

Clinical evaluation of the efficacy of *Vajraka ghrita* in management of *Vicharchika* (atopic dermatitis/eczema) – A single arm clinical study

Research Article

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Abstract

Background: Ayurveda, an ancient medical science, offers profound insights into skin health through its understanding of "Kushtha," a term encompassing various skin ailments. Ayurvedic texts detail the etiology, classification, prognosis, and treatment modalities for Kushtha, highlighting the significance of "Ghritakalpana" in its management. Ghritakalpanas, medicated ghee formulations, hold particular importance in Kushtha treatment. Material and Methods: This study delves into the efficacy of "Vajraka Ghrita," a specific Ghritakalpana mentioned in classical Ayurvedic texts, in managing "Vicharchika" - a type of Kshudrakushtha akin to Atopic Dermatitis/Eczema in modern medicine. The research methodology involves a comprehensive review of classical Ayurvedic literature to elucidate the conceptual framework of Ghritakalpana in Kushtha management. Additionally, clinical evaluation of Vajraka Ghrita's efficacy in Vicharchika management is conducted through a structured study design. It was a single arm clinical study with 40 subjects. The dose was 10 gms twice a day before meal with lukewarm water for a month. Results and Discussion: Preliminary findings indicate promising outcomes regarding the efficacy of Vajraka Ghrita in managing Vicharchika. By addressing symptoms such as severe itching, lichenification, and dryness, Vajraka Ghrita demonstrates potential as an adjunctive therapy for Atopic Dermatitis/Eczema. Vajraka Ghrita has very effective in treatment of Vicharchika about 7 patients having Marked relief which was >75%,29 patients having Moderate relief about 50-75%, 3 patients having Mild relief 25-50%, 1 patient having no relief i.e. < 25%. Further analysis and clinical trials are necessary to validate these findings and elucidate the mechanisms underlying Ghritakalpana's therapeutic effects. This study underscores the relevance of integrating ancient Ayurvedic wisdom with modern medical approaches for comprehensive healthcare delivery.

Keywords: Atopic dermatitis, Ghritkalpana, Kustha, Vajrak ghrita, Vicharchika.

Introduction

The Healthy skin is one of the greatest achievements of an individual in order to live confidently in Society. In present Era, Skin is the protective covering of an individual which is responsible for its protection from Heat, Cold, External, Environmental barriers.

Skin is an important reflection of our overall Health and well being. Healthy – Beautiful skin relies on well nourished, well-rested active body and mind. For Healthy skin that glows, it is important to improve the overall skin Health form the inside out. Skin problems are more than just Facial blemishes and

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marks. They affect the overall quality of life and Health and may worsen if left unchecked. They may cause Social and Emotional distress leading to low selfesteem and confidence. These problems affect work productivity and may lead to Anxiety and Depression and affect Healthy Functioning of skin. Ayurveda the medical science has a lot of precious knowledge and remedies embedded in it. Ayurveda considered the skin problems under the term "Kushtha". Ayurveda has a deep theory related to 'Kushtha' along with its thorough treatment. Kushtha is explained as 'The condition caused due to vitiation as well as discolouration of the skin'. Aacharya Charaka and Sushruta has explained "Saptakodravya" (combination of seven bodily elements) i.e. Tvaka (skin), Rakta (blood elements), Mamsa (muscle tissue), Lasika (lymph) along with Tridoshdushti (vitiation of three bodily elements), responsible for the etiopathogenesis of Kushtha.(1) All the details about the etiopathogenesis of Kushtha, classifications, prognosis, treatment of Kushtha are described in Ayurveda literature. One of the treatments which are precisely used nowadays by Ayurvedic

