Effect of Yoga on Quality of Life in Patients with Pulmonary Tuberculosis: A Randomized Control Trial

Abstract

Introduction: Yoga is emerging as one of the holistic approaches to respiratory diseases. The scope of yoga is expanding in communicable diseases with physical, mental, and societal benefits. Aim and Objective: The present study aims to evaluate the effect of integrated yoga as an adjuvant therapy to the National Tuberculosis Elimination Programme (NTEP) on assessing health-related Quality of Life (QoL) in patients with pulmonary tuberculosis (PTB). Setting and Design: A randomized controlled trail study was conducted in a tertiary care teaching hospital. Methodology: The study screened 826 PTB patients; 72 patients were found suitable and agreed to participate. The PTB patients were randomly assigned to either a yoga group (n = 36)or a control group (n = 36) using the sequentially numbered opaque sealed envelope technique. The control group received standard-of-care treatment as per NTEP, and the yoga group practiced 45 min of integrated yoga for 8 weeks along with standard of care. The World Health Organization Quality of Life (WHOQOL-BREF) questionnaire was used to collect the data at baseline and after 8 weeks of intervention. Results: The results of within-group comparisons in both the groups showed that there was a significant improvement in physical (P < 0.01), psychological (P < 0.01), and social (P < 0.01), with $P \le 0.05$ being considered statistically significant except environmental domain. Between groups, analysis shows that in the preintervention, there was no difference between the yoga and control group as P > 0.05. After the yoga intervention, there was an enhancement in QoL scores with three domains except the environmental domain (P = 0.28). Conclusion: The study evidence supports the use of yoga as a complementary therapy for the NTEP in patients with PTB may improve their QoL.

Keywords: Integrated yoga, pulmonary tuberculosis, quality of life, yoga, yoga therapy

Introduction

Pulmonary tuberculosis (PTB) is a contagious bacterial infection that primarily affects the lungs and can cause significant morbidity and mortality. The World Health Organization (WHO) report 2022 shows that 10.6 million incidence cases among 1.4 million deaths occurred in 2021.[1-3] India is one of the major contributors to TB.^[4] While there have been significant in improvements tuberculosis (TB) treatment over the past few decades, the disease remains a significant global health problem, particularly in low-income and middle-income countries. In many parts of the world, TB patients continue to experience significant social, economic, and psychological challenges that can impact their quality of life (OoL) and can lead to symptoms such as coughing, fever, weight

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loss, night sweats, anxiety and depression, and fatigue.[5-7] All of these can significantly impact their daily lives and lead to lower OoL in TB patients. In addition, the side effects of TB medications, such as nausea, vomiting, and liver damage, can further impact a patient's OoL. The standard treatment for TB typically involves a combination of antibiotics for patients' recovery, but complementary therapies such as yoga may also support patients' health and well-being. Yoga is a form of mind-body practice that combines physical postures, breathing techniques, and meditation or relaxation exercises. Previous research has suggested that yoga may have a range of health benefits for other respiratory disorders like asthma, chronic obstructive pulmonary disease, lung cancer, and COVID-19, such as reducing stress and anxiety, improving mood, improving physical function, and enhancing

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the QoL.^[8-12] In the current scenario, very few randomized studies are available on Yoga and PTB. Hence, the present study suggests the complementary role of yoga therapy in PTB patients to enhance their health-related QoL.

Methodology

The study was conducted at the department of pulmonology, a tertiary care teaching hospital. The Institutional Ethical Committee of Sri Devaraj Urs Academy of Higher Education and Research has approved the study (SDUAHER/IEC/ MJ/13/22-23), and the study was registered under the CTRI (CTRI/2023/01/049012). The study was conducted from January 2023 to September 2023. It was a randomized control trial design. The sample size was calculated using nMaster 2.0 software. which was developed by the Biostatistics Training and Resource Center, Department of Biostatistics, Christian Medical College, Vellore, Tamil Nadu, India. Based on the forced expiratory volume in 1 second (FEV), as reported in the study conducted by Visweswaraiah and Telles (2004) reported that an average variance estimated of 0.16 in FEV1.[7] Considering the power of 90% with Alpha error of 0.05. The sample estimated per group was 30. The final estimated sample size per group was 36, and the overall sample size was 72, with a dropout rate of 20%. The study participants were selected based on the inclusion criteria: new cases of microbiologically diagnosed and clinically diagnosed PTB patients who will be receiving treatment under the National Tuberculosis Elimination Programme (NTEP); age group of patients between 18 and 60 years; and both male and female patients with PTB. The exclusion criteria are as follows: TB with HIV; multiple drug resistance MDR-TB; PTB with HIV; Extra PTB; patients with psychosis and delirium; no recent major surgeries in the last 4 months; and any form of yoga practice in the last 3 months excluded from the study. Before commencement of the study, the purpose and complete procedures were clearly explained to the participants and their caretakers. Then, written informed consent was obtained voluntarily from each participant.

