AYU

Access this article online

Website: www.ayujournal.org

DOI: 10.4103/0974-8520.110536

Quick Response Code:

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.

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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.), *Jatiphala* (*Myristica fragrance Houtt*.), *Lavanga* (*Sygizium aromaticum* Linn.), *Twak* (*Cinnamomum zeylanicum*), *Ela* (*Elatteria cardamomum*), *Tamalapatra* (*Cinnamomum tamala*), *Nagakesara* (*Messua ferrea*), and *Gudam* (old cane jaggery).[4] 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[5,6] 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 Vayu 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[6] 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.

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)[5]	

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* for 2 or 3 months i.e., during the intensive phase of the DOTS	Only DOTS for 6 or 8 months

DOTS: Directly observed treatment short-course chemotherapy

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

Category	Regimen*
I	$2\ (HRZE)_3\ 4\ (HR)_3$
II	$2\ (HRZES)_3\ 1\ (HRZE)_3\ 5\ (HRE)_3$
III	$2\ (HRZ)_3\ 4\ (HR)_3$

*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

Subjective parameters

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

1. *Amsaparsabhitapah* (Pain in costal and scapular region)
2. *Santapakarapadayoh* (Burning sensation in palms and soles)
3. *Jwara* (Pyrexia)
4. *Bhaktadwesha* (Anorexia)
5. *Swasa* (Dyspnoea)
6. *Kasa* (Cough)
7. *Shonita darsanam* (Hemoptysis)
8. *Swarabheda* (Hoarseness of voice)
9. *Anilath shula* (Pain in visceral organs)
10. *Samkochamsaparshyoh* (Shoulder and scapular emaciation)
11. *Daha* (Burning sensation)
12. *Atisara* (Diarrhea)
13. *Pittat raktasya chagama* (Hematemesis)
14. *Sirasah paripoornata* (Heaviness in the head)
15. *Kantadwamsa* (Tracheal shift)

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-1, 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 ($t_{30} = 2.25$, $P < 0.05$, 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 ($t_{20} = 1.77$, $P > 0.05$). 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

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

Cat: Category

Table 5: Incidence of age

Age group	Test group			Control group			Total (%)
	Cat-I	Cat-II	Cat-III	Cat-I	Cat-II	Cat-III	
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	0	1	1	3 (5)
61-70	0	0	0	1	0	0	1 (1.7)
Total	16	11	3	16	11	3	

Cat: Category

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			Control group			Total
	Cat-I	Cat-II	Cat-III	Cat-I	Cat-II	Cat-III	
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

Cat: Category, BCG: Bacillus calmette guerin

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

Cat: Category

Table 9: Results-category-I

Symptoms in cat-I	CG (*n*=AT/BT)	% of relief	TG (*n*=AT/BT)	% of relief
Amsaparsabhitapah	6/16	37.5	16/16	100
Samtapakarapadayoh	2/5	40	6/7	85.7
Jwara	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	2/3	66.7	3/3	100
Swarabheda	0/2	0	2/2	100
Anilath shula	2/3	66.7	2/2	100
Samkochamsaparshyoh	2/11	18.2	5/9	55.6
Daha	0/2	0	1/1	100
Atisara	1/2	50	-	-
Pitta raktasya chagama	0/1	0	1/1	100
Sirasah paripoornata	6/8	75	6/7	85.7
Kantadwamsa	-	-	-	-

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

in TG patients is statistically significant ($t_4 = 5.02$, $P < 0.01$, 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-2) 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 importance for the CAT-III patients (6) i.e., Sputum –ve cases. However, the observations made on the skiagrams of 22 patients (TG patients-3 Cat-III + 3 Cat-II + 6 Cat-1 and CG patients-3 Cat-III, 3 Cat-II, 4 Cat-I) before and after treatment is being presented in Table 13.

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 (sputum –ve); stage-II is *Shadrupavastha* (group of six symptoms) and corresponds to Cat-I patients (sputum + 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

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
Swarabheda	-	-	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
Kantadwamsam	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	-	-
Swarabheda	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
Cat-III	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-II	Cavities with fibrosed walls and consolidation without much improvement	Clearing of the consolidation and resolution of fibrotic changes noted
Cat-I	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 the 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. *Swarabheda* (Hoarseness of voice): The relief from this symptom was also statistically insignificant as it was observed in few cases (only six cases). Better relief in TG patients can be attributed to the lessening of cough and easy expectoration within 15 days.
9. *Anilath Shula* (Pain in visceral organs): Presence of this symptom implies the early involvement of visceral organs as systemic manifestation of the disease. The complete relief from this symptom in TG patients could be explained by improved appetite and better absorption and assimilation of digested foods.
10. *Sankochamsaparshyoh* (Shoulder and scapular emaciation): This symptom was clearly observed in Cat-II patients, which implies that the manifestation of this symptom is chronic in nature. Relief from this symptom occurs with increase in bulk of muscles in the body, over a period of time. This was very encouraging in TG patients over the CG.
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. *Sirasaha paripoonata* (Heaviness in the head): This symptom was manifested due to *Kapha Dosha* predominance. All the TG patients were relieved from this

symptom within 10 days of treatment and 3-4 months' duration in the CG patients.

