ROLE OF PUSHKARA GUGGULU IN THE MANAGEMENT OF ISCHAEMIC HEART DISEASE

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ABSTRACT: On the basis of authentic references from the literature of ayurveda and on our own observations, Puskara-Guggulu, a combination of oleoresin of C. mukul and I-recemosa, has been clinically tried on a series of ECG proved 50 patients of ischaemic heart disease. This has been administered in the dose of 6 gms per day, in three divided doses upto a period of four months. Precordial pain, discomfort and dyspnoea on effort have been controlled. Mean Serum cholesterol has been found to be decreased by 17.47%. Apart from that, marked improved in the E. C. G. pattern in 30% cases has been recorded in terms of ST-segment and T wave changes, On the whole the result was cured 10% relieved 60%, improved 20% and unchanged 10%, offering a great hope for the prevention and cure of ischaemic heart disease.

Introduction

Coronary heart disease is known to be the cause of greatest mortality in the developed countries. But it dose not mean that this problem is of lesser importance for us. The recent hospital statistics has shown that it’s incidence is increasing with a tremendous speed in our country. Hence it is no more wise to postpone our attention till we are in the full grip of this disease, like western countries rather it will be advisable to focus our attention, invest our time, money and resources to prevent this agonizing and dreadful disease at the earliest.

Although, atherosclerotic heart disease has a multifactorial origin, but in majority of the cases it is associated with hypercholesterolaemia, hyper lipidaemia and higher concentration of VLDL in the blood. To overcome this problem many new coronary care units are being established. But we have to remember that west has failed in bringing down the morbidity and mortality of much significance by this approach. Hence, the W.H.O. is emphasizing to promote the concept of “Preventive cardiology” units. It requires the facility for prediction and early detection of the lesion which can be achieved by the identification of the risk factors as follows:

Non-modifiable risk factors:
   a) Age   b) Sex   c) Heredity Modifiable risk factors: a) Major risk factors:
   i) Elevated serum lipids (cholesterol and triglycerides),
   ii) Habitual diet high in total calories, total fats, saturated facts,
cholesterol, refined carbohydrates and salt;

iii) Hypertension;
iv) Cigarette smoking
v) Carbohydrate intolerance;
vi) Obesity and
vii) Hypothyroidism

b) Minor risk factors:
i) Oral contraceptives,
ii) Sedentary living;
iii) Personality type and
iv) Psychosocial tension

Among the above modifiable risk factors, the management of hypercholesterolaemia and hypertension is of utmost importance. Combined together they prove to be highly pathognomonic. According to Framingham Heart Study, hypercholesterolaemia or hypertension have positive correlation with the incidence of I. H. D. and when present together, they become doubly dangerous. (Kannel, 1971). Thus the importance of treatment of even moderate hypercholesterolaemia and mild hypertension is also of great value for its prevention. Subclinical hypothyroidism has been also identified as one of the major risk factors.

The scope of Ayurvedic drugs in treating the acute myocardial infraction is yet to be decided as it involves emergency care and a lot of instrumentation. But sufficient data has accumulated that these remedies can be of great help for managing the risk factors viz.. hypercholesterolaemia, hyperlipidaemia (Tripathi, et al 1968; Tripathi et al; 1973, and Upadhayay et al, 1976); subclinical hypothyroidism (Tripathi, et al 1974; Tripathi, et al 1978 and Tripathi Y. B. 1983); mild hypertension (Tripathi et al 1979); and early diabetes (Tripathi et al 1982). Thus there seems to be a great hope from this ancient science for "Preventive Cardiology."

In this study a mixture of oleoresin of C. mukul (Guggulu) and powder of Inula racemosa (Puskaramula) has been tried in the patients of I. H. D.

