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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *DASHANG SUNTHI LEPA* IN MANAGEMENT OF *SANDHI SHOTHA* AND *SHULA*

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ABSTRACT

Sandhi (Joints) *Shotha* (Swelling) and *Shula* (Pain) are widely observed symptoms in many diseases like *Aamvata* (Rheumatoid Arthritis*), Vatarakta* (Gouti Arthritis), *Avabhahuka (*Frozen Shoulder), *Vatakantaka* (Ankle Sprain), *Sandhigatavata* (Osteoarthritis). The Present Study is aimed at finding out an effective remedy for *Sandhi Shotha* and *Shula*. In this study, after going through the different treaties of Ayurveda we selected *Lepa* a *Bahirparimarjana Chikitsa (*Application of medicine externally*)* in treating *Sandhi Shotha* and *Shula*. Following formulation *Dashang Sunthi* and placebo for *Bahirparimarjana Chikitsa* (Application of medicine externally) to judge their efficacy in management of *Sandhi Shotha* and *Sandhi Shula* were selected. *Dashang Sunthi* are having 11 herbs and possessing *Tridoshahara* and *Vata Kaphashamaka* property were selected in management of *Sandhi Shotha* and *Shula*. The aim of selecting the *Dashang Sunthi lepa* as modern medicine asking for the evidence based studies on various preparations used in Ayurveda we decided to clinically and scientifically evaluate it and gather evidences based medicine which further can be helpful to other Vaidyas, Doctor fraternity and general public as well and therefore this study has been taken up.

KEYWORDS: *Dashang Sunthi, Shulahar Lepa, Shothashulahara*, Anti-inflammatory, Analgesic.

INTRODUCTION

Lepa the act of smearing, plastering, anointing of medicinal paste is called '*lepa.*[1] *Aalepa, Lipta, Lepa, Lepan* are used as synonyms[2] for *lepa. Acharya Sushruta* has cited the following version while explaining the efficiency of *Lepas* in the context of *Vrana Chikitsa*· viz. By pouring water over a burning house, the fire is extinguished immediately; in the same manner the *Lepa* pacifies the provoked *Doshas* by local application.[3] In this Study we selected *Dashang Sunthi lepa* for local application. The name suggest it contain *Dashang* means ten herbs plus addition of *Sunthi* in it. *Dashang lepa* is mentioned in many Ayurvedic text[4] and described as *Vranasophaghna* (antiinflammatory) *Jwarhara, Kushtaghna* and indicated in *Visarp, Sleepada, Shotha* for local application. *Sunthi* is described as *Vishwabeshaja*[5] *Sunthi* is unctuous**,** *Ushna, Katu,* useful in *Shotha, Udar, Shwas, Sleepada.* It pacifies *Kapha Vata, Shothahara, Shula Nashan, Krimigna.* It is *Digestive, cardio* tonic.[6]

Since Goa is *Anupa Desha Klinnata* is predominant in Goa and therefore we see *Klinnata* in *Dosha* and *Vyadhis* like *Krimi* are also predominant. It has been clinically observed when we add *Krimighna Aushadhi* in *Chikitsa* the result has been better. In order to remove the *Klinnata* in *Sandhi Shotha* and *Shula*. *Sunthi* which is *Dipana, Pachana, Laghu Guna, Katu in Rasa* and *Krimighna* was added to the already established *Dashang lepa*.

Sandhi Shotha and *Shula* are prevalent in society and large number of patients are seen in our OPD and IPD. Diseases like *Vatarakta* (Gout), *Avabhahuka* (Frozen shoulder), *Krostruka Shirsha, Sandhigatavata* (arthritis) are mostly seen with *Shotha* and *Shula* in *Sandhis. Dashang Sunthi Lepa* is easily available and cost effective. The drugs mentioned in *Lepa* are *Vata Kaphahara, Shothahara, Shulahara* and therefore can be used in treating *Sandhi Shotha* and *Shula*. It is observed that *Dashang Sunthi Lepa* is widely used since my undergraduate days in our OPD and IPD and found to be very effective. So it is proposed to evaluate it on classical basis so that it can be used to contribute to upliftment of society.

METHODS

AIM- A clinical study To evaluate the efficacy of *Dashang Sunthi Lepa* in management of *Sandhi Shotha* and *Shula*.

OBJECTIVES

i) PRIMARY OBJECTIVES.

1. To assess the changes in ESR on 1st day before application of *Dashang Sunthi Lepa*, on *7th* day and on 14th day after application of *Dashang Sunthi Lepa*.
2. To assess the changes in CRP on 1st day before application of *Dashang Sunthi Lepa*, 7th day and on 14th day post application of *Dashang Sunthi Lepa*.
3. To assess the efficacy of *Dashang Sunthi Lepa* using VAS scale before and after treatment.

ii) SECONDARY OBJECTIVES

1. To study adverse drug reaction of *Dashang Sunthi Lepa* if any.

METHODOLOGY

a) DIAGNOSTIC CRITERIA

Diagnosis were made on the basis of classical signs and symptoms of *Sandhi Shotha* and *Shula.*

b) SELECTION OF PATIENTS

30 patients fulfilling the clinical diagnostic criteria of *Sandhi Shotha* and *Shula* were randomly selected between the age group 20 to 60yrs irrespective of their sex, religion, occupation etc. from the OPD no 3 and IPD of Kamakshi Arogyadham attached to the Gomantak Ayurveda Mahavidyalaya and Research Center Shiroda Goa.

