



## Clinical Research

## A clinical study of some Ayurvedic compound drugs in the assessment quality of life of patients with *Eka Kushtha* (psoriasis)

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### Abstract

Psoriasis is a chronic disease that can have substantial psychological and social impact on patient's life. Psoriasis has been shown to affect health-related Quality of Life to an extent similar to the effects of other chronic diseases such as depression, myocardial infarction, hypertension, etc. The modern treatment options not only provide temporary relief but also have serious side effects. Thus, the chronic and recurring nature of the disease hampers the Quality of Life to a great extent. In the present study, patients were randomly divided into two groups. *Koshtha Shuddhi* was done by *Eranda bhrushta haritaki* (6 g at night with *ushnodaka*) in patients of both the groups for 3 days before starting the treatment. A total of 111 patients were selected for the present study and were grouped into two. Patients of group A (45) were given "*Navayasa rasayana leha*" and "*Dhatryadhyo lepa*" for external application. Stress is a well-known precipitating factor of Psoriasis. Hence, to study the efficacy of *Medhya rasayana* drugs, patients of group B (49) were given *Medhya rasayana* tablet along with the application of *Dhatryadhyo lepa*. The duration of the study was 3 months and follow-up was done for one month. Both the groups showed equally good results on improving the quality of life in the patients in terms of Dermatology life quality index and Psoriasis disability index.

**Key words:** Psoriasis, *Dhatryadhyo lepa*, *Navayasa Rasayana leha*, *Medhya Rasayana*

### Introduction

Psoriasis can have a significant impact on a patient's Quality of Life, sometimes profoundly altering their everyday life. Quality of Life patient survey published in the *Archives of Dermatology* in 2001 showed that physicians underestimate disease severity. 78% of severe psoriatics are frustrated by lack of efficacy of treatment and 26 minutes is the average time to apply topical medications per day.

Information from Quality of Life surveys suggest that 78% of psoriatics indicate the negative impact on their life quality, whereas 21% of patients suggest neither a positive nor a negative effect.<sup>[1]</sup> It is important to note that the types of psoriasis are based on the effect of psoriasis on life quality as follows:

- Mild: Disease that does not alter Quality of Life
- Moderate: Disease that alters Quality of Life. Therapies

would be expected to improve Quality of Life with minimal risk of side effects

- Severe: Disease that does alter Quality of Life, and the response to treatments which have minimal side effects is ineffective. These patients will accept life-altering side effects to achieve better Quality of Life.

Also, it is interesting fact that any new intervention in patients of psoriasis initially gives good results, but later on, the therapy does not respond very well. This is also the major cause of impaired life quality in patients of psoriasis. Thus, looking at the impact of psoriasis on life quality, the present study was designed to find out the effect of *Navayasa Rasayana leha*, *Dhatryadhyo lepa* and *Medhya Rasayana* tablet on life quality of the patients.

### Aims and objectives

1. To evaluate the effect of *Navayasa Rasayana leha* and *Dhatryadhyo lepa* in improving the Quality of Life in patients of psoriasis.
2. To evaluate the effect of *Medhya Rasayana* tablet and *Dhatryadhyo lepa* in improving the Quality of Life in patients of psoriasis.

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## Materials and Methods

A detailed study of *Eka kushtha* (psoriasis) and its effect on life quality was done, along with study of drugs selected for the present study. Various books of Ayurveda, Modern science and internet related to the subject were referred.

### Drugs

The trial drug *Navayasa Rasayana leha* is taken from *Chakradatta Kushthaadhikara*. The ingredients are *Dhatri*, *Aksha*, *Haritaki*, *Vidanga*, *Chitraka*, *Shuddha Bhallataka*, *Bakuchi*, *Loha bhasma*, *Bhrungraj* and *Tila Taila* (Q.S.)<sup>[2]</sup> in increasing proportion. The fine powder of the drugs is to be licked with *Tila Taila*.

