Clinical Research

Clinical efficacy of Bhringarajasava as Naimittika Rasayana in Rajayakshma with special reference to pulmonary tuberculosis

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Abstract

The clinical study was conducted at the Out Patient Department of State TB Training and Demonstration Centre, S.R. Nagar, Hyderabad, Andhra Pradesh, India, during June 2003 to December 2004. A group of 60 patients of PTB were included in the study and were divided into two equal groups. Both the groups were on the Directly Observed Treatment Short – course chemotherapy (DOTS) regime. The test group was given DOTS + Bhringarajasava (30 ml thrice a day) and the control group was only on DOTS. The study was to evaluate whether the addition of Bhringarajasava as Naimittika Rasayana (complementary drug) is beneficial in providing faster and better relief or not. Both subjective and objective parameters were considered for the assessment of results. Among the specific symptomatology, Amsaparsabitapah (pain in costal and scapular region), Kasa (cough), Jwara (pyrexia), Swasa (dyspnoea) and Bhaktadwesha (anorexia) were the symptoms manifested by all the patients. Results of the present study indicate that better, safer, and faster relief provided by the addition of Bhringarajasava to DOTS. This is an effort to utilize drugs from the vast Ayurvedic pharmacopoeia as safe adjuvant to DOTS regime so that toxicity and associated side effects of the DOTS can be ameliorated. This process of using therapies from two disparate systems of medicine could potentially lead to further enhancements in the field of complementary medicine and create a symbiosis between the different systems, which may lead to Rasayana DOTS (R-DOTS) in future.

Key words: Ayurveda, Bhringarajasava, pulmonary tuberculosis, Rajayakshma, Rasayana

Introduction

Resistance of the malaria and tubercle bacilli has thwarted the objective of attainment of good health for all the people of the world. Tuberculosis (TB) remains a worldwide public-health problem, despite the fact that the causative organism was discovered more than 100 years ago and highly effective drugs and vaccines are available. Eradication of this disease does not appear to be an attainable goal for decades to come.

TB was declared a global health emergency by the World Health Organization (WHO) in 1993. This has been mainly due to the emergence of Multiple Drug Resistant (MDR) strains and the synergy between tubercle bacilli and HIV. According to WHO, 1.7 billion persons (1/3 of world’s population) harbor tuberculosis bacilli, 8-10 million new cases appear annually and some 3 million die of TB every year. About five people succumb to this dreaded disease every minute globally and every seventh patient of TB in the World is an Indian. 500,000 deaths from this disease occur in India every year. It is estimated that between 2002 and 2020 approximately, a billion people will be newly infected, over 150 million people will get sick, and 36 million people will die of TB if proper control measures are not instituted. [1]

Concept of Naimittika Rasayana is a unique concept in Ayurveda, proved for its beneficial role in the patients suffering from chronic diseases in promoting vitality, and ability to withstand the devastating effects of these diseases. This concept brings a new dimension into the health-care, and promotes an integrated approach between different modalities in the field of medicine. [2]

Ayurveda has described a large number of Rasayana, which can provide protection against toxic substances and diseases. They promote both physical and mental-health, improve the status of the Dhatu (tissues), confer immunity and rejuvenate the system. [3] The Rasayana of Ayurveda and the chemotherapeutic drugs of modern medicine, used in combination, will not only promote healing may also improve vitality in these patients.
So the present study has been carried out to establish that Bhringarajasava, improves immunity in patients with pulmonary tuberculosis (PTB) and pacifies the side-effects of the chemotherapeutic agents of anti-TB treatment i.e. Directly Observed Treatment Short-course chemotherapy (DOTS) regime. And to establish the specific symptomatology of Rajayakshma (Pthisis) described in Ayurveda on clinical basis in PTB patients.

