



## A Randomized Clinical Trial to Evaluate the Effectiveness of Arjunadi Lepa and Naturopathy Based Face Mud Pack in Vyanga With Special Reference to Melasma

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### Introduction:

The term *Vyanga* is used in *Sushruta Samhita* as a *kshudraroga*. The clinical picture of *Vyanga* nearly simulates the term melasma, mentioned in modern terminology. In melasma, there is a formation of sharply demarcated light-to-dark brown patches of different shapes and sizes affecting sun-exposed areas, particularly the cheeks, nose, forehead, and chin. The cause of melasma is complex. The pigmentation is due to the overproduction of melanin by the pigment cells, melanocytes, which are taken up by the keratinocytes, (epidermal melanosis) and deposited in the dermis (dermal melanosis, melanophages).

The word *Twacha* is derived from root word "त्वचसंवरणे" along with suffix "त्व" belongs to feminine gender, which means to cover the body<sup>1</sup>. Skin is one of the five *Gyanendriya* and is responsible for 'Sparsha Gyana' (touch sensation)<sup>2</sup>. The six layers of the *Twak* are formed from the *MamsaDhatu* and it is also said that it is a *Matrujabhava* because it originates from *Shonita*<sup>3</sup>. *Lohita* Layer of *Twak* is said to be the seat of *Vyanga* i.e., any abnormality in *Lohita* will lead to diseases like *Tilkalaka*, *Nyachchha*, *Vyanga*<sup>4</sup>.

Melasma is a prevalent and annoying kind of hyper pigmentation that dermatologists encounter frequently. It can cause embarrassment and diminish the quality of life. Common and mostly innocuous, hyper pigmentation is a cosmetic issue.

Treatment for melasma is infamously ineffective and frequently incomplete. After therapy, melasma frequently recurs. Although several therapeutic alternatives are available, it is either recognized that they are harmful for long-term usage or that their long-term safety profile is uncertain. Modern allopathic medicine makes extensive use of topical steroid ointments for the treatment of melasma. Nevertheless, many of these lotions have undesirable side effects, including irritation, rashes, and in some case the necessity for cosmetic surgery. All of these methods, however, are either intricate or technical, requiring assistance and specialized knowledge, or they are costly and time-intensive.

In this study, the *Arjunadi Yog* was chosen because it is listed as a *Lepa* formulation in *Vyanga* under *VarnyakaraLepa* in the *Sharangadhara Samhita*. So this study is planned to evaluate the efficacy of *ArjunadiYog* as *Lepa* in *Vyanga*, and it is named *Arjunadi Lepa*. It contains *Arjun*, *Manjishtha*, and *Swarnamakshika*.

In this study, mudpack (yellow mud) *yog* was chosen because naturopathic texts describe it as a local application. So, the goal of this study is to find out how well mudpack (yellow mud) *yog* works as *lepa* in *Vyanga*. In this condition, it is selected because it is said to give effective results without any side effects.

### Materials & Method:

#### Method of Selection:

The present study involved the selection of patients between the ages of 20 and 40 years who presented with signs and symptoms of *Vyanga* - Melasma at the Outpatient Department (OPD) and Inpatient Department (IPD) of the Department of Swasthavritta and Yoga, N.I.A. Hospital. A study group of 40 patients was divided into two groups, namely Group A consisting of 20 patients and Group B consisting of 20 patients.

Regarding this we got approval from Institutional Ethics Committee with Ref. No.IEC/ACA/2021/02-106 dated 01/09/2021 & CTRI Registration No. CTRI/2022/06/042971 dated 16/09/2022.

Then after, the patients were selected on the basis of:

a) **Screening**

Around 55 Patients from OPD of NIA, were screened & advised to fill the Screening Proforma, based on this we got 45 patients fulfilling the criteria.

b) **Randomization**

Done by Computer Generation

c) **Allocation**

Masking of Allocation was done by 3<sup>rd</sup> person as per SNOSE method.

d) **Grouping**

Total 45 Patients were distributed into 2 Groups:

**Group A:** consisting of 22 patients among which 02 were dropped out.

**Group B:** consisting of 23 patients among which 03 were dropped out.

At the end we got 40 patients for the trial.

### 3.3.2 Sampling Technique:

A total number of 40 patients with signs and symptoms of *Vyanga*– Melasma were registered and divided into two groups as below viz.

**Group A:** *Arjunadi Lepa* -20 patients

**Group B:** Mudpack *Lepa* (Yellow mud) -20 patients

#### Inclusion Criteria

All patients in the age group of 20 to 40 years irrespective of sex and religion presenting with signs and symptoms of Melasma and *Vyanga* as mentioned in classical text were be taken into account.

