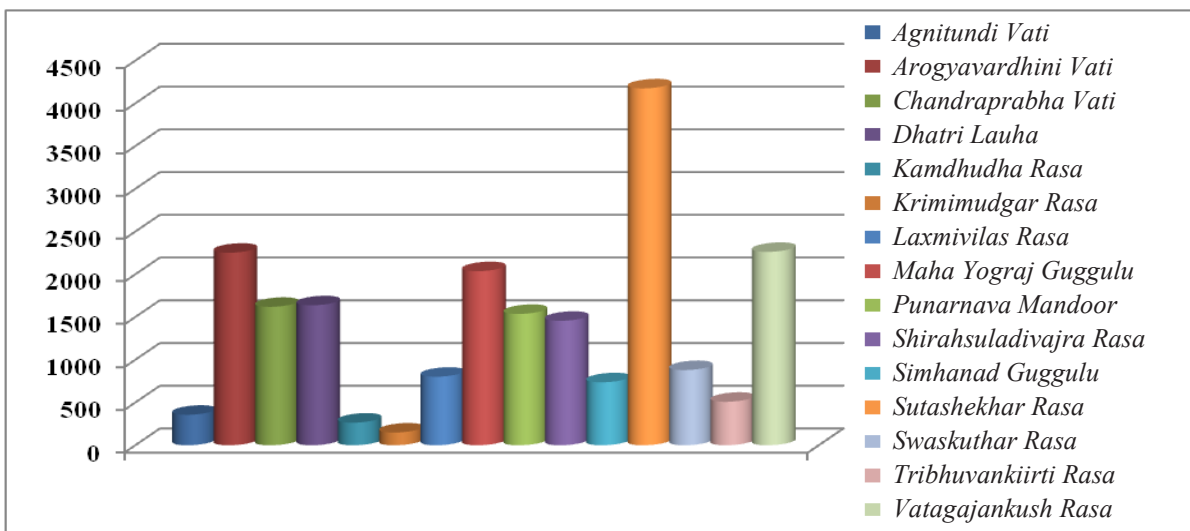
**Figure 4.** Total patients consumed respective *Rasa Aushadhis* for up to two weeks.



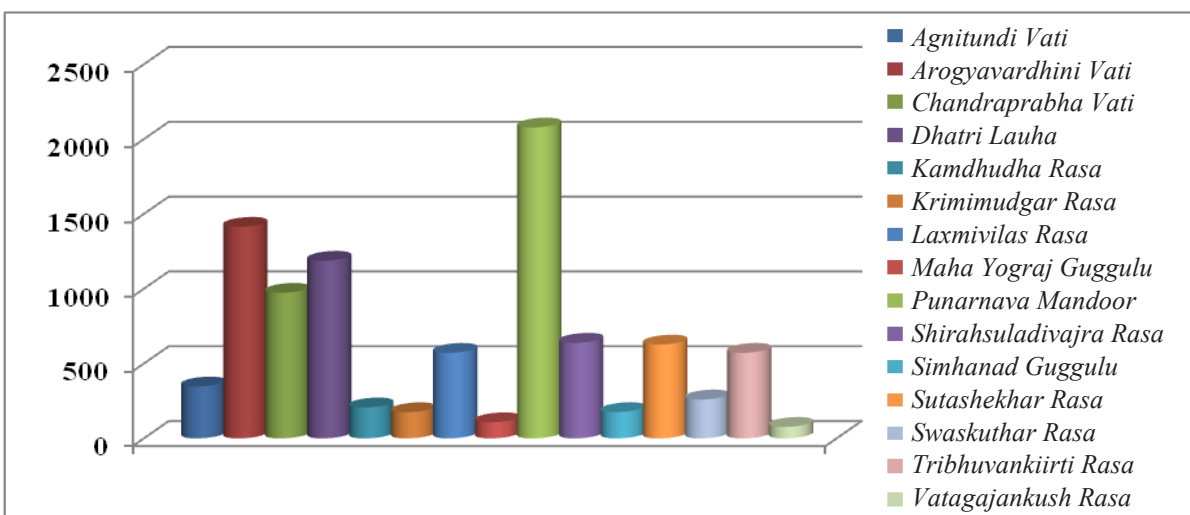
**Figure 5.** Total patients consumed respective *Rasa Aushadhis* for up to four weeks.



**Figure 6.** Total patients consumed respective *Rasa Aushadhis* for up to 8 weeks.



**Figure 7.** Total patients consumed respective *Rasa Aushadhis* for up to 12 weeks.



**Figure 8.** Total patients consumed respective *Rasa Aushadhis* for more than 12 weeks.



present study highlight that overall 1,09,307 patients were treated with selected *Rasa Aushadhis* during 2012-2017. There were no signs/symptoms or any kind of complaints noticed or recorded about any Adverse Drug Reactions (ADR) or Adverse Reactions (AE) associated with the prescribed *Rasa Aushadhis* during treatment as well as later/ after follow-up<sup>17</sup>.

