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Editorial

COST OF SERVICES AND PRICE OF HEALTH

The health status of a population is influenced greatly by the nature and distribution of the area health services, among several other things. Some of the other key factors are nutrition, sanitation, water supply, income, housing and educational levels. The quality of the services, in turn, depends on the budget, closeness of health institutional network, staffing patterns and staff training, extent of supervision over the services and efficiency of corrective actions taken. All the mentioned attributes flow out of the political system in place, the political will, allocation of resources, health and manpower policies and strategies, choice of health technology and, in the final analysis, upon people's cooperation and involvement in taking care of their own health ; a multi-factorial complex indeed.

The complexity of the subject of health of people, who constitute the motor which turns the wheels of economy and prosperity is pretty obvious. Governments, therefore, would like to keep their people healthy, for which health services are the requisite. The cost of health services should be a relatively less important consideration, as long as the economy can tolerate the burden. But, such logic may not be the ground reality in the context of the mentioned complexity of the situation- Nor should facile assessments about health services or solutions suggested to correct their ills constitute the entire truth.

India is a poor country, in dire need of socio-economic development. It is all the more important for us to have good health services in order to have a healthy people lending their hands in socio-economic development and removal of poverty Considerable progress has already been made and lot of the people is much better than what it was at the time of Independence, although it is not always apparent due to the population explosion. The health services infrastructure has enormously expanded, especially in the rural areas where there was next to nothing 50 years ago. Nonetheless, the more we progress in the area of health services, the more we remain where we were, regarding health of the people. True, several indices of health have improved : birth rate declined from 41.7 per 1000 in 1951 to 24.0 per thousand in 1992, crude mortality from 27 to 10 per thousand and infant mortality from 85 per thousand live births to less than 50 per thousand live births, over the same period[1]. It is equally true that several sickness indices have deteriorated : morbidity statistics of hypertension and coronary heart disease, diabetes, cancer, tuberculosis, etc. are really disquieting. Environmental degradation and urban atmospheric pollution have emerged as the new health hazards[2]. Paucity of funds is the most commonly cited reason for our inability to cope with sickness. Are we not paying a high price in the shape of poor health of the people because we do not provide the modest cost of our health services?

Investment in health appears to have received lower priority compared to other sectors of development in our Five Year Plans. For example, the plan allocation for health during the third plan was 2.6% of the total plan outlay; the proportionate share continued to decline slightly in each subsequent plan and reached 1.8% in the seventh plan; the share of housing steadily improved from 1.5% to 3.0% and of agriculture from 12.7% to 16.4% over the same period[1]. Agriculture appears to have done well, housing perhaps languishes, as does health, and poverty

refuses to go away. Gunnar Myrdal's aphorism that sickness leads to poverty which causes sickness may be our problem.

Besides inadequate investment in health, there are other problems which are leading to an imbalance. For instance, there is an unhealthy competition between curative and preventive services in cornering the meagre resources available. Equally disconcerting is the fact that 70% to 80% of the budget gets spent on salaries and allowances of staff, leaving a pittance for medicines and supplies for the people. Can efficient and effective services be expected under the circumstances?

Just because curative services use the modern but highly expensive diagnostic and therapeutic measures, which sponge up most of the meagre resources, is it reason enough to decry and starve them? Curative services meet the felt needs of the people and bring the sick directly back to work and[4] to looking after of their families. Yet, public health services are vital too because these reduce the need for curative services. Ideally, both have to be there, working hand in hand, which means an obligatory meeting of their costs, on priority basis. A disturbing development of late, at least in cities, is that most diagnostic and therapeutic services oblige patients to pay for medicines, ultrasounds and even disposable syringes. Middle class and poor patients often face the Hobson's choice of continuing to be sick or coming nearer to bankruptcy. A situation to be avoided at any cost.

Another dilemma for public health oriented health services is to choose between integrated (horizontal) and specialised (vertical) strategies. Vertical programmes are more efficient because it is easier to supervise and improve them. But they are frightfully expensive, have less coverage of the population and are sometimes not in accord with the felt needs of the people. The national tuberculosis programme is a good example of this difficult choice, especially when cost is as crucial as the ravages of the disease which the programme aims to bring under control.

Health services, at least in this country, have been traditionally regarded as a social service, and health as one of the fundamental rights of the people. This has been the basic philosophy of our planned development, after Independence. Over the years, high technology hospitals and clinics, which offer "five star type" comforts along with modern health care at a very high price have come up, on the lines of the thriving health care industry in the West. A mushroom growth of private nursing homes has taken place in most cities which extract high charges but do not necessarily give high quality of health care. An invidious situation is developing where the elite have access to good but highly expensive services, the poor have somewhat limited access to free services after paying for expensive items and the middle class stand between the two models of health services not knowing where to go. It would appear that a serious reconsideration of the health services is needed in order to place the cost of services in the context of the price people are paying to keep healthy.

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MYCOBACTERIOLOGY LABORATORY - ROLE AND RESPONSIBILITIES

The microbes never fail to surprise. Like terrorists, they go underground, formulate fresh strategies and strike again whenever the conditions are conducive. *Mycobacterium tuberculosis* has been no exception, and taking advantage of our complacency has once again struck the whole world, this time with an armamentarium of drug resistance. Unfortunately, our laboratories, which are the only places that act as sentinels, were taken unawares and most of them did not even possess the expertise to detect the deadly new development.

From the day Robert Koch demonstrated the blue bacilli against the brown background and then cultured them on artificial media, it was. clear that laboratories would play a pivotal role in the diagnosis and control of tuberculosis. However, the advent of X-rays and the effective anti-tuberculosis drugs, like Streptomycin (1944), PAS (1946) and INH (1952) overshadowed the scenario and the bacillus was pushed into oblivion, so much so that even in the highly academic institutes, mycobacteriology became practically non-existent, surviving only on smear microscopy. It was not until two decades ago that the medical community, particularly in developing countries, re-awoke to the fact that the role of mycobacteriology laboratory is not restricted merely to smear examination but is much wider.

ROLE OF THE LABORATORY

A mycobacteriology laboratory plays a major role in breaking the chain of events that lead to the transmission of disease in the community. It begins with education, isolation, identification and drug susceptibility report on the etiological agent and ends with epidemiology, surveillance and research. Timely report on the isolate helps not only in the management of the patient but also initiates the process of contact tracing, detection and prevention of outbreaks. Thus, the laboratories that supply the report in the minimum possible time actually provide the key to the lock that will finally bolt out tuberculosis.

During the past decade, the laboratory diagnosis of tuberculosis has undergone a revolution and the use of modern technology has ensured that the reports on acid fast bacilli examination reach the clinicians within 24 hours, identification of tuberculosis within 10-14 days and drug susceptibility tests within 15-30 days of specimen collection[1]. However, the laboratories in the developing countries can not afford this technology and must make the best of what they have. They must address the task by correctly following the laid down procedures[2] and keep abreast of the simple technical improvements in the conventional methods being introduced and published from time to time. Some of these make the techniques more sensitive while the others help in bringing down the reporting time. Reference may be made to the use of transport cum concentration methods[3,4], introduction of one liquid medium along with one solid medium to increase the sensitivity of isolation, particularly for specimens from extra-pulmonary sources^, and the use of paraffin baiting technique of selectively isolating non-tuberculous mycobacteria[6]. Setting up of direct sensitivity test in smear positive cases has been recently re-evaluated[7] in order to decrease the reporting time. In our laboratory also, we have found an excellent correlation between direct and indirect sensitivity tests. The extent of agreement for all the four drugs (Streptomycin, INH, Rifampicin and Pyrazinamide) was 90% or more in specimens which were (2+ or more) heavily positive for AFB by Ziehl Neelsen smear microscopy. By direct sensitivity test, reports could be given within 6-8 weeks of receipt of the sample giving a minimum advantage of 4-6 weeks over indirect

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sensitivity test.

Smear microscopy is the cheapest method of diagnosing pulmonary tuberculosis but its efficacy is limited only to sputa containing at least 5 x 10^3 tubercle bacilli/ml of the material. This investigation forms the main-stay of our National Tuberculosis Programme and the rationale is that for all practical purposes, smear negative cases are not infectious[8]. Nonetheless, it has been reported[9] and shown in field studies[10] that almost 50% of the cases detected in any epidemiological survey are culture positive and smear negative. Moreover, around 25% of these culture positive subjects are also radiologically negative[10]. Today, with the outbreak of MDR tuberculosis, it has become all the more important to detect the early excretors of the bacilli. Culture has the added advantage of examining the isolate for drug susceptibility, which in addition of the programme operators to patient's benefit, acts as an important epidemiological tool. It draws the attention to the breakdown of good therapeutic practice and delineates the population in which there is a high incidence of drug resistance". It is quite understandable that culture facilities are not feasible at the periphery but it is equally important that the medical officers are made sensitive enough to refer either the patient or his sample to the nearest laboratory which performs the test, particularly if the patient is symptomatic, with cough of more than 2 weeks' duration or is not responding to chemotherapy. The bacilli in the sputum can remain viable at room temperature for 3 days with minimal loss of viability and 7 days with some loss of viability[12] and culture being a very sensitive technique can detect as few as 10 viable bacilli[8] in the specimen.

TEAM WORK

No laboratory can work in isolation. Even the most sophisticated laboratory with fully dedicated workers will be helpless if the clinicians fail to provide good and adequate specimens. Diagnosis of tuberculosis in a patient is a team work where the laboratory and the treating physician must work hand in hand, which is generally not observed. It is a well established fact that 2 consecutive (one spot and one collection) sputum smear examinations are almost equivalent in sensitivity to culture[13], but the laboratories rarely get more than one sample from the suspected symptomatic, Samples like pieural fluid and CSF, once in a while, find their way into the laboratories but tissues are almost never sent. The concept that tuberculosis can be diagnosed in tissues only on histopathology is no longer true and a number of studies have demonstrated that bacilli may be detected on culture even before the histopathological features appear[14,15,16]. Similarly, sputum is probably not the only specimen which can be stained for acid fast bacilli. Fine needle aspiration from tissues yields good results [17,18] even staining of the impression smear from the cut surface of the lymph node has been reported to be a sensitive technique[14]. No doubt the laboratory must win the confidence of the clinicians and give the proper feedback but at the same time clinicians must be aware that no single method is fool proof and all efforts must be made in the interest of the patient and the community to establish the diagnosis in every suspected case of tuberculosis. Any tissue from such cases must be sent for culture as well as histopathology.

LABORATORY RESPONSIBILITIES

An efficient laboratory recognises that delay in diagnosing tuberculosis not only prevents the patient from getting proper chemotherapy but also seriously hampers public health control measures. The patient continues to infect others and creates a pool in the community which is dangerous, particularly if the case is of multi-drug resistant tuberculosis. The laboratory must also realise that it has to remain well versed not only with the techniques but the total disease scenario as well. The picture of tuberculosis with AIDS is totally different from the conventional tuberculosis. Sputum smear examination may be negative in these patients while blood and stools may be more useful specimens.

Non-tubercular Mycobacteria (NTMs) or Mycobacteria Other Than Tuberculosis (MOTT), as they are sometimes called, albeit opportunistic, are also known to cause disease

and are now being reported from India as well[19,20,21]. There are also innumerable reports[22] from the west on the nosocomial outbreaks by these organisms. An efficient laboratory is expected to rise to the occasion and respond by isolating and differentiating between the actual and the pseudo-outbreaks. Unfortunately, not many laboratories today are equipped with the expertise to identify even a few of the known 50 odd mycobacterial species.

Maintaining quality control is another major responsibility of the laboratory. While investigating, the laboratory must ensure that the positivity is not a result of contamination, either at the source or in the laboratory. Contamination at source generally results from bronchoscopes or automated endoscope washers". In the laboratory, the bacteria are often transferred from a positive slide on to a negative slide either during the staining procedures or if the oil dropper is allowed to touch the slide or if the microscope objectives have not been wiped properly after examination of the slide. False positive cultures result if the loop is not properly flamed after inoculating a positive specimen on the culture medium or if the distilled water and other fluids used for concentration method are already contaminated with mycobacteria. New and more sophisticated techniques are not immune to contamination either. Mycobacteria have been transferred among BACTEC broth vials during automated reading in the laboratory[23]. These false positive cultures can only be recognised by molecular typing of the strains and facilities of this type should be available in special reference laboratories. The CDC, Atlanta has helped establish six regional centres in USA for typing of these strains in cases of pseudo outbreaks and cross contamination[14]. In India, Department of Biotechnology, Govt. of India has recently established Mycobacterial Repository Centre at Central JALMA Institute, Agra which has epidemiological characterisation of strains by molecular methods as one of its objectives. It is now for the other laboratories to make use of this facility.

All laboratories must ensure safe environment for their staff. Transmission of tuberculosis results essentially from inhalation of 0.5 pm diameter size aerosoles containing tubercle bacilli. It has been reported that the risk of disease is 2-5 times more in laboratory workers than the general population[25]. Every individual in the laboratory should be so trained that his techniques do not give rise to aresole formation with these potentially dangerous droplet nuclei. He should feel responsible for his owr safety and that of his co-workers. The pride of the laboratory should be in possessing biological safety cabinets with high efficiency particulate air filters rather than air conditioners.

STATUS OF MYCOBACTERIOLOGY LABORATORIES

Based on the suggestions of WHO and IUATLD, Mitchison[26], recommended 3 types of laboratory systems for the developing countries : Peripheral, Intermediate and Central.

1. Peripheral laboratories perform only direct smear microscopy and are generally attached to PHCs or small hospitals having multipurpose laboratories.
2. The Intermediate laboratories do smear microscopy (ZN and fluorescent) and may inoculate culture media for transportation to a Central laboratory. These laboratories may be in district hospitals.
3. The Central laboratories are like reference laboratories fully equipped to do smear microscopy, culture, identification, drug sensitivity and research. They also take up the responsibility of organising training and quality control programmes. These laboratories are part of large general hospitals, academic and research institutes.

The pattern in India more or less conforms to these recommendations. Our peripheral laboratory system, because of the constant vigilance of the national programme, is well monitored but there is altogether no data available on the status of our Intermediate and Central laboratories.

The Centres for Disease Control (CDC), in

1991[27], conducted a survey of their 50 state laboratories and six territorial public health laboratories in order to determine the types of diagnostic technologies being used in each laboratory and whether rapid methods for identification and drug susceptibility testing had been adopted or not. Questions were asked on methods used for acid fast microscopy, routine culture, species identification and drug susceptibility testing along with the manner and length of time taken to report the results. The survey revealed that while 71% of laboratories were using fluorescent microscopy in preference to the conventional basic fuchsin staining, almost the same proportion were still using conventional methods for culture and drug susceptibility testing in preference to rapid radicmetric methods. The survey advocated the use of rapid technology as it considerably shortens the turn around time for laboratory diagnosis and recognition of drug resistance.

It is time we conducted similar surveys in our country to assess the status of our tuberculosis laboratories. While USA and UK have well organised public health laboratory systems, we in India have all kinds of laboratories, not all "contributing" toward the diagnosis of the disease. Smear microscopy has been our main diagnostic method for National Tuberculosis Programme and, therefore, we have an excellent working manual on it, brought out by the Ministry of Health and Family Welfare" but, beyond that, standard operating procedures for culture, sensitivity and identification of the mycobacteria are significantly missing, resulting in the accumulation out of all kinds of incomparable data. It is needless to repeat that tuberculosis today is the leading killer out of all infectious diseases and if we want to control it, strengthening of mycobacteriology laboratories is equally important. We have neglected them far too long. It is not necessary to provide all laboratories with modern equipment but it is imperative to assess their status and bring them all up to a certain acceptable standard. It is equally important to recognise institutes doing good work in tuberculosis, equip them with latest technology, provide manpower and give them the status of regional reference laboratories where cases from the region/state could be referred. Research may or may not be an important component of these laboratories. At the same time, it would also be necessary to have National Reference Laboratories which could take up the responsibilities of performing special tests including drug sensitivity to second line drugs, undertake research and shoulder the burden of assessing the level of quality control in other laboratories.

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LEAVES FROM HISTORY – 2

Wilhelm Konrad Roentgen
(1845-1923)

X-rays were discovered by the German physicist, Wilhelm Konrad Roentgen in Wurzburg (Germany) on 8 November 1895. The discovery was made while investigating the effects of cathode rays (a stream of electrons emitted from the cathode or negative electrode of a vacuum glass tube or one filled with gases travelling through the gap towards the anode or positive electrode, by the passage of electricity). Although many scientists had studied the properties of cathode rays, Roentgen found that a surface coated with a barium salt would shine (fluoresce) and photographic plates would become fogged if placed in the vicinity of the vacuum glass tube, during the experiment. He correctly deduced that invisible radiations had come out of the tube. He, therefore, covered the tube with black paper and repeated the experiment but the invisible radiations penetrated the black paper as wells as some other impediments. He named the yet unknown and invisible rays as X-rays.

Experimenting further, Roentgen found that X-rays passed through the flesh of his hand but were stopped by the bones and the wedding ring on the finger. His joy knew no bounds. The earliest application of x-rays was, therefore, in the field of medicine - both diagnosis and therapy - for locating bone fractures and diseases of bones, metal, foreign bodies deep inside the flesh and for treating cancers. The use of X-rays revolutionized medical and surgical techniques. For diagnosis of tuberculosis. X-rays became the sheet-anchor. X-rays also led the research into the structure of atom.

In 1901, Roentgen won the first Noble Prize in Physics for discovering X-rays. He was then working as the Professor of Physics at Wurzburg University. For long years, X-rays continued to be called Roentgen rays, in his honour.

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APPLICATION OF POLYMERASE CHAIN REACTION (PCR) FOR DETECTION OF M. *TUBERCULOSIS* IN SPUTUM SPECIMENS*

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Summary : In all, 55 patients were divided into cases and controls on the basis of clinical history, physical examination, haematocrit values, radiographic presentation, sputum smear as well as culture for AFB and pyogenic bacteria.

PCR was found to be positive in all the AFB smear and culture positive cases, whereas it was negative in all the controls. PCR was found to be 100% specific and 83.35% positive in smear negative and 62.50% in culture negative cases.

Key words: Polymerase chain reaction, Tuberculosis case-finding.

INTRODUCTION

Confirmation of the diagnosis of tuberculosis is still a challenging problem. Conventional methods available for diagnosis namely, tuberculin test, radiological examination, and sputum smear microscopy have their own limitations. Sputum smear microscopy requires 10,000 to 1,00,000 organisms/ml and specificity is not always certain[1]; in less bacterial load conditions, sensitivity varies from 25-95%[2]. Culture is more sensitive and presently the yardstick for diagnosis, but the time required and frequent negative results in paucibacillary specimens are important limitations[3]

The advent of recombinant DNA technique has led to a better understanding of the genomic structure of *Mycobctcterium tuberculosis. A* new generation of rapid methods based on molecular biology techniques has emerged and will eventually lead to direct detection and identification of mycobacteria in clinical specimens[4]. Based on the knowledge about the specific gene sequence of M. *tuberculosis,* various gene probes targeting DNA & RNA have been developed. Further, several gene amplification techniques (PCR or isothermal) have been developed[5-10], which can detect 1-10 bacilli/ml[11] and results are available in about 12 hours onward[3]. Though a variety of PCR methods for detection of M *tuberculosis* have been developed, the experience about actual application is limited. The application of IS6110 sequence suggests differences within Indian and western strains[12]. A big proportion of the Indian strains have been reported to have no or limited sequences. The overall experience with the technique developed abroad has been limited in Indian set ups. This study reports the application of a PCR technique developed in India[13] for use in sputum specimens for detection of M. *tuberculosis.*

MATERIAL AND METHODS

Sputum specimens obtained from 55 patients (35 cases of pulmonary tuberculosis and 20

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controls) of various age groups and belonging to both sexes were included in this study. The patients were classified into the following groups:

(A) Definitely tuberculous - on the basis of clinical and radiological findings, sputum smear and culture of *Mycobacterium tuberculosis*

(B) Probably tuberculous-sputum negative but having suggestive history, clinical and radiological evidence of tuberculosis

(C) Non-tuberculous - those having chronic obstructive airway disease (COPD), empyema, carcinoma lung, pneumonia, interstitial lung disease, hydatid disease of lung and bronchiectasis

Early morning sputum specimens were collected in properly sterilised disposable containers and kept at -20°C. Transportation of samples was done on the same day or as soon as possible to avoid any harm to bacilli.

