



AN OPEN LABEL CLINICAL NON - RANDOMIZED STUDY TO EVALUATE THE EFFICACY OF PATOLA-NIMBADI BASTI IN THE MANAGEMENT OF PSORIASIS W.S.R. TO EKA KUSHTHA- A STUDY PROTOCOL

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ABSTRACT

Background: Psoriasis is one of the most common dermatological diseases. It is a complex, chronic, multi-factorial, non-contagious inflammatory skin disease characterized by erythematous, sharply demarcated papules and rounded plaques, covered by silver shiny scale. Eka kushtha consists of sign and symptoms i.e. Aswedanam, mahavastu and matsya shakalopam avastha which can be compared with psoriasis and hence it has been taken analogue to psoriasis in present research work. In present study, basti chikitsa is selected because acharya sushrut described the indication of basti in sansargaj and sannipataj vikara. Due to dominance of tridosha in kushtha and mainly vata, kapha in eka kushtha, favoured the treatment of Patol-nimbadi basti. The dravya of Patol-nimbadi basti is tikta rasatmaka. Tikta dravya are deepak, pachak and kaphaghana, lekhan and vishghana in nature and the effect on skin is kandughana, daha-prashaman and sthirikaran. Therefore, Patol-nimbadi basti is selected in management of Psoriasis. **Aim:** Evaluation of Patol-nimbadi Basti in management of Psoriasis (Eka kushtha). **Objective:** To evaluate efficacy of Patol-nimbadi Basti in management of Psoriasis (Eka kushtha). **Methodology:** 30 patients will be selected of Psoriasis on the basis of selection criteria. All patients will be given Patol-nimbadi Niruha basti and Goghrit Anuvasan basti as per the schedule of kala basti for 16 days. Observations will be done on the basis of before and after subjective and objective parameters.

KEYWORD: Psoriasis, eka-kushtha, basti, Panchkarma.

INTRODUCTION

Psoriasis^[1] is one of the most common dermatologic diseases. It is a complex, chronic, multi-factorial, non-contagious inflammatory skin disorder characterized by erythematous, sharply demarcated papules and rounded plaques, covered by silvery shiny scale. The cause of psoriasis is not exactly known, but it is believed to have an autoimmune, genetic component and it can be triggered by a prolonged injury to the skin. Factors that may aggravate Psoriasis include stress, withdrawal of systemic corticosteroids, excessive alcohol consumption, and smoking. There are many treatments available, but because of its chronic recurrent nature psoriasis is a challenge to treat.

Worldwide prevalence of Psoriasis is 3 - 4%. In India its prevalence is 0.4%-2.8%.

Ayurveda texts do not give a direct reference towards a single disease which can be compared with the modern

day "Psoriasis". Many entities like "Kitibha", "Charmadala" and "Eka Kushtha" are compared with it. The disease Kitibha does not have scaling as such but Shyava Varna and Khara Sparsha can be noted. Charmadala on the other hand has Sphota and Ruja as the important signs along with scaling.

Eka kushtha^[2] consists of the signs and symptoms i.e. Aswedanam, Mahavastu and Matsya shakalopam Avastha which can be compared with Psoriasis and hence it has been taken as the analogue to Psoriasis in the present research work. And in present study we have choose Basti Chikitsa in the management of Psoriasis (Eka Kushtha) because Acharya Sushruta^[3] described the indication of Basti in sansargaj and sannipataj vikara. Due to dominance of tridosha in kushtha and mainly vata, kapha in Eka Kushtha favored the treatment of Patola- Nimbadi Basti.^[4] In present study most of the dravya of the Patola-Nimbadi Basti is tikta- rasatmaka. Tikta ras dravya are Deepak, Pachak and Kaphaghana,

Lekhana and *Vishaghna* in nature and the effect of *tikta ras* on skin is *Kandughana*, *Kushthaghana*, *Daha-prashmana* and *Sthirakarana*. Therefore, we have to choose *Patola-Nimbadi Basti* in management of psoriasis (*eka-kushtha*)

AIMS AND OBJECTIVE

Aim: Evaluation of *Patola-Nimbadi Basti* in the management of Psoriasis (*Eka Kushtha*).

Primary Objective: To evaluate the efficacy of *Patola-Nimbadi Basti* in the management of Psoriasis (*Eka Kushtha*)

Secondary Objectives

- To improve quality of life of patient.
- To provide specific *Basti Chikitsa* as the line of treatment of Psoriasis.
- Remove the stress factor of Psoriasis patient.

Case Definition

Patient having symptoms of Psoriasis such as erythematous, sharply demarcated papules and rounded plaques, covered by silvery shiny scale.

Research Question

Does *Patola-Nimbadi Basti* effective in the management of Psoriasis (*Eka Kushtha*) ?

