CLINICAL EVALUATION OF MEDHYA RASAYANA COMPOUND IN CASES OF NON-DEPRESSIVE ANXIETY NEUROSI S

A.K. KOUSHIK AND R.H. SINGH

Department of Kayachikitsa, Institute of medical Sciences Banaras Hindu University, Varanasi-221005, India.

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ABSTRACT: The data emerging out of the clinical trial indicated significant clinical relief and favourable shift of grades of the clinical components of anxiety namely nervousness, palpitation, insomnia, irritability, lack of concentration etc. Following Medhya Rasayana therapy. The elements of underlying depression as measured by a depression scale were also found reduced. The patients reported an increasing feeling of well being and showed a tendency of gain in body weight besides corrections of pulse rate and blood pressure.

Introduction:

Caraka has described four Classical Medhya Rasayana drugs in Cikitsa Sthana chapter 1 namely Sankhapuspi Mandukaparni, Guduci and Yastimadhu. The Medhya Rasayanas in general are considered as brain tonics besides their anti-anxiety activity as reported by Singh and associates (1977). The Four Medhya Rasayanas of Caraka Samhita have been studied individually by Sinha (1981) clinically as well as experimentally. The present study intends to undertake a clinical evaluation of the combined use of all the Four Medhya Rasayanas. Sinha (1981) reported that when evaluated individually only two of the Four Medhya Rasayana drugs namely Sankhapuspi and Mandukapatni act as significant anti-anxiety agents. The remaining two drugs namely Amrta and Yastimadhu did not show significant antianxiety effect on psychological parameters, However, it was postulated that these latter two drugs may have adjuvant effects of some unknown kind in Medhya Rasayana therapy. Therefore we thought to combine all the Four Medhya Rasayana drugs and use them in the form of a compound in the treatment of anxiety neurosis to assess the efficacy of the compound Medhya Rasayana as an anti-anxiety drug.

Materials and Methods

A series of 28 cases of Anxiety Neurosis were selected from Kayachikitsa outpatient department, S.S. Hospital, B.H.U. The patients were registered for the present study with the help of a proforma prepared for the purpose. Each case was interviewed individually and his basal condition was assessed on following parameters.

1. General Clinical Presentation: The form of clinical presentation and the psycho-social background was worked out in each case.
2. **Clinical Anxiety Scale** - was applied to measure the degree of clinical anxiety syndrome in terms of major symptoms produced by anxiety such as nervousness, palpitation insomnia, lack of concentration, irritability, headache, tremors anorexia and certain other features of gastrointestinal neurosis. The scale applied for the purpose gives a semi-objective measurement of the severity of the symptoms (Table 1).

**TABLE –I**

**Clinical Anxiety Scale**

| S. No | Symptoms       | Grading          | Scores |
|------|----------------|------------------|--------|
| 1    | Nervousness    | Always           | -3     |
|      |                |Often             | -2     |
|      |                |At occasions      | -1     |
|      |                |Never             | 0      |
| 2    | Palpitation    | Always           | -3     |
|      |                |Often             | -2     |
|      |                |At occasions      | -1     |
|      |                |Never             | 0      |
| 3    | Tremors        | Marked           | -3     |
|      |                |Fine              | -2     |
|      |                |Minor             | -1     |
|      |                |No                | 0      |
| 4    | Headache       | Always           | -3     |
|      |                |Often             | -2     |
|      |                |Sometimes         | -1     |
|      |                |No                | 0      |
| 5    | Anorexia       | Marked           | -3     |
|      |                |Minor             | -2     |
|      |                |Very minor        | -1     |
|      |                |No                | 0      |
| 6    | Insomnia       | Insomnia         | -3     |
|      |                |Poor sleep        | -2     |
|      |                |Disturbed sleep   | -1     |
|      |                |No                | 0      |
| 7    | Lack of        | Troublesome      | -3     |
|      | concentration  |Marked            | -2     |
|      |                |Minor             | -1     |
|      |                |No                | 0      |
| 8    | Dyspepsia/Flatulence | Troublesome | -3 |
|      |                |Marked            | -2     |

3. A mini Depression Scale was applied in each case in the form of a limited questionnaire which measures the degree of depression. Though we selected cases who had no obvious depression, on measurement with this scale all cases showed some degree of depression.

