Assessment of Factors Responsible for Dropout to Multi Drug Therapy for Leprosy

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This study was conducted over 2 years period at two leprosy centers of a Tertiary Care Service Hospitals one located in Eastern Uttar Pradesh and second in northern India to assess the factors resulting in pre-mature termination of anti-leprosy treatment in patients. A total of 124 patients, undergoing treatment for leprosy who consumed MDT for at least a month, then stopped it and thereafter reported to us for various reasons, were included. It was observed that 41.1% (51/124) patients dropped out on MDT. 33% (41/124) of the patients who stopped the medication were not formally educated. Most common disease forms observed in these patients was Borderline Lepromatous (BL) and Lepromatous Leprosy in 41.1% (51/124). 49.1% (61/124) patients completed 2-5 months of therapy with MDT prior to stopping it and 38.7% (48/124) patients reported back to us within 2-5 months after suspension of MDT. Reason for reporting in 31.4% (39/124) of these patients was development of deformities while 25% (31/124) reported due to weakness of hands and feet. 23.3% (29/124) developed lepra reaction becoming the reason for their reporting to us for review. Social stigma was the most common factor leading to termination of drug therapy against advice in 25.8% (32/124) patients, 21.7% (27/124) cited loss of occupational hours while 11.2% (14/124) patients felt there was no need to take MDT. To conclude non-compliance to multi drug therapy for leprosy is one of the major obstacles in achieving a leprosy free world and we need to look into all the personal, health care related and social factors responsible for it. Although these factors may vary depending upon the region, society, efficiency of the health care system and the individual commitment level of the patients, the need for better communication at professional and user level is apparent. Focus should be on psychological counselling, motivation of patients, their families and a receptive society to reduce the source of infection, complications and deformities which are otherwise largely preventable and adherence to treat will also prevent of emergence of resistance to MDT. Modified strategy(ies) addressing the factors as identified in this study well in time can make a difference.

Keywords : Multidrug Therapy, Compliance, Leprosy, Drop outs

Introduction

Leprosy continues to be a major public health problem in India despite the availability and implementation of an effective multidrug Therapy (MDT) three decades back. India is home to approximately 58.8% of leprosy patients of the world (WHO 2015).

Although a powerful tool in controlling leprosy,

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adherence to MDT has always been challenging due to number of personal, psychosocial, economic and medical factors. A significant number of patients' defaults or become irregular or dropout on the treatment (Rao 2008). Compliance to MDT is the key factor for leprosy elimination; hence, a high rate of noncompliance to it has negatively affected the leprosy control program and has set the stage for emergence of drug resistance, which results in failure of the treatment, deformities, disabilities and ultimately causing failure of leprosy control program (Honrado et al 2008). The low adherence to MDT is attributed to a variety of diverse factors that differ according to the cultural, socio-economical, psychosocial, behavioral and various drug and health care related factors (Trindade et al 2003, Heijnders 2004). In a study done in India stigma was attributed as a leading cause of dropout on MDT (Rao 2008). Though the data on the percentage of defaulters in Indian setting is not known, other national programs have reported that 40% of newly detected patients are defaulters (Griffiths and Rean 2001, Coebergh and Buddingh 2004). The recent scientific literature on the factors associated with default or dropout is highly varied from across the world, hence it is prudent that the countries where leprosy continue to be a public health issue, these factors are identified and reported, so as to define high risk group and to follow them through the course of the therapy. This will not only reduce the rate of dropout, but will also address the issues like development of drug resistance, deformities and a persistent source of infection in the society. The data in present study comes from two different settings, an urban special population and rural population from eastern Uttar Pradesh to assess the factors causing dropout on therapy.

