e-ISSN: 2456-4435
September 2019 | Vol. 03rd | Issue:4th
International Journal of Research in Indian Medicine

Comparative Clinical Assessment of Efficacy of *Shataputi Abhrak Bhasma* Along With *Chausasti Pippali* as an Adjuvant to AKT in Pulmonary TB

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Abstract-

Worldwide, tuberculosis (TB) is one of the top 10 causes of death, and the leading cause from a single infectious agent. It has been reported that millions of people continue to fall sick with TB each year. Since 1994, with endorsement from WHO; DOTS, Directly Observed Treatment Short course strategy has been implemented worldwide for control of TB. However, the increasing incidence of TB suggests need of newer medicines especially from Ayurveda. *Rajayakshma* has been correlated with pulmonary tuberculosis due to a great deal of similarities in their manifestations. *Abhraka Bhasma* and *Chausasti Pippali* are widely used by Ayurvedic physicians for treatment of various respiratory diseases. This study was designed to elucidate their anti-tubercular efficacy as adjuvant to DOTS therapy. The study was conducted on 60 patients diagnosed with Pulmonary TB and showing signs and symptoms of *Rajayakshma*. They were divided into two groups. The study duration was two months. As per the observations, it was seen that, though both groups were receiving anti-tubercular drugs; the response in the group B patients (DOTS with *Shataputi Abhraka Bhasma* and *Chausasti Pippali*) was comparatively better and earlier in some of the symptoms studied.

Subjective feeling of the sense of well being was enhanced and reported earlier by the patients of Group B. It can be concluded that co-administration of *Shataputi Abhrak Bhasma* and *Chausasti Pippali* along with AKT provided better outcome.

Keywords- TB, DOTS, *Abhrak Bhasma*, *Chausasti Pippali*

Introduction-

Worldwide, tuberculosis (TB) is one of the top 10 causes of death, and the leading cause from a single infectious agent. It has been reported that millions of people continue to fall sick with TB each year. According to WHO report, there were an estimated 10.0 million new cases of TB (range, 9.0–11.1 million), equivalent to 133 cases (range, 120–148) per 100000 population[1]. India has been listed as a high burden country in this report. Thus, it still remains an enigma for healthcare professionals in India and worldwide. Since 1994, with endorsement from WHO; DOTS, Directly Observed Treatment Short course strategy has been implemented worldwide for control of TB. However, the increasing incidence of TB suggests need of newer medicines especially from Ayurveda.

Rajayakshma represents a group of diseases caused by vitiation of *Tridosha* and *Sapta Dhatu* due to excessive indulgence in *Sahasa*, suppression of *Vega*, *Kshaya* of *Dhatu* and *Vishamashana*[2]. It has been correlated with pulmonary tuberculosis due to a great deal of similarities in their manifestations. Various treatises of Ayurveda enlist number of medicines for treatment of *Rajayakshma*. It is need of hour to test their efficacy as an adjuvant to current standard of care. *Abhraka Bhasma* and *Chausasti Pippali* are such medicines which have been widely used by Ayurvedic physicians. This study was designed to elucidate their anti-tubercular efficacy as adjuvant to DOTS therapy.

Materials and Methods:

The study was conducted on 60 patients diagnosed with Pulmonary TB and showing signs and symptoms of *Rajayakshma* selected from OPD & IPD of M. A. Podar Hospital, Worli, Mumbai. They were randomly divided into two groups irrespective to sex and religion. The type of this study was open labelled, randomized, parallel add-on, controlled prospective clinical study. The study was approved by Institutional Ethics Committee of M. A. Podar Hospital, Worli, Mumbai.

Inclusion Criteria: i) age group of 15 to 60 years were selected irrespective of their gender. ii) newly diagnosed cases of sputum test positive for AFB.

Exclusion Criteria: i) Age below 15 years and above 60 years. ii) Having HIV positive status; iii) cases of relapsed TB iv) Patients on steroid therapy v) Patients with immuno-compromised conditions such as chronic liver diseases, renal failure etc vi) Pregnant and lactating females vii) Body weight less than 30 kg.

