A COMPARATIVE STUDY OF EYE AFFECTIONS IN LEPROSY WITH MULTI DRUG THERAPY AND MONO THERAPY
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ABSTRACT

BACKGROUND

Leprosy is one of the common neuro-paralytic disease in a developing country like India. It reduces functional integrity of the different parts of our body and subsequently as it reduces the sensation, so anatomical disfiguration follows. Having a complex neuronal supply, eye is also commonly affected in Leprosy.

MATERIALS AND METHODS

In this study done in rural areas of West Bengal, after clinical and bacteriological diagnosis, leprosy patients were divided into two standard groups i.e. Multi-Bacillary (M.B.) Pauci-Bacillary (P.B.). After randomization by computer generated randomization technique, both the groups are divided into two sub-groups. One group receives Multi-Drug therapy and the other receives single drug therapy. After collection of data in follow up period, the data is compared and tabulated.

RESULTS

This study was done on 2317 adult Leprosy patients. Total Eye complications in M.B. cases were 30% and 10% in P.B. cases. Incidence of Eye complications in M.B. cases reduced to 4% within 3 months of the onset of M.D.T. The Morphological index which was in the range of 25-75% also reduced to 0 within 3 months of the onset of M.D.T. in 92% of cases. Monotherapy did not have any significant effect in reducing the incidence of Eye complications in M.B. cases. In P.B. cases both M.D.T. and Monotherapy were equally effective in reducing the incidence of eye complications. (2% and 3% respectively within 3 months of the onset of therapy).

CONCLUSION

Multidrug therapy is very much helpful in reducing the ophthalmologic complications in multi-bacillary cases though it has no such effect in pauci-bacillary cases.

KEYWORDS

Leprosy, Eye Complications, M. D. T, Monotherapy, M.B. and P.B. Cases.

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BACKGROUND

Leprosy, caused by Mycobacterium leprae, mainly affects skin, nasal mucosa, peripheral nerves, eye and may lead to disabilities and blindness. It presents a large spectrum of clinical and pathological manifestations that depend on bacterial load, the type and intensity of the patient’s immune response to the bacteria.¹ So early detection and treatment not only cure the disease but also prevents its complications. On the basis of clinical appearance of skin lesions, involvement of nerves and number of lepra bacilli in skin biopsys, Leprosy is classified as multibacillary leprosy (MB) and paucibacillary leprosy (PB).² The eye is affected in this disease in four ways: i.e. (i) by direct invasion of lepra bacilli which reach the ciliary body through blood stream and then spread into other structures, (ii) secondary to involvement of facial nerve and ophthalmic division of trigeminal nerve, (iii) in the form of hypersensitivity reaction to the antigenic substances released in the breakdown of lepra bacilli which are present in the circulating blood; and (iv) secondary to changes in the skin and support tissue of the lids, tear drainage system. One or more of the factors may be responsible for eye lesions, especially when the disease is long standing and in advanced stage. Ophthalmologic manifestations in leprosy is not only due to involvement of cranial nerves, but also due to cutaneous anesthesia and chronic inflammatory sequelae. The manifestations in M.B. Cases ranged relatively benign conditions like madarosis, conjunctivitis, to serious conditions like uveitis, interstitial Keratitis and secondary glaucoma. In P.B. cases the eyes were less frequently involved. Lagophthalmos, exposure keratitis leading to ulceration were seen.³ Early detection of Leprosy followed by Multidrug therapy (M.D.T.)⁴ and simple medications with atropine, broad spectrum antibiotic drops and ointment helped in markedly reducing the incidence of ocular complications and corneal blindness.
Aims and Objectives
1. To detect and describe the ocular lesions in Leprosy and its correlation with bacteriological load.
2. To determine the outcome of ocular lesion and bacteriological load following drug treatment.

MATERIALS AND METHODS

Inclusion Criteria
1. Clinically and microbiologically diagnosed Leprosy patients
2. Age >12 years and <60 years
3. Patients giving informed consent

Exclusion Criteria
1. Patients having any other neurological disease
2. Patients having any systemic disease which may have neurological complications
3. Previous trauma causing neurological damage or during study period that may alter the treatment outcome as per assessor.

