OPEN PRAGMATIC CLINICAL TRIAL EVALUATING THE EFFECT OF VIRECHANA KARMA AND TUVARAKA RASAYANA IN EKAKUSHTA/ PSORIASIS

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ABSTRACT

Objective: To evaluate the remission of the symptoms of Ekakushta / psoriasis in patients treated with Virechana karma followed by Tuvaraka Rasayana. Design of Study: It is an open pragmatic clinical study with pre test post test design. Settings: SDM Hospital of Ayurveda, Udupi, Karnataka. Sample Selection: 20 patients suffering from Ekakushta/Psoriasis were selected for the study during the period of November 2013 to March 2014. Intervention: Selected patients were treated with Kramatala Virechana karma followed by Tuvaraka Rasayana. Main Outcome of Measures: The response following the intervention was assessed before and after the treatment by adapting the individual symptom score and PASI scoring method. Further the changes observed by the completion of the treatment were subjected to paired t test to know the statistical significance. Results: The administration of the Virechana and Tuvaraka Rasayana proved to be effective in decreasing the severity of symptoms. There was marked reduction in the mean score of anhydrosis from 0.700 to 0.150 after treatment. The reduction in severity was statistically significant. The criteria of Pruritis showed improvement by reduction in mean score from 2.600 before treatment to 0.600 after treatment which was statistically highly significant. The symptom of desquamation before treatment was 3.404 which reduced to 0.613 after treatment which was statistically highly significant. Infiltration in the lesion was reduced from 3.292 before treatment to 0.559 after treatment and was statistically highly significant. The Erythema showed improvement by reduction in mean score from 3.163 to 0.783 after treatment, was statistically highly significant. The PASI scoring showed reduction in mean score from 23.512 before treatment to 4.885 after treatment which was statistically highly significant. Also, an overall improvement of 81.10% was observed in the present clinical trial.
INTRODUCTION

The skin is the boundary between human being and the world surrounding him. This is an important sense organ, the largest organ, and plays a major role in controlling the heat and water loss. The internal changes in the body are reflected through skin and it reacts to the external ones. Usually it adapts easily and returns to a normal state. But sometimes it fails to do so, resulting in the manifestation of a skin disorder.

Tvak is the Upadhatu of Mamsa Dhatu, and is in direct relation with the Rasa Dhatu for its Poshana. Accordingly the Tvak Saara been mentioned instead of Rasa Saara in the context of Saara Purusha Lakshana. Under Rakta Pradoshaja Vikara, most of the symptoms are the Tvakgata Vikara, which explains the relation of Rakta with Tvak and hence healthy Rasa Dhatu with Rakta Dhatu is most essential for the maintenance of normal structure and function of Tvak.

Tvak dhatu gets afflicted with various skin manifestations such as Visarpa, Kaksha, Nyacha, Vyanga etc. Kushta is one among such various skin manifestations. Kushta is further classified into Maha Kushta and Kshudra Kushta. The presence of the premonitory symptoms and involvement of the deeper Dhatu is the symptom of Maha Kushta which differentiates it from the Kshudra Kushta. In Kshudra Kushta there are 11 types mentioned, and Ekakushta is one among them, and it is Vata- Kaphaja disorder,\(^1,2\) which is frequently seen illness with clinical symptoms like reduced perspiration/ anhydrosis, large sized lesion, scales simulating the scales as that of fishes, with blackish and pinkish discoloration of the lesions. This very much matches with the symptoms explained under Psoriasis.

The author of Charaka Samhita has emphasized the invariable involvement of all the three Dosha in the causation of Kushta. It has been mentioned under the Santarpanajanya vyadhi\(^7\) and Rakta Pradoshajanya Vyadhi\(^8\). The mismanagement of various diseases in the form of Sthambhana in Raktapitta, Amatisara and Raktarshamay lead to the Kushta. Virudha Ahara Vihara is the foremost cause in the manifestation of the disease Kushta\(^6\). Pravara Snehana and Agnikarma\(^5\) is contraindicated in the disease and Kushta is a Lekhana and Prachhana Yogya Vyadhi\(^7\).

