DOI: 10.7860/JCDR/2017/27594.10401

Original Article

Community Medicine Section

Home Based Care as an Approach to Improve the Efficiency of treatment for MDR Tuberculosis: A Quasi-Experimental Pilot Study

NEHA TANEJA[1], VINOTH GNANA CHELLAIYAN[2], SHAILAJA DARAL[3], MRINMOY ADHIKARY[4], TIMIRESH KUMAR DAS[5]

ABSTRACT

Introduction: Multi Drug Resistant Tuberculosis (MDR TB) has emerged as a significant public health problem in India. The prolonged treatment duration in MDR TB is a challenge in achieving treatment completion and poses a threat to TB control in the country. Home based care is an approach accepted by patients because it helps in ameliorating their understanding of TB, improving the compliance and reducing stigma in the community.

Aim: To assess the outcome of Home-Based Care (HC) versus No Home-Based Care (NHC) on the treatment of MDR TB patients registered at two chest clinics in Eastern Delhi.

Materials and Methods: A quasi-experimental study was done among diagnosed MDR TB patients receiving Category IV regimen under Revised National Tuberculosis Control Programme (RNTCP) from two government chest clinics in Eastern Delhi during May 2014 to May 2016. In the control arm, 50 MDR TB patients at one of the chest clinics were offered the standard Category IV regimen under RNTCP; while in the intervention arm, 50 MDR TB patients at the second chest clinic were provided home based care (counselling, support for completion of treatment, rehabilitation, and nutritional support) along with the standard treatment. The primary outcome assessed was outcome of treatment, while secondary outcomes included stigma faced due to the disease, and impact of disease on family and community life.

Results: The primary outcome data was available for 32 (64%) participants in the intervention arm, and 38 (76%) participants in control arm. The treatment was significantly more successful in the intervention arm ($p<0.03$). The data on secondary outcomes was available for all participants. Stigma due to disease was significantly lower in the intervention arm ($p<0.01$); also rejection faced by participants from family and community due to disease was significantly lower among the HC group ($p<0.05$).

Conclusion: Home-based care in MDR TB treatment holds potential in improving treatment outcomes of patient.

Keywords: Domiciliary care, Multidrug resistant tuberculosis, Stigma

INTRODUCTION

MDR TB is defined as Tuberculosis resistant to Isoniazid and Rifampicin, the two most powerful first line anti-TB drugs [1]. MDR-TB has become a significant public health problem in several countries, and remains a threat to the global tuberculosis control effort. In 2015, a total of 480,000 of the 10.4 million incident TB cases globally were MDR TB [2]. An estimated 1.3 lakhs incident multi-drug resistant TB patients emerge annually in India which includes 79,000 MDR-TB patients estimates among notified pulmonary cases [3].

The prolonged treatment associated with MDR TB and the often-severe adverse effects of second line drugs increase the challenges in achieving treatment completion. Treatment compliance of MDR treatment is a major challenge even for a well-motivated patient. With the RNTCP in place for more than two decades now, India, has made remarkable progress in TB control and met the Millenium Development Goals (MDG) 2015 target for TB control [3]. Yet, MDR TB is increasingly becoming an organizational and financial challenge to the programme. One approach for control of MDR TB is by providing facilities for adequate support to patients and their families at domiciliary level. This is viewed as a safe approach conducive to recovery, facilitating psychological and emotional support allowing more free time and earning potential for patients and caregivers [4]. Implementation of such an approach will warrant a team of well-trained vigilant health workers who will provide treatment drugs, as well as supportive care for their side effects so as to ensure compliance to treatment [5].

There is limited literature on home based care approach to MDR TB in India. Our study was an approach to explore the importance of home based care in MDR TB with the objective of assessing the outcome of Home Based Care (HC) versus Non-Home Based Care (NHC) among MDR TB patients presenting to two chest clinics in Eastern Delhi.

MATERIALS AND METHODS

The study was a two group quasi-experimental study. The recruitment period for the study was during April 2014 to May 2014. Ethical approval was obtained from Ethical Committee of VMMC and Safdarjung Hospital, New Delhi. Written informed consent was obtained from study participants. The confidentiality of the study participants was maintained at throughout the study.

Patients diagnosed with multidrug resistance TB during the recruitment period were chosen. The intervention period was between May 2014 to May 2016. This was a pilot study which assessed the feasibility and acceptability of an upcoming community trial in Delhi.

Inclusion and Exclusion Criteria

The study population was patients diagnosed and treated for MDR TB under Category IV regimen of the Revised National Tuberculosis Control Programme [3]. Inclusion criteria were those MDR TB patients, whose duration of treatment was more than six months, were recruited in the study. MDR TB patients with any form of disability and comorbidities and pregnant MDR TB females were excluded from the study.

