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COMPARATIVE ANALYSIS OF THE EFFECTIVENESS OF DAILY VERSUS INTERMITTENT ANTI-TUBERCULAR MEDICATION REGIMENS IN PATIENTS WITH CATEGORY 1 TUBERCULOSIS

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ABSTRACT

Background: Tuberculosis is a serious health problem that has been observed in Indian individuals. It has a significant impact on the country's social and economic standing as well as the healthcare system. **Aim**: The purpose of this study was to evaluate and compare the effectiveness of anti-tubercular medications administered to patients with category 1 TB on a daily vs an intermittent basis.

Methods: 120 patients with a confirmed diagnosis of tuberculosis, of both genders, were included in the current observational prospective clinical study from the institute's pulmonary medicine outpatient department. Of the 120 participants, 60 were on an intermittent regimen (DOTS), and the other 60 were on a daily regimen.

Results: According to the research's findings, there was no statistically significant variation between the study subjects' sputum conversion rate at the conclusion of the intense non-conversion rate or default rate. **Conclusion**: The current study reveals that in TB individuals, the default and conversion rates are similar for both the daily and intermittent regimens.

Keywords: sputum, sputum conversion rate, daily regimen, intermittent regimen, antitubercular medications.

INTRODUCTION

Mycobacterium tuberculosis is the infectious illness that causes TB, which is the second leading cause of death worldwide. Tuberculosis has a significant negative impact on the social, medical, and economic spheres of emerging nations such as India.

Approximately 6 lakh fatalities in India are attributed to TB annually, or almost two deaths every three minutes. Controlling TB is a major concern for the Indian economic and health sectors, since the illness burden on the healthcare system remains high.1.

When it comes to TB, those who have strong, frequent and extended contact and exposure are more likely to get the disease—nearly 22% of cases occur as a result. An untreated individual with active TB can infect around ten to fifteen individuals annually. One individual has the potential to infect ten or more subjects annually. With 1.21 billion people, just 20% of the world's cases of TB are present in India.

Additionally, India bears the largest worldwide burden of TB relative to all other nations.2. The Revised National Tuberculosis Control Programme was introduced in 1993 and was based on the DOTS (Directly Observed Treatment Strategy). Subsequently, this programme gained international recognition for its ability to reduce tuberculosis (TB) through the use of sputum smear microscopy, standardised regimens, political commitment, reporting, and documentation of notified cases and treatment outcomes. The short-course, conventional anti-tuberculosis chemotherapy regimen, which calls for continuous medication intake of streptomycin (SM), ethambutol (EMB), pyrazinamide (PZA), rifampicin (RFP), and isoniazid (INH) every other day for six to nine months, is a crucial part of DOTS.3.

The present study was carried out to compare and evaluate the efficacy of anti-tubercular drugs given daily versus intermittent regimens in category 1 tuberculosis subjects. Even after the functioning and introduction of DOTS in India for more than a decade, tuberculosis remains the leading cause of mortality in the Indian subjects, with two subjects every three minutes and nearly 1000 cases per day. New smear-positive cases in India had increased from 1997 with 28/ 1 lakh population to 41 per 1 lakh in 2003. In 2010, the World Health Organisation revised the condition and recommended the initiation of a daily regimen wherever feasible.

Materials and Methods: This study was carried out to evaluate and compare the effectiveness of anti-tubercular drugs administered on a daily versus an intermittent basis in subjects with tuberculosis in category 1. It was conducted at... from.. to... with approval from the relevant Ethics Committee. An additional objective of the study was to evaluate the default rate and sputum conversion rate in the two groups of subjects: the intermittent and daily regimen groups. The study population consisted of patients who visited the Institute's Department of Pulmonary Medicine.

