

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH

SJIF Impact Factor 7.523

Volume 6, Issue 11, 931-941.

Research Article

ISSN 2277-7105

EVALUATION OF CLINICAL EFFICACY OF GANDHAKAKALPA IN VICHARCHIKA

Dr. Madhubabu G.*¹, G. Rameshbabu² and K. Harshavardhan Appaji³

¹PG Scholar, Department of Rasa Śastra and Bhaiśajya Kalpana, S. V. Ayurvedic College, Tirupati, Andhra Pradesh. (India).

²Assistent Professor, Department of Rasa Śastra and Bhaiśajya Kalpana.

Article Received on 01 August 2017,

Revised on 22 August 2017, Accepted on 12 Sept. 2017

DOI: 10.20959/wjpr201711-9627

*Corresponding Author Dr. Madhubabu G.

PG Scholar, Department of Rasa Śastra and Bhaiśajya Kalpana, S. V. Ayurvedic College, Tirupati, Andhra Pradesh. (India).

ABSTRACT

Skin disorders are the most common diseases which most of the physicians come across in their routine clinical practice. In Ayurveda all types of skin disorders were explained under a common heading Kustha and the description given for Vicharchika type of Kśudra Kuśtha closely resembles with Eczema. In Ayurveda Rasauśadhies are known for their high potency, fast action and capable of alleviating dreadful and incurable diseases. "GandhakaKalpa" is one such herbomineral formulation described to have ability to cure almost all types of diseases when given with suitable anupāna. The main ingredients are Gandhaka, Triphala, Trikatu, Vidanga and Chitrakamula. An attempt has been made to study its efficacy

clinically on Vicharchika through "Non-Randomised open labeled Trial over a sample of 30 patients with restricted/purposive sampling. GandhakaKalpa has shown complete remission in 10% patients, marked improvement in 46.66% patients, improvement in 30% patients, and no relief in 13.33% patients. It has given statistically highly significant relief (p<0.001) in Kandu, Pidaka, Śyāva Rukshata and Srāva symptoms and significant relief (p<0.05) in Rāji.

KEYWORDS: Gandhaka Kalpa, Vicharchika, Eczema.

INTRODUCTION

Skin is the most common organ to get afflicted with diseases in man. Almost 12.4% among the total patients who approach for treatment to general practitioners complain of skin related ailments. Any ailment occurring on the Skin-the largest organ of the body will certainly

³Associate Professor, Department of Panchakarma, S. V. Ayurvedic College, Tirupati, A. P.

disturb the psyche of the patient until it gets relived off. Throughout the world, among the people who seek treatment for skin conditions, Eczema-dermatitis makes up 30%. In 2013, with prevalence rate of 10%, the population affected across India from skin diseases was estimated at nearly 15.1 crore and by 2015 it was about 18.8 crore. As per 2015 report on growth of skin diseases in India "Among all types of skin ailments Eczema and Psoriasis are becoming predominant", so keeping this in view, it was decided to conduct a study on one of the most prevalent skin disorder of present times -Eczema. Based on the available descriptions in classics, Eczema can be correlated with Vicharchika. Acharya Charaka's description resembles wet form while Acharya Sushruta's description resembles dry form of Eczema. Many herbal and mineral formulations are described for treatment of Kustha. GandhakaKalpa is a unique herbo-mineral formulation described in Basavarajeeyam said to cure almost all diseases when given with suitable anupana/vehicle. So it can be inferred that it will cure Kustha. This drug is not in usage by the current practitioners, and no pharmacy is preparing this preparation. No previous works were conducted by any institute or pharmacy regarding study of the Clinical efficacy of this drug.

OBJECTIVES

The present clinical study has been planned to evaluate the therapeutic efficacy of Gandhaka Kalpa in Vicharchika.

MATERIALS AND METHODS

> Materials

Drug – GandhakaKalpa. The drug was prepared in the Department of Rasa Śastra & Bhaiśajya Kalpana, S. V. Ayurvedic College, Tirupati.

Patients – Patients attending the O.P.D of P. G. Department of Rasa Sastra & Bhaisajya Kalpana and Department of Panchakarma of S. V. Ayurvedic Hospital, Tirupati were selected.

