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RESEARCH ARTICLE

FACTOR ASSOCIATED WITH UNFAVOURABLE TREATMENT OUTCOME AMONG ADULT TUBERCULOSIS PATIENTS IN AGRA: A CROSS-SECTIONAL STUDY

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Tuberculosis, Sociodemographic Factor, Knowledge, Perception, Treatment Outcome

Abstract

Background: Tuberculosis has remained a disease of public health importance since ages and is known to inflict large quantum of socioeconomic cost on the society. Risk of TB is high among population living in poverty, low socioeconomic groups, low income, immune-suppressed, and extreme age groups, certain ethnicity, migrants, and those exposed to animals.[1,2]Factors that delay diagnosis similarly increase the length of exposure to an infectious TB patient. Malnutrition increases the susceptibility to disease[3,4].

Aims and Objectives: In our study we identified the sociodemographic factor, knowledge and perception of the subjects about the disease that will cause the unfavourable treatment outcome.

Material and Methods: The study was cross sectional study and conducted at designated microscopic centre of Sarojni Naidu medical college Agra.Total number of patients registered during the period of July to September 2017 were taken. Two follow up were done during the course of treatment.

Result: The overall success rate (cure plus completed) in our study was 80.0%. The subjects who had no knowledge regarding curability have more unfavourable treatment outcome (43.7%) as compare to those subjects who had knowledge of curability (15.73%) (p value=0 .009).

Conclusion: Symptomatic relief by medicine, side effect and forgetfulness of medicine directly affected the treatment outcome.

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Introduction:-

India accounts for about a quarter of the global TB burden. In 2019 the estimated TB incidence was 2,640,000. TB treatment & care in India is provided in the public sector by the government's National Treatment Elimination Program (previously the RNTCP) as well as through private sector health providers. India has 21.02 lakh cases in 2018, reported treatment success was 80%, The Death rate was 4%, Lost to follow-up after treatment initiation was 4%, Treatment failure and regimen change was together about 2%, and an overall of 7% cases was not evaluated after notification.[5] The emergence of multidrug-resistant TB (MDR-TB) poses a major threat to global TB care; only 1 in 5 needing MDR-TB treatment were treated.[6] The NSP proposes bold strategies with commensurate resources to rapidly decline TB incidence and mortality in India by 2025, five years ahead of the global End TB targets and Sustainable Development Goals to attain the vision of a TB-free India.[7] One of the major problems in controlling the TB burden is the poor awareness about disease and knowledge regarding treatment availability.[8,9] This study was designed to identify sociodemographic factors, knowledge about treatment related factor correlated with treatment outcomes among the population of Agra.

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Aim & Objective(s):-

In our study we identified the socio-demographic factor, knowledge and perception of the subjects about the disease that will cause the unfavourable treatment outcome.

Materials and Methods:-

Study Design:
This study was Cross-sectional study.

Study Area:
Department of S.N. Medical College Agra.

Study Population:
Newly diagnosed pulmonary tuberculosis patients registered at T.B.chest department of S.N.M.C. Agra.

Inclusion criteria:
All patients age equal or more than 18 who registered and starting DOT in tertiary Center and the Category-I patients who were not seriously ill.

Exclusion criteria:
Transfer in and transfer out patients. Patients not Residing in Agra. Patients who were seriously ill & infected with HIV,extrapulmonary TB and other than Category – I patients.

Data Collection:
The questionnaire was prepared in hindi and containing both closed and open-ended question. Data was collected by personal interview method after optaining informed written consent by the participants.Two follow up were done during the course of treatment. Sociodemographic data was taken with in the 5 days of registration of the patients. First follow up was done after the complition of intensive phase and the second was done in the end of the continuation phase(5^{th} to 6^{th} month of the treatment).

Since the number of patient's registration is maximum at D.M.C. Sarojni Naidu Medical college Agra, so to achieve desired sample size this D.M.C. was purposively chosen.Total number of patients registered during the period of July to September 2017 were 518, of which 210 were 'old pulmonary' and 'old extrapulmonary' patients, 288 were 'new pulmonary' and 'new extra pulmonary' patients and 80 patients were 'treatment lost to follow up'.Of the 288 new pulmonary & extrapulmonary patients, 123 were pulmonary patients.All the 123 new pulmonary tuberculosis patients (both smere +ve and smere -ve) were included in the study. 18 patients were loss to follow up after registration thus final effective sample size was 105 for futher follow up study (figure 1).