All the sputum samples were subjected to routine microbiological examination by initial culture of one part on Mueller-Hinton medium. The other part was decontaminated by modified Petroff's method[14]. The final suspension was divided into two parts : one part was subjected to microbiological examination (smear for AFB and culture on LJ media)[15] while the other part was processed for extraction of nucleic acids[8,9].

For the extraction of nucleic acid, following steps were followed : About 1-5 ml of decontaminated suspension was taken into microcentrifuge tube and heated for 20 minutes at 80°C to kill mycobacterial cells. The suspension was centrifuged for 5 minutes at 10000 g and supernatant was discarded. The pellet was suspended in 500 µl TE buffer by vortex; 50 ul of 10 mg/ml lysozyme was added, vortexed and incubated for 1 hour at 37°C. Then, 70 ul of 10% sodium deodecyl sulphate (10% SDS) on 6 µl of 10 mg/ml proteinase-K was added. After vortexing, the sample was incubated for 10 minutes at 65°C, 100 ml of 5 M-NaCl solution was added and vortexed; 80 µl of CTAB/NaCl solution was added next and vortexed until the contents became white, and then incubated for 10 minutes at 65°. -Approximately an equal volume (0.7-0.8) of chloroform isoamyl alcohol (24 : 1) was added, vortexed for 10 sec and centrifuged in a microcentrifuge at room temperature for 5 minutes at 10000 g. The aqueous supernatant in 180 ul amount was then transferred to a fresh microcentrifuge tube and 0.6 volume of isopropanolol was added to precipitate the nucleic acids. The precipitate was kept for 30 minutes at -20°C, centrifuged for 15 minutes at room temperature at 10000 g, DNA pellet was washed with 70% cold ethanol to remove residual CTAB/NaCL and subjected to a respin for 5 minutes. The supernatant was removed and the pellet was left to dry at room temperature for 5 minutes, redissolved in 20 ul 0.1 TE buffer and stored at -20°C

Amplification of DNA (PCR) was done by the method and primers described by Khandekar *et* al/[13] in a thermal cycle machine (PTC-100 MJ Research). For each cycle, the conditions of denaturation, annealing and polymerisation were : 94°C for 1 minute, 55°C for 1 minute and 72°C for 2 minutes, respectively. Amplicons were analysed by gel electrophoresis and ethidium bromide staining, southern transfer[16], and molecular hybridization with digoxigenin lavelled PCR amplified probes. The presence of 169 bp fragment was taken as proof of identity[17]. The results were analysed in the context of clinical, radiological, hematological investigations as well as treatment status of patients.

FINDINGS

All the patients were having more than one symptom : common presentations were fever,

Table 1. Clinical Profile of Patients

Symptoms	Cases		Controls	
	No.	%	No.	%
Cough	22	62.85	15	75.00
Fever	24	68.57	9	15.00
Haemoptysis	6	25.71	3	18.57
Breathlessness	18	65.71	12	20.00
Chest Pain	11	31.42	4	15.00
Others	27	76.00	17	85.00

Patients had multiple symptoms

Table 2. distribution of Controls According to Clinical Diagnosis and Culture Result

Diagnosis	No.	Bacterial growth obtained
Hydatid disease of lung	1	—
Empyema	2	2 *(Pseudomonas* 1 *and Streptococcus Pyogenes* 1*)*
Interstitial lung disease	2	—
Chronic obstructive pulmonary disease	5	—
Carcinoma lung	4	—
Pneumonia	1	1 - (H. *influenzae)*
Bronchiectasis	5	*5 (2 Streptococcus pyogenes,* 2 *Klebsiella and* 1 *Pseudomonas)*
Total	20	8

breathlessness and cough followed by chest pain, haemoptysis (Table 1)

Among the 20 controls, growth of pyogenic bacteria (done on Mueller-Hinton medium) was obtained in 5 bronchiectasis, 2 empyema and 1 pneumonia cases, as shown in Table 2.

Among the 35 pulmonary tuberculosis cases included-in the study, 17 (48.57%) were sputum smear positive for AFB and 18 (51.42%) were smear negative. While PCR positivity among smear positive cases was 100%, only 83.33% of the smear negative cases were PCR positive (Table 3). All the controls were PCR negative.

Of the 35 cases studied, 27 (77.14%) showed growth on LJ medium and were confirmed as *M, tuberculosis.* The PCR positivity was 100% in culture positive cases and 62% in culture negative cases.

DISCUSSION

Smear examination for Acid Fast Bacilli (AFB) is an important test for diagnosis of tuberculosis. Sputum smear for AFB in this study was positive in 48.57% of the 35 patients diagnosed as tuberculosis cases and all of them were PCR positive. In the remaining 18 sputum smear negative cases, PCR positivity was seen in 83.33%. The study suggests that PCR can be used to significantly enhance the diagnosis of pulmonary tuberculosis. In smear negative cases, culture is the gold standard for confirming the diagnosis of tuberculosis. In this study, 27 (77.14%) of the 35 case were culture positive. All the culture positive cases were PCR positive. Out of the 8 culture negative cases, PCR positivity was seen in 5 (62.5%). The 3 cases who were PCR negative were also sputum smear and culture negative : 2 cases had presented with hemoptysis and one had pyopneumothorax, who had been defaulters and had history of irregular anti-tuberculosis therapy. Our study confirms the usefulness of the system developed by Reddi *et al*[8] and evaluated later by Khandekar *et al*[13]. The technique was found to be 100% specific and highly sensitive (100% in smear and culture positive cases, 83.35% in smear negative cases

Table 3, Distribution of patients according to PCR and sputum smear results

Smear for AFB	Casses			Controls		
	No.	PCR +	%	No.	PCR +	
Positive	17	17	100.00	0	0	0
Negative	18	15	83.33	20	0	0

Table 4. Distribution of patients according to PCR and mycobacterial culture results

Mycobac-	Cases			Controls		
Culture	No.	PCR +	%	No.	PCR +	%
Positive	27	27	100.00	0	0	0
Negative	8	5	62.00	20	0	0

and 62.5% in culture negative cases). In general, 66.7% to 98% sensitivity of different PCR techniques for the detection of M. *tuberculosis* has been reported.

PCR is now accepted as a highly sensitive technique, but the main drawback appears to be false positivity due to contamination and also biological factors like inadequately tested primers[18]. In our study, no false positivity was observed while specificity was 76%". It appears that strict procedure of sample collection and laboratory assay can significantly reduce the false positivity.

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TREATMENT DYNAMICS AND PROFILE OF TUBERCULOSIS PATIENTS UNDER THE DISTRICT TUBERCULOSIS PROGRAMME (DTP) - A PROSPECTIVE COHORT STUDY*

Sophia Vijay[1], V.H. Balasangameshwara[2] and N. Srikantaramu[3]

Summary: A prospective cohort study among new smear positive pulmonary tuberculosis cases initiated on short course chemotherapy was undertaken in Kolar district of Karnataka. The objective was to study the treatment outcome and patient profiles of treatment adherent (completed) and non-adherent (tost) patients. Data collection was done through interviews based on pretested structured schedules, soon after diagnosis and at the end of treatment. Of the 224 available patients in the cohort, 120 (53.6%) completed treatment, 68 (30.4%), were lost, 29 (12.9%) died and 7 (3.1%) migrated outside the district.

Persistence of cough at the end of treatment was significantly more among lost patients. The general profile of the patients, relating to socio-economic, demographic, literacy and employment details did not differ significantly between the 2 subgroups. However, the treatment related factors like distance from health centre, Knowledge of treatment duration, advice on treatment given after diagnosis, payments made to staff and for tonics were significantly more among patients tost to treatment. Raising of money to meet the expenditure, particularly through selling of valuables too was proportionately more among lost patients. Defaulter retrieval action was not taken for more than 85% of all eligibles, both among completed and lost groups.

Key words: DTP, Profile of TB patients.

INTRODUCTION

Finding infectious cases of pulmonary tuberculosis and their cure hold the key to effective control of tuberculosis, both in developed and developing countries[1]. During 1996, India accounted for estimated 9,35,134 sputum smear positive cases, the highest number for any individual country in the world[2]. Of these, an estimated 31.1% cases were reported to have been detected and initiated on treatment; 0.7% with Directly Observed Treatment Short Course (DOTS) under the Revised National Tuberculosis Control Programme (RNTCP) and the rest under the National Tuberculosis Programme (NTP)[2]. The cure rate for those treated under DOTS strategy was 75.5%, for the year 1995[2]. During the same period, the treatment completion rate for those treated under NTP was 58% for those put on Short Course Chemotherapy (SCC)[3]. The revision of NTP, by the incorporation of DOTS strategy is obviously a better proposition but operationally, the desired goal of >85% cure rate is demanding[4,5]. Until the phased implementation of RNTCP covers the whole country, a majority of the patients would be treated under the NTP. Ensuring adherence to treatment has long been acknowledged as the weakest component of the NTP in India, being responsible for its low treatment efficiency[6]. Several studies have attempted to investigate the factors responsible for non-adherence to treatment[7-10]. The crucial role of treatment organization in ensuring treatment adherence has been highlighted in one prospective study conducted in an urban TB clinic with standard drug regimens[7]. Recent

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studies with SCC were retrospective in nature, seeking information through interviews at the end of treatment[6-9]. The treatment behaviour of patients is complex and dynamic : Several factors may shape the behaviour till the final outcome.

A cohort of newly diagnosed smear positive cases initiated on SCC in a DTP was, therefore, followed up prospectively to study the dynamics of patients' treatment behaviour, from diagnosis till the final treatment outcome. The specific objectives were to study :

Treatment outcome including persistence of symptoms and bacteriological status.

Profile of treatment adherent (completed treatment) and non-adherent (lost) patients to identify the probable causes of non-adherence.

Reasons for stopping treatment by patients "lost" to treatment.

MATERIAL AND METHODS

Study Design and Area : The prospective cohort was taken in Kolar district of Karnataka because it represents an average Indian district in terms of area and demographic characteristics, a reasonably good case-finding activity and for operational convenience. The centres selected were the District Tuberculosis Centre (DTC), Kolar, and all the eight Peripheral Health Institutions (PHIs) offering SCC to the new smear positive patients. Based on the data available from the previous quarterly reports of that DTP[9], the intake period was prefixed as January to September 1997 to get at least 200 new smear positive patients. Availability of adequate supply of SCC drugs in the selected centres was ensured throughout the study period. Besides, availability of Medical officer, Pharmacist/ Treatment Organizer, Microscopist, Laboratory Technician with a fully functioning laboratory was also ensured.

Study Cohort : All new smear positive patients aged >15 years, initiated on SCC regimen R_A 2EHRZ/6T(E)H - from 1.1.1997 onwards in the selected centres-formed the study cohort. They were followed up prospectively through the treatment period. These patients were expected to make a total of 10 drug-collections (fortnightly in the intensive phase of two months and monthly thereafter) during the treatment period of eight to nine months from the respective treatment centres, as per the DTP guidelines,

Data Collection : Data collection was done by administration of a pre-tested structured schedule, through patient interview, by experienced social investigators. Information regarding new smear positive patients, diagnosed and initiated on treatment was collected through scrutiny of the centres' records every month. All these patients were then contacted at their residence and interviewed after a briefing given regarding the purpose of the visit. Patients' demographic details, educational and socio-economic status, particulars .of diagnosis and treatment were recorded on the structured interview schedule.

All the available patients were subjected to a final interview immediately after completion of their prescribed treatment period irrespective of their treatment adherence status. Details regarding their treatment regularity, subsequent treatment taken, family and social support extended, patient-provider interaction and financial loss incurred due to disease were collected. The interviewers were not aware of the treatment adherence status of the patient prior to the final interview. One spot sputum specimen was collected from these patients at the time of interview for smear microscopy at the centre as well as the National Tuberculosis Institute laboratory. The recall period for both initial and final interviews did not exceed two months. Proxy interviews were not permitted.

Data analysis: Analysis was done using Epi Info 6.1 and SPSS software package. The statistical tests used for comparison of proportions and distributions were Chi square and Mann Whitney U (MW Test).

Definitions

Completed Treatment: Patients collecting eight or more drug collections out of 10, i.e. > 80% of the total collections due

without interruption of >1 month within the prescribed duration of treatment.

Lost; Patients interrupting treatment for *>l* month and making < 8 of the total 10 collections due, i.e. <80% before stopping treatment.

Subsequent treatment: Treatment taken elsewhere than the centre where treatment was initiated by patients who were "lost" to treatment.

FINDINGS

During the intake period, 279 new smear patients were diagnosed in the nine centres. Among these, 55 (19.7%) could not be contacted due to either wrong address or migration of the patients outside the district. Hence, they were excluded from the cohort (Fig. 1).

TREATMENT OUTCOME (SYMPTOM AND BACTERIOLOGICAL STATUS)

Among the available 224 patients, whose final treatment outcome could be ascertained, 120 (53.6%) "completed treatment," 68 (38.4%) were "lost" to treatment while 29 (12.9%) were reported "dead" and 7 (3.1%) had "migrated" outside the district during the treatment period,

Bacteriological Status : Considering the bacteriological status and treatment adherence, the proportion found smear negative at the end of treatment *("cured")* was 47.3% for the entire cohort (Fig. 1) but was 88.3% among the "completed group" of 120 patients; 45 (66.2%) of the patients "lost" to treatment were also found to be smear negative. Analysis regarding the initial and subsequent treatment of these 45 patients revealed that 22 had received subsequent treatment (7 had also received ≥4 collections during their initial treatment). Of the remaining 23 who did not receive any subsequent treatment, 14 had made ≥ 4 collections during the initial treatment. Thus, 36 of 45 (80.0%) "lost" patients who were sputum negative at the end of treatment period had either completed the intensive phase of treatment (>4 collections) during the initial treatment or had received subsequent treatment (Table 1). 51.5 % of the 68 "lost" patients had stopped treatment before the end of intensive phase at the centre,

Subsequent treatment received by "lost" patients : Of the 68 patients "lost" to treatment at the centres 27 (79.4%) had approached either DTC (10) or sanatorium (17) and received subsequent treatment for various durations.

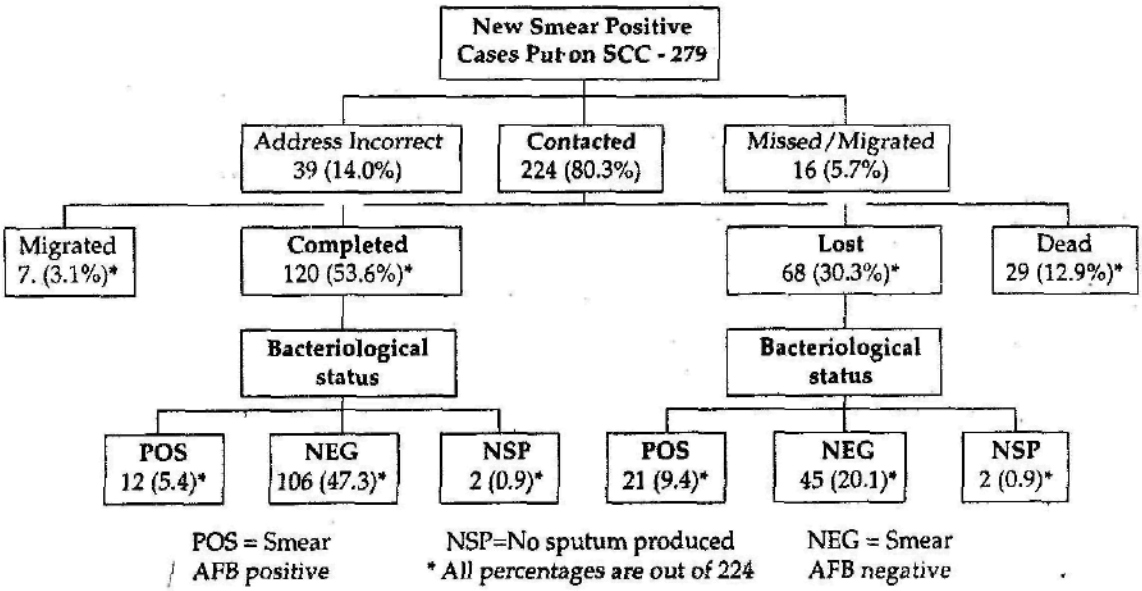

Fig. 1. Study Cohort (January-September, 1997) with treatment outcome

Reasons stated by 31 of these 34 patients for changing the source of treatment were accessibility (14) (in terms of distance/timing cost of service) or better treatment given by the second centre (9) or as advised by the previous centre (8) (Not in Table).

In all, nearly half of the patients put on SCC and followed up till the end of treatment were cured. The cure rate was 88% among those who completed their treatment satisfactorily; It was 66% even among those who got "lost" to treatment.

Symptom status : Cough, either alone or with other cardinal chest symptoms was the predominant symptom at the time of diagnosis, as majority of the patients (95.7%) had cough for >2 weeks. However, at the end of treatment, 91 patients (48.4%) had persistence of cough. This proportion was (60.3%) among "lost" patient, significantly higher compared to the (41.7%) in "completed" group of patients (χ^2= 5.80, p = 0.016). Irrespective of the treatment adherence, among those who remained sputum positive, 75.8% had persistence of cough compared to 43% among those who were negative at the end of treatment period (χ^2= 11.63, p = 0.00006) (Table 2).

PROFILE OF PATIENTS

The 187 patients interviewed satisfactorily out of 188 available were analyzed for patients who completed treatment (120) and those who got lost to treatment (68), to identify differentiating factors. Provision was made for more than one response to some questions.

Table 2. ***Distribution of Lost patients according to initial & subsequent treatment taken and result of treatment***

Initial	Subsequent treatment				Total
Number of collections	Taken = 34		Not taken = 32*		N= 68
	Treatment result		Treatment results		
	Positive	Negative	Positive	Negative	
≤3	8	15	3	9	35
4-7	4	7	6	14	31*
Total	12	22	9	23	66*

*Excludes 2 who could not produce sputum.

Table 2. Distribution of cases who had persistence of cough at the end of treatment, according to sputum smear status

	Lost cases		Completed group		Total	
Sputum smear	No.	With cough No. (%)	,No.	With cogh No. (%)	No.	With cough No. (%)
Positive	21	16 (76.2)	12	9 (75.0)	33	25 (75.8)*
Negative	45	25 (55.6)	106	40 (37.7)	151	65 (43.0)*
NSP	2	0	2	1	4	1
Total	68	41 (60.3)**	120	50 (41.7)**	188	91 (48.4)

* χ^2 = 11.63, P = 0.0006 NSP = No sputum produced
** χ^2 = 5.80, p = 0.016

Table 3. General profile according to treatment adherence

	Lost group	Completed group
Demography :		
Mean age	41.8Yrs	40.9 Yrs
Sex ratio (M : F)	1:0.4	1 :0.4
Employment and economic status :		
Mean household size	5	6
Mean no. of members employed	2	2
Mean monthly household income	Rs. 1898	Rs. 2211
Mean household expenditure	Rs. 1274*	Rs. 1602*
Mean per capita income	Rs. 394	Rs. 403
Education :		
Literacy	50.7%	62.5%
Social data:		
Habits (drinking, smoking, etc)	92.5%	83.3%
Involvement in social **activities**	17.9%	25.8%

***p = .014**

Of the "lost" to treatment patients, who had been found cured, 80% had either completed the intensive phase of medication satisfactorily or had received additional treatment from elsewhere subsequently.

General profile : The variables studied were demography, i.e. employment and economic status, literacy and social data (Table 3).

