An open labelled, single armed, prospective, phase I, clinical study to evaluate efficacy of “mukhkanti lepa” in vyanga (facial melanosis)

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ABSTRACT:

Smooth & glowing complexion of the face increases the beauty of a person & gives self confidence. Vyanga is a disease, which decreases the glowing complexion of the face & affects the skin. The prevalence of vyang is increasing in the society due to changed life style. Hence a clinical study was planned on 36 patients having symptoms of Vyanga (Facial melanosis). They were given “Mukhakanti lepa” for local application for 30 days. The skin texture was observed before and after treatment and Niruja mandala was observed under two criteria, number of patches and colour of patches on face before and after treatment. Promotion in skin texture was seen along with decrease in Vyanga (Niruja Mandala).

KEYWORDS: Mukhkanti lepa, vyang, Niruja Mandala

INTRODUCTION:

Ayurveda is gaining popularity these days due to its organic products, which can be used as medicines and cosmetics too. Cosmetics are the substances applied on to skin to enhance the appearance of the human body. Due to the changed life style, pollution and stress many people have problems with their complexion, whether it be uneven colour, texture, pigmentation and wrinkles. Vyanga is characterized by the presence of Niruja (painless), Tanu...
Shyav varna Mandala (bluish black patches) on face (1) occurs due to vitiation of vata, pitta followed by Rakta dosha (2). In modern medical science topical steroids have been described in management of facial melanosis (3), but topical steroids are not completely free from adverse effects such as irritation, rashes (4). In Ayurveda, varnya (complexion promoter) drugs are mentioned for internal as well as external use. The herbal paste applied on face to treat acne, scars, marks and vyanga and to improve Mukhakanti are known as “Varnya mukhalepa” (5). Mukhakanti refers to the natural colour, texture, and appearance of the skin of face (6).

Hence this study was planned to evaluate the efficacy of Mukhakanti lepa as mentioned in Sharangadhar Samhita (8) and Bhavprakash (11) for promotion of Mukhakanti and decrease in vyanga in middle age group.

AIM:

To evaluate efficacy of Mukhakanti lepa in Vyanga (Facial melanosis).

OBJECTIVES:

1) Primary - To evaluate efficacy of Mukhakanti lepa in Vyanga (Facial melanosis).
2) Secondary - To evaluate Mukhakanti lepa in improvement of facial skin texture.

HYPOTHESIS:

A) Sharangdharokta “Mukhakanti lepa” is effective in Vyanga (Facial melanosis).

B) Mukhakanti lepa is effective in improvement of skin texture.

STUDY DESIGN: Open labeled, single armed, prospective, Phase I, Clinical study.

MATERIALS AND METHODS:

36 patients suffering from Vyanga (Facial melanosis) were given the Mukhakanti lepa (8) to be applied on the face once daily and removed after drying. This was carried out for 30 days. Thus the action of the lepa was observed and noted.

CRITERIA FOR SELECTION:

Inclusion criteria:
- Age – 18 to 45 years
- Sex – both (male & female)
- Person from any economical class were selected.
- Chronicity less than 5 years
• Niruj mandalas (pigmented patch) present over the face
Exclusion criteria:
• Age below 18 years and above 45 years were excluded.
• Inflammatory pigmentation.
• Malignant melanoma.

INVESTIGATIONS: Routine investigations of blood, urine and stool were carried out before treatment to rule out any systemic disease.

PARAMETERS:

Subjective: Skin type - dry and oily skin
Vyang (Niruja madala) – Number of patches and colour of patches

DRUG:

रक्तचंदन मंजिलांशुकुटप्रयंगद्
वटाकुं पुरुर्गच व्यंगना मुखकांतिदाः
श.म.ड.०.१

Mukhakanti lepa:
Contents:
Stem of Raktachandan (Ptero-carpus santalinus),
Root of Manjishtha (Rubia cordifolia),
Stem bark of Lodhra (Symplocos racemosus),
Roots of Kushtha (Saussurea lappa),
Seeds of Priyangu (Callicarpa macrophylla),
Vatankura (Ficus Bangalensis), leaf buds Seeds Masura (Red lentil).

All the ingredients of this lepa were procured in powder form from GMP certified company. They were mixed in equal proportions. This mixture was applied on face by mixing with water for oily skin or milk for dry skin, once daily and was removed after drying.

The mukhakanti lepa was applied to dry skin by mixing it with milk and for oily skin it was applied by mixing with water.

GRADATION: Skin type:

1. Dry skin (Ruksha)
Grade 0- Normal
Grade 1- Mild
Grade 2- Moderate
Grade 3- Severe
2. **Oily skin (Snigdh)**

Grade 0 - Normal
Grade 1 - Mild
Grade 2 - Moderate
Grade 3 - Severe

3. **Vyanga (nirujamandal)**

   a) Number of patches
   - Grade 0 - No mandal (patch)
   - Grade 1 - Mild (1 to 4)
   - Grade 2 - Moderate (5 to 10)
   - Grade 3 - Severe (above 10)

   b) Colour of patches:
   - Grade 0 - Normal skin
   - Grade 1 - Light brown
   - Grade 2 - Dark brown
   - Grade 3 - Blue black

**OBSERVATION:**

1. **According to sex distribution of 36 patients –**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>06</td>
<td>17%</td>
</tr>
<tr>
<td>Female</td>
<td>30</td>
<td>83%</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>100%</td>
</tr>
</tbody>
</table>

2. **Assessment of complexion:**

The complexion was assessed on the basis of four factors before and after treatment.