Materials and Methods

Drugs
Bhringarajasava is a compound herbal formulation consisting of Bhringaraja (Eclipta prostrate Linn.), as active ingredient along with Haritaki (Terminalia chebula Retz.), Pippali (Piper longum Linn.), Jatiphal (Myristica fragrance Houtt.), Lavanga (Syzygium aromaticum Linn.), Twak (Cinnamomum zeylanicum), Ela (Elatteria cardamomum), Tamalapatra (Cinnamomum tamala), Nagakesara (Messua ferrea), and Gudam (old cane jaggery). It is prepared by dissolving jaggery in the juice of Bhringaraja (watery extract) and adding coarse powders of the remaining drugs. It is allowed to ferment in a vessel, resulting in an Asava (fermented liquid preparation) after the period of 1 month.

Selection of the patients
Sixty patients of different age groups were selected after obtaining informed consent. Sampling of the patients done based on the inclusion and exclusion criterion. Details of criteria are given in Table 1.

Diagnosis
Patients were diagnosed based on the Revised National TB Control Programme (RNTCP) pattern[7] by the Medical Officer – TB Control, State TB Training and Demonstration Centre (STDC), S.R. Nagar, Hyderabad.

Treatment regime
(i) Administration of Bhringarajasava:
Dosage: 30 ml with equal quantity of water, thrice a day Time of administration: ½ an hour after food (Prana Vaya Kala)
Duration: 2-3 months during the intensive phase of DOTS
Follow-up: 6-8 months based on treatment category.

(ii) Method of allocation:
The study is a non-randomized controlled open trial. Sixty patients were divided into two equal groups, Test Group (TG) and Control Group (CG) considering the design of the study. Both the groups were given standard RNTCP regimen i.e., DOTS chemotherapy regime, whereas TG patients were additionally given adjuvant drug i.e., Bhringarajasava. Details are given in Table 2.

DOTS-Category wise treatment regime
Based on RNTCP treatment protocols, duration and treatment regime was decided. DOTS category and corresponding treatment regime are listed[8] in Table 3.

Assessment criteria
Both the subjective and objective parameters were taken into consideration to assess the severity of the disease and response of the adjuvant treatment.

Subjective parameters
The symptomatology of Rajayakshma (pthisis) is discussed in groups i.e., Trirupa (symptom triad), Shadrupa (group of six symptoms), Ekadasaru (group of 11 symptoms) in Ayurveda. These were used as subjective parameters[7]

Table 1: Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| Sputum +ve cases (cat-I) | Extrapulmonary TB |
| Sputum –ve cases (cat-III) | HIV and TB coinfection |
| Relapse cases (cat-II) | MDR TB patients (cat-IV) |
| Defaulters (cat-II) | Severely ill patients |
| Failure cases (cat-II) | Pregnant with pulmonary TB |

(These categories included under RNTCP program)[8]

Cat: Category, TB: Tuberculosis, MDR: Multiple drug resistant, RNTCP: Revised national TB control programme, +ve: Positive, –ve: Negative

Table 2: Treatment allocation

| Test group | Control group |
|------------|---------------|
| DOTS for 6 or 8 months + Bhringarajasava | Only DOTS for 6 or 8 months |
| for 2 or 3 months i.e., during the intensive phase of the DOTS |

DOTS: Directly observed treatment short-course chemotherapy

Table 3: Directly observed treatment short-course category and treatment regime

| Category | Regimen* |
|----------|----------|
| I        | 2 (HRZE)₂₅ 4 (HR)₃ |
| II       | 2 (HRZES)₂₅ 1 (HRZE)₃ 5 (HRE)₅ |
| III      | 2 (HRZ)₂₅ 4 (HR)₃ |

*The number before the letters refers to the number of months of treatment, The subscript after the letters refers to the number of doses per week, H: Drug (abbreviation)-Isoniazid, R: Rifampicin, Z: Pyrazinamide, E: Ethambutol, S: Streptomycin

Objective parameters
(1) Weight (2) Sputum for Acid Fast Bacilli (AFB) (3) Chest X-ray (CXR) (Skiagram) - Clinical assessments are made before,
during and at the end of the treatment with the follow-up for 6 or 8 months.

