Dr. O. Rodriguez, Mexico

Lucio s Leprosy is a variety of lepromatous leprosy, called spoted or lazarine , by Ladislao de la Pascua (1844), described with those names by Rafael Lucio and Ignacio Alvarado (1852), and identified by Fernando Latapi in 1936.

Clinical features : Skin generalized infiltration, suculent or atrophic, without nodules. Telangiectases on the face and chest, rosacea-like appearence of the face, milia cysts (advanced cases) and livedo of the limbs (early cases). Rinitis, saddle nose. Slow but total eyelashes, eyebrows and down hair alopecia. Without ocular lesions. Panneuritis, impairment of sensation over whole body. Visceral lesions and special kind of lepra reaction : erythema necrotisans with Lucio s penomena, chills, high fever, insomnia...

Bacteriologically : Plenty acid fast bacilli not only in nasal mucosa but in any part of the skin.

Histologically : Lepromatous infiltrates in small foci around vessels, nerves and appendages. Infiltrates are more dense in deep dermis and hypodermis. During lepra reaction : Epidermal necrosis intraepidermall bullae and ulceration. Vascularitis with trombosis of small and medium caliber blood vessels, surrounded by polynuclear foci with numerous acid fast bacilli.

Immunologically : Lepromin reaction is always negative but 4-6 hours after injection of 0.01 ml lepromin, the Lucio s phenomenon in its first stages is reproduced. VDRL is positive in almost all cases.

Prognosis : Lucio s Leprosy represents the maximal expression of immunological depression, and therefore it is the most serious form of the disease.

Treatment : Sulfones, rifampicin and clofazimine are as effective in these cases as they are in nodular ones.

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Ch 36

A STUDY OF FACTORS INFULENCING PATIENT COMPLIANCE IN AN URBAN OUT PATIENT LEPROSY CLINIC

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Dhoolpet Leprosy Research Centre is an urban leprosy outpatient clinic, where patients are self drawn or referred by city dermatologists & private practitioners. The clinic has developed into a referral centre for the management of reactions & nerve damage besides regular leprosy diagnosis and treatment services. The city also has 9 other leprosy control units & 5 outpatient treatment centres scattered over the city s radius of about 35 Km.

We present the data on patient compliance at our centre and relate it to variables, like age, classification, clinic distance, occupation and deformity. Patients who completed 6 doses of PB MDT in 9 months and 12 doses of MB MDT in 18 months were considered compliant. Since patients come to the centre from as far as 300 km; we also studied compliance in relation to the operational necessity of giving the patient more than a month s dose of MDT.

231 PB leprosy patients and 136 MB leprosy patients were studied separately and together. Overall, the PB patients were more compliant than MB patients. Tuberculoid patients showed highest compliance. The age group of 15 to 35 was found to be more compliant then the older age group and children. There was no difference in regularity between males & females. Although there was a sharp drop in compliance from patients beyond the city limits it was interesting to note that patients beyond 100 km showed reasonably good degree of regularity.

The results also show that patients who received more than 1 month of MDT had the highest regularity (78% among PB patients and 70.5% among MB patients). The data suggest that literacy and education have a positive influence on patient regularity. Patients with no deformity were found to be less regular than those with grade 1 & 2 deformity.

The above results and possible reasons for compliance and non-compliance of patients and the impact of other leprosy programmes in the city will be discussed.

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Ch 51

SINGLE DOSE TREATMENT FOR SINGLE LESION LEPROSY - HISTOPATHOLOGICAL OBSERVATIONS

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Some of the problems encountered with single dose of ROM (ROM-I) therapy in single lesion PB patients as reported so far are : 1) Persistence of existing lesion, 2) Increase in the size of old lesion 3) Appearance of new lesions. Delayed clearance of granuloma may be associated with such clinical problems. However, no histopathological study has been reported, following ROM-1 therapy.

We report on histopathological observations on 26 patients with single patch leprosy treated with ROM therapy. All patients underwent pre-treatment, as well as

post-treatment skin biopsy at the end of 12-18 months. Granuloma Index (GI) was studied in H & E sections. GI is the fraction of the dermis in a section occupied by the granuloma. The GI is observed under low power objective and expressed decimally, e.g. 1 indicates the whole of the dermis is occupied by the granuloma, whereas 0.1 indicates that 1/10th is occupied by the granuloma. Histopathological changes were termed as active when there was dermal infiltrate of epitheloid gnrnuloma and the GI was more than 0.1 in the dermal tissue with nerve inflammation. It was termed as resolving when the GI was less than 0.1 and inactive when granuloma was absent and/or lymphocytic infiltrate was approximately < 5%.

