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Original Research Article

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A comparison of treatment outcomes among HIV positive tuberculosis patients receiving DOTS and fixed dose combination in Visakhapatnam

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ABSTRACT

Background: Tuberculosis is a communicable disease which requires special attention in HIV patients. According to newer guidelines, the treatment regimen for tuberculosis has been changed from intermittent DOTS to daily FDC. This study was taken up to explore effectiveness of fixed dose combination in comparison to intermittent DOTS. Objective was to compare the treatment outcomes for tuberculosis among HIV positive TB patients receiving intermittent DOTS with those receiving daily fixed dose combination (FDC).

Methods: A retrospective cohort study was done during November 2017. The data was collected from patient records in an ART centre, attached to King George Hospital, Visakhapatnam. All the HIV patients newly registered for anti-tubercular treatment at the ART center, during 1st quarter of 2016(intermittent DOTS) were compared with those registered during 1st quarter of 2017(FDC). The treatment outcomes include (1) treatment success (completed/ cured), and (2) other treatment outcomes (lost to follow up (LFU), Death). Data was analysed using MS Excel. Association of factors affecting treatment outcomes was tested using chi-square test.

Results: Out of a total 83 patients, 34 were on intermittent DOTS and 49 on FDC. The percentage of treatment success in intermittent DOTS was higher than FDC (p=0.06, chi-square value=3.42). The percentage of deaths in FDC is high when compared to intermittent DOTS (P=0.74, chi-square=3.1762). In subject receiving FDC, it was observed that more females had treatment success as compared to males (p=0.28, chi square=1.13).

Conclusions: There is no statistically significant difference in the TB treatment outcomes of intermittent DOTS and FDC.

Keywords: DOTS, FDC, HIV positive TB, Treatment success, Treatment outcome

INTRODUCTION

Tuberculosis (TB) is a communicable disease requiring prolonged treatment. The incidence of TB globally for the year 2016 was 10.4 million and in India it was found to be 2.8 million accounting for $1/4^{th}$ of global TB incidence. The incidence of TB along with HIV in India during the year 2016 was found to be 6.6 per 1,00,000 population. Coinfection with HIV leads to challenges in both the diagnosis and treatment of TB. The therapeutic regimens as recommended by WHO has been shown to be highly effective for treating tuberculosis but poor

adherence to treatment has been a major barrier to its global control.³ With a main motto of improving compliance of patients to TB treatment, daily fixed dose combinations regimen has been started during December 2016 among HIV patients in Andhra Pradesh under RNTCP. This study was taken up to explore effectiveness of FDC of daily regimens in the treatment of TB in comparison to intermittent regimens.

Objective of the study was to compare the treatment outcomes for TB among HIV positive TB patients receiving intermittent DOTS with those receiving FDC.

METHODS

Study design

A retrospective cohort study was done during November 2017. The data was collected from patient records in one ART centre, attached to King George Hospital, Visakhapatnam.

Study subjects were patients with HIV who were diagnosed with TB and are registered for anti-TB treatment at the ART centre. All the patients registered newly during 1st quarter of 2016 (January, February, March) and during 1st quarter of 2017 (January, February, March) for anti-tubercular treatment at the ART center were the two comparison groups. During 2016, the cohort of HIV-TB co-infection patients were on intermittent DOTS whereas the cohort were on FDC during 2017. The demographic details; clinical details and treatment outcomes were retrieved from the RNTCP treatment card and documented on a predesigned case record form. The treatment outcomes were classified as per the latest RNTCP guidelines. The treatment outcomes of antitubercular treatment include treatment completed, cured (treatment success) and LFU, death (other treatment outcomes). Other variables include age, gender, type of TB (pulmonary/EPTB), non-compliance to TB treatment

Case definitions⁴

Cured: Treatment completed as recommended by the national policy without evidence of failure and three or more consecutive cultures taken at least 30 days apart during CP are negative including culture at the end of treatment.

Treatment completed: Treatment completed as recommended by the national policy without evidence of failure but no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.

Died: A patient who dies for any reason during the course of treatment.

Lost to follow-up: A patient whose treatment was interrupted for one month or more for any reasons prior to being declared as failed.

Noncompliance: Missing more than 2 constitutive weeks of DOTS was taken as non-compliance.⁵

Data was entered in excel sheet and qualitative data is represented as proportions and percentages. Association of factors affecting treatment outcomes was tested using chi-square test. A p \leq 0.05 was considered as statistically significant.

Ethical consideration

Permission from district TB officer was taken. The records of the patients were accessed and data was collected. Patient's identity was kept confidential.

RESULTS

In the first quarter of 2016, 34 patients received intermittent DOTS and in 2017, 49 patients received FDC for TB in the selected ART center.

