Field treatment of leprosy reactions in northern Nigeria: feasibility, including the use of prednisolone in blister packs

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Introduction

We report here a field study on the effectiveness of steroid treatment in leprosy reactions, measured by nerve function testing before and after treatment. We also compared treatment with either loose or blister-packed prednisolone tablets. The present study was commissioned after we had found that 133/204 (65%) of suspected reaction cases, after referral, had not reached hospital and therefore these patients had not received steroid treatment.

Materials and methods

The study was run by district leprosy supervisors from January 1999 to July 2000 in seven districts in Kaduna State, Nigeria. District supervisors were tested on their knowledge of leprosy reactions before starting the study: 7/16 passed. Only supervisors who passed the test were included in the study. ILEP definitions for the diagnosis and treatment of leprosy reactions were used. Treatment consisted of a 12-week prednisolone course, as advised by WHO and ILEP. All reaction patients ($n = 139$) in these districts were included in the study.

For patient assessment, a standard form was used at health centre level that included criteria for diagnosis and referral, and nerve function tests. Scores for nerve function tests were calculated at the beginning and end of steroid treatment. Sensory testing (ballpoint method) scored a maximum of 40 points if hands and feet had lost all sensation. Voluntary muscle testing scored a maximum of 30 if all tested muscles were paralysed.

Patients were not randomly allocated to loose or blister pack treatment. Patients were given loose tablets in the period January 1999 until September 1999 and then blister packs were used until the end of the study. Towards the end of the study, loose tablets were again used when the blister packs ran out. Patient compliance was assessed by outcomes
Table 1. Improvements in sensory testing (ST) and voluntary muscle testing (VMT) in individual patients (n = 139) after 12 weeks of prednisolone

<table>
<thead>
<tr>
<th>Score</th>
<th>ST</th>
<th>VMT</th>
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<tbody>
<tr>
<td>Begin = end = 0 (other reaction signs)</td>
<td>23 (16.5%)</td>
<td>56 (40.3%)</td>
</tr>
<tr>
<td>Full recovery (score at end = 0)</td>
<td>35 (25.2%)</td>
<td>22 (15.8%)</td>
</tr>
<tr>
<td>Partial recovery (at least 2 points)</td>
<td>53 (38.1%)</td>
<td>10 (7.2%)</td>
</tr>
<tr>
<td>Same as before (0–1 points different)</td>
<td>15 (10.8%)</td>
<td>44 (31.7%)</td>
</tr>
<tr>
<td>Worse (at least 2 points)</td>
<td>6 (4.3%)</td>
<td>0</td>
</tr>
<tr>
<td>Not known</td>
<td>7 (5.0%)</td>
<td>7 (5.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>139 (100%)</td>
<td>139 (100%)</td>
</tr>
</tbody>
</table>

(completion rate and treatment results) and process indicators (pill count etc.). For this purpose, a semi-structured questionnaire was given by sociology students from Ahmadu Bello University, Zaria during a home visit.

One hundred and thirty-nine patients were included in the study, 99% MB cases, 88.5% type 1 reactions and 11.5% type 2 reactions. Ninety patients were treated with loose prednisolone tablets 49 with blister-packed prednisolone. The group treated with blister packs contained more women (53.1% versus 36.7%) and had a lower literacy rate (14.3% versus 31.1%) than the loose tablet group.

In 87.8% of cases, steroid treatment was started when a reaction was diagnosed, rising to 97.1% within 6 weeks. Only eight patients needed referral for further management and seven of these were lost to follow-up (Table 1).

Results

The improvements in sensory scores were considerable: 25% of the patients recovered fully, and 38% did so partially (Table 1). The findings were similar for motor scores: 16% fully recovered and 7% partially recovered. Of the patients, 40% had no motor dysfunction, but had other signs or symptoms of reaction. They were included in the evaluation because of the possibility of deterioration during treatment. No differences in sensory or motor scores were found between patients taking either loose or blister-packed prednisolone tablets.

Average scores for sensation and motor function showed significant improvements for the field group as a whole (Figure 1) (all P-values < 0.05).

We analysed various aspects of compliance: pill count (78.7% correct), duration of intake (93.5% correct), frequency of intake (95.8% correct), timing in the day (91.1% correct) and timing after a meal (78.7% correct). The completion rate was 94.3%. There were no significant differences in compliance between patients treated with either loose or blister-packed prednisolone.

Discussion

The careful selection of supervisors might have led to better than average treatment results. Common monitoring parameters such as ‘steroid start rate’ and ‘steroid completion rate’ will
therefore only represent good practice on the assumption of good staff performance. Notwithstanding, field treatment of reactions in Nigeria reaches more patients than hospital-based treatment alone.

Opinions differ regarding the best steroid regimen for leprosy reactions. Several authors plead for regimens longer than 3 months\textsuperscript{6–8} or individualized treatment schedules.\textsuperscript{9} In this study, nerve function improvement was significant after a standard 12-week prednisolone regimen. Other studies with comparable regimens show similar results. In Ethiopia, a steroid regimen of 12 weeks was used for BT reaction cases and 20 weeks for BL cases. Reactions could easily be treated in the field (>70%). The improvement rate was ± 80%\textsuperscript{10,11}. In Bangladesh, field patients received a steroid regimen of 16 weeks: there was 61.5% sensory improvement and 49.4% motor function improvement.\textsuperscript{12}

Croft, however, found that sensory function improved spontaneously after 4 months in 45% of the nerves involved, while in the treated group this percentage was 73%. This difference became less apparent after 12 months: 62% in the untreated group versus 68% in the treated group.\textsuperscript{13} Results of steroid treatments must be seen against this background.

Our finding that compliance is good confirms another field study in Ethiopia, where completion rates were also more than 90%.\textsuperscript{5}

In conclusion, treatment of reactions in the field reaches more patients and is feasible in Northern Nigeria, assuming active supervision of the quality of diagnosis and treatment. It was further found that prednisolone in blister packs did not have advantages in terms of treatment outcome and compliance measures.

Acknowledgement

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References