GI before and after ROM-I

Granuloma Index No. of cases

Pre-treatment Post-treatment

0.4 4 (20%) 2 (10%)

0.3 5 (25%) 2(10%)

0.2 5 (25%) Zero

O.1 3 (15%) 1 (5%) < 0.1 3 (15%) Zero

Total 20 5 (25%)

Continued on next page Out of 26 patients, 20 patients had granulomatous infiltrate and 6 patients showed perivascular, periappendageal and perineural lymphocytic infiltrate suggestive of indeterminate leprosy, prior to initiation of therapy. These 20 patients were further studied for resolution of granuloma using the GI scale. At the end of study only 5 patients had granulomatous infiltrate, with total clearance of granuloma in remaining 15 patients, indicating marked improvement following therapy. Out of these 5 patients with granlomatous infiltrate, 2 patients had G.I. of < 0.1, suggestive of resolving granuloma, whereas only 3 patients had active granuloma at the end of the study. Striking solution of granuloma was observed in patients with high GI.

Histopathologically signs of reaction were observed in one patient in the form of edema and extravasation of RBCS. One patient with indeterminate picture before therapy, showed granulomatous reaction (GI of 0.1) at the end of therapy while the remaining 5 patients with indeterminate histology had reached inactive stage. One patient who developed new lesion showed reduction in GI in old lesion (0.3 to 0.1) but the biopsy from the new patch showed GI of 0.3. None of the patients showed presence of AFB before or after theapy.

The hislological improvement in 81% of cases after 18 months following ROM-I therapy can be considered as satisfactory and is comparable to PB-MDT, as reported in the literature. Though histopathological improvement with reduction in granuloma size may take longer time, eventually they all regress irrespective of treatment with PB-MDT or ROM-1.

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Ch 57

RARE SITES AND IMMUNE ZONES FOR LEPROSY - WHERE ARE YOU?

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Some of the parts of human anatomy were earlier considered immune or rare for development of leprosy lesions. This, however, no longer holds true.

We present our collection of 12 cases with involvement of unusual sites seen over the last 15 years. The sites involved were hairy scalp, glans penis, penile shaft, scrotum, eyebrows, upper eyelid, tongue and palms. Most of the patients had paucibacillary leprosy with lesions exclusively seen on the above sites. One patient had lepromatous leprosy with lesions over the tongue also.

This paper highlights the occurence of leprosy lesions over rare sites. It emphasises the importance of entertaining the possibility of leprosy, even in lesions on unusual sites and stresses the need for complete skin examination in all the patients.

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Ch 80

DAPSONE SYNDROME : REPORT OF 9 CASES FROM NEPAL

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INTRODUCTION: Dapsone/diaminodiphenylsulphone (DDS) syndrome is a rare hypersensitivity reaction of dapsone reported to occur in 0.3%-0.6% of patients receiving this drug. It is characterized by exfoliative dermatits, fever, lymphadenopathy, hepatitis, hepatosplenomegaly developing within 2 - 6 weeks of starting the drug. The incidence of this reaction was high during the initial period after its introduction for use in leprosy in 1940s. The incidence declined during next 2 decades but more cases are being reported from 1970s onwards. We present our experience of 9 cases of this syndrome seen over a short span of 18 months from March 1998 to September 1999 in a recently started tertiary level teaching medical college (BP Koirala Institute of Health Sciences, Dharan) in Eastern Nepal.

CLINICAL DATA : Nine patients (6M, 3F) with age ranging from 12-64 years of DDS syndrome were seen. Eight patients were receiving dapsone as part of MDT for leprosy whereas one patient had bullous pemphgoid. All the patients presented with fever, generalized maculopapular rash evolving into exfoliative dermatitis of 1-4 weeks duration appearing within 2-6 weeks of starting the drug. Rash was accompanied by itching in 5 patients. Clinical features included icterus in 6 patients, pallor (7), generalized lymphadenopathy (8), hepatomegaly (6), splenomegaly (2) and pedal edema in 4 patients each respectively. No mucosal involvement or peripheral cyanosis was seen in any of the patients. One patient had suffered from similar condition twice in the past 2 years. Investigations revealed anemia in 6 patients, leucocytosis (7), eosinophilia (4), raised ESR (9), deranged liver functions in 6 and raised serum creatinine and blood urea in one patient each respectively. Routine urinalysis, stool examination, chest x-ray were normal in all patients. Sserum HbsAg was positive in one patient only. All patients except one having mild reaction were treated as inpatients. Four patients developed secondary bacterial infection, 2 of whom went on to develop septicemia. Herpes zoster in 2 and herpes labialis appeared in one patient each respectively. All patients were treated by stopping dapsone and giving IV fluids, antibiotics, antipyretics, antihistamines, emollients, and good nursing care. Oral prednisolone 40-60 mg OD was given to 5/9 patients.