The study was conducted in rural areas of Burdwan where after clinical diagnosis of leprosy Bacteriological investigation was done for confirmation of diagnosis. Smear taken by slit and scrape method from active thickened margin of the skin lesion.
- Earlobes.
- Nose by scraping method.

It is stained by Modified Ziehl-Neelsen method. Bacteriological index was recorded in Dharmendra Scale. Morphological index was also recorded.

In this study on 2317 adult Leprosy patients out of which 595 were M.B. cases and rest were P.B. cases. The M.B. cases were again divided into two groups of 298 and 297 patients randomly. Pharmacotherapy to one group was given combination therapy with Dapsone, Rifampicin and Clofazimine. Daily supervised treatment was given during the initial intensive phase for 14 days with the following drugs:
- Rifampicin 600 mg if body weight >35 kg, 450mg if less than 35 kg.
- Clofazimine 100 mgm.
- Dapsone 100 mgm.

Continuation phase treatment with the following drugs- Rifampicin 600 mg once monthly supervised. Dapsone 100 mgm daily self-administered. Clofazimine 300 mgm once monthly supervised and 50 mg daily self-administered.

The other group was given only Dapsone in a dose of 100 mg daily.

In the same way the P.B. cases were divided into two groups of 361 each randomly and one group was given combination therapy with Rifampicin and Dapsone. Rifampicin 600 mgm once monthly supervised for adults greater than 35 kg and 450 mg for adults less than 35 kg and Dapsone 100 mg daily self-administered. The other group was just given Dapsone in a dose of 100 mg daily.

RESULTS

Total Eye complications in M.B. cases were 30%. Incidence of Eye complications in M.B. cases reduced to 4% within three months of the onset of M.D.T. The Morphological index which was in the range of 25-75% also reduced to 0 within three months of the onset of M.D.T in 92% of cases.

In case of M.B. cases receiving Monotherapy the incidence of Eye complications in M.B. cases only slightly reduced to 22% within 3 months of the onset of Monotherapy. It reduced to 8% within 6 months of the onset of Monotherapy. The Morphological index which was in the range of 25-75% also reduced to 0 within 6 months of the onset of Monotherapy in 85% of cases.

The incidence of eye complications again increased from 8% to 13% on ninth month of Monotherapy.

Total Eye complications in P.B. cases were 10%. Incidence of Eye complications in P.B. cases reduced to 2% within 3 months of the onset of M.D.T. In case of P.B. cases receiving Monotherapy the incidence of eye complications also reduced to 3% within 3 months of the onset of M.D.T.
Both eyes were affected in 96% cases.

**Table 1. Ocular Complication of MB Cases at the Onset of M.D.T. and at Quarterly Follow up for a Year.**
(Total M.B. Patients receiving M.D.T. were 298)

<table>
<thead>
<tr>
<th>Onset of M.D.T.</th>
<th>Lid and Ocular Adnexa</th>
<th>Conjunctiva</th>
<th>Corneal Lesion</th>
<th>Ant Uveitis</th>
<th>Lacrimal Sac inf.</th>
<th>IOP High/Normal/ Low</th>
<th>No PL</th>
<th>V. Acuity CF 3/60</th>
<th>V. Acuity 3/60-6/60</th>
<th>V. Acuity 3/60-6/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd Month</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3/294/1</td>
<td>do</td>
<td>2</td>
<td>22</td>
<td>60</td>
</tr>
<tr>
<td>6th month</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2/295/1</td>
<td>do</td>
<td>1</td>
<td>20</td>
<td>63</td>
</tr>
<tr>
<td>9th Month</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2/295/1</td>
<td>do</td>
<td>1</td>
<td>18</td>
<td>65</td>
</tr>
<tr>
<td>12th Month</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1/296/1</td>
<td>do</td>
<td>1</td>
<td>15</td>
<td>68</td>
</tr>
</tbody>
</table>

Both eyes were affected in 96% cases.

