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A COMPARATIVE CLINICAL STUDY OF KUSTHADI LEPA AND DARVYADI LEPA ALONG WITH KUSTHAGHNA MAHAKASHAYA KWATH IN MANAGEMENT OF SIDHMA KUSTHA

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ABSTRACT

Now a day skin disease are very common. Skin disease are common at any age of the individual but they are particularly frequent in the elderly. All the skin disease in Ayurveda have been under the heading of *Kustha*. Which are further divided into *Mahakustha* and *Kshudrakustha*. Sidhma is considered as *Mahakustha* according to *Acharya charka* but *Kshudrakustha* according to *Acharya sushruta*. Its *Dosha* predominance *Vata-Kapha*. Thus, *Sidhma* can be defined as a clinical entity characterized by hypo-pigmented lesions primarily on the upper body. Lesions itch rarely and may be hyper-pigmented in certain people, scaling occurs only if the lesion is scratched off with a blunt scalpel; there is no spontaneous scaling. As per symptomatology *Sidhma Kustha* is widely consider to be *Tinea versicolor* (tinea pityriasis) in modern science. **Aims:** To assess the efficacy of *Kusthadi Lepa* and *Darvyadi Lepa* along with *Kusthaghna Mahakashaya Kwath*

in management of *Sidhma Kustha*, To compare the efficacy of *Kusthadi Lepa* and *Darvyadi Lepa* along with *Kusthaghna Mahakashaya Kwath*. **Materials & methods:** sixty clinically diagnosed patients of *Sidhma Kustha* were selected and divided into two groups. **Pattern of study:** Randomized, Parallel, and interventional clinical trial. **Results:** The result was highly significant for all the subjective and objective parameters. **Conclusion:** It can be concluded from *Upasayatmaka* study that *Darvyadi Lepa* is proved more efficient than *Kusthadi Lepa*.

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KEYWORDS: Sidhma Kustha, Kusthadi Lepa, Darvyadi Lepa and Kusthaghna Mahakashaya Kwath.

INTRODUCTION

Skin the outer covering of the body and is the largest part of the body. The skin acts as anatomical barrier from physical, chemical and biological external agent. Skin is the mirror that refelect both external and internal pathology in the body which give better clue for diagnosis.

Now a day skin disease are very common. Skin disease are common at any age of the individual but they are particularly frequent in the elderly.

All the skin disease in Ayurveda have been under the heading of *Kustha*. Which are further divided into *Mahakustha* and *Kshudrakustha*. *Sidhma* is considered as *Mahakustha*^[1] according to *Acharya charka* but *Kshudrakustha*^[2] according to *Acharya Sushruta*. *Sidhma Kustha* present with symptoms^[3] namely *Swetam*(white in colour), *Tamram*(copper in colour), *Tanu*(thin lesion), *Alabupushpa*(flower of Lagenaria Sicareria), *Rajo Ghrishtom Vimunchti*(dust on itching) on rubbing or scratching. Specific location *Prayan Urasi-Sidhma* can occur anywhere but it generally manifests on the chest. Its *Dosha* predominance *Vata-Kapha*. ^[4] As per symptomatology *Sidhma Kustha* is widely consider to be *Tinea versicolor* (tinea pityriasis) in modern science.

Tinea versicolor a common fungal infection that causes small discoloured patches of skin. *Tinea versicolor* is caused by an over growth of yeast on the skin. It most common effect teen and young adult. The condition is not contagious. Patches of skin lighter or darker than the surrounding skin. Usually on the back, chest, neck and upper arms. A conceptual aspect of the diseases is expatiated here in details.

Thus, *Sidhma* can be defined as a clinical entity characterized by hypo-pigmented lesions primarily on the upper body. Lesions itch rarely and may be hyper-pigmented in certain people, scaling occurs only if the lesion is scratched off with a blunt scalpel; there is no spontaneous scaling.

Sidhma is Kapha-Vata dominant disease. Sidhma is Rasagata and Raktagata manifestations. Local application is more useful in skin disorders as it directly acts on lesions. Internal medicine is also necessary to bring balanced status of affected *Dosha*. So, the drug which has

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property of Kaphashamak, Vattashamak & Raktashodhak can reverse the condition and can

be used for long time without any harmful effect. The result of this trial is being presented

here.

AIMS AND OBJECTIVES

> To assess the efficacy of Kusthadi Lepa and Darvyadi Lepa along with Kusthaghna

Mahakashaya Kwath in management of Sidhma Kustha.

