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Original Research Article

Decentralising drug-resistant tuberculosis centre services by offering virtual consultancy- a Kozhikode model

Sunny George[1]*, Rajagopal T. P.[1], Annamma P. C.[2], James P. T.[1], Ravindran Chetambath[1]

[1]Department of Pulmonary Medicine, Institute of Chest Diseases, Government Medical College, Kozhikode, Kerala, India
[2]Medical officer, DRTB centre, Government Medical College, Kozhikode, Kerala, India

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***Correspondence:**
Dr. Sunny George,
E-mail: sunsuna1@gmail.com

ABSTRACT

Background: Programmatic management of Drug Resistant Tuberculosis (PMDT) recommends one week and one month hospitalisation for pre-treatment evaluation and initiation of second line medications to MDR and XDR patients respectively. Our experience in dealing with these patients prompted us to resort to decentralising DOTs plus services by offering a virtual consultancy to those cases which did not actually require hospitalisation. Aim of the study was to analyze the feasibility of decentralisation strategy adopted in DOTs plus patients to recommend it as a nationwide strategy.
Methods: The study was an observational analysis conducted in the Department of Pulmonary Medicine in 373 MDR-TB patients enrolled under DOTs Plus programme for CAT-IV regime during the period between February 2009 and April 2013 and analysed the strategy of decentralization using the internet and expertise of Medical officers at the periphery.
Results: The percentage utilisation of virtual consultancy was 83.7% which emphasises the fact that this is a feasible operational modification. Adverse events reported to this DRTB centre were 29.2% in the pre-proposed model period which is comparable to the model group (30.2%).
Conclusions: This study shows that in a properly functioning DRTB centre decentralising the services to its peripheral centres is a feasible option utilising the virtual consultancy model as proposed.

Keywords: Decentralisation, DRTB centre, MDR-TB, PMDT, Virtual consultancy

INTRODUCTION

Programmatic management of drug resistance (PMDT) recommends one week and one month hospitalisation for pretreatment evaluation and initiation of second line medications to MDR and XDR patients respectively. Kerala being a linear strip of land along the Arabian coast with 14 districts and estimated 32 million population, DOTs plus services were instituted for the southern 7 districts with the first DOTs plus site at Thiruvananthapuram in December 2008. The northern 7 districts have their DOTs plus site located at Kozhikode which started functioning in February 2009, second of its kind in the state.[1,2] During our four years of experience in managing about 373 MDR-TB cases, we felt that in areas where specialist services are available, decentralizing DOTs plus programme will improve patient compliance and is resource rewarding as the patients who were not sick enough to be admitted could avoid travelling around 300 km (farthest district) just for the sake of fulfilling the guidelines. Moreover, these patients were financially unstable due to the disease affecting, in a large majority,

the earning member.[3] The spouse also gets detained as bystander, as the programme recommends admission of these patients, even when it is not absolutely indicated. This strategy doesn't seem logical and could be easily rectified by offering a virtual consultancy to those cases which did not actually require hospitalisation. This process effectively picked up those cases really requiring admission. Majority of unnecessary admissions could be avoided thus proving it to be a more patient, community and resource friendly strategy.[4,5]

RNTCP always had room for operational research and allowed subsequent strategic modification in the programme to adapt to the prevailing health system of the particular geographic area. Hence this, Kozhikode model could be applied where there is infrastructure to support the same. Fortunately, in Kerala, there is a well-functioning health system.

This study was aimed to analyze the feasibility of decentralization in DOTs plus patients in the Kozhikode DOTs Plus site (now re designated as DRTB centre-Drug resistant TB care centre), as a model.

METHODS

This study was a observational study (STROBE) which was conducted at DRTB centre, Institute of Chest Diseases, Government Medical College, Kozhikode, Kerala, India from February 2009 to April 2013.

Inclusion criteria

All patients who got enrolled for the CAT-IV regime as per RNTCP for multidrug resistant tuberculosis in this DRTB centre between February 2009 - January 2012 were included in the study as the Pre-model group and those patients who were enrolled one year and four months from January 2012 were included under the Kozhikode Model (decentralised group). None were excluded.