The informed consent of all the patients were taken prior to any study related procedure.

The patients were randomized in two groups as follows-

- **Group A (Control group)** -The patients were given standard regimen of Pulmonary TB under RNTCP (Revised National Tuberculosis Control Programme) protocol[3] as- i) Isoniazid (H) 600 mg, ii) Rifampicin (R) 450 mg, iii) Pyrazinamide (Z) 1500mg, iv) Ethambutol (E) 1200 mg
    - Thrice a week on alternate days as DOTS
    - Duration: 60 days (2 months)
- **Group B (Study group)** - The patients were given *Shataputi Abhrak Bhasma* + *Chausasti Pippali* daily along with the standard regimen of AKT same as that of Group A.
    - Dose of *Shataputi Abhrak Bhasma*- 125 mg thrice a day with water
    - Dose of *Chausasti Pippali*- 250 mg thrice a day with water
    - Duration: 60 days (2 months)

Both the drugs i.e. *Shataputi Abhrak Bhasma* and *Chausasti Pippali* were procured from a GMP certified reputed Ayurvedic pharmacy. *Abhrak Bhasma* is a reputed medicine for various respiratory disorders and lung diseases[4]. *Chausasti Pippali*, which has potentiated Piper longum as ingredient is known to help in treatment of TB[5].

-Diet & lifestyle Recommendation - All the patients were advised to continue their normal routine diet and lifestyle

-Investigations: The below investigations were carried out.

1) CBC, ESR, LFT- on Day 0, Day 15, Day 30, Day 60

2) Urine routine examination and BSL- on Day 0 and Day 60

3) X-ray chest PA view- On Day 0, Day 30 and Day 60

4) Sputum test for AFB- on Day 0, Day 15, Day 30, on completion of study for three consecutive days

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

Table no. 1- Showing criteria of assessment of signs and symptoms

Sr. No.	Symptom	Grade	
1	***Kasa* (Cough)**	0	Absent
		1	One to five bouts of cough in every three hours
		2	Six to ten bouts of cough in every three hours
		3	More than ten bouts of cough in every three hours and chest pain due to excessive coughing
2	***Shwas* (Dyspnoea)**	0	Absent, Respiratory Rate(RR) is normal, i. e. 16-18/min
		1	Occasional breathlessness, but patient can continue routine activities, RR – 20-24/min
		2	Frequent episodes of breathlessness with difficulty in continuing routine work, RR – 24-28/min
		3	Recurrent episodes of severe breathlessness that requires hospitalization, RR > 28-32/min
3	***Jwara* (Fever)**	0	Normal body temperature (97-98^0 F)
		1	Body temperature 98-100^0 F
		2	Body temperature 100-102^0 F
		3	Body temperature > 102^0 F
4	***Arochaka* (Tastelessness)**	0	Normal taste for food and normal appetite
		1	Dislike for food because of distaste and food consumption is slightly reduced
		2	Dislike for food because of distaste and food consumption is markedly reduced
		3	The patient does not eat due to tastelessness in mouth and may feel nauseating or may vomit on forceful consumption of food
5	***Swarabheda***	0	Normal voice

	(Hoarseness of voice)	1	The patient has to give slight stress to be audible and slight hoarseness of voice
		2	The patient has to give extensive stress to be audible and complete hoarseness of voice
		3	The patient's voice is just audible with extreme stress on the vocal chords
6	***Shiraso Paripurnatvam* (Feeling of fullness in the head)**	0	Absent
		1	Heaviness in the head but the patient can bear with it
		2	Heaviness in the head and the patient requires medication to relieve the pain
		3	Unbearable heaviness in the head and the patient requires frequent medication orally and may be parentally also for transient relief
7	***Ansamarda* (Pain in scapular region)**	0	Absent
		1	Mild bearable pain, but constant feeling of discomfort is present.
		2	Moderate local pain and requires the rest and analgesics to relieve the pain
		3	Severe local pain, not relieved even after taking analgesics
8	***Shleshma Chhardana* (Vomiting with mucus)**	0	Absent
		1	One to five times vomiting in every three hours
		2	Six to ten times vomiting in every three hours
		3	More than ten times vomiting in every three hours
9	***Shonita Shthivana* (Haemoptysis)**	0	Absent
		1	Occasional appearance streaks of blood in the expectoration
		2	Frank bleeding with mucus present in the expectoration
		3	Frank blood bouts of expectoration and requires immediate management