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practitioners for 'Kushtha' is 'Ghritakalpana' (medicated clarified butter). 'Ghritakalpanas' are drug of choice in Kushtha rather than any other disease. So it is our duty to highlight such Ghritakalpanas in all aspects regarding their Ingredients, Doses, Anupana, Uses, Karmukata (action) etc. There are many Ghritas like Tiktashatapal Ghrita, Mahatikta Ghrita, Panchatikta Ghrita, Khadiradi Ghrita, Mahavajrak Ghrita, Vajrak Ghrita, Amrita Ghrita, Panchatikta Ghrita Guggulu etc. are widely used in treatment of Kushtha. important to study role of Ghrita in management of Skin Disorders. 'Vajraka Ghrita' is one of the Ghritakalpana mentioned in treatment of Kushtha by Ashtang Hridayam (2) and other classical texts. Like Vangasena Samhita, Chakradatta etc. Vicharchika (Atopic dermatitis) is the type of Kshudrakushtha (minor skin ailment) which is characterized by presence of severe Itching, Lichenification, Oozing, Dryness, and Blackishness etc. Vicharchika in Ayurveda may be correlated with Atopic Dermatitis / Eczema in modern medical science. Atopic Dermatitis / Eczema is an allergic Condition that is characterized by presence of family Atopic histories, Pruritus, Vesicles etc. Excoriations, Weeping, Crusting may be predominant. (3)

3% of world population is suffering from Atopic Dermatitis/Eczema. (4) So in order to study *Kushtha* thoroughly in terms of the *Nidanpanchaka* (5 components in diagnosing disease) treatment and study the *Ghritakalpanas* critically along with *Vicharchika*. Ayurvedic view and Atopic Dermatitis /Eczema thoroughly; to study and evaluate the efficacy of Vajraka Ghrita on Vicharchika present study was done and entitled as 'Conceptual study of Ghritakalpana in Kushtha and clinical evaluation of "Vajraka Ghrita" in management of *Vicharchika* (Atopic Dermatitis/| Eczema)'.

Aims and Objectives

- To study the concept of *Ghritakalpana* in *Kushtha* and to evaluate *Vajraka Ghrita* clinically in *Vicharchika*.
- To form the Conceptual base of *Ghritakalpanas* in treatment of *Kushtha*.
- To study *Vicharchika* according to Ayurveda and Atopic Dermatitis/Eczema according to Modern Medicine in detail.
- To assess the efficacy of 'Vajraka Ghrita' as a 'Shamana Sneha'
- To evaluate the remission of the symptoms of *Vicharchika*/Atopic Dermatitis in patients treated with *Vajraka Ghrita*

Hypoothesis

- Null hypothesis (h₀): *Vajraka ghrita* has no effect on
- Vicharchika
- Alternate hypothesis (h_A): Vajraka ghrita has effect on Vicharchika.

Review of Literature Ghrita

All the Aacharyas while explaining about the etiopathogenesis of diseases has explained that all the diseases occurs due to disturbance in *Jatharagni* (Digestive Fire) and *Dhatvagni* (metabolisms) so to hamper the process of establishment of disease- the correction and aggravation of disturbed *Agni* (digestive fire) is necessary. Taking this as a base Aacharya might have described Ghritakalpanas and *Snehapan* (intake of oil) as a primary treatment in *Kushtha*.

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Ghrita is explained as the Ingestion of Ghee is like offering the finest fuels into the fires of Digestion i.e. Agni. Ghrita is explained as *Amrita* (ambrosia) essential for lives by Ancient Aacharyas which is used to aggravate Holy Fire as well i.e. Havana.

In accordance with this, *Ghrita* builds the Aura, makes all organs soft, builds up the internal juices of the body- Rasa which are destroyed Aging and increases the most refined element of Digestion, *Shukra* (semen) or *Ojas* (immune system), the underlying basis of all Immunity and the essence of body tissues.(5)

Latin Name of Ghrita is Butyrum Penataru included in Gana (Group) named Madhur Skandha (sweet taste origin medicine). Properties are Madhura (sweet), Snigdha (oily), Guru (heavy), Sheeta (cold) and Katu (pungent) vipaki with Tridoshaghna action. Rasayana, Vajikara, Rasa Vardhaka, Svarya, Varnya, It is beneficial for Oja, Medha, Smriti, Agni, Indriyabala. It is useful in Bala, Vriddha, Aabala and Kshina. (6)

The Skin not only protects the body but also performs some Execreatory and Metabolic functions. It is a link between Internal and External Environment and is also a seat of complexion which maintains Beauty and Personality.

Changes in Skin colour may indicate Homeostatic Imbalance in the body. Diseases of Skin are a common occurrence as latest survey displays that a very large proportion of the population suffers from Skin diseases. So important is the Skin to one's image that people spend much time and money to restore skin to a more normal and youthful appearance.

In Ayurveda almost all the Skin diseases have explained by various Aacharyas under the heading "Kushtha". Ayurveda has a very scientific and skillful approach for the treatment and diagnosis of Skin diseases i.e. *Kushthas*.