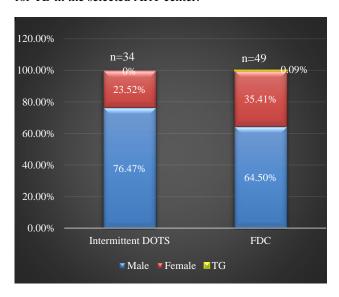


Figure 1: Gender distribution of patients.

In both groups there were more males than females accounting for nearly $3/4^{\rm th}$ to $2/3^{\rm rd}$ of subjects respectively. The differences in gender were not statistically significant.

The commonly affected age group remains same in both intermittent DOTS and FDC (31-40 years).

Table 1: Distribution of treatment outcomes among intermittent DOTS and FDC.

Regimen	Treatment completed number (%)	Cured number (%)	LFU number (%)	Death number (%)
Intermittent DOTS (n=34)	21 (61.7)	8 (23.5)	3 (8.8)	2 (5.8)
FDC (n=49)	31 (63.2)	2 (4.08)	3 (6.1)	13 (26.5)

The above table describes the distribution of treatment outcomes in patients on intermittent DOTS and FDC.

The treatment success rate with intermittent DOTS was 85.29% when compared to 67.3% in FDC. Although the

percentage of treatment success in intermittent DOTS was higher than FDC, the difference was not statistically

significant (p=0.06, chi-square value=3.42).

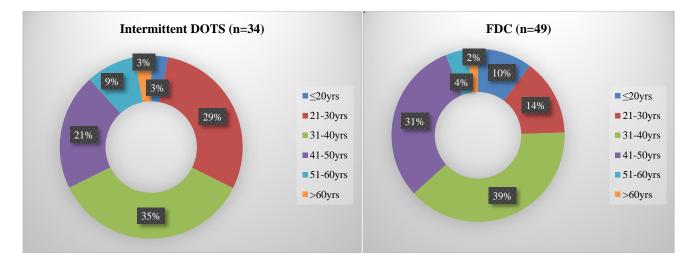


Figure 2: Age distribution of patients.

Table 2: Comparison of gender and treatment outcomes.

Regimen	Gender	Treatment success number (%)	Other treatment outcomes number (%)	P value	
Intermittent DOTS	Male	22 (84.6)	4 (15.38)	0.04	
	Female	7 (87.5)	1 (12.5)		
FDC	Male	19 (61.29)	12 (38.7)	0.28	
	Female	13 (76.4)	4 (23.5)		

The table above shows that the treatment success was similar in males and females receiving intermittent DOTS. In subject receiving FDC, it was observed that more females had treatment success as compared to males.

These differences are not statistically significant as the p>0.05 for both intermittent DOTS and FDC.

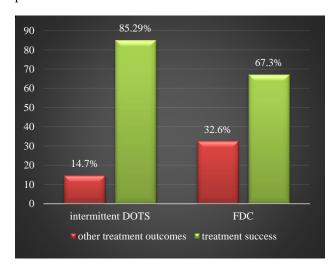


Figure 3: Comparison of treatment outcomes.

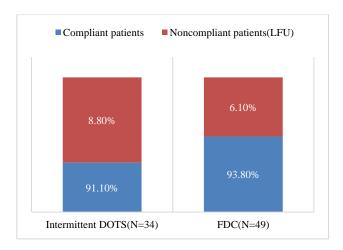


Figure 4: Comparison of compliance.

The percentage of noncompliance was found to be less among patients taking FDC when compared to those taking intermittent DOTS (p=0.64, chi-square=0.21).

DISCUSSION

In the present study, though the treatment success was better in FDC, it was not statistically significant. Similar results were also obtained in a randomized control trial conducted by Lienhardt et al, which compared the efficacy and safety of FDC when compared to separate drugs. Gallardo et al, in their systematic review reported that, the treatment success was better with FDC when compared to single drug formulations.

The present study shows more number of deaths in the FDC group as compared to intermittent regimen group. This is in contrast to the results according to the systematic review done by Gallardo et al.⁷

The non-compliance to treatment reported in the present study was <10% in both the groups. This is much lesser than that reported by Rai et al which was 19.9% in the intermittent DOTS group.⁵

Similar to the present study, no difference in the outcomes was also seen in a study done by Al-Shaer et al.⁸

CONCLUSION

From the present study, proportion of treatment success was more in FDC when compared to Intermittent DOTS.

The number of deaths is more in FDC when compared to intermittent DOTS.

The percentage of noncompliance is less among people taking FDC when compared to intermittent DOTS.

Limitations

The limitations of the study are the small sample size and that it is record based. Further studies of longitudinal nature may provide more information on treatment compliance and other factors which can influence treatment outcome.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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