Clinical Research

Clinical evaluation of Rasayana compound as an adjuvant in the management of tuberculosis with anti-Koch’s treatment

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Abstract

Tuberculosis (TB) continues to intimidate the human race since time immemorial not only due to its effects as a medical malady, but also by its impact as a social and economic tragedy. At the dawn of the new millennium, we are still mute witnesses to the silent yet efficient march of this sagacious disease, its myriad manifestations and above all its unequalled, vicious power. Through the millennia, TB never ever disappeared from the developing world. In 1991, the World Health Assembly (WHA) resolution recognized TB as a major global public health problem. The DOTS strategy was launched in 1994, and became the global recommended strategy for TB control since then. The present study deals with clinical evaluation of Rasayana drugs considering of Amalaki (Emblica officinalis Gaertn.), Guduchi (Tinospora cordifolia Willd.), Ashwagandha (Withania somnifera L.) Dunal, Yastimadhu (Glycyrrhiza glabra Linn.), Pippali (Piper longum Linn.), Sariva (Hemidesmus indicus R. Br.), Kustha (Saussurea lappa Falc.), Haridra (Curcuma longa Linn.) and Kuljnan (Alpinia galangal Linn.) as an adjuvant therapy with anti-Koch’s treatment. The results obtained revealed that Rasayana compound was found to decrease cough (83%), fever (93%), dyspnea (71.3%), hemoptysis (87%) and increase body weight (7.7%) with statistically highly significant (P<0.001).

Key words: Anti-Koch’s treatment, DOTS, Rasayana, tuberculosis

Introduction

Tuberculosis (TB) is always the result of gross defects in social organization and in the management of individual lives. It is truly a social sin which can and must be stamped out.

The estimates of the global burden of disease caused by TB in 2009 are as follows: 9.4 million incident cases (range, 8.9–9.9 million), 14 million prevalent cases (range, 12–16 million), 1.3 million deaths among HIV-negative people (range, 1.2–1.5 million) and 0.38 million deaths among HIV-positive people (range, 0.32–0.45 million). Most cases were in the South-East Asia, African and Western Pacific regions (35%, 30% and 20%, respectively). An estimated 11–13% of incident cases were HIV-positive; the African Region accounted for approximately 80% of these cases. There were 5.8 million notified cases of TB in 2009, equivalent to a case detection rate (CDR, defined as the proportion of incident cases that were notified) of 63% (range, 60–67%), up from 61% in 2008.

Of the 2.6 million patients with sputum smear-positive pulmonary TB in the 2008 cohort, 86% were successfully treated.

In 2010, there were 8.8 million (range, 8.5–9.2 million) incident cases of TB, 1.1 million (range, 0.9–1.2 million) deaths from TB among HIV-negative people and an additional 0.35 million (range, 0.32–0.39 million) deaths from HIV-associated TB.[1]

The 20th century opened with infectious diseases and witnessed therapeutic advances that promised control over them. At the close of the century there are abundant grim reminders that the history of infectious diseases is unfinished. There had been steady stream of anti-mycobacterium agents with ever broader spectrum of activity. There is an incoming tide of concern about the problems of antimicrobial resistance. In most of the conditions, either due to infection or stress or metabolic disturbance is the key factor in the integrity of immune system in direct or indirect manner. These factors may have a role in the spread of new or resurgent infectious diseases, the susceptibility being dependant on type and degree of immune perturbation. Ayurveda stresses the need to enhance the body immunity while following specific therapeutic regimen indicated for the condition. The main cause behind TB is lowered immunity. Considering preventive aspect of the disease, in spite of repeated failure

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and disappointment in the medical fraternity is engaged in trying to find a specific cure for the disease. Ayurveda has its complete solution in form of Rasayana Drugs (rejuvenating drugs). *Rasayana* has the potential to provide strength and immunity. The *Rasayana* therapy was established in ancient era in order to enhance self-defense mechanism of the body.

Considering the concept of *Rasayana* therapy, the present study is planned with the objectives to evaluate the i) efficacy of *Rasayana* compound as an adjuvant treatment of TB, ii) to design a therapeutic regimen for TB comparing with concomitant administration of the formulation with Anti-Koch’s Treatment (AKT), and iii) how far the *Rasayana* compound is capable to counteract the Adverse Drug Reactions (ADR) caused by AKT and improve the quality of life of the patient.

