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Original Research Article

Pilot testing of sticker tool method for monitoring DOTS providers under revised national tuberculosis control program in Khammam: operational research

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ABSTRACT

Background: Globally, tuberculosis (TB) is one of the leading causes of death. In 2016, 10.4 million people were affected with TB and accounted for 1.7 million deaths. India ranks the first among the seven leading countries that account for 64% of the total burden of TB. To fill the gaps in adherence to therapy and to make the TB Control programs successful, evidence based supplementary low cost effective monitoring tools and techniques are needed. The aims were to determine whether the new sticker tool method acts as supplementary to direct observation component of 'Directly observed treatment, short course (DOTS) strategy' used for monitoring adherence to anti-tuberculosis therapy among newly diagnosed sputum positive TB patients; and to compare Sputum smear conversion rate between the intervention group and control group at the end of Intensive phase (IP).
Methods: A pragmatic cluster randomized control trial was conducted for a period of 9 months from April 2018 to December 2018 in Rural Khammam district. Data was represented in frequencies and percentages and Means.
Results: The delay in sending SMS decreased after field visit (1st week of therapy) but delay again increased as the days passed. The study measured indirectly measured the adherence to the therapy by sputum conversion rate (83.3%). It was noticed that 45.5% stickers did not tally with the date of consumption of TB medications or with the date of sticking on the sticker chart.
Conclusions: The study shows self administration is also a good option. There may be other factors that play an important role in adherence to anti tuberculosis treatment (ATT).

Keywords: Adherence to therapy, Anti-tuberculosis treatment, Directly observed treatment short course providers, Sticker tool method

INTRODUCTION

Globally, tuberculosis (TB) is one of the leading causes of death. In 2016, 10.4 million people were affected with TB and accounted for 1.7 million deaths. According to WHO estimates, 82% of TB deaths among HIV-negative people occurred in the African and the South-East Asia Regions. The Incidence rate of tuberculosis was high in the South East Asia (45%), followed by the African (25%) and the Western Pacific (17%).[1,2] India ranks the first among the seven leading countries that account for 64% of the total burden of TB. India has the highest burden of TB with 2.79 million new cases and accounted for 33% of global TB deaths in 2016.[1-3]

Adherence to tuberculosis therapy makes the patient cured of the disease and prevents the spread of infection; prevents development of drug resistance; and reduces the risk of relapse. The adherence to therapy can be know by several methods adopted and used, and some methods are pilot tested.[4-6]

Recently, 99DOTS introduced in India, to ensure 99% cure rates. This approach needs skills of operating mobile phones. India is a developing country where people have mobile phones and literacy to operate mobile phone acts as one of limiting factor.[7,8] Several other approaches like Medication Event Monitoring System (MEMS), mobile phone text messaging, video Observed therapy are costly or more technology dependent or laboratory investigations are laborious process.[5,9]

To fill the gaps in adherence to therapy by monitoring the work of the DOTS care provider, and to make the TB Control programs successful, evidence based supplementary low cost effective monitoring tools and techniques are needed. Aims of the study were to determine whether the new sticker tool method acts as supplementary to direct observation component of 'Directly observed treatment, short course (DOTS) strategy' used for monitoring adherence to anti-tuberculosis treatment among newly diagnosed sputum positive TB patients; and to compare Sputum smear conversion rate between the intervention group and control group at the end of Intensive phase (IP).

METHODS

Study design, study settings and study participants

A pragmatic cluster randomized control trial was conducted for a period of 9 months from April 2018 to December 2018 in Rural Khammam district. The area under 18 Primary health centres (PHCs) was divided into 18 clusters; and these were randomized into 9 intervention group PHC areas and 9 control group PHC areas. The new cases which were sputum positive tuberculosis were taken from these clusters.

The intervention cluster cases along with DOTS providers had an addition sticker tool and followed; while the control group TB cases along with DOTS providers were followed as usual as specified in the Revised National Tuberculosis Control Program (RNTCP). New sputum positive TB cases along with their DOTS provider who were willing to participate were included in the study. Extra pulmonary TB cases, TB patients with-HIV, uncontrolled diabetes, uncontrolled hypertension, and patients with history of renal failure, angina and myocardial infarction were excluded from the study.

Sticker tool method

In this method, the tool consists of stickers on the blister packets and sticker chart. The blister strip with added stickers will be with the TB patient. The sticker chart will be with the DOTS provider (Figure 1 and 2).

