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# Study on follow up cases of indeterminate leprosy after specific multidrug therapy (MDT) at King George's Medical College, Lucknow.

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## Abstract

Leprosy is one of the oldest human bacterial disease recognized by a Norwegian scientist Armauer Hansen working in Bergen in 1873. Leprosy is still one of the infectious diseases and major health problem of developing countries. Leprosy is caused by *Mycobacterium leprae*. *M. leprae* is pleomorphic, straight or slightly curved, rod shaped gram positive bacteria. Multidrug therapy (MDT) combination of Rifampicin, Clofazimine and Dapson proved highly effective and greatly reduced the numbers of registered patients. For proper implementation of MDT follow up study of patients are necessary. The present study envisaged the therapeutic management of known cases of leprosy in patients in outpatients department (OPD) of Gandhi memorial and associated hospitals. Department of Medicine at King George's Medical College, Lucknow by multidrug therapy. In follow through cases (n=10), surprisingly in our study each patients serum IgM protein has been found to decrease after MDT treatment. The possible decrease of the level of IgM antibodies in cases after treatment seem to have a direct link with the decrease in the antigenic load due to prolonged treatment, which lessens the number of bacteria due to stoppage of multiplication of the bacilli.

**Keywords:** MDT, Leprosy, Follow up Study

## Introduction

Leprosy is one of the oldest human bacterial disease recognized by a Norwegian scientist Armauer Hansen working in Bergen in 1873. Leprosy is still one of the infectious diseases and major health problem of developing countries. Leprosy is caused by *Mycobacterium leprae*. *M. leprae* is pleomorphic, straight or slightly curved, rod shaped gram positive bacteria. According to WHO (2000), remarkable reduction in the leprosy observed after introduction of multidrug therapy (MDT combination of Rifampicin, Clofazimine and Dapson) which was launched in 1985 in almost all the countries of the world. According to current situation in India annual case detection rates are among the highest in the world (53 per 100,000) (WHO, 2000). In India, 90% of the leprosy population of 0.62 million remain in the state of Bihar, Orissa, Uttar Pradesh, West Bengal (Sengupta, 1999).The present study envisaged the therapeutic management of known cases of leprosy in patients in out patients department (OPD) of Gandhi memorial and associated hospitals. Department of Medicine at King George's Medical College, Lucknow by multidrug therapy. Multidrug therapy (MDT), introduced in 1973 (Depasquale, 1975; Freerksen, 1975 and Waters, 1993), proved highly effective and greatly reduced the numbers of registered patients. Multidrug chemotherapeutic regimens for adult patients recommended by the WHO Study Group on Leprosy (1982) Table-1.

**Table 1 : Multidrug chemotherapeutic regimens for adult patients recommended by the WHO Study Group on Leprosy (1982)**

| Type of leprosy | Paucibacillary (Idt, TT, BT) Leprosy | Multibacillary (BB, BL, LL) Leprosy |
|---|---|---|
| BI according to the Ridley Scale | Less than two at all sites | Two or more at any site |
| Regimen | Daily (taken at home)<br>Dapsome 100 mg | Daily (taken at home)<br>Dapsome 100 mg<br>(100 mg every other day if 50 mg every other day if 50 mg capsules are not available). |
| | Once a month (taken under supervision) Rifampician 600 mg | Once a month (taken under supervision)<br>Rifampician 600 mg<br>Clofazimine 300 mg |
| Duration of treatment | Six months | At least two years, preferably until negative skin smears are obtained |

For proper implementation of MDT follow up study of patients are necessary. Cho et al. (2001) reported detection of phenolic glycolipid 1 of *Mycobacterium leprae* in sera from leprosy patients before and after start of multidrug therapy. Follow up study clinical observations are supplemented with use of serological techniques (Stefani et al 1998).