There are so many remedies explained in *Kushtha-chikitsa* (treatment protocol for skin diseases) out of which *Ghritakalpanas* explained in *Kushtha* are widely used by Ayurvedic practitioners in contrast to this Aacharya Charaka explained in Apasmar Nidan Adhyay- "*Havishprashat Kushtha Prameha*" (intake of clarified butter used in offerings in sacred fire causes skin diseases and diabetes) but practically the consumption of *Ghritas* mentioned in *Kushthachikitsa* by *Kushtharogi* (skin disease sufferer) shows improvement of *Kushtha* i.e. Skin diseases many times.(7)

So in order to explain the role of *Ghritas* Consumption in *Kushtha* i.e. Skin disease and role of Vajraka Ghrita in Vicharchika (Atopic Dermatitis)



details study of Kushtha including Vicharchika and Ghritakalpana is needed.

Samprapti Ghataka (8)

Doshas are Tridosha. Dushya are Tvak, Rakta, Mansa, Lasika. Strotas involved are Rasa, Rakta, Mansa, Udakavaha Agnidushti occurred at Jatharagni, Dhatvagnimandya.

Rogamarga is Bahya (Tiryagsira sanchar). Swabhava is Chirkari (chronic). Adhishthana is Tvacha.

Materials and Methods

Vajraka Ghrita (9)

The Ghrita was prepared as per reference from Ashtang Hriday Chikitsasthan 19 i.e. *Kushtha Chikitsa Adhyay*. The Ingredients of *Vajraka Ghrita* were as follows:

- Vasa (Adhatoda vasica Linn.): 1P 1 kg
- Amrita (Tinospora cordifolia (Willd.)): 1P 1 kg
- Nimba (Azadirachta indica A. Juss): 1P 1 kg
- Patol (Trichosanthes dioica Roxb):1P 1 kg
- Vara (Emblica officinalis Gaertn, Terminalia bellirica (Gaertn.) Roxb Terminalia chebula Retz): 1P
 1 kg
- Vyaghri (Solanum surattense Burm): 1P 1 kg
- Karanj (Pongamia pinnata(Linn.) Merr.): 1P 1 kg
- *Ghrita* :28P 28 kg

Kalka

Each drug was taken in equal part i.e. 7 part of *Kalka* (paste) was prepared after proper identification of drugs i.e. Fresh Herbs.

Sneha Dravya

Ghrita i.e. "Goghrita" was used as a Sneha dravya in 28 parts.

Drava Dravya

The *kwatha* (Decoction) and medicated clarified butter prepared from all the above 7 dravyas by procedure of making decoction as per acharya sharangadhara.

Drug Administration Details

Vajraka Ghrita had been chosen for management of "Vicharchika" and used as a shaman sneha.

- **Drug Dose** 10 gm twice a day
- **Time of Drug** Before meal when one feels hungry.
- Route of Administration : Oral
- Duration of Treatment:

Treatment was done for 1 months (30 days) follow up was taken at every 7th, 14th and 21st day and last day of treatment for the duration of one month.

Source of Data

Patient of either sex coming to the OPD and IPD of this Hospital having complaints of *Vicharchika* (Atopic Dermatitis/Eczema).

Total 40 patients were selected for study under a single group.

Criteria for Selection of Patients

The patient presenting with the signs and symptoms of *Vicharchika* (Atopic Dermatitis/Eczema). The main criteria for diagnosis was the presence of clinical symptoms and signs like *Kandu* (Pruritus), *Pidaka* (Lichenification, Pustules etc) *Shyava* (Blackish Discolouration), *Bahustrava* (Oozing); which are nothing but the symptoms and signs of *Vicharchika* mentioned in classical texts.

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Inclusion Criteria

- Patients presenting with clinical features of Vicharchika (Atopic Dermatitis/Eczema)
- Patients of either sex of age group 16 years above.
- Patients fit for intake of medicated clarified butter and ready for the research study.

Exclusion Criteria

- Lactating and pregnant women
- Patients on oral Corticosteroid treatment
- Lesions with Secondary Infection
- Patients suffering from Systemic disorders which interface with the course of treatments like Diabetes, Vericosity, Venous ulcers.
- Patients with Blood Coagulopathic disorders.