The drug selected for local application in both the groups, i.e. *Dhatryadhyo lepa*, has been described in *Bharat Bhaishjya Ratnakara*.<sup>[3]</sup> It has ingredients like *Amalaki*, *Bibhitaki*, *Haritaki*, etc. The fine powder of the drugs was mixed with *Tila Taila* and was given for local application to the patients. *Medhya Rasayana* tablet is *Anubhuta yoga*. It contains *Vacha*, *Haritaki*, *Jatamansi*, *Jyotishmati*, *Yashtimadhu*, *Shuddha Bhallataka*, *Guduchi*, *Brahmi* and *Shankhpushphi* in increasing proportion.

For the clinical study, patients consulting the OPD, Department of Kayachikitsa, IPGT and RA, Jamnagar, were selected.

### Criteria for selection

Patients having signs and symptoms of *Eka kushtha* (psoriasis) like well-circumscribed erythematous papules/plaques covered with dry, brittle, silvery grayish, white micaceous scales, Auspitz sign, Koebner phenomenon, Candle grease sign, etc. were selected. A special proforma including all the etiological factors of *Kushtha* with *dashti lakshana* of *Dosha*, *Dushya*, *Srotas* etc. was made for assessing the patients.

### Inclusion criteria

- Age 13–70 years.
- Cardinal symptoms of *Eka kushtha*.
- Positive signs of psoriasis like Auspitz sign, Candle grease sign, etc.

### Exclusion criteria

1. Patients suffering from systemic diseases like Diabetes Mellitus, Cancer, AIDS, TB, etc. and other skin diseases like seborrhic dermatitis, lichen simplex chronicus, etc.
2. Age less than 13 years and more than 70 years.

### Laboratory investigations

1. Blood – Hemoglobin (Hb), total count (TC), differential count (DC), erythrocyte sedimentation rate (ESR), total red blood cells (RBC), peripheral blood picture.
2. Urine – Routine and microscopic examination.
3. Biochemical – Fasting blood sugar (FBS), serum creatinine, serum glutamate oxaloacetate transaminase (SGOT), serum calcium, total protein, albumin/globulin (A/G) ratio.

### Plan of treatment

Patients were divided by random sampling method into two groups. Informed consent was taken from the patients for participation in the study. *Koshtha Shuddhi* was done by *Eranda bhrushta Haritaki* (6 g at night with *ushnodaka*) in patients of

both the groups for 3 days before starting the treatment. The grouping was as follows.

Group A: *Navayasa Rasayana leha* with local application of *Dhatryadhyo lepa*

Dose of *leha*: 2 g - twice a day

*Anupana*: *Koshna Jala*

Dose of *lepa*: Q.S. (as per the area of distribution of the lesion.)

Duration: 3 months

Group B: *Medhya Rasayana* tablet with the local application of *Dhatryadhyo lepa*.

Dose of tablet: 2 tablets (each tablet 500 mg), twice a day

*Anupana*: *Koshna Godugdha*

Dose of *lepa*: Q.S. (as per the area of distribution of the lesion)

Duration: 3 months

### Follow-up

Follow-up was carried out for 1 month after completion of the treatment.

### Dietary restrictions

The patients were strictly advised to follow the *Pathyapathya* of *Kushtha roga*.

Total 56 patients were registered in group A, out of which 11 dropped out and 45 patients completed the treatment, while in group B, a total of 55 patients were registered, out of whom 6 dropped out and 49 patients completed the treatment.

### Criteria for assessment

1. Dermatology life quality index (DLQI)<sup>[4]</sup>
2. Psoriasis disability index (PDI)<sup>[5]</sup>

The DLQI is a questionnaire relating to the previous activities and feelings. Work, school, leisure, daily activities as well as the symptoms and feelings are measured as well as personal relationships and the impact of treatment.

### Scoring

The scoring of each question is as follows:

Very much	scored 3
A lot	scored 2
A little	scored 1
Not at all	scored 0
Not relevant	scored 0
Question unanswered	scored 0
Question 7: "prevented work or studying"	scored 3

The DLQI is calculated by summing the score of each question, resulting in a maximum of 30 and a minimum of 0. The higher the score, the more the Quality of Life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30.