“Psoriasis is a non-infectious, chronic inflammatory disease of the skin, characterized by well-defined erythematous plaques with silvery scale, with a predilection for the extensor surfaces and scalp and a chronic fluctuating course”\(^8\). Definite cause of which is still unknown. However, there is often a genetic predisposition, and sometimes an obvious environmental trigger.

Psoriasis is characterized by the development of erythematous, well defined, dry, scaly papules and plaques of size ranging from pin head to palm sized or larger. The scales are abundant, loose, dry and silvery white or micaceous. Whiteness due to the presence of air trapped in between the layers of scales. Candle
grease test, Auspitz sign and Koebner phenomenon are the Confirmatory tests for the disease. Characteristic coherence of the scales can be seen as if one scratches a wax candle. This is the positive candle grease test. When the scales are completely scrapped off, the stratum mucosum is exposed and the surface is seen as moist red and the dilated capillaries can be seen as red spots. On further scrapping there occur multiple bleeding spots. This is a characteristic feature of psoriasis and is known as positive Auspitz sign. The development of isomorphic lesions at the sites of local trauma is known as the Koebner phenomenon.

Study of patients attending clinics and hospitals showed a prevalence of 0.8% to 5.6% in India. A high familial occurrence of Psoriasis (7.36%) suggests that genetic factor play a role in its etiology. Psoriasis occurs with almost equal frequency in males and females, and appears most often between 15 – 40yrs. Its course is unpredictable but is usually chronic with exacerbations and remissions.

Ayurveda propounds a very distinct principle of biopurification because of the complex nature of its aetipathogenesis. Panchkama is very unique therapeutic procedure, because of it is preventive, promotive, prophylactic and rejuvenative properties as well as providing the radical cure. Virechana is one of the best therapies mentioned in Ayurveda classics for various disorders.

For the chronic lingering, perpetuating and recurring diseases Rasayana is the line of management. Analysis of various studies carried out shows, study related to Shodhana and Shamana has been carried out and no study has been done in relation to Rasayana. Hence to fulfill the lacuna this study has been taken. Among the various Rasayana mentioned, Tuvaraka Rasayana which is mentioned has the indication for Ekakushta has been selected for this study.

**MATERIAL AND METHODS**

**Source of data:**
Total of 20 patients diagnosed as Ekakushta / Psoriasis fulfilling the diagnostic/ inclusion and exclusion criteria were taken for study from IPD of S.D.M. Ayurveda Hospital, Udupi, Karnataka during the period of November 2013 to March 2014.

**Method of collection of data:**
A special proforma was prepared (Annexure-Proforma) incorporating all the clinical manifestation and assessment criteria including laboratory investigation findings of the Ekakushta / Psoriasis. Complete clinical data was collected from all the selected patients as per this proforma before the intervention and until the completion of the study. Results obtained were statistically analyzed by adapting the paired‘t’ test.

**Design of the study:**
It is an open pragmatic clinical study with pre test post test design.
Intervention:

Poorvakarma:
- Deepana-Pachana with ChitrakadiVati for 3 days.
- Snehapana with Guggulu Tiktaka Gritha for 3-5 days.
- Abhyanga with Streekutaja oil.
- ParishEka with SiddhartakaSnana Choorna Kvatha Parisheka for 4 days.

PradhanaKarma:
- Virechana with Trivrit Leha 40gms.
- Peyadi Samsarjana and Rasa Samsarjana Krama for 3 to 7 days.
- Tuvaraka Rasayana after Samsarjana for 5 days.
- Samsarjana after Tuvarakarasayana

Duration of the study: 25-30 days.

Follow up: 30 days.
- Streekutaja oil was given for local application.

Diagnostic criteria:
1. The patchy skin lesions with symptom of Matsyashakalopama / scaling must be present
2. Symptoms like Asvedana (anhydrosis), Mahavastu (large sized lesions), Rakta Varna (erythema), ArunaVarna (pinkish), Shyava Varna (bluish), Raksha (dryness of the skin), Parusha (hard), Khara (rough), Sthira (stable), Utseda (infiltration), Snigdha (unctuous), and Kandu (pruritis) may be present.
3. Symptoms like Sparsha Ajnana (hypoesthesia, anesthesia), Svalpanamapi Vrananam Dushti (easy ulceration), Vrananam Asamrohanam (chronic non healing ulceration), Uttarothara Dhatu Anupravesha (progressive involvement of the deeper Dhatu) should not be present.
4. Presence of symptoms of Psoriasis that includes erythematous papules, plaques covered with silvery white scales.