Patients and Methods

This was a prospective study conducted over a period of 2 years (June 2015 - May 2017) at two leprosy centers of Service Hospitals catering for a special population and their dependents located in northern India and another at Eastern Uttar Pradesh. Permission from Institutional Ethics Committee was obtained and written informed consent was taken from the patients after explaining the nature of the study. All the patients were diagnosed and classified as per Ridley Jopling and IAL classification and were accordingly started on MDT. (Ridley and Jopling 1966, IAL 1982). Patients who had completed at least one month of therapy but subsequently stopped the drugs on their own without the advice of the treating physician and reported to us after varied interval of time for various reasons on their own for further treatment were included. While patients unwilling to participate, or those who stopped the drugs in less than one month of initiations of therapy were excluded from the study. Their demographic details, type of leprosy, duration of MDT completed and the duration between the stoppage of MDT and subsequent presentation was enquired. The cause of stopping the therapy earlier and the reason for present visit was enquired during the interview conducted over 15-20 minutes and data was collected in pro forma and analyzed subsequently.

Results

A total number of 726 patients were registered in both the centers for treatment in two years of study duration. Out of which 17% (124/726) patients who fulfilled the criteria were included in the study. 12.5% (91/124) patients who dropped out on treatment and never reported to us till the time this study was done. Of 124 patients included in the study, males were 63.7%

(79/124) while 36.2% (45/124) were females. Male to Female ratio was 1.75. Of all the dropout patients, 41.1% (41/124) were in the age group of 31 to 45 years while 1.6% (2/124) patients were more than 65 years of age. 33% (41/124) patients had no formal education in comparison to only 2.4% (3/124) completed graduation. The patients were classified as per Ridley-Jopling

Table 1 : Demographic profile of the leprosy patients who dropped out

Parameters	Number	Percentage
Gender of the patients		
- **Males**	79	63.7%
- **Females**	45	36.2%
Age distribution (years)		
18-30	17	13.7%
31-45	51	41.1%
46-55	25	20.1%
56-65	29	23.3%
>65	02	1.6%
Education level		
No formal education	41	33%
Primary level	36	29%
High School	26	20%
Secondary	18	14.5%
Graduation	03	2.4%
Postgraduate	00	00
Type of leprosy		
Tuberculoid Tuberculoid	02	1.6%
Borderline Tuberculoid	27	21.7%
Borderline Lepromatous	51	41.1%
Lepromatous lepromatous	42	33.8%
Pure Neuritic	06	4.8%
Per Capita monthly Income of family		
Rs >10,000	14	11.2%
Rs 5000-10000	21	16.9%
Rs 2500-5000	32	25.8%
Rs 2500-1000	41	33%
Rs 1000-500	11	8.8%
Rs <500	05	4%

Table 2 : Duration of MDT intake, interruption and causes of present visit

Parameters	Number	Percentage
Duration of MDT completed prior to stoppage (months)		
< 2 months	19	15.3%
2-5	61	49.1%
5-7	38	30.6%
8-10	06	4.8%
Duration of discontinuation (months)		
1-2 months	06	4.8%
2-5 months	48	38.7%
5-10 months	42	33.8%
10-16 months	12	9.6%
16-24	09	7.2%
>24	07	5.6%
Reason for reporting again		
Skin patch (new/ increase in size)	19	15.3%
Weakness of hands/Feet	31	25%
Deformity	39	31.4%
Lepra reaction	29	23.3%
Others	06	4.8%

Table 3 : Factors stated to be associated with termination of MDT

Parameters	Number	Percentage
Factors associated with stoppage of MDT		
Loss of occupational hours	27	21.7%
Transport not available/ distance	21	16.9%
Fear of social stigma	32	25.8%
Adverse drug reaction to MDT	12	9.6%
Ill health	18	14.5%
Does not feel medication is required	14	11.2%

and IAL classification. Most common clinical type observed in patients who dropped-out on treatment was Borderline Lepromatous (BL) in 41.1% (51/124) followed by 42 LL (33.8%), 27 BT (21.7%), 6 Polyneuritic (4.8%) and 1.6% (2/124) patients in Tuberculoid tuberculoid (TT) pole. 41.1% (41/124) patients had per capita monthly income between 2500-1000 rupees followed by