Study proper

We provided the referring units from the periphery a structured format for data collection which included the demographic data, current smoking status, alcoholic status, diabetic status and medication details of the patients. Co morbidities, contact history and any other relevant details including drug sensitivity were also mentioned in the format. All these could be easily recorded by even non-medical staff. This data along with the drug-o gram (a document which records all previous treatment schedules the patient received for tuberculosis detailing the various drugs to which the patient got exposed to in the past), culture and sensitivity report from the IRL (Intermediate reference laboratory) and HIV screening from a VCTC can easily be generated as the system has been working in a smooth manner over the past four years. Most of the Medical officers working in District Tuberculosis centers were either Chest specialists or those who have had proper DOTs Plus training. Hence arranging for a pre-treatment evaluation as per the current recommendation was not a big deal at the periphery. The check list for investigations should include, blood routine, urine routine, Chest X-ray PA view, LFT, RFT, FBS/PPBS, HbA1C (optional), TFT, ECG, uric acid (Optional), Pregnancy test in females in the reproductive age group.

Once all these data are made available it could be transmitted to the DRTB centre utilizing the internet services. The Chest X-ray could be sent either via courier (preferable) or as photo images. Virtual consultancy model offered by the Kozhikode DOTs plus site took decisions on treatment initiation for patients who were not sick enough to warrant an admission and in those patients in whom the pretreatment evaluation was acceptable.

The recommended follow up investigations were performed as per protocol. In the event of occurrence of any minor side effects, patients were managed at the concerned District TB centre (DTC) after proper consultation and advice from the site. Major adverse events or those requiring specialist consultations for modifying the CAT-IV regime alone had to visit the DRTB centre. This was the modus operandi of the Proposed "Kozhikode Model".

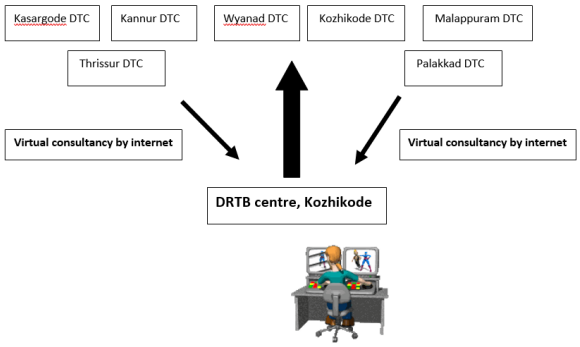

Figure 1: Flow chart for Kozhikode model.

RESULTS

There was a total of 373 patients enrolled in CAT-IV regime during the period February 2009 to April 2013 who were referred from the seven-respective northern District TB centre's of Kerala, India. Amongst these patients, the virtual consultancy model was applied in 178 cases while 195 were managed as per PMDT guidelines (Figure 2).

When patients were managed as per the proposed, "Kozhikode Model", we observed that as compared to the first three years, there was a phenomenal increase in the number of patients registered under the DOTs Plus regime as evidenced by more than 100 % increase in the

enrolment trend noticed from the fourth year onwards prior to which was when decentralisation was introduced for the first time. (Figure 3). This was due to the mitigation of unwanted delay in starting the treatment by handling more numbers of patients from the periphery in consultation with the DOTs Plus site which is the highlight of this operational modification. Hereby the patients could be started on treatment in time and hence possible spread to the community also could be minimized.

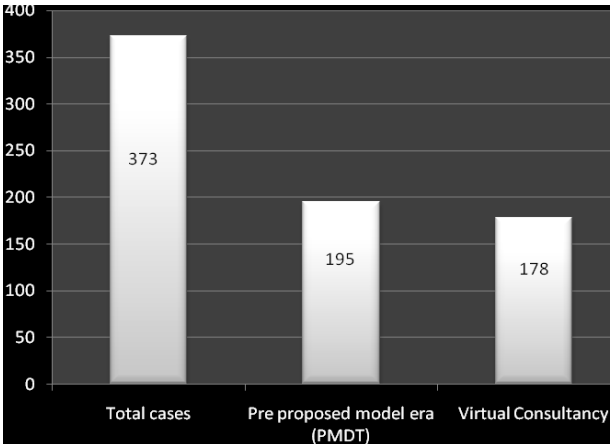

Figure 2: MDR cases as per DRTB service offered.

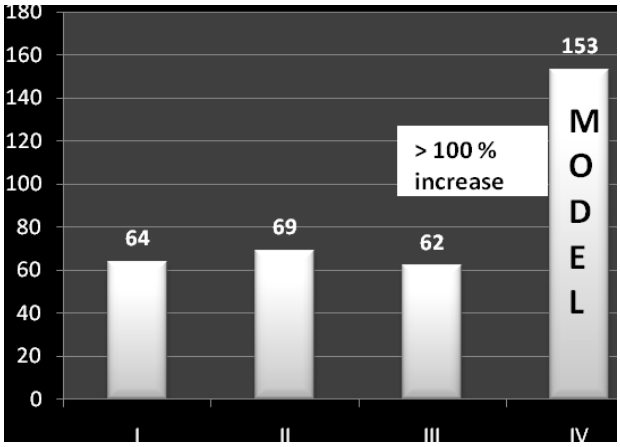

Figure 3: Enrolment trend of cases.

