

EFFECT OF AYURVEDIC IMMUNOMODULATOR ON TREATMENT OF TUBERCULOSIS: A CASE CONTROL STUDY



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DOI: <https://doi.org/10.29121/granthaalayah.v8.i5.2020.202>

Article Type: Case Study

Article Citation: Dr. K. Venugopal, Dr. Sreelatha P.R, and Dr. Thresiamma T.P. (2020). EFFECT OF AYURVEDIC IMMUNOMODULATOR ON TREATMENT OF TUBERCULOSIS: A CASE CONTROL STUDY. International Journal of Research -GRANTHAALAYAH, 8(5), 390-394.
<https://doi.org/10.29121/granthaalayah.v8.i5.2020.202>

Received Date: 16 May 2020

Accepted Date: 31 May 2020

Keywords:

Ayurvedic Immunomodulator
Treatment
Tuberculosis

ABSTRACT

Tuberculosis is on increase worldwide. WHO estimates that nearly 1.7 Billions are infected with Mycobacterium Tuberculosis, out of which approximately 20 Millions are active cases. 3 Million die each year and 8 Million new cases occur in each year. [1] India is one of the 22 high burden countries. Here nearly 300 Million people are infected with Mycobacterium tuberculosis [2]. 12 to 14 Million have active disease and there are about 5 lakh deaths per year. [3],[4] The problem in India is on the verge of an explosion with the emergence of increasing HIV infection and spread of Multi drug Resistant TB.

1. INTRODUCTION

Revised National TB Control Programme (RNTCP) is being implemented all over India since 1993. Today more than 90% of country has been covered under RNTCP. It has been noticed from many districts that a high-grade smear positive cases are unlikely to be converted to negative at the end of the intensive phase. [5],[6] The patient is infectious during this sputum positivity period. A supplementary medication is advisable with intermittent therapy for rapid smear conversion.

Tuberculosis is an infection where the host immune responses are highly determining the outcome. Hence an immuno modulatory drug supplementing the anti-mycobacterial therapy is relevant. In India, there are many traditional Ayurvedic medicines with immuno modulatory action used in various clinical conditions. Here we are trying to evaluate the effect of such an immunomodulator given as supplement to DOTS for high grade smear positive cases.

2. OBJECTIVES

To study the effect of Ayurvedic Immunomodulator supplementation on sputum conversion, in patients with sputum positive pulmonary tuberculosis put on DOTS

3. METHODOLOGY

The study population included all newly diagnosed cases of sputum smear positive pulmonary TB, registered in the Alappuzha Tuberculosis Unit (TU), during the period June 2002 – December 2002. Patients with diseases like diabetes mellitus, HIV infection etc which depress the immunity and those on immuno suppressant drugs were excluded from the study.

By the method of simple randomization, cases were selected to receive the immunomodulator drug during the intensive phase of anti tuberclose therapy under DOTS. Rest of the study population was taken as the control group who received DOTS alone as per the RNTCP guidelines.

The patients were followed up regularly with periodic sputum examination and weight recording as per the guidelines. ESR was also repeated at the end of the intensive phase.

The results were analyzed statistically by the test of proproportion.

4. OBSERVATION

During the study period, 84 cases were registered in Alappuzha TU, who satisfied the selection criteria. 21 of them were selected to receive the immunomodulator drug along with ATT, during the intensive phase (IP). Rest of them had ATT alone. All the patients were under DOTS regime.

The age of the patients ranged from 14 years to 76 years with a mean of 46 years in the study group and 21 to 78 years with a mean of 43 years in the control group (Table 1 & Figure 1). The male – female ratio was 1.5: 1 and 3.6: 1 in the study and control groups respectively. Thus, a male preponderance was seen in both groups, which was more evident in the control group.

