Qualitative Assessment of Medication Adherence at an Urban Leprosy Outpatient Clinic in Hyderabad, India

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Summary
Objectives: The objective of this study was to measure medication adherence amongst outpatients attending an urban leprosy clinic in Hyderabad, India.
Design: In this study of observational design, the urine spot test and Morisky Scale questionnaire were concurrently used as qualitative measures of medication adherence.
Results: Fifty two patients met the inclusion criteria for this study; 13 patients (25%) were non-adherent according to the Morisky scale questionnaire and 17 patients (33%) according to the urine spot test. 48% of patients were non-adherent on the basis of the urine spot test and/or the Morisky scale questionnaire.
Conclusion: The results suggest that poor medication adherence remains an ongoing issue in the management of outpatients with leprosy.

Introduction

Medication adherence in the treatment of leprosy was once an issue of great concern but, since the successful introduction of multi-drug therapy (MDT), interest has generally declined. Published non-adherence rates range from 13–68%2–8 and poor adherence has been linked to treatment failure, persistent infectious sources and poor therapeutic success.9–11 Although MDT resistance is not currently a serious problem,11 the prospect of MDT-resistant leprosy is taken seriously by the World Health Organization (WHO).12,13
The objective of this study was to measure adherence amongst outpatients attending the Blue Peter Research Centre (BPRC), in Hyderabad, India.

Materials and Methods

This observational study was carried out over a 7 week period in early 2008. The population under investigation included all outpatients with leprosy attending the BPRC, a purpose-built research centre with dedicated clinical staff. Patients received either 6 months or 12 months of treatment with MDT for pauci-bacillary (PB) or multi-bacillary (MB) leprosy, respectively. Rifampicin was administered under supervision on a monthly basis.

Inclusion criteria dictated that all patients needed to provide informed consent, be at least 18 years of age, and taking MDT for adults. Patients were excluded from the study if they had taken less than four days of MDT or if they had been prescribed any sulphonamide drug, which could confound the results of the urine spot test.

Two qualitative measures were used to simultaneously assess adherence, which has been shown to increase the accuracy and reliability of results obtained. The Morisky Scale questionnaire is an interviewer-administered self-reporting tool, which was translated into Telugu and administered by BPRC staff members. Patients were considered non-adherent if they answered ‘yes’ to any of the following structured questions:

1. Some patients are a little careless when taking their medicines. Are you careless at times about taking your medicines?
2. Sometimes if you feel better, do you stop taking your medicines?
3. Sometimes if you feel worse, do you stop taking your medicines?
4. Some patients forget to take their medicines. Do you ever forget to take your medicines?

The second measure of adherence was the urine spot test. Strips of Whatman filter paper were impregnated with a solution of reagent consisting of p-dimethylanilinealdehyde, oxalic acid and sodium dodecylbenzene sulfonate dissolved in 70% ethanol. Impregnated filter paper was stored in an airtight container and used within 6 weeks of preparation. Negative control solution was made of 1 mol/L HCl and urine from a person not taking dapsone. For the positive control solution a standardised dilution of crushed dapsone tablets in 1 mol/L HCl was added to the negative control solution. Tests were read immediately on application of urine to the impregnated filter paper. Patients were considered adherent if the orange central spot was equal in colour or darker than the positive control. More effective differentiation between urea and dapsone is achieved by adding a drop of 1N HCl, which has also been shown to correct both false negatives due to a high pH and false positives due to cross-reacting sulphonamides.

Patients did not receive prior notice that a urine sample would be requested.

Results

Fifty six outpatients taking MDT attended the clinic during the study period. This corresponded to 66.7% of the 84 patients receiving MDT according to pharmacy data.
Four patients did not meet the inclusion criteria. Mean age was 32 years and 69% were male. Two patients were diagnosed with PB leprosy and 50 with MB leprosy. 33% of patients had been on MDT for 1–4 months and 30% had been on MDT for 10 or more months. Eighteen patients (35%) were more than 3 days late in collecting their prescribed MDT.

Questionnaire results suggested that 13 patients (25%) were non-adherent. Five patients (10%) admitted to forgetting to take their medicines and seven patients (13%) admitted to being careless at times about taking their medicines. One patient admitted to stopping the medicines when feeling worse on them. None of the patients admitted to stopping the medicines if they felt better as a result of taking them. Only one patient gave a positive response to more than one of the questions.

According to the urine spot test, 17 patients (33%) were non-adherent. Table 1 compares the results of the urine spot test and Morisky scale questionnaire. Results of the two measures overlapped in 31 patients (60%).

Discussion

The results of this study suggest that medication adherence remains an ongoing issue in the management of outpatients with leprosy. Due to the qualitative and subjective nature of the measures used, however, patients could only be considered wholly adherent or wholly non-adherent. The degree of medication adherence required before the development of any adverse effects is largely unknown.

Alternative measures of adherence to those used in this study include analysis of pharmacy records and pill-counting. Other questionnaires have been devised and effectiveness can vary depending on the method of administration. Subjective judgement of adherence by physicians based on clinical suspicion is not considered accurate. Although quantitative measures of adherence, such as the dapsone/creatinine ratio test, are preferable to assess adherence, they are generally more time-consuming, technically demanding and expensive. Results of the urine spot test have been shown to correlate well with those of the dapsone/creatinine ratio test.

Study findings were reflected upon by BPRC staff and efforts were made to improve adherence by discussing relevant issues with patients and reiterating the benefits of completing treatment as prescribed.

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This study was carried out as a service review under supervision from Professor W.C.S. Smith and Professor Indira Nath. Complete details regarding the elective proposal were presented to the University of Aberdeen’s elective committee. It was agreed that ethics approval was not required but full informed consent needed to be obtained from all participating patients. Comprehensive standard consent forms were produced, which were translated into Telugu and discussed with patients and relatives. All signed/printed consent forms are stored at the BPRC in Hyderabad.

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References