**Table 2. Ocular Complication of MB Cases at the Onset of Dapsone Therapy and at Quarterly Follow Up for a Year (Total M.B. Patients Receiving M.D.T. were 297)**

**Table 3. Bacteriological and Morphological Index of MB Cases at the Onset of M.D.T. and at Quarterly Follow up for a Year. (Total M.B. Patients Receiving M.D.T. were 298)**

<table>
<thead>
<tr>
<th>At onset of Monotherapy</th>
<th>0 to 1+</th>
<th>1+ to 2+</th>
<th>2+ to 3+</th>
<th>3+ to 4+</th>
<th>0-25%</th>
<th>25-50%</th>
<th>50-75%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd Month</td>
<td>280</td>
<td>120</td>
<td>90</td>
<td>38</td>
<td>9</td>
<td>200</td>
<td>90</td>
</tr>
<tr>
<td>6th month</td>
<td>292</td>
<td>15</td>
<td>3</td>
<td>Nil</td>
<td>274</td>
<td>24</td>
<td>Nil</td>
</tr>
<tr>
<td>9th Month</td>
<td>296</td>
<td>6</td>
<td>1</td>
<td>Nil</td>
<td>290</td>
<td>8</td>
<td>Nil</td>
</tr>
<tr>
<td>12th Month</td>
<td>2</td>
<td>Nil</td>
<td>Nil</td>
<td>298</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

**Table 4. Bacteriological and Morphological Index of MB cases at the onset of Dapsone Monotherapy and at Quarterly Follow up for a Year (Total M.B. Patients Receiving Dapsone Monotherapy were 297) B I (Dharmendra)**

**Bacteriological Index (Dharmendra).**

<table>
<thead>
<tr>
<th>At Onset of M.D.T.</th>
<th>0 to 1+</th>
<th>0 to 1+1+1 to 2+</th>
<th>2+ to 3+</th>
<th>3+ to 4+</th>
<th>0-25%</th>
<th>25-50%</th>
<th>50-75%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd Month</td>
<td>213</td>
<td>70</td>
<td>11</td>
<td>4</td>
<td>160</td>
<td>128</td>
<td>10</td>
</tr>
<tr>
<td>6th month</td>
<td>250</td>
<td>46</td>
<td>2</td>
<td>Nil</td>
<td>253</td>
<td>45</td>
<td>Nil</td>
</tr>
<tr>
<td>9th Month</td>
<td>225</td>
<td>68</td>
<td>5</td>
<td>Nil</td>
<td>230</td>
<td>68</td>
<td>Nil</td>
</tr>
<tr>
<td>12th Month</td>
<td>205</td>
<td>84</td>
<td>8</td>
<td>1</td>
<td>214</td>
<td>82</td>
<td>2</td>
</tr>
</tbody>
</table>
DISCUSSION

“There is no disease which so frequently gives rise to disorders of the eye, as Leprosy does”10 - in our present study we have seen that ocular complications in leprosy occurred in 30% of M.B. cases and 10% of P.B. cases. There are three main ways in which the eyes can be damaged.

1. Exposure and anaesthesia
2. Bacillary invasion. In lepromatous leprosy the eye is invaded through the blood stream. Leproma may form on the conjunctiva and infiltration extends onto the cornea.
3. Hypersensitivity II reaction. This is especially true of the iris and ciliary body.

Associated factors which can keep the eye always at risk in the leprosy patients are-

a) Infected insensitive ulcerated extremities
b) Deformed extremities
c) Infection at the focus namely osteomyelitis.

The degree of positivity of the bacteriological index in M.B. cases had a direct relationship with the eye affections.11 As the positivity of the bacteriological index decreased with the onset of therapy, ocular manifstations also improved in our present study. The Morphological index which was in the range of 25 - 75 % also reduced to 0 within 3 months of the onset of M.D.T. in 92% of cases.

