

99 DOTS

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ABSTRACT

India figures conspicuously among the 22 high burden countries, as per WHO's Global Tuberculosis Report 2015. The estimated incidence in India for all forms of TB is at 22 lakhs; HIV associated TB at 1.1 lakhs and Multidrug resistant (MDR) TB cases being 71000 cases. The DOT and intermittent therapy for tuberculosis patients was implemented through Revised National Tuberculosis Control Programme (RNTCP). It was found in a systematic review, that in all the studies from India; relapse rate is almost 10% which is higher as compared to the international studies. Since the treatment is for longer duration, many of the patients stop taking treatment in between because of unpleasant side effects. Thus, leading to development of drug resistance. Need for constant motivation, assurance, reminders and health education is felt. Implementation is possible through easy availability of Mobile phones, covering all these areas and be a boon in bringing compliance and thus TB cure for patients.

99DOTS is a pharmaco-economic approach for monitoring and improving adherence to TB medication. 99DOTS introduces anti-TB blister pack wrapped in a custom envelope, which includes hidden phone numbers that are visible only when doses are dispensed. This is a novel method and almost foolproof. After taking daily medication, patients make a free call to the popped up phone number which is hidden till then, yielding high confidence that the dose was "in-hand" and has been taken. As a very high success rate (of about 99%) is expected by this remote in-built techno-supervision, it is termed as 99DOTS.

Keywords: FDC, Technosupervision, MDR- TB, ATT, Relapse, 99DOTS

INTRODUCTION

India figures conspicuously among the 22 high burden countries, as per WHO's Global Tuberculosis Report 2015.¹ The estimated incidence in India for all forms of TB is at 22 lakhs; HIV associated TB at 1.1 lakhs and Multidrug resistant (MDR) TB cases being 71000 cases. The matter of our utmost concern is dual infection of HIV-TB and MDR-TB.²

The HIV epidemic warrants for more cautious efforts, especially for patients with TB-HIV co-infection. The life time risk of developing TB in presence of HIV increases to about 60% from a lowly risk of 10% due to hampered immunity.³ This is because of increased frequency of developing active TB from the initial latent TB; relapsing TB after stopping treatment (ATT); becoming re-infected with a second strain of TB and also the increased mortality among the patients.

The DOT and intermittent therapy for tuberculosis patients was implemented through Revised National Tuberculosis Control Programme (RNTCP). The efficacy of anti-TB Regimen is considered successful by the early outcomes like high sputum conversion and high treatment success and also by the long-term outcomes like a "low relapse and low emergence of drug resistance".

CHALLENGES

It was found in a systematic review, that in all the studies from India; relapse rate is almost 10% which is higher as compared to the international studies. Drug irregularity initial drug resistance, smoking and alcoholism were found as risk factors in this review. However, sex and weight which were found as risk factors in international studies were not found to be significant in this part of world. There were doubts that whether the category II treatment is adequate for these patients or not.⁴ Kulkarni PY et al in his study on Non-adherence of new Pulmonary Tuberculosis patient to ATT, concluded that male gender (P=0.035), lack of knowledge of importance of regular treatment (P=0.001) and female sex worker are Independent risk factors for non-adherence.⁵

Also, in a study conducted in Tiruvallur district of south India, among new smear positive patients, who were treated under DOTS in RNTCP, a relapse rate of 12.3% was reported.⁶

Since the treatment is for longer duration, many of the patients stop taking treatment in between because of unpleasant side effects. Thus, leading to development of drug resistance. Hence, a demand for ongoing, repeated and very effective health education and motivation to patient and his family members, is the need of the hour. So, it is important to provide information about their dosage, treatment schedule, reminders and alerts, then their progress can be tracked and we can be assured regarding the adherence to treatment.⁵

SOLUTION

A RCT (Randomized Control Trial) was undertaken at NIRT, Chennai, comparing daily versus intermittent treatment (6 months) in reducing Failures and Emergence of Acquired Rifampicin Resistance (ARR) in patients with HIV and PTB. The interim analysis of this study is available. The outcome at the end of daily versus intermittent treatment was analysed as favourable and unfavourable (includes failure, death, default and any reported drug toxicity). The results were found statistically significant (p=0.026), because of supremacy of the daily regimen as compared to intermittent regimen.⁷