The age and sex-wise analysis of data/ patients who attended the OPDs of all the institutes shows a maximum number of female patients were treated with *Rasa Aushadhis*. Most of the patients were in between the 41-60 years age group, followed by the 26-40 years of age group (Figure 1). The reason behind more female patients found in *Rasa Aushadhis* treatment may be due to the nascent popularity of *Rasa Aushadhis* in chronic female/gynaecological disorders (*Yonivyapad*). The study shows several female patients with gynaecological ailments such as *Artavadushti/Rajadosha* (menstrual disorders), *Swetpradara* (leucorrhoea), *Raktapradara* (menorrhagia/ metrorrhagia/ dysfunctional uterine bleeding), *Artavakshaya* (oligomenorrhoea) were treated with *Rasa Aushadhis*. The reason behind the maximum number of patients falling in the 41-60 years group may be because the 41-60 years group is crucial for afflicting with several pathological conditions, including senile disorders, which are, in fact, manageable by the different *Rasa Aushadhis*<sup>18</sup>.

For analysing the prescription trends, all the patients were categorised into three groups as per their visit/ prescription of *Rasa Aushadhis* (i.e. prescribed in 1<sup>st</sup> prescription or visit, 2<sup>nd</sup> visit, and 3<sup>rd</sup> visit). The data of total number of patients treated with different *Rasa Aushadhis* in OPDs of the selected institutes shows a maximum of 17,196 patients were treated with *Arogyavardhini Vati*, followed by 14,974 patients were treated with *Punarnava Mandoor* and 12,427 patients were treated with *Sutashekhar Rasa*. Meanwhile, 11,807 patients were treated with *Chandraprabha Vati*, and 10,175 patients were treated with *Dhatri Lauha* (Table 4).

While analysing the individual-prescribed *Rasa Aushadhis*, it is found that *Arogyavardhini Vati* is one of the most preferred *Rasaushadhi* among the *Ayurveda Rasavaidyas* (Figures 3 to 8). Though the formulation is mentioned in *Rasaratnasamucchaya* under *Visarpadi chikitsa*, it is famous for its multi-dimensional indications. The medicine is praised by Acharya

Nagarjuna and quoted as '*Sarvarogaprashamani*', i.e., the medicine that is useful in all the pathological conditions of the body<sup>19</sup>. Therefore, in the present study also, *Arogyavardhini Vati* was found the most prescribed *Rasa Aushadhis*.

Data of overall prescription trends of *Rasa Aushadhis* shows a maximum of 73,677 patients attended in the OPDs were advised for *Rasa Aushadhis* treatment in their 1<sup>st</sup> prescription/visit followed by 25,269 patients in their 2<sup>nd</sup> prescriptions/visits and 10,361 patients in their 3<sup>rd</sup> prescriptions/visits were advised for *Rasa Aushadhis*. Data also highlights that a maximum of 35,967 patients continued the prescribed *Rasa Aushadhis* for up to 2 weeks, whereas 9,412 patients followed the *Rasa Aushadhis* treatment for more than 12 weeks (Figure 2, Figures 3 to 8). Therefore, the study points out that, generally, physicians prefer *Rasa Aushadhis* at the early stages of the treatment, which is frequently preferred to continue for up to two weeks. Besides, the study also shows that a total of 9,412 patients consumed the prescribed *Rasa Aushadhis* for More than 12 weeks (i.e. more than 84 Days) without any complications. The trend shows that most of the patients (35,967) consumed *Rasa Aushadhis* for two weeks ( up to 14 days), but 9,412 patients consumed *Rasa Aushadhis* for a maximum duration, i.e. more than 12 weeks/ 84 days and no untoward effects/action was reported. (Table 3) Moreover, 21,284 patients of more than 60 years of age group and 4,905 patients of less than 15 years of age followed the treatment with *Rasa Aushadhis* without any complaints/ ADR, which supports the evidence-based safety potential of all the prescribed *Rasa Aushadhis* irrespective of age, sex and clinical conditions.