In M.B. cases receiving Monotherapy the incidence of eye complications decreased significantly (8%) within 6 months of the onset of Monotherapy. But the eye complications again increased from 8% to 13% on 9th month of Monotherapy. This is most probably due to organisms developing drug resistance to Dapsone and Type 2 Lepra reaction. Monotherapy did not have long term beneficial effect in reducing the incidence of eye complications in M.B. cases. A study12 conducted by Daniel E et al. has revealed approximately 5.6% of patients with M.B. who have completed MDT per year, can be expected to develop new ocular complications of leprosy, which often (3.9%) are potentially vision threatening.

Incidence of eye complications in P.B. cases reduced to 2% from 10% within 3 months of the onset M.D.T. In case of P.B. cases receiving Dapsone Monotherapy the incidence of eye complication also reduced to 3% within 3 months of the onset of M.D.T. so, in P.B. cases both M.D.T. and Monotherapy were equally effective in reducing the incidence of eye complications. A study13 by K V Desikan showed multibacillary as well as paucibacillary cases are cured faster by multi-drug therapy than monotherapy. As the ocular complications are proportionately related to microbiological burden, so leprosy cases will have less ocular complications if active pharmacotherapy is started in time. Since the advent of MDT, the pattern of leprosy has drastically changed. The cases are more towards the drug treatment and not due to spontaneous cure. As per the data available, 95% of the cases are cured faster by multi-drug therapy than monotherapy. As the ocular complications are proportionately related to microbiological burden, so leprosy cases will have less ocular complications if active pharmacotherapy is started in time. Since the advent of MDT, the pattern of leprosy has drastically changed. The cases are more towards the drug treatment and not due to spontaneous cure. As per the data available, 95% of the cases are cured faster by multi-drug therapy than monotherapy.

CONCLUSION

Leprosy is one of the common systemic diseases involving the eye in the developing country. Early diagnosis and aggressive multi-drug treatment are very much helpful in reducing ocular lesion and reducing bacterial load. As recurrences or appearances of new lesions is common, periodic follow up with slit-lamp examination is mandatory.

REFERENCES


Table 5. Ocular Complications of P.B. Cases at the Onset of M.D.T and at Quarterly Follow up for 6 Month (Total P.B. Patients Receiving M.D.T. were 361)

<table>
<thead>
<tr>
<th>Onset of M.D.T.</th>
<th>Lid and Ocular Adnexa</th>
<th>Conjunctival lesion</th>
<th>Corneal lesion</th>
<th>Ant Uveitis</th>
<th>Lacrimal Sac infection</th>
<th>IOP High/Normal/Low</th>
<th>No PL</th>
<th>V. Acuity CF-3/60</th>
<th>V. Acuity 3/60-6/60</th>
<th>V. Acuity 6/60-6/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>3</td>
<td>22</td>
<td>2</td>
<td>1</td>
<td>20/337/4</td>
<td>Nil</td>
<td>5</td>
<td>12</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>3rd Month</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>Nil</td>
<td>3/357/1</td>
<td>Nil</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>6th Month</td>
<td>1</td>
<td>Nil</td>
<td>1</td>
<td>Nil</td>
<td>Nil</td>
<td>1/359/1</td>
<td>Nil</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Table 6. Ocular Complications of P.B. Cases at the Onset of Dapsone Monotherapy at Quarterly Follow Up for 6 Months. (Total P.B. Patients receiving Dapsone Monotherapy were 361)

<table>
<thead>
<tr>
<th>Onset of Monotherapy</th>
<th>Lid and Ocular Adnexa</th>
<th>Conjunctival lesion</th>
<th>Corneal lesion</th>
<th>Ant Uveitis</th>
<th>Lacrimal Sac infection</th>
<th>IOP High/Normal/Low</th>
<th>No PL</th>
<th>V. Acuity CF-3/60</th>
<th>V. Acuity 3/60-6/60</th>
<th>V. Acuity 6/60-6/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>2</td>
<td>20</td>
<td>4</td>
<td>2</td>
<td>21/339/1</td>
<td>Nil</td>
<td>4</td>
<td>15</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>3rd Month</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>5/355/1</td>
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<td>5</td>
</tr>
<tr>
<td>6th Month</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Nil</td>
<td>2/359/0</td>
<td>Nil</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>


