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A Study of 922 Bacteriologically Positive Leprosy Cases[1]

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In an earlier study we reported ([1]) bacteriologic follow up of lepromatous cases with respect to their age, sex, stage of disease, reactional episodes and treatment status. In that study, the age and sex of the patients had no bearing on the attainment of bacteriologic negativity, but the stage of the disease was significantly related to the time required to attain negativity. Early lepromatous cases became negative sooner than more advanced, nodular cases. Recurrent reactions delayed the time required to reach negativity. A majority of the patients that had remained positive had taken dapsone (DDS) for less than 36 months. A majority of those patients who had taken DDS for more than 48 months had become negative.

In the present study in addition to lepromatous cases, other bacteriologically positive cases, namely borderline (comparable to BB and BL in the Ridley-Jopling classification) ([2]) and reactional tuberculoid (RT) (comparable to BT) are also included to study the relationship, if any, between attainment of negativity and regularity of treatment, type of leprosy, reactions, sex, and age of the patients. We wished to compute the approximate period of DDS treatment required for rendering different types of bacteriologically positive patients negative, and to study at least the major factors which affect the time required to attain bacteriologic negativity.

MATERIALS AND METHODS

In this retrospective study, records of 922 initially positive cases (492 lepromatous, 222 borderline, and 208 reactional tuberculoid) were studied from our out-patient registers from 1 January 1962 through 31 December 1974 (13 years).

Routine bacteriologic assessments are done in lepromatous patients by removing wedge-shaped pieces of skin from one elbow and one ear and pressing the tissue on a microscope slide to make an impression smear. For borderline and reactional tuberculoid cases, one of the pieces of skin is removed from one ear and the other from an active-looking lesion. The slides are stained by the Ziehl-Neelsen method; 100 microscopic fields (×600) are examined and the results expressed on the Ridley scale ([3]). For the purposes of the present study, the findings were noted only as either positive or negative. Bacteriology is routinely done twice a year, except for certification purposes, when it is done more often. A patient who is negative (no acid-fast bacilli seen in 100 microscopic fields) thrice consecutively is termed negative and, in this case, the date of the first negative bacteriology is taken to be the time the patient became bacteriologically negative.

All patients who had taken DDS (600 mg weekly for adults) for at least six months out of the year for a period of five years (or less than five years if the patient had become negative) were included in the study. Patients were termed regular if their actual period of treatment (the time for which they had collected DDS for out-patient treatment) was 75% or more of the total period of treatment. Those who collected sufficient DDS for treatment for a period less than 75% of the total span of treatment are termed irregular.

Statistical analysis was by means of the chi-square test.

RESULTS AND DISCUSSION

Regularity of treatment. Of these 922 initially bacteriologically positive patients followed for at least five years on DDS monotherapy (or until attaining negativity), all

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took DDS monotherapy at least 50% of the time as measured by collecting medication from the clinic. Of these 922 patients, 634 took treatment regularly (≥75% of the treatment period) and 288 were irregular (collecting sufficient medication for 50% to 75% of the treatment period). Overall, 57.4% of the regular patients become bacteriologically negative during the period of the study; while only 20.8% of the irregular patients become negative. These differences are highly significant ($p < 0.001$). Thus, regularity of treatment is significantly associated with the attainment of bacteriologic negativity. To evaluate the remaining factors affecting the results of treatment, only the 634 regular cases were considered in the evaluation.

Sex. Of the 634 regular cases, 90% were males. Overall, 57.7% of the males became negative during the period of the study as compared to 54.5% of the females. These differences are not significant. Thus, gender has no bearing on whether or not a patient attains negativity on regular DDS monotherapy.

Age. The percentage of negatives varied from a minimum of 50.0% in the group of patients from 0 to 14 years of age to 61.7% in the 45- to 59-year-old age group. None of the differences are statistically significant. Thus, age had no bearing on whether or not a patient attains negativity on regular DDS monotherapy.

