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Determinants Associated with Outcomes among Tuberculosis Patients Who Received Prolongation Pouch in Gandhinagar District of Gujarat State, India

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Abstract:
Background*: Tuberculosis (TB) is a communicable disease and one of the leading causes of mortality in India. After 13 years of the launch of RNTCP which claims 100 per cent coverage of population become questionable with rising numbers of MDR and XDR TB with higher default rate. One month extended intensive phase (prolongation pouch) as a solution is not optimized as per need.*
Objectives*: The objectives of the study were to find risk factors and outcome of patients who receiving prolongation pouch.*
Materials and Methods*: A retrospective cross-sectional study is conducted with secondary data from TB treatment card of patients of Gandhinagar district of Gujarat. A list of the patients obtained as per TB treatment register of STS was collected from respective TUs.*
Results*:*
The study shows that middle age group, and male patients are more affected. Weight gain of patients is correlated with favorable outcome. Lesser the smear positivity, higher the chances of a favorable outcome with negative smear result have higher Odds (10.5) of favorable outcome than positive ones. The average duration of treatment is 22 and 27 days more than the expected average duration of treatment in CAT 1 and CAT 2 patients respectively.
Conclusion*: Male and persons from middle age group are affected more than others. Weight gain was positively correlated with a favorable outcome and smear result at the end of prolongation pouch was also predictor of outcome of patient.*
Keywords*: Outcome, Prolongation, Smear result, Tuberculosis, Weight*

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I. Introduction

India is the country with the highest TB burden in the world. An estimated global annual incidence of TB is 9.6 million and out of it, 2.2 million occur in India.[1,2] Annual estimation of death cases rises up to 0.22 million which leads to severe economic burden and human suffering. Potentially increasing numbers of co-infection with HIV and the increasing emergence of strains which are resistant to anti-TB drugs might worsen the situation.[3,4]. In 1993, Revised National Tuberculosis Control Programme (RNTCP) was launched which covered all areas of country by 2006 that leads to decrease in mortality of 0.22 million as compared to 0.33 million earlier and also in incidence and in prevalence but criticism raise on quality after large numbers of cases with failure and lack of access to treatment come onto surface. [3,4]

On a contrary part various obstacle e.g. a long course of treatment, non-adherence to treatment, socio-economic factors etc produce obnoxious outcome as default, failure,and drug resistance. Gender, working condition, the experience of contacting TB patient, the perceptionof health status, attitude, knowledge and social support were significantly associated with a favorableoutcome.[5,6[The unfavorable outcome is associated with immune suppression, higher age & co-morbidity.[7,8]. Anorexia is common complains TB patients have and it hampers to gain body weight which brings a patient on a verge of risk to unsuccessful outcome.[6,9]A long course of treatment makes a comfortable choice to abandon the treatment and produce a higher rate of defaulters.

Illiteracy, difficulty in accessing health facility and non-government DOTS center are identified risk factors for non-adherence of treatment.[10]Default, failure, and drug resistance are outcomes of non-adherence to treatment and ultimately produce unsatisfactory retreatment outcome.[11-14]

MDR and XDR TB are the upcoming challenges and defaulting facilitates the process of drug resistance. Nearly 2 times higher default rate is observed in CAT 2 patients as compared to CAT 1 with alcoholism in male gender as the predictive factor.[8] Default patients are likely to re-register for the treatment[6,7] and lower chances to produce favorable outcome.[12,14] Evidence suggested that there is a higher default rate in the self-drug administered group as compared to DOTS[15]and also in retreatment group.[16] To resolve the drugresistance issue it is obligatory to target defaulting [5][6] by strengthening DOTS activity.[5,13]

RNTCP has regular checks on the progress of treatment and bacillary load by sputum smear microscopy. Evidence suggests that higher sputum smear grading have significantly higher chances of a failure rate than of lower sputum smear grading[1,3,10,14]The intensive phase of treatment is critical for patients with the immense cavitary lesion and to target the defaults. The constant motivation for regular treatment and sustained commitment to control TB up to initial sputum smear or after Intensive phase sputum smear or extra one month extended Intensive phase would make a strong impact on default rate and its consequences.

