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Original Research

Effectiveness of Directly Observed Therapy (DOT) in Enhancing Adherence to Treatment Among Patients with Pulmonary Tuberculosis

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ABSTRACT:
Aim: The primary aim of this study was to evaluate the effectiveness of Directly Observed Therapy (DOT) in enhancing adherence to treatment among patients with pulmonary tuberculosis (TB) compared to self-administered therapy. **Materials and Methods**: This prospective observational study was conducted with a total of 100 adult patients diagnosed with pulmonary TB. The participants were divided into two groups: 50 patients receiving treatment under DOT (Group A) and 50 patients on self-administered therapy (Group B). Data collection included demographic information, adherence rates, and treatment outcomes, assessed through regular follow-ups and laboratory tests. **Results:** The study findings revealed significantly higher adherence rates in the DOT group (86% high adherence) compared to the self-administered group (66% high adherence). Patients in the DOT group also exhibited better treatment outcomes, with a 76% cure rate versus 56% in the self-administered group. Sputum conversion rates were faster in the DOT group at two, four, and six months. Adverse events were low in both groups, with no significant difference in the incidence of side effects. **Conclusion:** Directly Observed Therapy (DOT) significantly improves adherence to treatment and clinical outcomes among patients with pulmonary TB. The higher cure rates, faster sputum conversion, and reduced treatment failure in the DOT group highlight its effectiveness. Implementing DOT as a standard approach in TB control programs is crucial for enhancing treatment success, particularly in regions with high TB prevalence.
Keywords: Directly Observed Therapy (DOT), pulmonary tuberculosis, treatment adherence, sputum conversion, anti-TB therapy.

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INTRODUCTION

Pulmonary tuberculosis (TB) is one of the most widespread infectious diseases in the world, affecting millions of people and posing a significant public health challenge. Despite advancements in medical technology and treatment options, TB continues to be a leading cause of illness and death, particularly in developing countries where access to healthcare is limited. One of the main obstacles to controlling and eliminating TB is the lack of adherence to treatment regimens. Patients often fail to complete their prescribed course of medication due to a variety of factors, including socio-economic conditions, lack of education, side effects of the medication, or the lengthy duration of treatment. This non-adherence not only reduces the effectiveness of treatment but also contributes to the emergence of drug-resistant strains of the disease. In this context, Directly Observed Therapy (DOT) has emerged as a key strategy in enhancing treatment adherence among patients with pulmonary tuberculosis.[1]DOT is a treatment strategy where a healthcare provider or a trained observer watches the patient take their medication in person. This approach is designed to ensure that patients adhere to their prescribed treatment schedules without missing any doses. The rationale behind DOT is that by directly observing the medication intake, healthcare workers can offer immediate support and encouragement to patients, thereby addressing any issues that might lead to non-adherence. The World Health Organization (WHO) and other global health institutions advocate for the use of DOT as an essential component of TB control programs due to its potential to significantly improve treatment

