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Single-Dose ROM Treatment for Multilesion Paucibacillary Leprosy—Further Observations

To the Editor:

A single dose treatment with ROM in the single skin lesion-paucibacillary (SSL-PB) leprosy group has been well received by the leprosy control programs. A small proportion of relapses and other clinical problems have been reported ([2, 3]). ROM single dose (ROM-1) treatment in paucibacillary patients with two to five lesions (PB 2–5) is currently under trial and the initial observations including relapses have been reported ([2, 3]). It is necessary to record longterm follow-up of such cases before this regimen can be considered for leprosy control programs.

A treatment period cohort analysis of ROM-1-treated 335 PB (2–5) leprosy patients followed up for a period ranging from 6 months to 70 months is reported. The mean period of follow up was 2.8 years. All the clinical problems other than reactions were recorded. The reactions were noted separately. The clinical problems were mainly in the nature of new lesions, persistence of lesions and an increase in the size of the patches. All these problem cases were given steroids before they were labeled as relapses. The rate of relapse observed in this study is compared with already published relapse rates after PB-MDT. The confidence interval (CI) is calculated for all the values at 95%. Table 1 shows that 10.4% (95% CI 7.03, 13.78) of the patients presented with various clinical problems other than reactions. The relapse rate is 1.4% (95% CI 012, 2.68) or 5.3 relapses (95% CI 0.26, 1.32) per 1000 person years of follow up. The annual rate is 0.5%. Two of them were bacteriologically positive when they relapsed. One of these bacteriologically-positive patients relapsed after 26 months and the other one after 70 months. All these 5 relapses have been retreated.

Table 1. *Relapse rate after ROM-1 in PB (2–5) leprosy.*

Description of events	No.
Patients followed up	335
Person years of follow-up	940
Patients with clinical problems	35 (10.4%)
Patients relapsed	5 (1.4%)
Relapse rate/1000 person years (py)	5.3

TABLE 2. *Relapses in PB leprosy.*

Study	No. of patients	Follow-up (years)	No. of relapses	%	Annual rate %	Person years (PY)	Relapse/ 1000 PY
ROM-1 for PB (2–5) leprosy							
Revankar, *et al.* (current study)	335	2.8	5	1.4	0.5	940	5.3
WHO-PB MDT for PB leprosy[a]							
Li, *et al.* (1997) [1]	2,326	5	5	0.2	0.04	9,111	0.55
Indonesia WHO (1995) [4]	471	5	3	0.6	0.12	2,500	1.2
Malawi WHO (1995) [4]	484	4	12	2.5	0.63	2,000	6.0
Multicenter study WHO (1995) [4]	51,553	9	306	0.6	0.07	319,381	0.96

[a] Also includes single skin lesion-paucibacillary SSL-PB Leprosy.

The annual relapse rate (0.5%) in the ROM-1 treated PB (2–5) leprosy group is more or less comparable to the already reported annual relapse rate in the PB-MDT treated group (Table 2). This follow-up study indicated that ROM-1 dose in PB (2–5 lesion group) appears to be adequate because the relapse rate is well within acceptable limits and comparable to the PB-MDT treated group.

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A Phase 2 Open Trial of Pentoxifylline for the Treatment of Leprosy Reactions

TO THE EDITOR:

Pentoxifylline (PTX) is an immunomodulatory agent with rheologic properties.([11]) It diminishes the effect of TNF-α and IL-1 on polymorphonuclear cell (PMN) chemotaxis, adhesion and toxic radical formation. ([23, 24, 3]) PTX may modulate endothelial adhesion receptors leading to reduced PMN adhesion. ([8]) PTX has been shown to inhibit TNF-α production at both mRNA and protein levels in murine macrophages. ([22, 4]) On the other hand, PTX has little effect on IL-1 and IL-6 production but decreases induced leukocyte responsiveness. ([5, 27]) PTX inhibits human dermal fibroblasts *in vitro* and the production of collagen, glycosaminoglycan and fibronectin. ([2]) PTX also has a suppressive effect on natural killer cells. ([13]) PTX is thought to operate in part by increasing intracellular cyclic AMP. ([18, 16]) Thalidomide is another agent that inhibits TNF-α production which it does by enhancing the degradation of TNF-α mRNA. ([10]) Thalidomide has been used extensively along with corticosteroids in the treatment of erythema nodosum leprosum (ENL) in Hansen's disease. ([17]) Thalidomide is well-known for its teratogenic effects.

Hansen's disease is a chronic mycobacterial disease marked by multifaceted immunologic involvement in its pathogenesis. The spectrum of Hansen's disease is classified according to Ridley and Jopling into five categories. ([15]) The disease status is further complicated by different reactional states mainly erythema nodosum leprosum (ENL) and reversal reaction (RR). Clinically ENL is characterized by development of crops of new, small, tender subcutaneous nodules, which usually subside after a few days along with systemic features like