c) INCLUSION CRITERIA

All Patients presenting with signs and symptoms of *Sandhi Shotha* and *Shula*, Either sex, in the age group of between 20-60 years, Uncomplicated cases of *Sandhi Shotha* and *Shula*, *Aagantuja Shotha* without *Bhaghna* of *Sandhi* and Patients willing to participate in the trial are included in the clinical trial.

d) EXCLUSION CRITERIA

Patients of age less than 20yrs and more than 60, having complications of *Sandhi Shotha* and *Shula* like tuberculosis, bone metastasis, psoriatic arthritis are excluded from the clinical trial. Patients not willing to be part of trial and not giving written consent, were excluded from the study.

e) GROUPING WITH DOSE AND DURATION OF THERAPY

30 clinically diagnosed patients of *Sandhi Shotha* and *Shula* were equally divided into two groups A & B, 15 patients in each group.

GROUP - A: Treated by *Dashang Sunthi lepa* applied locally on the affected part. Direct demonstration of *lepa* application on day 1. *Lepa* was applied for continous 7 days and kept for 2 hrs one time a day for 7days.

GROUP – B Treated by placebo (rice flour) *lepa* for application for 7days daily for one times in a day and kept for 2 hours.

PHARMACOGNOSTICAL STUDY

a) COLLECTION OF SAMPLE

1. GROUP-A -*DASHANG SUNTHI LEPA*

Total 11 herbs are there in the trial drug formulation All the 10 herbs viz *Shirish (Albizzia lebbeck), Yashtimadhu (Glycyrrhiza glabra), Tagar(Veleriana wallichii), Raktachandan (Pterocarpus santalinus), Ela(Elettaria cardamomum), Jatamansi(Nordostachys jatamansi), Haridra(Cucurma longa), Daruharidra(Berberis aristata), Kushta(Saussurea lappa)* and *Usheer (Veteveria zizanioidis).* Bark of *Shirish (Albizzia lebbeck)*of 750 grams was cut and collected from Vazem village, sun dried and used. On drying 720 grams remained out of which 500grams was used for the study. *Haridra(Cucurma longa), Sunthi(Zingiber officinalis), Ela(Elettaria cardamomum). Jatamansi (Nordostachys jatamansi), Raktachandan (Pterocarpus santalinus), Daruharidra (Berberis aristata), Tagar (Veleriana wallichii), Kushta(Saussurea lappa), Usheer (Veteveria zizanioidis), Yashtimadhu(Glycyrrhiza glabra)* 500 grams each was procured from the Pharmacy of GAM&RC.

2. GROUP- B - PLACEBO - RICE FLOUR

Rice flour is used as Placebo (controlled drug) in this study. Rice flour was selected assuming that it does have any actions on *Shotha* and *Shula.* Surai variety Rice was purchased from market.

b) DRUG AUTHETICATION: All the drugs were identified by the department of *Dravyaguna* of GAM&RC. The pharmacognostical study of the above mentioned drugs was carried out in the department of pharmacognosy, GAM&RC, Shiroda as per the standard protocols of Ayurvedic Pharmacopoeia of India.

c) DRUG PREPARATION

1. GROUP - A *DASHANG SUNTHI LEPA*

Raw herbs collected/ procured were given to the Pharmacy of GAM&RC for drug preparation. All the 10 herbs were weighed and sun dried in shade (*Chaya Shushka*) thoroughly. Each drug weighing 500grams individually was ground into fine powder. This powder was then sieved in sieve with Mesh size No. 13. All the fine powders were then mixed together and final *Churna* named *Dashang Churna* was prepared. It was then sealed packed in plastic bags of (10 grams X 40) Demo Packs (DP-1).

Similarly 5000 grams of *Sunthi (Zingiber officinalis)***(TAP-2)**was ground into fine powder. This

powder was then sieved in sieve with Mesh size No. 13 and then sealed packed in plastic bags of (10 grams X 40) Demo Packs (DP-1).Take away packs (60 grams X 40) of ***Dashang Lepa*(TAP-1)** and (60 grams X 40) of *Sunthi*(DP-1 &**TAP-2)** were also packed. Separate packs for purpose of Demonstration and for purpose of application at home were made. *Dashang Lepa* prepared was packed as DP-1(Demo Pack) of 10 grams and TAP-1 (Take away Pack) of 60 grams. *Sunthi* (DP-2 of 10 grams and TAP-2 of 60 grams) was packed separately because if it is packed along with *Dashang Lepa* as a single unit after few days lumps of *Churna* get formed in the packs.

2. GROUP- B- PLACEBO - RICE FLOUR

Rice flour was selected as Placebo for which Surai rice was than washed and sun dried. After drying it was taken to a mill and rice flour was prepared. It was then packed and sealed in plastic bags (weighing 20 grams X 40) Demo packs and (120 grams X 40) take away packs. The Demo packs were used to demonstrate the procedure of *Lepa* to the patients whereas the take away packs were given to the patient which they had to take home and apply on the demonstrated surface daily, keep it for two hours and remove as demonstrated. Packets made are shown in fig no 1,2, 3, and 4.

