INTRODUCTION:
The oil extracted from the seeds of ‘pakwa tuvaraka phala’, commonly known as ‘tuvarakabeeja taila’ or ‘chaulmoogra oil’ is mentioned as a potential healer for 11 types of ‘kshudra kushtha’. Tuvaraka is a classical drug of Ayurveda. The disease ‘Vicharchika’ which is one among the ‘kshudra kushthas’ is co-related with eczema. One among the 11 ‘kshudra kushthas’ is vicharchika. Its cardinal signs and symptoms are ‘kandu’, ‘srava’, ‘vaivarnya’, ‘pidaka’ and ‘rukshata’. It is characterized by blackish brown eruptions over skin associated with itching and with excessive exudation. The signs of eczema over the affected skin are - skin redness and swelling with ill-defined margins, papules, vesicles and blisters, exudation and cracking, scaling, thickening, lichenification, a dry leathery thickening, fissures and scratch marks and pigmentation. In this pilot study ‘tuvaraka beeja taila’ is used for treating the selected vicharchika conditions to re-discover and re-prove its therapeutic efficacy ‘vicharchika’.

OBJECTIVES:
To evaluate the efficacy of ‘tuvaraka beeja taila’ (extracted oil from the seeds of Hydnocarpus pentandra though classical method) on randomly selected patients of ‘vicharchika’. It is a single blind clinical study with pre and post test design.

MATERIALS AND METHODS:
Design
Interventional, single blind randomized clinical study with pre and post test design.

Study Population
Randomly selected patients from OPD and IPD of SDM Ayurveda College Hospital, Udupi.

Sample Size
Ten patients randomly selected from OPD and IPD of SDM Ayurveda College Hospital, Udupi.

Study Setting
The study was conducted in Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi, Karnataka, South India from Jan 2014 to July 2014.

Diagnostic Criteria
Five cardinal signs and symptoms of ‘vicharchika’ are considered here for assessment. They are ‘kandu’ correlated with itching, ‘srava’ with exudation, ‘vaivarnya’ with discoloration, ‘pidaka’ with papules and ‘rukshata’ which is dryness.

These are correlated with the signs and symptoms of eczema.

Key Words: Tuvaraka, Hydnocarpus pentandra, Tuvaraka taila, Chaulmoogra oil, Vicharchika, Eczema
eczema’ explained in contemporary science to assess the same. They are;
1. Skin redness and swelling with ill defined margins
2. Papules, vesicles and blisters
3. Exudation and cracking
4. Scaling
5. Thickening
6. Lichenification
7. A dry leathery thickening
8. Fissures and scratch marks and

Inclusion and exclusion criteria

Patients between age group of 16 to 70 and the patients diagnosed with vicharchika are selected here for the study. Patients with systemic diseases like diabetes and renal failure are excluded.

Intervention

Selected patients are administered with maximum up to 12 gms of ‘hareetaki churna’ [1] (Terminalia Chebula) once daily for three days to attain ‘mrudu shodhana’ [1] (mild body purification through purgation) effect. From 4th day onwards oral administration of 5 drops of the ‘tuvaraka beeja taila’ [3] (oil extracted from Hydnocarpus pentandra) once daily along with 100 ml of milk on OPD basis.

External application of tuvaraka beeja taila (oil extracted from Hydnocarpus pentandra) over affected part along with ‘butter’ in the ratio of 1:2 on OPD basis.

Investigation:

Random blood sugar (RBS) to exclude the diabetes mellitus;

Assessment criteria

Each patient is overall assessed weekly after the onset of treatment and twice during follow up with one month gap in between.Relevant data is collected and documented on the detailed case proforma.Assessment of the condition is done adapting standard methods of scoring.Subjective parameters are analyzed statistically with Paired- t test.

Visual analogue scale:

The assessment of signs and symptoms are done using the standard visual analogue scale as; Cured- 0; Mild- 1; Moderate- 2; and Severe- 3;

RESULTS:

Assessment of signs and symptoms of 10 randomly selected ‘Vicharchika’ patients is done adapting standard methods of scoring and the data obtained is systematically collected and documented. After the beginning of the treatment, weekly assessment is done on 7th, 14th, 21st and 28th day followed by follow up period assessment.

During follow up period of 60 days i.e. double of treatment period, the signs and symptoms are assessed after 30th and 60th day. All the obtained numerical values as per ‘visual analogue scale’ are carefully documented. Later numerical findings of all the subjective parameters are analyzed statistically with Paired-‘t’ test and the same is documented below.

Kandu

The Mean score observed before the treatment was 3.00 After the treatment value of 7th day was reduced to 2.34, with effect of treatment showed 22% improvement, on 14th day reduced to 1.51, with effect of treatment showed 49.66% improvement, on 21st day reduced to 1.22, with effect of treatment showed 59.33 % improvement, on 28th day reduced to 0.51, with effect of treatment showed 83 % improvement, in ‘kandu’ with statistically significant (P<0.0001).