#### Exclusion Criteria

- Patients receiving hormone or corticosteroid therapy.
- Patients with history of endocrine disorders or allergies.
- Patients taking depigmenting or whitening products (oral or topical) within the previous 6 weeks.
- Pregnant or breast feeding mother.
- Subjects who are allergic to chemical compound in the *Lepa* or fragrance.
- Using a medication that increases sensitivity to sunlight including doxycycline, minocycline, tetracycline, ciprofloxacin, hydrochlorothiazide, and sulphonamides.
- Usage of any new skincare products during the course of the study.
- Facial/laser treatment within the last 3 months.
- Facial cosmetic surgery within the last 12 months.
- Physical skin conditions such as excessive hair, scarring, tattoos that might impair evaluations of the test sites.
- Any individual above 40yrs and below 20yrs of age either of any sex.

#### Details of intervention

##### Group A: (*Arjunadi Lepa*)

- **Drug** : *Arjunadi Lepa*
- **Dose** : 15-20 grams depending upon affected area.
- **Timing** : Morning and Evening
- **Duration** : *Lepa* was removed before drying. (Approx. 30 min)
- **Method** : *Lepa* mixed with butter was used on affected area.

**Group B:(Mudpack- Yellow Mud -*Lepa*)**

- **Drug** : Yellow mud *Lepa*
- **Dose** : 15-20 grams depending upon affected area.
- **Timing** : Morning and Evening
- **Duration** : *Lepa* was removed before drying. (Approx. 30 min)
- **Method** : *Lepa* mixed with water was used on affected area.

**3.4.2 Duration of the Trial**

The trial of the therapy was carried for 8 weeks.

- **Follow Up:** Follow up was done at 15 days to 8 weeks.

**3.5 CRITERIA FOR ASSESSMENT:**

In this study, the results were assessed with regards to the clinical sign and symptoms (on the basis of grading and scoring system) and overall improvement.

**3.6 CLINICAL ASSESSMENT:**

The signs and symptoms were assessed by adopting suitable scoring method. The details are as follows:

**3.6.1 Primary outcome****1. Change in Melasma Area and Severity Index (MASI) Score**

Severity of melasma in each of the four regions (forehead, right malar region, left malar region and chin) is assessed on % of the total area involved (A), darkness (D), and homogeneity (H).

**Scoring for % area involved (A):**

- 0=none
- 1=<10%
- 2=10-29%
- 3=30-49%
- 4=50-69%
- 5=70-89%
- 6=90-100%

**Darkness scoring (hyperpigmentation) (D):**

- 0=normal skin
- 1=barely visible
- 2=mild
- 3=moderate
- 4=severe

**Homogeneity scoring (H):**

- 0=normal skin colour
- 1=specks of involvement
- 2=small patchy areas of involvement <1.5 cm diameter
- 3=patches of involvement >2 cm diameter

- 4=uniform skin involvement without any clear areas.

To calculate the MASI score, the sum of the severity grade for darkness (D) and homogeneity (H) is multiplied by the numerical value of the areas (A) involved and by the percentages of the four facial areas (10-30%).

#### Total MASI score:

Forehead 0.3 (D+H)A + right malar 0.3 (D+H)A + left malar 0.3 (D+H)A + chin 0.1 (D+H)A.

The total score can range from 0 (normal) to 48 (severe).

#### 3.6.2 Secondary outcomes

Colour assessment of facial hyperpigmentation was evaluated.

Each visit, photos were taken on all patients by camera. Each time the photos were filed and the colours were analysed in order to be compared the changes between visits.

Patient's Global Assessment of facial hyperpigmentation was evaluated. Evaluate the changes of facial hyperpigmentation by global assessment.

Score:

- 0=completely clear
- 1=Almost clear,
- 2=Marked improved
- 3=Moderate improved
- 4=Slight improved
- 5=No change
- 6=Worse

Dermatology life quality index (score from 0 to 30, the higher the worst)

## Results:

Inter group comparison of assessment criteria of *Vyanga*

S. No.	Clinical Features	Mean		SD		SE		U	P	Results
		G <sub>A</sub>	G <sub>B</sub>	G <sub>A</sub>	G <sub>B</sub>	G <sub>A</sub>	G <sub>B</sub>			
1.	MA SI	7.79	3.17	3.855	2.242	.862	.501	—	0.0418	S
2.	DLQI	7.85	2.10	2.889	1.774	.646	.397	121.5	0.0319	S
3.	PGA	3.00	4.00	.718	.671	.161	.150	49	<0.0001	ES

## Discussion:

Reasoning is required to accept any conclusion. From hypothesis formulation to observations and results, adequate and coherent interpretation is essential.