DEMO PACK(DP)

Dashang Sunthi Lepa
(DP1- *DashangChurna*
DP 2- *Sunthi Churna*)

Fig.1

Rice Flour
(DP)

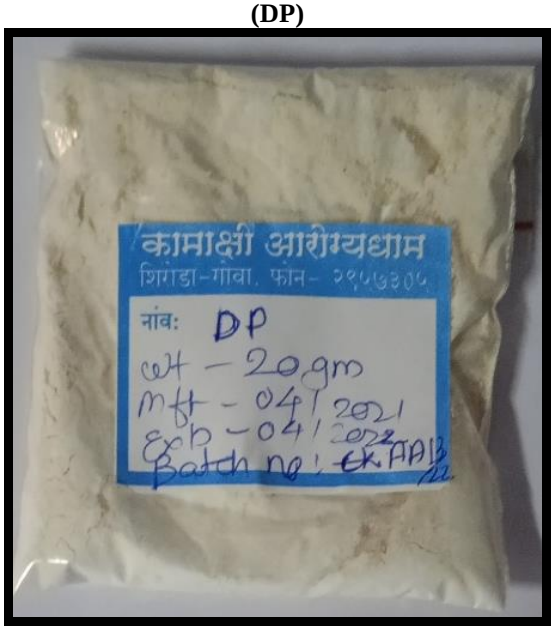

Fig. 2

TAKE AWAY PACK (TAP)

***DASHANG SUNTHI LEPA*(TAP 1)**

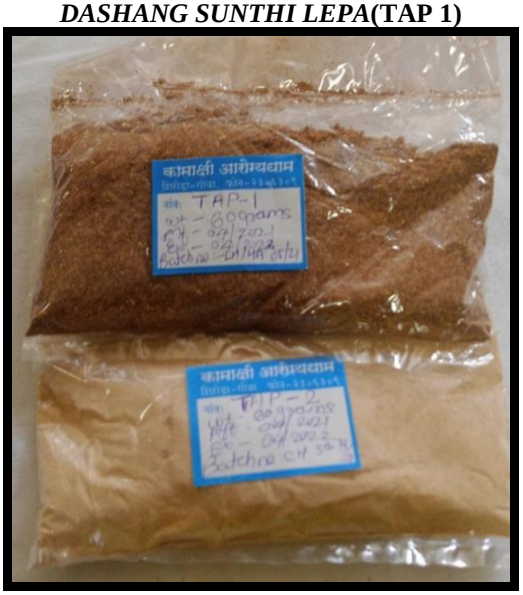

Fig.3

RICE FLOUR(TAP)

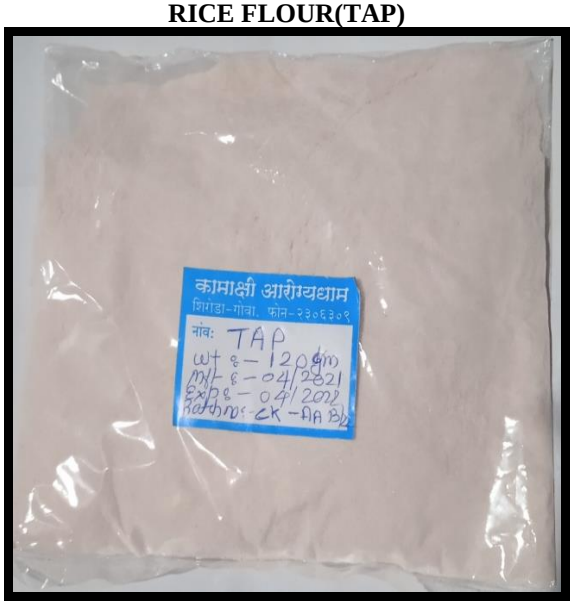

Fig. 4

d) STANDARDIZATION

Final drug *Dashang Sunthi Lepa* was then Standardized in Central Research lab of GAM&RC.

ETHICAL COMMITTEE CLEARANCE AND CONSENT AND CTRI REGISTRATION

The study has been approved by IEC with no. **GAM /IEC/Cert/11dated on 7/4/202** with **CTRI Registration No. CTRI/2021/05/033510.**

Table 1: INGREDIENTS *DASHANG SUNTHI LEPA*.

