

COMPARATIVE CLINICAL STUDY ON THE EFFECT OF AARAGVADHADI TAILA WITH AND WITHOUT ARSENIC COMPOUNDS ON SHWITRA

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ABSTRACT

Most of the classical Ayurvedic texts describe various primary and secondary *kalpana* i.e. preparations containing significant number of *rasaushadi* along with herbal medicines. Chakradutta is one of such *grantha*. Here *Aaragvadhadi Taila*¹ is mentioned describing its effect that it cures *Shwitra roga* very fast. Disease *Shwitra* is very tough to cure and is getting tougher as getting older and older as severity of this disease is described in various *samhita* telling quick action to take to treat this disease. As it is not available in market so it was decided to prepare this oil and to go for clinical trial. During study *hartala* and *manahshila* were found as its ingredients which made to think to use *gandhaka* as its ingredients replacing *hartala* and *manahshila* as these are comparatively poisonous in nature and *gandhaka* has no such lethal effect is also useful to treat various skin disorders. Finally it was decided to go for comparative study of clinical effect of *Aaragvadhadi Taila* with all its ingredients mentioned in Chakradutta and other oil *Aaragvadhadi Taila (X)*, having same contents replacing arsenic compounds i.e. *hartala* and *manahshila*, with *gandhaka*. For clinical study 40 clinically diagnosed patients of *Shwitra* who fulfill inclusion criteria were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed for grouping the patients into 2 groups. All the patients selected for the clinical trial were divided equally in two groups 'A' and 'B'. 20 patients of Group A were given *Aaragvadhadi Taila* for local application and rest of the 20 patients of Group B were given *Aaragvadhadi Taila (X)* for local application. Patients were asked to apply the given oil on affected part followed by exposure of sunlight for 20 minutes during morning hours. Total duration of the study for each group was 60 days.

Keywords: *Aaragvadhadi Taila, Shwitra*

INTRODUCTION

Since last decades this world faced and accepted lot of life style and environment related changes and these change are still continue. Need of the people has changed dramatically, similarly origin of various health related issues and new diseases made human

to rethink about his relation with nature and these days activities.

Lot of formulations are mentioned in various *samhita* and *grantha* but only few are available in market to treat respective disease, to know and vali-

date their clinical effects as described in books. *Aaragvadhadi Taila* was selected for study as *Shwitra* which is cosmetically one of the worst problem, is *rogadhiksar* of this *taila*.

Shwitra not only spoils beauty but also confidence of the affected person and till now no medical science has developed any permanent, safe and complete cure of this disease. It is fairly common disorder affecting 1-2% the world's population^{2,3} In India it is reported as 3%⁴. Vitiligo may develop at any age. Onset has been reported from birth to 81 years of age. Peak age of onset is 10-30 years^{4,5}. Both sexes are affected more or less equally. In few studies^{5,6,7} There is slight female preponderance, which is likely because females are more sensitive to cosmetic disfigurement. *Aaragvadhadi Taila* contains *hartala* and *manahshila* which being arsenic compounds are quite harmful to use if care not taken and not so easily available. This made to search suitable substitute of these two compounds and it was decided to prepare one more *sneha kalpana* with same ingredients replacing *hartala* and *manahshila* i.e. arsenic compounds, with *gandhaka Aaragvadhadi Taila (X)*.

AIM AND OBJECTIVES

- To explore and establish clinical efficacy of *Aaragvadhadi Taila* and *Aaragvadhadi Taila (X)* on *Shwitra*.
- To study comparative clinical effect of *Aaragvadhadi taila* and *Aaragvadhadi taila (X)* on *Shwitra*.

IMPORTANCE OF PRESENT STUDY

- Due to changing life style and food habits etc. there is increased incidence of *Shwitra* in practice and other systems fail to find a satisfactory solution for it. Therefore it is necessary to find a solution for it through Ayurved.
- An attempt is made to clinically evaluate the efficacy of *Aaragvadhadi Taila* and *Aaragvadhadi taila (X)* in the treatment of *Shwitra*.

- Since comparative study is to be done it will give a direction to discover substitute of any uncommon drug.