4. **Psychotic Symptom Scale** – Besides measuring the level of clinical anxiety and the degree of depression we subjected each case to a simple psychosis symptoms scale in order to work out the presence or absence of psychotic manifestations in thee cases. It may be pointed out that we excluded all such patients from our trial series where psychotic manifestation were encountered thus this scale was used for the purpose of exclusion (Table 2).

5. **Phychological and Biochemical Studies**: Each of this patients was evaluated for his physiological status in terms of B.P. pulse and body weight. Wherever possible we subjected these patients to biochemical investigations relevant to mental health.

**Clinical Trial of Medhya Rasayana**
After basal assessment of each case on above parameters the patients were subjected to the following schedule of therapy the efficacy of which was assessed on the following parameters

Each patient selected for the trial was prescribed Medhya Rasayana Kasaya in the dose of 50gm in two divided doses 50gm crude dry drug was boiled with 800 ml water reduced to 100ml administered in two divided doses. The same treatment was continued for 6 weeks and the patients were reassessed every fortnight for the effect of treatment given on the following parameters adapting a self control system.

1. – Clinical Recovery
2. – Change in Clinical anxiety Scale
3. – changes in Depression Scale
4. – Physiological and Biochemical changes
5. – General Health Improvement

TABLE –II
Psychosis Symptom Scale

| 1. | Excitement |
|----|------------|
|    | Negligible | -0 ( ) ( ) ( ) |
|    | Excited speech | -1 ( ) ( ) ( ) |
|    | Excited motor | -2 ( ) ( ) ( ) |
|    | Activity | -3 ( ) ( ) ( ) |
|    | violence | |

| 2. | Disorientation |
|----|---------------|
|    | No | -0 ( ) ( ) ( ) |
|    | Minor | -1 ( ) ( ) ( ) |
|    | Moderate | -2 ( ) ( ) ( ) |
|    | Severe | -3 ( ) ( ) ( ) |

| 3. | Perceptual disorder including hallucination and delusion |
|----|--------------------------------------------------------|
|    | No | -0 ( ) ( ) ( ) |
|    | Sometimes | -1 ( ) ( ) ( ) |
|    | Often | -2 ( ) ( ) ( ) |
|    | Always | -3 ( ) ( ) ( ) |

4. | Motor disturbances |
|----|----------------|
|    | No | -0 ( ) ( ) ( ) |
|    | Incoherence talk | -1 ( ) ( ) ( ) |
|    | Stereotype | -2 ( ) ( ) ( ) |
|    | Irrelevant talk | -3 ( ) ( ) ( ) |

5. | Disorders of thought and conceptual disorganization |
|----|----------------|
|    | No | -0 ( ) ( ) ( ) |
|    | Incoherence talk | -1 ( ) ( ) ( ) |
|    | Stereotype | -2 ( ) ( ) ( ) |
|    | Irrelevant talk | -3 ( ) ( ) ( ) |

6. | Depression and Apathy |
|----|----------------|
|    | No | -0 ( ) ( ) ( ) |
|    | General disinterest | -1 ( ) ( ) ( ) |
|    | Reduced motor activity | -2 ( ) ( ) ( ) |
|    | Guilt and suicidal ideas | -3 ( ) ( ) ( ) |
|    | Refuses to eat and drink | -3 ( ) ( ) ( ) |
|    | No care for urination and defaecation | -3 ( ) ( ) ( ) |

Results and Observations

1. **Clinical Anxiety Scale** – the subjective relief in these patients was recorded by quantitatively grading the major symptoms present in these patients such as nervousness, palpitation, insomnia, fatigue, dyspepsia, anorexia, lack of concentration, headache and irritability. Most of these symptoms were found quantitatively decreased after one month of treatment worth the trial drug. The grade scores of nervousness and headache showed maximum improvement (p<0.001) while lack of concentration and irritability showed moderate recovery (P<0.05) after 6 weeks of treatment (Table 3, 4).

2. **Clinical Depression Scale** – The effect of the treatment was also assessed in terms of the degree of depression. As can be seen from the
table the depression Index was found significantly reduced (p<0.01) after the course of therapy (Table 5).