Sr. No	Drug	*Rasa*	*Guna*	*Veerya*	*Vipak*	*Karma*	Parts used
1.	***Shirish*** (*Albizzia lebbeck*)	*Kashaya*	*Laghu, Ruksha*	*Ishad-Ushna*	*Katu*	*Tridoshhara*	Bark
2	***Yashtimadhu*** *(Glycyrrhiza glabra*)	*Madhura*	*Guru, Snigdha*	*Sheeta*	*Madhura*	*Vata-Pittashamak*	Root
3	***Tagar*** *(Veleriana wallichi)*	*Tikta, Katu, Kashaya*	*Laghu, Snigdha*	*Ushna*	*Katu*	*Kapha-Vatashamak*	Root
4	***Raktachandan*** *(Pterocarpus santalinus)*	*Tikta, Madhura*	*Guru, Ruksha*	*Sheeta*	*Katu*	*Kapha-Pitta Shamak*	Heartwood
5	***Ela*** (*Elettaria cardamomum)*	*Katu, Madhura*	*Laghu, Ruksha*	*Sheeta*	*Madhura*	*Tridoshahara*	Fruit-seed
6	***Jatamansi*** *(Nordostachys jatamansi)*	*Tikta, Kashaya, Madhura*	*Laghu, Snigdha, Tikshana*	*Sheeta*	*Katu*	*Kapha-Pittashamak*	Rhizome
7	***Haridra*** *(Cucurma longa*)	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vatashamak Pittarechak*	Rhizome
8	***Daruharidra*** *(Berberis, aristata)*	*Tikta, Kashaya*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vatashamak*	Root
9	***Kushta*** *(Saussurea lappa*)	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vatashamak*	Root
10	***Usheer (Vetiveria zizanioidis)***	*Tikta, Madhura*	*Laghu Ruksha*	*Sheeta*	*Katu*	*Pitta Vattashamak*	Root
11	***Sunthi*** *(Gingiber officinale)*	*Katu*	*Laghu, Snigdha*	*Ushna*	*Madhura*	*Vata Kaphahara*	Rhizome

Hrivera (Pavonia odorata) is controversial drug and is not available. Hence *Usheera (Vetiveria zizanioidis)* possessing similar quality drug is used equal quantity in place of *Hrivera.*

INTERVENTION

S.O.P OF *LEPA* PREPARATION

The procedure of application of *Dashang Sunthi Lepa* includes-

- *PoorvaKarma*
- *PradhanaKarma*
- *Pashchat Karma*

P00RVA KARMA

Patients's were examined for any cuts or injuries on affected area where *Lepa* was to be applied and after confirming that the subject was fit for *Lepa* application of *Lepa* was applied. According to the joint involved suitable position was given to the subjects. In case of hairy subjects shaving of the involved joint was done. The affected joint was then cleaned with cotton soaked in warm water and dried. Water was taken in vessel and heated on a gas stove and after water starts boiling 10 grams of *Dashang Lepa* (DP-1) was mixed with 10 grams of *Sunthi Churna* (DP-2) from the Demo packs were put in a vessel and stirred continuously till the consistency of *Lepa* was achieved.

PRADHAN KARMA

Lepa of thickness of *Aardramahishacharma*(0.5cm)[7] was applied in direction opposite to hair follicles (from below upwards).[8] *Lepa* was kept till it dries. *Lepa* was applied once a day daily for 7 days.

PASHCHAT KARMA

After the stipulated time, the *Lepa* is washed with luke warm water and patients is requested to rest for ½ hour. Practical demonstration of application of *Lepa* and its removal is demonstrated to patients on 1st day. After removal of *Lepa,* part should be washed with luke warm water.

Fig. 5.

Fig. 6.

Fig. 7.

PLAN OF STUDY

The whole plan of study is carried out in following steps as below:-

Clinical Study

↓

Patients is randomly selected

↓

Careful history taking of Patients

↓

Diagnosis of *Sandhi Shotha* and *Shula*

↓

Discussion of whole treatment plan with Patients and consent is taken

↓

Initial assessment done on 1st day

↓

Lepa application from 1st day to 7th day is given

↓

2nd assessment on 7th day post application of *Dashang Sunthi Lepa* and 14th day

↓

Follow up is taken on 7th & 14th day

↓

Observations were recorded in CRF

↓

Obtained Data were collected & analyzed statistically

↓

Conclusion were drawn.

Fig. 8.

ASSESSMENT CRITERIA

Assessment of patient were done by using subjective and objective criteria.

1. Subjective Parameters

Subjective parameters on bases of VAS SCALE for *Shotha* and VAS SCALE for *Shula* were assessed.

2. Objective Parameters

Change in ESR and CRP Quantitative before and after treatment on1st, 7th and 14th day are recorded in CRF form.

DURATION OF THE STUDY

Patient was examined on day1, 7th& 14th day. after treatment and follow-up is done on 7th and 14thday accordingly the parameters were recorded.

STATISTICAL METHOD: The data collected is analyzed statistically for significance between the group and within group using Wilcoxon rank sum test and unpaired T test, Mann Witney test respectively.

RESULT

Obtained Result of the study is as follows:

WITHIN THE GROUP

Table 2: Groups - A: *Dashang Sunthi Lepa.*

Group	N	BT Mean			Diff D	%	Wilcoxon rank test			
							SD	SEM	P	Significant
A	15	2.43	AT	0.43	2.00	82	0.51	0.12	<0.0001	ES
			AT 1	0.06	2.37	97	0.25	0.06	<0.0001	ES

In Test (*Dashang Sunthi*) group mean score observed before the treatment was 2.43.

After Treatment value reduced to 0.43, the effect of treatment showed 82 % improvement in Visual Analogue Scale of *Shotha* score with statistically extremely-significant (P<0.0001).

After 14 days of Treatment i.e at (AT 1) value reduced to 0.06, the effect of treatment showed 97 % improvement in Visual Analogue Scale of Swelling score with statistically extremely- significant (P<0.0001).

VISUAL ANALOGUE SCALE OF *SHOTHA*

Table 3: GROUP - B, PLACEBO (RICE FLOUR).

