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ORIGINAL ARTICLE

Randomized trial of yoga as a complementary therapy for pulmonary tuberculosis

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Randomized trial of yoga as a complementary therapy for pulmonary tuberculosis
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Objective: The present prospective, randomized trial compared the efficacy of anti-tuberculosis treatment (ATT) with two separate programs (yoga and breath awareness), on lung capacities and bacteriological status in pulmonary tuberculosis patients.
Methodology: A total of 1009 pulmonary tuberculosis patients were screened and 73 were alternately allocated, to yoga ($n = 36$) or breath awareness ($n = 37$) groups, with 48 patients completing the 2-month trial. Patients aged between 20 and 55 years, who were sputum-positive on three consecutive examinations, had no prior ATT, and no comorbidities or extrapulmonary tuberculosis were included. In addition to ATT, one group practised yoga ($n = 25$) and the other practised breath awareness ($n = 23$) for 6 h per week, each session being 60 min. The main outcome measures were: symptom scores, bodyweight, FVC, FEV_1, FEV_1/FVC%, sputum microscopy, sputum culture, and postero-anterior view of the CXR.
Results: At the end of 2 months, the yoga group showed a significant reduction in symptom scores (88.1%), and an increase in weight (10.9%), FVC (64.7%) and FEV_1 (83.6%) ($P = 0.001$, in all comparisons, paired *t*-test). The breath awareness group also showed a significant (paired *t*-test) reduction in symptom scores (16.3%, $P = 0.02$), and an increase in weight (2.1%, $P = 0.003$) and FEV_1 (63.8%, $P = 0.04$). Significantly more patients in the yoga group showed sputum conversion based on microscopy on days 30 and 45 compared to the breath awareness group ($P = 0.045$ and $P = 0.002$, respectively, χ^2 test). Ten of 13 in the yoga group had negative sputum culture after 60 days compared with four of 19 in the breath awareness group ($P = 0.005$, χ^2 test). Improvement in the radiographic picture occurred in 16/25 in the yoga group compared to 3/22 in the breath awareness group on day 60 ($P = 0.001$, χ^2 test).
Conclusions: The improved level of infection, radiographic picture, FVC, weight gain and reduced symptoms in the yoga group suggest a complementary role for yoga in the management of pulmonary tuberculosis.

Key words: pulmonary tuberculosis, randomized trial, yoga.

INTRODUCTION

Extensive parenchymal and pleural involvement in pulmonary tuberculosis results in residual fibrotic changes with reduced vital capacity and other lung volumes.[1] Yoga is an ancient Indian science, which includes physical postures (asanas), regulated breathing (pranayama), and meditation (dhyana).[2] In normal volunteers the practice of a combination of yoga techniques for 2.5 months was shown to increase the maximal voluntary ventilation and FVC.[3] After 9 months of yoga breathing exercises and postures, 11 patients with chronic severe airway obstruction showed significant improvement in objective tests for exercise tolerance.[4]

The practice of yoga is also known to bring about relaxation and reduce physiological signs of stress.[5] Previous studies have shown that stress can increase vulnerability to infections.[6] Hence, the present study examined yoga as a stress-reducing practice, influencing bacteriological status and level of infection

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as indicated by sputum conversion and changes in the radiographic picture in pulmonary tuberculosis patients.

Poor adherence to therapy is the most important cause of anti-tuberculosis treatment (ATT) failure, in both developed[7] and developing countries.[8] It has been shown that psychological factors such as the effectiveness of the patient–provider interaction influence compliance.[9] In the present study, individuals participating in yoga or breath awareness interacted closely with the instructor. Hence, the effects of these programs on patient compliance with ATT during the first 4 months of 10 months' domiciliary treatment were evaluated.

We developed a prospective, randomized trial to compare the efficacy of ATT with one of two programs, yoga or breath awareness, on lung performance, bacteriological status and treatment compliance.

METHODS

Participants

One thousand and nine patients with pulmonary tuberculosis who were admitted to the Government Tuberculosis Sanatorium, Bangalore, India were screened. The criteria for participation were: age between 20 and 55 years, sputum-positivity on direct microscopy,[10] no history of prior ATT and no evidence of comorbidities or extrapulmonary tuberculosis. Most patients were excluded as they were already being treated with ATT in varying combinations for varying durations. These patients were excluded as prior (often inadequate) treatment would have influenced their response to the ATT, with possible drug-resistance.[11] After screening, 73 patients fulfilled the criteria.

