A CLINICAL EVALUATION OF JATIPHALA CHURNA LEPA IN VYANGA WSR TO MELASMA

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ABSTRACT

Vyanga is the one of the Kshudra Roga, characterised by Niruja (painless), Shyava Varna Mandalas (bluish black patches) occurring especially on the face. While considering the pathogenesis of Vyanga, involvement of Pitta is more and it is Rakta Pradoshaja vyadhi. On the basis of clinical features it is correlated with melasma, or facial melanosis, one of the hyper pigmented disorders. Melasma is a common acquired hypermelanosis that affects sun-exposed areas of skin. This study is important since melasma is a disease causing mental side effects in patients, due to darkness and opacity of the skin; therefore, the treatment of melasma in terms of its psychological complication is of particular importance. Jatiphala (Myristica fragrans Houtt.) is an important drug which has got various medicinal uses. The seed and aril of Jatiphala (Myristica fragrans Houtt.) of family myristicaceae have the utilized therapeutically as medicine as well as a spice. Acharya Bhavamishra have mentioned Jatiphala (Myristica fragrans Houtt.) as a single herbal remedy for its action on Vyanga.

Intervention and duration: 30 patients having hyperpigmentation on face with clinical manifestations, fulfilling the diagnostic criteria of Vyanga, the prepared Lepa churma was applied over the affected area, once a day for 60 days. Pre test assessment was done on 15th day, 30th and 60th day. Results: The subjective and objective parameters of the study were graded and the results of the study were analysed statistically using descriptive statistics where the study has shown statistically significant in the subjective and objective parameters. Conclusion: This clinical study of Jatiphalachoorna lepa showed the result in 50-60% of people in the group of Vyanga.

KEYWORDS: Jatiphalachurana lepa, Vanga, Melasma, Jatiphalachoorna lepa.

INTRODUCTION

‘Face is the index of mind’. The clean and clear face plays important role in the individual's personal, emotional, and social well-being. Acquired hyperpigmentation disorders of the skin are among the most common complaint in a general dermatology clinic[1]. Melasma is a common pigmenary disorder. It is a form of acquired hypermelanosis and occurs in sun exposed parts. It develops mostly on the face but occasionally it can also develop on the neck. Rarely, it can also appear on the forearms as well. Melasma is resistant to treatment and often causes significant psychological impact on the patient. It affects both males and females but predominantly seen in females[2].

Hyperpigmentation (melanosis) is a group of disorders characterized by abnormally darker skin that results from increase in the concentration of pigment, which occurs either due to increase the number of melanocytes or increase activity of melanocytes[3]. Melanosis most commonly results from exposure to sunlight, due to air pollution, different cosmetic using habits, stressful life, dietary changes, inclination towards junk or fast food[3]. Nowadays Vyanga becomes one of the biggest problems of the society. Many people are suffering from Vyanga today. Among them women are commonly found due to changes occurring during pregnancy and use of cosmetic supplement[4].

In Ayurveda skin diseases are included under the heading of Kustha and Kshudra roga[4]. Acharya Sushrutha was the first person who has given a detail and separate description of the disease Vyanga in the chapter of ‘Kshudra Roga’. Vyanga is a pathological situation of the facial skin which is produced due to
In the context of Vyanga both Shodana and Shamana Chikitsa are explained in the form of Raktamoksha, Lepa, Abhyanga, and oral medication[6]. As the disease has local spread over the skin of the face, the local or external applications have immediate impact upon the characteristics features of the Vyanga, such as discoloration, dryness on the face, burning sensations, itching etc.

Alepa being mentioned under Bahyaupachaara and for correcting Bhrajakapitta located in the skin, absorbs the drug into the body through skin[7].

Acharya charaka has broadly classified chikitsa under three main headings, namely Antah Patimarjana, Bahir Parimarjana, and Shastra Prranidhana. Lepa kalpana is the Upakalpana, which comes under Bahir Parimarjana Chikitsa[8].

The Lepa which is applied on the face gives strength to the muscle of eyes, cheeks has to be thick which enhance face complexion which in turns cures Vyanga. Alepa normalizes Raktu and Pitta[9].

So, the Lepa which is one of the forms of external application for skin diseases is taken for this study.