The present study shows numerous remarkable clinical applications purely based on the knowledge and experiences of the physician. Core analysis of data put into words that prescribed classical *Rasa Aushadhis* is applied in patients with various manifold systemic ailments attended in OPDs. Though the General principles of dose and *Anupana* are mentioned by *Acharyas*, specific doses and *Anupana*, as per the requirement of the patient's condition, are prescribed by the physician. Study shows that the doses of the selected *Rasa Aushadhis* were prescribed in a range. Most of the *Aushadhis* were started in 125 mg TDS to 500 BID as per the requirement of the patient and

disease condition. *Rasa Aushadhis* work in smaller doses and are faster in action, therefore, they are required in smaller doses<sup>20,21</sup>. *Rasa Aushadhis* get absorbed quickly into the body. The study found all the selected 15 classical *Rasa Aushadhis* were prescribed at variant doses with *Anupana* in different geographical areas of the country, as per the conditions of *Roga/vyadhi* (disease) and *Rogi* (patients) depending on the assessment/clinical experience of physicians. Analysis shows the conditions of clinical application of the *Rasa Aushadhis* were duly based on fundamental concepts of *Ayurveda* (i.e. individualistic approach). A mere change in the *Anupana* of a drug changes the *Rogaadhikara* (target disease) of a drug. Several new/ different indications of the selected *Rasa Aushadhis* may serve as lead for future studies.

## 5. Limitation

There are a few potential limitations of the present study as the study procedure was limited to review and documentation of existing clinical records for reporting safety and prescription trends of *Ayurvedic Rasa Aushadhis* prescribed to the patients. Since the data was taken from paper records, only complete available retrospective data as per the format provided for retrieval was taken up for analysis. Therefore, the study itself is inherited with the disadvantage of retrospective analysis i.e., an inferior level of evidence compared with prospective studies. Many incomplete data with several other *Rasa Aushadhis* were excluded from the analysis; therefore, it can't be affirmed that the outcome is derived from the comprehensive retrospective data. The outcome of the study may confront the core indications of the prescribed *Rasa Aushadhis*. As the data shows, if any patient came with a further complaint in its 2<sup>nd</sup> or 3<sup>rd</sup> visit, an added *Rasa aushadhi* was prescribed for that complaint along with the *Rasa aushadhi*, which was prescribed during 1<sup>st</sup> visit; however, the main diagnosis was hung about the same as first visit that leads to show a higher number of patients in a particular disease which is not *Adhikar Kshetra* of that medicine.

## 6. Conclusion

The present study concluded that none of the patients falling into different age groups prescribed with

different *Rasa Aushadhis* for more than 84 days complained of any kinds of Adverse Drug Reactions (ADR) or Adverse Events (SE), during the full course of treatments or follow-up inferring the safety of the prescribed *Rasa Aushadhis*. Analysis of prescription trends indicates that *Arogyavardhini Vati* is the most preferred *Rasaushadhi* among the selected *Rasa Aushadhis*. Most of the *Ayurveda* physicians favoured *Rasa Aushadhis* at the first prescriptions/ visits of the patients. The study found that the highest number of patients are treated with *Arogyavardhini Vati*, followed by *Punarnava Mandoor*, *Sutashekhar Rasa*, *Chandraprabha Vati* and *Dhatri Lauha*. The study also shows that overall least prescribed *Rasaushadhi* is *Krimimudgar Rasa* followed by *Simhanad Guggulu*. The study also highlights a maximum number of patients treated with *Rasa Aushadhis* for up to 2 weeks. *Punarnava Mandoor* is the maximum prescribed *Rasaushadhi* for more than 12 weeks. Based on the analysis, the study also concludes that all the selected *Rasa Aushadhis* are prescribed at variant doses with *Anupana* in different geographical areas of the country, as per the conditions of *Roga/vyadhi* (disease) and *Rogi* (patients) based on the clinical experience/assessment/ knowledge of physicians. Analysis shows the conditions of clinical application of the *Rasa Aushadhis* are duly based on fundamental concepts of *Ayurveda* (i.e. individualistic approach). The several numbers of new/ different indications of the selected *Rasa Aushadhis* may serve as lead for future studies.

## 7. Acknowledgements

Authors are highly grateful to Prof. Shriram S. Savrikar, Former Vice Chancellor, Gujarat Ayurved University (GAU), Jamnagar; Prof. Pradeep Kumar Prajapati, Hon'ble Vice Chancellor Dr Sarvepalli Radhakrishnan Rajasthan Ayurved University (DSRRAU), Jodhpur; Prof. Anand Chaudhary, Chief proctor, Department of Rasa Shastra, Faculty of Ayurveda, IMS, BHU, Varanasi; Dr Galib, Associate Professor; Department of RS and BK, All India Institute of Ayurveda (AIIA), New Delhi for their technical inputs in this study as the member of National Consultation Team and Expert Reviewers. The authors are also thankful to all the participating scientists of CCRAS for their fruitful support in this study.

## 8. Financial support

This study was funded under the Intramural Research Project (IMR) by the Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush, Government of India.

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