Oleo-resin of Commiphora mukul (Guggulu) is now almost an established hypocholesterolaemic agent, probably acting by the physiological stimulation of the thyroid gland as evidenced by the thyroid function studies in human beings (Tripathi et al 1974; Tripathi et al 1978), as well as, in experimental studies (Tripathi, 1983). Clinical trials have also been done to establish the role of this hypocholesterolaemic agent in the treatment of I. H. D. (Upadhayay et al 1976). But it has been able to control the anginal pain after a long term use i. e. 3 to 9 months. In this period the patients often required Nitroglycerin like drugs to continue the treatment. Hence, Inula racemosa (Puskaramula) was added with this drug. Puskaramula has been described by Charak to be the best drug for relieving the precordial pain (Ch. Sutra. 25-40). In addition, this drug has been prescribed for the treatment of Heart disease in more than a dozen formulae described by Charak, either as a single or as a major drug. On clinicopharmacological studies, this drug has given a response similar to that of Nitroglycerin, as the effect of exercise on electrocardio-gram in clinically proved cases of I. H. D. has been prevented or minimised, i. e. the depression of the ST-segment has not been produced by the prior administration of the drug. Thus it seems to elevate the exercise tolerance in these cases which may be due to coronary dilation or some similar mechanism. By the addition of this drug with Guggulu, the need of Nitroglycerin like drugs has been minimised.

Material and Methods

Preparation and Administration of Puskara Guggulu
The roots of Puskaramula were procured from the local market of Varanasi and were identified as Inula racemosa and powdered.

Oleo-resin of C. mukul was also obtained from the market of Varanasi, as per description of Ayurveda-Mahisaksa type of Guggulu was available. It was purified (Shodhan) by the method of Rasa Tantra-Sara, Sidha Yoga Sangraha. On the basis of previous observations for the better absorption, the purified mass of Guggulu was converted into coarse powder-granules.

These powders of Inula racemosa and C. mukul were mixed in equal quantity by weight and pills of about 500 mg were prepared by Ayurvedic pharmacy, B. H. U., Varanasi. Twelve such pills were given in divided doses for a period of 4 months.

Selection of Patients

This clinical study is based on 50 patients suffering from ischaemic heart disease. The cases were selected from the General Kayacikitsa, O. P. D. from Cardio respiratory clinic. Some of the patients were referred from other O. P. D., particularly from Medical O. P. D...

Diagnosis of Ischaemic Heart Disease

The patients who were suspected to be suffering from ischaemic heart disease presenting with the precordial pain, breathlessness on exertion or with the history of angina and previous myocardial infraction were subjected to laboratory investigations. The history was recorded on the proforma with special attention on grade, duration, site, radiation, precipitating and relieving factors of chest pain and breathlessness. The other things to be given special attention were family history of I. H. D., body build and weight, dietary habits, socio-economic status, addiction, occupation and physical examination. Routine laboratory investigations were done for blood, urine and stool. Blood sugar, blood urea and serum cholesterol, were estimated. They were subjected to electrocardiographic study to observe the ischaemic changes i. e., depression of ST-segment and inversion of T-wave and the changes of myocardial infraction etc.. If necessary x-ray chest was also done to confirm, size and shape of the heart and to exclude any lung disease.

Estimation of Serum Cholesterol

The serum cholesterol has been estimated by Bloor, Pelham and Allen (1922) method modified by Kolmer et al. (1959). The serum cholesterol is extracted by an alcoholic ether mixture and the cholesterol determined calorimetrically in the filtrate, before and after precipitation by digitonin.

E. C. G. Diagnosis of Ischaemic Heart Disease

The patients having the symptoms of ischaemic heart disease were subjected to E. C. G. study. Tracing of three standard (Bipolar) limb leads i. e. L1, L2 and L3 unipolar limb leads i. e., aVR, aVL and aVF and six precordial leads i. e., V1 to V6 were recorded. The diagnosis was done on the criteria described by Goldman (1979). In doubtful cases tracings were done after exercise also.

Electrocardiographic Criteria of Myocardia-Ischaemia

i) Precordial leads: ST-segment depression or T-wave inversion (or both) in left precordial leads (V5-V6).

ii) Unipolar limb leads—changes similar to those described in precordial leads are seen in aVL or aVF (depending upon the direction of frontal plane vector). Reciprocal ST-segment elevation may be seen in aVR.

iii) Standard leads - these will reflect the pattern present in the limb leads. If the changes noted above are seen in aVL, they will be present in L1, if seen in aVF, they will be present in L3.

Diet

Regarding diet patients were advised to take their normal diet, excepting intake of excess fried eatables. They were permitted to use their usual fats and oil as cooking media. No
calory restriction was advised. Thus no deliberate attempt was made to impose dietary restriction or to prescribe major dietary management.