Treatment is divided intotwo-phase- Intensive and continuous phase. Intensive phase is important to achieve cure and sputum negativity. The intensive phase of treatment is extended by giving prolongation treatment to those patients who report sputum positive even after 2 months of intensive treatment in CAT 1 and 3 months in CAT 2. This regimen of prolongation phase is peculiar to the Indian RNTCP program.[17,18] Since such a regimen is not followed elsewhere in the world, the RNTCP programme has evinced interest in research to know the effectiveness or response of this regimen. This study will explore this area by studying treatment outcomes among patients receiving Prolongation treatment.

II. Materials And Methods:

This Retrospective Cross-sectional study was carried out for all patients who received prolongation pouch from the year 2010 to 2013 at Gandhinagar district of Gujarat state. A total of 464 subjects nrolled for the study and secondary data analysis.

Study Design: A Retrospective Cross-sectional

Sample size calculation: all patients who received prolongation pouch from the year 2010 to 2013 at Gandhinagar district of Gujarat state

Sample size: 464 patients

Subjects & selection method: These patients were identified from TB treatment register maintained by STS at District tuberculosis centre of Gandhinagar district, Gujarat. Treatment cards of these patients were collected and analyzed with reference to pre-tested and pre-decided variables. Patients who had received prolongation pouch in CAT 1 and CAT 2 (pulmonary) treatment started from 1st January 2010 to 31stDecember2013. Those patients who had taken treatment from private set up, from government hospitals and extrapulmonary TB cases were excluded from the study. For the data collection, a list of the patients obtained as per TB treatment register of STS and treatment cards of the patients were collected from respective TUs.

Procedure methodology:

This study includes secondary data analysis form already available records at District tuberculosis centre of Gandhinagar district. A useful data for result and analysis were extracted from Treatment card. Details of age, sex, weight, use of prolongation pouch along with favourable and unfavourable outcomes in sense of cured, default and failure of treatment etc., were recorded in well-designed questionnaire.

Statistical analysis:

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Data from treatment cards were entered in Epi-info format in Microsoft Excel and analyzed to meet the objectives.

III. Results

Table 1 shows, total 464 patients were identified for the study for a period of 2010 to 2013 with 289 (62%) were belong to CAT 1 and 175 (38%) were belong to CAT 2. Majority of the patients, 54% were from the age group of 21 to 40 years. Around 70% of patients got the favorable outcome (cure) after completing the treatment. CAT 2 patients were more vulnerable than CAT 1 patients as more than 70% of patients gotfavorable outcome while in CAT 2, less than 70% of patients get a favorable outcome in all age group. In an unfavorable outcome group; 38 patients were died during the course of treatment and out of it, 50% belong to the age group of 31 to 40 years. In the same age group e.g. 31 to 40 years 34% patients out of 38 patients were noticed with treatment failure. Default cases registered (38), 37% were only from the age group of 21 to 30 years. Out of 17

registered cases who switched to CAT 4 during the course of treatment, 53% were fromthe age group of 21 to 40 years.

Table 1: Age group wise distribution of outcome of treatment

Category	Age	Cured	Default	Died	Failure	Switched to CAT- 4	Transferred out	Transferred in	Total
CAT 1	0-10	0	0	0	0	0	0	0	0
	11-20	25	0	0	2	1	0	0	28
	21-30	58	7	4	2	4	1	0	76
	31-40	46	2	9	3	3	1	0	64
	41-50	43	3	3	2	0	1	0	52
	50+	55	4	3	4	1	2	0	69
CAT 2	0-10	0	0	0	0	0	0	0	0
	11-20	2	2	3	2	2	1	0	12
	21-30	35	7	6	7	0	2	0	57
	31-40	27	5	7	10	2	0	1	52
	41-50	16	5	1	4	2	0	0	28
	50+	17	3	2	2	2	0	0	26
Total		324	38	38	38	17	8	1	464