Randomization procedure

The study screened 826 PTB patients; 754 patients were excluded due to not meeting the inclusion criteria, and 72 patients were found suitable and agreed to participate. The PTB patients were randomly assigned to either a yoga group or a control group using the sequentially numbered opaque sealed envelope technique. Each envelope is of the same size and written as Group A (control) and Group B (experiential/yoga) separately mentioned in each envelope. The Group's A and B envelopes were mixed after writing inside the envelope. When the patients visited the department of pulmonology, they were asked to pick up an opaque sealed envelope. Thirty-six participants got Group-A envelopes; the other 36 got Group-B. Finally, 72 patients completed the study, as shown in Figure 1. The experimental

group participants received 45-min yoga session 5 days a week for 8 weeks, while the control group received standard care, i.e., anti-TB drugs as per weight band in NTEP.

Control group intervention

The control group intervened with standard-of-care treatment. Newly diagnosed PTB patients received the first line of anti-TB drugs, i.e., (isoniazid [H], rifampicin [R], pyrazinamide [Z], and ethambutol [E] [HRZE]) during the intensive phase of treatment as per the NTEP for 8 weeks. This four HRZE drugs were administered as per weight band-based fixed-dosage combination.^[13]

Fixed-dose combination provides a simple approach to deliver the correct number of drugs at the right dosage as all the necessary drugs are combined in a single tablet. It is used to deliver H/R/Z/E drugs of anti-TB treatment.^[14]

Yoga intervention

Yoga intervention consists of breathing exercises, loosening exercises, asanas (postures), pranayama (breathing exercises), relaxation techniques and meditation, and standard-of-care treatment. Initially, five sessions will be taught to the patients by a yoga trainer, and later, we have made an exclusive 45-min video of the yoga module with clear instructions to follow regularly, as shown in Table 1. The patient's adherence to daily yoga practice at their homes was checked and enquired through telephone calls and visits to their home once every 2 weeks. We informed all patients that any difficulty in practice or adverse effects needs to be brought to the notice of the investigator.

Table 1: Integrated yoga module	
Name of the practice	Duration (min)
Breathing exercises	6
Hands in and out breathing	0
Hands stretch breathing	
Sasankasana breathing (moon pose)	
Loosening exercises	4
Shoulder rotation	
Forward and backward bending ×3 rounds	
Instant relaxation technique	
Yogasanas/physical postures	10
Ardhakati cakrasana (lateral arc pose)	
Ardha cakrasana (half wheel pose)	
Bhujangasana (serpent pose)	
Deep relaxation technique	
Pranayama	15
Vibhagya pranayama (sectional breathing)	
Nadisudhi pranayama (alternate nostril breathing)	
Bhramari pranayama (bee breathing)	
Nadanusandhan	
Relaxation	10
Yoga nidra (guided meditation)	
Total duration	45



Figure 1: CONSORT flow diagram

Outcome measure

The WHOQoL-BREF, Health-related QoL questionnaire was administered by someone not involved in the study. In total, 10% of participants questionnaires were verified by someone not a part of the research team and designated not less than the assistant professor to nullify confounding investigators' bias variable. The baseline data were collected before the start of the intervention and after the intervention in the 8th week. The WHOQoL-BREF questionnaire comprises 26 items that provide information regarding four broad domains: physical health, psychological health, social relationships, and environment.^[15]

Statistical analysis

Data analysis was carried out using SPSS software Windows Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Normality was checked using Shapiro–Wilk test and the data were found normally distributed. We expressed data in terms of mean \pm standard deviation and effect of intervention was analyzed using paired *t*-test for within group analysis. The between group analysis was done using independent *t*-test. P < 0.05 was considered statistically significant.

Results

The 72 participants were in the mean age of 45 ± 10.04 in males and 45.95 ± 10.63 in females. Among the

participants, 60 (83.3%) were married and 12 (16.7%) were unmarried. In India incidence of PTB patients is lower in female compared to male.^[16] Other socioeconomic factors like gender, education, habitat, and marital status are shown in Table 2.

