

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF ASANATWAK LEPA IN AHIPUTANA W.S.R TO NAPKIN RASHA

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ABSTRACT

Ahiputana is a *Kapha Rakta* predominant disorder mentioned in Ayurvedic classics; it is one of the most common skin diseases during Infancy and Toddler, usually starts within the age of 3rd to 12th week and peaks its incidence in the age of 6th to 12th month, up to the age of 5years¹, which could be compared with “Napkin Rash” of contemporary science. It is caused by several factors, including warmth, excessive waterlogging of the local skin from stools and urine, and increased perspiration with sweat retention. It is said to be a sort of reaction to ammonia formed in the voided urine. The rash may be a mild erythematous reaction covering the perineal region, buttocks and genitalia. In others, it may be severe with papulovesicular lesions and ulcers². Many drugs are used for internal administration and external application, and prevention measures have been described in detail in *Ayurveda Samhithas* and modern science to overcome *Ahiputana*/Napkin Rash. So, a remedy which would be easy to follow, efficacious, cost-effective and free from all the side effects was adopted. *Asanatwak lepa*³ is mentioned in *Astanga Hrudaya*, where the bark of *Asana* is used to prepare *lepa*, which has *Kaphaghna*, *Pittaghna*, *Vranaropaka*, *Kledaghna* and *Raktashodhaka* properties. Hence, it is indicated in the treatment of *Ahiputana*. Therefore, an attempt was made to study the clinical evaluation of *Asanatwak lepa* in *Ahiputana* w.s.r. to Napkin

Rash. The sample size was a minimum of 30 subjects, fulfilling the diagnostic and inclusion criteria selected. Trial drug treatment, i.e. application of *Asanatwak lepa*, was given to the children—duration-7 days with Follow-up on the 10th & 14th day after treatment. Results obtained after the clinical trial were analysed statistically & all the observations were subjected to creative discussions. The final results showed that after seven days of the treatment, complete cure was observed in 24 (80%) children & there was marked improvement in 6 (20%) children.

Keywords: *Ahiputana*, *Asanatwak lepa*, Napkin rash.

INTRODUCTION

Ahiputana is considered under *Kshudra Roga* of acute onset & uncertain prognosis, caused by *Ashuchitwa* mainly, which aggravates Raktha & Kapha dosha⁴ in the anal region. Clinical features are Kandu, Daha, Pidaka, Kshipram Sphota, Tamravarna, Srava, etc., which can correlate with napkin Rash.

The selection of soap/detergents should be decided on pH, which must be closer to the tear & the product should not irritate the skin. Synthetic diapers do not absorb moisture. Thus, excess wetting because of sweat, urine & faeces irritates the skin & causes Napkin rashes.

Many drugs are used for internal administration and external application, and prevention measures have been described in detail in *Ayurveda Samhithas* and Modern Science to overcome *Ahiputana*/Napkin Rash. So, a remedy that would be easy to follow, productive, cost effective and free from all the side effects was adopted.

Asanatwak lepa is mentioned in *Astanga Hrudaya*, where the bark of *Asana* is used to prepare *lepa*, which has *Kaphaghna*, *Pittaghna*, *Vranaropaka*, *Kledaghna* and *Raktashodhaka* properties. Hence, it is indicated in the treatment of *Ahiputana*. Therefore,

an attempt was made to study the clinical evaluation of *Asanatwak lepa* in *Ahiputana* w.s.r. to Napkin Rash.

OBJECTIVE:

- To evaluate the clinical efficacy of *Asanatwak lepa* in *Ahiputana*.
- To assess the changes & improvement of symptoms in the Children of *Ahiputana*.

MATERIAL AND METHODS

SOURCE OF DATA

LITERARY SOURCE

Classical Ayurvedic textbooks, articles, and scientific databases were referred to in detail for this clinical study.

DRUG SOURCE

Raw required drugs will be collected under the guidance of Dravya Guna experts from the market and prepared at *Alvas Pharmacy, Mijjar*.