Group	N	BT Mean			Diff D	%	Wilcoxon rank test			
							SD	SEM	P	Significant
B	15	1.43	AT	0.66	0.73	51	0.72	0.18	0.0078	VS
			AT 1	0.33	1.06	74	0.61	0.15	0.0010	ES

In Placebo group (rice flour) mean score observed before the treatment was 1.43.

After 7 days of Treatment value reduced to 0.66, the effect of treatment showed 51 % improvement in Visual Analogue Scale of *Shotha* Score with statistically very-significant (P=0.0078).

After Treatment of 14days at AT1 the value reduced to 0.33, the effect of treatment showed 74 % improvement in Visual Analogue Scale of *Shotha* score with statistically extremely- significant (P=0.0010).

VISUAL ANALOGUE SCALE FOR *SHULA*

Table 4: Group - a: *Dashang Sunthi Lepa.*

Group	N	BT Mean			Diff D	%	Wilcoxon rank test			
							SD	SEM	P	Significant
A	15	2.64	AT	1.23	1.41	53	0.66	0.16	<0.0001	ES
			AT 1	0.41	2.23	84	0.50	0.12	<0.0001	ES

VISUAL ANALOGUE SCALE OF *SHULA*

Table 5: Group - B, Placebo(Rice Flour).

Group	N	BT Mean			Diff D	%	Wilcoxon rank test			
							SD	SEM	P	Significant
B	15	2.25	AT	1.26	0.93	41	0.79	0.20	0.0002	ES
			AT 1	0.80	1.40	62	0.86	0.22	0.0001	ES

MEASUREMENT OF DEGREE OF MOBILITY BY GONIOMETER

Table 6: Group-A- *Dashang Sunthi Lepa.*

Group	N	BT Mean			Diff D	%	Paired t test				Significant
							SD	SEM	T	P	
A	15	124	AT	138.82	-14.82	12	84.69	20.54	2.549	0.0214	**S**
			AT 1	127.64	-3.64	3	93.64	22.71	0.1372	0.8926	**NS**

Table 7: Placebos: Rice flour.

Group	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	T	P	
	15	123	AT	127.4	-7.33	5	88.49	22.84	2.244	0.0415	**S**
			AT 1	140.4	-20.3	16	107.65	27.79	1.429	0.1750	**NS**

ESR

Table 8: Group A: *Dashang Sunthi Lepa.*

Group	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	T	p	
	15	22	AT	26.18	-4.18	19	14.86	3.71	1.252	0.2299	**NS**
			AT 1	23.31	-1.31	6	14.50	3.62	0.5356	0.6001	**NS**

Table 9: Group – B Placebo (Rice Flour).

Group	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	T	p	
B	15	22.73	AT	22.86	-0.13	0.05	12.33	3.18	0.0538	0.9578	**NS**
			AT 1	17.66	5.06	22	15.38	3.97	2.669	0.0183	**S**

CRP

Table 10: Group -A: *Dashang Sunthi Lepa.*

Group	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	T	p	
	15	17.56	AT	9.06	8.49	48	14.20	3.55	0.988	0.3385	**NS**
			AT 1	8.46	9.09	52	24.14	6.03	0.7379	0.4720	**NS**

Table 11: Placebo: Rice Flour.

Group	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	T	p	
	17	9.27	AT	10.85	-1.58	17	24.51	6.32	0.5258	0.6073	**NS**
			AT 1	9.84	-0.57	6	32.89	8.49	0.0647	0.9493	**NS**

*BT-Before treatment,*AT-After treatment of post7 days, AT1-After treatment of post 14 days, *AF-After follow up* DIFF-Difference,*SD-Standard deviation,*SEM-Standard error of mean, *ES-Extremely significant,*VS-Very significant,*S-Significant,*NS-Not significant.
TAP- Take away Packs, DM- Demo Packs

DISCUSSION

EFFECT OF THERAPY ON *SHOTHA*: *Shotha* is considered as a symptoms or it can be disease independently caused due to accumulation of fluid in *twak* and *bhahya sira* causing inflammation, *utsedha*.[9] Causes which are obtained in this study were due to *Atishara, Amla, Vidahi Annasevan*, when there is *Agnimandya*. Leading to formation of *Shotha* due to improper food habits (*vishamashana*). Group A treated with *Dashang Sunthi lepa* showed significant improvement in sign and symptoms of *Shotha* percent of 82% to 97. Where as Group B showed 51% to 74% improvement in symptoms of *Shotha*. Trial group A shows better result in reduction of *Shula* in comparison to standard group (placebo) B. It is said no pain is caused without *Vata* hence drugs present in *Dashang Sunthi* directly acts on *Vata kapha* thus reducing *Shula*[10] caused by *Vata Dosha.*

PROBABLE MODE OF ACTION OF *DASHANG SUNTHI LEPA* ON *SANDHI SHOTHA* AND *SHULA*

- *Anti-inflammatory*: *Shirish, Tagar, Raktachandan, Ela, Haridra, Yashtimadhu, Sunthi Daruharidra, Kushta.*
- *Analgesic:Shirish, Tagar, Raktachandan, Jatamansi, Sunthi, Daruharidra, Yashtimadhu, Haidra.*
- *Shirish(Albizzia lebbeck)* possess *Madhura, Kasaya Rasa, Laghu, Ruksha, Titka Guna, Ushna Veerya, Katu Vipaka* balances *Tridoshara*.[11] It also posseses Anti-inflammatory, Analgesic, *Vishaghna*[12] properties among other. Indicated in *Visha.*
- *Yashtimadhu (Glycyrrhiza glabra)* possesses *Madhura Rasa, Snighdha, Guru Guna, Sheeta Veerya* and *Madhura Vipaka* due to which it reduces the *Pitta*[13] by its anti-inflammatory[14] action. Due to *Madhura Vipaka* and *Guru Guna* it *does Vata Shamana* thereby reducing *Vedana.* High levels of Potassium present in it help to regulate muscle contractions and nerve impulses.

