

Assessment of Health related Quality of Life in Tuberculosis Patients of South India

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INTRODUCTION:

Quality of life is defined as the general well being of a person or society, defined interims of health and happiness rather than wealth.¹ Health related quality of life(HRQoL) is a multidimensional concept that comprises domains of physical, mental, emotional and social functioning.² It measures the health status of normal functions of life. Impaired health related quality of life may lead to unhappiness and medication non adherence which can further lead to resistance to anti-TB drugs.³ Physicians and other health care officials have been using HRQoL for measuring the physical, mental and social well being of a patient. Measurement of HRQoL is essential among patients with long-standing disease like TB.⁴

Tuberculosis (TB) is a communicable disease caused by a bacterium called *Mycobacterium tuberculosis* that most often affects the lungs. Tuberculosis often presents as lung disease and also affects bone, urinary tract, intestine and sexual organs even the skin. It can easily spread from person to person via air droplets when the person with active tuberculosis coughs.⁵ Tuberculosis is the most frequently diagnosed disease in human immunodeficiency virus (HIV) infected patients world-wide.⁶ India accounted for 33% of global TB deaths among HIV-negative people, and for 26% of the combined total of TB deaths in HIV-negative and HIV-positive people. Globally, the TB mortality rate (per 100 000 population) fell by 37% between 2000 and 2016.⁷ The general symptoms of pulmonary tuberculosis are loss of weight, general weakness, persistent cough, lack of appetite, chills and body pain.⁸

Directly observed alternate day treatment (DOTS) for TB under Revised National Tuberculosis Control Program (RNTCP) in India had shown to be effective in TB patients with or without HIV infection.^{9,10} Increased awareness and knowledge about disease symptoms, treatment regimen and preventive measures achieve better treatment outcomes.¹¹ Considering the fact quality of life, Pulmonary Tuberculosis (PTB) patients had poor quality of life compared to general population.^{12 13} TB patients especially who have poor socio-economic background experiences various physiological, social problems and financial problems. These difficulties will have greater impact on quality of life.^{14 15} In addition to this; side

effects associated with Anti-TB drugs may further diminish the quality of life if the patient is not monitored continuously.¹⁶

HRQoL provides the information on patient's perception of improvement, besides routine clinical, bacteriological and radiological assessments.¹⁷ Hence it is an important tool for treating the TB patients with better outcomes. Very few studies available in medical literature regarding health related quality of life of tuberculosis patients in south India .With these voids in literature, the present study was conducted to evaluate health related quality of life of PTB patients and also factors affecting the poor quality of life.

MATERIALS AND METHODS

Study design and settings:

This was a prospective and observational study of quality of life of tuberculosis patients admitted to the Tuberculosis ward of Government Infectious disease hospital, Guntur, Andhra Pradesh, India from January 2017 to August 2018(twenty months).

Ethics approval and consent to participate:

All patients were informed about the study and had given their consent. The study protocol was prepared and submitted to the ethical committee of Govt. ID. Hospital and approved by the same.

Sources of data and study material:

The sources of data used for this study includes patient case records, personnel interviews of patients and their representatives. The study materials include Patient Information Sheet which includes the details of study design, Informed Consent Form which is designed to take consent from patient, Patient Data Collection (PDC) Form which was designed to collect the socio-demographic details and SF-36V2 Questionnaires for assessing HRQoL.

Inclusion criteria:

All patients either sex who were diagnosed with PTB, patients between 18 years and 69 years, patients on regular anti-tubercular therapy.

Exclusion criteria:

Patients who cannot complete a RAND SF-36 questionnaire due to cognitive Impairment, Dementia, Active Psychosis, patients with extra-pulmonary diseases and/or other co-morbidities that affect health related

quality of life, Patients discontinued the treatment and transferred to other hospital, Patients who refuse to complete questionnaire method.