SAMPLE SOURCE

Children attending *Kaumarabhritya* OPD & IPD of Alva's Ayurveda Medical College and Hospital *Moodbidri*, Other referrals and medical camps.

PREPARATION OF ASANATWAK LEPA

Ingredient of *Asanatwak Lepa*

SL NO	Ingredient	Latin Name	Proportion
1	<i>Asanatwak</i>	<i>Pterocarpus marsupium</i> linn.	6kg
2	<i>Sikta</i>	Wax	375gm
3	<i>Tilatail</i>	<i>Sesamum indicum</i> s	1500ml

METHOD OF PREPARATION

Part 1: *Asanatwak Kashaya* Preparation

- *Asanatwak* is collected with the help of a Dravyaguna expert from the market, dried in sunlight, and made into coarse and fine powder.

- The coarse powder of Asana was weighed and added to water kept on madhyamagni starting should continue till reduced to ¼th part, and *Kashaya* was filtered through pore cloth.
- *Sikta* was heated, and impurities were removed after being filtered through cloth.
- Fine powder of *Asantwak* mixed with water made into *Kalka*.

Part 2: Preparation of Ointment

- *Tila taila* is taken in a cleaned wide-mouth vessel, and mild heat is given.
- *Khashaya* and *Kalka* are added to the tail staring, which is done till the Tailapaak Sidhilakshana is achieved.
- Finally, the taila was filtered in a clean vessel, and *Sikta* was added to it. Then, this container was kept in the water bath and stirred continuously. Thus, prepared ointment must be preserved in a 10-gram container with tight-fitting corks.

METHODS OF DATA COLLECTION

SELECTION OF SUBJECTS

A **minimum** of 30 subjects fulfilling the diagnostic and inclusion criteria irrespective of their Gender, Religion and Socio-Economic status were selected for the study from Alvas Ayurveda Medical College and Hospital OPD, among other referrals.

METHOD OF COLLECTION

INTERVENTION

<i>Yoga</i>	<i>Asanatak lepa</i>
Mode of Administration	<i>Bhahirparimarjana Chikitsa</i> (external application)
Dose	Q.s
Duration	Seven days
Time	Three times day
Form of the drug	<i>Malahara</i> (ointment)

PERIOD OF OBSERVATION

The assessment was done on BT(0th), on the 3rd, 5th and 7th day after treatment.

Follow up – 10th and 14th day.

The total duration was 14 days.

ASSESSMENT CRITERIA

Clinical data was collected by direct interaction with parents, the child was examined, and details were noted in the specific case record format prepared for the study.

STUDY DESIGN: An Interventional Clinical Study.

SAMPLE SIZE: 30 Children suffering from *Ahiputana*.

DIAGNOSTIC CRITERIA

(a) Inclusion criteria

1. Children diagnosed with the case of *Ahiputana* /Napkin Rash with the presenting symptoms.
2. Children between the ages of 4 months to 2 years, irrespective of sex, religion, Socioeconomic status & food habits.
3. H/o of symptoms of *Ahiputana* / Napkin Rash not more than seven days.

(b) Exclusion criteria

1. Children above the age group of 2 years & below four months.
2. Children suffering from any other systemic disorders, eg. acute gastroenteritis with dehydration, Helminthic infection, Lactogen intolerance, Secondary Infection etc
3. Children with generalized skin infections other than *Ahiputana* are suffering from *Ahiputana* Due to *Dustastanyapana*.

A detailed Proforma will be prepared, and an assessment will be done based on subjective and objective parameters by grading them.