> Methods

Study design - A Non-Randomised Open-Label Clinical study.

Sampling - Restricted /Porpusive sampling

Sample size - 30. Total 35 patients with symptoms of Vicharchika were registered.

Out of them 30 patients completed the course of treatment.

Criteria for selection of patients

Inclusion criteria

- 1. Patients between age group of 16 years to 70 years.
- 2. Patients with typical features of Vicharchika as narrated by Acharya Charaka & Acharya Sushrutha both were selected.
- 3. Symptoms namely Kandu(Itching Sensation), Śyāvāta (discoloration), Pidaka (Eruption), Srāva (Exudations), Rūkśata (Dryness), Rāji (linings)

Exclusion criteria

1. Subjects with Secondary infection, with history of Tuberculosis, Diabetes Mellitus, Heart disease, Leprosy, with renal diseases and other malignant metabolic disorders are excluded.

Intervention

Internal Therapy : GandhakaKalpa

Dosage form : Vati (Tablet 500mg)

Dose : 3gms

Administration Time : Thrice in a day,

Route : Oral
Anupana : Madhu
Duration : 30 days

Advices

- Avoid Foods- Brinjal, oily, spicy foods, sour foods, pickles, Non-veg,
- Discontinuation of addictions if any
- Maintain Relaxed state of being, Cleanliness.
- Follow-up: Once in every 10 days for a total period of 30 days.

Preparation of GandhakāKalpa

The chief reference of Gandhaka kalpa was taken from Basavarajeeyam^[1] Themain ingredients are Gandhaka, Triphala, Trikatu, Vidanga and Chitrakamula. Shuddha Gandhaka & Shuddha Citrakamula were taken. Shodana was performed to Gandhaka [2000gms], Chitrakamula [350gms]. Choorna Nirmanawasdone for Triphala [360gms] Trikatu [360gms] Vidanga [150gms]. Gandhakakalpa was prepared by adding the mentioned amount of ingredients i.e Shoditha Gandhaka [1850gms], Shoditha Chitrakamula [325gms], Triphala

[350gms], Trikatu [350gms] Vidanga [140gms] to from homogenous mixture were made in to Gandhakakalpa [500mg] tablets.

Criteria for Assessment and Grading

Assessment was totally based on the changes in the clinical features of Vicharchika.

Subjective parameters

To measure intensity of the clinical features present be-fore and after the treatment a score index was designed for Kandu, Srāva, Pidaka, Śyāvta, Rāji, and Rūkśata with grades.

Table 1:

| S. no. | Parameter | G_{o} | G_1 | G_2 | G ₃ |
|--------|-----------|--------------------|---|--------------------------------------|---|
| 1. | Kandu | No Itching | Often mild type of Itching (1-2 times a day) Not disturbing normal activity | Moderate itching(3-4 times per day) | Severe itching episode more than 5 Times a day with blood spot coming out and even disturbing sleep |
| 2. | Pidaka | No Eruption | Scanty eruption in few lesion | Scanty eruption in 50% of the Lesion | Eruptions all over the lesions |
| 3. | Srava | No discharge | Moisture on the skin lesion | Moisture on the skin lesion | Weeping from the skin lesion followed by crusting |
| 4. | Syavata | Normal skin colour | Brownish red discolouration | Blackish red discoloration | Blackish discolouration |
| 5. | Raji | No Grooves | Mild Grooves with roughness over the skin surface level | Mild Grooves with roughness | Deep grooves with pain and bleeding |
| 6. | Rukshata | No dryness | Dryness with rough skin | Dryness with scaling | Dryness with cracking |

Statistical evaluation of results

The obtained information was analyzed statistically in terms of mean score(x), Standard Deviation (S.D.), Standard Error (S.E.), Paired t-Test was carried out at the level of 0.05, 0.01, and 0.001 of 'P' levels. For the more effectiveness of therapy paired t-Test was carried out. The results were interpreted as