Study procedure:

PTB patients visiting DOTS centre regularly were identified and consented. Patients were enrolled in the study based on inclusion and exclusion criteria. The validated and authorized health related quality of life questionnaire was used to measure patient's own perception on their health status and functioning. The Rand SF-36v2 has become one of the most widely used of the health related quality of life measures. It consists of 36 questions (items) measuring physical and mental health status in relation to eight health concepts: 1)Physical functioning(PF), 2)Role limitations due to physical health(RP), 3)Bodily Pain(BP), 4)General health perceptions(GH), 5)Vitality(energy/ fatigue) (VT), 6)Social functioning(SF), 7) Role limitations due to emotional health(RE), 8)Mental Health(MH). The first four domains were used to measure physical health and the next four used for measuring mental health Responses to each of the SF-36 items were scored and summed according to a standardized scoring protocol and expressed as a score on 0 – 100 scale for each of the eight health concepts. As well as the eight scales, two summary measures have been calculated: the physical component scores (PCS) and mental component scores (MCS). The summary scores are aggregated measures of the physical health and mental health dimensions underlying the SF-36 questionnaire¹⁸.

Statistical analysis:

Data were recorded on a pre-designed data collection form and managed on an MS Office Excel spread sheet. The descriptive statistics were represented by mean \pm standard deviation and percentages. The differences between the groups were determined by the parametric t-test & non-parametric statistical test: fisher's exact test or chi-square tests wherever appropriate. Graph Pad prism-5 statistical software was used for the data analysis. Data that was not normally distributed were analyzed using the Mann-Whitney *U* test or Kruskal-Wallis test according to the number of groups to compare. Statistical significance was defined as $p < 0.05$. All *P* values were two tailed.

RESULTS

Patient characteristics:

As per inclusion and exclusion criteria, 350 patients were enrolled in the study, 324 patients completed the study, 26 discontinued to take further treatment at different hospital TB centers. Among all patients, 256 (79.01%) were males and 68 (20.98%) were females. The age of the patients ranged from 17 to 83 years with a mean (SD) of 51.23(9.38) years. Majority of the patients were from 45-59 age group with 94 males and 14 females and least were found in the age group 16-29. Overall literacy rate was found to be 67.9%. Of 324 patients, only 20(6.17%) were graduated, 236(72.84%) were married, 201(62.03%) were employed. Nearly half of the males (101, 39.45%) and one third of females (16, 23.52%) had one or more forms of addiction to smoking. The Majority of patients (36.11%)

were smokers. Rural patients were badly affected by PTB than urban counterparts. Smear test and HIV test were positive in 246(75.92%) and 74(22.83%) patients respectively. Most of the patients (53.70%) were having 1 co-morbidity and 66.04% receiving Cat-I treatment. The socio-demographic and clinical characteristics of PTB were summarized in Table 1.

As highlighted in Table 2, Physical component scores and mental component scores of RAND SF 36v2 were calculated to assess physical health and mental health of the tuberculosis patient. The values are between two extremes 0 and 100, with zero indicating the lowest QoL and 100 indicates the better QoL. There was an improvement in all SF36v2 health domains. The values of PCS at base level, after initial phase and end of the treatment were 33.83 \pm 9.84, 61.74 \pm 12.82 and 69.49 \pm 12.66 respectively and the statistically significant improvement in physical health was seen between initiation of therapy and after two months and also between initiation and end of treatment. But there was no significant statistical difference in between after two months and end of therapy The total score of MCS at base level, after initial phase and end of the treatment were 38.10 \pm 8.62, 46.67 \pm 10.38 and 55.87 \pm 8.24 and the statistically significant development in mental health was observed between after initial phase and end of the treatment and also between initiation and end of treatment. But there was no significant statistical difference in between initiation and after initial phase of therapy (Table 3).