**Gradation of results**
Marked: Complete relief in subjective parameters (75-100%) with sputum conversion, weight gain (≥8 kg on average) and resolution of changes in skiagrams.

Moderate: Max. Relief in subjective parameters (50-75%) with sputum conversion, weight gain (5-8 kg on average) and mild changes in skiagrams.

Mild: 25-50% relief in subjective parameters with sputum conversion, weight gain (≤5 kg on average) and no changes in skiagrams.

Poor: Up to 25% relief in subjective parameters with sputum conversion, weight gain (<5 kg on average) and no changes in skiagrams.

**Observations and Results**

The demographic data in relation to sex, age, socio-economic status, immunization status (Bacillus Calmette Guerin [BCG] vaccination) and observations on subjective parameters and objective parameters were presented in the Tables 4-12.

Table 4 implies that there is not much gender variation in the incidence of the disease.

Of the total, 50 cases (83.33%) belong to age group below 40 years. This observation supports the knowledge that pulmonary TB (PTB) is commonly a disease of the young adults [Table 5].

Socio-economic status has pivotal role in the causation of disease. It is very clear that almost 90% of the cases belong to the poor and lower-middle class. These ratios may vary in other studies, since this study was conducted on the indigent population, the ability of whom to afford private care is compromised [Table 6].

Table 7 gives an idea of role of BCG vaccination in prevention of the disease and the number of people who have not been immunized so far. Protection from PTB following BCG vaccination is only 50%.

Among the observed 13 symptoms, the percentage of relief was more than 75% in the TG patients (except in shoulder and scapular emaciation). In the CG, relief was mild (marked relief in the control of temperature).

The subjective relief in the TG patients of category-II was marked. There was a mild improvement in the CG patients. Atisara, Pittatraktasya Chagama symptoms improved in both groups, Swarabheda in CG patients and Kantadwamsam in TG patients were not observed in the treatment category-II.

Complete relief of symptoms was observed in TG.

In the treatment category-I, the mean weight in CG patients before and after treatment was 42.87 and 46.56 (difference of 3.69), whereas in TG patients this was 47.06 and 52.18 (difference of 5.12). The improvement in weight gain in TG patients is statistically significant \(t_{10} = 2.25, P < 0.05\), significant at 5% level.

In the treatment category-II, the mean weight in CG patients before and after treatment is 39.54 and 44.00 (difference of 4.46) whereas in TG patients this value is 45.90 and 52.45 (difference of 6.55). The improvement in weight gain in TG patients is statistically not significant \(t_{10} = 1.77, P > 0.05\). Even though this change is statistically not significant, it was observed that the maximum weight gain was 12 kg.

In the treatment category-III, the mean weight in CG patients before and after treatment was 44.66 and 48.33 (difference of 3.67) whereas in TG patients this value was 43.33 and 50.66 (difference of 7.33). The improvement in weight gain

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**Table 4: Incidence of gender**

| Category | Test group | Control group |
|----------|------------|---------------|
| Cat I    | Male       | 10            | 10            |
|          | Female     | 6             | 6             |
| Cat II   | Male       | 8             | 3             |
|          | Female     | 3             | 8             |
| Cat III  | Male       | 2             | 2             |
|          | Female     | 1             | 1             |
| Total    |            | 30            | 30            |

**Table 5: Incidence of age**

| Age group | Test group Cat-I | Test group Cat-II | Test group Cat-III | Control group Cat-I | Control group Cat-II | Control group Cat-III | Total (%) |
|-----------|------------------|-------------------|-------------------|---------------------|----------------------|----------------------|-----------|
| 11-20     | 3                | 1                 | 2                 | 5                   | 2                    | 1                    | 14 (23.4) |
| 21-30     | 4                | 7                 | 1                 | 7                   | 3                    | 1                    | 23 (38.4) |
| 31-40     | 6                | 1                 | 0                 | 3                   | 3                    | 0                    | 13 (21.7) |
| 41-50     | 2                | 2                 | 0                 | 0                   | 2                    | 0                    | 6 (10)    |
| 51-60     | 1                | 0                 | 0                 | 1                   | 1                    | 1                    | 3 (5)     |
| 61-70     | 0                | 0                 | 0                 | 1                   | 0                    | 0                    | 1 (1.7)   |
| Total     | 16               | 11                | 3                 | 16                  | 11                   | 3                    | 60        |