MATERIAL AND METHODS

Two types of oil *Aaragvadhadi Taila (Group A)* and *Aaragvadhadi Taila (X) (Group B)* were prepared. Reference of *Aaragvadhadi Taila* is *Chakradutta* and *Aaragvadhadi Taila (X)* is a kalpit oil with most of the contents same as *Aaragvadhadi Taila* replacing arsenic compounds by *gandhaka*. The all raw drugs enumerated in this preparation were procured from the M.M.M. Govt. Ayurved College, Udaipur pharmacy, as procedure is performed here except Ketaki flower and Nalika. Ketaki flower were procured from a temple near Badi dam, Udaipur and Nalika were procured from garden located in our college campus.

➤ Source of patient:

Clinically diagnosed patients of *Shwitra* who fulfill inclusion criteria were selected from OPD of M.M.M. Govt. Ayu. College and hospital, Motichohata Hospital, Anusandhan Kendra (Udaipur). Patients were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed for grouping the patients into 2 groups.

PLAN OF STUDY

All the patients selected for the clinical trial were studied in two groups. The patients were asked to apply the oil on affected part followed by exposure of sunlight for 20 minutes during morning hours.

For clinical trial, a minimum sample of 40 patients diagnosed with *Shwitra* were equally distributed in two groups,

- Group A – Only local application of *Aaragvadhadi Taila* in 20 patients.
- Group B– Only local application of *Aaragvadhadi Taila (X)* in 20 patients.

Total duration of the study for each group was 60 days.

SELECTION CRITERIA

➤ *Inclusion criteria:*

- Patients diagnosed with *Shwitra* were selected for the present study.
- Patients presenting with the symptoms of *Shwitra roga*.
- Patients having age more than 10 years.
- Patients with history of *Shwitra* less than 5 years.

➤ *Exclusion criteria:*

- Patient who is not well diagnosed.
- Patient with history of *Shwitra* more than 5 years.

➤ *Criteria for withdrawal:*

- During the course of trial if any serious condition or any serious disease is found in patient.
- Patients herself/himself want to withdraw from the clinical trial.

PARAMETERS FOR ASSESSMENT

1. The colour of the patches.
2. The surface of the patches.
3. The margins of the patches.
4. The hair colour of the patches.
5. Burning sensation or intolerance of heat.
6. The Itching.
7. Spots on the patches
8. Size of the patches.
9. Number of the patches.
10. Number of black spots on the patches

OBSERVATIONS AND RESULTS

Intergroup Comparison of Group A & Group B for Subjective Parameters:

| Symptoms | Group | MD | SD | SE | t value | P Value | S |
|-----------------------------------|-------|------|------|------|---------|---------|----|
| 1. Colour of the patches | GP-A | 1.39 | .85 | .20 | 0.18 | 0.86 | NS |
| | GP-B | 1.44 | 0.98 | 0.23 | | | |
| 2. Margin of the patches | GP-A | 0.06 | 0.24 | 0.06 | 1.67 | .10 | NS |
| | GP-B | 0.17 | 0.51 | 0.12 | | | |
| 3. Hair Colour | GP-A | 0.28 | 0.83 | 0.19 | 1.43 | 0.16 | NS |
| | GP-B | 0.00 | 0 | 0 | | | |
| 4. Burning Sensation | GP-A | 0.00 | 0.0 | 0.0 | 1.00 | 0.32 | NS |
| | GP-B | 0.06 | 0.24 | 0.06 | | | |
| 5. Itching | GP-A | 0.00 | 0.65 | 0.15 | 0.74 | 0.46 | NS |
| | GP-B | 0.39 | 0.70 | 0.16 | | | |
| 6. Surface of the lesion | GP-A | 0.22 | 0.55 | 0.13 | 1.18 | 0.24 | NS |
| | GP-B | 0.06 | 0.24 | 0.06 | | | |
| 7. Colour of spots on the patches | GP-A | 0.00 | 1.64 | 0.39 | 1.27 | 0.21 | NS |
| | GP-B | 0.56 | 0.56 | 0.20 | | | |
| 8. Size of the Patch | GP-A | 0.50 | 0.84 | 0.20 | 0.62 | 0.54 | NS |
| | GP-B | 0.78 | 1.70 | 0.40 | | | |
| 9. No. of the patches | GP-A | 0.17 | 0.51 | 0.12 | 0.30 | 0.76 | NS |
| | GP-B | 0.11 | 0.58 | 0.14 | | | |
| 10. No. of spots on the patches | GP-A | 1.50 | 1.54 | 0.36 | 1.65 | 0.11 | NS |
| | GP-B | 0.72 | 1.27 | 0.30 | | | |