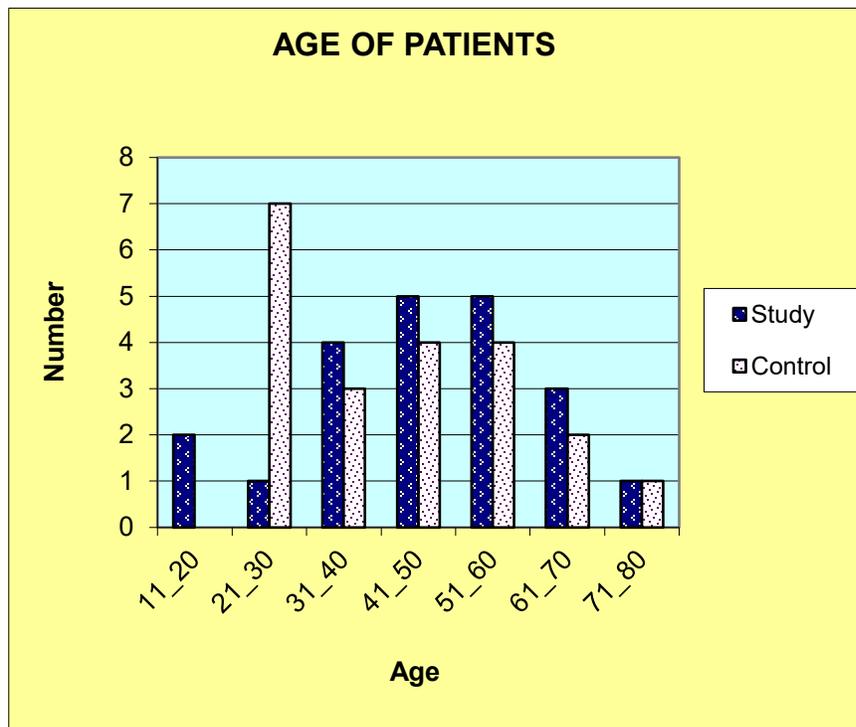


Figure 1

Table 1: Age Group of Study Population

Age Group	Study	Control
11-20	2	0
21-30	1	7
31-40	4	3
41-50	5	4
51-60	5	4
61-70	3	2
71-80	1	1
Total	21	21

The sputum status of the patients was as shown in Table 2. While there were more of sputum 2+ cases in the study group, more of 3+ cases were seen in the control group. But when the 2+ and 3+ cases were considered together; the two groups were comparable.

Table 2: Sputum Grade

Grade	Study	Control
Scanty	0	1
1+	5	4
2+	9	5
3+	7	11

At the end of the IP of ATT, 19 patients in study group and 15 in the control group became sputum negative. Thus, the sputum conversion rates were 90.5 % and 71.4 % respectively. The rest of the patients (9.5%) showed scanty bacilli in the sputum AFB smears in the study group and 6 patients (29%) remained positive in the control group. There was one death in the control group. The average weight gain during the two-month period was 2.5 Kg and 1.5 Kg respectively. A similar difference in the fall of ESR was also observed (30 mm/hr vs 20mm/hr). See Table 3

Table 3

	Study	Control
TOTAL	21	21
Negative at end of IP	19 (90.5%)	15 (71.4%)
Positive at the end of IP	2 (9.5%)	6 (28.6%)
Average Reduction in ESR	30mm/hr	20mm/hr
Average Wt. gain	2.5 Kg	1.5 Kg

5. DISCUSSION

Early sputum conversion and thus prevention of spread of infection are of prime importance in the TB Control Programmes. Even though late conversion is the recognized fact of DOTS therapy, it is more evident in the developing countries [7]. This is probably due to the peculiar socio-economic situation there, with poor living conditions and nutritional status of the individuals. Thus, a supplementary treatment is advisable for enhancing sputum conversion in high-grade positive cases. It will be more acceptable if cheaper and traditionally used supplements are considered. Many of the constituents of the immunomodulator preparation used in the present study are being utilized widely in India for their anti-bacterial, anti-inflammatory, immuno modulatory [8] and anti-oxidant activities. The commercially available preparation of IMMUNOCIN we used in the present study contains the following ingredients. Azadirachta indica (Neem), Tinospora cordifolia (Guduchi), Boerhaavia diffusa (Punarnava), Withania somnifera (Aswagandha), Curcuma Longa (Haridra), Piper longum (Pippali) and Ocimum sanctum (Tulasi). The extract of Neem is reported to increase the production of alpha and gamma interferon which are the most important defense factors against many infections and enhances the cell killing activities of phagocytes and natural killer cells. It also reported to increase the production of interleukin II [9],[10]. Guduchi has been reported to increase the number and function of neutrophils and monocytes while Punarnava, a Rasayana drug produces significant leucocytosis [11],[12]. The efficacy of Ashwagandha as an antistress agent and adaptogen has also been confirmed by many

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investigators [13] and its immunomodulating properties are also well studied [14]. Curcuma longa has been claimed of possessing the property of imparting immunity and increase body resistance against many diseases [15]. Immuno stimulatory, anti-allergic and anti-histaminic activity of piper longum is also well studied [16], [17]. Ocimum sanctum is also well evaluated for its anti-oxidant, immuno augmentory and anti-histaminic action [19], [20]. Review of these literature indicate that extract of these plants act by stimulating both nonspecific and specific immunity by either humoral and cell mediated immunity.