> To compare the efficacy of Kusthadi Lepa and Darvyadi Lepa along with Kusthaghna

Mahakashaya Kwath.

MATERIALS AND METHODS

The study was conducted under a strict protocol to prevent bias to reduce the sources of error

in the study.

Selection of patients

A total 60 patients of Sidhma Kustha age group above 18 yrs. With complaint of classical

sign and symptoms of Sidhma Kustha were randomly selected from survey study irrespective

of their sex, religion, occupation, etc., attending the O.P.D. and I.P.D. of Roga Nidana Evam

Vikrti Vigyana Department, National Institute of Ayurveda, Jaipur for the present study. The

patients had been given written information and a consent form. Before the trial began,

subjects were informed about the trial's purpose, procedures, and potential negative effects.

The patients with positive signs & symptoms of Sidhma Kustha were registered for the study

after random division into two groups.

Pattern of study: Randomized, Parallel, and interventional clinical trial.

Treatment period: 30 days.

Ethical Clearance

Due clearance was obtained for the study from the institutional ethics committee,

IEC/ACA/2021/02-78, DATED 01/09/21.

CTRI registration: This clinical trial has been registered under CTRI/2022/03/041144.

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Diagnostic Criteria

All the patients were diagnosed on the basis of classical signs and symptoms of *Sidhma Kustha*. For the purpose of perfect diagnosis and assessment, a special research proforma was designed for the study incorporating all the relevant points from both Ayurvedic and modern views.

Inclusion criteria

- ➤ Male or female patient in the age group of above 18 years.
- Patients presented with classical sign and symptoms of Sidhma Kustha-
- *Swetam*(white in colour)
- *Tamram*(copper in colour)
- *Tanu*(thin lesion)
- Alabupushpa varna(flower of Laganaria Sicareria)
- Rajoghrishtom Vimunchti(dust on itching)

Exclusion criteria

- ➤ Known case of any other skin disease except *Sidhma Kustha*.
- ➤ Known hypersensitivity to any of the ingredient used in study drug.
- > Pregnant and lactating female.
- ➤ Patient less than 18 years.
- > Patient present with vitiligo.
- Cases of burns.

Drug and method of its preparation

Kusthadi Lepa^[5], Darvaydi Lepa^[6] and Kusthaghna Mahakashaya Kwath^[7] was the drug selected for the trial. The medicine was prepared in the pharmacy of National Institute of Ayurveda Jaipur. All the subjects were advised to continue their regular diet and exercise regimen during the entire study.

Table 1: Composition of Kustha di Lepa.

S.n.	Ingredients	Botanical name	Used part	Ratio
1	Kuṣṭh	Saussuria Lepa	Mūla	1 Part
2	Tamalpatra	Sinnamomum Temala	Patra	1 Part
3	Maricha	Piper Nigrum	Phala	1 Part
4	Manahshila	Realgar (AS ₂ S ₂)		1 Part
5	Kasis	Ferrous sulphate (Feso ₄ .7H ₂ O)		1 part

Table 2: Composition of Darvyadi Lepa.

S.n.	Constituents	Botanical name	Used part	Ratio
1	Daruharidra	Berberis Aristata	Moola	1 Part
2	Moolaka Beeja	Raphanus Sativus	Beeja	1 Part
3	Hartal	Yellow Arsenic (AS ₂ S ₃)	-	1 Part
4	Devadaru	Cedrus Deodara	Kand	1 Part
5	Tambulapatra	Piper Betle	Patra	1 Part
6	Shankh bhasma			1/4 Part

Table 3: Composition of Kusthaghana Mahakashaya.

S.n.	Constiteuats	Botanical name	Used part	Ratio
1	Khadir	Acacia Catechu	Twak	1 Part
2	Haritaki	Terminalia Chebula	Phala	1 Part
3	Amalaki	Embelica Officinalis	Phala	1 Part
4	Haridra	Curcuma Longa	Kanda	1 Part
5	Bhalataka	Semicarpus Anacardium	Phala	1 Part
6	Saptaparna	Alstonia Scholaris	Twak	1 Part
7	Argavadha	Cassia Fistula	Moola Twak	1 Part
8	Karveera	Nerium Indicum	Moola	1 Part
9	Vidang	Embelia Ribes	Phala	1 Part
10	Jaati	Jasminum Officinale	Patra	1 Part

Administration of drug: Cases of *Sidhma Kustha* were selected for *Upashayatmaka* trail and were divided into two groups i.e. Group A and Group B.