**Table 6: Incidence of socio-economic status**

| Socio-economic status | Test group | Control group | Total | Percentage |
|-----------------------|------------|---------------|-------|------------|
| Poor                  | 19         | 28            | 47    | 78.33      |
| Lower-middle          | 9          | 0             | 9     | 15         |
| Upper-middle          | 2          | 2             | 4     | 6.66       |
| Higher                | 0          | 0             | 0     | 0          |
| Total                 | 30         | 30            | 60    |            |

**Table 7: Immunization status**

| Immunization status | Test group Cat-I | Test group Cat-II | Test group Cat-III | Control group Cat-I | Control group Cat-II | Control group Cat-III | Total |
|---------------------|------------------|-------------------|-------------------|---------------------|----------------------|----------------------|-------|
| BCG given           | 8                 | 7                 | 0                 | 9                   | 5                    | 0                    | 29    |
| Not given           | 8                 | 4                 | 3                 | 7                   | 6                    | 3                    | 31    |
| Total               | 16                | 11                | 3                 | 16                  | 11                   | 3                    | 60    |
Table 8: Incidence of clinical features

| Symptoms                                             | Cat-I (n) | Cat-II (n) | Cat-III (n) | Percentage |
|------------------------------------------------------|-----------|------------|-------------|------------|
| Amsaparsabhitapah (Pain in costal and scapular region) | 32        | 22         | 6           | 100        |
| Samtapakarapadayoh (Burning sensation in palms and soles) | 12        | 9          | 2           | 38.2       |
| Jwara (Pyrexia)                                       | 32        | 20         | 6           | 96.3       |
| Bhaktadwesha (Anorexia)                               | 30        | 21         | 6           | 94.6       |
| Swasa (Dyspnea)                                       | 32        | 21         | 5           | 96.3       |
| Kasa (Cough)                                          | 32        | 22         | 5           | 98         |
| Shonita darsanam (Hemoptysis)                         | 6         | 2          | 0           | 13.3       |
| Swarabheda (Hoarseness of voice)                      | 4         | 1          | 1           | 10         |
| Anilath shula (Pain in visceral organs)               | 5         | 2          | 1           | 13.3       |
| Samkochamsaparshyoh (Shoulder and scapular emaciation)| 20        | 16         | 2           | 63         |
| Daha (Burning sensation)                              | 3         | 3          | 2           | 13.3       |
| Atisara (Diarrhea)                                    | 2         | 0          | 1           | 5          |
| Pitta raktasya chagama (Hematemesis)                  | 2         | 0          | 0           | 3.7        |
| Sirasah paripoornata (Heaviness in the head)          | 15        | 10         | 2           | 45         |
| Kantadwamsa (Tracheal shift)                          | 0         | 1          | 0           | 1.7        |