10	***Parshwa Sanrujana* (pain in the flanks)**	0	Absent
		1	Mild bearable pain, but constant feeling of discomfort is present.
		2	Moderate local pain and requires the rest to relieve the pain
		3	Severe local pain and requires analgesics to relieve the pain
11	***Atisara* (Loose motions)**	0	Absent
		1	3 to 4 loose motions in 24 hours
		2	6 to 8 loose motions in 24 hours
		3	More than 10 episodes of loose motions in 24 hours and signs of dehydration are present in patient.
12	**Gain in body weight**	0	Patient's weight at the beginning of the trial
		1	Gain in weight by ½ - 1 kg
		2	Gain in weight by 1 - 2 kg
		3	Gain in weight by > 2 kg

Observations and results:

It was observed from the demographic data that, 38.33% patients belonged to age group of 41-60 years. It shows that both women and men with TB are likely to be after 40 years age.

Maximum patients (65%) were males which highlights that bio factors like gender, influence of the susceptibility and immunity of different genders towards TB.

Religion-wise maximum patients (85%) were Hindu which was probably due to Hindu majority area of patient inflow.

Maximum patients were married (80%) as TB affects mostly the middle age group where most people get married.

The 30% patients were illiterate, 33.33% primary educated, 20% HSC and 16.67% were graduates. Lower educational status and illiteracy plays an important role are exposed to unhygienic conditions which may be the causes for prevalence of the disease in them.

Occupation-wise 45% patients were doing job whereas 28.33% housewives were there. Due to illiteracy, many patients were hard workers which are

suggestive of the influence of excessive exertion (*Sahasa*) on disease manifestation. About 42% patients were belonging to poor class and 33.33% to lower middle class.

Diet wise, 80% patients were taking mixed diet; it shows unhygienic non-vegetarian food, heavy to digest, sometimes vitiates Agni and plays as a key factor in pathogenesis of Tuberculosis.

45% patients were addicted to tobacco. It is well known and proven fact that tobacco addiction predisposes the individual to various respiratory system disorders[6]. 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.

Maximum patients (60%) had *Vishamagni* which may be due to predominance of *Vatadosha* in pathophysiology of disease. 36.67% patients had *Mandagni*. The 53.34% patients had *Madhyam Koshtha*, 13.33% *Mrudu Koshtha* and 33.33% had *Krura Koshtha*.

Maximum patients had *Vata Pradhana Pittaunubandhi Prakriti* (23.33%), followed by *Kaphapradhana Pittanubandhi Prakriti* (20%) and *Vata pradhana Kaphanubandhi* (13.33%) which highlights the association of *Vata Dosha* in constitution of the patients.

Symptoms occurrence-wise distribution:

Table no.2- Showing distribution of occurrence of symptoms in group A and B

Sr. No.	Symptom	Patients in Group A		Patients in Group B	
		No.	%	No.	%
1	***Kasa***	30	100	30	100
2	***Shwasa***	22	73	19	63.33
3	***Jwara***	30	100	30	100
4	***Arochaka***	30	100	30	100
5	***Swarabheda***	06	20	06	20
6	***Shiraso Paripurnata***	21	70	13	43.33
7	***Ansamard***	27	90	20	73.33
8	***Shleshma Chhardana***	22	73.33	23	76.67
9	***Shonita Shthivana***	02	6.67	01	3.33
0	***Parshwa Sanrujana***	19	63.33	21	70.00
11	***Atisara***	01	3.33	01	3.33

Improvement in these symptoms during the course of the study was observed in

both the groups. The data generated through clinical study was analyzed with appropriate statistical tests.

