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Original Article

Leprosy beyond MDT: study of follow-up of 100 released from treatment cases

N Vara[1], M Agrawal[2], Y Marfatia[1]

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Appearance of new skin and/or nerve lesions during or after fixed duration of multidrug therapy (MDT), in leprosy, is not uncommon. It could be a lesion due to leprosy reaction or relapse. Differentiation is easy in classical reactions both clinically and histopathologically. But, difficult in other situations especially when the relapse cases present with features of reaction at the onset. A study was done to find the reasons for released from treatment (RFT) cases to come to clinic and to follow in terms of clinical and neurological activity, leprosy reactions and deformity progression. Out of them, 14 cases and 86 cases had received paucibacillary (PB) and multibacillary (MB) multidrug therapy respectively. Skin lesions either old or new were noticed in 74% cases which might be due to inactivity or activity were noticed in 74% cases which might be due to inactivity or activity in forms of relapse and reaction. Relapse was seen in 26 cases. Out of these,10 and 16 cases were previously diagnosed as PB and MB cases respectively. PB cases relapsed into MB cases while MB cases relapsed into MB cases. 46 cases presented with either type 1 or type 2 reaction. After declared as RFT, parasthesia in 34 cases, weakness in 18 cases, paresis and paralytic deformity in 6 cases were seen. So, all the RFT cases need regular follow- up, IEC and physiotherapy to prevent deformity and to diagnose relapse and reactions at the earliest.

Key words : MDT, RFT, Leprosy

Introduction

Leprosy, a unique dermatological as well as neurological condition, is highly associated with disfigurement and social stigma. Inappropriate treatment leads to relapses followed by psychological upset. Early diagnosis and appropriate treatment to prevent relapses is the basis of national leprosy eradication programme (NLEP) in India.

In spite of this, there are many problems related with FD-MDT. Many of the cases have residual disease activity even after completion of treatment, stopping treatment in such situation is not convincing to the patient.

In highly bacilliferous cases, fall of bacteriological (BI) is slow and stopping treatment at fixed point of time is not desirable. In these cases, what we call this as “chance smear positivity” where a few bacilli, yet to be cleared by immune system, are picked up by routine skin smear examination (Vijayakumaran et al 1995).

Relapses are often diagnosed as reversal react-

N Vara, MD, Assistant professor
M Agrawal, MD, Consultant Dermatologist
Y Marfatia, MD, Professor and Head
[1] Department of Skin and VD, Medical College and SSG Hospital, Raopura, Vadodara-390 001, India
[2] 351-Vikram Tower, Sapna-Sangita Road, Indore-452 010, India
Correspondence to: N Vara **Email:** nipulvara@yahoo.co.in

ions despite the absence of symptoms and signs of acute inflammation. The number and extent of lesions including skin and nerve when more than 5 and covering 3 or more areas of body is found to be associated with higher relapse rate. In patients treated with WHO-MDT regimen, relapse rate is 0.1 % for PB patients and 0.06% for MB patients (WHO 1994). In pre-MDT era, it was higher due to dapsone resistance. The relapse after FD-MDT is 10 times lower in comparison to dapsone monotherapy (WHO 1995).

It has been proved that the disability might develop and worsen after completion of MDT (Jacob and Mathai 1988). The overall incidence of disability is reduced after starting FD-MDT which is better than pre-treatment status (Samant et al 1999). Thickening of $\geq$ 3 nerves and BI $\geq$ 4 is associated with higher risk of disability (Selvaraj et al 1998).

The possibility of nerve paralysis due to intraneural microreaction and fibrosis consequent to the continued presence of dead bacillary remnants should be seriously considered (Job et al 1996). Long term evaluation of FD-MDT is a mammoth task and time consuming. In the present study, we have made an attempt to study RFT cases. We have tried to find out the reasons for such cases to come back to leprosy clinic.

Materials and Methods

A total of 100 RFT cases having symptoms related to or as a consequence of leprosy were studied in Department of Skin and VD, Medical College and SSG Hospital, Vadodara from period June 1999 to December 2002.

Inclusion criteria

1. Any case that is released from fixed duration-multidrug therapy (FD-MDT) and coming with any clinical symptoms and signs related to activity or consequence of leprosy.

All RFT cases with clinical symptoms were studied on the basis of:

i. Signs of activity, either in skin lesions or in nerves.

ii. Neurological symptoms-tingling/numbness /burning.

iii. Symptoms and signs of leprosy reaction.

iv. Skin smear for acid-fast bacilli (AFB).

v. Skin biopsy along with Fite-Faraco staining (FF staining) in doubtful cases.