Jatiphaladi Choorna Lepa is a formulation mentioned in Bhavaprakasha. Jatiphal (Myristica fragrans Houtt.) it has properties like Katu Tikta Rasa, Laghu Tikshna Guna, Ushna Virya, Katu Vipaka, Vatakapha hara, Varnya, Dipana, Grahi in action. Classics say that the fine powder of these drug, made into paste using water and applied over the Mukha Pradesha, relieves Vyanga[10].

In Jatiphal madrystin present, is known to be useful in reducing the production of melanin secretion in skin. It also has antioxidant properties which act on free radicals. It was also observed that Jatiphal have got exfoliating property, which help in formation of new fresh healthy skin removing unhealthy layer[11].

Hence the present study was undertaken to evaluate the efficacy of Jatiphaladi choorna Lepa in the management of Vyanga with special reference to melasma on face with the hope of quicker action.

MATERIALS AND METHODS
Phase 1: Collection and preparation of Jatiphal churna
Phase 2: Clinical studies.

Source of Data
Literary source: The literary data was collected from classical Ayurvedic texts, modern text books, Samhitas, Nighantus, websites, articles and various journals.

Source of drugs: Botanically identified drug of *Jatiphal* (*Myristica fragrans* Houtt.) was collected from its natural habitat. The test drug was prepared from Rasa Shastra & Bhaishajya kalpana department Rasashala of Ramakrishna Ayurvedic Medical College, Yelahanka, Bangalore.

Source of patients: patients who attended OPD of RAMC hospital, medical camps and other referrals with the compliance of macular brownish/blackish discolouration over the face, nose, forehead, upper lip with the diagnosis of Vyanga or melasma were selected fulfilling the inclusion and exclusion criteria.

Selection of patients
Patients suffering from signs and symptoms of Vyanga roga were selected from OPD of RAMCH, Bengaluru, Medical camps, and other reference irrespective of their sex, religion, occupation etc. Detailed history was taken and a special research proforma was prepared for the study incorporating all the relevant points from both Ayurvedic and Modern views.

Study design
It is an open label single arm clinical study. 30 patients will be selected from random sampling procedure.

Sample size: A total of 30 patients were studied.

Dosage: Quantity sufficient

Plan of treatment
Patients were apply the paste of *Jatiphal churna* with water over affected area for 60 days with the thickness of ½ *Angula* once in a day.

Duration: The duration of the study was 60 days.

Follow up: Follow up was done at an interval of 15 days up to 2months.

Inclusion criteria
- Patients from the age group 26-60. (of either gender, religion, occupation, socio- economic status).
- Patient representing signs and symptoms of Hypermelanos (Vyanga) who were willing to participate in study.

Exclusion criteria
- Patients having systemic and endocrinl diseases, like Addison’s diseases, Cushing’s syndrome etc.
- Hyperpigmentation since birth.
- Hyperpigmentation caused by tumor like malignant melanoma.
- Patients with drug induced chloasma.
- Patients who were not willing to participate.

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Ethical consideration
Ethical clearance was obtained from the institutional ethical committee of Ramakrishna Ayurvedic Medical College and Hospital, Yelahanka, Bengaluru.

Criteria of withdrawal
- Increase symptoms like redness of the skin, Kandu (itching), and excessive burning sensation.
- Patients who are not willing to continue.

Diagnostic criteria
Patients are diagnosed as per clinical features mentioned in classics.
1. Niruja – painless patches.
2. Tanu – light brown pigmentation on facial skin.
3. Shyava – dark brown pigmentation on facial skin.

Objective parameter

| Table 1: Objective parameter size |
|-------------------------------|------------------|
| Size         | Score |
| 0-1 cm       | 1     |
| 1-3 cm       | 2     |
| 3-6 cm       | 3     |
| >6 cm        | 4     |

| Table 2: Objective parameter colour |
|-----------------------------------|------------------|
| Colour               | Score |
| Very fair            | 1     |
| Fair                 | 2     |
| Medium               | 3     |
| Olive                | 4     |
| Brown                | 5     |
| Dark brown           | 6     |

Subjective parameter

Assessment criteria
The subjective and objective parameter of baseline data to pre and post medication was compared for assessment of the results.