Type of leprosy. L1 or early lepromatous cases have shiny, oily skin, generalized infiltration, but no distinct patches or nodules. L2 or advanced lepromatous cases may have, in addition, thickening of the skin, skin nodules, loss of eyebrows, a depressed bridge of the nose, or a leonine face. Both L1 and L2 are usually bacteriologically highly positive (6+ on the Ridley scale) ([3]). Of the 634 cases, 230 (36%) were L2 cases, 81 (13%) were L1, 161 (25%) were borderline (B), and 162 (26%) were reactional tuberculoid (RT) cases. Overall, 39.1% of the 230 L2 cases attained negativity during the period of the study; 53.1% of the 81 L1 cases; 64.1% of the borderline cases; and 75.9% of the RT cases. These differences are highly significant ($p < 0.001$). Thus, the type of leprosy has a significant bearing on whether or not a patient attains negativity on regular DDS treatment. The time required to attain bacteriologic negativity for the different types of patients is given in Figure 1a. RT cases become negative earlier, followed by borderline patients, and then the lepromatous groups. This observation was further confirmed by the study of the relationship between the duration of treatment and the type of leprosy.

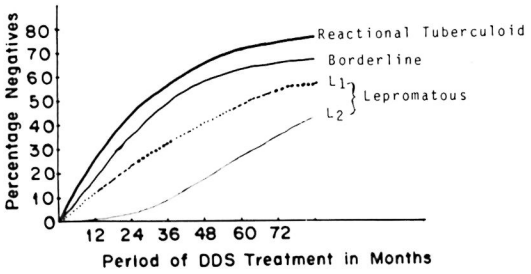

FIG. 1a. Percentage of patients attaining bacteriologic negativity in relation to months of treatment for different types of leprosy.

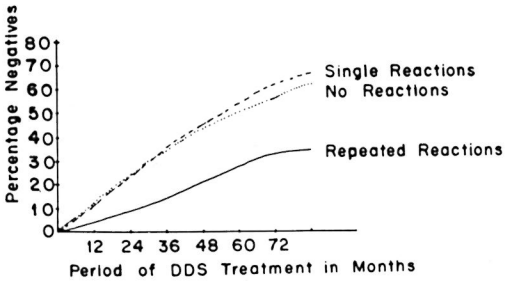

FIG. 1b. Percentage of patients attaining bacteriologic negativity in relation to months of treatment and reactional episodes.

Reactions. During reactions, DDS was routinely discontinued. Corticosteriods were never used systemically. Analgesics, sedatives, antimalarials, and antimonials were all employed, as needed, for the management of the reactions. Reactions in lepromatous cases consisted of erythema nodosum leprosum (ENL). Reactions in borderline cases consisted of both ENL and reversal reactions. Reactional tuberculoid cases experienced reversal reactions. Of the 634 regular patients as a whole, 66.3% had no reactions (NR), 15.1% had a single episode of reaction (SR), and 18.6% had recurrent episodes of reactions (RR). Overall, 62.1% of the NR group, 65.6% of the SR group, and 33.9% of the RR group obtained bacteriologic negativity during the period of