**Rest**

 Majority of the patients were ambulatory and getting treatment from out patient department. Some of them were hospitalized in the beginning for investigations and then advised to continue as O.P.D. patients. During this period they were advised to avoid strenuous exercise. They were allowed to attend their normal duties, as long as they do not get chest pain or dyspnoea. They were advised to rest on full stomach, i.e. after meals.

**Assessment of the results**

In order to evaluate the response of Puskara Guggulu in the management of ischaemic heart disease, the assessment of the result has been done from three aspects as follows:

a) Clinical assessment
b) Biochemical assessment for hypercholesterolaemia
c) Electrocardiographic assessment

(a) **Clinical Assessment**

In clinical assessment the main stress has been on precordial pain, dyspnoea on effort and body weight. For this purpose the patients have been classified into grades before treatment, during treatment and after treatment and the improvement in grade has been recorded. As regards body weight, it was recorded before and after treatment in kg. on empty stomach with usual dress. The grading of precordial pain and dyspnoea is as follows:

(b) **Biochemical Assessment**
For the assessment of hypocholesterolaemic action of Puskara-Guggulu, the estimation of serum cholesterol was done at monthly intervals.

(c) Electrocardiographic Assessment

(d) E. C. G. was done after monthly intervals and response on E. C. G. changes have been graded as follows:

1. Significant improvement
2. Improvement
3. No improvement

| Symptoms | Grade I | Grade II | Grade III | Grade IV |
|----------|---------|----------|-----------|----------|
| Precordial pain | Pain is only provoked by hurrying or walking up hills or several flights of stairs | Walking on the level at an average speed causes pain, usually within the 1st 300 yards | Pain occurs even when walking slowly | Paint at rest and total incapacity |
| Dyspnoea | Dyspnoea is only provoked by hurrying or walking up hills or several flights of stairs | Walking on the level at an average speed causes dyspnoea usually within the first 300 yards | Dyspnoea occurs even when walking slowly | Dyspnoea at rest and total incapacity |

1. Significant improvement
Complete improvement in depression of ST-segment and achievement of normal pattern of T-wave in all the leads.

2. Improvement

Partial improvement in ST-segment and normal pattern of T-wave in some of the
leads or improvement in the level of inversion of T-wave.

3. No improvement
Either no improvement in ST-segment and T-wave or deterioration.

Over All Assessment of Result
1) Cured
If the patients do not get precordial pain, their E. C. G. and serum cholesterol are normal at the end of trial.

4) Unchanged
When there is no improvement in precordial pain E. C. G. and serum cholesterol at the end of clinical trial.

2) Relieved
If there is improvement in precordial pain and E. C. G. or serum cholesterol are normal at the end of trial.

3) Improved
If there is improvement in precordial pain at the end of this clinical trial and E. C. G. and serum cholesterol do not show any betterment.

while rest of them belonged to upper middle or lower middle class. It is against the common belief that heart disease is confined to rich people only.

Observations

Age and sex incidence
In this series of 50 cases, 82 p. c. patients had the age group between 30 to 60 years, which is the common age for this disease. Also, 74% cases were male and 26% females. Our observation conforms with that of the previous workers that males are more prone to I. H. D. than females particularly before menopause.

Dietary habits
As regards the nature of the food, vegetarians and non-vegetarians both have been found to be affected.

Environment
60% of our patients came from urban areas and rest of the 40% came from rural areas and small towns, which shows that though the disease is common in urban area, it is not uncommon in rural areas.

Economic Status
Only 16% patients had income from the above Rs. 2000/- per month income group, while rest of them belonged to upper middle or lower middle class. It is against the common belief that heart disease is confined to rich people only.

Education
Similarly, higher education (38%) as well as lower education (38%) groups were found to be equally affected. Rather 24% cases had no school education at all.

Occupational Status
Regarding occupation, this study showed that people from every walk of life are affected and no occupation is exempted as 18% came from business community, 6% from medical profession, 42% from service class and 8% were farmers.

Incidence of Addiction
In this study 68% patients were addicted to tobacco smoking/chewing. It is the confirmity of the fact that smoking is one of the major risk factors. About 16% patients were addicted to alcohol, while rest 16% had no addiction at all.