When the district TB centre (DTC) wise distribution of these cases were analysed, it was observed that all these cases were uniformly distributed except Wyanad DTC centre which reported the least number, possibly owing to the comparatively low population of the district and the less number of actual cases existent in that District.

Wyanad geographically comes under the difficult rural area and hence decentralizing services is all the more useful to all those patients who were otherwise healthy and could avoid travelling just for initiating the treatment from the DRTB centre which was about 100 km away (Figure 4). All the seven Districts had effective communication with the DRTB centre utilising proper internet services. 149 patients out of 178 patients who were in the model group could be managed successfully from the periphery.

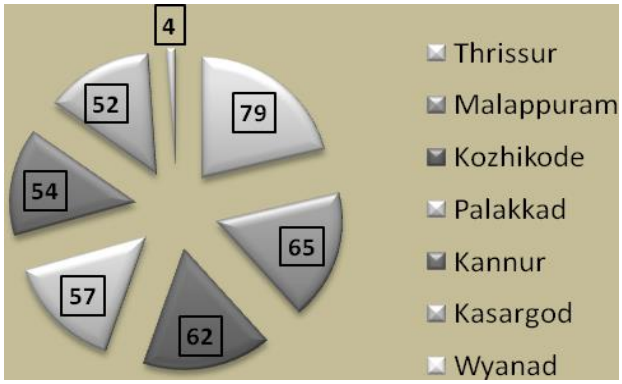

Figure 4: District wise distribution of MDR TB cases.

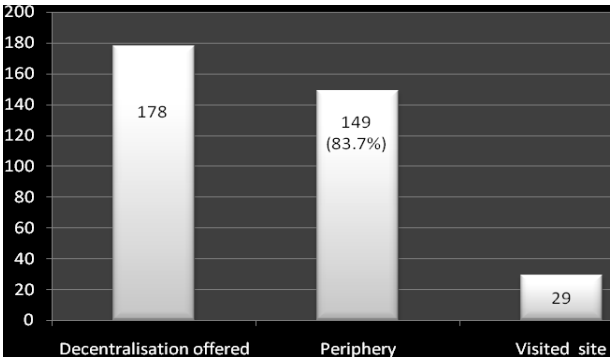

Figure 5: Percentage utilisation of the service.

The percentage utilisation of this service was hence 83.7% (Figure 5). This emphasises the fact that it is a feasible and cost effective operational modification. Only 29 (16.3%) patients required a pre-treatment visit to the DRTB centre. It is obvious that a lot of money could be saved by not spending on the travel of all the patients to the DRTB centre and also unnecessary travel in public transport system to the DRTB centre could be avoided thus saving the community to a great extent from airborne transmission of this dreaded bacillus.

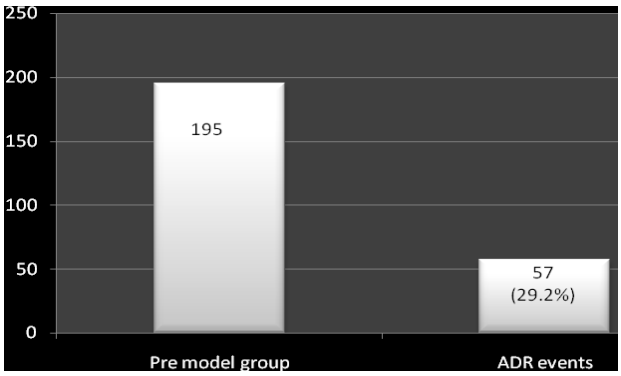

Figure 6: Visit to DRTB centre for adverse effects (Pre-model group).

In the pre-model group, it was observed that 29.2% (57/195) patients had to attend the DRTB centre during the course of the treatment for the management of adverse effects, which is comparable to that of the decentralized group in which case it was 30.3 % (54/178) which again supported the stability of the proposed model (Figure 6 and 7).

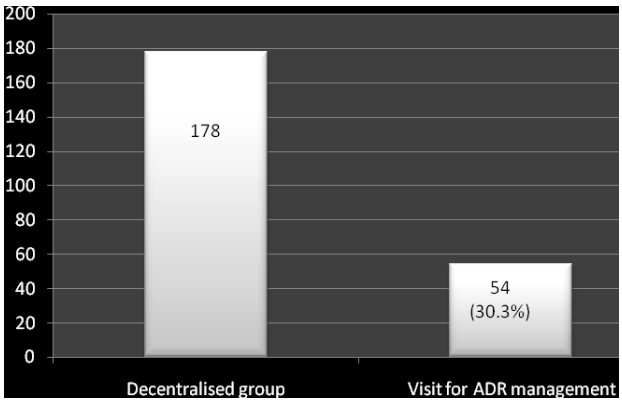

Figure 7: Visit to DRTB centre for adverse effects (Decentralised group).