### Meaning of DLQI scores

- 0–1 = no effect at all on patient's life
- 2–5 = small effect on patient's life
- 6–10 = moderate effect on patient's life
- 11–20 = very large effect on patient's life
- 21–30 = extremely large effect on patient's life

The DLQI can be analyzed under six headings as follows:

Symptoms and feelings	Questions 1 and 2
Daily activities	Questions 3 and 4
Leisure	Questions 5 and 6
Work and school	Question 7
Personal relationships	Questions 8 and 9
Treatment	Question 10

1. Over the last week, how itchy, sore, painful or stinging has your skin been?
  - Very much
  - A lot
  - A little
  - Not at all
2. Over the last week, how embarrassed or self-conscious have you been because of your skin?
  - Very much
  - A lot
  - A little
  - Not at all
3. Over the last week, how much has your skin interfered with you going for shopping or looking after your home or garden?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all
4. Over the last week, how much has your skin influenced the clothes you wear?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all
5. Over the last week, how much has your skin affected any social or leisure activities?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all
6. Over the last week, how much has your skin made it difficult for you to do any sport?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all
7. Over the last week, has your skin prevented you from working or studying?
  - Yes  Not relevant
  - No

If "No", over the last week, how much has your skin been a problem at work or while studying?

  - A lot
  - A little
  - Not at all
8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all
9. Over the last week, how much has your skin caused any sexual difficulties?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all

10. Over the last week, how much of a problem has the treatment for your skin been, for example, by making your home messy, or by taking up time?
  - Very much  Not relevant
  - A lot
  - A little
  - Not at all

### The psoriasis disability index

This is a questionnaire addressing 15 aspects including daily activities, personal relationships, vacation, work as well as the effects of actual treatment. This has been used in a number of clinical studies.

#### Daily activities

1. How much has your psoriasis interfered with you carrying out work around the house or garden?
  - Very much  A lot  A little  Not at all
2. How often have you worn different types or colors of clothes because of your psoriasis?
  - Very much  A lot  A little  Not at all
3. How much more have you had to change or wash your clothes?
  - Very much  A lot  A little  Not at all
4. How much of a problem has your psoriasis been at the hairdressers?
  - Very much  A lot  A little  Not at all
5. How much has your psoriasis resulted in you having to take more baths than usual?
  - Very much  A lot  A little  Not at all

There are two different versions of Questions 6, 7 and 8. If you are at regular work or at school, please answer the first set of Questions 6–8. If you are not at work or school, please answer the second set of Questions 6–8.

#### Work or school (if appropriate)

6. How much has your psoriasis made you lose time off work or school over the last 4 weeks?
  - Very much  A lot  A little  Not at all
7. How much has your psoriasis prevented you from doing things at work or school over the last 4 weeks?
  - Very much  A lot  A little  Not at all
8. Has your career been affected by your psoriasis? (e.g. promotion refused, lost a job, asked to change a job)
  - Very much  A lot  A little  Not at all

#### If not at work or school: Alternative questions

6. How much has your psoriasis stopped you from carrying out your normal daily activities over the last 4 weeks?
  - Very much  A lot  A little  Not at all
7. How much has your psoriasis altered the way in which you carry out your normal daily activities over the last 4 weeks?
  - Very much  A lot  A little  Not at all
8. Has your career been affected by your psoriasis? (e.g. promotion refused, lost a job, asked to change a job)
  - Very much  A lot  A little  Not at all

**Personal relationships**

- 9. Has your psoriasis resulted in sexual difficulties over the last 4 weeks?  
Very much  A lot  A little  Not at all
- 10. Has your psoriasis created problems with your partner or any of your close friends or relatives?  
Very much  A lot  A little  Not at all

**Leisure**

- 11. How much has your psoriasis stopped you from going out socially or to any special functions?  
Very much  A lot  A little  Not at all
- 12. Is your psoriasis making it difficult for you to do any sport?  
Very much  A lot  A little  Not at all
- 13. Have you been unable to use, criticized or stopped from using communal bathing or changing facilities?  
Very much  A lot  A little  Not at all
- 14. Has your psoriasis resulted in you smoking or drinking alcohol more than you would do normally?  
Very much  A lot  A little  Not at all