Sampling Method

The list of hospitals where patients were diagnosed and treated for MDR TB under Category IV regimen under Revised National

Tuberculosis Control Programme was obtained. Cluster trial was being planned in twenty hospitals in Delhi, therefore this pilot study was planned to be conducted with two hospitals. Among the hospitals two hospitals- Malviya Nagar Government Hospital and Nehru Nagar Chest Clinic were selected by simple random sampling using lottery method. During April 2014 and May 2014, the patients who fulfilled inclusion criteria were recruited in both hospitals. Assuming standardized effect size of 0.25, with 95% confidence interval, using Upper Confidence Limit (UCL) approach, and adjusting for an inflation rate of 1.450, the sample size per arm for a pilot trial was 50. The main trial would be planned based on the estimate of the standard deviation from the pilot study. Then the main trial sample size based on the UCL approach would be 716. This method would result in a total overall sample size of 762 participants.

Finally, a total of 100 confirmed MDR TB cases were recruited, out of which 50 patients from Malviya Nagar Government Hospital received home based care and remaining 50 from and Nehru Nagar Chest Clinic did not receive home based care.

A. Intervention Arm

Those who were undergoing treatment under Delhi Government Hospital, Malviya Nagar.

A team of two trained homecare providers provided comprehensive home based care to MDR TB patients and their family members in form of:

1. **Counseling:** Patients and family members were counseled about the disease, importance of treatment adherence and their emotional needs were addressed. Health education about coughing etiquettes, avoiding risk to family members etc., were provided.
2. **Support for continuing treatment:** Nursing care and referral of sick and mentally ill patients to other higher centres.
3. **Rehabilitation:** Physical, mental and vocational rehabilitation were provided to the patients. The home care team helped them in availing relevant Government schemes, and by bringing them to normal stream of life – getting re-admission to schools and or encouraging to start working.
4. **Nutritional support:** In the form of eggs and nutritious multigrain provision and attends counselling regarding high protein diet and other nutritional needs.

The team visited all the participants of home care group in a phased manner. The participants in this group were visited by home care team every fortnightly in intensive phase and every 45 days during continuation phase till they completed the treatment regimen. During each visit apart from providing health education and counselling the team assessed the progress of the patients recording their body weight, side-effects of medicines and complications of the disease. The team also motivated the patients to go for sputum microscopy, X-Ray, sputum culture and other relevant investigations as and when required according to the RNTCP guidelines.

B. Control Arm

The control arm received regular treatment and investigations as per RNTCP guidelines. The progress of the patients was monitored by recording their body weight, side-effects of medicines and complications of the disease every time they visited hospitals for refilling of drugs.

Outcomes

The primary outcome of interest was treatment outcome of DOTS- Cured, treatment completed, default, failure, conversion to extremely drug resistance TB and deaths. The secondary outcomes were stigma faced due to the disease and impact of disease on family and community life.

Follow Up

During each visit apart from providing health education and counseling they assessed the progress of the patients by recording their body weight, side-effects of medicines and complications of the disease. A separate file was maintained for each patient and it was duly filled during each visit duly recording all the data. The team maintained a coalition touch with RNTCP health care team at central and local levels during the treatment period.

STATISTICAL ANALYSIS

Data analysis was done with Statistical Package for Social Sciences SPSS version 21.0. (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) The primary outcome of the study is described in the form of proportions and quantitative variables are described in the terms of mean, median, range and standard deviation. Data was checked for normality before applying appropriate tests of significance. Significance of difference in proportions (qualitative variables) was calculated using chi-square test. Significance of p-value was taken as $p<0.05$.

RESULTS

Mean age of the patients was 28±1.39 years. Majority of the study subjects were in the age group <30 years (72% in NHC group and 64% in HC) group and majority were males (64% in NHC group and 54% in HC group). About, 16% were illiterate among the NHC group while 20% were illiterate in the HC group. Majority of the study population in both the groups were Hindus [Table/Fig-1]. Among the risk factors 24% family members were currently suffering from TB in NHC group however, in HC group only 6% family members were suffering from TB. Similarly, death due to TB was reported in 14% of family members among the NHC group in comparison to only 2% in homecare group. Both the risk factors found out to be statistically significant ($p<0.05$) [Table/Fig-1].

Attitude towards the disease was assessed in both group at the end of continuation phase. Rejection and stigma faced by the participants due to disease were assessed [Table/Fig-2,3]. With regards to impact on family life 26% participants among the NHC group faced rejection by family members whereas, only 6% participants from the HC group faced rejection. Likewise, 28% participants from the NHC group were rejected by the community while only 10% participants from HC group were rejected by the community. Both these factors were statistically significant ($p<0.05$) [Table/Fig-2]. An 86% of participants among NHC group faced some form of stigma due to the disease unlike HC group where only 28% participants faced any form of stigma and this difference was statistically significant ($p<0.05$).