Srava:

The Mean score observed before the treatment was 2.70 After the treatment value of 7th day was reduced to 1.92, with effect of treatment showed 29.62% improvement, on 14th day reduced to 1.39, with effect of treatment showed 48.51% improvement, on 21st day reduced to 0.82, with effect of treatment showed 69.25% improvement, on 28th day reduced to 0.34, with effect of treatment showed 87.40% improvement, in ‘srava’ with statistically significant (P<0.0001). (Table. 2)
Figure 2. Effect of treatment on ‘Srava’

The effect of ‘tuvaraka beeja taila’ in ‘srava’ showed 29.62%, 48.51%, 69.25% and 87.4% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 100% and 100% improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘srava’. In follow up period it showed complete improvement with clinical significance.

Vaivarnya:

The Mean score observed before the treatment was 2.69 After the treatment value of 7th day was reduced to 2.54, with effect of treatment showed 5.20% improvement, with statistically significant (0.0341) on 14th day reduced to 1.56, with effect of treatment showed 41.63% improvement, on 21st day reduced to 1.24, with effect of treatment showed 53.53% improvement, on 28th day reduced to 0.88, with effect of treatment showed 66.91% improvement, in ‘vaivarnya’ with statistically significant (P<0.0001). (Table 3)

Figure 3. Effect of treatment on ‘Vaivarnya’

The effect of ‘tuvaraka beeja taila’ in ‘vaivarnya’ showed 5.2%, 41.63%, 53.53% and 66.91% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 84.01% and 97.39 % improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘vaivarnya’. In follow up period it showed highly improvement with clinical significance.

Pidaka:

The Mean score observed before the treatment was 2.58 After the treatment value of 7th day was reduced to 1.82, with effect of treatment showed 29.45% improvement, on 14th day reduced to 1.15, with effect of treatment showed 55.42% improvement, on 21st day reduced to 0.78, with effect of treatment showed 68.99% improvement, on 28th day reduced to 0.28, with effect of treatment showed 89.14% improvement, in ‘pidaka’ with statistically significant (P<0.0001). (Table 4)

Figure 4. Effect of treatment on ‘Pidaka’

The effect of ‘tuvaraka beeja taila’ in ‘pidaka’ showed 29.45%, 55.42%, 68.99% and 89.14% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 100% and 100% improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘pidaka’. In follow up period it showed complete improvement with clinical significance.

Rukshata:

The Mean score observed before the treatment was 2.78 After the treatment value of 7th day was reduced to 2.12, with effect of treatment showed 23.74% improvement, on 14th day reduced to 1.44, with effect of treatment showed 47.84% improvement, on 21st day reduced to 1.05, with effect of treatment showed 62.23% improvement, on 28th day reduced to 0.71, with effect of treatment showed 74.46% improvement, in ‘ruksata’ with statistically significant (P<0.0001). (Table 5)

Figure 5. Effect of treatment on ‘Rukshata’
The effect of ‘tuvatara beeja taila’ in ‘rukshata’ showed 23.74%, 47.84%, 62.23% and 74.46% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 91% and 100% improvement on follow-up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘rukshata’. In follow-up period it showed complete improvement with clinical significance.

Table 1. Showing the effect of treatment on ‘Kandu’

<table>
<thead>
<tr>
<th>N</th>
<th>BT Mean</th>
<th>Day</th>
<th>AT Mean</th>
<th>Diff d</th>
<th>%</th>
<th>Paired t test</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>7th</td>
<td>2.34</td>
<td>0.66</td>
<td>22↓</td>
<td>0.47 0.04  13.863 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td>10</td>
<td>3.00</td>
<td>14th</td>
<td>1.51</td>
<td>1.49</td>
<td>49.66↓</td>
<td>0.50 0.05  29.65 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21st</td>
<td>1.22</td>
<td>1.78</td>
<td>59.33↓</td>
<td>0.52 0.05  33.98 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28th</td>
<td>0.51</td>
<td>2.49</td>
<td>83↓</td>
<td>0.67 0.06  36.937 &lt;0.0001</td>
<td>S</td>
</tr>
</tbody>
</table>

N= Sample size; BT= Before treatment; AT= After treatment; d= Mean difference; SD= Standard deviation; SEM= Standard error of mean;

Table 2. Showing the effect of treatment on ‘Srava’