RAND SF-36 scores:

Table 4 represents Rand SF-36 scores by socio-demographic and clinical variables. Males (PCS: 59.36 \pm 17.82, MCS: 66.96 \pm 15.64) scored slightly higher, but statistically significant, than females (PCS: 46.14 \pm 16.60, MCS: 57.40 \pm 15.82) on all scales. Our results demonstrated that increased age was associated with lower QOL. Younger patients in the current study reported significantly better QOL. It was observed that among all patients elderly patients (> 60 years) had greatly affected in domains such as RP (39.38), PF (40.31), VT (51.03) and have significantly reduced PCS (49.70) and MCS (50.91) scores.

The mean PCS and MCS scores of Illiterate patients were found to be 44.43 \pm 21.09 and 59.81 \pm 14.78 respectively which indicated that they had poor quality of life. Graduated patients had a good score in both PCS (66.15) and MCS (68.60) scores which showed that they had a good quality of life when compared to all the other categories which was proved statistically .

Statistically significant difference was found among different occupation groups. Unemployed patients had poor QoL (PCS:44.20 \pm 16.67; MCS: 53.22 \pm 13.34). Patients who were employed had very good QoL (PCS:63.88 \pm 15.79; MCS: 70.00 \pm 14.41) compared to other occupation groups. Physical health domains like PF and RP were more affected in unemployed patients.

Table 1: Socio-demographic and clinical characteristics of the study participants.

Variable	No. of males(256)	No. of females(68)	Total (324)
Age			
16-29	20(52.63)	18(47.36)	38(11.72)
30-44	66(75)	22(25)	88(27.16)
45-59	94(87.04)	14(12.96)	108(33.33)
> 60	76(84.4)	14(15.56)	90(27.78)
Education			
Illiterate	76(73.08)	28(26.92)	104(32.1)
Primary	121(87.68)	17(12.31)	138(42.59)
Secondary	52(83.87)	10(16.13)	62(19.13)
Graduate	7(35)	13(65)	20(6.17)
Marital Status			
Married	189(80.08)	47(19.91)	236(72.84)
Unmarried	24(82.75)	5(17.24)	29(8.95)
Divorced	39(92.86)	3(7.14)	42(12.96)
Widowed	0	17(5.24)	17(5.24)
Smoking Status			
Smoker	101(86.32)	16(13.68)	117(36.11)
Non smoker	40(48.78)	42(51.22)	82(25.30)
Past smoker	51(87.93)	7(12.07)	58(17.90)
Chain smoker	64(95.52)	3(4.48)	67(20.68)
Occupation			
Employed	188(93.53)	13(6.47)	201(62.03)
Unemployed	44(51.76)	41(48.24)	85(26.23)
Retired	24(63.15)	14(36.84)	38(11.72)
Location			
Rural	204(80.63)	49(19.37)	253(78.1)
Urban	52(63.15)	19(26.76)	71(21.91)
Type of treatment			
Cat-I	189(88.32)	25(11.68)	214(66.04)
Cat-II	67(60.91)	43(39.09)	110(33.95)
Smear test			
Positive	213(86.59)	33(13.41)	246(75.92)
Negative	43(55.13)	35(44.87)	78(24.1)
HIV status			
Positive	47(63.51)	27(36.49)	74(22.83)
Negative	209(83.60)	41(16.40)	250(77.16)
Total Chronic Co-morbidities			
None	48(66.67)	24(33.33)	72(22.22)
1	148(85.05)	26(14.94)	174(53.70)
2	54(75)	18(25)	72(22.22)
≥ 3	6(100)	0	6(1.85)

Table 2: SF 36v2 health domain scores at base line, 2 months and end of the treatment

Scales	Before initiating therapy	After 2 months	End of the treatment
PF	53.57±7.73	61.45±8.62	68.46±9.38
RP	39.93±8.54	65.28±11.74	74.42±10.57
BP	41.82±13.42	64.56±18.47	71.75±15.93
GH	36.95±9.67	55.67±12.45	63.34±14.76
PCS	33.83±9.84	61.74±12.82	69.49±12.66
VT	36.95±6.71	43.53±9.87	54.21±8.68
SF	27.35±12.41	38.90±8.93	46.63±5.72
RE	42.45±6.75	49.36±8.90	62.74±12.72
MH	45.66±8.62	54.89±13.82	59.91±5.87
MCS	38.10±8.62	46.67±10.38	55.87±8.24