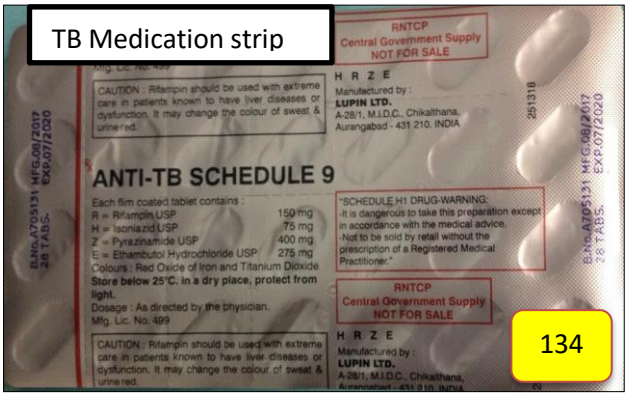

Figure 1: TB medication strip with sticker for 4th week of ATT in the first month.

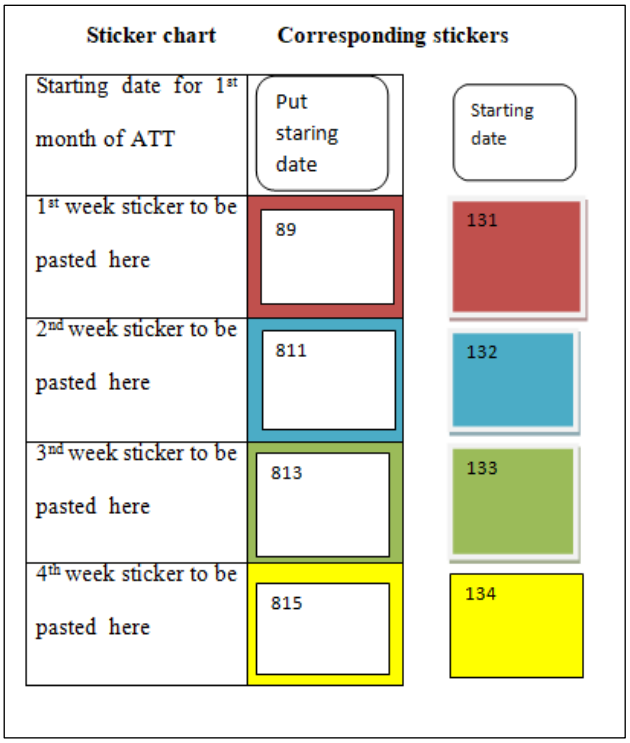

Figure 2: Sticker chart with corresponding stickers for 1st month of ATT.

The sticker chart and the corresponding stickers on the blister packet strip will have unique codes- which is unique to a patient for the completed one week of treatment of that month. These codes help in accessing the patients' current week and the month of completed TB treatment (Table 1).

Data collection

The DOTS providers will do SMS (Short Message Service), commonly referred to as text messaging through her/his mobile phone, the "unique code on the

sticker" (of the strip) for the completed week of treatment to the monitor or investigator. If the treatment is incomplete "corresponding code on the sticker chart" will sent. The DOTS providers will also collect the sticker from the strip and paste to the corresponding colour in the sticker chart.

If SMS not send by the DOTS provider, then the monitor will call the DOTS provider within 1-2 days for not doing SMS; if patient was missing, retrieval of the patient will be attempted.

Table 1: Example for unique coding for the 1st month of ATT.

Identification number (ID) of the patient	1st month corresponding sticker	1st month corresponding sticker chart code
1	111	81
1	112	83
1	113	85
1	114	87
2	121	82
2	122	84
2	123	86
2	124	88
3	131	89
3	132	811
3	133	813
3	134	815

Example: code 134
First number 1- corresponds to month
Second number 3- corresponds to patient ID
Third number 4- corresponds to the week

Note: Distinguish between sticker code and sticker chart code can be made from starting number-8 allotted to the sticker code.

Field visits

To know whether DOTS provider providing the correct information or not, the monitor will check once in a month after 1st week of treatment by making field visits. The monitor will tally the stickers on the chart with the stickers on the strips of blister packs and check the emptiness of the medication strip. The monitor used a questionnaire to monitor the correct intake of the drugs, and also to assess whether sticker method acts as supplement to direct observation component of DOTS. The TB patients were followed for a period of 2months through SMS and field visits till the end of the intensive phase.

Statistical analysis

Data was represented in frequencies and percentages and Means. It was analysed by using IBM SPSS software version 21.

RESULTS

In the study, 12 individuals were in the intervention group (from 9 clusters) and 12 individuals were in the control group (from 9 clusters). There are 8 males and 4 females in the intervention group; and in the control group there were 10 males and 2 females. Mean age of the intervention group was 44.83±15.7 and the control group was 40.75±17.7. More than 50% individuals were in the weight band of 40-54kgs.

Intervention group

In the first month, out of 12 field visits to the patient's home, one visit was not done due to non availability of DOTS provider. In the second month, out of 12 visits to the patient's home one visit was not due to non availability of the patient. Several observations were made during the field visits (Table 2 and 3).