25.8% (32/124) between 2500-5000 and only 4% (5/124) claimed to have less than 500 as per capita monthly income (Table 1). MDT was taken for 2 to 5 months duration by 49.1% (61/124) patients in comparison to 15.3% (19/124) patients who had only 02 months of regular treatment. The duration elapsed between stopping the therapy and reporting again to the treating physician was 2 to 5 months in 38.7% (48/124) patients followed by 33.8% (42/124) while 4.8% (6/124) presented in less than 2 completed months. Most common reason for reporting was grade 1 and 2 deformity in 31.4% (39/124) patients (Table 2). Commonest cause of dropout was social stigma associated with leprosy reported by 25.8% (32/124) patients. Other reasons for non-adherence are shown in Table 3 that included distance/transport not available, adverse drug reactions and ill health.

Discussion

Multi Drug Therapy (MDT) has proven to be a commanding tool in control of leprosy ever since its introduction more than three decades back. MDT is highly effective particularly when started early and taken regularly. However, treatment adherence remains a challenge and dropout is frequently reported. Non-adherence to MDT has detrimental consequences like persistent source of infection in community, disease transmission to a susceptible host, development of deformities and disabilities which are often irreversible and resistance to MDT. It is an established fact that the completion of therapy is governed by a large number of factors, which vary all across the length and breadth of the world and more so in India where a wide variation exists in socioeconomic factors and variation in education level of the patients. All these influence their understanding and behavior in terms of drug compliance (Piscitelli et al 1993).

Reasons for dropout to MDT include a number of personal issues like stigma associated with the disease, psychological and economic reasons like cost of travel, loss of work hours, medical factors like developing reactions, worsening of symptoms, side effect of drugs, or feeling of cure by self, and health care related factors as found by Rao (2008) in Indian setting. Kumar et al (2012) in their analytical cross-sectional study from Nepal reported a significant association between treatment completion and gender wherein a significantly higher numbers of males completed their therapy in contrast to females, on other hand Heukelbach et al (2011) found no significant association between gender, age and civil status and treatment completion. (Kumar et al 2004, Heukelbach et al 2011). Another study by De Araujo and De Oliveira (2005) revealed that most male patients who dropped-out on treatment were in the productive age group which highlights the social cost of this disease on population having greater productive capacity. Present study found a higher number of males stopped MDT as compared to females and most common age group where dropout was noted was between 31 to 45 years which is a productive age group. This variation in the demographic profile of patients who are non-compliant in studies from different regions of the world may be related to the different social context in these countries.

In this study, 33% (41/124) patients had no formal education while only 2.4% (3/124) were graduates. Dropout was most commonly seen in patients who had per capita income between 2500-1000 while 4% (5/124) had income less than 500 rupees. Kar and colleagues reported similar findings in their study from Assam, where a statistically significant association was found between literacy level, socioeconomic factors, per capita income and the adherence

to therapy (Kar et al 2010). However, studies from Brazil and Philippines have not found any significant association between income and rate of dropout. A significantly higher default rate has been reported in patients who were not briefed about the disease and when the drugs were not provided by the health centre where the diagnosis was made in some studies (Honrado et al 2008). In present study setting however all the patients were given counseling by the treating physician and the paramedical staff and drugs were provided by the institute itself hence the findings by Honrado et al (2008) could not be disputed or established.

Social stigma associated with the disease has been identified as one of the important causes for non-compliance to MDT. Fear of being known as a case of leprosy by society and being ostracized by community results in reluctance in treatment continuation. Lusli et al (2016) found that trauma and stress arising as a result of societal behavior towards leprosy patients has the capability to affect their attitude and behavior towards treatment. In present study, social stigma associated with disease was most common reason for drop-out reported by 25.8% (32/124) patients followed by loss of occupational hours in 21.7% (27/124). 9.6% (12/124) patients who developed adverse drug reaction stopped therapy and did not report again. In study done by Honrado, adverse reaction to drug was leading cause of non-adherence to therapy while loss of working hours was most common cause followed by adverse effects to drugs in another study from India (Honrado et al 2008, Kar et al 2010).