### Materials and Methods

The study was conducted on 133 patients of TB (Category-I) selected from 1) I.P.G.T. and R.A. Hospital, Gujarat Ayurved University, Jamnagar, 2) District Tuberculosis Centre and Hospital, Jamnagar and 3) Guru Govind Singh Hospital, P. N. Marg, Jamnagar. They were randomly divided into two groups irrespective to sex and religion. The study is a single blind controlled study. Patients judged, eligible by the inclusion and exclusion criteria were formally informed about the study and those who consented were enrolled and randomly allotted to the study (n=79) and control (n=54) groups. The trial was conducted at OPD level.

Informed consent - The consent of patient was taken. The patients were free to withdraw from the study at any time without having to explain their action. The research study was cleared by Institutional Ethics Committee of I.P.G.T. and R.A.

### Groups

**Group A (Control group)**

The patients were given standard regimen of category I Pulmonary TB which includes administration of HRZE thrice a week on alternate days under RNTCP (Revised National Tuberculosis Control Programme) protocol.

Dose and drugs: i) Isoniazid (H) 600 mg, ii) Rifampicin (R) 450 mg, iii) Pyrazinamide (Z) 150 mg, iv) Ethambutol (E) 1200 mg

Duration: 60 days (2 months); Anupana: Water

**Group B (Study group)**

In study group, patients were administered *Rasayana* compound daily along with the standard regimen of AKT which include Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Ethambutol (E) thrice a week on alternate days.

Dose and drugs: 450 mg capsule of *Rasayana* compound: Three capsules morning and two capsules evening.

Duration: 60 days (2 months); Anupana: Milk. Preparation of the drug (*Rasayana* compound): The composition formulation is depicted at Table 1. Spray-dried aqueous extracts were procured from Konark Herbal Pharmaceuticals, Vapi, Gujarat. Capsule filling was done at Pharmacy, Gujarat Ayurved University, Jamnagar, Gujarat.

Inclusion Criteria: i) only sputum smear-positive patients from category I of pulmonary TB or extra pulmonary TB; ii) age group of >15 years were selected for the present study.

### Table 1: Ingredients of *Rasayana* compound

| Name of drug | Latin name | Part used | Proportion |
|--------------|------------|-----------|------------|
| Amalaki | *Emblica officinalis* | Pericarp | 1 part |
| Ashwagandha | *Withania somnifera* (L.) Dunal | Root | 1 part |
| Guduchi | *Tinospora cordifolia* (wild.) | Stem | 1 part |
| Yashtimadhu | *Glycyrrhiza glabra* Linn. | Root | ½ part |
| Sariva | *Hemidesmus indicus* R.Br. | Root | ½ part |
| Haridra | *Curcuma longa* Linn. | Rhizome | ½ part |
| Pippali | *Piper longum* Linn. | Fruit | ¼ part |
| Kushta | *Saussurea lappa* (Falc.) | Root | ¼ part |
| Kulinjana | *Alpinia galanga* | Rhizome | ¼ part |

Exclusion Criteria: i) complicated cases of pulmonary TB, pulmonary TB with HIV; ii) Age < than 15 years; iii) seriously ill patients and those who suffered either hepatic injury or hepatitis in the last six months.

Diet Recommendation - All the patients registered in this study were advised to follow a normal routine diet as per the status of their Agni.

### Investigations:

The below investigations were carried out.

1. Hematological and biochemical investigations Hb gm%, TLC, DLC, ESR, C- reactive Protein (Quantitative), Peripheral smear; Liver Function tests: SGOT, SGPT, Serum Protein, A: G Ratio, Serum Bilirubin-Direct and Indirect, Serum Alkaline Phosphatase
2. Sputum smear examination for acid-fast bacilli
3. Radiological investigations: X-ray chest PA view

Serious adverse events - Serious adverse events other than of AKT were neither expected nor encountered during the study course.

