Evaluation of the effectiveness of *Pongamia pinnata* seed powder on Pityriasis versicolor (Themal)

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**Abstract:** This is a single blind comparative clinical study in order to evaluate the effectiveness of an external application of ointment which was prepared from seed powder of *Pongamia pinnata*. Two different concentrations, 5% and 10%, of the drug were prepared. Patients were selected from the outdoor patient division, Rural Siddha Ayurvedic Hospital, Kobalapuram. Thirty patients with bilateral involvement were selected for the survey and categorized into test1, test2, standard and control each containing 15 lesions. Ointment prepared from the seed powder of *P. pinnata* was given to apply twice a day on the selected lesion in the test groups. Observation was done after two weeks and follow up week. At the end of the treatment, p-value for skin pigmentation reduction t1 and t2 were 0.003 and 0.000 respectively indicating that significant improvement was achieved compared to the control group (p-value of 0.104). The p-values for the area size difference of the two groups were 0.001 and 0.001 respectively. It shows the effectiveness of the area reduction of both groups were significant and same. But the p-value for the control group was 0.153 and it implies an increase of the lesion area. So the improvement of the pigmentation reduction of the lesion and reduction of area size can be seen with the external application of the ointment prepared from the seed powder of *P. pinnata*.

**Keywords:** Themal, Pityriasis versicolor, *Pongamia pinnata*.

**INTRODUCTION**

Dermatological disorders, more commonly known as skin diseases have become one of the major health issues throughout the world. Thus when assigning health priorities, it is given less priorities, concern and attention by the health practitioners. The disease *themal* can be introduced as the most common communicable disease among the dermatological disorders seen today even in Sari Lanka.

The disease is called as *themal* in Tamil, Tinea versicolor/ pityriasis versicolor in English, Aluham in sinhala and it is called “pethi gomara” or “mal gomara” among the villagers.

*Themal* is one of the *Melthol punjai noi* in siddha medicine that compared to the Tinea versicolor in Allopathic medicine (Anandhan, 2009). Krishnamoorthy (2004) *Themal* is also known as Alagu themal or Alakku themal.

Pityriasis versicolor is a common yeast infection of the skin, in which flaky discoloured patches appear on the chest and back. The term “Pityriasis” is used to describe skin conditions in which the scale appears similar to bran. The multiple colour of Pityriasis versicolor give rise to the second part of the name, “Versicolor”. Pityriasis versicolor is sometimes called Tinea versicolor (Oakley, 2014).

This is a mild, chronic usually asymptomatic (Paniker, 2005) infection of the stratum corneum which produces a patchy discoloration of the skin caused lipophilic yeasts of the genus Malassezia. The yeasts are common members of the normal skin flora and most infections are thought to be endogenous (Greenwood et al., 2002).
This superficial skin infection is caused by the filamentous fungus *Malassezia furfur*, pale brown, fine scaly macules develop on the upper chest or back, forming an irregular pattern, which appears pale brown in a white skinned person, or slightly pale in a dark skin, there is little or no inflammation, and sensation is normal in the affected areas (Bannister et al., 2006).

This affects young adults more frequently and is slightly common in men than in women. It can also affect children, adolescents and older adults. It is more common in hot, humid climates than in cool, dry climates. It often affects people that perspire heavily. It may clear in the winter months and recur each summer. Although it is not considered infectious in the conventional sense, Pityriasis versicolor sometimes affects more than one member of a family (Oakley, 2014).

The *P. pinnata* is widely used as a traditional medicine commonly known as ‘*pungai*’ in Tamil. It is a source of biomedicines have been used as a crude drug for the treatment of tumours, piles, skin diseases, itches, abscess, painful rheumatic joints wounds, ulcers, diarrhoea etc. (Kumar et al., 2016). According to the Siddha literature review, the stanza postulates that the *P. pinnata* seed has the potency to cure the *Themal* (Murugesamudaliyar, 2013).

**Background and justification**

According to the above quotation mentioned in Murugesamudaliyar (2013) the *pungam vidai* (seeds of *P. pinnata*) cures wounds, *kiranthi*, *karappan*, ear diseases, eye diseases, *themal*, *padai*, vatha diseases in the knee joint.

Fungal skin infections are the most common skin disease condition within Sri Lanka as per the statistics, out of which the majority is Tinea vesicolor which accounts a prevalence of 10.5% (Perera et al., 2000).