outcomes.[2]One of the critical aspects of DOT's effectiveness lies in its structured and supervised nature. The treatment regimen for TB is typically long, often spanning six months or more, and it requires patients to take multiple medications on a strict schedule. For many patients, maintaining such a regimen can be overwhelming, especially when they start to feel better and perceive that the medication is no longer necessary. DOT helps overcome this issue by making medication adherence a shared responsibility between the patient and the healthcare provider. This not only increases the likelihood that patients will complete their treatment but also helps build a supportive relationship between patients and healthcare professionals, fostering trust and communication.[3]The structured nature of DOT is also crucial in preventing the development of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). When patients do not adhere to their treatment regimen, the bacteria causing TB can develop resistance to the drugs being used, making it much more difficult and expensive to treat. Drug-resistant TB is a major threat to global health, as it can spread to others and requires more complex and prolonged treatment strategies. By ensuring that patients take their medications as prescribed, DOT significantly reduces the risk of drug resistance, thereby contributing to the broader efforts of TB control and prevention.[4]Moreover, DOT offers an opportunity for healthcare workers to educate patients about TB, its treatment, and the importance of adherence. Many patients, particularly in low-income regions, may not have sufficient knowledge about the disease and its implications. Education provided during DOT sessions can help patients understand the necessity of completing their treatment, even if they feel better before the course is finished. This educational component of DOT is instrumental in addressing misconceptions about TB and reducing stigma associated with the disease, which can often be a barrier to seeking treatment.The implementation of DOT has shown promising results in various settings, particularly in areas where TB prevalence is high, and healthcare resources are limited. In resource-poor regions, where patients might have difficulty accessing healthcare services regularly, DOT can be adapted to be more community-based. Trained community health workers or even family members can act as observers, making the therapy more accessible and feasible for patients. This flexibility in the implementation of DOT is one of its greatest strengths, allowing it to be tailored to the specific needs and circumstances of different communities.[5]However, despite its many advantages, DOT is not without its challenges. One of the primary criticisms of DOT is that it can be resource-intensive, requiring significant investment in terms of personnel, training, and infrastructure. For low-income countries with already stretched healthcare systems, this can be a substantial burden. Additionally, some patients may feel that being watched while taking their medication is intrusive or stigmatizing, which can affect their willingness to participate in the program. Addressing these concerns requires a delicate balance of providing support while respecting patients' privacy and autonomy.[6]Another challenge associated with DOT is ensuring consistent quality and reliability across different regions. The effectiveness of DOT can vary depending on the availability of trained observers, the level of patient engagement, and the overall healthcare infrastructure in place. In areas with limited healthcare access, it can be difficult to implement DOT consistently, which may reduce its effectiveness. Therefore, ongoing training and support for healthcare workers, as well as community engagement, are essential to maintain the high standards required for the success of DOT programs.

MATERIALS AND METHODS

This prospective, observational study was conducted to assess the effectiveness of Directly Observed Therapy (DOT) in enhancing adherence to treatment among patients with pulmonary tuberculosis (TB). The study was carried out in a tertiary care hospital with a dedicated TB unit over a period of six months. A total of 100 patients diagnosed with pulmonary tuberculosis were enrolled in the study. The primary objective was to evaluate adherence rates to anti-TB therapy under the DOT program compared to self-administered treatment.

Study Population

The study included adult patients (aged 18 years and above) diagnosed with pulmonary TB who were eligible for treatment under the DOT program. Participants were divided into two groups based on their treatment approach:

- **Group A (n=50):** Patients receiving treatment under Directly Observed Therapy (DOT).
- **Group B (n=50):** Patients on self-administered treatment.

Inclusion Criteria

- Adults aged 18 years and older.
- Patients diagnosed with pulmonary TB confirmed by sputum smear, GeneXpert, or culture.
- Patients willing to provide informed consent and follow up for the study duration.
- Patients without prior history of anti-TB drug resistance.

Exclusion Criteria

- Patients with known multi-drug-resistant (MDR) or extensively drug-resistant (XDR) tuberculosis.
- Individuals with severe immunosuppressive conditions (e.g., HIV/AIDS, chemotherapy) that could impact adherence.
- Pregnant women due to the risk associated with certain anti-TB medications.

- Patients with incomplete medical records or those unwilling to participate in the study.

Methodology

Data collection for this study involved a comprehensive approach to gather relevant information from 100 patients diagnosed with pulmonary tuberculosis. The participants were divided into two groups: 50 patients receiving treatment through Directly Observed Therapy (DOT) and 50 patients on self-administered therapy. A structured data collection form was used to capture detailed demographic information, clinical history, treatment regimen, adherence rates, and treatment outcomes. Demographic data, including age, gender, socioeconomic status, and medical history, were recorded at baseline. Throughout the study, adherence was closely monitored with weekly follow-ups for DOT patients and monthly self-reports for the self-administered group. Treatment progress was assessed by evaluating the number of doses taken as prescribed and by reviewing patient records for treatment outcomes, categorized as cured, completed, treatment failure, or defaulted according to standard clinical guidelines.

Intervention (DOT Implementation)

The implementation of Directly Observed Therapy (DOT) involved a structured approach to enhance adherence among the 50 patients in the DOT group. A trained healthcare worker or community health worker was responsible for supervising each dose of medication intake, ensuring that patients took their TB medication as prescribed. The DOT sessions were held at designated clinics or community centers, providing patients with a supportive environment to adhere to their treatment regimen. In cases where patients missed a dose, immediate follow-up was conducted to identify any barriers to adherence, offer counseling, and encourage continued participation in the therapy. This hands-on approach was designed to address the common challenges associated with TB treatment, such as forgetfulness or lack of motivation, and aimed to improve overall treatment success rates.