- *Tagar (Veleriana wallichii)* possesses *Katu, Tikta, Kashaya Rasa, Laghu, Snighda Guna, Ushna Veerya, Katu Vipaka,* balances *Kaphavatashamaka*.[15] It posses Anti inflammatory, Analgesic, *Shothahara* properties.[16]
- *Raktachandan(Pterocarpus santalinus) Tikta, Madhura Rasa, Guru Ruksha Guna, Sheeta Veerya, Katu Vipaka,* balances *Kaphapitta.*[17] It posses Anti inflammatory, Analgesic, Antiarthritic, *Shothahara, Raktaprasadaka, Raktashodak* properties[18] among others. *Raktachandan* is *Madhura Rasatmaka, Guru* is & *Sheeta Veeryatmaka* helps of proper circulation of *Rasa Rakta* by *Prasandan* action thus help in *Ropan* of affected *Sthan.*
- *Ela(Elettaria cardamomum)* is *Katu, Madhura Rasa, Laghu, Ruksha Guna, Sheeta Veerya, Madhura Vipaka* balances *Vata*.[19] It posses Anti inflammatory, Analgesic, *Shothahara* properties.[20]
- *Jatamansi(Nordostachys jatamansi)* possesses *Tikta, Kashaya, Madhura Rasa, Laghu, Snighda, Tikshana Guna, Sheeta Veerya, Katu Vipaka,* balances *Tridosha*.[21] It possess *Analgesic, Shothara, Antispasmodic* properties.[22] It also has *Sukshma Guna, Aakasha Mahabhuta* dominantdue to which it eaches to minute *Srotas.* It produces relaxation of muscles pain and depression of *CNS* and relaxation of sckeletol muscle.
- *Haridra(Cucurma longa)* possesses *Katu, Tikta, Kashaya Rasa, Ruksha, Laghu Guna, Ushna Veerya, Katu Vipaka* and decreases *Kapha Vata*.[23] It possesss Anti-inflammatory, Analgesic, *Shothahara* properties[24] and is also indicated in *Twakdosh, Shotha, Pandu* among others.
- *Daruharidra(Berberis aristata)* possesses *Tikta, Katu, Kashaya Rasa, Laghu, Ruksha Guna, Ushna Veerya, Katu Vipaka,* balances *Kapha*.[25] It possesss Anti-inflammatory, Analgesic, *Shothahara* properties[26] also indicated in *Visarpa,* skin diseases among others.
- *Kushta(Saussurea lappa)* possesses *Katu, Tikta, Madhura Rasa, Laghu, Ruksha Guna, Ushna Veerya, Katu Vipaka,* balances *Kaphavata*.[27] It possesses Anti inflammatory, *Analgesic,* and *Vishashara* property[28] among others.
- *Usheer(Veteveria zizanioidis) is Tikta, Madhura Rasa, Laghu, Ruksha Guna, Sheeta Veerya, Katu Vipaka,* balances *Pittavatashamaka*.[29] It posses Anti-spasmodic properties, indicated in *Daurganda, Trishna, Daha*.[30]
- *Sunthi(Zingiber officinalis)* possesses *Katu Rasa, LaghuSnighdha Guna, Ushna Veerya, Madhura Vipaka,* and reduces *Kapha* and *Vata*.[31] It posses Anti inflammatory, Analgesic, *Shothahara* properties[32] *Sunthi* is *Ushna Veerya* therefore it reduces the *Sheeta guna of Vata* and *Kapha* thus helping in reducing pain and stiffness of the joint. It is also indicated in *Shotha, Shleepada, Pandu, Shula,* and *Nadivrana.* Gingerols act as potent inhibitor of prostagland in biosynthesis enzymes.

MODE OF ACTION OF *LEPA*

Dashang Sunthi Lepa when applied to affected joints *Lepa* works on body by following ways

1) *Raktaprasadan Ushna Veerya*.

Due to *Raktaprasdan and Ushna Veerya* qualities of *Dravyas* Veerya (active principles) of the *Lepa* enters the skin via *Romkupa, Swedavahi Srotas, Rasa Raktavahi Srotasa. Raktaprasadan* dravyas enhance the action of the *Lepa* by enhancing the flow of blood into affected areas of skin and increasing for tissue perfusion of the skin.

*Veerya (a*ctive principles) in the *Lepa* reaches the skin where *Bhrajak Pitta* performs *Bhrajan* (metabolism*)*of *Lepa* applied on skin.

2) *Laghu Guna*

Drugs in like *Shirish, Tagar, Kustha, Jatamansi* due to their *Laghu, Sukshama Guna* enters site of *Shotha* and *Shula.*Further *Laghu Guna* increases permeability of skin making *Veerya* of *Lepa* to penetrate easily into the skin.