Inclusion Criteria:
1. Patients presenting with signs and symptoms of Ekakushta/ Psoriasis.
2. Patients who are in the age group of 16-70 yrs.
3. Patients of both genders.
4. Patients fit for Virechana Karma.

Exclusion Criteria:
1. Patients with anesthesia, frequent worsening of the ulcers, non healing ulcers even if it is small, involvement of deeper Dhatu.
2. Patients suffering from Psoriatic Arthritis, Exfoliating Dermatitis.
3. Patients with any other systemic illness like Diabetic Mellitus.
4. Patients suffering from allergic manifestation like Bronchial Asthma.

Assessment Criteria:

Subjective Parameters:
The improvement in the patients was assessed on the basis of relief in the signs & symptoms of the disease.

Objective Parameters:
1. Samyak Virechana Lakshana (to assess the amount of Shodhana achieved).
2. P.A.S.I (PsoriasisArea and Severity Index)

RESULT-Patients who were diagnosed as suffering from the disease Eka kushta were
subjected to Kramataha Shodhana and Rasayana. The study was an open pragmatic clinical trial with pre and post test design. The effect of treatment was assessed periodically with regards to outcome of Snehapana, outcome of Virechana, outcome of Tuvaraka Rasayana, and its effect on the assessment parameters of the disease Ekakushta such as matsyashakloppamam, Aswedana, kandu, Utsedha, Vaivarnya, PASI score had a significant change in the score after treatment with a p value of <0.001. The details of the above are given in the tables and illustration.

**Overall assessment of treatment**

In the study carried out on the 20 patients, from the analysis of data collected it was observed that 81.10% of overall improvement was observed in the patients.

In the study group of 20 patients it was observed that 10% of patients found complete relief from illness and maximum of 60% patients had significant relief of illness. 20% patients had moderate relief of illness and 10% of patients had mild relief of illness. None of the patients had no relief or aggravation of symptoms. Details of the same are given in the below table and figure.

**DISCUSSION**

In a nut shell, 20 Patients of either gender suffering from Ekakushta between the age group of 16 to 70 were subjected to an open pragmatic clinical trial with a pre and post test design, treated with Kramataha Shodhana i.e., Virechana and followed with Tuvaraka Rasayana after the Samsarjana krama for five days. The study showed statistically significant improvement in almost all the outcome measures of Ekakushta that included anhidrosis, kandu, Mahavastu, Rakta/Aruna/Shyava Varna, desquamation, infiltration and PASI scoring. This implies that Virechana along with Tuvaraka Rasayana is effective in the correction of all the morbidities of Vata, Kapha, Pitta, Rasa, Rakta, Mamsa, Lasika that are invariably involved in the development of the disease Ekakushta.

Tuvaraka rasayana has properties like kaphvata hara, kushtaghna, krimighna, pramehaghna, kandughna Ubhayabhaga Shodhana and the drug has the specific indicated in the disease of Kushta.

Streekutaja Taila was used for the purpose of Abhyanga. Several research works has been carried out on the use of oil in the disease psoriasis. Also the drug has the indicated in disease Kushta.

As the disease Ekakushta is a illness of Bahu-doshavastha and is incurable by nature. Taking this into consideration in the present study Shodhana along with the Rasayana was planned as a line of management. The study reveals that in all the patients there was highly significant improvement seen. And 2 patients had complete remission of the disease. Ekakushta is a chronic lingering disease; therefore it may be suggested to repeat the Shodhana with Rasayana until complete remission of the illness. From this discussion it can be confidently said that, Virechana with Tuvaraka Rasayana is very effective in the treatment of Ekakushta. Thus this study opens more pave for further research in this regard in relation to addition of oral medication, continuation of topical medication, repetition of
Shodhana and Rasayana treatment. Ultimately it is the patient who may be more benefited by such evidence based clinical practice.