Study design

Seventy-three patients were randomly assigned to two groups, yoga and breath awareness. The characteristics of the yoga group were as follows: average age 32.2 ± 10.0 years; gender, 17 males; drug sensitivity, 13 sensitive, six resistant, and six contaminated. The characteristics of the breath awareness group were as follows: average age 37.3 ± 9.6 years; gender, 13 males; drug sensitivity, 13 sensitive, seven resistant, and three contaminated. Forty-eight completed the trial. Out of 73 patients, 25 were excluded for the following reasons: (i) they left the sanatorium against medical advice before the 2 months of their prescribed stay was over, and (ii) they failed to stay continuously in the sanatorium for 2 months.

The protocol was approved by the directorate of the tuberculosis control program, Department of Health and Family Welfare, Government of Karnataka, India and by the superintendent of the Government Tuberculosis Sanatorium, Bangalore, Karnataka, India. Written informed consent was obtained from all participants. All assessments were made at commencement and at the end of 2 months stay in the sanatorium. Treatment compliance was the only measurement that was made every month for the 4 months after the patients were discharged from the sanatorium, during which time patients were asked to continue the intervention to which they had been allocated. However, they were not supervised.

Outcome measures

The outcome measures were symptom scores, bodyweight, FVC, FEV_1, FEV_1/FVC%, sputum microscopy, sputum culture, and CXR. The method and frequency of the measures are detailed in Table 1.

Interventions

The ATT regimen used in the trial consisted of 2 months of an intensive phase of treatment with 0.75 mg of streptomycin (intramuscular injection administered daily), 300 mg of isoniazid (orally, daily), and 150 mg of thioacetazone (orally, daily). This was followed by a 10 month continuous phase of 300 mg isoniazid, and 150 mg thioacetazone (orally, daily).[12]

The yoga group practised 60 min of yoga techniques. The 60 min consisted of simple breathing exercises (30 min), specific yoga voluntarily regulated breathing (pranayamas, 20 min), and relaxation in a supine posture (10 min). During simple breathing exercises the following points were noted: (i) inhalation and exhalation were in the ratio of 1 : 2, (ii) inhalation and exhalation were synchronized with separate body movements (e.g. stretching the arms wide during inhalation and bringing them together during exhalation), and (iii) awareness of breathing. This was followed by the specific yoga breathing practices (pranayamas). These practices are traditionally believed to reduce body temperature and to be especially useful for diseases of the respiratory system.[13] During pranayamas, as for breathing exercises, the same inhalation : exhalation ratio (1 : 2) was maintained with awareness of breathing, along with other voluntary regulations of breathing.[13] The session ended with relaxation in shavasana (the corpse posture), practised for 10 min.

The non-yoga group performed breath awareness (as a control treatment), so that they would also have intervention and interaction with the instructor. It was hoped that this would reduce any difference between the groups due to the psychological benefits that have been ascribed to additional care.[14] During the breath awareness session, there were no body movements or changes in the inhalation : exhalation ratio. Patients were asked to direct their awareness to their breathing during the 60-min session, keeping their eyes closed. Breath awareness was selected as it is one of the aspects of yoga that does not include the following: (i) body movements synchronized with breathing (called 'breathing exercises'), (ii) changing the inhalation : exhalation ratio voluntarily, and (iii) relaxation while supine (called shavasana). Breath