Sample Size

A single group of 40 patients fulfilling Diagnostic criteria was selected after prior consent.

Investigation

Routine blood investigations like Hb%, TLC, DLC, ESR, RBS were done before treatment to rule out pathologies.

Criteria of Assessment

The assessment was done on the basis of the following subjectives and objective parameters before and after treatment and during follow up.

Subjective Parameters

- Kandu (Itching)
- *Pidika* (papules)
- Strava (discharge)

Grading Parameters

Kandu (Itching)

- 0. Score: No Itching
- 1. Score: Mild itching (Can be tolerated)
- 2. Score: Moderate Itching (cannot be tolerated with mild excoriation)
- 3. Score: Severe Erruptions occurs in massive cluster.

Pidaka (Erruptions/Papulation)

- 0. Score: No Erruption
- 1. Score: Mild, Discreat erruption without clustering
- 2. Score: Moderate with eruptions occuring in small cluster
- 3. Score: Severe erruptions occurring in massive cluster.



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Srava (discharge)

- 0. Score: No Discharge
- 1. Score: Mild Discharge, Appear mildly moist
- 2. Score: Moderate, Increased discharge where patients have to use cloths to keep dry.
- 3. Score: Severe, Profused Discharge, patient not able to control with cloths.

Result Assessment

Assessment of result was done detailed proforma adopting standard method of scoring of grading parameters and was statistically analyzed. The appropriate tests were used as per methods. Changes in clinical features of *Vicharchika* before and after treatment

The results were categorised as

- Marked Relief: Above 75% Improvement
- Moderate Relief: 50 75% Improvement
- Mild Relief: 20 50% Imporvement
- No Relief: Below 25% Improvement (10)

Effect of Vajraka Ghrita on Vicharchika

Figure 1: Before Treatment Figure 2: After treatment





Observations and Results Effect of Thearapy-Vajraka Ghrita on Vicharchika:-

In this study, the effect of *Vajraka Ghrita* as a *Shaman Sneha* was studied in 40 patients suffering from *Vicharchika* (Atopic Dermatitis / Eczema), fulfilling the inclusion criteria.

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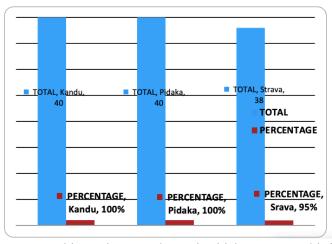
During the study, the observations were made before and after the treatment and after the follow up.

- Number of Patients registered for the study: 40
- Number of Patients completed the study: 40
- Number of Drop out: 00

Table 1: Distribution of 40 patients according to the presenting complaint

Presenting complaints	Total	Percentage
Kandu	40	100%
Pidaka	40	100%
Strava	38	95%

Graph 1



In this series Kandu and Pidaka was a chief presenting complaint in all 40(100%) patients followed by strava as a complaint was present in 38 (95%) patients.

Effect of Therapy - Statistical Analysis

Table 2: Effect of Vajraka Ghrita on Kandu

Sample Size	Chief Complaint	Mean		Mean Diff.	Sem.	Df.	4.	_
Sample Size		BT	AT	Mean Dill.	Sem.	DI.	LO	р.
40	Kandu	2.45	0.625	-1.825	79158	39	23.055	0.000

At the end of the treatment schedule, the effect of drug was assessed on Kandu (Itching) which was amongst the chief complaints. As shown in Table as the t_0 is 23.055088 which is > 1.96 so we reject the Null Hypothesis i.e. Vajraka Ghrita has no effect on *Kandu*. *Vajraka Ghrita* has highly significant results in *Kandu*.

Effect of Vajraka Ghrita on Pidaka in Vicharchika Patients

At the end of the treatment Schedule, i.e. *Vajraka Ghrita* consumption as a *Shaman Sneha*, the effect was assessed statistically on *Pidaka* (Lichenification) which was amongst chief complaint.

Table 3: Effect of Vairaka Ghrita on Pidaka

		Table 5	· Lincer o	i vajiaka Gii	iiia on i idaka			
Sampla Siza	e Chief Complaint	Mean		Mean Diff.	Sem.	Df.	4	_
Sample Size	Cinei Compianit	BT	AT	wican Dill.	Sem.	DI.	t ₀	р.
40	Pidaka	2.225	1.55	-0.675	0.097319	39	6.93589	0.000

As shown in above table as to is 6.93589 which is > 1.96 so we reject Null Hypothesis that Vajraka Ghrita has no effect on *Pidaka*. Thus *Vajraka Ghrita* has significant effect on *Pidaka*.