Precordial pain and dyspnoea on effort are the main symptoms of I. H. D.. Majority of the cases who subjected themselves for clinical trial, were early cases of I. H. D.. On the other hand 26% cases had already suffered from M. I. and thus they were
advanced cases and were not satisfied with the present available treatment.

The E. C. G. of all 50 patients was done for the diagnostic purpose.

Out of those cent per cent cases showed positive E. C. G. changes and in none of the cases the pattern was within normal limit. Among the 50 cases there was ST-segment depression and T-wave inversion in different leads according to the site of the lesion. Thirteen E. C. G. tracings showed the presence of myocardial infraction along with ischaemic changes.

In all the 50 cases, there was precordial pain before treatment, grade IV-1, grade III-11, grade 11-36 and in grade 1-2. After four months treatment, there was no precordial pain in 5 patients and rest also showed reduction in the grade of precordial pain After treatment, position of the grade was as follows: Grade II-9, Grade I-36 and Grade 0-5. Thus there was significant improvement in precordial pain.

Dyspnoea on effort was observed in 15 cases out of 50. Five cases were in Grade II, and 10 cases in Grade I. After four month treatment 8 cases reported complete improvement in dyspnoea on effort and only 7 patients were having dyspnoea of Grade I. thus there was improvement in dyspnoea on effort after four month treatment, with Puskara Guggulu

### Clinical features observed in the 50 patients of I. H. D

| Signs and symptoms               | No. of cases | Percentage |
|---------------------------------|--------------|------------|
| 1. Precordial Pain              | 50           | 100        |
| Grade I                         | 2            | 4          |
| Grade II                        | 36           | 72         |
| Grade III                       | 11           | 22         |
| Grade IV                        | 1            | 2          |
| 2. Dyspnoea                     | 15           | 30         |
| Grade I                         | 10           | 20         |
| Grade II                        | 5            | 10         |
| Grade III                       | -            | -          |
| Grade IV                        | -            | -          |
| 3. Palpitation                  | 13           | 26         |
| 4. History of M. I.             | 13           | 26         |
| 5. Obesity                      | 10           | 20         |
| 6. Hypertension                 | 6            | 12         |
| 7. Diabetes mellitus            | 11           | 22         |
| 8. C. H. F.                     | -            | -          |
| 9. Flatulence                   | 11           | 22         |
| 10. Burning pain in epigastrium | 4            | 8          |
| 11. Constipation                | 3            | 6          |
### RESULTS CLINICAL IMPROVEMENT

**Response of treatment on precordial Pain; after 4 months Treatment**

| Grade before treatment | IV | III | II | I | 0 (No pain) |
|------------------------|----|-----|----|---|------------|
| IV                     | 1  | -   | -  | 1 | -          |
| III                    | 11 | -   | -  | 7 | 3          |
| II                     | 36 | -   | -  | 1 | 33         |
| I                      | 2  | -   | -  | - | 2          |
| Total                  | 50 | -   | -  | 9 | 36         |

**Response of treatment of Dyspnoea in patients of I. H. D. after 4 months Treatment**

| Grade before treatment | IV | III | II | I | 0 (No dysp.) |
|------------------------|----|-----|----|---|--------------|
| IV                     | -  | -   | -  | - | -            |
| III                    | -  | -   | -  | - | -            |
| II                     | 5  | -   | -  | - | 5            |
| I                      | 10 | -   | -  | - | 2            |
| Total                  | 15 | -   | -  | - | 7            |

**Response of Treatment on Body-weight (kg.) after four months**

| Mean body weight (kg) | Reduction | percentage |
|-----------------------|-----------|------------|
| Before treatment      | 59.48     |            |
| After treatment       | 56.74     | 2.74       |
|                       |           | 4.6        |

Statistical Analysis:
- Standard error: ± 0.3
- ‘t’: ± 9.14
- P: < 0.001

**Effect of 4 month treatment on E. C. G. in 50 cases of I. H. D. with Puskara Guggulu**

| Improvement | No. of cases | Percentage |
|-------------|--------------|------------|
|             |              |            |
The initial average body weight of 50 patients was 59.48 kg. After four months treatment, it was reduced to 56.74 kg. The average fall in body weight was about 2.74 kg. On statistical analysis it was highly significant (P<0.001).