Table 9: Results-category-I

| Symptoms in cat-I                                             | CG (n=16) | % of relief | TG (n=16) | % of relief |
|--------------------------------------------------------------|-----------|-------------|-----------|-------------|
| Amsaparsabhitapah (Pain in costal and scapular region)       | 6/16      | 37.5        | 16/16     | 100         |
| Samtapakarapadayoh (Burning sensation in palms and soles)    | 2/5       | 40          | 6/7       | 85.7        |
| Jwara (Pyrexia)                                              | 13/16     | 81.3        | 16/16     | 100         |
| Bhaktadwesha                                                 | 7/16      | 43.8        | 14/14     | 100         |
| Swasa                                                        | 10/16     | 62.5        | 15/16     | 93.8        |
| Kasa                                                         | 10/16     | 62.5        | 16/16     | 100         |
| Shonita darsanam (Hemoptysis)                                | 2/3       | 66.7        | 3/3       | 100         |
| Swarabheda                                                   | 0/2       | 0           | 2/2       | 100         |
| Anilath shula (Pain in visceral organs)                      | 2/3       | 66.7        | 2/2       | 100         |
| Samkochamsaparshyoh (Shoulder and scapular emaciation)       | 2/11      | 18.2        | 5/9       | 55.6        |
| Daha                                                         | 0/2       | 0           | 1/1       | 100         |
| Atisara                                                      | 1/2       | 50          | -         | -           |
| Pitta raktasya chagama (Hematemesis)                         | 0/1       | 0           | 1/1       | 100         |
| Sirasah paripoornata (Heaviness in the head)                 | 6/8       | 75          | 6/7       | 85.7        |
| Kantadwamsa (Tracheal shift)                                 | -         | -           | -         | -           |

Discussion

Rajayakshma (Pthisis) is described in Ayurveda with specific reference to etiology (Nidana Chatushka) and symptomatology. These correspond to the clinical experience in PTB.

Stage-I is Trirupavasta (symptom triad) which corresponds to Cat-III patients (spumtum –ve); stage-II is Shadrupavastha (group of six symptoms) and corresponds to Cat-I patients (spumtum + ve) and stage-III is 5-8 symptoms of Ekadasarupas (group of 11 symptoms) and corresponds to Cat-II patients (with relapse). Complete establishment of Ekadasarupas is the stage with complications, as in MDR TB (Cat-IV) patients.

The Lakshanas of Kaphaja Krimi (mucosal bacteria) seems to resemble Mycobacterium tuberculosis and its effect on the patient. The ingredients of Bhringarajasava possess properties of Krimighna (anti-bacterial) and Kshayahara. The purpose of selecting Bhringarajasava as Naimittika Rasayana was fulfilled by these criteria.

Results were statistically analyzed in relation to treatment categories mentioned under RNTCP.

Subjective parameters

1. Amsaparsabhitapah (Pain in costal and scapular region): This symptom was observed in all the 60 patients, but it has no reference in texts in modern medicine. The relief in this symptom after treatment was around 35% in CG patients and was 100% in TG patients.

2. Samtapakarapadayoh (Burning sensation in palms and soles): Relief from this symptom in TG patients is about 75% in comparison to 50% in CG patients (Complete relief in Cat-III patients of CG).

3. Jwara (Pyrexia): There was complete abatement of febrile morbidity in TG patients over the CG (<75% improvement on average).

4. Bhaktadwesha (Anorexia): In TG patients there was increased appetite (almost 100%) whereas mild appetite was increased in TG patients is statistically significant ($t_1 = 5.02, P < 0.01$, significant at 1% level).

Objective parameter – Sputum for AFB

All the TG patients are reported with sputum conversion within the stipulated time i.e. after intensive phase of treatment whereas 10 patients out of 30 cases (6 CAT-I, 4 Cat-II) of CG were placed on the prolongation phase.

Objective parameter – Skiagrams

CXR was not given much importance in Sputum + ve cases (Cat-I and Cat-II) and it was given much importance for the CAT-III patients (6) i.e., Sputum –ve cases. However, the observations made on the skigrams of 22 patients (TG patients-3 Cat-III + 3 Cat-II + 6 Cat-I and CG patients-3 Cat-III, 3 Cat-II, 4 Cat-I) before and after treatment is being presented in Table 13.
Table 10: Results-category-II