Subjective

a. *Kandu*

b. *Ruja*

Objective

a. Dimensions (W shape distribution)

b. *Vivarnatha* (skin colour)

c. *Pidaka* (papulo-vesicular)

d. *Srava* (discharge)

Assessment criteria Gradings

Parameters	0	1	2	3	Grade
Dimensions	Absent	<30cm ³ / (Mild)	30-60 cm ³ / (Moderate)	>60 cm ³ / (Severe)	
<i>Kandu</i>	No itching at all	Mild itching	Moderate	Severe	
<i>Ruja</i>	No pain	Mild pain	Moderate pain	Sever pain	
<i>Vivarnatha</i>	Normal	Mild Redness	Moderate redness	Severe redness	
<i>Pidaka</i>	Absent	Skin lesion palpa- ble elevated	Fluid filed Lesion	Raised lesion. containing pus.	
<i>Srava</i>	No discharge	Mild discharge	Moderate dis- charge	Severe discharge-	

STATISTICAL ANALYSIS

OBSERVATION	PREDOMINANCE	PERCENTAGE	INTERPRETATION
AGE	<1year	66.67%	<i>Balaka</i> is said to be <i>Sukumara</i> , where <i>Klesha Sahanana</i> of the child is very poor. In infancy, stratum corneum layer is thin, so more prone to get affected with infection.
GENDER	Male	60%	There may not be any relation of gender in the manifesta- tion of the disease <i>Ahiputana</i> .
RELIGION	Muslim	50%	There is no such reference regarding the high incidence of the disease in a particular religion.
SOCIOECONOMIC STATUS	Middle class	43.33%	This may be due to lack of health consciousness & poor sanitation.
GEO- GRAPHICAL AR- EA	Urban	66.77%	The reason may be due to intake of the artificial feeding (bottle or spoon feeding) which was more in urban area.
DIET HABIT	B.F/ F.F. along with the weaning food	66.67%	The reason for more children suffering from Napkin rash may be due to improper cleaning of bottle, nipple, spoon & formula fed etc.
BOWEL HABIT	4-6 times/day	46.67%	This may be due to improper maintenance of hygiene.
<i>KOSHITA</i>	<i>Mrudu</i>	66.67%	Frequently passing stools is one of the features of <i>Ahipu- tana</i> which is more Common in <i>Mrudu Koshta</i> children.
<i>NIDRA</i>	Disturbed	80%	This may be because of increased local irritability & itch- ing.
DURATION-DAYS	4-5days	66.67%	Study shows that the duration of the disease i.e. Napkin rash is acute one.
NUTRITIONAL STATUS	Normal Nutrition	80%	There may not be any relation of Nutrition in the mani- festation of the disease <i>Ahiputana</i>
<i>BALAKA AVASTHA</i>	<i>Kshirapa</i>	53.33%	It shows clearly that child is dependent on mother for food & all other activities because of ' <i>Paratantra</i> ', so in the cases of unhygienic conditions of child the mother is the victim.
<i>NIDANA</i>	<i>Adoutha Apane</i>	80%	Improper cleaning of anal region creates nidus for infec- tion & excessive sweat also creates positive environment

