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**COMPARATIVE STUDY OF EFFECT OF SHATPALA GHRUTA +CAT 1
AND ONLY CAT 1 IN RAJAYAKSHAMA VYADHI WITH SPECIAL
REFERENCE TO PULMONARY TUBERCULOSIS**

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ABSTRACT:

Rajayakshma one among the eight mahagad mentioned in Samhitas was challenging, and the epidemiologically survey have explained the gravities of the disease worldwide. Keeping these two points in mind the research work on Rajayakshma was selected. It is fact that Ayurvedic management alone may not be able to kill the bacterial population completely and modern management has its lacunae due to adverse effects and toxicity of chemotherapy. Therefore it is a need of today to implement such an integrated system of medicine that can ensure complete cure as well as quality of life to the future of country. Among 178 formulation mentioned in Bruhatrayi, Shatpala Ghruta was selected as because while going through the ekal dravya chikitsa maximum no of drugs mentioned under the heading of Shatpala ghruta are been referred for the chikitsa of Shosha. Open comparative study of effect of shatpala Ghruta +Cat 1 and only Cat 1 in the management of Rajayakshma with special reference to pulmonary tuberculosis. Group A - (CAT 1) + Shatpala Ghruta (Trial group) Group B – (CAT 1) only (Control group). Duration of study :- 3 month. Effect of Shatapala with cat 1 provided on an average two week early recovery of symptoms as compare to control group where only the cat 1 is advocated.

Key words: Ayurveda, Chikitsa, Rajayakshma, mahagad, Shatpala Ghruta,

INTRODUCTION

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Tuberculosis is one of the oldest disease know to the mankind, one among the hardest to conquer. The concept of contagious disease was known to the *Acharyas* thousands of year back and they have beautifully quoted this, in their classics as follows. With the best attempts, distributing free Antitubercular drugs in the market, Indian government in trailing back, finding difficult to conquer this disease, every second day there are breaking new about MDR and TDR, proving to be a tough job for the doctors as well as government worldwide. After so many years when the promising results of Ancients science are coming forwards governments is also taking stringent step to encourage research in these corners.

The data put forward by WHO is literally shocking and so is one among the six targeted disease by WHO expanded programme of the immunisation. On the other hand report submitted by central bureau of the health, are even dreadful

and appalling, which quotes that about three million people die from tuberculosis every year worldwide certain surveys have revealed that the number of cases have reached from 610,531 in 1977 to 852,334 in 1987. Four to five million new cases of acute, highly contagious pulmonary tuberculosis emerge annually. In addition to this an equal number of less serious forms appear bringing the world total to 10 million new cases every year.

It is fact that Ayurvedic management alone may not be able to kill the bacterial population completely and modern management has its lacunae due to adverse effects and toxicity of chemotherapy. Therefore it is a need of today to implement such an integrated system of medicine that can ensure complete cure as well as quality of life to the future of country. The extended help of herbal medicine for growing no of cases of Koch's might come like a boon to health sciences. Especially to the scientists who are working in the same direction.

Among 178 formulation mentioned in *Bruhatrayi*, *Shatpala Ghruta* was selected as because while going through the *ekal dravya chikitsa* maximum no of drugs mentioned under the heading of *Shatpala Ghruta* are been referred for the *chikitsa* of *Shosha*. There are many references and supporting studies on the effect of these single drugs mentioned

above in treatment of tuberculosis. Going through many references in *Samhita*, Peer review Journals this particular formulation was the only one which has shown the better chances in treatment of tuberculosis. The world is looking intensely with hopes towards the ancients' methods of healing as because of growing resistance to the modern drugs. The best example of which is the addition of *Pipali* to Rifampicin to increase the availability and decreasing the resistance of Rifampicin. Taking all these points under consideration this formulation was selected.

AIMS & OBJECTIVES

1) Open comparative study of effect of *shatpala Ghruta*+Cat 1 and only Cat 1 in the management of *Rajayakshma* with special reference to pulmonary tuberculosis.

Group A - (CAT 1) + *Shatpala Ghruta* (Trial group)

Group B – (CAT 1) only. (Control group)

2) To study the available literature on “*Rajayakshma*” and pulmonary tuberculosis especially the diagnostic, prognostic and treatment modalities along with recently published literature available on topic.

(3) To suggest the mode & onset of action of *Shatpala Ghruta* +Cat 1.