| Symptoms in cat-II | CG (n=AT/BT) | % of relief | TG (n=AT/BT) | % of relief |
|-------------------|--------------|-------------|--------------|-------------|
| Amsaparsabhitapah | 4/11         | 36.4        | 11/11        | 100         |
| Samtapakarapadayoh| 0/2          | 0           | 5/7          | 71.4        |
| Jwara             | 6/9          | 66.7        | 10/11        | 91          |
| Bhaktadwesha      | 5/10         | 50          | 10/11        | 91          |
| Swasa             | 6/10         | 60          | 10/11        | 91          |
| Kasa              | 5/11         | 45.5        | 11/11        | 100         |
| Shonita darsanam  | 0/1          | 0           | 1/1          | 100         |
| Swarabhedha       | -            | -           | 1/1          | 100         |
| Anilath shula     | 0/1          | 0           | 1/1          | 100         |
| Samkochamsaparshyoh| 3/10        | 30          | 3/6          | 50          |
| Daha              | 1/2          | 50          | 1/1          | 100         |
| Atisara           | -            | -           | -            | -           |
| Pitta raktasya chagama| -         | -           | -            | -           |
| Sirasah paripoornata| 1/6        | 16.7        | 3/4          | 75          |
| Kantadwamsa       | 1/0          | 0           | -            | -           |

AT/BT: After treatment no. of patients relieved/before treatment no. of patients presented, Cat: Category, TG: Total group, CG: Control group

Table 11: Results-category-III

| Symptoms in category–III | CG (n=AT/BT) | TG (n=AT/BT) |
|--------------------------|--------------|--------------|
| Amsaparsabhitapah        | 1/3          | 3/3          |
| Samtapakarapadayoh       | 2/2          | -            |
| Jwara                    | 2/3          | 3/3          |
| Bhaktadwesha             | 2/3          | 3/3          |
| Swasa                    | 2/3          | 2/2          |
| Kasa                     | 2/3          | 2/2          |
| Shonita darsanam         | -            | -            |
| Swarabhedha              | 0/1          | -            |
| Anilath shula            | -            | 1/1          |
| Samkochamsaparshyoh      | 0/2          | -            |
| Daha                     | 0/1          | 1/1          |
| Atisara                  | 0/1          | -            |
| Pitta raktasya chagama   | -            | -            |
| Sirasah paripoornata     | 0/1          | 1/1          |
| Kantadwamsa              | -            | -            |

AT/BT: After treatment no. of patients relieved/before treatment no. of patients presented, TG: Total group, CG: Control group

Table 12: Objective parameter-weight

| Category | Control group (mean±SEM) | Test group (mean±SEM) | P value | Remarks |
|----------|--------------------------|-----------------------|---------|---------|
|          | Before treatment | After treatment | Before treatment | After treatment |         |
| Cat-I    | 42.87±1.21           | 46.56±1.4             | 47.06±1.19 | 52.18±1.27 | <0.05  | Significant |
| Cat-II   | 39.54±2.29           | 44±2.22               | 45.90±2.56 | 52.45±2.28 | >0.05  | Not significant |
| Cat-III  | 44.66±3.17           | 48.33±3.75            | 43.33±2.02 | 50.66±2.76 | <0.01  | More significant |

Cat: Category

Table 13: Objective parameter-CXR

| Category | Control group | Test group |
|----------|---------------|------------|
|          | Patches of infiltrations in one or both the lungs are seen before and after treatment | Density of the opacity is less than the previous pictures |
| Cat-III  | CAVITIES WITH FIBROSIZED WALLS AND CONSOLIDATION WITHOUT MUCH IMPROVEMENT | CLEARING OF THE CONSOLIDATION AND RESOLUTION OF FIBROTIC CHANGES NOTED |
|          | Patches of infiltration with cavity formation observed even after treatment | THERE IS LESSENING AND RESOLUTION OF THE AREA OF THE CAVITIES |

Cat: Category, CXR: Chest X-ray

improvement in appetite was observed in some cases of CG.

5. Swasa (Dyspnea): Marked relief in the TG patients (>90%) whereas it was <65% in CG.

6. Kasa (Cough): Cough progressively diminished and ultimately became occasional and non-productive with easy expectoration within 15 days of treatment in TG patients and moderate relief was observed in CG over the period of 6-8 months.