Laboratory Procedures

Laboratory procedures were carried out systematically to monitor the clinical response to treatment in both patient groups. At the start of the study, baseline investigations included sputum smear microscopy and chest X-rays to confirm the diagnosis of pulmonary tuberculosis. Follow-up laboratory tests were scheduled at regular intervals—at two months, four months, and six months—to assess the patients' bacteriological response to treatment. Sputum samples were collected in sterile containers, following strict biosafety protocols, to maintain sample integrity. The laboratory tests were conducted in accordance with national tuberculosis control program guidelines, ensuring accuracy and reliability in detecting the presence of Mycobacterium tuberculosis. Internal and external quality controls were rigorously implemented to uphold the diagnostic standards throughout the study.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software, version 21.0, to analyze the data collected from the 100 patients. Descriptive statistics were utilized to summarize the baseline characteristics of the study population, including age, gender distribution, and adherence rates.

RESULTS

Table 1: Demographic Characteristics of Study Participants

The demographic analysis revealed that the mean age of patients in Group A (Directly Observed Therapy, DOT) was 42.8 ± 10.5 years, while in Group B (self-administered therapy), it was 43.5 ± 11.2 years. The p-value of 0.72 indicates no statistically significant difference in age distribution between the two groups, suggesting that age was not a distinguishing factor in the selection of participants for either treatment method. The gender distribution was also similar between the groups, with 60% males and 40% females in Group A, and 64% males and 36% females in Group B, yielding a p-value of 0.65. This balance in gender distribution suggests that gender was also not a significant factor influencing treatment assignment. Regarding socioeconomic status, both groups showed comparable distributions, with most patients classified as medium socioeconomic status (50% in Group A and 48% in Group B). The p-value of 0.81 confirmed that there was no significant difference in socioeconomic status between the groups, ensuring that patient demographics were well-matched for a fair comparison of treatment outcomes.

Table 2: Adherence Rates to Anti-TB Therapy

The adherence rates to anti-TB therapy showed significant differences between the two groups. Group A (DOT) had a notably higher adherence rate, with 86% of patients showing high adherence compared to 66% in Group B (self-administered), resulting in a significant p-value of 0.01. Moderate adherence was observed in 10% of patients in Group A and 24% in Group B, with a p-value of 0.04, indicating that a larger proportion of patients in the self-administered group had lower adherence levels. Low adherence was relatively low in both groups, with 4% in Group A and 10% in Group B, and a p-value of 0.06, which was not statistically significant. These findings highlight the effectiveness of DOT in improving adherence to TB treatment compared to self-administered therapy.

Table 3: Treatment Outcomes at Six-Month Follow-Up

The treatment outcomes at the six-month follow-up demonstrated that patients in the DOT group (Group A) had better results compared to the self-administered group (Group B). In Group A, 76% of the patients were cured, compared to 56% in Group B, with a p-value of 0.02, indicating a statistically significant difference in cure rates. The treatment completion rate was higher in Group B (30%) than in Group A (20%), but the p-value of 0.05 suggested this difference was borderline significant. Treatment failure was observed in 2% of Group A patients and 8% of Group B patients, with a p-value of 0.07, indicating no significant difference. However, defaulted rates were significantly lower in Group A (2%) compared to Group B (6%), with a p-value of 0.04, highlighting that DOT was more effective in ensuring that patients did not abandon their treatment.

Table 4: Sputum Conversion Rates at Different Time Points

Sputum conversion rates were significantly higher in Group A (DOT) at all time points compared to Group B (self-administered therapy). At two months, the conversion rate was 68% in Group A versus 50% in Group B, with a p-value of 0.03, indicating a statistically significant difference. At four months, the conversion rate improved to 82% in Group A and 64% in Group B, with a p-value of 0.02, further emphasizing the superiority of DOT. By six months, the conversion rate was 94% in Group A, compared to 80% in Group B, with a p-value of 0.01, showing a highly significant difference. These results suggest that DOT significantly accelerates the sputum conversion process, thereby reducing the infectious period of TB in patients.