Insignificant : p>0.05 Significant : p<0.05

Highly significant : p<0.01, p<0.001

OBSERVATIONS

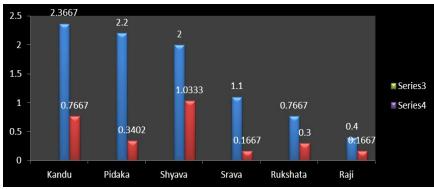
Maximum number of patients i.e. 9 (30%) were between the age group of 30-40 years. Maximum numbers of patients i.e. 17 (56.66%) were male and rests of the patients i.e. 13 (43.33%) were female. Maximum number of patients i.e. 25 (85.33%) were Hindus. Majority of the patients i.e. 10 (33.33%) of them were Farmers. Maximum number of patients i.e. 12 (40%) were doing labour work. Maximum number of patients i.e.17 (56.66%) were from urban habitat. 24 (80%) patients were educated and 6 (20%) of patients were uneducated. Maximum number of patients i.e. 14 (46.66%) were from lower middle class. Maximum number of patients i.e. 21 (70%) had gradual onset. Maximum numbers of patients i.e. 22 (73.33%) were of mixed diet. Maximum 17 (56.66%) patients had disturbed sleep. Maximum number of patients i.e. 10 (33.33%) had Occupation as their aggravating factor. Maximum number of patients i.e. 14 (56.66%) didn't have any addictions. Maximum 17 (56.66%) patients had emotional stress. Maximum number of patients i.e. 18 (60%) had constipation. Maximum number of patients i.e. 11 (36.33%) had Mandāgni. Maximum numbers of patients were of Vāta Kapha Prakruti i.e.15 (50%), 8 (26.66%) were of Kapha Pittaja Prakruti and 7 (23.33%) were of Vāta Pittaja Prakruti. Maximum number of patients i.e. 15 (50%) were having krurakostha. Maximum number of patients i.e. 15 (50%) were having Madhyama kostha. Maximum numbers of patients i.e. 19 (63.33%) had lesion in Lower limb. 24 patients (83.33%) took prior medication.

RESULTS

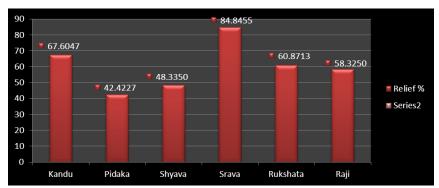
Table 2: Showing effect of Gandhakakalpa on Subjective parameters in 30 patients.

| Crimintonia | No. | Mean | | Mean | Relief | S.D. | S.E. | 4, | P |
|-------------|-----|--------|--------|------------|---------|--------|--------------|---------|---------------|
| Symptoms | | B.T. | A.T. | difference | % | S.D. | 5. L. | | P |
| Kandu | 30 | 2.3667 | 0.7667 | 1.6 | 67.6047 | 1.1103 | 0.2.27 | 12.1048 | < 0.001 |
| Pidaka | 30 | 2.2 | 0.3402 | 0.9333 | 42.4227 | 0.8206 | 0.1498 | 7.3928 | < 0.001 |
| Shyava | 27 | 2 | 1.0333 | 0.9667 | 48.3350 | 0.9296 | 0.1697 | 7.9181 | < 0.001 |
| Srava | 22 | 1.1 | 0.1667 | 0.9333 | 84.8455 | 0.8227 | 0.1502 | 6.9112 | < 0.001 |
| Rukshata | 19 | 0.7667 | 0.3 | 0.4667 | 60.8713 | 0.6756 | 0.1234 | 5.0374 | < 0.001 |
| Raji | 8 | 0.4 | 0.1667 | 0.2333 | 58.3210 | 0.6132 | 0.112 | 2.5357 | <0.05(0.0317) |

Note: -n- No. of patients suffering with symptom, B.T.: Arithmetic mean of scoring Before Treatment, A.T.:Arithmetic mean of scoring After Treatment, S.D.: Standard Deviation, S.E.: Standard Error, P-value: Indicates significance of treat-ment on specific symptom. S.D, S.E, t and p-value were calculated substituting 'n' value as actual number of patients suffering from that specific symptom (But not the total number of patients)



Graph 1: Showing effect of Gandhakakalpa on Symptoms.