The mean age of "lost" patients was 41.7 ± 13.21 years, median age 41.0 years, range 17-70 years); for "completed" group 40.8 ± 15 years, median age 40.5 years, range 15-76 years. The age sex distribution did not reveal significant differences.

Income, as stated by the patient, generated through employment, data on income through other sources and assets will be analyzed separately. The house-hold size, number of members employed, mean monthly income and mean per capita income did not show significant difference between the two groups. However, the mean monthly expenditure was more among the "completed" group (M-W test p = 0.01). The frequency distribution of the overall per capita income revealed that 88.2% of the patients (lost-91%, Comp 86.7%) had per capita income of $\leq$ Rs.600 (range Rs 60. - 2500).

Literacy among the two groups did not differ, nor did habit of drinking or involvement in social activity (member of village panchayat, bhajan/youth mandal, etc).

Overall, the general profile of "lost" and "completed" groups of patients did not differ significantly except for the mean monthly-expenditure being more among completed group.

Treatment Related Profile: The parameters considered were distance from treatment centre, patient - provider interaction, family and social support and overall financial repercussions due to the disease.

Persistence of cough at the end of treatment period was 40% among those who had completed their treatment satisfactorily compared with 60% among those who had been "lost" to treatment.

Distance From Treatment Centre : The mean distance travelled by the patients to the centre for drug collection was 20 km for "lost" patients and 16 km for "completed" group, which was significantly different (M.W. Test, p = 0.0319). While 40% of the patients in "completed" group travelled a distance of less than 5 km, a majority of "lost" patients (83.6%) had to travel $\geq$ 5 kms. Further, 61% of the "lost" patients had to travel $\geq$15 kms

whereas 42.5% of the completed group did so ($\chi^2 = 5.29$, p = 0.02) (Table 4).

Patient Provider Interaction *:* Factors like knowledge about tuberculosis, information given by centre staff, advice given to the patient on diagnosis and treatment thereafter, were considered as a part of patient-provider interaction. Payments demanded by the centre staff for investigation and treatment were also taken into account.

Only 3.7% of the patients had correct knowledge about the cause of the disease. More than 85% of the cohort was aware that the disease could be cured with regular treatment. Despite this, the proportion of correct responses to duration of treatment was significantly lower (55.2%) among the "lost" group ($x^2 = 5.57$, p = 0.02) (Table 5).

Irrespective of adherence to initial treatment, 80% of those who had positive sputum smear at the end of treatment had persistence of cough compared with 40% even among those who had been cured. Therefore, retreatment must be guided by persistnet positive smear and not persistent cough.

Table* 4. *Distance to health centre according to treatment adherence

	Distance to treatment centre (Kms)				Total
	0-4	5-14	15-24	>25	
Lost*	11 (16.4)@	15	18	23 (83.6)	67'
Com-pleted**	48 (40.0)@	21	16	35 1 (60.0)	120
Total	59 (31.6)	36	34	58 (68.4)	187

() percentage @ x^2=10.01, p = .0015600

* mean distance travelled 20 km, median 18 km (range 1-65 km)

** mean distance travelled 16.5 km, median 9.5 km (range 1-75 km)

1. No information for one case

Majority of the patients had been given additional information. However, undue emphasis was given by the staff on special nutritious diet and rest as essential components of treatment (Table 5).

Overall, 86.5% of the patients (including those lost) who were eligible for defaulter retrieval actions stated that the centre staff took no action.

In all, except in 12 of 187 cases, the diagnosis was revealed to the patient by the staff. However, advice to continue their treatment at the centre, after their diagnosis, was given to 51 (71.6%) and 111 (92.0%) of the "lost" and "completed" patients respectively. The rest were asked to go to DTC/sanatorium/ Bangalore for treatment, even though the facility for treatment was available at the centre itself.

More than one-third of patients, "lost" and "completed", stated that they had paid for the investigations done at the centre. Also, 43.3% and 20.0% of the lost and completed patients

Table* 5. *Patient - provider interaction *according to* ***treatment adherence***

	Lost N = 68	Completed N = 120
1. Knowledge		
i. Cause of TB	3 (4.5)	4 (3.3)
ii. How is TB cured	58 (86.6)	112 (93.3)
iii. Treatment duration	37 (55.2)*	88 (73.3)*
iv. Treatment regularity	61 (91.0)	112 (93.3)
2. Information given by staff		
i. Special Diet		
ii. Rest essential	56 (83.6)	111 (92.5)
iii. Precaution while coughing	47 (70.1) 46 (68.6)	90 (75.0) 84 (70.0)
iv. Sputum disposal	41 (61.2)	87 (72.5)
3. Advice received		
i. Diagnosis revealed to patient	61 (91.0)	114 (95.0)
ii. Treatment from other sources/No advice	16 (23.9)*	9 (7.5)**
4. Payment for		
i. Investigation	25 (37.3)	41 (34.2)
ii. Treatment (drugs)	29 (43.3)@	24(20.0)@

[4] χ* = 5.57; p = 0.018; @χ^1 = 10.36; p = 0.0013;** χ^2 = 8.6; p = 0.003; () = percentage

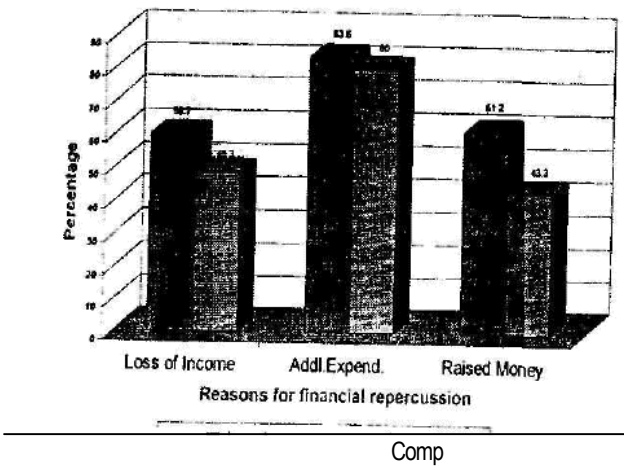

Fig. 2 Financial repercussion due to illness (Lost 68 and Completed = 120)

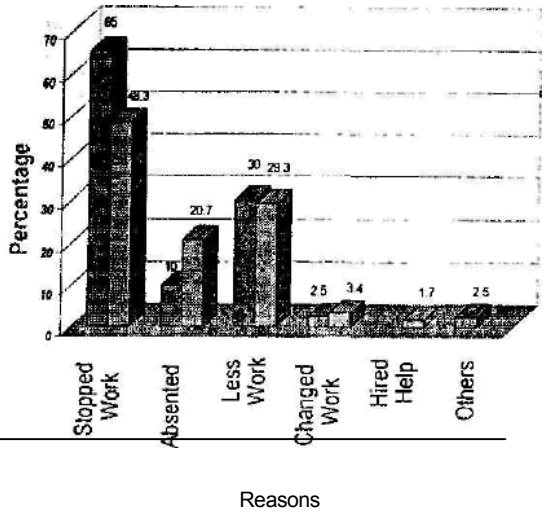

Fig. 3 Reasons for Loss of Income (Lost = 40 and Completed = 58)

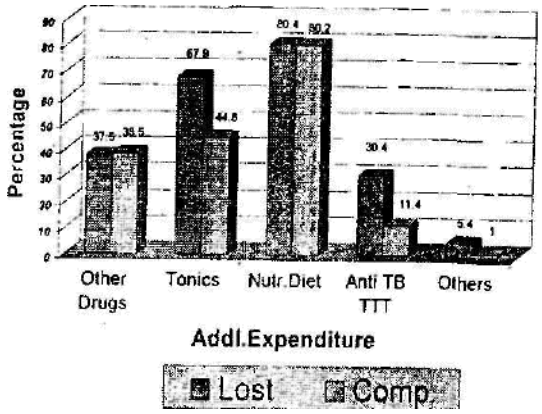

Fig. 4 Reasons for additional expenditure incurred (Lost = 56 and Completed = 96)

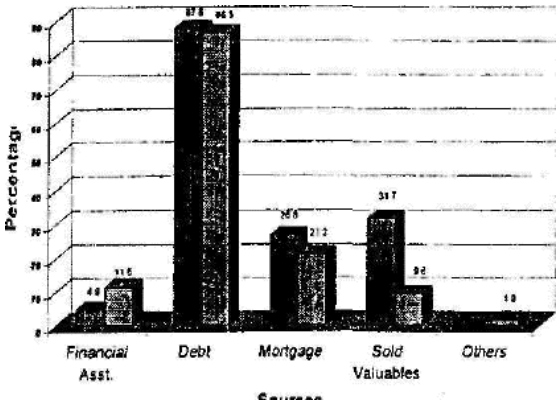

Fig. 5 Sources for raising money (Lost = 41 and Completed = 52)

respectively reported that the centre staff expected money for drugs (X^2 =10.36, p = 0.001) (Table 5).

Family and Social Support Extended : **All except one patient had disclosed the diagnosis of tuberculosis to their family members and 160 (86%) to even friends and neighbours. While in a majority of the cases, the family members exhibited a supportive attitude, only three patients among the "lost" group had faced rejection. Overall, 42.8% of the patients received co-operation of their family members in treatment either by reminders or by supervising the drug consumption. This proportion among "lost" and 'completed" groups was 34.3% and 47.5% respectively**

Financial repercussions of tuberculosis : Overall, 98 (52.4%) patients (lost - 59.7% and completed - 48.3%) stated that they had incurred loss of income (Fig. 2) due to stopping work-less work or frequent absenteeism etc. (Fig. 3). The proportion stopping work among lost (65%) and completed (48.8%) groups did not differ significantly. However, the financial loss was higher among the "lost" patients. (Mean Rs 1758, Range : Rs 300-9000) compared to the completed group (Mean Rs 962, Range : Rs 450-3000) [MW Test p = 0.05] (not in Table).

Besides, 152 (81.3%) patients (lost 83.6%, completed 80.0%) had incurred additional expenditure (Fig. 2) mainly to supplement the diet (Fig. 4). A higher proportion of "lost" patients had spent on tonics (67.9%) (MW Test

Table 6. Factors showing significant differences between "lost" patients and "completed" treatment in respect of non-adherence to treatment

	%	%	level ('p')
Distance to centre > 5 km	83.6	60.0	0.001
Knowledge of treatment duration	55.2	70.0	0.018
Advised to get treatment from other sources	23.9	7.5	0.003
Payment made to staff	43.3	20.0	0.001
Incurred expenditure on ATT	30.4	11.4	0.003
Incurred expenditure on tonics	67.9	44.8	0.043
Raised money to meet expenditure	61.2	43.3	0.03
Sold valuables to raise money	31.7	9.6	0.01

p= 0.04), and on anti-tuberculosis drugs (30.4%) (MW Test p = 0.004) compared to those who completed treatment (Fig. 4). The mean amount spent on nutritious diet by the "completed" group (Rs 1503, range - Rs 100-8000) was significantly higher than by the "lost" group (Rs 975, range - Rs 100-5000) (MW Test p = 0.017) (not in Table).

Nearly, half of the patients (lost-61.2% & completed-43%) had raised money through different sources to meet the loss of income and additional expenditure incurred. This proportion among "lost " patients was significantly higher (x^2= 4.8, p = 0.03) (Fig. 2). A majority of the 93 patients had raised money by incurring debts, with no difference between the two groups. Moreover, a higher proportion of "lost" patients compared to those "completed" had resorted to selling of valuables (MW Test, p = 0.01) (Fig. 5).

Factors showing significant differences between the two groups

The factors which showed significant difference between the two groups, for non-adherence to treatment, have been listed in Table 6. Highly significant differences were seen with respect to distance from Centre, advice to take treatment elsewhere and payment for anti-tuberculosis drugs.

REASONS FOR STOPPING INITIAL TREATMENT

All the "lost" patients were asked to give the reasons for non-adherence to treatment. Totally, 58 of 68 patients responded to this question. Provision was made for 3 responses and 23, 26 and 9 patients gave one, two or three reasons respectively. These reasons were categorized as provider, patient or treatment related (Table 7). In all, 51 (87.9%) of the "lost" patients stated reasons related to the treatment organization (provider) for stopping treatment. Among them, 34 stated distance from the centre or

Table 7. Reasons for stopping treatment (N ~ 58)*

Reasons	Res-pon-ses	No. of "lost"	%
I. Provider related		51	87.9
1. Inaccessibility of centre	34		
i. Distance (23)			
ii. Cost of service (8)			
iii. Staff behaviour (2)			
iv. Timing (1)			
2. Inadequate instructions**	11		
3. Advised togo elsewhere	6		
II. Treatment related		41	70.7
i. Drugs did not suit	24		
ii. No improvement	11		
iii. Took treatment elsewhere	6		
III Patient related		10	17.2
i. Domestic problem	5		
ii. Loss of wages	1		
iii. No time	4		

* Nine patients did not respond to the questions
** "disappearance of symptom" and "identity card lost.

demands for payment as the main reasons. The patient related reasons were given by 10 (17.2%) patients, while 38% of the patients reported that the drugs did not agree with them (Table 7).

DISCUSSION

One of the main factors which decides effectiveness of chemotherapy is the cure rate resulting from treatment given under 100% compliance[11]. The word 'adherence' has been used in this paper, instead of compliance, as it reflects the active role of the patient in self-management of treatment[12]. A prospective cohort study was undertaken to highlight some of the important aspects related to treatment adherence, using SCC.

The cure rate of 47.3% for the cohort of 224 cases, as observed in this study was unacceptably low compared to the desired cure rate of >85%, as emphasized by the WHO[5]. Obviously, high proportions of "lost" (31,4%) cases and dead (13%) were the major contributing factors for a low cure rate. In an established DTP, a death rate of 13% is a matter of concern.

If all the 279 patients diagnosed in the cohort period were considered for the treatment outcome, the cure rate would be 38% Further, if 100% drug collection were taken as the criterion for treatment completion[13], the number completing treatment would be 97, smear negative among them 87, and the cure rate, then, would further go down to 31.8%. The incorrect addresses (14%) and migration (8.8%) were found responsible for low cure rate in previous studies[7] as well. While migration is a natural phenomenon, the DTP could have ensured the continuity of treatment of migrating patients by transfer of cards to the respective districts. The proportion of incorrect address recording could be brought down by effective initial communication with the patients.

It was encouraging to note that a substantial proportion of lost patients (66%) were smear negative at the end of the treatment period. It is necessary to know the stability of the smear negativity so achieved.

That 27 out of 68 lost patients were still within the purview of the programme, getting subsequent treatment from the DTC and Sanatorium on the advice of the PHI doctors. **suggests that referral system, as recommended in the programme[13], should be followed strictly. These patients, then, would not have been considered as "lost".**

Persistence of cough was significantly more among lost patients compared to the completed group. This could be a factor for patients to stop treatment, as "no improvement in health" was stated by 11 lost patients as the reason for stopping the treatment. Premature stoppage of treatment could have also resulted in the persistence of symptoms. Persistence of cough **among 37.7% of cured patients needs to remind the providers to avoid unnecessary retreatment in the absence of smear positvity[14].**

Search for factors responsible for treatment non-adherence through the comparison of patient profiles did not reveal significant differences in socio-economic & demographic characteristics, as suggested in earlier studies". Such variables, however, are not inherently casual for non-adherence[12].

A few treatment related parameters showed significant differences between the "completed" and "lost" patients (Table 6). Distance to health centre plays a key role in case-finding process[15]. In an ambulatory treatment service, needing repeated visits for drug collection, distance certainly assumes a greater significance, as observed in this study. Implementation of only 11% of the total PHIs under SCC in the whole district may have been a major contributing factor. In addition, significantly more of the "lost" patients had been advised to take treatment form other sources, like DTC/Sanitorium, which were not conveniently located with respect to distance suggests an improperly functioning referral system.

Emphasis on treatment duration and regularity of treatment is an essential component of motivation to ensure treatment adherence. The fact that significantly fewer of "lost" patients were aware of the prescribed duration of treatment indicates the need for retraining of the centre staff on the proper motivation of patients. This recommendation is

strengthened by the observation that wrong information had been given on special diet and rest, which are commonly not recommended in the treatment policy[13].

At government health centres services are supposed to be free of cost[13]. It is inconceivable to accept the statement made by patients regarding payment they made for investigations and drugs. The payment to staff, if made, may have influenced the patients to stop the treatment as a higher proportion of "lost" patients had to pay for drugs. Besides, there is a tendency among the patients to interrupt or reduce their routine work, with loss of income to the patients. The emphasis given to rest by the centre staff could have further encouraged these patients to stop work.

It is a common practice to provide nutritious diet to sick people. Additional expenditure was incurred by 81% of the patients to supplement their diet. The mean expenditure on nutritious diet was more among the "completed" group, probably due to their being longer on treatment compared to the "lost" patients who had given up treatment. Considering that the advice on rest and nutritious diet, was given by centre staff, there is strong need to wipe out these prevailing social concepts by education and a tactful patient-provider interaction. Demand from patients often compels the doctors to prescribe tonics, which increases the expenditure incurred by the patient. Both the providers and patients need to be educated and convinced that the use of tonics, additional nutritions food and rest are unneccessary.

As suggested in some earlier studies[8,10], stigmatization had not been translated into lack of family and social support in our study : 48% of the patients had even received support of their family members in drug administration.

Patients were not subjected to defaulter retrieval action, yet a proportion of patients completed treatment, indicating strength of their motivation. Even in the DTC, where specialized staff is provided, defaulter retrieval was poor. For this DTP, a doubt arises as to who is the actual defaulter, the patient or the provider?

The question is who is the defulter, patient or the provider? Hardly any defaulter retrieval had been done, by the DTC or peripheral centres, yet over one half of the patients completed their treatment satisfactorily.

Factors studied indicate that most of the factors which cause non-adherence to treatment could be rectified by corrective actions, like increasing the number of PHIs put under SCC, decentralisation of treatment activity by referral to nearest centre, proper patient-provider interaction and strict adherence to the recommended treatment policy of providing free services[13]. Effective supervision by the state and district health authorities would go a long way in sustaining the corrective actions enforced.

During the study period, the Kolar DTC did not have a trained DTO which caused a major set back, specially in supervision. The programme performance in the study centres, constituting 10% of the whole district, was much below the expected level. With proper corrective actions, as discussed above, a higher treatment completion, and cure, rate could have been achieved. This is also necessary for launching the DOTS strategy which demands a fully geared up and committed treatment organisation[16]. The present situation, of an improperly managed NTP and the delay in launching the operationally demanding DOTS strategy may lead to total confusion, if timely efforts are not made in the right direction.

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Information for Smokers

HOW TO QUIT SMOKING?

The very first step for quitting is to shun ambivalence about quitting. And, making a firm resolve to quit at any cost. No sacrifice is big enough to justify giving up in midstream.

First, list all the perceived reasons why you must continue to smoke. Some of the common reasons listed by smokers are : fear of suffering caused by the withdrawal; frequent bouts of anger; weight gain or loss; less than usual appetite; lower mental concentration while at work.

Then, list all the benefits that accrue from quitting : that irritating whaking cough gone; fresh non-foul smelling breath; lower risk of developing lung cancer or other respiratory disorders; avoiding the considerable damage which tobacco use (smoking, sniffing, chewing) inflicts on heart and blood vessels; the money saved would become available for buying nutritional supplements, education of children, purchase of medicines for minor sickness, etc.

The comparison is so overwhelming in favour of quitting that almost any one could resolve to quit and gather the required motivation and self-confidence to do so.

YOU HAVE TO QUIT

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Original Article *Ind. J. Tub., 1999, 46, 251*

KNOWLEDGE OF TUBERCULOSIS IN A SOUTH INDIAN RURAL COMMUNITY, INITIALLY AND AFTER HEALTH EDUCATION

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Summary : A study was undertaken in a south Indian rural community to assess the initial level of knowledge of tuberculosis (TB) and again after providing health education on TB, to evaluate the effectiveness of health education, after 2 years. A total of 466 respondents from 24 randomly selected villages in Sriperumpudur taluk, Tamitnadu were interviewed. The community was then educated about the important aspects of tuberculosis by means of pamphlets, film shows, exhibitions, role plays and group discussions. After 2 years, the respondents were revisited and interviewed using the same interview scheduie. There was an overall increase of knowledge on various aspects of TB, ranging from 18% to 58%.