Table 1 Assessments

Assessments	Method	Frequency
1. Body weight	Using a spring balance	Weekly
2. Symptom scores: cough, expectoration, chest pain, fever, haemoptysis, weakness, anorexia and insomnia	Graded as follows: absent = 0; mild = 1 (symptoms present but no inconvenience); moderate = 2 (symptoms present, inconvenient for the patient, not disrupting their routine); severe = 3 (symptoms present, disrupting their routine).	Daily
3. FEV_1 (litres) and FVC (litres)	Best of three exhalations recorded with a ventilometer (Clement Clarke, UK).	Weekly
4. Sputum microscopy	Three over-night sputum samples produced on demand on three consecutive days, stained using Ziehl-Neelsen method.[10] Grading (number of bacilli per 200 fields (b.p.f.)): Grade 0 = no b.p.f.; Grade 1 = 1–10 b.p.f.; Grade 2 = >10 b.p.f.; Grade 3 = several clumps of b.p.f.	
5. Sputum culture	One over-night sample produced on demand, cultured using a standard method.[10] Sputum culture was not quantified, but noted as positive or negative.	Monthly
6. Radiograph	A full plate postero-anterior CXR was taken and graded as follows: Grade 0 = clear; Grade 1 = slight to moderate opacities without cavitation, including bilateral lesions not exceeding the volume of lung superior to the second costochondral junction; Grade 2 = slight to moderate opacities not exceeding one third of the lung volume, including bilateral lesions, with a cavity less than 4 cm wide; Grade 3 = lesions more extensive than Grade 2.	Two monthly
7. Patient compliance	The number of patients who returned for drug collection, was recorded for 4 months after their sanatorium stay.	Monthly

awareness need not be given with instructions to relax.

The patients had no knowledge or experience of either of the interventions before they started practising them for the study. Both groups had equal interaction with the instructor. The instructor for both types of sessions (yoga and breath awareness) recorded the participation of the patients every day. The patients who completed the trial were without exception able to attend all the sessions (six sessions per week, for 8 weeks). Hence there were 48 sessions of each intervention, during the 2-month stay at the sanatorium.

Randomization

Eligible patients were randomized by alternate allocation on admission to the two groups (initially designated as group 1 and group 2), by a medical officer authorized to admit the patients but who had no role in the trial. The two groups were then designated as the 'yoga group' and the 'breath awareness group' by the superintendent of the sanatorium who was blinded to the patient allocation, and whose other involvement in the trial was as one of the three readers of the coded CXR of the patients.

Masking

It is difficult to assess yoga practices in double blind trials because the intervention requires active participation of the subject and hence the identities of the interventions become known after allocation.[15] However, the assessments for symptoms, bodyweight, sputum microscopy, sputum culture, and CXR were made and scored by a blinded investigator. CXR were read independently by three radiologists. Two consistent readings were considered for analysis, using the rating scale detailed in Table 1. This was possible in all cases. The spirometry recordings were made by the instructor administering the interventions (yoga and breath awareness), under the supervision of a doctor who did not otherwise participate in the trial.

Statistical methods

The *t*-test for unpaired data was used to compare the baseline (i.e. day 1) values for the yoga and the breath awareness groups with respect to: (i) symptom scores, (ii) bodyweight, (iii) FEV_1, (iv) FVC, and (v) FEV_1/FVC%. The McNemar's test for significance of change was used to compare the number of patients with dif-

ferent grades in the two groups at baseline with respect to sputum microscopy, culture and CXR.

The *t*-test for paired data was used to compare the day 1 and day 60 values for each group separately, with respect to: (i) symptom scores, (ii) bodyweight, (iii) FVC, (iv) FEV_1, and (v) FEV1/FVC%. Separate χ^2 analyses were carried out on data for sputum microscopy comparing day 1 with days 30, 45, and 60. For sputum culture and radiography, day 1 was compared to day 60 (χ^2 analysis). The χ^2 test was used to compare the number of patients in the two groups who (i) improved by changing from a higher to a lower grade, (ii) showed no change, or (iii) worsened by changing from a lower to a higher grade.

RESULTS

The trial profile is shown in Fig. 1.

The baseline and post-treatment group mean values ± SD for symptom scores, bodyweight, FVC, FEV_1, and FEV_1/FVC% are given in Table 2. The number of patients with different grades of sputum microscopy, sputum culture (based on 13 subjects in the yoga group and 19 subjects in the control group), and CXR for both groups on days 1 and 60 are shown in Table 3.

The two study groups were similar at baseline with respect to symptom scores, bodyweight, FEV_1 and FEV_1/FVC% ($P > 0.05$, unpaired *t*-test). The difference between the FVC values of the two groups at baseline was close to being significant ($P = 0.05$, unpaired *t*-test). At baseline the grades of sputum microscopy, culture, and CXR were not significantly different ($P > 0.05$, McNemar's test for significance of change). No patient had a negative or clear CXR at baseline.