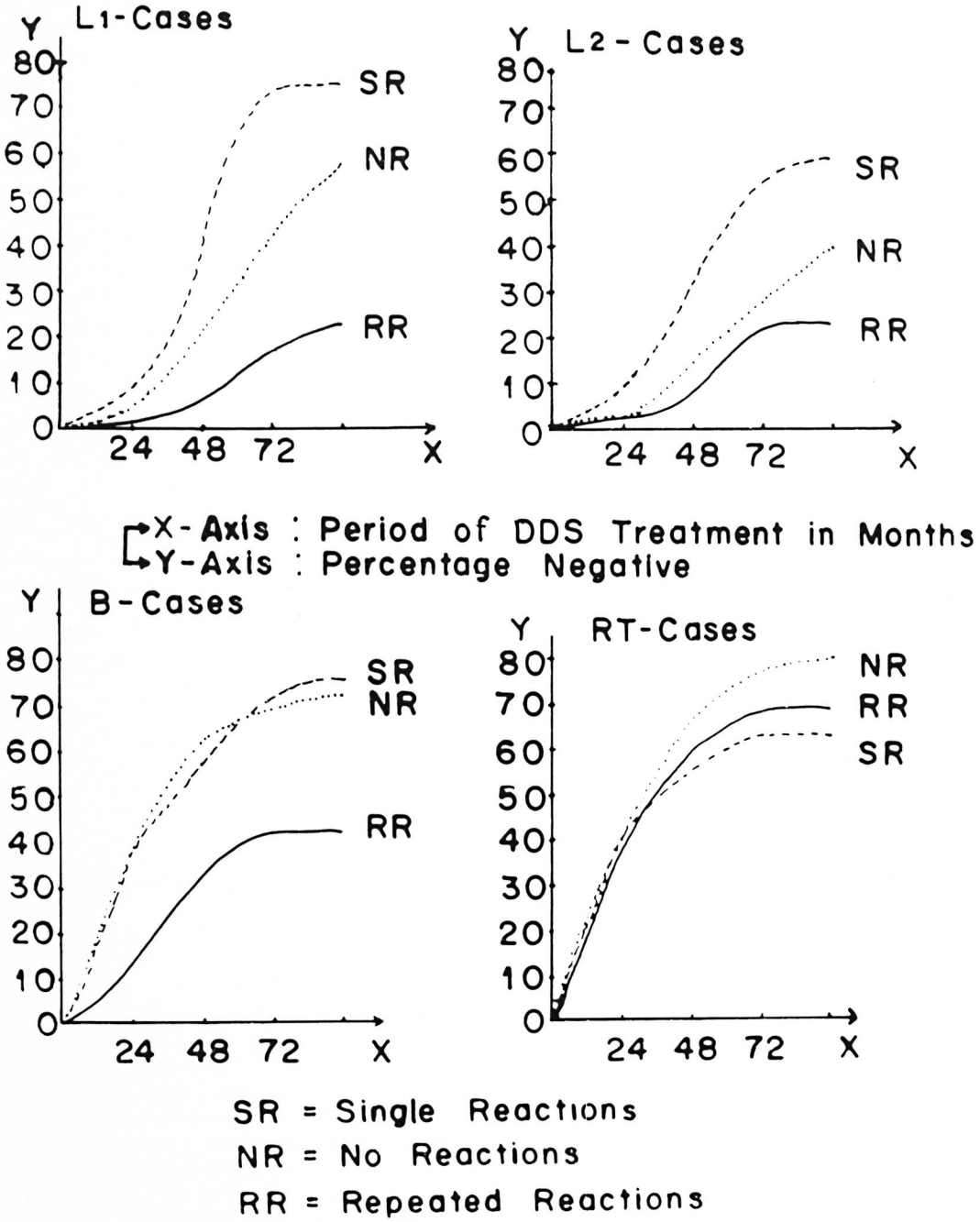

FIG. 2. Percentage of patients attaining bacteriologic negativity in relation to months of treatment by classification and reactional episodes.

the study. These differences are highly significant ($p < 0.001$). Thus, repeated reactions (RR) are associated with a lack of attaining bacteriologic negativity (Fig. 1b).

Duration of treatment. Figure 1a depicts the percent of negative cases of each type of leprosy in relation to the duration of treatment (yearly class intervals). In lepromatous (L2 plus L1) cases, 42.8% became negative during the period of study. This is the lowest observed among the three types. In the early periods of treatment, only

a few cases became negative. The mean (±standard deviation) duration of regular DDS therapy necessary for the attainment of bacteriologic negativity for this group is 51 (±18.9) months. For borderline cases, the mean duration of treatment necessary to attain negativity is 26.8 (±20.0) months. For reactional tuberculoid cases the mean period of treatment to attain negativity is 21.6 (±20.5) months.