Continued on next page It was tapered in next 4-6 weeks. All patients except one improved completely in 3-6 weeks. One patient having concomitant intestinal obstruction leading to perforation and peritonitis died.

CONCLUSION : Dapsone syndrome constituted 0.08% of all new dermatology patients seen over a period of 18 months. It can be easily managed if recognized early by stopping the drug, good nursing care, with/without systemic corticosteroids depending upon severity of the syndrome. Dapsone is increasingly being used for many dermatological conditions besides leprosy. Awareness among physicians of this being the probable cause in any patient developing fever and rash within 6 weeks of starting dapsone is warranted as rarely it can be fatal.

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CH 129

MULTICENTRIC FIELD TRIAL IN PB LEPROSY WITH 2-5 LESIONS

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A multicentric double blind controlled clinical trial is done to compare the efficacy of a combination of Rifampicin (600 mg) Ofloxacin (400 mg) and Minocycline (100 mg) administered as a single dose with that of standard six months WHO/MDT/PB Regimen.

The study subjects consisted of 1592 patients with 2-5 lesions. The randomization was done at individual patient basis with some patients getting a single dose of ROM and others with WHO MDT.

Total duration of the study will be 48 months (six months of intake phase, six months of treatment phase and 36 months of post treatment follow-up).

Six different centres are taking part in this study. Four follow-ups were completed so far. The improvement / deterioration observed so far in this trial study without decoding, will be presented in this paper.

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CH 135

RESPONSE IN SINGLE LARGE LESION TO SINGLE DOSE THERAPY - A CASE REPORT

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A single dose treatment with Rifampicin (R), Ofioxacin (0) and Minocycline (M) combination (ROM-1) for single skin lesion (SSL) leprosy is being practised and the initial experiences on its efficacy as well as the delayed clinical problems have been published. Such treatment in PB leprosy with 2-5 lesions is also under trial and initial experiences show favourable outcome in terms of clinical regression and relapses within acceptable limits. The question often asked is whether ROM - 1 can be given to a very large single lesion. Will such lesion regress or progress soon after initiation of treatment? There is also an apprehension that relapses / reaction may be encountered in greater frequency in large lesions after ROM - 1 on account of insufficient chemotherapy. Hence we proposed to study patients with large lesions treated with ROM-1 in a series of single lesion cases. We record our minute observations on clinical response after treatment with ROM-1 in a case with a large single skin lesion.

Patient RK, 30 years, male, presented with a hypo-pigmented patch with raised margins, of size 9" X 6", on the left knee with pseudopodial extensions towards the medial and lateral sides of the upper third of the leg. There was no nerve involvement. BI was negative. He

was administered a single dose of ROM on 10th Feb. 2000. Photographs were taken from various angles initially and during the surveillance period to record the progress of the lesion. The dimensions of the lesion were charted out. On subsequent follow-up after 6 months, the borders were found to be flattened and the lesions appeared faint and regressing well. The patient will be periodically observed further.

We conclude that single large lesion treated with ROM-1 regimen also shows regression and the clinical behaviour is similar to the pattern observed in the lesions of smaller size. The other similar cases in the series also continue to show regression and no reactions were encountered during the period of follow-up. It should be noted that these observations are made to answer the questions raised purely from a clinical standpoint to record the response soon after treatment on a short-term basis. Whether the response will be sustained or whether there will be progression after initial regression (as compared to the results in smaller lesions) or whether there will be greater proportion of reaction / relapse, etc. over a long period of time can only be answered in course of time.

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Ch 286

A CASE OF HYPERSENSITIVITY REACTION DUE TO BOTH DDS AND B663

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Twenty one days after starting the treatment of WHO/MDT MB regime, the reported case complained of gastrointestinal symptoms, such as vomiting and abdominal pain, and generalized pruritus. After withdrawal of MDT drugs for 7 days by himself, he continued to take MDT drugs. Ten days later, a sudden and serious attack of symptoms and signs of exfoliative dermatitis, such as generalized erythema and vesicles, occurred. The patients was diagnosed as having dennatitis medicamentosa (exfoliative dermatitis form) . After withdrawal of MDT drugs and giving emergency treatment with anti-allergic measures, the patient was finally out of danger, and the MDT treatment, exclusive of DDS, was continued. But only about 15 minutes after intake of B663 and RFP, the above described symptoms and signs manifested again, and disappeared spontaneous after withdrawal of anti-leprosy drugs. From then on only oral administration of RFP was continued and there was no side reaction as mentioned above. The clinical evidence revealed that the patient was undoubtedly sensitive to both DDS and B663, the first case reported in China.