Table 2 shows the relation of gender to the treatment outcome. 73% were male while 27% were female. In both gender groups,CAT 1 patients are higher in numbers in than CAT 2. In female group, 61% patients were of CAT 1 while 39% were of CAT 2.In the male group, 67% and 37% patients were of CAT 1 and CAT 2 respectively. Asymmetry found in the patients who died during the course of the treatment where more number of patients found in CAT 2 as compared to CAT 1 in female patients while in male patients more number of patients were found in CAT 1 than CAT 2. The same asymmetry followed in the patients who switched to CAT 4. Symmetrical result e.g. number of patients found in CAT 1 is more as compared to CAT 2 in both the gender was observed with cured, default and failure of treatment outcome.

Table 2: Sex distribution to outcome

Outcome	Female			Male			Total
	CAT 1	CAT 2	Total	CAT 1	CAT 2	Total	
Cured	70	18	88	157	79	236	324
Default	4	7	11	12	15	27	38
Died	5	8	13	14	11	25	38
Failure	0	8	8	13	17	30	38
Switched to CAT 4	5	0	5	4	8	12	17
Transferred out	1	1	2	4	2	6	8
Transferred in	0	0	0	0	1	1	1

Table 3 shows that as the treatment progress, the number of the patients decreases gradually because of higher default and death rate. At the start of treatment, patients with 3+ to 2+ sputum positivity had 1.1 times higher chances of unfavorable outcome than patients with 1+ to scanty sputum positivity with OR of 1.1. At end of an Intensive phase or the start of prolongation pouch, patients with 1+ to scanty had 2.4 times higher chances of favorable outcomes than with 3+ to 2+ sputum smear positivity with OR of 2.4. At the end of treatment,the binary result may come forward inevitably – negative or positive (3+ to scanty). At end of the extended intensive phase, patients with negative sputum smear result had 10.5 times higher chance of favorable outcome than with positive (3+ to scanty) sputum smears result with OR of 10.5.

Table 3: Sputum smears result to the outcome

Time of sputum examination	Smear result	Outcome		Total	Odds ratio (OD)	Confidence Interval (CI)
		Favourable	Unfavourable			
At start of treatment (1st smear)	3+ to 2+ 1+ to scanty Total	253 71 324	100 31 131	353 102 455	1.1	0.68-1.78
End of Intensive phase (2nd smear/ 1st follow up)	3+ to 2+ 1+ to scanty Total	54 270 324	30 63 93	84 333 417	2.4	1.41-4.02
End of Extended intensive phase (3rd	3+ to scanty Negative	35 289	42 33	77 322	10.5	5.92-8.68

smear/ 2nd follow up)	Total	324	75	399		

Analysis of change in weight was carried out only in cured patients due to completion of data in terms of weight before starting treatment and at the completion of treatment in table 4. Out of 324 cured patients, 227 (70.06%) patients were from CAT 1 and 97 (29.93%) patients were of CAT 2. In CAT 1, 70 (30.83%) and 157 (69.16%) patients were female and male respectively. In CAT 2, 18 (18.55%) were female while 79 (81.44%) were male patients. Average weight of Patients at the end of treatment and at the end of intensive phase is higher as compared to start of the treatment.

Table 4: Weight comparison with treatment progress

Duration of treatment	Category	Sex	Mean (Kg)	Patients No.	SE (mean)	SD
Start of treatment	CAT 1	Female	35.74	70	0.79	6.67
		Male	43.31	157	0.68	8.62
	CAT 2	Female	37.83	18	1.51	6.42
		Male	42.82	79	0.81	7.18
	Total		40	324	0.95	7.23
End of Intensive Phase	CAT 1	Female	36.41	70	0.86	7.24
		Male	44	157	0.68	8.51
	CAT 2	Female	38.61	18	1.51	6.4
		Male	43.38	79	0.77	6.91
	Total		40.6	324	0.95	7.27
End of Extended Intensive phase	CAT 1	Female	37.3	70	0.87	7.32
		Male	44.62	157	0.68	8.59
	CAT 2	Female	39.22	18	1.41	5.97
		Male	43.91	79	0.78	6.95
	Total		41.2	324	0.64	7.21
End of Treatment	CAT 1	Female	38.77	70	0.92	7.66
		Male	46.05	157	0.68	8.62
	CAT 2	Female	40.67	18	1.48	6.28
		Male	45.07	79	0.79	7.02
	Total		42.6	324	0.97	7.4