Assessment chart

| Sl no | Parameter          | Before treatment | Review after 30 days | After treatment (60 days) |
|-------|--------------------|------------------|-----------------------|----------------------------|
| 1.    | Neerujam           | Yes/no           | Yes/no                | Yes/no                     |
| 2.    | Shyavam            | Yes/no           | Yes/no                | Yes/no                     |
| 3.    | Tanu               | Yes/no           | Yes/no                | Yes/no                     |
| 4.    | Mukhamaagatya mandala | Yes/no       | Yes/no                | Yes/no                     |
Observation and Result

Table 4: Objective Parameter

| Sl no | Parameter | Score |
|-------|-----------|-------|
|       |           | Before treatment | Review after 30 days | After treatment 60 Days |
| 1.    | Size      | 1.00-3.00        | 0.00-2.00            | 0.00-2.00              |
| 2.    | Colour    | 2.00-6.00        | 1.00-5.00            | 1.00-5.00              |

Result assessment:
Finally overall result was calculated by taking average of all parameter results.

Statistical methods
Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumption on data is made.

Observation and Results
The study was conducted to evaluate the efficacy of Jatiphalo choorna on Vyangawsr to Melasma. A total of 30 patients were selected randomly for the intended study. All the patients were assessed before and after treatment for the grading of their subjective and objective parameters. The observations and results are presented as follows.

Study design: An observational clinical study.

Table 5: Age distribution of patients studied

| Age in years | No. of patients | %   |
|--------------|-----------------|-----|
| <30          | 3               | 10.0|
| 30-40        | 10              | 33.3|
| 41-50        | 12              | 40.0|
| 51-60        | 5               | 16.7|
| Total        | 30              | 100.0|

Mean ± SD: 41.67±8.69

In the age wise distribution of the patients it was observed maximum of 12 (40%) were under the age group of 41-50 years, 10 (33.3%) were under the age group of 30-40 years, 5 (16.7%) were under the age group of 51-60 years and 3 (10%) were under the age group of 16-30 yrs.

Table 6: Gender distribution of patients studied

| Gender | No. of patients | %   |
|--------|-----------------|-----|
| Male   | 3               | 10.0|
| Female | 27              | 90.0|
| Total  | 30              | 100.0|

In the present study among the 30 subjects, 27 (90%) were female and 3 (10%) were male.

Table 7: Religion distribution in patients studied

| Religion | No. of patients | %   |
|----------|-----------------|-----|
| Hindu    | 14              | 46.7|
| Muslim   | 8               | 26.7|
| Christian| 8               | 26.7|
| Total    | 30              | 100.0|

In the present study among 30 subjects, a maximum of 14 (46.7%) belong to Hindu religion, 8 (26.7%) belonged to Christian and 8 (26.7%) belonged to Muslim religion.
Table 8: Education distribution in patients studied

| Education       | No. of patients | %  |
|-----------------|-----------------|----|
| Illiterate      | 7               | 23.3|
| Elementary education | 7              | 23.3|
| Higher secondary | 5               | 16.7|
| Graduate        | 9               | 30.0|
| Post graduate   | 2               | 6.7 |
| Total           | 30              | 100.0|

In the present study, it was observed that 7 subjects (23.3%) were Illiterate, 7 (23.3%) had elementary education, 5 (16.7%) had higher secondary education, 9 (30%) were graduates and 2 (6.7%) were post graduate.

Table no 9: Marital Status distribution in patients studied

| Marital Status | No. of patients | %  |
|----------------|-----------------|----|
| Unmarried      | 1               | 3.3 |
| Married        | 29              | 96.7|
| Total          | 30              | 100.0|

In this study among 30 subjects, 29 (96.7%) were married and 1 (3.3%) were unmarried.

Table no 10: Occupation distribution in patients studied

| Occupation   | No. of patients | %  |
|--------------|-----------------|----|
| Field work   | 2               | 6.7 |
| Office work  | 8               | 26.7|
| House work   | 11              | 36.7|
| Agriculture  | 5               | 16.7|
| Student      | 1               | 3.3 |
| Teacher      | 3               | 10.0|
| Total        | 30              | 100.0|

In the present study among 30 subjects 11 (36.7%) were House makers, 8 (26.7%) were Office Workers, 5 (16.7%) were Agriculturist, 3 (10%) were Teachers, 2 (6.7%) were Field workers and 1 (3.3%) was a Student.