Table 3: Statistical analysis of PCS and MCS at initiation of therapy, after 2 months and end of treatment

	PCS(Mean± SD)	Paired t test	MCS(Mean± SD)	Paired t test
Before initiating therapy	33.83±9.84	0.003**	38.10±8.62	0.10 NS
After 2 months	61.74±12.82		46.67±10.38	
After 2 months	61.74±12.82	0.072 NS	46.67±10.38	0.032**
End of the treatment	69.49±12.66		55.87±8.24	
Before initiating therapy	33.83±9.84	<0.001***	38.10±8.62	<0.001***
End of the treatment	69.49±12.66		55.87±8.24	

Table 4: Rand SF-36 scores by socio-demographic and clinical Variables

Variable	PF	RP	BP	GH	PCS	VT	SF	RE	MH	MCS
Gender										
Males	51.65	57.76	72.46	55.57	59.36	51.55	73.14	68.77	74.39	66.96
Females	39.98	34.77	56.07	53.72	46.14	50.83	53.08	64.17	61.52	57.40
Age										
16-29	84	74	79	74	76.81	59	71.76	75	83.72	72.37
30-44	63.17	71.22	67.96	57.78	65.03	56.50	69.83	68.00	76.78	67.78
45-59	53.48	60.35	69.67	54.50	59.50	50.67	67.40	60.80	78.79	64.42
> 60	40.31	39.38	64.60	54.50	49.70	51.03	63.49	45.89	43.23	50.91
Education										
Illiterate	31.24	36.07	57.97	52.42	44.43	48.58	56.34	64.91	69.42	59.81
Primary	56.76	57.91	75.02	58.79	62.12	59.00	78.17	63.67	65.67	66.63
Secondary	45.25	40.96	57.63	50.84	48.67	46.01	66.04	65.84	62.22	60.03
Graduate	47.33	65.67	87.33	64.27	66.15	56.14	72.36	70.71	75.19	68.60
Occupation										
Employed	58.35	66.04	75.48	55.65	63.88	54.00	76.31	70.42	79.25	70.00
Unemployed	37.33	37.06	48.58	53.81	44.20	47.33	47.07	61.79	56.67	53.22
Retired	41.86	39.48	69.64	54.91	51.47	50.71	68.11	67.14	68.25	63.55
Marital Status										
Married	48.11	49.23	68.47	56.48	55.57	50.84	67.33	66.78	70.58	63.88
Unmarried	67.75	80.25	82.75	46.71	69.37	50.25	74.00	72.00	74.00	67.56
Divorced	53.67	60.00	68.00	49.41	57.77	53.67	74.00	74.27	76.78	69.68
Widowed	30.36	35.36	48.55	52.30	41.64	52.64	47.56	60.27	56.57	54.26
Smoking Status										
Smoker	45.29	42.43	62.06	55.37	51.29	51.35	64.79	66.59	67.63	62.59
Non smoker	48.42	66.31	73.41	55.98	61.03	50.67	71.60	67.79	79.77	67.46
Past smoker	54.16	55.09	74.61	53.15	59.25	52.70	67.42	68.91	70.09	64.78
Chain smoker	24.00	24.00	32.75	57.33	34.52	36.50	49.00	57.00	32.33	43.71
Location										
Rural	60.45	64.28	63.56	54.67	60.74	42.45	54.79	46.63	56.74	50.15
Urban	52.19	38.93	40.82	37.95	42.47	45.71	43.23	54.21	62.14	51.32
Type of treatment										
Cat-I	49.16	60.83	75.85	54.81	60.16	51.22	67.22	65.36	74.55	64.59
Cat-II	47	54.13	64.04	56.08	55.31	52.75	60.88	63.91	67.62	61.29
Smear test										
Positive	48.11	50.23	68.47	56.48	55.82	47.96	54.48	64.49	62.84	57.44
Negative	53.67	60	69	50.41	58.27	66.5	76.17	80.63	58.37	70.42
HIV status										
Positive	26	35	32.44	57.88	37.83	36.5	49	57	32.33	43.71
Negative	44.29	43.54	62.09	55.67	51.40	51.35	64.79	66.59	67.63	62.59
Total Chronic Co-morbidities										
None	66.50	80.25	79.63	58.37	71.19	49.00	86.50	71.83	71.22	69.64
1	59.00	61.50	86.50	59.77	66.69	51.81	69.71	69.24	76.78	66.89
2	52.93	48.33	69.41	55.05	56.43	52.45	68.91	67.94	67.97	64.32
≥3	46.02	57.69	56.26	43.28	50.81	54.00	57.13	53.00	74.00	59.53