Table 2: Observations made during 1st month field visits

1st month visit findings	Yes (%)	No (%)	Remarks
Sticker chart present with DOTS provider	5 (45.5)	6 (54.5)	-
Did DOTS provider filled Sticker chart with stickers at least once	7 (63.7)	3 (27.3)	1 sticker chart missing
(Ask the patient) Are you taking TB medications regularly	10 (90.9)	1 (9.1)	1 patient c/o abdominal discomfort (3 patients c/o of rash)
Stickers tally with the date of consumption of TB medications or with the date of sticking on the sticker chart.	6 (54.5)	5 (45.5)	-
Field investigator can be able to assess DOTS provider	11 (100)	0 (0.0)	-

%- percentage

There are several reasons noted for the delay in SMS. Busy with other programs, personal works, festivals, health problems, and problems in their family, non availability of the patient, alcoholism, side effects of TB medications (Table 4).

In the study, as self reported by the patient's family members or by the DOTS providers more than 50% males in the intervention group were alcoholics.

Table 3: Observations made during 2nd month field visits

2nd month visit findings	Yes (%)	No (%)	Remarks
Sticker chart present with DOTS provider	6 (54.5)	5 (45.5)	-
Did DOTS provider filled sticker chart with stickers at least once	8 (72.7)	3 (27.3)	-
(Ask) Are you taking TB medications regularly	10 (90.9)	1 (9.1)	1 patient is alcoholic
Stickers tally with the date of consumption of TB medications or with the date of sticking on the sticker chart.	6 (54.5)	5 (45.5)	-
Field investigator can be able to assess DOTS provider	11 (100)	0 (0.0)	-

%- percentage

Table 4: Delay in sending SMS by the DOTS provider to the investigator.

Delay in sending SMS after 2-3 reminders	1st week	2nd week	3rd week	4th week	Total month
Average delay in 1st month	3.33 days	1.91 days	1.16 days	2.16 days	2.14 days
Average delay in 2nd month	2.83 days	1.25 days	2.08 days	2.25 days	2.10 days

Note: Several reasons for delay in SMS were noted (but not quantified)

Table 5: Skill of doing SMS by the DOTS providers.

Month	1st month		2nd month	
	Yes(%)	No(%)	Yes(%)	No(%)
Number of DOTS provider having the skill of doing SMS	9 (81.8)	2 (18.2)	10 (90.9)	1 (9.1)

%- percentage

Table 6: Average rating of sticker tool method as a supplementary to direct observation component of DOTS on a 5 point scale.

Average rating	During 1st month of treatment in IP	During 2nd month of treatment in IP
Average rating given by the patient	4.18	4.27
Average rating given by the DOTS provider	4.01	3.74
Average rating given by the investigator	4.36	4.19

Majority of the DOTS providers can do SMS by themselves (Table 5). The average rating of the DOTS provider was relatively lower than the rating given by the patients and the investigator (Table 6).

Control group

Control group was followed by the DOTS provider as prescribed by the RNTCP program. Sputum conversion rate at the end of the IP in intervention group and control group was same at 83.3%.

DISCUSSION

The delay in sending SMS decreased after field visit (1st week of treatment) but delay again increased as the days passed (Table 4). Therefore, the concerned authorities must make frequent field visits to ensure the performance of DOTS providers.

Though DOTS providers in the intervention group were monitored by Sticker Tool Method the sputum conversion rate (83.3%) was the same as in the control group. Therefore, the tool seems to be of no use; but it also shows self administration is also a good option. A Systematic review by Volmink J, et al., showed that DOT alone did not improve adherence to therapy and there was no significant improvement when compared to self administered drugs, and there are other factors affecting adherence to therapy.[10] A pilot study done on 99DOTS in Rajkot district in India showed the cure rates of tuberculosis among TB patients and TB-HIV co-infection patients was 78.5% and 67.6% respectively.[11]

The study measured indirectly measured the adherence to the therapy by sputum conversion rate (83.3%). In a pilot study conducted in Washington, the adherence to TB medication measured by the drug intake by DOTS method and video DOTS method.[12] In the study, the average delay in sending SMS shows the performance of the DOTS provider i.e., 2.14 days in first month and 2.10 days in the second month of the Intensive phase. It was observed that 45.5% stickers did not tally with the date of

consumption of TB medications or with the date of sticking on the sticker chart. A study from North India showed that DOTS component direct observation of treatment was followed in less than 50% of the centres and 60% of DOT providers said that they were counselling all patients. The number of empty blisters did not tally with the treatment card entries in 38% of DOT centres.[13]

CONCLUSION

The government should revise the policy of alcohol sales and consumption as in the intervention group more than 50% males were alcoholic. The advertisements 'fight against tuberculosis should also address risk factors like alcoholism, stress, under-nutrition. Further, studies needed to quantify the risk factors like alcoholism and stress and their causality with TB should be investigated. Further, studies should be carried out for discovery of vaccines against adult TB.

Limitations of this study to small sample size of the sample; and the sticker tool method followed was new, needed to be standardized.

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