Statistical analysis:
The information collected in Microsoft excel sheet and then it was cleaned for missing values and typing errors. It was imported in to (EPI info 7 & IBM SPSS statistics version 22.0) dataset.The p-value less than 0.05 is considered statistically significant.

1. **Case definition:**
2. **Classification based on history of TB treatment** [10]
3. **New patients** have never been treated for TB or have taken anti-TB drugs for less than 1 month.
4. **Treatment outcome definitions**
5. **Cured** A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
6. **Treatment completed** A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable**.**
7. **Treatment failed** A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
8. **Died** A TB patient who dies for any reason before starting or during the course of treatment**.**
9. **Lost to follow-up** A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.

10. **Not evaluated** A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
11. **Treatment success** the sum of cured and treatment completed.
12. **Transfer out** A patient who has been transferred to another recording and reporting unit and whose treatment outcome is unknown.
13. **Favourable treatment outcome:** In our studycure and treatment completed patients was considered as favourable treatment outcome.
14. **Unfavourable treatment outcome:** In our study died, failure, lost to follow up and defaulter patients were considered as unfavourable treatment outcome.

Results:-

The table 1 shows that overall success rate (cure plus completed) in present study was 80.0%. The success rate among male was comparatively more (83.3%) as compare to female (75.5%). Among 21 subjects with unfavourable treatment outcome the commonest reason was lost to follow-up (9.52%) followed by defaulter (6.66). Sex wise analysis reveals that though lost to follow-up was commonest cause of unfavourable treatment outcome among both male and female, but defaulter to treatment was more common among female (11.0%) as compare to male (3.33%). However, no significant association had been shown by age, sex, education, socioeconomic status, caste, marital status and the type of family.

The table 2 shows that nearly half of them belong to lost to follow up category (47.6%), followed by defaulter (33.3%), die (14%), and then failure (4.76%).

The table 3 shows that unfavourable outcome remains similar irrespective of the status of addiction as it was 22.2% among non-addict and 18.3% among addicts. However, analysis of type of addiction shows that though there was insignificant difference in the treatment outcome among those addicted to tobacco chewing or smoking but a highly significant statistical difference was observed in the unfavourable outcome among alcoholic (41.2%) subjects **(p value=0 .025)**

It was observed that half of the patients with a favourable outcome had some knowledge regarding prevention of tuberculosis; while in unfavourable outcome group only one fourth (5 out of 21) had some knowledge regarding prevention of tuberculosis (**p value=0.030**).

The subjects who had no knowledge regarding curability have more unfavourable treatment outcome (43.7%) as compare to those subjects who had knowledge of curability (15.73%) **(p value=0.009).** On the other hand, knowledge regarding consequences of treatment interruption have no significant association.

The table depict various medicinal factors and treatment outcome among the study subjects. It was observed that among favourable outcome group, almost 100% got the symptomatic relief while such symptomatic relief among unfavourable group was only 28.75% **(p value=0 .000).** Among favourable outcome group, only 47% have some side effect while in unfavourable group 85.71% reported having some side effects.Amongunfavourable outcome group, 85.71% forgot to take medicine while on the contrary, in favourable group 91.66% never forgot to take medicine **(p value=0 .000)** All these differences were found to be statistically significant.

Discussion:-

The national strategic plan 2012-17aimed achieved 90% success rate in new cases because the new case has a higher survival rate.[7] It is necessary to the study the determinants of treatment outcome, both favourable and unfavourable, so that we might know the local factor where will help in planning to achieve 90% success rate. In our study 20% subjects experienced unfavourable treatment outcome and the rate of defaulter was found 6.66%. Vasudevan K. et al, Chadha SL et al and Jonnalagada S et al also have similar finding. [11-13] The risk of unfavourable treatment outcome was higher in those have age 36 and above. Similar finding was observed by Babalik A et al.[14] This may be because of age related comorbidities. Our study shows that favourable outcome was better (82.5%) among the subjects who were educate 6th and above. Kanungo S. et al also found that favourable outcome was more (92.18%) among literate than those who were illiterate (77.27%).[15] Similarly, study carried out in Amritsar by Sadana P et alobservedfavourable outcome maximum (92.1%) in subjects who were educate above matric (89.3%) than those who were illiterate (77.4%).[16] Shophia V et alalsofound that the subjects who were literate having lower percentage