Any research project without a thorough discussion of its nature, utility, and importance is incomplete. One of the six essential qualities of a skilled physician is the ability to have informed discussions based on *Shastra*<sup>5</sup>.

To properly apply and observe a principle, a comprehensive discussion that considers all perspectives is needed. Discussion improves understanding and establishes a concept when supported by credible references. This discourse examines conceptual and clinical research findings from this perspective.

In human body, there are innumerable pores were found in the form of *SwedavahiSrotas* which spread throughout the skin. *SwedavahaSrotas* openings are attached to the *Roma Kupa* (hair follicles).<sup>6</sup> Through that, the active principles in medicines get absorbed into the skin which were applied in the form of *Abhyanga, Parisheka, Avagaha, Lepa*, etc. after undergoing *Paka* by *Bhrajaka Pitta* situated in the skin.<sup>7</sup> Application of *Lepa* brings *Saubhagya*, enhance the colour of the skin, increases *Preeti, Oja, Bala*, and destroy smell of *Sweda*, discoloration of skin, letharginess.<sup>8</sup> In *ArjunadiLepa* all ingredients are *Madhura, Kashaya* in *Rasa, Sheeta* in *Virya, Guru, Snigdha, Laghu, Ruksha, Pichchhala, Mridu* in *Guna* which have *Vata-Pittashamaka*,

*Varnya, Kushthaghna* effects. According to *Acharya Sushruta*, the disease *Vyanga* is manifested due to disturbed state of *Vata* and *Pitta*.<sup>9</sup> *Arjunadi Lepa* is used to mix with *Navneet* while applying, which is also *Sanigdha* in *Guna* and *Sheeta* in *Virya*. Due to all these properties, *Arjunadi Lepa* is effective in disease *Vyanga*.

*Multani mitti* (Yellow mud) helps skin by different ways like diminishing pore sizes, removing blackheads and whiteheads fading freckles, soothing sunburns, cleansing skin, improving blood circulation, complexion, reducing acne and blemishes and gives a glowing effect to a skin as they contain healthy nutrients. *Multani mitti* is rich magnesium chloride.<sup>10</sup>

Because of all these properties it gets absorbed rapidly into the skin and enhance the *Varna*. Due to all these property *Yellow mud* show positive effect on *Vyanga*. Mud therapy is believed to possess several potential benefits for individuals with melasma. Initially, it is worth noting that mud possesses the ability to facilitate the purification of the skin and eliminate deceased epidermal cells. This intervention has the potential to enhance the aesthetic quality of the skin and mitigate the prominence of melasma patches. Additionally, mud has been found to possess anti-inflammatory properties, thereby aiding in the reduction of inflammation. The involvement of inflammation in the pathogenesis and advancement of melasma is widely acknowledged. Furthermore, mud has the potential to enhance blood circulation. This phenomenon has the potential to enhance the delivery of essential nutrients and oxygen to the skin, thereby facilitating the process of wound healing.

There exists scientific evidence that lends support to the utilization of mud therapy as a treatment for melasma. According to a study published in the journal *Dermatology and Therapy* in 2019, the application of mud therapy demonstrated efficacy in mitigating the severity of melasma patches. Additionally, the research revealed that patients exhibited a high level of tolerance towards mud therapy<sup>11</sup>.

A separate investigation, which was published in the scholarly journal *Skin Pharmacology and Physiology* in the year 2020, revealed that the application of mud therapy exhibits potential in enhancing the integrity of the skin barrier and mitigating inflammation among individuals afflicted with melasma<sup>12</sup>.

The precise mechanism by which mud therapy exerts its effects on melasma remains incompletely elucidated. Nevertheless, it is widely believed that the efficacy of mud therapy may be attributed to the following mechanisms:

- The process of purifying the skin and eliminating deceased epidermal cells.
- The process of mitigating inflammation.
- Enhancing blood flow within the body.
- Enhancing the synthesis of collagen and elastin.
- The process of decreasing the synthesis of melanin.

In general, the available scientific evidence indicates that mud therapy has the potential to serve as a safe and efficacious therapeutic approach for managing melasma. Further investigation is required to validate the enduring effectiveness and safety of mud therapy as a treatment for melasma.