Interactions among type of leprosy, frequency of reactions, and duration of treatment (Fig. 2). There were more negatives in the reactional tuberculoid group than in the borderline group for a similar duration of treatment and for a similar frequency of reactions. Repeated reactions (RR) delay the attainment of negativity in borderline cases but not in reactional tuberculoid cases. A possible reason for this is that reactions in reactional tuberculoid cases are always milder than those in borderline cases. Thus, DDS was not interrupted in RT cases with repeated reactions for as long periods as in borderline cases with repeated reactions. In both borderline and reactional tuberculoid cases, single reactions do not adversely affect the attainment of bacteriologic negativity. The frequency of reactions was not significantly different between the borderline and reactional tuberculoid patients.

As expected, the lepromatous cases attained bacteriologic negativity at a slower rate than the borderline and reactional tuberculoid patients. For similar durations of treatment, there were less negatives in the L2 group than in the L1 group. Among the lepromatous patients as a whole, single episodes of reaction are associated with more rapid attainment of bacteriologic negativity than no reactions. Multiple reactions, on the other hand, are associated with delays in attaining negativity. The reasons for this are unknown but the observation has been a consistent one.

SUMMARY

Nine hundred twenty-two bacteriologically positive leprosy cases were registered over a period of 13 years (1962–1974) at the Acworth Leprosy Hospital in Bombay, and studied for a minimum period of five years. Two hundred eighty-eight were found to take antileprosy medication irregularly. The remaining 634 patients, who took their medication regularly, were analyzed with respect to the effects of age, sex, type of disease, frequency of reactions, and duration of treatment on the attainment of bacteriologic negativity. Overall, 57.4% of those patients taking medication regularly became bacteriologically negative; while only 20.8% of those taking medication irregularly became bacteriologically negative. Age and sex did not appear to influence the attainment of bacteriologic negativity. The type of disease, reactions, and duration of treatment all influenced the time required to attain bacteriologic negativity.

RESUMEN

En un periodo de 13 años (1962–1974), se registraron 922 casos de lepra bacteriológicamente positivos, en el Acworth Leprosy Hospital de Bombay, mismos que se estudiaron por un periodo mínimo de 5 años. Se encontró que 288 pacientes tomaban su medicación antileprosa de manera irregular. Los restantes 634 pacientes, que sí tomaban su medicación en forma regular, se analizaron en cuanto a los efectos de la edad, sexo, tipo de enfermedad, frecuencia de reacciones y duración del tratamiento, sobre la negativización bacteriológica. Globalmente, el 57.4% de los pacientes bajo tratamiento regular llegaron a ser bacteriológicamente negativos mientras que sólo el 20.8% de los irregulares llegaron a la negatividad bacteriológica. La edad y el sexo no parecieron influir en la negativización bacteriológica. El tipo de enfermedad, de reacciones, y la duración del tratamiento, influyeron, todos, el el tiempo requerido para alcanzar la negatividad bacteriológica.

RÉSUMÉ

Au cours d'une période de 13 ans (1962–1974), on a enregistré 922 cas de lèpre bactériologiquement positive, suivie pour une période minimum de 5 ans, à l'Acworth Leprosy Hospital à Bombay. On a relevé que 288 de ces malades prenaient leur médicament de manière irrégulière. Les 634 autres malades, qui prenaient leur médicament régulièrement, ont été analysés en vue d'étudier les effets de l'âge, du sexe, du type de la maladie, de la fréquence des réactions, et de la durée du traitement, sur l'évolution bactériologique. Dans l'ensemble, 57.4% des malades prenant leur médicament régulièrement, sont devenus bactériologiquement négatifs, alors que seulement 20.8% de ceux qui prenaient leur médicament irrégulièrement, sont devenus bactériologiquement négatifs. Il n'est pas apparu que l'âge ou le sexe influençait la négativation bactériologique. Le type de maladie, les réactions, la durée du traitement avaient une influence sur le temps requis pour atteindre la négativité bactériologique.

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