3. **Physiological Studies** – The follow up studies showed a trend increase in body weight in patients receiving Medhya Rasayana for one month. The average pulse rate of these patients was found significantly (p<0.05) reduce. The blood pressure was also found slightly lowered. Thus there is a definite physiological rectification and biological improvement in persons receiving Medhya Rasayana therapy.

4. **General Health Improvement** – The patients reported a growing feeling of wellbeing and improvement in general health with increase in body weight during the course of Medhya Rasayana therapy. Such a feeling of wellbeing appears to be a secondary attribute to the anti-anxiety and adaptogenic effect of the trial drug besides its general restorative effects.

**Discussion**

As stated at the outset, the present investigation aims to undertake a clinical evaluation of the combined Medhya Rasayana therapy in Manas Roga. As anxiety forms the major component of almost all Manas Rogas, in the present context we

**TABLE – III**

**Showing the pattern of reduction in clinical anxiety as observed during 1st follow up of 28 cases of anxiety neurosis after 2 weeks of treatment with Medhya Rasayana**

| S. No | Symptoms            | Initials Mean ± S.D. | Follow up Mean ± S.D. | t   | p     |
|-------|---------------------|----------------------|-----------------------|-----|-------|
| 1     | Nervousness         | 2.35 ± 0.271         | 1.88 ± 0.598          | 3.79| <0.001 |
| 2     | Palpitation         | 2.10 ± 0.631         | 1.46 ± 0.786          | 3.38| <0.001 |
| 3     | Tremors             | 1.35 ± 0.925         | 6.00 ± 0.811          | 2.90| <0.01  |
| 4     | Headache            | 1.92 ± 0.774         | 1.17 ± 0.816          | 3.63| <0.001 |
| 5     | Anorexia            | 1.92 ± 0.819         | 1.35 ± 0.498          | 3.16| <0.01  |
| 6     | Insomnia            | 1.71 ± 1.037         | 1.07 ± 1.060          | 2.17| <0.01  |
| 7     | Lack of concentration | 2.14 ± 0.18       | 1.53 ± 1.020          | 2.46| <0.02  |
| 8     | Dyspepsia / Flatulence | 2.14 ± 0.675    | 1.35 ± 0.905          | 3.70| <0.001 |
| 9     | Fatigue / Exhaustion | 2.60 ± 1.073    | 1.46 ± 0.912          | 4.26| <0.001 |
| 10    | Irritability        | 2.28 ± 1.020         | 1.64 ± 0.859          | 2.41| <0.02  |

Values are Mean Grade Scores ± S.D. Difference compared wit respective initial values
TABLE – IV

Showing the pattern of reduction in clinical anxiety as observed during II$^{nd}$ follow up of 12 cases of anxiety neurosis after 1 month of treatment with Medhya Rasayana

| S. No | Symptoms         | Initials Mean ± S.D. | Follow up Mean ± S.D. | t    | p    |
|-------|------------------|----------------------|-----------------------|------|------|
| 1     | Nervousness      | 2.35 ± 0.926         | 1.88 ± 0.597          | 4.542| < 0.001|
| 2     | Palpitation      | 1.91 ± 0.659         | 0.66 ± 0.472          | 3.364| < 0.001|
| 3     | Tremors          | 1.56 ± 0.957         | 0.50 ± 0.763          | 2.829| < 0.01 |
| 4     | Headache         | 1.66 ± 0.760         | 0.78 ± 0.593          | 3.533| < 0.01 |
| 5     | Anorexia         | 2.08 ± 0.650         | 0.60 ± 0.630          | 5.440| < 0.01 |
| 6     | Insomnia         | 1.66 ± 0.641         | 0.50 ± 0.763          | 5.272| < 0.001|
| 7     | Lack of concentration | 2.08 ± 0.961     | 0.75 ± 0.721          | 6.385| < 0.001|
| 8     | Dyspepsia / Flatulence | 2.00 ± 1.080     | 6.66 ± 0.480          | 3.927| < 0.001|
| 9     | Fatigue / Exhaustion | 2.25 ± 0.325     | 0.21 ± 0.649          | 6.870| < 0.001|
| 10    | Irritability     | 2.33 ± 1.704         | 0.83 ± 0.557          | 2.900| < 0.01 |