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Ch 314

CHANGES IN THE PREVALENCE OF DAPSONE RESISTANT LEPROSY SINCE THE IMPLEMENTATION OF MDT

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Dapsone resistance has been recognized as a problem in leprosy since 1964. Dapsone monotherapy was introduced into Nepal in 1956 and multi-drug therapy (MDT) in 1983. However, MDT coverage only recently exceeded 95%. A mouse footpad laboratory has been established since 1980 and all new previously untreated multibacillary cases and relapses have been screened for dapsone and rifampicin resistance by the MFP culture. Our results from 1987, are as follows :

1987-1991 1992-1995 1996-1998

Primary 3/55 (5.5%) 5/69 (7.2%) 14/69(20%)

Secondary (DDS monotherapy) 11/25 (44%) 10/15 (66%) 0/9 (0%)

Secondary (MDT patients) Nil 0/2 (0%) 0/3 (0%)

Secondary dapsone resistance has almost entirely disappeared as the remaining dapsone monotherapy patients have died or been treated with MDT. Secondary dapsone resistance does not develop in MDT regimens. While 7/21 secondary dapsone resistant strains were resistant at high dose, only a single case (of 22 cases) of primary resistance was at high dose dapsone. No cases of rifampicin resistance (at 10mg/kg) have been found by the MFP method over the study period The possible reasons for these changes in the rates of dapsone resistance and the implications for MDT treatment will be discussed.

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Ch 322

RAPID DIAGNOSIS OF RIFAMPICIN RESISTANCE IN LEPROSY

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The extent and trends in resistance of leprosy to rifampicin are unknown. The major impediment to measuring this important fact is the difficulty in measuring such resistance by the traditional mouse footpad method. The molecular basis of rifampicin resistance in Mycobacterium leprae has been known for some time and a new rapid method has been developed and field tested in Nepal. The new method uses polymerase chain reaction (PCR) to amplify a 388 base pair section of the RNA polymerase P chain gene (rpoB) and a set of oligonucleotide probes immobilized on a nylon membrane is used to probe for mutations associated with rifampicin resistance. The test combined positive and negative controls and used chemiluminesence for detection.

In initial studies, results were obtained from 9 strains (5 from skin biopsies and 4 from mouse footpad samples) Of these, 6 were found to have rifampicin resistance associated mutations. 5/6 were serine to phenylalanine substitutions and one an apparent double mutation serine to phenylalanine and serine to methionine. All except the double mutation were confirmed by sequence analysis. Resistance genotypes were found in biopsies from two patients with a failure to respond to MDT demonstrated by a failure for the bacterial index to fall. Other resistant strains were isolated from mouse footpad samples : one the primary isolate of a previously untreated LL case and three from strains passaged 5, 13 and 14 times in mice. All four isolates had been shown to be sensitive to 10 mg/kg rifampicin in the mouse footpad assay.

We have extended these observations and present data on a set of more than a dozen M.leprae strains genotyped for rifampicin resistance and tested at full (10 mg) and half (5 mg) doses in new mouse footpad cultures. The validation of genotype methods of detecting drug resistance in leprosy is critical for their wider use in monitoring this important problem.