This clearly shows that decentralization has not interfered with the existing adverse event management protocols. Amongst the patients who had to come to the DRTB centre, only 6.2 % (11/178) had severe disease and were very sick enough to warrant institutionalized care. Five patients required pretreatment psychiatry evaluation, four patients had borderline renal derangement and hence were evaluated by the nephrologist, while three patients had to undergo ENT evaluation for suspected sensorineural hearing loss. Two patients each were referred to the site for initiating treatment after default, extrapulmonary MDR-TB and possible alcohol related hepatic derangement (Table 1).

Table 1: Reasons for initial visit to the DRTB site (De-centralised group).

Total number of model group patients	178
Patient requiring initial DRTB centre visit	29 (16.3%)
Very sick patients	11(6.2%)
Pre-treatment psychiatry evaluation	5 (2.8%)
Pre-treatment renal evaluation	4 (2.2%)
Pre-treatment ENT evaluation	3 (1.7%)
Pre-treatment gastro evaluation	2 (1.1%)
Extra pulmonary MDR	2 (1.1%)
TAD (Treatment after default)	2 (1.1%)

Overall adverse effect reported was 42.6% (159/373). Gastritis, arthralgia, sensorineural hearing loss, psychiatric abnormalities, nephrotoxicity, hypothyroidism, peripheral neuropathy, hepatic derangement, severe skin rashes, visual abnormality occurred in the descending order of frequency (Table 2).

Table 2: CAT-IV patient's adverse events.

Adverse events	No. of patients
Gastritits	44
Arthralgia	31
Hearing loss	28
Psychosis	20
Renal dysfunction	18
Hypothyroidism	6
Neuropathy	5
Hepatic derangement	3
Severe skin rashes	3
Visual abnormality	1
Total adverse events	159/373 (42.6%)

Overall mortality of MDR-TB patients registered under DOTs Plus was 12.3% (46/373). Of these deaths, only 17.4% (8/46) cases could be attributed to serious adverse effect to CAT-IV drugs. When the total numbers of patients on CAT-IV regime were taken in to account, deaths due to drug toxicity further narrowed down to the tune of 2.1% (8/373). Hence apprehension of the peripheral centres over the possible increase in mortality, if decentralization is applied more widely, appears farfetched Figure 8.

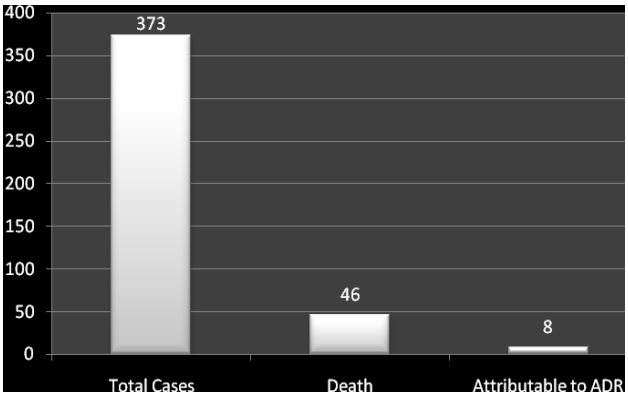

Figure 8: Mortality attributable to adverse events.

Table 3: Interim performance analysis.

Status of treatment (Interim analysis)	No. of patients
Total cases registered	373
Ongoing treatment	266
Results analyzed	107
Successful	73 (68.2%)
Death	16
Default	10
Others	8

An interim analysis on the standards of care offered by this DRTB centre (This is only for a specific period, hence the results cannot be extrapolated to all the 373 patients as the group analysed were the first 107 patients enrolled at this site) was attempted as a performance

indicator from the data of outcome declared from the first quarter 2009 to the third quarter 2010 and it was found that out of the 107 cases, 73 successfully completed the treatment which brings up the success rate to 68.2% (73/107). This is well in accordance with international standards (Table 3).[1]

A further break up of those patients with a successful outcome, revealed 46.7% (50/107) as declared cured and another 21.5% (23/107) as having an outcome as completed treatment, which is when the patient has completed treatment per guidelines but does not meet the definition for cure or treatment failure due to lack of bacteriological results. Together these two figures make up a success rate of 68.2% which is a good indicator of a properly functioning DOTs plus programme (Figure 9).