Hypothesis

Research Hypothesis (H_1)

Research Hypothesis (H_1):- *Patola-Nimbadi Basti* is effective in the management of Psoriasis (*Eka Kushtha*).

Null Hypothesis (H_0):- *Patola-Nimbadi Basti* is not effective in the management of Psoriasis (*Eka Kushtha*).

Experimental Source

It will be a pure Human Clinical trial; no animal experiment will be done.

MATERIALS AND METHODS

To fulfil the Aim and Objectives, the study plan is divided into 2 sections

- Literary review
- Clinical study.

Study design

- Type of Trial – Interventional
- Design- Non-randomized clinical trial
- Purpose – Treatment
- Masking- No, Open Label
- Timing- Prospective
- End Point- Efficacy
- Duration of trial- 18 months
- Phase of trial- phase 2
- Subjects- 30
- Statistical tool- Appropriate tool will be apply

Selection of patients: The patients fulfilling the criteria and attending *Panchkarma* OPD and IPD of *Panchkarma* department of the I.A.S.R Kurukshetra Haryana will be selected for research study.

Inclusion criteria

1. Subjects presenting with clinical features of Psoriasis.
2. Patients suffering from Psoriasis with less than 50% of the body surface involvement.
3. Subjects with chronicity of disease more than 6 months and less than 5 yrs.
4. Subjects of either sex between age group of 20-60 yrs.
5. The patient who is fit for *Basti Karma* (*Basti Yogya*).

Exclusion criteria

1. Patient presenting with clinical features other than psoriasis like generalized skin lesions, herpes simplex, herpes zooster, scabies, acne, urticaria and immunological mediated skin diseases like pemphigus vulgaris, dermatitis herpetiformis, guttate psoriasis, pustular psoriasis, lupus erythematosus, psoriatic arthropathy etc.
2. Patient suffering from severe psoriasis with more than 50% of the body surface involvement.
3. Patient with chronicity of disease less than 6 months and above 5 yrs.
4. Subjects of either sex age below 20 years and above 60 years.
5. Patient on medication like corticosteroids, phototherapy, biologics, antidepressant and any other drugs that may have an influence on the outcome of the study.
6. Alcoholics or drug abusers.
7. Systemic Lupus Erythematosus and other Auto Immune disorders.
8. Patients having systematic pathologies like cardiac diseases, renal diseases and endocrine disorders.
9. Pregnant and lactating women.
10. Patient who are contra-indicated for *Basti Karma* (*Basti Ayogya*).

Withdrawal criteria

- During clinical trial, if any serious condition or serious adverse effect develops which require urgent treatment.
- Irregulars follow up.
- If patient wants to withdraw from the clinical trial.

Investigations

For assessing the general condition of patient and exclusion of other pathogenesis the following investigation may be performed:

Blood and Serological test:-

- a. Complete blood count
- b. Erythrocyte sedimentation rate
- c. C-reactive protein
- d. Random blood sugar

MATERIAL AND METHODS

Clinical study materials: patients indicated and fit for trial were selected from outpatient & in patient department of Panchkarma, I.A.S.R. Kurukshetra Haryana.

Conceptual study materials: Literary references are be collected from *Ayurvedic Samhitas* and their Commentaries, Modern literature, Research journals,

online portal like PubMed, Ayush research portal, Google scholar are analyzed to frame the conceptual work.

Drug Review**Trial drug:- Patola-Nimbadi Basti**

Materials for Basti: *Basti yantra*, *Makshika* (Honey), *Saindhava* (Rock Salt), *Go-ghrita*, *Kalka dravya* (paste of herbs), gloves, *Kharal*, catheter, syringe.

KWATHA DRAVYAS OF PATOLA-NIMBADI BASTI^[6]

Sr. No	Name of Drug	Latin Name	Matra
1.	<i>Nimba</i>	<i>Azadirachta indica</i>	40 gm
2.	<i>Guduchi</i>	<i>Tinospora cordifolia</i>	
3.	<i>Adusa</i>	<i>Justicia adhatoda</i>	
4.	<i>Patola</i>	<i>Trichosanthea diocia</i>	
5.	<i>Kantakari</i>	<i>Solanum xanthocarpum</i>	
6.	<i>Sarshapa</i>	<i>Brassica juncea</i>	

KALKA DRAVYAS OF PATOLA-NIMBADI BASTI

Sr. No	Name of Drug	Latin Name	Matra
1.	<i>Nimba</i>	<i>Azadirachta indica</i>	40 gm
2.	<i>Guduchi</i>	<i>Tinospora cordifolia</i>	
3.	<i>Adusa</i>	<i>Justicia adhatoda</i>	
4.	<i>Patola</i>	<i>Trichosanthea diocia</i>	
5.	<i>Kantakari</i>	<i>Solanum xanthocarpum</i>	
6.	<i>Sarshapa</i>	<i>Brassica juncea</i>	