Group A –Patients of this group were administrated with *Kusthadi Lepa Churna* 10-20gm mixed with mustard oil for the local application once a day in the morning along with *Kusthaghna Mahakashaya Kwath* 40 ml twice a day orally at morning and evening before meal.

Intervention period was of 30 days and assessment was done on 10th day, 20th day, and 30th day.

Group B–Patients of this group were administrated with *Darvyadi Lepa Churna* 10-20gm mixed with mustard oil for the local application once a day in the morning along with *Kusthaghna Mahakashaya Kwath* 40 ml twice a day orally at morning and evening before meal.

Intervention period was of 30 days and assessment was done on 10th day, 20th day, and 30th day.

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Method of Assessment

The assessment of *Sidhma Kustha* was done at the interval of 10th days on the basis of relief in Classical sign and symptom of *Sidhma Kustha*. The data will be collected before, during, and after treatment.

Withdrawal Criteria

Patient will be withdrawn from the trial for the following reasons.

- Participant will be considered as a dropout if he/ she does not report for a follow up visit for more than 30 days after the scheduled date of visit,
- If the participant withdraws the consent for any reason,
- If the participant is lost to follow up.
- If the participants clinical condition worsens in spit of currently prescribed medication.

Assessment criteria

The assessment was done by considering changes in the subjective parameters before and after the treatment. The primary and secondary efficacy variables were recorded, some at every visit and others, before and after treatment.

- Clinical sign and symptom of Sidhma Kustha were recorded before and after treatment.
 These included clinical signs and symptoms of Sidhma Kustha which were i.e., Sweta Varna, Tamra Varna, Alabupushpa Varna, Rajo-ghristom and Kandu etc.
- All patients were contacted via phone prior to each follow up to inquire about medicine dose and any adverse events (AEs).
- Patients were questioned at every visit for common drug related symptoms as per a
 predetermined checklist and encouraged to add any other symptom they considered as a
 drug-related side effect. At the end of study, no adverse event was found.

OBSERVATIONS

Out of 61 registered patients, 60 completed the study. One patients dropped out as they didn't complete the follow-up. The age range of 18-30 years had the highest numbers of patients (70%), female (55%). Maximum no. of patients was married (60%) and Hindu (83.33%). In the study, 88.33% of patients were graduate.

Discussion on Dashavidha Atura Pariksha

In present study maximum patients i.e. 55% had *Vata-Kapha Prakriti*, 33.33% had *Pitta - Kapha* while 28.33% had *Vata-Pitta Prakriti*, indicate the role of *Vata &Kapha Dosha* in the

disease of *Sidhma Kustha*, maximum no. patients i.e. 61.67% were having *Madhyama Sara*, maximum no. of patients i.e. 60% were having *Madhyama Samhanana*, maximum no. of patients i.e. 73.33% were having *Madhyama Pramana*, maximum no. of patients i.e. 61.67% were having *Madhyama Satva*, maximum no. patients i.e. 53.33% had *Mishraras satmya*, maximum no. of patients i.e. 71.67% were having *Madhyama Abhyavaharana Shakti*, maximum no. of patients i.e. 68.33% were having *Madhyama Jarana Shakti*, maximum no. patients i.e. 63.33% were having *Madhyama Vyāyam Shakti*.

Review of the personal dietary history showed that majority of case i.e. 51.67% were non-vegetarian, maximum no. patients i.e. 46.66% were taking *Kaṭu Rasa*, 31.67% were taking *Madhura Rasa* while 21.66% of were had taking *Amla Rasa* dominant diet. Maximum no. patients i.e. 38.33% had *Akalabhojana*, 30% had *Kalabhojana*, 21.67% had *Vismaṣana* while 10% patients had *Adhyasana*. Majority of case i.e. 71.67% had *Samyaka Kṣudhā*, Majority of case i.e. 55% had *Sama Agni*.

Review of the personal history showed that Majority of patients i.e. 68.33% had 'Clear' bowel habit, Maximum no. patients i.e. 70% had normal sleep and most of the patients i.e. 53.33% were addicted to tea.

Chief complaints observed in patients were *Sweta varna* (86.67%) and Tamra Varna (71.66), *Alabupuṣpa Varṇa* (63.33), *Rajo-ghrishtom* (93.33) and *Kanḍu*(48.33).

