

## **Is bacteriological examination by skin smear necessary in all paucibacillary leprosy patients in mass control programmes?**

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*Summary* Skin smear bacteriological examination results of 11,255 paucibacillary leprosy patients from 8 leprosy control units under the National Leprosy Eradication Programme (NLEP) in South India and the Outpatient Department (OPD) of the Central Leprosy Teaching & Research Institute (CLT&RI), Chengalpattu, between 1987 and 1989 were collected and analysed. Only 0.05% of the smears from leprosy control units and 2.49% from the OPD of CLT&RI were found to be positive. Not a single smear from indeterminate, tuberculoid and pure neuritic types of leprosy out of 8263 examined was found positive under field conditions. The relevance of carrying out routine bacteriological examination in mass leprosy control programmes is discussed.

### **Introduction**

Leprosy patients of all types are being grouped into paucibacillary (PB) and multibacillary (MB) for treatment purposes with the advent of multidrug therapy (MDT). Indeterminate (I) and tuberculoid (T) under the Madrid classification, indeterminate (I), tuberculoid (TT) and borderline-tuberculoid (BT) leprosy in the Ridley-Jopling classification whenever diagnosed clinically or histopathologically, with a bacteriological index of  $<2+$  on the Ridley-Jopling scale at any site were included in the PB leprosy group<sup>1</sup>. Indeterminate, tuberculoid, borderline-tuberculoid (BT) and pure neuritic (PN) leprosy patients are grouped under PB as per consensus classification of the Indian Association of leprologists 1981<sup>2</sup>. However, it was recommended that any case belonging to I, TT or BT leprosy groups according to the Ridley-Jopling classification with skin-smear positivity will be classified as MB for the purpose of MDT Programmes.<sup>3</sup> The guidelines under NLEP in India also states that all skin-smear positive patients irrespective of their clinical classification should be brought under MB MDT. As a result, it becomes absolutely necessary to carry out the bacteriological examination of all leprosy cases detected before giving them treatment. Most of the textbooks on leprosy state that skin-smear results are seldom positive in I and TT types which form the bulk of PB cases.<sup>4-7</sup>

There is no literature on the extent of positivity of skin smears of patients who are I, TT, BT and PN under field conditions in mass programmes on a large scale and at routine examinations in out-patient departments (OPD) in leprosy institutions. An attempt has been made in this paper to find out the above information and analyse it as to the relevance of routine bacteriological skin smear examination in PB leprosy patients in mass control programmes.

### Materials and methods

Under NLEP in India, on detection of the new leprosy cases actively or passively, they are confirmed and classified clinically by medical officers. A smear examination is then carried out for allocation to either PB or MB MDT regimens. Some of the medical officers working in leprosy control units in Krishna, Cuddappah and Chittoor Districts in Andhra Pradesh State were requested through their district leprosy officer to furnish information relating to bacteriological examination results of newly detected PB leprosy patients (I, TT, BT & PN) for the years 1987, 1988 and 1989 through a format sent to them. The medical officers were personally briefed and requested to collect information by examining individual patient care-cards of all new cases detected during the period under reference. They were specifically told to include all such I, TT, BT, and PN cases receiving MB treatment in the data furnished by them. The same information has been collected from the Field Operational Area and OPD of CLT&RI for the above period. Similar information from a leprosy control unit in Tamil Nadu State has been collected from the database which has been computerized as a part of an on-going in-depth evaluation of MDT project in the Institute. The units were picked up as per operational convenience and to render data of reasonable validity. The smears were collected from a minimum of 3 sites and read on the Ridley-Jopling scale as per NLEP guidelines by a trained laboratory technician at each of the centres reported. A limited cross-check of about 5% smears was reported by one unit (Machilipatnam) on the smear examination at the District Leprosy Office of Krishna District with no variation of results. All the units mentioned above have been implementing MDT projects since 1987.

### Results

Information collected from 8 leprosy control units (including the field operational area of the Institute) and the OPD of CLT&RI were summarized in Table 1.

Out of the 12,686 new cases detected/reported between 1987 and 1989, in 11,255 (88.7%) patients the slit-skin smear bacteriological examination has been carried out. Coverage of examination ranged from 58.6% in the CLT&RI field area to 100% in a number of the centres (Pileru, Palamaner, Produturu & OPD of CLT&RI).

The total positive cases were 39 (0.35%) of the total examined cases. The positivity in various centres ranged from 0% in several units to 2.49% in OPD of CLT&RI. In all the field units positivity was reported as 0% except in Pileru and Palamaner units where the positivity was 0.25% and 0.29% respectively.