On the other hand, limited studies have been done to identify the effectiveness of *P. pinnata* toward its anti-fungal activity.

Hence, the present study will be an initiative to find out the anti-fungal activity of its seeds such that it could be effectively used for the Tinea versicolor condition.

**METHODOLOGY**

**Study Design**

This is a single blind comparative clinical study in order to evaluate the effectiveness of seed powder of *P. pinnata* on Pityriasis versicolor (*Themal*).

**Study Area**

The patients were selected according to the inclusive criteria from the skin clinic at the rural Siddha Ayurveda Hospital, Kobalapuram during the period of January 5 2019 to February 5 2019.

**Study Unit**

Thirty patients were selected for the study by systematic randomization. The patients with bilateral involvement of the lesions were selected and categorized each to the Test 1(T1), Test 2(T2), Standard(S) and Control(C) groups respectively, such that 15 lesions were included in each group. Altogether 60 lesions were selected for the study.

**Study Duration**

This study was conducted for a period of one month from 02/03/2019 to 02/04/2019.

**Selection of patients**

Patients were selected according to the inclusive and exclusive criteria from the outpatient department of the rural Siddha Ayurveda Hospital, Kobalapuram. The purpose of trial was explained to the patients and got their consent. All the selected patients were interviewed by the researcher in first visit to the OPD.

**Inclusive criteria**

1. Male or female patients, aged 19 – 50 years.
2. Clinical presentation of Tinea versicolor
   a. Presence of visible skin lesion face, neck, upper chest, upper back and abdomen.
   b. White, black or silvery color lesion.
   c. Pruritus
3. The ability to provide informed consent (including photography release).

**Exclusive criteria**
1. Use of topical antifungal to the affected area in the past 30 days.
2. Use of topical steroid to the affected area in the past 14 days.
3. If female, positive urine pregnancy test at screening (female patients of child bearing potential must be practicing a reliable method of birth control, not be a planning pregnancy, not be breast feeding during the study).
4. Patients with a dermatological condition in the region of the treatment site that in the investigator’s opinion may interfere with the study results.
6. Any medical or psychiatric condition that may interfere with treatment or compliance.

**Plant Material**

**Selection of the plant**
The plant *P. pinnata* was selected from the quotation of general character of *P. pinnata* which is mentioned in the text book of Kunapadam (Part 1) *Porutpanpu nool* written by Murugesu Muthaliyar (2013).

**Collection of the plant**
The seeds of *P. pinnata* were collected from the local area of Trincomalee district.

**Authentication of the plant**
The seeds of *P. pinnata* was authenticated by the supervisor.

**Preparation of the medicine**
The seeds were collected and it was cleaned, de-shelled naturally and dried. Then seeds were finely powdered using the grinder. The prepared powder was mixed with the emulsifying ointment and 5% and 10% ointment was prepared.

**Methodology**
Thirty patients with bilateral involvement of the lesions were selected. The assessment of the disease was done through history taking, general examination and the systemic examination. The prepared ointment of two concentrations 5% and 10% were given to test 1 (T1) and test 2 (T2) respectively. It was given to be applied externally twice a day for a period of 2 weeks with a follow up period of 1 week.

The ketoconazole cream was given as the standard drug for the standard group (S). The control group (C) was treated with emulsifying ointment.

The clinical evaluation of the patients was performed at week 1, week 2 and week 3. In the first day at baseline, a target area was identified and clinical assessment was done in each subject. The evaluation of the skin pigmentation and size of the lesion were done according to the following criteria.

**Clinical evaluation**
Clinical evaluation visits were made at baseline, week 1, week 2 and week 3. Effect of treatment was evaluated on the basis of the clinical parameters; reduction in the skin pigmentation, affected area size difference and each were recorded at every visit.

**Evaluation of the hyperpigmentation / hypopigmentation**
Hyperpigmentation/ erythema and hypopigmentation was evaluated by using IGA scale for hyperpigmentation. 