***Key words**: Health education, Awareness about tuberculosis, Effect of health education.*

INTRODUCTION

Tuberculosis case-finding under the National Tuberculosis Programme (NTP) in India is a passive process limited to chest symptomatics in the community who attend the Government health institutions on their own for relief of symptoms. It is, therefore, essential that the community is aware of the basic facts about tuberculosis and that necessary facilities are available under NTP. Hence, the Tuberculosis Research Centre, Chennai, undertook a study in a south Indian rural community, with the following objecfives:

1. To find out the existing level of knowledge of tuberculosis and,
2. After providing health education on TB to the community, to reevaluate the level by repeating the exercise, after 2 years.

The study was conducted in 24 randomly selected villages of Sriperumpudur taluk, Chengai Anna district, Tamilnadu.

MATERIAL AND METHODS

A voluntary agency - "PREPARE" is rendering comprehensive welfare services, including health, in 48 villages of Sriperumpudur Taluk, Chengai Anna district. A random sample of 24 villages was chosen from this area and every 5th household, starting from a randomly chosen location, was visited by a Medical Social Worker. The head of household or in his/her absence, any other responsible family member was interviewed to find out the initial level of knowledge of tuberculosis using a pre-tested, semi-structured interview schedule. The interview schedule (a copy can be requested) contained questions on signs and symptoms of TB, knowledge of availability of investigation and treatment facilities in the government health institutions, duration of treatment, necessity of investigating the close contacts of TB patients, preventive measures and categories of people getting affected by tuberculosis. Subsequently,

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the community was educated on basic facts about tuberculosis by various health education methods available.

Health Education Methods

1. *Pamphlet :* A one-page pamphlet containing important facts on tuberculosis in the local language (Tamil) was given to each respondent and he/she was asked to read it or, get it read, if illiterate. They were requested to pass on the pamphlet to a neighbour or friend after reading it.
2. *Film show* on tuberculosis was arranged in all the villages at strategic places at a time converiientio the majority of the residents.
3. *Exhibition* on tuberculosis was organised in two central places, exhibiting posters, charts and photographs. Medical officers and social workers explained the posters and charts to the villagers. Information about the arranged exhibition was given to the villagers by the field staff of "PREPARE".
4. Periodical training and health education programmes on tuberculosis were organised in the form of lectures with slides, flash, cards, role plays, film shows, group"' Discussions, and field demonstration to *Dais* (traditional birth attendants) by selected Animators, Youth Volunteers and Community Health Assistants belonging to these villages. These people are in close contact with the community and were requested to spread the facts on TB to the community.

Two years later, another visit was paid to the same respondents to evaluate their then knowledge of TB following earlier health education.

RESULTS

In the 24 randomly selected villages, 466 respondents were interviewed to find out their initial knowledge of TB. After 2 years, in the same households 433 (93%) respondents were interviewed using the same interview schedule; 33 persons could not be contacted due to reasons like death, migration, nonavailability at repeated visits and refusal to the second interview.

Table 1. Distribution of the respondents according to sex, age and literacy

Total respondents		433*
Sex		%
	- Males	34
	- Females	66
Age (in years)	18-24	22
	25-34	27
	35-44	23
	45-54	15
	55 and above	14
Literacy	Illiterate	53
	Literate	47

* Each respondent represents one household

Two thirds of the respondents were female (Table 1) and half of them were in the age group of 25-44 years. As regards literacy status, 53% were illiterate.

Knowledge about TB before and after health education

The levels of knowledge of tuberculosis, initially and 2 years after health education are given in Table 2. In all, 45% of the respondents initially, and 91% after health education, answered correctly that both rich and poor are affected by tuberculosis. Initially, 38% were aware that both adults and children are affected by TB and afterwards, 93% were aware of this fact. Prior to health education, 37% knew prevalence of TB is similar in urban and rural areas; after health education this proportion increased to 95%. Regarding knowledge that investigation and treatment facilities are available free of cost at all government health institutions, 67%, to begin with and almost all (98%) afterwards, responded correctly. Prior to health education, 15% mentioned 6 months as the duration of treatment and afterwards 50% of them

Table 2. Knowledge of tuberculosis before and after health education

Question	Expected correct answer	Correct answers (n = 433)		
		Pre-%	Post-%	Change %
1.	TB affects			
	(i) both rich and poor	45	91	+46
	(ii) both adults and children	38	93	+55
	(iii) persons from rural and urban areas	37	95	+58
2.	Investigations and treatment are done free at Govt. health institutions	67	98	+31
3.	Duration of treatment is 6 months/12 months*	15	50	+35
4.	There is need for investigating family members of TB patients	67	98	+31
5.	Mouth should be covered while coughing	15	48	+33
6.	BGC vaccination is preventive measure	14	48	+34

* Conventional treatment is for 12 months

answered correctly. Around 67% of the respondents knew initially about the need for examining the close family members of TB patients and after health education almost all (98%) of them answered correctly. Regarding cough hygiene, initially, 15% responded that patients should cover mouth while coughing but after education 48% knew about it; 14% of them had mentioned prophylactic BCG vaccination initially but the proportion increased to 48% after education.

A similar comparison about the symptoms of tuberculosis is shown in Table 3; there was an overall increase of 3% to 18% in correct knowledge after health education.

As regards the source of information on TB, 70% mentioned verbal communication, that is through TB patients and others (friends, relatives and health workers), as the major source, followed by pamphlets (21%), mass media (14%) and others (15%). Some respondents mentioned more than one source.

DISCUSSION

This study brings out the effectiveness of direct and indirect methods of making the community more knowledgeable on tuberculosis in addition to their basic understanding of TB. Distribution of pamphlets, film shows and exhibitions were the direct methods used. Periodic training given to *Dais,* Community Health Assistants, Youth Volunteers and Animators, who can influence the community, was the indirect method used. Improvement in knowledge (Table 2) varied from 31% to 58% under different heads.

In the present study, as regards symptoms of tuberculosis cough, haemoptysis and fever were mentioned by 60%, 15% and 8% of the respondents, respectively, before health education. Mukund Uplekar and Sheela Rangan[1] had reported similar findings (66%, 13% and 6% mentioning cough, haemoptysis and fever) confirming a fairly high degree of base line knowledge about symptoms.

It was found that 14% of the respondents, before health education, and 32% after health education mentioned BCG vaccination being a preventive measure against tuberculosis compared with 54% reported by S.C. Kirn *et al*[2].

The author had earlier reported[3] that verbal communication was the main source of information in rural, urban and metropolitan areas; in the present study also, verbal

Table 3. Awareness of symptoms of tuberculosis

Symptom	Persons aware (n = 433)		
	Pre- %	Post- %	Change %
Cough	60	57	-3
Haemoptysis	15	20	+5
Fever	8	13	+5
Chest pain	5	22	+17
Loss of weight	13	31	+18
Loss of appetite	6	14	+8
Others	25	28	+3
No idea	36	0	-36

communication was the main source of information. S.G Kim *et al*[2] had observed mass media to be the major source of information compared with only 14% in the present study. It is necessary to consider the type of community and the available resources while planning health education strategies. For health education to be effective and sustained, it should be a continuous process.

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PLEURAL FLUID CHOLESTEROL AND SERUM CHOLESTEROL RATIO AS A PARAMETER TO DIFFERENTIATE BETWEEN PLEURAL TRANSUDATE AND EXUDATE*

K.B. Gupta, Sanjeev Tandon, G.P. Singh, O.P Dhania and A.K. Janmeja

Summary : Pleural fluid cholesterol (PCHOL) and pleura! fluid serum cholesterol ratio (P/SCHOL) have been estimated in 70 patients of pleural effusion. The results are compared with Light's criteria to distinguish transudates from exudates.The mean PCHOL value in transudates was 42.85 ± 9.74 mg% while in exudates it was 88.52 ± 26.31 mg%. The P/SCHOL ratio was 0.20 ± 0.06 in transudates and 0.56 ± 0.19 in exudates. The differences were statistically highly significant ($p < 0.001$). Only 3 out of 70 cases (4.2%) were misclassified with the use of these parameters, showing sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and efficiency upto 95%, 96%, 90%, 97.95%, and 95.71% respectively, compared with 80%, 92.4%, 94.1%, 92.4% and 92.8% respectively for Light's criteria. Thus, PCHOL and P/SCHOL are simple, extremely cost effective, and useful parameters with better discriminatory capability than Light's parameters in distinguishing pleural transudates from exudates.

***Key words**: Pleural fluid cholesterol, Pleural effusion, Serum cholesterol, Pleural transudates, Pleural exudates.*

INTRODUCTION

Pleural effusion occurs in a number of diseases, both pulmonary and extra-pulmonary, often being the only manifestation of illness[1]. Based on the underlying pathological abnormality, effusions are either transudates or exudates[2]. Analysis of pleural effusions often gives an indication of the underlying patho-physiological process. Diagnostic and therapeutic approach to be adopted in pleural effusion depends on whether an effusion is transudate or exudate.

Although many criteria have been established to distinguish a transudate from an exudate, none has a 100% sensitivity and specificity[3]. The most commonly accepted are Light's criteria based on : (1) pleural fluid protein divided by serum protein being greater than 0.5; (2) pleural fluid lactic de-hydrogenase (LDH) divided by serum LDH being greater than 0.6; (3) pleural fluid LDH being greater than two thirds of the upper normal limit of serum LDH[4].

Many workers have found Light's criteria as unsatisfactory[1,5]. The application of Light's criteria for exudate confirmation may be found to be correct upto 100%, but in the case of transudates a high percentage of effusions are incorrectly classified (35-40%). It also seems impossible to draw a dividing line between the different types of effusions on the basis of total protein content without encountering frequent exceptions. The ratio between total protein concentration of pleural fluid and that of plasma is more accurate but some exceptions still occur[5].

The cholesterol content of pleural fluid (PCHOL) and its ratio with serum cholesterol P/SCHOL have been found to be very valuable in distinguishing transudates from exudates. It is a better parameter than those proposed by Light *et al* and is extremely cost efficient[5,6]. Furthermore, even when diuretic treatment is

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administered to these patients, PCHOL and or P/SCHOL continue to give good result, together and separately.

The present study was planned to evaluate the usefulness of estimating pleural fluid cholesterol (PCHOL) and pleural /serum cholesterol (P/SCHOL) ratio as parameters to differentiate pleural fluid exudates from transudates under our conditions.

MATERIAL AND METHODS

The present study was carried out in the Department of Tuberculosis and Chest Diseases in collaboration with Department of Biochemistry at Pt. B.D. Sharma Post-graduate Institute of Medical Sciences, Rohtak. A total of 70 patients having pleural effusion of diverse aetiology were taken in this study. The cases were divided into two groups :

Group I (Transudates) : This group comprised 20 cases suffering from congestive cardiac failure, nephrotic syndrome, hypoproteinemia and liver cirrhosis.

Group II (Exudates): This group comprised 50 patients suffering from tuberculosis (20 cases), malignancy (primary as well as metastatic-20 patients) and synpneumonia (10 patients).

The cases in which either no aetiology was definitely diagnosed or more than one cause were present, pseudochylothorax and chyliform effusions were excluded.

All the cases were subjected to detailed history taking, clinical examination, investigations which included routine tests, thoracentesis and detailed pleural fluid analysis, serum analysis for protein- and cholesterol estimation and pleural biospy.

Cholesterol estimation : Total cholesterol was determined by enzymatic colorimetric method[7] using reagent kits supplied by Autospan.

The following parameters were assessed for detailed comparison to distinguish pleural transudates from exudates:

1. Pleural fluid cholesterol (PCHOL)
2. Pleural fluid cholesterol/serum cholesterol ratio (P/SCHOL).
3. Pleural fluid LDH (PLDH).
4. Pleural fluid LDH/serum LDH ratio (P/SLDH).
5. Pleural fluid total protein (PPROT).
6. Pleural fluid protein/Serum protein ratio (P/SPROT).
7. Pleural fluid cytology.
8. Pleural biopsy.

Statistical analysis : The significance of statistical differences between the means of different parameters studied was tested by Student's unpaired *"t"* test.

RESULTS

For the total 70 patients, mean age was 44.45 ± 16.21 years. There were 48 males and 22 females. Table 1 gives the clinical diagnosis established for patients in both the groups.

Table* I.** ***Aetiological cause of pleura effusion

Cause	No. of cases
Group 1	9
Congestive heart failure	8
Nephrotic syndrome	3
Hypoproteinemia	20
Group II	
Tuberculosis	
Malignancy	20
Synpneumonia	10
Total	70

Table 2 shows the values adopted from literature in respect of the different parameters studied for comparison of the findings.

Table 2. Reference values adopted for various parameters used to differentiate betiveen exudates and transudates

Parameter	Transudate	Exudate
PPROT (gm%)	<3	>3
P/SPROT	<5	>5
PLDH (IU/L)	<160	>160
P/SLDH (1 U/L)	<0.6	>0,6
PCHOL (mg%)	<55	>55
P/SCHOL	<0.3	>0.3

Tables 3 and 4 give the values obtained in the study in respect of 20 pleural transudates and 50 pleural exudates, for the various given aetiologies (Table 1).

The values obtained for all the parameters studied were significantly higher for exudates compared with transudates, as grouped for various aetiologies established clinically

Table 5 gives the extent of misclassification of the nature of pleural fluid as established clinically and by the parameters studied, respectively.

The percentages of misclassification varied between 5% and 20%, While all the parameters contributed to the misclassification, pleural cholesterol value and pleural / serum cholesterol ratio had the fewest misclassif ications.

Table 6 and 7 give the detailed misclassifications by the use of protein content estimation according to range of protein content in respect of exudates and transudates compared with PCHOL and P/SCHOL parameters.

Table3. Showing parametric values obtained in transudative and exudative pleural effusions

Parameter	Transudates (n = 20)	Exudates (n = 50)
PPROT (g%>		
Mean	2.25	4,62*
SD	0.85	1.12
P/SPROT		
Mean	0.42	0.72*
SD	0.12	0.14
PLDH (I.U./L)		
Mean	127.28	398.41*
SD	47.04	177.06
P/SLDH		
Mean	0.42	0.94*
SD	0.14	0.37
PCHOL (mg%)		
Mean	42.85	88.52*
SD	9.74	26.31
P/SCHOL		
Mean	0.20	0.56*
SD	0.06	0.19

*p < 0.001 highly significant

Table 8 summarises the comparisons of the various parameters in terms of the accepted norms.

Table 4. Showing parametric values obtained in different aetiologies of exudative pleural effusions

Parameter	Malig-nant (n = 20)	Tuber-culous (n = 20)	Synpneu-monic . (n = 10)
PPROT (g%)			
Mean	3.94*	5.12	5.23**
SD	1.42	0.67	0.99
P/SPRQT			
Mean	0.65*	0.75	0.78**
SD	0.17	0.09	0.10
PLDH (I.U./L)			
Mean	300*	430	414.80**
SD	169.3	134.48	177.00
P/SLDH			
Mean	0.92*	1.01	0.84**
SD	0.36	0.45	0.34
PCHOL (mg%)			
Mean	85.40*	89.20	93.40*
SD	24.17	30.70	22.31
P/SCHOL			
Mean	0.51*	0.62	0.53**
SD	0.14	0.26	0.07

"The values in malignant/**synpneumonic **cases** were not statistically different from tuberculous cases

Table5. Distribution of misclassified cases in the two groups according to reference valuesadopted for each parameter studied

Parameter	Transudate (n = 20)		Exudate (n=;50)	
	No.	%	No.	%
PPROT	4	20	5	10
P/SPROT	2	10	4	8
PLDH	3	15	10	20
P/SLDH	2	10	8	16
PCHOL	1	5	3	6
P/SCHOL	1	5	2	4

Table 6. Showing number of pleural exudates with PPROT values of transudate range but PCHOL and PISCHOL values of exudates

PPROT range (g%)	Number misclassi-fied	Aetiological diagnosis
1-1.5	Nil	
1.6-2	1	Malignant
2-1-2.5	Nil	
2.5-3	4	3 Malignant 1 Synpneumonic
Total	5	4 Malignant 1 Synpneumonic

Table7. Showing number of pleural transudates with PPROT values of exudative range but PCHOL and PISCHOL values of transit-dates

PPROT range <g%>	Number misclassi-fied	Aetiological diagnosis
3.1-3.5	1	Congestive heart failure
3.6-4	3	Congestive heart failure
4.1-7	Nil	
Total	4	All congestive heart failures

Table 8. Sensitivity, specificity, positive predictive value (PPV), negative predictive valve (NPV) and efficiency of parameters studied and Lights crietria

Parameter	Percent				
	Sensitivity	Specificity	PPV	NPV	Efficiency
PPRT	80	92	76	92	87
P/SPROT	90	92	82	96	91
PLDH	85	80	62	93	81
P/SLDH	90	84	69	95	86
PCHOL	95	94	86	97	94
P/SCHO1	95	96	90	98	96
Light's criteria	80	92	94	92	93
PCHOL and /or PISCHOL	90	94	86	96	93

Table 9. Showing serum cholesterol (SCHOL) and pleural fluid cholesterol (PCHOL) level in transudates and exudates

Parameter	Transudate	Exudate
SCHOL (mg%)		
Mean	224.75	164.22*
SD	82.56	44.35
PCHOL (mg%)		
Mean	42.85	88.52*
SD	9.74	26.31

* p = < 0.001 **highly significant**

Table 9 shows serum cholesterol (SCHOL) **and pleural** fluid cholesterol (PCHOL) **values** in transudates and exudates as the most efficient criterion for distinguishing transudates from **exudates.** Table 10 gives **correlation** coefficients between transudates and exudates of different aetiologies.

DISCUSSION

Pleural effusion is encountered by chest physicians in approximately 4% of all attendances at chest clinics. The initial step for diagnosis and treatment is to distinguish

Table10.Correlation Cofficients *for comparisons between cholesterol levels (CHOL) of pleural fluid transudates and exudates of different aetiologies*

type of effusion	'r'	*'p'*
transudate	0.487	< 0.001*
Malignant	0.536	< 0.001*
tubercular	0.200	< 0.001*
Synpneumonie	0.720	< 0.001*

trailsudates from exudates. The criteria used to do §0 af€ baled on biochemical parameters proposed by Light *et al*[4]. Since no single test has yet proved to be completely satisfactory, the search for improved methods is kept alive.

Using total protein level of 3 g% as the dividing line, it is common to find around 6% of exudates and 16% of transudates misclassified. Even Light *et al*[6] in a study of 150 cases of effusion, erroneously classified 8% of exudates and 11% of transudates. Luetscher, in 1941, had found that it was impossible to draw a dividing line between exudates and transudates, using total protein content of pleural fluid without encountering frequent exceptions[5].

In the present study, the use of pleural fluid protein level of 3.0 g% for separating transudates from exudates resulted in erroneous classification of 20% of the transudates and 10% of exudates. Instead, fluid/serum protein ratio was a better parameter than fluid total protein; still 10% of the transudates and 8% of exudates were misclassified. Our observation is inconsistent with the finding of Light *et al*[8].

Chakko *et* a/[6] have confirmed the belief that treatment of congestive heart failure may convert an associated transudative pleural effusion into a "pseudo-exudative" one. In the present study, all the 4 misclassified transudative pleural effusions were of congestive heart failure patients put on treatment

Light *et al*[8] had demonstrated an improvement in diagnostic accuracy by including pleural fluid LDH estimation as a parameter. Though the ratio of pleural fluid to serum LDH improved the situation, it did not yield much better results than the protein estimation. In the present study, protein ratio estimation was found to be, a better discriminant with only 8% of misclassifications as compared to pleural fluid PLDH with 20% misclassifications. Moreover, LDH evaluation in pleural fluid is non-specific.

