PLANTAR LESIONS IN TUBERCULOID LEPROSY: A REPORT OF 3 CASES

Sir,

We report 3 histologically confirmed tuberculoid leprosy (TT) cases involving the sole of the foot which were detected at the outpatient clinic and in the field operational area of the Central Leprosy Teaching and Research Institute (CLTRI), Chengalpattu.

The plantar surface of the foot is an area of the body that is rarely affected by leprosy. Rarity of occurrence of such lesions and paucity of reports in the literature necessitated this report.

CASE A

A 26-year-old male presented to the outpatient clinic of CLTRI with a history of having a single patch of 6 months' duration over the right foot extending halfway onto the sole. On examination

Figure 1. Plantar lesion in Case B (8" x 4") well-defined having impairment of sensation of touch on the left foot extending into the sole.
the lesion was found to be well-defined and erythematous, measuring $6'' \times 5''$ over the medial side of the dorsum of the right foot extending well onto the sole. There was definite sensory loss for all the modalities (touch, pain and thermal). Response to lepromin was 9 mm with ulceration. Mantoux was 0 mm. A biopsy from the lesion showed histopathology consistent with tuberculoid leprosy and was immunoperoxidase positive for *Mycobacterium leprae*.

CASE B

An 18-year-old male presented at the outpatient with 2 skin patches, 1 over the left elbow and the other over the left foot extending onto the sole. The lesion on the elbow which had first been noticed by the patient about 3 months ago was located over the lateral aspect of the left elbow joint. It was $5'' \times 2''$, erythematous and anaesthetic. The lesion over the left foot which had been noticed about 6 months earlier measured $8'' \times 4''$, was erythematous, well defined with a raised margin, and had impairment of sensation for touch, pain and thermal modalities (Figure 1). All the peripheral nerves were normal. Histopathology results were consistent with a diagnosis of tuberculoid (TT) leprosy (Figure 2). Lepromin was 9 mm and Mantoux was 0 mm. Treatment with MDT for PB leprosy was started. About 2 months after the start of treatment the patient developed acute neuritis of the left common peroneal nerve. He was prescribed steroids for which the response was partial and therefore necessitated decompression of the nerve. The lesion on the elbow resolved completely but not the one on the foot, which showed a histopathology picture on a repeat biopsy of BT leprosy.

CASE C

An 8-year-old boy was brought to the field clinic by his father with a history of a patch on the right foot which had been noticed about 2 months earlier. The lesion on examination was $5'' \times 4''$, erythematous, anaesthetic, well defined with raised margins, and situated on the medial side of the
dorsum of the foot and extending onto the sole. The histopathology result was consistent with tuberculoid (TT) leprosy.

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COMMENT: REVERSAL REACTION IN MULTIBACILLARY LEPROSY PATIENTS FOLLOWING MDT WITH AND WITHOUT IMMUNOTHERAPY WITH A CANDIDATE FOR AN ANTILEPROSY VACCINE, MYCOBACTERIUM W. H. K. KAR ET AL.

Sir,

It was with much interest that I read the above paper published in Lepr Rev (1993) 64, 219–26. The immunotherapy described holds promise, and in particular the apparent rapid clearing of Mycobacterium leprae from the tissues is a very interesting phenomenon. It is also commendable that Kar et al. have not only thought of the possibility that such therapy might increase the risk of reversal reaction, but that they have actually set up a trial to investigate this possibility. The conclusion they draw from the trial seems reassuring: the difference between the proportions of patients that developed a reversal reaction in each group, 22.6% in the vaccine group vs 15.1% in the control group, was not statistically significant. Similarly, the proportion of severe reactions was only ‘marginally higher’ in the vaccine group (43.7% vs 33.3%). This leads the authors to conclude, ‘Thus, the vaccine did not precipitate any additional neurological complication—an important observation in the context of introducing an immunomodulator’ [italics mine].

I fully agree that the latter observation is essential not only when introducing an immunomodulator, but for any new leprosy treatment that is introduced.1 The problem with the above study is that they did find an increase in risk of reaction over a 2-year period of 7.5% overall, 10.3% in the BL/LL group and 10.4% in risk of severe reaction. These differences were not statistically significant with the given sample size, which was only 53 patients in each group.

‘Significantly’ (the z-value) of any given difference is proportional to the sample size: a small sample size is likely to give a nonsignificant result and a bigger sample size increases the chance of finding a significant difference if it truly exists. This can be illustrated using the number of reactions observed in the above study. If the whole study had been 10 times as big, the observed number of reactions in the vaccine group would have been 120/530 (22.6%); in the control group 80/530 (15.1%). The difference would still be 7.5%, the z-value is now 3.12, corresponding to a p-value of 0.0018, a highly significant result! The difference in the BL/LL group would have been 80/390 vs 40/390, giving a z-value of 3.99, p < 0.0001. The conclusion of the study would have been very different. The relative risk of vaccine vs control would have been 1.50 (1.13–1.97). This means that the vaccine seems to be associated with an increase in the risk of reversal reaction of 50% (95% confidence interval 13–97%). It would be unlikely that the authors would have concluded that the vaccine ‘can be safely used’. For a study such as conducted by Kar et al. the required sample size should be calculated in advance on the basis of the minimum difference that is clinically relevant to detect. The formula giving the sample size in each of the trial groups in the case of a difference between proportions is:2

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n = \frac{p_1 \times (1 - p_1) + p_2 \times (1 - p_2)}{(p_2 - p_1)^2} \times f_{(\alpha, \beta)}
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where \(p_1\) is the proportion in the control group, \(p_2\) is the proportion in the intervention group (in this case the vaccine group), and \(f_{(\alpha, \beta)}\) is a constant value that depends on the type I and type II