Within this short time, improvement has been observed in 30 per cent cases out of which it was significant in 10% cases. The nature of improvement was normalization in ST-segment depression and in T-wave inversion. No improvement could be observed in 70% cases among them most of the cases had M. I. pattern or Bundle branch block which are known to be irreversible type of changes. Of course, it was expected that the percentage of improvement in E. C. G. many increase by further treatment and follow-up study.(Fig. 1a, 1b)

**Effect of Treatment Of Serum Cholesterol in I. H. D. (50 cases) After one month treatment**

| Initial | After one month treatment | Reduction | Percent reduction |
|---------|---------------------------|-----------|------------------|
| Mean 248.66 | 235.44 | 13.22 | 5.23 |
| Statistical Analysis |
| S. E. ± 6.81 | ± 5.15 | ± 2.52 |  |
| ‘t’ | 9.33 |  |
| P | ≤0.001 |  |

**After two months treatment**

| Initial | After two months treatment | Reduction | Percent reduction |
|---------|---------------------------|-----------|------------------|
| Mean 248.66 | 224.86 | 23.80 | 9.57 |
| Statistical Analysis |
| S. E. ± 6.81 | ± 5.15 | ± 2.52 |  |
| ‘t’ | 9.44 |  |
| P | ≤0.001 |  |

**After three months treatment**

| Initial | After three months treatment | Reduction | Percent reduction |
|---------|-----------------------------|-----------|------------------|
| Mean 248.66 | 214.57 | 34.09 | 13.71 |
| S. E. ± 6.81 | ± 4.47 | ± 3.33 |  |
| ‘t’ | 10.08 |  |
| P | ≤0.001 |  |

**After four months treatment**
Fifty cases in this series were treated with Puskara Guggulu in the dose of 6 gms a day, in four divided doses. The initial average serum cholesterol was 248.66 mgm% (±6.81). It was reduced to 235.44 mgm%(±5.98) first month, 224.86 mgm% (±5.15) second months, 214.57 mgm% (±4.47), third months and 205.22 mgm% (4.08) after four months of treatment. The average reduction was 13.22 mgm% (±1.40), 23.80 mgm% (±2.52), 34.09 mgm% (±3.33) and 43.44 mgm% (±4.04) in first, second, third and fourth months, respectively. On statistical analysis, it was highly significant (P<0.001). The percent reduction was 5.32%, 9.57%, 13.71% and 17.47% at the end of first, second and third and fourth months respectively (shown in tables). Thus the serum cholesterol lowering effect of Puskara Guggulu was found to be highly significant. (Fig. 2).

Further the data has been broken and presented to show the degree of response and present cases. It has been found that the 82% of the cases the reduction in serum cholesterol was more than 15 mgm% and in 62% cases the reduction was between 30 to 100 mgm/100 ml. The inference can be drawn from the data that hypcholesterolaemic effect of Puskara Guggulu is of greater degree and of significant value in higher number of patients.

In this four months trial of Puskara Guggulu in 50 patients of I. H. D., the overall assessment of result is represented in the above tables. In this trial 10% cases were cured, i.e. they did not have precordial pain and the serum cholesterol and E. C. G. were within normal limits after 4 months treatment. The percentage of the relieved patients was 60% in these cases, there was improvement in precordial pain and any one of the serum cholesterol or E. C. G. were within normal limits after 4 months treatment. The percentage of improved patients was 20% i.e. in the cases in which there is only improvement in precordial pain, but no improvement in serum cholesterol or E. C. G. In this series, 10% cases were unchanged i.e. they showed no improvement in precordial pain, serum cholesterol and E. C. G. at the end of four months trial. The treatment for a longer time and further follow up was expected to show some change in this unchanged group.

### Overall assessment of Result in clinical Trial

| S. No. | Result   | No. of patients | percentage |
|-------|----------|----------------|------------|
| 1     | Cured    | 5              | 10         |
| 2     | Relieved | 30             | 60         |
| 3     | Improved | 10             | 20         |
| 4     | Unchanged| 5              | 10         |
| Total |          | 50             | 100        |

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