Effect of Vajraka Ghrita on Strava (Oozing) in Vicharchika

The effect of *Vajraka Ghrita* on Strava in Vicharchika from the series of 40 patients was assessed statisfically as follows:

Table 4: Effect of Vajraka Ghrita on Strava (Oozing)

Sample Size	Chief Complaint	Me	an	Mean Diff.	Sem.	Df.	4	n
Sample Size	Cinei Compianit	BT	AT	Mican Dill.	Sem.	Di.	L.	p.
40	Strava	1.525	0.275	-1.25	0.105914	39	11.80193	0.000

As the to is 11.80193 which > 1.96 so here we reject the Null Hypothesis that *Vajraka Ghrita* has no effect on *Strava* in *Vicharchika*. Thus *Vajraka Ghrita* has effect on *Strava* in *Vicharchika* which is highly significant.

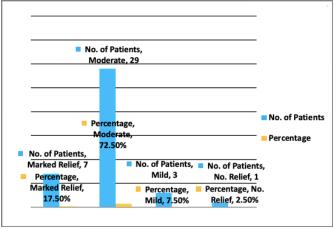
Subjective Parameters

There was also reduction in complaints of patient like *Kandu*, *Daha*, *Ruja* of patient due to the Pacification of associated *Dosha*.

Overall effect of therapy on *Vicharchika*Table 5: Showing the overall effect of the therapy

Relief	Number of	Percentage
Marked Relief	7	17.5%
Moderate	29	72.5%
Mild	3	7.5%
Number Relief	1	2.5%

Graph 2



In this series of 40 patients about 29 patient i.e. 72.5% got Moderate Relief, followed by 7 patient i.e. 17.5% patient got Marked Relief, 3 patient i.e. 7.5% got Mild Relief and 1 patient i.e. 2.5% was not having any relief.

Discussion

The excruciation Skin ailments are attacking the mankind since the past ages. Vaidic literatures provide multiple evidences of such efforts in form of prayers and Herbs by naming all the Skin disease under the term *Kushtha*. *Kushtha* is always *Tridoshaja* in origin. Charaka opines at this to treat the Dominent *Dosha*. (11)

The classical texts have described *Vicharchika* as having three main features as *Kandu* (Itching), *Pidaka* (Lichenification), *Bahustrava* (Oozing), on basis of these *Vicharchika* is considered as a clinical condition in which the *Shyava* (dusky) coloured lesion i.e. *Pidaka* with profused *Itching* or *Ruja* may develop anywhere in body and meight be wet or dry. It is quite similar to the Atopic Dermatitis/Eczema as two classical criteria; the

eruptions in Eczema are that itches and causes Vesication or blistering skin. The first manifestation is Erythema or Reddening of skin. There may be oozing from the affected area. (12) The persistence of this condition leads to thickening and scales in skin. *Kushtha* is mentioned as Kushtha Dirgharoganam (13) (Chronic long term diseases) and hence there is complete packaged treatment of Kushtha is mentioned by Aacharyas. Amongst all the diseases Kushtha is the only disease where the Ghritakalpanas in classical texts are widely uses. Kalayukta Sneha administration is mentioned by Aacharyas. There are so many Ghritakalpanas are mentioned in classical texts. (14) On consumption of Vajraka Ghrita as a Shamana Sneha for duration of 30 days; In series of 40 patients, The drug was highly effective in Kandu. All 40 patients were having relief in Kandu symptom. This meight have occurred as Vajrak Ghrita contains of Vyaghri, Karanj, Triphala, Patol, Nimba which are nothing but Kandughna Dravyas.Ghrita caused reduction in Rukshata and might had caused Snehana which pacified vitiated Vata and the drugs processed with it were Kaphashamak so meight had pacified vitiated Kapha and so as Kandu.

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In this series ,all 38 patients i.e.100% patients complaining *Strava* got relief in *strava* which is cardinal symptom of *Pitta*. The drug *Amrita*, *Nimb*, *Patol*, *Vasa*, *Triphala Ghrita* are *Pittashamak* so they pacifies vitiated *Pitta* and so the *Strava*. The Herbs used are *Krimighna*, *Grahi*, *Stambhak* so they reduced *Strava* significantly.