MATERIALS & METHODS

INCLUSION CRITERIA

- Patient showing classical symptoms and signs of *Rajayakshama* and having sputum positive for AFB were selected from the TB (Dots) OPD of Y.M.T.Ayurvedic Hospital.
- Patient of both the sexes were included and those who gave voluntary informed consent were included.
- Patient between age group of 18 to 60 yrs of age.

EXCLUSION CRITERIA

- Patient with Extra pulmonary TB, M.D.R. TB.
- Pulmonary Tuberculosis along with co-morbid condition i.e. D.M., C.O.P.D., Jaundice, CA of any organ.
- Age below 18 yrs and above 60 yrs.
- Pregnant and lactating mothers.
- Acute life threatening condition.
- Immuno compromised patients.

DRUG REVIEW

Ingredients of *Shatpala Ghruta*:

- 1) *Pipali*
 - 2) *Pipalimoola*
 - 3) *Chavya*
 - 4) *Chitrak*
 - 5) *Shunthi*
 - 6) *Yavakshar*
- } each one is 1 part.

- 7) *Ghruta* - 4 parts
8) Godugdha - 4 parts

The drug has been selected from text
Charak Samhita, Chikitsa Sthan,
Chapter 8/169

Ch.chi.8/169

PLAN OF STUDY

Type of study : Open Comparative
Clinical Study.

Follow up study : Every fifteen days

Number of patients: - 60 Patients 30 in
each group

Drug : *Shatapala Ghruta*.

Group A - (CAT 1) + *Shatapala
Ghruta*(Trial group)

Dose of drug: 15 ml BD. orally/day
before meals.

Group B – (CAT 1) only. (Control group)

Anupan: Luke warm water

Duration of study: 3 month

Diet : Patient was encouraged to have
their usual diet.



Table: No :01 Gradation of Subjective Criteria for assessments:

No.	Symptoms	Grade 0	Grade 1	Grade 2	Grade 3
1)	Sakapha kasa(Cough with expectoration)	No cough	4-5 Bouts of cough/day	8-10 Bouts/day	Continous cough causes insomnia patients has to seat on the bed.
2)	Jwara (fever)	Normal body temperature	Body tem upto 100°f	Body tem upto 102°f	Body tem above 102°f
3)	Aansantap (Pain around shoulder joint)	No Pain	Dull Pain	Patient has lie down to relieve pain.	Patient has to lie down continuously due to Pain.
4)	Swarbheda (Hoarseness of voice)	Normal Voice	Slight hoarseness of voice	Hoarseness of voice but word understandable	Hoarseness of voice but words not understandable
5)	Parshvashool (Pain in flank region)	No Pain	Pain during inspiration tolerable.	Pain during inspiration,exp iration and slight breathlessness after talking.	Continuous Pain with breathlessness.
6)	Shirshool (Headache)	No Pain	Dull tolerable ache.	Patients has to hold head require analgesic	Severe Pain can not tolerate without medication and has to have repeated dose of

				medication.	medication.
7)	Raktastivan/Raktava man(Haemoptysis.	No blood in sputum/Vomiting.	Slight streaks blood in sputum.	Copious blood about 10 cc to 60cc in sputum.	Severe blood loss require blood transfusion about 300cc/coffe ground vomiting.
8)	Shawas (Breathlessness)	No breathlessness	Breathlessness after exercise or long talk about 10 min	Breathlessness Continuous without exercise and cynosis	Continuous breathlessness with cyanosis.
9)	Aruchi (Testlessness)	No testlessness	No test of food but eats normally	Feels vomiting sensation on the sight of food of the patients liking.	Nauseating feeling at thought of food and smell.
10	Kshudamandya (Loss of appetite)	Normal appetite	Patients eats 3 times/day but less quantity	Patients eats 2 times/day but less quantity	Patients eats only 1 times/day.
11	Daurbalya (Generlised weakness)	No weakness	Generlised weakness occurs after 30 min after regular exercise	Generlised weakness occurs after 10 min after regular exercise	Generlised weakness occurs at rest

Objective: CBC, ESR every second follows up X-ray at beginning and end of study, sputum and weight examination every 15 day

Criteria for overall assessment of therapy

1) Markedly improved:

- 1) 100% relief in sign and symptoms.
- 2) Weight gain >3 to 5 kg.
- 3) Sputum negativity within 15 day.

2) Moderately Improved:

- 1) 75 to 99% relief in sign and symptoms
- 2) Weight gain > 1 to 3 kg.
- 3) Sputum negativity after 15 day within 1 month.