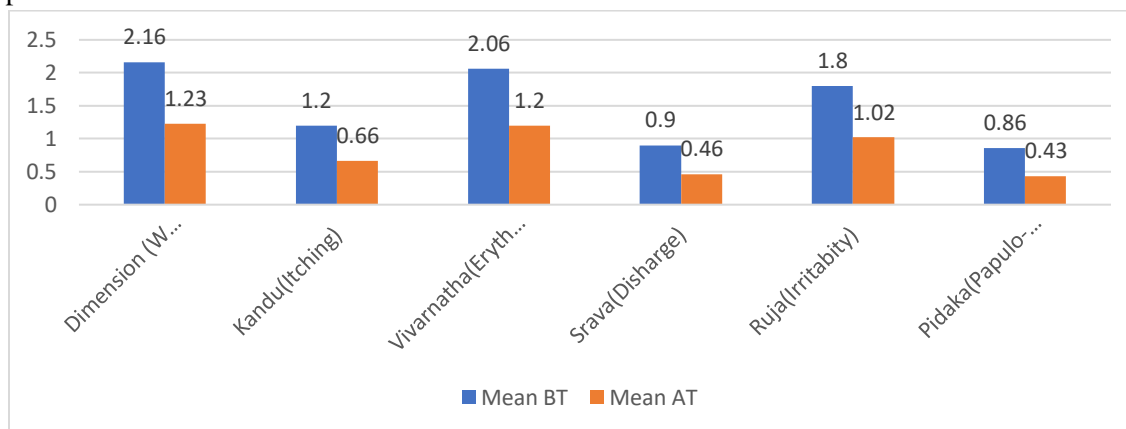
			for bacterial growth.
HYGIENIC CON- DITIONS	UNHYGIENIC	66.67%	<ul style="list-style-type: none"> ➤ As discussed earlier unhygienic condition is one of the main causes of Napkin rashes. ➤ <i>Sushruta</i> has emphasized the important cause of <i>Ahiputana</i> is "<i>Adhoue Apane</i>". Similarly, study disclosed Synthetic Diaper was used. ➤ Another important cause was detected i.e. cleaning of Diaper with the use of Detergent may increase alkalinity which causes local burning & irritation leading to Napkin rash.
	SYNTHETIC DIA- PER	60%	
	DETERGENT	86.66%	

RESULT

ASSESSMENT OF PARAMETER ON 3RD DAY OF TREATMENT

Parameter	Mean BT	Mean AT	Mean BT-AT	% of Impro	SD	SEM	P Value	Remarks
Dimension	2.16	1.23	0.93	43.05	0.53	0.09	<0.001	Significant
<i>Kandu</i>	1.20	0.66	0.54	45.00	0.71	0.13	<0.001	Significant
<i>Vivarnata</i>	2.06	1.20	0.86	41.74	0.45	0.082	<0.001	Significant
<i>Srava</i>	0.90	0.46	0.44	48.88	0.50	0.092	<0.001	Significant
<i>Ruja</i>	1.83	1.033	0.80	43.71	0.49	0.089	<0.001	Significant
<i>Pidaka</i>	0.86	0.43	0.42	48.83	0.50	0.092	<0.001	Significant

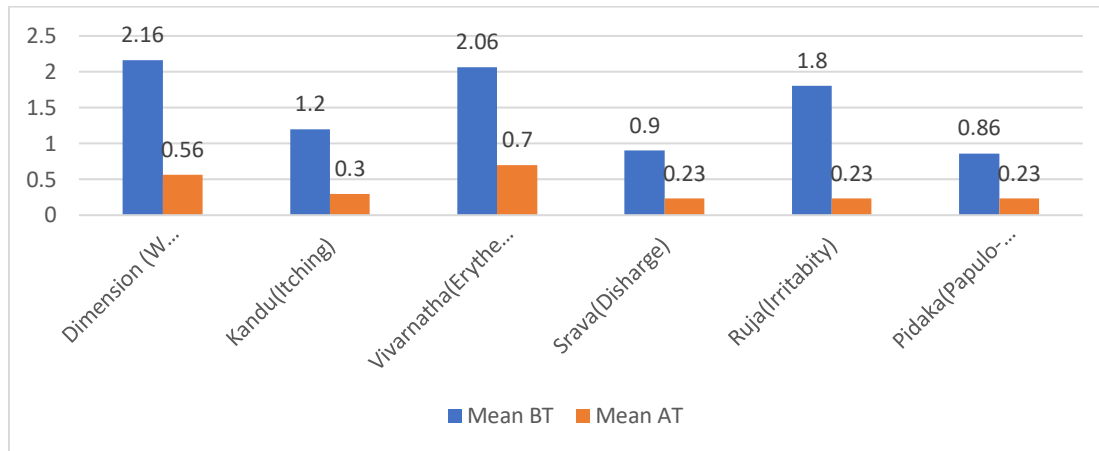
The effect of trial drug was found statistically significant in all the signs and symptoms on 3rd day of treatment with the p value <0.001.