**Treatment**

- 15. To what extent has your psoriasis or treatment made your home messy or untidy?  
Very much  A lot  A little  Not at all

The Psoriasis Disability Index (PDI) can be analyzed under five headings as follows:

Daily activities	Questions 1, 2, 3, 4 and 5
Work or school or alternative questions	Question 6, 7 and 8
Personal relationships	Questions 9 and 10
Leisure	Questions 11, 12, 13 and 14
Treatment	Question 15

It is noteworthy that till date, no research work has been done regarding the assessment of this treatment on life quality of psoriatic patients as per the author’s knowledge. Also, very few works have been done to find out the assessment of Ayurvedic drugs on life quality of psoriatic patients.

**Observations**

As per the DLQI scores, the effect of psoriasis on life quality was found as follows:

Effect on life quality	Effect in % before treatment (both groups)
No effect	0.90
Small effect	22.52
Moderate effect	12.61
Very large effect	44.14
Extremely large effect	19.81

Thus, it can be understood that maximum patients had very large and extremely large effect of psoriasis on their life quality before treatment.

**Results**

The effect of therapy on both DLQI and PDI was analyzed before and after treatment as follows.

Effect on PDI: It is observed that highly significant relief has been reported for all questions by patients in group A [Table 1].

Effect on PDI: It is observed that highly significant relief has been reported for almost all the questions of PDI by patients in group B [Table 2].

Thus, it can be understood from Table 3 that both the groups showed equally good results in all subdivisions of PDI. The overall effect on PDI shows that both the therapies showed highly significant relief ( $P < 0.001$ ), but percentage wise, group A showed better relief by 72.20% whereas group B showed relief by 65.99%. On comparing the effect of therapies by  $\chi^2$  method, it was found that in daily activities and personal relationships, group A showed better relief in comparison to group B, while in all other parameters, both the groups showed almost equal effect. Also, on comparing the overall effect of both the therapies by  $\chi^2$  method, insignificant difference was found between the effect of both the groups ( $P > 0.10$ ) which means that both the therapies were equally effective.

On analyzing the effect of both therapies on DLQI the following results were found [Tables 4 and 5].

Effect on DLQI: It is observed that highly significant relief has been reported for almost all the questions of DLQI by patients in group A [Table 4].

Effect on DLQI: It is observed that highly significant relief has been reported for almost all the questions of DLQI by patients in group B [Table 5].

Thus, it can be understood from Table 6 that both the groups showed equally good results in all subdivisions of DLQI. When we look at the overall effect of therapy, group A showed 70.26% relief, whereas group B showed 67.64% relief. On comparing the overall effect of both the therapies by  $c^2$  test, insignificant difference was found between the effects in both the groups ( $P > 0.10$ ) which means that both the treatments were equally effective.

**Discussion**

Psoriasis is not a cosmetic problem. In a survey study, nearly 60% reported their disease to be a large problem in their everyday life. Nearly 40% with psoriatic arthritis reported their disease to be a large problem in everyday life. Patients with psoriasis covering more of their body (more extensive skin disease) experienced a greater negative impact on their Quality of Life.

Psoriasis has a greater impact on the Quality of Life in women and younger patients.<sup>[6]</sup>

In a 2008 National Psoriasis Foundation survey of 426 psoriasis sufferers,<sup>[7]</sup>

- 71% reported that the disease was a significant problem in everyday life;
- more than half reported significant feelings of self-consciousness (63%) and embarrassment (58%); and
- more than one third said they avoided social activities and limited dating or intimate interactions.

A 2009 study looked at the impact of psoriasis by using interviews with dermatologists and exploring the patient’s