The cholesterol found in pleural fluid is a result of the underlying disease and not a reflection of the serum cholesterol level. These levels are elevated in exudative pleural effusions of much shorter duration[5]. The cause of the increased cholesterol concentration in pleural exudates is unknown. Cellular degeneration, mainly of white and red blood cells which contain high concentration of these metabolites, as well as decreased pleural fluid movement, as assumed for chyliform effusion, may be a reasonable explanation. Another hypothesis is increased pleural permeability leading to accumulation of cholesterol in pleural exudates due to "serum leakage". Cholesterol is found in all tissues and is uniformly found in all pleural effusions[10].

Valdes *et al*[11] have reported that, until lately, the cholesterol content of pleural fluid had only been used together with concentration of other lipid fractions to distinguish between chylothorax and pseudo-chylothorax. Considering that pleural cholesterol level reflected the aetiology of pleural effusion, they used pleural cholesterol level (PCHOL) and pleural/serum cholesterol ratio (P/SCHOL) for differentiating transudates from exudates. Since then, PCHOL determination has been used by many workers to differentiate transudates from exudates, taking 55 mg% as the threshold or cut-off value for PCHOL. In the present series, PCHOL and more so the P/ SCHOL ratio proved to be more useful parameters in distinguishing between transudates and exudates. The mean value of PCHOL was found to be significantly lower in transudates (42.85 + 9.74 mg%) than in exudates (88.52 + 26.31 mg%) : the difference was statistically highly significant ($p < 0.001$).

In the present study, the cut off point for PCHOL, as > 55 mg%, gave positive predictive value (PPV) of 86.36% and negative predictive value (NPV) of 97.91%, misclassifying just one of the 20 transudates (5%) and 3 of the 50 exudates (6%), that is overall 4.28%

misclassification in all types of effusions. However, our observation is not consistent with the findings of other workers[1,5,6]. A statistically significant difference ($p < .001$) was observed by us in P/SCHOL level among transudates and exudates, that is 0.307 ± 0.06 and 0.56 ± 0.19 respectively, with PPV of 90% and NPV of 97.95% (Table 8). Thus, the P/SCHOL ratio had similar NPV but PPV improved to 90%. It misclassified the same number of transudates but only 2 exudates (4%), and (4.2%) misclassifications for all effusions.

By applying the cut-off point > 0.3 for P/ SCHOL level, sensitivity of 95% and specificity of 96% was observed, giving an overall efficiency of 95.71% in differentiating transudates from exudates (PCHOL efficiency = 94.28%). Although there was no significant difference in misclassification of pleural exudates between PCHOL and/or P/SCHOL and the Light *et al* criteria, the former parameters performed better among transudates, with only 2 incorrectly classified compared with 4 by the Light *et al* criteria. In all, those cases where PCHOL and/or P/ SCHOL failed, some of the Light *et al* criteria also failed. Furthermore, it is also important to note that despite the diuretic treatment administered to these patients, PCHOL and/or P/SCHOL estimations retained their value. This seems to indicate that while concentration of protein and LDH may vary with diuretic treatment, PCHOL value remains stable.

The present study suggests that PCHOL and P/SCHO1 ratio have better discriminatory capacity than the Light's Criteria in distinguishing transudates from exudates. The cut-off points used in the present study were 55 mg% for PCHOL and 0.3 for P/SCHOL ratio.

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Original Article *Ind.}. Tub., 1999,46, 261*

QUALITY OF SYMPTOM ELICITATION IN AN EPIDEMIOLOGICAL SURVEY ON TUBERCULOSIS

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Summary ; The quality of symptom elicited by health workers in an epidemiologicat survey on tuberculosis was assessed by again subjecting a 10% random sample of the persons interviewed, by the supervisory staff, independently. Three thousand four hundred and forty nine persons were thus interviewed twice. The overall estimates for over-diagnosis and under-diagnosis in the elicitation of symptoms by health workers were to the extent of 16% and 8% respectively, with minimal yield of sputum positivity from the discordant groups of persons. The additional load of 16% for sputum examination can thus be considerably reduced if health workers are well trained in symptom-elicitation-screening of the population and their work is monitored through spot supervisory checks

Key words: Symptom elicitation, Tuberculosis survey.

INTRODUCTION

In community surveys conducted to obtain epidemiological information, like disease prevalence and incidence, the population is first screened by application of pre-determined criteria before case detection. The field investigator has got a target population for screening. While eliciting the symptoms, he may miss a real symptomatic and/or pick up an asymptomatic as a symptomatic. In the former case, there could be a chance that a real case is missed which results in under-estimation of the prevalence. On the latter instance, sputum examination done for a wrong person could result in overload of the work. So, it would be worth studying the extent to which the field investigators miss real symptomatics (under-diagnosis) and wrongly identify non-symptomatics as symptomatics (over-diagnosis). With this background, an exercise was carried out to assess the quality of symptoms elicited by the health worker (a field investigator registering and screening the population) in an epidemiological survey.

OBJECTIVE

To estimate the proportion of symptomatics missed (under-diagnosis) and non-symptomatics wrongly identified as symptomatics (over-diagnosis) by health workers in an epiolemiological survey.

MATERIAL AND METHODS

An epidemiological survey for surveillance of tuberculosis was undertaken in 1990 in two panchayat unions of Kadambathur and Tiruvelangadu of Tiruvallur taluk in Chingleput district (now Tiruvallur district) of Tamil Nadu. Thirty villages with a population of about 54,000 were included in the survey-Two screening methods, namely, Symptom and X-ray were used for detection of cases. The health worker visited the households and registered all the persons aged 10 years and above. He identified the symptomatics using the definition of symptomatic as adopted in the

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District Tuberculosis Programme (DTP) and directed all persons for X-ray examination. During the resurvey, which was started in 1993, a routine random check was introduced in the elicitation of symptoms. The quality of the symptoms elicited by the health worker, every day was assessed by a senior staff member on the same day from a random sample of individuals by visiting them and eliciting the symptoms independently.

Sample Size and Sampling Procedure

A 10% random sample of the eligible population screened by the health worker was included in the shady. The sample was selected from the list of persons who reported for X-ray, as directed by the technician after symptom screening. The 10% random sample was selected from the list in the following way :

The last digit of the serial number of the first individual who turned up for chest X-ray was noted which could be any number between 0 and 9. A systematic sample was then taken by selecting every 10th individual starting from the said digit. Thus, a 10% random sample of the population screened every day was obtained for re-elicitation of symptoms by a supervisory staff member. The persons listed for random examination were visited at home by a supervisory staff member who elicited symptoms independently and recorded them in a separate proforma in a manner similar to that used by the health worker. The health worker remained unaware of the identity of the individuals cross-checked by the supervisory staff. Similarly, the supervisory staff was unaware of the nature and duration of symptoms as elicited by the health worker. Sputum was also collected from the new symptomatics as identified by the supervisory staff

Analysis

The analysis was carried out on the assumption that symptoms elicited by the supervisory staff member were more reliable and these were taken as the standard to be compared with those of the health worker in order to find out the extent of agreement.

Table 1. Extent** of agreement bettveen health ivorker and supervisory staff in elicitation of **symptoms

Health worker	Supervisory staff		Total
	Sympto-matics	sympto-matics	
Symptomatics	690	129	819
Asymptomatics	204	2426	2630
Total	894	2555	3449

Objective assessment of the reliability of the supervisory staff member was not made.

The random sample consisted of 3,449 persons from a population of about 35,000 persons screened for the survey.

RESULTS

Extent of agreement between health worker and supervisory staff

Table 1 shows the extent of agreement between health worker and supervisory staff in identifying the symptomatics. Of the 819 persons identified as symptomatics by the health worker, 129 (15.8%) had no symptom (over diagnosis by the health worker), as elicited by the supervisory staff. Similarly, of the 2630 persons identified as symptomatics by the health worker, 204 (7.8%) had symptoms (under-diagnosis), as elicited by the super-visory staff. The proportion of symptomatics as elicited by the supervisory staff was 25.9% (894 of 3449) compared with 23.7% (819 of 3449) by the health workers. The difference was statistically significant ($P < 0.01$).

Extent of agreement between different health workers and supervisory staff

In all, 35 health workers screened the population. Of these, 6 health workers who had screened a sufficient segment of the population (at least 150) from the sample were used for this comparison. Table 2 shows the comparison between health workers and the supervisory staff in terms of over-diagnosis, under-diagnosis, accuracy and Kappa

Table 2. Extent of agreement between health workers in comparison with supervisory staff in elicitation of symptoms

Validity measures (%)	Health Workers					
	1	2	3	4	5	6
No. of persons screened	694	396	329	531	157	263
Over-diagnosis	18.1	18.1	16.3	16.5	17.1	17.2
Under-diagnosis	7.1	9.9	7.6	6.0	6.0	6.3
Accuracy	90.2	88.4	90.0	91.3	90.5	91.3
Kappa	73.9	67.2	75.4	77.1	75.4	75.0

Table 3. Distribution of symptimaties by duration of cough

Duration as elicited by health worker	Duration as elicited by supervisory staff			Total
	0<2 weeks	2 weeks - < 1 month	>1 month	
0-< 2 weeks	2883	38	102	3023
2 weeks- < 1 month	34	55	33	122
> 1 month	48	19	237	304
Total	2965	112	372	3449

statistics. It canjse observed that all the health workers, except Health Worker 2 performed well in terms of the extent of agreement with the supervisory staff.

The distribution of the identified symptomatics in terms of duration of symptoms is given, in Table 3. Persons having cough of duration less than two weeks were considered as having no cough- Of the 122 persons having cough of duration more than two weeks to less than 1 month, as elicited by health worker, the supervisory staff did not find cough in 34 (27.9%) persons. Three hundred and four persons had cough of duration 1 month and above, as elicited by health worker. Among these, only 237 (78,0%) had cough of 1 month and above, as elicited by the supervisory staff. The over-diagnosis and under-diagnosis by health worker by duration of cough was to the extent of 19.2% (82 of 426) and 4.6 (140 of 3923) respectively.

DISCUSSION

The extent of agreement, in eliciting symptoms, between health workers and supervisory staff revealed over-diagnosis by health worker to the extent of 16% which resulted in an additional load of sputum examination. Similarly, under-diagnosis by health workers in elicitation of symptoms was 8% reducing load of sputum examination in respect of these persons. Even though over-diagnosis meant additional load of sputum examinations, it may help in diagnosing more cases which would he missed while screening the population. In the case of under-diagnosis, sputum examination is not done unless their X-ray is abnormal, calling for sputum examination. A high proportion of under-diagnosis may cause underestimation of the prevalence of the disease.

The extent of agreement between various health workers and supervisory staff in eliciting symptoms in general was the same for ail the health workers, in terms of accuracy and Kappa statistics which adjusted for any chance agreement between the health worker and supervisory staff.

The duration of symptoms, like cough and chest pain, varied as elicited by health workers in comparison with supervisory staff. Among persons having cough of, less than 1 month duration as elicited by health worker, about one fourth did not have cough as elicited by supervisory staff. Similarly, among persons having cough of 1 month or more by health worker, about three-fourth were correctly

categorized but another 16% did not have cough at all, as elicited by supervisory staff. However, the overall agreement (symptom vs no symptom) in eliciting cough and chest pain, irrespective of the duration was satisfactory for health workers and supervisory staff: K = 0.72 (95% CI: 0.66-0.78).

Sputum positivity in the two discordant groups (symptomatic by health worker but asymptomatic by supervisory staff and asymptomatic by health worker but symptomatic by supervisory staff) was negligible. The overall proportion of persons eligible for sputum examination based on symptom screening by health worker is about 10%$_r$ of which 16% are really asymptomatics and sputum examination is not required for them. Thus, the overload of sputum examination can be reduced considerably if the population is screened better for identification of symptomatics followed by their sputum examination. This can be achieved by careful monitoring through spot checks by supervisory staff and in-service training given to them, if necessary.

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CT GUIDED PERCUTANEOUS CATHETER DRAINAGE OF TUBERCULOUS PSOAS ABSCESS - A CASE REPORT

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(Received on 17,11.1998; Accepted on 8.6.1999)

Summary : A young adult suffering from pulmonary and spinal tuberculosis developed large bilateral psoas abscesses while on chemotherapy. Abscesses were drained successfully by percutaneous catheter drainage. Ureteric obstruction required stenting initially and surgery later to free the ureter.

INTRODUCTION

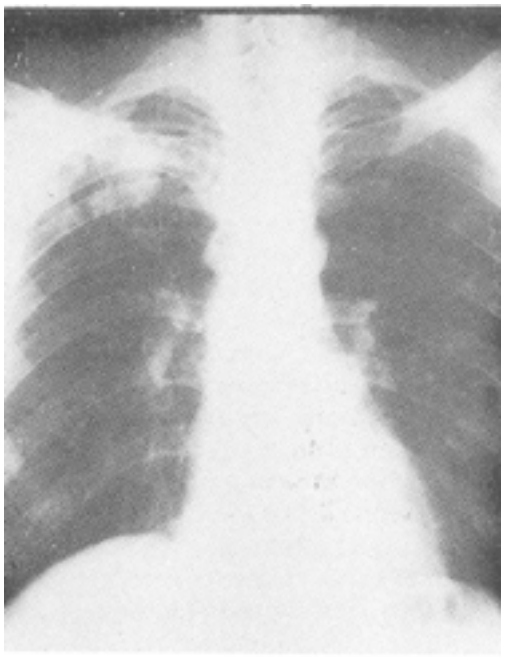
Spinal tuberculous involvement is the second commonest extra-pulmonary involvement, after lymphnodes[1,2]. Psoas abscess is a common complication of spinal tuberculosis[3]. Pressure effects of a large psoas abscess on vital organs are not seen frequently. Percutaneous catheter drainage of such abscesses is recently being reported from centres around the world[14,5].

CASE REPORT

A 34 year old soldier was referred to the cardiorespiratory centre at Military Hospital, Pune with fever, weight loss, cough and backache of six weeks' duration. Clinical history, examination and X-ray chest showing parenchymal apical infiltrates (Fig. 1) were suggestive of tuberculous disease. He had tenderness over D 11-12 spine. X-ray spine confirmed tuberculosis of spine. He was started on the standard four drug anti-tuberculosis therapy (EHRZ). He remained ill with fever and backache, though cough subsided after six weeks. X-ray spine, CT scan (and later MRI) confirmed bilateral large psoas abscesses (Figs. 2, 3) His blood urea had risen to 68 mg% and serum creatinine was 1.8 mg%.

MRI showed lateral displacement of both kidneys. Intravenous urography (IVU) showed no excretion of dye from left kidney and pressure effect over the right ureter at pelvo-ureteric (PU) junction.

A CT guided percutaneous catheter drainage was done using Malecot catheter. Later, as left PU junction compression was not seen to be relieved, the ureter was stented successfully using Double J stent. Repeat IVU after stent



X-Ray chest PA view showing nght upper zone lesions

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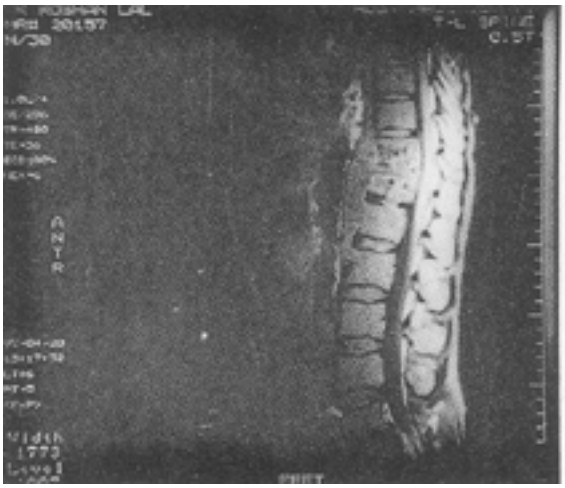

Fig. 2 MRI spine showing the psoas abscess

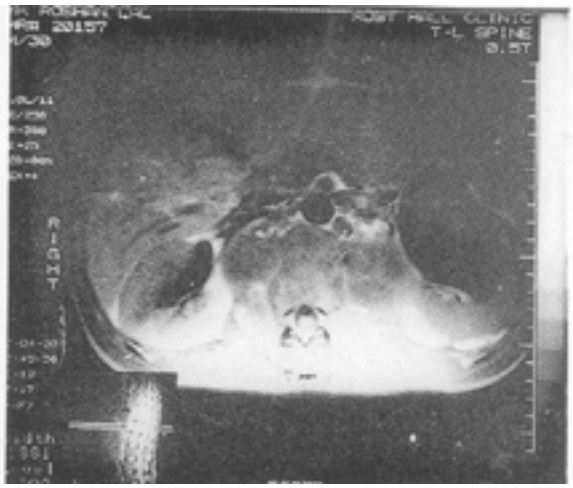

Fig- 3 MRI spine showing the psoas abscess

removal still showed delayed excretion from left kidney. DTPA renal scan showed LT kidney GFR 39.9% RT kidney GFR 76.4% He was then operated for left PU junction obstruction. Subsequently, after nine months of anti-tuberculosis treatment, the patient was asymptomatic.

DISCUSSION

Spinal tuberculosis is the second most common extra-pulmonary involvement in Asian countries[2]. With the rising incidence of tuberculosis in other countries, after HIV/ AIDS epidemic, spinal tuberculosis is increasingly being reported[6-7] from the western world. Theoretically, large spinal abscesses can cause pressure effect on other organs, yet bilateral compromise of renal function has not been reported in literature.

Percutaneous ultrasonic or CT guided drainage of psoas abscesses is recently being reported in the world literature[4,5]. This procedure can be employed even in very ill patients. In our case, left renal function recovered partially, after releasing obstruction, and the uretric compression was successfully tackled by the stenting procedure.

Percutaneous catheter drainage of psoas abscess is a very safe and effective procedure even in very ill patients. Our case is unique because of bilateral renal functional compromise, successful stenting followed by surgery to open up one of the ure'ters.

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Case Report *Ind.J. Tub., 1999,46,267*

PULMONARY TUBERCULOSIS WITH ANAL AND PERIANAL ULCERATION ASSOCIATED WITH *MYCOBACTERIUM SCROFULACEUM*- A CASE REPORT

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(Received on 1.12.1998; Accepted on 28.5.1999)

Summary : A case of pulmonary tuberculosis with anal and perianal ulceration associated with *Mycobacterium scrofulaceum* is presented.

INTRODUCTION

Although anorectal and perianal involvement in pulmonary tuberculosis is rare, cases have been reported from time to time[1-3]. However, the causative organism of such an involvement has never been isolated from ulcers in the cases reported. We have not come across any report of pulmonary tuberculosis with anal and perianal involvement associated with *M. scrofulaceum.*

CASE REPORT

A 28 year old male was referred to the cancer O.P.D. from a peripheral hospital with diagnosis of carcinoma of anus. Since the patient was having dry cough, shortness of breath and opacities in chest x-ray, he was referred to the Department of TB and Chest Diseases for evaluation.

The patient gave history of an increasing and painful ulceration around the anus of 11/2 years' duration with loss of appetite and weakness of 6 months duration. He had developed dry cough and fever during the preceding two months.

On examination, patient was found to be extremely emaciated (weighing 29 kg) and pale. He had no peripheral lymphadenopathy. The rate of respiration was 36 per minute. Examination of chest revealed diffuse bilateral coarse crepitations and rhonchi.

He had an irregular ulcer involving the anal sphincter and perianal skin extending along the groin (Fig. 1). The ulcer was covered with a thin whitish slough and it bled on touching.