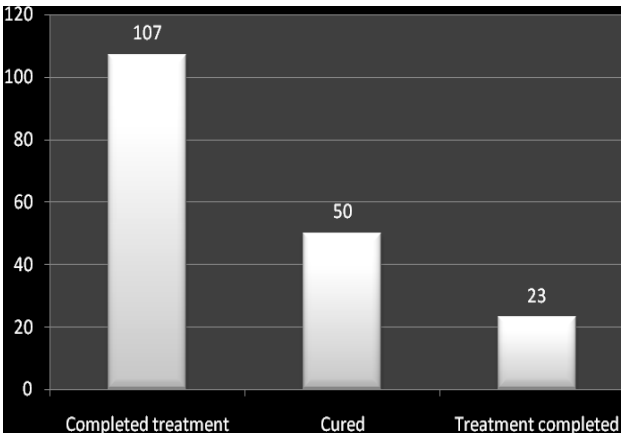

Figure 9: Treatment success analysis.

Hence we recommend that before decentralizing, any DRTB centre should achieve good success rates which is an indirect validation of a properly working DOTs Plus channel.

DISCUSSION

The recent WHO report indicates that the prevalence of tuberculosis in India is 283 per 100,000 population with approximately 2.8 per cent of prevalent cases being problematic multidrug resistant (MDR) TB. An estimated 440,000 new cases of MDR TB occur annually around the world, causing an estimated 150,000 deaths (with a range of 53,000 to 170,000).[2,3]

DOTs Plus programme should reach the beneficiary without much delay. Availability of efficient internet services as well as the expertise of trained specialists in the periphery has been underutilized for a very long time by the programme possibly owing to lack of a proper model. This study however was an earnest attempt in this regard which found that instituting a virtual consultancy model did not compromise the quality of the service provided, but in addition proved to be one which could save time, money and manpower. The undesired communicability of this dreaded disease while commuting the patient from the periphery to the DRTB centre in not really indicated situations in public conveyance facilities could also be minimized to the least possible extent proving it to be a community friendly approach.

Virtual consulting room as a web-based application has been accepted by the international medical fraternity as an effective method to bridge the gap between primary and higher health care facilities.[4] Investigators have opined that there is a definite need for rigorous operational research in programmatic settings to get information on the best use of existing and new interventions in TB control strategies.[5] Hence this endeavour seems justified. The percentage utilisation of this service was 83.7% which emphasises the fact that this is a feasible operational modification (Table 4).

Table 4: Comparison of PMDT versus Kozhikode model.

Variable	PMDT	"Kozhikode model" virtual consultancy applied group
Total number of patients	195	178
% utilization of service	Not applicable	83.7%
Adverse event	29.2%	30.3%
Change in patient enrollment trend on decentralization	62	153 (>100% increase)

New estimates suggest that there are about half a million MDR-TB cases per year including new and previously treated cases, half of them in India and China. Globally, only 11 percent of the estimated 440,000 new MDR TB cases annually are reported.[6] So delay in initiating treatment after diagnosis cannot be tolerated at any cost. The major concern from the peripheral centres over decentralisation was the possibility of overlooking any life threatening adverse events in terms of delay in picking up signs or due to lack of timely investigations. This issue was specifically looked in to and we found that adverse events reporting remained almost the same as before, with the reporting rates being 29.2% and 30.3% in the pre-proposed model group (PMDT) and the decentralized group respectively. Virtual consultancy, being a new step, could prove to be a leap in MDR-TB.

For attaining good results, the timing of decentralization should be dictated by the performance status of the DRTB centre under consideration. Decentralization should only be attempted as a second step in a well-functioning DRTB centre with at least the first 100 treated cases yielding a success rate of 60% or more, keeping up with the currently acceptable success standards of managing these cases in reputed centres. In our case, we offered the virtual consultancy after achieving this success rate which ensured a proper network and a feasible channel for programme operation in this modified manner.

CONCLUSION

This study clearly endorses the view that in a properly functioning DRTB centre, decentralizing the services is a feasible and resource friendly option utilizing the virtual consultancy model (Kozhikode Model). It was observed that there was a rapid increase in the enrolment rates of these patients following decentralization which was due to the successful mitigation of any technical time delay that might have prevailed earlier in the system. Hence the Kozhikode Model could be promoted on a nationwide basis provided the DRTB centre instituting this strategy has proved its mettle through its performance markers for a sufficient period of time before decentralizing its services.

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