- ***Kasa***: The mean grade score of *Kasa* in group A was 2.23 ± 0.68 before treatment which got reduced to 0.2 ± 0.55 at the end of 8 weeks. The improvement in *Kasa* was statistically significant too (P < 0.001). The mean grade score of *Kasa* in group B was 1.73 ± 0.64 before treatment which got reduced to 0.07 ± 1.513 at the end of 8 weeks. The improvement in *Kasa* was statistically significant too (P < 0.001).
- ***Shwasa***: The mean grade score of *Shwasa* in group A was 1.03 ± 0.80 before treatment which got reduced to 0.1 ± 0.402 at the end of 8 weeks. The improvement in *Shwasa* was statistically significant too (P < 0.001). The mean grade score of *Shwasa* in group B was 0.83 ± 0.75 before treatment which got reduced to 0.06 ± 1.81 at the end of 8 weeks. The improvement in *Shwasa* was statistically significant too (P < 0.001).
- ***Jwara***: The mean grade score of ***Jwara*** in group A was 1.13 ± 0.345 before treatment which got reduced to 0.1 ± 0.305 at the end of 8 weeks. The improvement in ***Jwara*** was statistically significant too (P < 0.001). The mean grade score of ***Jwara*** in group B was 1.23 ± 0.43 before treatment which got reduced to 0.03 ± 0.182 at the end of 8 weeks. The improvement in ***Jwara*** was statistically significant too (P < 0.001).
- ***Arochaka***: The mean grade score of *Arochaka* in group A was 1.5 ± 0.63 before treatment which got reduced to 1.23 ± 0.345 at the end of 4 weeks. The improvement in *Arochaka* was statistically significant too (P < 0.001). This improvement continued upto 8th week. The mean grade score of *Arochaka* in group B was 1.5 ± 0.63 before treatment which got reduced to 0.16 ± 0.46 at the end of 8 weeks. The improvement in *Arochaka* was statistically significant too (P < 0.001).
- ***Swarabheda***: The mean grade score of *Swarabheda* in group A was 0.32 ± 0.68 before treatment which was almost absent the end of 4 weeks. The improvement in *Swarabheda* was statistically significant too (P < 0.001). At the end of 8th week, this symptom was absent in all 6 patients. The mean grade score of *Swarabheda* in group B was 0.2 ± 0.41 before

treatment which got reduced to almost zero at the end of 6 weeks. The improvement in *Swarabheda* was statistically significant too (P < 0.001).

- ***Shiraso Paripurnatvam***: The mean grade score of *Shiraso Paripurnatvam* in group A was 0.76 ± 0.62 before treatment which was almost absent the end of 8 weeks. The improvement in *Shiraso Paripurnatvam* was statistically significant too (P < 0.001). The mean grade score of *Shiraso Paripurnatvam* in group B was 0.47 ± 0.57 before treatment which got reduced to almost 0 at the end of 6 weeks. The improvement in *Shiraso Paripurnatvam* was statistically significant too (P < 0.001). After 6 weeks the *Shiraso Paripurnatvam* was absent in both the groups.

- ***Ansamarda***: The mean grade score of *Ansamarda* in group A was 1.05 ± 0.525 before treatment which was 0.4 ± 0.49 at the end of 8 weeks. The improvement in *Ansamarda* was statistically significant too (P < 0.001). The mean grade score of *Ansamarda* in group B was 0.93 ± 0.78 before treatment which got reduced to 0 at the end of 8 weeks. The improvement in *Ansamarda* was statistically significant too (P < 0.001).

- ***Shleshma Chhardana***: Though all the patients had Kapha Nishthivana, the amount of expectoration in 8 patients was very less. Hence those patients did not complain of this symptom. 22 patients had marked expectoration which drew their own attention. The mean grade score of *Shleshma Chhardana* in group A was 0.96 ± 0.81 before treatment which got reduced to 0.7 ± 0.595 at the end of 3 weeks. The improvement in *Shleshma Chhardana* was statistically significant too (P < 0.001). The trend of reduction of this disturbing symptom continued till the end of the study.