ASSESSMENT OF PARAMETER ON 5TH DAY OF TREATMENT

Parameter	Mean BT	Mean AT	Mean BT-AT	% of Impro	SD	SEM	P value	Remarks
Dimension	2.16	0.567	1.60	74.07	0.50	0.09	<0.001	Significant
<i>Kandu</i>	1.20	0.30	0.90	75.00	0.46	0.081	<0.001	Significant
<i>Vivarnata</i>	2.06	0.70	1.36	66.01	0.46	0.085	<0.001	Significant
<i>Srava</i>	0.90	0.23	0.67	74.44	0.43	0.070	<0.01	Significant
<i>Ruja</i>	1.83	0.23	1.60	87.43	0.43	0.078	<0.001	Significant
<i>Pidaka</i>	0.86	0.23	0.63	73.25	0.43	0.078	<0.001	Significant

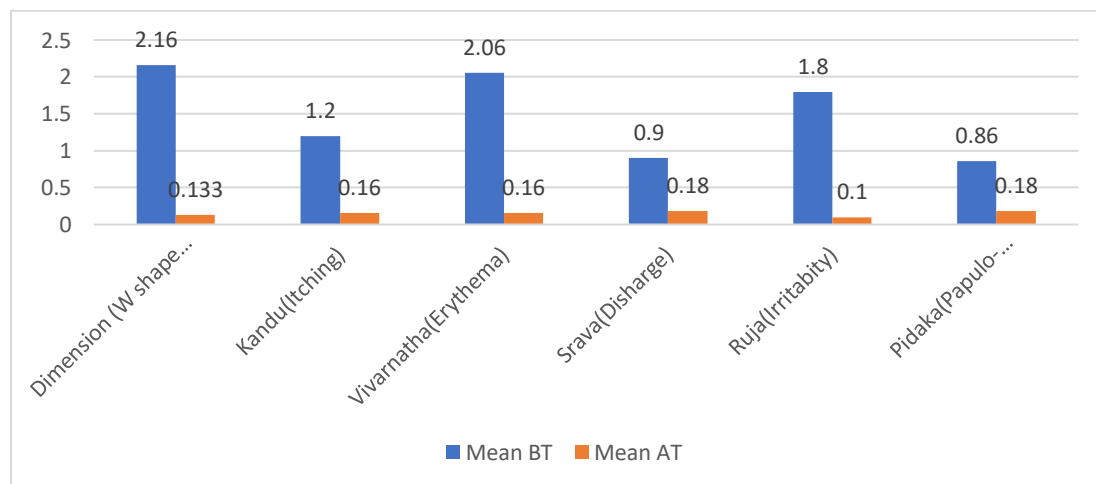
The effect of trial drug was found statistically significant in all the signs and symptoms on 5th day of treatment with the p value <0.001.



ASSESSMENT OF PARAMETER ON 7TH DAY OF TREATMENT

Parameter	Mean BT	Mean AT	Mean BT-AT	% of Impro	SD	SEM	P value	Remarks
Dimension	2.16	0.133	2.02	93.51	0.34	0.063	<0.001	Significant
<i>Kandu</i>	1.20	0.16	1.04	86.66	0.37	0.069	<0.001	Significant
<i>Vivarnata</i>	2.06	0.16	1.90	92.23	0.37	0.069	<0.001	Significant
<i>Srava</i>	0.90	0.18	0.75	80.88	0.35	0.069	<0.001	Significant
<i>Ruja</i>	1.83	0.10	1.73	96.11	0.30	0.055	<0.001	Significant
<i>Pidaka</i>	0.86	0.18	0.62	77.37	0.30	0.055	<0.001	Significant

The effect of trial drug was found statistically significant in all the signs and symptoms on 7th day of treatment with the p value <0.001.