### Assessment criteria:

Grading symptoms were developed for clinical evaluation of the patients as under

#### Cough (Kasa)

- None 0
- Cough sometimes 1
- Frequent cough but not troublesome 2
- Cough troublesome but does not disturbs the sleep 3
- Cough very troublesome, not even allowing to sleep at night 4

#### Fever (Jwara)

- None 0
- Few days in a week 1
- Alternate day fever 2
- Mild fever everyday 3
- Moderate fever everyday 4

#### Hemoptyis (Raktanisthivan)

- No hemoptyis 0
Sometimes blood streaks in sputum 1
Sputum always streaked with blood 2
Blood-streaked sputum 3
Frank blood in sputum 4
Dyspnoca (Shwasakastata) 0
Dyspnea after heavy work relieved by rest 1
Dyspnea after coughing episode not relieved after completion of episode 2
Dyspnea continue whole day 3
Continues dyspnea day and night 4
Chest pain (Urah shula) 0
Pain on deep pressure 1
Pain on exertion 2
Continuous pain but not restricting the respiratory movements 3
Continuous pain restricting the respiratory movements 4

Associated complaints

Aruchi
Equally willing toward all the Bhojya padarthha. 0
Willing toward some specific Aahara/Rasavisheha. 1
Willing only toward favorite foods not toward others. 2
Unwilling for food but could take the meal. 3
Totally unwilling for meal. 4

Fatigue (Klama)
None 0
Increased fatigue over base line but normal activities not altered 1
Moderate i.e., difficulty to perform few activities 2
Severe i.e., loss of ability to perform few activities 3
Bedridden or disabling 4

Night sweating (Ratri Prasweda)
None 0
Mild (sometimes a week) 1
Moderately (moderately night sweat which disturbs the sleep) 2
Severe (moderately night sweat which disturbs the sleep and patients wake up to change wet clothes) 3

Observation and Results

It was observed from the demographic data that, 33.08% patients belonged to age group of 21-30 years. It shows that both women and men with TB are likely to be in their most reproductive age, i.e., 15-44 years. Maximum patients (70.67%) were male, which highlights that bio factors, like gender, influence of the susceptibility and immunity of different sexes towards TB. Religion-wise maximum patients (77.44%) were Hindus which reflects the hospital attendance and community distribution in Jamnagar and its surroundings.

Maximum patients were married (69.92%) as TB affects mostly the middle age group where most people get married. Previous studies indicate that the stigma associated with TB adds to the burden of disease for both men and women particularly if they are of marriageable age. The 22.55% patients were uneducated, 36.69% primary educated, 45.15% HSC and 3% were graduates. Lower educational status and illiteracy plays an important role and utterly follow unhygienic norms which may be the causes for prevalence of the disease in them. Occupation wise 48.87% patients were hard workers and 50.37% moderate workers which is suggestive of the influence of excessive exertion on disease manifestation. Establishing the Sahasa as major etiological factor the 39.09% patients were very poor, whereas 41.35% lower middle.

The 24.81% patients had positive family history. The problem lies in their failure to understand this complex disease. The early ‘contagion theory’ protagonists, including students of Hippocrates and other Greek scholars, were clearly on the right track.

Diet wise, 79.69% patients were taking mixed food; it shows unhygienic nonvegetarian food sometimes hamper Agni and plays as a key factor in pathogenesis. Evaluating the dominant Rasa, maximum patients (79.69%) had a Katu Rasa dominant diet followed by Lavana Rasa dominant diet (45.86%). Caraka Samhita has elaborately discussed the symptoms caused due to extreme indulgences of Katu Rasa.