Sweta Varṇa, Tamra Varṇa, Alabupuṣpa Varṇa, Rajo-ghrishtom, and Kanḍu all these sign and symptoms are depending on nature of disease, etiological factor and chronicity of Sidma Kustha.

Statistical Analysis

All the calculationswere calculated through "Graph Pad Prism" software 10.

These statistical test were used for intragroup and intergroup assessment.

For subjective parameters intragroup assessment Wilcoxon matched paired signed rank test and intergroup assessment Mann – Whitney test

For objective parameters intragroup assessment Paired 't' test, intergroup assessment Unpaired 't' test.

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RESULT
Effect of Therapy in Intragroup

Table 4: Showing effect of *Kusthadi Lepa* along with *Kusthaghna Mahakashaya Kwath* on subjective parameters in Group A.

Crimitania	N	Mean		%	±	SEM	W	P Value	Result	
Symptoms	11	BT	AT	Diff.	Change	SD	SEM	VV	P value	Resuit
Sweta Varṇa	30	1.93	1.03	-0.90	46.55%	0.75	0.14	-231	< 0.0001	ES
Tamra Varṇa	30	1.43	0.67	-0.77	53.48%	0.67	0.12	-190	< 0.0001	ES
No.of lesion	30	2.47	1.93	-0.53	21.62%	0.92	0.17	-45	0.0039	VS
Alabupuṣpa varṇa Varṇa	30	1.20	0.70	-0.50	41.66%	0.56	0.10	-105	0.0001	HS
Rajo-gristom	30	1.33	0.57	-0.77	57.50%	0.56	0.10	-55	0.0020	VS
Kanḍu	30	0.57	0.27	-0.30	52.94%	0.46	0.09	-45	0.0039	VS

In group A local application of *Kustha di Lepa* with *Sarsap Tail* along with *Kusthaghna Mahakashaya Kwath* 46.55% patients were found improvement in reduction in *Sweta Varṇa*, 53.48% patients were found improvement in reduction in no. of lesion, 41.66% patients were found improvement in reduction in *Alabupuṣpa Varṇa*, 57.50% patients were found improvement in reduction in *Rajo-ghrishtom*, 52.94% patients were found improvement in reduction in *Kandu*.

Table 5: Showing effect of *Darvyadi Lepa* along with *Kusthaghna Mahakashaya Kwath* on Subjective parameters in Group B.

Camptoms	N		Mea	n	%	±	SEM	\mathbf{W}	P Value	Result
Symptoms	17	BT	AT	Diff	Change	SD	SEM	VV	r value	Kesuit
Sweta Varṇa	30	1.73	0.30	-1.43	82.69%	0.96	O.18	-325	< 0.0001	ES
Tamra Varṇa	30	1.17	0.27	-0.90	77.14%	0.83	0.15	-190	< 0.0001	ES
No. of lesion	30	2.50	1.47	-1.03	41.33%	1.28	0.24	-116	0.0002	HS
Alabupuṣpa Varṇa	30	0.77	0.30	-0.47	60.87%	0.56	0.10	-91	0.0002	HS
Rajo-ghristom	30	1.40	0.17	-1.23	88.09%	0.67	0.12	-378	< 0.0001	ES
Kanḍu	30	0.57	0.03	-0.53	94.11%	0.62	0.11	-105	0.0001	HS

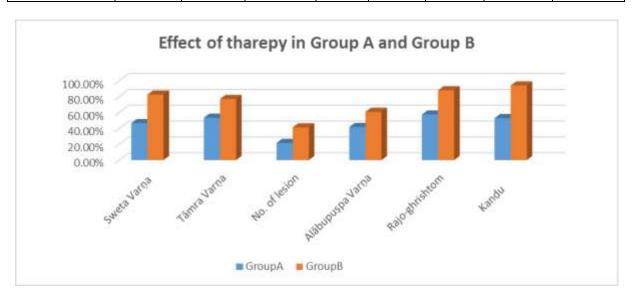
In group B local application of *Darvyadi Lepa* with *Sarsap Tail* along with *Kusthaghna Mahakashaya Kwath* 82.69% patients were found improvement in reduction in *Sweta Varṇa*, 77.14% patients were found improvement in reduction in *Tamra Varṇa*, 41.33% patients were found improvement in reduction in no. of lesion, 60.87% patients were found improvement in *Alabupuṣpa Varṇa*, 88.09% patients were found improvement in

reduction in *Rajo-ghrishtom*, 94.11% patients were found improvement in reduction in *Kanḍu*.