7. Shonita Darshanam (Hemoptysis): The relief from this symptom was not statistically significant (<5 cases) in the CG. These patients were given another modern drug to control the bleeding. However, encouraging results were observed in TG patients.

8. Swarabhedha (Hoarseness of voice): The relief from this symptom was manifested due to Vata Dosha predominance. All the TG patients were relieved from this symptom in 4 weeks.

9. Atisara (Diarrhea): No TG patients were reported with this symptom during the treatment.

10. Pittaraktasyachagama (Hematemesis): This symptom was observed only in two cases and was controlled immediately in TG patient.

11. Daha (Burning sensation): There was complete relief from this symptom in TG patients.

12. Atisara (Diarrhea): No TG patients were reported with this symptom during the treatment.

13. Pittaraktasyachagama (Hematemesis): This symptom was observed only in two cases and was controlled immediately in TG patient.

14. Sirasah paripoornata (Heaviness in the head): This symptom was manifested due to Kapha Dosha predominance. All the TG patients were relieved from this
In summary, the addition of supportive therapy with Bhringarajasava ensures increased appetite and creates a general sense of subjective well-being. Additionally, it controls temperature elevation, promotes weight gain, abolishes night sweats, reduces cough, and encourages expectoration. The response in TG patients of Cat-I was optimum and moderate in CG patients. Moderate improvement was seen in TG patients of Cat-II as compared to mild improvement in CG patients. Substantial improvement was observed in TG patients of Cat-III in comparison with poor improvement in CG patients. The same was shown in Table 14.

Probable mode of action

Bhringarajasava improves immunity and enhances the defensive mechanism of the body. Stimulation of the Reticulo Endothelial System (RES) activates the mesenchyme and accelerates healing at the tubercular sites. In turn, this process results in destruction of killer cells and formation of new healthy tissue.[9]

Addition of Bhringarajasava to DOTS offers hepato protection due to the presence of Wedelolactone – Hepatoprotective principle present in the leaves of Bhringaraja. It has immunomodulatory properties, which create the subjective well-being and cause remarkable changes in the objective parameters. The concept of Naimittika Rasayana is well-known in the field of Ayurveda in the treatment of chronic disorders.[9,10]

Weight loss and cachexia in PTB points to the presence of cytokine and tumor necrosis factor-α (TNF-α), in addition to the immuno-pathological effects, such as tissue necrosis and fever.[11]

Bhringarajasava possesses dynamic properties and is capable of correcting and restoring errors of the Koshtagni and Dhatuagni (metabolic and digestive fire in the tissues). Its other properties include include Balyam (nutritive), Brimhanam (tonic), Rasayanam (Rejuvenative), Hiridyam (cardiotonic), Vishaharam (anti-toxic) and Krimighnam (anti-bacterial).

**Table 14: Final result**

| Treatment category | Mode of response | Control group | Test group |
|---------------------|------------------|---------------|-----------|
| Cat-I               | Moderate         |               | Marked    |
| Cat-II              | Mild             |               | Moderate  |
| Cat-III             | Poor             |               | Marked    |

**Conclusion**

Naimittika Rasayana, plays a complementary, adjuvant, supportive role in the management of communicable diseases. Utilization of this modality in the practice of modern medicine appears to be minimal. This study offers an opportunity to incorporate a herbal rejuvenative in the management of PTB, a chronic debilitating disorder, the incidence and devastating effects of which is on the rise, especially, with the emergence of resistant tubercle bacilli. It is the fervent hope of the participants of this study that mainstream medicine will give serious consideration to the availability of other such products in the vast Pharmacopoeia of Ayurveda, which can substantially enhance the effect of the drugs in its armamentarium.

The purpose of this supportive therapy is to improve the resistance of the patient to damage caused by the tubercle bacilli, and to create an environment in the body unsuitable for proliferation of the bacilli.