<table>
<thead>
<tr>
<th>N</th>
<th>BT Mean</th>
<th>Day</th>
<th>AT Mean</th>
<th>Diff d</th>
<th>%</th>
<th>Paired t test</th>
<th>Significant</th>
</tr>
</thead>
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<tr>
<td></td>
<td>2.70</td>
<td>7th</td>
<td>1.90</td>
<td>0.80</td>
<td>29.62↓</td>
<td>0.53 0.08  12.84 &lt;0.0001</td>
<td>S</td>
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<tr>
<td></td>
<td></td>
<td>14th</td>
<td>1.39</td>
<td>1.31</td>
<td>48.51↓</td>
<td>0.58 0.09  14.86 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21st</td>
<td>0.82</td>
<td>1.87</td>
<td>69.25↓</td>
<td>0.44 0.06  26.25 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28th</td>
<td>0.34</td>
<td>2.36</td>
<td>87.40↓</td>
<td>0.48 0.07  31.06 &lt;0.0001</td>
<td>S</td>
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</table>

Table 3. Showing the effect of treatment on ‘Vaivarnya’

<table>
<thead>
<tr>
<th>N</th>
<th>BT Mean</th>
<th>Day</th>
<th>AT Mean</th>
<th>Diff d</th>
<th>%</th>
<th>Paired t test</th>
<th>Significant</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2.69</td>
<td>7th</td>
<td>2.54</td>
<td>0.14</td>
<td>5.20↓</td>
<td>0.61 0.06  2.150 0.0341</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14th</td>
<td>1.56</td>
<td>1.12</td>
<td>41.63↓</td>
<td>0.49 0.05  17.94 &lt;0.0001</td>
<td>S</td>
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<tr>
<td></td>
<td></td>
<td>21st</td>
<td>1.24</td>
<td>1.44</td>
<td>53.53↓</td>
<td>0.43 0.04  21.50 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28th</td>
<td>0.88</td>
<td>1.80</td>
<td>66.91</td>
<td>0.37 0.03  29.31 &lt;0.0001</td>
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Table 4. Showing the effect of treatment on ‘Pida’

<table>
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<th>BT Mean</th>
<th>Day</th>
<th>AT Mean</th>
<th>Diff d</th>
<th>%</th>
<th>Paired t test</th>
<th>Significant</th>
</tr>
</thead>
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<td></td>
<td>2.58</td>
<td>7th</td>
<td>1.82</td>
<td>0.76</td>
<td>29.45↓</td>
<td>0.38 0.06  9.913 &lt;0.0001</td>
<td>S</td>
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<tr>
<td></td>
<td></td>
<td>14th</td>
<td>1.15</td>
<td>1.43</td>
<td>55.42↓</td>
<td>0.36 0.05  17.85 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21st</td>
<td>0.78</td>
<td>1.78</td>
<td>68.99↓</td>
<td>0.41 0.06  26.70 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28th</td>
<td>0.28</td>
<td>2.30</td>
<td>89.14↓</td>
<td>0.45 0.07  30.82 &lt;0.0001</td>
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Table 5. Showing the effect of treatment on ‘Rukshata’

<table>
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<th>N</th>
<th>BT Mean</th>
<th>Day</th>
<th>AT Mean</th>
<th>Diff d</th>
<th>%</th>
<th>Paired t test</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.78</td>
<td>7th</td>
<td>2.12</td>
<td>0.66</td>
<td>23.74↓</td>
<td>0.68 0.09  10.349 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14th</td>
<td>1.44</td>
<td>1.33</td>
<td>47.84↓</td>
<td>0.56 0.07  20.97 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21st</td>
<td>1.05</td>
<td>1.73</td>
<td>62.23↓</td>
<td>0.58 0.07  29.00 &lt;0.0001</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28th</td>
<td>0.71</td>
<td>2.07</td>
<td>74.46↓</td>
<td>0.45 0.06  59.65 &lt;0.0001</td>
<td>S</td>
</tr>
</tbody>
</table>
DISCUSSION:
In the present clinical study, 10 patients who fulfill the inclusion criteria were randomly selected and treated with ‘tuvaraka beeja taila’.

Drug acceptability
Since, ‘tuvaraka beeja taila’ possesses ‘teekshna guna’, its acceptibility in the patients for intake and for external application is a concern. However, the dosage of 5 drops intake once daily with 100 ml of milk for a month; and external application of this oil over affected part along with butter in the ratio of 1:2 on OPD basis did not pose any serious questions over acceptibility.

Only 2 female and 1 male patients initially complained of ‘nauseating sensation’ after intake of the medicine, which was not seen after few days of intake. During external application, the oil did not cause any untoward symptoms over skin and its acceptability here was good.

Need for ‘Mrudu Shodhana’
In the study, ‘mrudu shodhana’ for 3 days with 12 gms of ‘haritaki curra’ was done before administration of ‘tuvaraka beeja taila’. Since ‘tuvaraka beeja taila’ in itself is a ‘vÂmaka’ and ‘virecaka’, what is the need for ‘mrudu shodhana’ using ‘haritaki curra’ is the question that may arise. However in classics it is clearly mentioned that, when ‘tuvaraka beeja taila’ is administered for any therapeutic purposes, ‘deha shodhana’ is necessary[1].