Graph 2: Percentage relief in symptoms.

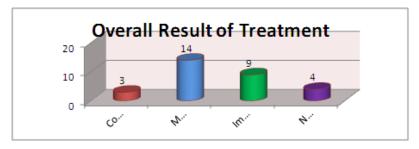
Above data clearly shows that Gandhakakalpa has given statistically highly significant relief in Kandu, Śyāva, Pidaka, Srāva Rukshta(p<0.001) and statisti-cally significant relief in Rāji, (p<0.05).

Overall Assessment of Clinical trial

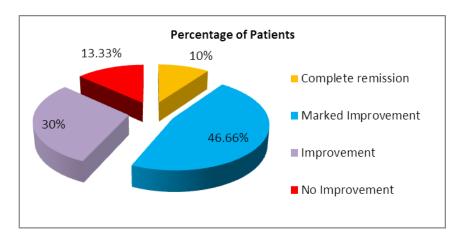
The overall effect of Gandhakakalpa on Vicharchika is shown as follows.

Table 3: Showing overall assessment of Clinical trial.

| Result | No. of Patients | % Patients |
|--------------------|-----------------|------------|
| Complete remission | 03 | 10 |
| Marked improvement | 14 | 46.66 |
| Improvement | 9 | 30 |
| No improvement | 4 | 13.33 |



Graph 3: Showing overall assessment of Clinical trial.



The therapy had shown complete remission in 3 (10%) of patients, marked improvement in 14 (46.66%) of patients, Improvement in 9 (30%) patients and no Improvement in 4 (13.33%) patients.

DISCUSSION

- ➤ Highest incidence was seen in the age group between 30-40 years. Now-a-days adopting busy life style in race for better life settlement, habituating to unhealthy food habits and irregular daily regimens, stress, addictions are increasing more in this age group. This might be a reason for the people of this age group to become more prone to diseases like Vicharchika.
- > As the study was done in a Hindu predominant area, most of the registered patients were Hindus.
- ➤ The majority of the patients i.e. 86.6% were married and 13.3% were unmarried. As per age wise incidence, majority of the patients were in 30-40 years and with in this age group people will be married. But it doesn't show any specific relevance in particular to this disease.
- ➤ Majority of the patients were Farmers, house wives, drivers, teachers, policemen. Constant exposure to pesticides in farmers, getting more contact with water and detergents in house wifes, more contact to atmospheric pollution, irregular diet and sleep, excessive exposure to heat from vehicles among drivers and policemen. These might be the reason for developing skin ailments like Vicharchika among them.
- ➤ People who were habituated to laborious work, stressful work, working at irregular timings- were more affected. It is known that the healthy condition of Rasa dhātu was described under Tvak sāra laksanas^[2] and Tvak is also the upadhātu of Māmsa dhātu^[3] Hridaya is the srothomūla of Rasavaha srothas.^[4] Activities like atichintana-stress,^[5] im-