Investigations revealed haemoglobin 6.4 g%, TLC 8,400/cmm, neutrophils, lymphocytes, eosinophils 62%, 34% and 4% respectively, and ESR 104 mm at the end of one hour. He was non-diabetic and negative for HIV by

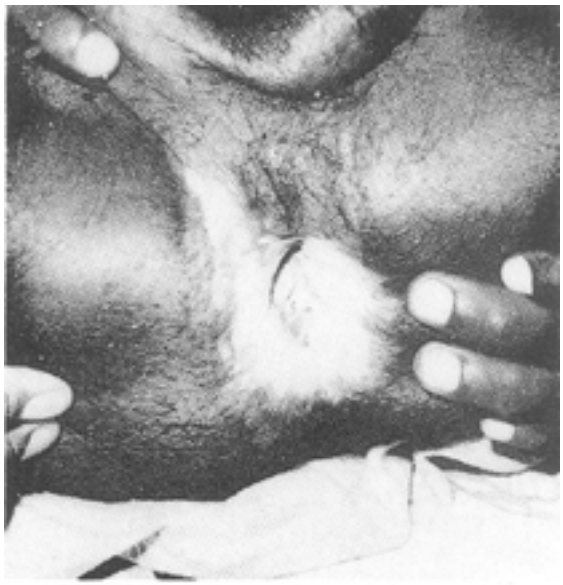

Fig. 1 Ulcer in anal and perianal region

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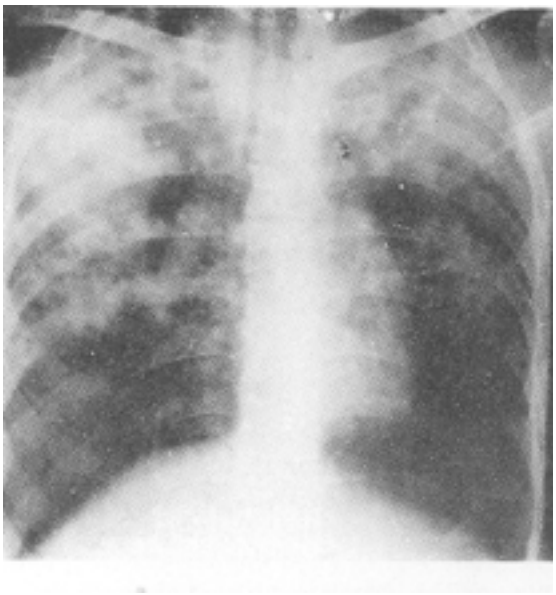

Fig. 2 Initial chest radiograph showing bilateral mottling and breakdown

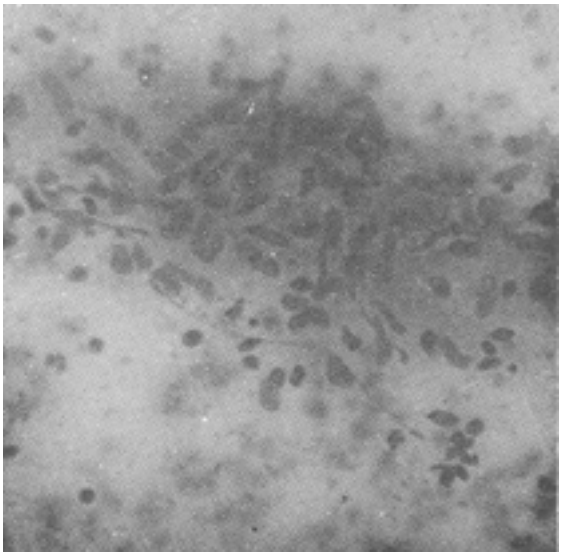

Fig. 3 Cytology of the ulcer scraping showing epithelioid cell granuloma

ELBA test. The chest radiograph (Fig. 2) showed dense airspace consolidation with breakdowns over both lung fields, predominantly in the upper and middle lung zones. The extent of disease was more in the right lung than the left.

ZN smear examination of the scrapings from the ulcer showed plenty of acid-fast bacilli.

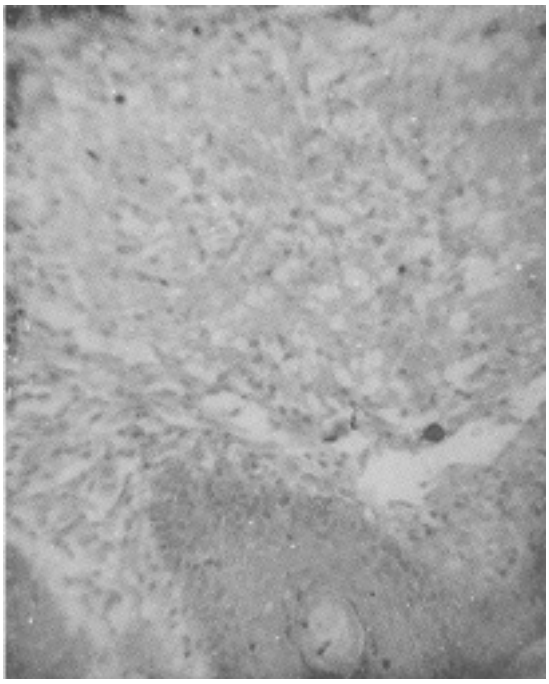

Fig. 4 Wedge - biopsy from the ulcei showing collection of epithelioid cells

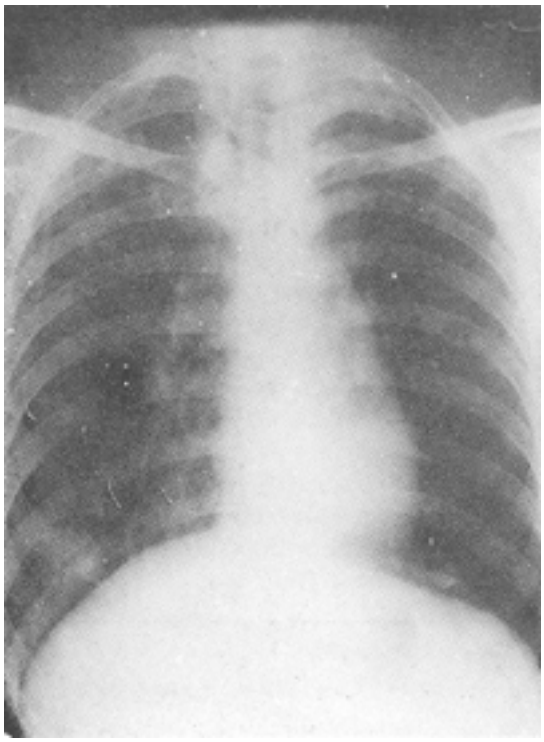

Fig. 5 Chest radiograph after two months of treatment (2 EHRZ)

Chart I.

Culture Characteristics:

Aerobic Culture : Negative on Blood Agar and MacConkey Agar
L-J Medium : Cultured on duplicate tubes of L-J Medium, incubated at 22°C, 37°C and 42°C respectively.

Growth was observed after 12 days.

Culture Characteristics on L-J Medium

Growth rate in days	Growth at different temperature 20oC	37oC		42oC	Pigmentation
12 days (> 7 days-slow)		Covered	Uncovered		
	+	+	+	—	+

Biochemical Tests

Niacin	Nitrate	Tween-80 hydrolysis	Heat resistant catalase	Urease
—	—	—	+	+

Result: On the basis of growth rate and growth at different temperatures the strain was found to be a *slow grower and scotochromogen.*

Biochemically it was identified as *Mycobacterium scrofulaceum.*

Scraping-cytology revealed features of epithelioid cell granuloma (Fig. 3). Histopathology (Fig. 4) of the ulcer showed typical tuberculous granuloma.

Although there was extensive involvement of both lungs, the patient could not produce any sputum for smear or culture examination. Culture of scraping from the ulcer grew M. *scrofulaceum* (Chart I)[4].

The patient was put on the standard regimen of EHRZ with doses according to body weight. He tolerated the drugs well and had a dramatic improvement (Fig. 5) with complete healing of the ulcer. He is now in the continuation phase of the treatment.

DISCUSSION

Association of pulmonary and anal/perianal tuberculosis is extremely rare. In the present case, aetiological diagnosis was confirmed bacteriologically as well as histopathologically in respect of the perianal ulcer. Although the patient could not bring out sputum for bacteriological study, the marked improvement on anti-tuberculosis therapy established the diagnosis of pulmonary tuberculosis therapeutically.

Mycobacterium scrofulaceum is known to commonly involve the lymphnodes. Could this organism cause pulmonary pathology with additional perianal ulceration? Alternatively, could our case have both pulmonary tuberculosis and the comparatively rare perianal ulceration, associated withM. *scrofulaceum?*

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Case Report *Ind.J. Tub., 1999, 46,271*

TUBERCULOUS GASTRIC ULCER PRESENTING AS HEMETEMESIS - A CASE REPORT

S. Sevvel[1], V. Kate[2], C. Ratnakar[3]* and N. Ananthakrishnan[4]

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Summary : A case of hemetemesis which on investigation was found to have a gastric ulcer was reported to be benign on biopsy. Four weeks of omeprazole therapy failed to heai the ulcer. During surgical operation, wedge resection of the gastric ulcer was done due to the presence of multiple peritoneal tubercles. Histology of the resected tissue revealed a tuberculous ulcer. Anti-tuberculosis therapy was started post-operatively leading to uneventful recovery.

INTRODUCTION

Tuberculous gastric ulcer is rare. There are only a few reports in literature. Most cases present with hemetemesis[1-3]. While the gastrointestinal tract is common location for tuberculous disease, the gastroduodenal area is the least involved. Gastric tuberculous ulcer could be easily mistaken for a peptic ulcer, unless proved by biopsy, We report here a patient who had a tuberculous gastric ulcer and presented with hemetemesis.

CASE REPORT

A 23-year old man was admitted to the hospital with a single episode of hemetemesis. There was no history of gastric ulcer disease, alcohol abuse or malena. However, history of use of non-steroidal anti-inflammatory drugs was present. There were no systemic symptoms. Clinical examination was unremarkable except for skin pallor. Abdomen was soft with minimal tenderness in the epigastrium. There were no other findings.

Chest X-ray was normal. Upper gastro-intestinal endoscopy revealed a 6 mm size gastric ulcer on the greater curvature of the stomach. The ulcer was clean-cut with slightly raised edges. The surrounding mucosa was normal. Biopsy of the ulcer margin did not suggest malignancy or tuberculosis. The patient was put on Omeprazole 20 mg daily for a 4 weeks' duration. Repeat endoscopy after this period showed a persistent gastric ulcer with no change in size or appearance. Resectional surgery was therefore planned.

At laparotomy, there was a 0.5 x 0.5 cm size ulcer on the greater curvature of the stomach with minimal induration. There were multiple tubercles on the peritoneum along with multiple mesenteric lymph nodes of varying size. In view of the findings, a wedge resection of the gastric ulcer was performed. One lymph node from the mesentery was also excised for biopsy.

Histology revealed a punched out ulcer extending from the mesentery upto the submucosa with some induration at the base. Sections showed tuberculous ulcer (Fig. 1). The lymph node showed extensive caseation. Search for AFB was negative. Patient was started on anti-tuberculosis therapy and made an uneventful recovery

DISCUSSION

Tuberculous involvement of the stomach occurs in 0.02 to 0.22% of the gastrointestinal tuberculosis cases[3]. The involvement of the stomach is always secondary to a tuberculous lesion elsewhere, usually in the lung, and tends to be a part of widespread disease. Our case had no

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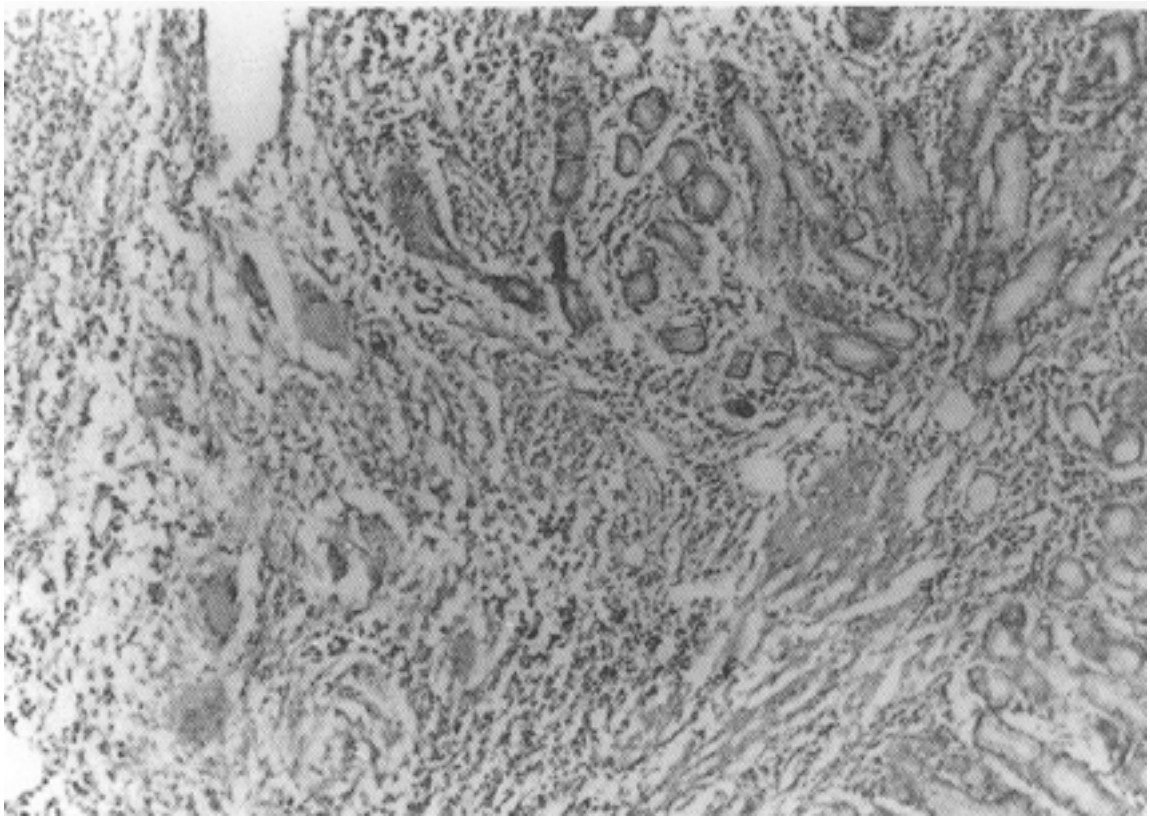

Fig. 1 Photomicrograph showing gastric mucosa with ulceration. Submucosa shows epithelioid granuloma with Langhans giant cells (H & E x 50)

obvious pulmonary involvement. The infrequent involvement of the stomach is due to the relative resistance of the gastric mucosa, lack of lymphoid tissue in the stomach and rapid passage of gastric contents into the intestines. Any part of the stomach can be involved but the usual sites are the lesser curvature and the antrum[3]. The routes by which infection may occur are through the mucosa (direct spread), blood stream (commonest route of spread), the lymphatic stream and contiguous spread from adjacent structures.

Usually, it is a small ulcer with undermined edges. A tumourous variety resembling carcinoma and a fibrosing variety appearing as linitis plastica or gastric outlet obstruction are the other clinical presentations. The most common presentation is hemetemesis. Bleeding can sometimes be exsanguinating, requiring surgical intervention[2]. Most often, the diagnosis is made post-operatively. Surgical intervention in the form of limited resection and anti-tuberculosis therapy give impressive results.

The prognosis is related to the severity of disease and extent of lesion. A gastric ulcer at an unusual site should arouse suspicion. A biopsy should be performed before starting anti-ulcer treatment. If there is no improvement on endoscopy at 4 weeks, a repeat biopsy or surgery is mandatory. Surgery usually consists of a simple wedge resection of the lesion.

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PUBLIC HEALTH, ETHICS AND TUBERCULOSIS

Ritu Priya[1]

porter and Qgden, authprs, of the lead article in the January 1999 issue of the *Indian journal of Tuberculosis*[1] must be congratulated for positing ethics as the prime criterion when formulating and implementing a public health tuberculosis programme. Equally impprtant are their propositions that (0 the bio-medical and socio-pplitical perspectives need to be brought together, *(it)* health is more than just bio-medical and, therefore, that any specific disease programme must demand resources in proportion to the qverall health and development inputs and *(in)* that "ethics needs to be put into action. 'Mere philosophical discussion is not enough".

Keeping their first two points as the guiding principles, this response hopes to move in the direction of the third i.e. concretizing the principles for action in India. It is being written jn the spirit of the article under reference which jnvifes a debate.

At the outset, I wish to add the specific public health dimension to the general ethical principles enunciated in the article. Public health/ by its very content and objectives, has to work at a mags Jevel in an inter-disciplinary manner integrating different dimensions of any problem to evolve its own perspective. This includes consideration of number of cases and cures b,y different regimens on one hand and consideration of patients' living and working cpnditipns on the other[2]. Maximum benefit to the maximum number is the working rule in public health for meeting the ethical requirements, set out by Porter and Ogden, of beneficence, equity and justice. This may be translated into : Public Health Effectiveness = Efficacy x Coverage under real life field cpnditions. Thus, a system with highest efficacy of drug regimen but low coverage will be less effective (i.e. have low beneficence) than one with moderate to high efficacy and high coverage.

BEYOND PHILOSOPHICAL DISCUSSION

In order to incorporate all the ethical principles within a national level tuberculosis programme, some Aspects of the epidernio-logical and social context must be considered.

Issues of Coverage and Access

Large scale migration of the ppor, as manual labourers, both rural-rural and rural-urban, is a significant social phenomenon in India with 8-50% of rural population of different states migrating for employment[3]. It is also a significant epidemiological phenomenon with negative health impacts for the most vulnerable sections of the population. The migrant poor are a large mobile section, moving to and fro between the region of origin and of immigration and within one city or district. Ensuring access to tuberculosis treatment for this large section of the population is an ethical imperative. The functioning of DOTS, as theoretically enunciated and as observed in pilot study areas, clearly negates this aspect.

The RNTCP actively discourages temporary residents of any area from enrolling for treatment. Take for instance the case of Delhi[4]. Delhi's most vulnerable 40% population consists of the urban poor, largely rural migrants and those with insecure housing. Porter and pgden had referred to a study evaluating the pilot projects implementing DOTS in Delhi among this population[4]. My observations at the peripheral RNTCP centres and interviews with peripheral as well as supervisory workers of the same project areas

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revealed mechanisms employed to discourage or prevent their enrolment in DOTS, e.g. the demand for documentary evidence of at least one year's residence in the locality, which is well known to be difficult for the migrant poor. Not putting their names on the DOTS register till they 'prove' compliance by regular attendance for 3-4 turns was another functional mechanism to discourage such potential 'defaulters'. Migrant status was found to be the single most common reason for not registering patients under DOTS. An important ethical rationale for such practices is of 'non-maleficence' considering that moving from the area will mean discontinuation of treatment and the danger of development of multi-drug resistance. Given the context, is it not then essential that a uniform programme be implemented everywhere within the city and in the migrants' region of origin, i.e., in all parts of the country? The RNTCP, however, envisages coverage of only a limited number of districts (only about one-fourth of the Indian population) because of high resource inputs. In a situation where even the NTP coverage is of 70% of total districts (as of 1996)[5], is it justified to initiate a much more exclusivist and resource intensive system without ensuring full coverage? Certainly the answer is 'no', if the ethical principle of equity of access is the primary consideration. However, such a system is being justified by pitting 'equity' against bio-medical 'non-maleficence'. Combining bio-medical and sociological perspectives, this opposition of the two does not appear to hold, as the following discussion will show.

The fact that coming every alternate day to the DOTS centre for treatment is most difficult for the daily wage earner (and for the severely ill) is another feature which limits the access of the poorest sections[6]. Presently, those patients who are unable to satisfy the sociological requirements of DOTS-in practice-are being put on to the pre-existing National Tuberculosis Programme (NTP), in spite of bio-medical criteria to the contrary and in spite of the fact that they are the ones who need greatest support for completion of treatment. The significance of this can be appreciated by the small proportion of diagnosed cases being put on DOTS even in the pilot areas (30-50% by informed reports). With further weakening of the implementation of NTP due to additional distraction by the parallel DOTS system, it is this iniquitous bias which will lead to greater number with incomplete treatment i.e. maleficence. What ethical public health practice demands is establishing a system which addresses the needs of both equity and 'non-maleficence' together. Combining the positive features of NTP and DOTS could help evolve such a system.