Diagnosis of type of relapse cases leprosy according to Ridley-Jopling Classification was done clinically and skin smear for AFB. Relapse cases were differentiated clinically from leprosy reactions and by skin biopsy in doubtful cases. All relapse cases were restarted FD-MDT. Patients with leprosy reaction were treated accordingly. Physiotherapy was advised to all RFT cases on preventive and curative basis.

Results

In the present study, 100 cases of RFT were involved. Out of these, 74 (74%) cases with skin lesion, 34 (34%) with paraesthesia, 100 (100%) with sensory impairment, 26 (26%) with relapse, 40 (40%) with deformity and 46 (46%) cases with lepra reaction were presented. 14 (14%) cases had received PB treatment while 86 cases had received MB treatment (Table 1). Skin lesions were noticed in terms of inactive lesions, new lesions or any lesions of leprosy reaction.

In the present study, out of 100 cases, 26 cases were presented with relapse. Out of 26 cases, 10 cases previously diagnosed as TT were given PB therapy for 6 months. They came with relapse in form of 8 cases of BT and 2 case of BB. The cause of relapse might be initial wrong labelling as PB on the basis clinical findings and smear report without going for histopathology. 14 cases of BT were given MB treatment previously of which 10 cases relapsed in BT, 2 cases in BB and 2 cases in LL while 2 cases of LL came with relapse into same type (Table 2). Few cases of relapsing MB cases might not have taken FD-MDT regularly. Most PB patients relapsed into MB due to wrong classification and insufficient therapy (Li et al 1997).

Table 1 : Profile of RFT cases (n=100)

Clinical features	Present study
Skin lesions	74 (74.0%)
Parasthesia	34 (34.0%)
Sensory deficit	100 (100.0%)
Motor deficit	28 (28.0%)
Relapse	26 (26.0%)
Reactions	46 (46.0%)
Deformity	40 (40.0%)
PB treatment	14 (14.0%)
MB treatment	86 (86.0%)

In the present study, 61.53% cases relapsed within 1 year as compared to 27.83% of cases while 31% cases relapsed within 1-2 years as compared to 66.64% of cases. As compared to TT cases, BT cases took longer time to relapse (Table 3).

In the present study, 69.23% cases relapsed as BT leprosy as compared to CS with 47.61% BT leprosy. In the present study, 15.38% cases relapsed as BB leprosy as compared to CS with 9.52% of BB leprosy (Table 4). In the present study, no cases relapsed as TT, pure neuritic or BL.

Out of 100 RFT cases, 16 (16%) PB cases and 12 (12%) MB cases presented with late reversal reaction while 18 (18%) cases presented with ENL reaction (Table 5). All these cases are more prone to nerve damage or damage to organs and thereby complications. 4 cases presented with erythema nodosum necroticans and 2 cases with epididymo-orchitis. All these patients were treated with NSAIDS, oral steroids and chloroquin and clofazimine in anti-reactional dose (esp. in type 2 reaction).

Out of 100 RFT cases, 34 cases presented with paraesthesia while 18 cases with weakness, 2 cases with paresis (claw hand), 4 cases with paralytic (facial palsy) and 14 cases presented with trophic ulcer (Table 6). So, 40% cases presented with disabilities. Survey among RFT cases showed prevalence of deformities to be variable between 17% to 50% (Djumhana 1991,

Table 2 : Type at initial diagnosis and type at relapse

Previous diagnosis	No.	Previous treatment	Type at relapse (n = 26) BT	BB	LL
TT	10	PB	8	2	-
BT	14	MB	10	2	2
LL	2	MB	-	-	2

Table 3 : Time taken for relapse after RFT (n=100)

Time to relapse	TT		BT		LL		PNL	
	PS	CS	PS	CS	PS	CS	PS	CS
1 year	8 (30.76%)	1 (4.76%)	6 (23.07%)	-	2 (7.69%)	-	-	-
1-2 years	2 (7.69%)	4 (19.04%)	8 (30.76%)	10 (47.61%)	-	-	-	1 (4.76%)
2-3 years	-	1 (4.76%)	-	3 (14.28%)	-	-	-	1 (4.76%)

PS (present study) : Total cases 26
CS (Chopra et al 1990) : Total cases 21

Table 4 : Type of leprosy at relapse (n=26)

Study	TT	I	P	BT	BB	BL	LL	Total
PS	-	-	-	18 (69.23%)	4 (15.38%)	-	4 (15.38%)	26
CS	5 (23.80%)	1 (4.76%)	1 (4.76%)	10 (47.61%)	2 (9.52%)	1 (4.76%)	1 (4.76%)	21

