Summary and Conclusion

The assignment impressed on me covers a "Study on the effect of Ayurvedic medicine on the bioavailability on antitubercular drugs". There is an evidence of the disease Pulmonary Tuberculosis in Vedic literature and Charak Samhita (chikitsa-8/7) mentioned as Rajyaksham (Ch.Chi-8-13) due to over exertion without proper nutritional causes wasting and ultimately it causes immunosuppression.

The present study opened a new vista in the management of PTB patients. Prevailing knowledge of Ayurvedic medicine could be intricated with the existing medical system for better treatment. It is known from vedic period that for quality of life optimum quantity and quality of Life Principle "*oja*" is essential. *Oja* also considered as immunomaterial. The drugs under study (Aswagandha, Silajit, and Chawyanprash) known to possesses immuno-modulatory activity by means of '*ojavardhaka*' activity. Hence, the reference made in vedic literature.

Atharba 6/13/1

"Oh, diseased person I am the oja, I can help to get rid from obscure diseases like Rajayakshma (Pulmonary tuberculosis) with the strength to curb the poison".

It was contemplated to evaluate the role of immunomodulatory Ayurveda Rasayan drugs on the therapeutic management of pulmonary tuberculosis patients. All investigations were done on new patients (those not consumed ATD earlier) as adjunct to 4 regimen (HREZ) AT Drug. The present report comprise 4 phases of clinical trial with 136 patients.

1. While starting the Phase I clinical trial, the objectives fixed required to change subsequently as the trial progresses.

2. In Phase I, we concentrated on the study, whether addition of Immunomodulatory Ayurvedic drugs the appreciable physical change along with increased body weight observed is due to bio-availability of AT Drugs or not? As such we studied blood isoniazid concentration after 2h of (HREZ) AT drug administration Aswagandha or Silajit was added in the therapy thereafter 28 days of treatment two blood samples were drawn again on day 29, one at 0'hour and another 2h after ATD. Investigation of some samples of blood revealed there was 10-15% increment in blood isonizid concentration. But the basal level (μg/ml) on 0'day (after 2h) no uniformity was observed. There were wide variations. We presumed that the differences among he patients may be due to individual variation on bioavailability in PTB patients.

3. In Phase II study, 5 patients in each group were included comprising 4 groups with inclusion of Chawyanprash. Emphasis was given on the blood isoniazid concentration estimation. Blood samples were drawn 0'day at 1h, 2h, 4h after AT Drug. The study was repeated on day 29' where 4 samples were drawn 0h and 1h, 2h, 4h after ATD. In Phase I after the study period in 2 patient of ATD group out of 12 patients sputum was positive. Similar results was also deserved in Phase II with ATD group.

4. In Phase III, we concentrated on all the parameters systematically with symptom scoring clinical trials 40 patients were included, 10 in each group. We estimated blood pyrazinamide concentration before (0'day) and after (29'day) treatment. IgA and IgM could not be estimated due to limitation.

5. In some of the patients of ATD group after drug therapy liver function profile was raised, while in two patient on entry raised LFT was detected. In those patients in the course of ATD + Ayurvedic drugs treatment, the raised LFT profile came down

to normal level. In two patients raised blood sugar was detected on entry. After treatment with ATD + Ayurveda drugs came down to normal.

6. In Phase III study the objectives was modified and we concentrated to investigate the sputum bacterial load serially starting from day 10' onwards. It was observed that the bacterial load coming down and the decrease was significant in comparison to AT Drug group. The sputum bacterial load started becoming negative from day 17' onwards and completed by day 26'. While on day 29' in ATD group 50% of the patients receiving only ATD remained positive, confirmed our earlier observations of Phase I and Phase II.

7. In Phase IV study the objectives was the same and it was conducted to repeat and verify the earlier results. It sputum bacterial load, routine blood picture, blood biochemistry and well being corroborated finding of Phase III clinical trial.

8. Other interesting information came to our notice that while on inspection appreciable physical change could be observed which corroborate our symptom study including well being scale. We could not keep the photograph of individual or group of patients. After discontinuation of Immunomodulatory Ayurveda Rasayan drugs AT Drug continued as per schedule in all the groups, in total 136 patients.

9. Out of 136 patients included in this study, 2 patient died in between the treatment.