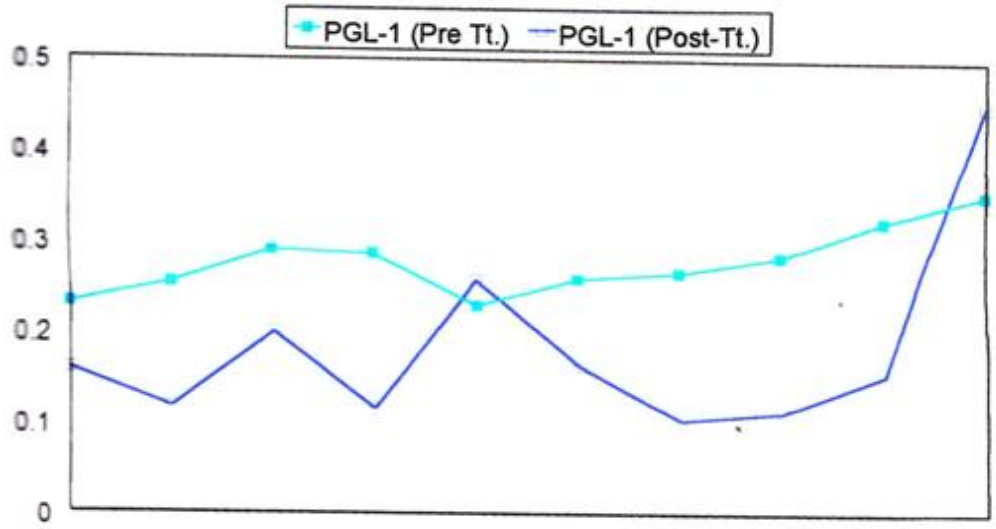
## Materials and Methods

In this study was carried out in serum samples that were obtained from confirmed cases of the disease and collected after 12 months of specific multidrug therapy (MDT). Study samples comprised of 10 positive cases of indeterminate leprosy. All patients were assessed for clinical and serological changes before (Table-2) as well as after (Table 3) 12 months of the commencement of multidrug therapy. An indirect ELISA was carried out using PGL-1 and MLSE antigen. The mean value plus two standard deviation of sera from healthy individuals were taken as the cut of value.

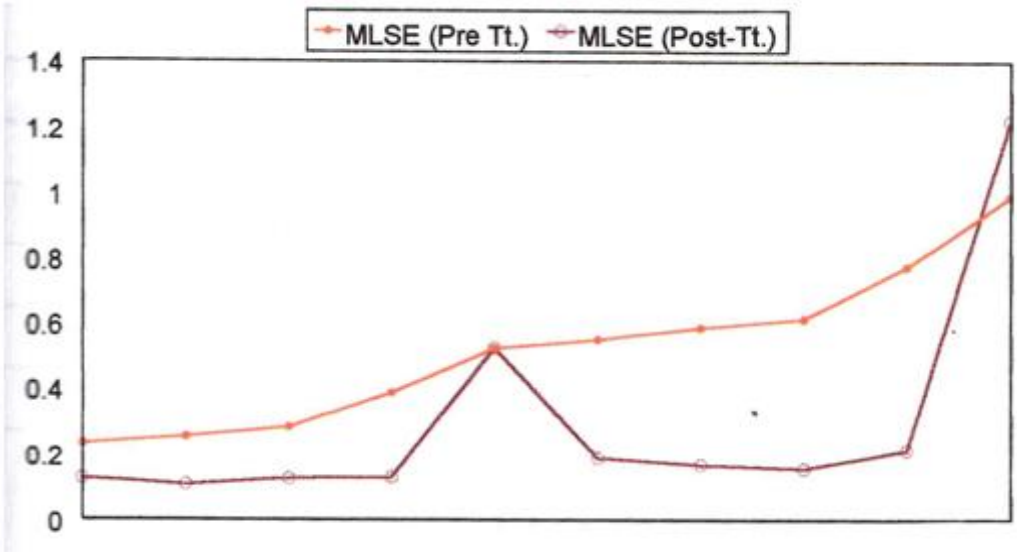
**Table-2: Pretreatment clinical symptoms in follow-up cases (n=10)**

| S. No. | Case No. | Clinical finding | Follow-up period (in months) |
|---|---|---|---|
| 1. | 4 | Hypopigmented hypoanaesthetic single maclue with well define margin. | 4 months |
| 2. | 8 | Two hypopigmented and hypoanaesthetic macule present left ulnar and left greater auricular nerve thickened. Hair loss and anhydrosis present. | 8 months |
| 3. | 22 | Single hypopigmented and hypoanaesthetic macule present. Left unlar nerve thickened. Anhydrosis and hairloss present. | 2 months |
| 4. | 36 | Few hypopigmented and hypoanaesthetic macule present. Left ulnar nerve thickened. Hair loss present. | 12 months |
| 5. | 48 | Two hypopigmented and hypoanaesthetic macule present. Nerve thickening absent. Hair loss & anhydrosis present. | 8 months |