OTHER DRAVYAS OF PATOLA-NIMBADI BASTI

Sr. No	Name of Drug	Latin Name	Matra
1.	<i>Madhu</i>	Honey	60ml
2.	<i>Ghrita</i>	Ghee	80 ml
3.	<i>Saindhav</i>	Rock salt	10 gm

AYURVEDIC PROPERTIES OF PATOLA-NIMBADI BASTI

Sr. No	Drug Name	Ras	Guna	Virya	Vipak
1	<i>Patolaa</i>	<i>Tikta</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
2	<i>Nimba</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>
3	<i>Putika</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
4	<i>Rasna</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
5	<i>Saptarna</i>	<i>Tikta</i>	<i>Snigdha</i>	<i>Ushna</i>	<i>Katu</i>
6	<i>Guduchi</i>	<i>Tikta, Kashaya</i>	<i>Guru, Snigdha</i>	<i>Ushna</i>	<i>Madhur</i>
7	<i>Adusa</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>
8	<i>Kantakari</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
9	<i>Sarshapa</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>
10	<i>Madhu</i>	<i>Madhur, Kashaya</i>	<i>Guru, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>
11	<i>Ghrita</i>	<i>Madhur</i>	<i>Guru, Snigdha</i>	<i>Sheeta</i>	<i>Madhur</i>

Methods**Plan of study:**

To follow the above objective, the research work has been planned as follow:

1. Review of literature

Literary references will be collected from *Ayurvedic Samhitas* and Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar and will be analyzed to frame conceptual work.

2. Clinical study

Clinical study will be done in patients under direct

supervision, considering the inclusion and exclusion criteria.

Sample size -30

Method Of Prepration

1. *Madhu* is mixed with *saindhava lavana* in *kharal* and mixed up properly.
2. *Ghrita* is added to the mixture and mixed thoroughly.
3. *Kalka* is added and mixed and finally *kwatha* is added in the mixture and mixed well until the homogenous mixture is formed.

Plan of Study

Sr. No	Procedure	Drug	Dose	Duration
1.	<i>Poorva Karma</i>			
	a) Local <i>Kati Sphik Abhyanga</i>	<i>Tila tailam</i>	Q.S	5-7 min
	b) Local <i>Kati Sphik Sweda</i>	--	--	Till <i>Samyak Swinna Lakshana</i> appears
2.	<i>Pradhan Karma</i>			
	A) <i>Niruha Basti (Patola-Nimbadi)</i>	<i>Madhu</i>	1/8 th of <i>Kwatha</i>	6 <i>Patola-Nimbadi Basti</i>
		<i>Ghrita</i>	1/6 th of <i>Kwatha</i>	
		<i>Kalka</i>	4 <i>Karsh</i>	
		<i>Kwatha</i>	5 <i>Prasritika</i>	
		<i>Saindhav</i>	1 <i>Karsh</i> /10 gm	
	B) <i>Anuvasana Basti (Go ghrita)</i>	<i>Go - ghrita</i>	120ml	10 <i>Anuvasana Basti</i>
3.	<i>Pashchat Karma (after Niruha)</i>	The patient should be bathed and then feed.		
	<i>Pashchat Karma (after Anuvasana)</i>	Lifting legs, padding to the buttock, anti- clockwise message to abdomen etc.		3-5 mins

Dose^[7]: Dose of *Patola-Nimbadi Basti* is decided from the *Sushruta Samhita*.

Niruha Basti of *Patola-Nimbadi* shall be given on empty stomach and *Anuvasana Basti* shall be given immediately after morning meal.

Schedule of the Basti

Kala Basti in which total 16 *Basti* having 10 *Anuvasana Basti* of *Go-ghrita* and 6 *Patola- Nimbadi Basti* were given.

N is Niruha Basti and A is Anuvasana Basti

Time	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9
Morning	A	A	N	A	N	A	N	A	N
	Day10	Day11	Day12	Day13	Day14	Day15	Day16		
Morning	A	N	A	N	A	A	A		

Route of administration- Rectal route

Follow up

After completing trial for 16 days, patient will be re-assessed again on 15th day, 30th day, 45th day.

ASSESSMENT CRITERIA

Assessment will be done on the basis of improvement in sign and symptoms. Patients will be assessed with subjective and objective parameters before and after the treatment and percentage relief obtained along with statistical evaluation. All the signs & symptoms were assigned scores by W.H.O Standard Scoring pattern for psoriasis, depending upon their severity to assess the effect objectively.