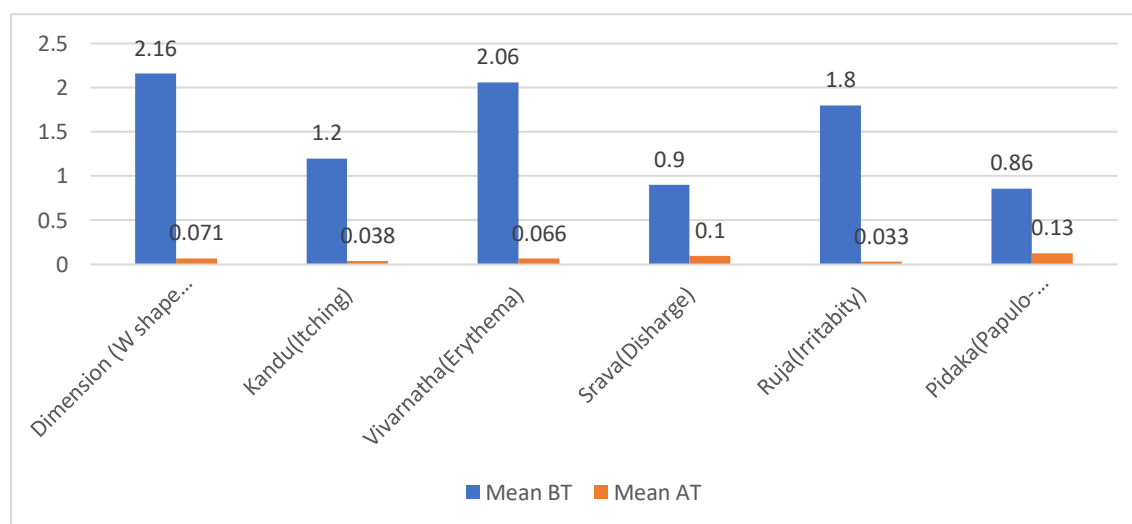
ASSESSMENT OF PARAMETER ON 10TH DAY FOLLOW UP

Parameter	Mean BT	Mean AT	Mean BT-AT	% of Im-pro	SD	SEM	P Value	Remarks
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Dimension	2.16	0.071	2.08	96.29	0.26	0.049	<0.001	Significant
<i>Kandu</i>	1.20	0.038	1.16	96.66	0.19	0.038	<0.001	Significant
<i>Vivarnata</i>	2.06	0.066	1.99	96.60	0.25	0.046	<0.001	Significant
<i>Srava</i>	0.90	0.100	0.83	89.20	0.20	0.031	<0.001	Significant
<i>Ruja</i>	1.83	0.033	1.79	97.81	0.18	0.003	<0.001	Significant
<i>Pidaka</i>	0.86	0.130	0.67	83.67	0.18	0.032	<0.001	Significant

The effect of trial drug was found statistically significant in all the signs and symptoms on 10th day of treatment with the p value <0.001.

After the treatment, during follow up period, hygienic care advised to the caretaker of the child. On 14th day recurrence of the disease was not observed in any of the children of the study group.



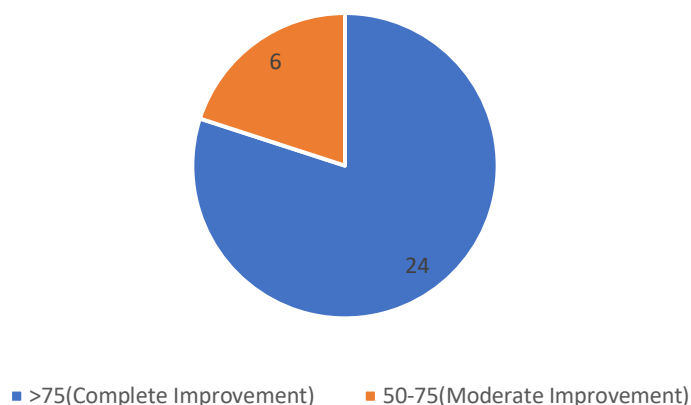
OVERALL EFFECT OF ASANATWAK LEPA IN AHIPUTANA FOUND BT-AT

% of improvement	No. of Children	Percentage
>75 (Complete Improvement)	24	80
50-75 (Moderate Improvement)	06	10

The Study shows that 80% of children got Complete Improvement and 20% got Moderate Improvement by administering *Asanatwak lepa*.