Intergroup Comparison

Table 6: Statistical Comparison of effect of therapies on subjective parameters in Group A and Group B.

Symptoms	Group	Mean diff.	% change	±SD	SEM	·U'	P Value	Result
Sweta Varna	A	-0.90	46.55%	0.75	0.14	310	0.0295	S
Sweia varņa	В	-1.43	82.69%	0.96	O.18	310	0.0293	S
Tamaa Varra	A	-0.77	53.48%	0.67	0.12	410.5	0.6010	NIC
Tamra Varṇa	В	-0.90	77.14%	0.83	0.15	419.5	0.6812	NS
No of losion	A	-0.53	21.62%	0.92	0.17	363.5	0.1518	NS
No. of lesion	В	-1.03	41.33%	1.28	0.24			
Alabupuṣpa	A	-0.50	41.66%	0.56	0.10	435.5	0.9120	NS
Varṇa	В	-0.47	60.87%	0.56	0.10	433.3		
Rajo-	A	-0.77	57.50%	0.56	0.10	291.5	0.0083	V.S.
ghrishtom	В	-1.23	88.09%	0.67	0.12			v.S.
Kanḍu	A	-0.30	52.94%	0.46	0.09	366	0.1742	NC
	В	-0.53	94.11%	0.62	0.11	300	0.1742	NS



Overall Effect of therapy

Table 7: Showing the overall improvement in Group A and Group B.

Sign and	Group A		Group B	
symptoms	% change	Impression	% change	Impression
Sweta Varṇa	46.55%	Mild improvement	82.69%	Marked improvement
Tamra Varṇa	53.48%	Moderate improvement	77.14%	Marked improvement
No. of lesion	21.62%	Unchanged	41.33%	Mild improvement
Alabupuṣpa Varṇa	41.66%	Mild improvement	60.87%	Moderate improvement
Rajo-ghrishtom	57.50%	Moderate improvement	88.09%	Marked improvement

Kanḍu	52.94%	Moderate improvement	94.11%	Marked improvement
Average % change		45.63%		74.04%

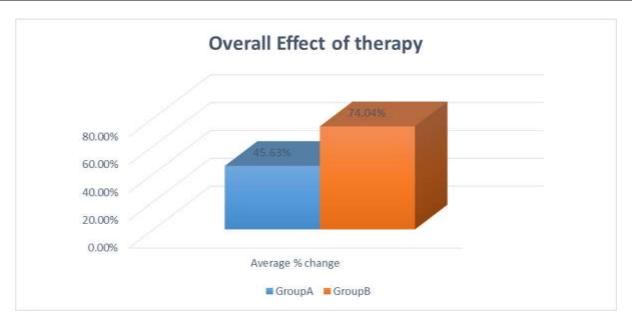


Table no. 7 showing that average % of relief was higher in group B i.e. 74.04% followed by group A (45.63%). In comparison to group A, the effect of therapy was greater in group B. It's because of the study is only 30 days long. If the study lasts longer than 30 days, changes in subjective parameters may be discovered.

Intra-group (paired 't' test)

Effect of therapy in objective parameters (lab investigations) in group A

Statistically very significant result (P Value = 0.0022) was observed in basophils

Statistically very significant result (P Value = 0.0024) was observed in RBS.

Statistically not significant result was found in RBC, Hb, Hct, mcv, mch, mchc, Rdw-cv, Rdw-sd, WBC, Neutrophils, Lymphocytes, Eosinophils, Monocytes, platelets and ESR.

Effect of therapy in objective parameters (lab investigations) in group B

Statistically not significant result was found in RBC, Hb, Hct, mcv, mch, mchc, Rdw-cv, Rdw-sd, WBC, Neutrophils, basophils, Lymphocytes, Eosinophils, Monocytes, platelets, RBS and ESR.

Inter-group (unpaired 't' test)

Statistically insignificant variations in intergroup laboratory parameters of both groups were reported. This demonstrates that there is no statistically significant difference in the efficacy of both therapies.