**Table 1: Effect of therapy on Psoriasis Disability Index in group A**

Questions	n	BT	AT	x	% of relief	±SD	±SE	t	P
Q-1	30	2.33	0.7	1.63	70	0.85	0.155	10.52	<0.001
Q-2	25	2.08	0.64	1.44	69.23	1.08	0.216	6.64	<0.001
Q-3	27	2.25	0.555	1.70	75.40	0.95	0.183	9.28	<0.001
Q-4	28	2.35	0.428	1.92	81.81	0.93	0.177	10.85	<0.001
Q-5	30	2.2	0.533	1.66	75.75	0.99	0.181	9.18	<0.001
Q-6	28	2	0.535	1.46	73.21	0.96	0.181	8.05	<0.001
Q-7	27	2.25	0.592	1.66	73.77	0.91	0.177	9.41	<0.001
Q-8	10	1.4	0.6	0.8	57.14	1.54	0.489	1.63	>0.10
Q-9	3	2	1	1	50	1	0.577	1.73	>0.10
Q-10	30	1.96	0.6	1.366	69.49	0.96	0.176	7.76	<0.001
Q-11	31	2.25	0.7419	1.516	67.14	0.96	0.172	8.77	<0.001
Q-12	8	2.12	0.37	1.75	82.35	0.70	0.25	7	<0.001
Q-13	12	2.41	0.833	1.583	65.51	0.51	0.14	10.65	<0.001
Q-14	8	2.12	1	1.125	52.94	0.99	0.35	3.210	>0.05
Q-15	39	2.30	0.56	1.743	75.55	0.93	0.15	11.60	<0.001

**Table 2: Effect of therapy on Psoriasis Disability Index in group B**

Questions	n	BT	AT	x	% of relief	±SD	±SE	t	P
Q-1	39	2.333	0.769	1.564	67.03	0.787	0.126	12.39	<0.001
Q-2	36	2.194	0.805	1.388	63.29	0.802	0.133	10.38	<0.001
Q-3	36	1.97	0.833	1.138	57.74	0.960	0.160	7.11	<0.001
Q-4	30	2.5	0.933	1.566	62.6	0.85	0.15	9.99	<0.001
Q-5	39	2.10	0.66	1.43	68.29	0.82	0.13	10.92	<0.001
Q-6	30	2	0.6	1.4	70	0.67	0.12	11.36	<0.001
Q-7	31	2.03	0.64	1.38	68.25	0.76	0.13	10.15	<0.001
Q-8	6	1.66	0.83	0.83	50	0.75	0.30	2.71	<0.05
Q-9	1	2	1	1	50	-	-	-	-
Q-10	41	2.09	0.63	1.46	69.76	0.80	0.12	11.57	<0.001
Q-11	40	2.175	0.675	1.5	68.96	0.87	0.13	10.81	<0.001
Q-12	11	2.18	0.81	1.36	62.5	0.50	0.15	8.96	<0.001
Q-13	18	1.94	0.83	1.11	57.14	0.83	0.19	5.66	<0.001
Q-14	9	1.88	0.88	1	52.94	0.70	0.23	4.24	<0.01
Q-15	45	2.42	0.68	1.73	71.55	0.78	0.11	14.89	<0.001

**Table 3: Effect of therapy on subdivisions of PDI**

Subdivisions	Group A (relief in %)	Group B (relief in %)
Daily activities	74.6	64.07
Work or school	71.07	67.66
Personal relationships	67.69	69.31
Leisure	66.91	63.8
Treatment	75.55	71.55

viewpoint. It found that in cases of mild and severe psoriasis, itch contributed the most to the diminished health-related quality of life (HRQoL). Here, it can be seen that both the therapies provide significant effect on improving the life quality of the patients as shown in Table 7.

As, described previously, the effect of psoriasis in patients was very large effect in 44.14% and extremely large effect in 19.81% patients, which reduced completely showing that there were no patients

having very large and extremely large effects on the Quality of Life. Also, after treatment, maximum number of patients in group A had small effect (40%), whereas maximum number of patients in group B had moderate effect (57.14%) [Table 7].

Also, based on the results, it can be inferred that both the groups showed highly significant relief in all the questions of DLQI and PDI. On comparing the overall effect of therapy by  $\chi^2$  test, insignificant difference was found which proves that both the treatments were equally effective in improving the life quality of the patients.

## Conclusion

Thus, it can be concluded that today psoriasis is a great problem hampering the life quality of the patients and the aim of the therapy should be focused on improving it. Both the therapies provided highly significant improvement in life quality of the patients.