A total of 13 participants among NHC group lost their jobs due to disease while only 5 participants of the HC group lost their jobs. A total of 4 children with TB infected parents had to discontinue school among NHC group whereas only 1 children had to discontinue school in the HC group due to the disease. Among the NHC group 14 married females were sent back to their homes while only 4 married female patients were sent back to their homes in the HC group. A total of 12 participants in the NHC group were not allowed to attend any social function, however, only 4 participants were stopped from attending any social function in HC group [Table/Fig-3].

Out of 50 participants in the NHC group the outcome of 38 patients were available. Among the HC group outcome of 32 patients were available [Table/Fig-4]. Rest of the participants in the respective groups were lost to follow up variably before they complete their treatment regimen. A total of 23.6% participants among the NHC group were successful in completing the treatment unlike HC group where 40.6% participants had successfully completed their treatment and this difference was statistically significant ($p<0.03$).

Treatment successful includes treatment complete and cured. Approximately, 5 (13.1%) of NHC group and 1 (3.1%) of HC group were transferred out to other tuberculosis units as they migrated. Defaulters who did not comply with the regimen were present in both the groups.

Variable		No home care (n = 50) n (%)	Home care (n = 50) n (%)
1. Age (in years)	<30	36 (72%)	32 (64%)
	31-40	08 (16%)	09 (18%)
	41-50	03 (6%)	06 (12%)
	>50	3 (6%)	3 (6%)
2. Gender	Male	32 (64%)	27 (54%)
	Female	18 (36%)	23 (46%)
3. Educational status	Illiterate	08 (16%)	10 (20%)
	Primary school	10 (20%)	11 (22%)
	Middle school	14 (28%)	19 (38%)
	Secondary school	18 (36%)	10 (20%)
4. Religion	Hindu	45 (90%)	38 (76%)
	Muslim	4 (8%)	12 (24%)
	Others	1 (2%)	0 (0%)
5. Family members with TB	Yes	12 (24%)	3 (6%)
	No	38 (76%)	47 (94%)
6. Death of family member due to TB	Yes	7 (14%)	1 (2%)
	No	43 (86%)	49 (98%)

[Table/Fig-1]: Baseline characteristics of the study population. (N=100)

Sl No.	Impact of disease	No Home care (n = 50) n(%)	Home care (n = 50) n(%)	Statistic
1.	Rejection faced in family Yes No	 13 (26) 37 (74)	 3(6) 47 (94)	$\chi^2 = 7.44$ p = 0.006
2.	Rejection faced in community Yes No	 14 (28) 36 (72)	 5 (10) 45 (90)	$\chi^2 = 5.26$ p = 0.02
3.	Stigma faced Yes No	 43 (86) 7 (14)	 14 (28) 36 (72)	$\chi^2 = 34.31$ p<0.001

[Table/Fig-2] Distribution of study population according to Impact of disease. (N=100)
Chi square text applied, p value <0.05 is significant.

Sl No.	Stigma faced	No Home care (n = 43) n(%)	Home care (n = 14) n(%)	p-value
1.	Loss of employment	13 (30.23)	5 (35.71)	0.12
2.	Children with TB infected parents discontinue study	4 (9.3)	1 (7.14)	0.54
3.	Married female TB patients sent to her parents house	14 (32.55)	4 (28.57)	0.02
4.	Family member with TB were not allowed to attend any social function	12 (27.90)	4 (28.57)	0.04

[Table/Fig-3]: Response of study population facing stigma.
Chi-square test applied, p-value <0.05 is significant.

Sl No.	Treatment outcome	No home care (n = 38) n(%)	Home care (n = 32) n(%)	p-value
1.	Cured	5 (13.1)	7 (21.8)	0.05
2.	Treatment completed	9 (23.6)	13 (40.6)	0.03
3.	Death	7 (18.4)	6 (18.7)	0.3
4.	Defaulter	9 (23.7)	4 (12.5)	0.24
5.	XDR	3 (7.9)	1 (3.1)	0.10
6.	Transfer out	5 (13.1)	1 (3.1)	–

[Table/Fig-4]: Comparison of treatment outcome of patient in control intervention group.
Chi-square test applied, p-value <0.05 is significant.