Table 11: Habitat distribution in patients studied

| Habitat | No. of patients | %  |
|---------|-----------------|----|
| Urban   | 15              | 50.0|
| Rural   | 15              | 50.0|
| Total   | 30              | 100.0|

In the present study it was observed that maximum subjects i.e. 15 (50%) belong to Urban locality and 15 (50%) were from Rural locality.

Table no 12: Diet pattern distribution in patients studied

| Diet   | No. of patients | %  |
|--------|-----------------|----|
| Veg    | 8               | 26.7|
| Mixed  | 22              | 73.3|
| Total  | 30              | 100.0|

In this study, 22 (73.3%) subjects were used to mixed diet and 8 (26.7%) subjects were vegetarians.
Table 13: Prakruthi distribution in patients studied

| Prakruthi       | No. of patients | %    |
|-----------------|-----------------|------|
| Vataja pittaja  | 14              | 46.7 |
| Vata kaphaja    | 6               | 20.0 |
| Kapha pittaja   | 10              | 33.3 |
| Total           | 30              | 100.0|

In this study, 14 (46.7%) subjects are having Vata pittaja prakruthi, 10 (33.3%) are having Kapha pittaja prakruthi, and 6 (20%) are having Vata kaphaja prakruthi.

Table 14: Onset of disease distribution in patients studied

| Onset      | No. of patients | %    |
|------------|-----------------|------|
| Gradual    | 30              | 100.0|
| Sudden     | 0               | 0.0  |
| Total      | 30              | 100.0|

In this study, the observation regarding the mode of onset of Vyanga in individual subjects in this study that majority of them 30 (100%) had gradual and 0% had insidious onset.

Table 14: Previous Treatment distribution in patients studied

| Previous Treatment | No. of patients | %    |
|--------------------|-----------------|------|
| Fresh              | 25              | 83.3 |
| Treated            | 5               | 16.7 |
| Total              | 30              | 100.0|

In this study 25 subjects (83.3%) approached the hospital for the first time to take treatment and 5 (16.7%) had already taken different forms of treatment of different systems of varying duration.

**Effects on Treatment**

**Objective Parameters**

Table 15: Size - An assessment at before and after treatment of patients studied

| Size     | Before Treatment | 30 days | After Treatment | % difference |
|----------|------------------|---------|-----------------|--------------|
| 0-1cm    | 0 (0%)           | 3 (10%) | 11 (36.7%)      | 36.7%        |
| 1-3cm    | 4 (13.3%)        | 18 (60%)| 16 (53.3%)      | 40.0%        |
| 3-6cm    | 19 (63.3%)       | 9 (30%) | 3 (10%)         | -53.3%       |
| >6cm     | 7 (23.3%)        | 0 (0%)  | 0 (0%)          | -23.3%       |
| Total    | 30 (100%)        | 30 (100%)| 30 (100%)       | -            |

Improvement of 76.7% up to 3 cm after treatment is significant with P<0.001**, paired proportion test

Table 16: Colour - An assessment at before and after treatment of patients studied

| Colour   | Before Treatment | 30 days | After Treatment | % difference | P value |
|----------|------------------|---------|-----------------|--------------|---------|
| Very fair| 0 (0%)           | 1 (3.3%)| 4 (13.3%)       | 13.3%        | 0.020*  |
| Fair     | 1 (3.3%)         | 3 (10%) | 4 (13.3%)       | 10.0%        | 0.088+  |
| Medium   | 3 (10%)          | 6 (20%) | 11 (36.7%)      | 26.7%        | 0.013*  |
| Olive    | 6 (20%)          | 9 (30%) | 10 (33.3%)      | 13.3%        | 0.220   |
| Brown    | 9 (30%)          | 11 (36.7%)| 1 (3.3%)       | -26.7%       | 0.004** |
| Dark brown| 11 (36.7%)  | 0 (0%)  | 0 (0%)          | -36.7%       | 0.0004**|
| Total    | 30 (100%)        | 30 (100%)| 30 (100%)       | -            |
Melasma or hyperpigmentation is the one among the top five leading conditions in Asia. Ethnicity, genetic factors, and sun exposure play important roles. The accurate prevalence of melasma world wide is unknown. This is attributed to the fact that melasma is a cosmetic problem and most patients may choose to consult their dermatologist privately. Hence, a low prevalence of melasma is recorded in most public dermatology clinics. Although melasma affects women more and occurs during child bearing age. Melasma occurs 10-15% of pregnant women, 10-25% of women taking oral contraceptives. The major etiological factors include genetic influences, chronic sun exposure and female sex hormones.