**IGA scale Hyperpigmentation**
- 0 - Clear of hyperpigmentation
- 1 - Almost clear of hyperpigmentation
- 2 - Mild, but noticeable hyperpigmentation
- 3 - Moderate hyperpigmentation
- 4 - Severe hyperpigmentation
- 5 - Very severe hyperpigmentation

**Calculation of effectiveness of the drug**
The efficacy of the drug was analyzed statistically on the symptoms mentioned in the assessment criteria. The mean and the significance among the 15 patients were calculated by the paired t test in each and every group.
Calculation of effectiveness of the drug

Effectiveness of the drug = \( \frac{\text{No. of pigmentation reduced patients}}{\text{Total no. of patients}} \times 100 \)

On the basis of grading pattern and percentage of improvement of skin de-pigmentation, patients were classified according to the following criteria.

| Table 2-1 Drug effectiveness criteria based on skin pigmentation |
|--------------------|----------------|
| **Percentage of de-pigmentation** | **Result** |
| 0                  | Nil          |
| 1-20               | Mild         |
| 21-40              | Moderate     |
| 41-60              | Good         |
| 61-80              | Better       |
| 81-100             | Best         |

| Table 2-2 Evaluation criteria of the overall effectiveness of the drug |
|------------------------|----------------|
| **Drug effectiveness (%)** | **Result** |
| <50                    | Good         |
| 50-75                  | Better       |
| >75                    | Best         |

**RESULTS & OBSERVATIONS**

According to the evaluation criteria, the skin pigmentation of each and every patient in all groups were noted as follows.

According to the table 5-4, in group 1 6.7% of the patient’s almost clear hyperpigmentation and 6.7% mild pigmentation were noted. Further 46.6% and 40% were noted as moderate and severe pigmentation respectively.

Clear pigmentation was observed in 20 of the patients while 26.7%, 20% and 33.3% were noted as almost clear, mild and moderate pigmentation respectively in group 2.

In the standard group Clear of pigmentation was noted in 26.7% of the patients and almost clear, mild and moderate pigmentation were noted in 20%, 46.6%, and 6.7% respectively. Moderate, severe and very severe pigmentation were recorded in 13.3%, 46.7% and 40% respectively of the control group after the treatment.

**Table 3-1 skin pigmentation variation before and after Treatment in each group**

<table>
<thead>
<tr>
<th>Skin pigmentation</th>
<th>Test group 1</th>
<th>Test group 2</th>
<th>Standard group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td>BT</td>
<td>AT</td>
</tr>
<tr>
<td>No. %</td>
<td>No. %</td>
<td>No. %</td>
<td>No. %</td>
<td>No. %</td>
</tr>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>13.3</td>
<td>7</td>
<td>46.6</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>66.7</td>
<td>6</td>
<td>40</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>20</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Figure 3-1 Before treatment in test group 1**

**Figure 3-1 After treatment in test group 1**

**Figure 3-2 before treatment in test group 2**

**Figure 3-4 After treatment in test group 2**
1. Clear of hyperpigmentation
2. Almost clear of hyperpigmentation
3. Mild, but noticeable hyperpigmentation
4. Moderate hyperpigmentation
5. Severe hyperpigmentation
6. Very severe hyperpigmentation

**Evaluation of effectiveness of the test drug compared with the control**

Table 5-8 shows the mean values of skin hyperpigmentation before and after treatment of the test group 1 ($t_1$) as 4.07 and 3.20 and for test group 2 ($t_2$) as 4.13 and 1.67 respectively while for the standard group ($s$) the mean was 4.27 and 1.6 before and after the treatment. And for the control group ($c$) was 4.00 and 4.27 respectively. The $P$-value for the $T_1$, $T_2$, standard and the control were 0.003, 0.000, 0.000 and 0.104 respectively.

| Table 3-2 Evaluation of skin pigmentation in test 1, test 2, standard and control groups |
|---------------------------------|----------------|----------------|----------------|----------------|----------------|
| Test 1(T1)                     | Test 2(T2)   | Standard(S)  | Control (C)   |
| BT   | AT   | BT   | AT   | BT   | AT   | BT   | AT   |
| Mean | 4.07 | 3.20 | 4.13 | 1.67 | 4.27 | 1.33 | 4.00 | 4.27 |
| Mean difference                | - .867       | - 2.467       | - 2.933       | - .267         |
| Std. deviation                 | - .915       | - .915        | - .799        | - .594         |
| Std. error mean                | - .236       | - .236        | - .206        | - .153         |
| Df                             | 14            | 14             | 14            | 14             |
| Paired $t$                     | 3.66          | 10.43          | 14.22         | -1.740         |
| $P$                            | 0.003         | 0.000          | 0.000         | 0.104          |

The mean difference of the $T_1$ is 0.867 while in $T_2$ 2.467. So the skin pigmentation reduction has increased in the $T_2$. The mean difference of the standard group was 2.933. So it shows skin pigmentation reduction has increased with compared to $T_2$. The mean difference in the control group is -0.267 and it shows that there is an increase in the pigmentation in the control group. The $p$-value of $T_1$ is 0.003 and $T_2$ is 0.000. Since that the $T_2$ is more significant compared to the $T_1$. 