Table 5: Comparison of physical component scores and mental component scores by socio-demographic and clinical Variables

Variable	Frequency (%)	PCS score (Mean ± SD)	P-Value	MCS score (Mean ± SD)	P-Value
Gender					
Males	256(79.01)	59.36 ± 17.82	< 0.0001 ^b	66.96 ± 15.64	< 0.0001 ^b
Females	68(20.98)	46.14 ± 16.60		57.40 ± 15.82	
Age					
16-29	38(11.72)	76.81 ± 9.34	0.0008 ^a	72.37 ± 7.56	0.0007 ^a
30-44	88(27.16)	65.03 ± 11.98		67.78 ± 14.95	
45-59	108(33.33)	59.50 ± 19.00		64.42 ± 14.93	
> 60	90(27.78)	49.70 ± 18.13		50.91 ± 17.11	
Education					
Illiterate	104(32.1)	44.43 ± 21.09	< 0.0001 ^a	59.81 ± 14.78	< 0.0001 ^a
Primary	138(42.59)	62.12 ± 15.80		66.63 ± 19.31	
Secondary	62(19.13)	48.67 ± 16.87		60.03 ± 17.54	
Graduate	20(6.17)	66.15 ± 21.37		68.60 ± 16.46	
Occupation					
Employed	201(62.03)	63.88 ± 15.79	< 0.0001 ^a	70.00 ± 14.41	< 0.0001 ^a
Unemployed	85(26.23)	44.20 ± 16.67		53.22 ± 13.34	
Retired	38(11.72)	51.47 ± 17.73		63.55 ± 16.78	
Marital Status					
Married	236(72.84)	55.57 ± 18.89	0.1198 ^a	63.88 ± 16.51	0.1158 ^a
Unmarried	29(8.95)	69.37 ± 11.01		67.56 ± 15.47	
Divorced	42(12.96)	57.77 ± 17.12		69.68 ± 14.00	
Widowed	17(5.24)	41.64 ± 15.31		54.26 ± 14.02	
Smoking Status					
Smoker	117(36.11)	51.29 ± 17.04	0.1320 ^a	62.59 ± 16.64	0.1450 ^a
Non smoker	82(25.30)	61.03 ± 16.46		67.46 ± 15.06	
Past smoker	58(17.90)	59.25 ± 20.00		64.78 ± 16.44	
Chain smoker	67(20.68)	34.52 ± 24.30		43.71 ± 3.24	
Location					
Rural	253(78.1)	60.74 ± 14.32	0.1168 ^a	50.15 ± 14.76	0.1751 ^a
Urban	71(21.91)	42.47 ± 8.67		51.32 ± 11.81	
Type of treatment					
Cat-I	214(66.04)	60.16 ± 10.65		64.59 ± 9.1	
Cat-II	110(33.95)	55.31 ± 13.83		61.29 ± 11	
Smear test					
Positive	246(75.92)	55.82 ± 11.74	0.1566 ^a	57.44 ± 8.21	0.1115 ^a
Negative	78(24.1)	58.27 ± 8.65		70.42 ± 13.82	
HIV status					
Positive	74(22.83)	37.83 ± 9.40		43.71 ± 7.81	
Negative	250(77.16)	51.40 ± 12.29	0.0021 ^a	62.57 ± 12.71	0.0085 ^a
Total Chronic Co-morbidities					
None	72(22.22)	71.19 ± 10.88		69.64 ± 16.54	
1	174(53.70)	66.69 ± 17.38		66.89 ± 14.96	
2	72(22.22)	56.43 ± 18.13		64.32 ± 15.98	
≥3	6(1.85)	50.81 ± 19.69	0.0041 ^b	59.53 ± 17.32	0.0072 ^b