Values are Mean Grade Scores ± S.D. Difference compared with respective initial values

TABLE – V

Showing the pattern of reduction in Depression Index in cases of Anxiety Neurosis after treatment with Medhya Rasayana

| Observation | Initial value Mean ± S.D. | Follow up-I (20 cases) Mean ± S.D. | t    | p    |
|-------------|----------------------------|-------------------------------------|------|------|
| Depression Index | 9.58 ± 2.81 (19)       | 6.57 ± 2.60 (19)                  | 3.424| < 0.01|

Observation

| Initial value | Follow up-I (20 cases) |
|---------------|------------------------|
| Mean ± S.D.   | Mean ± S.D.            |

Depression Index | 10.00 ± 2.73 (8) | 5.00 ± 2.78 (8) | 3.626 | < 0.01 |

Values are Mean Raw Scores.

Number of observations within parenthesis
Have selected Anxiety Neurosis as the subject of study. Thus it is essential to point out at the outset that the present study does not encompass the total spectrum of Manas Roga and relates only to an important aspect of the diathesis of mental illness.

It may further be clarified that Medhya Rasayana therapy in the present context refers to a combined treatment with the four classical Medhya Rasayana described in caraka samhita namely Sankhapuspi, Mandukaparni, Guduci and Yastimadhu.

The role of these drug has already been evaluated individually for their anti-anxiety effect earlier by other workers in our group. The object of the present study is to evaluate the role of the combined use of these four Medhya Rasayana drugs in Anxiety Neurosis.

Most of the compound and single drugs described for the treatment of mental diseases consists of Medhya and Rasayana drug of herbomineral origin. Among the drugs which are advocated with priority for the treatment of mental disease, the Medhya Rasayanas are the most important ones. It is in view of their uses mentioned in Ayurvedic classics as well as their prevalent use, that we selected these drugs for their evaluation in the management of mental diseases.

The beneficial effects of Medhya Rasayana therapy in the present series of patients appears to be due to the possible anti-anxiety activities of Medhya Rasayana drugs especially Sankhapuspi and Mandukoparni, besides the general Rasayana and adaptogenic effects of these drugs. The remaining two drugs namely Guduci and Yastimadhu may not necessarily possess psychotropic action, but they appear to contribute adjuvant effects through other restorative attributes. The Medhya rasayana could develop varying degree of resistance against stress and could adopt well with stressful situation.

In view of the contributory activities of the Four Medhya Rasayana drugs including antianxiety, anti-depressant, adaptogenic and restorative effective effects it appears useful to combine these drugs in form of a compound Rasayana with predominant Medhya effect. This combination appears to be further benefitted by the healing properties of Yastimadhu and the bitter tonic effect of Guduci besides their general Rasayana and restorative effects. Madhuyasti being a mild laxative specially suits the patient of different type of Manas Roga because most of these patients are constipated and measure affording laxation and Vatanulomana always produce beneficial effects. As also observed by some of our colleagues, a regular mild Virecana therapy is an useful adjuvant in the care of mental patients.

Thus there are many benefits of combing four Medhya Rasayana drugs to develop a routine treatment for all forms of mental illness. The Medhya rasayana Kasaya use in the present trial is a simple cheap an safe remedy or all kinds of minor mental diseases. These drugs may be helpful even in major mental diseases if used in higher doses. However, it could be a best treatment as a maintenance therapy for mental patients including the patients of residual psychosis.
The present trial has shown no undesirable side effects in this drug and the treatment appears fairly safe and moderately effective. It is not possible to comment at this stage on the problem of addiction of these drugs because ours is only a short term trial and we have not studied their withdrawal effects. Moreover, in view of the moderate activity and the general adaptogenic restorative effects the chances of addiction are minor. Thus the present study undertaken for clinical evaluation of Medhya rasayana therapy in Manas Roga has yielded evidence to suggest that the combined Medhya rasayana therapy is safe and moderately effective remedy for the care of a wide range of minor and moderate mental illhealth problem.

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