DISCUSSION

Home-based care, an alternative service delivery model has been developed to fill the gap left by overstretched and under resourced health systems [6]. In the present study, home based care was provided to MDR TB patients in their own homes through family participation. There was a significant difference in MDR-TB treatment outcome between home based care and non-home based care approach. Our study showed successful treatment in 40% MDR TB patients receiving home based care, against only 23.6% in patients receiving non-home based care. This is consistent with the findings from Uganda where a case report demonstrated successful treatment of MDR-TB using home-based approach as opposed to facility based treatment [7]. Similar higher success rate and lower default rate have been reported in a study done in India [8]. Almost 91% of successful treatment outcome and higher treatment adherence have been reported among home based care recipients in Armania [9]. Home based care has been proven to be effective in developing countries including South Africa [10,11]. Clearly, home based care has been an excellent option as a service delivery model, it could promote integrated management for better treatment compliance and outcome worldwide.

In our study, a total of 12.5% participants receiving home based care defaulted, while 23.7% of those receiving non-home based care turned defaulters. This is in line with existing evidence from other parts of the world, which have shown home based strategies to be effective in improving treatment adherence [12,13]. Utilisation of community health workers remained significant in enhancing treatment adherence in a study done in both urban and rural settings in Kenya [14]. Dropping out of the programme and non –compliance among MDR TB patients are more likely as people who have defaulted previously are more likely to default [15-17]. Provider-related issues include poor communication, health education and lack of attention and care from health personnel including DOTS providers [15].

Our study also showed that five participants receiving home based care were not able to continue their jobs, while the proportion is higher in non-home based care group. The reasons that could be attributed include appropriate counselling, rehabilitation services and nutrition supplement to HC group which might have contributed in continuing their current job with positive attitude. Deaths of participants due to TB, and risk of disease among family member due to contact with the patient in their family were also lower among participants receiving home based care. These positive outcomes can be attributed to patient empowerment, with correct knowledge about the disease and its control.

Home-based care has been shown to be effective in improving family support to MDR TB patients [18]. In our study, while 26% participants with non-home based care faced rejection from their family, only 6% of the participants receiving home based care faced rejection from their family. Similarly, while 28% participants in the non-home based care group were rejected by the community, only 10% were rejected by the community in the home based care group. These findings suggest that home based approach results in the development of strong emotional bonds between the patients, their families and the community. Evidence from South Africa has indicated that mandating MDR TB patients to stay away from their families can have devastating consequences, and patients are unlikely to comply with this advice [4]. By fostering the bond of patients with their families and community, a unique opportunity is created in disease education which is likely to have long term effect on disease perceptions of the population, and treatment adherence in the patients. These findings were also reported in a study done in India [19]. In general, engaging family members as supportive individuals in their family's medical care have illustrated

better outcomes including decreased rate of loss of follow up and adherence regardless of the disease type. Involvement of family members for home care has contributed to better treatment adherence especially in developing countries [20,11].

Patients with MDR TB are on a longer therapy, and more complex regimens. Such patients need a periodic and consistent domiciliary support for better compliance and treatment success. Community based care could bring self-reliance and empowerment to communities by having those most affected by TB participate in their TB programmes. Potential limitation of this study includes issues with documentation (incomplete data) due to migration of few participants to other tuberculosis units.

CONCLUSION

Home based care approach for management of MDR TB holds promise in effective management of the disease, as well as improving lives of patients and their families. Similar findings are expected in the main community trial. More studies are necessary in this domain to demonstrate the effectiveness of home based care in MDR TB treatment and to explore further options and approach to MDR TB care at community level. Role of public private partnerships for active delivery of rehabilitation, village health sanitation and nutrition committee for nutritional counseling and community volunteers for incessant motivation are future prospects.

ACKNOWLEDGEMENTS

We are thankful to Malviya Nagar Govt. Hospital and Nehru Nagar Chest Clinic, District TB officer for their support in conducting the study.

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PARTICULARS OF CONTRIBUTORS:
1. Senior Resident, Department of Community Medicine, NDMC Medical College and Hindu Rao Hospital, Delhi, India.
2. Assistant Professor, Department of Community Medicine, Chettinad Hospital and Research Institute, Chennai, Tamil Nadu, India.
3. Senior Resident, Department of Community Medicine, VMMC and Safdarjung Hospital, New Delhi, India.
4. Assistant Professor, Department of Community Medicine, Murshidabad Medical College and Hospital, Murshidabad, West Bengal, India.
5. Senior Resident, Department of Community Medicine, VMMC and Safdarjung Hospital, New Delhi, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Vinoth Gnana Chellaiyan,
Assistant Professor, Department of Community Medicine, Chettinad Hospital and Research Institute,
Chennai-603103, Tamil Nadu, India.
E-mail: drchellaiyan@gmail.com

FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **Feb 15, 2017**
Date of Peer Review: **Apr 05, 2017**
Date of Acceptance: **Jul 16, 2017**
Date of Publishing: **Aug 01, 2017**