^aStatistical significance of differences calculated using the Kruskal-Wallis test ; ^bStatistical significance of differences calculated using the Mann-whitney U test

Table 6: Differences of SF-36 domains between survival and deceased patients

Sf-36 Domain	Surviving Patients	Deceased Patients	P- Value(t-test)
Physical Component Summary	60.48±17.01	26.53±6.15	< 0.0001*
Physical Functioning(PF)	51.61±22.38	26.82±19.40	0.0018*
Role limitations due to physical health(RP)	55.32±41.82	18.18±29.77	0.0020*
Bodily Pain(BP)	71.21±24.45	38.86±23.96	0.0011*
General Health perceptions(GH)	56.99±15.63	48.25±16.39	0.2180
Mental Component Summary	67.08±15.09	40.55±9.17	< 0.0001*
Vitality(VT)	53.67±13.24	39.55±11.28	0.0021*
Social functioning(SF)	70.71±25.61	40.91±27.44	0.105
Role limitations due to emotional health(RE),	69.13±13.79	60.73±10.71	0.309
Mental Health(MH).	66.1± 19.3	57.1±17.8	0.248

*Statistically significant

Widowed patients had poor physical (41.64±15.31) and mental (54.26±14.02) health scores. Physical health scores were found to be high in unmarried patients and mental health scores were found to be in high divorced patients. But there was no statistically significant difference among the groups in PCS and MCS scores.

There was a strong association between smoking and reduced QoL scores. It had been found that chain smokers showed poor PCS (34.52±24.30) and MCS (43.71±3.24) scores which indicated lower levels of QOL. Chain smoker had showed poor scores in domains like PF (24), RP (24), BP (32.75), MH (32.33), VT (36.50), SF (49). Non smoker had a good QoL.

There was no significant difference between rural and urban patients in physical and mental health scores. Patients of urban areas have more mental strength than rural counter parts and in contrast rural patients were physically stronger than urban patients. (MCS: 51.32±11.81 vs 50.15±14.76; PCS: 60.74±14.32 vs 42.47±8.67).

Patients who were on Cat-I treatment had better quality of life scores than patients on Cat-II treatment. Cat-II patients were significantly affected in physical functioning (PF:47).

patients who were negative for smear test had lower scores of PCS (58.27) and MCS (70.42) indicating that they had poor quality of life whereas patients were positive smear test result had good scores of PCS (56.48) and MCS(57.44) indicating that they had poor quality of life.

Moreover HIV negative patients had good scores than HIV positive patients in all domains. There was significant difference between HIV negative and HIV positive patients in PCS (51.40±12.29 vs 37.83±9.40) and MCS (62.57±12.71 vs 43.71±7.81).

It was also found that there was a strong relationship between number of co-morbidities and all the domains of quality of life. Patients with more number of co-morbidities associated with poor PCS (50.81±19.69) and MCS (59.53±17.32) scores significantly. However there were a few patients had no co-morbidities showing good scores of all domains of QOL.

The mean PCS and MCS scores were 55.02±11.77 and 46.88±9.08 respectively. In PCS and MCS there were significant differences between participant groups according to gender, age, education, occupation, type of treatment, HIV status and no of co-morbidities (p -value < 0.05) but there were no significant differences according to marital status, smoking status, location and smear test. Comparison of physical component scores and mental component scores socio-demographic and clinical variables were shown in Table 5.