The overall effect of *Asanatwak lepa* in *Ahiputana* found BT-AT.

Overall effect of *Asanatwak Lepa* in *Ahiputana*



DISCUSSION

Ahiputana is considered one of the *Kshudra Rogas*. In classics, the word '*Kshudra*' is defined as 'Swalpe athame korure⁵; it means "the group of disorders which possesses acute onset, less Doshic signs & symptoms, some originate in private parts of the body & had unspecific prognosis". On the other hand, the group of diseases which, some have *Manda Vega* (Late onset) & some have *Maha Vega* (Acute onset). Along with this, some diseases exhibit more pain & some with less pain or without pain. The prognosis of

these diseases is also categorised under two groups viz *Mahat* (Poor) prognosis & *Alpa* (Good) prognosis.

Ahiputana is a condition occurring mainly because of unhygienic & excess contact of skin with Mala like Shakrit, Mutra & Sweda, characterised by skin erythema, itching, discharge & irritability. The onset is acute & has a good prognosis if treated properly. This condition is correlated with a Napkin rash / Diaper rash.

A Comparative statement of *Ahiputana* & Napkin rashes about clinical features:

<i>Ahiputana</i>	Napkin Rashes
<i>Vivarnata(roga)</i>	Erythema
<i>Kandu</i>	Itching
<i>Ruja</i>	Pain/ Irritability
<i>Pidaka</i>	Eruptions (Papules/Vesicles/Pustules)
<i>Srava</i>	Discharge
<i>Daha</i>	Burning Sensation
<i>Adhoue Guda Pradesh</i>	Improper cleanness of Diaper area
<i>Shishaba Kala</i>	Infancy

Numerous herbals & herb mineral compound formulations are advised in treating *Ahiputana* in classics that possess their own therapeutic values. *Asanatwak lepa* was chosen to evaluate its effect on Napkin rash, which is mentioned in *Astanga Hrudya*, *Yoga Ratnakara* & *Vangasena Samhita*.

The pH of *Siktha tail*, an acidic pH of around 6.5, was tested. This acidic pH supports the development

of the acidic skin mantle formed in the first few months of life. This mantle is essential to protect the skin from environmental factors.

Discussion on the probable mode of action of the drug

In the present study, *Ahiputana* was treated with the external application of *Asanatwak lepa*. As rightly said by all Acharyas, some drugs may act through *Rasa*, some through *Guna* or *Veerya*. *Vipaka* or

Prabhava may be the combined effect of all the ingredients. Maximum percentage of drug of *Asanatwak lepa* are having *Kashaya Pradhana, Katu, Madhura Tikta Rasa, Guru, Snigdha Guna, Sheeta Veerya, Madhura Vipaka, PittaKaphaShamaka, Sarvarujahara, Kandugna, Vranaropana & Shodhana, Krimighna, Twachya (Varnya), Raktashodhak Karma*.

Kashaya Rasa:

As described by *Acharya Susurta*, *Kashaya Rasa* has the property of *Sandhana* Medicines, which *Kashaya rasi* helps in clotting blood & *Vrana Sandhana* property of *Kashaya rasi* initiates wound healing. Other properties of *Kashaya Rasi* described by *Acharya Charaka*⁶ in *Su.26* are *Kapha Rakta Pitta Prashamana, Pidana, Ropan, Shoshana, & Stambhana*.

Tikta Rasa:

As described by *Acharya Charaka*, *Tikta Rasi* has the property of *Raktaprasadana, Vishaghna, Kushthaghna, Kandughna & Daha Prashamana*, And *Kaphaghna* property.