The paired *t*-test was used to compare values on day 60 with those on day 1 for each of the groups separately for the following: (i) symptom scores; (ii) bodyweight; (iii) FVC; (iv) FEV_1, and (v) FEV_1/FVC%. The yoga group showed a significant decrease in symptom scores ($P = 0.001$, 88.1%), increase in bodyweight ($P = 0.001$, 10.9%), increase in FVC ($P = 0.001$, 64.7%), and FEV_1 ($P = 0.001$, 83.6%). The breath awareness group also showed a significant reduction in symptom scores ($P = 0.02$, 16.3%), increase in bodyweight ($P = 0.003$, 2.1%), and increase in FEV_1 ($P = 0.04$, 63.8%), but no change in FVC.

Comparing the number of patients in the two groups who improved, who showed no change or who worsened (χ^2 test), significantly more patients from the yoga group showed sputum conversion based on microscopy on days 30 and 45 compared to the breath awareness group. On day 30, for the yoga group, 19 improved, none worsened, and six showed no change, and for the breath awareness group, 10 improved, none worsened, and 13 showed no change ($P = 0.045$). On day 45, for the yoga group, 24 improved, none worsened, and one showed no change, and for the breath awareness group, 12 improved, two worsened, and nine showed no change ($P = 0.002$). Ten of the 13 in the yoga group had negative sputum culture after 60 days compared with 4/19 in the breath awareness group ($P = 0.005$, χ^2 test). Improvement in the CXR occurred in 16/25 in the

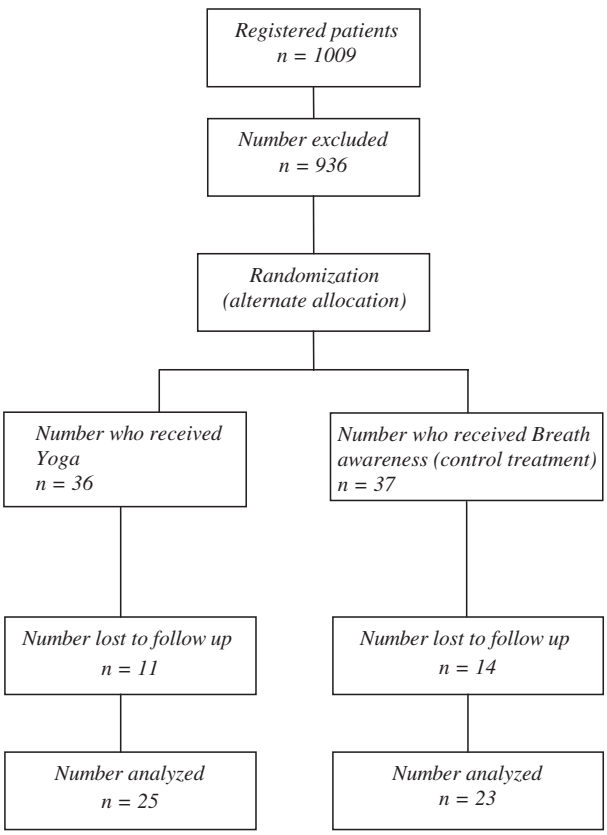

Figure 1 Trial profile.

Table 2 General measurements (values are group mean ± SD)

Measurements	Yoga group ($n = 25$)		Breath Awareness group ($n = 23$)	
	Day 1	Day 60	Day 1	Day 60
Symptom scores	11.8 ± 3.0	1.4*** ± 2.3	12.2 ± 4.0	10.2* ± 4.4
Weight (kg)	41.1 ± 8.6	45.6*** ± 9.4	36.9 ± 7.1	37.7** ± 7.2
FVC (litres)	0.8† ± 0.5	1.4*** ± 0.4	0.6 ± 0.4	0.8 ± 0.4
FEV_1 (litres)	0.7 ± 0.4	1.2*** ± 0.4	0.6 ± 0.4	0.8* ± 0.4
FEV_1/FVC%	84.6 ± 33.8	88.4 ± 11.8	93.4 ± 25.4	97.2 ± 25.0

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$, day 60 *vs* day 1, *t*-test for paired data; †p = 0.05, day 1 (yoga) *vs* day 1 (breath awareness—control group), *t*-test for unpaired data.