(HS: Highly Significant S: Significant NS: Non Significant)

Effect of therapy on Colour of the patch (Twak vaivarnaya) score:

- In **Group A** after treatment, relief of 37.3% found which was statistically highly significant.(P = 0.0001, P< 0.05)
- In **Group B** after treatment, relief of 38.8% found which was statistically highly significant.(P = 0.0001, P< 0.05)

Effect of therapy on Margin of the patch score:

- In **Group A** after treatment, relief of 7.2% found which was statistically not significant.(P = 0.17, P> 0.05)
- In **Group B** after treatment, relief of 15.8% found which was statistically not significant.(P = 0.09, P> 0.05)

Effect of therapy on Hair colour score:

- In **Group A** after treatment, relief of 41.7% found which was statistically not significant.(P = 0.09, P> 0.05)
- In **Group B** after treatment, relief of 0 % found which was statistically NA.(P = 0.00)

Effect of therapy on Burning sensation score:

- In **Group A** after treatment, relief of 0 % found which was statistically NA.(P = 0.00)
- In **Group B** after treatment, relief of 100% found which was statistically not significant.(P = 0.17, P> 0.05)

Effect of therapy on Itching score:

- In **Group A** after treatment, relief of 100% found which was statistically not significant.(P = 0.08, P> 0.05)
- In **Group B** after treatment, relief of 88% found which was statistically significant.(P = 0.02, P< 0.05)

Effect of therapy on Surface of the lesion score:

- In **Group A** after treatment, relief of 100% found which was statistically significant.(P = 0.05)
- In **Group B** after treatment, relief of 35.2% found which was statistically not significant.(P = 0.17, P> 0.05)

Effect of therapy on Colour of the spots on the patches score:

- In **Group A** after treatment, relief of 0% found which was statistically not significant.(P = 0.50, P> 0.05)
- In **Group B** after treatment, relief of 56% found which was statistically significant.(P = 0.01, P< 0.05)

Effect of therapy on Size of the patches score:

- In **Group A** after treatment, relief of 10% found which was statistically significant.(P = 0.01, P< 0.05)
- In **Group B** after treatment, relief of 13% found which was statistically significant.(P = 0.03, P< 0.05)

Effect of therapy on Number of the patches score:

- In **Group A** after treatment, relief of 2.6% found which was statistically not significant.(P = 0.09, P> 0.05)
- In **Group B** after treatment, relief of 3% found which was statistically not significant.(P = 0.21, P> 0.05)

Effect of therapy on Number of spots on the patches score:

- In **Group A** after treatment, relief of 123% found which was statistically highly significant.(P = 0.00, P< 0.05)
- In **Group B** after treatment, relief of 42% found which was statistically significant.(P = 0.01, P< 0.05)

Intergroup Comparison:- To access the efficacy of two therapies intergroup comparison was done.

After the comparative study of clinical effect of *Aaragvadhadi Taila* (Group-A) and *Aaragvadhadi Taila* (X) (Group-B) on colour of the patches (*twakvaivarnaya*), margin of the patches, hair colour (*romavaivarnaya*), burning sensation (*daha*), itching (*kandu*), surface of the lesion, colour of spots on the patches, size of the patches, number of the patches and number of spots on the patches studied in 18 patients in each group i.e. total 36 patients, it was found that the P >0.05 in all of the above men-

tioned symptoms selected for comparative study of clinical effect of both the oils in *Shwitra* which is statistically non significant which shows that there is no statistical difference in efficacy of both oils.