For the present observational study, The study included 120 subjects of both genders, 60 of whom were treated with an intermittent regimen based on the DOTS, and 60 of whom were managed with a daily regimen on an outpatient department basis. The inclusion criteria for the study included subjects between the ages of 16 and 82 who had a confirmed diagnosis of tuberculosis (TB), were receiving treatment with DOTS, and were classified as falling under the RNTCP regimen category 1 and attending the Institute's pulmonary medicine department. The tuberculosis was diagnosed through X-ray chest, sputum examination, clinical history, and other investigations. The study excluded pregnant and lactating females, those with hepatic, renal, or cardiac dysfunctions, histories of drug abuse, alcohol intake, and psychotic disorders, and history of drug abuse.

After explaining the detailed study design, informed consent was taken from all the subjects in both written and verbal form. Following the research subjects' final inclusion, each patient underwent a thorough examination and a comprehensive history was taken. All the data was recorded on a pre-made proforma, and each month, the individuals were evaluated in accordance with their replies. In addition, the participants were requested to report back on any significant issues or unfavourable occurrences. The study's outcomes were evaluated in relation to the following factors: factors for treatment failure, recurrence, factors for participants who died during treatment, and factors for subjects who were cured. At the conclusion of the intensive phase, the study examined the effects of anti-tubercular medicines (ATT) for both regimens for both groups, and the defaulter's rate evaluated the subjects' compliance.

The study findings were statistically analyzed using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$ for outcomes assessment within the group and between the two groups. Also, a comparison was done.

RESULTS

The goal of the current study was to evaluate and compare the effectiveness of anti-tubercular medications administered to patients with category 1 TB on a daily vs an intermittent basis. The current study also sought to evaluate the two groups on intermittent and daily regimens with regard to default and sputum conversion rates. The current study comprised 120 participants from both genders in the age range of 16-82 years, where 60 subjects of Group I were treated with the intermittent regimen based on the DOTS, and the Group II subjects were handled with the daily regimen in the Outpatient Department basis. Table 1 contains a list of the research individuals' demographic details.

The study subjects' mean age was 36.6±4.82 years. Of the study subjects in Group I, 50% were in the age range of 36–50 years, while Group II had 48.3% (n=29) in the same age range as well as 33.3% (n=20) in the 20–35 years range (Table 1). When the treatment outcomes were compared between the two groups of study subjects, Group I had more therapy alterations (8.3% n=5) than Group II (6.66% n=4). The results indicate that Group II had a higher default rate (15%) compared to Group I's 11.6% (n=7) subjects; Group I had a higher failure rate (6.66%; n=4) compared to Group II's 5% (n=3) subjects; Group I also had a higher rate of relapse (13.3%) in Group I's intermittent regimen (n=9) compared to 10% (n=6) in Group II's intermittent regimen; and Group II had a higher percentage of cured subjects (63.3%; n=38) subjects compared to 60% (n=36) subjects in Group I. Between the two groups, all of these parameters had $p>0.05$ and were statistically non-significant (Table 2).

With regard to the sputum conversion rate, it was observed that there were 8 defaults (13.3%) in Group I (intermittent regimen) against 10. defaults (166.6%) in Group II (daily regimen) care. The purpose of this study was to compare and evaluate the effectiveness of anti-tubercular drugs given daily versus intermittent regimens in

category 1 tuberculosis subjects. It also sought to evaluate the default rate and sputum conversion rate in the two intermittent and daily regimen groups. The non-conversion was 8.33% (n=5) in Group I compared to 11.6% (n=7) in the Group II, and at the end of intensive therapy, the sputum conversion rate was higher in Group I with 78.3% (n=47) subjects compared to 71.6% (n=43) in the Group II. All of these sputum conversion rate factors between the two study groups were statistically non-significant with p>0.05, as indicated in Table 3.