Table 01: Effect on treatment on different parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean Score BT(±SE)</th>
<th>Mean Score AT(±SE)</th>
<th>Difference In Mean</th>
<th>Paired ‘T’ Test</th>
<th>S.D</th>
<th>S.E.M.</th>
<th>‘t’</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matsyashakalopamam</td>
<td>3.404 (0.174)</td>
<td>0.613 (0.162)</td>
<td>2.792</td>
<td></td>
<td>1.078</td>
<td>0.241</td>
<td>11.584</td>
<td>P=&lt;0.001</td>
</tr>
<tr>
<td>Aswedana</td>
<td>0.700 (0.206)</td>
<td>0.150 (0.0819)</td>
<td>0.550</td>
<td></td>
<td>0.759</td>
<td>0.170</td>
<td>3.240</td>
<td>P=&lt;0.01</td>
</tr>
<tr>
<td>Kandu</td>
<td>2.600 (0.234)</td>
<td>0.600</td>
<td>2.000</td>
<td></td>
<td>0.795</td>
<td>0.178</td>
<td>11.255</td>
<td>P=&lt;0.001</td>
</tr>
<tr>
<td>Utsedha</td>
<td>3.292 (0.132)</td>
<td>0.559 (0.146)</td>
<td>2.733</td>
<td></td>
<td>0.701</td>
<td>0.157</td>
<td>17.426</td>
<td>P=&lt;0.001</td>
</tr>
<tr>
<td>Vaivarnya</td>
<td>3.163 (0.144)</td>
<td>0.783 (0.137)</td>
<td>2.379</td>
<td></td>
<td>0.926</td>
<td>0.207</td>
<td>11.487</td>
<td>P=&lt;0.001</td>
</tr>
<tr>
<td>PASI score</td>
<td>23.515 (4.645)</td>
<td>4.885 (1.363)</td>
<td>18.630</td>
<td></td>
<td>17.982</td>
<td>4.021</td>
<td>4.633</td>
<td>P=&lt;0.001</td>
</tr>
</tbody>
</table>

Figure 01: Effect of Treatment of Symptoms

Figure 02: Effect of Treatment on Pasi Score
Figure 03: Effect on Matsyashaklopamam during the Course of Treatment

Figure 04: Effect on Aswedana during the course of treatment

Figure 05: Effect of treatment on kandu during the course of treatment
**Figure 06:** Effect of treatment on utseda during the course of treatment

**Figure 07:** Effect of treatment on vaivarnya during the course of treatment

**Figure 08:** Effect of treatment on PASI score during the course of treatment
Table 02: Overall relief of disease ek kushta

<table>
<thead>
<tr>
<th>% of relief</th>
<th>No. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>12</td>
<td>60%</td>
</tr>
<tr>
<td>&gt;50%</td>
<td>4</td>
<td>20%</td>
</tr>
<tr>
<td>&gt;25%</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>&lt;25%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No change</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Aggravation</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**CONCLUSION**

*Ekakushta* is a unique variety of *Kshudra Kushta* caused by morbidity of all three *Dosha* with dominance of *Vata* and *Kapha Dosha* and four *Dushya* including *Tvak, Rakta, Mamsa* and *Lasika*. The clinical symptoms of *Ekakushta* match with that of psoriasis. Whole regimen comprising sequential administration of *Virechana karma* and *Tuvaraka Rasayana* in conjunction with *bahiparimarjana chikitsa* is effective in complete remission of the symptom in 10% of patients. Significant remission in 60% of patients. Moderate remission in 20%. Mild remission in 10% *Kramataha Virechana* is effective in reducing the *Eka*/psoriasis as evidenced by reduction in PASI score. *Tuvaraka Rasayana* is effective in reducing the *Ekakushta*/psoriasis as evidenced by reduction of PASI score. External application of *streekutaja* oil in conjunction with *Rasayana* is effective in reducing the severity of *Ekakushta*/psoriasis. The improvement observed by the medication is definite as proved by tests of statistical significance. The treatment is effective and equally safe. Repetition of the regimen may be required in some for the complete remission of the illness.

**REFERENCES**

1. Agnivesha, Charaka Samhita, revised by Charaka & Dridabala, with Ayurveda Dipika commentary by Chakrapanidatta, fo-

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