It is assumed that default is more likely, if a patient is staying far away from the treatment centre due to the distance required to be travelled and cost involved in it, contrary to it some patients prefer to travel to a further place to get treated as they wish to remain anonymous

(Rao 2008). 16.9% (21/124) patients in present study attributed distance or lack of transport as a cause of dropout. Contrary to it, Hacker et al (2012) did not find any association between distance travelled and rate of dropout. These findings are indicative of the fact that the factors associated with non-compliance are multifaceted and are society, patient attitude and health care related factors.

31.4% (39/124) patients in present study reported again for treatment after developing deformities of various grades while 23.3% (29/124) had lepra reaction at the time of reporting again. In a study carried out by Kumar et al (2012), 10.9% defaulters in MB MDT group developed grade 1 and 2 deformity, 0.4% in PB and 4.2% in MB group had reaction after default. 49.1% (61/124) had taken MDT regularly only for 2 to 5 months while 4.8% (6/124) patients had completed 8-10 months therapy. Duration of discontinuation was 2 to 5 months in 38.7% (48/124) patients. Kumar et al (2012) reported 13.7% patients in PB group defaulting in first month of therapy and by 5th month of therapy 26.9% of the patients had defaulted. In MB group 6.9% defaulted in first month, which increased to 10.4% by 2nd month followed by 32.5% by 11th month of therapy. We noticed that the chances of drop-out was more during initial phases of therapy which reduced as the therapy progressed. Interestingly, most of our patients returned for therapy early in 2-5 months and very few visited after 24 months of dropout. Similarly, Kumar et al (2012) reported that a maximum chance of dropout was the first month of the therapy. It is pertinent to note that 93 of these 124 patients in our study (74.9%) belonged to BL/LL types many of whom are likely to retain infectivity potential after a short therapy and thus have relevance in serving as sources of infection as well.

Interesting to note is that 11.2% (14/124) patients in present study who discontinued the therapy on their own reported during interview that since the signs and symptoms of the disease disappeared, they felt no need to continue the drugs. This fact indicates the lack of counseling or understanding on the part of the patient at the initiation of the therapy.

Abandonment and irregularity of the therapy has always been a concern for countries like India, where it is continuously been reported in higher numbers in recent years. The duration of the therapy is long and pill burden is another challenge the patient has to face apart from various other reasons we encountered while doing this study. Formulation of suitable strategies like social marketing techniques and greater emphasis on operational guidelines on handling the social and psychological aspects of the disease by the healthcare providers may go a long way in reducing the dropout. India poses a unique challenge due to its social, cultural and geographical variations hence; it becomes prudent that strategic interventions are made at various levels and to avoid totally on health care providers to deal with this mammoth task (Heijnders et al 2000).

Out study was an attempt to highlight these issues faced by patients and the situation health care providers has to deal with. However, the limitation of our study is that we did not attempt to compare the demographic profile of the patients who dropped-out during the course of therapy with those who successfully completed it. A study where demographic profile and factors leading to dropout are compared in the two group will be more meaningful. Another limitation of our study is that we do not have data of patients who never reported back to us and the reason for the same to be included in the study. It is recommended that another study is done where these factors can be compared in the two groups.

Conclusion

Although MDT has revolutionized the treatment of leprosy world-over, the issue of dropouts however, continues to haunt us. Successful completion of the therapy is uniformly imperative along with increased need of community participation at present. In this study social stigma and loss of occupational hours have been identified as two major reasons for drop out from therapy in leprosy. Long distance/ lack of transport, adverse reactions and ill health were other factors for drop out which can be addressed by better communication and making arrangements to deliver drugs to patients under such circumstances. A section of patients did not feel the need to continue the treatment, such individuals need better counseling. The health care providers and affected individuals need to be updated better of various challenges/ consequences in terms of continued potential to spread disease to their near and dear ones as well as others and also having a very high risk of getting disabilities. All these risks can be avoided by addressing the issues well in time. Incentives may be added to both the health care providers and patients. Modified strategy to ensure better and effective counselling even to those who are uneducated/semi-literates, improving the access to treatment can go a long way in addressing issue of dropout.

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