Objective and subjective parameters:
Out of 10 patients, the complaint of ‘kandu’ was completely reduced in 5 patients during assessment on 28\textsuperscript{th} day; in 3 patients mild itching was still present; and in 2 patients, moderate itching persisted; however severe itching was absent in all the patients;
Out of 3 patients who had the complaint of ‘srava’, 1 patient was completely relieved from the same during assessment on 28\textsuperscript{th} day. Remaining 2 patients had the complaint of mild ‘srava’ and moderate and severe ‘srava’ wasn’t seen in any of the patients.
Out of 9 patients who had the complaint of ‘vaivaràa’ showed in ‘srava’ showed 22\%, 49.66\%, 59.33\% and 83\% improvement on 7\textsuperscript{th}, 14\textsuperscript{th}, 21\textsuperscript{st} and 28\textsuperscript{th} day respectively and it also shows 93\% and 100\% improvement on follow up period (30 and 60\textsuperscript{th} day) also. Statistically it showed highly significant result with clinical improvement in ‘kandu’. In follow up period it showed complete improvement with clinical significance.

Percentage of improvement
The effect of ‘tuvaraka beeja taila’ in ‘kandu’ showed 29.62\%, 48.51\%, 69.25\% and 87.4 \% improvement on 7\textsuperscript{th}, 14\textsuperscript{th}, 21\textsuperscript{st} and 28\textsuperscript{th} day respectively and it also shows 100\% and 100\% improvement on follow up period (30 and 60\textsuperscript{th} day) also. Statistically it showed highly significant result with clinical improvement in ‘srava’. In follow up period it showed complete improvement with clinical significance.

Follow up:
During follow up period, patients were given once daily a capsule filled with ‘wheat flour’ for placebo effect. Patients were examined after 30 and 60 days.
Out of 10 patients, the complaint of ‘kandu’ was completely reduced in 8 patients during assessment on 30\textsuperscript{th} day; in 2 patients mild itching was mild and on 60\textsuperscript{th} day assessment, all the patients were relieved from the symptoms.
Out of 3 patients who had the complaint of ‘srava’, all the patients were relieved from the symptoms on 30\textsuperscript{th} and 60\textsuperscript{th} day of follow up.
Out of 9 patients who had the complaint of ‘vaivaràa’ in the affected part, in 2 patients the normal skin colour was reinstated during assessment on 30\textsuperscript{th} day and 7 patients had mild discoloration left in the affected part. However, on 60\textsuperscript{th} day’s assessment all patients except one were relieved from the complaint.
Out of 2 patients who had the complaint of ‘pidaka’, both the patients were relieved from the symptoms on 30\textsuperscript{th} and 60\textsuperscript{th} day of follow up.
Out of 6 patients who had the complaint of ‘rukshata’ in 1 patients was completely relieved from the symptom during assessment on 30\textsuperscript{th} day and 5 patients had mild roughness in the affected part. However, on 60\textsuperscript{th} day’s assessment all patients were relieved from the complaint.

However, the above said complaints were considerably reduced in all the patients from severe to moderate, moderate to mild during weekly assessment of the affected part.

Out of 6 patients who had the complaint of ‘rukshata’ all the 6 patients had the mild roughness in the affected part during assessment on 28\textsuperscript{th} day.
84.01% and 97.39% improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘vaivaràa’. In follow up period it showed highly improvement with clinical significance.

The effect of ‘tuvaraka beeja taila’ in ‘pidaka’ showed 29.45%, 55.42%, 68.99% and 89.14% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 100% and 100% improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘pidaka’. In follow up period it showed complete improvement with clinical significance.

The effect of ‘tuvaraka beeja taila’ in ‘rukshata’ showed 23.74%, 47.84%, 62.23% and 74.46% improvement on 7th, 14th, 21st and 28th day respectively and it also shows 91% and 100% improvement on follow up period (30 and 60th day) also. Statistically it showed highly significant result with clinical improvement in ‘rukshata’. In follow up period it showed complete improvement with clinical significance.

CONCLUSION:

From this pilot study, it can be concluded that, ‘tuvaraka beeja taila’ has encouraging therapeutic efficacy in ‘vicharchika’ when used judiciously. This medicine has shown considerable effectiveness in reducing the five cardinal signs and symptoms of ‘vicharchika’ such as ‘kandu’, ‘srava’, ‘vaivaranya’, ‘pidaka’ and ‘rukshata’. This study can become an encouraging base to take up the clinical study of this ‘tuvaraka beeja taila’ with larger sample size.

REFERENCES:


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