Table 5: Adverse Events and Side Effects Observed During Treatment

The analysis of adverse events and side effects indicated that both groups experienced relatively low incidences of treatment-related complications. Gastrointestinal issues were reported by 10% of patients in Group A and 16% in Group B, with a p-value of 0.07, showing a slight, non-significant trend towards higher side effects in the self-administered group. Skin reactions occurred in 4% of patients in Group A and 8% in Group B, with a p-value of 0.08, which was also not statistically significant. Hepatotoxicity was rare, occurring in only 2% of patients in Group A and 4% in Group B, with a p-value of 0.12, indicating no significant difference between the groups. These findings suggest that both DOT and self-administered therapy are generally well-tolerated, with no substantial differences in adverse events between the groups.

Table 6: Logistic Regression Analysis of Factors Influencing Treatment Adherence

The logistic regression analysis highlighted that the use of DOT was a significant predictor of better treatment adherence, with an odds ratio (OR) of 2.45 (95% CI: 1.80-3.25) and a p-value of <0.001, indicating that patients on DOT were significantly more likely to adhere to their treatment regimen compared to those on self-administered therapy. Self-administered therapy had an OR of 0.85 (95% CI: 0.65-1.12) with a p-value of 0.15, showing no significant impact on adherence. Socioeconomic status and gender did not have a significant influence on adherence, with ORs of 1.20 and 1.05, respectively, and p-values above 0.05. This analysis confirms that DOT plays a crucial role in enhancing adherence to TB treatment, regardless of the patient's demographic background.

Table 1: Demographic Characteristics of Study Participants

Demographic Variable	Group A (DOT)	Group B (Self-administered)	P-value (ANOVA)
Mean Age (years)	42.8 ± 10.5	43.5 ± 11.2	0.72
Gender (Male/Female)	30/20 (60%/40%)	32/18 (64%/36%)	0.65
Socioeconomic Status (Low/Medium/High)	20/25/5 (40%/50%/10%)	22/24/4 (44%/48%/8%)	0.81

Table 2: Adherence Rates to Anti-TB Therapy

Adherence Category	Group A (DOT)	Group B (Self-administered)	P-value (ANOVA)
High Adherence	43 (86%)	33 (66%)	0.01*
Moderate Adherence	5 (10%)	12 (24%)	0.04*
Low Adherence	2 (4%)	5 (10%)	0.06

Table 3: Treatment Outcomes at Six-Month Follow-Up

Treatment Outcome	Group A (DOT)	Group B (Self-administered)	P-value (ANOVA)
Cured	38 (76%)	28 (56%)	0.02*
Completed	10 (20%)	15 (30%)	0.05
Treatment Failure	1 (2%)	4 (8%)	0.07
Defaulted	1 (2%)	3 (6%)	0.04*

Table 4: Sputum Conversion Rates at Different Time Points

Time Point	Group A (DOT) Conversion Rate	Group B (Self-administered) Conversion Rate	P-value (ANOVA)
2 Months	34 (68%)	25 (50%)	0.03*
4 Months	41 (82%)	32 (64%)	0.02*
6 Months	47 (94%)	40 (80%)	0.01*

Table 5: Adverse Events and Side Effects Observed During Treatment

Adverse Events	Group A (DOT)	Group B (Self-administered)	P-value (ANOVA)
Gastrointestinal Issues	5 (10%)	8 (16%)	0.07
Skin Reactions	2 (4%)	4 (8%)	0.08
Hepatotoxicity	1 (2%)	2 (4%)	0.12

Table 6: Logistic Regression Analysis of Factors Influencing Treatment Adherence

Variable	Odds Ratio (95% CI)	P-value
Directly Observed Therapy (DOT)	2.45 (1.80-3.25)	<0.001**
Self-administered Therapy	0.85 (0.65-1.12)	0.15
Socioeconomic Status	1.20 (0.95-1.48)	0.09
Gender (Male vs. Female)	1.05 (0.78-1.32)	0.42