The aforesaid properties of the Bhringarajasava are invaluable, not only for correcting low vitality state and predisposition for TB but also in treatment of the disease. Bhringarajasava can be easily administered as an adjunct to DOTS. DOTS drugs are known to cause hepatotoxicity. Improved weight gain in TG patients in comparison to CG indicates the supportive effect of Bhringarajasava and its regulatory effect on the activity of TNF-α.

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हिन्दी सारांश

भूंगराजासव का नैमितिक रसायन के रूप में राजयक्ष्मा में प्रयोग –
एक विचित्रत्वीय अध्ययन

सत्यां एन. डोर्नाला, स्नेहलता एस. एन. डोर्नाला

प्रस्तुत अध्ययन का उद्देश्य यह देखना है कि क्या भूंगराजासव नामक आयुर्वेदिक रसायन पत्तनोंरी ट्यूबकुलोसिस के रोगियों की लगभग श्रमण को बढ़ाता है ? साथ ही क्या यह रसायन औषध का राजयक्ष्मा की विकिरण में प्रभावित होने वाली आयुर्वेदिक रोगों (डॉल्से रेजिमथ) के दुःखास्त्रों को प्रभावी रूप से कम करता है ? आयुर्वेद में वर्णित राजयक्ष्मा के विशिष्ट लक्षण व्यवहारिक रूप से पत्तनोंरी ट्यूबकुलोसिस के रोगियों में पाए जाते हैं। नॉन रैब्याईजड कार्टीलाद ऑपन टायल के अन्तर्गत यह विचित्रत्वीय अध्ययन स्टेट टी.वी. ट्रेटिंग एंड डिमांस्ट्रेशन सेंटर (एस.टी.डी.टी.), एस.आर.नर, हैदराबाद, आंध्र प्रदेश के बाहिरंग विभाग में जुले 2003 से दिसम्बर 2004 तक संपन्न किया गया। इस शोध में पत्तनोंरी ट्यूबकुलोसिस (पी.टी.पी.) के 60 रोगियों को जाँच वर्ग और नियंत्रण वर्ग 2 वर्गों में बांटा गया। दोनों ही वर्गों को डॉल्स रेजिम पर प्रयोग गया। जाँच वर्ग को डॉल्स तथा भूंगराजासव (30 मि.ली. दिन में तीन बार) तथा नियंत्रण वर्ग को केवल डॉल्स दिया गया। परिणामों का आंकलन करने के लिए संवेदिक (आक्निमिक) तथा ऑब्लेक्टिव (वस्तुविक) दोनों प्रकार में वर्गों के मापदंडों को ध्यान में रखा गया। विशिष्ट लक्षणों में अंतर्पारिवर्तन, कास, जवर, श्वास तथा भक्षुण तम्म मापित किया गया। संक्रमणशास्त्रीय संदर्भों: तथा संताप:करणापाद्यों: वे अन्य दो मुख्य लक्षण हैं। वर्तमान शोध के परिसर में यह देखा गया है कि डॉल्स के साथ आयुर्वेदिक रसायनों के प्रयोग से अधिक सुधारित तथा शीर्ष लाभ मिलता है। यह आयुर्वेदिक फार्मेकोरिया में से आयुर्वेदिक रोगों को डॉल्स रेजिम के एक अन्य तथा सहायक के रूप में प्रयोग करने का प्रयास है जिससे डॉल्स के दुःखास्त्रों को कम किया जा सकता है। इस प्रकार दो वर्ण रूप से भिन्न चिकित्सा पद्धतियों के सिद्धांतों का प्रयोग करने से आयुर्वेदिक चिकित्सा के क्षेत्र में उन्नति बिखारी और विभिन्न चिकित्सा पद्धतियों के मध्यविचित्रत्वीय संबंध स्थापित किया जा सकता है, जिससे भविष्य में रसायन डॉल्स का निर्माण संभव है।