The *Kleda* is absorbed by *Ruksha Guna Dravyas* like *Ela, Tagar, Haridra, Daruharidra Kushta* which works as *Shothahara* thereby reducing *Shotha*. *Kashaya Rasatmaka* drugs like *Shirish, Tagar, Daruharidra, Jatamansi* helps to constrict the dilated capillaries there by not allowing plasma to move from the intravascular spaces into the extravascular spaces thereby reducing swelling.

Drugs like *Sunthi, Jatamansi* on account of acts on relaxation of pain within muscles and depression of *CNS* and relaxation of sckeletal muscle.

3) Base

Jala which is used as base for preparing *lepa* helps to bind the constituents together and prevents irritation of the skin. *Jala* along with *Rasa Dhatu* performs *Preenan* of *Twaka* thereby increasing its permeability and penetrability due to which *Veerya* of *Lepa* enters into *Rakta* which travelling along the *Triryagavahi Dhamani, Swedavahi Srotas* and *Rasa Raktavahasrotas* reaches the whole body performing *Sarvadehika* action of *Lepa.*

In this way *Lepa* performs *Sarvadehika* action like *Vishanashana, Tridoshshamaan, Vata Shamana* etc. and localized action it helps to reduce *Shula, Shotha,* and helps for healing of tissues by *Ropan* action.

The above seen action is presented in diagramatic presentation as below.

LEPA* WHEN APPLIED ON *TWAK

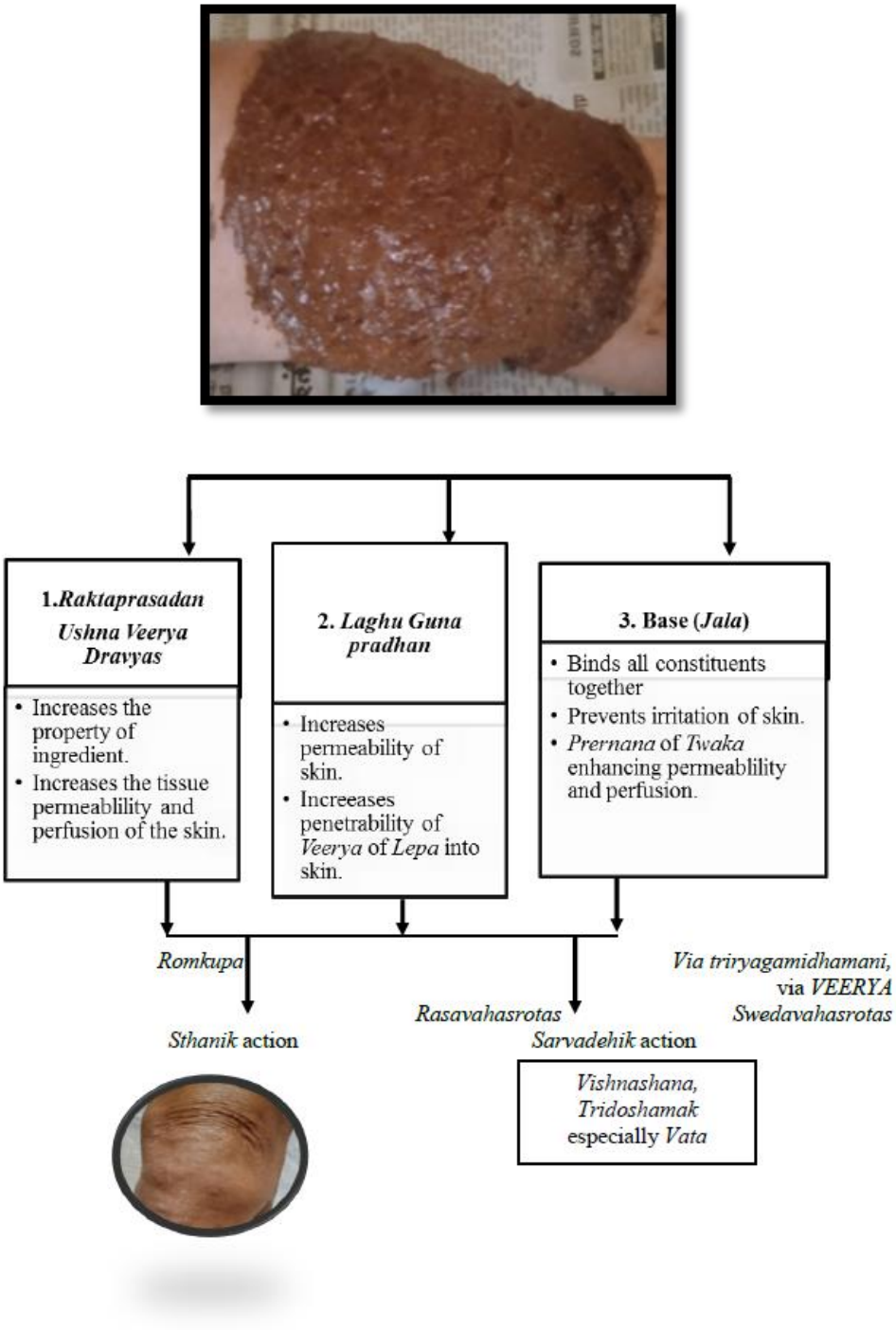

Fig. 9.