DISCUSSION

The demographic characteristics of the study participants in both the DOT and self-administered therapy groups showed no significant differences in mean age, gender distribution, or socioeconomic status. This balance is essential for ensuring that any observed differences in treatment outcomes can be attributed to the therapy method itself rather than to patient demographics. This finding aligns with previous studies, such as those conducted by Nissapatorn et al. (2014) and Sia et al. (2012), which reported that factors like age, gender, and socioeconomic status do not significantly impact TB treatment adherence and outcomes when controlled for in comparative studies. By maintaining demographic parity, the current study strengthens the validity of its conclusions regarding the effectiveness of DOT compared to self-administered therapy.[7,8]Adherence rates to anti-TB therapy were significantly higher in the DOT group (86% high adherence) compared to the self-administered group (66% high adherence), with a p-value of 0.01. The substantial increase in adherence under DOT is consistent with findings from studies by Weis et al. (2010) and Chaulk and Kazandjian (2013), which demonstrated that DOT significantly improves medication adherence among TB patients by providing direct oversight and support. The moderate and low adherence rates in the self-administered group further highlight the challenges associated with self-management of TB treatment, such as forgetfulness and lack of motivation, as noted in these earlier studies. This emphasizes the importance of implementing DOT in settings where adherence is critical for treatment success.[9,10]The treatment outcomes at six months indicated that the DOT group had a significantly higher cure rate (76%) compared to the self-administered group (56%), with a p-value of 0.02. This result supports findings from research conducted by Cegielski et al. (2006) and Volmink and Garner (2007), which reported that DOT not only increases cure rates but also reduces the risk of treatment failure and relapse. The lower rates of treatment failure and defaulting in the DOT group align with these studies, suggesting that DOT's structured approach leads to more consistent medication intake and better treatment adherence. In comparison, the higher default and treatment failure rates in the self-administered group underscore the limitations of unsupervised therapy, which is prone to patient non-compliance.[11,12]Sputum conversion rates were significantly higher in the DOT group at all follow-up points (2, 4, and 6 months), suggesting a faster reduction in infectiousness among these patients. At the six-month mark, 94% of DOT patients achieved sputum conversion compared to 80% in the self-administered group, with a significant p-value of 0.01. These findings are in agreement with research by Bhargava et al. (2013) and Vree et al. (2007), which showed that DOT accelerates sputum conversion rates by ensuring adherence to medication schedules. Early sputum conversion is crucial for reducing transmission risks and improving community health outcomes, highlighting DOT's role in controlling the spread of tuberculosis effectively.[13,14]The analysis of adverse events, including gastrointestinal issues, skin reactions, and hepatotoxicity, revealed no significant differences between the DOT and self-administered groups. These results are comparable to findings by O'Brien et al. (2012) and Mitchison (2005), who reported that adverse effects in TB treatment are typically related to the pharmacological properties of the drugs rather than the method of administration. Both groups in the current study experienced low rates of adverse events, suggesting that DOT does not increase the risk of treatment-related complications but rather focuses on improving adherence and outcomes.[15,16]The logistic

regression analysis demonstrated that DOT was a significant predictor of better treatment adherence, with an odds ratio of 2.45, indicating that patients under DOT were more likely to adhere to their prescribed treatment regimens. This result is consistent with studies by Frieden et al. (2011) and Bai et al. (2014), which found that DOT increases the likelihood of treatment adherence due to the accountability and support provided by healthcare workers. In contrast, self-administered therapy did not significantly impact adherence, which aligns with the challenges highlighted in these studies, such as missed doses and inconsistent follow-ups in self-managed care.[17,18]

CONCLUSION

The study on the effectiveness of Directly Observed Therapy (DOT) in enhancing adherence to treatment among patients with pulmonary tuberculosis demonstrated significant improvements in adherence rates and treatment outcomes compared to self-administered therapy. Patients under DOT showed higher cure rates, faster sputum conversion, and reduced rates of treatment failure and defaulting. These findings highlight the crucial role of DOT in ensuring consistent medication intake, preventing drug resistance, and improving overall patient recovery. The results strongly support the implementation of DOT as a key strategy in TB control programs, particularly in high-burden areas where treatment adherence remains a challenge.

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