3) Mild improvement:

- 1) 50 to 75% relief in signs and symptoms
- 2) Weight gain <1 kg.
- 3) Sputum negativity after 1 month.

The data obtained from the patients was subjected to statistical analysis. Group wise analysis of data was done using Unpaired" t" test.

OBSERVATION & RESULTS

Sakpha kasa: as both group received cat 1 regimen anti tubercular medication. The response to Sakpha kasa in patients of control group A Which was trial group *Shatapala Ghruta* with Cat 1 regimen antitubercular drugs is statistically highly significant, right from first follow-up that is at the end of first 15 days .Complete relief in Sakapha kasa was seen in trial group at the end of 5th follow up as compared to control group.

Jwara-It is interesting to note that initial mean grade score are quite comparable i.e 2.767 for both the groups but the Group A patients response to the trial drug was statistically highly significant at the end of first follow up (T=8 p<0.001)where as group B patients did not show any marked improvement statistically at the end of first followup (T=4.39,P<0.001) improvement was only seen after two weeks.

Table: No :02, Hetu wise distribution:

Hetu	Trial Group patients		Contol Group patients	
	No	%	No	%
Vishamshan	20	66.6	18	60
Sahas	4	13.3	5	16.6
Vegavarodh	2	6.6	4	13.3
Kshaya	4	13.3	3	10
Total	30	100	30	100

The present data shows maximum number of patients in both Group belonging to hetu vishamashan.

Diet: In the present study Majority of the Patients were vegetarians compare to non

veg diet. Thus we can conclude that those consuming nonveg diet are less likely to suffer from pulmonary tuberculosis. Because the one who consume nonveg diet are likely to get more protein which is an important factor for building immunity.

EFFECT ON SYMPTOMS

Table: No :03, Observations

Sr. No.	Symptom	Trial Group		Control Group	
		% of patients affected	% of Relief	% of patients affected	% of Relief
1.	Sakapha Kasa	100%	100%	100%	96.56%

2	Jwara	100%	100%	100%	96.33%
3	Hoarseness of voice	66%	100%	66%	100%
4	Loss of appetite	100%	97.68%	100%	65.52%
5	Raktastivan	50%	100%	50%	100%
6	Shirashool	76%	100%	70%	96.47%
7	Aruchi	100%	97.1%	90%	67.58%
8	Generlised weakness	100%	94.11%	96.67%	76.46%
9	Shwasa	93.3%	92.48%	100%	76.06%

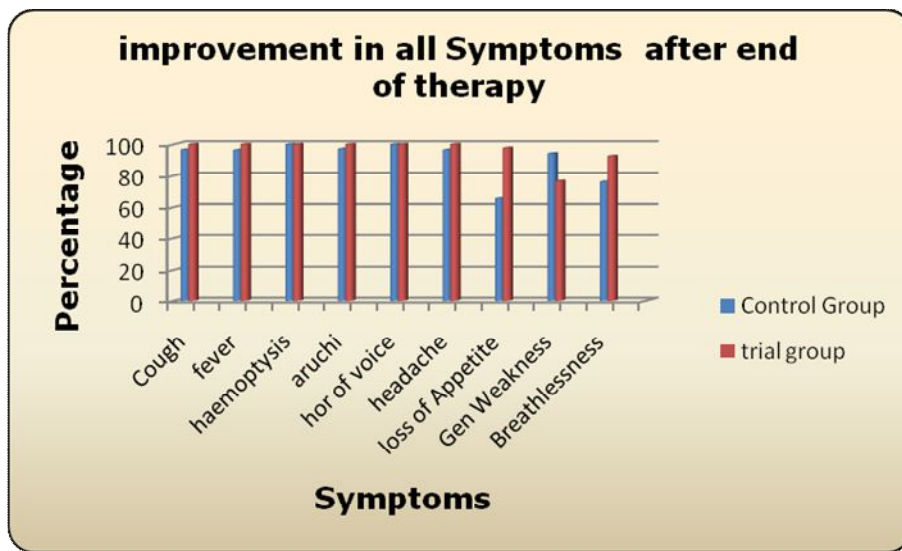


Table: No :04, 1) Symptoms wise improvement

Improvement in Percentage	Trial Group	Control Group
Marked	55.5	22.2
Moderate	44.4	55.5
Mild	0	22.2

Table: No :05, 2) Sputum wise improvements-

Improvement in Percentage	Trial Group %	Control Group %
Marked	100	0
Moderate	0	90
Mild	0	10

Table: No :06, 3) Improvement in weight:

Improvement in Percentage	Trial Group	Control Group
Marked	80	10
Moderate	20	90
Mild	0	0

DISCUSSION

Probable mode of action

Properties of *Shatapala Ghruta*

Rasa: Tikta, Katu

Virya: UShna

Vipak: Madhur, katu.