- proper food and sleep causes Rasa duśti ultimately affects Rakta, Māmsa dhātus. According to Acharya Charaka, vali, pālitya come under Rasa pradośaja^[6] and all types of skin diseases come under Raktapradośaja vikaras.^[7]
- ➤ Compared to lower and higher class people, middle class 26% and lower middle class 36.66% people were more affected. Struggle they face in day to day life can be seen more in these categories than the other. This might be an important factor for causing Vicharchika.
- ➤ 60% patients were from urban habitat and 40% patients were from rural habitat. Both were affecting almost equally. Urbanisation leads to increase in pollution, changing food habits and daily regimens, usage of fast foods, food additives, adulter-ants and preservatives which in turn alters the immunity and makes the man susceptible to many diseases. Now-a-days adopting urban lifestyle in rural areas is also increasing gradually. This might be a reason for people becoming more prone to develop various skin diseases like Vicharchika.
- Maximum number of patients i.e. 80% had gradual onset and 20% had acute onset. According to Acharya Charaka among four types of dośa dūśyasammūrchana, Kuśta is of ''चिरेन विकार जननं'' [8] i.e. Even though dośa vitiation occurs after exposure to etiological factors dośa-dūśya sammūrchana occurs after a long time. Hence the onset is gradual.
- Maximum 70% of the effected patients are of mixed diet. Excess intake of spicy foods i.e. Katu, Amla, Lavana rasas not only damages internal mucosa of GIT, but also damages skin-'The largest external protective organ of the body'.
- Maximum 56.66% of patients had disturbed sleep. The disturbed sleep might be due to symptom Kandu and also due to stress. Lack of sleep vitiates Vāta dośa. The vitiated vāta in the Kutha rogi further vitiates the Tvak, Lasika, Māmsa and Rakta which inturn strengthen the disease and this continues making the disease chronic.
- Maximum in 30% of patients, disease was aggravating after taking foods like brinjal, fish and chicken. Vārtaka-brinjal is pittakara^[9] and tvak is the sthāna of Bhrājaka pitta. Intake of brinjal vitiates the Pitta dośa and thus leads to the aggravation of symptoms. Fish being Ānupa māmsa causes Kapha vrudhi and hence the symptoms like Kandu and Srāva increase with its intake. 36.66% of patients had climate (Kāla) as their aggravating factor. Śītatva present in damp climate causes Kapha duśti in body leading to further aggravation of the symptoms in the Vicharchika patients.

- Maximum 46.66% didn't have any addictions, because among 30 patients, 14 patients were females and they didn't have any addictions. The rest 16 males had smoking and alcohol addictions. Smoking causes srotoabhisyandhata of Prānavaha srotas and ultimately causing Vāta kopa. Madhya causes pitta duśti in the body and ultimately vitiates the Bhrājaka pitta of Tvak. In the people effected with Kuśta, the addictions will further strengthen the vitiated dośa and increase the Rogabala.
- » Maximum 56.66% of patients had emotional stress and same percent of patients were with Avara satva.' "विषादो रोग वर्धनं" (M.ni)^[10]- i.e. depression increases the disease. People who are psychologically weak will suffer more from the diseases. Avara satva persons are psychologically weaker than pravara and madhyama satva persons. As per Dr. S. Gibbs Studies show that atleast 30% of all dermatology patients have some underlying psychological problem that often goes unaddressed, it can have a very positive and powerful impact in improving the skin conditions. This is because the brain and skin are developed from the same cells. [11]
- Maximum 60% of effected patients had constipated bowel movement. "Purīśam vāyu agni dhāranam" [12] Purīśa maintains agni and vāyu functions. Any impairment in its function causes Vāyu and Agni duśti and ultimately leads to the onset and aggravation of disease.
- Maximum 50% of patients were having Krurakośta. Intake of fast foods and junk foods makes people easily vulnerable to diseases. As per Chriss Kresser-"epidemiological evidences shows that there is a clear association between gut and skin problems. Intestinal permeability causes both systemic and local inflammation, which inturn causes skin diseases". [13]
- Maximum 47%, were of Kapha Pittaja prakruti, 30% were of VātaKaphaja Prakruti and 30% were of VātaPittaja Prakruti. Prakruti is having important role in treating the patient. The patients having Prakruti contrary to the disease will be cured easily. Even the same was mentioned by Acharya Charaka^[14] that the curabilty of the disease is based on the factors like Dūśya, Dośa, Prakruthi, Kāla, Deśa, Gati and time of onset of the disease. Thus Prakruti helps in assessing the prognosis of the disease. In this study among 30 patients, 14 patients were of PithaKaphaja prakruti. The maximum percentage relief in over all symptoms in 10 of them was 50-70. only and in the remaining four patients the percentage of relief was ≤ 35.. This indicates krichhra sādhyata of the disease due to the similarity in the rogi prakruti.