MODE OF ACTION

Hartala (Ra. Cu. 11/34), *Manahshila* (Ra. Cu. 11/57) and *Gandhaka* (Ra. Cu. 11/5) as Aaragvadhadi (Ra. Ni. *Prabhadradi Varga* 10/47), Dhava (Ra. Ni. *Pippalyadi Varga* 7/215), Kustha (Ra. Ni. *Chandanadi Varga* 13/116), Haridra (Ra. Ni. *Pippalyadi Varga* 7/199) and Daruharidra (Ra. Ni. *Pippalyadi Varga* 7/202 and *Prabhadradi Varga* 10/120) have *twachya* or similar property. *Paka kriya* is a phenomenon which takes place when a substance comes in contact of *Agni*. Due to *Paka Kriya*, previous color is given up and new colors are formed. *Agni* which is responsible for *Paka*, is the main cause for color transformation. As described In Ayurved *twacha* is the seat of *bhrajaka pitta* (A.H.Su. 12/14) and gives complexion to the skin. It performs *Pachan* of the substance used for *Abhyanga* or external application which later on stimulate or give rise to new metabolite formation that leads to *Varna* generation in *Twacha*.

DISCUSSION

Relief of 37.3% in colour of the patches in group A was statistically considered highly significant as most of the patient got relief may it be minor. 41.7% relief on hair colour in group A was not significant statistically as only two cases got relief. 100% relief found on burning sensation in group A was not significant statistically as only single patient was sufferer who got relief. Similarly for itching symptom in group A too. Relief of 123% on number of spots

on the patches in group A was found as this parameter don't need grading for assessment and itself is expressed by numerical value.

CONCLUSION

As per intergroup comparison both *Aaragvadhadi Taila* and *Aaragvadhadi Taila (X)* can be considered statistically clinically comparable, showing *gandhaka* can be used as substitute of *hartala* and *manahshila* in such *kalpana* to treat *Shwitra* when applied externally. But it will be impatience to consider *gandhaka* as substitute of *hartala* and *manahshila* on the basis of this study since all other components of both the preparations were same, each having clinical effect on skin disorders.

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PARAMETERS AND GRADING FOR ASSESSMENT

| | |
|---|--------|
| 01. For the colour of the patches. | Grades |
| • Normal skin colour (0) | 0 |
| • Reddish colour patches (1) | 1 |
| • Light reddish colour patches (2) | 2 |
| • Reddish and whitish colour(mixed) (3) | 3 |
| • Whitish colour patches (4) | 4 |
| 02. For the surface of the patches. | Grades |
| • Surface of affected skin is normal on touch. (0) | 0 |
| • Affected skin patch is smooth on touch. (1) | 1 |
| • Affected skin patch is rough on touch. (2) | 2 |
| • Lesion on skin is secretory (Sravayukta). (3) | 3 |
| 03. For the margins of the patches. | Grades |
| • No clear demarcation of margin. (0) | 0 |
| • Very clear demarcation & separate margin(1) | 1 |
| • Very clear demarcation & attached margin (2) | 2 |
| • Very clear demarcation, separate & fused margin. (3) | 3 |
| • Very clear demarcation & fused margin. (4) | 4 |
| 04. For the hair colour of the patches. | Grades |
| • Normal blackish colour. (0) | 0 |
| • Blackish to brownish colour. (1) | 1 |
| • Total brown colour. (2) | 2 |
| • Brownish to whitish colour. (3) | 3 |
| • Complete white colour. (4) | 4 |
| 05. Burning sensation or intolerance of heat. | Grades |
| • No feeling of burning at site of patches. (0) | 0 |
| • Experience of burning on direct exposure to sunlight. (1) | 1 |
| • Occasional burning sensation even without sunlight.(2) | 2 |
| • Frequent burning but doesn't require medicine. (3) | 3 |
| • Severe burning sensation which requires medicine. (4) | 4 |
| 06. For the Itching (kandu). | Grades |
| • No itching at all. (0) | 0 |
| • Itching at site of patches when exposed to sunlight. (1) | 1 |
| • Occasional itching even without sunlight. (2) | 2 |
| • Frequent itching but doesn't require medicine. (3) | 3 |
| • Itching causes disturbance in sleep, requires medicines (4) | 4 |
| 07. For spots on the patches | Grades |
| • Absent. (0) | 0 |

| | |
|---------------------------------------|---|
| • Spots with skin colour. (1) | 1 |
| • Spots with dark reddish colour. (2) | 2 |
| • Spots with moderate redness. (3) | 3 |
| • Spots with mild redness. (4) | 4 |