Towards Rational Integration of DOTS and NTP

NTP was based on domiciliary treatment with fortnightly to monthly collection of drugs and follow-ups. The drug regimen was flexible with first line therapy to all patients and shift to second line drugs in the event of non-response and drug resistant organisms. Initiated in 1962, it had established passive case-finding based on symptoms and sputum examination backed up by clinical suspicion and radiology as the effective diagnostic tools for a mass programme in the Indian context, considering the overall resources available for the health services and the social sectors. Other strengths of NTP'S planning included the systems evolved for patient cards which could be transferred from one centre to another across the country when the patient moved so that the same treatment could continue through the government run programme anywhere in the country. The follow up of patients through post card for collection of drugs in time was also built into the programme[7]. The major weaknesses in its implementation include:

(i) Low priority given to tuberculosis within the government health services. Incomplete coverage across the country even after thirty years and little attention given to it in functioning at all levels is evident.

(ii) Low priority given to follow up of 'defaulters' and low treatment completion rates.

(iii) Irregular supply of drugs[8].

These problems certainly need to be addressed. Further, the problem of increasing drug resistance, primary and secondary, needs to be assessed and addressed. Existing data suggests only about 15% primary resistance[9], i.e. 85% do not need the SCC on this ground (though this may vary in different parts of the country). The question is, will DOTS provide the solutions to these problems?

DOTS implementation has certainly improved management systems in some ways by (fl) refocussing attention on Tuberculosis (b) improving supply of drugs, and (c) effective follow up of 'defaulters'. This has, however, been done through high and intensive resource inputs in terms of a vertical infrastructure and manpower for DOTS paid for by the World Bank soft loan and other international funding, which is only for the initial five years. The issue is, are the improved systems sustainable over a long-term as the problem of tuberculosis is not expected to decrease markedly in the next two decades? All previous experience of internationally funded projects has been that the infra-structure becomes dysfunctional after funds stop[10]. In the case of DOTS, its current form of implementation poses the question of sustainability very centrally. Its implementation without addressing this issue belies the ethical principle of non-maleficence. Its discontinuation will lead to an even more chaotic situation with discrediting of the standard regimen and NTF in the public perception, a greater number of cases with incomplete treatment, and increasing MDR. In the process of implementing DOTS, the management of NTP components is getting further undermined and by the time funding for DOTS stops even that limping system would have collapsed. Do other, more sustainable, options exist for improving treatment completion rates? Studies evaluating observation of treatment by local health staff instead of patients going to a centre for observed drug administration[11] and the so-called better interaction and health education of patients by service providers[12] have demonstrated very satisfactory results. Thus, strengthening and using NTP infrastructure, improving functioning of its logistical systems as in DOTS, using a socially adapted version for 'observed therapy' instead of DOTS and a flexible, rational system of combining different drug regimens could marry the requirements of equity and non-maleficence and develop a biomedical-cum-socially optimal RNTCP.

Need for Generation of Data and Ethics of Data Sharing

A third issue that must be addressed from the ethical perspective is that of transparency about data on changes in epidemiology of tuberculosis and on evaluations of NTP and DOTS. The 'allegations' of maleficence against DOTS, or NTP for, that matter, can be checked only on the basis of epidemiological data. 'Empowerment' without the right to basic information is an abstraction at best. The fact that data on the functioning of the pilot projects of DOTS and its evaluation outcomes are not made public or easily available even to public health analysts does not allow genuine informed debate. The debate then is based on assumptions with biases of experts, the assumptions often arising from contexts very different from the Indian.

Some Conceptual Issues

Besides these concrete issues related to the ethics of DOTS in India, some issues of perspective raised by Porter and Ogden are also being addressed here.

Individual and Collective Good

They pose the issue of the individual versus the collective good as a basic ethical issue of 'autonomy' of the individual. This manner of posing it is a part of the individualist thrust of the now controversial 'enlightenment project' upon which dominant modern development is premised. It stands in stark contrast to the world-view and perceptions of the majority of peoples of the third world who do not view the two as dichotomous or mutually exclusive, rather that the good or well-being of both the individual and the collective is intertwined[13]. While one stream of thought within -public health has always maintained this latter perspective, the more recent public health

debate on AIDS and human rights recognizes and highlights this as well[14]. Two dimensions of the intertwined relationship between the individual and the collective concern us here - (0 that individual health and health behaviour are socially structured and, therefore, public health action must address these at the societal level so as to facilitate the most healthy conditions and behaviour of maximum number of individuals within the community and *(ii)* that the right to protection from and care during ill-health of each individual requires that the measures be accessible to all and provided 'according to need' without jeopardizing the access of others. Therefore, Porter and Ogden's basic premise or definition of an individualistic ethics is debatable.

Understanding and using the world-view of the socially most vulnerable is probably the most 'empowering' for them. That their world-view is rapidly losing out in a globalizing world should be a matter for concern, especially when its dimensions of positive value for human well-being and community based communitarianism are being eroded[15].

Experts' Assumptions and Peoples' Perceptions

That passive case-finding decreases access of the most vulnerable to diagnosis and treatment, and active case-finding will improve access is again an assumption which does not seem to take into consideration the reality of peoples' perceptions and behaviour in relation to their socio-economic context and the existing services available to them-

Even as early as the 1950s, the sociological basis of the passive case-finding strategy was soundly grounded in a pioneering study of perceptions and behaviour of tuberculosis cases, combined with eidemiological aspects of the disease[16]. This and subsequent studies[1718] have shown that even the illiterate poor know the symptoms of tuberculosis, that majority of cases seek treatment and yet are unable to complete treatment for various reasons - imperatives of their working conditions, limited resources at hand to invest in treatment, the attitude of service providers, the irregular supply of drugs, etc. The discouraging experience of those attempting treatment deters others of their communities from acknowledging their own symptoms or going for treatment. Therefore, 'empowerment' of the people should naturally begin with ensuring definite access for cases coming for treatment in a patient-friendly manner. The basic assumptions and structure of DOTS denies both the patients' rationality and their convenience. Where it has provided an effective management tool which builds confidence in patients is in earmarking a separate box of drugs with supply for the complete duration of therapy which is kept aside for each registered patient. This can be integrated into the NTP as well. The issue here is of incorporating within the experts' perspective the peoples' perceptions as a legitimate view-point and a crucial input for programme formulation.

The Universal and the Contextualised

This brings us to the question raised about the universal value of ethics and human rights versus contextualising them in local situations. Ethics, universal when in the abstract, have of necessity to be contextualised for putting into action. Ample examples appear in the discussion above to illustrate this point.

That the definition of ethics itself depends upon world view and, therefore, may differ is an issue for further consideration. Core moral values and basic human rights, such as right to life, truth and honesty are probably universal to all human societies. However, detailing moral values and ethics further is dependant upon the social and cultural context. What appears to contradict the universal code may, within differing contexts, actually be its application. For instance, consider the issue of child labour. While it genuinely draws attention to the inhuman exploitation of children, merely banning it, as the international community is trying to do, can only further worsen the conditions and even survival chances of the children and their poverty-striken families in countries such as India. Exploring more creative options rooted in 'view from below' might lead to the most humane approach[19]. Imposing a universal (i.e.

north-centred or elite based) ethical and moral code unrelated to local context can go counter to its very objective.

Suggestions for Action

We now return to the issue of concrete action, appreciating the value of Porter and Ogden's suggestion that different sides of the debate in India be reconciled for best outcomes. Another article appearing in *IJT* earlier[20] also provides an integrative view, incorporating the two sides of the debate Porter and Ogden describe, with concrete suggestions for improving coverage and implementation of DOTS. Some directi6ns arising out of the foregoing discussion are summarised below :

(a) People's perceptions and behaviour, interpreted within their context, must be an important consideration for all planning and programme formulation.

(b) DOTS and NTP must not be put in opposition but integrated into one flexible programme. The same infrastructure and management systems should be applied for both, with spread across the whole country in a manner which is sustainable over the long term. Then, an effective defaulter retrieval networking system can be developed for migrant cases as well.

Using infra-structure of the general health service and NTP, strengthening the latter where necessary, emphasising treatment organisation through modified DOTS i.e., support to the patient and observation of drug intake by key community persons {taking feasibility and patients' convenience into consideration) and stringent follow up by health workers, as in DOTS, assured supply of drugs with a separate box of complete requirement per patient, are some possible ways of doing so. Based on levels of primary and secondary drug resistance in the population, different combinations of drug regimens could be worked out.

(c) Generating data to evaluate efficacy of different components of NTP and DOTS with evaluation of why and how they perform, as they do, including perceptions of cases and the local populations. For instance, comparisons in NTP areas and DOTS pilot project areas of diagnosis rates, treatment undertaken and completed of all estimated cases in the population and, after several years of implementation, of annual rate of infection (ARI) could provide an overall assessment of the two systems. Evaluation of management components and processes of organisational functioning could help identify the positive aspects of both to be incorporated into a common frame. Data on drug resistance levels throughout the country would be needed to evolve appropriate regimens based on efficacy, cost, safety and sustainability.

(d) All these data should be transparent and made accessible to all concerned to provide a wider base for evaluation.

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STATEMENT ON AIR POLLUTION*

India is facing a serious double burden of disease. Most of the old infectious diseases like malaria, filariasis and kala-azar have not yet disappeared; indeed they are bouncing back. At the same time, other chronic non-communicable diseases such as cancer, cardiovascular disease and respiratory disorders are becoming more dominant.

It is becoming clear that the pattern of economic growth that we are adopting is becoming increasingly associated with environmental pollution and industrial pollution A study comparing the rates of economic growth and of vehicular pollution and industrial pollution shows that during 1975-1995 the Indian economy grew by 2.5 times, the industrial pollution load grew by 3.47 times and the vehicular pollution load by 7.5 times[1]. Indeed, Indian cities are being exposed to high levels of air pollution and the people living in these cities are paying a price for the deterioration of air quality. The World Bank has estimated that Indians are spending Rs 4,550 crore every year on treatment of health problems caused by ambient air pollution[2].

Air quality in Delhi is deteriorating. Levels of primary pollutants, suspended particulate matter (SPM), nitrogen oxide and sulphur dioxide have gone up significantly in the last decade[3], The consistently high levels of total suspended particulate matter are worrying. Limited data available from the Central Pollution Control Board indicate that the levels of small particles, less than 10 micron (PM10) are very high. This size of particulates is known to cause severe damage to lungs. In fact, the World Health Organisation (WHO) has gone to the extent of saying that there is no safe level for particulate matter emissions[4]. International studies have confirmed association between elevated levels of particulate air pollution and decline in lung function or increase in respiratory symptoms such as cough, shortness of breath, wheezing and asthma attacks. Studies have also found association between particulate air pollution and rates of hospitalisation, chronic obstructive pulmonary disease and restricted activity due to illness[5]. A World Bank study on the health effects of air pollution in Delhi revealed that SPM in Delhi alone led to premature death of 7491 persons in 1991-92[2]. The study, repeated for the year 1995, shows an increase to about 10,000 in just three years, which means a death rate of one person per hour due to air pollution[6].

It is not known on what scientific database Such as epidemiological studies, morbidity and mortality patterns are the air quality standards, published for India arrived at. Given the knowledge of the harmful effects of particulate pollution and the high concentration of particulate matter in Delhi's air, we need to generate regular information on the ambient concentration levels of small particulates of diameters less than 10 micron and/or 2.5 micron and take urgent steps to control emissions of these particles.

It is well known that combustion of diesel generates small particulate matter, nitrogen oxide (NO_X), sulphur dioxide (SO_2) and polycyclic aromatic hydrocarbons (PAH). Dieselisation of private vehicles is accelerating in Delhi. The relatively low price of diesel is promoting its use further, which is a factor that encourages automobile manufacturers to introduce diesel versions of their vehicles. This development is bound to worsen the air quality of Delhi bringing in its wake a number of related health problems.

The new scientific information emerging from international studies indicates that the cancer causing potential of diesel exhaust is very high. The Scientific Review Panel of the California Air Resources Board points out, based on human epidemiological data, that

*As submitted to Environmental Pollution Control Authority of the National Capital Region, Delhi by a panel of experts comprising. Drs. V. Ramalingaswami, S.K. Chhabra, Praful Desai, N.K. Ganguly, K. Gopaiakrishnan, S.K. Kacher, Veena Kaira, S.R, Kamat, V. Kochupillai, Devika Nag, J.N. Pande, Vinod Raina, P.K. Ray, H. Saiyed, P.K. Seth, Naresh Trehan and H.S. Wasir

chronic exposure to 1 μg/cum of diesel exhaust will lead to 300 additional cases of lung cancer per million people[7]. On this basis, for a population of ten million people in Delhi, there would be 3,000 extra cases of lung cancer with chronic exposure to 1 μg/cum of diesel exhaust. A WHO study done on rats shows that chronic exposure to 1 μg/cum of diesel exhaust can lead to 16 to 71 additional cases of lung cancer per million exposed rats[4]. Recently, Japanese researchers have discovered a compound, 3-nitrobenzan throne, in the exhaust of diesel engines that may be the most carcinogenic compound ever analysed[8].

Many studies have established that diesel exhaust causes mutations in chromosomes and damage to DNA, triggering cancer. Diesel exhaust, rich in polycyclic aromatic hydrocarbons (PAH) and particulate matter, causes 10 times more mutation than leaded petrol, which in turn is 10 times more mutagenic than unleaded petrol according to Swedish tests. One 1993 US study, that covered six cities, found a significant association between air pollution and mortality due to lung cancer and cardiovascular disease. The study found that the probability of death increased significantly with an increase in exposure to fine particulates (PM 10 and PM 2.5) and sulfate particles than with an increase in total particulate pollution, aerosol acidity, sulphur dioxide or nitrogen dioxide. Specifically, the study found that when people were exposed to average PM 10 levels of 47 ug/cum they suffered a mortality rate as much as 48 per cent higher than those exposed to lower levels. Similar death rates were associated with sulfate particles, average levels of which went up to 13 μ.g/cum in the cities[5].

The results of the above studies are of concern in the Indian context as diesel exhaust accounts for a significant proportion of small particles including sulfates in the air. In fact, the first survey of PM10 in Delhi shows that they reach extremely high levels-as much as 500 μg/cum or 5 times higher than the standard prescribed by the Central Pollution Control Board[10,11]. Diesel also produces NO_X that is easily absorbed in the blood and then reduces the oxygen carrying capacity of the blood. It makes the lung tissues brittle and leathery and can cause lung cancer and emphysema (severe breathing problems)". At the ITO Crossing, NO_2 is above the standard in one out of every five days[13]. Even more disturbing is the fact that NO^ from diesel, once out in the air forms ozone, yet another harmful gas.

Ozone causes inflammation of the airways (bronchus and bronchioles) which leads to respiratory problems. Ozone may pose its worst health threat to those who already suffer from respiratory diseases, such as asthma, emphysema and chronic bronchitis[14-15]. Ozone levels in Delhi are disturbing. A1993 study by the Central Road Research institute, New Delhi showed that average ozone levels were 10-40 per cent above WHO standards[16].

Diesel also produces carbon monoxide which causes severe heart problems. A US study estimated that 6 per cent of the cities' congestive heart failures and hospitalizations were related to increasing carbon monoxide in ambient air[17]. Carbon monoxide aggravates heart disease by binding to the haemoglobin, thereby decreasing oxygen transport to the tissues.

There is an urgent need for comprehensive epidemiological studies to show how ambient air pollution is affecting people's health and quantify this information in order to provide policy tools for air quality planning. For instance, no nationwide survey on asthma sufferers has been conducted so far even though the cumulative prevalence rate of asthma, in a place such as Delhi is estimated to be 1 to 2 children out of every 10[18]. According to one study, as many as 65 per cent of the people in Delhi are estimated to suffer from morning cough and phlegm and other respiratory symptoms[19].

In other countries, governments have set up national level institutional mechanisms for medical research and monitoring in the area of air pollution with a view to influence policies. Medical Associations have addressed the health issues related to air pollution and have pressurized governments to take corrective action. Most notable is the recent statement from the Australian Medical Association condemning the new reform package in Australia promoting the use of diesel by slashing taxes on diesel[20].

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CONTEMPORARY ISSUES

AIDS AND CHIMPANZEES

The chance discovery of HIV in a laboratory frozen tissue section of a chimpanzee and the failure so far to transmit HIV to chimpanzees, as full blown AIDS, has opened up the possibility of chimpanzees being the original carriers and reservoir of the HIV infection. Studies are now on to find out how chimpanzees are able to overcome HIV infection in their bodies in the hope to find a natural cure for AIDS.

THALIDOMIDE STAGES A COME BACK

After earning notoriety as a principal cause of congenital defects in the newborns and after being banned from clinical use for decades, Thalidomide has staged a comeback and won fresh approval from the Federal Food and Drug Administration (FDA) in USA, though under very strict control.

Approved tor use in leprosy, AIDS and cancer cases only, none is permitted to prescribe or consume the drug without undergoing a brief safety training. Pregnant women and children who *must* take the drug have to remain under close therapeutic and ultrasonic observation. Thalidomide quickly heals the skin ulceration in leprosy, as well as severe weight loss and mouth/ oesophageal ulcers in AIDS.

In the 1950s, Thalidomide was introduced as a mild sedative in Europe and came to be used extensively, till the end of 1960.

AIDS IN INDIA

The technical, social, economic and behavioural issues surrounding the HIV/AIDS epidemic in India are likely to be studied soon by some researchers to replace the currently available projections based on the experiences in other socio-cultural milieus. Identified first in the USA, in 1980s, the HIV/AIDS epidemic first spread within the western world, then travelled to Africa and has finally arrived in Asia, where huge populations are at risk.

Detection of the HIV infection is done through finding the antibodies to P_{24} antigen in serum, nucleic acid based tests or viral culture. There are 2 viral types: HIV-1 and HIV-2 (having 40-60% aminoacid homology) with HIV-1 having A to I and O subtypes. Understandably, there is considerable under-diagnosis and under-reporting of HIV/AIDS, especially in the Asian countries. Epidemiological studies on it are few. Surveillance, restricted to high risk groups, has been going on in India for over a decade. The limited information available from surveillance points to a high potential for HIV spread through commercial sex workers, shared needles among drug abusers, careless health workers and during parturition in infected females, particularly in the main port cities of India and the north-east hill States.

There is a high male preponderance among the reported HIV/AIDS patients in other countries but it has not yet been seen in India. The information campaigns about AIDS and counselling to individuals is also not making much headway in India. Sexuality and sex practices in this country could be very different, which may the reason why the campaigns modelled on the programmes in other countries are not succeeding. The anticipated explosive increase in the number of HIV/AIDS patients, as gathered from Western projections, has also not occurred so far. The status of women in the developing countries may also be a factor. Social support to a gender or group has often a protective effeqt on their health. Women in our social set up may be more vulnerable to HIV because they have a secondary social, economic and decision making role to play. It appears less likely that HIV/AIDS epidemic in India will follow the pattern in the West or in Africa. It is high time multicentric studies of a comprehensive design are taken up in India.

FORUM

MDR-TB : Treatment with an unconventional regimen

We were taken aback on seeing in the April 1999 issue of the *Indian Journal of Tuberculosis* Dr. Bedi's uncalled for comments, which were not in scientific taste . We were surprised that the letter was published without being referred to us.

It appears that Dr. Bedi has written without checking the details :

(a) Nowhere in our article *(Ind j Tuberc* 1998; 45 : 227) has it been mentioned that the Tibetan patient was poor. He was a first class government officer who was referred to us from 1500 kms. away. Presumably, government does take care of the medical bills' reimbursement. "Tibetan" was mentioned in the article as there is an impression that tuberculosis is more common and virulent in this racial group.

(b) Dr. Bedi has suggested that the patient had defaulted 5 times, as given in Table 1. Nowhere in the Table is there a suggestion of default on the part of the patient. He had been receiving continuous treatment and the first line in the "Discussion" clearly states that "the development of drug resistance in our patient can be attributed to the erratic treatment by the treating physicians".