As the sample of Vicharchika patients have to be selected within predetermined inclusive criteria, Purposive/Restricted type of sampling was taken instead of other sampling methods. It is a Primary level of study carried out at institute level within limited period of time. To get optimal un-biased result a clinical study was designed with single group, small sample size of 30 patients. In actual reference the dose of Gandhakākalpa is mentioned the dose as 1Niska (3Gms)^[15]The disease Vicharchika is a Kapha pradhāna Tridośaja roga as per Acharya Charaka, Acharya Vagbhata and as per Acharya Sushruta, it is Pitta pradhāna Tridośaja roga. Honey is having Yogavahi, Kapha Pitta hara, Tridośaghna, Chedanakara properties and indicated specifically in Kuśta roga^[16,17,18] Hence it was selected as Anupana dravya. Gandhakā Kalpa has given statistically highly significant relief in Kandu, Śyāva, Pidaka, Srāva and Rukshata and statistically significant relief in Rāji, by its Tridośahara, Rasāyana, Kuśtahara, Yogavāhi and kandughna properties. Thus by the specific Tridosagna proper-ties of ingredients it is acting against the hetu of Vicharchika (Kapha pradhana tridośa as per Charaka and Pitta pradhana tridośa as per Sushrutha) and by the Kuśtaghna, Twakdośahara properties of ingredients it is acting against Vicharchika.

ACKNOWLEDGEMENT

I acknowledge my Guide Dr. G. Ramesh babu and my Co-guide Dr. K. Harshavardhan Appaji, S. V. Ayurveda College, T.T.D, Tirupati for providing me proper direction and suggestions in conducting the clinical study.

CONCLUSION

Gandhakakalpa is one of the important formulations of Ayurveda that can cure many diseases when given with suitable anupāna. In this study its therapeutic efficacy was studied on one of the common disease Vicharchika. Gandhakakalpa has shown statistically highly significant results in symptoms like Kandu, Pidaka Śayva, Srāva and Significant results in symptoms like Rāji, Rūkśata. Among all symptoms, maximum relief was seen in Srāva with 84% and minimum relief of 58% in Rāji.

REFERENCES

- 1. Basavarajeeyam chapter no.6, Sloka, 161; 248-253.
- Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Vimana sthana-8/103, 1995.

- 3. Sarngadhara Samhita of Sharngadhara Acharya with the commentary Adhamall's Dipika & Kashirama's Gudhartha Dipika, Chaukhambha Orientalia Varanasi, purva kanda-5/29, 2000.
- 4. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Vimana sthana-5/7, 1995.
- 5. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr. Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Vimana sthana-5/13, 1995.
- Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Sutra Sthana-28/9,10, 1995.
- 7. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Sutra Sthana-28/11,12, 1995.
- 8. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Nidana Sthana, 1995; 4.
- 9. Astanga Hridaya of Acharya Vagabhatta, with Vidyotini commentary by Kaviraj Atrideva Gupta, Chaukhamba Sanskrit Sansthana, Varanasi, Sutra Sthana-6/81, 1997.
- 10. Madhava Nidana I & IInd Madhukosa Sanskrit and Vidyotini Hindi commentary by Yadunandana Upadhyaya, 23rd Edition, Chaukhambha Samskrita Sansthana, Varanasi, 1st chapter, Madhukosha commentary, 1994.
- 11. http://WWW.m.webmd.com/healthy-beauty/features/effects-of-stress-on-your -skin.
- 12. Astanga Samgraha of Acharya Vagbhatta, Sarvanga Sundari Vyakhya by Pandit Lalacandra Sastri Vaidya, Vaidyanth Ayurveda Bhavana, Nagpur, Sutra Sthana-19, 1988.
- 13. http://chriskresser.com > The gut-skin connection.
- 14. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Sutra Sthana-10/11, 1995.
- 15. Basavarajeeyam chapter no.6 Sloka, 161: 248-253.
- 16. Caraka Samhita Vidyotini Hindi comm. by Pandit Kasinatha Sastri and Dr.Gorakha Natha Chaturvedi, Chaukhambha Bharati Academy, Varanasi, Sutra Sthana-25/40, 1995.
- 17. Susruta Samhita with Nibandha Sangraha comm. of Sri Dalhanacarya, Chaukhambha Orientalia, Varanasi, Sutra Sthana- 45/132, 1997.
- 18. Astanga Hridaya of Acharya Vagabhatta, with Vidyotini commentary by Kaviraj Atrideva Gupta, Chaukhamba Sanskrit Sansthana, Varanasi Sutra Sthana-6/51-54, 1997.