Criteria for Assessment

Assessment is done based on improvement in the subjective parameters such as-

- Aswedanam
- Mahavastu
- Mandala
- Bahaltva
- Unnati
- Matsyashalopam
- Kandua

- Twak vaivarnya
- Auspitz sign
- Koebner phenomenon
- Candle grease sign

And objective parameters –

- PASI score

The results will be evaluated on the basis of clinical parameters obtained before and after the completion and the assessment will be carried out on further findings in below mention criteria:

S. No.	Positive Result Findings	Assessment
1.	Less than 25%	Non-satisfactory
2.	25% to 50%	Good
3.	50% to 75%	Satisfactory
4.	75% to 100%	Excellent

Outcomes

Primary outcome

- Mild, Moderate or Complete relieve in the sign and symptoms of Cervical Spondylosis.

Secondary outcome

- The lifestyle of patient improved after the treatment.
- Patient can perform daily routine activity without any trouble.

Sample Size

$$N = \frac{p_0 q_0 \left\{ z_{1-\alpha/2} + z_{1-\beta} \sqrt{\frac{p_1 q_1}{p_0 q_0}} \right\}^2}{(p_1 - p_0)^2}$$

$$q_0 = 1 - p_0$$

$$q_1 = 1 - p_1$$

$$N = \frac{0.7 \times 0.3 \left\{ 1.96 + 0.84 \sqrt{\frac{0.8 \times 0.2}{0.7 \times 0.3}} \right\}^2}{(0.8 - 0.7)^2}$$

$$N = 152$$

P0 = proportion (incidence) of population i.e, 45%

P1 = proportion (incidence) of study group i.e, 55%

N = sample size for study group

α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.2)

z = critical Z value for a given α or β

- Sample size should be 152.
- Due to limitation of time period and other resources during PG studies, I will take 30 patients.

Statistical Analysis

The observations and results will be analyzed and presented on the basis of respective and applicable statistical tests.

Ethical Clearance & CTRI Registration

Study was started after obtaining ethical clearance from the Institutional Ethics Committee, I.A.S.R. Kurukshetra. SKAU/Acad/2024/10697

Study was registered in CTRI: -CTRI/2024/06/086050.

OBSERVATION AND RESULT

The observations and results will be analysed statistically with relevant tests and level of significance will be reported.

DISCUSSION

The obtain results will be discussed on the basis of ayurvedic concept and modern parameters.

REFERENCES

1. Kasper, Fauci A.S at el. Harrison's Principles of Internal Medicine. 18th ed. MC Graw-Hill Medical., 1(52): 398.
2. Shastri K, Chaturvedi G. Charak Samhita. Varanasi: Chaukhamba Bharati Academy; 2020 Part 2 Chikitsa Sthana Page no 252 Chapter 07 Verse 21.
3. Shastri A. Sushruta Samhita. Varanasi: Chaukhamba Sanskrit Sansthan; 2010 Part 1 Chikitsa Sthana Page No.189 Chapter 35 Verse 06.
4. Sharma N.K. Ashtanga Sangrah. Varanasi: Chaukhamba Krishnadas Academy; Kalpa Sthana Page No 154 Chapter 04 Verses 24.
5. Munjal Yashpal, API Textbook of Medicine; 9th Edition; Published by: Jaypee Brother MEDICAL Publisher (New Delhi) 2012; 1. Section 11 Chapter 07: 494.
6. Shasilekha. Ashtanga Sangrah. Kalpa Sthana Page No 599 Chapter 04 Verses 20.
7. Shastri A. Sushruta Samhita. Varanasi: Chaukhamba Sanskrit Sansthan; 2010 Part 1 Chikitsa Sthana Chapter 38 Verse 30-31.
8. Baghel M.S, S Gopala Developing Guidelines for Clinical Research Methodology in Ayurveda Jamnager: ITRA, 2011.
9. Journal of the American Academy of Dermatology, October 2004; 51(4): 563-569.
10. Tewari P.V. Charak Samhita English Translation of text with Ayurvedadipika Commentary of Cakarpanidatta. Chikitsa Sthana Page no 25 Chapter 07 Verse 21.
11. Gupta K.V. Ashtanga Hridaya Varanasi: Chaukhamba Krishnadas Academy; Reprint 2007. Chikitsa Sthana Chapter 19 Verses 11.

BIBLIOGRAPHY

- API text book of Medicine
- Ashtanga Hridaya
- Ashtanga Sangraha
- Ayurvediya Panchkarma Vigyan by Vaidya Haridas Kasture
- Bhava Prakash Samhita
- Bhela Samhita
- Chakradutta Tika
- Charaka Samhita
- Davidson's Principles and Practice of medicine
- Harita Samhita
- Harrison's Principles of Internal Medicine
- Kaya Chikitsa by Dr. Ajay Kumar Sharma
- Madhava Nidana
- Roga Vigyan by Dr.Vinay Kumar
- Sushruta Samhita
- Yoga Ratnakara