Symptoms having quantitative value:

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|--|
| 08. Size of the patches. |
| 09. Number of the patches. |
| 10. Number of black spots on the patches |

Effect of clinical recovery of symptoms in *Shwitra* patients treated with external application of *Aaragvadhadi Taila* (Group-A) and *Aaragvadhadi Taila (X)* (Group-B):

| Symptoms | Group | Mean | | MD | % Relief | SD | SE | t val. | P Val. | S |
|-----------------------------------|-------|------|------|------|----------|------|------|--------|--------|----|
| | | BT | AT | | | | | | | |
| 1. Colour of the patches | GP-A | 3.72 | 2.33 | 1.39 | 37.3 | .85 | .20 | 6.93 | .000 | HS |
| | GP-B | 3.72 | 2.28 | 1.44 | 38.8 | 0.98 | 0.23 | 6.23 | 0.00 | HS |
| 2. Margin of the patches | GP-A | 0.83 | 0.89 | 0.06 | 7.2 | .24 | .06 | 1.00 | 0.17 | NS |
| | GP-B | 1.06 | 0.89 | 0.17 | 15.8 | 0.51 | 0.12 | 1.37 | 0.09 | NS |
| 3. Hair Colour | GP-A | 0.67 | 0.39 | 0.28 | 41.7 | 0.83 | 0.19 | 1.43 | 0.09 | NS |
| | GP-B | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 | 0 | 0 | NA |
| 4. Burning Sensation | GP-A | 0.00 | 0.00 | 0.00 | 00 | 0.0 | 0.0 | 0 | 0 | NA |
| | GP-B | 0.06 | 0.00 | 0.06 | 100 | 0.24 | 0.06 | 1.0 | 0.17 | NS |
| 5. Itching | GP-A | 0.22 | 0.00 | 0.22 | 100 | 0.65 | 0.15 | 1.46 | 0.08 | NS |
| | GP-B | 0.44 | 0.06 | 0.39 | 88 | 0.70 | 0.16 | 2.36 | 0.02 | S |
| 6. Surface of the lesion | GP-A | 0.22 | 0.00 | 0.22 | 100 | 0.55 | 0.13 | 1.72 | 0.05 | S |
| | GP-B | 0.17 | 0.11 | 0.06 | 35.2 | 0.24 | 0.06 | 1.00 | 0.17 | NS |
| 7. Colour of spots on the patches | GP-A | 0.89 | 0.89 | 0.00 | 0.0 | 1.64 | 0.39 | 0.00 | 0.50 | NS |
| | GP-B | 1.00 | 0.44 | 0.56 | 56 | 0.56 | 0.20 | 2.75 | 0.01 | S |
| 8. Size of the Patch | GP-A | 5.06 | 4.56 | 0.50 | 10 | 0.84 | 0.20 | 2.52 | 0.01 | S |
| | GP-B | 6.08 | 5.31 | 0.78 | 13 | 1.70 | 0.40 | 1.94 | 0.03 | S |
| 9. No. of the patches | GP-A | 6.39 | 6.22 | 0.17 | 2.6 | 0.51 | 0.12 | 1.37 | 0.09 | NS |
| | GP-B | 3.56 | 3.44 | 0.11 | 3 | 0.58 | 0.14 | 0.81 | 0.21 | NS |
| 10. No. of spots on the patches | GP-A | 1.22 | 2.72 | 1.50 | 123 | 1.54 | 0.36 | 4.12 | 0.00 | HS |
| | GP-B | 1.72 | 2.44 | 0.72 | 42 | 1.27 | 0.30 | 2.40 | 0.01 | S |

Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Ramesh Kumar Chaturvedi et al: Comparative Clinical Study On The Effect Of Aaragvadhadi Taila With And Without Arsenic Compounds On Shwitra. International Ayurvedic Medical Journal {online} 2018 {cited December, 2018} Available from: http://www.iamj.in/posts/images/upload/2616_2622.pdf