Karma: Deepan Pachan, Lekhan, Vatanuloman.

Effect: *Samprapti Bhang*, Tridoshnashak.

As described earlier during the Pathogenesis agnimandya is the first step involved. Katu, Tikta rasa, Laghu Ushna, tikshna guna and Ushna virya of the drug will help to combat agnimandya. It is well established fact that Tikta, katu rasa has deepan, pachan, Shodhana and Strotovivaran properties. Contents of the *Shatapala Ghruta* have Kshyagna properties which is clearly mentioned by different Nighantus.

Second major step i.e strotorodh and dhatwagnimandya are key points in pathogenesis of *Rajayakshma*. The study formulation drug comprises of Pipali, *GoGhruta* which have Yogavahi properties meaning there by it enhances the efficacy of the drug with which it is used. Panchkola have katu, Tikta rasa and ushna Virya, Vatakaphagna properties which removes the obstruction from all strotas and leads Strotovivaran effect.

Yavakshar is mentioned to have Lekhan, Chedhan, Bhedhan Ushna, tikshna guna and Strotoshodhan properties which ultimately augments agni and also help to withheld the further progress of the disease.

Pipali, Chitrak is said to have rasayan properties, which plays important role in pacifying doshas at level of dhatvagni and helps to combat Dhatvagni mandya. Acharya Charaka have mentioned Pipali in *Rajayakshma* i.e vardhaman Pipali Rasayan which is approved remedie on both the ground i.e increasing local immunity (pranavahastrotas) and to fight infection.

As already mentioned pipali has synergistic effect once combined with rifampicin. There are established studies which prove how the dose of antitubercular drug can be reduced or cut down to half once combined with the herbal drugs pertaining anti tubercular action.

The first thing that is required to combat any infectious disease is to bring down the infection. No doubt that all the antitubercular drugs have bacteriostatic and bacteriocidal effects, but an added effect of certain herbal drug definitely helps to bring down the infection rapidly and decrease the overall tenure of

antitubercular drugs. There are many supported study which have proved the bacteriostatic action of many single herbal drugs, the promising antibacterial antiviral effects of these herbal drugs have directed many scientist in the world to study in the direction of combining the herbal drugs to modern drugs. These might be true with this formulation i.e. *Shatpala Ghruta* where the majority of content hold the antibacterial properties.

Patient suffering from kochs presents with fever, breathlessness, pain. If we only consider breathlessness as of know we can confidently say that *shatpal Ghrutam* helps to combat the inflammation of the wind pipe, clear the excessive mucoid secretion. Contents such as *yavakshar, pipali, chitrak, sunthi* have proved anti inflammatory as well as expectoration properties, which thus helps to relieve cough and breathlessness due to

obstruction. added effect to the antitubercular drug might be because of these propertie of herbal drugs as the anti tubercular drug dosenot have good expectoration properties. It is important to combat infection but at the same time it is also important to expectorate the unsterile mucoid secretion, where herbal drugs have there atmost importance.

All antitubercular drugs are hepatotoxic and have tendency to form gastritis, which is the leading cause for anorexia. Authentic studies have shown that maximum drop out while treating the patients are because of gastritis and anorexia. This problem can be easily tackled with the help of *shatpal Ghrutam* which easily tackles anorexia and provides a protected coating over gastric mucosa and avoid condition like gastritis and anorexia. +

CONCLUSION

1. Effect of *Shatapala* with cat 1 provided on an average two week early recovery of symptoms as compare to control group where only the cat 1 is advocated.
2. The haematological parameters have shown significant changes in reduction of total leucocytes count and ESR in all the patients. And there was significant

improvement in Hemoglobin in Trial Group as compare to control group.

3. In trial group there were significant improvements in the weight gain of the patients i.e. approximately (3.5-5kg) as compare to Control groups.

4. A striking observation during the research works was early sputum negativity which is

the best part of study as because the open (15day).
infection can be limited to a shortest tenure

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