  The mean grade score of *Shleshma Chhardana* in group B was 0.97 ± 0.71 before treatment which got reduced to 0.53 ± 0.50 at the end of 4 weeks. The improvement in *Shleshma Chhardana* was statistically significant too (P < 0.001). Thereafter the improvement gradually continued and at the end of the trial, the mean grade score was 0 which is an encouraging finding.

- ***Shonita Shthivana***: Small amount of blood stained sputum was reported by 2 patients enrolled in group A which

did not show any improvement till the end of 2nd week. At the end of 3rd week, this symptoms was absent in both the patients. The mean grade score of *Shonita Shthivana* in group A was 0.06 ± 0.25 before treatment which was absent at the end of 3 weeks. The improvement in *Shonita Shthivana* was statistically significant too (P < 0.001). Small amount of blood stained sputum was reported by 1 patient enrolled in B group. The mean grade score of *Shonita Shthivana* in group B was 0.1 ± 0.31 before treatment which got reduced to 0 at the end of 3 weeks. The improvement in *Shonita Shthivana* was statistically significant too (P < 0.05). There was no *Shonita Shthivana* was seen in patients of both the groups.

- ***Parshwa Sanrujana***: The mean grade score of *Parshwa Sanrujana* in group A was 0.7 ± 0.65 before treatment which got reduced to 0.03 ± 0.182 at the end of 8 weeks. The improvement in *Parshwa Sanrujana* was statistically significant too (P < 0.001). The mean grade score of *Parshwa Sanrujana* in group B was 0.87 ± 0.68 before treatment which got reduced to 0.33 ± 0.48 at the end of 8 weeks. The improvement in *Parshwa Sanrujana* was statistically significant too (P < 0.001).
- ***Atisara***: *Atisara* symptom was present in only one patient in each group. It was of mild variety (grade 1) which got subsided in one week of commencement of treatment.
- **Gain in body weight**: In group A - Considering the mean grade score of weight gain in the first week as 0, at the end of 4th week the mean grade score was 0.3 ± 0.66 and t value was 3.33 (P < 0.01), showing a significant weight gain. At the end of the trial, mean grade score was 1.1 ± 0.48 which was statistically significant too (P < 0.01). In group B - Considering the mean grade score of weight gain in the first week as 0, at the end of 4th week the mean grade score was 0.6 ± 0.49 and t value was 7.5 (P < 0.01), showing a significant weight gain. At the end of the trial, mean grade score was 1.6 ± 0.48 which was statistically significant too (P < 0.01).
- **Laboratory investigations**: All patients of Rajayakshma included in the trial were evaluated for SGOT, SGPT, Serum Bilirubin, Haemoglobin, ESR, Urine analysis and blood sugar levels. These investigations were done at the entry after 30 days and at the end of the

trial. There were no significant changes observed in any of the parameters.

- **X-ray chest**- The changes in the chest X-ray of both groups were similar and there was no notable difference.
- **Sputum**- Sputum for AFB was examined initially and at the end of 2 weeks, 4 weeks and 8 weeks of the study. Practically all the patients responded at the end of 2nd week barring two patients, one each in both groups. They also responded at the same time i.e. by the end of 4th week.

Discussion & Conclusion-

As per the above observations, it was seen that, though both groups were receiving anti-tubercular drugs; the response in the group B patients was comparatively better and earlier in some of the symptoms studied. Subjective feeling of the sense of well being was enhanced and reported earlier by the patients of Group B.

It can be concluded that co-administration of *Shataputi Abhrak Bhasma* and *Chausasti Pippali* along with AKT provided better outcome. The results seen in this study seem to be encouraging. It seems that the symptoms of TB got alleviated earlier. Sense of well being and weight gain in Group B patients were also better. Hence, it appears that such kind of synergistic regimen may prove in achieving national goal to care and cure for TB patients.

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Cite this article:

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Ayurline: International Journal of Research In Indian Medicine 2019; 3(4) : 1 - 12