During the 20 months follow-up period, eighteen patients (5.55%) died. Table 6 compares the characteristics of the deceased and surviving patients. Both the mental health dimension score and Physical health dimension score were significantly higher in surviving patients (67.08±15.09, 60.48±17.01) when compared with that of deceased patients (40.55±9.17, 26.53±6.15) respectively. There

were significant differences between surviving and expired patients in BP, PF, RP and VT.

DISCUSSION:

This study was carried out in tuberculosis patients to assess how quality of life was changed before and after anti-tubercular therapy. To measure the physical health and mental well-being, RAND SF-36 vs2 was used and there was a gradual improvement in scores of physical component (PCS) and mental component summaries (MCS). A few studies had used a DR-12 questionnaire and SF-12 instrument.^{19, 20, 21}

Both PCS and MCS scores were less than 50 before initiation of the treatment. At the start of the treatment, compared with PCS, lower MCS scores showed that the patients experienced more psychological distress and role limitation due to emotional problems than the physical problems.

TB treatment had significantly improved physical health of the patients in initial phase. A similar trend was observed between baseline of the treatment and end of the treatment. The most affected health domains were RP and GH which mean that the patients had severe problems in performing their daily life activities due to limitation in physical activity. Physical health scores were quickly improved than mental health scores in the first two months of initial phase of the treatment similar to previous study.²²

However patients rated their overall health as poor even after initial phase. With regard to the mental health score there was a gradual improvement seen between baseline of the treatment and after initial phase but significant improvement was observed at the end of the treatment. Because patient experienced more psychological problems than physical problems which is agreed with previous study.²³

The findings of our study showed that there were more males (79.01%) than females (20.98%). in contrary to this, study carried out by Marra et al indicated more female patients. 22 Males had scored slightly higher on all domains of SF-36v2 which implied that they had better quality of life than females as mentioned in a previous study.²⁴

Among 324 patients who were involved in the study; they belong to different age groups in which highest number of patients were of age group 45-59 years, which was not similar to the study conducted by Muhammad Miandad et.al, in which highest affected population here was 21-30years.²⁵ Age groups involved in study showing significant difference in PCS &MCS scores and elderly age group showed showing poor PF (40.31), RP (39.38), RE (45.89) & MH (43.23) scores. Similarly Muhammad Atif et al demonstrated that patients aged <45 years scored lowest PCS and MCS scores²⁶

Among education levels, illiterate patients were showed lower scores of PCS (44.43±21.09) and MCS (59.81±14.78) which indicate poor quality of life. Low level of awareness about tuberculosis led to poor quality of life and education is the prerequisite for improving the living standards and also quality of life.²⁵

With regard to SF-36 domains, there was a significant difference among employed, unemployed and retired patients. Unemployed patients were more affected in scores of PF (37.33) and RP (37.06) VT(47.33) & SF(47.07). This might be due to the fact that education leads to more adaptability in life and motivation for self-care which overall improves vitality and social functioning.^{27, 28}

In this study, out of 324 patients who were involved in the study highest population is married (72.84%) with gender distribution ratio of men and women were 80.08 & 19.91% respectively. This was similar to the study conducted by Muhammad atif et.al.²⁶ With regard to HRQoL scores, widowed patients showed poor quality of life. This is in similar to a study carried out by Julia Louw et al.²⁹

The ratio of smokers and non smokers was evaluated showing highest number of population were smokers with 36.11% and non-smokers were 25.30%. Smoking doesn't show significant difference between PCS & MCS values but poor response was seen by chain smokers in all domains of PCS & MCS. The most affected domains were PF (24.00) and RP (24.00) indicated poor physical activity and limitation in performing physical activities. A case control study found that smoking cessation showed improved results in quality of life.³⁰ There are various pathological mechanism poor quality of life in smoking patients. Tobacco smoking and indoor pollution were identified as risk factors for TB.³¹ Chronic exposure to tobacco impairs host defensive mechanism by clearance of secretions of Mycobacterium tuberculosis on the tracheobronchial mucosal surface.³² Smoking also diminishes the phagocytic ability of pulmonary alveolar macrophages.³³