Maximum patients (62.41%) addicted to tobacco. It is well known and proven fact that tobacco addiction predisposes the individual to various respiratory system disorders. Tobacco smoking was associated with a two fold increased risk of active TB in a representative cohort of Taiwan’s population. The finding that smoking increases the risk of TB suggests that tobacco control be considered as an important component in the global effort to eliminate TB. The 52.63% patients had Madhyam Koshtha and 30.07% had Krura Koshtha. Kathina Malapravriti (hard stool) was found in 30.40% patients whereas, 15% patients had Drava Malapravriti (loose stool) and 6% patients were having Alpashamala Malapravriti (less fecal matter). These may be considered as one of the associated causative factors of disease as it vitiates Agni. Maximum patients had Vata Pradhana Pittaunubandhi Prakriti (54.13%), followed by vata pradhana kaphamhandhi (37.59%) and Kaphapradhana Pittaunubandhi Prakriti (6.01%) which highlights the association of Vata Dosha in constitution of the patients. 63.90% patients had Rajasika Prakriti and 35.33% Tamasa Prakriti. Rajas and Tamasa are the Doshas pertaining to mind and the types of morbidity caused by them are passion, anger, greed, attachment, envy, ego, pride, grief, worry, anxiety, fear, excitement, etc. Avara Sara was reported in 81.20% patients; Avara Samhanna 71.4%; Avara Satmya 87.96%; Avara Vyavamshakti 80.45%; Avara Satwa 78.19% and BMI <20 (71.4%) which was consider as Avara Pramana. All these conditions lead to lowered immunity and malnutrition. Agni wise prakrititala Ruchi was Pravara in 60.15% patients and it converts in to Avara (91.725) at Vikriti condition. Moreover, Abhyayahara Shakti in also converts Madhyam (46.62%) to Avara (84.21%) Jarana Shakti. Prakrititalaha Madhyamna (47.36%) Pravara (30.82%) and Avara Jarana Shakti (21.80%) in contrast to Vikriti condition of Madhyam Jarana Shakti (51.12%) and Avara Jarana Shakti was observed in 48.87% of patients. The status of Ruchi, Abhyayahara Shakti and Jarana Shakti in Vikriti condition shows hampered agni level in the disease condition.
Discussion

In Rasayana compound-treated group, Kasa (cough) was relieved by 85% \( (P<0.001) \) whereas it was relieved by 43% \( (P<0.001) \) in Control group. The calculated value of \( \chi^2 \) (45.21) is greater than the table value 18.47, corresponding to \( P<0.001 \), hence it is highly significant at 1% level. Thus, the drug Rasayana Compound with AKT is highly efficacious against Cough in comparison to control group. The patients of Rajayakshma, while coughing, spits out Rasa mixed with phlegm. Behind this coughing the pathogenesis of Pratishaya play major role.\(^\text{[8]}\) In the patients whose head is filled up with vitiated Vayu, the Kapha, Rakta (blood) or Pitta located in the upper portion of the nasal passage, moves towards the Vayu as result of which Pratishihaya, which is of serious nature and causes emaciation of the body, is manifested. During excessive expectoration of phlegm, it is Vayu which stimulates the phlegm to come out. Therefore, the physician has to treat such a condition with the help of unctuous and hot remedies.\(^\text{[7]}\) In this pathogenesis Vayu plays major role so, the drugs like Pippali, Haridra, Kushta, Kulinjana as ingredients of Rasayana compound having Tikshna, Ushna, Sukshma Gunas are useful. Phyllanthus emblica shows a dose dependant cough suppressive effect at a minimum dose of 50 mg/kg body weight. A higher dose (200 mg/kg body wt.) orally was seen to be more effective in decreasing the number of cough efforts and frequency of cough.\(^\text{[9]}\) Glycyrrhetinic acid is a pentacyclic triterpenoid derivative of the \( \beta \)-amyrin type. It has expectorant and antitussive properties. Expectorants are used to decrease the viscosity of tenacious mucus, or to increase the secretion of mucus in dry irritant unproductive cough, thereby, lubricating the air passages and making coughing more productive.\(^\text{[9]}\)

Raktanisthavana disappeared in 87% patients in study group \( (P<0.01) \). However, in control group it was relieved with 76.19% \( (P=0.05) \). The calculated value of \( \chi^2 \) (1.163) is lower than the table value 3.36, corresponding to 0.5. Hence, it is insignificant. Thus the drug Rasayana Compound with AKT is not efficacious against hemoptysis in comparison to control group. In Rajayakshma, Rakta does not get nourished from Rasa. Therefore, quantity of other Dhatus is diminish. Even this small quantity of blood in the body gets accumulated because of obstruction in its channel of circulation to Mamsa Dhatu, etc. This blood instead of going downwards comes upwards to the throat.\(^\text{[10]}\) In this condition the use of drugs having Raksha, Snigdha and Sheeta Guna are useful. Rasayana compound drugs like Amalaki, Haridra, Kushta have above qualities. Shonitasthapana Dravyas are also indicated in such condition; which restores blood in its pure form after eliminating its vitiating Doshas.\(^\text{[11]}\) Rasayana compound containing Yashtimadhu can be characterized under this category.