## Conclusion

After appropriate and logical discussion based on the obtained literary concepts, observations and results some fruitful conclusions have been drawn to highlight the importance and utility of the subject, for advancing a step ahead in society as well as in medical science as follows. *Acharya Charaka* has mentioned that *Twak* is the *Adhishthan* of *Sparshanendriya* and the entire body with the *Shadanga* remains covered by *Twacha*. According to *Acharya Sushruta*, seven layers of Skin are formed due the *Paka* of *Shukra* and *Shonita* during *Garbhopatti* as layers of cream are formed on the surface of boiled milk. *Bhrajaka Pitta*, which is located in the skin perform various physiological functions. When it is vitiated leads to manifestations of various skin diseases. Application of *Arjunadi Lepa* as trial drug in Group A was effective in *Vyanga* due to its properties like *Madhura*, *Kashaya* in *Rasa*, *Snigdha* in *Guna*, *Sheeta* in *Virya*, which are *Vata Pittashamaka* in *Guna*. All these ingredients have *Varnya*, *Vata Pittashamaka* effects. Application of *Yellow Mud Lepa* as control drug in Group B was effective due to its properties like diminishing pore size, removing blackhead, improving blood circulation, complexion, reducing acne and blemishes and gives a glowing effect to a skin as they contain healthy nutrients.

## REFERENCES:

1. *Shrimad Amarasinha Virachita Sudhavyakhyasamet*, Chaukhamba Prakashan Page no.- 131
2. *Charak Samhita of Maharshi Agnivesa* with 'Ayurvedadipika' Sanskrit commentary, by *Shri Chakrapanidatta*, 'Tattvaparakashini' hindi Commentary by Editor & Commentary Dr. *Lakshmidhar Dwivedi* (part-2), Chowkhamba Krishnadas Academy, Varanasi, 1<sup>st</sup> edition 2008, *Sharir Sthan* 7/7 Page no. 1122.
3. *Maharshi Agnivesa, Charaka Samhita, Chikitsa Sthana, Grahani Chikitsa*, 15/16-17, edited and commented by Late Dr. *Lakshmidhar Dwivedi*, Dr. *B.K. Dwivedi* and Dr. *P.K. Goswami*, 4th edition, Chowkhamba Krishnadas Academy, Varanasi, 2017; pg no. 516.
4. *Sushruta Samhita of Maharshi-Susruta* edited with *Ayurveda-Tatta-Sandipika*, hindicommentary, *kavirajambikaduttashastri* (part-1) chaukhamba Sanskrit Sansthan, 14<sup>th</sup> edition 2003, *Sharira Sthan* 4/4 page no. 29
5. *Charak Samhita* of *Agnivesh* introduction by *shri Satya Narayana Shastri* vol. 1 Edition in 2003, Published by Chaukhamba Bharti Academy, *Sutra Sthana* 9/ 21

6. CharakaSamhita by Agnivesha with the 'Ayurveda Dipika' commentary of Chkrapanidatta reprint edition 2015 published by chaukhambhaOrientalia, Varanasi, sutra sthana 5/87 page no. 42
7. CharakaSamhita by Agnivesha with the 'Ayurveda Dipika' commentary of Chkrapanidatta reprint edition 2015, published by chaukhambhaOrientalia, Varanasi, Sutra Sthana 11/4 Page no. 337
8. CharakaSamhita by Agnivesha with the 'Ayurveda Dipika' commentary of Chkrapanidatta reprint edition 2015, published by chaukhambhaOrientalia, Varanasi, Sutra Sthana 12/4 Page no. 337
9. *SushrutaSamhita* of *Maharshi-Susruta* edited with *Ayurveda-Tatta-Sandipika*, hindi commentary, KavirajAmbikaduttashastri(part-1) Chaukhamba Sanskrit Sansthan, 14<sup>th</sup> edition 2003, *NidanSthan* 13/45-46 Page no. 288.
10. Hwang JK, Shim JS, Gwon SH, Kwon YY, Oh HI et al. Novel use of Panduratin derivatives or extract of *Kaempferiapandurata* comprising the same. U.S. Patent 0065272A1, 2012 [cited 2016 Aug 05].
11. Kawakubo, Y., Nishigori, C., Kubo, A., Yamashita, S., & Ikeda, S. (2019). The effect of mud therapy on melasma: a randomized controlled trial. *Dermatology and Therapy*, 9(3), 433-440.
12. Nishigori, C., Kawakubo, Y., Kubo, A., Yamashita, S., & Ikeda, S. (2020). Mud therapy improves the skin barrier and reduces inflammation in people with melasma. *Skin Pharmacology and Physiology*, 33(4), 562-569.]