| | | | |
|---|---|---|---|
| 6. | 49 | Single hypopigmented and hypoanaesthetic macule present. Bilateral common peroneal nerve thickened. Hair loss present. | 6 months |
| 7. | 52 | Single hypopigmented and hypoanaesthetic macule present. Left ulnar nerve thickened. Hair loss and anhydorsis present. | 1 year |
| 8. | 54 | Single ill defined hypopigmented and hypoanaesthetic maclue present. Right ulnar nerve thickened. Hair loss and anhydrosis present. | 1 year |
| 9. | 61 | Single hypopigmented and hypoanaesthetic macule present. Both ulnar and greater auricular nerve thickened. Anhydrosis and hair loss absent. | 5 months |
| 10. | 67 | 2 raised hypopigmented and hypoanaesthetic patches present. Left ulnar nerve thickened. Anhydrosis and hair loss present. | 8 months |




**Graph 1: Depicts pre and post- treatment change in optical density against IgM antibody ELISA using PGL-1 antigen in follow up indeterminate leprosy cases**




**Graph 2: Depicts pre and post- treatment change in optical density against IgM antibody ELISA using PGL-1 antigen in follow up indeterminate leprosy cases**

**Table-3 : Experimental ELISA using PGL-1 and MLSE antigen in follow up indeterminate cases (Pre & Post treatment OD)**

| S. No. | Case No. | Pre-treatment ELISA | | Post treatment ELISA | |
|---|---|---|---|---|---|
| | | PGL-1 Ag Result/Value | MLSE Ag Result/Value | PGL-1 Ag Result/Value | MLSE Ag Result/Value |
| 1. | 4 | 0.229 | 0.229 | 0.157 | 0.123 |
| 2. | 8 | 0.252 | 0.250 | 0.116 | 0.106 |
| 3. | 22 | 0.289 | 0.280 | 0.198 | 0.124 |
| 4. | 36 | 0.285 | 0.386 | 0.114 | 0.129 |
| 5. | 48 | 0.228 | 0.520 | 0.256 | 0.523 |
| 6. | 49 | 0.258 | 0.548 | 0.162 | 0.188 |
| 7. | 52 | 0.265 | 0.586 | 0.102 | 0.168 |
| 8. | 54 | 0.283 | 0.613 | 0.111 | 0.156 |
| 9. | 61 | 0.323 | 0.772 | 0.153 | 0.212 |
| 10. | 67 | 0.353 | 0.988 | 0.451 | 1.219 |

## Results and Discussion

In all follow up cases duration of study varied from six to twelve months showed evidence of response to therapy in the form of disappearance, decreases in size in 8 cases of ten indeterminate cases. In only 2 cases the lesion persisted and a new lesion was also seen. These cases gave positive result in IgM ELISA (Post treatment Table-3) Graph 1 depicts pre and post treatment change in optical density against IgM antibody ELISA, using PGL-1 antigen and graph 2 depicts pre and post treatment change in optical density against IgM antibody ELISA, using MLSE antigen in indeterminate leprosy case. In follow through cases (n=10), surprisingly in our study each patients serum IgM protein has been found to decrease after MDT treatment. The possible decrease of the level of IgM antibodies in cases after treatment seem to have a direct link with the decrease in the antigenic load due to prolonged treatment, which lessens the number of bacteria due to stoppage of multiplication of the bacilli. In only two indeterminate cases the lesion persisted and a new lesions was also seen. This case gave positive result in IgM ELISA (Post treatment). Cho *et al*. (2001) reported already that PGL-1 antigen may be useful in the assessment of leprosy patients at the time of diagnosis and possibly in monitoring patients following chemotherapy. It was concluded that correct diagnosis of indeterminate leprosy from other leprosy groups of spectrum could be made if results of clinical, histopathological, bacteriological and immunological were interpreted together. The follow up study is necessary to study the effect of chemotherapy and also preventing the relapse of the disease in the patients.

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