Shwasa was relieved by 71.3% in study group whereas it was relieved by 33.33% in control group both of which are statistically highly significant \( (P<0.001) \). The calculated value of \( \chi^2 \) (28.27) is greater than the table value 18.47, corresponding to 0.001, hence it is highly significant at 1% level. Thus the Rasayana Compound with AKT is highly efficacious against dyspnoea in comparison to control group. These patients suffer from Shwasa because of obstruction of Pranavaha Srotas by Vayu and Kapha\(^\text{[12]}\) and drugs having Kaphaghna and Vatahna properties are effective on it. Rasayana compound containing Haridra, Pippali, Kushta, Kulinjan and Ashwagandha falls in this category. Amalaki, Guduchi and Sariva having Trioshagha properties work on this condition. In Study group, Jwara (fever) was relieved by 95%, whereas in Control group it was relieved by 33.33% both of which were statistically highly significant \( (P<0.001) \). The calculated value of \( \chi^2 \) (12.06) is lower than the table value 13.28, corresponding to 0.01, hence it is insignificant. Thus the drug Rasayana Compound with AKT is not efficacious against fever in comparison to control group. Guduchi and Pippali both being Pachaka, Ushna and Deepana in nature causes Aamapancha as well as relieves the provoked Vata and Kapha thus providing relief fever. Guduchi has been traditionally used in the treatment of fever. The animal studies have produced inconsistent results regarding its potential antipyretic activity.\(^\text{[12-15]}\) Studies established significant anti-pyretic activity of different samples of Guduchi Ghrita (900 mg/kg, single dose) in yeast induced pyrexia.\(^\text{[16]}\) Parshwashoola was relieved by 79% in study group whereas it was relieved by 50.53% in control group both statistically highly significant \( (P<0.001) \). The calculated value of \( \chi^2 \) (24) is greater than the table value 18.47, corresponding to 0.001, hence it is highly significant at 1% level. It has smooth muscle relaxant and mild anti-inflammatory effect. In bronchial asthma this drug relaxes the bronchi and decreases the bronchial inflammation. The inflammatory process may be defined as a sequence of events that occurs in response to noxious stimuli infection. These responses are orchestrated by a highly modulated interaction between mediators of inflammation (e.g., cytokinase) and inflammatory cells. Cytokines represent a group of multifunctional substances that are involved in many steps of the inflammatory response. Cytokines are produced by both resident and migrating cells, macrophages and neutrophils and after release; they can act either locally or systemically. It has been widely shown that most cytokine actions involve the activation and transcription factors and protein kinases that, in turn regulate the expression of many target genes indispensable to the maintenance of the inflammatory state.

In study group decreased appetite was improved by 86% whereas it was improved by 42.06% in control group both of statistically highly significant \( (P<0.001) \). The calculated value of \( \chi^2 \) (55.97) is greater than the table value 18.47, corresponding to 0.001, hence it is highly significant at 1% level. Thus Rasayana compound with AKT is highly efficacious against decreased appetite in comparison to control group. This symptom is caused by the Dosa situated in Aamashtya and Agni vitiated by provoked Dosa and leads to formation of Ama. Guduchi, Pippali and Kulinjana are effective on this pathogenesis to wipe out Ama to make Agni active in the improvement of decreased appetite.

In study group fatigue was relieved by 75% whereas it was relieved by 39.72% in control group both are statistically highly significant \( (P<0.001) \). The calculated value of \( \chi^2 \) (46.37) is greater than the Table value 18.47, corresponding to 0.001, hence it is highly significant at 1% level. Thus Rasayana Compound with AKT is highly efficacious against fatigue in comparison to control group. Fatigue can be described as a range of afflictions, varying from a general state of lethargy to specific work induced fatigue. It can be both physical and mental. Physical fatigue is the inability to continue functioning at the level of one’s abilities. It is ubiquitous in everyday life, but usually becomes
particularly noticeable during heavy exercise. Mental fatigue on the other hand, rather manifests in somnolence. Fatigue, infection and oxidative stress are interrelated. The researches strongly suggest that during immunological activation, there is a significant increase in oxidative stress and curcumin can be a valuable option in the treatment of chronic fatigue syndrome.\cite{17} β-carotene and triphethen have nootropic activity which is present in Yastimadhu, works on immunological depression to inhibit the excess secretion of catecholamine and cortisone.