of poor outcome (31%) as compare to the illiterate patients (35%).[17] In our study Caste wise analysis indicate that proportion of favourable treatment outcome was 86.4%, 78.3% among General, and others (SC/ST & OBC) respectively. Study carried out by Bagga R V et alin Panjab reported that unfavourable treatment outcome more (16.3%) among the subjects belonging to the SC caste as compare to subjects belonged to non-SC caste (15.5%).[18] Present study found favourable outcome was more among married subjects (80.9%) as compared to the others (78.4%), however the difference was statistically insignificant. Contrary to our finding, Bagga R V et alreported unmarried (88.9%) having higher favourable treatment outcome compared to married (80.8%).[18] In our study it was observed that unfavourable treatment outcome was more (21.34%) among subjects living in a joint family as compared to those living in a nuclear family (12.5%).Kanungo S et al also found that unsuccessful outcome was more among subjects living in nuclear family (12.0%) as compare to the those who living in joint family (8.0%).[15] The difference in findings of the above-mentioned studies in comparison to our study perhaps may be due to the difference in socio cultural background of these studies, besides Bagga et al, Kanungo et al & Sadana et al studies have larger sample size and were drawn from wider areas. Unfavourable outcome was maximum (41.2%) among alcohol addicts as compared to subjects having addiction with tobacco and smoking in our study and the association was found to be statistically significant (p value=0 .025). The study conducted by Bagga R V et alandKliiman k et alalsofound that unfavourable treatment outcome more among the alcohol addicts (16.7%) & (15.9%) than nonaddicts (15.5%) & (5.5%) respectively.[18,19]

Our study found that the subjects who were not aware about disease transmission had more (25.0%) unfavourable outcome as compared to those (15.09%) having knowledge about fact that disease is transmitted by coughing and sneezing. Putera et al also found that the subjects who had correct knowledge of disease transmission had less (9.41%) unfavourable treatment outcome as compared to those having no knowledge (22.3%).[20] Our study shows that favourable outcome was more (89.3%) among the subjects having knowledge regarding prevention of tuberculosis as compared to those having no knowledge about it (72.4%) (p value=0.030), similarly Putera et al found unfavourable treatment outcome more (21.32%) among the subjects having incorrect knowledge regarding disease prevention as compared to those subjects having correct knowledge (9.75%).[20, 24]

In our study the subjects having lack of knowledge regarding disease curability had more (43.7%) unfavourable outcome as compared to those who had knowledge (15.73%), (p value=0 .009).Similarly, Putera et al observed that unsuccessful outcome was more (32.35%) among the subjects who had no knowledge of disease curability as compared to those having knowledge (12.78%).[20]

In our study more (71.42%) unfavourable outcome was found among subjects who did not get the symptomatic relief as compared to those getting symptomatic relief (28.57%), the association between symptomatic relief by medicine and treatment outcome was found statistically highly significant (p value=0.000). A statisticaly high significant association was observed between treatment outcome and forgetfulness to take medicine as among unfavourable outcome group 85.71% forgot to take medicine while on the contrary in favourable group only 8.33% forgot to take medicine.

Conclusion:-

The study concludes that the treatment outcome was not significantly associated with socioeconomic characteristics. Alcohol directly affected the treatment outcome. Those not aware about disease prevention measure and the curability of the disease having poor outcome. Delayed in care may also lead to multiple visits of a patients to facilities and consequently a delayed diagnosis after care seeking it may also lead to loss to follow-up of patients.[21]Stigma also associated with delay in tretment and defaulting.[22] The tuberculosis control program has also proposed long term follow-up of patients every 6 monthly to detect the cases of relapse early. This can effectively reduce the delay and related morbidity and mortality due to T.B.[23]

Recommendation:-

It is needed that more research is required at community level so that we can generalize for the whole population.

Table 1:- Distribution of Study Group according to treatment outcome.

Treatment outcome	Male (N=60)		Female (N=45)		Total (N=105)	
	n	%	n	%	n	%
Cure	32	53.34	21	46.66	53	50.47
Completed	18	30.00	13	28.80	31	29.53
Defaulter	2	3.33	5	11.00	7	6.66
Died	3	5.00	0	0.00	3	2.85
Lost to follow-up	4	6.66	6	13.33	10	9.52
Treatment failure	1	1.60	0	0.00	1	.95

Table 2:- Distribution of unfavourable treatment outcome of study group.