Katu Rasa:

One property of *Katu Rasi* described by *Acharya Charaka Su. 26* is *Marganvivruti*, "which means it dilates the *Srotas* & thus acts on the cellular level & stops the uncontrolled production of cells, which causes *Hyper keratinisation*. Other properties of *Katu rasi* described by *Acharya Charak* are *Vishnghna, Kandughna & Vranaprasadana, Sweda Kleda Malampahanti*.

Madhura Rasa:

As described by *Acharya Charaka in Su 26*. *Madhura rasi* has *Pittavatahara, Twachya, Daha Prashamana, Vishahara & Kshata Sadhankara* properties.

Asanatwak lepa, by its Doshaghnta & Karma, can be explained as follows:

It can be clearly understood that maximum drugs of the *Asanatwak lepa* have *Kaphapitta Shamaka, Tridosahara & Vatashamaka* properties, which directly act on the causative *Doshas* i.e. *Rakta Kapha*, respectively. Also, the drugs have *Rujahara & Kandughna* property. Thus, the mode of action of the *Asanatwak lepa* can be understood as alleviating the

aggravated *Kapha & Rakta Doshi*, which are responsible for the manifestation of *Ahiputana*.

THE PROBABLE MODE OF ACTION OF LEPA

The probable mode of action of *Lepa* can be described in two steps as follows:

1) PILOSEBACEOUS UPTAKE⁷

2) CUTANEOUS BIOTRANSFORMATION

1)PILOSEBACEOUS UPTAKE

When a *Lepa* is applied over the surface of skin opposite to the direction of hairs on it, through a proper base, the active principles of the ingredients of *Lepa* are released into that base. After that, this combination enters the *Romakupa* & further gets absorbed through the *Swedavahi Srotas & Siramukh*⁸. However, it should be remembered that the *Pilosebaceous Uptake*, i.e. absorption of *Lepa*, differs as per the site variation, skin condition & more important, the base through which it is applied.

2) CUTANEOUS BIOTRANSFORMATION:

After that, it is subjected to *Pachana* by *Bharajakagni*, viz., the viable epidermis starts off the catabolic degradation of the absorbed material with the help of essential enzymes.

In due course of the above transformation, some new metabolites might be forming, which soothe the provoked *Doshas* locally & thus break the pathogenesis cycle, alleviating the symptoms.

The *Asanatwak lepa* Contains the *Asanatwak Tila* tail, and *Siktha* is used as a base. All these have conferred *Asanatwak lepa* with properties like *Sheeta Veerya, Guru, Snigdha Guna & Kashaya Pradhan, Katu, Madura Rasi & Madura Vipaka*. This *lepa* also has *Sukshma* property, which helps to clear all the channels.

CONCLUSION

- *Ahiputana* is a *Kapha Rakta* predominant disorder, which can be compared with the "*Napkin Rash*" of contemporary science. It is one of the most common ailments seen in infants.
- Out of the various etiologiical factors related to *Ahiputana*, unhygienic conditions are the main causative factors.

- The onset of *Ahiputana* is acute & has a good prognosis if treated properly.
- The present study conducted on *Asanatkak lepa* has revealed a remarkable efficacy in *Ahiputana* w.s.r. to Napkin rash with a significant cure rate in most of the criteria adopted for the assessment, establishing the multicenter action of the formulation.
- The formulation *Asanatkak lepa* is a safe drug in Pediatric practice without any adverse reactions.
- *Siktha Taila* was tested with an acidic pH of around 6.5. This acidic pH supports the development of the acidic skin mantle formed in infancy. This mantle is essential to protect the skin from environmental factors.
- The *Asanatkak lepa* is a productive, cost-effective, safe remedy, used only externally & and free from all side effects. *Asanatkak lepa* has proven to be a better anti-ulcer activity, anti-inflammatory, and anti-bacterial drug compound in treating Napkin Rash.

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