**Table 1.** New PB cases detected skin smears examined and positive cases in different centres, 1987–89

S.no.	Name of the leprosy control unit	Indeterminate			Tuberculoid			Borderline-tuberculoid			Pure neuritic			Total		
		R	E	P	R	E	P	R	E	P	R	E	P	R	E	P
1	Nuzvid	15	6 (40.0)	0	1025	1014 (98.9)	0	572	433 (75.7)	0	11	6 (54.5)	0	1623	1459 (89.9)	0
2	Machilipatnam	1188	962 (81.0)	0	1314	1012 (77.0)	0	406	260 (64.0)	0	202	147 (72.8)	0	3110	2381 (76.6)	0
3	Assisi	10	4 (40)	0	989	706 (71.4)	0	19	19 (100)	0	1	1 (100)	0	1019	730 (71.6)	0
4	Pileru	0	0	0	698	698 (100)	0	417	417 (100)	3 (0.72)	63	63 (100)	0	1178	1178 (100)	3 (0.25)
5	Palamaner	18	18 (100)	0	450	450 (100)	0	206	206 (100)	2 (0.97)	23	23 (100)	0	697	697 (100)	2 (0.29)
6	Proddatur	225	225 (100)	0	1651	1651 (100)	0	29	29 (100)	0	34	34 (100)	0	1939	1939 (100)	0
7	Nammakkal	0	0	0	1106	1035 (93.6)	0	261	244 (93.5)	0	2	2 (100)	0	1369	1281 (93.6)	0
8	CLT&RI field area	2	2 (100)	0	350	200 (57.1)	0	33	22 (66.7)	0	4	4 (100)	0	389	228 (58.6)	0
9	Subtotal	1458	1217 (83.5)	0	7583	6766 (89.2)	0	1943	1630 (83.9)	5 (0.31)	340	280 (82.4)	0	11,324	9893 (87.4)	5 (0.05)
10	CLT&RI outpatient	97	97 (100)	2 (2.06)	281	281 (100)	4 (1.42)	984	984 (100)	28 (2.85)	0	0	0	1362	1362 (100)	34 (2.49)
11	Grand total	1555	1314 (84.5)	2 (0.15)	7864	7047 (89.6)	4 (0.06)	2927	2614 (89.3)	33 (1.26)	340	280 (82.4)	0	12,686	11,255 (88.7)	39 (0.35)

R, registered; E, examined; p, positive; Figures in brackets are percentages.

How necessary is BI examination in all PB patients?

POSITIVITY AND TYPE OF DISEASE

All types of PB leprosy cases except PN showed positivity ranging from 0.06% in TT to 1.26% in BT when results from all cases were taken together. However, the smears from I, TT & PN from all LCUs (including field operational area of CLT&RI) were reported negative. Only 2 LCUs out of the 8 reported positivity and they were 0.25% and 0.29% in Pileru and Palamaner respectively. The positivity of smears from OPD of CLT&RI ranged from 1.42% in TT cases to 2.85% in BT cases.

TYPE DISTRIBUTION OF SKIN SMEAR EXAMINED CASES

Of the 11,255 cases examined for skin smear bacteriology 11.7%, 62.6%, 23.2% and 2.5% belonged to I, TT, BT and PN respectively. The proportion of different types ranged from 0 to 40.4%, 20.6% to 96.7%, 1.5% to 72.2% and 0 to 6.2% in different centres for I, TT, BT and PN respectively.

BACTERIOLOGICAL INDEX (BI) OF POSITIVE CASES (Table 2)

Of the 39 positive cases, the BI at any one site was more than 1+ on Ridley's scale in only 11 cases (28.2%). All the cases with a BI of more than 1+ belonged to the BT group.

DISCUSSION

Skin smear bacteriological positivity in the PB group of leprosy patients has been reported as high as 21.8% with a BI of 1+ on Ridley's scale.<sup>8</sup> However, it was reported in

Table 2. BI of positive cases

BI*	Type			Total
	I	TT	BT	
1+	2	4	22	28 (71.8)
2+	—	—	7	7 (17.9)
3+	—	—	4	4 (10.3)
Total	2 (5.1)	4 (10.3)	33 (84.6)	39 (100)

\* Maximum bacteriological index at any examined site.