Table 3 Number of patients showing different grades of sputum microscopy, culture and radiography in yoga and breath awareness groups

Groups	Day of test	Sputum microscopy Sample (*n*)	Grades 0	1	2	3	Sputum culture* Sample (*n*)	Result Positive	Negative	Radiography** Sample (*n*)	Grades 0	1	2	3
Yoga	Day 1	25	0	19	6	0	13	13	0	25	0	1	9	15
	Day 60	25	23	1	1	0	13	3	10	25	6	3	9	7
Breath awareness	Day 1	23	0	15	7	1	19	18	1	22	0	0	14	8
	Day 60	23	9	11	3	0	19	14	5	22	0	1	12	9

*P = 0.005, **P = 0.001, comparing numbers of patients with different results (sputum culture) or grades (radiography) in the yoga and breath awareness (control) groups on days 1 and 60 (χ^2 analysis).

yoga group and in 3/22 in the breath awareness group (P = 0.001).

With respect to patient compliance, there was no significant difference between the numbers of participants in the yoga group compared to the number from the breath awareness group who returned for drug collection every month until the fourth month (14 *vs* 15, respectively).

DISCUSSION

Pulmonary tuberculosis patients who practised yoga in addition to receiving ATT, showed a significant decrease in symptom scores, a gain in weight, and an increase in FVC and FEV_1 after 60 days. The group with breath awareness combined with ATT also showed a significant decrease in symptom scores, a gain in weight, and an increase in FEV_1. However, in all cases the magnitude of change was less than that of the yoga group. FVC did not increase significantly in the breath awareness group.

There were also significantly more patients in the yoga group compared to the breath awareness group who showed improvement in sputum microscopy at 30 and 45 days and in sputum culture and radiography after 60 days.

It has already been shown that the lung capacity increases following yoga practice in normal volunteers.[3] This was attributed to increased development of the respiratory musculature following the regular practice of yoga.[16] The FVC is also an indicator of the extent of disease in pulmonary tuberculosis, with subsequent changes indicating progression or improvement.[17] The increase in FVC in the yoga group after 60 days suggests improvement, while the absence of change in the breath awareness group could suggest 'no improvement' or could be related to the lower FVC values at baseline.

The sequelae of pulmonary tuberculosis can result in a restrictive disorder, characterized by the following spirometry changes: lower FEV_1 and FVC compared to normal, and a higher FEV_1/FVC% than normal.[18] Hence, the significant increase in FEV_1 in both groups suggests that restriction may not have developed.

The improvement in the symptom scores and weight in both groups on day 60, demonstrated the efficacy of the ATT. Since the magnitude of change was greater in the yoga group, this suggests that the practice of yoga facilitates the response to ATT.

The improvement in the yoga group with respect to bacteriological status (sputum microscopy, culture) and radiography suggests that yoga potentiates the action of chemotherapy in converting an active infection to a passive one. Macrophage activation by lymphokines produced by sensitized T cells is the predominant defence mechanism in tuberculosis.[19] A replicated finding in the literature is the association between times of psychological distress and reduction in the proliferation of lymphocytes cultured with mitogens that activate T cells.[20] Further support for a relationship between psychosocial variables and altered immune responses was provided by an intervention (i.e. relaxation training), which decreased distress and increased NK cell activity.[21] No immunological assessments were made in the present study and there are no previous reports on changes in immune status following yoga practice.

There was no difference between the number of patients in the two groups (14/25 in the yoga group and 15/23 in the breath awareness group), who returned for monthly drug collection, suggesting no difference in compliance between the groups. These results were comparable to previously reported treatment compliance with ATT alone, in India.[22] The cited study assessed compliance with a short course of chemotherapy. The short course of chemotherapy had two phases (as did the present study): an intensive phase (also of 2 months) and a continuation phase (which lasted 6 months). During the continuation phase, 44% of patients did not comply. In the present study, the percentage of patients who did not comply during the continuation phase was 44% for the yoga group (11/25) and 35% (8/23) for the breath awareness group.