(c) As regards the omission of amoxycillin-clavunate in the case report, we have carefully gone through the original manuscript which clearly mentions that the patient was given the above drug also. This discrepancy appears to have occurred inadvertently. *The Indian journal of Tuberculosis* does not send galley-proofs to authors.

(d) Giving intramuscular aminoglycosides 5 days a week is an accepted practice. Monitoring kidney functions is a must in a case receiving aminoglycoside for long period and, as already stated, the patient was approximately 1500 kms away from Delhi.

The objective of our case-report was, first and foremost, to underscore the fact that multidrug resistant tuberculosis, in our conditions, is often caused by erratic treatment by our colleagues and the second that other drugs with anti-tuberculosis activity can often be useful when one's hands are tied.

Inder Mohan Chugh,
Anil K. Agarwal and Ashok Shah
V.P. Chest Institute,
Delhi

Stop TB, the Probable Answer

Sir,

I would like to congratulate Dr. Ian smith on his excellent oration "Stop TB : Is DOTS the answer?" which I was fortunate enough to read in your journal and unlucky not to have heard in person. I have written a response to it for all to discuss. The battle against tuberculosis will be fought and decided in only one country, that is, India, for it accounts for nearly one third of the global TB burden. It will be a battle royal between "Rajyakshma" or "King's evil" and (us) doctors entrusted with tuberculosis control in the country. One death per minute from a disease which is " fully curable" with "effective treatment", if taken for "proper duration". The three key phrases need to be emphasised with respect to a poor country with high prevalence of tuberculosis. The so called "poor" patient in this country invariably spends more than Rs 2,000 (about $ 50) on unsuccessful and incomplete diagnosis and treatment recommended by "incompetent" doctors, *both qualified and unqualified.* This is roughly the cost of an effective course of treatment required for a single patient. So the time honoured pleas ot

lack of funds to treat the disease should be abandoned. The patients in the country perhaps have the buying power provided they have uniform access to the finest level of expertise to diagnose and treat tuberculosis.

Therefore, it is "lack of expertise and awareness" and not funds which is standing between the cure and the patient. DOTS is only a partial answer, for even the mighty DOTS can fail, as seen by the South African experience. DOTS is being and should be implemented rapidly in our country for it is technically a very sound programme with proven success, at low cost. But, it will be a while (5-7 years) before we can cover the entire country with DOTS, a duration for which the bacilli will not wait. Thus, the need for generating the necessary 'expertise and awareness' to combat and stop tuberculosis should be accorded top priority. This can be achieved if:

(a) We can train all the existing and future medical students from the first year in medical college to diagnose and treat tuberculosis effectively. And test them in each professional examination till their final passing out, as interns. This will include pre-set module (on the pattern of DOTS training module) and all the trouble shooting required to rr,.mage side-effects, MDR-TB, special conditions, motivation factors and preventing transmission. In this way, we will ensure that we do not have a single inadequately informed doctor with regard to tuberculosis whichever speciality he/she may choose to take up and practice ultimately. The questions and *viva voce* to test these future tuberculosis trouble shooters should be compulsory and uniform all over the country for the next five years.

(b) We can extend the above mentioned measures to all the students of alternative systems of medicine in the country to increase our power even more. Moreover, these doctors of other systems should be motivated to act responsibly and with confidence to refer their patients to DOTS or other clinics without delay. The training can also be imparted to the students in para-medical courses such as Nursing, Pharmacy and to medical technicians.

The same set of modules can be set into action for all the existing staff of Govt. and non-Govt. institutions (medics and para-medics) on a compulsory basis. Private physicians can be roped in by starting a short certificate course of four to six weeks' suspended duration with IMA. In the process, the country will gain reasonably trained doctors who will decrease the case load and reduce the net burden.

fc) Finally, motivation of the patient plays, a key role in determining the compliance trend observed in the TB clinic or DOTS centre. This can be increased manifold if we educate all the existing primary and higher secondary school students about tuberculosis by including health education in their curriculum. These students' enthusiasm to score marks by learning these topics on a compulsory basis can be put to good use as a tool to motivate TB patients in their family to take drugs regularly. Again, these questions on TD should be made compulsory and uniform throughout the country for a period of five years in all the Board examinations. The following points if taken into consideration can strengthen DOTS to a great extent:

1. Motivation of patient by health education is lacking in DOTS and can be included in it. Simple facts such as regular first line treatment costs about $ 50 or Rs. 2,200 and is sixty times cheaper than second line MDR-TB treatment can be the biggest motivator to an economically minded Indian . It will drastically reduce the default rate. Second 'sure shot' motivator
   is the fear of death and transmission of disease amongst family members which can be instilled in the minds of initial defaulters to keep them motivated. Reward systems, both for the patients and the doctors can be worked out to improve the results.
2. Media is a powerful tool with ubiquitous presence and is being exploited by other national programmes. This has been under-utilised for tuberculosis. It is high time that we use it to its full potential.

The above mentioned suggestions will build

a society with responsible and educated citizens in the health sector to achieve our end. To be successful, any programme (howsoever, good it may be) must be carried out by a group of enthusiastic, dynamic and well-educated individuals. For, it is these individuals' brilliance, of which there should be no dearth in our country, which will ultimately tilt the balance in our favour.

SanjayRajpal
Medical Officer
New Delhi TB Centre

RNTCP and Private Practitioners

Sir,

In order to rectify the shortcomings of NTP, the revised strategy (RNTCP) was launched in a phased manner five years ago. As over 50% of tuberculosis cases in our country are managed by private practitioners (PPs), one of the important steps planned was to fully involve PPs in RNTCP. Till today, no action whatsoever has been taken in this direction, even in the pilot areas.

In India, PPs include everybody from quacks to consultants, cutting across the barriers of allopathic and non-allopathic systems of medicine. Most of them do not know the ABC of managing a tuberculosis patient. As a result, there are as many ways of treatment as there are treating doctors. Our PPs can manage only self-administered therapy and not directly supervised therapy (DOT) due to their limited means and manpower. Therefore, intermittent regimens (which are effective only if fully supervised) are not practicable and can have dangerous consequences, if used by our PPs. The above mentioned statements may appear aggressive and even provocative, but are hard facts, based on systematic studies.

Unfortunately, many of our pharmaceutical companies are employing wrong tactics just to boost their sales. Already the Indian market is flooded with so many "Anti-TB Kits" and "Fixed-dose combinations" leading to a totally chaotic situation, even for consultants, what to talk of an ordinary general practitioner. Recently, a national level pharmaceutical company (Le Sante, Ahmedabad) has launched "intermittent weekly anti-TB-kits" all over the country on a war-footing. These packs are available for self-administration, without supervision and any one can purchase them over the counter, just like purchasing a cold drink or a tooth paste. For promotion of their products, they are leaving no stone unturned, without realising that they are selling and sowing seeds of MDR-TB for our future generations.

In our country, these pharmaceutical companies have become "preachers" (from "promoters") to our doctors; and a majority of our PPs do not realise that information provided by most of our medical representatives is often biased and may well be wrong.

I do not expect any guidelines from our policy makers to counter the sale of such products. I will request only my colleagues not to become a party to the "sinister designs" of these companies and try to control tuberculosis only by following simple principles of good chemotherapy, as are applicable in our country.

Rajinder Singh Bedi
Patiala

NEWS AND NOTES

54TH NATIONAL CONFERENCE ON TUBERCULOSIS AND CHEST DISEASES

The 54th National Conference on Tuberculosis and Chest Diseases will be held under the auspices of the Tuberculosis Association of India and the Bihar Tuberculosis Association from 26th to 29th December, 1999. Those who wish to attend the conference can obtain the Registration Form from the Secretary General, Tuberculosis Association of India, 3,"Red Cross Road, New Delhi -110 001.

TB HEALTH VISITORS' COURSE

The TB Health Visitors' Course for 1999-2000 conducted by the Tuberculosis Association of India at the New Delhi Tuberculosis Centre has commenced from 1st July, 1999.

INAUGURATION OF THE 50TH TB SEAL CAMPAIGN

The 50th TB Seal Campaign of the Tuberculosis Association of India was inaugurated on Saturday, the 2nd October, 1999 by His Excellency the President of India, Shri K.R. Narayanan at Rashtrapati Bhawan, when the TB seals depicting the Madhubani paintings were presented to him by Dr. S.P. Agarwal, Director General of Health Services and Chairman, Tuberculosis Association of India. The respected President commended the role of the Association in combating Tuberculosis.

The special TB Seal Souvenir brought out on the occasion and the health education material were presented to His Excellency the President, Shri K.R. Narayanan. The solemn function was covered on TV and radio.

CHARU CHANDRA DAS TRUST

Under the joint auspices of the Charu Chandra Das Trust and the IMA, Gorakhpur Branch, a Refresher Course was organised on Tuberculosis and Chest Diseases in L.N. Mishra Railway Hospital, Gorakhpur in February 1999. Prof. V.K, Arora, Director, LRS Institute of Tuberculosis and Allied Diseases, New Delhi and Dr. J.C. Suri, Head, Department of Critical Care, Safdarjang Hospital, New Delhi participated,

The Charu Chandra Das Trust also offers every year an award - "Charu Chandra Das Memorial Award"-through the Tuberculosis Association of India carrying a cash prize of Rs. 5000/- to a person, not more than 45 years in age, who has rendered meritorious services in any field of tuberculosis.

Rotary-Delhi TB Association's Mobile TB Clinic

The Rotary Club of Delhi South and the Delhi Tuberculosis Association jointly inaugurated a new project called the "Rotary-Delhi TB Association Mobile TB Clinic" in March 1999. The Rotary Club of Vancouver (Canada), Rotary Foundation of Rotary International and Canadian Rotary Committee International have collaborated in this project. Dr. A.K. Walia, Hon'ble Health Minister, Government of Delhi was the Chief Guest on the occasion. Mr. Peter Walker, the Canadian High Commissioner in India was present.

RESEARCH AWARD IN BIO-MEDICAL SCIENCES

The Rameshwardas Birla Smarak Kosh has instituted an annual award of rupees two lakh for outstanding research in bio-medical sciences including clinical and other related areas such as agriculture (relating to nutrition), entomology, ethno-botany, toxicology, zoology, etc. by an Indian national working in India.

Nominations for the 20th year's Award i.e. for the year 2000, are being accepted till 30th September, 1999. There is no prescribed form for nomination. While sending the nomination(s) the following information must be given, with seven copies of each of the following ;

(i) complete *curriculum vitae* of the nominee,

(ii) concise information about the research work which is cited in support of the nomination, and its importance in the relevant field,

(iii) reprints or a copy each of only those research papers which are considered useful for assessing the merit of the research work cited,

(iv) names of persons who may be consuited for their expert opinion about the research work and the nominee; and

(v) a recent passport size photo of the nominee.

A candidate can nominate himself/herself. Those who were nominated in the past five years need not be nominated again.

For further information, please contact the Director, the Rameshwardas Birla Smarak Kosh, Medical Research Centre, Bombay Hospital Avenue, Mumbai - 440 020.

NEW HONORARY GENERAL SECRETARY FOR ANDHRA PRADESH TB ASSOCIATION

Dr. P. Gangadhar Goud has taken over as the Honorary General Secretary of the Tuberculosis Association of Andhra Pradesh on 12th July, 1999 *vice* Dr.I. Ranga Rao who has resigned.

CONFERENCE OF THE INDIAN ASSOCIATION OF PREVENTIVE AND SOCIAL MEDICINE

The XXVIIth National Conference of the Indian Association of Preventive and Social Medicine will be held in Osmania Medical College, Hyderabad from 10th to 12th February, 2000. Reproductive and child health and infectious diseases are central topics of the Conference. For more details, please contact. Dr. B.V. Brahmeshwara Rao, Organising Secretary, Prof, and Head, Department of SPM, Osmania Medical College, Koti, Hyderabad - 500195 (Andhra Pradesh).

PROF. P.R.J. GANGADHARAM PASSES AWAY

In August 1999, the scientific community in India lost untimely an illustrious bacteriologist and a devoted tuberculosis worker due to a massive heart attack suffered in Chicago.

Born in 1930, Dr. Gangadharam finished his Ph.D. in Microbiology from the Indian Institute of Science, Bangalore, in 1954, joining the Tuberculosis Chemotherapy Centre, Madras in 1956, he rapidly rose to the position of the Head of Laboratories in the TRC.

Dr. Gangadharam was appointed Director, Microbacteriology Laboiatories, Jefferson Davis Hospital, Houston, Texas (USA) in 1969 and subsequently became Director, Mycobacteriology Research, National Jewish Centre for Immunology and Respiratory Medicine, Denver, Colorado. It was at the National Jewish Centre that he discovered and patented a new antibiotic Gangamycin - found effective against *M. avium complex* disease. In 1990, Dr. Gangadharam was appointed as Professor of Medicine, Microbiology and Pathology/ Director of Mycobacteriology Research, University ot Illinois College of Medicine, Chicago USA. One of the earliest of his awards (1982) was the Robert Koch Centenary Award from the Tuberculosis Association of India. Dr. Gangadharam was a person of whom India can feel proud.

DR. S.P. KHANNA IS NO MORE

Dr. Satya Priya Khanna, Ex-Director, New Delhi Tuberculosis Centre breathed his last on 28.9.1999 due to cardiac arrest. Dr. Satya Priya Khanna was born on 4th January, 1953. He completed his DTCD in 1980 and MD in TB and Respiratory Diseases in 1982 from V.P. Chest Institute, University of Delhi.

After his post-graduation, he joined New Delhi Municipal Committee, as Medical Officer in 1983, becoming a Senior Chest Physician in 1990. He took over as Director, New Delhi TB Centre in 1995, on deputation from NDMC, and held the post till 1998. He was posted a* OSD TB Control under Delhi Government in 1998.

Dr. Khanna was a recognised teacher and examiner for DTCD and MD students of TB and Chest Diseases of Delhi University. In his death the country has lost a dynamic and energetic chest physician and a conscientious worker.

ABSTRACTS

An Approach to the Problem of Diagnosing and Treating Adult Smear-Negative Pulmonary Tuberculosis in High HIV-Prevalence Settings in Sub-Saharan Africa

AD Harries, D Maker, P Nw/w, *Bull. Wld. tilth. Org.,1998,76(6): 651*

The criteria set for diagnosing smear negative pulmonary TB, the degree to which clinicians follow the criteria and the problem of how to exclude other respiratory diseases have been reviewed and discussed. It is recommended that SCC is preferable to the standard 12-month regimen for the treatment of sputum negative pulmonary TB in order to get better adherence to treatment and best final follow up results.

Awareness about Tuberculosis Among Nurses working in a Tuberculosis Hospital and in a General Hospital in Delhi

Singla Neeta, PP Shanna, RC Jain, Int. J. Tuberc. and Lung Dis., 1998, 2 (U): 1005

A pre-tested questionnaire was served to 213 nurses of the LRS Institute of Tuberculosis and Allied Diseases and those in a general hospital. A substantial number of nurses in either hospital had inadequate awareness about tuberculosis. If 75% correct response is made the cut-off point for judging adequate knowledge, then 40.2% of tuberculosis nurses and 10.7% of general hospital nurses qualified for being aware. Age of the respondent and years of experience had no relation to the level of awareness.

Prospective Evaluation of WHO Criteria to assist Diagnosis of Tuberculosis in Children

KAF Houwert, PA Borggreven, HS *Schajf, E Nel, PR Donald,J Stolk, European Respiratory Journal; 1998,11 (5): 1116*

The WHO has proposed a hierarchial system of diagnosing tuberculosis among children using history, certain clinical features, etc. to help improve the diagnosis of tuberculosis in children and control tuberculosis in a community. The study evaluated the system recommended, prospectively. In 627 children, who presented themselves at the paediatric outpatients department of a tertiary hospital (Western Cape Province) during October, 1995 to February, 1998, from a high prevalence community, and having at least one suggestive symtom. Full investigations were carried out (clinical examination, Mantoux Test," Chest X-ray, TB culture of gastric aspirate). In 206 children (33%), one or more diagnostic criteria were present, and culture confirmation was available in 5% of children. After the diagnostic work up, 23 children (11%) were considered to have probable TB, whereas 173 (84%) children were found to have no TB, after 8 weeks of observation. The WHO criteria were found to have a predictive value of 63%.

Pharmacokinetics of Isoniazid under Fasting Conditions, with Food and with Antacids

CA Peloquin, R Namdar, AA Dodge, DE Nix, Int. J. Tuberc. Lung. Dis., 1999,3 (8): 703

Intra-and inter-subject variability when Isoniazid was taken fasting, with food and with antacids, was studied. A randomized, four-period cross-over design was used. In Phase 1,14 healthy male and female volunteers were used who ingested 300 mg of Jsoniazid, fasting, twice, with high fat meal and with aluminium magnesium antacid. They also received standard doses of Rifampicin, Pyrazinamide and Ethambutol.

Mean INH C_{max} was 5.53 ± 2.92 μg/ml; T_{max}, 1.02 ± 1.10 hours and AUC_0 of 20.16 ± 12.45 μg hr/ml. These findings were similar to those reported previously. Antacids did not alter significantly (C_{mAX} 5.62 ± 2.53 μg/ml, T_{max} 0.71 ± 0.56 hours and AUC_0 20.27 ± 11.39 μg hour/

ml) the fasting parameters but the high fat meal, recommended by the FDA, reduced C_{max}, by 51% doubled the T_{max} and reduced AUC_0 by 12%.

Cutaneous Tuberculosis : A Twenty-Year Prospective Study

B Kumar, 5 Muralidliar, Int. four. Tuberc. Lung Disea,, 1999, 3 (6): 494

In a tertiary hospital, 0.1% of dermatology patients had cutaneous tuberculosis, between 1975 and 1995. Of them, 154 (55%) had lupus vulgaris, 75 (26.8%) had scrofuloderma, 17 (6%) had tuberculous verrucosa cutis, 15 (5.4%) tuberculous gumma and 19 (6.8%) had tuberculids. There was no correlation between tuberculin reaction and the extent of disease : disseminated disease was more commonly associated with scrofuloderma and gumma. There were more BCG unvaccinated individuals in the group with disseminated disease.

Comparative Bio-equivalence Study of Rilampicin and tsoniazid Combinations in healthy volunteers

KA Padgaonkar, SN Revankar, AD Bhntt, }A Vaz, ND Desai, S, D'Sa, VShah, K Candeivar, Int. Jour. Tuberc. Lung. Dis., 1999, 3 (7): 627

The mean Value of RMP in brand N (C_{max} 6.49 ± 0.52 μg/ml; T_{max} 2.33 ± 0.18 h; AUCw-a h) 39.83 ± 3.44 μg/ml h) were comparable with those obtained with brand R (C_{max} 5.22 ± 0.59 μg/ml; T_{max} 2.50 ± 0.12 h; AUC_{10-24} h) 33.33 ± 3.47 μg/ml h). The mean values of RMP in brand I (C_{max} 3.05 ± 0.52 μg/ml; T_{max} 3.79 ± 0.57 h and AUC_{10-24} h) 21.78 ± 3.67 μg/ml h) were significantly different from those of brand R. Nevertheless, all of the pharmacokinetic parameters obtained for INH and ACINH in all brands were comparable.

To Philanthropists and Well Wishers

Donate Generously

Donations to the Tuberculosis Association of India are exempt from payment of income tax under Section 80-G of the Indian Income Tax Act, 1961.

Donations for specific research work in tuberculosis and allied diseases of the chest given to the Tuberculosis Association of India, are exempt from Income Tax under Rule 6 Clause (ii) of sub section (1) of section 35 of the Income Tax Act, 1961 under the category "Institution" vide notification No. 1149 (R No. DG/ IT (E)/ND-49/35(l) (ii)/90-91 dated 9th June, 94 published in part II section 3 (ii) of Gazette of India, Ministry of Finance (Department of Revenue), validated upto 31.3.1996 (and applied for revalidation).

TUBERCULOSIS IS A PROBLEM WHICH CONCERNS THE ENTIRE COMMUNITY