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Ch 352

ADVERSE EFFECTS OF MULTI-DRUG THERAPY IN LEPROSY PATIENTS

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Hansen s disease was considered incurable and along the history, many therapies were experienced to break the bacteria s chain of transmission. Nowadays, it is certain that the progress of the treatment has been reached with the use of multidrug therapy (WHO/MDT), composed by three drugs, dapsone, clofazimine and rifampin, which has enabled the healing to this disease, since it does not cause primary and secondary resistence as the use of isolated drugs did. However, the abolition of Leprosy still has to go through many stages in order to fight the several collateral effects, that has been underestimated, and is a cornerstone to increase the adhesiveness of the patients to the treatment. With the objective of determining the magnitude of MDT adverse effects and its transcendence about patient s adhesiveness to treatment the aiming of this proposition is to conduct protocols for the health basic services network, the promptuary of patients treated with MDT. This study was revised, from January of 1995 to May of 2000, in school s health centre (CSE) - Jaragua - UFU. By means of Records of Inquiry of Adverse Effects occur of MDT. 67 (37.8%) out of the 187 patients analysed were paucibacillary (PB) and 120 (62.2%) multibacillary (MB).Among the 113 side effects evidenced, 80 (70.7%) were caused by dapsone, whose major reactions were gastritis with 18 (22.5%). Other occurrences are hemolytic anemia 15 (18.8%); such rifampin side effects are consequences of medicines as follow: 7 (6.2%) harmful effects; standing out colic was mentioned in 2 (28.6%) cases. Ichthyosis with 18 (69.2%) occurrences was the most expressive side effect related to clofazimine appointed like the drug that cause more adverse effects 26 (20.5%) within the 113. In the 113 conducts adapted for those side effects, 29 (25.7%) were medicine s prescriptions and 28 (24.8%) were changes in the treatment. Among the 17 patients who abandoned the treatment, 5 (29.4%) had some type of side effects related to one of the 3 MDT S drugs, 9 (52.9%) of them were MD, and 8 (47.1%) were PB. This survey discusses the importance in considering the adverse effects of MDT as limitations of the adhesion of the patient to the treatment and consequently the eradication of Hansen s disease as a problem of public health and it enhances the importance of elaboration of a protocol conducts for side effects. The ground work of the health groups, and the possibility of using an alternative chemotherapy are extremely important in order to improve the patient s adhesion to the process of cure of Hansen s disease, which is quite long and very distressing for the patient.

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Ch 368

CHEMOPROPHYLAXIS :A SYSTEMATIC REVIEW OF THE LITERATURE AND META-ANALYSIS

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Objective : To quantify the efficacy of chemoprophylaxis against leprosy based on a systematic review of the literature and meta-analysis of trials.

Method : A literature search identified 127 published papers relating to the prevention of leprosy and the use of chemotherapy in leprosy was critically appraised. Sixteen trials were selected and grouped into three categories according to the level of randomisation of the trial groups. The Relative Risk (RR) with 95% confidence intervals was calculated from the raw data using a random effects model. To estimate the cost effectiveness of chemoprophylaxis treatment, a further analysis of the rates of disease in the trial and control groups was done. The numbers needed to be treated (NNT) to prevent one new case of leprosy was then estimated (incidence in non-exposed minus incidence in the exposed equals reduced rate, 1 divided by RR equals NNT)

Results : The overall results of the meta-analysis shows that chemoprophylaxis gives 60% protection against leprosy, and when given to close contacts of index cases, this protection increases to as much as 99% in some studies. The numbers needed to treat were found to be low in trials of household contacts and high in community based studies.

Conclusion : The evidence shows that chemoprophylaxis against leprosy is a feasible and cost-effective way to reduce the future incidence of leprosy through a targeted approach. The role of chemoprophylaxis needs to be re-examined using newer drugs.

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Ch 416

RELAPSE CASES AMONG THOSE RFT

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Objective: To find out details of relapses among those RFT

Design: Retrospective study patients returned with relapse during surveillance out of RFT.

Setting: The Leprosy Mission Hospital, a large referral centre at Naini, Allahabad, Uttar Pradesh, India.

Participants: Records of relapse cases out of surveillance

Main Outcome Measures:

Percentage of relapse out of RFT patients.

Conclusion: The trends of relapse of ratio over the past 9 years among RFT patients here were evaluated. There was a variation in the percentage of relapse among RFT patients.

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Oc 279

OCULAR COMPLICATIONS IN LEPROSY : AN EPIDEMIOLOGICAL STUDY OF 219 PATIENTS

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One hundred and thirty cases of the 219 patients surveyed were found to have ocular complications, an overall prevalence rate of 59.36%. The peak prevalence was seen in hospitalized patients (68.87%, 104/151), next in cures after discharge (55.8%, 24/43) and the lowest in newly detected cases (8%, 2/25). Visual disability rate in the study group is 21.6% including 12.33% blind sufferers. The main causes leading to visual impairments are lids involvement (lagophthalmos, ectropion) accounted for 24.66%, iris impairments 11.4%, corneal diseases 8.6%, and panophthalmitis 5.94%.. Adapting measures, such as surgical correction, self-care, functional exercise and topical medication, visual acuity of 85 cases (65%) could be improved or kept unchanged.

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Ne 99

ULTRASTRUCTURAL NEURAL-PATHOLOGY IN LEPROMATOUS LEPROSY

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Involvement of the peripheral nerves is a basic pathological phenomenon observed in leprosy whose manifestation are seen right from the early stage with hypo-anaesthetic and hypo-pigmented patches to the advanced forms of the disease with multiple deformities. In the present investigation we have studied the Schwann cell and endothelial cells of endo-neural blood vessels.