Type of Un-favourable Treatment outcome	Number of Patients (n=21)	Type of Un-favourable Treatment outcome	Number of Patients (n=21)
Defaulter	7 (33%)	Die	3 (14%)
Lost to Follow up	10 (47.6%)	Failure	1 (4.76%)

Table3:- Association between sociodemographic factor and knowledge about tuberculosis disease and Treatment outcome among study population.

characteristics	Treatment outcome		Total (n=105)	P value
	Favourable (n=84)	Unfavourable (n=84)		
Biological characteristics				
Age group (in years)				
18-35	51(83.60%)	10(16.39%)	61(58.09%)	.276
36 and above	33(75.00%)	11(25.00%)	44(41.90%)	
Sex				
Male	50(83%)	10(16.6%)	60(57%)	.324
Female	34(75.5%)	11(24.4%)	45(42%)	
Sociodemographic characteristic's				
Education				
(Illiterate + up to 5th class)	51(78.46%)	14(21.53%)	65(61.90%)	.615
Educate 6th & above	33(82.5%)	7(17.5%)	40(47.61%)	
Socioeconomic status				
Upper (+Upper middle)	3(60.00%)	2(40.00%)	5(4.76%)	.251
Lower (+Lowermiddle)	81(77.14%)	19(18.09%)	100(95.2%)	
Caste				
General	19(86.4%)	3(13.6%)	22(20.95%)	.401
Others (OBC, SC/ST)	65(78.3%)	18(21.68%)	83(79.04%)	
Marital Status				
Married	55(80.9%)	13(19.1%)	68(64.76%)	
Others	29(78.4%)	8(21.6%)	37(35.23%)	.759
Type of family				
Joint	70(78.65%)	19(21.34%)	89(84.76%)	.415
Nuclear	14(87.5)	2(12.5%)	16(15.23%)	
Addiction habit				
-No	35 (77.8%)	10 (22.2%)	45 (42.9%)	.622
-Yes*	49 (81.7%)	11 (18.3%)	60 (57.1%)	
Tobacco	19 (70.4%)	8 (29.6%)	27 (25.7%)	.122
Alcohol	10 (58.8%)	7 (41.2%)	17 (16.2%)	**.025**
Smoking	21 (91.3%)	2 (8.7%)	23 (21.9%)	.103
Knowledge about the Disease				
Mode of transmission				
Not known	39 (75.0%)	13 (25.0%)	52 (49.5%)	.204
Known-	45 (84.90%)	8 (15.09%)	53 (50.47%)	
Prevention				

No	42 (72.4%)	16 (27.5%)	58(55.23%)	**.030**
Yes	42 (89.3%)	5 (10.63%)	47 (44.76%)	
Curability of Disease				
Don't Known	9(56.2%)	7(43.7%)	16(15.2%)	**.009**
Known	75(84.26%)	14(15.73%)	89(84.6%)	

Table 4:- Association between medicinal factor and Treatment outcome among study population.

Medicinal Factor	**Treatment outcome**		**(n=91)**	**P-value**
	Favourable (n=84)	**Unfavourable (n=7) ***		
Perception about number of drugs consumed per day				
It is too much	24(28.57%)	4(57.14%)	28(30.7%)	.115
Not too much	60(71.42%)	3(42.85%)	63(69.23%)	
Symptomatic relief by medicine				
Yes	83(98.8%)	2(28.57%)	86(94.50%)	**.000**
No	1(2.2%)	5(71.42%)	5(5.49%)	
Side effect of Medicine				
Yes	40(47%)	6(85.71%)	46(50.54%)	**.152**
No	44(52.38%)	1(14.28%)	45(49.45%)	
Forget to take Medicine				
Yes	7(8.33%)	6(85.71%)	13(14.28)	**.000**
No	77(91.66%)	1(14.28%)	78(85.71%)	
Out of pocket expenses for medicine				
Yes	26(30.95%)	2(28.57%)	28(30.6%)	.89
No	58(69.4%)	5(71.42%)	63(69.23%)	

*Only defaulters give the response about medicinal factor at the time of 5^{th} to 6^{th} month of the treatment duration.

Limitation of the study

The study was conducted only for one quarter of the year, so we cannot find out the annual case detection rate. Further we followed up these patients for 6 to 8 months for the treatment outcome, so due to limited duration of the study period we chose only one quarter of registered patient in the O.P.D.

Relevance of the study

Identified the high-risk groups such as contacts, residents of poor neighbourhoods, Coverage them under TB control strategies.

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