The present study suggests a complementary role for yoga in the management of pulmonary tuberculosis, with symptomatic relief, better weight gain, increased lung capacity, and better sputum conversion during the intensive phase of ATT. In the breath awareness group as compared to the yoga group, the lesser magnitude of change in symptom scores, weight gain, and FEV_1, and the difference in bacteriological status, implies that yoga with the components of body movements, breath regulation,

relaxation and breath awareness, was of greater use in these patients, compared with awareness of breath alone. However, in view of the sample size and the trial being restricted to the intensive phase of ATT, these findings must be considered preliminary.

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REFERENCES

1 American Thoracic Society. Diagnostic standards and classification of tuberculosis. *Am. Rev. Respir. Dis.* 1990; **142**: 725–35.
2 Nagendra HR. *Yoga—Its Basis and Applications.* Swamy Vivekananda Yoga Prakashana, Bangalore, 2000.
3 Makwana K, Khirwadkar N, Gupta HC. Effect of short-term yoga practice on ventilatory function tests. *Indian J. Physiol. Pharmacol.* 1988; **32**: 202–8.
4 Tandon MK. Adjunct treatment with yoga in chronic severe airways obstruction. *Thorax* 1978; **33**: 514–17.
5 Wallace RK. Physiological effects of transcendental meditation. *Science* 1970; **167**: 1751–4.
6 Kiecolt-Glaser JK, Marucha PT, Malarkey WB, Mercado AM, Glaser R. Slowing of wound healing by psychological stress. *Lancet* 1995; **346**: 1194–6.
7 Gaudette LA, Ellis E. Tuberculosis in Canada: a focal disease requiring distinct control strategies for different risk groups. *Tuber. Lung Dis.* 1993; **74**: 244–53.
8 Ramachandran P, Prabhakar R. Defaults, defaulter action and retrieval of patients during studies on tuberculous meningitis in children. *Tuber. Lung Dis.* 1992; **73**: 170–3.
9 Snider DE, Hutton MD. *Improving Patient Compliance in Tuberculosis Treatment Programs*. Centers for Disease Control, Atlanta, 1986.
10 National Tuberculosis Institute. *National Tuberculosis Institute Laboratory Technician Manual for District Tuberculosis Program (DTP).* National Tuberculosis Institute, Bangalore, 1993.
11 Crudu V, Arnadottir T, Laticevschi D. Resistance to antituberculosis drugs and practices in drug susceptibility testing in Moldova, 1995–1999. *Int. J. Tuberc. Lung Dis.* 2003; **7**: 336–42.
12 National Tuberculosis Institute. *Introduction to District Tuberculosis Program*, 4th edn. National Tuberculosis Institute, Bangalore, 1994.
13 Vivekananda Kendra. *Yoga: An Introduction Booklet.* Vivekananda Kendra Publication, Madras, 1997.
14 Delbanco T. The healing roles of doctor and patient. In: Moyers B (ed.). *Healing and the Mind.* David Grubin Productions, New York, 1993; pp. 7–23.
15 Singh V, Wisniewski A, Britton J, Tattersfield A. Effect of yoga breathing exercises (pranayama) on airway reactivity in subjects with asthma. *Lancet* 1990; **335**: 1381–3.
16 Bhole MV. Treatment of bronchial asthma by yogic methods—a report. *Yoga Mimamsa* 1967; **9** (3): 33–41.
17 Garay SM. Pulmonary tuberculosis. In: Rom WN, Garay SM (eds). *Tuberculosis*. Little, Brown Co., Boston, 1995; 373–412.
18 West JB. *Respiratory Physiology*, 5th edn. Williams & Wilkins, Baltimore, 1990.
19 Restrepo LM, Barrera LF, Garcia LF. Natural killer cell activity in patients with pulmonary tuberculosis and in healthy controls. *Tubercle* 1990; **71**: 95–102.
20 Biondi M, Pancheri P. Mind and immunity: a review of methodology in human research. *Adv. Psychosom. Med.* 1987; **17**: 234–51.
21 Kiecolt-Glaser JK, Glaser R. Psychological influences on immunity: implications for AIDS. *Am. Psychol.* 1988; **27**: 892–8.
22 Chaudhari K, Jagota P, Parimala N. Results of treatment with a short course chemotherapy regimen used under field conditions in district tuberculosis program. *Indian J. Tuber.* 1993; **40**: 83–9.