I. **Skin type:**

According to skin type of 36 patients:

<table>
<thead>
<tr>
<th>Skin type</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry</td>
<td>16</td>
<td>44</td>
</tr>
<tr>
<td>Oily</td>
<td>20</td>
<td>56</td>
</tr>
<tr>
<td>Normal</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>100%</td>
</tr>
</tbody>
</table>

A. **Dry skin:**

<table>
<thead>
<tr>
<th>Grade</th>
<th>0th day</th>
<th>15th day</th>
<th>30th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Chi square: 31.59

p<0.05     P<0.001
Before treatment (at 0th day) patients with dry skin having grade 2 were maximum i.e. 8 out of 16.

After treatment patients with normal skin (grade 0) were maximum i.e. 13 out of 16 (at 30th day). Observed difference was statistically highly significant.

B. Oily skin:

<table>
<thead>
<tr>
<th>Grade</th>
<th>0th day</th>
<th>15th day</th>
<th>30th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
<td>9</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Chi square : 40.25

P < 0.05  P < 0.001

Before treatment patients with oily skin having grade 2 were maximum i.e. 9 out of 20 and having grade 3 were 7 patients.

After treatment patients with normal skin (grade 0) and grade 1 were maximum i.e. 11 and 9 out of 20. Observed difference was statistically highly significant.

2) Vyanga (niruja mandal):

A) Number of patches

<table>
<thead>
<tr>
<th>Grade</th>
<th>0th day</th>
<th>15th day</th>
<th>30th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>36</td>
<td>36</td>
</tr>
</tbody>
</table>
Chi sq: 64.91297    P<0.05
      P<0.001

Before treatment (at 0th day) patients with Vyanga having grade 2 and 3 were maximum i.e. respectively 15 and 13 (total 28 out of 36)

After treatment (at 30th day) patients with Vyanga having grade 0 and 1 were maximum i.e. respectively 13 and 21 (total 34 out of 36).

Observed difference was statistically significant.

B) Vyanga (niruja mandal) : colour

<table>
<thead>
<tr>
<th>Grade</th>
<th>0th day</th>
<th>15th day</th>
<th>30th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>36</td>
<td>36</td>
</tr>
</tbody>
</table>

Chi square value: 62.922

P<0.05   P<0.001

Pattern of changes in the colour of Mandalas with the treatment of Mukhakanti Lepa:

Amongst 36 patients, before treatment, in 13 patients the Mandalas were blue black coloured, in 14 patients the Mandalas were dark brown coloured and in 9 patients the Mandalas were light coloured.

On 15th day of observation 3 patients had bluish black coloured patches, 13 patients had dark brown patches, 17 patients had light brown coloured patches and 3 patients attained the normal skin colour. At the end of the treatment in 3 patients the patches were dark brown in colour, in 21 patients the patches were light brown in colour and 12 patients attained normal skin colour. Out of 36 patients 12 patients were cured completely, which was statistically significant at the level of P<0.05.
21 patients have shown marked improvement and 3 patients showed slight improvement.

Statistically significant result was obtained in the symptom blackish/brownish patch over the face.

DISCUSSION:

The observed difference is due to combined effects of the dravya present in Mukhkantilepa.

The properties of each dravya of Mukhkantilepa are explained below.

- **Raktachandan** is Twagdoshahar, Rakta pitta shamak, Raktashodhak and Kushthagna and has guna such as guru and ruksha.
- **Manjisjtha** is from Varnya gana and its application is
- Useful in many skin diseases and has guna such as guru and ruksha.
- The dravya *Lodhra* is also used in skin diseases and has laghu and ruksha guna.
- **Kushtha** is Raktashodhak, Kushthaghna, Varnya having laghu, Ruksha guna.

- **Priyangu** is Raktashodhak, Twagdoshahar and very useful in skin diseases having guru and ruksha guna.
- **Vatankur and Masur** are Varnykar and also having ruksha guna as explained by Bhavprakash.
- Thus all the dravyas in the Mukhkanti lepa have the properties such as Varnya and Twagdoshahar due to which they are used in this study.

Assessment of vyanga:

1. **Skin type:**

According to Chi square test, *Mukhkanti lepa* was statistically significant in dry and oily skin type were equally effective. This study shows that *Mukhkanti lepa* was effective in all skin types.

In case of oily skin type lepa was effective due to Ruksha guna, of all the dravya included in *Mukhkanti lepa*. In case of dry skin, lepa was also found effective as the lepa was applied by mixing with milk. Since the base was snigdha and the raktachandan and manjishttha mainly acting on Bhrajak pitta the artistically dryness of skin was reduced and skin showed normal texture after treatment.
2. Varnya(Nirujamandal) :
According to Chi square test the Mukhkanti lepa was statistically highly significant in reducing number of pigmented patches. Normal colour of skin was attained at the site of patches.

CONCLUSION:

- **Mukhkanti lepa** is effective in reducing the pigmentation (niruja mandal) of face.

- **Mukhkanti lepa** is also effective in improving skin texture and colour.

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