Within study (yoga) group comparison of World Health Organization Quality of Life-BREF scores

All the domains of QoL scores showed that the significant improvement, i.e., physical (P < 0.001), psychological (P < 0.001), and social (P < 0.001) except environmental domain, was not significant with P = 0.893 using paired *t*-test analysis as shown in Table 3.

Within control group (pre and post) comparison of World Health Organization Quality of Life-BREF scores

The scores showed that the improvement in physical (P < 0.001), psychological (P < 0.001), and social (P < 0.001) except environmental domain was not significant with P = 0.88 using paired *t*-test analysis as shown in Table 4.

Between groups (yoga vs. control) comparison of World Health Organization Quality of Life-BREF

At the baseline/preintervention, there was no difference between yoga and control group as P > 0.05. After the yoga intervention, there was an enhancement in QoL scores with three domains of physical (P < 0.001),

Table 2: Socioeconomic data					
Characteristics	All participants	Control group, n (%)	Yoga group, n (%)		
Gender	Male - 52 (72.22)	24 (67)	28 (78)		
	Female - 20 (27.77)	12 (33)	8 (22)		
Age (mean±SD)	Male - 45±10.04	46.54±10.75	45.21±9.74		
	Female - 45.95±10.63	46.83±9.47	44.62±13.35		
Marital status	Married - 60 (83.3)	32 (89)	28 (78)		
	Unmarried - 12 (16.7)	4 (11)	8 (22)		
Education	Uneducated - 20 (27.8)	13 (36)	7 (19)		
	Primary school - 12 (16.7)	7 (19)	5 (14)		
	Middle school - 12 (16.7)	8 (22)	4 (11)		
	High school - 16 (22.2)	7 (19)	9 (25)		
	Preuniversity - 6 (8.3)	0	6 (17)		
	Graduation and above - 6 (8.3)	1 (3)	5 (14)		
Habitat	Rural - 46 (63.9)	22 (61)	24 (67)		
	Urban - 8 (11.1)	4 (11)	4 (11)		
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n: Number of participants, SD: Standard deviation

Table 3: Within yoga group comparison - quality of life domains					
QoL domains	Yoga group (mean±SD)		Df	Effect	Р
	Preintervention	Postintervention		size	
Physical domain QoL	35.98±4.24	79.05±7.54*	35	7.6037	< 0.001
Psychological domain QoL	$47.04{\pm}7.48$	69.90±11.22*	35	2.3898	< 0.001
Social domain QoL	35.99±2.66	48.26±4.15*	35	3.5173	< 0.001
Environmental domain QoL	49.30±9.52	51.38±12.15	35	0.1907	0.893 (NS)

Data are expressed in Mean \pm Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Comparison of preand post intervention data was done using paired *t*-test. *P*<0.05 was considered statistically significant; **P*<0.001- highly significant, NS-Not significant, Df-Degree of freedom

Table 4: Within control group pre- and post-comparison - quality of life domains					
QOL domains	Control group, mean±SD		Df	Effect	Р
	Preintervention	Postintervention		size	
Physical domain QoL	36.34±5.04	59.60±8.78*	35	3.248	< 0.001
Psychological domain QoL	48.09±13.00	58.91±11.95*	35	0.866	< 0.001
Social domain QoL	36.69±5.25	42.70±5.01*	35	1.171	< 0.001
Environmental domain QoL	48.26±13.15	51.38±12.15	35	0.006	0.882 (NS)

Data are expressed in Mean \pm Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Comparison of date pre- and post intervention was done using paired *t*-test. *P*<0.05 was considered statistically significant; **P*<0.001- highly significant, NS-Not significant, Df-Degree of freedom

psychological (P < 0.002), and social (P < 0.001) except environmental domain (P = 0.283) using independent *t*-test analysis as shown in Table 5.

There was a significant improvement in the yoga group compared to the control group after 8 weeks of postintervention.

Discussion

The yoga group also significantly improved their QoL, as measured by the WHO BREF-QoL questionnaire. The study suggests that the improvement in QoL may be due to the stress-reducing effects of yoga and its potential to improve respiratory function.