15. *Kantadwamsa* (Tracheal shift): This was observed only in one case with fibrosed and consolidated lung.

Objective parameters

1. Weight: In some patients of CG, further weight loss occurred, but in the TG none experienced weight loss and every patient gained a minimum of 5 kg weight. This was statistically highly significant in Cat-III patients ($P < 0.01$), statistically significant in Cat-I patients ($P < 0.05$) and statistically not significant in Cat-II patients ($P > 0.05$). The maximum weight gain observed was 12 kg.
2. Sputum for AFB: All the TG patients were reported with sputum conversion within the stipulated time i.e., after intensive phase of treatment. Ten patients out of 30 (6 CAT-I, 4 CAT-II) in the CG were placed on the prolongation phase.
3. Skiagram (CXR): Density of the opacity in the CXR was less than on previous studies, with lessening of the cavities and resolution of fibrotic changes noted in the TG patients.

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.[8]

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), *Hridyam* (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

Cat: Category

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 *Bringarajasava* 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.

Acknowledgments

Authors would like to acknowledge Dr. A.V.V. Sathyanarayana (Director, STDC) for his acceptance to conduct clinical trials at the center. The mentorship, constant encouragement provided by Dr. V.V.S. Rama Sastry (Retired Professor), Dr. Prakash Chander (Associate Professor), and Dr. V. Vijaya Babu (Retired Professor) from Govt. Ayurveda College, Hyderabad are also acknowledged herewith.

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हिन्दी सारांश

भृंगराजासव का नैमित्तिक रसायन के रूप में राजयक्ष्मा में प्रयोग – एक चिकित्सीय अध्ययन

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प्रस्तुत अध्ययन का उद्देश्य यह देखना है कि क्या भृंगराजासव नामक आयुर्वेदिक रसायन पल्मोनरी ट्यूबरकुलोसिस के रोगियों की रोग प्रतिरोधक क्षमता को बढ़ाता है ? साथ ही क्या यह रसायन औषध राजयक्ष्मा की चिकित्सा में प्रयुक्त होने वाली औषधियों (डॉट्स रेजिम) के दुष्प्भावों को प्रभावी रूप से कम करती है ? आयुर्वेद में वर्णित राजयक्ष्मा के विशिष्ट लक्षण व्यवहारिक रूप से पल्मोनरी ट्यूबरकुलोसिस के रोगियों में पाए जाते हैं । नॉन रैन्डमाइज्ड कन्ट्रोल्ड ओपन ट्रायल के अन्तर्गत यह चिकित्सीय अध्ययन स्टेट टी.बी. ट्रेनिंग एंड डिमॉन्स्ट्रेशन सेन्टर (एस.टी.डी.सी.), एस.आर.नगर, हैदराबाद, आंध्र प्रदेश के बहिरंग विभाग में जून २००३ से दिसंबर २००४ तक संपन्न किया गया। इस शोध में पल्मोनरी ट्यूबरकुलोसिस (पी.टी.बी.) के ६० रोगियों को जाँच वर्ग और नियंत्रण वर्ग २ वर्गों में बांटा गया । दोनों ही वर्गों को डॉट्स रेजिम पर रखा गया । जाँच वर्ग को डॉट्स तथा भृंगराजासव (३० मि.ली. दिन में तीन बार) तथा नियंत्रण वर्ग को केवल डॉट्स दिया गया । परिणामों का आंकलन करने के लिए सब्जेक्टिव (आत्मनिष्ठ) तथा ऑब्जेक्टिव (वस्तुनिष्ठ) दोनों प्रकार के मापदण्डों को ध्यान में रखा गया । विशिष्ट लक्षणों में अंसपार्श्वाभिताप, कास, ज्वर, श्वास तथा भक्तद्वेष सभी रोगियों में पाये गये। संकोचश्चांसपार्श्वयोः तथा संतापःकरपादयोः ये अन्य दो मुख्य लक्षण हैं। वर्तमान शोध के परिणाम यह दर्शाते हैं कि डॉट्स के साथ आयुर्वेदिक रसायन औषधियों के प्रयोग से अधिक सुरक्षित तथा शीघ्र लाभ मिलता है । यह आयुर्वेदिक फार्माकोपिया में से औषधियो को डॉट्स रेजिम के एक सुरक्षित सहायक के रूप में प्रयोग करने का प्रयास है जिससे कि डॉट्स के दुष्प्रभाव को कम किया जा सकता है । इस प्रकार दो पूर्ण रूप से भिन्न चिकित्सा पद्धतियों के सिद्धान्तों का प्रयोग करने से आधुनिक चिकित्सा के क्षेत्र में उत्तरोत्तर विकास और विभिन्न चिकित्सा पद्धतियों के मध्यचिकित्सीय संबंध स्थापित किया जा सकता है, जिससे भविष्य में रसायन डॉट्स का निर्माण संभव है ।