![Figure 3-3 Relation of change in pigmentation in four different groups](image1)

![Figure 3-6 Relation of change in pigmentation in four different groups](image2)

![Figure 3-7 Relation of change in pigmentation in four different groups](image3)
Evaluation of drug effectiveness

Effectiveness of the drug in T2 group = \( \frac{\text{No. of pigmentation reduced patients}}{\text{Total no. of patients}} \times 100 \)

\[ = \frac{3}{15} \times 100 = 6.66\% \]

Effectiveness of the drug in T2 group = \( \frac{\text{No. of pigmentation reduced patients}}{\text{Total no. of patients}} \times 100 \)

\[ = \frac{3}{15} \times 100 = 20\% \]

Table 3-3 Drug effectiveness

<table>
<thead>
<tr>
<th></th>
<th>T1</th>
<th>T2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
</tr>
<tr>
<td>M</td>
<td>DE (%)</td>
<td>M</td>
</tr>
<tr>
<td>SPR</td>
<td>4.07</td>
<td>0</td>
</tr>
<tr>
<td>BT</td>
<td>- Before Treatment</td>
<td></td>
</tr>
<tr>
<td>AT</td>
<td>- After Treatment</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>- Mean</td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>- Drug Effectiveness</td>
<td></td>
</tr>
<tr>
<td>SPR</td>
<td>- Skin Pigmentation Reduction</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

*P. pinnata* is a medicinal plant used for treating many diseases. According to Murugesu mudaliyar, the seeds of *P. pinnata* can be used in the management of Pityriasis versicolor. It possesses Karangin which has the antiseptic and insecticide properties. So it can be used for the skin conditions such as chronic eczema, psoriasis, scabies, ringworm and pityriasis (Jayaweera, 2006). In the present study, change of skin pigmentation was observed in the two different concentrations of the test drug. According to the table 3-1, almost clear pigmentation was observed in 6.7% of the patients in the test group 1 (T1) and 20% clear pigmentation in the test group 2 (T2). Clear pigmentation in 26.7% and 20% almost clear pigmentation in standard group (S) was observed. There was no pigmentation reduction in the control group while increase density of the pigmentation was noted. The P-value for pigmentation variation of the test group 1 was 0.003 and it was 0.000 for the test group 2 and standard group while P-value of the control group was 0.104. It showed that the pigmentation reduction in both test groups were significant and it is highly significant in the test group 2. The T2 and S group’s P value are same and it shows similar reduction. But in the control group instead of the reduction, there was an increase of the pigmentation during the treatment period. According to the siddha text by Kuppusami muthliyar (2016) the Kapha become prominent in the pundareeka kuttam. Additionally it is also mentioned in Kanthasami Muthaliyar (2012) that at the severe stage of the disease condition the body becomes oedematous. The seed of *P. pinnata* possesses the suvai (taste) astringent and bitter, viriyum (potency) hot and vipakam (output) pungent. The panchaboothic composition of Kapha dosha is earth and water and that of astringent and bitter taste is, air + earth and air + space respectively. Hence, the seed part of the *P.pinnta* can be used in the management of Pityriasis versicolor (thermal) by balancing the vitiated Kapha dosha. The table 5-10 shows the effectiveness of the drug before and after the treatment which was calculated based on the skin pigmentation reduction. There for the effectiveness can be shown as from the total patients in the group how many patients has reduced the pigmentation. So it is 6.66 % in T1 and 20% in T2.

According to the table 4-1 mild to moderate effectiveness of action of the drug could be seen. The overall effectiveness of the drug is good.

CONCLUSION

Drug effectiveness based on skin pigmentation reduction in T1 is 6.7% and T2 is 20%. Therefore the overall effectiveness of the drug is good. And 10% ointment is better than the 5% ointment in the skin pigmentation reduction of the lesion. Hence the seed powder of *P. pinnata* shows effectiveness on Pityriasis versicolor. Suggestions- Further studies with a large number of patients with pityriasis versicolor in order to verify the actual potential. Increase the time period of evaluation.
REFERENCES