Ayurveda explains Vyanga as a disease which is mainly characterized by dark discolouration of the skin over face. It is a pathological situation of the facial skin which is produced due to the vitiation of Vata, Pitta, and Rakta producing cardinal features such as Niruja, Tanu, Shyava Mandala.

Discussion on procedure

Jatiphala seed was taken and it was pounded into small pieces using Khalva yantra and then it was put into pulveriser and powdered and it was packed into small zip lock airtight poly bags of about 30 gm each. Dose of the drug was not fixed depend on the area of the patches on the face.

Probable mode of action

The Katu Tikta Kashaya Rasa of Jatiphala tackles Srodusthi caused by Agnisada (which forms Ama and leads to Srotdusthi). The Tikta Rasa of Jatiphala causes Pitta Samaka which is vitiated due to intake of Pitta Ahara Dravyas.

Discussion on selection on problem

Since the disease Vyanga is considered the disease of disturbed Bhrajaka Pitta, Rasa, Rakta Vaha Sroto Dusti, Vata and Pitta Prakopa also involving Kapha which obstructs Rasavaha Srotas leading to Syavatwam of the skin by causing the Prakopita Bhrajaka Pitta to be deposited below the skin layers that is in epidermis.

Tikta Rasa Usna Virya of Jatiphala mitigates Vata Dosha and the same time it stimulates Bhrajaka Pitta and help in scraping of the rough, thick, black dark layers formed on the skin.

The Laghu Guna, Tikshna Guna and Ushna Virya properties along with Katu Rasa clears the channels helping the healthy Bhrajaka Pitta and opens the free movement of Bhrajaka Pitta on to the skin. Bhrajaka Pitta is responsible for Varna, Chayya, and Prabha. In Ashtanga Hridaya sutra sthana 12th chapter mentioned that Pitta located in the skin in Bhrajaka, because it helps exhibition of colour and complexion.

Prabha and Chayya also effect on Varna. Acharya Charaka has written that Prabha is said to be highlighter of complexion.

Myristicin present in Jatiphala is known to be useful in reducing the production of melanin secretion in skin. It also has antioxidant properties which act on free radicals.

It was also observed that Jatiphala have got exfoliating property, which help in information of new fresh healthy skin removing unhealthy layer.

Discussion on clinical study:
- The clinical study was carried out on 30 patients.
- The type of skin lesion here in all subjects generally is Macule, as there is only discoloration, no pain, no discharge, no swelling.
- Patients were asked to apply the Lepa triturated with water only, as it was clearly mentioned in Dipika commentary of Sharangadhara Samhita.
• Patients experienced slight burning sensation for about 5-10 minutes during the time of application of Lepa, this is due to the acidic nature of the Lepa.
• There were no adverse effects or any other side effects like rashes, redness, itching etc observed during the time of application of Lepa.
• Patients were asked not to get exposed to excessive sunlight during the one month of treatment as it leads to further Vata and Pitta Prakopa.
• Thickness of Lepa should be Ardha Angula (which is approximately 0.88cm) as it is difficult to measure the thickness of the Lepa, patient was asked to apply the Lepa as thick as possible.
• As seat of Vyanga is the 2nd layer of skin, that is Lohita according to Susrutha and Asrukdhara according to Charaka, the thickness of Lepa is such that it penetrates the second layer of the skin.

Discussion on observations of clinical study

The observations made in the present study were based on the clinical study conducted in a single group on 30 subjects. The data was collected in the proforma and analyzed after the completion of the study.

Age

In the present study among 30 subjects who completed the clinical trial, a maximum of 10 (33.3%) were under the age of 30-40 years, 3 (10%) were under the age group 16-30 years and 12 (40.0%) were under the age group of 41-50 years and 5 (16.7%) was under the age group of 51-60 years.