With regard to fatigue Ayurveda sees main issues as i) Vata Doshas (imbalance of Vata may be seen as an imbalance of the nervous system. This imbalance may cause insomnia, pain headaches, anxiety, sensitivity, etc); ii) increase in toxic substances within the body (toxin pollution of the body changes the correct balance of the Doshas an may cause of the symptoms of fatigue); iii) Reduction of the body’s ability to heal (immunity); iv) overuse, misuse or no use of mental or physical energy that may cause stress of different level (physical, mental, chronic, etc.)\cite{18} Ratriprasadwa was relieved by 92% in study group, whereas it was relieved by 48.58% in control group both statistically highly significant (P<0.001). The calculated value of χ² (31.14) is greater than the Table value 18.47, corresponding to 0.001, hence it is highly significant at 1% level. Thus Rasayana Compound with AKT is highly efficacious against night sweating in comparison to control group.

Body weight was gained by 7.7% in study group whereas 2.04% in control group, both of which statistically highly significant (P<0.001). Anabolic activity reported for Amalaki helps in increasing positive nitrogen balance and total protein level leads to increased body weight.\cite{19} In study group there was decrease in the total leukocyte count by 22.08% (positive result) which was statistically highly significant (P<0.001). The level of Hb gm% was increased by 5.29% and decrease in ESR was by 47.12% both of which are statistically highly significant (P<0.001) whereas the results in lymphocytes, eosinophils and monocytes were negative so no statistical scale could be applied. In control group, total leukocyte count was decreased by 21.26% (P<0.01) and Hb gm% was increased by 6.29% (P<0.01) and the ESR was decreased by 1.94% which was insignificant, whereas the results in lymphocytes, eosinophils and monocytes were negative so no statistical scale could be applied. Guduchi appears to exert a variety of immunomodulatory effects including stimulation of phagocytic functions, macrophage and mitogenic activity, antibody responses, synthesis of interleukins, and humoral and cell-mediated immunity both in vitro and in vivo. The extract of Tinospora caused an increase in body weight, total hemoglobin and hepatic hexokinase.\cite{20} The ethanolic extract of Sanjuresa lappa was found to have exerted a stimulating effect on leukocyte phagocytic activity in dose-dependent manner which justifies its use in autoimmune and chronic inflammatory disorders.\cite{21} Curcumin is a potent immunomodulatory agent that can modulate the activation of T cells, B cells, macrophages, neutrophils, natural killer cells, and dendritic cells. Interestingly, however, curcumin at low doses can also enhance antibody responses.\cite{22} The C-reactive protein (quantitative) was decreased with statistically highly significant (P<0.001) results in both the group, it shows improvement in acute inflammatory condition in this infectious disease. Dhatukshaya Lakshana was found in Meda and Rasa Kshaya and it was statistically highly significant (P<0.001) in study group whereas it was significant (P<0.01) in control group. Rakta Dhatu Kshaya was also improved with significant level at (P<0.01) in contrast to control group where it was insignificant. Majja and Shukra Kshaya were also improved with statistically highly significant (P<0.001) results. All these improvements in Dhatu Kshaya were because of rejuvenating properties of Rasayana compound.

Conclusions

The study revealed that simultaneous administration of general as well as organ-specific Rasayana drugs dealing with respiratory tract along with AKT provides better physical and mental well being to the patients by potentiating therapeutic efficacy of AKT and also counteracting the unwanted effects caused by AKT. Rasayana therapy has antioxidant effect along with nutritive value, immunomodulator, immunoprotective properties and free radical scavenging property. Hence, it has contributed significantly to achieve the goal of health for all particularly in National Health Programme to combat TB to make the ailing society healthy and happy.

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Vyas, et al.: Role of Rasayana compound as an adjuvant in Tuberculosis with AKT

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