Among the study population involved in the study here highest percentage belongs to the Rural area with 78.1% and with a percentage of 21.91 from urban locality since rural patients have poor economical status so that they approach nearby Govt serviced DOTS centers where medications are offered at free of cost. Rural patients had good mean scores in physical health where as urban patients had good mean scores in mental health. This might be due to most of the rural patients were illiterate and unaware of disease and drug regimen and also medication non-adherence. Patients from urban areas low vitality and decreased social activity.^{34, 35}

Our study showed that patients on Cat-II drugs had low scores in all domains of physical and mental health.

Cat-II treatment involves three months of initial phase and 6 months of continuous phase. In initial phase of Cat-II treatment streptomycin is added to HRZE combination for the first two months and later HRZE will be continued for one more month. There a clear difference in number of medications and duration of treatment between CAT-I and Cat-II treatment here will be more chances of ADRs and multi drug resistance (MDR) cases.

According to WHO guidelines, CAT II regimen is recommended for patients who have failed the CAT I regimen. On the other hand prevalence of multidrug-resistant tuberculosis (MDR TB) is relatively high among

CAT II patients compared to CAT I patients.³⁶ Some times Therapeutic Drug Monitoring (TDM) is also required to know whether the plasma drug concentration reached above the level of maximum safety concentration.³⁷

The population infected with Mycobacterium Tuberculosis was differentiated into smear positive and smear negative of which highest percentage is smear positive i.e, 75.92%. Even though smear test remains most important diagnostic parameter in Tuberculosis there is no significant difference between Smear positive and negative but Smear positive population showed poor improvement in VT of MCS. Most of the smear positive patients were converted to smear negative. Overall the anti-TB treatment showed positive effect on improving patients' HRQoL.²⁶

There was a significant difference in physical and mental health perception between only TB and TB with HIV. Presence of HIV itself can contribute to other opportunistic infections which may affect patient's nervous system and lead to changes in patient social behavior and functioning. Similarly patient co-infected with TB has increased risk for developing mood, anxiety and cognitive disorders. This might be the reason for decreased social functioning and energy levels and mental health scores were observed in TB with HIV patients^{38, 39}

Satisfactory improvement in HRQoL was not seen in patients those affected by ≥ 3 co-morbid conditions. Our study proved through statistical analysis with good significant difference for PCS & MCS values. Higher the numbers of co-morbidities lower the PCS and MCS scores. Presence of number of co-morbidities increase levels of depression and anxiety which is in agreement with a number of studies.²⁷

In our study 18 patients were died during the 20 months follow up period. . All deceased patients health scores were get worsen day by day with unsatisfactory result with treatment. These patients had Aspergilloma fungal infection, pneumonia and respiratory failure. The risk factor for cause of death in pulmonary tuberculosis patients are fungal infections and other respiratory illness.⁴⁰

CONCLUSION:

Anti-tubercular treatment had encompassing impacts and positive effect on patients' quality of life. There was expeditious improvement in physical health status while gradual improvement was seen in mental health well being. Smoking, alcohol, illiteracy, HIV status had influenced markedly mental well being of patient. Awareness about Medication adherence and patient understanding on disease and duration of treatment further more improve quality of life.

Authors' contributions

RP gathered the data, and was involved in collating and analysing it. SRC conceptualized the study, and were involved in analyzing the data. SRC also contributed for the preparation of article. MKA and HMN contributed in writing paper. BRMV and RRD read, revised and approved the final manuscript.

Acknowledgement:

Authors would like to thank the head of Govt. ID Hospital, Guntur, India and staff members of TB clinic for providing support and facilitating the data collection.

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