Table 5 shows the relation of actual duration of treatment with expected duration of treatment among cured CAT 1 and CAT 2 patients. The duration for CAT 1 patient to complete the treatment after taking prolongation pouch (extended intensive phase) was 210 days while 270 days for CAT 2 patient. Out of 324 cured patients, 70.06% patients were from CAT 1 and 29.93% were of CAT 2. In 227 CAT 1 patients, actual mean time to complete treatment was 232 days which was 22 days more than the expected duration of the treatment while in 97 CAT 2 patientswere 297 days which was 27 days more than the expected duration.

Table 5: Actual duration of treatment with expected duration of treatment among cured CAT 1 and CAT 2 patients

Category	Sex	Expected duration of treatment (days)	Actual duration of treatment (Mean) (days)	SE mean	Patients No.	SD
CAT 1	Female	210	231	2.914	70	24.38
	Male		233	2.747	157	34.43
	Total		232	5.66	227	29.4
CAT 2	Female	270	300	7.071	18	30
	Male		294	5.192	79	46.15
	Total		297	6.13	97	38

IV. Discussion

As per global TB report 2017, India with incidence of 2.74 million accounting for quarter of world TB cases.[18] An estimated mortality due to TB has risen to 0.41 million in India which leads to severe economic burden and human suffering.[18] The condition might be worsening due to increase in co-infection with HIV and increasing strains those are resistance to anti-TB drugs.[3]In 1993, RNTCP was launched which cover entire country by 2006. Though incidence and mortality has decreased with implementation of highly effective DOTS regimens but still TB treatment coverage among notified patients was 65% and treatment success rate was 69% in 2017.[18]This present study had explored the various obstacles to treatment success among the patients who had received prolongation treatment.

In the present study, maximum i.e. 54% patients were from age group of 21-40 years. Male patients were more involved and also defaulted more as compares to female patients which shows the similarity with the finding observed in study done by V.Chandrasekaran 2005.[6]The present study found that at the end of extended phase, those with negative smear initially had 10.5 times higher chances of favourable outcome than with positive. A similar observation was found in studies done by Mukherjee A et al.[1] and Rajpal S et al.[3] Krapp F et al.[9] demonstrates that at the end of treatment, less than 5% body weight gain is a predictor of unfavourable outcome. Similarly in the present study, average weight gain of the patients at the end of the treatment and also at the end of extended intensive phase was less than 5% of the average weight of the patients at the start of the treatment. In the study, an average duration for completion of the treatment as compared to the expected duration was 22 and 27 days higher for CAT1 and CAT 2 respectively which leads non-adhernce, failure, increase bacterial load of infectors and high risk of occurance of drug resistance case.[6]

V. Conclusion

A study is conducted to ascertain the importance of extended intensive phase with the outcome and a conclusion come that middle age group is more affected and male are more vulnerable than female. As the treatment progresses the patients give a progressive sign with an increase in body weight and in the study, patient's body weight correlate with a favorable outcome. Sputum smear result can be indicative and speculative for the favorable result and it is proven inevitably true in the study that as positivity is higher, the chance of prolongation of the intensive phase of treatment increases and leads an unfavorable outcome. Average time to complete the treatment is higher than the expected duration of treatment.

LIMITATIONS

Due to lack of time, it could not be possible to relate the significance of this data set against the backdrop of all registered TB cases in Gandhinagar District.

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CONFLICT OF INTEREST: There are no any conflicts of interest.

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