**Table 4: Effect of therapy on Dermatology Life Quality Index in group A**

Questions	n	BT	AT	x	% of relief	±SD	±SE	t	P
Q-1	45	2.35	0.82	1.53	65.09	0.62	0.09	16.45	<0.001
Q-2	42	2.21	0.71	1.5	67.74	1.04	0.16	9.33	<0.001
Q-3	29	2.17	0.58	1.58	73.01	0.824	0.153	10.36	<0.001
Q-4	24	2.29	0.58	1.70	74.54	0.85	0.17	9.74	<0.001
Q-5	24	2.08	0.70	1.37	66	0.875	0.17	7.69	<0.001
Q-6	9	2.11	0.55	1.555	73.68	0.52	0.17	8.85	<0.001
Q-7	17	1.76	0.70	1.058	60	0.74	0.18	5.83	<0.001
Q-8	27	2	0.55	1.44	72.2	0.75	0.14	9.99	<0.001
Q-9	4	2.5	0.75	1.75	70	0	0.2	7	<0.01
Q-10	36	2.63	0.58	2.055	77.89	0.75	0.12	16.36	<0.001

**Table 5: Effect of therapy on Dermatology Life Quality Index in group B**

Questions	n	BT	AT	x	% of relief	±SD	±SE	t	P
Q-1	49	2.51	0.79	1.71	68.29	0.54	0.07	22.21	<0.001
Q-2	46	2.54	0.78	1.76	69.23	0.79	0.11	15.04	<0.001
Q-3	40	2.25	0.72	1.52	67.77	0.78	0.12	12.30	<0.001
Q-4	36	2.19	0.72	1.47	67.08	0.87	0.14	10.06	<0.001
Q-5	40	2.37	0.77	1.6	67.36	0.744	0.11	13.59	<0.001
Q-6	10	2.3	1	1.3	56.52	0.67	0.21	6.09	<0.001
Q-7	30	1.9	0.56	1.33	70.17	0.80	0.14	9.10	<0.001
Q-8	40	2.15	0.75	1.4	65.11	0.744	0.11	11.89	<0.001
Q-9	2	1	0.5	0.5	50	0.70	0.5	1	>0.10
Q-10	44	2.5	0.77	1.72	69.09	0.72	0.10	15.75	<0.001

**Table 6: Effect of therapy on subdivisions of DLQI**

Subdivisions	Group A (relief in percentage)	Group B (relief in percentage)
Symptoms and feelings	66.33	68.75
Daily activities	73.72	67.45
Leisure	68.11	65.25
Work and school	60	70.17
Personal relationships	71.87	64.77
Treatment	77.89	69.09

**Table 7: Comparative effect of both the therapies on life quality in patients of Psoriasis**

Effect on life quality	Group A (%)	Group B (%)
No effect	26.66	22.44
Small effect	40	20.4
Moderate effect	33.33	57.14
Very large effect	0	0
Extremely large effect	0	0

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## हिन्दी सारांश

# एककुष्ठ के रोगियों के जीवन की गुणवत्ता पर नवायस रसायन लेह, मेध्य रसायन वटी तथा धात्र्याद्यो लेप का तुलनात्मक अध्ययन

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एककुष्ठ (सोरीयासीस) एक जीर्ण रोग है जो आतुर की जीवनशैली को बहुत प्रभावित करता है। वर्तमान में कुल १११ आतुरों को पंजी कृत करके सामान्य वितरण पद्धति से दो वर्गों में विभाजित किया। वर्ग अ में नवायस रसायन लेह २ ग्राम दिन में दो बार उष्णोदक के साथ दिया गया। साथ ही धात्र्याद्यो लेप का बाह्य प्रयोग करवाया गया। वर्ग ब में मेध्य रसायन वटी २ गोली दिन में दो बार कोष्ण गोदुग्ध के साथ दी गई। साथ ही धात्र्याद्यो लेप का बाह्य प्रयोग करवाया गया। दोनों वर्गों में आतुरों पर औषध का जीवनगुणवत्ता पर प्रभाव देखा गया। पाये गये परिणामों से यह साबित हुआ कि दोनों वर्ग में रूग्णों की जीवनशैली पर अच्छे परिणाम प्राप्त हुए।

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