DISCUSSION

Probable mode of action of drugs

Every drug's action is determined by its dominant Pharmacodynamic properties i.e. *Rasa, Guna, Veerya, Vipaka*, and *Prabhava* are the pharmacodynamic properties. Some drugs work through *Rasa*, some through *Guṇa*, some through *Veerya*, some through *Vipaka*, and some through *Prabhava*. In *Ayurveda*, treatment is primarily based on *Dosha Cikitsa Sidhma* is a *Kapha-Vata* illness. When applied topically, the active ingredients of the *Lepa* penetrate deeper tissues via the *Siramukha* and *Swedavahi Srotas* and stain them with their *Sukshma* and *Tikṣṇa* properties. It de-blocks the impediment in *Swedavahi Srotas* and lets the local toxins to flow out through the *Sweda*, thus clearing out the micro channels due to its *Uṣṇa, Tikṣṇa*, Viṣad, and *Sukṣma* characteristics. The *Uṣṇa Veerya* of *Kustha di Lepa, Darvyadi Lepa*, and *Snigdha Guṇa* of its carrier i.e. *Sarsap Tail*, produces pacification of *Vata* and *Kapha*, which creates the *Samprapti* and therefore alleviates symptoms. *Kanḍu* was greatly eased in the majority of the patients due to the *Kandughna* property of *Manhashila, kasis, hartal*, and *Devadaru*. The scale reduction should be attributed to the *Snigdh Guṇa* of *Manhashila, Hartal, Devadaru* and *Sarsap Tail*.

Kapha-Vata Samaka properties of *Kustha*, *Tamalpatra*, *Marich*, Kasis, *Devadaru*, *Moolak beeja* and *Tambulapatra*. *Kapha-Vata* dominant of *Sidhma Kustha* disease, the therapy reverting the pathology and bringing back normalcy.

Moolak Beeja^[43] (Raphanus sativus)-Moolak has Katu Rasa, Katu Vipak and Sheet Veerya which having Vata-Kapha Shamana property which help to cure Sidhma Kushta.

Tikta Rasatmak Dravya having property of Raktaprasadan. For example Kustha, Tamalpatra, Manhashila, Kasis, Daruaridra, Hartal and Devadāru.

Katu Dravya having property of Agnideepana and cure Kushta, for example Kustha, Tamalpatra, Marich, Manhashila, Moolak beeja, Tambulapatra, hartal and Shankh Bhasma.

Kashaya Dravyas Absorbs Sharirgata Kleda due this reason it will cure Kushta. For example Daruharidra, Tambulapatra, Hartal and Shankh Bhasma.

Khadir curing skin diseases main drug among all the Kustha gna Dravyas Khadir is describe as a Agrya by Acharya Charaka it will work on Dushta Kapha and having Raktashodhan

property, it will absorb *Raktagata Kleda*, *Khadir* is a drug which is rapidly absorb *Kleda*. Hence it is acting as *Shreshta kushtghna*.

Haritaki it having it removes toxins by its *Malaanulomana* property the toxins which produces *Kushta* specially which are *Kledajnya* type of *Kushta*.

Amalaki having Sharirshuddhi, Raktashuddhi property so it will act as a Twakprasadak.

Haridra has Raktadhatushodhan property& Raktaprasadan property which act on Dushta Raktagata Kapha it has bactericidal property therefore it used in Kushta Aragwadha (Cassia Fistula)-It having Madhur Rasa, Madhur Vipaka, Sheet veerya due to Madhuryata Pitta Shaman and having Sanstrana property which removes toxin from body.

Vidanga (Emblia Ribes)-Due to effect of killing parasites and specially act on Agnimandya, Ajeerna janit kushta due to its Katu Vipak and Ushna Veerya.

Kustha gna Mahakashaya Kwath have anti-inflametory, Kustha ghna, Kundughna properties. All the drug have Raktashodhaka property due to this Kustha gna Mahakashaya Kwath act as blood purifier.

CONCLUSION

Analysed data of all these extreme exposure of *Nidana* may provide a significant role for diagnosis, prognosis, as well as prevention of the *Kustha*. Avoidance of these aetiologies is concluded to be the first step in the direction of control and management of *Sidhma Kustha*. This study was undertaken to evaluate and rediscover this ancient science of dietetics in Ayurveda in today's perspective both conceptually and clinically.

The effect of both the drug i.e. *Kusthadi Lepa* and *Darvyadi Lepa* in various sign and symptoms of *Sidhma Kustha* in two groups was found that average % of relief was higher in group B i.e. 74.04% followed by group A(45.63%).

It can be concluded from *Upasayatmaka* study that *Darvyadi Lepa* is proved more efficient than *Kusthadi Lepa*.

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