The study results indicate that those patients who received the immunomodulator drug as an adjunct to DOTS, showed a statistically significant higher sputum conversion rate (91% Vs 71%; $p < 0.01$).

The cost of therapy with the immunomodulator was around Rs. 5/- per day. Thus, the total rise in the treatment cost will be approximately Rs. 300/- for the entire course. Hence this mode of supplementing anti tuberculous treatment may be acceptable for low income countries.

The sample size of the study is too small to arrive at definite conclusions. Standardization in terms of sex and nutritional status was not obtained in the study. The immunomodulator preparation contains various ingredients; the effect of each could not be assessed individually.

Hence a more elaborative multi centric study needs to be conducted using more refined preparation containing the individual ingredients separately, with better quality control of these products.

6. CONCLUSIONS

Sputum positive pulmonary TB patients showed a better sputum conversion rate when treated with the Ayurvedic Immunomodulator, along with DOTS. An elaborate multi centric study in a larger population needs to be conducted using more refined preparations of the ingredients of the presently used drug (Immunocin) with better quality control. Thus, we can probe in to the possibility of utilizing our indigenous medicines in the treatment of tuberculosis, there by contributing our own share in fighting with this enemy of mankind.

SOURCES OF FUNDING

None.

CONFLICT OF INTEREST

None.

ACKNOWLEDGMENT

The authors wish to thank Gufic Biosciences Ltd., Mumbai for providing them with the Immunocin. The authors are also grateful to Dr. Sairu Philip, Asst. Professor of Community Medicine, MCH, Alappuzha for assisting in statistical analysis of the data.

REFERENCES

- [1] The global tuberculosis situation and the new control strategy of the WHO. Tubercle 1991; 72.
- [2] Ind. J. Tub, 1995, 45, 75
- [3] Dhanragir H: The changing spectrum of tuberculosis. Excerpta Medica 1995.
- [4] Dolin PJ, Raviglione MC and Kochi A. Global tuberculosis incidence and monthly during 1990 – 2000. Bull Wld Hlth Org: 1994; 72:213.
- [5] Dr. G.R. Khatri, RNTCP: A Status Report on First 1 Lakh Patients; Ind. J. Tub., 1999, 46, 157
- [6] Proceedings of 56th National Conference of TAI at Chennai.
- [7] Managing RNTCP in your Area (Module 1-4)– Central TB Division (GOI) 1998, 15.
- [8] Pri. A. et al., (1994). J. Ethnopharmacol., 42 :31.
- [9] Upadhyaya R.K. et. Al. J. Res. Ind. Med. Yoga. Home 1978 13: 127.
- [10] Chttopadhyay. R. R. "Possible biochemical mode of anti-inflammatory action of Azadirachta indica A. Juss. In rats" Indian J Exp Biol, 1998;36(4) : 418-20.

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- [11] Nadkarni, K.M. et al., (1982) Indian Materia Medica Vol. 1 : 1292.
- [12] Nadkarni, K.M. et al., (1982) Indian Materia Medica Vol. 1 : 965.
- [13] Shobat, B., et al., (1978). Biomedicine, 28 :18.
- [14] Dadkar, V.N. et al., (1987). Ind. J. Clin. Blochem., 2:101.
- [15] Abhang, R. Y., (1976). Deerghayu, 2:3.
- [16] Tripathi.D.M, Gupta. N., Lekshmi. V, et al. "Antigiardial and immunostimulatory effect of piper longum on giardiasis due to Giardia lamblia" Phytither Res, 1999; 13 (7): 561-5.
- [17] Charaka Samhita (Ed), (1983). G.S. Pandeya, Chowkhambha Sanskrit Sansthan, Varanasi.
- [18] Dahanukar, S. et al., (1982). Ind. Drugs. 19: 271.
- [19] Singh. S., Majumdar, D.K., "Effect of Ocimum sanctum fixed oil on vascular permeability and leucocytes migration" Indian J Exp Boil. 1999: 37 (11): 1136 – 8.
- [20] Role of free radicals and antioxidants in tuberculosis patients. – Y.N. Reddy, S.V. Murthy, D.R. Krishna and M.C. Prabhakar 213 Indian J. Tuberculosis, Oct2004