DISCUSSION

The study comprised 120 participants of both sexes, ranging in age from 16 to 82 years. Of these, 60 subjects in Group I received treatment on an intermittent basis based on the DOTS, while the remaining subjects in Group II received treatment on a daily basis in the Outpatient Department. The gender distribution of the subjects was as follows: 43.33% (n = 26) were female in Group I and 31.6% (n = 19) in Group II, while 56.66% (n = 34) were male in Group I and 68.3% (n = 41) in Group II. The mean age of the subjects was 36.6±4.82 years. In Group I, the majority of subjects (n = 30) were in the 36–50 years range, while in Group II, 48.3% (n = 29) subjects in the 36–50 years range were followed by 33.3% (n = 20) subjects in the 20–35 year range.

These demographics were comparable to the studies of Taher M et al[5] in 2006 and Chhetri AK et al[6] in 2008 where authors assessed subjects with comparable demographics as in the present study.

When the treatment outcomes for the two groups of study participants were compared, it was observed that Group I had a higher rate of therapy alteration (8.3%) compared to Group II's 6.66% (n=4) subjects; Group II had a higher default rate, with 15% (n=9) subjects compared to 11.6% (n=7) subjects in Group I; Group I also had a higher failure rate (6.66%) compared to 5% (n=3) subjects in Group II; Group I also had a higher rate of relapse (13.3%) compared to 10% (n=6) in Group II (intermittent regimen); and Group II had a higher percentage of cured subjects compared to 60% (n=36) subjects in Group I.

In the case of the sputum conversion rate, it was observed that the number of defaults was 13.3% (n=8) in Group I (intermittent regimen) compared to 16.66% (n=10) in Group II (daily regimen) therapy; the non-conversion was 8.33% (n=5) in Group I compared to 11.6% (n=7) in the Group II; and the sputum conversion rate at the end of intensive therapy was higher in Group I with 78.3% (n=47) subjects compared to 71.6% (n=43) in the Group II. All these parameters were statistically non-significant between the two groups with p>0.05.

All these sputum conversion rate factors between the two study groups were statistically non-significant with p>0.05. Sputum negativity rates did not differ significantly between the two groups of the study showing similar efficacy between the two groups of anti-tubercular treatment. The present study had a few limitations, including a small sample size, shorter monitoring period, and geographical area biases. Nevertheless, within its limitations, the present study concludes that both the daily regimen and the intermittent regimen have equal default and conversion rates in the subjects with tuberculosis. The studies of Chennaveerappa P.K. et al.9 in 2011 and Yadav S et al.10 in 2011, where authors have reported similar results for sputum conversion rates as in the present study.

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TABLES

S. No	Characteristics	Group I % (n=60)	Group II % (n=60)	Total % (n=120)
1.	**Gender**			
a)	Females	43.33 (26)	31.6 (19)	37.5 (45)
b)	Males	56.66 (34)	68.3 (41)	62.5 (75)
2.	**Mean age (years)**	36.6±4.82		
3.	**Age range (years)**			
a)	20-35	36.6 (22)	33.3 (20)	35 (42)
b)	36-50	50 (30)	48.3 (29)	49.16 (59)
c)	51-82	13.3 (8)	18.3 (11)	15.83 (19)

Table 1: Demographic characteristics of the study subjects

S. No	Outcomes following treatment	Group I (n=60)		Group II (n=60)		p-value
		%	n	%	n	
1.	**Therapy alteration**	8.3	5	6.66	4	>0.05
2.	**Default**	11.6	7	15	9	>0.05
3.	**Failure**	6.66	4	5	3	>0.05
4.	**Relapse**	13.3	8	10	6	>0.05
5.	**Cured**	60	36	63.3	38	>0.05

Table 2: Treatment outcomes in the two groups of the study subjects

S. No	Sputum conversion rate	Group I % (n)	Group II % (n)	p-value
1.	**Number of defaults**	13.3 (8)	16.66 (10)	>0.05
2.	**Non- conversion**	8.33 (5)	11.6 (7)	>0.05
3.	**Sputum conversion rate at the intensive therapy end**	78.3 (47)	71.6 (43)	>0.05

Table 3: Comparison of drug effects between the two study groups