Hence, the inference can be drawn that the prevalence of Vyanga is more in middle aged people or Madhyama vayah. Vyanga is caused mainly due to Vata and Pitta Prakopa as Pitta Dosha is Prakupita in Madhyama Vayah, Vyanga is more prevalent in middle age.

Gender

In the present study among the 30 subjects, maximum of 27 (90%) were female and 3 (10%) were male.

Among 27 female subjects, majority of them are workers and home makers having history of more sun exposure and stress/worry. Majority of them have acquired Vyanga post pregnancy, thus the prevalence in females may be attributed to post pregnancy sun exposure and stress/worry.

Occupation

In the present study, among 30 subjects 2 (6.7%) were field workers, 11 (36.7%) were house makers, 1 (3.3%) were students and 3 (10%) were teachers, 8 (26.7%) was office work or businessman, 5 (16.7 %) were agriculture.

In all the above occupations people are exposed to sunlight and ultra violet rays. This attributes to the fact that Vyanga is prevalent more in the people who are more exposed to sunlight.

Habitat

In the present study, it was observed the maximum subjects i.e. 15 (50%) belong to urban locality and 15 (50%) were from rural locality. However no conclusion can be drawn, because of the small sample size.

Deha prakruthi

In the study, 14 (46.7%) subjects are having Vata Pittaja Prakruti, 10 (33.3%) subjects, are having Kapha Pittaja Prakruthi, 6 (20%) subjects are having Vata Kaphaja Prakruti.

This attributes to the fact that Vyanga is more seen in people with Vata Pittaja Prakruti.

Fresh/Treated

In this study, 25 subjects (83.3%) approached the hospital for the first time to take treatment and 5 (16.7%) had already taken different forms of treatment of different systems of varying duration.

This indicates recurrent/episodic nature of the disease and lack of permanent treatment for Vyanga in other systems of medicine which requires early management.

Family history of Vyanga

In the present study among 30 subjects, family history of Vyanga with special reference to hyper pigmentation on face was totally absent, which is shows that there is no involvement of genetic factors.

Religion, Educational Status, Diet

No significant relationship can be drawn in the above parameters in relation to Vyanga with special reference to hyper pigmentation on face.

Discussion on results of clinical study

In the present study the results of subjective parameters which were assessed such as colour of the patch area and size of the patch area showed statistically highly significant reduction with the p value less than 0.05.

This can be attributed chiefly to the Varnya, Vatapitta Shamaka, Kapha Pitta Shamaka, Sheeta Veerya, Katu Vipaka, cooling, disinfectant and blood purifying anti-inflammatory properties of the drugs present in the intervention, decreases about Vata and Pitta in the Twacha and enhances Varna of Twacha. Therefore the pathological disintegration –
The decreased in the mean suggests significant reduction in the Vyanga. It also indicates that after each day of intervention the severity of the condition is getting relieved, which can be attributed to the Varnya, Vata Pitta Shamaka, Kapha Pitta Shamaka, Sheeta Veerya, Katu Vipaka, cooling, disinfectant and skin purifying anti-inflammatory properties of the drugs present in the intervention.

Hence, it was inferred that the intervention selected for the present study has shown combined effect in the management of Vyanga vis-a-vis hyper pigmentation on face.

CONCLUSION

On the basis of reviews collected, analysis of analytical study, results and observations on the clinical study, the following conclusions may be drawn.

Acharya Bhavamishra clearly mentioned Jatiphala as a single herbal remedy for its action on Vyanga. The Katu, Tikta Rasa of Jatiphala removes Srodusti thereby helping free movement of healthy Bhrajaka Pitta to the skin. Tikta Rasa and Usna Vrnga of Jatiphala prevent Vata Dosha thereby reducing Kharatwa and Krishnatwa of skin.

The Snigdha, Soumya, Sita, and Twak Prasadana properties along with Rasayana property help in reducing Vyanga and skin in more permeable to lipids than aqueous solution. The Lepa procedure helps in micro absorption and improves micro circulation of chemical constituents of drugs due to the disintegration of drug particles into the finest form.

The chemical compound ‘Myristicin’ present in it may help to reduce the production of melanin in skin.

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IMAGES

Image 1: Jati plant

Image 2: Jatiphala

Image 3: Jatiphalabeeja

Image 4: Jatiphala beeja Choorna preparation

Image 5: Jatiphal beeja Choorna