In the series 26 patients got relief in *Pidaka* which occurred due to *Rasa, Mansa, Rakta, Pitta Dushti*. These drugs Pacifies *Rasa, Rakta, Pitta* and so the *Pidaka*. The proportion of reduction is less as compaired to other 2 symptoms; it might be due to less tendency of *Ghrita (Vajraka Ghrita)* for *Chhedana*.

Probable Mode of Action of Vajraka Ghrita:

Vicharchika is a Result of vitiated Vata, Pitta, and Kapha. The Dushyas involved are Tvak, Rakta, Mansa, Lasika. The Disease is having Bahya Rogamarga i.e. mode of Entry Bahya. (15)

According to Aacharya Dalhana *Tvacha* and *Rasa Dhatu* are similar to each other. So *Rasavaha strotas Dushti* and *Raktavaha Strotodushti* is involved in Skin Diseases.

Being tridoshaj there is involvement in *Vicharchika* along with *Kapha* dominancy. (16) The selected drugs must be *Tridosha Shamaka* along with *Kaphashamana*. The experimental (Present) drug



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Vajraka Ghrita is referenced from Ashtang Hridayam, Chikitsasthan Adhaya 19 in Kushthachikitsadhikar which is found to be very effective in Vicharchika. (9)

There are 7 drugs i.e. Herbs taken in all in equal quantity along with ghrita in quantity of 4 times that of Herbs, all the 7 herbs used in preparation are having *Tikta Rasa*, 4 drugs having *Katu Rasa*. Out of these, 3 drugs having *Laghu* and *Ruksha Guna*. *Katu* and *Tikta Rasa* acts on *Kapha dosha*. *Laghu* and *Ruksha gunas* are *Kapha-shamak*. *Kashay Rasa* acts as *Stambhan* along with *Kapha shaman* it might have caused reduction in *Strava*. *Snigdha guna* of acts *Vatashamak* along with suppressing the *Rookshata* (Dryness) *Madhura Rasa* along with combiniting drugs in *Ghrita* acts on *Pitta*. (17)

Drugs like Guduchi, Vasa, Patol, Nimba, Vara, Karanj, Vyaghri acts as Kushthaghna, Kandughna, Tridoshashamak togetherly. The Ghrita might have pacified vitiated Vata dosha along with Pitta dosha. When it was processed with all these 7 Herbs it also pacified the Kapha Dosha.

Vajraka Ghrita when given in Shaman matra might have pacified Tridosha along with improvement in symptoms and signs like Pitika, Shyavata, Kandu, Daha, Ruja etc.

Vajraka ghrita has dominent Tikta, Katu, Kashay Rasa, Laghu Rooksha Guna, Ushnavirya, Katu vipak. It acts mainly for Kapha Vata Dosha, so along with pacifying Doshas during Shamana Snehapana it causes symptomatic relief.

Conclusion

After the completion of study, final Conclusions drawn on the basis of deductive reasoning of data obtained from the Conceptual and Clinical work are as follows:

Vajraka Ghrita was effective in Kandu symptom of patient which was observed highly significant statistically. In this study all the 40 patients were having improvement in Kandu. It is due to the Snigdha Guna of Vajraka Ghrita along with Kushthaghna, Kandughna, Krimighna properties of drugs with which it was processed. Vajraka Ghrita was effective in Strava (P< 0.001) which was statistically highly significant. The drugs used in Vajraka Ghrita having Tikta-Kashay Rasa as dominant leading to Kledopashoshan and Grahi which resulted in reduction of Strava in all 39 patients. Vajraka Ghrita was effective in reduction of Pidaka (P< 0.001) which was statistically highly significant due to Lekhana Karma, Kaphaghna properties of drugs used in it. But practically there was reduction of Pidaka in 26 patients.

Vajraka Ghrita has very effective in treatment of Vicharchika about 7 patients having Marked relief which was >75%,29 patients having Moderate relief about 50-75%,3 patients having Mild relief 25-50%,1 patient having no relief i.e.< 25%. Vajraka Ghrita has significant role in treating Vicharchika (Atopic Dermatitis/Eczema)

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