PS : Present study
CS : Chopra et al 1990

Table 5 : leprosy reactions after RFT (n=100)

Study	LRR		Type 2		Total cases
	PB	MB	PB	MB	
Present study	16 (16%)	12 (12%)	-	18 (18%)	100

LRR = Late reversal reaction

Table 6 : New deformity after RFT

Study	Deformity				
	Sensory paraesthesia	Weakness	Motor paresis	Paralytic	Trophic changes
Present study (n=100)	34 (34.0%)	18 (18.0%)	2 (2.0%)	4 (4.0%)	14 (14.0%)

Jesudasan and Rao 1996). As there is poor recovery in neurological deficit, appearance of new deformity or pro-gression of existing one is very likely. All these need education, continuous physiotherapy and regular follow-up.

Discussion

Relapse in leprosy is defined as “re-occurrence of the disease at any time after the completion of a full course of MDT”. Relapse is indicated by the appearance of new skin lesions and, in the case of an MB relapse, by evidence on a skin smear of an increase in BI of 2 or more units at any site. However, MB relapses should be investigated by using skin smears and histopathology (WHO 1995).

100 RFT cases with presenting symptoms of any extension of skin lesions, appearance of new lesions, any signs of active neurological damage, symptoms and signs of leprosy reactions. They were evaluated on the basis of skin smear for AFB and skin biopsy to diagnose the doubtful cases of relapses. Nerve conduction study and electro-myogram were done in doubtful cases.

Out of 100 RFT cases, 74 (74%) cases presented with new skin lesion, 34 (34%) cases with paraesthesia (neuropathic pain), 100 (100%) cases with sensory impairment, 26 (26%) cases with relapse, 46 (46%) cases with reaction and 40 (40%) cases with deformity. 14 (14%) cases were given PB treatment while 86 (86%) cases were given MB treatment.

26 (26%) cases presented with relapse. Out of these 26 relapsed cases, 6 cases had taken PB treatment for 6 months as they were diagnosed as

TT. All these cases relapsed into MB cases; so, in these cases, relapse might be due to wrong classification and consequently inadequate treatment. These patients presented with early relapse within a year of stopping the of treatment. A majority of relapses occurred in first three years after RFT (Ali et al 2005). Most of these relapsed into BT leprosy. 16 relapsed cases had received MB treatment.

Few of MB cases might not have taken FD-MDT regularly. Out of 26 relapsed cases, 16 cases presented within 1 year of stopping the treatment and 10 cases presented between 1 to 2 years. As compared to TT cases, BT cases took longer time to relapse. Relapse in leprosy after treatment with rifampicin-containing regimens are known to occur at least 5 ± 2 years after stopping treatment (Jamet and Ji 1992, 1995; Waters 1995). Relapses may be either due to persisters or reinfection (Waters 1995).

46 RFT cases presented with leprosy reaction, out of these, 28 (28%) presented with late reversal reaction and 18 (18%) with ENL reaction. The incidence of leprosy reaction seemed to be three times more common in borderline (BB) leprosy than lepromatous (LL) leprosy (Vijayakumaran et al 1995).

Out of 100 RFT cases, 34 (34%) cases presented with parasthesia while 18 (18%) cases with weakness, 22 (22%) cases with paresis, 4 (4%) cases with paralytic deformity and 14 (14%) cases with trophic ulcer.

Concluding Remarks

The question whether the chances of relapse are more in cases having residual activity is still not answered convincingly. Common problems in RFT cases observed were leprosy reactions, relapse and paraesthesia (neuropathic pain). All these cases need proper management on follow-up. Since long-term follow-up may not be cost-effective or feasible and education of the patient and his/her family members to report soon after appearance of new skin lesions or appearance of any new deformity may perhaps be the best option in the integrated settings. MDT should be continued in high BI cases (>4+) till smear negativity or at least for 2 years.

It is essential that primary health care staff is trained to recognize and treat leprosy reactions early. Preventing disabilities is critical to the success of the programme. Proper referral system should be established to enable primary health care workers to refer them to middle or tertiary level for assessment and steroid therapy to treat reactions and prevent further nerve damage and deformity.

In national leprosy eradication programme (NLEP), implementation of FD-MDT may sound logical but as and when required individual modification related to duration of therapy is essential. The needs of leprosy cases are beyond FD-MDT, what they need is continuum of care, counselling and social support.

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