The JMM (Joint Monitoring Mission) for TB, recommends that

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all patients receive the “Standards for TB Care for India”. The JMM urged the MOHFW to “Accelerate implementation of the transition, to daily dosing using fixed-dosed combinations, with a clear timeline, addressing the necessary planning and procurements”.⁸

The National Expert Committee for Diagnosis and Management of TB has approved 100 districts for starting pilot projects for daily regimen with fixed dose combinations (FDCs) of four drugs and three drugs for Intensive phase and continuation phase, respectively. The FDCs shall be given in daily dosages. The pilot studies shall be conducted to demonstrate operational feasibility and benefits of daily DOT over alternate day.⁸

India has developed its own standards for TB care, 26 in number which are a benchmark for all care providers managing TB patients in India. As per Standard 7, treatment with first line regimen; in initial phase isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E) to be given for two months, HRE in continuation phase for four months.⁹

Fixed Dose Combinations (FDCs) has many advantages, visually, simplicity of treatment, increased patient acceptance because of fewer tablets to swallow, which in turn will prevent ‘concealed’ irregularity and selective drug avoidance.¹⁰ Also, the health worker compliance will increase as (s)he will have fewer tablets to handle, hence quicker supervision of DOT and easy drug management. There will be reduced use of monotherapy, lower risk of misuse of single drugs, hence lower risk of emergence of drug resistance.

A NOVEL APPROACH

Mobile phones can cover all these areas and be a boon in bringing compliance and thus TB cure for patients. Andrew et al. in his study on Using Mobile Phones to Monitor Adherence to Tuberculosis Medications found that Over 90% of all doses were reported correctly using 99DOTS.¹¹

99 DOTS: Programme has initiated use of various ICT (information Communication Technology) enabled treatment adherence mechanism including 99DOTS which is based on missed call, mobile based Active compliance including Video DOT, and smart pill box.

99DOTS is a cheaper approach for improving the compliance to anti tuberculosis treatment. There are hidden phone numbers in each anti-TB blister pack which is revealed only after the drug doses are dispensed i.e. when the patient takes the medication. Patient makes a free call to that hidden phone number, thus ensuring the on time intake of TB medication.

As, the sequence of hidden numbers cannot be predicted by the patients, but is known only by the system for each blister pack prescribed; the system offers high confidence that patients who respond correctly have indeed taken their medication.

Hence, we have an accurate monitoring at very low cost. ART staff nurse/counsellors will collect patient details (such as phone numbers) and the ART data manager will enter details on 99DOTS website. The medical officer, ART counsellors, staff nurse and STS/TBHV of nodal Tuberculosis Unit (TU) will provide initial counseling on 99DOTS. The pharmacist will track inventory in coordination with DTC (District Tuberculosis Centre).

The mechanism has intelligent reminders for patients, alerts for providers and analytics for supervisors. This remote observation,

will reduce patient burden, increase provider efficiency and differentiated care can be provided, as some of the patients can take drugs independently, few will need some counseling with some needing a focused counseling and also, not forgetting a class of patients who never called as they don't have access to mobile phone.

This tool, being scaled up as a project involving 3,000 patients in Mewat District of Haryana in India, links patients and the communities to support treatment of TB using:

Mass communication: Text/SMS messages, mobile gaming and social media engagement.

Training and learning tools: mobile patient training, e-learning for directly observed treatment, short-course (DOTS) providers and community training tools.

Universal management approach: open source platform, remote compliance and reporting.

Adherence tools: active compliance system, community-led supervision tools.^{7,12}

CONCLUSION

It is found that majority of Indian population is using mobile phones but Patients have to be trained for using mobile features such as reminders, alerts etc. Some incentives in the form of free services; talktime and SMS in local languages will enhance the effectivity.

The website is www.99dots.org. As a very high success rate (of about 99%) is expected by this remote in-built techno-supervision, that's why, it is termed as 99DOTS.

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