Similar results were obtained in the previous randomized control trial showing improvement in QoL, pulmonary

function, reduced symptoms scores, and sputum conversion rates. One more case report suggests that after 8 weeks of yoga, there is an improvement in health-related QoL, symptoms scores, weight gain, and pulmonary parameters.^[6]

Similar study results were found in other respiratory diseases by improving the QoL in asthma,^[7-19] chronic obstructive pulmonary disorder,^[20-22] lung cancer,^[11] and COVID-19.^[23,24] The effects of yoga on symptoms of breathlessness in 34 patients with PTB were assessed in Indonesia and observed that who practices yoga there was an improvement in breathlessness symptoms. Hence, the study adds that yoga can be a respiratory management intervention in PTB.^[25] Another study on Tuberculosis patients in Himachal Pradesh, India, who practice yogic exercises found that they improved their pulmonary

Table 5: Between groups (yoga vs. control) comparison					
QoL domains	Pre/post-intervention	Between groups (mean±SD)		Df	Р
		Control group	Yoga group		
Physical domain QoL	Pre	36.34±5.04	35.98±4.24	70	0.633 (NS)
	Post	59.60 ± 8.78	79.05±7.54*	70	0.001
Psychological domain QoL	Pre	48.09±13.00	$47.04{\pm}7.48$	70	0.699 (NS)
	Post	58.91±11.95	69.90±11.22*	70	0.002
Social domain QoL	Pre	36.69±5.25	35.99±2.66	70	0.653 (NS)
	Post	42.70±5.01	48.26±4.15*	70	0.001
Environmental domain QoL	Pre	48.26±13.15	49.30±9.52	70	0.656 (NS)
	Post	48.30±11.68	51.38±12.15	70	0.283 (NS)

Data are expressed in Mean \pm Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Between group Comparison (Control vs. Yoga) was done using independent *t*-test. When P<0.05 was considered statistically significant, *P<0.001-highly significant, NS-not significant, Df-Degree of freedom

parameters, i.e., forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), FEV1/FVC ratio, and peak expiratory flow rate (PEFR), thereby reducing respiratory distress.^[26]

The underline mechanism that yoga acts to improve autonomic functions by triggering neurohormonal mechanisms by the suppression of sympathetic activity through downregulation of the hypothalamic–pituitary– adrenal axis.^[27] The study suggests that manipulated nostril breathing could alter the systolic and diastolic pressure shows the possible therapeutic effect of yoga.^[28]

The physical domain of WHOQOL-BREF includes sleep, mobility, fatigue, pain, and work capacity. Study results suggest that improvement in the experimental group scores compared to the control group may be due to yoga acting on reduced pain, fatigue, sleep, and mobility.

The psychological domain has shown improvement in the yoga group compared to control in all the facets like learning, feelings, spirituality, thinking, self-esteem, and memory. This improvement may be due to reduced stress, anxiety, and depression.^[29]

The social domain scores are better in the yoga intervention group than the control group of enhanced interpersonal relationships and social support in the PTB patients. In contrast to this in the environmental domain, we observed no significant change in both groups, as the home environment remained the same throughout; this might have been the reason.

There have been a limited number of randomized controlled trials examining the effects of yoga on QoL in patients with PTB. One study published in 2018 in the reputed international journal found that a 12-week yoga intervention led to significant improvements in QoL, as well as reductions in anxiety and depression symptoms, among TB patients in India.

The study being Randomized controlled trial (RCT) design had more strength in terms of yoga addressing psychological issues, noninvasive, cost-effective, and easy to learn and practice. It is the first interventional study with yoga that had addressed the health-related aspects of QoL in PTB. However, few limitations are essential to note that this study had a small sample size, single district covered, study duration was not assessed in the continuation phase of TB treatment, and further research with higher sample size is needed to confirm these findings.

Conclusion

The study provides evidence to support the use of yoga as a complementary therapy for the NTEP in patients with PTB to improve their QoL. By enhancing QoL and respiratory function, yoga may help patient's better cope with TB's physical and psychological challenges, ultimately leading to better treatment outcomes and a better QoL.

Future suggestions

More research is needed to confirm these findings with large sample sizes, multicentric trials, different parameters, and types of yoga for patients with PTB. However, with appropriate care and support, many patients can manage their symptoms and achieve a good QoL. Hence, the yoga module may be included in future NTEP programs for better patient care.

Ethical statement

The study was approved by the Institutional Ethics Committee of Sri Devaraj Urs Academy of Higher Education and Research with Approval Ref: SDUAHER/ IEC/MJ/13/22-23.

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Conflicts of interest

There are no conflicts of interest.

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