Figures in brackets are percentages.

the same study that relapses could not be correlated with the initial bacteriological status using three different drug regimens including the WHO recommendation, at 3½ years follow-up. Interobserver variation in reading the smears as negative while actually they are positive and vice versa has also been reported to the extent of 5.6% and 2.3% respectively.<sup>9</sup> The weakness and shortcomings in laboratory services are by no means new; they have been continuously identified over 20 years in numerous publications in leprosy and tuberculosis literature and this situation is unlikely to improve to the desired standards.<sup>10</sup> Organizing bacteriological examination of skin smears of all cases has been identified as a bottleneck by successive independent evaluation teams in India.<sup>11-13</sup> The bulk of the new leprosy cases detected (70-80%) belong to the PB group. In the present analysis, about 22.2% were found to be of the BT type. Under field conditions, it is only 0.31% of BT type and 0.05% of all types of the PB group that were found to be bacteriologically positive and none of the I, TT and PN group were positive. It is evident from the observations of successive independent evaluation team reports that perhaps it is almost impossible to improve the laboratory services in a mass control programme. The question is, with the very low positivity rates that are obtained above under field conditions, whether it would be worthwhile to carry out routine skin-smear examination in the PB group of leprosy patients in a mass control programme? It appears, perhaps, that it is not necessary to do skin smear bacteriology as a routine in all new PB group of patients, except BT type, especially when they are clinically confirmed by a medical person before commencement of treatment. Even under ideal conditions such as the OPD of CLT&RI, which can not be produced in field laboratories, the overall positivity was only 2.49%. Surveillance after release from treatment with MDT regimen is more or less mandatory for a period of 2 years in all control programmes. As such even those few cases which should have received MB MDT, had the bacteriological positivity been detected before commencement of treatment, could be taken care of during the surveillance period by way of detecting signs of clinical activity of the disease and instituting necessary MB treatment.

At present a lot of time is being spent by laboratory technicians on collection and examination of skin smears of PB leprosy patients, with a limited purpose served considering the effort involved, since nearly 70% to 80% of the new cases belong to this group. Further, if this routine examination is given up, they may well spend their time on bacteriological examination of MB cases, where it is actually needed for monitoring response to chemotherapy and deciding the time of release from treatment (RFT). Other advantages in giving up this routine examination are:

- 1 the saving of resources;
- 2 possibly better compliance of patients to clinic attendance;
- 3 saving the patients from unnecessary inconvenience due to pain; and
- 4 preventing the patients from possible exposure to AIDS, hepatitis B etc., due to faulty sterile techniques.

## **Conclusion**

Skin smear bacteriological examination is perhaps not necessary in the PB group of newly detected leprosy patients (except the BT group) as a routine in a mass control programme when the clinical confirmation of diagnosis is made by a medical person.

There are several advantages if the above examination is given up, without jeopardizing the interests of the individual patient seriously.

Further analysis using more extensive data would be useful in identifying which of the BT cases would need smear examination with reference to clinical features.

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### L'examen bactériologique par la méthode des frottis cutanés est-il nécessaire chez tous les patients lépreux paucibacillaires dans le cadre des programmes de contrôle à grande échelle?

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*Résumé* Entre 1987 et 1989 furent recueillis et analysés les résultats de l'examen bactériologique par frottis cutanés de 11.255 lépreux paucibacillaires provenant de 8 centres de contrôle de la lèpre dans le cadre du Programme national d'Eradication de la Lèpre (NLEP) dans le sud de l'Inde et des consultations hospitalières externes OPD de l'Institut central de Recherche et d'Enseignement de la Lèpre (CLT&RI) à Chengalpattu. Seuls

0,05% des frottis provenant des centres de contrôle de la lèpre et 2,49% provenant des consultations hospitalières externes du CLT&RI se sont avérés positifs. Aucun frottis du type lèpre indéterminée, LT ou purement névritique provenant des 8263 patients examinés ne s'est avéré positif sur le terrain. L'importance des examens bactériologiques de routine dans le cadre des programmes de contrôle de la lèpre à grande échelle est discuté.

### **¿Es el examen bacteriológico del frotis de piel necesario en todos los pacientes leprosos paucibacilarios en los programas de control en masa?**

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*Resumen* Se recolectaron y analizaron los resultados de los exámenes bacteriológicos de los frotis de piel de 11.255 pacientes leprosos paucibacilarios de 8 unidades de control de lepra bajo el Programa Nacional de Erradicación de la Lepra (NLEP) en el Sur de la India y el Departamento de Pacientes Ambulatorios (OPD) del Instituto Central de Investigación y Enseñanza de la Lepra (CLT&RI), Chengalpattu, entre 1987 y 1989. Sólo el 0,05% de los frotis de las unidades de control de la lepra y el 2,49% de OPD de CLT&RI fueron encontrados ser positivos. Ni siquiera un frotis de lepra de tipo indeterminado, tuberculoide o puramente Neurítico de 8263 casos examinados se encontró que era positivo en las condiciones de estudio. Se discute la relevancia de llevar a cabo exámenes bacteriológicos de rutina como una rutina en los programas de control de la lepra en masa.