CONCLUSION

1. In this study subjects presenting with symptoms of *Sandhi Shotha* and *Shula* were managed by application of *Dashang Sunthi Lepa.*
2. The signs and symptoms of *Shotha* and *Shula* in *Sandhi* were relieved over a period 14 days by application of *Dashang Sunthi Lepa* and results were statistically extremely significant.
3. In Overall effect of *Lepa Chikitsa* on *Sandhi Shotha* and *Shula* it was found that 33% patients got complete cure, 50% of patients got moderate relief, 13% patients got mild relief and 3% patients found no relief at all. From the above it can be concluded that the external *Lepa Chikitsa* alone can help in curing *Shotha* and *Shula* without the use of internal medications in considerable amount of patients. Hence this treatment modality which is economical can be prescribed safely to the patients.
4. In the overall effect of therapy improvement in *Shotha* was 82% after 7 days of *Lepa* applicaton and 97% after 14 days of *Lepa* application which was

statistically extremely significant from which we can conclude that *Dashang Sunthi Lepa* was highly effective in reducing swelling. If the *Dashang Sunthi Lepa* was applied for a longer period of time 14 days then the effect was more significant 97% then when it was applied for a shorter period of time 82% in 7 days.

5. In the Overall effect of therapy improvement in *Shula* from 53% after 7 days of *Lepa* application and 84 % after 14 days of Lepa application which was extremely significant from which we can conclude that *Dashang Sunthi Lepa* was highly effective in reducing pain. If the *Dashang Sunthi Lepa* was applied for a longer period of time 15 days then the effect was more significant 84% then when it was applied for a shorter period of time 53% in 7days.
6. From the above 2 we can conclude that *Dashang Sunthi Lepa* shows extremely significant Anti-inflammatory, Analgesic effects and can be safetly given for a longer period of time 14 days without any Adverse Drug Reactions and untoward effects.
7. *Dashang Sunthi Lepa* was well tolerated and there were no reported incidences of adverse drug reactions or untoward effects noted during the study as well as in follow-up period indicating that *Dashang Sunthi Lepa* is exceptionally effective and free of side effects and safe for long term use. There were no adverse drug reactions(ADR) or untowards effects
8. The fact that the placebo group (rice flour) showed statistically extremely significant results indicates that the *Lepa Chikitsa* by itself can be used to treat *Shotha* and *Shula* but when a particular type of *Lepa* for eg. *Dashang Sunthi Lepa* used in this study is used then the result will be extremely significant. This contribution can be attributed to the *Veerya* (active principles) present in the herbs which actually enter into skin and shows localised action on account of its presence locally and generalised action due to the *Veerya* which spreads through the whole body through via the *Triyagavahi Dhamanya*. This mode of action has been elaborated in detail in the fig no. 33
9. From this study we can conclude the constituent given in the study do not actually enter through the skin but the actions take place on account of the *Veerya (Active principles), Rasa, Guna, Vipaka* of the constituents of the *Lepa.*
10. Statistically significant reduction in subjective parameters *Shotha* and *Shula* were observed.
11. Statistically insignificant results in objective parameters viz. Goniometry, ESR and CRP were observed, this could be attributed to the fact that a smaller sample size was taken ie. 15 subjects in each group.
12. No analgesics were prescribed to patients during the comensment till end of this study except *Dashang Sunthi Lepa* alone, which indicates that *Dashang Sunthi Lepa* alone can be safetly used in the treatment of *Sandhi Shotha* and *Shula.*
13. After completion of this study it can be concluded that *Dashang Sunthi Lepa* is extremely useful in management of *Shotha* and *Shula* in *Sandhi* and also showed marked improvement in quality of life.
14. Looking at the above facts we reject the null hypothesis and accept alternate hypothesis i.e. *Dashang Sunthi Lepa* is effective in management of *Sandhi Shotha* and *Shula*.

SUGGESTIONS FOR FURTHER STUDY

1. Present study was carried out on a small sample size; we recommend that a larger sample size be taken for further studies especially to draw better results in the objective parameters viz. Goniometry, ESR and CRP.
2. Since 33% patients were completly cured and 50% got moderate relief there is a scope to add an internal medication along with *Lepa Chikitsa* and formulate a management protocol for making the treatment of *Shotha* and *Shula* quicker thereby relieving the distress of subjects afflicted.
3. Since *Dashang Sunthi Lepa* is not available in the market on basis of this study further studies can be undertaken and all doubts cleared regarding efficacy of the drug and then the product can be aggressively marketed.
4. Different bases for *Lepa* preparation and application could be tried eg. alcohol, *Ghrita, Kanji* etc. to get quicker and better results.
5. Studies indicate that nano particles are absorbed through the skin. In further studies the constituents of the *Lepa* could be reduced to Nano particle size and used in an attempt to obtain desired results.
6. Further studies on *Dashanga Sunthi Lepa* can be conducted where *Dashang Sunthi Lepa* can be applied for more than 14 days and checked in how much time period maximum relief or cure from *Shotha* and *Shula* can be achieved without observing any ADR's or untoward incidents.

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